

IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS

PUBLIC HEALTH AND MEDICAL
PROFESSIONALS FOR TRANSPARENCY,

Plaintiff,

-against-

FOOD AND DRUG ADMINISTRATION,

Defendant.

Civil Action No. 4:21-cv-01058-P

JOINT REPORT

Plaintiff, Public Health and Medical Professionals for Transparency (“PHMPT”), by and through its attorneys, and Defendant, the U.S. Food and Drug Administration (the “FDA”), by and through its attorney, hereby submit this Joint Report in compliance with the Court’s Order of October 18, 2021, ECF No. 16. The parties provide the following in response to the Court’s inquiries:

1. Meeting of Counsel and Progress Toward Settlement: On November 3, 2021, lead counsel for PHMPT, Aaron Siri, and lead counsel for FDA, Courtney Enlow, met in Arlington, Virginia. Although no settlement was reached, the parties continued to negotiate in good faith a production schedule for the non-exempt portions of records responsive to PHMPT’s Freedom of Information Act (“FOIA”) request.

2. Summary of Claims and Defenses:

- a. PHMPT brought this action under the FOIA, 5 U.S.C. § 552, and 21 C.F.R. § 601.51(e), seeking from FDA: “All data and information for the Pfizer Vaccine enumerated in 21 C.F.R. § 601.51(e) with the exception of publicly available reports on the Vaccine Adverse Events Reporting System.”

- b. FDA raised two defenses in its answer: (1) Some or all of the requested records or information may be exempt from disclosure, in whole or in part, under 5 U.S.C. § 552(b); and (2) Plaintiff's FOIA request is improper to the extent it does not reasonably describe the records requested, as required by 5 U.S.C. § 552(a)(3)(A).

3. Proposed Time Limit to Amend Pleadings and Join Parties: Plaintiff reserves the right to amend the pleadings and join parties as provided in the FRCP and Defendant's position is that no amendment of pleadings or joinder of parties is necessary in this FOIA action.

4. Proposed Time Limit to File Various Types of Motions, Including Dispositive Motions: The Plaintiff's position is that the FDA should make "immediately available" all documents underlying the licensure of Pfizer's Covid-19 vaccine, as required by 21 C.F.R. § 601.51(e). Plaintiff therefore intends to file a motion for summary judgment seeking to compel the production of these documents as required by 21 C.F.R. § 601.51(e).

Defendant's Position: FDA respectfully submits that it is premature to set deadlines for dispositive motions, as such briefing in a FOIA case is appropriate not to compel production, as Plaintiff implies, but rather to litigate the adequacy of the search or the propriety of redacted information under FOIA exemptions.¹ Defendant respectfully requests that the Court not set a

¹ Continuation of Defendant's Position: Contrary to Plaintiff's suggestion, FDA's regulations do not require or suggest that FDA will release all publicly releasable data immediately after a biologics license application is approved. When read in context, it is clear that FDA's regulations establish when information in a biological product file is held in strict confidence by the agency and when certain data can be released to the public, for instance in response to standard processing of a request submitted under the Freedom of Information Act. *See generally* 21 C.F.R. 601.51. Put another way, the regulations establish the point in time when records that may previously have been unavailable for public disclosure lose their status as confidential and thus become available for public release "immediately" upon occurrence of the triggering event. Specifically, under 21 C.F.R. 601.51, the existence of a biological product file will not be disclosed by FDA prior to BLA approval unless it has been previously disclosed or acknowledged, and no data or information in that file is available for public disclosure. 21 C.F.R. 601.51(b, c). If the existence of the biological product file has been acknowledged before a license has been issued, FDA generally still will not make information and data in the file available for public disclosure prior to issuance of a BLA license. 21 C.F.R. 601.51(d). Once a license has been issued, however, certain data and information in the biological product file become "immediately" available for public disclosure. 21 C.F.R. 601.51(e). That means that if a properly submitted FOIA request is received

deadline for dispositive motions at this stage in the litigation and instead set a processing schedule. Once FDA has completed its production of records responsive to Plaintiff's FOIA request, Defendant proposes that the parties file a joint status report wherein they propose a schedule for summary judgment briefing.

5. Proposed Time Limit for Designation of Experts: At this time, the parties agree that designations of experts will likely be unnecessary in this FOIA action. Indeed, the U.S. District Court for the District of Columbia—which handles “[a] significant portion of the nation’s FOIA actions”—explains in a comment to their Local Rule 16.3(b) that actions under FOIA are actions that “typically do not require discovery or actions in which an initial disclosure requirement would not make sense.”

6. Proposed Time Limit for Objection to Experts: The parties agree that objections to experts are likely unnecessary for the reason set forth in paragraph 5.

7. Proposed Plan and Schedule for Discovery: The parties agree that a proposed plan and a schedule for discovery are not necessary at this stage in the proceedings for the reasons set forth in paragraph 5.

8. Statement on Limitations for Discovery: The parties agree that such limitations are not necessary at this stage of the proceedings for the reasons set forth in paragraph 5.

9. Statement on the Method for Disclosing and Conducting Discovery: The parties agree that such a statement is not necessary at this stage in the proceedings for the reasons set forth in paragraph 5.

for data and information listed in 21 C.F.R. 601.51(e), FDA may publicly release such information in response to such request, without need for additional agency action to reclassify as publicly releasable data and information that had previously been deemed confidential. Many BLAs, including the one at issue in this case, contain hundreds of thousands of pages. It is not feasible for FDA to review and produce such large volumes of data immediately upon the approval of each BLA, and FDA does not interpret its regulations to require such.

10. Proposals Regarding the Handling and Protection of Privileged or Trial Preparation Material: The parties agree that such a proposal is unnecessary for the reasons set forth in paragraph 5.

11. Proposed Trial Date: The parties agree that a proposed trial date is unnecessary at this stage in the litigation because “[m]ost FOIA cases are resolved by the district court on summary judgment, with the district court entering judgment as a matter of law.” *Animal Legal Def. Fund v. U.S. Food & Drug Admin.*, 836 F.3d 987, 989 (9th Cir. 2016).

12. Proposed Mediation Deadline: The parties agree that mediation is not necessary in this FOIA action.

13. Statement on Initial Disclosures: The parties agree that initial disclosures are not necessary in this FOIA action for the reasons set forth in paragraph 5 and request that the Court waive the initial disclosures requirement. *See* U.S. District Court for the District of Columbia, Local Rule 16.3(b) comment, 40 (describing FOIA cases as “actions that typically do not require discovery or actions in which an initial disclosure requirement would not make sense”), https://www.dcd.uscourts.gov/sites/dcd/files/local_rules/Local%20Rules%20Sept_2021_0.pdf.

14. Statement of Whether Parties Will Consent to a Trial Before a Magistrate Judge: The parties do not consent to a trial before a magistrate judge.

15. Whether a Conference with the Court is Desired:

Plaintiff’s Position: Plaintiff respectfully requests a conference with the Court as soon as practicable. The Plaintiff – comprised of highly accomplished scientists from prestigious universities from across the country – seeks a copy of the data provided by Pfizer to the FDA for the licensure of its COVID-19 vaccine (the “**Pfizer Vaccine**” or “**Comirnaty**”). The FDA received and reviewed this data and licensed Pfizer’s vaccine in under four months. Pursuant to

FDA's own regulation, this data is to be made "immediately available for public disclosure." 21 C.F.R. § 601.51(e). Nonetheless, despite the passage of two and half months since licensure, the FDA has not made a single page of Pfizer's submission public. The FDA position appears to be that while it was able to review the over 300,000 pages provided by Pfizer, including extensive and complex statistical analysis and review, in less than four months, it can only review for public production a few hundred pages this month. The FDA provided Plaintiff with a PDF copy of the index of the documents provided by Pfizer (copy attached) and in an attempt to compromise, the Plaintiff asked if the FDA would produce the following by the end of this month:

1. *PDF page 27*: CRFs for site 1055
2. *PDF page 31*: CRFs for site 1081
3. *PDF page 38*: CRFs for site 1096
4. *PDF page 46*: CRFs for site 1128
5. *PDF page 10*: Program Files/SAS files. They want 3 to 4 SAS files as a sample, in the first instance, so that they client can assess whether it would like to prioritize the complete universe of SAS files.
6. *PDF page 1*: 5.2 - Tabular Listing of all Clinical Studies
7. *PDF page 1*: 4 – Nonclinical Study Reports
8. *PDF page 2*: 5.3.6 - Reports of Postmarketing Experience
9. *PDF page 3*: 16.1.1 - Protocol and/or Amendment, and specifically, Final Analysis Interim Independent Oversight Committees
10. *PDF page 6*: Under the Analysis Datasets (ADaM), the Analysis Data Reviewers Guide, Analysis Dataset Definition, and Analysis Dataset Definition Stylesheet
11. *PDF page 11*: Tabulation Datasets

The FDA rejected this proposal and only offered to provide item 6 on this list and one of the SAS files. At that rate of production, it would take over 80 years to produce the data Pfizer submitted to the FDA to license its COVID-19 vaccine.

The FDA's position is also incredible given that the federal government is mandating that millions of Americans receive Pfizer's vaccine under penalty of being fired from their jobs while at the same time giving immunity to Pfizer for any injuries from this product. This unique situation demands the FDA (as its own regulations reflect) **immediately** make the data underlying the

licensure of this product public, including to the dozens of independent scientists on whose behalf this request was submitted. Plaintiff therefore seeks an immediate conference with the Court to address the FDA's refusal to timely produce the data underlying the licensure of Pfizer's COVID-19 vaccine.²

Defendant's Position: Defendant respectfully requests a conference with the Court to set a schedule for the processing of records responsive to Plaintiff's FOIA request.

FDA is committed to transparency, in general, and in particular with respect to records related to the Biological License Application ("BLA") for the Comirnaty vaccine.³

Plaintiff's FOIA request effectively seeks all publicly releasable information from the Comirnaty BLA. FDA has conducted an initial assessment of the number of records responsive to Plaintiff's FOIA request and has determined that more than 329,000 pages of documentary records, plus other files, typically containing data in a format similar to a spreadsheet that are not captured in this page count, such as SAS data files, are responsive to Plaintiff's FOIA request. Some of those spreadsheets themselves are extremely large, containing dozens of columns and more than ten thousand rows of data.

In processing records responsive to FOIA requests, FDA must conduct a careful review of records before they are released, often on a line-by-line basis. This review is entirely different from the review conducted by FDA's scientists when reviewing a BLA. The review that must be conducted in this case, which is conducted by government information specialists, is necessary to ensure that no information exempt from the FOIA is released. Plaintiff has requested records that

² The FDA claims it has released a significant amount of information on its website, but those documents are all the FDA's own analysis. Not the data provided by Pfizer to the FDA for licensure of Comirnaty.

³ Indeed, FDA released a significant amount of information related to the Comirnaty approval on its website shortly after the BLA was approved. That information includes, among other things, the package insert, the approval letter, a summary of FDA's basis for action, and over a dozen FDA review memoranda. U.S. Food and Drug Admin., "Cominarty," <https://www.fda.gov/vaccines-blood-biologics/comirnaty> (last accessed: Nov. 4, 2021).

comprise information submitted by the vaccine sponsor (Pfizer-BioNTech). From FDA's experience with other FOIA requests, such records can be expected to contain both confidential business and trade secret information of Pfizer or BioNTech and personal privacy information of individuals who participated in clinical trials. This type of information is exempt from production under the FOIA. *See* 5 U.S.C. § 552(b)(4), (b)(6). To ensure protection of this information, and other information subject to withholding under the FOIA exemptions, FDA must carefully review and, if necessary, redact exempt information on a line-by-line basis. Due to the vast size of Plaintiff's request, FDA's limited resources for processing FOIA requests, and currently extraordinary demand for FDA records,⁴ it is not feasible for FDA to review and produce the substantial volume of records that Plaintiff seeks to obtain on a short timeframe.

FDA has worked with Plaintiff in an attempt to develop a production schedule that would prioritize production of the portion of the biological product file of most interest to Plaintiff. Plaintiff has provided a priority list to FDA, but Plaintiff's most recent proposal would require FDA to review and process over 20,000 pages in less than a month.

FDA is committed to processing Plaintiff's FOIA request as soon as practicable and has taken affirmative steps to do so. FDA proposes to process and produce the non-exempt portions of the following records by the following dates:

- November 17:
 - From Section 5.2 of the BLA file:

⁴ Because of FDA's size and the large number of records generated during the course of agency business, and the different components within FDA, the agency's FOIA program is decentralized. Plaintiff's FOIA request is being processed by the Access Litigation and Freedom of Information Branch (the "Branch") in FDA's Center for Biologics Evaluation and Research ("CBER"). The Branch has a total of ten employees, including the director and two trainees. It is currently responsible for processing a total of approximately 400 currently pending FOIA requests, including Plaintiff's. CBER is currently involved in 6 active FOIA litigation matters.

- The Tabular Listing
- The Listing of Clinical Sites
 - The Reports of Postmarketing Experience from Section 5.3.6 of the BLA file
 - One SAS file.⁵
- December 1: remainder of section 5.2 of the BLA file.

After the December 1 production, FDA proposes to work through Plaintiff's priority list in order of priority and process and release the non-exempt portions of those records to Plaintiff on a rolling basis.

This proposal is a reasonable processing schedule that takes into account FDA's obligations to respond to other document requests, meet its stipulated document processing deadlines in other matters, and thus, fairly respond to other FOIA requestors, including the many with requests that were received ahead of Plaintiff's. Moreover, this proposed processing schedule is consistent with those entered by courts around the country.⁶

⁵ Plaintiff has requested to receive the SAS files in their native format. FDA customarily converts SAS files to PDF files because PDFs can be redacted to prevent the release of non-exempt information. However, FDA is willing to produce SAS files to Plaintiff (if it is feasible for FDA to do so) with the parties' understanding that FDA may have to delete, rather than redact, exempt information from those files to prevent disclosure of exempted information.

⁶ See, e.g., *Documented NY v. U.S. Dep't of State*, No. 20 Civ. 1946 (AJN) (S.D.N.Y.) Dkt. 26 p.2 (denying plaintiff's processing rate demand of 2,500 pages per month and adopting Department of State's proposed 300 pages per month); *NYCLU v. Admin. for Children & Families*, No. 20 Civ. 183 (MKV), Dkt. No. 30 (S.D.N.Y. May 5, 2020) (400 pages per month); *Color of Change v. U.S. Dep't of Homeland Sec.*, 325 F. Supp. 3d 447, 451 (S.D.N.Y. 2018) (500 pages per month); *Davis v. U.S. Dep't of Homeland Sec.*, No. 11-cv-203 (ARR) (VMS), 2013 WL 3288418, at *1 (E.D.N.Y. June 27, 2013) (500 pages per month); *Blakeney v. FBI*, No. 17-cv-2288 (BAH), 2019 WL 450678, at *2 (D.D.C. Feb. 5, 2019) (500 pages per month); *Colbert v. FBI*, No. 16 Civ. 1790 (DLF), 2018 WL 6299966, at *3 (D.D.C. Sept. 3, 2018) (500 pages per month); *Middle E. Forum v. U.S. Dep't of Homeland Sec.*, No. 17 Civ. 767 (RCL) (GMH), 2018 WL 1178022, at *3–4 (D.D.C. Mar. 5, 2018) (500 pages per month); *id.* at *3 n.3 (noting that, "[i]n a number of recent cases in this District, a production rate of 500 pages per month has been approved," and collecting cases); *Republican Nat'l Comm. v. U.S. Dep't of State*, No. 16 Civ. 486 (JEB), 2016 WL 9244625, at *1 (D.D.C. Sept. 16, 2016) (500 pages per month); *Energy & Env't Legal Inst. v. U.S. Dep't of State*, No. 17 Civ. 340 (D.D.C.), Minute Order of August 22, 2017 (300 pages per month); *Judicial Watch, Inc. v. U.S. Dep't of State*, No. 17 Civ. 205 (D.D.C.), Minute Order of June 30, 2017 (300 pages every four weeks); *Am. Ctr. for Law & Justice v. U.S. Dep't of State*, No. 16 Civ. 2516 (D.D.C.), Minute Order of June 27, 2017 (process 400 pages per month); *Citizens United v. U.S. Dep't of State*, No. 16 Civ. 67 (D.D.C.), Dkt. 17 at 3 (declining "to adopt Plaintiff's proposed production order of 2000 pages per month" and instead holding State "to its 300-page commitment"); *Freedom Watch v. Bureau of Land Mgmt.*, No. 16

16. Other Information and Proposals: FDA has conducted an initial assessment of the volume of records responsive to PHMPT's request and has determined that there are at least 329,000 pages responsive to PHMPT's request. The parties have conferred in good faith on several occasions in October and November 2021 to develop a proposed schedule for FDA to process and produce the non-exempt portions of records responsive to PHMPT's request to PHMPT. The parties failed to reach agreement.

Dated: November 5, 2021

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Civ. 2320 (D.D.C.), Minute Order of June 13, 2017 (500 pages every 30 days); *Citizens United v. U.S. Dep't of State*, No. 15 Civ. 1720 (D.D.C.), Dkt. 11 ¶ 10 (500 pages every four weeks); *Judicial Watch, Inc. v. U.S. Dep't of State*, No. 15 Civ. 687 (D.D.C.), Minute Order of April 4, 2017 (500 pages per month).

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ATTACHMENT

▲ 0001 --> 125742/0.0 (Original Application) - Recd 2021-05-06 - DATS# 1067058

- ▶ 1 Administrative Information and Prescribing Information
- ▶ 2 Common Technical Document Summaries
- ▶ 4 Nonclinical Study Reports

▲ 5 Clinical Study Reports

- ▶ 5.2 Tabular Listing of all Clinical Studies
- ▶ 5.3 Clinical Study Reports
- ▶ 5.4 Literature References

▲ 5 Clinical Study Reports

▲ 5.2 Tabular Listing of all Clinical Studies

[0001] Tabular Listing ~12 pages

[0001] Listing of Clinical Sites and CVs ~289 page

- ▶ 5.3 Clinical Study Reports
- ▶ 5.4 Literature References

5 Clinical Study Reports	
5.2 Tabular Listing of all Clinical Studies	
5.3 Clinical Study Reports	
5.3.1 Reports of Biopharmaceutic Studies	
5.3.5 Reports of Efficacy and Safety Studies	
5.3.6 Reports of Postmarketing Experience	
[0001] Postmarketing Experience	~38 pages
5.4 Literature References	~240 pages (~20 journal articles)

Index not being provided for section 5.3.1 (would need disclosure review first)

Details of 5.3.5 are provided below

5.3.5

5.3.5 Reports of Efficacy and Safety Studies	
5.3.5.1 Study Reports of Controlled Clinical Studies Pertinent to the Claimed Indication	
[0001] C4591001 - A Phase 1/2/3, Placebo-Controlled, Randomized, Observer-Blind, Dose-Finding Study	
[0001] BNT162-01 - A Multi-Site, Phase I/II, 2-Part, Dose-Escalation Trial Investigating the Safety and Immunogenicity of BNT162-01	
5.3.6 Reports of Postmarketing Experience	
[0001] Postmarketing Experience	
5.4 Literature References	

There are 2 studies, shown here. The record descriptions for each follow

Expanded sections for the Phase 1 / 2 / 3 study are below

5.3.5 Reports of Efficacy and Safety Studies	
5.3.5.1 Study Reports of Controlled Clinical Studies Pertinent to the Claimed Indication	
[0001] C4591001 - A Phase 1/2/3, Placebo-Controlled, Randomized, Observer-Blind, Dose-Finding Study	
Study Report Body Chapter	
[0001] C4591001 - Final Analysis Interim Synopsis	~31 pages
[0001] C4591001 - Interim 6-Month Synopsis	~48 pages
[0001] C4591001 - Final Analysis Interim Report Body	~2033 pages
[0001] C4591001 - Final Analysis Interim Errata	~1 page
[0001] C4591001 - Final Analysis Interim Narrative (sensitive)	~3611 pages
[0001] C4591001 - Interim 6-Month Report Body	~1584 pages
[0001] C4591001 - Interim 6-Month Errata	~2 pages
[0001] C4591001 - Interim 6-Month Narrative	~3697 pages
[0001] Ad Hoc Label	~14 pages

16. APPENDICES

16.1. Study Information

16.1.1 Protocol and/or Amendment

-  [0001] C4591001 - Final Analysis Interim Protocol or Amendment
-  [0001] C4591001 - Final Analysis Interim Independent Oversight Committees
-  [0001] C4591001 - Interim 6-Month Protocol or Amendment
-  [0001] C4591001 - Interim 6-Month Independent Oversight Committees

16.1.2 Sample CRF

-  [0001] C4591001 - Final Analysis Interim Sample Case Report Form
-  [0001] C4591001 - Interim 6-Month Sample Case Report Form

16.1.3 IEC and IRB and Consent Form Listings

-  [0001] C4591001 - Final Analysis Interim IEC IRB Consent Form List
-  [0001] C4591001 - Interim 6-Month IEC IRB Consent Form List

16.1.4 Description of Investigators and Sites

-  [0001] C4591001 - Final Analysis Interim List Description Investigator Site
-  [0001] C4591001 - Interim 6-Month List Description Investigator Site

16.1.5 Signatures of principal or coordinating investigator(s) or sponsor's responsible me

16.1.5 Signatures of principal or coordinating investigator(s) or sponsor's responsible medical

-  [0001] C4591001 - Final Analysis Interim Signatures Sponsors
-  [0001] C4591001 - Final Analysis Interim Signatures Investigators
-  [0001] C4591001 - Interim 6-Month Signatures Sponsors
-  [0001] C4591001 - Interim 6-Month Signatures Investigators

16.1.6 Listing of patients receiving test drug(s) from specified batch

-  [0001] C4591001 - Final Analysis Interim List Patients With Batches
-  [0001] C4591001 - Interim 6-Month List Patients With Batches

16.1.7 Randomisation Scheme

-  [0001] C4591001 - Final Analysis Interim Randomization Scheme
-  [0001] C4591001 - Final Analysis Interim Randomization Scheme (Sensitive)
-  [0001] C4591001 - Interim 6-Month Randomization Scheme (Sensitive)
-  [0001] C4591001 - Interim 6-Month Randomization Scheme

16.1.8 Audit Certificates or similar documentation

-  [0001] C4591001 - Final Analysis Interim Audit Certificates
-  [0001] C4591001 - Interim 6-Month Audit Certificates

16.1.9 Documentation of statistical methods and interim analysis plans

16.1.10 Documentation of Inter-laboratory Standardization Methods and Quality Assurance

- ▲  16.1.9 Documentation of statistical methods and interim analysis plans
 -  [0001] C4591001 - Final Analysis Interim Statistical Methods Analysis Plan
 -  [0001] C4591001 - Interim 6-Month Statistical Methods Analysis Plan
- ▲  16.1.10 Documentation of Inter-laboratory Standardization Methods and Quality Assurance
 -  [0001] C4591001 - Final Analysis Interim Inter Laboratory Standardisation Methods Quality Assurance
 -  [0001] C4591001 - Interim 6-Month Inter Laboratory Standardisation Methods Quality Assurance
- ▲  16.1.11 Publications Based on the Study
 -  [0001] C4591001 - Final Analysis Interim Publications Based on Study
 -  [0001] C4591001 - Interim 6-Month Publications Based on Study
- ▲  16.2. Patient Data Listings
 - ▲  16.2.1 Discontinued Patients Listing
 -  [0001] C4591001 - Final Analysis Interim Discontinued Patients
 -  [0001] C4591001 - Interim 6-Month Discontinued Patients
 - ▲  16.2.2 Protocol Deviation Listing
 -  [0001] C4591001 - Final Analysis Interim Protocol Deviations
 -  [0001] C4591001 - Final Analysis Interim Protocol Deviations (Sensitive)
 -  [0001] C4591001 - Interim 6-Month Protocol Deviations
 - ▲  16.2.3 Patients Excluded from Efficacy Analysis Listing

▲ 16.2.3 Patients Excluded from Efficacy Analysis Listing

▲ [0001] C4591001 - Final Analysis Interim Patients Excluded from Efficacy Analysis (Sensitive)

▲ [0001] C4591001 - Final Analysis Interim Patients Excluded from Efficacy Analysis

▲ [0001] C4591001 - Interim 6-Month Patients Excluded from Efficacy Analysis (Sensitive)

▲ [0001] C4591001 - Interim 6-Month Patients Excluded from Efficacy Analysis

▲ 16.2.4 Demographic Data Listing

▲ [0001] C4591001 - Final Analysis Interim Demographic Data

▲ [0001] C4591001 - Interim 6-Month Demographic Data

▲ 16.2.5 Compliance and/or Drug Concentration Data Listing

▲ [0001] C4591001 - Final Analysis Interim Compliance and Drug Concentration Data (Sensitive)

▲ [0001] C4591001 - Final Analysis Interim Compliance and Drug Concentration Data

▲ [0001] C4591001 - Interim 6-Month Compliance and Drug Concentration Data (Sensitive)

▲ [0001] C4591001 - Interim 6-Month Compliance and Drug Concentration Data

▲ 16.2.6 Individual Efficacy Response Data Listing

▲ [0001] C4591001 - Final Analysis Interim Individual Efficacy Response Data

▲ [0001] C4591001 - Interim 6-Month Individual Efficacy Response Data

▲ 16.2.7 File contains Adverse Event Listings

▲ 16.2.7 File contains Adverse Event Listings

▲ [0001] C4591001 - Final Analysis Interim Adverse Event Listings

▲ [0001] C4591001 - Interim 6-Month Adverse Event Listings

▲ [0001] C4591001 - Interim 6-Month Adverse Event Listings (Sensitive)

▲ 16.2.8 Individual Laboratory Measurements Listed by Patient

▲ [0001] C4591001 - Final Analysis Interim Listing Individual Laboratory Measurements

▲ [0001] C4591001 - Final Analysis Interim Listing Individual Laboratory Measurements (Sensitive)

▲ [0001] C4591001 - Interim 6-Month Listing Individual Laboratory Measurements (Sensitive)

▲ Datasets

▲ Analysis Datasets

- Analysis Datasets (Legacy)
 - [0001] Annotated Case Report Form - Suppl**
 - Analysis Datasets (ADaM)
 - [0001] Analysis Data Reviewers Guide
 - [0001] Analysis Dataset Definition
 -  [0001] Analysis Dataset Definition Stylesheet
 - [0001] bmi-12-15-scale - PDF
 -  [0001] bmi-12-15-scale - XLSX
 - [0001] c4591001-phase-1-subjects-from-dmw - PDF

- [0001] c4591001-phase-1-subjects-from-dmw - PDF
-  [0001] c4591001-phase-1-subjects-from-dmw - XLSX
- [0001] c4591001-subject-list-for-12-25-immuno-analysis-27jan2021 - PDF
-  [0001] c4591001-subject-list-for-12-25-immuno-analysis-27jan2021 - XLSX
- [0001] comorbidity-categories - PDF
-  [0001] comorbidity-categories - XLSX
- [0001] first-c4591001-360-participants-enrolled-v1-13aug2020-update - PDF
-  [0001] first-c4591001-360-participants-enrolled-v1-13aug2020-update - XLSX
- [0001] newlist-c4591001-6k-participants-enrolled-v3-17sep2020 - PDF
-  [0001] newlist-c4591001-6k-participants-enrolled-v3-17sep2020 - XLSX
- [0001] report-cci-aids-hiv - PDF
-  [0001] report-cci-aids-hiv - XLSX
- [0001] report-cci-any-malignancy - PDF
-  [0001] report-cci-any-malignancy - XLSX
- [0001] report-cci-cerebrovascular - PDF
-  [0001] report-cci-cerebrovascular - XLSX
- [0001] report-cci-chf - PDF
-  [0001] report-cci-chf - XLSX

-  [0001] report-cci-chf - XLSX
-  [0001] report-cci-dementia - PDF
-  [0001] report-cci-dementia - XLSX
-  [0001] report-cci-diabetes-with-comp - PDF
-  [0001] report-cci-diabetes-with-comp - XLSX
-  [0001] report-cci-diabetes-without-comp - PDF
-  [0001] report-cci-diabetes-without-comp - XLSX
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-  [0001] report-cci-hemiplegia - XLSX
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-  [0001] report-cci-lymphoma - XLSX
-  [0001] report-cci-metastatic-tumour - PDF
-  [0001] report-cci-metastatic-tumour - XLSX
-  [0001] report-cci-mi - PDF
-  [0001] report-cci-mi - XLSX
-  [0001] report-cci-mild-liver - PDF

-  [0001] report-cci-mild-liver - PDF
-  [0001] report-cci-mild-liver - XLSX
-  [0001] report-cci-mod-sev-liver - PDF
-  [0001] report-cci-mod-sev-liver - XLSX
-  [0001] report-cci-peptic-ulcer - PDF
-  [0001] report-cci-peptic-ulcer - XLSX
-  [0001] report-cci-periph-vasc - PDF
-  [0001] report-cci-periph-vasc - XLSX
-  [0001] report-cci-pulmonary - PDF
-  [0001] report-cci-pulmonary - XLSX
-  [0001] report-cci-renal - PDF
-  [0001] report-cci-renal - XLSX
-  [0001] report-cci-rheumatic - PDF
-  [0001] report-cci-rheumatic - XLSX
-  [0001] 201114-hiv-preferred-terms - PDF
-  [0001] 201114-hiv-preferred-terms - XLSX
-  [0001] Analysis Dataset Definition - Suppl
-  [0001] Analysis Dataset Definition Stylesheet - Suppl

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Program Files

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 CRF's

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-  [0001] Supplemental Analysis Reviewer Guide - Suppl
-  [0001] Roadmap for SDTM Dataset Updates - Suppl
-  [0001] Summary of Differences (CSR vs Update) - Suppl
-  [0001] Updated Reactogenicity TLFs - Suppl
-  [0001] Final Reactogenicity Tables (Track Changes) - Suppl
-  [0001] Data Tabulation Data Definition - Suppl
-  [0001] Data Tabulation Data Definition Stylesheet - Suppl

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-  [0001] Clinical Study Data Reviewers Guide
-  [0001] Data Tabulation Data Definition
-  [0001] Data Tabulation Data Definition Stylesheet
-  [0001] Annotated Case Report Form

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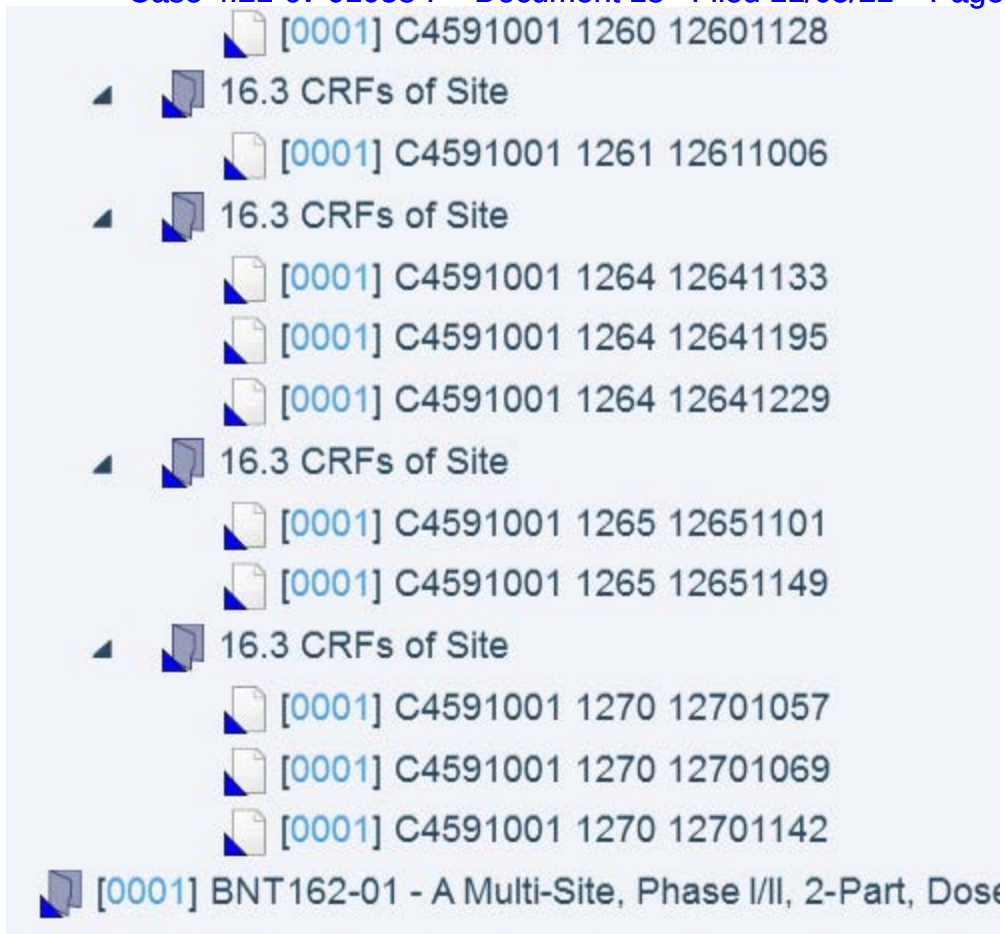
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That is the end of the first study

See below for the Phase I/II study

▲	▲	▲	[0001]	BNT162-01 - A Multi-Site, Phase I/II, 2-Part, Dose-Escalation Trial Investigating the Safety and
	▲	▲		Study Report Body Chapter
		▲	▲	[0001] BNT162-01 - Third Interim Synopsis
			▲	[0001] BNT162-01 - Third Interim Report Body
			▲	[0001] BNT162-01 - Third Interim Notes for the Reader
	▲	▲		16. APPENDICES
		▲	▲	16.1. Study Information
			▲	16.1.1 Protocol and/or Amendment
			▲	[0001] BNT162-01 - Third Interim Protocol or Amendment
			▲	16.1.2 Sample CRF
			▲	[0001] BNT162-01 - Third Interim Sample Case Report Form
			▲	16.1.3 IEC and IRB and Consent Form Listings
			▲	[0001] BNT162-01 - Third Interim IEC IRB List
			▲	16.1.4 Description of Investigators and Sites
			▲	[0001] BNT162-01 - Third Interim List Description Investigator Site
			▲	16.1.5 Signatures of principal or coordinating investigator(s) or sponsor's responsible me
			▲	[0001] BNT162-01 - Third Interim Signatures Investigators

-  [0001] BNT162-01 - Third Interim Signatures Investigators
-  [0001] BNT162-01 - Third Interim Signatures Sponsors
- ▲  16.1.6 Listing of patients receiving test drug(s) from specified batch
 -  [0001] BNT162-01 - Third Interim List Patients with Batches
- ▲  16.1.9 Documentation of statistical methods and interim analysis plans
 -  [0001] BNT162-01 - Third Interim Statistical Methods Analysis Plan
- ▲  16.1.12 Publications Referenced in the Study Report
 -  [0001] BNT162-01 - Third Interim Publications Referenced in Report
 -  [0001] BNT162-01 - Third Interim List of Sponsor Personnel who Mater
- ▲  16.2. Patient Data Listings
 - ▲  16.2.1 Discontinued Patients Listing
 -  [0001] BNT162-01 - Third Interim Discontinued Patients
 - ▲  16.2.2 Protocol Deviation Listing
 -  [0001] BNT162-01 - Third Interim Protocol Deviations
 - ▲  16.2.3 Patients Excluded from Efficacy Analysis Listing
 -  [0001] BNT162-01 - Third Interim Patients Excluded from Efficacy Analy
 - ▲  16.2.4 Demographic Data Listing
 -  [0001] BNT162-01 - Third Interim Demographic Data

-  [0001] BNT162-01 - Third Interim Demographic Data
- ▲  16.2.5 Compliance and/or Drug Concentration Data Listing
 -  [0001] BNT162-01 - Third Interim Reports
 -  [0001] BNT162-01 - Third Interim Compliance and Drug Concentration Data
- ▲  16.2.7 File contains Adverse Event Listings
 -  [0001] BNT162-01 - Third Interim Adverse Event Listings
- ▲  16.2.8 Individual Laboratory Measurements Listed by Patient
 -  [0001] BNT162-01 - Third Interim Listing of Individual Laboratory Measurements
- ▲  Datasets
 - ▲  Analysis Datasets
 - ▲  Analysis Datasets (ADaM)
 -  [0001] Analysis Dataset Definition
 -  [0001] Analysis Dataset Definition Stylesheet
 -  [0001] Analysis Data Reviewers Guide
 - ▶  Datasets
 - ▲  Tabulation Datasets
 - ▲  Tabulation Datasets (SDTM)
 -  [0001] Data Tabulation Data Definition

▲ Tabulation Datasets

▲ Tabulation Datasets (SDTM)

 [0001] Data Tabulation Data Definition

 [0001] Clinical Study Data Reviewers Guide

  [0001] Data Tabulation Data Definition Stylesheet

 [0001] Annotated Case Report Form

▲ Datasets

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5.3.6 Reports of Postmarketing Experience

5.4 Literature References