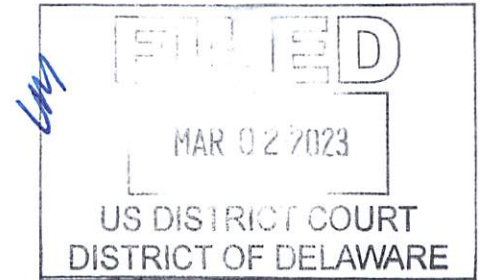


INTERVENORS' EXHIBIT 2



BNT162b2

5.3.6 Cumulative Analysis of Post-authorization Adverse Event Reports

5.3.6 CUMULATIVE ANALYSIS OF POST-AUTHORIZATION ADVERSE EVENT REPORTS OF PF-07302048 (BNT162B2) RECEIVED THROUGH 28-FEB-2021

Report Prepared by:

Worldwide Safety

Pfizer

The information contained in this document is proprietary and confidential. Any disclosure, reproduction, distribution, or other dissemination of this information outside of Pfizer, its Affiliates, its Licensees, or Regulatory Agencies is strictly prohibited. Except as may be otherwise agreed to in writing, by accepting or reviewing these materials, you agree to hold such information in confidence and not to disclose it to others (except where required by applicable law), nor to use it for unauthorized purposes.

CONFIDENTIAL

090177e196ea1800\Approved\Approved On: 30-Apr-2021 09:26 (GMT)

BNT162b2

5.3.6 Cumulative Analysis of Post-authorization Adverse Event Reports

TABLE OF CONTENTS

LIST OF TABLES3

LIST OF FIGURES3

APPENDICES3

LIST OF ABBREVIATIONS.....4

1. INTRODUCTION5

2. METHODOLOGY5

3. RESULTS6

 3.1. Safety Database6

 3.1.1. General Overview6

 3.1.2. Summary of Safety Concerns in the US Pharmacovigilance Plan9

 3.1.3. Review of Adverse Events of Special Interest (AESIs)16

 3.1.4. Medication error26

4. DISCUSSION28

5. SUMMARY AND CONCLUSION29

090177e196ea1800\Approved\Approved On: 30-Apr-2021 09:26 (GMT)

CONFIDENTIAL



BNT162b2

5.3.6 Cumulative Analysis of Post-authorization Adverse Event Reports

LIST OF TABLES

Table 1.	General Overview: Selected Characteristics of All Cases Received During the Reporting Interval.....	7
Table 2.	Events Reported in ≥2% Cases.....	8
Table 3.	Safety concerns.....	9
Table 4.	Important Identified Risk.....	10
Table 5.	Important Potential Risk.....	11
Table 6.	Description of Missing Information.....	12
Table 7.	AESIs Evaluation for BNT162b2.....	16
Table 8.	ME PTs by seriousness with or without harm co-association (Through 28 February 2021).....	27

LIST OF FIGURES

Figure 1.	Total Number of 13vPnC AEs by System Organ Classes and Event Seriousness.....	8
-----------	---	---

APPENDICES

APPENDIX 1 LIST OF ADVERSE EVENTS OF SPECIAL INTEREST.....	30
--	----

090177e196ea1800\Approved\Approved On: 30-Apr-2021 09:26 (GMT)

CONFIDENTIAL

BNT162b2

5.3.6 Cumulative Analysis of Post-authorization Adverse Event Reports

LIST OF ABBREVIATIONS

Acronym	Term
AE	adverse event
AESI	adverse event of special interest
BC	Brighton Collaboration
CDC	Centers for Disease Control and Prevention
COVID-19	coronavirus disease 2019
DLP	data lock point
EUA	emergency use authorisation
HLGT	(MedDRA) High Group Level Term
HLT	(MedDRA) High Level Term
MAH	marketing authorisation holder
MedDRA	medical dictionary for regulatory activities
MHRA	Medicines and Healthcare products Regulatory Agency
PCR	Polymerase Chain Reaction
PT	(MedDRA) Preferred Term
PVP	pharmacovigilance plan
RT-PCR	Reverse Transcription-Polymerase Chain Reaction
RSI	reference safety information
TME	targeted medically event
SARS-CoV-2	severe acute respiratory syndrome coronavirus 2
SMQ	standardised MedDRA query
SOC	(MedDRA) System Organ Class
UK	United Kingdom
US	United States
VAED	vaccine-associated enhanced disease
VAERD	vaccine-associated enhanced respiratory disease
VAERS	vaccine adverse event reporting system

090177e196ea1800\Approved\Approved On: 30-Apr-2021 09:26 (GMT)

CONFIDENTIAL

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.