Pfizer/BioNTech
FDA Approval Letter

EUA COVID-19 Vaccine
BNT162b - COMIRNATY

https://www.fda.gov/media/151710/download

U.S. FOOD & DRUG ADMINISTRATION

Our STN: BL 125742/0

BLA APPROVAL

August 23, 2021

BioNTech Manufacturing GmbH
Attention: Amit Patel
Pfizer Inc.
235 East 42nd Street
New York, NY 10017

Dear Mr. Patel:

Please refer to your Biologics License Application (BLA) submitted and received on May 18, 2021, under section 351(a) of the Public Health Service Act (PHS Act) for COVID-19 Vaccine, mRNA.

LICENSING

We are issuing Department of Health and Human Services U.S. License No. 2229 to BioNTech Manufacturing GmbH, Mainz, Germany, under the provisions of section 351(a) of the PHS Act controlling the manufacture and sale of biological products. The license authorizes you to introduce or deliver for introduction into interstate commerce, those products for which your company has demonstrated compliance with establishment and product standards.

Under this license, you are authorized to manufacture the product, COVID-19 Vaccine, mRNA, which is indicated for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older.

The review of this product was associated with the following National Clinical Trial (NCT) numbers: NCT04368728 and NCT04380701.

Pfizer BioNTech FDA Approval Letter Vaccine BNT162b - Comirnaty

FDA LOT RELEASE

Please submit final container samples of the product in final containers together with protocols showing results of all applicable tests. You may not distribute any lots of product until you receive a notification of release from the Director, Center for Biologics Evaluation and Research (CBER).

BIOLOGICAL PRODUCT DEVIATIONS

You must submit reports of biological product deviations under 21 CFR 600.14. You should identify and investigate all manufacturing deviations promptly, including those associated with processing, testing, packaging, labeling, storage, holding and distribution. If the deviation involves a distributed product, may affect the safety, purity, or potency of the product, and meets the other criteria in the regulation, you must submit a report on Form FDA 3486 to the Director, Office of Compliance and Biologics

https://www.fda.gov/media/151710/download

Pfizer BioNTech FDA Approval Letter Vaccine BNT162b - Comirnaty

LABELING

We hereby approve the draft content of labeling including Package Insert, submitted under amendment 74, dated August 21, 2021, and the draft carton and container labels submitted under amendment 63, dated August 19, 2021.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the final content of labeling (21 CFR 601.14) in Structured Product Labeling (SPL) format via the FDA automated drug registration and listing system, (eLIST) as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the Package Insert submitted on August 21, 2021. Information on submitting SPL files using eLIST may be found in the

https://www.fda.gov/media/151710/download

Pfizer BioNTech FDA Approval Letter Vaccine BNT162b - Comirnaty

POSTMARKETING REQUIREMENTS UNDER SECTION 505(o)

We have determined that an analysis of spontaneous postmarketing adverse events reported under section 505(k)(1) of the FDCA will not be sufficient to assess known serious risks of myocarditis and pericarditis and identify an unexpected serious risk of subclinical myocarditis.

Furthermore, the pharmacovigilance system that FDA is required to maintain under section 505(k)(3) of the FDCA is not sufficient to assess these serious risks.

Therefore, based on appropriate scientific data, we have determined that you are required to conduct the following studies:

https://www.fda.gov/media/151710/download

Pfizer BioNTech FDA Approval Letter Vaccine BNT162b - Comirnaty

POSTMARKETING REQUIREMENTS UNDER SECTION 505(o)

4. Study C4591009, entitled "A Non-Interventional Post-Approval Safety Study of the Pfizer-BioNTech COVID-19 mRNA Vaccine in the United States," to evaluate the occurrence of myocarditis and pericarditis following administration of COMIRNATY.

We acknowledge the timetable you submitted on August 21, 2021, which states that you will conduct this study according to the following schedule:

Final Protocol Submission: August 31, 2021

Monitoring Report Submission: October 31, 2022

Interim Report Submission: October 31, 2023

Study Completion: June 30, 2025

Final Report Submission: October 31, 2025

https://www.fda.gov/media/151710/download

Pfizer BioNTech FDA Approval Letter Vaccine BNT162b - COMIRNATY

POSTMARKETING REQUIREMENTS UNDER SECTION 505(o)

5. Study C4591021, entitled "Post Conditional Approval Active Surveillance Study Among Individuals in Europe Receiving the Pfizer-BioNTech Coronavirus Disease 2019 (COVID-19) Vaccine," to evaluate the occurrence of myocarditis and pericarditis following administration of COMIRNATY.

Final Report Submission: September 30, 2024

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6. Study C4591021 substudy to describe the natural history of myocarditis and pericarditis following administration of COMIRNATY.

Final Report Submission: September 30, 2024

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7. Study C4591036, a prospective cohort study with at least 5 years of follow-up for potential long-term sequelae of myocarditis after vaccination (in collaboration with Pediatric Heart Network).

Final Report Submission: May 31, 2027

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8. Study C4591007 substudy to prospectively assess the incidence of subclinical myocarditis following administration of the second dose of COMIRNATY in a subset of participants 5 through 15 years of age.

Final Report Submission: May 31, 2024

https://www.fda.gov/media/151710/download

Pfizer BioNTech FDA Approval Letter Vaccine BNT162b - COMIRNATY

POSTMARKETING REQUIREMENTS UNDER SECTION 505(o)

9. Study C4591031 substudy to prospectively assess the incidence of subclinical myocarditis following administration of a third dose of COMIRNATY in a subset of participants 16 to 30 years of age.	Final Report Submission: December 31, 2022
10. Study C4591022, entitled "Pfizer-BioNTech COVID-19 Vaccine Exposure during Pregnancy: A Non-Interventional Post-Approval Safety Study of Pregnancy and Infant Outcomes in the Organization of Teratology Information Specialists (OTIS)/MotherToBaby Pregnancy Registry."	Final Report Submission: December 31, 2025
11. Study C4591007 substudy to evaluate the immunogenicity and safety of lower dose levels of COMIRNATY in individuals 12 through <30 years of age.	Final Report Submission: May 31, 2024

https://www.fda.gov/media/151710/download

Pfizer BioNTech FDA Approval Letter Vaccine BNT162b - Comirnaty

POST APPROVAL FEEDBACK MEETING

New biological products qualify for a post approval feedback meeting. Such meetings are used to discuss the quality of the application and to evaluate the communication process during drug development and marketing application review. The purpose is to learn from successful aspects of the review process and to identify areas that could benefit from improvement. If you would like to have such a meeting with us, please contact the Regulatory Project Manager for this application.

https://www.fda.gov/media/151710/download

July 7. 2020 – Moderna's Patent for Current Vaccine

Modified Polynucleotide or Production of Secreted Proteins

(57) **ABSTRACT**

A pharmaceutical composition which has a plurality of lipid nanoparticles that has a mean particle size of between 80 nm and 160 nm and contains a modified mRNA encoding a polypeptide. The lipid nanoparticles include a cationic lipid, a neutral lipid, a cholesterol, and a PEG lipid. The mRNA contains a 5'-cap, 5'-UTR, N1-methyl-pseudouridine, a 3'-UTR, and a poly-A region with at least 100 nucleotides.

US010703789B2

(12) **United States Patent**
De Fougerolles et al.

(10) **Patent No.: US 10,703,789 B2**
(45) **Date of Patent: *Jul. 7, 2020**

(54) **MODIFIED POLYNUCLEOTIDES FOR THE PRODUCTION OF SECRETED PROTEINS**

(71) Applicant: **ModernaTX, Inc.**, Cambridge, MA (US)

(72) Inventors: **Antonin De Fougerolles**, Waterloo (BE); **Justin Guild**, Framingham, MA (US)

(73) Assignee: **ModernaTX, Inc.**, Cambridge, MA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **16/438,978**

(22) Filed: **Jun. 12, 2019**

(65) **Prior Publication Data**

US 2020/0017565 A1 Jan. 16, 2020

Related U.S. Application Data

(63) Continuation of application No. 14/987,328, filed on Jan. 4, 2016, now Pat. No. 10,385,106, which is a (Continued)

(51) **Int. Cl.**

A61K 48/00	(2006.01)
A61K 38/17	(2006.01)
A61K 47/54	(2017.01)
A61K 9/127	(2006.01)
C07K 14/535	(2006.01)
C12N 15/88	(2006.01)
A61K 9/50	(2006.01)
C07K 14/47	(2006.01)
A61K 31/7088	(2006.01)
C07K 19/00	(2006.01)
C12N 15/85	(2006.01)
A61K 38/18	(2006.01)
A61K 38/19	(2006.01)
A61K 38/48	(2006.01)
A61K 9/14	(2006.01)
A61K 47/10	(2017.01)
A61K 38/21	(2006.01)
A61K 38/36	(2006.01)
A61K 38/44	(2006.01)
A61K 39/395	(2006.01)

(Continued)

(52) **U.S. Cl.**

CPC ***C07K 14/535*** (2013.01); ***A61K 9/1271*** (2013.01); ***A61K 9/1272*** (2013.01); ***A61K 9/1277*** (2013.01); ***A61K 9/14*** (2013.01); ***A61K 9/5031*** (2013.01); ***A61K 31/7088*** (2013.01); ***A61K 38/1767*** (2013.01); ***A61K 38/1816*** (2013.01); ***A61K 38/1866*** (2013.01); ***A61K 38/191*** (2013.01); ***A61K 38/193*** (2013.01); ***A61K 38/212*** (2013.01); ***A61K 38/215*** (2013.01); ***A61K 38/36*** (2013.01); ***A61K 38/363*** (2013.01); ***A61K 38/44*** (2013.01); ***A61K 38/4833*** (2013.01); ***A61K 38/4846*** (2013.01); ***A61K 39/3955*** (2013.01); ***A61K 47/10*** (2013.01); ***A61K 47/54*** (2017.08); ***A61K 47/542*** (2017.08); ***A61K 48/0033*** (2013.01); ***A61K 48/0066*** (2013.01); ***A61K 48/0075*** (2013.01); ***C07K 14/47*** (2013.01); ***C07K 14/475*** (2013.01); ***C07K 14/505*** (2013.01); ***C07K 14/525*** (2013.01); ***C07K 14/56*** (2013.01); ***C07K 14/565*** (2013.01); ***C07K 14/745*** (2013.01); ***C07K 14/75*** (2013.01); ***C07K 16/2887*** (2013.01); ***C07K 16/32*** (2013.01); ***C07K 19/00*** (2013.01); ***C12N 9/0069*** (2013.01); ***C12N 9/644*** (2013.01); ***C12N 15/85*** (2013.01); ***C12N 15/88*** (2013.01); ***C12Y 113/12007*** (2013.01); ***C12Y 304/21005*** (2013.01); ***C12Y 304/21022*** (2013.01); ***A61K 9/0019*** (2013.01); ***A61K 48/00*** (2013.01); ***C12N 2840/00*** (2013.01)

(58) **Field of Classification Search**

CPC C07H 21/02; C12N 15/67; C12N 15/11

See application file for complete search history.

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(Continued)

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Anderson et al., "Incorporation of pseudouridine into mRNA enhances translation by diminishing PKR activation," Nucleic Acids Res. 38(17):5884-92 (2010).

(Continued)

Primary Examiner — Antonio Galisteo Gonzalez
(74) *Attorney, Agent, or Firm* — Clark & Elbing LLP

(57) **ABSTRACT**

A pharmaceutical composition which has a plurality of lipid nanoparticles that has a mean particle size of between 80 nm and 160 nm and contains a modified mRNA encoding a polypeptide. The lipid nanoparticles include a cationic lipid, a neutral lipid, a cholesterol, and a PEG lipid. The mRNA contains a 5'-cap, 5'-UTR, N1-methyl-pseudouridine, a 3'-UTR, and a poly-A region with at least 100 nucleotides.

14 Claims, 14 Drawing Sheets

Specification includes a Sequence Listing.

MODERNA US 10,703,789, B2. July 7, 2020

diameter particle that can remain stable at high temperatures (150° C.) (Grabow and Jaegar, Nature Materials 2012, 11:269-269; herein incorporated by reference in its entirety). Additionally these microsponges may be able to exhibit an extraordinary degree of protection from degradation by ribonucleases.

In another embodiment, the polymer-based self-assembled nanoparticles such as, but not limited to, microsponges, may be fully programmable nanoparticles. The geometry, size and stoichiometry of the nanoparticle may be precisely controlled to create the optimal nanoparticle for delivery of cargo such as, but not limited to, polynucleotides, primary constructs and/or mmRNA.

In one embodiment, the polymer based nanoparticles may comprise a core of the polynucleotides, primary constructs and/or mmRNA disclosed herein and a polymer shell. The polymer shell may be any of the polymers described herein and are known in the art. In an additional embodiment, the polymer shell may be used to protect the polynucleotides, primary construct and/or mmRNA in the core.

In yet another embodiment, the polymer based nanoparticle may comprise a non-nucleic acid polymer comprising

Articles 219, 220: LNP may be a gel, like Hydrogel

- Nanoparticles may form into a gel when injected into the subject
- Polymer-based self-assembled nanoparticles…may be fully programmable

In one embodiment, the semi-conductive and/or metallic nanoparticles may comprise a core of the polynucleotides, primary constructs and/or mmRNA disclosed herein and a polymer shell. The polymer shell may be any of the polymers described herein and are known in the art. In an additional embodiment, the polymer shell may be used to protect the polynucleotides, primary constructs and/or mmRNA in the core.

Gels and Hydrogels

In one embodiment, the polynucleotides, primary constructs and/or mmRNA disclosed herein may be encapsulated into any hydrogel known in the art which may form a gel when injected into a subject. Hydrogels are a network of polymer chains that are hydrophilic, and are sometimes

found as a colloidal gel in which water is the dispersion medium. Hydrogels are highly absorbent (they can contain over 99% water) natural or synthetic polymers. Hydrogels also possess a degree of flexibility very similar to natural tissue, due to their significant water content. The hydrogel described herein may used to encapsulate lipid nanoparticles which are biocompatible, biodegradable and/or porous.

As a non-limiting example, the hydrogel may be an aptamer-functionalized hydrogel. The aptamer-functionalized hydrogel may be programmed to release one or more polynucleotides, primary constructs and/or mmRNA using nucleic acid hybridization. (Battig et al., J. Am. Chem. Society. 2012 134:12410-12413; herein incorporated by reference in its entirety).

As another non-limiting example, the hydrogel may be a shaped as an inverted opal.

The opal hydrogels exhibit higher swelling ratios and the swelling kinetics is an order of magnitude faster as well. Methods of producing opal hydrogels and description of opal hydrogels are described in International Pub. No. WO2012148684, herein incorporated by reference in its entirety.

In one embodiment, the nucleic acid self-assembled nanoparticles may comprise a core of the polynucleotides, primary constructs or mmRNA disclosed herein and a polymer shell. The polymer shell may be any of the polymers described herein and are known in the art. In an additional embodiment, the polymer shell may be used to protect the polynucleotides, primary constructs and mmRNA in the core.

Polymer-Based Self-Assembled Nanoparticles

Polymers may be used to form sheets which self-assembled into nanoparticles. These nanoparticles may be used to deliver the polynucleotides, primary constructs and mmRNA of the present invention. In one embodiment, these self-assembled nanoparticles may be microsponges formed of long polymers of RNA hairpins which form into crystalline 'pleated' sheets before self-assembling into microsponges. These microsponges are densely-packed sponge like microparticles which may function as an efficient carrier and may be able to deliver cargo to a cell. The microsponges may be from 1 um to 300 nm in diameter. The microsponges may be complexed with other agents known in the art to form larger microsponges. As a non-limiting example, the microsponge may be complexed with an agent to form an outer layer to promote cellular uptake such as polycation polyethyleneime (PEI). This complex can form a 250-nm

Polymer Journal

Review | Published: 08 May 2020

Graphene oxide-incorporated hydrogels for biomedical applications

Jongdarm Yi, Goeun Choe, Junggeon Park & Jae Young Lee

Polymer Journal **52**, 823–837 (2020) | Cite this article

1362 Accesses | **14** Citations | **31** Altmetric | Metrics

Abstract

Graphene and graphene derivatives (e.g., graphene oxide (GO)) have been incorporated into hydrogels to improve the properties (e.g., mechanical strength) of conventional hydrogels and/or develop new functions (e.g., electrical conductivity and drug loading/delivery). Unique molecular interactions between graphene derivatives and various small or macromolecules enable the fabrication of various functional hydrogels appropriate for different biomedical applications. In this mini-review, we highlight the recent progress in GO-incorporated hydrogels for biomedical applications while focusing on their specific uses as mechanically strong materials, electrically conductive scaffolds/electrodes, and high-performance drug delivery vehicles.

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HUNDREDS of Studies of Graphene-Oxide Incorporated Hydrogels

MiFiGHT

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Pfizer/BioNTech vs Moderna Efficacy and "Breakthrough COVID-19" Cases

MAYO Clinic – 5 States – 636,053 Subjects – 18 and older

Dec 1, 2020 – July 19, 2021

Comparison of two highly-effective mRNA vaccines for COVID-19 during periods of Alpha and Delta variant prevalence

Arjun Puranik[1+], Patrick J. Lenehan[1+], Eli Silvert[1], Michiel J.M. Niesen[1], Juan Corchado-Garcia[1], John C. O'Horo[2], Abinash Virk[2], Melanie D. Swift[2], John Halamka[2], Andrew D. Badley[2], A.J. Venkatakrishnan[1], Venky Soundararajan[1]

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Abstract

Although clinical trials and real-world studies have affirmed the effectiveness and safety of the FDA-authorized COVID-19 vaccines, reports of breakthrough infections and persistent emergence of new variants highlight the need to vigilantly monitor the effectiveness of these vaccines. Here we compare the effectiveness of two full-length Spike protein-encoding mRNA vaccines from Moderna (mRNA-1273) and Pfizer/BioNTech (BNT162b2) in the Mayo Clinic Health System over time from January to July 2021, during which either the Alpha or Delta variant was highly prevalent. We defined cohorts of vaccinated and unvaccinated individuals from Minnesota (n = 25,589 each) matched on age, sex, race, history of prior SARS-CoV-2 PCR testing, and date of full vaccination. Both vaccines were highly effective during this study period against SARS-CoV-2 infection (mRNA-1273: 86%, 95%CI: 81-90.6%; BNT162b2: 76%, 95%CI: 69-81%) and COVID-19 associated hospitalization (mRNA-1273: 91.6%, 95% CI: 81-97%; BNT162b2: 85%, 95% CI: 73-93%). However, in July, the effectiveness against infection was considerably lower for mRNA-1273 (76%, 95% CI: 58-87%) with an even more pronounced reduction in effectiveness for BNT162b2 (42%, 95% CI: 13-62%). Notably, the Delta variant prevalence in Minnesota increased from 0.7% in May to over 70% in July whereas the Alpha variant prevalence decreased from 85% to 13% over the same time period. Comparing rates of infection between matched individuals fully vaccinated with mRNA-1273 versus BNT162b2 across Mayo Clinic Health System sites in multiple states (Minnesota, Wisconsin, Arizona, Florida, and Iowa), mRNA-1273 conferred a two-fold risk reduction against breakthrough infection compared to BNT162b2 (IRR = 0.50, 95% CI: 0.39-0.64). In Florida, which is currently experiencing its largest COVID-19 surge to date, the risk of infection in July after full vaccination with mRNA-1273 was about 60% lower than after full vaccination with BNT162b2 (IRR: 0.39, 95% CI: 0.24-0.62). Our observational study highlights that while both mRNA COVID-19 vaccines strongly protect against infection and severe disease, further evaluation of mechanisms underlying differences in their effectiveness such as dosing regimens and vaccine composition are warranted.

Data Availability

After publication, the data will be made available upon reasonable requests to the corresponding author. A proposal with a detailed description of study objectives and the statistical analysis plan will be needed for evaluation of the reasonability of requests. Deidentified data will be provided after approval from the corresponding author and the Mayo Clinic.

* Correspondence to: Venky Soundararajan (venky@nference.net)

https://www.medrxiv.org/content/10.1101/2021.08.06.21261707v1.full.pdf

moderna Pfizer miFIGHT

Complication	Incidence Rate mRNA-1273 (n = 106) Events/Person-Days [Per 1000 Person-Days]	Incidence Rate BNT162b2 (n = 220) Events/Person-Days [Per 1000 Person-Days]	IRR mRNA-1273 / BNT162b2 (exact 95% CI)
ARD ALI	4 / 2,206 [0.18%]	10 / 4,335 [0.23%]	0.79 (0.18, 2.73)
Acute kidney injury	5 / 2,052 [0.24%]	15 / 4,062 [0.37%]	0.66 (0.19, 1.91)
Anemia	9 / 1,729 [0.52%]	8 / 3,853 [0.21%]	2.51 (0.86, 7.47)
Cardiac arrest	1 / 2,230 [0.045%]	2 / 4,521 [0.044%]	1.01 (0.02, 19.47)
Cardiac arrhythmias	9 / 1,686 [0.53%]	20 / 3,216 [0.62%]	0.86 (0.34, 1.97)
Chronic fatigue syndrome	1 / 2,233 [0.045%]	0 / 4,591 [0%]	inf (0.05, inf)
Disseminated intravascular coagulation	0 / 2,238 [0%]	0 / 4,591 [0%]	NA
Encephalopathy Delirium	2 / 2,148 [0.093%]	4 / 4,360 [0.092%]	1.01 (0.09, 7.08)
Heart failure	5 / 2,043 [0.24%]	7 / 4,149 [0.17%]	1.45 (0.36, 5.31)
Hyperglycemia	3 / 2,045 [0.15%]	5 / 3,988 [0.13%]	1.17 (0.18, 6.01)
Hypertension	8 / 1,295 [0.62%]	24 / 2,137 [1.1%]	0.55 (0.21, 1.27)
Myocardial infarction	2 / 2,143 [0.093%]	5 / 4,364 [0.11%]	0.81 (0.08, 4.98)
Numbness	4 / 1,873 [0.21%]	5 / 3,930 [0.13%]	1.68 (0.33, 7.8)
Pleural effusion	5 / 2,140 [0.23%]	8 / 4,240 [0.19%]	1.24 (0.32, 4.29)
Pulmonary embolism	2 / 2,208 [0.091%]	5 / 4,393 [0.11%]	0.8 (0.08, 4.86)
Respiratory failure	5 / 2,199 [0.23%]	10 / 4,335 [0.23%]	0.99 (0.26, 3.17)
Sepsis	3 / 2,142 [0.14%]	2 / 4,418 [0.045%]	3.09 (0.35, 37.04)
Septic shock	1 / 2,217 [0.045%]	0 / 4,557 [0%]	inf (0.05, inf)
Stroke	0 / 2,204 [0%]	5 / 4,307 [0.12%]	0.0 (0, 2.13)
Venous thromboembolism	3 / 2,173 [0.14%]	3 / 4,382 [0.068%]	2.02 (0.27, 15.06)

Table 8. Incidence rates of potential COVID-19 associated complications in breakthrough patients. The columns are: **(1) Complications:** phenotypes that are written with positive-sentiment in the clinical notes and occur -3 to +30 days relative to COVID diagnosis and do not occur -180 to -4 days relative to COVID diagnosis; **(2) Incidence Rate of Complications in mRNA-1273 Breakthrough cases:** the number of mRNA-1273-vaccinated individuals experiencing the complication divided by the number of at-risk patient days contributed by mRNA-1273-vaccinated breakthrough cases; **(3) Incidence Rate of Complications in BNT162b2 Breakthrough cases:** the number of BNT162b2-vaccinated individuals experiencing the complication divided by the number of at-risk patient days contributed by BNT162b2-vaccinated breakthrough cases; **(4) IRR mRNA-1273 / BNT162b2:** the IR of the complication in the mRNA-1273 breakthrough cohort divided by the IR of the complication in the BNT162b2 breakthrough cohort.

Inclusion Criteria for "COVID-19 Breakthrough Complications" Per Table 8. Definition

1. Positive PCR test 3 days before or up to 30 days after 'COVID-19 Breakthrough Complications'
2. The number of Moderna subjects who experienced 'COVID-19 Breakthrough Complications'
3. The number of Pfizer subjects who experienced 'COVID-19 Breakthrough Complications'

https://www.medrxiv.org/content/10.1101/2021.08.06.21261707v1.full.pdf

FDA Safety Surveillance of COVID-19 Vaccines :
DRAFT Working list of possible adverse event outcomes
Subject to change

FDA VRBPAC Meeting: October 22. 2020

- Guillain-Barré syndrome
- Acute disseminated encephalomyelitis
- Transverse myelitis
- Encephalitis/myelitis/encephalomyelitis/ meningoencephalitis/meningitis/ encepholapathy
- Convulsions/seizures
- Stroke
- Narcolepsy and cataplexy
- Anaphylaxis
- Acute myocardial infarction
- Myocarditis/pericarditis
- Autoimmune disease
- Deaths
- Pregnancy and birth outcomes
- Other acute demyelinating diseases
- Non-anaphylactic allergic reactions
- Thrombocytopenia
- Disseminated intravascular coagulation
- Venous thromboembolism
- Arthritis and arthralgia/joint pain
- Kawasaki disease
- Multisystem Inflammatory Syndrome in Children
- Vaccine enhanced disease

https://www.fda.gov/media/143557/download