VERSION HISTORY

Version	***Effective Date***	***Change Type*** *(New, Revise, Admin)*	***Summary of Revisions***
1.0	*5-4-2021*	*New*	*New statistical analysis plan drafted*

Non-Interventional Study Protocol
C4591008

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

Interim Reporting Statistical Analysis Plan
(SAP)

Version: 1.0

Author: Merrill, Peter; Shostak, Jack; Wen, Jun; (b) (6)
Duke Clinical Research Institute

Date: 4 May 2021

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

1. AMENDMENTS FROM PREVIOUS VERSION(S)

Not Applicable.

2. INTRODUCTION

Note: in this document, any text taken directly from the non-interventional (NI) study protocol is ***italicised***.

In December 2019, a viral pneumonia outbreak of unknown origin was identified in Wuhan, China.[1] By January 2020, the outbreak was confirmed to be caused by a novel coronavirus named severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).[2] The outbreak quickly reached pandemic levels, spreading to 213 countries and territories worldwide. In February 2020, the World Health Organization formally named the disease caused by SARS-CoV-2 the coronavirus disease 2019 (COVID-19).[3] As of October 2, 2020, a total of 34.6 million confirmed cases and over 1 million deaths related to COVID-19 have been reported.[4] Healthcare workers have been disproportionately affected by the pandemic, with an infection risk 11 times that of the general population.[5] Due to this increased risk, the National Academies of Science, Engineering, and Medicine has prioritized healthcare workers for early receipt of vaccines to prevent SARS-CoV-2 infection.[6]

Given the public health emergency caused by the virus, Pfizer-BioNTech was granted authorization of emergency use of their COVID-19 vaccine by the Food and Drug Administration on 11 December 2020, prior to full approval of the biologic license application (BLA) for the prevention of Coronavirus Disease 2019 (COVID-19) for individuals 16 years of age and older. Detailed distribution plans for the COVID-19 vaccine within the US are 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 health workers, their families, and their communities for two years after vaccination.

This document will outline the statistical analysis plan for the interim reporting for the HERO-TOGETHER study. The interim analysis will be descriptive. The final analyses will include comparative analysis and will be described in detail in a separate Final Analysis SAP prior to conduct of analyses.

2.1. Study Design

HERO-TOGETHER is a prospective, observational cohort study of the incidence rates of adverse events of special interest (AESI) and other clinically significant events within a cohort of healthcare workers (HCWs), their families, and their communities who receive a coronavirus disease 2019 (COVID-19) vaccine in the United States. Enrolment began 17 December 2020. Approximately 20,000 vaccinated HCWs will be enrolled and followed for up to 24 months over a 30-month study period. From the time of the first dose of the vaccine, follow-up time points are at 1 week, 2 weeks, 4 weeks, 8 weeks, 12 weeks, and then at 6, 9, 12, 18, and 24 months. Participants will be followed from date of enrolment until the end of

the 24-month period following first vaccine dose (index date), end of the study period, death, loss-to-follow up, or discontinuation from study. Participants must enrol within 60 days of vaccination and inclusion into the Primary Analysis Safety population will be restricted to those that enrol within 10 days of first vaccine dose.

Study population

The study will enrol approximately self-selected, self-enrolled 20,000 US-based vaccinated healthcare workers, their families, and their communities. Receipt of a vaccine to prevent COVID-19 is required for inclusion in the study, but the decision to be vaccinated is made at the discretion of the recipient.
Study participants will be primarily recruited from three sources:

- An existing registry study, the Healthcare Worker Exposure Response and Outcomes (HERO) Registry Study, which was launched in April 2020 to characterize COVID-19 risk factors and outcomes among US healthcare workers by the Duke Clinical Research Institute (DCRI).
- The Project Baseline Community Study platform operated by Verily. This study was launched in April 2019 by Verily Life Sciences and provides an opportunity to acquire, organize, analyze, and activate phenotypic data for a group of participants over time.
- 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. Once receiving systems are identified, study navigators will be identified for vaccination sites within systems and activated to ensure broad geographic diversity in the study.

Inclusion and Exclusion 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

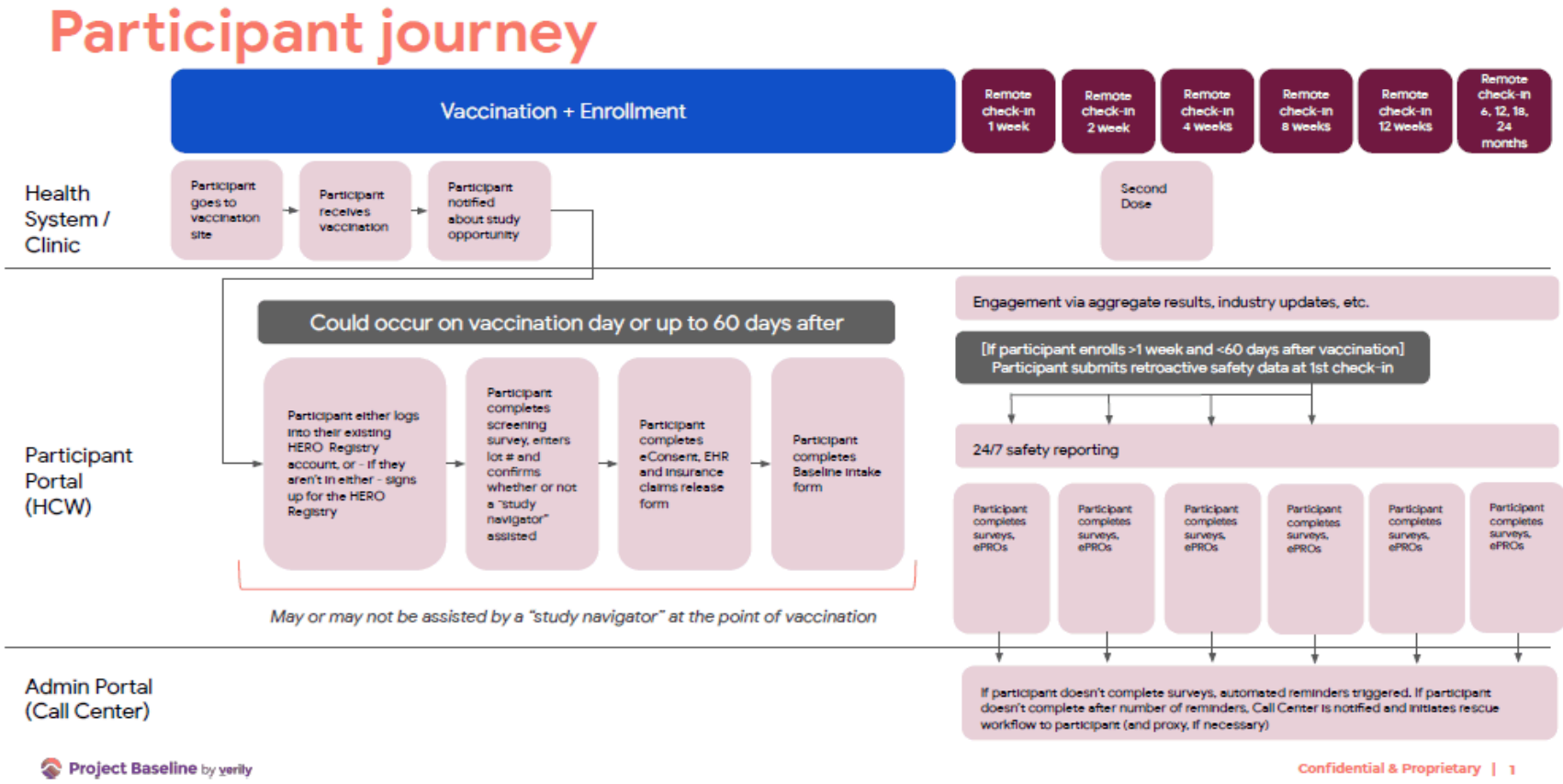
  3. Anyone in the surrounding community

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.*

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

Figure 1. Overall Study Design



Data sources

Data for the study will be collected from several different sources described below.

Participant self-report

Participants will use an online portal to report a variety of data. Data in the self-reporting forms contain information on demographic, medications, medical history, COVID-19 diagnosis, and follow-up visits. Participants will also report hospitalizations and AESIs that did not result in hospitalization for adjudication. Individuals with more than a 2-day interval between vaccination and enrolment will be administered a retrospective assessment to capture self-reported safety information occurring within this interval. Table 1 below presents the planned schedule of assessments.

DCRI Call Center

The DCRI Call Center will follow-up on non-responsive participants and request medical records for participants reporting hospitalization or diagnosis of an AESI according to a predetermined schedule outlined in the Call Center Project Management Plan.

Clinical Events Ascertainment (CEA)

When an AESI is reported, the CEA committee will use collected medical records to make a determination of whether the event occurred. The CEA will also provide an adjudicated event date. This process, the timelines and the AESI definitions will be documented in the CEA charter. When necessary, the CEA committee will also provide data regarding the status of patient reported events undergoing the adjudication process as well as the patient reported events that cannot be adjudicated.

HERO registry

All participants in HERO-TOGETHER are required to be enrolled in the parent HERO registry. Data from the HERO registry for participants in HERO-TOGETHER may be used to supplement the data collected by the study. Additionally, data about HCWs in the HERO registry that are not participating in the study may be used to provide context as a comparison group.

Table 1. HERO-Together Schedule of Assessments

	Enrolment 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						

Table 1. HERO-Together Schedule of Assessments

	Enrolment Data Collection	***Follow-up Data Collection***					
Vaccine Dose 1 information • Date • Lot number • Site	X						
Vaccine Dose 2 information • Date • Lot number • Site				X (and subsequent visits if second dose not reported as received)			
Medical release	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	X	X

Table 1. HERO-Together Schedule of Assessments

	Enrolment Data Collection	***Follow-up Data Collection***					
Health questionnaire • Potential safety events of interest or clinically significant events • Pregnancy status	X	X	X	X	X	X	X

2.2. Study Objectives

Primary Objective

- *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 EUA.* (For the first interim report, incidence proportion will be measured.)

Secondary Objectives

- *Evaluate whether vaccine recipients experience increased risk of safety events of interest and other clinically significant events post-vaccination.* (This objective is not explored in interim reporting)

- *Estimate the incidence rates of safety events of interest and other clinically significant events among subcohorts of interest such as pregnant women, immunocompromised people, and stratified by age.* (For the first interim report, incidence proportion will be measured.)

3. INTERIM ANALYSES

Interim reports are scheduled for distribution 30 June 2021, 31 December 2021, 30 June 2022, and 31 December 2022. The interim reports will include subject disposition and retention, vaccination information, demographic and baseline characteristics, vaccination second dose status. There are no plans for any formal stopping rules based on the results in interim reporting.

Vaccination, baseline characteristics and AESIs will be summarized using descriptive statistics, including measures of central tendency and dispersion (means, medians, standard deviations) for continuous variables. Categorical variables will be summarized by counts and percentages.

3.1. Disposition and retention

The count of subjects enrolled will be reported. Additional disposition reports will contain the count of subjects enrolled, count of subjects completing each followup timepoint, number who withdrew consent or discontinued from study early, number lost to follow-up, number of deaths, and number who have completed the study.

3.2. Demographic and baseline characteristics

Several demographic, medical history, and other baseline characteristics will be summarized for the All Consented (AC) and Primary Analysis Safety populations. These characteristics will include, but will not be limited to:

- Age in years
- Sex at birth
- Race
- Ethnicity
- Occupation/employment characteristics
- Medical and surgical history
- Select medications
- Pregnancy
- Influenza vaccination
- Timing from initial COVID-19 vaccination dose to enrolment
- COVID-19 vaccination second dose receipt and timing from initial dose
- COVID-19 history

3.3. Safety Evaluations

The AESIs that will be evaluated in this study are listed in Table 2. Details for each AESI will include reported hospitalizations,death, and confirmation/adjudication status. This may be refined as new information emerges. During follow-up time points, participants will provide information on hospitalizations and diagnoses of AESI.

The count and incidence for each AESI will be calculated overall, and within subgroups of interest. Data permitting, results may also be stratified by other baseline characteristics, such as work setting and geographic region data permitting.

Generally, reporting of adjudicated events will be targeted for these safety evaluations. However, in the first interim report, adjudication results will not be available. In these situations, participant reports of AESIs will be included in the interim reporting. Incidence rates will not be provided alongside participant-reported AESIs. Participant-reported AESIs and outcomes will be categorized based on the status of the reported event in the confirmation and adjudication processes.

4. HYPOTHESES AND DECISION RULES

Interim analyses are descriptive (see instructional test above for justification). No hypotheses will be evaluated.

5. ANALYSIS SETS/POPULATIONS

5.1. Full analysis set

The AC population is defined as all enrolled participants. The AC population will be used for secondary analyses and safety evaluations.

5.2. PRIMARY Analysis Safety set

The Primary Analysis Safety population is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine, as indicated on the baseline data collection form. Additionally, the Primary Analysis Safety population will only include participants who enrolled within 10 days of the first dose of the vaccination to mitigate the risk of selective enrolment and disproportionate representation of higher risk participants. The Primary Analysis Safety population will be employed to investigate the primary objective of the study.

5.3. Other analysis sets

The following subsets of the AC population will also be considered in certain reports

- Consented but not in Primary Analysis Safety Population: Participants that are members of the AC population, but are not members of the Primary Analysis Safety population, and the following subsets:
    - Participants that have received the Pfizer-BioNTech COVID-19 vaccine who enrolled after 10 days of the first dose of the vaccination.
    - Participants that received a non-Pfizer vaccine and enrolled within 10 days of the first or only dose of the vaccination.
    - Participants that received a non-Pfizer vaccine and enrolled after 10 days of the first or only dose of the vaccination.

5.4. Subgroups

Tables will be presented overall and in the following subgroups: Pregnant women (participant reported at enrolment)

- Immunocompromised participants, defined as a participant who self reports at least one of the following:
    - Medical history of organ transplant
    - Medical history of HIV/AIDS
    - Use of inhaled or systemic corticosteroids
    - Use of immunosuppressant medications
- Categorical age groups (at time of first vaccination)
    - 18-29 years old
    - 30-39 years old

  - 40-49 years old
  - 50-59 years old
  - 60-69 years old
  - 70 or more years old
- Vaccine dosage groups
  - 1 dose group: participants who have received only one dose of a COVID-19 vaccine.
  - 2 dose group: participants who have received a planned second dose of a COVID-19 vaccine. This will be stratified by time frame between doses.
    - Note that it will be possible for participants initially in the 1 dose group to enter into the 2 dose group if they receive their second dose during the follow-up period.

6. ENDPOINTS AND COVARIATES

6.1. Efficacy/Effectiveness Endpoint(s)

Since the objectives of this study are centered on safety, there are no planned efficacy endpoints.

6.2. Safety Endpoints

Table 2 below contains a listing of the AESIs that serve as the endpoints of the study to investigate safety of the vaccine. AESIs will be self-reported by study participants, and adjudicated by the CEA. The CEA charter contains the definitions for each AESI used to confirm and adjudicate the event. Hospitalization for an AESI will also serve as a safety endpoint.

6.3. Other Endpoints

There are no other planned endpoints for this study.

6.4. Covariates

The planned analyses for the interim reporting do not utilize any covariates.

Table 2. Safety Events of Interest

AESI
Neurologic: • Generalized convulsion/seizures • Guillain-Barre Syndrome • Aseptic meningitis

Table 2. Safety Events of Interest

• 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* • Arrythmia* • Deep vein thrombosis

Table 2. Safety Events of Interest

• Pulmonary embolus • Cerebrovascular stroke • Limb ischemia* • Hemorrhagic disease* • Acute kidney injury* • Liver injury • Chillblain-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

7. HANDLING OF MISSING VALUES

Missing data in interim reports will be noted for cleaning and improvements to data collection, but there are no plans for imputation of missing data.

8. STATISTICAL METHODOLOGY AND STATISTICAL ANALYSES

8.1. Statistical methods

8.1.1 Estimation of Incidence Proportion and Rates

Incidence proportions for hospitalizations, AESIs, and confirmed AESIs will be calculated as the number of patient reported outcomes, and confirmed events divided by total population throughout the follow-up period. Incidence proportions will be reported in the first interim report. Incidence rates will be reported in future reports and will be described in a respectively amended SAP.

Incidence rates for hospitalizations and AESIs, and confirmed AESIs will be calculated as the number of patient reported outcomes, and confirmed events divided by the total follow-up time in the population. This basic formulation may be multiplied by a value as needed to improve reporting and interpretation of the rates (i.e. presenting rates per 100 person-years). Incidence rates will not be calculated in the first interim report, which will include only participant-reported outcomes.

Index date for a participant's follow-up time will be the date of the first dose of the vaccine. Further description of dose 2 IR estimation will be detailed in subsequent reports, but presented descriptively in the first interim reports. Follow-up will end on the earliest of the following dates: the date of the study 24 month follow-up, date of withdrawal from the study, date of loss to follow-up, date of death, or the date of the end of the study period.

8.2. Statistical Analyses

The planned analyses for the interim reporting are described in detail in Section 3 of this document. Analyses for the final report will be described in a separate Final Analysis SAP

8.2.1. Safety Analyses

Section 3.3 details the planned safety evaluations for the interim reporting. Analysis to address the specific study objectives at the end of the study will be described in a separate Final Analysis SAP.

9. LIST OF TABLES AND TABLE SHELLS

9.1. Section 1. Disposition and Retention

Table 15.5.1 Disposition and Retention

	All Consented Population[1] (N = xxx)	**Primary Analysis Safety Population[2] (N=xxx)**	**Consented but not in Primary Analysis Safety Population (N=xxx)**
Participants Enrolled	Xx	Xx	Xx
Participants Completed the Study	Xx/xx (xx.x%)	Xx/xx (xx.x%)	Xx/xx (xx.x%)
Participants Alive and Remaining in the Study	Xx/xx (xx.x%)	Xx/xx (xx.x%)	Xx/xx (xx.x%)
Days in the Study Since 1st Vaccine[3]			
N	xx	xx	xx
Median (Q1, Q3)	Xx (xx, xx)	Xx (xx, xx)	Xx (xx, xx)
Min, Max	Xx, xx	Xx, xx	Xx, xx
Days Between 1st Vaccine and Enrolment			
N	xx	xx	xx
Median (Q1, Q3)	Xx (xx, xx)	Xx (xx, xx)	Xx (xx, xx)
Min, Max	Xx, xx	Xx, xx	Xx, xx
Days Between 1st Vaccine and 2nd Vaccine[3]			
N	xx	xx	xx
Median (Q1, Q3)	Xx (xx, xx)	Xx (xx, xx)	Xx (xx, xx)
Min, Max	Xx, xx	Xx, xx	Xx, xx
Participants Who Did Not Complete the Study	Xx/xx (xx.x%)	Xx/xx (xx.x%)	Xx/xx (xx.x%)

	All Consented Population[1] (N = xxx)	Primary Analysis Safety Population[2] (N=xxx)	Consented but not in Primary Analysis Safety Population (N=xxx)
Death	Xx/xx (xx.x%)	Xx/xx (xx.x%)	Xx/xx (xx.x%)
Cause of Death related to COVID-19	Xx/xx (xx.x%)	Xx/xx (xx.x%)	Xx/xx (xx.x%)
Lost to Follow Up	Xx/xx (xx.x%)	Xx/xx (xx.x%)	Xx/xx (xx.x%)
Withdrawal by Subject	Xx/xx (xx.x%)	Xx/xx (xx.x%)	Xx/xx (xx.x%)
Study Terminated by Sponsor	Xx/xx (xx.x%)	Xx/xx (xx.x%)	Xx/xx (xx.x%)
Other	Xx/xx (xx.x%)	Xx/xx (xx.x%)	Xx/xx (xx.x%)
Reason for Withdrawal by Participants	Xx/xx (xx.x%)	Xx/xx (xx.x%)	Xx/xx (xx.x%)
Technical Problems	Xx/xx (xx.x%)	Xx/xx (xx.x%)	Xx/xx (xx.x%)
Too Time Intensive	Xx/xx (xx.x%)	Xx/xx (xx.x%)	Xx/xx (xx.x%)
Illness	Xx/xx (xx.x%)	Xx/xx (xx.x%)	Xx/xx (xx.x%)
Non-compliance	Xx/xx (xx.x%)	Xx/xx (xx.x%)	Xx/xx (xx.x%)
Safety	Xx/xx (xx.x%)	Xx/xx (xx.x%)	Xx/xx (xx.x%)
Behavioral	Xx/xx (xx.x%)	Xx/xx (xx.x%)	Xx/xx (xx.x%)
Administrative Reasons	Xx/xx (xx.x%)	Xx/xx (xx.x%)	Xx/xx (xx.x%)
Other	Xx/xx (xx.x%)	Xx/xx (xx.x%)	Xx/xx (xx.x%)

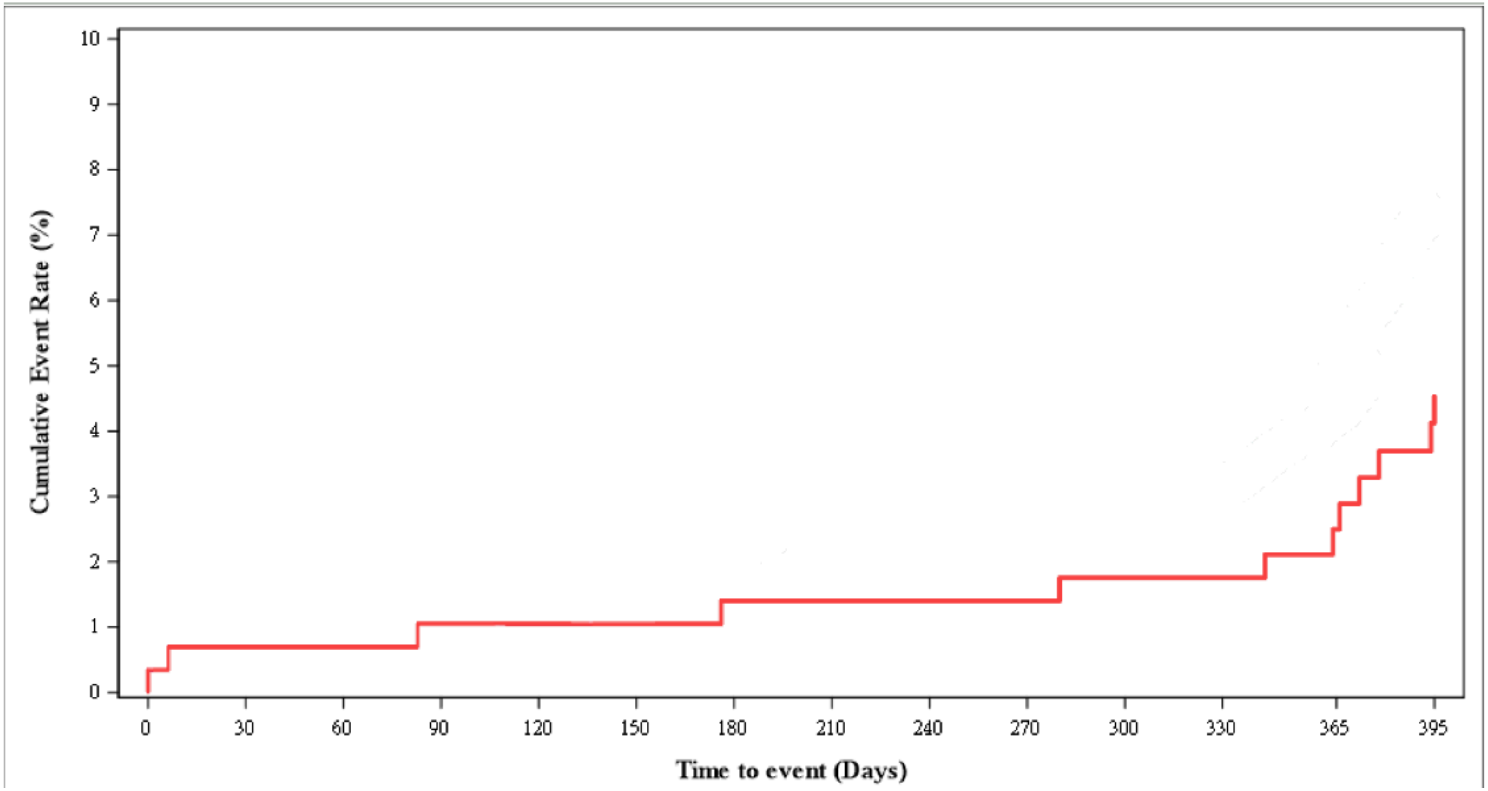
Note 1: All Consented population is defined as all enrolled participants.

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.

4: Data as of DDMMMYYYY and generated from /path/programname.sas on DDMMMYYYY HH:MM

Figure 15.5.1.1 Cumulative Rate of Study Discontinuation – All Consented Population[1]



Note 1: All Consented population is defined as all enrolled participants.
2: Data as of DDMMMYYYY and generated from /path/programname.sas on DDMMMYYYY HH:MM

Figure 15.5.1.2 Cumulative Rate of Study Discontinuation – Primary Analysis Safety Population[1]

Repeat Figure 15.5.1.1 for Primary Analysis Safety population.

Note 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.

2: Data as of DDMMMYYYY and generated from /path/programname.sas on DDMMMYYYY HH:MM

Table 15.5.2 Visit Completion

Participants Completed Survey at	All Consented Population[1] (N = xxx)		Primary Analysis Safety Population[2] (N=xxx)		Consented but not in Primary Analysis Safety Population (N=xxx)	
	Expected	Completed	Expected	Completed	Expected	Completed
Week 1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 2	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 4	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 8	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Week 12	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Month 6	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Month 9	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Month 12	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Month 18	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Month 24	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note 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: Data as of DDMMMYYYY and generated from /path/programname.sas on DDMMMYYYY HH:MM

4: As patients may enroll up to 60 days after vaccination, it is possible that not all patients may have been enrolled in week 1

9.2. Section 2. Demographic and Baseline Characteristics

Table 15.1.1 Baseline Demographics

Participant Characteristics	All Consented Population[1] (N = xxx)	Primary Analysis Safety Population[2] (N=xxx)	Consented but not in Primary Analysis Safety Population (N=xxx)
Age at First Dose in Years			
N	xx	xx	xx
Mean (SD)	xx.x(xx.xx)	xx.x(xx.xx)	xx.x(xx.xx)
Median (Q1, Q3)	xx(xx, xx)	xx(xx, xx)	xx(xx, xx)
Min, Max	Xx,xx	Xx,xx	Xx,xx
Age at First Dose in Years			
18-29	Xx/xx (xx.x%)	Xx/xx (xx.x%)	Xx/xx (xx.x%)
30-39	Xx/xx (xx.x%)	Xx/xx (xx.x%)	Xx/xx (xx.x%)
40-49	Xx/xx (xx.x%)	Xx/xx (xx.x%)	Xx/xx (xx.x%)
50-59	Xx/xx (xx.x%)	Xx/xx (xx.x%)	Xx/xx (xx.x%)
60-69	Xx/xx (xx.x%)	Xx/xx (xx.x%)	Xx/xx (xx.x%)
70 and above	Xx/xx (xx.x%)	Xx/xx (xx.x%)	Xx/xx (xx.x%)
Sex			
Female	Xx/xx (xx.x%)	Xx/xx (xx.x%)	Xx/xx (xx.x%)
Male	Xx/xx (xx.x%)	Xx/xx (xx.x%)	Xx/xx (xx.x%)
Undifferentiated	Xx/xx (xx.x%)	Xx/xx (xx.x%)	Xx/xx (xx.x%)
Race			
White	Xx/xx (xx.x%)	Xx/xx (xx.x%)	Xx/xx (xx.x%)
Black or African American	Xx/xx (xx.x%)	Xx/xx (xx.x%)	Xx/xx (xx.x%)
American Indian or Alaska Native	Xx/xx (xx.x%)	Xx/xx (xx.x%)	Xx/xx (xx.x%)
Asian	Xx/xx (xx.x%)	Xx/xx (xx.x%)	Xx/xx (xx.x%)

Participant Characteristics	All Consented Population[1] (N = xxx)	Primary Analysis Safety Population[2] (N=xxx)	Consented but not in Primary Analysis Safety Population (N=xxx)
Native Hawaiian or Other Pacific Islander	Xx/xx (xx.x%)	Xx/xx (xx.x%)	Xx/xx (xx.x%)
Multiple	Xx/xx (xx.x%)	Xx/xx (xx.x%)	Xx/xx (xx.x%)
Not Reported	Xx/xx (xx.x%)	Xx/xx (xx.x%)	Xx/xx (xx.x%)
Unknown	Xx/xx (xx.x%)	Xx/xx (xx.x%)	Xx/xx (xx.x%)
Ethnicity			
Hispanic or Latino	Xx/xx (xx.x%)	Xx/xx (xx.x%)	Xx/xx (xx.x%)
Not Hispanic or Latino	Xx/xx (xx.x%)	Xx/xx (xx.x%)	Xx/xx (xx.x%)
Not Reported	Xx/xx (xx.x%)	Xx/xx (xx.x%)	Xx/xx (xx.x%)
Unknown	Xx/xx (xx.x%)	Xx/xx (xx.x%)	Xx/xx (xx.x%)

Note 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: Data as of DDMMMYYYY and generated from /path/programname.sas on DDMMMYYYY HH:MM

Table 15.1.2.1 Baseline Medical History (Participant Reported)

	All Consented Population[1] (N = xxx)	Primary Analysis Safety Population[2] (N=xxx)	Consented but not in Primary Analysis Safety Population (N=xxx)
Hypertension (high blood pressure)	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)
Diabetes mellitus	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)
Obesity/Overweight	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)
Prior heart attack	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)
Heart failure/cardiomyopathy	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)
Coronary artery disease	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)
Prior stroke or mini-stroke (TIA)	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)
Peripheral arterial or vascular disease	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)
Chronic obstructive pulmonary disease (COPD)	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)
Asthma	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)
Smoking	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)
Chronic kidney disease	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)
Cancer (localized)	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)
Cancer (metastatic)	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)
Lymphoma	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)
Leukemia	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)
Liver disease	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)
Peptic ulcer disease	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)
Connective tissue disease	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)
Autoimmune disease	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)
Organ transplant	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)
HIV/AIDS	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)
Previous COVID-19 diagnosis	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)

	All Consented Population[1] (N = xxx)	Primary Analysis Safety Population[2] (N=xxx)	Consented but not in Primary Analysis Safety Population (N=xxx)

Note 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: Data as of DDMMMYYYY and generated from /path/programname.sas on DDMMMYYYY HH:MM

Table 15.1.2.2 Baseline Medical History Stratified by Pfizer vs Non-Pfizer Vaccine (Participant Reported) and By Enrolment Within 10 Days

	Pfizer COVID 19 Vaccine (N=xxx)		Other COVID 19 Vaccine Manufacturer	
	Enrolled within 10 days after vaccine[1]	Enrolled more than 10 days after vaccine	Enrolled within 10 days after vaccine	Enrolled more than 10 days after vaccine
Hypertension (high blood pressure)	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)
Diabetes mellitus	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)
Obesity/Overweight	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)
Prior heart attack	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)
Heart failure/cardiomyopathy	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)
Coronary artery disease	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)
Prior stroke or mini-stroke (TIA)	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)
Peripheral arterial or vascular disease	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)
Chronic obstructive pulmonary disease (COPD)	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)
Asthma	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)
Smoking	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)
Chronic kidney disease	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)
Cancer (localized)	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)
Cancer (metastatic)	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)
Lymphoma	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)
Leukemia	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)
Liver disease	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)
Peptic ulcer disease	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)
Connective tissue disease	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)
Autoimmune disease	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)
Organ transplant	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)
HIV/AIDS	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)
Previous COVID-19 diagnosis	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)

	Pfizer COVID 19 Vaccine (N=xxx)		Other COVID 19 Vaccine Manufacturer	
	Enrolled within 10 days after vaccine[1]	**Enrolled more than 10 days after vaccine**	**Enrolled within 10 days after vaccine**	**Enrolled more than 10 days after vaccine**

Note 1 This is the Primary Analysis Safety population, which is defined as all enrolled participants who received the Pfizer-BioNTech COVID-19 vaccine and enrolled within 10 days of vaccination.

2: Data as of DDMMMYYYY and generated from /path/programname.sas on DDMMMYYYY HH:MM

Table 15.1.3 Baseline Medications

	All Consented Population[1] (N = xxx)	Primary Analysis Safety Population[2] (N=xxx)	Consented but not in Primary Analysis Safety Population (N=xxx)
Participants with Any Medications Below	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)
Inhaled corticosteroids	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)
Systemic corticosteroids	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)
Immunosuppressant medications	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)

Note 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: Data as of DDMMMYYYY and generated from /path/programname.sas on DDMMMYYYY HH:MM

Table 15.1.4 Baseline Pregnancy / Baseline Vaccine History

	All Consented Population[1] (N = xxx)	Primary Analysis Safety Population[2] (N=xxx)	Consented but not in Primary Analysis Safety Population (N=xxx)
Were you or your partner pregnant At the time of your firstst COVID-19 vaccine dose?			
Yes	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)
Yes, I was pregnant	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)
Yes, my partner was pregnant	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)
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	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)

Note 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: Data as of DDMMMYYYY and generated from /path/programname.sas on DDMMMYYYY HH:MM

9.3. Section 3. Safety Evaluations

Note: Tables using adjudicated events will be revised once the adjudicated data are available.

Table 15.3.1.1 Participant Reported Unplanned Hospitalization[1] Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine

	All Consented Population[2] (N = xxx)		Primary Analysis Safety Population[3] (N=xxx)		Consented but not in Primary Analysis Safety Population (N=xxx)	
	Participants N (%)	Hospitalizations[4] N	Participants N (%)	Hospitalizations N	Participants N (%)	Hospitalizations N
Participants Reported Unplanned Hospitalization[5]	x (x x%)	x	x (x x%)	x	x (x x%)	x
Event In Process[6]	x (x x%)	x	x (x x%)	x	x (x x%)	x
Suspected event[7]	x (x x%)	x	x (x x%)	x	x (x x%)	x
Probable event[8]	x (x x%)	x	x (x x%)	x	x (x x%)	x

Note 1: Hospitalization is any hospitalization at any time during the study and after vaccination

2: All Consented population is defined as all enrolled participants.

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.

4: 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.

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

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

7: Hospitalization with a link from the Verily eCRF to CEA spreadsheet with confirmation status as “No”.

8: Hospitalization with a link from the Verily eCRF to CEA spreadsheet with confirmation status as “Yes”.

9: Data as of DDMMMYYYY and generated from /path/programname.sas on DDMMMYYYY HH:MM

Table 15.3.1.2 Participant Reported Unplanned Hospitalization[1] Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Vaccine Type – Pfizer

All Consented Population[2]

	Enrolled within 10 days after vaccine (N=xxx)		Enrolled more than 10 days after vaccine (N=xxx)		Total (N=xxx)	
	Participants N (%)	Hospitalizations[3] N	Participants N (%)	Hospitalizations N	Participants N (%)	Hospitalizations N
Participants Reported Unplanned Hospitalization[4]	x (x x%)	x	x (x x%)	x	x (x x%)	x
Event In Process[5]	x (x x%)	x	x (x x%)	x	x (x x%)	x
Suspected event[6]	x (x x%)	x	x (x x%)	x	x (x x%)	x
Probable event[7]	x (x x%)	x	x (x x%)	x	x (x x%)	x

Note 1: Hospitalization is any hospitalization at any time during the study and after vaccination
2: All Consented population is defined as all enrolled participants.
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”.
8: Data as of DDMMMYYYY and generated from /path/programname.sas on DDMMMYYYY HH:MM

Table 15.3.1.3 Participant Reported Unplanned Hospitalization[1] Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Vaccine Type – Other Covid-19 Vaccine

All Consented Population[2]

	Enrolled within 10 days after vaccine (N=xxx)		Enrolled more than 10 days after vaccine (N=xxx)		Other Covid-19 Vaccine (N=xxx)	
	Participants N (%)	Hospitalizations[3] N	Participants N (%)	Hospitalizations N	Participants N (%)	Hospitalizations N
Participants Reported Unplanned Hospitalization[4]	x (x x%)	x	x (x x%)	x	x (x.x%)	x
Event In Process[5]	x (x x%)	x	x (x x%)	x	x (x.x%)	x
Suspected event (Unknown)[6]	x (x x%)	x	x (x x%)	x	x (x.x%)	x
Probable event[7]	x (x x%)	x	x (x x%)	x	x (x.x%)	x

Note 1: Hospitalization is any hospitalization at any time during the study and after vaccination

2: All Consented population is defined as all enrolled participants.

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”.

8: Data as of DDMMMYYYY and generated from /path/programname.sas on DDMMMYYYY HH:MM

Table 15.3.1.4 Participant Reported Unplanned Hospitalization[1] Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Pregnancy

Primary Analysis Safety Population[2]

	Pregnancy[3] (N = xxx)		Not Pregnancy (N = xxx)		Primary Analysis Safety Population[2] (N = xxx)	
	Participants N (%)	Hospitalizations[4] N	Participants N (%)	Hospitalizations N	Participants N (%)	Hospitalizations N
Participants Reported Unplanned Hospitalization[5]	x (x x%)	x	x (x x%)	x	x (x x%)	x
Event In Process[6]	x (x x%)	x	x (x x%)	x	x (x x%)	x
Suspected event (Unknown)[7]	x (x x%)	x	x (x x%)	x	x (x x%)	x
Probable event[8]	x (x x%)	x	x (x x%)	x	x (x x%)	x

Note 1: Hospitalization is any hospitalization at any time during the study and after vaccination

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: Pregnancy at time of enrolment includes both the participant and the partner pregnancy.

4: 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.

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

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

7: Hospitalization with a link from the Verily eCRF to CEA spreadsheet with confirmation status as “No”.

8: Hospitalization with a link from the Verily eCRF to CEA spreadsheet with confirmation status as “Yes”.

9: Data as of DDMMMYYYY and generated from /path/programname.sas on DDMMMYYYY HH:MM

Table 15.3.1.5 Participant Reported Unplanned Hospitalization[1] Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Age Group

Primary Analysis Safety Population[2]

	18-29 3 **(N = xxx)**		**30-39 (N = xxx)**		**40-49 (N = xxx)**		**50-59 (N = xxx)**		**60-69 (N = xxx)**		**70 and above (N = xxx)**		**Primary Analysis Population (Safe)**2 **(N = xxx)**	
	Participants N (%)	**Hospitalizations**4 **N**	**Participants N (%)**	**Hospitalizations N**	**Participants N (%)**	**Hospitalizations N**	**Participants N (%)**	**Hospitalizations N**	**Participants N (%)**	**Hospitalizations N**	**Participants N (%)**	**Hospitalizations N**	**Participants N (%)**	**Hospitalizations N**
Participants Reported Unplanned Hospitalization5	x (x x%)	X	x (x x%)	x	x (x x%)	x	x (x x%)	x	x (x x%)	x	x (x.x%)	x	x (x x%)	x
Event In Process6	x (x x%)	x	x (x x%)	x	x (x x%)	x	x (x x%)	x	x (x x%)	x	x (x.x%)	x	x (x x%)	x
Suspected event (Unknown) 7	x (x x%)	x	x (x x%)	x	x (x x%)	x	x (x x%)	x	x (x x%)	x	x (x.x%)	x	x (x x%)	x
Probable event8	x (x x%)	x	x (x x%)	x	x (x x%)	x	x (x x%)	x	x (x x%)	x	x (x.x%)	x	x (x x%)	x

	18-29 3 (N = xxx)		30-39 (N = xxx)		40-49 (N = xxx)		50-59 (N = xxx)		60-69 (N = xxx)		70 and above (N = xxx)		Primary Analysis Population (Safe)2 (N = xxx)	
	Participants N (%)	Hospitalizations4 N	Participants N (%)	Hospitalizations N	Participants N (%)	Hospitalizations N	Participants N (%)	Hospitalizations N	Participants N (%)	Hospitalizations N	Participants N (%)	Hospitalizations N	Participants N (%)	Hospitalizations N

Note 1: Hospitalization is any hospitalization at any time during the study and after vaccination

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

4: 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.

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

6: Self-reported Hospitalization in Verily eCRF, but no linkage in the CEA spreadsheet yet.

7: Hospitalization with a link from the Verily eCRF to CEA spreadsheet with confirmation status as “No”.

8: Hospitalization with a link from the Verily eCRF to CEA spreadsheet with confirmation status as “Yes”.

9: Data as of DDMMMYYYY and generated from /path/programname.sas on DDMMMYYYY HH:MM

Table 15.3.1.6 Participant Reported Unplanned Hospitalization[1] Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Immunocompromised status

Primary Analysis Safety Population[2]

	Yes[3] (N = xxx)		No (N = xxx)		Primary Analysis Safety Population[2] (N = xxx)	
	Participants N (%)	Hospitalizations[4] N	Participants N (%)	Hospitalizations N	Participants N (%)	Hospitalizations N
Participants Reported Unplanned Hospitalization[5]	x (x x%)	x	x (x.x%)	x	x (x x%)	x
Event In Process[6]	x (x x%)	x	x (x.x%)	x	x (x x%)	x
Suspected event (Unknown)[7]	x (x x%)	x	x (x.x%)	x	x (x x%)	x
Probable event[8]	x (x x%)	x	x (x.x%)	x	x (x x%)	x

Note 1: Hospitalization is any hospitalization at any time during the study and after vaccination

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: Immunocompromised status= Yes is defined based on 1) having Organ transplant or HIV/AIDS from baseline medical history and 2) taking any Inhaled corticosteroids, Systemic corticosteroids, or Immunosuppressant medications.

4: 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.

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

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

7: Hospitalization with a link from the Verily eCRF to CEA spreadsheet with confirmation status as “No”.

8: Hospitalization with a link from the Verily eCRF to CEA spreadsheet with confirmation status as “Yes”.

9: Data as of DDMMMYYYY and generated from /path/programname.sas on DDMMMYYYY HH:MM

Table 15.3.1.7 Participant Reported Unplanned Hospitalization[1] Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Dose Status

Primary Analysis Safety Population[2]

	2 Doses[3] (N = xxx)		1 Dose Only (N = xxx)		Primary Analysis Safety Population[2] (N = xxx)	
	Participants N (%)	Hospitalizations[4] N	Participants N (%)	Hospitalizations N	Participants N (%)	Hospitalizations N
Participants Reported Unplanned Hospitalization[5]	x (x x%)	x	x (x.x%)	x	x (x x%)	x
Event In Process[6]	x (x x%)	x	x (x.x%)	x	x (x x%)	x
Suspected event (Unknown)[7]	x (x x%)	x	x (x.x%)	x	x (x x%)	x
Probable event[8]	x (x x%)	x	x (x.x%)	x	x (x x%)	x

Note 1: Hospitalization is any hospitalization at any time during the study and after vaccination

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: Participants who took 2 doses of vaccine.

4: 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.

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

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

7: Hospitalization with a link from the Verily eCRF to CEA spreadsheet with confirmation status as “No”.

8: Hospitalization with a link from the Verily eCRF to CEA spreadsheet with confirmation status as “Yes”.

9: Data as of DDMMMYYYY and generated from /path/programname.sas on DDMMMYYYY HH:MM

Table 15.3.1.2.1 Adjudicated Hospitalization[1] Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine

[Not Applicable for June 2021 Delivery]

Participants with one or more event(s)	All Consented Population[2] (N = xxx)	Primary Analysis Safety Population[3] (N=xxx)	Consented but not in Primary Analysis Safety Population (N=xxx)
Any Hospitalization	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)
# of hospitalizations per participant			
1	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)
2	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)
…			
Have you been discharged from the hospitalization for this condition?	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)
Yes	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)
No	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)
Days between 1st dose Vaccine and 1st Hospitalization			
N	xx	xx	xx
Mean (SD)	xx.x(xx.xx)	xx.x(xx.xx)	xx.x(xx.xx)
Median (Q1, Q3)	xx(xx, xx)	xx(xx, xx)	xx(xx, xx)
Min, Max	Xx,xx	Xx,xx	Xx,xx
How many days were you hospitalized?			
N	xx	xx	xx
Mean (SD)	xx.x(xx.xx)	xx.x(xx.xx)	xx.x(xx.xx)
Median (Q1, Q3)	xx(xx, xx)	xx(xx, xx)	xx(xx, xx)
Min, Max	Xx,xx	Xx,xx	Xx,xx

Participants with one or more event(s)	All Consented Population[2] (N = xxx)	Primary Analysis Safety Population[3] (N=xxx)	Consented but not in Primary Analysis Safety Population (N=xxx)

Note 1: Hospitalization is any hospitalization at any time during the study and after vaccination

2: All Consented population is defined as all enrolled participants.

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

Table 15.3.1.2.2. Adjudicated Hospitalization[1] Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccineby Vaccine Type – Pfizer

[Not Applicable for June 2021 Delivery]

Participants with one or more event(s)	Enrolled within 10 days after vaccine[2] (N=xxx)	Enrolled more than 10 days after vaccine (N=xxx)	Pfizer (N=xxx)
Any Hospitalization	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)
# of hospitalizations per participant			
1	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)
2	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)
…			
Have you been discharged from the hospitalization for this condition?	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)
Yes	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)
No	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)
Days between 1st dose Vaccine and 1st Hospitalization			
N	xx	xx	xx
Mean (SD)	xx.x(xx.xx)	xx.x(xx.xx)	xx.x(xx.xx)
Median (Q1, Q3)	xx(xx, xx)	xx(xx, xx)	xx(xx, xx)
Min, Max	Xx,xx	Xx,xx	Xx,xx
How many days were you hospitalized?			
N	xx	xx	xx
Mean (SD)	xx.x(xx.xx)	xx.x(xx.xx)	xx.x(xx.xx)
Median (Q1, Q3)	xx(xx, xx)	xx(xx, xx)	xx(xx, xx)
Min, Max	Xx,xx	Xx,xx	Xx,xx

Note 1: Hospitalization is any hospitalization at any time during the study and after vaccination

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 15.3.1.2.3 Adjudicated Hospitalization[1] Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccineby Vaccine Type – Other Covid-19 Vaccine

[Not Applicable for June 2021 Delivery]

Participants with one or more event(s)	**Enrolled within 10 days after vaccine (N=xxx)**	**Enrolled more than 10 days after vaccine (N=xxx)**	**Other Covid-19 Vaccine (N=xxx)**
Any Hospitalization	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)
# of hospitalizations per participant			
1	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)
2	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)
…			
Have you been discharged from the hospitalization for this condition?	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)
Yes	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)
No	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)
Days between 1st dose Vaccine and 1st Hospitalization			
N	xx	xx	xx
Mean (SD)	xx.x(xx.xx)	xx.x(xx.xx)	xx.x(xx.xx)
Median (Q1, Q3)	xx(xx, xx)	xx(xx, xx)	xx(xx, xx)
Min, Max	Xx,xx	Xx,xx	Xx,xx
How many days were you hospitalized?			
N	xx	xx	xx
Mean (SD)	xx.x(xx.xx)	xx.x(xx.xx)	xx.x(xx.xx)
Median (Q1, Q3)	xx(xx, xx)	xx(xx, xx)	xx(xx, xx)
Min, Max	Xx,xx	Xx,xx	Xx,xx

Table 15.3.1.2.4 Adjudicated Hospitalization[1] Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Pregnancy

Primary Analysis Safety Population

[Not Applicable for June 2021 Delivery]Participants with one or more event(s)	**Pregnancy (N = xxx)**	**Not Pregnancy (N = xxx)**	**Primary Analysis Safety Population[2] (N = xxx)**
Any Hospitalization	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)
# of hospitalizations per participant			
1	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)
2	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)
…			
Have you been discharged from the hospitalization for this condition?	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)
Yes	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)
No	Xx (xx.x%)	Xx (xx.x%)	Xx (xx.x%)
Days between 1st dose Vaccine and 1st Hospitalization			
N	xx	xx	xx
Mean (SD)	xx.x(xx.xx)	xx.x(xx.xx)	xx.x(xx.xx)
Median (Q1, Q3)	xx(xx, xx)	xx(xx, xx)	xx(xx, xx)
Min, Max	Xx,xx	Xx,xx	Xx,xx
How many days were you hospitalized?			
N	xx	xx	xx
Mean (SD)	xx.x(xx.xx)	xx.x(xx.xx)	xx.x(xx.xx)
Median (Q1, Q3)	xx(xx, xx)	xx(xx, xx)	xx(xx, xx)
Min, Max	Xx,xx	Xx,xx	Xx,xx

[Not Applicable for June 2021 Delivery]Participants with one or more event(s)	**Pregnancy (N = xxx)**	**Not Pregnancy (N = xxx)**	**Primary Analysis Safety Population[2] (N = xxx)**

Note 1: Hospitalization is any hospitalization at any time during the study and after vaccination

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 15.3.1.2.5 Adjudicated Hospitalization Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Age Group

[Not Applicable for June 2021 Delivery]

Table 15.3.1.2.6 Adjudicated Hospitalization Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Immunocompromised status

[Not Applicable for June 2021 Delivery]

Table 15.3.1.2.7 Adjudicated Hospitalization Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Dose Status

[Not Applicable for June 2021 Delivery]

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

	All Consented Population[1] (N = xxx)		Primary Analysis Safety Population[2] (N=xxx)		Consented but not in Primary Analysis Safety Population (N=xxx)	
	Participants N (%)	Events[3] n	Participants N (%)	Events n	Participants N (%)	Events n
Any Adverse Event of Special Interest[4]	x (x.x%)	x	x (x x%)	x	x (x x%)	x
Hospitalized[5,6]	x (x.x%)	x	x (x x%)	x	x (x x%)	x
Event In Process[7]	x (x.x%)	x	x (x x%)	x	x (x x%)	x
Suspected event (unknown)[8]	x (x.x%)	x	x (x x%)	x	x (x x%)	x
Suspected event (not validated)[9]	x (x.x%)	x	x (x x%)	x	x (x x%)	x
Probable event[10]	x (x.x%)	x	x (x x%)	x	x (x x%)	x
Not Hospitalized[11]	x (x.x%)	x	x (x x%)	x	x (x x%)	x
Event In Process[7]	x (x.x%)	x	x (x x%)	x	x (x x%)	x
Suspected event (unknown)[8]	x (x.x%)	x	x (x x%)	x	x (x x%)	x
Suspected event (not validated)[9]	x (x.x%)	x	x (x x%)	x	x (x x%)	x
Probable event[10]	x (x.x%)	x	x (x x%)	x	x (x x%)	x
Neurologic[12]	x (x.x%)	x	x (x x%)	x	x (x x%)	x
Event In Process[7]	x (x.x%)	x	x (x x%)	x	x (x x%)	x
Suspected event (unknown)[8]	x (x.x%)	x	x (x x%)	x	x (x x%)	x
Suspected event (not validated)[9]	x (x.x%)	x	x (x x%)	x	x (x x%)	x
Probable event[10]	x (x.x%)	x	x (x x%)	x	x (x x%)	x
Generalized convulsion/seizures[12]	x (x.x%)	x	x (x x%)	x	x (x x%)	x

	All Consented Population[1] (N = xxx)		Primary Analysis Safety Population[2] (N=xxx)		Consented but not in Primary Analysis Safety Population (N=xxx)	
	Participants N (%)	Events[3] n	Participants N (%)	Events n	Participants N (%)	Events n
Event In Process[7]	x (x.x%)	x	x (x x%)	x	x (x x%)	x
Suspected event (unknown)[8]	x (x.x%)	x	x (x x%)	x	x (x x%)	x
Suspected event (not validated)[9]	x (x.x%)	x	x (x x%)	x	x (x x%)	x
Probable event[10]	x (x.x%)	x	x (x x%)	x	x (x x%)	x
…	x (x.x%)	x	x (x x%)	x	x (x x%)	x

Note 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 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.

4: 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.

5: Verily eCRF reported adverse events of special interest collapsing on hospitalization date from the unplanned hospitalization forms.

6: If more than one event was collected for the same hospitalization, all events will have the same confirmation status on CEA spreadsheet.

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

8: Adverse events of special interest with a link from the Verily eCRF to CEA spreadsheet with confirmation status as “Suspected event (unknown)”.

9: Adverse events of special interest with a link from the Verily eCRF to CEA spreadsheet with confirmation status as “Suspected event (not validated)”.

10: Adverse events of special interest with a link from the Verily eCRF to CEA spreadsheet with confirmation status as “Probable event”.

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

12: 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.

13: Data as of DDMMMYYYY and generated from /path/programname.sas on DDMMMYYYY HH:MM

Table 15.3.2.1.2 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[1]

	Enrolled within 10 days after vaccine (N=xxx)		Enrolled more than 10 days after vaccine (N=xxx)		Pfizer (N=xxx)	
	Participants N (%)	Events[2] n	Participants N (%)	Events n	Participants N (%)	Events n
Any Adverse Event of Special Interest[3]	x (x x%)	x	x (x x%)	x	x (x x%)	x
Hospitalized[4,5]	x (x x%)	x	x (x x%)	x	x (x x%)	x
Event In Process[6]	x (x x%)	x	x (x x%)	x	x (x x%)	x
Suspected event (unknown)[7]	x (x x%)	x	x (x x%)	x	x (x x%)	x
Suspected event (not validated)[8]	x (x x%)	x	x (x x%)	x	x (x x%)	x
Probable event[9]	x (x x%)	x	x (x x%)	x	x (x x%)	x
Not Hospitalized[10]	x (x x%)	x	x (x x%)	x	x (x x%)	x
Event In Process[6]	x (x x%)	x	x (x x%)	x	x (x x%)	x
Suspected event (unknown)[7]	x (x x%)	x	x (x x%)	x	x (x x%)	x
Suspected event (not validated)[8]	x (x x%)	x	x (x x%)	x	x (x x%)	x
Probable event[9]	x (x x%)	x	x (x x%)	x	x (x x%)	x
Neurologic[11]	x (x x%)	x	x (x x%)	x	x (x x%)	x
Event In Process[6]	x (x x%)	x	x (x x%)	x	x (x x%)	x
Suspected event (unknown)[7]	x (x x%)	x	x (x x%)	x	x (x x%)	x
Suspected event (not validated)[8]	x (x x%)	x	x (x x%)	x	x (x x%)	x
Probable event[9]	x (x x%)	x	x (x x%)	x	x (x x%)	x

	Enrolled within 10 days after vaccine (N=xxx)		Enrolled more than 10 days after vaccine (N=xxx)		Pfizer (N=xxx)	
	Participants N (%)	Events[2] n	Participants N (%)	Events n	Participants N (%)	Events n
Generalized convulsion/seizures[11]	x (x x%)	x	x (x x%)	x	x (x x%)	x
Event In Process[6]	x (x x%)	x	x (x x%)	x	x (x x%)	x
Suspected event (unknown)[7]	x (x x%)	x	x (x x%)	x	x (x x%)	x
Suspected event (not validated)[8]	x (x x%)	x	x (x x%)	x	x (x x%)	x
Probable event[9]	x (x x%)	x	x (x x%)	x	x (x x%)	x
…	x (x x%)	x	x (x x%)	x	x (x x%)	x

Note 1: All Consented population is defined as all enrolled participants.

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.

5: If more than one event was collected for the same hospitalization, all events will have the same confirmation status on CEA spreadsheet.

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

7: Adverse events of special interest with a link from the Verily eCRF to CEA spreadsheet with confirmation status as “Suspected event (unknown)”.

8: Adverse events of special interest with a link from the Verily eCRF to CEA spreadsheet with confirmation status as “Suspected event (not validated)”.

9: Adverse events of special interest with a link from the Verily eCRF to CEA spreadsheet with confirmation status as “Probable event”.

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

11: 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.

12: Data as of DDMMMYYYY and generated from /path/programname.sas on DDMMMYYYY HH:MM

Table 15.3.2.1.3 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

Table 15.3.2.1.4 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[1]

	Pregnancy[2] (N=xxx)		Not Pregnancy (N=xxx)		Primary Analysis Safety Population[1] (N=xxx)	
	Participants N (%)	Events[3] n	Participants N (%)	Events n	Participants N (%)	Events n
Any Adverse Event of Special Interest[4]	x (x x%)	x	x (x x%)	x	x (x x%)	x
Hospitalized[5,6]	x (x x%)	x	x (x x%)	x	x (x x%)	x
Event In Process[7]	x (x x%)	x	x (x x%)	x	x (x x%)	x
Suspected event (unknown)[8]	x (x x%)	x	x (x x%)	x	x (x x%)	x
Suspected event (not validated)[9]	x (x x%)	x	x (x x%)	x	x (x x%)	x
Probable event[10]	x (x x%)	x	x (x x%)	x	x (x x%)	x
Not Hospitalized[11]	x (x x%)	x	x (x x%)	x	x (x x%)	x
Event In Process[7]	x (x x%)	x	x (x x%)	x	x (x x%)	x
Suspected event (unknown)[8]	x (x x%)	x	x (x x%)	x	x (x x%)	x
Suspected event (not validated)[9]	x (x x%)	x	x (x x%)	x	x (x x%)	x
Probable event[10]	x (x x%)	x	x (x x%)	x	x (x x%)	x
Neurologic[12]	x (x x%)	x	x (x x%)	x	x (x x%)	x
Event In Process[7]	x (x x%)	x	x (x x%)	x	x (x x%)	x
Suspected event (unknown)[8]	x (x x%)	x	x (x x%)	x	x (x x%)	x
Suspected event (not validated)[9]	x (x x%)	x	x (x x%)	x	x (x x%)	x
Probable event[10]	x (x x%)	x	x (x x%)	x	x (x x%)	x

	Pregnancy[2] (N=xxx)		Not Pregnancy (N=xxx)		Primary Analysis Safety Population[1] (N=xxx)	
	Participants N (%)	Events[3] n	Participants N (%)	Events n	Participants N (%)	Events n
Generalized convulsion/seizures[12]	x (x x%)	x	x (x x%)	x	x (x x%)	x
Event In Process[7]	x (x x%)	x	x (x x%)	x	x (x x%)	x
Suspected event (unknown)[8]	x (x x%)	x	x (x x%)	x	x (x x%)	x
Suspected event (not validated)[9]	x (x x%)	x	x (x x%)	x	x (x x%)	x
Probable event[10]	x (x x%)	x	x (x x%)	x	x (x x%)	x
…	x (x x%)	x	x (x x%)	x	x (x x%)	x

Note 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.

2: Pregnancy at time of enrolment includes both the participant and the partner pregnancy.

3: 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.

4: 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.

5: Verily eCRF reported adverse events of special interest collapsing on hospitalization date from the unplanned hospitalization forms.

6: If more than one event was collected for the same hospitalization, all events will have the same confirmation status on CEA spreadsheet.

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

8: Adverse events of special interest with a link from the Verily eCRF to CEA spreadsheet with confirmation status as “Suspected event (unknown)”.

9: Adverse events of special interest with a link from the Verily eCRF to CEA spreadsheet with confirmation status as “Suspected event (not validated)”.

10: Adverse events of special interest with a link from the Verily eCRF to CEA spreadsheet with confirmation status as “Probable event”.

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

12: 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. 13: Data as of DDMMMYYYY and generated from /path/programname.sas on DDMMMYYYY HH:MM

Table 15.3.2.1.5 Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Age group

Primary Analysis Safety Population

Table 15.3.2.1.6 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

Table 15.3.2.1.7 Participants Reported Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Dose Status

Primary Analysis Safety Population

Table 15.3.2.2.1 Adjudicated Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine

Primary Analysis Safety Population
[Not Applicable for June 2021 Delivery]

	All Consented Population[1] (N = xxx)		Primary Analysis Safety Population[2] (N=xxx)		Consented but not in Primary Analysis Safety population (N=xxx)	
	Participants N (%)	Events n	Participants N (%)	Participants N (%)	Events n	Participants N (%)
Any Adverse Event of Special Interest	x (x.x%)	x	x (x x%)	x	x (x x%)	x
Hospitalized	x (x.x%)	x	x (x x%)	x	x (x x%)	x
Not Hospitalized	x (x.x%)	x	x (x x%)	x	x (x x%)	x
Neurologic						
Generalized convulsion/seizures	x (x.x%)	x	x (x x%)	x	x (x x%)	x
Guillain-Barre Syndrome	x (x.x%)	x	x (x x%)	x	x (x x%)	x
…						

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

Table 15.3.2.2.2 Adjudicated Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Vaccine Type – Pfizer

[Not Applicable for June 2021 Delivery]

Table 15.3.2.2.3 Adjudicated Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Vaccine Type – Other Covid-19 Vaccine

[Not Applicable for June 2021 Delivery]

Table 15.3.2.2.4 Adjudicated Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Pregnancy

Primary Analysis Safety Population
[Not Applicable for June 2021 Delivery]

	Pregnancy (N=xx)		**Not Pregnancy (N=xx)**		**Primary Analysis Safety Population[1] (N =xx)**	
	Participants n (%)	Events n	Participants n (%)	Events n	Participants n (%)	Events n
Any Adverse Event of Special Interest	x (x.x%)	X #records	x (x.x%)	x	x (x.x%)	x
Hospitalized	x (x.x%)	X #records	x (x.x%)	x	x (x.x%)	x
Not Hospitalized	x (x.x%)	X #records	x (x.x%)	x	x (x.x%)	x
Neurologic						
Generalized convulsion/seizures	x (x.x%)	x	x (x.x%)	x	x (x.x%)	x
Guillain-Barre Syndrome	x (x.x%)	x	x (x.x%)	x	x (x.x%)	x
…						

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

Table 15.3.2.2.5 Adjudicated Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Age group

[Not Applicable for June 2021 Delivery]

Table 15.3.2.2.6 Adjudicated Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Baseline Immunocompromised Individuals

[Not Applicable for June 2021 Delivery]

Table 15.3.2.2.7 Adjudicated Adverse Events of Special Interest Anytime After Receipt of at Least 1 Dose of COVID-19 Vaccine by Dose Status

Primary Analysis Safety Population
[Not Applicable for June 2021 Delivery]

Table 15.3.3.1 Adjudicated Hospitalization / AESI following Dose 1

Primary Analysis Safety Population
[Not Applicable for June 2021 Delivery]

Cases / Surveillance Time per 1000 p-yrs	**Primary Analysis Safety Population[1]** **(N=xxx)**
Hospitalization	Xx /x xxx
Death	Xx /x xxx
Mean (Days since 1st Vaccine)	
Any AESI	Xx /x xxx
Neurologic	Xx /x xxx
Guillain-Barre Syndrome	Xx /x xxx
…..	Xx /x xxx

Note 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 15.3.3.2 Adjudicated Hospitalization / AESI following Dose 1 by Baseline Pregnancy

Primary Analysis Safety Population[Not Applicable for June 2021 Delivery]

Cases / Surveillance Time per 1000 p-yrs	**Pregnancy (N=xxx)**	**Not Pregnancy (N=xxx)**	**Primary Analysis Safety Population[1] (N=xxx)**
Hospitalization	Xx /x xxx	Xx /x xxx	Xx /x.xxx
Death	Xx /x xxx	Xx /x xxx	Xx /x.xxx
Any AESI	Xx /x xxx	Xx /x xxx	Xx /x.xxx
Neurologic	Xx /x xxx	Xx /x xxx	Xx /x.xxx
Guillain-Barre Syndrome	Xx /x xxx	Xx /x xxx	Xx /x.xxx
…..	Xx /x xxx	Xx /x xxx	Xx /x.xxx

Note 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 15.3.3.3 Adjudicated Hospitalization /AESI following Dose 1 by Baseline Age group

[Not Applicable for June 2021 Delivery]

Table 15.3.3.4 Adjudicated Hospitalization following Dose 1 by Baseline Immunocompromised Individuals

[Not Applicable for June 2021 Delivery]

9.4. Section 4. Listings

Listing 7.7.1. Withdrawn Subjects

Subject ID	Age/Sex/Race	Date of Study Exit	Reason for Non-Completion	Withdrawal by Subject Reason

Listing 7.7.2. Participant Reported Death

Subject ID	Age/Sex/Race	Vaccination Date	Days since 1st Vaccine to Death	Covid-19 Related

Listing 7.7.3. Subjects Excluded from the Analysis

Subject ID	Age/Sex/Race	Exclusion Reason

Listing 7.7.4. Demographic Data

Subject ID	Age/Sex/Race	Ethnicity

Listing 7.7.5. Medication/Treatment Data

Subject ID	Age/Sex/Race	Dose Number	Date of Dose	Maufacturer	Lot Number	Injection Site	Facility

Listing 7.7.6. Participant reported Unplanned Hospitalization

Subject ID	Age/Sex/Race	Vaccination Date	Admission Date	Days Hospitalized	Condition(s) Causing hospitalization

Listing 7.7.7. Participant reported Non-Hospitalization Medical Events

Subject ID	Age/Sex/Race	Vaccination Date	Reported Condition	Onset Date	What caused you to seek medical care for this condition

10. REFERENCES

1. WHO Novel coronavirus – China. Jan 12, 2020. http://www.who.int/csr/don/12-january-2020-novel-coronavirus-china/en/.

2. Jiang S, Xia S, Ying T, Lu L. A novel coronavirus (2019-nCoV) causing pneumonia-associated respiratory syndrome. *Cell Mol Immunol.* 2020;17(5):554.

3. World Health Organization. Naming the coronavirus disease (COVID-19) and the virus that causes it. Accessed October 2, 2020. Available: https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/naming-the-coronavirus-disease-(covid-2019)-and-the-virus-that-causes-it.

4. COVID-19 Dashboard by the Center for Systems Science and Engineering (CSSE) at Johns Hopkins University (JHU). https://coronavirus.jhu.edu/map.html.

5. Nguyen LH, Drew DA, Graham MS, et al. Risk of COVID-19 among front-line health-care workers and the general community: a prospective cohort study. *Lancet Public Health.* 2020;5(9):e475-e483.

6. National Academies of Sciences, Engineering, and Medicine. Framework for Equitable Allocation of COVID-19 Vaccine. 2020.Available: https://www.nap.edu/catalog/25917/framework-for-equitable-allocation-of-covid-19-vaccine#resources.

7. Anderson S. CBER Plans for Monitoring COVID-19 Vaccine Safety and Effectiveness. Presentation at the CDC Adivsory Committee on Immunization Practices. October 28, 2020. Available: https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2020-10/COVID-Anderson.pdf.

8. Farrington CP. Relative Incidence Estimation From Case Series for Vaccine Safety Evaluation. *Biometrics*. 1995;51:228-235

9. Whitaker HJ, Farrington CP, Spiessens B, Musonda P. Tutorial in Biostatistics: The Self-Controlled Case Series Method. *Statist Med*. 2006;25:1768-1797