NON-INTERVENTIONAL (NI) INTERIM STUDY REPORT

Study Information

Title	HERO-Together: A Post-Emergency Use Authorization Observational Cohort Study to Evaluate the Safety of the Pfizer-BioNTech COVID-19 Vaccine in US Healthcare Workers, Their Families, and Their Communities
Protocol number	C4591008
Version identifier of the interim study report	v. 1.0
Date	22 June 2021
EU Post Authorization Study (PAS) register number	EUPAS38671
Active substance	N/A
Medicinal product	COVID-19 Vaccine BNT162b2
Research question and objectives	The research questions addressed by this study are: a) what are the incidence rates of safety events of interest and other clinically significant events among persons vaccinated with the Pfizer-BioNTech COVID-19 vaccine in a cohort of US healthcare workers, their families, and their communities and b) how do those rates compare to expected rates of those events? *Primary study objectives:* • Estimate the real-world incidence of safety events of interest and other clinically significant events among

	US healthcare workers, their families, and their communities +who are vaccinated with the Pfizer-BioNTech COVID-19 vaccine following Emergency Use Authorization. *Secondary objectives* • Evaluate whether the vaccine recipients experience increased the risk of safety events of interest and other clinically significant events post-vaccination. • Estimate the incidence rates of safety events of interest and other clinically significant events among subcohorts of interest such as individuals who are pregnant, individuals who are immunocompromised, and stratified by age.
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Not applicable

1. ABSTRACT (STAND-ALONE DOCUMENT)

2. LIST OF ABBREVIATIONS

Abbreviation	Definition
ACP	All Consented Population
ADaM	Analysis Data Model
AESI	Adverse Event of Special Interest
CEA	Clinical Events Ascertainment
CNPASP	Consented but Not in the Primary Analysis Safety Population
DCRI	Duke Clinical Research Institute
EUA	Emergency Use Authorization
GEP	Good Epidemiological Practice
GPP	Good Pharmacoepidemiology Practices
HCW	Health care worker
HERO	Healthcare Worker Exposure Response and Outcomes
ICF	Informed Consent Form
IEA	International Epidemiological Association
IEC	Independent Ethics Committee
IRB	Institutional Review Board
PASS	Post-Authorization Safety Study
PASP	Primary Analysis Safety Population
SAP	Statistical analysis plan
SDTM	Study Data Tabulation Model
SOP	Standard operating procedure

3. INVESTIGATORS

Principal Investigator(s) of the Protocol

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4. OTHER RESPONSIBLE PARTIES

Not applicable.

5. MILESTONES

Milestone	Planned date	Actual date	Comments
Start of data collection	17 December 2020	17 December 2020	
End of data collection	30 June 2023		
Registration in the EU PAS register	Prior to start of data collection, December 2020		
Interim Reports	30 June 2021 31 December 2021 30 June 2022 31 December 2022	22 June 2021	
Final report of study results	31 December 2023		

6. RATIONALE AND BACKGROUND

In the US, Pfizer-BioNTech COVID-19 vaccine was approved for emergency use authorization (EUA) to prevent Coronavirus Disease 2019 (COVID-19) for individuals 16 years of age and older on December 11, 2020. Detailed distribution plans for the COVID-19 vaccine within the US are currently determined by local jurisdictions based on federal recommendations to prioritize vaccination of healthcare workers and people living in long term care facilities under an EUA. This study is designed to provide early real-world safety information on a cohort of vaccinated healthcare workers, their families, and their communities for two years after vaccination.

This non-interventional study was designated as a Post-Authorization Safety Study (PASS) and was committed to the FDA in the US PVP.

7. RESEARCH QUESTION AND OBJECTIVES

The research questions addressed by this study are: a) what are the incidence rates of adverse safety events of interest and other clinically significant events among persons vaccinated with the Pfizer-BioNTech COVID-19 vaccine in a cohort of US healthcare workers, their families, and their communities and b) how do those rates compare to expected rates of those events?

Primary study objectives:

- Estimate the real-world incidence of safety events of interest and other clinically significant events among US healthcare workers, their families, and their communities who are vaccinated with the Pfizer-BioNTech COVID-19 vaccine following Emergency Use Authorization.

Secondary objectives

- Evaluate whether vaccine recipients experience increased risk of safety events of interest and other clinically significant events post-vaccination.

- Estimate the incidence rates of safety events of interest and other clinically significant events among subcohorts of interest such as individuals who are pregnant, individuals who are immunocompromised, and stratified by age.

8. AMENDMENTS AND UPDATES

Table 1. Amendments to the Protocol

Amendment number	Date	Protocol section(s) changed	Summary of amendment(s)	Reason
1	22 January 2021	• Title page • Abstract • Milestones • Rationale and Background	• Added field for EU PAS registration number on title page. • Removed interim report on 31 March 2021. • Removed designation as Category 3 post-authorization safety study in EU risk management plan (RMP) and noted study is included in the US PVP.	• EU PAS registration number was inadvertently left out. • Data from the first quarter of 2021 are limited. US vaccinations program not fully deployed until January • Study was not included in final RMP
2	20 April 2021	• Title page • Abstract • Research question and objectives • Research methods	• Expanded population to include HCW families and community members	• Revisions in response to FDA protocol review comments • Expanded population

Table 1. Amendments to the Protocol

Amendment number	Date	Protocol section(s) changed	Summary of amendment(s)	Reason
		• Inclusion criteria • Participant follow-up • Clinical events ascertainment • Data analysis	• Added Project Baseline Community Study to recruitment sources • Updated subgroups • Additional detail about CEA Committee process and event confirmation • Additional recruitment strategies • Removed medical release requirement for enrollment	• Recruitment pathway through Project Baseline Community Study added • Event confirmation step added • Removal of medical release requirement from inclusion criteria only • Editorial changes

9. RESEARCH METHODS

9.1. Study design

This study is a prospective observational study designed to evaluate the incidence rates of safety events of interest and other clinically significant events within a cohort of healthcare workers, their families, and their communities who receive the Pfizer-BioNTech COVID-19 vaccine under the EUA program in the United States. The study is a primary data collection study with review of medical records. Receipt of the vaccine is required for inclusion in the study, but the decision to be vaccinated is made at the discretion of the recipient.

As described in the protocol (see Appendix 2), this study will enroll and follow 20,000 vaccinated healthcare workers, their families, and their communities during a 30-month study period. Information on hospitalization and diagnosis of safety events of interest are collected from participant report at regular intervals following vaccination, primarily using a secure, participant-facing web portal. Participant reports of safety events of interest and/or hospitalization trigger a request for and review of participant medical record information for confirmation and adjudication of the event (see Figure 1 for additional details). To address the primary objective, incidence rates of safety events will be estimated based on cases that are positively adjudicated. To address the secondary objective regarding assessment of increased risk, a self-matched comparative analysis will be undertaken for feasible safety events (e.g., events with a known risk interval and sufficient case counts). Additional context for the rates observed in vaccinated individuals will be sought from population background rates and/or unvaccinated person years in the HERO Registry.

As no participant reported events had completed adjudication as of April 29, 2021, this interim report 1 descriptively summarizes self-reported hospitalizations and safety events of interest that have been confirmed. Future interim reports will summarize the comparative analyses performed on fully adjudicated events.

9.2. Setting

In this study, there are no treating-healthcare providers serving as investigators that oversee the recruitment, enrollment, or data collection for study participants. Rather, participants self-enroll via a secure, participant-facing web portal, either at the vaccination site or remotely.

While participants may enroll from anywhere in the US, the study is actively promoted through three main settings. The first setting is the Healthcare Worker Exposure Response and Outcomes (HERO) Registry Study, launched in April 2020 to characterize COVID-19 risk factors and outcomes among healthcare workers (HCWs) in the United States by the Duke Clinical Research Institute (DCRI). In April 2021, due to HERO Registry members consistently identifying the family unit as an important focus area for research and as vaccine supply has grown sufficient to make vaccine more widely available outside of limited occupational and age groups, the HERO Registry was expanded to include HCW families and community members (defined as the group of people that live, work, or interact with healthcare workers in their households, or anyone in the community). The overall goal of the HERO Registry is to create and engage a community of healthcare workers, their families, and their communities, who may be eligible for participation in future research studies, including studies of COVID-19 prophylaxis and treatment. The HERO registry currently comprises over 30,000 participants in all 50 states and is recruiting new participants for inclusion on an ongoing basis. Due to the broad population definition and limited inclusion/exclusion criteria, the registry supports enrollment of a diverse population and greater generalizability of results. The population for this first interim report includes only healthcare worker participants who enrolled prior to study expansion (30 April 2021).

Existing HERO Registry participants are sent notifications of the opportunity for healthcare workers, their families, and community members to participate in a study of long-term outcomes after vaccination.

The demographic characteristics of the HERO Registry as of December 2020 are described in Table 2 and Table 3.

Table 2. HERO Registry Participants (Preliminary Data) as of December 2020

Total HERO Registry Participants (n=15,629)	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Physician	3265	20.89	3265	20.89
Nurse (RN/LPN)	5202	33.28	8467	54.17
Paramedic/Emergency Medical Technician	463	2.96	8930	57.14
Other (free text)	2442	15.62	11372	72.76
Physician's assistant/Nurse practitioner (PA/NP)	1226	7.84	12598	80.61
Other Health Diagnosing and Treating Practitioners	1321	8.45	13919	89.06
Health technologists, technicians, and clinical support staff	343	2.19	14262	91.25

Table 2. HERO Registry Participants (Preliminary Data) as of December 2020

Total HERO Registry Participants (n=15,629)	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Healthcare support, administrative, and research staff	1367	8.75	15629	100.00
Frequency Missing = 220				

Table 3. Demographic Composition of the HERO Registry (Preliminary Data) as of December 2020

		Gender			
		Male	Female	Other[a]	Total
Race	White	2,973 (18.56%)	10,507 (65.59%)	41 (0.26%)	13,521 (84.41%)
	Black or African American	123 (0.77%)	487 (3.04%)	2 (0.01%)	612 (3.82%)
	American Indian or Alaska Native	7 (0.04%)	33 (0.21%)	1 (0.01%)	41 (0.26%)
	Asian	364 (2.27%)	588 (3.67%)	2 (0.01%)	954 (5.96%)
	Native Hawaiian or Other Pacific Islander	4 (0.02%)	16 (0.10%)	0 (0.00%)	20 (0.12%)
	Other	81 (0.51%)	180 (1.12%)	0 (0.00%)	261 (1.63%)
	Multi-race	72 (0.45%)	237 (1.48%)	2 (0.01%)	311 (1.94%)
	Not Available (Prefer not to answer)	94 (0.59%)	184 (1.15%)	21 (0.13%)	299 (1.87%)
Ethnicity	Yes, Hispanic (Latino/Latina)	303 (1.89%)	961 (6.00%)	4 (0.02%)	1,268 (7.92%)
	No, not of Hispanic, Latino, or Spanish origin	3,347 (20.89%)	11,137 (69.52%)	46 (0.29%)	14,530 (90.70%)
	Not Available (Prefer not to answer)	68 (0.42%)	134 (0.84%)	19 (0.12%)	221 (1.38%)
Total		3,718 (23.21%)	12,232 (76.36%)	69 (0.43%)	16,019 (100.00%)

a. Gender = Other include male-to-female, female-to-male, gender expansive/variant, gender not listed, and prefer not to answer

The second setting is major health systems distributing Pfizer-BioNTech COVID-19 vaccine to its employees, their families, and community members as determined by local jurisdictional EUA rollout plans. Recruitment efforts focused on healthcare systems allocated large number of Pfizer COVID-19 vaccine doses, feasibility of recruitment and geographic diversity. Study navigators at some sites facilitated enrollment of vaccine recipients. At the data lock point for this interim report, families and community members from this setting were not eligible for the study and therefore their data is not included in this report.

A third setting for recruiting patients is the Project Baseline Community Study platform launched in April 2019 by Verily Life Sciences to acquire, organize, analyze, and activate phenotypic data for a group of participants over time. At the data lock point for this interim report, families and community members from this setting were not eligible for the study and therefore their data is not included in this report.

9.3. Subjects

Subjects in HERO-Together include healthcare workers, their families, or anyone in the surrounding community who is 18 years or older as of December 17, 2020 (date of study launch). The population for this first interim report includes only healthcare worker participants who enrolled prior to study expansion (30 April 2021) reflecting initial inclusion criteria for this study.

9.3.1. Inclusion Criteria

Participants must be one of the following:

1. A healthcare worker (individual currently working in a setting where individuals receive healthcare in the US including emergency medical services);

OR

2. Part of a family to which healthcare workers may also belong*

OR

3. Anyone in the surrounding community*

Participants must also be all of the following:

- Age ≥18 years.
- Able to speak and read English or Spanish**.
- Receipt of the first dose of a COVID-19 vaccine for prevention of SARS-CoV-2 infection within the past 60 days.
- Evidence of informed consent indicating that the participant (or a legally acceptable representative) has been informed of all pertinent aspects of the study.

* Recruitment criteria added with 20 April 2021 protocol revision.

** Spanish language recruitment materials, study materials and Baseline Community Study web portal were not available in Spanish during the reporting period for this interim report (17 December 2020 to 29 April 2021).

9.3.2. Exclusion Criteria

There are no exclusion criteria for this study. All participants meeting inclusion criteria will be eligible for analysis.

9.3.3. Recruitment

All methods for recruitment and retention are detailed in a separate recruitment and retention workplan, which is continuously updated with ongoing and planned recruitment efforts. Recognizing the limitations of an entirely participant-driven study, there are several strategies in place to ensure that recruitment goals are met, while minimizing missing and inaccurate data, and loss to follow-up.

A potential participant may learn about the opportunity to receive a COVID-19 vaccine through a variety of mechanisms that may include their employer or by email sent to existing HERO Registry or Project Baseline Community Study members. Recruitment materials may also be present in the vaccine administration area.

In addition to registry and health system-based recruitment, promotion efforts leverage public communication, social media and other advertising, and printed enrollment materials with information about the study at vaccination sites. These efforts include 5 primary strategies: 1) Digital promotion through online advertising; 2) Partnerships with local health organizations (for example, NC Department of Health and Human Services) and professional societies (for example, the American Society for Clinical Oncology and the American Association for Respiratory Care) for dissemination of information 3) Grand rounds/educational presentations to institutional audiences provided by HERO-Together investigators; 4) Social media influencer partnerships; and 5) Participant-driven outreach including tag-a-friend campaigns and “Why I joined” videos on the study website. Each of these strategies are anticipated to broaden our reach beyond major health systems and facilitate connection with healthcare workers, and members of their families and communities who may have had later access to vaccines. Additionally, given that the primary analysis will include recipients of the Pfizer-BioNTech vaccine, digital promotion efforts target the geographic regions represented in current Pfizer-BioNTech vaccine distribution plans. Participant enrollment through these channels is actively tracked and recruitment plans will be revised to reflect the highest-yield strategies.

All recruitment materials focus on enrollment into a research study on vaccine safety and avoid language promoting the Pfizer-BioNTech COVID-19 vaccine itself.

Diversity-Focused Recruitment

The study team is currently implementing 3 strategies focused on enhancing diversity in HERO-Together specifically. These include 1) an extended recruitment plan with broad strategies to reach healthcare workers, their families and their communities who may not be connected to major healthcare systems, including those who work in long-term care facilities; 2) culturally sensitive electronic and printed recruitment materials to ensure that imagery reflects a diverse population with respect to race/ethnicity and professional role; and 3) customized recruitment materials for specific professional roles (for example, long-term care

facility staff, dental health providers, and first responders). The demographic and professional role distributions of enrolled participants are continually monitored and diversity-focused recruitment strategies will be refined accordingly.

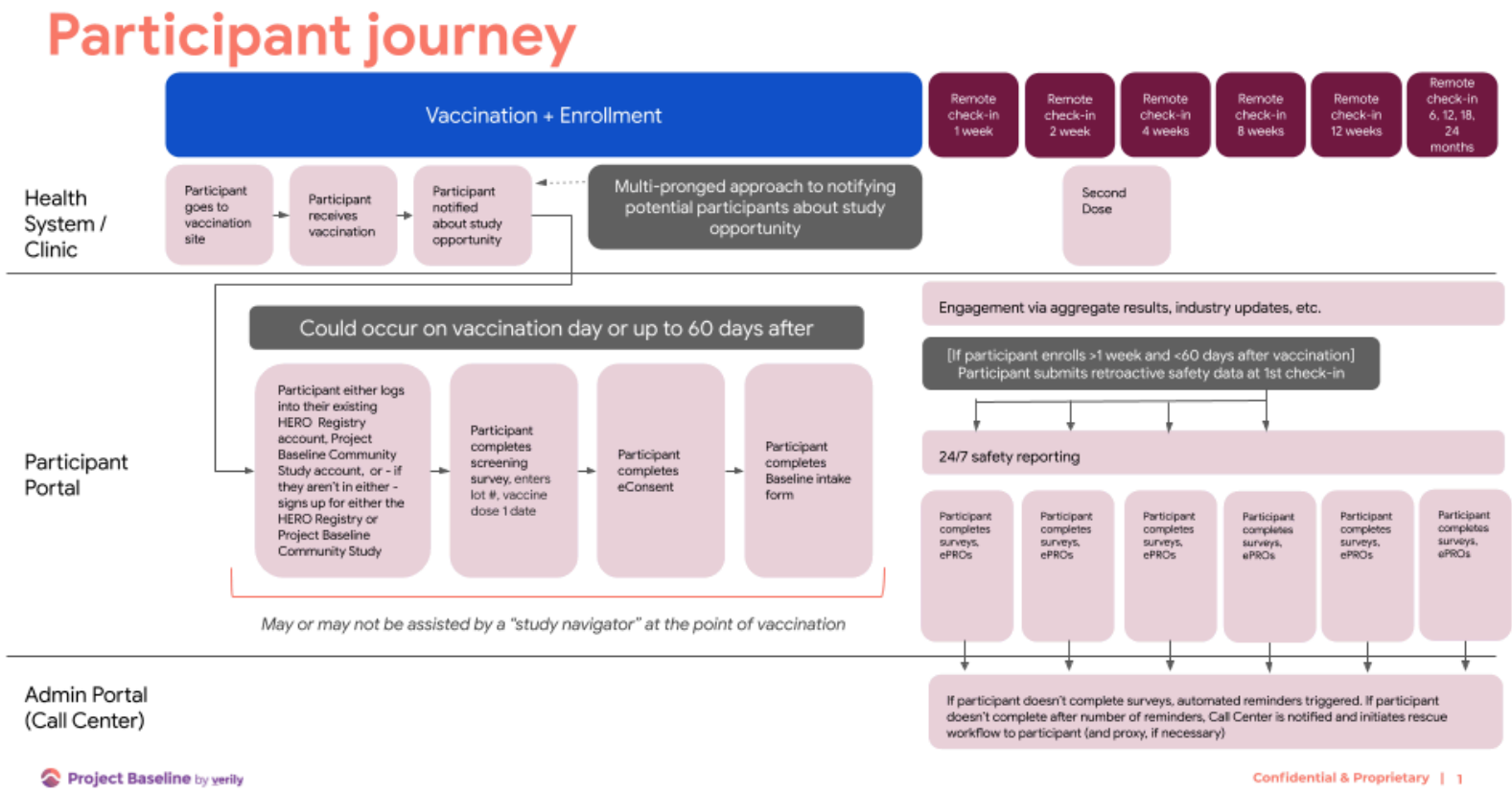
Recruitment of HCWs, and their families and communities not participating in the HERO Registry occur via public communication, social media and other advertising, and printed enrollment materials with information about the study at vaccination sites.

9.3.4. Enrollment

Participants may enroll at the vaccination site or may self-enroll remotely. At select vaccination sites, study navigators are available to assist with recruitment and enrollment after individuals are vaccinated. Virtual study navigators may also assist with enrollment via phone and/or text. Study navigators may assist with entry of vaccine -related information (date, manufacturer, lot #) in the web portal to ensure accuracy. Based on conversations with many institutions affiliated with the HERO Registry, optimal navigator workflow is determined depending on institutional plans for vaccination. For example, at some institutions, the navigator will interact with the potential participant shortly before receiving the vaccine (e.g., at the time of registration, or at check-in to the vaccine administration area), while others may interact with potential participants in the recovery area where recipients will spend time after the vaccine.

As shown in Figure 1, existing members of the HERO Registry and the Project Baseline Community Study are instructed to complete a screening questionnaire and an informed consent form (ICF), at which point they are enrolled in the study. Non-members are enrolled in the HERO Registry or in the Project Baseline Community Study Community and then directed to complete the screening questionnaire and informed consent form. In addition, proxy contact information is collected at enrollment to support data capture in the event that the participant cannot be reached (e.g., participant is hospitalized).

Figure 1. Participant Journey



9.3.5. Retention

As part of the HERO Registry, participant engagement is sought by a series of community building activities and modules that are informed by the participant's "voice." Prior to the launch of HERO-Together, HERO Registry participants have demonstrated high responsiveness. As described below, "rescue" strategies to prompt survey completion have resulted in substantially improved completion.

Additionally, there is an automated system built into the Verily web portal that notifies the DCRI Call Center when a participant has not completed a survey. The DCRI Call Center, with their staff of bilingual interviewers (Spanish and English), operates 7 days a week, offers toll-free lines for participant use, and includes time zone accommodations. Interviewers undergo extensive orientation, ethics training, and are taught standardized interviewing techniques. The DCRI Call Center provides follow-up support to participants who do not complete their digital surveys - this process is known as "rescue". In addition, the Call Center is available to answer questions about the study prior to and during enrollment.

The role of the DCRI Call Center is to rescue surveys that are not completed, or are missing key components, by contacting participants, using contact information provided by the participant at baseline. Participants are offered preferred times to call and a toll-free line to use at their convenience.

9.3.6. Participant Follow-up and Data Collection

Participants are followed from date of enrollment until the end of the 24-month period following first vaccine dose, end of the study period, death, loss-to-follow up (no response after a notable interval of attempted Call Center contacts), or withdrawal from study.

Following enrollment, all participants enter data into a secure, participant-facing web portal at 1 week, 2 weeks, 4 weeks, 8 weeks, 12 weeks, and 6-, 9-, 12- 18-, and 24-months following receipt of the first dose of the vaccine. Second dose information is solicited during follow up. Participants are queried regarding their general health and events requiring medical attention. Participants who do not complete data entry within a notable period of time of the expected completion date for a given time point are contacted by the Call Center for an update on health status. Participants who report a clinically important medical event (e.g., non-routine visit to medical provider or hospitalization) are prompted to complete a medical record release form in the web portal, which is used to collect medical records for review by the Clinical Event Ascertainment group for confirmation of the occurrence of a safety event of interest. For any participant who reports a potential safety event of interest, medical records during the year prior to vaccination may also be reviewed to support a self-matched comparative analysis. Only descriptive analyses are presented in this report. Self-

matched comparative results will be presented in future reports, after participant reported events have been fully adjudicated.

9.4. Variables

Variable	Role	Data Source(s)
Date of 1st dose COVID-19 vaccination	Exposure	Participant
Site where 1st dose COVID-19 vaccine was administered	Exposure	Participant
COVID-19 vaccine lot number (1st dose)	Exposure	Participant
Date of 2nd dose COVID-19 vaccination	Exposure	Participant
Site where 2nd dose COVID-19 vaccine was administered	Exposure	Participant
COVID-19 vaccine lot number (2nd dose)	Exposure	Participant
Pregnancy Information (pregnancy status and estimated due date)	Outcome (utilization analyses) and covariate (safety analyses)	Participant
Demographics	Outcome (utilization analyses) and covariate (safety analyses)	Participant
Medical History	Outcome (utilization analyses) and covariate (safety analyses)	Participant
Employment characteristics of the participant	Outcome (utilization analyses) and covariate (safety analyses)	Participant
Vaccination details	Exposure variable	Participant
Concomitant medications	Outcome (utilization analyses) and covariate (safety analyses)	Participant
Participant-reported outcomes	Outcome	Participant
Safety events of interest (Section 9.4.1)	Outcome	Participant, proxy, or medical record/insurance claims review
COVID-19 Diagnosis	Outcome	Participant, proxy, or medical record/insurance claims review
Hospitalizations	Outcome	Participant, proxy, or medical record/insurance claims review
Death	Outcome	Proxy, or medical record/insurance claims review

9.4.1. Safety events of interest

For this first interim report, all participant-reported safety events are awaiting full clinical adjudication and should be treated as preliminary. The safety events of interest in this study

are based on the Priority List of Adverse Events of Special Interest from the Brighton Collaboration's Safety Platform for Emergency vACcines (SPEAC) Project[1] and CDC enhanced safety monitoring recommendations[2]). The safety events of interest in this study include:

Neurologic:

- Generalized convulsion/seizures
- Guillain-Barre Syndrome
- Aseptic meningitis
- Encephalitis/encephalomyelitis
- Other acute demyelinating diseases
- Transverse myelitis
- Multiple sclerosis
- Optic neuritis
- Bell's palsy

Immunologic:

- Anaphylaxis
- Vasculitides*
- Arthritis/arthralgia
- Multisystem inflammatory syndrome (in adults)
- Kawasaki disease
- Fibromyalgia
- Autoimmune thyroiditis

COVID-19:

- Severe COVID-19 disease*
- Microangiopathy*
- Heart failure and cardiogenic shock*
- Stress cardiomyopathy*
- Coronary artery disease*
- Arrhythmia*
- Deep vein thrombosis
- Pulmonary embolus
- Cerebrovascular stroke
- Limb ischemia*
- Hemorrhagic disease*
- Acute kidney injury*
- Liver injury
- Chilblain-like lesions
- Single organ cutaneous vasculitis*
- Erythema multiforme*

Cardiac:

- Myocarditis
- Pericarditis
- Acute myocardial infarction

Hematologic:

- Thrombocytopenia

- Disseminated intravascular coagulation

Other:

- Pregnancy outcomes
- Death
- Narcolepsy and cataplexy;
- Non-anaphylactic allergic reactions

*Hospitalized manifestations only

9.5. Data sources and measurement

Data are captured through several mechanisms, described below. All data collected in the context of this study are stored and evaluated per applicable regulatory requirements and guidance for electronic records. Data are stored and evaluated in a manner that protects participant confidentiality in accordance with the legal stipulations applying to confidentiality of data.

9.5.1. Participant report

Participants provide information on COVID-19 vaccination, baseline characteristics, seeking of non-routine medical care (including hospitalization) and potential occurrence of safety events of interest. Following enrollment, the participant enters data into a secure, participant facing web-portal. Data entry occurs according to the schedule of assessments described in Table 4. Participants who miss assessments during follow-up, and individuals with longer than a 2-day interval between vaccination and enrollment are administered a retrospective assessment to capture participant-reported safety information occurring within this interval. If an assessment is incomplete after a notable period of time, the participant will be contacted by the Call Center for completion of missed assessments.

Table 4. Schedule of Assessments

	Enrollment Data Collection	***Follow-up Data Collection***					
	Baseline	After 1st dose					
		1 week	2 weeks	4 weeks	8 weeks	12 weeks	6, 9, 12, 18, 24 months
E-consent	X						
Eligibility criteria confirmed	X						
Vaccine Dose 1 information • Date • Lot number • Site	X						

Table 4. Schedule of Assessments

	Enrollment Data Collection	***Follow-up Data Collection***					
	Baseline	After 1st dose					
		1 week	2 weeks	4 weeks	8 weeks	12 weeks	6, 9, 12, 18, 24 months
Vaccine Dose 2 information • Date • Lot number • Site				X (and subsequent visits if second dose not reported as received)			
Medical record release	X**	X**	X**	X**	X**	X**	X**
Demographics • Demographics form	X						
Medical history • Medical history form	X						
Employment Information • Employment information form	X						
Concomitant medications • All current medications reported at baseline • Changes to medications reported at follow-up	X						X*
PROs • Fatigue severity scale • PROMIS Global 10 • CDC Impact Scale	X	X	X	X	X	X	X*
COVID-19 Information • Positive COVID-19 test with date • COVID-19 diagnosis (presumptive)	X			X	X	X	X
Health questionnaire • Potential safety events of interest or clinically significant events • Pregnancy status	X	X	X	X	X	X	X*

* Follow-up pregnancy, PROs and medication information collected only at 6, 12, 18, and 24 month intervals.

** Medical record release collected at the time of reporting a health event of interest.

9.5.2. Call Center Data Collection

The DCRI Call Center serves two main functions in this study:

1. To serve as a "rescue" mechanism to minimize incomplete data from non-response and loss to follow-up, and

2. To request medical records for confirmation of the occurrence of safety events of interest.

If a participant does not complete an assessment after a notable period of time, the DCRI Call Center is alerted to contact the participant using participant contact information transferred from the participant-facing web portal into the communications system used by the Call Center. This communications system manages call queues, scheduling, and call processing information. The study data obtained by the DCRI Call Center is entered directly into the web portal. For a given survey assessment, if the participant is not reached after a notable interval of call attempts, the participant data will be considered missing.

At enrollment, participants provide contact information for a proxy to complete assessments in the situation where the participant is non-responsive to survey prompts. If a proxy cannot be reached, the call center will continue to contact the participant for a defined period of time, after which the data for that assessment will be marked as "missing". Future assessments will be targeted for completion according to the planned schedule

9.5.3. Clinical Events Ascertainment (CEA)

The DCRI Call Center requests medical records for all participants reporting a hospitalization or potential safety event of interest at any point during follow-up. The following components of medical records are sought as appropriate:

- Emergency room notes
- Discharge summary/death summary
- Admission history and physical exam
- Progress/clinic/urgent care notes
- Diagnostic tests
- Laboratory reports
- Medication records

Event assessment proceeds through two phases: confirmation and adjudication. As no participant-reported events have yet been adjudicated, only events that have undergone the confirmation process are summarized in this interim report. Future reports will summarize fully adjudicated events. The DCRI Call Center provides a listing of events reported and status of source documents obtained to the DCRI CEA Confirmation Team for review and confirmation of the event. During the confirmation phase, the DCRI CEA Clinical Trial Coordinator or CEA Project Leader reviews the available source documents for discharge diagnosis/diagnostic code consistent with the reported event. During the confirmation stage, each event will be classified as suspected event (unknown), suspected event (not confirmed),

or probable event (diagnosis code consistent with reported AESI is present in source document). DCRI CEA provides the listing with these categories to the DCRI Statistical Group for interim reporting analysis. Probable events will then proceed to clinical event adjudication, where each event will be classified into one of the following categories:

- Negatively adjudicated event
- Positively adjudicated event

The "probable event" category is defined for interim reporting purposes and does not constitute a final classification. The below provides the definitions for final event classifications.

Table 5. Description of Final Event Classifications

#	Category	Description
1	Suspected event (unknown)	Participant reports an AESI on the web portal, but requests for medical records are not successful
2	Suspected event (not confirmed)	Medical records are received, but the diagnosis code list does not indicate an event consistent with the participant report
3	Negatively adjudicated event	Medical records are reviewed by the CEA Committee, but the event does not meet the event definition in the CEA Charter or there is insufficient information
4	Positively adjudicated event	Medical records are reviewed by the CEA Committee, and the event does meet the event definition in the CEA Charter

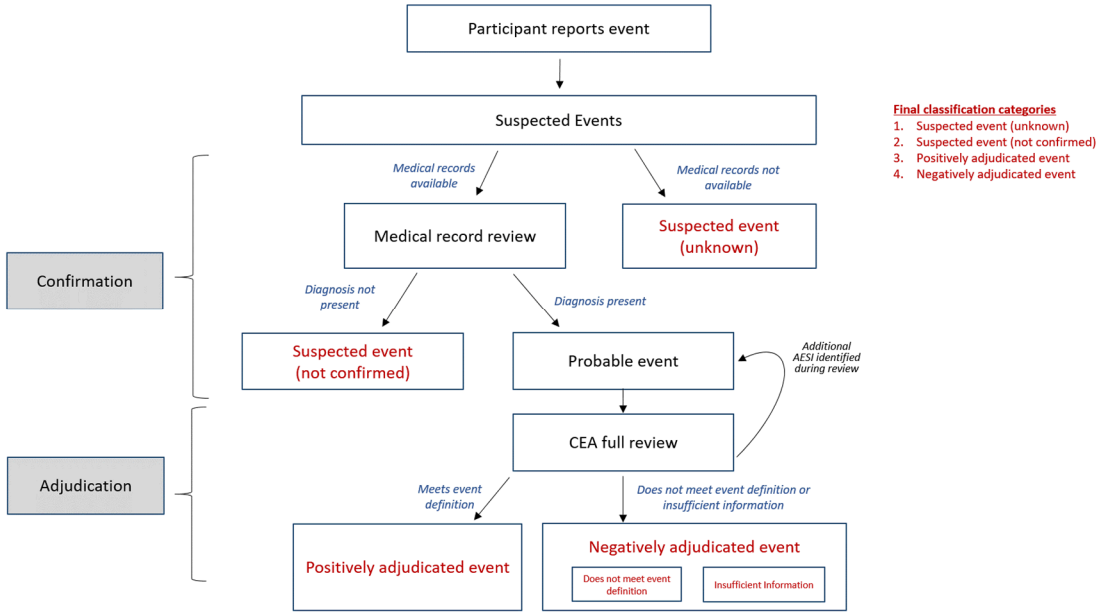
Upon completion of the CEA Charter and CEA adjudication platform system, these events will be adjudicated by CEA physician reviewers trained on the HERO-Together study protocol and CEA charter.

All events classified as "Probable" during the confirmation process will proceed to CEA adjudication. Following confirmation, for each probable event, the DCRI Clinical Event Ascertainment (CEA) group will review the medical records and confirm the occurrence of an event as part of an adjudication process. Safety event definitions will be specified a priori in the clinical events ascertainment (CEA) charter as appropriate. Refer to the below Figure 2 for a summary of this process.

The CEA group is responsible for ongoing analysis of potential safety events of interest or other clinically significant diagnoses and of their adjudication as study endpoints.

The CEA group includes specialists relevant to the safety events of interest, including cardiologists, immunologists, neurologists, and other specialists. Additional details about review procedures will be provided in an adjudication charter.

Figure 2. Confirmation of Safety Events of Interest During Follow-up



9.6. Bias

At the time of data lock, most outcomes consist of participant reported safety events of interest, which may be subject to inaccurate reporting of clinical diagnosis. As events are adjudicated, outcomes will more accurately reflect the clinical definition of the events. Participants electing to participate in the study may be more or less motivated to report events that would bias the event rate in unknown ways. In particular, participants may enroll anytime within 60 days of vaccine and may elect to participate only after experiencing an event.

9.7. Study Size

This study will aim to enroll 20,000 HCWs and members of their families and communities who have received a COVID-19 vaccine for prevention of COVID-19. This study size will help ensure a diverse population of participants with respect to geography, primary work setting, and demographics, and stratification by important subgroups of professional role, age, and region.

As the primary objective is descriptive, this sample size target is designed to ensure adequate precision for a plausible range of AE and SAE rates in the population of vaccinated HCWs

and members of their families and communities. Table 6 displays anticipated precision (95% confidence interval widths) generated using the Clopper-Pearson exact method for a range of safety event rates in a sample of 20,000 participants (overall) and samples of 5,000 and 10,000 participants (potential subgroups and allowing for some exclusions due to attrition). As shown below, precision is high for observed event rates ranging from 0.1% to 20.0%.

Table 6. Estimated Precision of Observed Event Rates*

Observed Rate	Exact 95% Confidence Interval (n=5,000)	Exact 95% Confidence Interval (n=10,000)	Exact 95% Confidence Interval (n=20,000)
0.1%	0.0, 0.23	0.0, 0.18	0.0, 0.15
0.5%	0.32, 0.74	0.37, 0.66	0.41, 0.61
1%	0.74, 1.32	0.81, 1.21	0.87, 1.15
2%	1.63, 2.43	1.73, 2.29	1.81, 2.20
5%	4.41, 5.64	4.58, 5.45	4.70, 5.31
10%	9.18, 10.87	9.42, 10.60	9.59, 10.42
20%	18.90, 21.14	19.22, 20.80	19.45, 20.56

*From the Clopper Pearson Exact Method[3]

The following forecasts for this study are based on experience to date with the HERO registry: a 2% withdrawal rate, a 75% survey completion rate and enrollment of n=200 participants (1%) who would be excluded from primary analyses due to receipt of non-Pfizer-BioNTech vaccine. This would result in withdrawal of n=400 people, exclusion of n=200 participants due to receiving a non-Pfizer-BioNTech vaccine and no or partial questionnaire data for ~4,900 participants. Therefore, it is anticipated that enrollment of approximately 20,000 participants will result in comprehensive questionnaire data for approximately 14,500 participants.

To address the second objective regarding assessment of increased risk of safety events in vaccinated individuals, informal comparisons will made with hospitalization rates among non-vaccinated participants available from the HERO Registry. To formally evaluate whether vaccinated persons experience increased risk, a self-matched comparative analysis will be conducted for feasible events, such as those with an adequate case count and known risk interval. Statistical power to detect various effect sizes assuming a range of background incidence rates in a self-matched comparative analysis will be described in the statistical analysis plan for the final report.

9.8. Data transformation

Detailed methodology for data transformations, particularly complex transformations (e.g., many raw variables used to derive an analytic variable), are documented in the statistical analysis plan (SAP) and associated programming specifications, which are dated, filed and maintained by the sponsor (Appendix 4).

Several key general data processing rules implemented during interim reporting include:

- Analysis preference is given to Call Center records over Participant reported records whenever there is source data from both reporters.
- Events/hospitalizations recorded as happening before the first vaccine date are suppressed from the reporting.
- Unique events or hospitalizations that have multiple reporting for the same date are collapsed into a single unique event or hospitalization for that date.
- CEA event status for a hospitalization date is applied to all events for that hospitalization date.
- Participants who were vaccinated more than 60 days prior to enrollment or after enrollment are not included in analysis.

9.9. Statistical methods

9.9.1. Main summary measures

- Categorical demographics and baseline medical characteristics are summarized using frequencies and percentages.

- Continuous demographics and baseline medical characteristics are summarized by the count of non-missing values, the mean, the standard deviation, the median, 25th and 75th percentiles, and the minimum and maximum values.

- Participant-reported hospitalizations and safety events of interest are summarized by frequencies and proportions and for the total number of reports as well as the number of participants reporting an event.

9.9.2. Main statistical methods

Since this report only includes the participant-reported events, this analysis is confined to the calculation of the summary statistics described in Section 9.9.1. The summary measures are provided across several populations based on vaccine received and days from first vaccination to enrollment.

These include:

- Full Analysis/All Consented Population (ACP)

  The full analysis population is defined as all consented participants. The ACP will be used for secondary analyses and safety evaluations.

- Primary Analysis Safety Population (PASP)

  The Primary Analysis Safety Population is defined as participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled in this study within 10 days of the first dose of the vaccination. The primary objective of the study will be analyzed within the PASP to mitigate the risk of enrolment and disproportionate representation of participants enrolling after experiencing a health event proximate to receipt of vaccine.

- Consented But Not In The Primary Analysis Population (CNPASP)

  Consented but not in Primary Analysis Safety Population includes participants that are members of the ACP, but are not members of the PASP. This population includes the following subsets:

  - Participants who received the Pfizer-BioNTech COVID-19 vaccine, but enrolled more than 10 days after the first dose of the vaccination.

No hypothesis testing occurred in this analysis, and all statements comparing the results between populations are based solely on the summary measures.

9.9.3. Missing values

In general, the processing of missing values is handled in the statistical programming specifications in precise detail. Of note, if the first vaccination date is missing on the vaccination data collection form, then it is obtained from the screening form. Also, if a subject is missing data on the manufacturer of the vaccine received at one dose but it is present at another dose for subjects with a two-dose regimen, then we impute the missing manufacturer from the dose that is present.

9.9.4. Sensitivity analyses

None.

9.9.5. Amendments to the statistical analysis plan

None.

9.10. Quality control

The statistical reporting for this project was conducted under the control of DCRI SOP ST-S-010 as well as the Pfizer Programming Plan per CT24-WI-GL14-RF01. All statistical programming work was specified in advance per DCRI SOP ST-S-009 and verified via the quality control measures per DCRI SOP ST-S-010. The vast majority programing was confirmed through independent repeated double programming. This was done for all derived datasets (e.g., SDTM, ADaM) as well as for the tables, figures, and listings that the report is based on.

9.11. Protection of human subjects

Subject information and consent

Informed consent Appendix 2 was obtained electronically prior to the subject entering the study (before initiation of study protocol-specified procedures); the nature, purpose, and duration of the study was explained to each subject. Each subject was informed that he/she could withdraw from the study at any time and for any reason. Each subject was given sufficient time to consider the implications of the study before deciding whether to participate. Subjects who chose to participate electronically signed an informed consent document.

Independent Ethics Committee (IEC)/Institutional Review Board (IRB)

The final protocol, any amendments, and informed consent documentation were reviewed and approved by an IRB(s) and/or IEC(s) for each site participating in the study. This direct-to-participant study is being conducted by DCRI as the sole site.

Ethical conduct of the study

The study was conducted in accordance with legal and regulatory requirements, as well as with scientific purpose, value and rigor and follow generally accepted research practices described in the Guidelines for Good Pharmacoepidemiology Practices (GPP) issued by the International Society for Pharmacoepidemiology, and Good Epidemiological Practice (GEP) guidelines issued by the International Epidemiological Association (IEA).

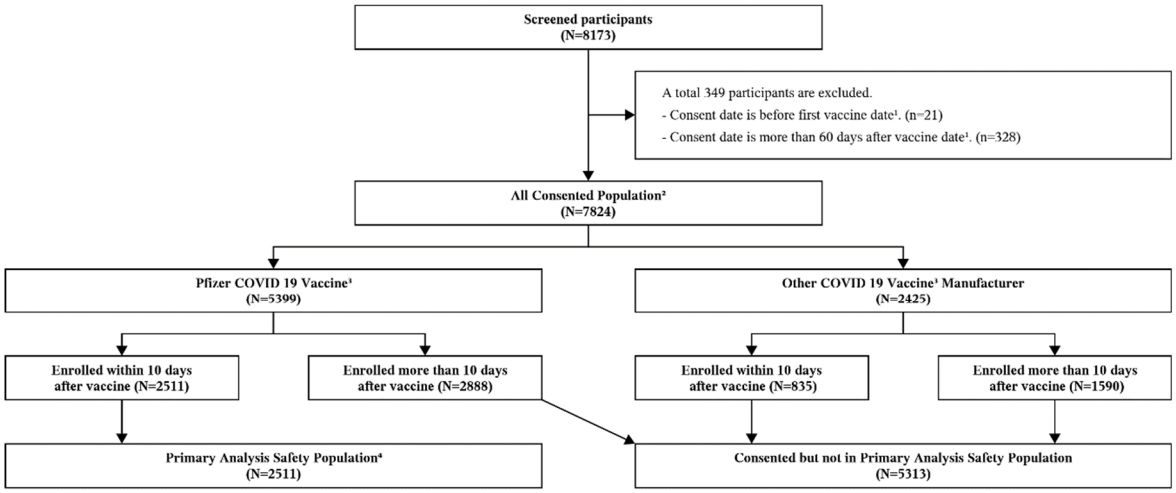
10. RESULTS

At the time of this report, no participant reported events had undergone full adjudication. Participant-reported events for which medical records were available had undergone the confirmation process (see Section 9.5.3). As such, all events in this report should be interpreted with caution.

10.1. Participants

The data for this interim report include subjects enrolling before 29 April 2021, prior to a protocol amendment expanding eligibility criteria to include participants beyond health care workers. The following CONSORT diagram in Figure 3 shows the flow of the subjects through the study.

Figure 3. CONSORT Diagram



1: Vaccine date from 'Screening Form' is used when vaccine date is missing in 'COVID-19 Vaccine Dose 1 Form'.
2: All Consented Population is defined as all enrolled participants.
3: For vaccines with two doses; missing data on manufacturer for one dose is imputed to non-missing manufacturer from the other dose.
4: Primary Analysis Safety Population is defined as all enrolled participants who recieved the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.

Survey completion rates for the applicable time period of this interim report are described in Table 7, Completion rates for analysis populations. Of note, survey completion rates are reflective of the fact that the study is ongoing and participants may not have reached a survey point. Additionally participants were eligible to enroll up to 60 days after vaccination and may not have required a survey, e.g., at week 1.

Table 7. Completion rates for analysis populations

	All Consented Population (ACP) (N=7824)		Primary Analysis Safety Population (PASP) (N=2511)		Consented but not in Primary Analysis Safety Population (CNPASP) (N=5313)	
Participants Completed Survey at	**Expected**	**Completed**	**Expected**	**Completed**	**Expected**	**Completed**
Week 1	3767 / 7824 (48.1%)	709 / 3767 (18.8%)	2511 / 2511 (100%)	446 / 2511 (17.8%)	1256 / 5313 (23.6%)	263 / 1256 (20.9%)
Week 2	4515 / 7824 (57.7%)	1700 / 4515 (37.7%)	2510 / 2511 (>99.0%)	871 / 2510 (34.7%)	2005 / 5313 (37.7%)	829 / 2005 (41.3%)
Week 4	6677 / 7824 (85.3%)	3763 / 6677 (56.4%)	2502 / 2511 (>99.0%)	1570 / 2502 (62.7%)	4175 / 5313 (78.6%)	2193 / 4175 (52.5%)
Week 8	7685 / 7824 (98.2%)	4522 / 7685 (58.8%)	2478 / 2511 (98.7%)	1609 / 2478 (64.9%)	5207 / 5313 (98.0%)	2913 / 5207 (55.9%)
Week 12	5910 / 7824 (75.5%)	5319 / 5910 (90.0%)	2175 / 2511 (86.6%)	1946 / 2175 (89.5%)	3735 / 5313 (70.3%)	3373 / 3735 (90.3%)

Source: Table 15.5.2

Note: Expected completion is based on time from vaccination date. Many of the first participants to enroll did so very close to the end of the inclusion criteria. As such, the window between enrollment and completion of the first set of surveys was very short, and many were not able to complete those surveys within the time allotted for rescue. This resulted in depressed Week 1 and Week 2 survey completion rates

10.2. Descriptive data

The demographic characteristics of the ACP and PASP can be found in Table 15.1.1, Figure 4 and Figure 5. Some observations from the demographics table include:

- The PASP subset has less missing sex, race, and ethnicity data than the broader ACP.
- About 75% of the overall ACP and subset PASP and CNPASP populations are between 30 and 60 years of age (76.9% of ACP, 80.1% of PASP, and 75.4% of CNPASP)
- Most participants are female in the overall ACP (66.1%) and the subset PASP (70.3%)
- Most participants in the overall ACP (72.1%) and the PASP subset reported White race.

- Most participants in the overall ACP (74.1%) and PASP subset (82.0%) identified as Not Hispanic or Latino ethnicity.

Other descriptive findings include:

- The proportion of participants who withdrew from the study is less than 2% in the overall ACP (1.2%) and in the PASP (1.8%) (see Table 15.5.1). These is less than the estimated forecast of 2% described in the protocol (see Protocol Section 9.5). Most participants who withdrew cited "other" reason (60%). The most frequently cited specific reason for subject withdrawal was due to the study being too time-intensive (38%).

- The top four medical histories are: obesity/overweight (PASP: 23.6%, ACP: 20.9%), hypertension (PASP: 11.4%, ACP: 11.3%), asthma (PASP: 11.1%, ACP: 10.7%), and previous COVID-19 diagnosis (PASP: 8.8%, ACP: 8.3%) (see Table 15.1.2.1) When looking at these four histories by vaccination manufacturer, slightly higher proportions of these histories were observed in the Pfizer-BioNTech vaccine group compared with the other vaccines group (see Table 15.1.2.2).

- The proportions of baseline pregnancy and 6 month prior vaccination status were also numerically similar for the two populations (PASP: 81.1%, ACP: 78.4%) (see Table 15.1.4).

Figure 4. Distribution of Age in the PASP and CNPASP

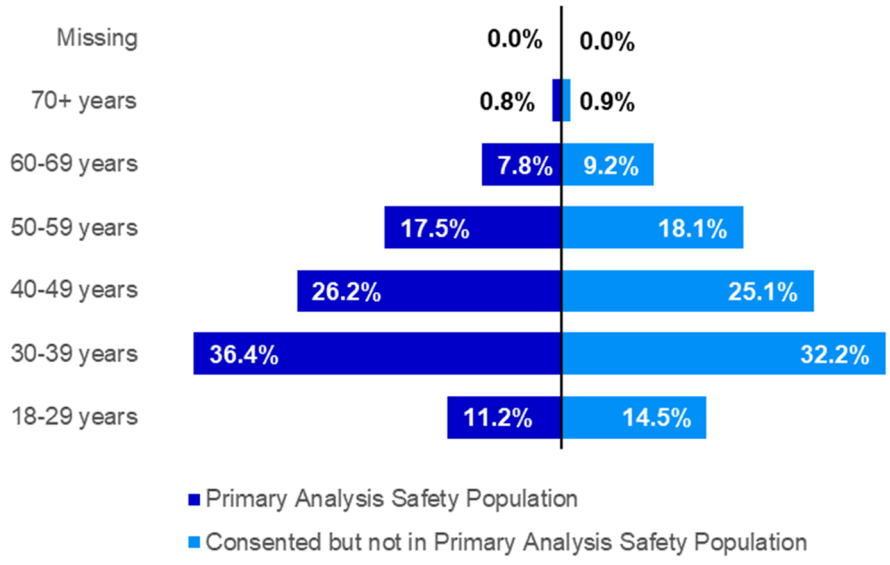
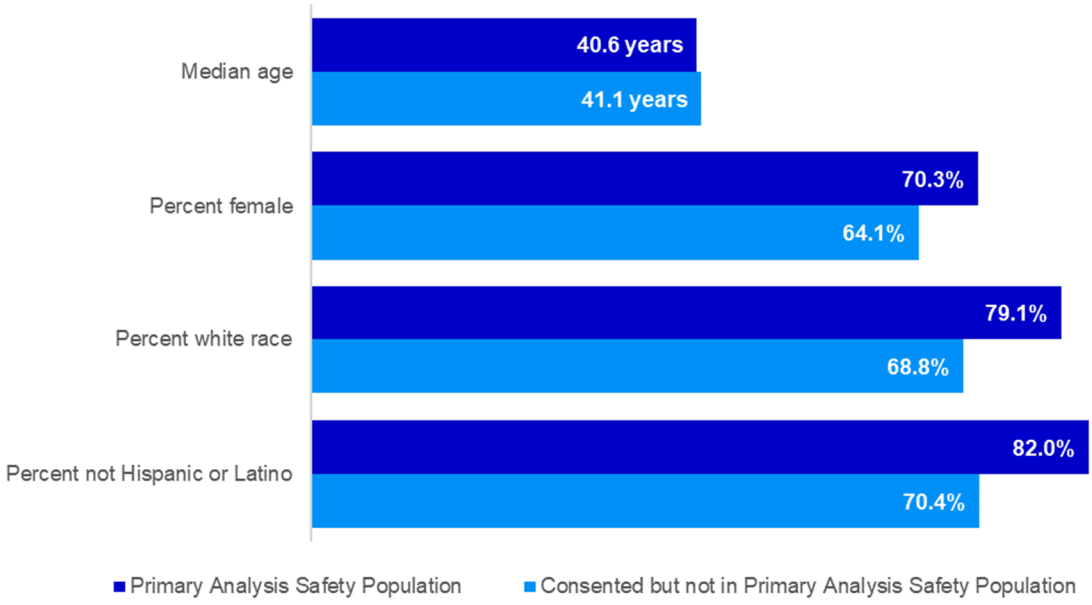


Figure 5. Baseline Demographics of the PASP and CNPASP



10.3. Main results

Hospitalization reported by participants for the overall ACP and PASP and CNPASP subsets are reported. Additional details are provided for the PASP, the population of interest for the primary objective of the study. At the time of this report, no participant reported events had undergone full adjudication. However, any participant-reported events for which medical records had been received have undergone the confirmation process (Section 9.5.3). As such, event counts in this interim report are likely an underrepresentation of the final count and should be interpreted with caution.

Participants reported unplanned hospitalization any time after receipt of 1 dose of COVID-19 vaccine for subjects enrolled (as of 29 April 2021).

Primary Analysis Safety Population

- Fewer than 1% (16/2511) of participants reported hospitalization (see Table 15.3.1.1).
- Hospitalization was reported in 5.9% (6/101) of participants who also reported that they or their partner were pregnant at the time of vaccination (see Table 15.3.1.4)
- The age group reporting the highest percentage of hospitalizations is 30-39 year old participants and the rate is <1% (7/915) (see Table 15.3.1.5)

- Reported hospitalizations were <1% (1/181) in patients identifying as immunocompromised (see Table 15.3.1.6)

Full Analysis / All Consented Population

- Fewer than 1% (63/7824) of participants reported hospitalization (see Table 15.3.1.1).

Consented But Not In The Primary Analysis Population

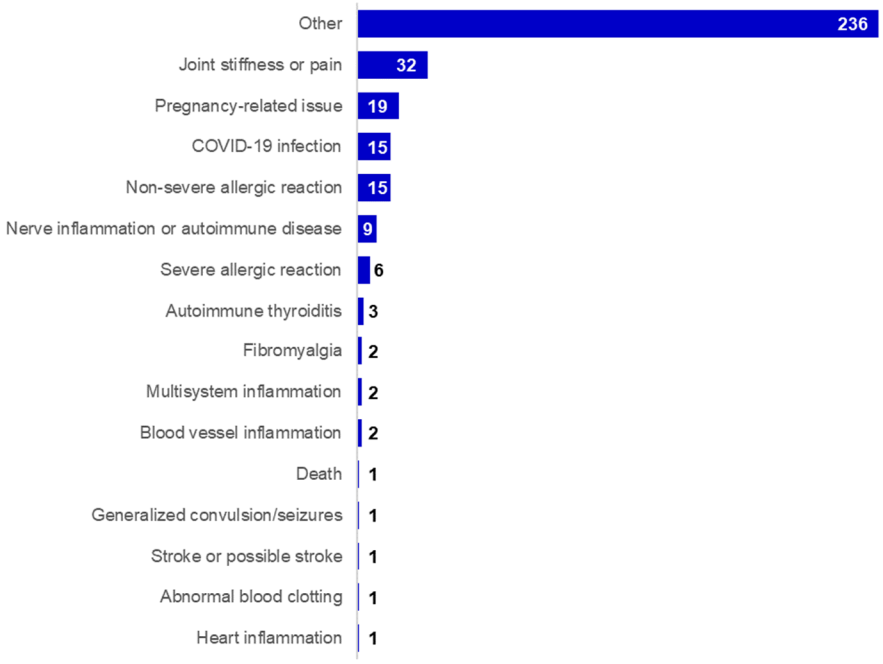
- Fewer than 1% (47/5313) of participants reported hospitalization (see Table 15.3.1.1).

Participant reported Safety Event of Interest any time after receipt of at least 1 dose of COVID-19 through 29 April 2021:

Primary Analysis Safety Population

- A safety event of interest was reported in 12.7% (320/2511) of participants (see Table 15.3.2.1.1).
- As shown in Figure 6, the top 5 self-reported safety events of interest were:
  1. Other (9.4%; 236/2511) (see Table 15.3.2.1.1)
  2. Joint stiffness or pain (e.g., arthralgia, arthritis) (1.3% ; 32/2511) (see Table 15.3.2.1.1)
  3. Pregnancy-related issue (<1%; 19/2511) (see Table 15.3.2.1.1)
  4. Non-severe allergic reaction (<1%; 15/2511) (see Table 15.3.2.1.1)
  5. COVID-19 infection (<1%; 15/2511) (see Table 15.3.2.1.1)

Figure 6. Counts of Participants who had Adverse Events of Special Interest in the PASP



- One death was reported but it was not reported as COVID-19 related (see Listing 7.7.2).
- Approximately 16.8% (17/101) of participants and their partners reporting pregnancy reported any safety events of interest (see Table 15.3.2.1.4)
- The proportion of participants reporting at least one safety event in this population were 21.5% (39/181) for immunocompromised participants and 12.1% for participants not identifying as immunocompromised (281/2330) (see Table 15.3.2.1.6)
- The age group with highest proportion (13.6%; 124/915) of participants reporting at least one safety event is 30-39 year old (see Table 15.3.2.1.5)

Full Analysis / All Consented Population

- At least one safety event of interest after any dose of COVID-19 vaccine was reported by 11.9% (928/7824) of participants (see Table 15.3.2.1.1).
- Two deaths were reported, but they were not reported as COVID-19 related (see Listing 7.7.2).

Consented But Not In The Primary Analysis Population

- 11.4% (608/5313) of participants reported a safety event of interest (see Table 15.3.2.1.1).
- One death was reported, but it was not reported as COVID-19 related (see Listing 7.7.2).

10.4. Other analyses

None.

10.5. Safety events / adverse reactions

The primary objective of this study is to describe the incidence rates of safety events of interest and other clinically significant events among US healthcare workers, their families, and members of their communities who are vaccinated with the Pfizer-BioNTech COVID-19 vaccine following Emergency Use Authorization. At the time of the data cut for this interim report, only participant-reported information is available and these events have not undergone full adjudication. Per the statistical analysis plan, only the proportion of participants who report safety events of interest are reported. Rates will be reported in future reports as data on adjudicated events mature. All event tables are summarized in Section 10.3.

11. DISCUSSION

11.1. Key results

Data in this report are limited to the population of healthcare workers enrolled prior to the expansion to family and community members.

This interim report presents descriptive statistics on the demographic and clinical characteristics of the first 7824 participants enrolled in HERO-Together between 17 December 2020 and 29 April 2021. Given the theoretical potential for preferential self-enrollment of individuals experiencing a safety event (or early symptoms of a safety event), the primary analysis safety population was limited to those who received their first dose of the Pfizer-BioNTech COVID-19 vaccine within 10 days (n=2511). The median days since vaccination among participants in this group enrolled as of 29 April 2021 was just 3 days, supporting the characterization of this safety population as prospective and minimizing the potential for bias due to selective over-enrollment of higher risk participants at later time periods.

The HERO-Together study was designed to maximize comprehensive capture of safety information over time through a secure, participant-facing web portal with periodic reminder emails and a centralized call center to minimize missed surveys and reduce loss-to-follow-up. For example, approximately three-quarters of the consented population were expected to complete the week 12 survey as of 29 April 2021; of these, approximately 90% of participants completed surveys as expected. HERO-Together withdrawal for the all-

consented population was also low (1.2%), with the primary reported reasons for withdrawal including "other" (58.9%) and "too-time intensive" (37.8%).

Population demographics reflect the healthcare worker inclusion criterion, the online nature of the study and the requirement for vaccination prior to enrollment. Consistent with participants in the HERO Registry, the population of HERO-Together is primarily white, female, and under the age of 50.[4] A recent report from the US Department of Health and Human Services, Health Resources and Services Administration suggests that the demographic distribution of participants may in part be a function of professional role.[5] Nationally, men represent approximately 52.8% of the US healthcare worker workforce, with greater male representation among physicians (65.1%) and EMTs/Paramedics (68.5%), and less representation among registered nurses (9.6%) and medical assistants (7.8%). Given that the HERO Registry has greater representation from registered nurses and medical assistants,[5] the predominance of female gender is consistent with expectations. Additionally, Black/African American healthcare workers represent 11.6% of the national healthcare worker population, but only 3.0% of the consented HERO-Together population. A number of factors, including lower initial national vaccination rates among racial/ethnic minority populations and lower representation of non-white participants in the HERO Registry, may have contributed to lower enrollment of Black/African American participants.

Prevalence of common cardiovascular risk factors, including hypertension, obesity, and diabetes mellitus, was relatively low, [6,7] likely in part due to the younger age of study participants, and that they are generally healthy workers. Fewer than 1% of participants reported a prior history of significant cardiovascular disease, such as heart failure, stroke, or myocardial infarction. However, prevalence of both asthma and autoimmune disease were comparable to current estimates of general population prevalence.[8,9] Pregnant participants comprised 3.4% of all HERO-Together participants with complete information on pregnancy, with the majority reporting receipt of other vaccines in the 6 months prior to the first COVID-19 vaccine dose. The proportion of participants reporting a previous diagnosis of COVID-19 at enrollment was 8.4%, in line with cumulative incidence estimates for total confirmed cases in the US.[10]

Participant self-reported safety event data collected as of 29 April 2021 have not yet undergone full adjudication. Given the participant-reported nature of this information, these events should be regarded as preliminary pending full adjudication (review of source documentation to determine whether standard event definitions are met). As of 29 April 2021, the participant reported hospitalization proportion was 0.8% in the total consented population and 0.6% in the PASP. Based on the initial confirmation process, 25.4% of participant self-reported events resulted in classification as "probable" based on presence of diagnostic information in source materials that was consistent with a safety event of interest. This proportion was similar in the PASP, though the number of probable hospitalized self-reported events to date was small (n=4). In the total consented population, 11.5% of participants reported a non-hospitalized AESI. Of these, the majority were still pending medical record review and confirmation; however, 24.8% were classified as suspected, and

1.0% were classified as probable in the total consented population. Proportions were similar in the primary consented safety population.

The most commonly reported AESIs in the total study population included joint stiffness or pain (1.4%), pregnancy-related issue (0.7%), non-severe allergic reaction (0.6%), and COVID-19 infection (0.5%). The most commonly reported AESIs in the PASP were similar in magnitude, with 1.3% reporting joint stiffness or pain, 0.8% pregnancy-related issue, 0.6% non-severe allergic reaction, and 0.6% COVID-19 infection. Approximately 8.6% of participants reported an event classified as "other" in the total population, with a comparable proportion in the primary safety population (9.4%). Source documentation will be requested for these participant-reported events to determine occurrence of any AESIs consistent with study definitions.

11.2. Limitations

This study is intended to provide comprehensive real-world safety information about the Pfizer-BioNTech COVID-19 vaccine in US healthcare workers. To date, the number of participant-reported events was low for most pre-specified AESIs, and all events were still in the process of full adjudication. Prior studies have demonstrated bias in participant-reported event information. Therefore, all reported AESIs in this report should be interpreted with caution, particularly given the large number of reported AESIs collected and the multiple subgroups of interest. Additionally, allowing for enrollment several days or weeks following vaccination may introduce the potential for preferential self-enrollment of individuals experiencing a safety event (or early symptoms of a safety event). As a result, the primary safety population is restricted individuals enrolling within 10 days of first vaccination dose.

As participants enroll voluntarily, the generalizability of study results is a function of the diversity of the enrolled sample. While the inclusion criteria for HERO-Together are intentionally broad, the racial/ethnic diversity of the initial population is lower than anticipated. Future efforts to enhance diversity will include recruitment efforts that preferentially target racial/ethnic minority populations. Finally, this observational study is susceptible to confounding due to measured and unmeasured confounders. Future analyses of adjudicated events will implement bias reduction strategies including use of standardized event definitions and self-matched comparative analyses.

11.3. Interpretation

This report includes interim descriptive analyses of participant-reported outcomes after vaccination which may not be due to vaccination itself. Given that data collection is underway and lack of adjudicated event availability at the time of this first interim report and the known limitations of participant-reported event information, all events in this report should be interpreted with caution. Final analyses will use self-matched controls and subgroup analyses of adjudicated events to inform risk-benefit assessment of the Pfizer-BioNTech COVID-19 vaccine in this real-world population.

11.4. Generalizability

As described in Section 11.1 Key Results, the distribution of participant characteristics in the enrolled population to date is consistent with expectations, given the HERO Registry population and patterns of early vaccination uptake. The inclusion criteria for HERO-Together (including the definition of "healthcare worker" as anyone who works in a setting where people receive healthcare) are intentionally broad. Additionally, use of an online web portal for screening, consent, and data collection enables study participation for a geographically diverse population, and withdrawal rates to date are low, minimizing potential selection bias. However, racial/ethnic diversity of the initial population is lower than anticipated.

12. OTHER INFORMATION

Not applicable.

13. CONCLUSIONS

The initial study population enrolled in HERO-Together is primarily white, female, and had a low comorbidity burden at baseline. The proportion of participants reporting safety events of interest, including hospitalizations, were low and most commonly included joint stiffness or pain, pregnancy-related issue, non-severe allergic reaction, and COVID-19 infection. Future analyses of adjudicated events will provide additional insight into the rates of safety events in vaccinated persons and any increased risk of certain safety events of interest after vaccination overall and among subpopulations of interest.

14. REFERENCES

1. Brighton Collaboration Priority List of Adverse Events of Special Interest: COVID-19. Accessed March 4, 2021. Available: https://brightoncollaboration.us/priority-list-aesi-covid/.

2. Shimabukuro T. "Enhanced safety monitoring for COVID-19 vaccines in early phase vaccination." September 22, 2020. Available: https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2020-09/COVID-03-Shimabukuro.pdf.

3. C.J. Clopper ESP. The Use of Confidence or Fiducial Limits Illustrated in the Case of the Binomial. Biometrika, Volume 26, Issue 4, December 1934, Pages 404–413, https://doi.org/10.1093/biomet/26.4.404.

4. Forrest CB, Xu H, Thomas LE, et al. Impact of the Early Phase of the COVID-19 Pandemic on US Healthcare Workers: Results from the HERO Registry. J Gen Intern Med. 2021;36(5):1319-1326.

5. U.S. Department of Health and Human Services Health Resources and Services Administration. Sex, Race, and Ethnic Diversity of U.S. Health Occupations (2011-2015). August 2017. Available: https://bhw.hrsa.gov/sites/default/files/bureau-health-workforce/data-research/diversity-us-health-occupations.pdf.

6. Virani SS, Alonso A, Aparicio HJ, et al. Heart Disease and Stroke Statistics-2021 Update: A Report From the American Heart Association. Circulation. 2021;143(8):e254-e743.

7. Centers for Disease Control and Prevention. Underlying Cause of Death, 1999–2018. CDC WONDER Online Database. Atlanta, GA: Centers for Disease Control and Prevention; 2018. Accessed March 12, 2020.

8. Centers for Disease Control and Prevention. Most Recent National Asthma Data. 2019. Available: https://www.cdc.gov/asthma/most_recent_national_asthma_data.htm.

9. National Institutes of Health Autoimmune Diseases Coordinating Committee. "Progress in Autoimmune Disease Research". [Report to Congress]. Available: https://www.niaid.nih.gov/sites/default/files/adccfinal.pdf.

10. Johns Hopkins University & Medicine Coronavirus Resource Center. COVID-19 United States Cases by County. Accessed May 25, 2021. Available: https://coronavirus.jhu.edu/us-map.

15. LIST OF SOURCE TABLES AND FIGURES

Table 15.5.1
BNT162b2 Protocol C4591008
Disposition and Retention

	All Consented Population[1] (N = 7824)	Primary Analysis Safety Population[2] (N = 2511)	Consented but not in Primary Analysis Safety Population (N = 5313)
Participants Completed The Study	0 / 7824 (0%)	0 / 2511 (0%)	0 / 5313 (0%)
Participants Alive And Remaining In The Study	7731 / 7824 (98.8%)	2466 / 2511 (98.2%)	5265 / 5313 (>99.0%)
Days In The Study Since 1st Vaccine[3]			
N	7731	2466	5265
Mean (SD)	130.6 (19.42)	134.8 (17.64)	128.6 (19.90)
Median (Q1, Q3)	136.0 (126.0, 143.0)	141.0 (132.0, 145.0)	134.0 (124.0, 141.0)
Min, Max	14, 176	14, 155	14, 176
Days Between 1st Vaccine And Enrollment			
N	7824	2511	5313
Mean (SD)	20.7 (18.09)	3.6 (2.74)	28.7 (16.62)
Median (Q1, Q3)	16.0 (4.0, 34.0)	3.0 (1.0, 5.0)	28.0 (15.0, 42.0)
Min, Max	1, 61	1, 11	1, 61
Days Between 1st Vaccine And 2nd Vaccine[3]			
N	6035	2133	3902
Mean (SD)	24.3 (5.62)	22.7 (4.72)	25.2 (5.88)
Median (Q1, Q3)	22.0 (22.0, 28.0)	22.0 (22.0, 23.0)	23.0 (22.0, 29.0)
Min, Max	2, 109	2, 92	2, 109

1: All Consented Population is defined as all enrolled participants.
2: Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.
3: Vaccination dates are based on participants reported dates.
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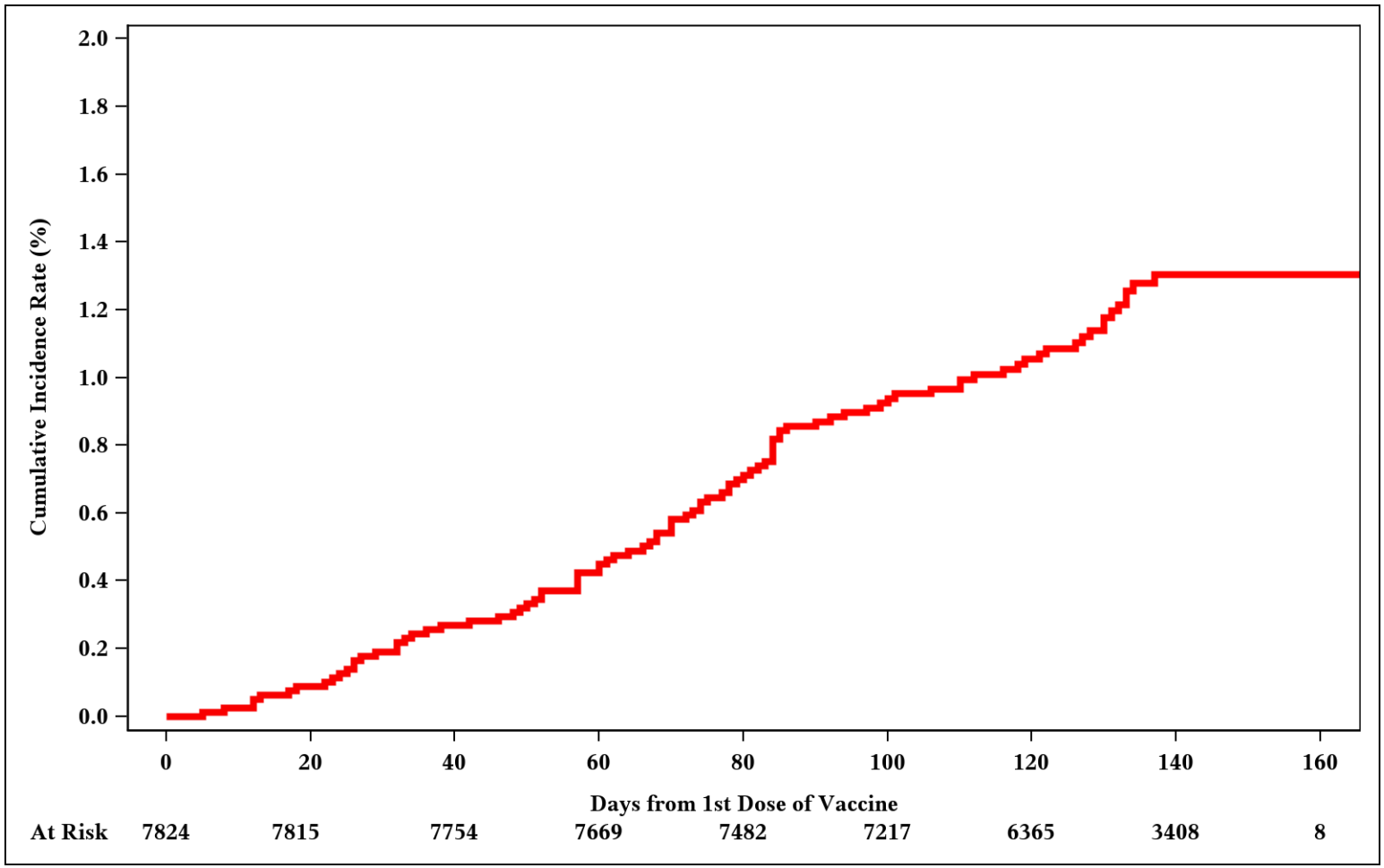
Table 15.5.1
BNT162b2 Protocol C4591008
Disposition and Retention

	All Consented Population[1] (N = 7824)	Primary Analysis Safety Population[2] (N = 2511)	Consented but not in Primary Analysis Safety Population (N = 5313)
Participants Who Did Not Complete The Study	93 / 7824 (1.2%)	45 / 2511 (1.8%)	48 / 5313 (<1.0%)
Death	2 / 93 (2.2%)	1 / 45 (2.2%)	1 / 48 (2.1%)
Cause Of Death Related To COVID-19	0 / 2 (0%)	0 / 1 (0%)	0 / 1 (0%)
Lost To Follow Up	0 / 93 (0%)	0 / 45 (0%)	0 / 48 (0%)
Withdrawal By Subject	90 / 93 (96.8%)	44 / 45 (97.8%)	46 / 48 (95.8%)
Study Terminated By Sponsor	0 / 93 (0%)	0 / 45 (0%)	0 / 48 (0%)
Other	1 / 93 (1.1%)	0 / 45 (0%)	1 / 48 (2.1%)
Reason For Withdrawal By Subjects			
Technical Problems	0 / 90 (0%)	0 / 44 (0%)	0 / 46 (0%)
Too Time Intensive	34 / 90 (37.8%)	17 / 44 (38.6%)	17 / 46 (37.0%)
Illness	0 / 90 (0%)	0 / 44 (0%)	0 / 46 (0%)
Non-compliance	0 / 90 (0%)	0 / 44 (0%)	0 / 46 (0%)
Safety	3 / 90 (3.3%)	1 / 44 (2.3%)	2 / 46 (4.3%)
Behavioral	0 / 90 (0%)	0 / 44 (0%)	0 / 46 (0%)
Administrative Reasons	0 / 90 (0%)	0 / 44 (0%)	0 / 46 (0%)
Other	53 / 90 (58.9%)	26 / 44 (59.1%)	27 / 46 (58.7%)

1: All Consented Population is defined as all enrolled participants.
2: Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.
3: Vaccination dates are based on participants reported dates.

Figure 15.5.1.1
BNT162b2 Protocol C4591008
Cumulative Rate of Study Discontinuation – All Consented Population



All Consented Population is defined as all enrolled participants.
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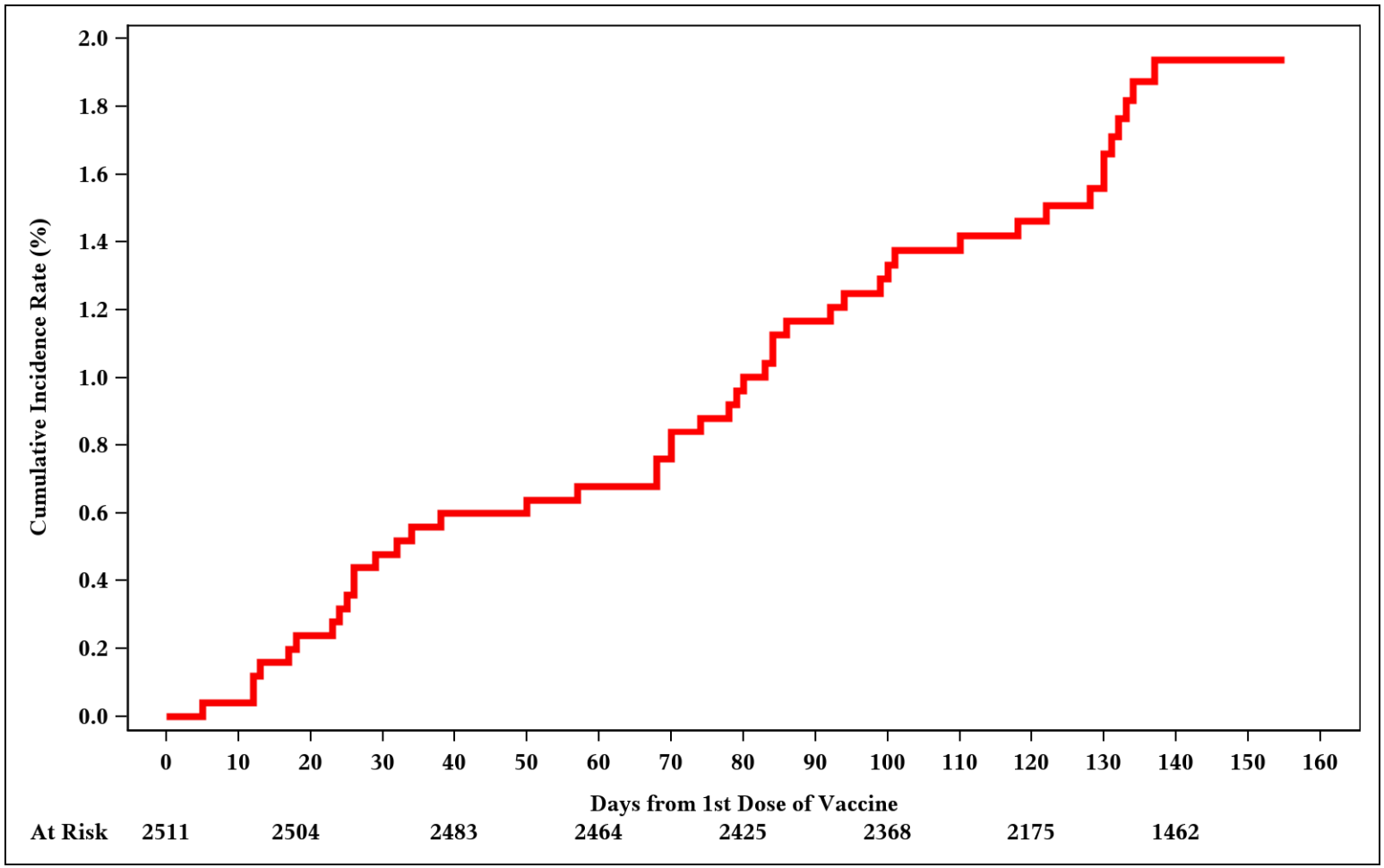
Generated from /dcri/ct/hero_together/figures/f_disc.sas on 24MAY2021 12:45

Figure 15.5.1.2
BNT162b2 Protocol C4591008
Cumulative Rate of Study Discontinuation – Primary Analysis Safety Population



Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.
PFIZER CONFIDENTIAL SDTM Creation: 11MAY2021:07:31:19 Data Cutoff: 29APR2021 Source Data: ADSL
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Table 15.5.2
BNT162b2 Protocol C4591008
Visit Completion

	All Consented Population[1] (N=7824)		Primary Analysis Safety Population[2] (N=2511)		Consented but not in Primary Analysis Safety Population (N=5313)	
Participants Completed Survey at[3]	**Expected**	**Completed**	**Expected**	**Completed**	**Expected**	**Completed**
Week 1	3767 / 7824 (48.1%)	709 / 3767 (18.8%)	2511 / 2511 (100%)	446 / 2511 (17.8%)	1256 / 5313 (23.6%)	263 / 1256 (20.9%)
Week 2	4515 / 7824 (57.7%)	1700 / 4515 (37.7%)	2510 / 2511 (>99.0%)	871 / 2510 (34.7%)	2005 / 5313 (37.7%)	829 / 2005 (41.3%)
Week 4	6677 / 7824 (85.3%)	3763 / 6677 (56.4%)	2502 / 2511 (>99.0%)	1570 / 2502 (62.7%)	4175 / 5313 (78.6%)	2193 / 4175 (52.5%)
Week 8	7685 / 7824 (98.2%)	4522 / 7685 (58.8%)	2478 / 2511 (98.7%)	1609 / 2478 (64.9%)	5207 / 5313 (98.0%)	2913 / 5207 (55.9%)
Week 12	5910 / 7824 (75.5%)	5319 / 5910 (90.0%)	2175 / 2511 (86.6%)	1946 / 2175 (89.5%)	3735 / 5313 (70.3%)	3373 / 3735 (90.3%)
Month 6	0	0	0	0	0	0
Month 9	0	0	0	0	0	0
Month 12	0	0	0	0	0	0
Month 18	0	0	0	0	0	0
Month 24	0	0	0	0	0	0

1: All Consented Population is defined as all enrolled participants.
2: Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.
3: For the June 2021 interim report, we had 19 records at Month 12 and 1 record at Month 18 which were impossible and that have been suppressed because they were created by interviewer error.

Table 15.1.1
BNT162b2 Protocol C4591008
Baseline Demographics

Participant Characteristics	All Consented Population[1] (N = 7824)	Primary Analysis Safety Population[2] (N = 2511)	Consented but not in Primary Analysis Safety Population (N = 5313)
Age At First Dose In Years			
N	7823	2511	5312
Mean (SD)	42.7 (11.63)	42.6 (11.16)	42.7 (11.85)
Median (Q1, Q3)	40.9 (33.6, 51.1)	40.6 (33.8, 50.5)	41.1 (33.3, 51.4)
Min, Max	18, 121	19, 85	18, 121
Missing	1	0	1
Age At First Dose In Years			
18 - 29	1051 / 7824 (13.4%)	282 / 2511 (11.2%)	769 / 5313 (14.5%)
30 - 39	2625 / 7824 (33.6%)	915 / 2511 (36.4%)	1710 / 5313 (32.2%)
40 - 49	1989 / 7824 (25.4%)	657 / 2511 (26.2%)	1332 / 5313 (25.1%)
50 - 59	1402 / 7824 (17.9%)	439 / 2511 (17.5%)	963 / 5313 (18.1%)
60 - 69	688 / 7824 (8.8%)	197 / 2511 (7.8%)	491 / 5313 (9.2%)
70 And Above	68 / 7824 (<1.0%)	21 / 2511 (<1.0%)	47 / 5313 (<1.0%)
Missing	1 / 7824 (<1.0%)	0	1 / 5313 (<1.0%)
Sex			
Female	5170 / 7824 (66.1%)	1766 / 2511 (70.3%)	3404 / 5313 (64.1%)
Male	1243 / 7824 (15.9%)	481 / 2511 (19.2%)	762 / 5313 (14.3%)
Undifferentiated	4 / 7824 (<1.0%)	1 / 2511 (<1.0%)	3 / 5313 (<1.0%)
Missing	1407 / 7824 (18.0%)	263 / 2511 (10.5%)	1144 / 5313 (21.5%)

1: All Consented Population is defined as all enrolled participants.
2: Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.

Table 15.1.1
BNT162b2 Protocol C4591008
Baseline Demographics

Participant Characteristics	All Consented Population[1] (N = 7824)	Primary Analysis Safety Population[2] (N = 2511)	Consented but not in Primary Analysis Safety Population (N = 5313)
Race			
White	5644 / 7824 (72.1%)	1987 / 2511 (79.1%)	3657 / 5313 (68.8%)
Black Or African American	191 / 7824 (2.4%)	48 / 2511 (1.9%)	143 / 5313 (2.7%)
American Indian Or Alaska Native	18 / 7824 (<1.0%)	8 / 2511 (<1.0%)	10 / 5313 (<1.0%)
Asian	340 / 7824 (4.3%)	116 / 2511 (4.6%)	224 / 5313 (4.2%)
Native Hawaiian Or Other Pacific Islander	6 / 7824 (<1.0%)	2 / 2511 (<1.0%)	4 / 5313 (<1.0%)
Multiple	126 / 7824 (1.6%)	51 / 2511 (2.0%)	75 / 5313 (1.4%)
Not Reported	71 / 7824 (<1.0%)	26 / 2511 (1.0%)	45 / 5313 (<1.0%)
Unknown	21 / 7824 (<1.0%)	10 / 2511 (<1.0%)	11 / 5313 (<1.0%)
Missing	1407 / 7824 (18.0%)	263 / 2511 (10.5%)	1144 / 5313 (21.5%)
Ethnicity			
Hispanic Or Latino	373 / 7824 (4.8%)	108 / 2511 (4.3%)	265 / 5313 (5.0%)
Not Hispanic Or Latino	5797 / 7824 (74.1%)	2059 / 2511 (82.0%)	3738 / 5313 (70.4%)
Not Reported	192 / 7824 (2.5%)	67 / 2511 (2.7%)	125 / 5313 (2.4%)
Unknown	55 / 7824 (<1.0%)	14 / 2511 (<1.0%)	41 / 5313 (<1.0%)
Missing	1407 / 7824 (18.0%)	263 / 2511 (10.5%)	1144 / 5313 (21.5%)

1: All Consented Population is defined as all enrolled participants.
2: Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.

Table 15.1.2.1
BNT162b2 Protocol C4591008
Baseline Medical History (Participant Reported)

Reported Term	All Consented Population[1] (N = 7824)	Primary Analysis Safety Population[2] (N = 2511)	Consented but not in Primary Analysis Safety Population (N = 5313)
Hypertension (High Blood Pressure)	888 / 7824 (11.3%)	286 / 2511 (11.4%)	602 / 5313 (11.3%)
Diabetes Mellitus	234 / 7824 (3.0%)	86 / 2511 (3.4%)	148 / 5313 (2.8%)
Obesity/Overweight	1633 / 7824 (20.9%)	593 / 2511 (23.6%)	1040 / 5313 (19.6%)
Prior Heart Attack	20 / 7824 (<1.0%)	6 / 2511 (<1.0%)	14 / 5313 (<1.0%)
Heart Failure/Cardiomyopathy	27 / 7824 (<1.0%)	7 / 2511 (<1.0%)	20 / 5313 (<1.0%)
Coronary Artery Disease	43 / 7824 (<1.0%)	16 / 2511 (<1.0%)	27 / 5313 (<1.0%)
Prior Stroke Or Mini-stroke (TIA)	32 / 7824 (<1.0%)	10 / 2511 (<1.0%)	22 / 5313 (<1.0%)
Peripheral Arterial Or Vascular Disease	25 / 7824 (<1.0%)	6 / 2511 (<1.0%)	19 / 5313 (<1.0%)
Chronic Obstructive Pulmonary Disease (COPD)	13 / 7824 (<1.0%)	3 / 2511 (<1.0%)	10 / 5313 (<1.0%)
Asthma	840 / 7824 (10.7%)	279 / 2511 (11.1%)	561 / 5313 (10.6%)
Smoking	182 / 7824 (2.3%)	50 / 2511 (2.0%)	132 / 5313 (2.5%)
Chronic Kidney Disease	26 / 7824 (<1.0%)	10 / 2511 (<1.0%)	16 / 5313 (<1.0%)
Cancer (Localized)	126 / 7824 (1.6%)	44 / 2511 (1.8%)	82 / 5313 (1.5%)
Cancer (Metastatic)	13 / 7824 (<1.0%)	5 / 2511 (<1.0%)	8 / 5313 (<1.0%)
Lymphoma	12 / 7824 (<1.0%)	0	12 / 5313 (<1.0%)
Leukemia	6 / 7824 (<1.0%)	1 / 2511 (<1.0%)	5 / 5313 (<1.0%)
Liver Disease	29 / 7824 (<1.0%)	16 / 2511 (<1.0%)	13 / 5313 (<1.0%)
Peptic Ulcer Disease	27 / 7824 (<1.0%)	9 / 2511 (<1.0%)	18 / 5313 (<1.0%)
Connective Tissue Disease	50 / 7824 (<1.0%)	18 / 2511 (<1.0%)	32 / 5313 (<1.0%)
Autoimmune Disease	423 / 7824 (5.4%)	140 / 2511 (5.6%)	283 / 5313 (5.3%)
Organ Transplant	6 / 7824 (<1.0%)	3 / 2511 (<1.0%)	3 / 5313 (<1.0%)
HIV/AIDS	13 / 7824 (<1.0%)	4 / 2511 (<1.0%)	9 / 5313 (<1.0%)
Previous COVID-19 Diagnosis	650 / 7824 (8.3%)	221 / 2511 (8.8%)	429 / 5313 (8.1%)

1: All Consented Population is defined as all enrolled participants.
2: Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.

BNT162b2 Protocol C4591008

Baseline Medical History Stratified by Pfizer vs Non-Pfizer Vaccine (Participant Reported) and by Enrolment Within 10 Days

	Pfizer COVID 19 Vaccine (N=5399)		Other COVID 19 Vaccine Manufacturer (N=2425)	
Reported Term	**Enrolled within 10 days after vaccine[1] (N=2511)**	**Enrolled more than 10 days after vaccine (N=2888)**	**Enrolled within 10 days after vaccine (N=835)**	**Enrolled more than 10 days after vaccine (N=1590)**
Hypertension (high blood pressure)	286 / 2511 (11.4%)	384 / 2888 (13.3%)	80 / 835 (9.6%)	138 / 1590 (8.7%)
Diabetes mellitus	86 / 2511 (3.4%)	95 / 2888 (3.3%)	18 / 835 (2.2%)	35 / 1590 (2.2%)
Obesity/Overweight	593 / 2511 (23.6%)	642 / 2888 (22.2%)	164 / 835 (19.6%)	234 / 1590 (14.7%)
Prior heart attack	6 / 2511 (<1.0%)	9 / 2888 (<1.0%)	1 / 835 (<1.0%)	4 / 1590 (<1.0%)
Heart failure/cardiomyopathy	7 / 2511 (<1.0%)	14 / 2888 (<1.0%)	2 / 835 (<1.0%)	4 / 1590 (<1.0%)
Coronary artery disease	16 / 2511 (<1.0%)	19 / 2888 (<1.0%)	3 / 835 (<1.0%)	5 / 1590 (<1.0%)
Prior stroke or mini-stroke (TIA)	10 / 2511 (<1.0%)	15 / 2888 (<1.0%)	3 / 835 (<1.0%)	4 / 1590 (<1.0%)
Peripheral arterial or vascular disease	6 / 2511 (<1.0%)	10 / 2888 (<1.0%)	4 / 835 (<1.0%)	5 / 1590 (<1.0%)
Chronic obstructive pulmonary disease (COPD)	3 / 2511 (<1.0%)	4 / 2888 (<1.0%)	3 / 835 (<1.0%)	3 / 1590 (<1.0%)
Asthma	279 / 2511 (11.1%)	338 / 2888 (11.7%)	87 / 835 (10.4%)	136 / 1590 (8.6%)
Smoking	50 / 2511 (2.0%)	73 / 2888 (2.5%)	28 / 835 (3.4%)	31 / 1590 (1.9%)
Chronic kidney disease	10 / 2511 (<1.0%)	14 / 2888 (<1.0%)	1 / 835 (<1.0%)	1 / 1590 (<1.0%)
Cancer (localized)	44 / 2511 (1.8%)	58 / 2888 (2.0%)	6 / 835 (<1.0%)	18 / 1590 (1.1%)
Cancer (metastatic)	5 / 2511 (<1.0%)	5 / 2888 (<1.0%)	1 / 835 (<1.0%)	2 / 1590 (<1.0%)
Lymphoma	0	8 / 2888 (<1.0%)	0	4 / 1590 (<1.0%)
Leukemia	1 / 2511 (<1.0%)	4 / 2888 (<1.0%)	0	1 / 1590 (<1.0%)
Liver Disease	16 / 2511 (<1.0%)	10 / 2888 (<1.0%)	2 / 835 (<1.0%)	1 / 1590 (<1.0%)
Peptic ulcer disease	9 / 2511 (<1.0%)	11 / 2888 (<1.0%)	2 / 835 (<1.0%)	5 / 1590 (<1.0%)
Connective tissue disease	18 / 2511 (<1.0%)	17 / 2888 (<1.0%)	3 / 835 (<1.0%)	12 / 1590 (<1.0%)
Autoimmune disease	140 / 2511 (5.6%)	182 / 2888 (6.3%)	31 / 835 (3.7%)	70 / 1590 (4.4%)
Organ transplant	3 / 2511 (<1.0%)	3 / 2888 (<1.0%)	0	0
HIV/AIDS	4 / 2511 (<1.0%)	5 / 2888 (<1.0%)	1 / 835 (<1.0%)	3 / 1590 (<1.0%)

1: Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.

BNT162b2 Protocol C4591008

Baseline Medical History Stratified by Pfizer vs Non-Pfizer Vaccine (Participant Reported) and by Enrolment Within 10 Days

	Pfizer COVID 19 Vaccine (N=5399)		Other COVID 19 Vaccine Manufacturer (N=2425)	
Reported Term	**Enrolled within 10 days after vaccine[1] (N=2511)**	**Enrolled more than 10 days after vaccine (N=2888)**	**Enrolled within 10 days after vaccine (N=835)**	**Enrolled more than 10 days after vaccine (N=1590)**
Previous COVID-19 diagnosis	221 / 2511 (8.8%)	237 / 2888 (8.2%)	80 / 835 (9.6%)	112 / 1590 (7.0%)

1: Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.

Table 15.1.3
BNT162b2 Protocol C4591008
Baseline Medications

	All Consented Population[1] (N = 7824)	Primary Analysis Safety Population[2] (N = 2511)	Consented but not in Primary Analysis Safety Population (N = 5313)
Participants With Any Medications Below	490 / 7824 (6.3%)	176 / 2511 (7.0%)	314 / 5313 (5.9%)
Inhaled Corticosteroids	319 / 7824 (4.1%)	104 / 2511 (4.1%)	215 / 5313 (4.0%)
Systemic Corticosteroids	53 / 7824 (<1.0%)	22 / 2511 (<1.0%)	31 / 5313 (<1.0%)
Immunosuppressant Medications	161 / 7824 (2.1%)	67 / 2511 (2.7%)	94 / 5313 (1.8%)

1: All Consented Population is defined as all enrolled participants.
2: Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.

Table 15.1.4
BNT162b2 Protocol C4591008
Baseline Pregnancy / Baseline Vaccine History

	All Consented Population[1] (N = 7824)	Primary Analysis Safety Population[2] (N = 2511)	Consented but not in Primary Analysis Safety Population (N = 5313)
Were You Or Your Partner Pregnant At The Time Of Your First COVID-19 Vaccine Dose?			
Yes	253 / 6417 (3.9%)	101 / 2248 (4.5%)	152 / 4169 (3.6%)
Yes, I Was Pregnant	218 / 253 (86.2%)	83 / 101 (82.2%)	135 / 152 (88.8%)
Yes, My Partner Was Pregnant	35 / 253 (13.8%)	18 / 101 (17.8%)	17 / 152 (11.2%)
Other Than Your COVID-19 Vaccine, Did You Received Any Vaccinations (e.g., Flu, Hepatitis) In The 6 Months Prior To Your First COVID-19 Vaccine Dose?			
Yes	5032 / 6417 (78.4%)	1823 / 2248 (81.1%)	3209 / 4169 (77.0%)

1: All Consented Population is defined as all enrolled participants.
2: Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.

Table 15.3.1.1
BNT162b2 Protocol C4591008
Participant Reported Unplanned Hospitalization Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine

	All Consented Population[1] (N=7824)		Primary Analysis Safety Population[2] (N=2511)		Consented but not in Primary Analysis Safety Population (N=5313)	
	Participants n/N (%)	Hospitalizations[3] N	Participants n/N (%)	Hospitalizations[3] N	Participants n/N (%)	Hospitalizations[3] N
Participants Reported Unplanned Hospitalization[4]	63 / 7824 (<1.0%)	68	16 / 2511 (<1.0%)	17	47 / 5313 (<1.0%)	51
Event Confirmation In Progress[5]	16 / 63 (25.4%)	18	2 / 16 (12.5%)	2	14 / 47 (29.8%)	16
Suspected Event[6]	31 / 63 (49.2%)	34	10 / 16 (62.5%)	11	21 / 47 (44.7%)	23
Probable Event[7]	16 / 63 (25.4%)	16	4 / 16 (25.0%)	4	12 / 47 (25.5%)	12

Hospitalization is any hospitalization at any time during the study and after vaccination.
1: All Consented Population is defined as all enrolled participants.
2: Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.
3: A subject may have more than one hospitalization, so a hospitalization row count can be larger than the row participant count and the sum of hospitalization rows can be more than the N in the header.
4: Verily eCRF reported hospitalization collapsing on hospitalization date from the unplanned hospitalization forms.
5: Hospitalization in Verily eCRF, but no linkage in the CEA spreadsheet yet.
6: Hospitalization with a link from the Verily eCRF to CEA spreadsheet with confirmation status as "No".
7: Hospitalization with a link from the Verily eCRF to CEA spreadsheet with confirmation status as "Yes".
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Table 15.3.1.2

BNT162b2 Protocol C4591008

Participant Reported Unplanned Hospitalization Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Vaccine Type - Pfizer

All Consented Population

	Enrolled within 10 days after vaccine (N=2511)		Enrolled more than 10 days after vaccine (N=2888)		Pfizer (N=5399)	
	Participants n/N (%)	Hospitalizations[1] N	Participants n/N (%)	Hospitalizations[1] N	Participants n/N (%)	Hospitalizations[1] N
Participants Reported Unplanned Hospitalization[2]	16 / 2511 (<1.0%)	17	27 / 2888 (<1.0%)	29	43 / 5399 (<1.0%)	46
Event Confirmation In Progress[3]	2 / 16 (12.5%)	2	7 / 27 (25.9%)	8	9 / 43 (20.9%)	10
Suspected Event[4]	10 / 16 (62.5%)	11	12 / 27 (44.4%)	13	22 / 43 (51.2%)	24
Probable Event[5]	4 / 16 (25.0%)	4	8 / 27 (29.6%)	8	12 / 43 (27.9%)	12

Hospitalization is any hospitalization at any time during the study and after vaccination.

All Consented Population is defined as all enrolled participants.

1: A subject may have more than one hospitalization, so a hospitalization row count can be larger than the row participant count and the sum of hospitalization rows can be more than the N in the header.

2: Verily eCRF reported hospitalization collapsing on hospitalization date from the unplanned hospitalization forms.

3: Hospitalization in Verily eCRF, but no linkage in the CEA spreadsheet yet.

4: Hospitalization with a link from the Verily eCRF to CEA spreadsheet with confirmation status as "No".

5: Hospitalization with a link from the Verily eCRF to CEA spreadsheet with confirmation status as "Yes".

Table 15.3.1.3

BNT162b2 Protocol C4591008

Participant Reported Unplanned Hospitalization Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Vaccine Type - Other COVID-19 Vaccine

All Consented Population

	Enrolled within 10 days after vaccine (N=835)		Enrolled more than 10 days after vaccine (N=1590)		Other COVID-19 vaccine (N=2425)	
	Participants n/N (%)	Hospitalizations[1] N	Participants n/N (%)	Hospitalizations[1] N	Participants n/N (%)	Hospitalizations[1] N
Participants Reported Unplanned Hospitalization[2]	2 / 835 (<1.0%)	2	18 / 1590 (1.1%)	20	20 / 2425 (<1.0%)	22
Event Confirmation In Progress[3]	1 / 2 (50.0%)	1	6 / 18 (33.3%)	7	7 / 20 (35.0%)	8
Suspected Event[4]	1 / 2 (50.0%)	1	8 / 18 (44.4%)	9	9 / 20 (45.0%)	10
Probable Event[5]	0	0	4 / 18 (22.2%)	4	4 / 20 (20.0%)	4

Hospitalization is any hospitalization at any time during the study and after vaccination.

All Consented Population is defined as all enrolled participants.

1: A subject may have more than one hospitalization, so a hospitalization row count can be larger than the row participant count and the sum of hospitalization rows can be more than the N in the header.

2: Verily eCRF reported hospitalization collapsing on hospitalization date from the unplanned hospitalization forms.

3: Hospitalization in Verily eCRF, but no linkage in the CEA spreadsheet yet.

4: Hospitalization with a link from the Verily eCRF to CEA spreadsheet with confirmation status as "No".

5: Hospitalization with a link from the Verily eCRF to CEA spreadsheet with confirmation status as "Yes".

Table 15.3.1.4

BNT162b2 Protocol C4591008

Participant Reported Unplanned Hospitalization Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Pregnancy

Primary Analysis Safety Population

	Pregnancy[1] (N=101)		Not Pregnancy (N=2147)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Hospitalizations[2] N	Participants n/N (%)	Hospitalizations[2] N	Participants n/N (%)	Hospitalizations[2] N
Participants Reported Unplanned Hospitalization[3]	6 / 101 (5.9%)	6	10 / 2147 (<1.0%)	11	16 / 2511 (<1.0%)	17
Event Confirmation In Progress[4]	1 / 6 (16.7%)	1	1 / 10 (10.0%)	1	2 / 16 (12.5%)	2
Suspected Event[5]	3 / 6 (50.0%)	3	7 / 10 (70.0%)	8	10 / 16 (62.5%)	11
Probable Event[6]	2 / 6 (33.3%)	2	2 / 10 (20.0%)	2	4 / 16 (25.0%)	4

Hospitalization is any hospitalization at any time during the study and after vaccination.

Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.

1: Pregnancy at time of enrolment includes both the participant and the partner pregnancy. There are 263 participants without pregnancy status due to no status being collected.

2: A subject may have more than one hospitalization, so a hospitalization row count can be larger than the row participant count and the sum of hospitalization rows can be more than the N in the header.

3: Verily eCRF reported hospitalization collapsing on hospitalization date from the unplanned hospitalization forms.

4: Hospitalization in Verily eCRF, but no linkage in the CEA spreadsheet yet.

5: Hospitalization with a link from the Verily eCRF to CEA spreadsheet with confirmation status as "No".

6: Hospitalization with a link from the Verily eCRF to CEA spreadsheet with confirmation status as "Yes".

Table 15.3.1.5

BNT162b2 Protocol C4591008

Participant Reported Unplanned Hospitalization Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Age Group

Primary Analysis Safety Population

	18-29[1] (N=282)		30-39[1] (N=915)		40-49[1] (N=657)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Hospitalizations[2] N	Participants n/N (%)	Hospitalizations[2] N	Participants n/N (%)	Hospitalizations[2] N	Participants n/N (%)	Hospitalizations[2] N
Participants Reported Unplanned Hospitalization[3]	1 / 282 (<1.0%)	2	7 / 915 (<1.0%)	7	5 / 657 (<1.0%)	5	16 / 2511 (<1.0%)	17
Event Confirmation In Progress[4]	0	0	1 / 7 (14.3%)	1	1 / 5 (20.0%)	1	2 / 16 (12.5%)	2
Suspected Event[5]	1 / 1 (100%)	2	4 / 7 (57.1%)	4	3 / 5 (60.0%)	3	10 / 16 (62.5%)	11
Probable Event[6]	0	0	2 / 7 (28.6%)	2	1 / 5 (20.0%)	1	4 / 16 (25.0%)	4

Hospitalization is any hospitalization at any time during the study and after vaccination.

Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.

1: Age is based on birth date and at 1st dose of COVID-19 vaccine date.

2: A subject may have more than one hospitalization, so a hospitalization row count can be larger than the row participant count and the sum of hospitalization rows can be more than the N in the header.

3: Verily eCRF reported hospitalization collapsing on hospitalization date from the unplanned hospitalization forms.

4: Hospitalization in Verily eCRF, but no linkage in the CEA spreadsheet yet.

5: Hospitalization with a link from the Verily eCRF to CEA spreadsheet with confirmation status as "No".

6: Hospitalization with a link from the Verily eCRF to CEA spreadsheet with confirmation status as "Yes".

BNT162b2 Protocol C4591008

Participant Reported Unplanned Hospitalization Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Age Group

Primary Analysis Safety Population

	50-59[1] (N=439)		60-69[1] (N=197)		70 and above[1] (N=21)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Hospitalizations[2] N	Participants n/N (%)	Hospitalizations[2] N	Participants n/N (%)	Hospitalizations[2] N	Participants n/N (%)	Hospitalizations[2] N
Participants Reported Unplanned Hospitalization[3]	3 / 439 (<1.0%)	3	0	0	0	0	16 / 2511 (<1.0%)	17
Event Confirmation In Progress[4]	0	0	0	0	0	0	2 / 16 (12.5%)	2
Suspected Event[5]	2 / 3 (66.7%)	2	0	0	0	0	10 / 16 (62.5%)	11
Probable Event[6]	1 / 3 (33.3%)	1	0	0	0	0	4 / 16 (25.0%)	4

Hospitalization is any hospitalization at any time during the study and after vaccination.

Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.

1: Age is based on birth date and at 1st dose of COVID-19 vaccine date.

2: A subject may have more than one hospitalization, so a hospitalization row count can be larger than the row participant count and the sum of hospitalization rows can be more than the N in the header.

3: Verily eCRF reported hospitalization collapsing on hospitalization date from the unplanned hospitalization forms.

4: Hospitalization in Verily eCRF, but no linkage in the CEA spreadsheet yet.

5: Hospitalization with a link from the Verily eCRF to CEA spreadsheet with confirmation status as "No".

6: Hospitalization with a link from the Verily eCRF to CEA spreadsheet with confirmation status as "Yes".

Table 15.3.1.6

BNT162b2 Protocol C4591008

Participant Reported Unplanned Hospitalization Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Immunocompromised Status

Primary Analysis Safety Population

	Yes[1] (N=181)		No (N=2330)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Hospitalizations[2] N	Participants n/N (%)	Hospitalizations[2] N	Participants n/N (%)	Hospitalizations[2] N
Participants Reported Unplanned Hospitalization[3]	1 / 181 (<1.0%)	2	15 / 2330 (<1.0%)	15	16 / 2511 (<1.0%)	17
Event Confirmation In Progress[4]	0	0	2 / 15 (13.3%)	2	2 / 16 (12.5%)	2
Suspected Event[5]	1 / 1 (100%)	2	9 / 15 (60.0%)	9	10 / 16 (62.5%)	11
Probable Event[6]	0	0	4 / 15 (26.7%)	4	4 / 16 (25.0%)	4

Hospitalization is any hospitalization at any time during the study and after vaccination.

Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.

1: Immunocompromised status= Yes is defined based on a) having organ transplant or HIV/AIDS from baseline medical history and b) taking any inhaled corticosteroids, systemic corticosteroids, or immunosuppressant medications.

2: A subject may have more than one hospitalization, so a hospitalization row count can be larger than the row participant count and the sum of hospitalization rows can be more than the N in the header.

3: Verily eCRF reported hospitalization collapsing on hospitalization date from the unplanned hospitalization forms.

4: Hospitalization in Verily eCRF, but no linkage in the CEA spreadsheet yet.

5: Hospitalization with a link from the Verily eCRF to CEA spreadsheet with confirmation status as "No".

6: Hospitalization with a link from the Verily eCRF to CEA spreadsheet with confirmation status as "Yes".

Table 15.3.1.7

BNT162b2 Protocol C4591008

Participant Reported Unplanned Hospitalization Anytime After Receipt of at Least 1 Dose of Pfizer COVID-19 Vaccine by Dose Status

Primary Analysis Safety Population

	2 Doses[1] (N=2201)		1 Dose Only (N=310)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Hospitalization[2] N	Participants n/N (%)	Hospitalization[2] N	Participants n/N (%)	Hospitalization[2] N
Participants Reported Unplanned Hospitalization[3]	16 / 2201 (<1.0%)	17	0	0	16 / 2511 (<1.0%)	17
Event Confirmation In Progress[6]	2 / 16 (12.5%)	2	0	0	2 / 16 (12.5%)	2
Suspected Event[7]	10 / 16 (62.5%)	11	0	0	10 / 16 (62.5%)	11
Probable Event[8]	4 / 16 (25.0%)	4	0	0	4 / 16 (25.0%)	4

Hospitalization is any hospitalization at any time during the study and after vaccination.

Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.

1: Participants who took 2 doses of vaccine.

2: A subject may have more than one hospitalization, so a hospitalization row count can be larger than the row participant count and the sum of hospitalization rows can be more than the N in the header.

3: Verily eCRF reported hospitalization collapsing on hospitalization date from the unplanned hospitalization forms.

4: Hospitalization in Verily eCRF, but no linkage in the CEA spreadsheet yet.

5: Hospitalization with a link from the Verily eCRF to CEA spreadsheet with confirmation status as "No".

6: Hospitalization with a link from the Verily eCRF to CEA spreadsheet with confirmation status as "Yes".

Table 15.3.2.1.1
BNT162b2 Protocol C4591008
Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine

	All Consented Population (N=7824)		Primary Analysis Safety Population (N=2511)		Consented but not in Primary Analysis Safety Population (N=5313)	
	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N
Any Adverse Event of Special Interest[2]	928 / 7824 (11.9%)	1107	320 / 2511 (12.7%)	378	608 / 5313 (11.4%)	729
Hospitalized[3]	63 / 7824 (<1.0%)	84	16 / 2511 (<1.0%)	17	47 / 5313 (<1.0%)	67
Event Confirmation In Progress[4]	16 / 63 (25.4%)	30	2 / 16 (12.5%)	2	14 / 47 (29.8%)	28
Suspected Event (Unknown)[5]	22 / 63 (34.9%)	28	6 / 16 (37.5%)	7	16 / 47 (34.0%)	21
Suspected Event (Not Validated)[6]	23 / 63 (36.5%)	24	8 / 16 (50.0%)	8	15 / 47 (31.9%)	16
Probable Event[7]	2 / 63 (3.2%)	2	0	0	2 / 47 (4.3%)	2

All Consented Population is defined as all enrolled participants.
Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.
1: A subject may have more than one event, so an event row count can be larger than the row participant count and the sum of event rows can be more than the N in the header.
2: Excluding any events with hospitalization date or seeking medical date prior to vaccine date; if a participant reported an event on both hospitalization and unplanned medical care form on the same date, the event will be counted only once as a Hospitalization.
3: Verily eCRF reported adverse events of special interest collapsing on hospitalization date from the unplanned hospitalization forms. If more than one event was collected for the same hospitalization, all events will have the same confirmation status on CEA spreadsheet.
4: Adverse events of special interest in Verily eCRF, but no linkage in the CEA spreadsheet yet.
5: Adverse events of special interest with a link from the Verily eCRF to CEA spreadsheet with confirmation status as "Suspected Event (Unknown)".
6: Adverse events of special interest with a link from the Verily eCRF to CEA spreadsheet with confirmation status as "Suspected Event (Not Validated)".
7: Adverse events of special interest with a link from the Verily eCRF to CEA spreadsheet with confirmation status as "Probable Event".
8: Verily eCRF reported adverse events of special interest collapsing on seeking medical date for the same event from the other unplanned medical care forms
9: Adverse events of special interest collected from both unplanned hospitalization form and unplanned medical care form. If the event was reported on both form at the same date, the event will be counted only once in the table.

BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine

	All Consented Population (N=7824)		Primary Analysis Safety Population (N=2511)		Consented but not in Primary Analysis Safety Population (N=5313)	
	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N
Not Hospitalized[8]	898 / 7824 (11.5%)	1023	313 / 2511 (12.5%)	361	585 / 5313 (11.0%)	662
Event Confirmation In Progress[4]	666 / 898 (74.2%)	746	233 / 313 (74.4%)	261	433 / 585 (74.0%)	485
Suspected Event (Unknown)[5]	161 / 898 (17.9%)	198	50 / 313 (16.0%)	66	111 / 585 (19.0%)	132
Suspected Event (Not Validated)[6]	62 / 898 (6.9%)	70	27 / 313 (8.6%)	31	35 / 585 (6.0%)	39
Probable Event[7]	9 / 898 (1.0%)	9	3 / 313 (1.0%)	3	6 / 585 (1.0%)	6

All Consented Population is defined as all enrolled participants.
Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.
1: A subject may have more than one event, so an event row count can be larger than the row participant count and the sum of event rows can be more than the N in the header.
2: Excluding any events with hospitalization date or seeking medical date prior to vaccine date; if a participant reported an event on both hospitalization and unplanned medical care form on the same date, the event will be counted only once as a Hospitalization.
3: Verily eCRF reported adverse events of special interest collapsing on hospitalization date from the unplanned hospitalization forms. If more than one event was collected for the same hospitalization, all events will have the same confirmation status on CEA spreadsheet.
4: Adverse events of special interest in Verily eCRF, but no linkage in the CEA spreadsheet yet.
5: Adverse events of special interest with a link from the Verily eCRF to CEA spreadsheet with confirmation status as "Suspected Event (Unknown)".
6: Adverse events of special interest with a link from the Verily eCRF to CEA spreadsheet with confirmation status as "Suspected Event (Not Validated)".
7: Adverse events of special interest with a link from the Verily eCRF to CEA spreadsheet with confirmation status as "Probable Event".
8: Verily eCRF reported adverse events of special interest collapsing on seeking medical date for the same event from the other unplanned medical care forms
9: Adverse events of special interest collected from both unplanned hospitalization form and unplanned medical care form. If the event was reported on both form at the same date, the event will be counted only once in the table.

BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine

	All Consented Population (N=7824)		Primary Analysis Safety Population (N=2511)		Consented but not in Primary Analysis Safety Population (N=5313)	
	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N
Brain Or Spinal Cord Inflammation (e.g., Meningitis, Encephalitis, Guillain-Barre Syndrome)[9]	3 / 7824 (<1.0%)	4	0	0	3 / 5313 (<1.0%)	4
Event Confirmation In Progress[4]	2 / 3 (66.7%)	3	0	0	2 / 3 (66.7%)	3
Suspected Event (Unknown)[5]	0	0	0	0	0	0
Suspected Event (Not Validated)[6]	1 / 3 (33.3%)	1	0	0	1 / 3 (33.3%)	1
Probable Event[7]	0	0	0	0	0	0

All Consented Population is defined as all enrolled participants.
Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.
1: A subject may have more than one event, so an event row count can be larger than the row participant count and the sum of event rows can be more than the N in the header.
2: Excluding any events with hospitalization date or seeking medical date prior to vaccine date; if a participant reported an event on both hospitalization and unplanned medical care form on the same date, the event will be counted only once as a Hospitalization.
3: Verily eCRF reported adverse events of special interest collapsing on hospitalization date from the unplanned hospitalization forms. If more than one event was collected for the same hospitalization, all events will have the same confirmation status on CEA spreadsheet.
4: Adverse events of special interest in Verily eCRF, but no linkage in the CEA spreadsheet yet.
5: Adverse events of special interest with a link from the Verily eCRF to CEA spreadsheet with confirmation status as "Suspected Event (Unknown)".
6: Adverse events of special interest with a link from the Verily eCRF to CEA spreadsheet with confirmation status as "Suspected Event (Not Validated)".
7: Adverse events of special interest with a link from the Verily eCRF to CEA spreadsheet with confirmation status as "Probable Event".
8: Verily eCRF reported adverse events of special interest collapsing on seeking medical date for the same event from the other unplanned medical care forms
9: Adverse events of special interest collected from both unplanned hospitalization form and unplanned medical care form. If the event was reported on both form at the same date, the event will be counted only once in the table.

BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine

	All Consented Population (N=7824)		Primary Analysis Safety Population (N=2511)		Consented but not in Primary Analysis Safety Population (N=5313)	
	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N
Severe Allergic Reaction (Anaphylaxis)[9]	14 / 7824 (<1.0%)	16	6 / 2511 (<1.0%)	7	8 / 5313 (<1.0%)	9
Event Confirmation In Progress[4]	4 / 14 (28.6%)	5	1 / 6 (16.7%)	1	3 / 8 (37.5%)	4
Suspected Event (Unknown)[5]	6 / 14 (42.9%)	7	4 / 6 (66.7%)	5	2 / 8 (25.0%)	2
Suspected Event (Not Validated)[6]	2 / 14 (14.3%)	2	1 / 6 (16.7%)	1	1 / 8 (12.5%)	1
Probable Event[7]	2 / 14 (14.3%)	2	0	0	2 / 8 (25.0%)	2

All Consented Population is defined as all enrolled participants.
Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.
1: A subject may have more than one event, so an event row count can be larger than the row participant count and the sum of event rows can be more than the N in the header.
2: Excluding any events with hospitalization date or seeking medical date prior to vaccine date; if a participant reported an event on both hospitalization and unplanned medical care form on the same date, the event will be counted only once as a Hospitalization.
3: Verily eCRF reported adverse events of special interest collapsing on hospitalization date from the unplanned hospitalization forms. If more than one event was collected for the same hospitalization, all events will have the same confirmation status on CEA spreadsheet.
4: Adverse events of special interest in Verily eCRF, but no linkage in the CEA spreadsheet yet.
5: Adverse events of special interest with a link from the Verily eCRF to CEA spreadsheet with confirmation status as "Suspected Event (Unknown)".
6: Adverse events of special interest with a link from the Verily eCRF to CEA spreadsheet with confirmation status as "Suspected Event (Not Validated)".
7: Adverse events of special interest with a link from the Verily eCRF to CEA spreadsheet with confirmation status as "Probable Event".
8: Verily eCRF reported adverse events of special interest collapsing on seeking medical date for the same event from the other unplanned medical care forms
9: Adverse events of special interest collected from both unplanned hospitalization form and unplanned medical care form. If the event was reported on both form at the same date, the event will be counted only once in the table.

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Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine

	All Consented Population (N=7824)		Primary Analysis Safety Population (N=2511)		Consented but not in Primary Analysis Safety Population (N=5313)	
	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N
Non-Severe Allergic Reaction[9]	48 / 7824 (<1.0%)	52	15 / 2511 (<1.0%)	17	33 / 5313 (<1.0%)	35
Event Confirmation In Progress[4]	11 / 48 (22.9%)	13	1 / 15 (6.7%)	2	10 / 33 (30.3%)	11
Suspected Event (Unknown)[5]	31 / 48 (64.6%)	33	11 / 15 (73.3%)	12	20 / 33 (60.6%)	21
Suspected Event (Not Validated)[6]	5 / 48 (10.4%)	5	3 / 15 (20.0%)	3	2 / 33 (6.1%)	2
Probable Event[7]	1 / 48 (2.1%)	1	0	0	1 / 33 (3.0%)	1

All Consented Population is defined as all enrolled participants.
Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.
1: A subject may have more than one event, so an event row count can be larger than the row participant count and the sum of event rows can be more than the N in the header.
2: Excluding any events with hospitalization date or seeking medical date prior to vaccine date; if a participant reported an event on both hospitalization and unplanned medical care form on the same date, the event will be counted only once as a Hospitalization.
3: Verily eCRF reported adverse events of special interest collapsing on hospitalization date from the unplanned hospitalization forms. If more than one event was collected for the same hospitalization, all events will have the same confirmation status on CEA spreadsheet.
4: Adverse events of special interest in Verily eCRF, but no linkage in the CEA spreadsheet yet.
5: Adverse events of special interest with a link from the Verily eCRF to CEA spreadsheet with confirmation status as "Suspected Event (Unknown)".
6: Adverse events of special interest with a link from the Verily eCRF to CEA spreadsheet with confirmation status as "Suspected Event (Not Validated)".
7: Adverse events of special interest with a link from the Verily eCRF to CEA spreadsheet with confirmation status as "Probable Event".
8: Verily eCRF reported adverse events of special interest collapsing on seeking medical date for the same event from the other unplanned medical care forms
9: Adverse events of special interest collected from both unplanned hospitalization form and unplanned medical care form. If the event was reported on both form at the same date, the event will be counted only once in the table.

Table 15.3.2.1.1
BNT162b2 Protocol C4591008
Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine

	All Consented Population (N=7824)		Primary Analysis Safety Population (N=2511)		Consented but not in Primary Analysis Safety Population (N=5313)	
	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N
Heart Inflammation (e.g., Myocarditis, Pericarditis)[9]	3 / 7824 (<1.0%)	4	1 / 2511 (<1.0%)	1	2 / 5313 (<1.0%)	3
Event Confirmation In Progress[4]	0	1	0	0	0	1
Suspected Event (Unknown)[5]	3 / 3 (100%)	3	1 / 1 (100%)	1	2 / 2 (100%)	2
Suspected Event (Not Validated)[6]	0	0	0	0	0	0
Probable Event[7]	0	0	0	0	0	0

All Consented Population is defined as all enrolled participants.
Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.
1: A subject may have more than one event, so an event row count can be larger than the row participant count and the sum of event rows can be more than the N in the header.
2: Excluding any events with hospitalization date or seeking medical date prior to vaccine date; if a participant reported an event on both hospitalization and unplanned medical care form on the same date, the event will be counted only once as a Hospitalization.
3: Verily eCRF reported adverse events of special interest collapsing on hospitalization date from the unplanned hospitalization forms. If more than one event was collected for the same hospitalization, all events will have the same confirmation status on CEA spreadsheet.
4: Adverse events of special interest in Verily eCRF, but no linkage in the CEA spreadsheet yet.
5: Adverse events of special interest with a link from the Verily eCRF to CEA spreadsheet with confirmation status as "Suspected Event (Unknown)".
6: Adverse events of special interest with a link from the Verily eCRF to CEA spreadsheet with confirmation status as "Suspected Event (Not Validated)".
7: Adverse events of special interest with a link from the Verily eCRF to CEA spreadsheet with confirmation status as "Probable Event".
8: Verily eCRF reported adverse events of special interest collapsing on seeking medical date for the same event from the other unplanned medical care forms
9: Adverse events of special interest collected from both unplanned hospitalization form and unplanned medical care form. If the event was reported on both form at the same date, the event will be counted only once in the table.
PFIZER CONFIDENTIAL SDTM Creation: 11MAY2021:07:31:19 Data Cutoff: 29APR2021 Source Data: ADSL, ADEVENT
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Table 15.3.2.1.1
BNT162b2 Protocol C4591008
Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine

	All Consented Population (N=7824)		Primary Analysis Safety Population (N=2511)		Consented but not in Primary Analysis Safety Population (N=5313)	
	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N
Blood Clot Inside A Vein In The Body (Thromboembolism)[9]	6 / 7824 (<1.0%)	6	0	0	6 / 5313 (<1.0%)	6
Event Confirmation In Progress[4]	1 / 6 (16.7%)	1	0	0	1 / 6 (16.7%)	1
Suspected Event (Unknown)[5]	4 / 6 (66.7%)	4	0	0	4 / 6 (66.7%)	4
Suspected Event (Not Validated)[6]	1 / 6 (16.7%)	1	0	0	1 / 6 (16.7%)	1
Probable Event[7]	0	0	0	0	0	0

All Consented Population is defined as all enrolled participants.
Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.
1: A subject may have more than one event, so an event row count can be larger than the row participant count and the sum of event rows can be more than the N in the header.
2: Excluding any events with hospitalization date or seeking medical date prior to vaccine date; if a participant reported an event on both hospitalization and unplanned medical care form on the same date, the event will be counted only once as a Hospitalization.
3: Verily eCRF reported adverse events of special interest collapsing on hospitalization date from the unplanned hospitalization forms. If more than one event was collected for the same hospitalization, all events will have the same confirmation status on CEA spreadsheet.
4: Adverse events of special interest in Verily eCRF, but no linkage in the CEA spreadsheet yet.
5: Adverse events of special interest with a link from the Verily eCRF to CEA spreadsheet with confirmation status as "Suspected Event (Unknown)".
6: Adverse events of special interest with a link from the Verily eCRF to CEA spreadsheet with confirmation status as "Suspected Event (Not Validated)".
7: Adverse events of special interest with a link from the Verily eCRF to CEA spreadsheet with confirmation status as "Probable Event".
8: Verily eCRF reported adverse events of special interest collapsing on seeking medical date for the same event from the other unplanned medical care forms
9: Adverse events of special interest collected from both unplanned hospitalization form and unplanned medical care form. If the event was reported on both form at the same date, the event will be counted only once in the table.
PFIZER CONFIDENTIAL SDTM Creation: 11MAY2021:07:31:19 Data Cutoff: 29APR2021 Source Data: ADSL, ADEVENT
Generated from /dcri/ct/hero_together/tables/t_event.sas on 24MAY2021 12:44 Page 27 of 284

BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine

	All Consented Population (N=7824)		Primary Analysis Safety Population (N=2511)		Consented but not in Primary Analysis Safety Population (N=5313)	
	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N
Blood Vessel Inflammation (e.g., Kawasaki Disease, Vasculitides)[9]	4 / 7824 (<1.0%)	4	2 / 2511 (<1.0%)	2	2 / 5313 (<1.0%)	2
Event Confirmation In Progress[4]	1 / 4 (25.0%)	1	0	0	1 / 2 (50.0%)	1
Suspected Event (Unknown)[5]	2 / 4 (50.0%)	2	1 / 2 (50.0%)	1	1 / 2 (50.0%)	1
Suspected Event (Not Validated)[6]	1 / 4 (25.0%)	1	1 / 2 (50.0%)	1	0	0
Probable Event[7]	0	0	0	0	0	0

All Consented Population is defined as all enrolled participants.

Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.

1: A subject may have more than one event, so an event row count can be larger than the row participant count and the sum of event rows can be more than the N in the header.

2: Excluding any events with hospitalization date or seeking medical date prior to vaccine date; if a participant reported an event on both hospitalization and unplanned medical care form on the same date, the event will be counted only once as a Hospitalization.

3: Verily eCRF reported adverse events of special interest collapsing on hospitalization date from the unplanned hospitalization forms. If more than one event was collected for the same hospitalization, all events will have the same confirmation status on CEA spreadsheet.

4: Adverse events of special interest in Verily eCRF, but no linkage in the CEA spreadsheet yet.

5: Adverse events of special interest with a link from the Verily eCRF to CEA spreadsheet with confirmation status as "Suspected Event (Unknown)".

6: Adverse events of special interest with a link from the Verily eCRF to CEA spreadsheet with confirmation status as "Suspected Event (Not Validated)".

7: Adverse events of special interest with a link from the Verily eCRF to CEA spreadsheet with confirmation status as "Probable Event".

8: Verily eCRF reported adverse events of special interest collapsing on seeking medical date for the same event from the other unplanned medical care forms

9: Adverse events of special interest collected from both unplanned hospitalization form and unplanned medical care form. If the event was reported on both form at the same date, the event will be counted only once in the table.

Table 15.3.2.1.1
BNT162b2 Protocol C4591008
Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine

	All Consented Population (N=7824)		Primary Analysis Safety Population (N=2511)		Consented but not in Primary Analysis Safety Population (N=5313)	
	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N
Abnormal Blood Clotting (e.g., Disseminated Intravascular Coagulation, Thrombocytopenia)[9]	3 / 7824 (<1.0%)	3	1 / 2511 (<1.0%)	1	2 / 5313 (<1.0%)	2
Event Confirmation In Progress[4]	0	0	0	0	0	0
Suspected Event (Unknown)[5]	1 / 3 (33.3%)	1	0	0	1 / 2 (50.0%)	1
Suspected Event (Not Validated)[6]	1 / 3 (33.3%)	1	0	0	1 / 2 (50.0%)	1
Probable Event[7]	1 / 3 (33.3%)	1	1 / 1 (100%)	1	0	0

All Consented Population is defined as all enrolled participants.
Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.
1: A subject may have more than one event, so an event row count can be larger than the row participant count and the sum of event rows can be more than the N in the header.
2: Excluding any events with hospitalization date or seeking medical date prior to vaccine date; if a participant reported an event on both hospitalization and unplanned medical care form on the same date, the event will be counted only once as a Hospitalization.
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4: Adverse events of special interest in Verily eCRF, but no linkage in the CEA spreadsheet yet.
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PFIZER CONFIDENTIAL SDTM Creation: 11MAY2021:07:31:19 Data Cutoff: 29APR2021 Source Data: ADSL, ADEVENT
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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine

	All Consented Population (N=7824)		Primary Analysis Safety Population (N=2511)		Consented but not in Primary Analysis Safety Population (N=5313)	
	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N
Bleeding Disorder (Hemorrhagic Disease)[9]	0	0	0	0	0	0
Event Confirmation In Progress[4]	0	0	0	0	0	0
Suspected Event (Unknown)[5]	0	0	0	0	0	0
Suspected Event (Not Validated)[6]	0	0	0	0	0	0
Probable Event[7]	0	0	0	0	0	0

All Consented Population is defined as all enrolled participants.
Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.
1: A subject may have more than one event, so an event row count can be larger than the row participant count and the sum of event rows can be more than the N in the header.
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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine

	All Consented Population (N=7824)		Primary Analysis Safety Population (N=2511)		Consented but not in Primary Analysis Safety Population (N=5313)	
	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N
Heart Attack (Myocardial Infarction)[9]	2 / 7824 (<1.0%)	3	0	0	2 / 5313 (<1.0%)	3
Event Confirmation In Progress[4]	1 / 2 (50.0%)	2	0	0	1 / 2 (50.0%)	2
Suspected Event (Unknown)[5]	1 / 2 (50.0%)	1	0	0	1 / 2 (50.0%)	1
Suspected Event (Not Validated)[6]	0	0	0	0	0	0
Probable Event[7]	0	0	0	0	0	0

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Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.
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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine

	All Consented Population (N=7824)		Primary Analysis Safety Population (N=2511)		Consented but not in Primary Analysis Safety Population (N=5313)	
	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N
Heart Failure/Cardiogenic Shock[9]	1 / 7824 (<1.0%)	1	0	0	1 / 5313 (<1.0%)	1
Event Confirmation In Progress[4]	1 / 1 (100%)	1	0	0	1 / 1 (100%)	1
Suspected Event (Unknown)[5]	0	0	0	0	0	0
Suspected Event (Not Validated)[6]	0	0	0	0	0	0
Probable Event[7]	0	0	0	0	0	0

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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine

	All Consented Population (N=7824)		Primary Analysis Safety Population (N=2511)		Consented but not in Primary Analysis Safety Population (N=5313)	
	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N
Stress Cardiomyopathy[9]	1 / 7824 (<1.0%)	1	0	0	1 / 5313 (<1.0%)	1
Event Confirmation In Progress[4]	1 / 1 (100%)	1	0	0	1 / 1 (100%)	1
Suspected Event (Unknown)[5]	0	0	0	0	0	0
Suspected Event (Not Validated)[6]	0	0	0	0	0	0
Probable Event[7]	0	0	0	0	0	0

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Table 15.3.2.1.1
BNT162b2 Protocol C4591008
Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine

	All Consented Population (N=7824)		Primary Analysis Safety Population (N=2511)		Consented but not in Primary Analysis Safety Population (N=5313)	
	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N
Coronary Artery Disease[9]	0	0	0	0	0	0
Event Confirmation In Progress[4]	0	0	0	0	0	0
Suspected Event (Unknown)[5]	0	0	0	0	0	0
Suspected Event (Not Validated)[6]	0	0	0	0	0	0
Probable Event[7]	0	0	0	0	0	0

All Consented Population is defined as all enrolled participants.
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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine

	All Consented Population (N=7824)		Primary Analysis Safety Population (N=2511)		Consented but not in Primary Analysis Safety Population (N=5313)	
	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N
Abnormal Heart Rhythm (Arrhythmia)[9]	1 / 7824 (<1.0%)	1	0	0	1 / 5313 (<1.0%)	1
Event Confirmation In Progress[4]	1 / 1 (100%)	1	0	0	1 / 1 (100%)	1
Suspected Event (Unknown)[5]	0	0	0	0	0	0
Suspected Event (Not Validated)[6]	0	0	0	0	0	0
Probable Event[7]	0	0	0	0	0	0

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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine

	All Consented Population (N=7824)		Primary Analysis Safety Population (N=2511)		Consented but not in Primary Analysis Safety Population (N=5313)	
	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N
Stroke Or Possible Stroke[9]	2 / 7824 (<1.0%)	3	1 / 2511 (<1.0%)	1	1 / 5313 (<1.0%)	2
Event Confirmation In Progress[4]	1 / 2 (50.0%)	1	1 / 1 (100%)	1	0	0
Suspected Event (Unknown)[5]	0	1	0	0	0	1
Suspected Event (Not Validated)[6]	1 / 2 (50.0%)	1	0	0	1 / 1 (100%)	1
Probable Event[7]	0	0	0	0	0	0

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	All Consented Population (N=7824)		Primary Analysis Safety Population (N=2511)		Consented but not in Primary Analysis Safety Population (N=5313)	
	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N
Blockage Of Blood Flow To Limbs (e.g., Limb Ischemia, Peripheral Artery Disease)[9]	0	0	0	0	0	0
Event Confirmation In Progress[4]	0	0	0	0	0	0
Suspected Event (Unknown)[5]	0	0	0	0	0	0
Suspected Event (Not Validated)[6]	0	0	0	0	0	0
Probable Event[7]	0	0	0	0	0	0

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	All Consented Population (N=7824)		Primary Analysis Safety Population (N=2511)		Consented but not in Primary Analysis Safety Population (N=5313)	
	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N
Acute Kidney Injury[9]	0	0	0	0	0	0
Event Confirmation In Progress[4]	0	0	0	0	0	0
Suspected Event (Unknown)[5]	0	0	0	0	0	0
Suspected Event (Not Validated)[6]	0	0	0	0	0	0
Probable Event[7]	0	0	0	0	0	0

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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine

	All Consented Population (N=7824)		Primary Analysis Safety Population (N=2511)		Consented but not in Primary Analysis Safety Population (N=5313)	
	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N
Liver Injury[9]	2 / 7824 (<1.0%)	2	0	0	2 / 5313 (<1.0%)	2
Event Confirmation In Progress[4]	1 / 2 (50.0%)	1	0	0	1 / 2 (50.0%)	1
Suspected Event (Unknown)[5]	1 / 2 (50.0%)	1	0	0	1 / 2 (50.0%)	1
Suspected Event (Not Validated)[6]	0	0	0	0	0	0
Probable Event[7]	0	0	0	0	0	0

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Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine

	All Consented Population (N=7824)		Primary Analysis Safety Population (N=2511)		Consented but not in Primary Analysis Safety Population (N=5313)	
	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N
Skin Immune Reaction (e.g., Chillblain-Like Lesions, Erythema Multiforme)[9]	0	0	0	0	0	0
Event Confirmation In Progress[4]	0	0	0	0	0	0
Suspected Event (Unknown)[5]	0	0	0	0	0	0
Suspected Event (Not Validated)[6]	0	0	0	0	0	0
Probable Event[7]	0	0	0	0	0	0

All Consented Population is defined as all enrolled participants.
Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.
1: A subject may have more than one event, so an event row count can be larger than the row participant count and the sum of event rows can be more than the N in the header.
2: Excluding any events with hospitalization date or seeking medical date prior to vaccine date; if a participant reported an event on both hospitalization and unplanned medical care form on the same date, the event will be counted only once as a Hospitalization.
3: Verily eCRF reported adverse events of special interest collapsing on hospitalization date from the unplanned hospitalization forms. If more than one event was collected for the same hospitalization, all events will have the same confirmation status on CEA spreadsheet.
4: Adverse events of special interest in Verily eCRF, but no linkage in the CEA spreadsheet yet.
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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine

	All Consented Population (N=7824)		Primary Analysis Safety Population (N=2511)		Consented but not in Primary Analysis Safety Population (N=5313)	
	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N
Multisystem Inflammation[9]	14 / 7824 (<1.0%)	15	2 / 2511 (<1.0%)	2	12 / 5313 (<1.0%)	13
Event Confirmation In Progress[4]	3 / 14 (21.4%)	3	0	0	3 / 12 (25.0%)	3
Suspected Event (Unknown)[5]	7 / 14 (50.0%)	8	0	0	7 / 12 (58.3%)	8
Suspected Event (Not Validated)[6]	4 / 14 (28.6%)	4	2 / 2 (100%)	2	2 / 12 (16.7%)	2
Probable Event[7]	0	0	0	0	0	0

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Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine

	All Consented Population (N=7824)		Primary Analysis Safety Population (N=2511)		Consented but not in Primary Analysis Safety Population (N=5313)	
	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N
Fibromyalgia[9]	5 / 7824 (<1.0%)	5	2 / 2511 (<1.0%)	2	3 / 5313 (<1.0%)	3
Event Confirmation In Progress[4]	2 / 5 (40.0%)	2	1 / 2 (50.0%)	1	1 / 3 (33.3%)	1
Suspected Event (Unknown)[5]	3 / 5 (60.0%)	3	1 / 2 (50.0%)	1	2 / 3 (66.7%)	2
Suspected Event (Not Validated)[6]	0	0	0	0	0	0
Probable Event[7]	0	0	0	0	0	0

All Consented Population is defined as all enrolled participants.
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Table 15.3.2.1.1
BNT162b2 Protocol C4591008
Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine

	All Consented Population (N=7824)		Primary Analysis Safety Population (N=2511)		Consented but not in Primary Analysis Safety Population (N=5313)	
	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N
Nerve Inflammation Or Autoimmune Disease (e.g., Multiple Sclerosis, Rheumatoid Arthritis)[9]	24 / 7824 (<1.0%)	28	9 / 2511 (<1.0%)	11	15 / 5313 (<1.0%)	17
Event Confirmation In Progress[4]	7 / 24 (29.2%)	8	2 / 9 (22.2%)	2	5 / 15 (33.3%)	6
Suspected Event (Unknown)[5]	10 / 24 (41.7%)	12	4 / 9 (44.4%)	5	6 / 15 (40.0%)	7
Suspected Event (Not Validated)[6]	6 / 24 (25.0%)	7	3 / 9 (33.3%)	4	3 / 15 (20.0%)	3
Probable Event[7]	1 / 24 (4.2%)	1	0	0	1 / 15 (6.7%)	1

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Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine

	All Consented Population (N=7824)		Primary Analysis Safety Population (N=2511)		Consented but not in Primary Analysis Safety Population (N=5313)	
	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N
Autoimmune Thyroiditis[9]	4 / 7824 (<1.0%)	4	3 / 2511 (<1.0%)	3	1 / 5313 (<1.0%)	1
Event Confirmation In Progress[4]	1 / 4 (25.0%)	1	1 / 3 (33.3%)	1	0	0
Suspected Event (Unknown)[5]	3 / 4 (75.0%)	3	2 / 3 (66.7%)	2	1 / 1 (100%)	1
Suspected Event (Not Validated)[6]	0	0	0	0	0	0
Probable Event[7]	0	0	0	0	0	0

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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine

	All Consented Population (N=7824)		Primary Analysis Safety Population (N=2511)		Consented but not in Primary Analysis Safety Population (N=5313)	
	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N
COVID-19 Infection[9]	38 / 7824 (<1.0%)	52	15 / 2511 (<1.0%)	20	23 / 5313 (<1.0%)	32
Event Confirmation In Progress[4]	6 / 38 (15.8%)	10	3 / 15 (20.0%)	4	3 / 23 (13.0%)	6
Suspected Event (Unknown)[5]	18 / 38 (47.4%)	26	6 / 15 (40.0%)	10	12 / 23 (52.2%)	16
Suspected Event (Not Validated)[6]	10 / 38 (26.3%)	12	5 / 15 (33.3%)	5	5 / 23 (21.7%)	7
Probable Event[7]	4 / 38 (10.5%)	4	1 / 15 (6.7%)	1	3 / 23 (13.0%)	3

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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine

	All Consented Population (N=7824)		Primary Analysis Safety Population (N=2511)		Consented but not in Primary Analysis Safety Population (N=5313)	
	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N
Generalized Convulsions/Seizures[9]	4 / 7824 (<1.0%)	5	1 / 2511 (<1.0%)	1	3 / 5313 (<1.0%)	4
Event Confirmation In Progress[4]	0	0	0	0	0	0
Suspected Event (Unknown)[5]	3 / 4 (75.0%)	4	0	0	3 / 3 (100%)	4
Suspected Event (Not Validated)[6]	1 / 4 (25.0%)	1	1 / 1 (100%)	1	0	0
Probable Event[7]	0	0	0	0	0	0

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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine

	All Consented Population (N=7824)		Primary Analysis Safety Population (N=2511)		Consented but not in Primary Analysis Safety Population (N=5313)	
	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N
Bell's Palsy[9]	0	0	0	0	0	0
Event Confirmation In Progress[4]	0	0	0	0	0	0
Suspected Event (Unknown)[5]	0	0	0	0	0	0
Suspected Event (Not Validated)[6]	0	0	0	0	0	0
Probable Event[7]	0	0	0	0	0	0

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BNT162b2 Protocol C4591008

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	All Consented Population (N=7824)		Primary Analysis Safety Population (N=2511)		Consented but not in Primary Analysis Safety Population (N=5313)	
	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N
Narcolepsy Or Cataplexy[9]	1 / 7824 (<1.0%)	1	0	0	1 / 5313 (<1.0%)	1
Event Confirmation In Progress[4]	0	0	0	0	0	0
Suspected Event (Unknown)[5]	1 / 1 (100%)	1	0	0	1 / 1 (100%)	1
Suspected Event (Not Validated)[6]	0	0	0	0	0	0
Probable Event[7]	0	0	0	0	0	0

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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine

	All Consented Population (N=7824)		Primary Analysis Safety Population (N=2511)		Consented but not in Primary Analysis Safety Population (N=5313)	
	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N
Joint Stiffness Or Pain (e.g., Arthralgia, Arthritis)[9]	113 / 7824 (1.4%)	139	32 / 2511 (1.3%)	43	81 / 5313 (1.5%)	96
Event Confirmation In Progress[4]	24 / 113 (21.2%)	32	3 / 32 (9.4%)	7	21 / 81 (25.9%)	25
Suspected Event (Unknown)[5]	65 / 113 (57.5%)	79	20 / 32 (62.5%)	25	45 / 81 (55.6%)	54
Suspected Event (Not Validated)[6]	23 / 113 (20.4%)	27	8 / 32 (25.0%)	10	15 / 81 (18.5%)	17
Probable Event[7]	1 / 113 (<1.0%)	1	1 / 32 (3.1%)	1	0	0

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	All Consented Population (N=7824)		Primary Analysis Safety Population (N=2511)		Consented but not in Primary Analysis Safety Population (N=5313)	
	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N
Pregnancy-Related Issue[9]	56 / 7824 (<1.0%)	68	19 / 2511 (<1.0%)	24	37 / 5313 (<1.0%)	44
Event Confirmation In Progress[4]	22 / 56 (39.3%)	27	8 / 19 (42.1%)	10	14 / 37 (37.8%)	17
Suspected Event (Unknown)[5]	20 / 56 (35.7%)	25	5 / 19 (26.3%)	7	15 / 37 (40.5%)	18
Suspected Event (Not Validated)[6]	14 / 56 (25.0%)	16	6 / 19 (31.6%)	7	8 / 37 (21.6%)	9
Probable Event[7]	0	0	0	0	0	0

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	All Consented Population (N=7824)		Primary Analysis Safety Population (N=2511)		Consented but not in Primary Analysis Safety Population (N=5313)	
	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N
Microangiopathy[9]	0	0	0	0	0	0
Event Confirmation In Progress[4]	0	0	0	0	0	0
Suspected Event (Unknown)[5]	0	0	0	0	0	0
Suspected Event (Not Validated)[6]	0	0	0	0	0	0
Probable Event[7]	0	0	0	0	0	0

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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine

	All Consented Population (N=7824)		Primary Analysis Safety Population (N=2511)		Consented but not in Primary Analysis Safety Population (N=5313)	
	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N
Death[9]	2 / 7824 (<1.0%)	2	1 / 2511 (<1.0%)	1	1 / 5313 (<1.0%)	1
Event Confirmation In Progress[4]	2 / 2 (100%)	2	1 / 1 (100%)	1	1 / 1 (100%)	1
Suspected Event (Unknown)[5]	0	0	0	0	0	0
Suspected Event (Not Validated)[6]	0	0	0	0	0	0
Probable Event[7]	0	0	0	0	0	0

All Consented Population is defined as all enrolled participants.
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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine

	All Consented Population (N=7824)		Primary Analysis Safety Population (N=2511)		Consented but not in Primary Analysis Safety Population (N=5313)	
	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N
Other[9]	670 / 7824 (8.6%)	688	236 / 2511 (9.4%)	242	434 / 5313 (8.2%)	446
Event Confirmation In Progress[4]	643 / 670 (96.0%)	660	228 / 236 (96.6%)	233	415 / 434 (95.6%)	427
Suspected Event (Unknown)[5]	11 / 670 (1.6%)	12	3 / 236 (1.3%)	4	8 / 434 (1.8%)	8
Suspected Event (Not Validated)[6]	15 / 670 (2.2%)	15	5 / 236 (2.1%)	5	10 / 434 (2.3%)	10
Probable Event[7]	1 / 670 (<1.0%)	1	0	0	1 / 434 (<1.0%)	1

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Table 15.3.2.1.2

BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Vaccine Type - Pfizer

All Consented Population

	Enrolled within 10 days after vaccine (N=2511)		Enrolled more than 10 days after vaccine (N=2888)		Pfizer (N=5399)	
	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N
Any Adverse Event of Special Interest[2]	320 / 2511 (12.7%)	378	397 / 2888 (13.7%)	467	717 / 5399 (13.3%)	845
Hospitalized[3]	16 / 2511 (<1.0%)	17	27 / 2888 (<1.0%)	35	43 / 5399 (<1.0%)	52
Event Confirmation In Progress[4]	2 / 16 (12.5%)	2	8 / 27 (29.6%)	11	10 / 43 (23.3%)	13
Suspected Event (Unknown)[5]	6 / 16 (37.5%)	7	8 / 27 (29.6%)	12	14 / 43 (32.6%)	19
Suspected Event (Not Validated)[6]	8 / 16 (50.0%)	8	9 / 27 (33.3%)	10	17 / 43 (39.5%)	18
Probable Event[7]	0	0	2 / 27 (7.4%)	2	2 / 43 (4.7%)	2

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Table 15.3.2.1.2

BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Vaccine Type - Pfizer

All Consented Population

	Enrolled within 10 days after vaccine (N=2511)		Enrolled more than 10 days after vaccine (N=2888)		Pfizer (N=5399)	
	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N
Not Hospitalized[8]	313 / 2511 (12.5%)	361	381 / 2888 (13.2%)	432	694 / 5399 (12.9%)	793
Event Confirmation In Progress[4]	233 / 313 (74.4%)	261	287 / 381 (75.3%)	324	520 / 694 (74.9%)	585
Suspected Event (Unknown)[5]	50 / 313 (16.0%)	66	68 / 381 (17.8%)	78	118 / 694 (17.0%)	144
Suspected Event (Not Validated)[6]	27 / 313 (8.6%)	31	21 / 381 (5.5%)	25	48 / 694 (6.9%)	56
Probable Event[7]	3 / 313 (1.0%)	3	5 / 381 (1.3%)	5	8 / 694 (1.2%)	8

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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Vaccine Type - Pfizer

All Consented Population

	Enrolled within 10 days after vaccine (N=2511)		Enrolled more than 10 days after vaccine (N=2888)		Pfizer (N=5399)	
	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N
Brain Or Spinal Cord Inflammation (e.g., Meningitis, Encephalitis, Guillain-Barre Syndrome)[9]	0	0	0	0	0	0
Event Confirmation In Progress[4]	0	0	0	0	0	0
Suspected Event (Unknown)[5]	0	0	0	0	0	0
Suspected Event (Not Validated)[6]	0	0	0	0	0	0
Probable Event[7]	0	0	0	0	0	0

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Table 15.3.2.1.2

BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Vaccine Type - Pfizer

All Consented Population

	Enrolled within 10 days after vaccine (N=2511)		Enrolled more than 10 days after vaccine (N=2888)		Pfizer (N=5399)	
	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N
Severe Allergic Reaction (Anaphylaxis)[9]	6 / 2511 (<1.0%)	7	3 / 2888 (<1.0%)	3	9 / 5399 (<1.0%)	10
Event Confirmation In Progress[4]	1 / 6 (16.7%)	1	0	0	1 / 9 (11.1%)	1
Suspected Event (Unknown)[5]	4 / 6 (66.7%)	5	1 / 3 (33.3%)	1	5 / 9 (55.6%)	6
Suspected Event (Not Validated)[6]	1 / 6 (16.7%)	1	0	0	1 / 9 (11.1%)	1
Probable Event[7]	0	0	2 / 3 (66.7%)	2	2 / 9 (22.2%)	2

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Table 15.3.2.1.2

BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Vaccine Type - Pfizer

All Consented Population

	Enrolled within 10 days after vaccine (N=2511)		Enrolled more than 10 days after vaccine (N=2888)		Pfizer (N=5399)	
	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N
Non-Severe Allergic Reaction[9]	15 / 2511 (<1.0%)	17	22 / 2888 (<1.0%)	23	37 / 5399 (<1.0%)	40
Event Confirmation In Progress[4]	1 / 15 (6.7%)	2	6 / 22 (27.3%)	7	7 / 37 (18.9%)	9
Suspected Event (Unknown)[5]	11 / 15 (73.3%)	12	14 / 22 (63.6%)	14	25 / 37 (67.6%)	26
Suspected Event (Not Validated)[6]	3 / 15 (20.0%)	3	1 / 22 (4.5%)	1	4 / 37 (10.8%)	4
Probable Event[7]	0	0	1 / 22 (4.5%)	1	1 / 37 (2.7%)	1

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Table 15.3.2.1.2

BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Vaccine Type - Pfizer

All Consented Population

	Enrolled within 10 days after vaccine (N=2511)		Enrolled more than 10 days after vaccine (N=2888)		Pfizer (N=5399)	
	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N
Heart Inflammation (e.g., Myocarditis, Pericarditis)[9]	1 / 2511 (<1.0%)	1	2 / 2888 (<1.0%)	3	3 / 5399 (<1.0%)	4
Event Confirmation In Progress[4]	0	0	0	1	0	1
Suspected Event (Unknown)[5]	1 / 1 (100%)	1	2 / 2 (100%)	2	3 / 3 (100%)	3
Suspected Event (Not Validated)[6]	0	0	0	0	0	0
Probable Event[7]	0	0	0	0	0	0

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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Vaccine Type - Pfizer

All Consented Population

	Enrolled within 10 days after vaccine (N=2511)		Enrolled more than 10 days after vaccine (N=2888)		Pfizer (N=5399)	
	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N
Blood Clot Inside A Vein In The Body (Thromboembolism)[9]	0	0	3 / 2888 (<1.0%)	3	3 / 5399 (<1.0%)	3
Event Confirmation In Progress[4]	0	0	0	0	0	0
Suspected Event (Unknown)[5]	0	0	2 / 3 (66.7%)	2	2 / 3 (66.7%)	2
Suspected Event (Not Validated)[6]	0	0	1 / 3 (33.3%)	1	1 / 3 (33.3%)	1
Probable Event[7]	0	0	0	0	0	0

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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Vaccine Type - Pfizer

All Consented Population

	Enrolled within 10 days after vaccine (N=2511)		Enrolled more than 10 days after vaccine (N=2888)		Pfizer (N=5399)	
	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N
Blood Vessel Inflammation (e.g., Kawasaki Disease, Vasculitides)[9]	2 / 2511 (<1.0%)	2	1 / 2888 (<1.0%)	1	3 / 5399 (<1.0%)	3
Event Confirmation In Progress[4]	0	0	1 / 1 (100%)	1	1 / 3 (33.3%)	1
Suspected Event (Unknown)[5]	1 / 2 (50.0%)	1	0	0	1 / 3 (33.3%)	1
Suspected Event (Not Validated)[6]	1 / 2 (50.0%)	1	0	0	1 / 3 (33.3%)	1
Probable Event[7]	0	0	0	0	0	0

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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Vaccine Type - Pfizer

All Consented Population

	Enrolled within 10 days after vaccine (N=2511)		Enrolled more than 10 days after vaccine (N=2888)		Pfizer (N=5399)	
	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N
Abnormal Blood Clotting (e.g., Disseminated Intravascular Coagulation, Thrombocytopenia)[9]	1 / 2511 (<1.0%)	1	0	0	1 / 5399 (<1.0%)	1
Event Confirmation In Progress[4]	0	0	0	0	0	0
Suspected Event (Unknown)[5]	0	0	0	0	0	0
Suspected Event (Not Validated)[6]	0	0	0	0	0	0
Probable Event[7]	1 / 1 (100%)	1	0	0	1 / 1 (100%)	1

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Table 15.3.2.1.2

BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Vaccine Type - Pfizer

All Consented Population

	Enrolled within 10 days after vaccine (N=2511)		Enrolled more than 10 days after vaccine (N=2888)		Pfizer (N=5399)	
	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N
Bleeding Disorder (Hemorrhagic Disease)[9]	0	0	0	0	0	0
Event Confirmation In Progress[4]	0	0	0	0	0	0
Suspected Event (Unknown)[5]	0	0	0	0	0	0
Suspected Event (Not Validated)[6]	0	0	0	0	0	0
Probable Event[7]	0	0	0	0	0	0

All Consented Population is defined as all enrolled participants.

1: A subject may have more than one event, so an event row count can be larger than the row participant count and the sum of event rows can be more than the N in the header.

2: Excluding any events with hospitalization date or seeking medical date prior to vaccine date; if a participant reported an event on both hospitalization and unplanned medical care form on the same date, the event will be counted only once as a Hospitalization.

3 Verily eCRF reported adverse events of special interest collapsing on hospitalization date from the unplanned hospitalization forms. If more than one event was collected for the same hospitalization, all events will have the same confirmation status on CEA spreadsheet.

4: Adverse events of special interest in Verily eCRF, but no linkage in the CEA spreadsheet yet.

5: Adverse events of special interest with a link from the Verily eCRF to CEA spreadsheet with confirmation status as "Suspected Event (Unknown)".

6: Adverse events of special interest with a link from the Verily eCRF to CEA spreadsheet with confirmation status as "Suspected Event (Not Validated)".

7: Adverse events of special interest with a link from the Verily eCRF to CEA spreadsheet with confirmation status as "Probable Event".

8: Verily eCRF reported adverse events of special interest collapsing on seeking medical date for the same event from the other unplanned medical care forms

9: Adverse events of special interest collected from both unplanned hospitalization form and unplanned medical care form. If the event was reported on both form at the same date, the event will be counted only once in the table.

BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Vaccine Type - Pfizer

All Consented Population

	Enrolled within 10 days after vaccine (N=2511)		Enrolled more than 10 days after vaccine (N=2888)		Pfizer (N=5399)	
	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N
Heart Attack (Myocardial Infarction)[9]	0	0	1 / 2888 (<1.0%)	1	1 / 5399 (<1.0%)	1
Event Confirmation In Progress[4]	0	0	0	0	0	0
Suspected Event (Unknown)[5]	0	0	1 / 1 (100%)	1	1 / 1 (100%)	1
Suspected Event (Not Validated)[6]	0	0	0	0	0	0
Probable Event[7]	0	0	0	0	0	0

All Consented Population is defined as all enrolled participants.

1: A subject may have more than one event, so an event row count can be larger than the row participant count and the sum of event rows can be more than the N in the header.

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9: Adverse events of special interest collected from both unplanned hospitalization form and unplanned medical care form. If the event was reported on both form at the same date, the event will be counted only once in the table.

BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Vaccine Type - Pfizer

All Consented Population

	Enrolled within 10 days after vaccine (N=2511)		Enrolled more than 10 days after vaccine (N=2888)		Pfizer (N=5399)	
	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N
Heart Failure/Cardiogenic Shock[9]	0	0	0	0	0	0
Event Confirmation In Progress[4]	0	0	0	0	0	0
Suspected Event (Unknown)[5]	0	0	0	0	0	0
Suspected Event (Not Validated)[6]	0	0	0	0	0	0
Probable Event[7]	0	0	0	0	0	0

All Consented Population is defined as all enrolled participants.

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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Vaccine Type - Pfizer

All Consented Population

	Enrolled within 10 days after vaccine (N=2511)		Enrolled more than 10 days after vaccine (N=2888)		Pfizer (N=5399)	
	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N
Stress Cardiomyopathy[9]	0	0	0	0	0	0
Event Confirmation In Progress[4]	0	0	0	0	0	0
Suspected Event (Unknown)[5]	0	0	0	0	0	0
Suspected Event (Not Validated)[6]	0	0	0	0	0	0
Probable Event[7]	0	0	0	0	0	0

All Consented Population is defined as all enrolled participants.

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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Vaccine Type - Pfizer

All Consented Population

	Enrolled within 10 days after vaccine (N=2511)		Enrolled more than 10 days after vaccine (N=2888)		Pfizer (N=5399)	
	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N
Coronary Artery Disease[9]	0	0	0	0	0	0
Event Confirmation In Progress[4]	0	0	0	0	0	0
Suspected Event (Unknown)[5]	0	0	0	0	0	0
Suspected Event (Not Validated)[6]	0	0	0	0	0	0
Probable Event[7]	0	0	0	0	0	0

All Consented Population is defined as all enrolled participants.

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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Vaccine Type - Pfizer

All Consented Population

	Enrolled within 10 days after vaccine (N=2511)		Enrolled more than 10 days after vaccine (N=2888)		Pfizer (N=5399)	
	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N
Abnormal Heart Rhythm (Arrhythmia)[9]	0	0	0	0	0	0
Event Confirmation In Progress[4]	0	0	0	0	0	0
Suspected Event (Unknown)[5]	0	0	0	0	0	0
Suspected Event (Not Validated)[6]	0	0	0	0	0	0
Probable Event[7]	0	0	0	0	0	0

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Table 15.3.2.1.2

BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Vaccine Type - Pfizer

All Consented Population

	Enrolled within 10 days after vaccine (N=2511)		Enrolled more than 10 days after vaccine (N=2888)		Pfizer (N=5399)	
	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N
Stroke Or Possible Stroke[9]	1 / 2511 (<1.0%)	1	1 / 2888 (<1.0%)	2	2 / 5399 (<1.0%)	3
Event Confirmation In Progress[4]	1 / 1 (100%)	1	0	0	1 / 2 (50.0%)	1
Suspected Event (Unknown)[5]	0	0	0	1	0	1
Suspected Event (Not Validated)[6]	0	0	1 / 1 (100%)	1	1 / 2 (50.0%)	1
Probable Event[7]	0	0	0	0	0	0

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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Vaccine Type - Pfizer

All Consented Population

	Enrolled within 10 days after vaccine (N=2511)		Enrolled more than 10 days after vaccine (N=2888)		Pfizer (N=5399)	
	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N
Blockage Of Blood Flow To Limbs (e.g., Limb Ischemia, Peripheral Artery Disease)[9]	0	0	0	0	0	0
Event Confirmation In Progress[4]	0	0	0	0	0	0
Suspected Event (Unknown)[5]	0	0	0	0	0	0
Suspected Event (Not Validated)[6]	0	0	0	0	0	0
Probable Event[7]	0	0	0	0	0	0

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Table 15.3.2.1.2

BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Vaccine Type - Pfizer

All Consented Population

	Enrolled within 10 days after vaccine (N=2511)		Enrolled more than 10 days after vaccine (N=2888)		Pfizer (N=5399)	
	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N
Acute Kidney Injury[9]	0	0	0	0	0	0
Event Confirmation In Progress[4]	0	0	0	0	0	0
Suspected Event (Unknown)[5]	0	0	0	0	0	0
Suspected Event (Not Validated)[6]	0	0	0	0	0	0
Probable Event[7]	0	0	0	0	0	0

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BNT162b2 Protocol C4591008
Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Vaccine Type - Pfizer
All Consented Population

	Enrolled within 10 days after vaccine (N=2511)		Enrolled more than 10 days after vaccine (N=2888)		Pfizer (N=5399)	
	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N
Liver Injury[9]	0	0	0	0	0	0
Event Confirmation In Progress[4]	0	0	0	0	0	0
Suspected Event (Unknown)[5]	0	0	0	0	0	0
Suspected Event (Not Validated)[6]	0	0	0	0	0	0
Probable Event[7]	0	0	0	0	0	0

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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Vaccine Type - Pfizer

All Consented Population

	Enrolled within 10 days after vaccine (N=2511)		Enrolled more than 10 days after vaccine (N=2888)		Pfizer (N=5399)	
	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N
Skin Immune Reaction (e.g., Chillblain-Like Lesions, Erythema Multiforme)[9]	0	0	0	0	0	0
Event Confirmation In Progress[4]	0	0	0	0	0	0
Suspected Event (Unknown)[5]	0	0	0	0	0	0
Suspected Event (Not Validated)[6]	0	0	0	0	0	0
Probable Event[7]	0	0	0	0	0	0

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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Vaccine Type - Pfizer

All Consented Population

	Enrolled within 10 days after vaccine (N=2511)		Enrolled more than 10 days after vaccine (N=2888)		Pfizer (N=5399)	
	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N
Multisystem Inflammation[9]	2 / 2511 (<1.0%)	2	4 / 2888 (<1.0%)	4	6 / 5399 (<1.0%)	6
Event Confirmation In Progress[4]	0	0	1 / 4 (25.0%)	1	1 / 6 (16.7%)	1
Suspected Event (Unknown)[5]	0	0	1 / 4 (25.0%)	1	1 / 6 (16.7%)	1
Suspected Event (Not Validated)[6]	2 / 2 (100%)	2	2 / 4 (50.0%)	2	4 / 6 (66.7%)	4
Probable Event[7]	0	0	0	0	0	0

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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Vaccine Type - Pfizer

All Consented Population

	Enrolled within 10 days after vaccine (N=2511)		Enrolled more than 10 days after vaccine (N=2888)		Pfizer (N=5399)	
	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N
Fibromyalgia[9]	2 / 2511 (<1.0%)	2	2 / 2888 (<1.0%)	2	4 / 5399 (<1.0%)	4
Event Confirmation In Progress[4]	1 / 2 (50.0%)	1	1 / 2 (50.0%)	1	2 / 4 (50.0%)	2
Suspected Event (Unknown)[5]	1 / 2 (50.0%)	1	1 / 2 (50.0%)	1	2 / 4 (50.0%)	2
Suspected Event (Not Validated)[6]	0	0	0	0	0	0
Probable Event[7]	0	0	0	0	0	0

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6: Adverse events of special interest with a link from the Verily eCRF to CEA spreadsheet with confirmation status as "Suspected Event (Not Validated)".

7: Adverse events of special interest with a link from the Verily eCRF to CEA spreadsheet with confirmation status as "Probable Event".

8: Verily eCRF reported adverse events of special interest collapsing on seeking medical date for the same event from the other unplanned medical care forms

9: Adverse events of special interest collected from both unplanned hospitalization form and unplanned medical care form. If the event was reported on both form at the same date, the event will be counted only once in the table.

BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Vaccine Type - Pfizer

All Consented Population

	Enrolled within 10 days after vaccine (N=2511)		Enrolled more than 10 days after vaccine (N=2888)		Pfizer (N=5399)	
	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N
Nerve Inflammation Or Autoimmune Disease (e.g., Multiple Sclerosis, Rheumatoid Arthritis)[9]	9 / 2511 (<1.0%)	11	9 / 2888 (<1.0%)	11	18 / 5399 (<1.0%)	22
Event Confirmation In Progress[4]	2 / 9 (22.2%)	2	1 / 9 (11.1%)	2	3 / 18 (16.7%)	4
Suspected Event (Unknown)[5]	4 / 9 (44.4%)	5	4 / 9 (44.4%)	5	8 / 18 (44.4%)	10
Suspected Event (Not Validated)[6]	3 / 9 (33.3%)	4	3 / 9 (33.3%)	3	6 / 18 (33.3%)	7
Probable Event[7]	0	0	1 / 9 (11.1%)	1	1 / 18 (5.6%)	1

All Consented Population is defined as all enrolled participants.

1: A subject may have more than one event, so an event row count can be larger than the row participant count and the sum of event rows can be more than the N in the header.

2: Excluding any events with hospitalization date or seeking medical date prior to vaccine date; if a participant reported an event on both hospitalization and unplanned medical care form on the same date, the event will be counted only once as a Hospitalization.

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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Vaccine Type - Pfizer

All Consented Population

	Enrolled within 10 days after vaccine (N=2511)		Enrolled more than 10 days after vaccine (N=2888)		Pfizer (N=5399)	
	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N
Autoimmune Thyroiditis[9]	3 / 2511 (<1.0%)	3	1 / 2888 (<1.0%)	1	4 / 5399 (<1.0%)	4
Event Confirmation In Progress[4]	1 / 3 (33.3%)	1	0	0	1 / 4 (25.0%)	1
Suspected Event (Unknown)[5]	2 / 3 (66.7%)	2	1 / 1 (100%)	1	3 / 4 (75.0%)	3
Suspected Event (Not Validated)[6]	0	0	0	0	0	0
Probable Event[7]	0	0	0	0	0	0

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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Vaccine Type - Pfizer

All Consented Population

	Enrolled within 10 days after vaccine (N=2511)		Enrolled more than 10 days after vaccine (N=2888)		Pfizer (N=5399)	
	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N
COVID-19 Infection[9]	15 / 2511 (<1.0%)	20	14 / 2888 (<1.0%)	21	29 / 5399 (<1.0%)	41
Event Confirmation In Progress[4]	3 / 15 (20.0%)	4	1 / 14 (7.1%)	4	4 / 29 (13.8%)	8
Suspected Event (Unknown)[5]	6 / 15 (40.0%)	10	7 / 14 (50.0%)	9	13 / 29 (44.8%)	19
Suspected Event (Not Validated)[6]	5 / 15 (33.3%)	5	4 / 14 (28.6%)	6	9 / 29 (31.0%)	11
Probable Event[7]	1 / 15 (6.7%)	1	2 / 14 (14.3%)	2	3 / 29 (10.3%)	3

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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Vaccine Type - Pfizer

All Consented Population

	Enrolled within 10 days after vaccine (N=2511)		Enrolled more than 10 days after vaccine (N=2888)		Pfizer (N=5399)	
	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N
Generalized Convulsions/Seizures[9]	1 / 2511 (<1.0%)	1	2 / 2888 (<1.0%)	2	3 / 5399 (<1.0%)	3
Event Confirmation In Progress[4]	0	0	0	0	0	0
Suspected Event (Unknown)[5]	0	0	2 / 2 (100%)	2	2 / 3 (66.7%)	2
Suspected Event (Not Validated)[6]	1 / 1 (100%)	1	0	0	1 / 3 (33.3%)	1
Probable Event[7]	0	0	0	0	0	0

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Table 15.3.2.1.2

BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Vaccine Type - Pfizer

All Consented Population

	Enrolled within 10 days after vaccine (N=2511)		Enrolled more than 10 days after vaccine (N=2888)		Pfizer (N=5399)	
	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N
Bell's Palsy[9]	0	0	0	0	0	0
Event Confirmation In Progress[4]	0	0	0	0	0	0
Suspected Event (Unknown)[5]	0	0	0	0	0	0
Suspected Event (Not Validated)[6]	0	0	0	0	0	0
Probable Event[7]	0	0	0	0	0	0

All Consented Population is defined as all enrolled participants.

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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Vaccine Type - Pfizer

All Consented Population

	Enrolled within 10 days after vaccine (N=2511)		Enrolled more than 10 days after vaccine (N=2888)		Pfizer (N=5399)	
	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N
Narcolepsy Or Cataplexy[9]	0	0	0	0	0	0
Event Confirmation In Progress[4]	0	0	0	0	0	0
Suspected Event (Unknown)[5]	0	0	0	0	0	0
Suspected Event (Not Validated)[6]	0	0	0	0	0	0
Probable Event[7]	0	0	0	0	0	0

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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Vaccine Type - Pfizer

All Consented Population

	Enrolled within 10 days after vaccine (N=2511)		Enrolled more than 10 days after vaccine (N=2888)		Pfizer (N=5399)	
	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N
Joint Stiffness Or Pain (e.g., Arthralgia, Arthritis)[9]	32 / 2511 (1.3%)	43	47 / 2888 (1.6%)	56	79 / 5399 (1.5%)	99
Event Confirmation In Progress[4]	3 / 32 (9.4%)	7	12 / 47 (25.5%)	15	15 / 79 (19.0%)	22
Suspected Event (Unknown)[5]	20 / 32 (62.5%)	25	27 / 47 (57.4%)	31	47 / 79 (59.5%)	56
Suspected Event (Not Validated)[6]	8 / 32 (25.0%)	10	8 / 47 (17.0%)	10	16 / 79 (20.3%)	20
Probable Event[7]	1 / 32 (3.1%)	1	0	0	1 / 79 (1.3%)	1

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Table 15.3.2.1.2

BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Vaccine Type - Pfizer

All Consented Population

	Enrolled within 10 days after vaccine (N=2511)		Enrolled more than 10 days after vaccine (N=2888)		Pfizer (N=5399)	
	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N
Pregnancy-Related Issue[9]	19 / 2511 (<1.0%)	24	28 / 2888 (1.0%)	35	47 / 5399 (<1.0%)	59
Event Confirmation In Progress[4]	8 / 19 (42.1%)	10	10 / 28 (35.7%)	13	18 / 47 (38.3%)	23
Suspected Event (Unknown)[5]	5 / 19 (26.3%)	7	13 / 28 (46.4%)	16	18 / 47 (38.3%)	23
Suspected Event (Not Validated)[6]	6 / 19 (31.6%)	7	5 / 28 (17.9%)	6	11 / 47 (23.4%)	13
Probable Event[7]	0	0	0	0	0	0

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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Vaccine Type - Pfizer

All Consented Population

	Enrolled within 10 days after vaccine (N=2511)		Enrolled more than 10 days after vaccine (N=2888)		Pfizer (N=5399)	
	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N
Microangiopathy[9]	0	0	0	0	0	0
Event Confirmation In Progress[4]	0	0	0	0	0	0
Suspected Event (Unknown)[5]	0	0	0	0	0	0
Suspected Event (Not Validated)[6]	0	0	0	0	0	0
Probable Event[7]	0	0	0	0	0	0

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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Vaccine Type - Pfizer

All Consented Population

	Enrolled within 10 days after vaccine (N=2511)		Enrolled more than 10 days after vaccine (N=2888)		Pfizer (N=5399)	
	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N
Death[9]	1 / 2511 (<1.0%)	1	1 / 2888 (<1.0%)	1	2 / 5399 (<1.0%)	2
Event Confirmation In Progress[4]	1 / 1 (100%)	1	1 / 1 (100%)	1	2 / 2 (100%)	2
Suspected Event (Unknown)[5]	0	0	0	0	0	0
Suspected Event (Not Validated)[6]	0	0	0	0	0	0
Probable Event[7]	0	0	0	0	0	0

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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Vaccine Type - Pfizer

All Consented Population

	Enrolled within 10 days after vaccine (N=2511)		Enrolled more than 10 days after vaccine (N=2888)		Pfizer (N=5399)	
	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N
Other[9]	236 / 2511 (9.4%)	242	293 / 2888 (10.1%)	298	529 / 5399 (9.8%)	540
Event Confirmation In Progress[4]	228 / 236 (96.6%)	233	284 / 293 (96.9%)	289	512 / 529 (96.8%)	522
Suspected Event (Unknown)[5]	3 / 236 (1.3%)	4	3 / 293 (1.0%)	3	6 / 529 (1.1%)	7
Suspected Event (Not Validated)[6]	5 / 236 (2.1%)	5	5 / 293 (1.7%)	5	10 / 529 (1.9%)	10
Probable Event[7]	0	0	1 / 293 (<1.0%)	1	1 / 529 (<1.0%)	1

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Table 15.3.2.1.3

BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Vaccine Type - Other COVID-19 Vaccine

All Consented Population

	Enrolled within 10 days after vaccine (N=835)		Enrolled more than 10 days after vaccine (N=1590)		Other COVID-19 vaccine (N=2425)	
	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N
Any Adverse Event of Special Interest[2]	85 / 835 (10.2%)	95	126 / 1590 (7.9%)	167	211 / 2425 (8.7%)	262
Hospitalized[3]	2 / 835 (<1.0%)	2	18 / 1590 (1.1%)	30	20 / 2425 (<1.0%)	32
Event Confirmation In Progress[4]	1 / 2 (50.0%)	1	5 / 18 (27.8%)	16	6 / 20 (30.0%)	17
Suspected Event (Unknown)[5]	1 / 2 (50.0%)	1	7 / 18 (38.9%)	8	8 / 20 (40.0%)	9
Suspected Event (Not Validated)[6]	0	0	6 / 18 (33.3%)	6	6 / 20 (30.0%)	6
Probable Event[7]	0	0	0	0	0	0

All Consented Population is defined as all enrolled participants.

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9: Adverse events of special interest collected from both unplanned hospitalization form and unplanned medical care form. If the event was reported on both form at the same date, the event will be counted only once in the table.

Table 15.3.2.1.3

BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Vaccine Type - Other COVID-19 Vaccine

All Consented Population

	Enrolled within 10 days after vaccine (N=835)		Enrolled more than 10 days after vaccine (N=1590)		Other COVID-19 vaccine (N=2425)	
	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N
Not Hospitalized[8]	84 / 835 (10.1%)	93	120 / 1590 (7.5%)	137	204 / 2425 (8.4%)	230
Event Confirmation In Progress[4]	60 / 84 (71.4%)	67	86 / 120 (71.7%)	94	146 / 204 (71.6%)	161
Suspected Event (Unknown)[5]	16 / 84 (19.0%)	18	27 / 120 (22.5%)	36	43 / 204 (21.1%)	54
Suspected Event (Not Validated)[6]	8 / 84 (9.5%)	8	6 / 120 (5.0%)	6	14 / 204 (6.9%)	14
Probable Event[7]	0	0	1 / 120 (<1.0%)	1	1 / 204 (<1.0%)	1

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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Vaccine Type - Other COVID-19 Vaccine

All Consented Population

	Enrolled within 10 days after vaccine (N=835)		Enrolled more than 10 days after vaccine (N=1590)		Other COVID-19 vaccine (N=2425)	
	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N
Brain Or Spinal Cord Inflammation (e.g., Meningitis, Encephalitis, Guillain-Barre Syndrome)[9]	0	0	3 / 1590 (<1.0%)	4	3 / 2425 (<1.0%)	4
Event Confirmation In Progress[4]	0	0	2 / 3 (66.7%)	3	2 / 3 (66.7%)	3
Suspected Event (Unknown)[5]	0	0	0	0	0	0
Suspected Event (Not Validated)[6]	0	0	1 / 3 (33.3%)	1	1 / 3 (33.3%)	1
Probable Event[7]	0	0	0	0	0	0

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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Vaccine Type - Other COVID-19 Vaccine

All Consented Population

	Enrolled within 10 days after vaccine (N=835)		Enrolled more than 10 days after vaccine (N=1590)		Other COVID-19 vaccine (N=2425)	
	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N
Severe Allergic Reaction (Anaphylaxis)[9]	1 / 835 (<1.0%)	1	4 / 1590 (<1.0%)	5	5 / 2425 (<1.0%)	6
Event Confirmation In Progress[4]	0	0	3 / 4 (75.0%)	4	3 / 5 (60.0%)	4
Suspected Event (Unknown)[5]	0	0	1 / 4 (25.0%)	1	1 / 5 (20.0%)	1
Suspected Event (Not Validated)[6]	1 / 1 (100%)	1	0	0	1 / 5 (20.0%)	1
Probable Event[7]	0	0	0	0	0	0

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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Vaccine Type - Other COVID-19 Vaccine

All Consented Population

	Enrolled within 10 days after vaccine (N=835)		Enrolled more than 10 days after vaccine (N=1590)		Other COVID-19 vaccine (N=2425)	
	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N
Non-Severe Allergic Reaction[9]	6 / 835 (<1.0%)	7	5 / 1590 (<1.0%)	5	11 / 2425 (<1.0%)	12
Event Confirmation In Progress[4]	2 / 6 (33.3%)	2	2 / 5 (40.0%)	2	4 / 11 (36.4%)	4
Suspected Event (Unknown)[5]	3 / 6 (50.0%)	4	3 / 5 (60.0%)	3	6 / 11 (54.5%)	7
Suspected Event (Not Validated)[6]	1 / 6 (16.7%)	1	0	0	1 / 11 (9.1%)	1
Probable Event[7]	0	0	0	0	0	0

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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Vaccine Type - Other COVID-19 Vaccine

All Consented Population

	Enrolled within 10 days after vaccine (N=835)		Enrolled more than 10 days after vaccine (N=1590)		Other COVID-19 vaccine (N=2425)	
	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N
Heart Inflammation (e.g., Myocarditis, Pericarditis)[9]	0	0	0	0	0	0
Event Confirmation In Progress[4]	0	0	0	0	0	0
Suspected Event (Unknown)[5]	0	0	0	0	0	0
Suspected Event (Not Validated)[6]	0	0	0	0	0	0
Probable Event[7]	0	0	0	0	0	0

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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Vaccine Type - Other COVID-19 Vaccine

All Consented Population

	Enrolled within 10 days after vaccine (N=835)		Enrolled more than 10 days after vaccine (N=1590)		Other COVID-19 vaccine (N=2425)	
	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N
Blood Clot Inside A Vein In The Body (Thromboembolism)[9]	0	0	3 / 1590 (<1.0%)	3	3 / 2425 (<1.0%)	3
Event Confirmation In Progress[4]	0	0	1 / 3 (33.3%)	1	1 / 3 (33.3%)	1
Suspected Event (Unknown)[5]	0	0	2 / 3 (66.7%)	2	2 / 3 (66.7%)	2
Suspected Event (Not Validated)[6]	0	0	0	0	0	0
Probable Event[7]	0	0	0	0	0	0

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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Vaccine Type - Other COVID-19 Vaccine

All Consented Population

	Enrolled within 10 days after vaccine (N=835)		Enrolled more than 10 days after vaccine (N=1590)		Other COVID-19 vaccine (N=2425)	
	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N
Blood Vessel Inflammation (e.g., Kawasaki Disease, Vasculitides)[9]	0	0	1 / 1590 (<1.0%)	1	1 / 2425 (<1.0%)	1
Event Confirmation In Progress[4]	0	0	0	0	0	0
Suspected Event (Unknown)[5]	0	0	1 / 1 (100%)	1	1 / 1 (100%)	1
Suspected Event (Not Validated)[6]	0	0	0	0	0	0
Probable Event[7]	0	0	0	0	0	0

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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Vaccine Type - Other COVID-19 Vaccine

All Consented Population

	Enrolled within 10 days after vaccine (N=835)		Enrolled more than 10 days after vaccine (N=1590)		Other COVID-19 vaccine (N=2425)	
	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N
Abnormal Blood Clotting (e.g., Disseminated Intravascular Coagulation, Thrombocytopenia)[9]	0	0	2 / 1590 (<1.0%)	2	2 / 2425 (<1.0%)	2
Event Confirmation In Progress[4]	0	0	0	0	0	0
Suspected Event (Unknown)[5]	0	0	1 / 2 (50.0%)	1	1 / 2 (50.0%)	1
Suspected Event (Not Validated)[6]	0	0	1 / 2 (50.0%)	1	1 / 2 (50.0%)	1
Probable Event[7]	0	0	0	0	0	0

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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Vaccine Type - Other COVID-19 Vaccine

All Consented Population

	Enrolled within 10 days after vaccine (N=835)		Enrolled more than 10 days after vaccine (N=1590)		Other COVID-19 vaccine (N=2425)	
	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N
Bleeding Disorder (Hemorrhagic Disease)[9]	0	0	0	0	0	0
Event Confirmation In Progress[4]	0	0	0	0	0	0
Suspected Event (Unknown)[5]	0	0	0	0	0	0
Suspected Event (Not Validated)[6]	0	0	0	0	0	0
Probable Event[7]	0	0	0	0	0	0

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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Vaccine Type - Other COVID-19 Vaccine

All Consented Population

	Enrolled within 10 days after vaccine (N=835)		Enrolled more than 10 days after vaccine (N=1590)		Other COVID-19 vaccine (N=2425)	
	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N
Heart Attack (Myocardial Infarction)[9]	0	0	1 / 1590 (<1.0%)	2	1 / 2425 (<1.0%)	2
Event Confirmation In Progress[4]	0	0	1 / 1 (100%)	2	1 / 1 (100%)	2
Suspected Event (Unknown)[5]	0	0	0	0	0	0
Suspected Event (Not Validated)[6]	0	0	0	0	0	0
Probable Event[7]	0	0	0	0	0	0

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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Vaccine Type - Other COVID-19 Vaccine

All Consented Population

	Enrolled within 10 days after vaccine (N=835)		Enrolled more than 10 days after vaccine (N=1590)		Other COVID-19 vaccine (N=2425)	
	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N
Heart Failure/Cardiogenic Shock[9]	0	0	1 / 1590 (<1.0%)	1	1 / 2425 (<1.0%)	1
Event Confirmation In Progress[4]	0	0	1 / 1 (100%)	1	1 / 1 (100%)	1
Suspected Event (Unknown)[5]	0	0	0	0	0	0
Suspected Event (Not Validated)[6]	0	0	0	0	0	0
Probable Event[7]	0	0	0	0	0	0

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Table 15.3.2.1.3

BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Vaccine Type - Other COVID-19 Vaccine

All Consented Population

	Enrolled within 10 days after vaccine (N=835)		Enrolled more than 10 days after vaccine (N=1590)		Other COVID-19 vaccine (N=2425)	
	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N
Stress Cardiomyopathy[9]	0	0	1 / 1590 (<1.0%)	1	1 / 2425 (<1.0%)	1
Event Confirmation In Progress[4]	0	0	1 / 1 (100%)	1	1 / 1 (100%)	1
Suspected Event (Unknown)[5]	0	0	0	0	0	0
Suspected Event (Not Validated)[6]	0	0	0	0	0	0
Probable Event[7]	0	0	0	0	0	0

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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Vaccine Type - Other COVID-19 Vaccine

All Consented Population

	Enrolled within 10 days after vaccine (N=835)		Enrolled more than 10 days after vaccine (N=1590)		Other COVID-19 vaccine (N=2425)	
	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N
Coronary Artery Disease[9]	0	0	0	0	0	0
Event Confirmation In Progress[4]	0	0	0	0	0	0
Suspected Event (Unknown)[5]	0	0	0	0	0	0
Suspected Event (Not Validated)[6]	0	0	0	0	0	0
Probable Event[7]	0	0	0	0	0	0

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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Vaccine Type - Other COVID-19 Vaccine

All Consented Population

	Enrolled within 10 days after vaccine (N=835)		Enrolled more than 10 days after vaccine (N=1590)		Other COVID-19 vaccine (N=2425)	
	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N
Abnormal Heart Rhythm (Arrhythmia)[9]	0	0	1 / 1590 (<1.0%)	1	1 / 2425 (<1.0%)	1
Event Confirmation In Progress[4]	0	0	1 / 1 (100%)	1	1 / 1 (100%)	1
Suspected Event (Unknown)[5]	0	0	0	0	0	0
Suspected Event (Not Validated)[6]	0	0	0	0	0	0
Probable Event[7]	0	0	0	0	0	0

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Table 15.3.2.1.3

BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Vaccine Type - Other COVID-19 Vaccine

All Consented Population

	Enrolled within 10 days after vaccine (N=835)		Enrolled more than 10 days after vaccine (N=1590)		Other COVID-19 vaccine (N=2425)	
	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N
Stroke Or Possible Stroke[9]	0	0	0	0	0	0
Event Confirmation In Progress[4]	0	0	0	0	0	0
Suspected Event (Unknown)[5]	0	0	0	0	0	0
Suspected Event (Not Validated)[6]	0	0	0	0	0	0
Probable Event[7]	0	0	0	0	0	0

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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Vaccine Type - Other COVID-19 Vaccine

All Consented Population

	Enrolled within 10 days after vaccine (N=835)		Enrolled more than 10 days after vaccine (N=1590)		Other COVID-19 vaccine (N=2425)	
	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N
Blockage Of Blood Flow To Limbs (e.g., Limb Ischemia, Peripheral Artery Disease)[9]	0	0	0	0	0	0
Event Confirmation In Progress[4]	0	0	0	0	0	0
Suspected Event (Unknown)[5]	0	0	0	0	0	0
Suspected Event (Not Validated)[6]	0	0	0	0	0	0
Probable Event[7]	0	0	0	0	0	0

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Table 15.3.2.1.3

BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Vaccine Type - Other COVID-19 Vaccine

All Consented Population

	Enrolled within 10 days after vaccine (N=835)		Enrolled more than 10 days after vaccine (N=1590)		Other COVID-19 vaccine (N=2425)	
	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N
Acute Kidney Injury[9]	0	0	0	0	0	0
Event Confirmation In Progress[4]	0	0	0	0	0	0
Suspected Event (Unknown)[5]	0	0	0	0	0	0
Suspected Event (Not Validated)[6]	0	0	0	0	0	0
Probable Event[7]	0	0	0	0	0	0

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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Vaccine Type - Other COVID-19 Vaccine

All Consented Population

	Enrolled within 10 days after vaccine (N=835)		Enrolled more than 10 days after vaccine (N=1590)		Other COVID-19 vaccine (N=2425)	
	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N
Liver Injury[9]	0	0	2 / 1590 (<1.0%)	2	2 / 2425 (<1.0%)	2
Event Confirmation In Progress[4]	0	0	1 / 2 (50.0%)	1	1 / 2 (50.0%)	1
Suspected Event (Unknown)[5]	0	0	1 / 2 (50.0%)	1	1 / 2 (50.0%)	1
Suspected Event (Not Validated)[6]	0	0	0	0	0	0
Probable Event[7]	0	0	0	0	0	0

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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Vaccine Type - Other COVID-19 Vaccine

All Consented Population

	Enrolled within 10 days after vaccine (N=835)		Enrolled more than 10 days after vaccine (N=1590)		Other COVID-19 vaccine (N=2425)	
	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N
Skin Immune Reaction (e.g., Chillblain-Like Lesions, Erythema Multiforme)[9]	0	0	0	0	0	0
Event Confirmation In Progress[4]	0	0	0	0	0	0
Suspected Event (Unknown)[5]	0	0	0	0	0	0
Suspected Event (Not Validated)[6]	0	0	0	0	0	0
Probable Event[7]	0	0	0	0	0	0

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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Vaccine Type - Other COVID-19 Vaccine

All Consented Population

	Enrolled within 10 days after vaccine (N=835)		Enrolled more than 10 days after vaccine (N=1590)		Other COVID-19 vaccine (N=2425)	
	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N
Multisystem Inflammation[9]	1 / 835 (<1.0%)	1	7 / 1590 (<1.0%)	8	8 / 2425 (<1.0%)	9
Event Confirmation In Progress[4]	0	0	2 / 7 (28.6%)	2	2 / 8 (25.0%)	2
Suspected Event (Unknown)[5]	1 / 1 (100%)	1	5 / 7 (71.4%)	6	6 / 8 (75.0%)	7
Suspected Event (Not Validated)[6]	0	0	0	0	0	0
Probable Event[7]	0	0	0	0	0	0

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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Vaccine Type - Other COVID-19 Vaccine

All Consented Population

	Enrolled within 10 days after vaccine (N=835)		Enrolled more than 10 days after vaccine (N=1590)		Other COVID-19 vaccine (N=2425)	
	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N
Fibromyalgia[9]	0	0	1 / 1590 (<1.0%)	1	1 / 2425 (<1.0%)	1
Event Confirmation In Progress[4]	0	0	0	0	0	0
Suspected Event (Unknown)[5]	0	0	1 / 1 (100%)	1	1 / 1 (100%)	1
Suspected Event (Not Validated)[6]	0	0	0	0	0	0
Probable Event[7]	0	0	0	0	0	0

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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Vaccine Type - Other COVID-19 Vaccine

All Consented Population

	Enrolled within 10 days after vaccine (N=835)		Enrolled more than 10 days after vaccine (N=1590)		Other COVID-19 vaccine (N=2425)	
	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N
Nerve Inflammation Or Autoimmune Disease (e.g., Multiple Sclerosis, Rheumatoid Arthritis)[9]	0	0	6 / 1590 (<1.0%)	6	6 / 2425 (<1.0%)	6
Event Confirmation In Progress[4]	0	0	4 / 6 (66.7%)	4	4 / 6 (66.7%)	4
Suspected Event (Unknown)[5]	0	0	2 / 6 (33.3%)	2	2 / 6 (33.3%)	2
Suspected Event (Not Validated)[6]	0	0	0	0	0	0
Probable Event[7]	0	0	0	0	0	0

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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Vaccine Type - Other COVID-19 Vaccine

All Consented Population

	Enrolled within 10 days after vaccine (N=835)		Enrolled more than 10 days after vaccine (N=1590)		Other COVID-19 vaccine (N=2425)	
	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N
Autoimmune Thyroiditis[9]	0	0	0	0	0	0
Event Confirmation In Progress[4]	0	0	0	0	0	0
Suspected Event (Unknown)[5]	0	0	0	0	0	0
Suspected Event (Not Validated)[6]	0	0	0	0	0	0
Probable Event[7]	0	0	0	0	0	0

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Table 15.3.2.1.3

BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Vaccine Type - Other COVID-19 Vaccine

All Consented Population

	Enrolled within 10 days after vaccine (N=835)		Enrolled more than 10 days after vaccine (N=1590)		Other COVID-19 vaccine (N=2425)	
	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N
COVID-19 Infection[9]	3 / 835 (<1.0%)	3	6 / 1590 (<1.0%)	8	9 / 2425 (<1.0%)	11
Event Confirmation In Progress[4]	1 / 3 (33.3%)	1	1 / 6 (16.7%)	1	2 / 9 (22.2%)	2
Suspected Event (Unknown)[5]	2 / 3 (66.7%)	2	3 / 6 (50.0%)	5	5 / 9 (55.6%)	7
Suspected Event (Not Validated)[6]	0	0	1 / 6 (16.7%)	1	1 / 9 (11.1%)	1
Probable Event[7]	0	0	1 / 6 (16.7%)	1	1 / 9 (11.1%)	1

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7: Adverse events of special interest with a link from the Verily eCRF to CEA spreadsheet with confirmation status as "Probable Event".

8: Verily eCRF reported adverse events of special interest collapsing on seeking medical date for the same event from the other unplanned medical care forms

9: Adverse events of special interest collected from both unplanned hospitalization form and unplanned medical care form. If the event was reported on both form at the same date, the event will be counted only once in the table.

Table 15.3.2.1.3

BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Vaccine Type - Other COVID-19 Vaccine

All Consented Population

	Enrolled within 10 days after vaccine (N=835)		Enrolled more than 10 days after vaccine (N=1590)		Other COVID-19 vaccine (N=2425)	
	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N
Generalized Convulsions/Seizures[9]	0	0	1 / 1590 (<1.0%)	2	1 / 2425 (<1.0%)	2
Event Confirmation In Progress[4]	0	0	0	0	0	0
Suspected Event (Unknown)[5]	0	0	1 / 1 (100%)	2	1 / 1 (100%)	2
Suspected Event (Not Validated)[6]	0	0	0	0	0	0
Probable Event[7]	0	0	0	0	0	0

All Consented Population is defined as all enrolled participants.

1: A subject may have more than one event, so an event row count can be larger than the row participant count and the sum of event rows can be more than the N in the header.

2: Excluding any events with hospitalization date or seeking medical date prior to vaccine date; if a participant reported an event on both hospitalization and unplanned medical care form on the same date, the event will be counted only once as a Hospitalization.

3: Verily eCRF reported adverse events of special interest collapsing on hospitalization date from the unplanned hospitalization forms. If more than one event was collected for the same hospitalization, all events will have the same confirmation status on CEA spreadsheet.

4: Adverse events of special interest in Verily eCRF, but no linkage in the CEA spreadsheet yet.

5: Adverse events of special interest with a link from the Verily eCRF to CEA spreadsheet with confirmation status as "Suspected Event (Unknown)".

6: Adverse events of special interest with a link from the Verily eCRF to CEA spreadsheet with confirmation status as "Suspected Event (Not Validated)".

7: Adverse events of special interest with a link from the Verily eCRF to CEA spreadsheet with confirmation status as "Probable Event".

8: Verily eCRF reported adverse events of special interest collapsing on seeking medical date for the same event from the other unplanned medical care forms

9: Adverse events of special interest collected from both unplanned hospitalization form and unplanned medical care form. If the event was reported on both form at the same date, the event will be counted only once in the table.

BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Vaccine Type - Other COVID-19 Vaccine

All Consented Population

	Enrolled within 10 days after vaccine (N=835)		Enrolled more than 10 days after vaccine (N=1590)		Other COVID-19 vaccine (N=2425)	
	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N
Bell's Palsy[9]	0	0	0	0	0	0
Event Confirmation In Progress[4]	0	0	0	0	0	0
Suspected Event (Unknown)[5]	0	0	0	0	0	0
Suspected Event (Not Validated)[6]	0	0	0	0	0	0
Probable Event[7]	0	0	0	0	0	0

All Consented Population is defined as all enrolled participants.

1: A subject may have more than one event, so an event row count can be larger than the row participant count and the sum of event rows can be more than the N in the header.

2: Excluding any events with hospitalization date or seeking medical date prior to vaccine date; if a participant reported an event on both hospitalization and unplanned medical care form on the same date, the event will be counted only once as a Hospitalization.

3: Verily eCRF reported adverse events of special interest collapsing on hospitalization date from the unplanned hospitalization forms. If more than one event was collected for the same hospitalization, all events will have the same confirmation status on CEA spreadsheet.

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6: Adverse events of special interest with a link from the Verily eCRF to CEA spreadsheet with confirmation status as "Suspected Event (Not Validated)".

7: Adverse events of special interest with a link from the Verily eCRF to CEA spreadsheet with confirmation status as "Probable Event".

8: Verily eCRF reported adverse events of special interest collapsing on seeking medical date for the same event from the other unplanned medical care forms

9: Adverse events of special interest collected from both unplanned hospitalization form and unplanned medical care form. If the event was reported on both form at the same date, the event will be counted only once in the table.

BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Vaccine Type - Other COVID-19 Vaccine

All Consented Population

	Enrolled within 10 days after vaccine (N=835)		Enrolled more than 10 days after vaccine (N=1590)		Other COVID-19 vaccine (N=2425)	
	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N
Narcolepsy Or Cataplexy[9]	1 / 835 (<1.0%)	1	0	0	1 / 2425 (<1.0%)	1
Event Confirmation In Progress[4]	0	0	0	0	0	0
Suspected Event (Unknown)[5]	1 / 1 (100%)	1	0	0	1 / 1 (100%)	1
Suspected Event (Not Validated)[6]	0	0	0	0	0	0
Probable Event[7]	0	0	0	0	0	0

All Consented Population is defined as all enrolled participants.

1: A subject may have more than one event, so an event row count can be larger than the row participant count and the sum of event rows can be more than the N in the header.

2: Excluding any events with hospitalization date or seeking medical date prior to vaccine date; if a participant reported an event on both hospitalization and unplanned medical care form on the same date, the event will be counted only once as a Hospitalization.

3: Verily eCRF reported adverse events of special interest collapsing on hospitalization date from the unplanned hospitalization forms. If more than one event was collected for the same hospitalization, all events will have the same confirmation status on CEA spreadsheet.

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5: Adverse events of special interest with a link from the Verily eCRF to CEA spreadsheet with confirmation status as "Suspected Event (Unknown)".

6: Adverse events of special interest with a link from the Verily eCRF to CEA spreadsheet with confirmation status as "Suspected Event (Not Validated)".

7: Adverse events of special interest with a link from the Verily eCRF to CEA spreadsheet with confirmation status as "Probable Event".

8: Verily eCRF reported adverse events of special interest collapsing on seeking medical date for the same event from the other unplanned medical care forms

9: Adverse events of special interest collected from both unplanned hospitalization form and unplanned medical care form. If the event was reported on both form at the same date, the event will be counted only once in the table.

BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Vaccine Type - Other COVID-19 Vaccine

All Consented Population

	Enrolled within 10 days after vaccine (N=835)		Enrolled more than 10 days after vaccine (N=1590)		Other COVID-19 vaccine (N=2425)	
	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N
Joint Stiffness Or Pain (e.g., Arthralgia, Arthritis)[9]	18 / 835 (2.2%)	19	16 / 1590 (1.0%)	21	34 / 2425 (1.4%)	40
Event Confirmation In Progress[4]	4 / 18 (22.2%)	4	5 / 16 (31.3%)	6	9 / 34 (26.5%)	10
Suspected Event (Unknown)[5]	9 / 18 (50.0%)	10	9 / 16 (56.3%)	13	18 / 34 (52.9%)	23
Suspected Event (Not Validated)[6]	5 / 18 (27.8%)	5	2 / 16 (12.5%)	2	7 / 34 (20.6%)	7
Probable Event[7]	0	0	0	0	0	0

All Consented Population is defined as all enrolled participants.

1: A subject may have more than one event, so an event row count can be larger than the row participant count and the sum of event rows can be more than the N in the header.

2: Excluding any events with hospitalization date or seeking medical date prior to vaccine date; if a participant reported an event on both hospitalization and unplanned medical care form on the same date, the event will be counted only once as a Hospitalization.

3: Verily eCRF reported adverse events of special interest collapsing on hospitalization date from the unplanned hospitalization forms. If more than one event was collected for the same hospitalization, all events will have the same confirmation status on CEA spreadsheet.

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6: Adverse events of special interest with a link from the Verily eCRF to CEA spreadsheet with confirmation status as "Suspected Event (Not Validated)".

7: Adverse events of special interest with a link from the Verily eCRF to CEA spreadsheet with confirmation status as "Probable Event".

8: Verily eCRF reported adverse events of special interest collapsing on seeking medical date for the same event from the other unplanned medical care forms

9: Adverse events of special interest collected from both unplanned hospitalization form and unplanned medical care form. If the event was reported on both form at the same date, the event will be counted only once in the table.

BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Vaccine Type - Other COVID-19 Vaccine

All Consented Population

	Enrolled within 10 days after vaccine (N=835)		Enrolled more than 10 days after vaccine (N=1590)		Other COVID-19 vaccine (N=2425)	
	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N
Pregnancy-Related Issue[9]	4 / 835 (<1.0%)	4	5 / 1590 (<1.0%)	5	9 / 2425 (<1.0%)	9
Event Confirmation In Progress[4]	2 / 4 (50.0%)	2	2 / 5 (40.0%)	2	4 / 9 (44.4%)	4
Suspected Event (Unknown)[5]	1 / 4 (25.0%)	1	1 / 5 (20.0%)	1	2 / 9 (22.2%)	2
Suspected Event (Not Validated)[6]	1 / 4 (25.0%)	1	2 / 5 (40.0%)	2	3 / 9 (33.3%)	3
Probable Event[7]	0	0	0	0	0	0

All Consented Population is defined as all enrolled participants.

1: A subject may have more than one event, so an event row count can be larger than the row participant count and the sum of event rows can be more than the N in the header.

2: Excluding any events with hospitalization date or seeking medical date prior to vaccine date; if a participant reported an event on both hospitalization and unplanned medical care form on the same date, the event will be counted only once as a Hospitalization.

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4: Adverse events of special interest in Verily eCRF, but no linkage in the CEA spreadsheet yet.

5: Adverse events of special interest with a link from the Verily eCRF to CEA spreadsheet with confirmation status as "Suspected Event (Unknown)".

6: Adverse events of special interest with a link from the Verily eCRF to CEA spreadsheet with confirmation status as "Suspected Event (Not Validated)".

7: Adverse events of special interest with a link from the Verily eCRF to CEA spreadsheet with confirmation status as "Probable Event".

8: Verily eCRF reported adverse events of special interest collapsing on seeking medical date for the same event from the other unplanned medical care forms

9: Adverse events of special interest collected from both unplanned hospitalization form and unplanned medical care form. If the event was reported on both form at the same date, the event will be counted only once in the table.

Table 15.3.2.1.3

BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Vaccine Type - Other COVID-19 Vaccine

All Consented Population

	Enrolled within 10 days after vaccine (N=835)		Enrolled more than 10 days after vaccine (N=1590)		Other COVID-19 vaccine (N=2425)	
	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N
Microangiopathy[9]	0	0	0	0	0	0
Event Confirmation In Progress[4]	0	0	0	0	0	0
Suspected Event (Unknown)[5]	0	0	0	0	0	0
Suspected Event (Not Validated)[6]	0	0	0	0	0	0
Probable Event[7]	0	0	0	0	0	0

All Consented Population is defined as all enrolled participants.

1: A subject may have more than one event, so an event row count can be larger than the row participant count and the sum of event rows can be more than the N in the header.

2: Excluding any events with hospitalization date or seeking medical date prior to vaccine date; if a participant reported an event on both hospitalization and unplanned medical care form on the same date, the event will be counted only once as a Hospitalization.

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7: Adverse events of special interest with a link from the Verily eCRF to CEA spreadsheet with confirmation status as "Probable Event".

8: Verily eCRF reported adverse events of special interest collapsing on seeking medical date for the same event from the other unplanned medical care forms

9: Adverse events of special interest collected from both unplanned hospitalization form and unplanned medical care form. If the event was reported on both form at the same date, the event will be counted only once in the table.

BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Vaccine Type - Other COVID-19 Vaccine

All Consented Population

	Enrolled within 10 days after vaccine (N=835)		Enrolled more than 10 days after vaccine (N=1590)		Other COVID-19 vaccine (N=2425)	
	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N
Death[9]	0	0	0	0	0	0
Event Confirmation In Progress[4]	0	0	0	0	0	0
Suspected Event (Unknown)[5]	0	0	0	0	0	0
Suspected Event (Not Validated)[6]	0	0	0	0	0	0
Probable Event[7]	0	0	0	0	0	0

All Consented Population is defined as all enrolled participants.

1: A subject may have more than one event, so an event row count can be larger than the row participant count and the sum of event rows can be more than the N in the header.

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6: Adverse events of special interest with a link from the Verily eCRF to CEA spreadsheet with confirmation status as "Suspected Event (Not Validated)".

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8: Verily eCRF reported adverse events of special interest collapsing on seeking medical date for the same event from the other unplanned medical care forms

9: Adverse events of special interest collected from both unplanned hospitalization form and unplanned medical care form. If the event was reported on both form at the same date, the event will be counted only once in the table.

BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Vaccine Type - Other COVID-19 Vaccine

All Consented Population

	Enrolled within 10 days after vaccine (N=835)		Enrolled more than 10 days after vaccine (N=1590)		Other COVID-19 vaccine (N=2425)	
	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N	Participants n/N (%)	Events[1] N
Other[9]	58 / 835 (6.9%)	59	83 / 1590 (5.2%)	89	141 / 2425 (5.8%)	148
Event Confirmation In Progress[4]	58 / 58 (100%)	59	73 / 83 (88.0%)	79	131 / 141 (92.9%)	138
Suspected Event (Unknown)[5]	0	0	5 / 83 (6.0%)	5	5 / 141 (3.5%)	5
Suspected Event (Not Validated)[6]	0	0	5 / 83 (6.0%)	5	5 / 141 (3.5%)	5
Probable Event[7]	0	0	0	0	0	0

All Consented Population is defined as all enrolled participants.

1: A subject may have more than one event, so an event row count can be larger than the row participant count and the sum of event rows can be more than the N in the header.

2: Excluding any events with hospitalization date or seeking medical date prior to vaccine date; if a participant reported an event on both hospitalization and unplanned medical care form on the same date, the event will be counted only once as a Hospitalization.

3: Verily eCRF reported adverse events of special interest collapsing on hospitalization date from the unplanned hospitalization forms. If more than one event was collected for the same hospitalization, all events will have the same confirmation status on CEA spreadsheet.

4: Adverse events of special interest in Verily eCRF, but no linkage in the CEA spreadsheet yet.

5: Adverse events of special interest with a link from the Verily eCRF to CEA spreadsheet with confirmation status as "Suspected Event (Unknown)".

6: Adverse events of special interest with a link from the Verily eCRF to CEA spreadsheet with confirmation status as "Suspected Event (Not Validated)".

7: Adverse events of special interest with a link from the Verily eCRF to CEA spreadsheet with confirmation status as "Probable Event".

8: Verily eCRF reported adverse events of special interest collapsing on seeking medical date for the same event from the other unplanned medical care forms

9: Adverse events of special interest collected from both unplanned hospitalization form and unplanned medical care form. If the event was reported on both form at the same date, the event will be counted only once in the table.

Table 15.3.2.1.4

BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Pregnancy

Primary Analysis Safety Population

	Pregnancy[1] (N=101)		Not Pregnancy (N=2147)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Any Adverse Event of Special Interest[3]	17 / 101 (16.8%)	22	300 / 2147 (14.0%)	353	320 / 2511 (12.7%)	378
Hospitalized[4]	6 / 101 (5.9%)	6	10 / 2147 (<1.0%)	11	16 / 2511 (<1.0%)	17
Event Confirmation In Progress[5]	1 / 6 (16.7%)	1	1 / 10 (10.0%)	1	2 / 16 (12.5%)	2
Suspected Event (Unknown)[6]	2 / 6 (33.3%)	2	4 / 10 (40.0%)	5	6 / 16 (37.5%)	7
Suspected Event (Not Validated)[7]	3 / 6 (50.0%)	3	5 / 10 (50.0%)	5	8 / 16 (50.0%)	8
Probable Event[8]	0	0	0	0	0	0

Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.
1: Pregnancy at time of enrolment includes both the participant and the partner pregnancy. There are 263 participants without pregnancy status due to no status being collected.
2: A subject may have more than one event, so an event row count can be larger than the row participant count and the sum of event rows can be more than the N in the header.
3: Excluding any events with hospitalization date or seeking medical date prior to vaccine date; if a participant reported an event on both hospitalization and unplanned medical care form on the same date, the event will be counted only once as a Hospitalization.
4: Verily eCRF reported adverse events of special interest collapsing on hospitalization date from the unplanned hospitalization forms. If more than one event was collected for the same hospitalization, all events will have the same confirmation status on CEA spreadsheet.
5: Adverse events of special interest in Verily eCRF, but no linkage in the CEA spreadsheet yet.
6: Adverse events of special interest with a link from the Verily eCRF to CEA spreadsheet with confirmation status as "Suspected Event (Unknown)".
7: Adverse events of special interest with a link from the Verily eCRF to CEA spreadsheet with confirmation status as "Suspected Event (Not Validated)".
8: Adverse events of special interest with a link from the Verily eCRF to CEA spreadsheet with confirmation status as "Probable Event".
9: Verily eCRF reported adverse events of special interest collapsing on seeking medical date for the same event from the other unplanned medical care forms
10: Adverse events of special interest collected from both unplanned hospitalization form and unplanned medical care form. If the event was reported on both form at the same date, the event will be counted only once in the table.

Table 15.3.2.1.4

BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Pregnancy

Primary Analysis Safety Population

	Pregnancy[1] (N=101)		Not Pregnancy (N=2147)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Not Hospitalized[9]	13 / 101 (12.9%)	16	297 / 2147 (13.8%)	342	313 / 2511 (12.5%)	361
Event Confirmation In Progress[5]	5 / 13 (38.5%)	6	226 / 297 (76.1%)	253	233 / 313 (74.4%)	261
Suspected Event (Unknown)[6]	5 / 13 (38.5%)	6	44 / 297 (14.8%)	59	50 / 313 (16.0%)	66
Suspected Event (Not Validated)[7]	3 / 13 (23.1%)	4	24 / 297 (8.1%)	27	27 / 313 (8.6%)	31
Probable Event[8]	0	0	3 / 297 (1.0%)	3	3 / 313 (1.0%)	3

Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.
1: Pregnancy at time of enrolment includes both the participant and the partner pregnancy. There are 263 participants without pregnancy status due to no status being collected.
2: A subject may have more than one event, so an event row count can be larger than the row participant count and the sum of event rows can be more than the N in the header.
3: Excluding any events with hospitalization date or seeking medical date prior to vaccine date; if a participant reported an event on both hospitalization and unplanned medical care form on the same date, the event will be counted only once as a Hospitalization.
4: Verily eCRF reported adverse events of special interest collapsing on hospitalization date from the unplanned hospitalization forms. If more than one event was collected for the same hospitalization, all events will have the same confirmation status on CEA spreadsheet.
5: Adverse events of special interest in Verily eCRF, but no linkage in the CEA spreadsheet yet.
6: Adverse events of special interest with a link from the Verily eCRF to CEA spreadsheet with confirmation status as "Suspected Event (Unknown)".
7: Adverse events of special interest with a link from the Verily eCRF to CEA spreadsheet with confirmation status as "Suspected Event (Not Validated)".
8: Adverse events of special interest with a link from the Verily eCRF to CEA spreadsheet with confirmation status as "Probable Event".
9: Verily eCRF reported adverse events of special interest collapsing on seeking medical date for the same event from the other unplanned medical care forms
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Table 15.3.2.1.4

BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Pregnancy

Primary Analysis Safety Population

	Pregnancy[1] (N=101)		Not Pregnancy (N=2147)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Brain Or Spinal Cord Inflammation (e.g., Meningitis, Encephalitis, Guillain-Barre Syndrome)[10]	0	0	0	0	0	0
Event Confirmation In Progress[5]	0	0	0	0	0	0
Suspected Event (Unknown)[6]	0	0	0	0	0	0
Suspected Event (Not Validated)[7]	0	0	0	0	0	0
Probable Event[8]	0	0	0	0	0	0

Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.
1: Pregnancy at time of enrolment includes both the participant and the partner pregnancy. There are 263 participants without pregnancy status due to no status being collected.
2: A subject may have more than one event, so an event row count can be larger than the row participant count and the sum of event rows can be more than the N in the header.
3: Excluding any events with hospitalization date or seeking medical date prior to vaccine date; if a participant reported an event on both hospitalization and unplanned medical care form on the same date, the event will be counted only once as a Hospitalization.
4: Verily eCRF reported adverse events of special interest collapsing on hospitalization date from the unplanned hospitalization forms. If more than one event was collected for the same hospitalization, all events will have the same confirmation status on CEA spreadsheet.
5: Adverse events of special interest in Verily eCRF, but no linkage in the CEA spreadsheet yet.
6: Adverse events of special interest with a link from the Verily eCRF to CEA spreadsheet with confirmation status as "Suspected Event (Unknown)".
7: Adverse events of special interest with a link from the Verily eCRF to CEA spreadsheet with confirmation status as "Suspected Event (Not Validated)".
8: Adverse events of special interest with a link from the Verily eCRF to CEA spreadsheet with confirmation status as "Probable Event".
9: Verily eCRF reported adverse events of special interest collapsing on seeking medical date for the same event from the other unplanned medical care forms
10: Adverse events of special interest collected from both unplanned hospitalization form and unplanned medical care form. If the event was reported on both form at the same date, the event will be counted only once in the table.

Table 15.3.2.1.4

BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Pregnancy

Primary Analysis Safety Population

	Pregnancy[1] (N=101)		Not Pregnancy (N=2147)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Severe Allergic Reaction (Anaphylaxis)[10]	0	0	6 / 2147 (<1.0%)	7	6 / 2511 (<1.0%)	7
Event Confirmation In Progress[5]	0	0	1 / 6 (16.7%)	1	1 / 6 (16.7%)	1
Suspected Event (Unknown)[6]	0	0	4 / 6 (66.7%)	5	4 / 6 (66.7%)	5
Suspected Event (Not Validated)[7]	0	0	1 / 6 (16.7%)	1	1 / 6 (16.7%)	1
Probable Event[8]	0	0	0	0	0	0

Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.
1: Pregnancy at time of enrolment includes both the participant and the partner pregnancy. There are 263 participants without pregnancy status due to no status being collected.
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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Pregnancy

Primary Analysis Safety Population

	Pregnancy[1] (N=101)		Not Pregnancy (N=2147)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Non-Severe Allergic Reaction[10]	0	0	15 / 2147 (<1.0%)	17	15 / 2511 (<1.0%)	17
Event Confirmation In Progress[5]	0	0	1 / 15 (6.7%)	2	1 / 15 (6.7%)	2
Suspected Event (Unknown)[6]	0	0	11 / 15 (73.3%)	12	11 / 15 (73.3%)	12
Suspected Event (Not Validated)[7]	0	0	3 / 15 (20.0%)	3	3 / 15 (20.0%)	3
Probable Event[8]	0	0	0	0	0	0

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Table 15.3.2.1.4

BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Pregnancy

Primary Analysis Safety Population

	Pregnancy[1] (N=101)		Not Pregnancy (N=2147)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Heart Inflammation (e.g., Myocarditis, Pericarditis)[10]	0	0	1 / 2147 (<1.0%)	1	1 / 2511 (<1.0%)	1
Event Confirmation In Progress[5]	0	0	0	0	0	0
Suspected Event (Unknown)[6]	0	0	1 / 1 (100%)	1	1 / 1 (100%)	1
Suspected Event (Not Validated)[7]	0	0	0	0	0	0
Probable Event[8]	0	0	0	0	0	0

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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Pregnancy

Primary Analysis Safety Population

	Pregnancy[1] (N=101)		Not Pregnancy (N=2147)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Blood Clot Inside A Vein In The Body (Thromboembolism)[10]	0	0	0	0	0	0
Event Confirmation In Progress[5]	0	0	0	0	0	0
Suspected Event (Unknown)[6]	0	0	0	0	0	0
Suspected Event (Not Validated)[7]	0	0	0	0	0	0
Probable Event[8]	0	0	0	0	0	0

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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Pregnancy

Primary Analysis Safety Population

	Pregnancy[1] (N=101)		Not Pregnancy (N=2147)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Blood Vessel Inflammation (e.g., Kawasaki Disease, Vasculitides)[10]	0	0	2 / 2147 (<1.0%)	2	2 / 2511 (<1.0%)	2
Event Confirmation In Progress[5]	0	0	0	0	0	0
Suspected Event (Unknown)[6]	0	0	1 / 2 (50.0%)	1	1 / 2 (50.0%)	1
Suspected Event (Not Validated)[7]	0	0	1 / 2 (50.0%)	1	1 / 2 (50.0%)	1
Probable Event[8]	0	0	0	0	0	0

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Table 15.3.2.1.4

BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Pregnancy

Primary Analysis Safety Population

	Pregnancy[1] (N=101)		Not Pregnancy (N=2147)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Abnormal Blood Clotting (e.g., Disseminated Intravascular Coagulation, Thrombocytopenia)[10]	0	0	1 / 2147 (<1.0%)	1	1 / 2511 (<1.0%)	1
Event Confirmation In Progress[5]	0	0	0	0	0	0
Suspected Event (Unknown)[6]	0	0	0	0	0	0
Suspected Event (Not Validated)[7]	0	0	0	0	0	0
Probable Event[8]	0	0	1 / 1 (100%)	1	1 / 1 (100%)	1

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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Pregnancy

Primary Analysis Safety Population

	Pregnancy[1] (N=101)		Not Pregnancy (N=2147)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Bleeding Disorder (Hemorrhagic Disease)[10]	0	0	0	0	0	0
Event Confirmation In Progress[5]	0	0	0	0	0	0
Suspected Event (Unknown)[6]	0	0	0	0	0	0
Suspected Event (Not Validated)[7]	0	0	0	0	0	0
Probable Event[8]	0	0	0	0	0	0

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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Pregnancy

Primary Analysis Safety Population

	Pregnancy[1] (N=101)		Not Pregnancy (N=2147)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Heart Attack (Myocardial Infarction)[10]	0	0	0	0	0	0
Event Confirmation In Progress[5]	0	0	0	0	0	0
Suspected Event (Unknown)[6]	0	0	0	0	0	0
Suspected Event (Not Validated)[7]	0	0	0	0	0	0
Probable Event[8]	0	0	0	0	0	0

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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Pregnancy

Primary Analysis Safety Population

	Pregnancy[1] (N=101)		Not Pregnancy (N=2147)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Heart Failure/Cardiogenic Shock[10]	0	0	0	0	0	0
Event Confirmation In Progress[5]	0	0	0	0	0	0
Suspected Event (Unknown)[6]	0	0	0	0	0	0
Suspected Event (Not Validated)[7]	0	0	0	0	0	0
Probable Event[8]	0	0	0	0	0	0

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Table 15.3.2.1.4

BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Pregnancy

Primary Analysis Safety Population

	Pregnancy[1] (N=101)		Not Pregnancy (N=2147)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Stress Cardiomyopathy[10]	0	0	0	0	0	0
Event Confirmation In Progress[5]	0	0	0	0	0	0
Suspected Event (Unknown)[6]	0	0	0	0	0	0
Suspected Event (Not Validated)[7]	0	0	0	0	0	0
Probable Event[8]	0	0	0	0	0	0

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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Pregnancy

Primary Analysis Safety Population

	Pregnancy[1] (N=101)		Not Pregnancy (N=2147)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Coronary Artery Disease[10]	0	0	0	0	0	0
Event Confirmation In Progress[5]	0	0	0	0	0	0
Suspected Event (Unknown)[6]	0	0	0	0	0	0
Suspected Event (Not Validated)[7]	0	0	0	0	0	0
Probable Event[8]	0	0	0	0	0	0

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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Pregnancy

Primary Analysis Safety Population

	Pregnancy[1] (N=101)		Not Pregnancy (N=2147)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Abnormal Heart Rhythm (Arrhythmia)[10]	0	0	0	0	0	0
Event Confirmation In Progress[5]	0	0	0	0	0	0
Suspected Event (Unknown)[6]	0	0	0	0	0	0
Suspected Event (Not Validated)[7]	0	0	0	0	0	0
Probable Event[8]	0	0	0	0	0	0

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Table 15.3.2.1.4

BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Pregnancy

Primary Analysis Safety Population

	Pregnancy[1] (N=101)		Not Pregnancy (N=2147)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Stroke Or Possible Stroke[10]	0	0	1 / 2147 (<1.0%)	1	1 / 2511 (<1.0%)	1
Event Confirmation In Progress[5]	0	0	1 / 1 (100%)	1	1 / 1 (100%)	1
Suspected Event (Unknown)[6]	0	0	0	0	0	0
Suspected Event (Not Validated)[7]	0	0	0	0	0	0
Probable Event[8]	0	0	0	0	0	0

Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.
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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Pregnancy

Primary Analysis Safety Population

	Pregnancy[1] (N=101)		Not Pregnancy (N=2147)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Blockage Of Blood Flow To Limbs (e.g., Limb Ischemia, Peripheral Artery Disease)[10]	0	0	0	0	0	0
Event Confirmation In Progress[5]	0	0	0	0	0	0
Suspected Event (Unknown)[6]	0	0	0	0	0	0
Suspected Event (Not Validated)[7]	0	0	0	0	0	0
Probable Event[8]	0	0	0	0	0	0

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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Pregnancy

Primary Analysis Safety Population

	Pregnancy[1] (N=101)		Not Pregnancy (N=2147)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Acute Kidney Injury[10]	0	0	0	0	0	0
Event Confirmation In Progress[5]	0	0	0	0	0	0
Suspected Event (Unknown)[6]	0	0	0	0	0	0
Suspected Event (Not Validated)[7]	0	0	0	0	0	0
Probable Event[8]	0	0	0	0	0	0

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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Pregnancy

Primary Analysis Safety Population

	Pregnancy[1] (N=101)		Not Pregnancy (N=2147)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Liver Injury[10]	0	0	0	0	0	0
Event Confirmation In Progress[5]	0	0	0	0	0	0
Suspected Event (Unknown)[6]	0	0	0	0	0	0
Suspected Event (Not Validated)[7]	0	0	0	0	0	0
Probable Event[8]	0	0	0	0	0	0

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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Pregnancy

Primary Analysis Safety Population

	Pregnancy[1] (N=101)		Not Pregnancy (N=2147)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Skin Immune Reaction (e.g., Chillblain-Like Lesions, Erythema Multiforme)[10]	0	0	0	0	0	0
Event Confirmation In Progress[5]	0	0	0	0	0	0
Suspected Event (Unknown)[6]	0	0	0	0	0	0
Suspected Event (Not Validated)[7]	0	0	0	0	0	0
Probable Event[8]	0	0	0	0	0	0

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Table 15.3.2.1.4

BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Pregnancy

Primary Analysis Safety Population

	Pregnancy[1] (N=101)		Not Pregnancy (N=2147)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Multisystem Inflammation[10]	0	0	2 / 2147 (<1.0%)	2	2 / 2511 (<1.0%)	2
Event Confirmation In Progress[5]	0	0	0	0	0	0
Suspected Event (Unknown)[6]	0	0	0	0	0	0
Suspected Event (Not Validated)[7]	0	0	2 / 2 (100%)	2	2 / 2 (100%)	2
Probable Event[8]	0	0	0	0	0	0

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Table 15.3.2.1.4

BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Pregnancy

Primary Analysis Safety Population

	Pregnancy[1] (N=101)		Not Pregnancy (N=2147)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Fibromyalgia[10]	0	0	2 / 2147 (<1.0%)	2	2 / 2511 (<1.0%)	2
Event Confirmation In Progress[5]	0	0	1 / 2 (50.0%)	1	1 / 2 (50.0%)	1
Suspected Event (Unknown)[6]	0	0	1 / 2 (50.0%)	1	1 / 2 (50.0%)	1
Suspected Event (Not Validated)[7]	0	0	0	0	0	0
Probable Event[8]	0	0	0	0	0	0

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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Pregnancy

Primary Analysis Safety Population

	Pregnancy[1] (N=101)		Not Pregnancy (N=2147)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Nerve Inflammation Or Autoimmune Disease (e.g., Multiple Sclerosis, Rheumatoid Arthritis)[10]	0	0	9 / 2147 (<1.0%)	11	9 / 2511 (<1.0%)	11
Event Confirmation In Progress[5]	0	0	2 / 9 (22.2%)	2	2 / 9 (22.2%)	2
Suspected Event (Unknown)[6]	0	0	4 / 9 (44.4%)	5	4 / 9 (44.4%)	5
Suspected Event (Not Validated)[7]	0	0	3 / 9 (33.3%)	4	3 / 9 (33.3%)	4
Probable Event[8]	0	0	0	0	0	0

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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Pregnancy

Primary Analysis Safety Population

	Pregnancy[1] (N=101)		Not Pregnancy (N=2147)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Autoimmune Thyroiditis[10]	0	0	3 / 2147 (<1.0%)	3	3 / 2511 (<1.0%)	3
Event Confirmation In Progress[5]	0	0	1 / 3 (33.3%)	1	1 / 3 (33.3%)	1
Suspected Event (Unknown)[6]	0	0	2 / 3 (66.7%)	2	2 / 3 (66.7%)	2
Suspected Event (Not Validated)[7]	0	0	0	0	0	0
Probable Event[8]	0	0	0	0	0	0

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Table 15.3.2.1.4

BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Pregnancy

Primary Analysis Safety Population

	Pregnancy[1] (N=101)		Not Pregnancy (N=2147)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
COVID-19 Infection[10]	1 / 101 (1.0%)	1	14 / 2147 (<1.0%)	19	15 / 2511 (<1.0%)	20
Event Confirmation In Progress[5]	0	0	3 / 14 (21.4%)	4	3 / 15 (20.0%)	4
Suspected Event (Unknown)[6]	1 / 1 (100%)	1	5 / 14 (35.7%)	9	6 / 15 (40.0%)	10
Suspected Event (Not Validated)[7]	0	0	5 / 14 (35.7%)	5	5 / 15 (33.3%)	5
Probable Event[8]	0	0	1 / 14 (7.1%)	1	1 / 15 (6.7%)	1

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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Pregnancy

Primary Analysis Safety Population

	Pregnancy[1] (N=101)		Not Pregnancy (N=2147)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Generalized Convulsions/Seizures[10]	0	0	1 / 2147 (<1.0%)	1	1 / 2511 (<1.0%)	1
Event Confirmation In Progress[5]	0	0	0	0	0	0
Suspected Event (Unknown)[6]	0	0	0	0	0	0
Suspected Event (Not Validated)[7]	0	0	1 / 1 (100%)	1	1 / 1 (100%)	1
Probable Event[8]	0	0	0	0	0	0

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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Pregnancy

Primary Analysis Safety Population

	Pregnancy[1] (N=101)		Not Pregnancy (N=2147)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Bell's Palsy[10]	0	0	0	0	0	0
Event Confirmation In Progress[5]	0	0	0	0	0	0
Suspected Event (Unknown)[6]	0	0	0	0	0	0
Suspected Event (Not Validated)[7]	0	0	0	0	0	0
Probable Event[8]	0	0	0	0	0	0

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8: Adverse events of special interest with a link from the Verily eCRF to CEA spreadsheet with confirmation status as "Probable Event".
9: Verily eCRF reported adverse events of special interest collapsing on seeking medical date for the same event from the other unplanned medical care forms
10: Adverse events of special interest collected from both unplanned hospitalization form and unplanned medical care form. If the event was reported on both form at the same date, the event will be counted only once in the table.

BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Pregnancy

Primary Analysis Safety Population

	Pregnancy[1] (N=101)		Not Pregnancy (N=2147)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Narcolepsy Or Cataplexy[10]	0	0	0	0	0	0
Event Confirmation In Progress[5]	0	0	0	0	0	0
Suspected Event (Unknown)[6]	0	0	0	0	0	0
Suspected Event (Not Validated)[7]	0	0	0	0	0	0
Probable Event[8]	0	0	0	0	0	0

Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.
1: Pregnancy at time of enrolment includes both the participant and the partner pregnancy. There are 263 participants without pregnancy status due to no status being collected.
2: A subject may have more than one event, so an event row count can be larger than the row participant count and the sum of event rows can be more than the N in the header.
3: Excluding any events with hospitalization date or seeking medical date prior to vaccine date; if a participant reported an event on both hospitalization and unplanned medical care form on the same date, the event will be counted only once as a Hospitalization.
4: Verily eCRF reported adverse events of special interest collapsing on hospitalization date from the unplanned hospitalization forms. If more than one event was collected for the same hospitalization, all events will have the same confirmation status on CEA spreadsheet.
5: Adverse events of special interest in Verily eCRF, but no linkage in the CEA spreadsheet yet.
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Table 15.3.2.1.4

BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Pregnancy

Primary Analysis Safety Population

	Pregnancy[1] (N=101)		Not Pregnancy (N=2147)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Joint Stiffness Or Pain (e.g., Arthralgia, Arthritis)[10]	0	0	31 / 2147 (1.4%)	42	32 / 2511 (1.3%)	43
Event Confirmation In Progress[5]	0	0	3 / 31 (9.7%)	7	3 / 32 (9.4%)	7
Suspected Event (Unknown)[6]	0	0	19 / 31 (61.3%)	24	20 / 32 (62.5%)	25
Suspected Event (Not Validated)[7]	0	0	8 / 31 (25.8%)	10	8 / 32 (25.0%)	10
Probable Event[8]	0	0	1 / 31 (3.2%)	1	1 / 32 (3.1%)	1

Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.
1: Pregnancy at time of enrolment includes both the participant and the partner pregnancy. There are 263 participants without pregnancy status due to no status being collected.
2: A subject may have more than one event, so an event row count can be larger than the row participant count and the sum of event rows can be more than the N in the header.
3: Excluding any events with hospitalization date or seeking medical date prior to vaccine date; if a participant reported an event on both hospitalization and unplanned medical care form on the same date, the event will be counted only once as a Hospitalization.
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Table 15.3.2.1.4

BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Pregnancy

Primary Analysis Safety Population

	Pregnancy[1] (N=101)		Not Pregnancy (N=2147)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Pregnancy-Related Issue[10]	13 / 101 (12.9%)	18	6 / 2147 (<1.0%)	6	19 / 2511 (<1.0%)	24
Event Confirmation In Progress[5]	3 / 13 (23.1%)	5	5 / 6 (83.3%)	5	8 / 19 (42.1%)	10
Suspected Event (Unknown)[6]	4 / 13 (30.8%)	6	1 / 6 (16.7%)	1	5 / 19 (26.3%)	7
Suspected Event (Not Validated)[7]	6 / 13 (46.2%)	7	0	0	6 / 19 (31.6%)	7
Probable Event[8]	0	0	0	0	0	0

Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.
1: Pregnancy at time of enrolment includes both the participant and the partner pregnancy. There are 263 participants without pregnancy status due to no status being collected.
2: A subject may have more than one event, so an event row count can be larger than the row participant count and the sum of event rows can be more than the N in the header.
3: Excluding any events with hospitalization date or seeking medical date prior to vaccine date; if a participant reported an event on both hospitalization and unplanned medical care form on the same date, the event will be counted only once as a Hospitalization.
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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Pregnancy

Primary Analysis Safety Population

	Pregnancy[1] (N=101)		Not Pregnancy (N=2147)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Microangiopathy[10]	0	0	0	0	0	0
Event Confirmation In Progress[5]	0	0	0	0	0	0
Suspected Event (Unknown)[6]	0	0	0	0	0	0
Suspected Event (Not Validated)[7]	0	0	0	0	0	0
Probable Event[8]	0	0	0	0	0	0

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1: Pregnancy at time of enrolment includes both the participant and the partner pregnancy. There are 263 participants without pregnancy status due to no status being collected.
2: A subject may have more than one event, so an event row count can be larger than the row participant count and the sum of event rows can be more than the N in the header.
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8: Adverse events of special interest with a link from the Verily eCRF to CEA spreadsheet with confirmation status as "Probable Event".
9: Verily eCRF reported adverse events of special interest collapsing on seeking medical date for the same event from the other unplanned medical care forms
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Table 15.3.2.1.4

BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Pregnancy

Primary Analysis Safety Population

	Pregnancy[1] (N=101)		Not Pregnancy (N=2147)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Death[10]	0	0	1 / 2147 (<1.0%)	1	1 / 2511 (<1.0%)	1
Event Confirmation In Progress[5]	0	0	1 / 1 (100%)	1	1 / 1 (100%)	1
Suspected Event (Unknown)[6]	0	0	0	0	0	0
Suspected Event (Not Validated)[7]	0	0	0	0	0	0
Probable Event[8]	0	0	0	0	0	0

Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.
1: Pregnancy at time of enrolment includes both the participant and the partner pregnancy. There are 263 participants without pregnancy status due to no status being collected.
2: A subject may have more than one event, so an event row count can be larger than the row participant count and the sum of event rows can be more than the N in the header.
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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Pregnancy

Primary Analysis Safety Population

	Pregnancy[1] (N=101)		Not Pregnancy (N=2147)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Other[10]	3 / 101 (3.0%)	3	231 / 2147 (10.8%)	237	236 / 2511 (9.4%)	242
Event Confirmation In Progress[5]	2 / 3 (66.7%)	2	224 / 231 (97.0%)	229	228 / 236 (96.6%)	233
Suspected Event (Unknown)[6]	1 / 3 (33.3%)	1	2 / 231 (<1.0%)	3	3 / 236 (1.3%)	4
Suspected Event (Not Validated)[7]	0	0	5 / 231 (2.2%)	5	5 / 236 (2.1%)	5
Probable Event[8]	0	0	0	0	0	0

Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.
1: Pregnancy at time of enrolment includes both the participant and the partner pregnancy. There are 263 participants without pregnancy status due to no status being collected.
2: A subject may have more than one event, so an event row count can be larger than the row participant count and the sum of event rows can be more than the N in the header.
3: Excluding any events with hospitalization date or seeking medical date prior to vaccine date; if a participant reported an event on both hospitalization and unplanned medical care form on the same date, the event will be counted only once as a Hospitalization.
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Table 15.3.2.1.5

BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Age Group

Primary Analysis Safety Population

	18-29[1] (N=282)		30-39[1] (N=915)		40-49[1] (N=657)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Any Adverse Event of Special Interest[3]	36 / 282 (12.8%)	41	124 / 915 (13.6%)	136	84 / 657 (12.8%)	107	320 / 2511 (12.7%)	378
Hospitalized[4]	1 / 282 (<1.0%)	2	7 / 915 (<1.0%)	7	5 / 657 (<1.0%)	5	16 / 2511 (<1.0%)	17
Event Confirmation In Progress[5]	0	0	1 / 7 (14.3%)	1	1 / 5 (20.0%)	1	2 / 16 (12.5%)	2
Suspected Event (Unknown)[6]	0	1	3 / 7 (42.9%)	3	1 / 5 (20.0%)	1	6 / 16 (37.5%)	7
Suspected Event (Not Validated)[7]	1 / 1 (100%)	1	3 / 7 (42.9%)	3	3 / 5 (60.0%)	3	8 / 16 (50.0%)	8
Probable Event[8]	0	0	0	0	0	0	0	0

Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.
1: Age is based on birth date and at 1st dose of COVID-19 vaccine date.
2: A subject may have more than one event, so an event row count can be larger than the row participant count and the sum of event rows can be more than the N in the header.
3: Excluding any events with hospitalization date or seeking medical date prior to vaccine date; if a participant reported an event on both hospitalization and unplanned medical care form on the same date, the event will be counted only once as a Hospitalization.
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Table 15.3.2.1.5
BNT162b2 Protocol C4591008
Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Age Group
Primary Analysis Safety Population

	18-29[1] (N=282)		30-39[1] (N=915)		40-49[1] (N=657)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Not Hospitalized[9]	36 / 282 (12.8%)	39	120 / 915 (13.1%)	129	82 / 657 (12.5%)	102	313 / 2511 (12.5%)	361
Event Confirmation In Progress[5]	30 / 36 (83.3%)	33	91 / 120 (75.8%)	98	57 / 82 (69.5%)	71	233 / 313 (74.4%)	261
Suspected Event (Unknown)[6]	6 / 36 (16.7%)	6	18 / 120 (15.0%)	19	14 / 82 (17.1%)	19	50 / 313 (16.0%)	66
Suspected Event (Not Validated)[7]	0	0	10 / 120 (8.3%)	11	9 / 82 (11.0%)	10	27 / 313 (8.6%)	31
Probable Event[8]	0	0	1 / 120 (<1.0%)	1	2 / 82 (2.4%)	2	3 / 313 (1.0%)	3

Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.
1: Age is based on birth date and at 1st dose of COVID-19 vaccine date.
2: A subject may have more than one event, so an event row count can be larger than the row participant count and the sum of event rows can be more than the N in the header.
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PFIZER CONFIDENTIAL SDTM Creation: 11MAY2021:07:31:19 Data Cutoff: 29APR2021 Source Data: ADSL, ADEVENT
Generated from /dcri/ct/hero_together/tables/t_event_age.sas on 24MAY2021 12:44

Table 15.3.2.1.5

BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Age Group

Primary Analysis Safety Population

	18-29[1] (N=282)		30-39[1] (N=915)		40-49[1] (N=657)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Brain Or Spinal Cord Inflammation (e.g., Meningitis, Encephalitis, Guillain-Barre Syndrome)[10]	0	0	0	0	0	0	0	0
Event Confirmation In Progress[5]	0	0	0	0	0	0	0	0
Suspected Event (Unknown)[6]	0	0	0	0	0	0	0	0
Suspected Event (Not Validated)[7]	0	0	0	0	0	0	0	0
Probable Event[8]	0	0	0	0	0	0	0	0

Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.
1: Age is based on birth date and at 1st dose of COVID-19 vaccine date.
2: A subject may have more than one event, so an event row count can be larger than the row participant count and the sum of event rows can be more than the N in the header.
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Table 15.3.2.1.5

BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Age Group

Primary Analysis Safety Population

	18-29[1] (N=282)		30-39[1] (N=915)		40-49[1] (N=657)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Severe Allergic Reaction (Anaphylaxis)[10]	0	0	3 / 915 (<1.0%)	3	2 / 657 (<1.0%)	2	6 / 2511 (<1.0%)	7
Event Confirmation In Progress[5]	0	0	1 / 3 (33.3%)	1	0	0	1 / 6 (16.7%)	1
Suspected Event (Unknown)[6]	0	0	2 / 3 (66.7%)	2	2 / 2 (100%)	2	4 / 6 (66.7%)	5
Suspected Event (Not Validated)[7]	0	0	0	0	0	0	1 / 6 (16.7%)	1
Probable Event[8]	0	0	0	0	0	0	0	0

Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.
1: Age is based on birth date and at 1st dose of COVID-19 vaccine date.
2: A subject may have more than one event, so an event row count can be larger than the row participant count and the sum of event rows can be more than the N in the header.
3: Excluding any events with hospitalization date or seeking medical date prior to vaccine date; if a participant reported an event on both hospitalization and unplanned medical care form on the same date, the event will be counted only once as a Hospitalization.
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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Age Group

Primary Analysis Safety Population

	18-29[1] (N=282)		30-39[1] (N=915)		40-49[1] (N=657)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Non-Severe Allergic Reaction[10]	2 / 282 (<1.0%)	2	5 / 915 (<1.0%)	6	7 / 657 (1.1%)	8	15 / 2511 (<1.0%)	17
Event Confirmation In Progress[5]	0	0	0	0	1 / 7 (14.3%)	2	1 / 15 (6.7%)	2
Suspected Event (Unknown)[6]	2 / 2 (100%)	2	4 / 5 (80.0%)	5	4 / 7 (57.1%)	4	11 / 15 (73.3%)	12
Suspected Event (Not Validated)[7]	0	0	1 / 5 (20.0%)	1	2 / 7 (28.6%)	2	3 / 15 (20.0%)	3
Probable Event[8]	0	0	0	0	0	0	0	0

Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.
1: Age is based on birth date and at 1st dose of COVID-19 vaccine date.
2: A subject may have more than one event, so an event row count can be larger than the row participant count and the sum of event rows can be more than the N in the header.
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Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Age Group

Primary Analysis Safety Population

	18-29[1] (N=282)		30-39[1] (N=915)		40-49[1] (N=657)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Heart Inflammation (e.g., Myocarditis, Pericarditis)[10]	0	0	1 / 915 (<1.0%)	1	0	0	1 / 2511 (<1.0%)	1
Event Confirmation In Progress[5]	0	0	0	0	0	0	0	0
Suspected Event (Unknown)[6]	0	0	1 / 1 (100%)	1	0	0	1 / 1 (100%)	1
Suspected Event (Not Validated)[7]	0	0	0	0	0	0	0	0
Probable Event[8]	0	0	0	0	0	0	0	0

Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.
1: Age is based on birth date and at 1st dose of COVID-19 vaccine date.
2: A subject may have more than one event, so an event row count can be larger than the row participant count and the sum of event rows can be more than the N in the header.
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Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Age Group

Primary Analysis Safety Population

	18-29[1] (N=282)		30-39[1] (N=915)		40-49[1] (N=657)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Blood Clot Inside A Vein In The Body (Thromboembolism)[10]	0	0	0	0	0	0	0	0
Event Confirmation In Progress[5]	0	0	0	0	0	0	0	0
Suspected Event (Unknown)[6]	0	0	0	0	0	0	0	0
Suspected Event (Not Validated)[7]	0	0	0	0	0	0	0	0
Probable Event[8]	0	0	0	0	0	0	0	0

Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.
1: Age is based on birth date and at 1st dose of COVID-19 vaccine date.
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Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Age Group

Primary Analysis Safety Population

	18-29[1] (N=282)		30-39[1] (N=915)		40-49[1] (N=657)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Blood Vessel Inflammation (e.g., Kawasaki Disease, Vasculitides)[10]	0	0	1 / 915 (<1.0%)	1	1 / 657 (<1.0%)	1	2 / 2511 (<1.0%)	2
Event Confirmation In Progress[5]	0	0	0	0	0	0	0	0
Suspected Event (Unknown)[6]	0	0	1 / 1 (100%)	1	0	0	1 / 2 (50.0%)	1
Suspected Event (Not Validated)[7]	0	0	0	0	1 / 1 (100%)	1	1 / 2 (50.0%)	1
Probable Event[8]	0	0	0	0	0	0	0	0

Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.
1: Age is based on birth date and at 1st dose of COVID-19 vaccine date.
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Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Age Group

Primary Analysis Safety Population

	18-29[1] (N=282)		30-39[1] (N=915)		40-49[1] (N=657)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Abnormal Blood Clotting (e.g., Disseminated Intravascular Coagulation, Thrombocytopenia)[10]	0	0	1 / 915 (<1.0%)	1	0	0	1 / 2511 (<1.0%)	1
Event Confirmation In Progress[5]	0	0	0	0	0	0	0	0
Suspected Event (Unknown)[6]	0	0	0	0	0	0	0	0
Suspected Event (Not Validated)[7]	0	0	0	0	0	0	0	0
Probable Event[8]	0	0	1 / 1 (100%)	1	0	0	1 / 1 (100%)	1

Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.
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Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Age Group

Primary Analysis Safety Population

	18-29[1] (N=282)		30-39[1] (N=915)		40-49[1] (N=657)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Bleeding Disorder (Hemorrhagic Disease)[10]	0	0	0	0	0	0	0	0
Event Confirmation In Progress[5]	0	0	0	0	0	0	0	0
Suspected Event (Unknown)[6]	0	0	0	0	0	0	0	0
Suspected Event (Not Validated)[7]	0	0	0	0	0	0	0	0
Probable Event[8]	0	0	0	0	0	0	0	0

Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.
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Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Age Group

Primary Analysis Safety Population

	18-29[1] (N=282)		30-39[1] (N=915)		40-49[1] (N=657)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Heart Attack (Myocardial Infarction)[10]	0	0	0	0	0	0	0	0
Event Confirmation In Progress[5]	0	0	0	0	0	0	0	0
Suspected Event (Unknown)[6]	0	0	0	0	0	0	0	0
Suspected Event (Not Validated)[7]	0	0	0	0	0	0	0	0
Probable Event[8]	0	0	0	0	0	0	0	0

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Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Age Group

Primary Analysis Safety Population

	18-29[1] (N=282)		30-39[1] (N=915)		40-49[1] (N=657)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Heart Failure/Cardiogenic Shock[10]	0	0	0	0	0	0	0	0
Event Confirmation In Progress[5]	0	0	0	0	0	0	0	0
Suspected Event (Unknown)[6]	0	0	0	0	0	0	0	0
Suspected Event (Not Validated)[7]	0	0	0	0	0	0	0	0
Probable Event[8]	0	0	0	0	0	0	0	0

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Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Age Group

Primary Analysis Safety Population

	18-29[1] (N=282)		30-39[1] (N=915)		40-49[1] (N=657)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Stress Cardiomyopathy[10]	0	0	0	0	0	0	0	0
Event Confirmation In Progress[5]	0	0	0	0	0	0	0	0
Suspected Event (Unknown)[6]	0	0	0	0	0	0	0	0
Suspected Event (Not Validated)[7]	0	0	0	0	0	0	0	0
Probable Event[8]	0	0	0	0	0	0	0	0

Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.
1: Age is based on birth date and at 1st dose of COVID-19 vaccine date.
2: A subject may have more than one event, so an event row count can be larger than the row participant count and the sum of event rows can be more than the N in the header.
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Table 15.3.2.1.5
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Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Age Group
Primary Analysis Safety Population

	18-29[1] (N=282)		30-39[1] (N=915)		40-49[1] (N=657)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Coronary Artery Disease[10]	0	0	0	0	0	0	0	0
Event Confirmation In Progress[5]	0	0	0	0	0	0	0	0
Suspected Event (Unknown)[6]	0	0	0	0	0	0	0	0
Suspected Event (Not Validated)[7]	0	0	0	0	0	0	0	0
Probable Event[8]	0	0	0	0	0	0	0	0

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Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Age Group

Primary Analysis Safety Population

	18-29[1] (N=282)		30-39[1] (N=915)		40-49[1] (N=657)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Abnormal Heart Rhythm (Arrhythmia)[10]	0	0	0	0	0	0	0	0
Event Confirmation In Progress[5]	0	0	0	0	0	0	0	0
Suspected Event (Unknown)[6]	0	0	0	0	0	0	0	0
Suspected Event (Not Validated)[7]	0	0	0	0	0	0	0	0
Probable Event[8]	0	0	0	0	0	0	0	0

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Table 15.3.2.1.5

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Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Age Group

Primary Analysis Safety Population

	18-29[1] (N=282)		30-39[1] (N=915)		40-49[1] (N=657)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Stroke Or Possible Stroke[10]	0	0	0	0	0	0	1 / 2511 (<1.0%)	1
Event Confirmation In Progress[5]	0	0	0	0	0	0	1 / 1 (100%)	1
Suspected Event (Unknown)[6]	0	0	0	0	0	0	0	0
Suspected Event (Not Validated)[7]	0	0	0	0	0	0	0	0
Probable Event[8]	0	0	0	0	0	0	0	0

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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Age Group

Primary Analysis Safety Population

	18-29[1] (N=282)		30-39[1] (N=915)		40-49[1] (N=657)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Blockage Of Blood Flow To Limbs (e.g., Limb Ischemia, Peripheral Artery Disease)[10]	0	0	0	0	0	0	0	0
Event Confirmation In Progress[5]	0	0	0	0	0	0	0	0
Suspected Event (Unknown)[6]	0	0	0	0	0	0	0	0
Suspected Event (Not Validated)[7]	0	0	0	0	0	0	0	0
Probable Event[8]	0	0	0	0	0	0	0	0

Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.
1: Age is based on birth date and at 1st dose of COVID-19 vaccine date.
2: A subject may have more than one event, so an event row count can be larger than the row participant count and the sum of event rows can be more than the N in the header.
3: Excluding any events with hospitalization date or seeking medical date prior to vaccine date; if a participant reported an event on both hospitalization and unplanned medical care form on the same date, the event will be counted only once as a Hospitalization.
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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Age Group

Primary Analysis Safety Population

	18-29[1] (N=282)		30-39[1] (N=915)		40-49[1] (N=657)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Acute Kidney Injury[10]	0	0	0	0	0	0	0	0
Event Confirmation In Progress[5]	0	0	0	0	0	0	0	0
Suspected Event (Unknown)[6]	0	0	0	0	0	0	0	0
Suspected Event (Not Validated)[7]	0	0	0	0	0	0	0	0
Probable Event[8]	0	0	0	0	0	0	0	0

Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.
1: Age is based on birth date and at 1st dose of COVID-19 vaccine date.
2: A subject may have more than one event, so an event row count can be larger than the row participant count and the sum of event rows can be more than the N in the header.
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Table 15.3.2.1.5

BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Age Group

Primary Analysis Safety Population

	18-29[1] (N=282)		30-39[1] (N=915)		40-49[1] (N=657)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Liver Injury[10]	0	0	0	0	0	0	0	0
Event Confirmation In Progress[5]	0	0	0	0	0	0	0	0
Suspected Event (Unknown)[6]	0	0	0	0	0	0	0	0
Suspected Event (Not Validated)[7]	0	0	0	0	0	0	0	0
Probable Event[8]	0	0	0	0	0	0	0	0

Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.
1: Age is based on birth date and at 1st dose of COVID-19 vaccine date.
2: A subject may have more than one event, so an event row count can be larger than the row participant count and the sum of event rows can be more than the N in the header.
3: Excluding any events with hospitalization date or seeking medical date prior to vaccine date; if a participant reported an event on both hospitalization and unplanned medical care form on the same date, the event will be counted only once as a Hospitalization.
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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Age Group

Primary Analysis Safety Population

	18-29[1] (N=282)		30-39[1] (N=915)		40-49[1] (N=657)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Skin Immune Reaction (e.g., Chillblain-Like Lesions, Erythema Multiforme)[10]	0	0	0	0	0	0	0	0
Event Confirmation In Progress[5]	0	0	0	0	0	0	0	0
Suspected Event (Unknown)[6]	0	0	0	0	0	0	0	0
Suspected Event (Not Validated)[7]	0	0	0	0	0	0	0	0
Probable Event[8]	0	0	0	0	0	0	0	0

Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.
1: Age is based on birth date and at 1st dose of COVID-19 vaccine date.
2: A subject may have more than one event, so an event row count can be larger than the row participant count and the sum of event rows can be more than the N in the header.
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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Age Group

Primary Analysis Safety Population

	18-29[1] (N=282)		30-39[1] (N=915)		40-49[1] (N=657)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Multisystem Inflammation[10]	0	0	2 / 915 (<1.0%)	2	0	0	2 / 2511 (<1.0%)	2
Event Confirmation In Progress[5]	0	0	0	0	0	0	0	0
Suspected Event (Unknown)[6]	0	0	0	0	0	0	0	0
Suspected Event (Not Validated)[7]	0	0	2 / 2 (100%)	2	0	0	2 / 2 (100%)	2
Probable Event[8]	0	0	0	0	0	0	0	0

Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.
1: Age is based on birth date and at 1st dose of COVID-19 vaccine date.
2: A subject may have more than one event, so an event row count can be larger than the row participant count and the sum of event rows can be more than the N in the header.
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Table 15.3.2.1.5
BNT162b2 Protocol C4591008
Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Age Group
Primary Analysis Safety Population

	18-29[1] (N=282)		30-39[1] (N=915)		40-49[1] (N=657)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Fibromyalgia[10]	0	0	2 / 915 (<1.0%)	2	0	0	2 / 2511 (<1.0%)	2
Event Confirmation In Progress[5]	0	0	1 / 2 (50.0%)	1	0	0	1 / 2 (50.0%)	1
Suspected Event (Unknown)[6]	0	0	1 / 2 (50.0%)	1	0	0	1 / 2 (50.0%)	1
Suspected Event (Not Validated)[7]	0	0	0	0	0	0	0	0
Probable Event[8]	0	0	0	0	0	0	0	0

Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.
1: Age is based on birth date and at 1st dose of COVID-19 vaccine date.
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PFIZER CONFIDENTIAL SDTM Creation: 11MAY2021:07:31:19 Data Cutoff: 29APR2021 Source Data: ADSL, ADEVENT
Generated from /dcri/ct/hero_together/tables/t_event_age.sas on 24MAY2021 12:44

BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Age Group

Primary Analysis Safety Population

	18-29[1] (N=282)		30-39[1] (N=915)		40-49[1] (N=657)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Nerve Inflammation Or Autoimmune Disease (e.g., Multiple Sclerosis, Rheumatoid Arthritis)[10]	1 / 282 (<1.0%)	1	2 / 915 (<1.0%)	2	2 / 657 (<1.0%)	2	9 / 2511 (<1.0%)	11
Event Confirmation In Progress[5]	0	0	1 / 2 (50.0%)	1	0	0	2 / 9 (22.2%)	2
Suspected Event (Unknown)[6]	1 / 1 (100%)	1	1 / 2 (50.0%)	1	1 / 2 (50.0%)	1	4 / 9 (44.4%)	5
Suspected Event (Not Validated)[7]	0	0	0	0	1 / 2 (50.0%)	1	3 / 9 (33.3%)	4
Probable Event[8]	0	0	0	0	0	0	0	0

Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.
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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Age Group

Primary Analysis Safety Population

	18-29[1] (N=282)		30-39[1] (N=915)		40-49[1] (N=657)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Autoimmune Thyroiditis[10]	0	0	1 / 915 (<1.0%)	1	2 / 657 (<1.0%)	2	3 / 2511 (<1.0%)	3
Event Confirmation In Progress[5]	0	0	0	0	1 / 2 (50.0%)	1	1 / 3 (33.3%)	1
Suspected Event (Unknown)[6]	0	0	1 / 1 (100%)	1	1 / 2 (50.0%)	1	2 / 3 (66.7%)	2
Suspected Event (Not Validated)[7]	0	0	0	0	0	0	0	0
Probable Event[8]	0	0	0	0	0	0	0	0

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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Age Group

Primary Analysis Safety Population

	18-29[1] (N=282)		30-39[1] (N=915)		40-49[1] (N=657)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
COVID-19 Infection[10]	0	0	5 / 915 (<1.0%)	5	7 / 657 (1.1%)	7	15 / 2511 (<1.0%)	20
Event Confirmation In Progress[5]	0	0	1 / 5 (20.0%)	1	2 / 7 (28.6%)	2	3 / 15 (20.0%)	4
Suspected Event (Unknown)[6]	0	0	2 / 5 (40.0%)	2	2 / 7 (28.6%)	2	6 / 15 (40.0%)	10
Suspected Event (Not Validated)[7]	0	0	2 / 5 (40.0%)	2	2 / 7 (28.6%)	2	5 / 15 (33.3%)	5
Probable Event[8]	0	0	0	0	1 / 7 (14.3%)	1	1 / 15 (6.7%)	1

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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Age Group

Primary Analysis Safety Population

	18-29[1] (N=282)		30-39[1] (N=915)		40-49[1] (N=657)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Generalized Convulsions/Seizures[10]	0	0	0	0	0	0	1 / 2511 (<1.0%)	1
Event Confirmation In Progress[5]	0	0	0	0	0	0	0	0
Suspected Event (Unknown)[6]	0	0	0	0	0	0	0	0
Suspected Event (Not Validated)[7]	0	0	0	0	0	0	1 / 1 (100%)	1
Probable Event[8]	0	0	0	0	0	0	0	0

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Table 15.3.2.1.5

BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Age Group

Primary Analysis Safety Population

	18-29[1] (N=282)		30-39[1] (N=915)		40-49[1] (N=657)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Bell's Palsy[10]	0	0	0	0	0	0	0	0
Event Confirmation In Progress[5]	0	0	0	0	0	0	0	0
Suspected Event (Unknown)[6]	0	0	0	0	0	0	0	0
Suspected Event (Not Validated)[7]	0	0	0	0	0	0	0	0
Probable Event[8]	0	0	0	0	0	0	0	0

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6: Adverse events of special interest with a link from the Verily eCRF to CEA spreadsheet with confirmation status as "Suspected Event (Unknown)".
7: Adverse events of special interest with a link from the Verily eCRF to CEA spreadsheet with confirmation status as "Suspected Event (Not Validated)".
8: Adverse events of special interest with a link from the Verily eCRF to CEA spreadsheet with confirmation status as "Probable Event".
9: Verily eCRF reported adverse events of special interest collapsing on seeking medical date for the same event from the other unplanned medical care forms
10: Adverse events of special interest collected from both unplanned hospitalization form and unplanned medical care form. If the event was reported on both form at the same date, the event will be counted only once in the table.

BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Age Group

Primary Analysis Safety Population

	18-29[1] (N=282)		30-39[1] (N=915)		40-49[1] (N=657)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Narcolepsy Or Cataplexy[10]	0	0	0	0	0	0	0	0
Event Confirmation In Progress[5]	0	0	0	0	0	0	0	0
Suspected Event (Unknown)[6]	0	0	0	0	0	0	0	0
Suspected Event (Not Validated)[7]	0	0	0	0	0	0	0	0
Probable Event[8]	0	0	0	0	0	0	0	0

Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.
1: Age is based on birth date and at 1st dose of COVID-19 vaccine date.
2: A subject may have more than one event, so an event row count can be larger than the row participant count and the sum of event rows can be more than the N in the header.
3: Excluding any events with hospitalization date or seeking medical date prior to vaccine date; if a participant reported an event on both hospitalization and unplanned medical care form on the same date, the event will be counted only once as a Hospitalization.
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5: Adverse events of special interest in Verily eCRF, but no linkage in the CEA spreadsheet yet.
6: Adverse events of special interest with a link from the Verily eCRF to CEA spreadsheet with confirmation status as "Suspected Event (Unknown)".
7: Adverse events of special interest with a link from the Verily eCRF to CEA spreadsheet with confirmation status as "Suspected Event (Not Validated)".
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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Age Group

Primary Analysis Safety Population

	18-29[1] (N=282)		30-39[1] (N=915)		40-49[1] (N=657)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Joint Stiffness Or Pain (e.g., Arthralgia, Arthritis)[10]	4 / 282 (1.4%)	5	5 / 915 (<1.0%)	5	12 / 657 (1.8%)	17	32 / 2511 (1.3%)	43
Event Confirmation In Progress[5]	1 / 4 (25.0%)	2	1 / 5 (20.0%)	1	1 / 12 (8.3%)	4	3 / 32 (9.4%)	7
Suspected Event (Unknown)[6]	3 / 4 (75.0%)	3	2 / 5 (40.0%)	2	7 / 12 (58.3%)	8	20 / 32 (62.5%)	25
Suspected Event (Not Validated)[7]	0	0	2 / 5 (40.0%)	2	3 / 12 (25.0%)	4	8 / 32 (25.0%)	10
Probable Event[8]	0	0	0	0	1 / 12 (8.3%)	1	1 / 32 (3.1%)	1

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1: Age is based on birth date and at 1st dose of COVID-19 vaccine date.
2: A subject may have more than one event, so an event row count can be larger than the row participant count and the sum of event rows can be more than the N in the header.
3: Excluding any events with hospitalization date or seeking medical date prior to vaccine date; if a participant reported an event on both hospitalization and unplanned medical care form on the same date, the event will be counted only once as a Hospitalization.
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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Age Group

Primary Analysis Safety Population

	18-29[1] (N=282)		30-39[1] (N=915)		40-49[1] (N=657)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Pregnancy-Related Issue[10]	2 / 282 (<1.0%)	2	15 / 915 (1.6%)	19	2 / 657 (<1.0%)	3	19 / 2511 (<1.0%)	24
Event Confirmation In Progress[5]	2 / 2 (100%)	2	5 / 15 (33.3%)	7	1 / 2 (50.0%)	1	8 / 19 (42.1%)	10
Suspected Event (Unknown)[6]	0	0	4 / 15 (26.7%)	5	1 / 2 (50.0%)	2	5 / 19 (26.3%)	7
Suspected Event (Not Validated)[7]	0	0	6 / 15 (40.0%)	7	0	0	6 / 19 (31.6%)	7
Probable Event[8]	0	0	0	0	0	0	0	0

Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.
1: Age is based on birth date and at 1st dose of COVID-19 vaccine date.
2: A subject may have more than one event, so an event row count can be larger than the row participant count and the sum of event rows can be more than the N in the header.
3: Excluding any events with hospitalization date or seeking medical date prior to vaccine date; if a participant reported an event on both hospitalization and unplanned medical care form on the same date, the event will be counted only once as a Hospitalization.
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Table 15.3.2.1.5

BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Age Group

Primary Analysis Safety Population

	18-29[1] (N=282)		30-39[1] (N=915)		40-49[1] (N=657)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Microangiopathy[10]	0	0	0	0	0	0	0	0
Event Confirmation In Progress[5]	0	0	0	0	0	0	0	0
Suspected Event (Unknown)[6]	0	0	0	0	0	0	0	0
Suspected Event (Not Validated)[7]	0	0	0	0	0	0	0	0
Probable Event[8]	0	0	0	0	0	0	0	0

Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.
1: Age is based on birth date and at 1st dose of COVID-19 vaccine date.
2: A subject may have more than one event, so an event row count can be larger than the row participant count and the sum of event rows can be more than the N in the header.
3: Excluding any events with hospitalization date or seeking medical date prior to vaccine date; if a participant reported an event on both hospitalization and unplanned medical care form on the same date, the event will be counted only once as a Hospitalization.
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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Age Group

Primary Analysis Safety Population

	18-29[1] (N=282)		30-39[1] (N=915)		40-49[1] (N=657)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Death[10]	0	0	0	0	0	0	1 / 2511 (<1.0%)	1
Event Confirmation In Progress[5]	0	0	0	0	0	0	1 / 1 (100%)	1
Suspected Event (Unknown)[6]	0	0	0	0	0	0	0	0
Suspected Event (Not Validated)[7]	0	0	0	0	0	0	0	0
Probable Event[8]	0	0	0	0	0	0	0	0

Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.
1: Age is based on birth date and at 1st dose of COVID-19 vaccine date.
2: A subject may have more than one event, so an event row count can be larger than the row participant count and the sum of event rows can be more than the N in the header.
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Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Age Group

Primary Analysis Safety Population

	18-29[1] (N=282)		30-39[1] (N=915)		40-49[1] (N=657)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Other[10]	29 / 282 (10.3%)	31	88 / 915 (9.6%)	88	63 / 657 (9.6%)	65	236 / 2511 (9.4%)	242
Event Confirmation In Progress[5]	28 / 29 (96.6%)	29	87 / 88 (98.9%)	87	60 / 63 (95.2%)	62	228 / 236 (96.6%)	233
Suspected Event (Unknown)[6]	0	1	1 / 88 (1.1%)	1	0	0	3 / 236 (1.3%)	4
Suspected Event (Not Validated)[7]	1 / 29 (3.4%)	1	0	0	3 / 63 (4.8%)	3	5 / 236 (2.1%)	5
Probable Event[8]	0	0	0	0	0	0	0	0

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1: Age is based on birth date and at 1st dose of COVID-19 vaccine date.
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Table 15.3.2.1.5

BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Age Group

Primary Analysis Safety Population

	50-59[1] (N=439)		60-69[1] (N=197)		70 and above[1] (N=21)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Any Adverse Event of Special Interest[3]	54 / 439 (12.3%)	63	20 / 197 (10.2%)	29	2 / 21 (9.5%)	2	320 / 2511 (12.7%)	378
Hospitalized[4]	3 / 439 (<1.0%)	3	0	0	0	0	16 / 2511 (<1.0%)	17
Event Confirmation In Progress[5]	0	0	0	0	0	0	2 / 16 (12.5%)	2
Suspected Event (Unknown)[6]	2 / 3 (66.7%)	2	0	0	0	0	6 / 16 (37.5%)	7
Suspected Event (Not Validated)[7]	1 / 3 (33.3%)	1	0	0	0	0	8 / 16 (50.0%)	8
Probable Event[8]	0	0	0	0	0	0	0	0

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1: Age is based on birth date and at 1st dose of COVID-19 vaccine date.
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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Age Group

Primary Analysis Safety Population

	50-59[1] (N=439)		60-69[1] (N=197)		70 and above[1] (N=21)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Not Hospitalized[9]	53 / 439 (12.1%)	60	20 / 197 (10.2%)	29	2 / 21 (9.5%)	2	313 / 2511 (12.5%)	361
Event Confirmation In Progress[5]	39 / 53 (73.6%)	41	14 / 20 (70.0%)	16	2 / 2 (100%)	2	233 / 313 (74.4%)	261
Suspected Event (Unknown)[6]	7 / 53 (13.2%)	10	5 / 20 (25.0%)	12	0	0	50 / 313 (16.0%)	66
Suspected Event (Not Validated)[7]	7 / 53 (13.2%)	9	1 / 20 (5.0%)	1	0	0	27 / 313 (8.6%)	31
Probable Event[8]	0	0	0	0	0	0	3 / 313 (1.0%)	3

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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Age Group

Primary Analysis Safety Population

	50-59[1] (N=439)		60-69[1] (N=197)		70 and above[1] (N=21)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Brain Or Spinal Cord Inflammation (e.g., Meningitis, Encephalitis, Guillain-Barre Syndrome)[10]	0	0	0	0	0	0	0	0
Event Confirmation In Progress[5]	0	0	0	0	0	0	0	0
Suspected Event (Unknown)[6]	0	0	0	0	0	0	0	0
Suspected Event (Not Validated)[7]	0	0	0	0	0	0	0	0
Probable Event[8]	0	0	0	0	0	0	0	0

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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Age Group

Primary Analysis Safety Population

	50-59[1] (N=439)		60-69[1] (N=197)		70 and above[1] (N=21)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Severe Allergic Reaction (Anaphylaxis)[10]	0	0	1 / 197 (<1.0%)	2	0	0	6 / 2511 (<1.0%)	7
Event Confirmation In Progress[5]	0	0	0	0	0	0	1 / 6 (16.7%)	1
Suspected Event (Unknown)[6]	0	0	0	1	0	0	4 / 6 (66.7%)	5
Suspected Event (Not Validated)[7]	0	0	1 / 1 (100%)	1	0	0	1 / 6 (16.7%)	1
Probable Event[8]	0	0	0	0	0	0	0	0

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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Age Group

Primary Analysis Safety Population

	50-59[1] (N=439)		60-69[1] (N=197)		70 and above[1] (N=21)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Non-Severe Allergic Reaction[10]	0	0	1 / 197 (<1.0%)	1	0	0	15 / 2511 (<1.0%)	17
Event Confirmation In Progress[5]	0	0	0	0	0	0	1 / 15 (6.7%)	2
Suspected Event (Unknown)[6]	0	0	1 / 1 (100%)	1	0	0	11 / 15 (73.3%)	12
Suspected Event (Not Validated)[7]	0	0	0	0	0	0	3 / 15 (20.0%)	3
Probable Event[8]	0	0	0	0	0	0	0	0

Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.
1: Age is based on birth date and at 1st dose of COVID-19 vaccine date.
2: A subject may have more than one event, so an event row count can be larger than the row participant count and the sum of event rows can be more than the N in the header.
3: Excluding any events with hospitalization date or seeking medical date prior to vaccine date; if a participant reported an event on both hospitalization and unplanned medical care form on the same date, the event will be counted only once as a Hospitalization.
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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Age Group

Primary Analysis Safety Population

	50-59[1] (N=439)		60-69[1] (N=197)		70 and above[1] (N=21)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Heart Inflammation (e.g., Myocarditis, Pericarditis)[10]	0	0	0	0	0	0	1 / 2511 (<1.0%)	1
Event Confirmation In Progress[5]	0	0	0	0	0	0	0	0
Suspected Event (Unknown)[6]	0	0	0	0	0	0	1 / 1 (100%)	1
Suspected Event (Not Validated)[7]	0	0	0	0	0	0	0	0
Probable Event[8]	0	0	0	0	0	0	0	0

Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.
1: Age is based on birth date and at 1st dose of COVID-19 vaccine date.
2: A subject may have more than one event, so an event row count can be larger than the row participant count and the sum of event rows can be more than the N in the header.
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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Age Group

Primary Analysis Safety Population

	50-59[1] (N=439)		60-69[1] (N=197)		70 and above[1] (N=21)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Blood Clot Inside A Vein In The Body (Thromboembolism)[10]	0	0	0	0	0	0	0	0
Event Confirmation In Progress[5]	0	0	0	0	0	0	0	0
Suspected Event (Unknown)[6]	0	0	0	0	0	0	0	0
Suspected Event (Not Validated)[7]	0	0	0	0	0	0	0	0
Probable Event[8]	0	0	0	0	0	0	0	0

Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.
1: Age is based on birth date and at 1st dose of COVID-19 vaccine date.
2: A subject may have more than one event, so an event row count can be larger than the row participant count and the sum of event rows can be more than the N in the header.
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Table 15.3.2.1.5

BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Age Group

Primary Analysis Safety Population

	50-59[1] (N=439)		60-69[1] (N=197)		70 and above[1] (N=21)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Blood Vessel Inflammation (e.g., Kawasaki Disease, Vasculitides)[10]	0	0	0	0	0	0	2 / 2511 (<1.0%)	2
Event Confirmation In Progress[5]	0	0	0	0	0	0	0	0
Suspected Event (Unknown)[6]	0	0	0	0	0	0	1 / 2 (50.0%)	1
Suspected Event (Not Validated)[7]	0	0	0	0	0	0	1 / 2 (50.0%)	1
Probable Event[8]	0	0	0	0	0	0	0	0

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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Age Group

Primary Analysis Safety Population

	50-59[1] (N=439)		60-69[1] (N=197)		70 and above[1] (N=21)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Abnormal Blood Clotting (e.g., Disseminated Intravascular Coagulation, Thrombocytopenia)[10]	0	0	0	0	0	0	1 / 2511 (<1.0%)	1
Event Confirmation In Progress[5]	0	0	0	0	0	0	0	0
Suspected Event (Unknown)[6]	0	0	0	0	0	0	0	0
Suspected Event (Not Validated)[7]	0	0	0	0	0	0	0	0
Probable Event[8]	0	0	0	0	0	0	1 / 1 (100%)	1

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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Age Group

Primary Analysis Safety Population

	50-59[1] (N=439)		60-69[1] (N=197)		70 and above[1] (N=21)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Bleeding Disorder (Hemorrhagic Disease)[10]	0	0	0	0	0	0	0	0
Event Confirmation In Progress[5]	0	0	0	0	0	0	0	0
Suspected Event (Unknown)[6]	0	0	0	0	0	0	0	0
Suspected Event (Not Validated)[7]	0	0	0	0	0	0	0	0
Probable Event[8]	0	0	0	0	0	0	0	0

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1: Age is based on birth date and at 1st dose of COVID-19 vaccine date.
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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Age Group

Primary Analysis Safety Population

	50-59[1] (N=439)		60-69[1] (N=197)		70 and above[1] (N=21)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Heart Attack (Myocardial Infarction)[10]	0	0	0	0	0	0	0	0
Event Confirmation In Progress[5]	0	0	0	0	0	0	0	0
Suspected Event (Unknown)[6]	0	0	0	0	0	0	0	0
Suspected Event (Not Validated)[7]	0	0	0	0	0	0	0	0
Probable Event[8]	0	0	0	0	0	0	0	0

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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Age Group

Primary Analysis Safety Population

	50-59[1] (N=439)		60-69[1] (N=197)		70 and above[1] (N=21)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Heart Failure/Cardiogenic Shock[10]	0	0	0	0	0	0	0	0
Event Confirmation In Progress[5]	0	0	0	0	0	0	0	0
Suspected Event (Unknown)[6]	0	0	0	0	0	0	0	0
Suspected Event (Not Validated)[7]	0	0	0	0	0	0	0	0
Probable Event[8]	0	0	0	0	0	0	0	0

Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.
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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Age Group

Primary Analysis Safety Population

	50-59[1] (N=439)		60-69[1] (N=197)		70 and above[1] (N=21)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Stress Cardiomyopathy[10]	0	0	0	0	0	0	0	0
Event Confirmation In Progress[5]	0	0	0	0	0	0	0	0
Suspected Event (Unknown)[6]	0	0	0	0	0	0	0	0
Suspected Event (Not Validated)[7]	0	0	0	0	0	0	0	0
Probable Event[8]	0	0	0	0	0	0	0	0

Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.
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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Age Group

Primary Analysis Safety Population

	50-59[1] (N=439)		60-69[1] (N=197)		70 and above[1] (N=21)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Coronary Artery Disease[10]	0	0	0	0	0	0	0	0
Event Confirmation In Progress[5]	0	0	0	0	0	0	0	0
Suspected Event (Unknown)[6]	0	0	0	0	0	0	0	0
Suspected Event (Not Validated)[7]	0	0	0	0	0	0	0	0
Probable Event[8]	0	0	0	0	0	0	0	0

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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Age Group

Primary Analysis Safety Population

	50-59[1] (N=439)		60-69[1] (N=197)		70 and above[1] (N=21)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Abnormal Heart Rhythm (Arrhythmia)[10]	0	0	0	0	0	0	0	0
Event Confirmation In Progress[5]	0	0	0	0	0	0	0	0
Suspected Event (Unknown)[6]	0	0	0	0	0	0	0	0
Suspected Event (Not Validated)[7]	0	0	0	0	0	0	0	0
Probable Event[8]	0	0	0	0	0	0	0	0

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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Age Group

Primary Analysis Safety Population

	50-59[1] (N=439)		60-69[1] (N=197)		70 and above[1] (N=21)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Stroke Or Possible Stroke[10]	0	0	1 / 197 (<1.0%)	1	0	0	1 / 2511 (<1.0%)	1
Event Confirmation In Progress[5]	0	0	1 / 1 (100%)	1	0	0	1 / 1 (100%)	1
Suspected Event (Unknown)[6]	0	0	0	0	0	0	0	0
Suspected Event (Not Validated)[7]	0	0	0	0	0	0	0	0
Probable Event[8]	0	0	0	0	0	0	0	0

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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Age Group

Primary Analysis Safety Population

	50-59[1] (N=439)		60-69[1] (N=197)		70 and above[1] (N=21)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Blockage Of Blood Flow To Limbs (e.g., Limb Ischemia, Peripheral Artery Disease)[10]	0	0	0	0	0	0	0	0
Event Confirmation In Progress[5]	0	0	0	0	0	0	0	0
Suspected Event (Unknown)[6]	0	0	0	0	0	0	0	0
Suspected Event (Not Validated)[7]	0	0	0	0	0	0	0	0
Probable Event[8]	0	0	0	0	0	0	0	0

Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.
1: Age is based on birth date and at 1st dose of COVID-19 vaccine date.
2: A subject may have more than one event, so an event row count can be larger than the row participant count and the sum of event rows can be more than the N in the header.
3: Excluding any events with hospitalization date or seeking medical date prior to vaccine date; if a participant reported an event on both hospitalization and unplanned medical care form on the same date, the event will be counted only once as a Hospitalization.
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Table 15.3.2.1.5

BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Age Group

Primary Analysis Safety Population

	50-59[1] (N=439)		60-69[1] (N=197)		70 and above[1] (N=21)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Acute Kidney Injury[10]	0	0	0	0	0	0	0	0
Event Confirmation In Progress[5]	0	0	0	0	0	0	0	0
Suspected Event (Unknown)[6]	0	0	0	0	0	0	0	0
Suspected Event (Not Validated)[7]	0	0	0	0	0	0	0	0
Probable Event[8]	0	0	0	0	0	0	0	0

Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.
1: Age is based on birth date and at 1st dose of COVID-19 vaccine date.
2: A subject may have more than one event, so an event row count can be larger than the row participant count and the sum of event rows can be more than the N in the header.
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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Age Group

Primary Analysis Safety Population

	50-59[1] (N=439)		60-69[1] (N=197)		70 and above[1] (N=21)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Liver Injury[10]	0	0	0	0	0	0	0	0
Event Confirmation In Progress[5]	0	0	0	0	0	0	0	0
Suspected Event (Unknown)[6]	0	0	0	0	0	0	0	0
Suspected Event (Not Validated)[7]	0	0	0	0	0	0	0	0
Probable Event[8]	0	0	0	0	0	0	0	0

Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.
1: Age is based on birth date and at 1st dose of COVID-19 vaccine date.
2: A subject may have more than one event, so an event row count can be larger than the row participant count and the sum of event rows can be more than the N in the header.
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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Age Group

Primary Analysis Safety Population

	50-59[1] (N=439)		60-69[1] (N=197)		70 and above[1] (N=21)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Skin Immune Reaction (e.g., Chillblain-Like Lesions, Erythema Multiforme)[10]	0	0	0	0	0	0	0	0
Event Confirmation In Progress[5]	0	0	0	0	0	0	0	0
Suspected Event (Unknown)[6]	0	0	0	0	0	0	0	0
Suspected Event (Not Validated)[7]	0	0	0	0	0	0	0	0
Probable Event[8]	0	0	0	0	0	0	0	0

Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.
1: Age is based on birth date and at 1st dose of COVID-19 vaccine date.
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Table 15.3.2.1.5

BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Age Group

Primary Analysis Safety Population

	50-59[1] (N=439)		60-69[1] (N=197)		70 and above[1] (N=21)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Multisystem Inflammation[10]	0	0	0	0	0	0	2 / 2511 (<1.0%)	2
Event Confirmation In Progress[5]	0	0	0	0	0	0	0	0
Suspected Event (Unknown)[6]	0	0	0	0	0	0	0	0
Suspected Event (Not Validated)[7]	0	0	0	0	0	0	2 / 2 (100%)	2
Probable Event[8]	0	0	0	0	0	0	0	0

Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.
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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Age Group

Primary Analysis Safety Population

	50-59[1] (N=439)		60-69[1] (N=197)		70 and above[1] (N=21)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Fibromyalgia[10]	0	0	0	0	0	0	2 / 2511 (<1.0%)	2
Event Confirmation In Progress[5]	0	0	0	0	0	0	1 / 2 (50.0%)	1
Suspected Event (Unknown)[6]	0	0	0	0	0	0	1 / 2 (50.0%)	1
Suspected Event (Not Validated)[7]	0	0	0	0	0	0	0	0
Probable Event[8]	0	0	0	0	0	0	0	0

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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Age Group

Primary Analysis Safety Population

	50-59[1] (N=439)		60-69[1] (N=197)		70 and above[1] (N=21)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Nerve Inflammation Or Autoimmune Disease (e.g., Multiple Sclerosis, Rheumatoid Arthritis)[10]	3 / 439 (<1.0%)	4	1 / 197 (<1.0%)	2	0	0	9 / 2511 (<1.0%)	11
Event Confirmation In Progress[5]	1 / 3 (33.3%)	1	0	0	0	0	2 / 9 (22.2%)	2
Suspected Event (Unknown)[6]	0	0	1 / 1 (100%)	2	0	0	4 / 9 (44.4%)	5
Suspected Event (Not Validated)[7]	2 / 3 (66.7%)	3	0	0	0	0	3 / 9 (33.3%)	4
Probable Event[8]	0	0	0	0	0	0	0	0

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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Age Group

Primary Analysis Safety Population

	50-59[1] (N=439)		60-69[1] (N=197)		70 and above[1] (N=21)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Autoimmune Thyroiditis[10]	0	0	0	0	0	0	3 / 2511 (<1.0%)	3
Event Confirmation In Progress[5]	0	0	0	0	0	0	1 / 3 (33.3%)	1
Suspected Event (Unknown)[6]	0	0	0	0	0	0	2 / 3 (66.7%)	2
Suspected Event (Not Validated)[7]	0	0	0	0	0	0	0	0
Probable Event[8]	0	0	0	0	0	0	0	0

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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Age Group

Primary Analysis Safety Population

	50-59[1] (N=439)		60-69[1] (N=197)		70 and above[1] (N=21)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
COVID-19 Infection[10]	2 / 439 (<1.0%)	4	1 / 197 (<1.0%)	4	0	0	15 / 2511 (<1.0%)	20
Event Confirmation In Progress[5]	0	0	0	1	0	0	3 / 15 (20.0%)	4
Suspected Event (Unknown)[6]	1 / 2 (50.0%)	3	1 / 1 (100%)	3	0	0	6 / 15 (40.0%)	10
Suspected Event (Not Validated)[7]	1 / 2 (50.0%)	1	0	0	0	0	5 / 15 (33.3%)	5
Probable Event[8]	0	0	0	0	0	0	1 / 15 (6.7%)	1

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Table 15.3.2.1.5
BNT162b2 Protocol C4591008
Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Age Group
Primary Analysis Safety Population

	50-59[1] (N=439)		60-69[1] (N=197)		70 and above[1] (N=21)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Generalized Convulsions/Seizures[10]	1 / 439 (<1.0%)	1	0	0	0	0	1 / 2511 (<1.0%)	1
Event Confirmation In Progress[5]	0	0	0	0	0	0	0	0
Suspected Event (Unknown)[6]	0	0	0	0	0	0	0	0
Suspected Event (Not Validated)[7]	1 / 1 (100%)	1	0	0	0	0	1 / 1 (100%)	1
Probable Event[8]	0	0	0	0	0	0	0	0

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PFIZER CONFIDENTIAL SDTM Creation: 11MAY2021:07:31:19 Data Cutoff: 29APR2021 Source Data: ADSL, ADEVENT
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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Age Group

Primary Analysis Safety Population

	50-59[1] (N=439)		60-69[1] (N=197)		70 and above[1] (N=21)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Bell's Palsy[10]	0	0	0	0	0	0	0	0
Event Confirmation In Progress[5]	0	0	0	0	0	0	0	0
Suspected Event (Unknown)[6]	0	0	0	0	0	0	0	0
Suspected Event (Not Validated)[7]	0	0	0	0	0	0	0	0
Probable Event[8]	0	0	0	0	0	0	0	0

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7: Adverse events of special interest with a link from the Verily eCRF to CEA spreadsheet with confirmation status as "Suspected Event (Not Validated)".
8: Adverse events of special interest with a link from the Verily eCRF to CEA spreadsheet with confirmation status as "Probable Event".
9: Verily eCRF reported adverse events of special interest collapsing on seeking medical date for the same event from the other unplanned medical care forms
10: Adverse events of special interest collected from both unplanned hospitalization form and unplanned medical care form. If the event was reported on both form at the same date, the event will be counted only once in the table.

Table 15.3.2.1.5

BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Age Group

Primary Analysis Safety Population

	50-59[1] (N=439)		60-69[1] (N=197)		70 and above[1] (N=21)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Narcolepsy Or Cataplexy[10]	0	0	0	0	0	0	0	0
Event Confirmation In Progress[5]	0	0	0	0	0	0	0	0
Suspected Event (Unknown)[6]	0	0	0	0	0	0	0	0
Suspected Event (Not Validated)[7]	0	0	0	0	0	0	0	0
Probable Event[8]	0	0	0	0	0	0	0	0

Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.
1: Age is based on birth date and at 1st dose of COVID-19 vaccine date.
2: A subject may have more than one event, so an event row count can be larger than the row participant count and the sum of event rows can be more than the N in the header.
3: Excluding any events with hospitalization date or seeking medical date prior to vaccine date; if a participant reported an event on both hospitalization and unplanned medical care form on the same date, the event will be counted only once as a Hospitalization.
4: Verily eCRF reported adverse events of special interest collapsing on hospitalization date from the unplanned hospitalization forms. If more than one event was collected for the same hospitalization, all events will have the same confirmation status on CEA spreadsheet.
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10: Adverse events of special interest collected from both unplanned hospitalization form and unplanned medical care form. If the event was reported on both form at the same date, the event will be counted only once in the table.

Table 15.3.2.1.5

BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Age Group

Primary Analysis Safety Population

	50-59[1] (N=439)		60-69[1] (N=197)		70 and above[1] (N=21)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Joint Stiffness Or Pain (e.g., Arthralgia, Arthritis)[10]	9 / 439 (2.1%)	11	2 / 197 (1.0%)	5	0	0	32 / 2511 (1.3%)	43
Event Confirmation In Progress[5]	0	0	0	0	0	0	3 / 32 (9.4%)	7
Suspected Event (Unknown)[6]	6 / 9 (66.7%)	7	2 / 2 (100%)	5	0	0	20 / 32 (62.5%)	25
Suspected Event (Not Validated)[7]	3 / 9 (33.3%)	4	0	0	0	0	8 / 32 (25.0%)	10
Probable Event[8]	0	0	0	0	0	0	1 / 32 (3.1%)	1

Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.
1: Age is based on birth date and at 1st dose of COVID-19 vaccine date.
2: A subject may have more than one event, so an event row count can be larger than the row participant count and the sum of event rows can be more than the N in the header.
3: Excluding any events with hospitalization date or seeking medical date prior to vaccine date; if a participant reported an event on both hospitalization and unplanned medical care form on the same date, the event will be counted only once as a Hospitalization.
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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Age Group

Primary Analysis Safety Population

	50-59[1] (N=439)		60-69[1] (N=197)		70 and above[1] (N=21)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Pregnancy-Related Issue[10]	0	0	0	0	0	0	19 / 2511 (<1.0%)	24
Event Confirmation In Progress[5]	0	0	0	0	0	0	8 / 19 (42.1%)	10
Suspected Event (Unknown)[6]	0	0	0	0	0	0	5 / 19 (26.3%)	7
Suspected Event (Not Validated)[7]	0	0	0	0	0	0	6 / 19 (31.6%)	7
Probable Event[8]	0	0	0	0	0	0	0	0

Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.
1: Age is based on birth date and at 1st dose of COVID-19 vaccine date.
2: A subject may have more than one event, so an event row count can be larger than the row participant count and the sum of event rows can be more than the N in the header.
3: Excluding any events with hospitalization date or seeking medical date prior to vaccine date; if a participant reported an event on both hospitalization and unplanned medical care form on the same date, the event will be counted only once as a Hospitalization.
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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Age Group

Primary Analysis Safety Population

	50-59[1] (N=439)		60-69[1] (N=197)		70 and above[1] (N=21)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Microangiopathy[10]	0	0	0	0	0	0	0	0
Event Confirmation In Progress[5]	0	0	0	0	0	0	0	0
Suspected Event (Unknown)[6]	0	0	0	0	0	0	0	0
Suspected Event (Not Validated)[7]	0	0	0	0	0	0	0	0
Probable Event[8]	0	0	0	0	0	0	0	0

Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.
1: Age is based on birth date and at 1st dose of COVID-19 vaccine date.
2: A subject may have more than one event, so an event row count can be larger than the row participant count and the sum of event rows can be more than the N in the header.
3: Excluding any events with hospitalization date or seeking medical date prior to vaccine date; if a participant reported an event on both hospitalization and unplanned medical care form on the same date, the event will be counted only once as a Hospitalization.
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Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Age Group

Primary Analysis Safety Population

	50-59[1] (N=439)		60-69[1] (N=197)		70 and above[1] (N=21)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Death[10]	1 / 439 (<1.0%)	1	0	0	0	0	1 / 2511 (<1.0%)	1
Event Confirmation In Progress[5]	1 / 1 (100%)	1	0	0	0	0	1 / 1 (100%)	1
Suspected Event (Unknown)[6]	0	0	0	0	0	0	0	0
Suspected Event (Not Validated)[7]	0	0	0	0	0	0	0	0
Probable Event[8]	0	0	0	0	0	0	0	0

Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.
1: Age is based on birth date and at 1st dose of COVID-19 vaccine date.
2: A subject may have more than one event, so an event row count can be larger than the row participant count and the sum of event rows can be more than the N in the header.
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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Age Group

Primary Analysis Safety Population

	50-59[1] (N=439)		60-69[1] (N=197)		70 and above[1] (N=21)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Other[10]	40 / 439 (9.1%)	42	14 / 197 (7.1%)	14	2 / 21 (9.5%)	2	236 / 2511 (9.4%)	242
Event Confirmation In Progress[5]	37 / 40 (92.5%)	39	14 / 14 (100%)	14	2 / 2 (100%)	2	228 / 236 (96.6%)	233
Suspected Event (Unknown)[6]	2 / 40 (5.0%)	2	0	0	0	0	3 / 236 (1.3%)	4
Suspected Event (Not Validated)[7]	1 / 40 (2.5%)	1	0	0	0	0	5 / 236 (2.1%)	5
Probable Event[8]	0	0	0	0	0	0	0	0

Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.
1: Age is based on birth date and at 1st dose of COVID-19 vaccine date.
2: A subject may have more than one event, so an event row count can be larger than the row participant count and the sum of event rows can be more than the N in the header.
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Table 15.3.2.1.6

BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Immunocompromised Individuals

Primary Analysis Safety Population

	Yes[1] (N=181)		No (N=2330)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Any Adverse Event of Special Interest[3]	39 / 181 (21.5%)	53	281 / 2330 (12.1%)	325	320 / 2511 (12.7%)	378
Hospitalized[4]	1 / 181 (<1.0%)	2	15 / 2330 (<1.0%)	15	16 / 2511 (<1.0%)	17
Event Confirmation In Progress[5]	0	0	2 / 15 (13.3%)	2	2 / 16 (12.5%)	2
Suspected Event (Unknown)[6]	0	1	6 / 15 (40.0%)	6	6 / 16 (37.5%)	7
Suspected Event (Not Validated)[7]	1 / 1 (100%)	1	7 / 15 (46.7%)	7	8 / 16 (50.0%)	8
Probable Event[8]	0	0	0	0	0	0

Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.
1: Immunocompromised status= Yes is defined based on a) having organ transplant or HIV/AIDS from baseline medical history and b) taking any inhaled corticosteroids, systemic corticosteroids, or immunosuppressant medications.
2: A subject may have more than one event, so an event row count can be larger than the row participant count and the sum of event rows can be more than the N in the header.
3: Excluding any events with hospitalization date or seeking medical date prior to vaccine date; if a participant reported an event on both hospitalization and unplanned medical care form on the same date, the event will be counted only once as a Hospitalization.
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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Immunocompromised Individuals

Primary Analysis Safety Population

	Yes[1] (N=181)		No (N=2330)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Not Hospitalized[9]	39 / 181 (21.5%)	51	274 / 2330 (11.8%)	310	313 / 2511 (12.5%)	361
Event Confirmation In Progress[5]	25 / 39 (64.1%)	31	208 / 274 (75.9%)	230	233 / 313 (74.4%)	261
Suspected Event (Unknown)[6]	7 / 39 (17.9%)	12	43 / 274 (15.7%)	54	50 / 313 (16.0%)	66
Suspected Event (Not Validated)[7]	7 / 39 (17.9%)	8	20 / 274 (7.3%)	23	27 / 313 (8.6%)	31
Probable Event[8]	0	0	3 / 274 (1.1%)	3	3 / 313 (1.0%)	3

Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.
1: Immunocompromised status= Yes is defined based on a) having organ transplant or HIV/AIDS from baseline medical history and b) taking any inhaled corticosteroids, systemic corticosteroids, or immunosuppressant medications.
2: A subject may have more than one event, so an event row count can be larger than the row participant count and the sum of event rows can be more than the N in the header.
3: Excluding any events with hospitalization date or seeking medical date prior to vaccine date; if a participant reported an event on both hospitalization and unplanned medical care form on the same date, the event will be counted only once as a Hospitalization.
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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Immunocompromised Individuals

Primary Analysis Safety Population

	Yes[1] (N=181)		No (N=2330)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Brain Or Spinal Cord Inflammation (e.g., Meningitis, Encephalitis, Guillain-Barre Syndrome)[10]	0	0	0	0	0	0
Event Confirmation In Progress[5]	0	0	0	0	0	0
Suspected Event (Unknown)[6]	0	0	0	0	0	0
Suspected Event (Not Validated)[7]	0	0	0	0	0	0
Probable Event[8]	0	0	0	0	0	0

Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.
1: Immunocompromised status= Yes is defined based on a) having organ transplant or HIV/AIDS from baseline medical history and b) taking any inhaled corticosteroids, systemic corticosteroids, or immunosuppressant medications.
2: A subject may have more than one event, so an event row count can be larger than the row participant count and the sum of event rows can be more than the N in the header.
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Table 15.3.2.1.6

BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Immunocompromised Individuals

Primary Analysis Safety Population

	Yes[1] (N=181)		No (N=2330)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Severe Allergic Reaction (Anaphylaxis)[10]	0	0	6 / 2330 (<1.0%)	7	6 / 2511 (<1.0%)	7
Event Confirmation In Progress[5]	0	0	1 / 6 (16.7%)	1	1 / 6 (16.7%)	1
Suspected Event (Unknown)[6]	0	0	4 / 6 (66.7%)	5	4 / 6 (66.7%)	5
Suspected Event (Not Validated)[7]	0	0	1 / 6 (16.7%)	1	1 / 6 (16.7%)	1
Probable Event[8]	0	0	0	0	0	0

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1: Immunocompromised status= Yes is defined based on a) having organ transplant or HIV/AIDS from baseline medical history and b) taking any inhaled corticosteroids, systemic corticosteroids, or immunosuppressant medications.
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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Immunocompromised Individuals

Primary Analysis Safety Population

	Yes[1] (N=181)		No (N=2330)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Non-Severe Allergic Reaction[10]	2 / 181 (1.1%)	3	13 / 2330 (<1.0%)	14	15 / 2511 (<1.0%)	17
Event Confirmation In Progress[5]	0	0	1 / 13 (7.7%)	2	1 / 15 (6.7%)	2
Suspected Event (Unknown)[6]	2 / 2 (100%)	3	9 / 13 (69.2%)	9	11 / 15 (73.3%)	12
Suspected Event (Not Validated)[7]	0	0	3 / 13 (23.1%)	3	3 / 15 (20.0%)	3
Probable Event[8]	0	0	0	0	0	0

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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Immunocompromised Individuals

Primary Analysis Safety Population

	Yes[1] (N=181)		No (N=2330)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Heart Inflammation (e.g., Myocarditis, Pericarditis)[10]	0	0	1 / 2330 (<1.0%)	1	1 / 2511 (<1.0%)	1
Event Confirmation In Progress[5]	0	0	0	0	0	0
Suspected Event (Unknown)[6]	0	0	1 / 1 (100%)	1	1 / 1 (100%)	1
Suspected Event (Not Validated)[7]	0	0	0	0	0	0
Probable Event[8]	0	0	0	0	0	0

Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.
1: Immunocompromised status= Yes is defined based on a) having organ transplant or HIV/AIDS from baseline medical history and b) taking any inhaled corticosteroids, systemic corticosteroids, or immunosuppressant medications.
2: A subject may have more than one event, so an event row count can be larger than the row participant count and the sum of event rows can be more than the N in the header.
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Table 15.3.2.1.6

BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Immunocompromised Individuals

Primary Analysis Safety Population

	Yes[1] (N=181)		No (N=2330)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Blood Clot Inside A Vein In The Body (Thromboembolism)[10]	0	0	0	0	0	0
Event Confirmation In Progress[5]	0	0	0	0	0	0
Suspected Event (Unknown)[6]	0	0	0	0	0	0
Suspected Event (Not Validated)[7]	0	0	0	0	0	0
Probable Event[8]	0	0	0	0	0	0

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Table 15.3.2.1.6

BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Immunocompromised Individuals

Primary Analysis Safety Population

	Yes[1] (N=181)		No (N=2330)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Blood Vessel Inflammation (e.g., Kawasaki Disease, Vasculitides)[10]	0	0	2 / 2330 (<1.0%)	2	2 / 2511 (<1.0%)	2
Event Confirmation In Progress[5]	0	0	0	0	0	0
Suspected Event (Unknown)[6]	0	0	1 / 2 (50.0%)	1	1 / 2 (50.0%)	1
Suspected Event (Not Validated)[7]	0	0	1 / 2 (50.0%)	1	1 / 2 (50.0%)	1
Probable Event[8]	0	0	0	0	0	0

Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.

1: Immunocompromised status= Yes is defined based on a) having organ transplant or HIV/AIDS from baseline medical history and b) taking any inhaled corticosteroids, systemic corticosteroids, or immunosuppressant medications.

2: A subject may have more than one event, so an event row count can be larger than the row participant count and the sum of event rows can be more than the N in the header.

3: Excluding any events with hospitalization date or seeking medical date prior to vaccine date; if a participant reported an event on both hospitalization and unplanned medical care form on the same date, the event will be counted only once as a Hospitalization.

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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Immunocompromised Individuals

Primary Analysis Safety Population

	Yes[1] (N=181)		No (N=2330)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Abnormal Blood Clotting (e.g., Disseminated Intravascular Coagulation, Thrombocytopenia)[10]	0	0	1 / 2330 (<1.0%)	1	1 / 2511 (<1.0%)	1
Event Confirmation In Progress[5]	0	0	0	0	0	0
Suspected Event (Unknown)[6]	0	0	0	0	0	0
Suspected Event (Not Validated)[7]	0	0	0	0	0	0
Probable Event[8]	0	0	1 / 1 (100%)	1	1 / 1 (100%)	1

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1: Immunocompromised status= Yes is defined based on a) having organ transplant or HIV/AIDS from baseline medical history and b) taking any inhaled corticosteroids, systemic corticosteroids, or immunosuppressant medications.
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Table 15.3.2.1.6

BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Immunocompromised Individuals

Primary Analysis Safety Population

	Yes[1] (N=181)		No (N=2330)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Bleeding Disorder (Hemorrhagic Disease)[10]	0	0	0	0	0	0
Event Confirmation In Progress[5]	0	0	0	0	0	0
Suspected Event (Unknown)[6]	0	0	0	0	0	0
Suspected Event (Not Validated)[7]	0	0	0	0	0	0
Probable Event[8]	0	0	0	0	0	0

Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.
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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Immunocompromised Individuals

Primary Analysis Safety Population

	Yes[1] (N=181)		No (N=2330)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Heart Attack (Myocardial Infarction)[10]	0	0	0	0	0	0
Event Confirmation In Progress[5]	0	0	0	0	0	0
Suspected Event (Unknown)[6]	0	0	0	0	0	0
Suspected Event (Not Validated)[7]	0	0	0	0	0	0
Probable Event[8]	0	0	0	0	0	0

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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Immunocompromised Individuals

Primary Analysis Safety Population

	Yes[1] (N=181)		No (N=2330)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Heart Failure/Cardiogenic Shock[10]	0	0	0	0	0	0
Event Confirmation In Progress[5]	0	0	0	0	0	0
Suspected Event (Unknown)[6]	0	0	0	0	0	0
Suspected Event (Not Validated)[7]	0	0	0	0	0	0
Probable Event[8]	0	0	0	0	0	0

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Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Immunocompromised Individuals

Primary Analysis Safety Population

	Yes[1] (N=181)		No (N=2330)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Stress Cardiomyopathy[10]	0	0	0	0	0	0
Event Confirmation In Progress[5]	0	0	0	0	0	0
Suspected Event (Unknown)[6]	0	0	0	0	0	0
Suspected Event (Not Validated)[7]	0	0	0	0	0	0
Probable Event[8]	0	0	0	0	0	0

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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Immunocompromised Individuals

Primary Analysis Safety Population

	Yes[1] (N=181)		No (N=2330)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Coronary Artery Disease[10]	0	0	0	0	0	0
Event Confirmation In Progress[5]	0	0	0	0	0	0
Suspected Event (Unknown)[6]	0	0	0	0	0	0
Suspected Event (Not Validated)[7]	0	0	0	0	0	0
Probable Event[8]	0	0	0	0	0	0

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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Immunocompromised Individuals

Primary Analysis Safety Population

	Yes[1] (N=181)		No (N=2330)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Abnormal Heart Rhythm (Arrhythmia)[10]	0	0	0	0	0	0
Event Confirmation In Progress[5]	0	0	0	0	0	0
Suspected Event (Unknown)[6]	0	0	0	0	0	0
Suspected Event (Not Validated)[7]	0	0	0	0	0	0
Probable Event[8]	0	0	0	0	0	0

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Table 15.3.2.1.6

BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Immunocompromised Individuals

Primary Analysis Safety Population

	Yes[1] (N=181)		No (N=2330)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Stroke Or Possible Stroke[10]	0	0	1 / 2330 (<1.0%)	1	1 / 2511 (<1.0%)	1
Event Confirmation In Progress[5]	0	0	1 / 1 (100%)	1	1 / 1 (100%)	1
Suspected Event (Unknown)[6]	0	0	0	0	0	0
Suspected Event (Not Validated)[7]	0	0	0	0	0	0
Probable Event[8]	0	0	0	0	0	0

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BNT162b2 Protocol C4591008

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Primary Analysis Safety Population

	Yes[1] (N=181)		No (N=2330)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Blockage Of Blood Flow To Limbs (e.g., Limb Ischemia, Peripheral Artery Disease)[10]	0	0	0	0	0	0
Event Confirmation In Progress[5]	0	0	0	0	0	0
Suspected Event (Unknown)[6]	0	0	0	0	0	0
Suspected Event (Not Validated)[7]	0	0	0	0	0	0
Probable Event[8]	0	0	0	0	0	0

Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.
1: Immunocompromised status= Yes is defined based on a) having organ transplant or HIV/AIDS from baseline medical history and b) taking any inhaled corticosteroids, systemic corticosteroids, or immunosuppressant medications.
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Table 15.3.2.1.6

BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Immunocompromised Individuals

Primary Analysis Safety Population

	Yes[1] (N=181)		No (N=2330)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Acute Kidney Injury[10]	0	0	0	0	0	0
Event Confirmation In Progress[5]	0	0	0	0	0	0
Suspected Event (Unknown)[6]	0	0	0	0	0	0
Suspected Event (Not Validated)[7]	0	0	0	0	0	0
Probable Event[8]	0	0	0	0	0	0

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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Immunocompromised Individuals

Primary Analysis Safety Population

	Yes[1] (N=181)		No (N=2330)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Liver Injury[10]	0	0	0	0	0	0
Event Confirmation In Progress[5]	0	0	0	0	0	0
Suspected Event (Unknown)[6]	0	0	0	0	0	0
Suspected Event (Not Validated)[7]	0	0	0	0	0	0
Probable Event[8]	0	0	0	0	0	0

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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Immunocompromised Individuals

Primary Analysis Safety Population

	Yes[1] (N=181)		No (N=2330)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Skin Immune Reaction (e.g., Chillblain-Like Lesions, Erythema Multiforme)[10]	0	0	0	0	0	0
Event Confirmation In Progress[5]	0	0	0	0	0	0
Suspected Event (Unknown)[6]	0	0	0	0	0	0
Suspected Event (Not Validated)[7]	0	0	0	0	0	0
Probable Event[8]	0	0	0	0	0	0

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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Immunocompromised Individuals

Primary Analysis Safety Population

	Yes[1] (N=181)		No (N=2330)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Multisystem Inflammation[10]	1 / 181 (<1.0%)	1	1 / 2330 (<1.0%)	1	2 / 2511 (<1.0%)	2
Event Confirmation In Progress[5]	0	0	0	0	0	0
Suspected Event (Unknown)[6]	0	0	0	0	0	0
Suspected Event (Not Validated)[7]	1 / 1 (100%)	1	1 / 1 (100%)	1	2 / 2 (100%)	2
Probable Event[8]	0	0	0	0	0	0

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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Immunocompromised Individuals

Primary Analysis Safety Population

	Yes[1] (N=181)		No (N=2330)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Fibromyalgia[10]	0	0	2 / 2330 (<1.0%)	2	2 / 2511 (<1.0%)	2
Event Confirmation In Progress[5]	0	0	1 / 2 (50.0%)	1	1 / 2 (50.0%)	1
Suspected Event (Unknown)[6]	0	0	1 / 2 (50.0%)	1	1 / 2 (50.0%)	1
Suspected Event (Not Validated)[7]	0	0	0	0	0	0
Probable Event[8]	0	0	0	0	0	0

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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Immunocompromised Individuals

Primary Analysis Safety Population

	Yes[1] (N=181)		No (N=2330)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Nerve Inflammation Or Autoimmune Disease (e.g., Multiple Sclerosis, Rheumatoid Arthritis)[10]	7 / 181 (3.9%)	9	2 / 2330 (<1.0%)	2	9 / 2511 (<1.0%)	11
Event Confirmation In Progress[5]	2 / 7 (28.6%)	2	0	0	2 / 9 (22.2%)	2
Suspected Event (Unknown)[6]	2 / 7 (28.6%)	3	2 / 2 (100%)	2	4 / 9 (44.4%)	5
Suspected Event (Not Validated)[7]	3 / 7 (42.9%)	4	0	0	3 / 9 (33.3%)	4
Probable Event[8]	0	0	0	0	0	0

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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Immunocompromised Individuals

Primary Analysis Safety Population

	Yes[1] (N=181)		No (N=2330)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Autoimmune Thyroiditis[10]	0	0	3 / 2330 (<1.0%)	3	3 / 2511 (<1.0%)	3
Event Confirmation In Progress[5]	0	0	1 / 3 (33.3%)	1	1 / 3 (33.3%)	1
Suspected Event (Unknown)[6]	0	0	2 / 3 (66.7%)	2	2 / 3 (66.7%)	2
Suspected Event (Not Validated)[7]	0	0	0	0	0	0
Probable Event[8]	0	0	0	0	0	0

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Primary Analysis Safety Population

	Yes[1] (N=181)		No (N=2330)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
COVID-19 Infection[10]	2 / 181 (1.1%)	5	13 / 2330 (<1.0%)	15	15 / 2511 (<1.0%)	20
Event Confirmation In Progress[5]	0	1	3 / 13 (23.1%)	3	3 / 15 (20.0%)	4
Suspected Event (Unknown)[6]	1 / 2 (50.0%)	3	5 / 13 (38.5%)	7	6 / 15 (40.0%)	10
Suspected Event (Not Validated)[7]	1 / 2 (50.0%)	1	4 / 13 (30.8%)	4	5 / 15 (33.3%)	5
Probable Event[8]	0	0	1 / 13 (7.7%)	1	1 / 15 (6.7%)	1

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Primary Analysis Safety Population

	Yes[1] (N=181)		No (N=2330)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Generalized Convulsions/Seizures[10]	0	0	1 / 2330 (<1.0%)	1	1 / 2511 (<1.0%)	1
Event Confirmation In Progress[5]	0	0	0	0	0	0
Suspected Event (Unknown)[6]	0	0	0	0	0	0
Suspected Event (Not Validated)[7]	0	0	1 / 1 (100%)	1	1 / 1 (100%)	1
Probable Event[8]	0	0	0	0	0	0

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Primary Analysis Safety Population

	Yes[1] (N=181)		No (N=2330)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Bell's Palsy[10]	0	0	0	0	0	0
Event Confirmation In Progress[5]	0	0	0	0	0	0
Suspected Event (Unknown)[6]	0	0	0	0	0	0
Suspected Event (Not Validated)[7]	0	0	0	0	0	0
Probable Event[8]	0	0	0	0	0	0

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Primary Analysis Safety Population

	Yes[1] (N=181)		No (N=2330)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Narcolepsy Or Cataplexy[10]	0	0	0	0	0	0
Event Confirmation In Progress[5]	0	0	0	0	0	0
Suspected Event (Unknown)[6]	0	0	0	0	0	0
Suspected Event (Not Validated)[7]	0	0	0	0	0	0
Probable Event[8]	0	0	0	0	0	0

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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Immunocompromised Individuals

Primary Analysis Safety Population

	Yes[1] (N=181)		No (N=2330)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Joint Stiffness Or Pain (e.g., Arthralgia, Arthritis)[10]	5 / 181 (2.8%)	6	27 / 2330 (1.2%)	37	32 / 2511 (1.3%)	43
Event Confirmation In Progress[5]	0	1	3 / 27 (11.1%)	6	3 / 32 (9.4%)	7
Suspected Event (Unknown)[6]	3 / 5 (60.0%)	3	17 / 27 (63.0%)	22	20 / 32 (62.5%)	25
Suspected Event (Not Validated)[7]	2 / 5 (40.0%)	2	6 / 27 (22.2%)	8	8 / 32 (25.0%)	10
Probable Event[8]	0	0	1 / 27 (3.7%)	1	1 / 32 (3.1%)	1

Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.
1: Immunocompromised status= Yes is defined based on a) having organ transplant or HIV/AIDS from baseline medical history and b) taking any inhaled corticosteroids, systemic corticosteroids, or immunosuppressant medications.
2: A subject may have more than one event, so an event row count can be larger than the row participant count and the sum of event rows can be more than the N in the header.
3: Excluding any events with hospitalization date or seeking medical date prior to vaccine date; if a participant reported an event on both hospitalization and unplanned medical care form on the same date, the event will be counted only once as a Hospitalization.
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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Immunocompromised Individuals

Primary Analysis Safety Population

	Yes[1] (N=181)		No (N=2330)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Pregnancy-Related Issue[10]	0	0	19 / 2330 (<1.0%)	24	19 / 2511 (<1.0%)	24
Event Confirmation In Progress[5]	0	0	8 / 19 (42.1%)	10	8 / 19 (42.1%)	10
Suspected Event (Unknown)[6]	0	0	5 / 19 (26.3%)	7	5 / 19 (26.3%)	7
Suspected Event (Not Validated)[7]	0	0	6 / 19 (31.6%)	7	6 / 19 (31.6%)	7
Probable Event[8]	0	0	0	0	0	0

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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Immunocompromised Individuals

Primary Analysis Safety Population

	Yes[1] (N=181)		No (N=2330)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Microangiopathy[10]	0	0	0	0	0	0
Event Confirmation In Progress[5]	0	0	0	0	0	0
Suspected Event (Unknown)[6]	0	0	0	0	0	0
Suspected Event (Not Validated)[7]	0	0	0	0	0	0
Probable Event[8]	0	0	0	0	0	0

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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Immunocompromised Individuals

Primary Analysis Safety Population

	Yes[1] (N=181)		No (N=2330)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Death[10]	0	0	1 / 2330 (<1.0%)	1	1 / 2511 (<1.0%)	1
Event Confirmation In Progress[5]	0	0	1 / 1 (100%)	1	1 / 1 (100%)	1
Suspected Event (Unknown)[6]	0	0	0	0	0	0
Suspected Event (Not Validated)[7]	0	0	0	0	0	0
Probable Event[8]	0	0	0	0	0	0

Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.
1: Immunocompromised status= Yes is defined based on a) having organ transplant or HIV/AIDS from baseline medical history and b) taking any inhaled corticosteroids, systemic corticosteroids, or immunosuppressant medications.
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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Immunocompromised Individuals

Primary Analysis Safety Population

	Yes[1] (N=181)		No (N=2330)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Other[10]	27 / 181 (14.9%)	29	209 / 2330 (9.0%)	213	236 / 2511 (9.4%)	242
Event Confirmation In Progress[5]	26 / 27 (96.3%)	27	202 / 209 (96.7%)	206	228 / 236 (96.6%)	233
Suspected Event (Unknown)[6]	0	1	3 / 209 (1.4%)	3	3 / 236 (1.3%)	4
Suspected Event (Not Validated)[7]	1 / 27 (3.7%)	1	4 / 209 (1.9%)	4	5 / 236 (2.1%)	5
Probable Event[8]	0	0	0	0	0	0

Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.
1: Immunocompromised status= Yes is defined based on a) having organ transplant or HIV/AIDS from baseline medical history and b) taking any inhaled corticosteroids, systemic corticosteroids, or immunosuppressant medications.
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Table 15.3.2.1.7
BNT162b2 Protocol C4591008
Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of Pfizer COVID-19 Vaccine by Dose Status
Primary Analysis Safety Population

	2 Doses[1] (N=2201)		1 Dose Only (N=310)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Any Adverse Event of Special Interest[3]	313 / 2201 (14.2%)	364	7 / 310 (2.3%)	14	320 / 2511 (12.7%)	378
Hospitalized[4]	16 / 2201 (<1.0%)	17	0	0	16 / 2511 (<1.0%)	17
Event Confirmation In Progress[5]	2 / 16 (12.5%)	2	0	0	2 / 16 (12.5%)	2
Suspected Event (Unknown)[6]	6 / 16 (37.5%)	7	0	0	6 / 16 (37.5%)	7
Suspected Event (Not Validated)[7]	8 / 16 (50.0%)	8	0	0	8 / 16 (50.0%)	8
Probable Event[8]	0	0	0	0	0	0

Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.
1: Participants who took 2 doses of vaccine.
2: A subject may have more than one event, so an event row count can be larger than the row participant count and the sum of event rows can be more than the N in the header.
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Table 15.3.2.1.7
BNT162b2 Protocol C4591008
Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of Pfizer COVID-19 Vaccine by Dose Status
Primary Analysis Safety Population

	2 Doses[1] (N=2201)		1 Dose Only (N=310)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Not Hospitalized[9]	306 / 2201 (13.9%)	347	7 / 310 (2.3%)	14	313 / 2511 (12.5%)	361
Event Confirmation In Progress[5]	230 / 306 (75.2%)	255	3 / 7 (42.9%)	6	233 / 313 (74.4%)	261
Suspected Event (Unknown)[6]	49 / 306 (16.0%)	62	1 / 7 (14.3%)	4	50 / 313 (16.0%)	66
Suspected Event (Not Validated)[7]	25 / 306 (8.2%)	28	2 / 7 (28.6%)	3	27 / 313 (8.6%)	31
Probable Event[8]	2 / 306 (<1.0%)	2	1 / 7 (14.3%)	1	3 / 313 (1.0%)	3

Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.
1: Participants who took 2 doses of vaccine.
2: A subject may have more than one event, so an event row count can be larger than the row participant count and the sum of event rows can be more than the N in the header.
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Table 15.3.2.1.7

BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of Pfizer COVID-19 Vaccine by Dose Status

Primary Analysis Safety Population

	2 Doses[1] (N=2201)		1 Dose Only (N=310)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Brain Or Spinal Cord Inflammation (e.g., Meningitis, Encephalitis, Guillain-Barre Syndrome)[10]	0	0	0	0	0	0
Event Confirmation In Progress[5]	0	0	0	0	0	0
Suspected Event (Unknown)[6]	0	0	0	0	0	0
Suspected Event (Not Validated)[7]	0	0	0	0	0	0
Probable Event[8]	0	0	0	0	0	0

Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.
1: Participants who took 2 doses of vaccine.
2: A subject may have more than one event, so an event row count can be larger than the row participant count and the sum of event rows can be more than the N in the header.
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Table 15.3.2.1.7

BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of Pfizer COVID-19 Vaccine by Dose Status

Primary Analysis Safety Population

	2 Doses[1] (N=2201)		1 Dose Only (N=310)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Severe Allergic Reaction (Anaphylaxis)[10]	6 / 2201 (<1.0%)	7	0	0	6 / 2511 (<1.0%)	7
Event Confirmation In Progress[5]	1 / 6 (16.7%)	1	0	0	1 / 6 (16.7%)	1
Suspected Event (Unknown)[6]	4 / 6 (66.7%)	5	0	0	4 / 6 (66.7%)	5
Suspected Event (Not Validated)[7]	1 / 6 (16.7%)	1	0	0	1 / 6 (16.7%)	1
Probable Event[8]	0	0	0	0	0	0

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1: Participants who took 2 doses of vaccine.
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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of Pfizer COVID-19 Vaccine by Dose Status

Primary Analysis Safety Population

	2 Doses[1] (N=2201)		1 Dose Only (N=310)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Non-Severe Allergic Reaction[10]	15 / 2201 (<1.0%)	17	0	0	15 / 2511 (<1.0%)	17
Event Confirmation In Progress[5]	1 / 15 (6.7%)	2	0	0	1 / 15 (6.7%)	2
Suspected Event (Unknown)[6]	11 / 15 (73.3%)	12	0	0	11 / 15 (73.3%)	12
Suspected Event (Not Validated)[7]	3 / 15 (20.0%)	3	0	0	3 / 15 (20.0%)	3
Probable Event[8]	0	0	0	0	0	0

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Table 15.3.2.1.7

BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of Pfizer COVID-19 Vaccine by Dose Status

Primary Analysis Safety Population

	2 Doses[1] (N=2201)		1 Dose Only (N=310)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Heart Inflammation (e.g., Myocarditis, Pericarditis)[10]	1 / 2201 (<1.0%)	1	0	0	1 / 2511 (<1.0%)	1
Event Confirmation In Progress[5]	0	0	0	0	0	0
Suspected Event (Unknown)[6]	1 / 1 (100%)	1	0	0	1 / 1 (100%)	1
Suspected Event (Not Validated)[7]	0	0	0	0	0	0
Probable Event[8]	0	0	0	0	0	0

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Table 15.3.2.1.7

BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of Pfizer COVID-19 Vaccine by Dose Status

Primary Analysis Safety Population

	2 Doses[1] (N=2201)		1 Dose Only (N=310)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Blood Clot Inside A Vein In The Body (Thromboembolism)[10]	0	0	0	0	0	0
Event Confirmation In Progress[5]	0	0	0	0	0	0
Suspected Event (Unknown)[6]	0	0	0	0	0	0
Suspected Event (Not Validated)[7]	0	0	0	0	0	0
Probable Event[8]	0	0	0	0	0	0

Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.
1: Participants who took 2 doses of vaccine.
2: A subject may have more than one event, so an event row count can be larger than the row participant count and the sum of event rows can be more than the N in the header.
3: Excluding any events with hospitalization date or seeking medical date prior to vaccine date; if a participant reported an event on both hospitalization and unplanned medical care form on the same date, the event will be counted only once as a Hospitalization.
4: Verily eCRF reported adverse events of special interest collapsing on hospitalization date from the unplanned hospitalization forms. If more than one event was collected for the same hospitalization, all events will have the same confirmation status on CEA spreadsheet.
5: Adverse events of special interest in Verily eCRF, but no linkage in the CEA spreadsheet yet.
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10: Adverse events of special interest collected from both unplanned hospitalization form and unplanned medical care form. If the event was reported on both form at the same date, the event will be counted only once in the table.

Table 15.3.2.1.7

BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of Pfizer COVID-19 Vaccine by Dose Status

Primary Analysis Safety Population

	2 Doses[1] (N=2201)		1 Dose Only (N=310)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Blood Vessel Inflammation (e.g., Kawasaki Disease, Vasculitides)[10]	2 / 2201 (<1.0%)	2	0	0	2 / 2511 (<1.0%)	2
Event Confirmation In Progress[5]	0	0	0	0	0	0
Suspected Event (Unknown)[6]	1 / 2 (50.0%)	1	0	0	1 / 2 (50.0%)	1
Suspected Event (Not Validated)[7]	1 / 2 (50.0%)	1	0	0	1 / 2 (50.0%)	1
Probable Event[8]	0	0	0	0	0	0

Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.
1: Participants who took 2 doses of vaccine.
2: A subject may have more than one event, so an event row count can be larger than the row participant count and the sum of event rows can be more than the N in the header.
3: Excluding any events with hospitalization date or seeking medical date prior to vaccine date; if a participant reported an event on both hospitalization and unplanned medical care form on the same date, the event will be counted only once as a Hospitalization.
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Table 15.3.2.1.7

BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of Pfizer COVID-19 Vaccine by Dose Status

Primary Analysis Safety Population

	2 Doses[1] (N=2201)		1 Dose Only (N=310)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Abnormal Blood Clotting (e.g., Disseminated Intravascular Coagulation, Thrombocytopenia)[10]	1 / 2201 (<1.0%)	1	0	0	1 / 2511 (<1.0%)	1
Event Confirmation In Progress[5]	0	0	0	0	0	0
Suspected Event (Unknown)[6]	0	0	0	0	0	0
Suspected Event (Not Validated)[7]	0	0	0	0	0	0
Probable Event[8]	1 / 1 (100%)	1	0	0	1 / 1 (100%)	1

Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.
1: Participants who took 2 doses of vaccine.
2: A subject may have more than one event, so an event row count can be larger than the row participant count and the sum of event rows can be more than the N in the header.
3: Excluding any events with hospitalization date or seeking medical date prior to vaccine date; if a participant reported an event on both hospitalization and unplanned medical care form on the same date, the event will be counted only once as a Hospitalization.
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Table 15.3.2.1.7
BNT162b2 Protocol C4591008
Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of Pfizer COVID-19 Vaccine by Dose Status
Primary Analysis Safety Population

	2 Doses[1] (N=2201)		1 Dose Only (N=310)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Bleeding Disorder (Hemorrhagic Disease)[10]	0	0	0	0	0	0
Event Confirmation In Progress[5]	0	0	0	0	0	0
Suspected Event (Unknown)[6]	0	0	0	0	0	0
Suspected Event (Not Validated)[7]	0	0	0	0	0	0
Probable Event[8]	0	0	0	0	0	0

Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.
1: Participants who took 2 doses of vaccine.
2: A subject may have more than one event, so an event row count can be larger than the row participant count and the sum of event rows can be more than the N in the header.
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Table 15.3.2.1.7
BNT162b2 Protocol C4591008
Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of Pfizer COVID-19 Vaccine by Dose Status
Primary Analysis Safety Population

	2 Doses[1] (N=2201)		1 Dose Only (N=310)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Heart Attack (Myocardial Infarction)[10]	0	0	0	0	0	0
Event Confirmation In Progress[5]	0	0	0	0	0	0
Suspected Event (Unknown)[6]	0	0	0	0	0	0
Suspected Event (Not Validated)[7]	0	0	0	0	0	0
Probable Event[8]	0	0	0	0	0	0

Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.
1: Participants who took 2 doses of vaccine.
2: A subject may have more than one event, so an event row count can be larger than the row participant count and the sum of event rows can be more than the N in the header.
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Table 15.3.2.1.7
BNT162b2 Protocol C4591008
Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of Pfizer COVID-19 Vaccine by Dose Status
Primary Analysis Safety Population

	2 Doses[1] (N=2201)		1 Dose Only (N=310)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Heart Failure/Cardiogenic Shock[10]	0	0	0	0	0	0
Event Confirmation In Progress[5]	0	0	0	0	0	0
Suspected Event (Unknown)[6]	0	0	0	0	0	0
Suspected Event (Not Validated)[7]	0	0	0	0	0	0
Probable Event[8]	0	0	0	0	0	0

Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.
1: Participants who took 2 doses of vaccine.
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Table 15.3.2.1.7
BNT162b2 Protocol C4591008
Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of Pfizer COVID-19 Vaccine by Dose Status
Primary Analysis Safety Population

	2 Doses[1] (N=2201)		1 Dose Only (N=310)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Stress Cardiomyopathy[10]	0	0	0	0	0	0
Event Confirmation In Progress[5]	0	0	0	0	0	0
Suspected Event (Unknown)[6]	0	0	0	0	0	0
Suspected Event (Not Validated)[7]	0	0	0	0	0	0
Probable Event[8]	0	0	0	0	0	0

Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.
1: Participants who took 2 doses of vaccine.
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BNT162b2 Protocol C4591008
Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of Pfizer COVID-19 Vaccine by Dose Status
Primary Analysis Safety Population

	2 Doses[1] (N=2201)		1 Dose Only (N=310)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Coronary Artery Disease[10]	0	0	0	0	0	0
Event Confirmation In Progress[5]	0	0	0	0	0	0
Suspected Event (Unknown)[6]	0	0	0	0	0	0
Suspected Event (Not Validated)[7]	0	0	0	0	0	0
Probable Event[8]	0	0	0	0	0	0

Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.
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Table 15.3.2.1.7

BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of Pfizer COVID-19 Vaccine by Dose Status

Primary Analysis Safety Population

	2 Doses[1] (N=2201)		1 Dose Only (N=310)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Abnormal Heart Rhythm (Arrhythmia)[10]	0	0	0	0	0	0
Event Confirmation In Progress[5]	0	0	0	0	0	0
Suspected Event (Unknown)[6]	0	0	0	0	0	0
Suspected Event (Not Validated)[7]	0	0	0	0	0	0
Probable Event[8]	0	0	0	0	0	0

Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.
1: Participants who took 2 doses of vaccine.
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Table 15.3.2.1.7

BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of Pfizer COVID-19 Vaccine by Dose Status

Primary Analysis Safety Population

	2 Doses[1] (N=2201)		1 Dose Only (N=310)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Stroke Or Possible Stroke[10]	1 / 2201 (<1.0%)	1	0	0	1 / 2511 (<1.0%)	1
Event Confirmation In Progress[5]	1 / 1 (100%)	1	0	0	1 / 1 (100%)	1
Suspected Event (Unknown)[6]	0	0	0	0	0	0
Suspected Event (Not Validated)[7]	0	0	0	0	0	0
Probable Event[8]	0	0	0	0	0	0

Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.
1: Participants who took 2 doses of vaccine.
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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of Pfizer COVID-19 Vaccine by Dose Status

Primary Analysis Safety Population

	2 Doses[1] (N=2201)		1 Dose Only (N=310)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Blockage Of Blood Flow To Limbs (e.g., Limb Ischemia, Peripheral Artery Disease)[10]	0	0	0	0	0	0
Event Confirmation In Progress[5]	0	0	0	0	0	0
Suspected Event (Unknown)[6]	0	0	0	0	0	0
Suspected Event (Not Validated)[7]	0	0	0	0	0	0
Probable Event[8]	0	0	0	0	0	0

Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.
1: Participants who took 2 doses of vaccine.
2: A subject may have more than one event, so an event row count can be larger than the row participant count and the sum of event rows can be more than the N in the header.
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Table 15.3.2.1.7

BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of Pfizer COVID-19 Vaccine by Dose Status

Primary Analysis Safety Population

	2 Doses[1] (N=2201)		1 Dose Only (N=310)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Acute Kidney Injury[10]	0	0	0	0	0	0
Event Confirmation In Progress[5]	0	0	0	0	0	0
Suspected Event (Unknown)[6]	0	0	0	0	0	0
Suspected Event (Not Validated)[7]	0	0	0	0	0	0
Probable Event[8]	0	0	0	0	0	0

Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.
1: Participants who took 2 doses of vaccine.
2: A subject may have more than one event, so an event row count can be larger than the row participant count and the sum of event rows can be more than the N in the header.
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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of Pfizer COVID-19 Vaccine by Dose Status

Primary Analysis Safety Population

	2 Doses[1] (N=2201)		1 Dose Only (N=310)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Liver Injury[10]	0	0	0	0	0	0
Event Confirmation In Progress[5]	0	0	0	0	0	0
Suspected Event (Unknown)[6]	0	0	0	0	0	0
Suspected Event (Not Validated)[7]	0	0	0	0	0	0
Probable Event[8]	0	0	0	0	0	0

Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.
1: Participants who took 2 doses of vaccine.
2: A subject may have more than one event, so an event row count can be larger than the row participant count and the sum of event rows can be more than the N in the header.
3: Excluding any events with hospitalization date or seeking medical date prior to vaccine date; if a participant reported an event on both hospitalization and unplanned medical care form on the same date, the event will be counted only once as a Hospitalization.
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10: Adverse events of special interest collected from both unplanned hospitalization form and unplanned medical care form. If the event was reported on both form at the same date, the event will be counted only once in the table.

BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of Pfizer COVID-19 Vaccine by Dose Status

Primary Analysis Safety Population

	2 Doses[1] (N=2201)		1 Dose Only (N=310)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Skin Immune Reaction (e.g., Chillblain-Like Lesions, Erythema Multiforme)[10]	0	0	0	0	0	0
Event Confirmation In Progress[5]	0	0	0	0	0	0
Suspected Event (Unknown)[6]	0	0	0	0	0	0
Suspected Event (Not Validated)[7]	0	0	0	0	0	0
Probable Event[8]	0	0	0	0	0	0

Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.
1: Participants who took 2 doses of vaccine.
2: A subject may have more than one event, so an event row count can be larger than the row participant count and the sum of event rows can be more than the N in the header.
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Table 15.3.2.1.7
BNT162b2 Protocol C4591008
Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of Pfizer COVID-19 Vaccine by Dose Status
Primary Analysis Safety Population

	2 Doses[1] (N=2201)		1 Dose Only (N=310)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Multisystem Inflammation[10]	2 / 2201 (<1.0%)	2	0	0	2 / 2511 (<1.0%)	2
Event Confirmation In Progress[5]	0	0	0	0	0	0
Suspected Event (Unknown)[6]	0	0	0	0	0	0
Suspected Event (Not Validated)[7]	2 / 2 (100%)	2	0	0	2 / 2 (100%)	2
Probable Event[8]	0	0	0	0	0	0

Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.
1: Participants who took 2 doses of vaccine.
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Table 15.3.2.1.7
BNT162b2 Protocol C4591008
Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of Pfizer COVID-19 Vaccine by Dose Status
Primary Analysis Safety Population

	2 Doses[1] (N=2201)		1 Dose Only (N=310)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Fibromyalgia[10]	2 / 2201 (<1.0%)	2	0	0	2 / 2511 (<1.0%)	2
Event Confirmation In Progress[5]	1 / 2 (50.0%)	1	0	0	1 / 2 (50.0%)	1
Suspected Event (Unknown)[6]	1 / 2 (50.0%)	1	0	0	1 / 2 (50.0%)	1
Suspected Event (Not Validated)[7]	0	0	0	0	0	0
Probable Event[8]	0	0	0	0	0	0

Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.
1: Participants who took 2 doses of vaccine.
2: A subject may have more than one event, so an event row count can be larger than the row participant count and the sum of event rows can be more than the N in the header.
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Table 15.3.2.1.7

BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of Pfizer COVID-19 Vaccine by Dose Status

Primary Analysis Safety Population

	2 Doses[1] (N=2201)		1 Dose Only (N=310)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Nerve Inflammation Or Autoimmune Disease (e.g., Multiple Sclerosis, Rheumatoid Arthritis)[10]	8 / 2201 (<1.0%)	9	1 / 310 (<1.0%)	2	9 / 2511 (<1.0%)	11
Event Confirmation In Progress[5]	2 / 8 (25.0%)	2	0	0	2 / 9 (22.2%)	2
Suspected Event (Unknown)[6]	3 / 8 (37.5%)	3	1 / 1 (100%)	2	4 / 9 (44.4%)	5
Suspected Event (Not Validated)[7]	3 / 8 (37.5%)	4	0	0	3 / 9 (33.3%)	4
Probable Event[8]	0	0	0	0	0	0

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Table 15.3.2.1.7

BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of Pfizer COVID-19 Vaccine by Dose Status

Primary Analysis Safety Population

	2 Doses[1] (N=2201)		1 Dose Only (N=310)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Autoimmune Thyroiditis[10]	3 / 2201 (<1.0%)	3	0	0	3 / 2511 (<1.0%)	3
Event Confirmation In Progress[5]	1 / 3 (33.3%)	1	0	0	1 / 3 (33.3%)	1
Suspected Event (Unknown)[6]	2 / 3 (66.7%)	2	0	0	2 / 3 (66.7%)	2
Suspected Event (Not Validated)[7]	0	0	0	0	0	0
Probable Event[8]	0	0	0	0	0	0

Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.
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Table 15.3.2.1.7
BNT162b2 Protocol C4591008
Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of Pfizer COVID-19 Vaccine by Dose Status
Primary Analysis Safety Population

	2 Doses[1] (N=2201)		1 Dose Only (N=310)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
COVID-19 Infection[10]	13 / 2201 (<1.0%)	17	2 / 310 (<1.0%)	3	15 / 2511 (<1.0%)	20
Event Confirmation In Progress[5]	3 / 13 (23.1%)	4	0	0	3 / 15 (20.0%)	4
Suspected Event (Unknown)[6]	5 / 13 (38.5%)	8	1 / 2 (50.0%)	2	6 / 15 (40.0%)	10
Suspected Event (Not Validated)[7]	4 / 13 (30.8%)	4	1 / 2 (50.0%)	1	5 / 15 (33.3%)	5
Probable Event[8]	1 / 13 (7.7%)	1	0	0	1 / 15 (6.7%)	1

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PFIZER CONFIDENTIAL SDTM Creation: 11MAY2021:07:31:19 Data Cutoff: 29APR2021 Source Data: ADSL, ADEVENT
Generated from /dcri/ct/hero_together/tables/t_event_doses.sas on 24MAY2021 12:44

BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of Pfizer COVID-19 Vaccine by Dose Status

Primary Analysis Safety Population

	2 Doses[1] (N=2201)		1 Dose Only (N=310)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Generalized Convulsions/Seizures[10]	0	0	1 / 310 (<1.0%)	1	1 / 2511 (<1.0%)	1
Event Confirmation In Progress[5]	0	0	0	0	0	0
Suspected Event (Unknown)[6]	0	0	0	0	0	0
Suspected Event (Not Validated)[7]	0	0	1 / 1 (100%)	1	1 / 1 (100%)	1
Probable Event[8]	0	0	0	0	0	0

Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.
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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of Pfizer COVID-19 Vaccine by Dose Status

Primary Analysis Safety Population

	2 Doses[1] (N=2201)		1 Dose Only (N=310)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Bell's Palsy[10]	0	0	0	0	0	0
Event Confirmation In Progress[5]	0	0	0	0	0	0
Suspected Event (Unknown)[6]	0	0	0	0	0	0
Suspected Event (Not Validated)[7]	0	0	0	0	0	0
Probable Event[8]	0	0	0	0	0	0

Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.
1: Participants who took 2 doses of vaccine.
2: A subject may have more than one event, so an event row count can be larger than the row participant count and the sum of event rows can be more than the N in the header.
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Table 15.3.2.1.7

BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of Pfizer COVID-19 Vaccine by Dose Status

Primary Analysis Safety Population

	2 Doses[1] (N=2201)		1 Dose Only (N=310)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Narcolepsy Or Cataplexy[10]	0	0	0	0	0	0
Event Confirmation In Progress[5]	0	0	0	0	0	0
Suspected Event (Unknown)[6]	0	0	0	0	0	0
Suspected Event (Not Validated)[7]	0	0	0	0	0	0
Probable Event[8]	0	0	0	0	0	0

Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.
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Table 15.3.2.1.7

BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of Pfizer COVID-19 Vaccine by Dose Status

Primary Analysis Safety Population

	2 Doses[1] (N=2201)		1 Dose Only (N=310)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Joint Stiffness Or Pain (e.g., Arthralgia, Arthritis)[10]	31 / 2201 (1.4%)	40	1 / 310 (<1.0%)	3	32 / 2511 (1.3%)	43
Event Confirmation In Progress[5]	3 / 31 (9.7%)	6	0	1	3 / 32 (9.4%)	7
Suspected Event (Unknown)[6]	20 / 31 (64.5%)	25	0	0	20 / 32 (62.5%)	25
Suspected Event (Not Validated)[7]	8 / 31 (25.8%)	9	0	1	8 / 32 (25.0%)	10
Probable Event[8]	0	0	1 / 1 (100%)	1	1 / 32 (3.1%)	1

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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of Pfizer COVID-19 Vaccine by Dose Status

Primary Analysis Safety Population

	2 Doses[1] (N=2201)		1 Dose Only (N=310)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Pregnancy-Related Issue[10]	18 / 2201 (<1.0%)	23	1 / 310 (<1.0%)	1	19 / 2511 (<1.0%)	24
Event Confirmation In Progress[5]	7 / 18 (38.9%)	9	1 / 1 (100%)	1	8 / 19 (42.1%)	10
Suspected Event (Unknown)[6]	5 / 18 (27.8%)	7	0	0	5 / 19 (26.3%)	7
Suspected Event (Not Validated)[7]	6 / 18 (33.3%)	7	0	0	6 / 19 (31.6%)	7
Probable Event[8]	0	0	0	0	0	0

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6: Adverse events of special interest with a link from the Verily eCRF to CEA spreadsheet with confirmation status as "Suspected Event (Unknown)".
7: Adverse events of special interest with a link from the Verily eCRF to CEA spreadsheet with confirmation status as "Suspected Event (Not Validated)".
8: Adverse events of special interest with a link from the Verily eCRF to CEA spreadsheet with confirmation status as "Probable Event".
9: Verily eCRF reported adverse events of special interest collapsing on seeking medical date for the same event from the other unplanned medical care forms
10: Adverse events of special interest collected from both unplanned hospitalization form and unplanned medical care form. If the event was reported on both form at the same date, the event will be counted only once in the table.

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Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of Pfizer COVID-19 Vaccine by Dose Status

Primary Analysis Safety Population

	2 Doses[1] (N=2201)		1 Dose Only (N=310)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Microangiopathy[10]	0	0	0	0	0	0
Event Confirmation In Progress[5]	0	0	0	0	0	0
Suspected Event (Unknown)[6]	0	0	0	0	0	0
Suspected Event (Not Validated)[7]	0	0	0	0	0	0
Probable Event[8]	0	0	0	0	0	0

Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.
1: Participants who took 2 doses of vaccine.
2: A subject may have more than one event, so an event row count can be larger than the row participant count and the sum of event rows can be more than the N in the header.
3: Excluding any events with hospitalization date or seeking medical date prior to vaccine date; if a participant reported an event on both hospitalization and unplanned medical care form on the same date, the event will be counted only once as a Hospitalization.
4: Verily eCRF reported adverse events of special interest collapsing on hospitalization date from the unplanned hospitalization forms. If more than one event was collected for the same hospitalization, all events will have the same confirmation status on CEA spreadsheet.
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8: Adverse events of special interest with a link from the Verily eCRF to CEA spreadsheet with confirmation status as "Probable Event".
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Table 15.3.2.1.7
BNT162b2 Protocol C4591008
Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of Pfizer COVID-19 Vaccine by Dose Status
Primary Analysis Safety Population

	2 Doses[1] (N=2201)		1 Dose Only (N=310)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Death[10]	0	0	1 / 310 (<1.0%)	1	1 / 2511 (<1.0%)	1
Event Confirmation In Progress[5]	0	0	1 / 1 (100%)	1	1 / 1 (100%)	1
Suspected Event (Unknown)[6]	0	0	0	0	0	0
Suspected Event (Not Validated)[7]	0	0	0	0	0	0
Probable Event[8]	0	0	0	0	0	0

Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.
1: Participants who took 2 doses of vaccine.
2: A subject may have more than one event, so an event row count can be larger than the row participant count and the sum of event rows can be more than the N in the header.
3: Excluding any events with hospitalization date or seeking medical date prior to vaccine date; if a participant reported an event on both hospitalization and unplanned medical care form on the same date, the event will be counted only once as a Hospitalization.
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BNT162b2 Protocol C4591008

Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of Pfizer COVID-19 Vaccine by Dose Status

Primary Analysis Safety Population

	2 Doses[1] (N=2201)		1 Dose Only (N=310)		Primary Analysis Safety Population (N=2511)	
	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N	Participants n/N (%)	Events[2] N
Other[10]	233 / 2201 (10.6%)	239	3 / 310 (1.0%)	3	236 / 2511 (9.4%)	242
Event Confirmation In Progress[5]	225 / 233 (96.6%)	230	3 / 3 (100%)	3	228 / 236 (96.6%)	233
Suspected Event (Unknown)[6]	3 / 233 (1.3%)	4	0	0	3 / 236 (1.3%)	4
Suspected Event (Not Validated)[7]	5 / 233 (2.1%)	5	0	0	5 / 236 (2.1%)	5
Probable Event[8]	0	0	0	0	0	0

Primary Analysis Safety Population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.
1: Participants who took 2 doses of vaccine.
2: A subject may have more than one event, so an event row count can be larger than the row participant count and the sum of event rows can be more than the N in the header.
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