IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS

PUBLIC HEALTH AND MEDICAL PROFESSIONALS FOR TRANSPARENCY, Plaintiff, v. UNITED STATES FOOD AND DRUG ADMINISTRATION, Defendant.	Civil Action No. 4:21-cv-01058-P

DEFENDANT'S BRIEF IN ADVANCE OF SCHEDULING CONFERENCE

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Pursuant to the Court's Order of November 18, 2021, ECF No. 21, Defendant, the U.S. Food and Drug Administration ("FDA"), respectfully submits this brief and attached appendix to assist the Court in setting a schedule for the processing of records responsive to Plaintiff's Freedom of Information Act ("FOIA") request.

LEGAL BACKGROUND

The Freedom of Information Act provides that any person has a right to obtain access to federal agency records subject to the Act, except to the extent that any portions of such records are protected from public disclosure by one or more of nine exemptions listed in the Act. *See* 5 U.S.C. § 552 (a)(3), (a)(4)(B), (b), (c); *see also Dep't of Air Force v. Rose*, 425 U.S. 352, 362–65 (1976) (stating that FOIA "assure[s] public access to all governmental records whose disclosure would not significantly harm specific governmental interests"). Under FOIA, a person may submit a request to a federal agency "reasonably decrib[ing]" records that s/he seeks to obtain. 5 U.S.C. § 552(a)(3)(A). An agency that has received a FOIA request is required, as relevant here, to "determine within 20 days (excepting Saturdays, Sundays, and legal public holidays) after the receipt of any such request whether to comply with such request." *Id.* § 552(a)(6)(A)(i). FOIA further provides that a requester "shall be deemed to have exhausted his administrative remedies with respect to such request if the agency fails to comply with the applicable time limit provisions." *Id.* § 552(a)(6)(C)(i).

FOIA's 20-working-day time period does not create a deadline for production. *Citizens for Responsibility & Ethics in Wash. v. FEC*, 711 F.3d 180, 189–90 (D.C. Cir. 2013).[1] Rather, "if the agency does not adhere to FOIA's explicit timelines, the 'penalty' is that the agency cannot rely on the administrative exhaustion requirement to keep cases from getting into court."

[1] Courts often rely on case law concerning FOIA from the D.C. Circuit, as it is "the federal appellate court with the most experience in this field." *Cooper Cameron Corp. v. U.S. Dep't of Labor*, 280 F.3d 539, 543 (5th Cir. 2002).

Id. No other provision in FOIA creates a specific timeframe for the release of records. *See* 5 U.S.C. §§ 552(a)(3)(A) (an agency shall make records responsive to a proper request "promptly available"), (a)(6)(C)(i) (same for litigated cases).

Indeed, the time required to process a FOIA request will inherently depend on the scope of the request and the nature of the information the requested records contain. Federal law generally prohibits the release of certain types of information, such as trade secrets and personal medical information. *See* 21 U.S.C. § 331(j); 18 U.S.C. § 1905; 21 C.F.R. §§ 20.61, 20.63. Consistent with these obligations to protect sensitive information, FOIA exempts several types of information from its production requirements. 5 U.S.C. § 552(b); *see Food Mktg. Inst. v. Argus Leader Media*, 139 S. Ct. 2356, 2366 (2019) ("FOIA expressly recognizes that 'important interests [are] served by [its] exemptions,' and '[t]hose exemptions are as much a part of [FOIA's] purpose[s and policies] as the [statute's disclosure] requirement.'" (brackets in original) (quoting *FBI v. Abramson*, 456 U.S. 615, 630–631 (1982); *Encino Motorcars, LLC v. Navarro*, 138 S. Ct. 1134, 1142 (2018))). As particularly relevant to this case, FOIA Exemption 4 permits withholding of "trade secrets and commercial or financial information obtained from a person and [that are] privileged or confidential.'" 5 U.S.C. § 552(b)(4). And Exemption 6 permits agencies to withhold or redact "personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy." 5 U.S.C. § 552(b)(6). To ensure protection of this information and other information that is exempt from disclosure under FOIA, government agencies must carefully review all records and redact exempt information before the records are released to the FOIA requester. *See Daily Caller v. Dep't of State*, 152 F. Supp. 3d 1, 14 (D.D.C. 2015) (stating that the government has a

"responsibility" when processing FOIA requests to "safeguard[] potentially sensitive information").

FACTUAL BACKGROUND

I. Plaintiff's FOIA Request

On August 27, 2021, FDA received a FOIA request from Plaintiff seeking "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." Ex. A (Decl. of Suzann Burk) ¶ 24 (hereinafter "Burk Decl.") (App011).[2] Because the regulation cited by Plaintiff, 21 C.F.R. § 601.51, addresses "data and information in applications for biologics licenses," FDA interpreted Plaintiff's FOIA request as a request for all publicly releasable information in the original biologics license application ("BLA") submitted by BioNTech-Pfizer for the Comirnaty vaccine with internal file number STN 125742/0/0 ("original Comirnaty BLA"). *Id.* ¶ 25 (App011–12).

Based on FDA's initial assessment of the number of records potentially responsive to Plaintiff's FOIA request, FDA determined that the original Comirnaty BLA requested by Plaintiff comprises more than 329,000 pages of records. *Id.* (App012). In addition to those 329,000 pages, the original Comirnaty BLA includes data files in a format similar to a spreadsheet for which a page count cannot readily be determined. *Id.* (App012). FDA has assessed that the original Comirnaty BLA contains at least 126 of these data files. *Id.* (App012). Many of those data files themselves are very large, containing dozens of columns and over ten thousand rows of data. *Id.* (App012).

[2] Pursuant to this Court's Motion Practice standard II.C., the portions of the appendix relied upon are underlined.

II. The Parties' Negotiations Concerning a Processing Schedule

After Plaintiff filed its Complaint, ECF No. 1, and FDA filed its answer, ECF No. 14, the parties engaged in negotiations concerning a schedule for the processing and production of the non-exempt portions of records responsive to Plaintiff's FOIA request.[3]

To assist in negotiations and to assist Plaintiff in prioritizing certain records for processing and production, FDA provided two lists to Plaintiff revealing the (non-confidential) titles of sections of the original Comirnaty BLA. Burk Decl. ¶ 26 (App013). Those two lists, which served as something analogous to an index to certain sections of the original biological license application, totaled nearly 90 pages. *Id.* (App013). Where feasible and as a courtesy, FDA also annotated portions of the longer list (hereinafter, the "Index") with approximate page counts per section of the original Comirnaty BLA to assist Plaintiff in identifying documents for priority processing. *See* Ex. B (Index) (App022–108).

Once subsequent discussions revealed that Plaintiff was most interested in Section 5.2 of the original Comirnaty BLA and the raw data contained in Section 5.3 of the original Comirnaty BLA, FDA searched its system for those sections to evaluate their size and scope. Burk Decl. ¶ 26 (App013). FDA assessed that Sections 5.2 and 5.3 comprise more than 321,000 pages of records (plus additional data files) and requested that Plaintiff use the provided Index to prioritize the production of certain records. *Id.* (App013).

III. Plaintiff's Priority List

On November 4, 2021, Plaintiff provided FDA with the below list of records they requested FDA prioritize for processing ("Plaintiff's Priority List") in order of priority:

1. CRFs for site 1055 (from page 27 of the provided Index)

[3] These negotiations were described in detail in the parties' two joint reports. *See* ECF Nos. 18, 20. Only the negotiations relevant to FDA's current processing proposal are repeated in this filing.

2. CRFs for site 1081 (from page 31 of the provided Index)

3. CRFs for site 1096 (from page 38 of the provided Index)

4. CRFs for site 1128 (from page 46 of the provided Index)

5. Program Files/SAS files. Plaintiff requested 3 to 4 SAS files as a sample, in the first instance, so that it could assess whether it would like to prioritize the complete universe of SAS files. (from page 10 of the provided Index)

6. Section 5.2 of the original Comirnaty BLA – Tabular Listing of all Clinical Studies (from page 1 of the provided Index)

7. Section 4 of the original Comirnaty BLA – Nonclinical Study Reports (from page 1 of the provided Index)

8. Section 5.3.6 of the original Comirnaty BLA – Reports of Postmarketing Experience (from page 2 of the provided Index)

9. Section 16.1.1 of the original Comirnaty BLA – Protocol and/or Amendment, and specifically, Final Analysis Interim Independent Oversight Committees (from page 3 of the provided Index)

10. In the Analysis Datasets (ADaM) Section -- the Analysis Data Reviewers Guide, Analysis Dataset Definition, and Analysis Dataset Definition Stylesheet (from page 6 of the provided Index)

11. Tabulation Datasets (from page 11 of the provided Index)

12. CRFs for site 1085 (from page 33 of the provided Index)

Ex. C (Emails from Aaron Siri to Courtney Enlow) (Nov. 4, 2021)) (App122). Government counsel proposed that FDA process certain documents on Plaintiff's priority list by November 17 and December 1, 2021, with the parties to confer after December 1 regarding future productions. Plaintiff rejected that proposal.

IV. FDA's Productions of Records to Plaintiff

Although Plaintiff rejected FDA's production proposal, FDA nevertheless has been working to process and produce the non-exempt portions of records from Plaintiff's Priority List. FDA completed its proposed November 17 and December 1 productions. Burk Decl. ¶ 27 (App013–14). Specifically, on November 17, 2021, FDA produced all publicly releasable

information from the following:

- A portion of Plaintiff's priority item #5:
    - One .txt file; and
    - One SAS (data) file;[4]
- A portion of Plaintiff's priority item #6:
    - From Section 5.2 of the original Comirnaty BLA: The Tabular Listing;
    - From Section 5.2 of the original Comirnaty BLA: The Listing of Clinical Sites;
- Plaintiff's priority item #8:
    - From Section 5.3.6 of the original Comirnaty BLA: The Reports of Postmarketing Experience.

Id. (App013–14). This production amounted to 91 pages of records, as well as the two data files (the .txt and SAS files). FDA redacted material from the 91 pages under FOIA Exemptions 4 and 6 to protect the disclosure of trade secrets and commercial or financial information that was obtained from a person outside the government and that is privileged or confidential and to protect personal privacy. Because FDA assessed that there was no exempt material in the data files included in this production, FDA made no deletions or redactions to those files.

On December 1, 2021, FDA made a second release. Burk Decl. ¶ 27 (App014–15). Specifically, FDA produced publicly releasable information from the remainder of Section 5.2 of the original Comirnaty BLA to Plaintiff, making redactions under FOIA Exemption 6 to protect personal privacy. With this 248-page production, FDA completed processing and production of item 6 on Plaintiff's Priority List. Thus, as of the time of this filing, FDA has produced to

[4] In communications between FDA and Plaintiff, Plaintiff indicated that it was interested in obtaining "sample" SAS files, but none of the files Plaintiff identified in its priority list was an SAS file. Instead, Plaintiff identified .txt files that included "SAS" in their file names. In an attempt to provide Plaintiff with the information it requested, FDA produced one of the .txt files Plaintiff requested, as well as one xpt (SAS) file even though Plaintiff did not specifically prioritize any SAS files in its priority list. As a result, FDA's November 17, 2021, production included more records than FDA initially proposed. Burk Decl. ¶ 27 n.5 (App013).

Plaintiff the non-exempt portions of 339 pages, as well as two data files, and has completed processing and production of two items on Plaintiff's Priority List (items 6 and 8).

V. FDA's Upcoming Production of Records to Plaintiff

Since the time the parties filed their Second Joint Report, ECF No. 20, FDA has had an opportunity to assess the amount of time it will take to review additional records on Plaintiff's Priority List and has determined that it can complete processing of certain records at a pace faster than the previously proposed 500-pages-per-month rate.[5] *See* Burk Decl. ¶¶ 27–29 (App014–16). Accordingly, by December 13, 2021, FDA anticipates producing publicly releasable information from the following:

- All documents related to Plaintiff's priority item #1 – CRF files for site 1055 (approximately 2,030 pages);
- All remaining documents related to Plaintiff's priority item #5 –
    - Four additional .txt files that were listed on page 10 of the Index;
    - Four additional SAS files (not specifically listed on Plaintiff's priority list, but Plaintiff has expressed interest in these files during the course of negotiations).
- Publicly releasable information from the following additional sections of the original Comirnaty BLA:
    - Section 2.5 – Clinical Overview (approximately 333 pages)
    - Section 2.7.3 – Summary of Clinical Efficacy (approximately 182 pages)
    - Section 2.7.4 – Summary of Clinical Safety (approximately 344 pages)

Id. ¶ 27 (App014–15).

Thus, by the time of the Court's status conference on December 14, 2021, FDA anticipates that it will have produced to Plaintiff more than 3,000 pages of responsive materials,

[5] In light of FDA's assessment, on December 1, 2021, undersigned counsel informed Plaintiff's counsel of FDA's updated proposed processing schedule (as set forth here and below) and asked if Plaintiff would be amenable to the proposed schedule. As of the time of this filing, Plaintiff has not indicated whether it would accept this proposal.

most of which were listed on Plaintiff's Priority List. *Id.* (App015). Moreover, FDA will have completed processing and production of four items on Plaintiff's Priority List (items 1, 5, 6, and 8). *Id.* (App013–15).

FDA'S UPDATED PROPOSAL FOR A PROCESSING SCHEDULE

In addition to the December 13 production, FDA expects to be able to produce the next three items on Plaintiff's Priority List (items 2, 3, and 4) before the end of January 2022. Burk Decl. ¶ 28 (App015–16). FDA proposes to produce the below records to Plaintiffs according to the following schedule:

- **Thursday, December 30, 2021**: FDA proposes to produce publicly releasable information from Plaintiff's priority item #2 – CRF files for site 1081 (approximately 3,380 pages);
- **Tuesday, January 18, 2022**: FDA proposes to produce publicly releasable information from Plaintiff's priority item #3 – CRF files for site 1096 (approximately 2,937 pages); and
- **Monday, January 31, 2022**: FDA proposes to produce publicly releasable information from Plaintiff's priority item #4 – CRF files for site 1128 (approximately 3,452 pages).

Id. (App015).

If the Court adopts this schedule, by the end of January 2022, FDA will have produced publicly releasable information from more than **12,000 pages** of records and 10 unpaginated .txt or SAS data files. *Id.* (App015). Moreover, FDA will have completed production of seven of the first eight items on Plaintiff's Priority List (items 1, 2, 3, 4, 5, 6, and 8). *Id.* (App015–16).

Because FDA has not yet had an opportunity to assess the amount of time it will take to process other records responsive to Plaintiff's FOIA request, following the January 31, 2022 production, FDA proposes to make one production at the end of each subsequent month totaling

a minimum of 500 pages.[6] *Id.* ¶ 29 (App016). FDA's general estimate is that it takes approximately 8 minutes per page to review records for a FOIA production. *Id.* ¶¶ 18, 29 (App007, App016). It is difficult for FDA to know whether records will take more or less than the estimated eight minutes per page until reviewers have had an opportunity to perform at least a preliminary review of those records. *Id.* ¶¶ 18, 29 (App007–08, App016). Certain records will likely include more confidential information, and thus more corresponding redactions, which will require more research and production time. *Id.* ¶¶ 18, 29 (App007, App016). Once FDA has an opportunity to assess processing times for other records responsive to Plaintiff's FOIA request, FDA may be able to process and produce the non-exempt portions of records to Plaintiff at a rate faster than 500 pages per month. *Id.* ¶ 29 (App016). Thus, although FDA proposes a minimum rate of 500 pages a month after the January 31, 2022 production, FDA will produce records at a faster rate where feasible. *Id.* (App016).

ARGUMENT

FDA's Processing Schedule is Reasonable and Fair to All Requesters

As demonstrated below, the Court should adopt FDA's proposed schedule because it properly balances the interest of Plaintiff in receiving records responsive to its FOIA request with the interests of the vaccine sponsor in the protection of its confidential information, the interests of clinical trial participants in the protection of their personal privacy information, and the interests of other FOIA requesters whose requests are being processed alongside Plaintiff's. The proposed schedule is also feasible for FDA to complete with its limited processing resources and is not only consistent with processing schedules entered by other courts, but would in fact

[6] For purposes of calculating a "page count" of data records that are not paginated, FDA proposes considering twenty lines of spreadsheet data the equivalent of one page. For example, production of a spreadsheet containing 2,000 lines of data would be counted the equivalent of a 100-page PDF record.

result in the FDA producing records to Plaintiff at a rate much faster than most courts order.

First, FDA's proposed schedule properly addresses the interest of Plaintiff in receiving records because the schedule would result in production of the non-exempt portions of more than 12,000 pages of records and 10 unpaginated .txt or SAS data files to Plaintiff in less than two months from the date of the scheduling conference. Burk Decl. ¶ 28 (App015). Moreover, this schedule would result in the expedited production of seven of the twelve items on Plaintiff's Priority List (items 1, 2, 3, 4, 5, 6, and 8). *Id.* (App015–16).

In addition, FDA's proposed schedule provides FDA adequate time to assess whether records contain material that is exempt from production under FOIA and redact that exempt information. Plaintiff has requested records that comprise information submitted by the vaccine sponsor (Pfizer-BioNTech) to FDA. *Id.* ¶ 24 (App011). From FDA's experience with other similar 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 patients who participated in clinical trials. *Id.* ¶ 36 (App019–20). FDA is required to protect certain information under the law and this type of information is exempt from production under the FOIA. *See* 5 U.S.C. § 552(b)(4), (b)(6); *F.B.I. v. Abramson*, 456 U.S. 615, 621 (1982) ("Congress realized that legitimate governmental and private interests could be harmed by release of certain types of information and provided nine specific exemptions under which disclosure could be refused."); *see also* Burk Decl. ¶ 9 (App004). 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. *See* Burk Decl. ¶¶ 11, 13, 34 (App005, App006, App0018–19); *see also Daily Caller*, 152 F. Supp. 3d at 14. Moreover, if FDA determines not to withhold information that might be confidential

commercial information, it is sometimes required by regulation to provide notice to the company that submitted the information and an opportunity to file a claim for injunctive relief (a "reverse FOIA" claim). *See, e.g.*, 21 C.F.R. §§ 20.47, 20.48, 20.61(e).

FDA has assessed it can conduct this necessary review at a faster rate than normal for the 12,000 pages and 10 data files that comprise FDA's proposed productions through January 31, 2022. Burk Decl. ¶ 28 (App015). But FDA has not yet had a chance to make an assessment concerning the time it will take to review records after the proposed January 31, 2022 production. *Id.* ¶ 29 (App016). FDA is therefore relying on its standard rate of 8 minutes per page for review to propose a processing rate of 500 pages per month for subsequent productions. *Id.* (App016).

Furthermore, FDA's proposed schedule adequately protects the interests of other FOIA requesters. FDA, and specifically, the Center for Biologics Evaluation and Research ("CBER"), which maintains the records requested by Plaintiff, has 459 pending FOIA requests. *Id.* ¶ 22 (App010). Of the 459 requests pending before CBER, approximately 329 were received before Plaintiff's. *Id.* ¶ 22 (App010). Many of these new requests, including the request at issue in this case, have sought large amounts of data that require significant resources to process. *Id.* ¶ 21 (App009). The branch responsible for processing FOIA requests for CBER-maintained documents, CBER's Access Litigation and Freedom of Information Branch, has ten staff members – one branch chief and nine full-time staff members.[7] *Id.* ¶¶ 4, 31, 35 (App003, App007, App019). Two of those members began working for the office within the last four months and, because they are new staff members, they are not yet able to review records at the same rate as more experienced staff members. *Id.* ¶ 31 n.7 (App017).

[7] Along with processing FOIA requests, these ten staff members are also responsible for helping to address non-FOIA litigation-related document requests.

FDA is not able to commit to processing Plaintiff's request at a faster rate than the 12,000 pages and 10 data files by January 31, 2022, and 500 pages per month thereafter, without diverting significant resources away from the processing of other FOIA requests that are also in litigation, requests that are ahead of Plaintiff's in CBER's processing queues, as well as other non-FOIA record requests (such as, for example, document review to respond to discovery requests and third-party subpoenas). *Id.* ¶¶ 5, 8, 17, 36 (App003, App004, App007, App019–20). Such diversion would adversely impact FDA's ability to meet stipulated document processing deadlines and would be fundamentally unfair to other FOIA requesters, the majority of whom submitted their FOIA requests before Plaintiff and who likely believe, as Plaintiff does, that their FOIA request is important and needs to be processed expeditiously. *See id.* ¶ 22 (App010–11); *see also Elec. Privacy Info. Ctr. v. Dep't of Justice*, 15 F. Supp. 3d 32, 47 (D.D.C. 2014) (denying motion for preliminary injunction requesting immediate production of documents pursuant to FOIA request and noting that allowing the plaintiff "to jump to the head of the line would upset the agency's processes and be detrimental to the other expedited requesters"); *Daily Caller*, 152 F. Supp. 3d at 14 (stating that "the plaintiff's effort to jump to the head of the FOIA processing line would work a significant burden on both the agency and numerous interested parties").

Finally, FDA's proposed schedule that will result in production of the non-exempt portions of more than 12,000 pages and 10 data files by January 31, 2022, and 500 pages per month thereafter, Burk Decl. ¶ 28 (App015–16), is a processing rate that is much faster than other courts have ordered. As the D.C. Circuit has recognized, an agency's policy of processing 500 pages per request per month "serves to promote efficient responses to a larger number of requesters." *Nat'l Sec. Counselors v. Dep't of Justice*, 848 F.3d 467, 471–72 (D.C. Cir. 2017).

Numerous other courts have entered processing schedules requiring production of the non-exempt portions of 500 pages per month. *See, e.g.*, *Blakeney v. FBI*, No. 17-cv-2288 (BAH), 2019 WL 450678, at *2 (D.D.C. Feb. 5, 2019); *Republican Nat'l Comm. v. Dep't of State*, No. 16-cv-486, 2016 WL 9244625, at *1 (D.D.C. Sept. 16, 2016); *Color of Change v. Dep't of Homeland Sec.*, 325 F. Supp. 3d 447, 451 (S.D.N.Y. 2018); *Davis v. Dep't of Homeland Sec.*, No. 11-cv-203 (ARR) (VMS), 2013 WL 3288418, at *1 (E.D.N.Y. June 27, 2013). Courts do not waiver from the standard 500 page per month processing rate even when a FOIA request would take significant time to process. *See, e.g.*, *Colbert v. FBI*, No. 16-CV-1790 (DLF), 2018 WL 6299966, at *3 (D.D.C. Sept. 3, 2018) (permitting a processing rate of 500 pages per month for 71,000 responsive records).

In sum, FDA's proposed processing schedule is fair to Plaintiff. It results in the non-exempt portions of 12,000 pages and 10 data files produced to Plaintiff in less than 60 days and accommodates Plaintiff's request to prioritize production of numerous records. Burk Decl. ¶ 28 (App015–16). It is fair to the vaccine sponsor and individuals who participated in clinical trials, as the schedule allows FDA adequate time to review the records for confidential commercial information and information that would result in an unwarranted invasion of personal privacy. *Id.* ¶ 36 (App019–20). And it is fair to other FOIA requesters, who should not be prejudiced merely because Plaintiff has the resources to file a lawsuit in an attempt to obtain a faster processing schedule. *Id.* (App019–20).

CONCLUSION

For the foregoing reasons, Defendant respectfully requests that the Court enter FDA's proposed processing schedule.

Dated: December 6, 2021

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on December 6, 2021, I electronically transmitted the foregoing to the parties and the clerk of court for the United States District Court for the Northern District of Texas using the CM/ECF filing system.

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Exhibit A

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

DECLARATION OF SUZANN BURK

I, Suzann Burk, hereby declare as follows:

1. I am the Director of the Division of Disclosure and Oversight Management ("DDOM"), Office of Communication Outreach and Development, Center for Biologics Evaluation and Research ("CBER"), United States Food and Drug Administration ("FDA"), in Silver Spring, Maryland.

2. As the Director of DDOM, I have overall responsibility for the disclosure of documents officially maintained by CBER, the center in FDA that regulates biological products such as blood, vaccines, gene therapy, and human cells, tissues, and cellular and tissue-based products. I have been the Director of DDOM since June 24, 2018. Prior to that date, I was the Team Lead of the Electronic Disclosure Team in DDOM for approximately nine and one-half years. Before that, I was a member of the Congressional and Oversight Branch in DDOM for two years and a member of the Access Litigation and Freedom of Information Branch ("ALFOI") in DDOM for four years.

3. DDOM is composed of the ALFOI, the Congressional and Oversight Branch, and the Electronic Disclosure Team.

4. ALFOI consists of one branch chief and nine full time branch members who handle the day-to-day work involved in the document disclosure duties described in paragraph 5. Two of those staff members are new employees who began working in ALFOI within the last four months.

5. ALFOI is responsible for the review and disclosure of CBER-maintained documents in response to: (a) Freedom of Information Act ("FOIA") requests; (b) litigation-related document requests; and (c) c ertain other requests that do not fall within established categories assigned to the other teams in DDOM. Litigation-related document production covers disclosure in response to discovery requests, third-party subpoenas, and court orders to process records in response to FOIA requests. ALFOI also responds to consults from other federal agencies and other FDA components that are processing FOIA requests for records that contain information related to CBER's equities. These records need to be reviewed, redacted, and returned to the original government entity for production.

6. The statements contained in this declaration are based upon my personal knowledge, and upon information provided to me in my official capacity.

7. The purpose of this declaration is to explain ALFOI's process for handling FOIA requests, and to explain ALFOI's receipt and handling of the FOIA request submitted by Plaintiff Public Health and Medical Professionals for Transparency ("Plaintiff"), which was assigned the tracking number 2021-5683 ("Plaintiff's Request").

8. As explained below, CBER has experienced a significant increase in incoming FOIA requests, with an unprecedented volume of pending requests. This surge began in 2019. It

accelerated in 2021, largely as the result of requests related to FDA's work pertaining to the COVID-19 pandemic. Along with the increase in FOIA requests, CBER experienced an increase in FOIA litigation over the last three years. This increased volume, when combined with the Agency's existing FOIA and non-FOIA workload, prevents FDA's FOIA reviewers from committing to processing Plaintiff's request at a faster rate than 500 pages per month without diverting significant resources away from the processing of other FOIA requests that are also in litigation, requests that are ahead of Plaintiff's in CBER's queues, as well as other non-FOIA record requests. Such diversion would adversely impact the Agency's ability to meet stipulated document processing deadlines and prejudice other pending requests.

LEGAL OBLIGATIONS TO PROTECT CONFIDENTIAL INFORMATION

9. The majority of documents that are responsive to FOIA requests received by CBER contain information that is exempt from disclosure (for example, trade secret, confidential commercial, and/or personal privacy information). The Federal Food, Drug, and Cosmetic Act ("FDCA") prohibits the release of trade secret information to persons other than Department of Health and Human Services employees, to Congress, or to the courts where relevant in cases brought under the FDCA. 21 U.S.C. § 331(j). The Trade Secrets Act prohibits the release of trade secret information unless otherwise authorized by law. 18 U.S.C. § 1905. In addition, FDA regulations provide, *inter alia*, that: (a) trade secret and privileged or confidential commercial information is unavailable for public disclosure; and (b) identifying information in medical or similar files, which, if disclosed, would be an unwarranted invasion of personal privacy, is unavailable for public disclosure. 21 C.F.R. §§ 20.61, 20.63, respectively.

10. Consistent with these requirements to protect confidential information, FOIA exempts several categories of information from its disclosure requirements. 5 U.S.C. § 552(b).

For example, FOIA exempts from its disclosure requirements: trade secrets and confidential commercial or financial information obtained from a person, 5 U.S.C. § 552(b)(4); and personnel, medical, and similar files if disclosure would result in a clearly unwarranted invasion of personal privacy, 5 U.S.C. § 552(b)(6).

11. As a result, it is important for FDA to perform a careful line-by-line, word-by-word review of all responsive records before producing them in response to a FOIA request to ensure exempt material is not disclosed.

ALFOI'S PROCESS FOR HANDLING FOIA REQUESTS

12. FOIA requests for CBER-maintained documents are forwarded from FDA's Division of Freedom of Information ("DFOI") in the Office of the Executive Secretariat, Office of the Commissioner, FDA. ALFOI places each request in one or more of six queues of pending requests, based on the complexity and/or subject matter of the requested documents. Requests in each queue are generally assigned to reviewers for processing on a first-in, first-out basis. ALFOI's queues consist of the Fast, Simple, 510(k), Adverse Event, Influenza, and Complex Tracks. The Adverse Event and Influenza queues have simple and complex sub-queues. Requests related to FDA's work related to the COVID-19 pandemic could fall under any of the Fast, Simple, Adverse Event, or Complex queues.

13. When a request is assigned to a reviewer for processing, the reviewer must search for and collect potentially responsive records from various file locations, including hard copy and electronic filing systems. In addition, a reviewer may need to contact CBER personnel and direct them to search their individual files. After the reviewer collects potentially responsive records, s/he conducts an initial review to verify that the records are, in fact, responsive to the requests. Records available only in hard-copy are scanned into electronic files. Next, the

reviewer conducts a line-by-line, word-by-word disclosure review of the responsive records to determine which, if any, FOIA exemptions apply, and then electronically redacts the material, as appropriate. ALFOI's review may (and often does) require research to evaluate whether certain information falls within a FOIA exemption. For example, an ALFOI reviewer may perform on-line research to determine whether certain information has been made public (i.e., is not "confidential").

14. ALFOI may consult with FDA's Office of Chief Counsel to resolve questions on complex or novel disclosure issues. Then, the reviewer conducts a quality control check to ensure that the responsive records have been properly prepared for public disclosure and, finally, prepares copies of the responsive records for delivery to the requester. Throughout the process, the ALFOI branch chief or I may provide substantive input regarding the search's scope and whether the records may be disclosed.

15. Additionally, if a document contains information belonging to other equity holders, such as other federal agencies, FDA will send out that document to the relevant federal agencies for consultation. These consultations can occur more than once in the review process and inform FDA's determination about the applicability of any FOIA exemption.

16. After the necessary review and internal and external consultations have been performed, records may be transmitted to FDA's Office of the Chief Counsel and the Department of Health and Human Services' Office of General Counsel for legal defensibility review. This process can also involve the U.S. Department of Justice counsel for matters that are in litigation. Once that legal review is completed, a senior FOIA reviewer conducts a quality control review to ensure that the responsive documents have been properly prepared for public disclosure.

17. To produce documents in response to discovery requests, third-party subpoenas, and court orders to process records in response to FOIA requests, reviewers perform all of the tasks in paragraphs 13-15, plus additional steps that can increase, by at least two-fold, the time to process the request. The extra responsibilities associated with litigation-related document production typically include bates-stamping, preparing for creation of a *Vaughn* Index[1] or privilege log, and conducting a quality control check of the index/log to assure its accuracy and completeness. ALFOI must shift resources away from processing other FOIA requests to meet strict timetables generally set for producing documents in response to discovery requests, FOIA litigation, or third-party subpoenas.

18. When calculating processing rates for disclosure of records under FOIA, the agency must account for all of the steps listed in paragraphs 13-15 and ensure that there is adequate time for a careful review that will ensure that all confidential information is protected while all releasable information is disclosed. ALFOI typically estimates that it will take an average of eight minutes per page to perform the tasks listed above and produce records to the requester. To be sure, some records can be produced at a faster rate if they do not contain much sensitive information or if review can proceed with minimal research or consultation. But some records may also take longer, especially if they contain a significant amount of confidential information interspersed with releasable information or if they require much consultation with others outside of ALFOI. It is generally difficult to know whether particular records (or particular portions of a large record, such as an entire original BLA submission) will take more or less than the estimated eight minutes per page until reviewers have had an opportunity to

[1] "A *Vaughn* index is a routine device through which the defendant agency describes the responsive documents withheld or redacted and indicates why the exemptions claimed apply to the withheld material." *Batton v. Evers*, 598 F.3d 169, 174 (5th Cir. 2010) (quotation omitted).

perform at least a preliminary review of those records.

CBER'S EFFORTS TO INCREASE EFFICIENCY

19. CBER's DDOM and ALFOI have implemented organizational changes, work process changes, and other measures to increase their operational efficiency and reduce backlogs. DDOM and ALFOI have prioritized the recruiting and hiring of new employees; proactively posted frequently requested records on FDA's website to increase transparency; evaluated requests to triage to ensure assignment to appropriate tracks; and, where appropriate, proactively contacted FOIA requesters to negotiate the scope of requests in order to produce documents more quickly if possible. A GS-14 Science Disclosure Analyst position was added in February 2019 to the immediate office of the director in DDOM. This position is tasked with processing FOIA requests for personnel records and also independently processing complex FOIA requests, alleviating some of the workload of the ALFOI branch chief and branch staff. ALFOI hired 2 new employees that started work in August and October of 2021. DDOM recently advertised for a GS-14 Science Disclosure Analyst detail to focus on decreasing the backlog of CBER FOIA requests. DDOM recently established a contract for assistance with accessibility remediation of records to ensure that frequently-requested materials proactively posted online are compliant with federal requirements intended to make records accessible to all users regardless of disability. All of these efforts have been undertaken in an effort to expand CBER's capacity for responding to FOIA requests and improving response time.

IMPACT OF RECENT EVENTS, INCLUDING COVID-19, ON ALFOI'S OPERATIONS

20. A significant recent surge in interest in CBER records, including interest in records related to FDA's work pertaining to the global COVID-19 pandemic, has impacted ALFOI's operations in a number of ways. First, there has been a significant recent uptick in

FOIA requests submitted to CBER. From 2014 through 2018, CBER received an average of 295 FOIA requests per year. Over that same time period, CBER closed an average of 289 FOIA requests per year. Thus, although ALFOI had always been working at full capacity, CBER was able to keep its FOIA queues relatively stable until recently. From 2014 through2017, CBER closed each calendar year with a backlog of fewer than 70 FOIA requests in its queue.

21. Beginning in 2019, CBER began to see a dramatic increase in the number of FOIA requests it received. That increase in volume has been exacerbated by requests related to the COVID-19 global pandemic. Between 2019 and 2021, CBER received an average of 443 FOIA requests per year.[2] Many of these new requests, including the request at issue in this case, have sought large amounts of data that have required significant resources to process. As a result, the number of requests pending in CBER's queue has increased dramatically in the last several years – from 64 in 2017 to 459 as of November 26, 2021. The following charts illustrate the increase in FOIA requests CBER has received and the length of CBER's FOIA queue at the end of each calendar year.

[2] This number includes requests received through November 26, 2021. It is likely that the number of FOIA requests received in 2021 will increase once requests received between November 27, 2021 and the end of the year are accounted for.

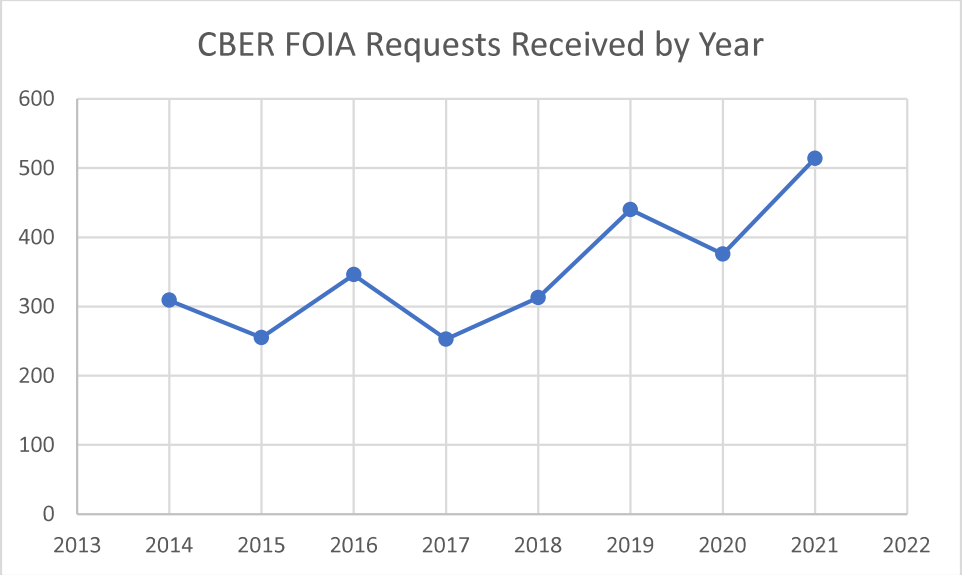


Figure 1: *Number of FOIA requests received by year. (2021 data includes only FOIA requests received as of November 26, 2021.)*

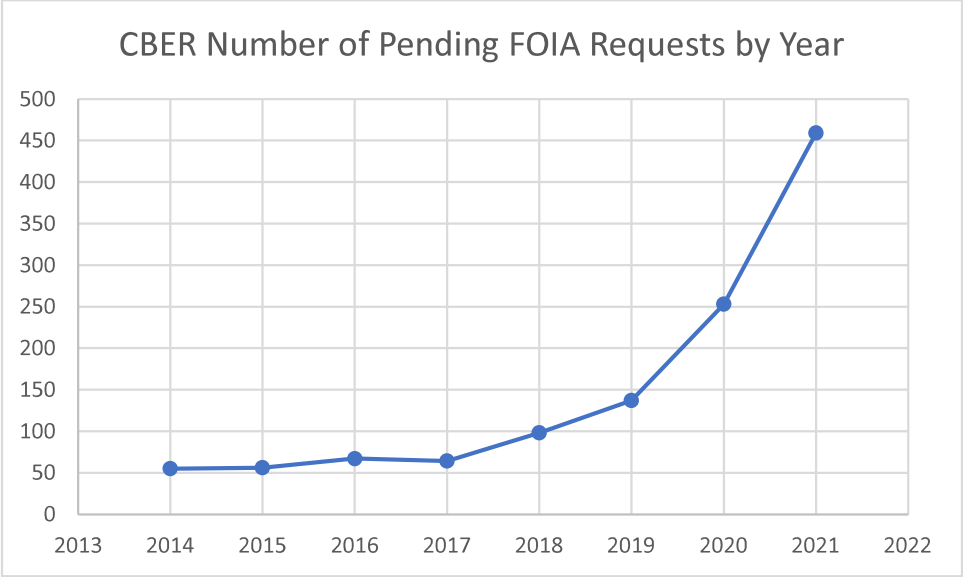


Figure 2: *Number of pending FOIA requests pending in CBER at the end of each calendar year. (2018 value was taken from end of January 2019 because December 2018 data were unavailable due to government shutdown. 2021 value is current as of November 26, 2021.)*

22. Of the 459 requests currently pending before CBER, approximately 329 were received before Plaintiff's. Doubtless, many of those other FOIA requesters who submitted their FOIA requests ahead of Plaintiff's would insist, similarly to Plaintiff here, that their requests are

critically important and need to be processed expeditiously. But processing of other requests would be adversely impacted by any order requiring ALFOI to devote more of its scarce resources to this Plaintiff's request by processing it at a rate faster than 500 pages per month.

23. In addition, there has been an uptick in the amount of FOIA litigation to which ALFOI has been required to respond. There have been 12 lawsuits filed regarding requests pending before CBER between 2019 and the present; seven of those lawsuits are ongoing. Several of those pending lawsuits require periodic productions pursuant to production agreements and/or Court orders or are in preliminary stages of litigation prior to a production schedule being established. In those other litigations, CBER is currently obligated to produce a minimum of a total of 950 pages of responsive records per month. That obligation will increase to a total of approximately 1,500 pages per month beginning in January 2022 when productions in another litigation begin and may increase further if production schedules are ordered or modified in any active cases.

ALFOI'S HANDLING OF PLAINTIFF'S REQUEST

24. On August 27, 2021, FDA received Plaintiff's Request seeking "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." The regulation cited in Plaintiff's Request, 21 C.F.R. § 601.51(e), is not a regulation that requires immediate disclosure of any information. Rather, that regulation establishes how the agency will treat the confidentiality of information in the biological product file at various times throughout the life cycle of a biological product.

25. ALFOI interpreted Plaintiff's Request as a request for all publicly releasable information in the original biologics license application submitted by BioNTech-Pfizer for the

Comirnaty vaccine with internal file number STN 125742/0/0 ("original Comirnaty BLA"), as contemplated by 21 C.F.R. § 601.51(e).[3] ALFOI searched FDA's internal system for maintaining BLA files and determined that the original Comirnaty BLA includes over 329,000 pages of records for which pages could feasibly be counted. In addition to those 329,000 pages, the original Comirnaty BLA includes additional data files in a format similar to a spreadsheet for which a page count cannot readily be generated. There are 126 of these data files in Section 5 of the original Comirnaty BLA alone, and there may be more in other sections. Many of those data files themselves are very large, containing dozens of columns and over ten thousand rows of data. The data files are in a format that requires specialized software to access. ALFOI rarely reviews or produces these types of files, so they create additional processing limitations. When ALFOI first discovered these files, it had to have special "reader" software installed on its computers that allowed it to view the files. That software did not allow ALFOI to make redactions or edit the files.[4] To address this limitation, ALFOI was able to obtain assistance from an FDA employee in a different part of the agency who was able to assist ALFOI with performing necessary conversions or making deletions in lieu of redactions. But due to the very large size of these data files and ALFOI's limited experience processing them, ALFOI has

[3] FDA interpreted Plaintiff's Request to seek data and information from the original Comirnaty BLA because Plaintiff's Request seeks, "[a]ll data and information for the Pfizer Vaccine enumerated in 21 C.F.R. § 601.51(e)…" The title of 21 C.F.R. § 601.51 is "Confidentiality of data and information in applications for biologics licenses." 21 C.F.R. § 601.51. Thus, FDA interpreted Plaintiff's Request to seek information from the application for biologics license (i.e., the original Comirnaty BLA). If Plaintiff's Request were to be interpreted to incorporate other records related to the Comirnaty BLA, the size of its request – and thus the strain it would place on FDA's resources – would also increase. For example, if BLA supplements, amendments, and product correspondence are included, the scope of Plaintiff's Request could expand by approximately 39,000 pages beyond FDA's initial estimate. Similarly, if the investigational new drug applications were included, the scope of Plaintiff's Request would likely increase by tens of thousands of additional pages.

[4] 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. If it is not feasible for FDA to produce in SAS format, it will first attempt to convert to Excel format and produce in that format if feasible before resorting to producing in PDF format.

continued to encounter technical difficulties that have required consultation with information technology staff and slowed ALFOI's processing capabilities.

26. Working through Department of Justice counsel, ALFOI has worked to negotiate a production schedule that would both be feasible for the agency and provide Plaintiff with the records it prioritized first. As part of that process, FDA made an initial proposal to provide certain summary sections of the file that, in FDA's experience, are typically of most interest to requesters. Plaintiff summarily rejected that proposal. FDA continued to attempt to work with Plaintiff by next providing two separate breakdowns to Plaintiff, revealing the (non-confidential) titles of sections of the original Comirnaty BLA. FDA provided these breakdowns in an attempt to assist Plaintiff in identifying which sections of the Comirnaty BLA it prioritized. Alone, those breakdowns, which served as something analogous to an index to certain sections of the original biological license application, totaled nearly 90 pages. Once subsequent discussions revealed that Plaintiff was most interested in Section 5.2 of the original Comirnaty BLA and the raw data contained in Section 5.3 of the original Comirnaty BLA, FDA searched its system for those sections to evaluate their size and scope. FDA assessed that Sections 5.2 and 5.3 comprise more than 321,000 pages of records (plus additional data files) and requested that Plaintiff use the provided index to prioritize the production of certain records.

27. From the index FDA provided, Plaintiff then submitted a list of priority items to FDA through government counsel by email on November 4, 2021. Government counsel proposed that FDA process certain documents on Plaintiff's priority list by November 17 and December 1, 2021, with the parties to confer after December 1 regarding future productions. Although Plaintiff rejected that offer, FDA nevertheless has been working to produce records from Plaintiff's priority list and has completed the proposed November 17 and December 1

productions. Specifically:

- On November 17, 2021, FDA produced all publicly releasable information from the following:
  - ***A Portion of Plaintiff's priority item #5***
    - One .txt file; and
    - One SAS (data) file;[5]
  - ***A Portion of Plaintiff's priority item #6-*** From Section 5.2 of the Comirnaty original BLA 125742/0/0:
    - The Tabular Listing;
    - The Listing of Clinical Sites;
  - ***Plaintiff's priority item #8-*** The Reports of Postmarketing Experience from Section 5.3.6 of the BLA file.
- On December 1, 2021, FDA produced publicly releasable information from:
  - ***Completion of Plaintiff's priority item #6*** - The remainder of section 5.2 of the original Comirnaty BLA.
- By December 13, 2021, ALFOI plans to produce publicly releasable information from:
  - ***Plaintiff's priority item #1-*** CRF files for site 1055 (~2,030 pages);
  - ***Completion of Plaintiff's priority item #5-***
    - Four additional .txt files that were listed on p. 10 of the index;
    - Four additional SAS files (not specifically listed on Plaintiff's priority list,

[5] In communications between FDA and Plaintiff, Plaintiff indicated that it was interested in obtaining "sample" SAS files, but none of the files Plaintiff identified in its priority list was an SAS file. Instead, Plaintiff identified .txt files that included "SAS" in their file names. In an attempt to provide Plaintiff with the information it requested, ALFOI produced one of the .txt files Plaintiff requested, as well as one xpt (SAS) file even though Plaintiff did not specifically prioritize any SAS files in its priority list. As a result, ALFOI's November 17, 2021, production included more records than FDA initially proposed.

but mentioned as something Plaintiff was interested in).

- Publicly releasable information from the following additional sections of the original Comirnaty BLA:
  - Section 2.5 – Clinical Overview (~333 pages)
  - Section 2.7.3 – Summary of Clinical Efficacy (~182 pages)
  - Section 2.7.4 – Summary of Clinical Safety (~344 pages)

Thus, by the time of the Court's status conference on December 14, 2021, FDA anticipates that it will have produced to Plaintiff over 3,000 pages of responsive materials, most of which were listed on Plaintiff's priority list.

28. Going forward, ALFOI expects to be able to produce the next three items on Plaintiff's priority list quickly, completing production on all of them before the end of January 2022. ALFOI has begun its review of those records and determined that because they appear to contain less confidential information than average records, ALFOI will be able to review them at a pace faster than the average rate of 8 minutes per page. As a result, ALFOI proposes to produce them to Plaintiffs according to the following schedule:

- By December 30, 2021, ALFOI plans to produce publicly releasable information from ***Plaintiff's priority item #2*** – CRF files for site 1081 (~3,380 pages);
- By January 18, 2022, ALFOI plans to produce publicly releasable information from ***Plaintiff's priority item #3*** – CRF files for site 1096 (~2,937 pages); and
- By January 31, 2022, ALFOI plans to produce publicly releasable information from ***Plaintiff's priority item #4*** – CRF files for site 1128 (~3,452 pages).

Thus, by the end of January 2022, FDA expects to have produced publicly releasable information from over 12,000 pages of records and 10 unpaginated .txt or SAS data files. FDA will also

have completed production of seven of the first eight items on the priority list Plaintiff provided to FDA on November 4, 2021.

29. Following its January 31, 2022 production, ALFOI proposes to make one production at the end of each subsequent month totaling a minimum of 500 pages.[6] To the extent feasible, ALFOI plans to continue to prioritize records from Plaintiff's priority list. Although ALFOI proposes a minimum rate of 500 pages a month, ALFOI will produce records at a faster rate where feasible (such as with files like the CRF files discussed in the preceding paragraph). But ALFOI cannot guarantee that all records can be reviewed or produced at the rate that is possible for the CRF files. That is because other types of records will likely include more confidential information, and thus more corresponding redactions, which will require more research and production time. It is generally difficult to know whether particular records (or particular portions of a large record, such as an entire original BLA submission) will take more or less than the estimated eight minutes per page until reviewers have had an opportunity to perform at least a preliminary review of those records. As discussed above, ALFOI estimates that it takes approximately eight minutes per page to review records for a FOIA production. The CRF records discussed in paragraph 28 will take less time than that, but it is possible that other types of records will take longer than the estimated rate of eight minutes per page to review.

PLAINTIFF'S PROPOSED PRODUCTION SCHEDULE

30. In its portion of the November 15, 2021, joint report filed with this Court, Plaintiff requested that FDA be ordered to complete its response to Plaintiff's Request by March 3, 2022. Although FDA values transparency and would like to make as much non-confidential

[6] For purposes of calculating a "page count" of data records that are not paginated, we propose considering twenty lines of spreadsheet data the equivalent of one page. For example, production of a spreadsheet containing 2,000 lines of data would be counted the equivalent of a 100-page PDF record.

information public as soon as possible, Plaintiff's proposed schedule is simply not feasible.

31. There are 79 days (or approximately 11 weeks) between the December 14, 2021, status conference and Plaintiff's proposed deadline of March 3, 2022. As discussed above, CBER estimates that it takes approximately eight minutes per page to review responsive records. *See*, *supra*, ¶ 18. ALFOI includes ten staff members – one branch chief and nine full-time staff members. *See*, *supra*, ¶ 4. In an attempt to illustrate the challenges with producing approximately 329,000 pages plus data files by March 3, 2022, we have calculated the number of pages ALFOI can expect to produce in that time using an assumption *that each of those ten staff members*[7] *could allocate all of their review time*[8] over the next 11 weeks doing nothing but processing Plaintiff's request. Even using those unrealistic assumptions, ALFOI would only expect to be able to produce about 25,410 pages by March 3, 2022. ((10 staff members × 11 weeks × 30.8 hours/week × 60 minutes/hour) ÷ 8 minutes/page = 25,410 pages) . Thus at this hypothetical rate, which likely far exceeds what is feasible in reality, ALFOI could not reasonably be expected to produce even ten percent of what Plaintiff is asking this Court to order.

32. And the rate assumed in the calculation in the paragraph above is not at all feasible in practice. In addition to the administrative limitations on staff time discussed in footnotes 7-8, the calculation assumes that ALFOI could devote *all* of its working time to this single request. But that would require ALFOI to neglect the other 400+ FOIA requests in its

[7] Not all staff members can contribute equally at this time. As discussed above, ALFOI has two new staff members who began working in ALFOI within the last four months. Although those employees can productively work on reviewing records, the new staff members require more training and oversight. Thus, their effective review rate can be expected to be slower than more senior staff.

[8] It is not reasonable to estimate that any staff member can spend a full forty hours per week performing substantive FOIA reviews. Some time will necessarily be diverted to other tasks, such as administrative tasks (timekeeping, leave, training, etc.). Thus, we approximate that each staff member can allocate 30.8 hours per week to performing substantive reviews.

queue. ALFOI would also need to ignore production schedules entered in other FOIA litigations involving CBER, putting the agency at risk of sanctions. This is simply not feasible, and is unfair to other FOIA requesters, many of whom submitted their FOIA request before Plaintiff.

33. I understand that Plaintiff has suggested that because FDA completed its review of the original Comirnaty BLA in 108 days, it must be feasible for FDA to review and produce all 329,000+ pages of the original Comirnaty BLA in a comparable time period. Such a comparison of the substantive BLA review and the disclosure review is wholly inapt for several reasons.

34. First, although both reviews require careful consideration of the information in the materials, the nature of the reviews are inherently different. The substantive review requires analysis of the data collectively to evaluate the safety, potency, and purity of the biological product. The disclosure review requires an individualized, line-by-line analysis of each discrete piece of information to evaluate, for example, whether the information may be trade secret or confidential commercial information or whether disclosure of the information could result in unwarranted invasion of personal privacy (in other words, whether the information is exempt from disclosure under FOIA). As discussed above, the disclosure review often requires independent research and/or consultation to ensure that all confidential information is protected while all releasable information is disclosed. Further, the review of large volumes of records adds a level of complexity, as reviewers must protect all instances of confidential information in a consistent manner across all records being produced. The disclosure review also requires staff to carefully add redaction boxes that cover all exempt information but no releasable information. Finally, there also needs to be a quality control check at the end of the review process to make sure that all redaction boxes that were intended to be made actually were made and applied and

that the exemption codes are correct.

35. Second, in the face of a global pandemic unparalleled in recent memory, FDA marshaled all available resources to protect the public by ensuring that the public had access to all safe and effective medical products as soon as possible. Specifically in CBER, more than 100 different people were involved in the review of the Comirnaty BLA. Further, the sponsor (Pfizer-BioNtech) submitted data to FDA on a rolling basis, even in advance of the formal BLA submission, meaning that substantive data review occurred over a longer period than the 108 days Plaintiff notes. By contrast, ALFOI has a total of ten staff members responsible for reviewing and responding to over 400 pending FOIA requests – not just Plaintiff's. Any suggestion that FDA should be able to produce the original Comirnaty BLA in the same number of days it took to substantively review the file fails to account for these significant differences.

CONCLUSION

36. CBER is committed to processing Plaintiff's Request as soon as practicable and has taken affirmative steps to do so. However, given the many constraints posed by the agency's highly demanding workload, technical constraints, and workforce challenges stemming from the COVID-19 pandemic, it would be unduly burdensome for CBER to commit to processing Plaintiff's request at a rate higher than 500 pages per month. If required to process Plaintiff's request at faster rate, FDA would likely need divert its employees from other duties, which could adversely impact the Agency's ability to respond to other document requests, cause FDA to miss its stipulated document processing deadlines in other matters, and thus, prejudice other requestors, including the many with requests that are ahead of Plaintiff's. Thus, FDA's proposed schedule adequately balances the interests of the Plaintiff in responsive records with the interests of the vaccine sponsor in the protection of its confidential information, the interests of clinical

trial participants in the protection of their personal privacy information, and the interests of other FOIA requesters whose requests are being processed alongside Plaintiff's.

Pursuant to 28 U.S.C. § 1746, I declare under the penalty of perjury that the foregoing is true and correct.

Executed on December 6, 2021, in Bethesda, Maryland.

Suzann H. Burk -S

Digitally signed by Suzann H. Burk -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Suzann H. Burk -S, 0.9.2342.19200300.100.1.1=1300129983
Date: 2021.12.06 13:51:41 -05'00'

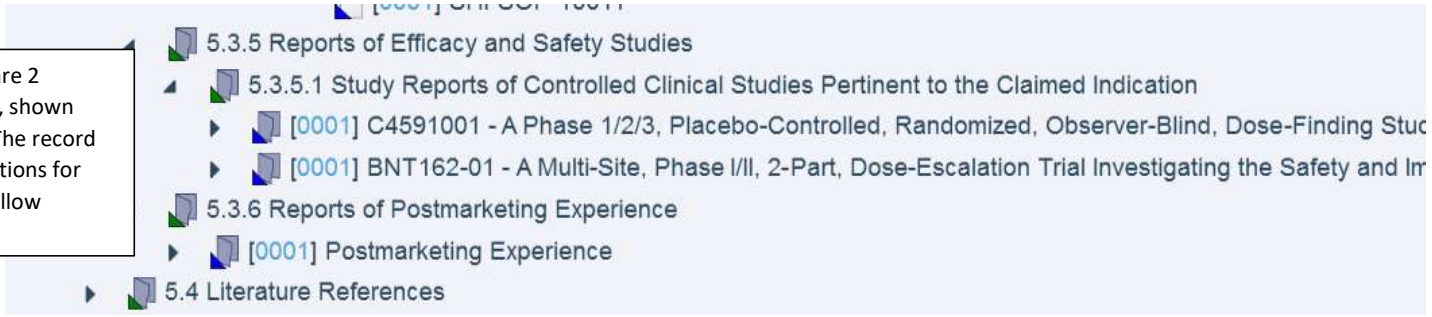
Suzann Burk
Director
Division of Disclosure and Oversight Management,
Office of Communication, Outreach and Development
Center for Biologics Evaluation and Research
Food and Drug Administration
U.S. Department of Health and Human Resources

Exhibit B

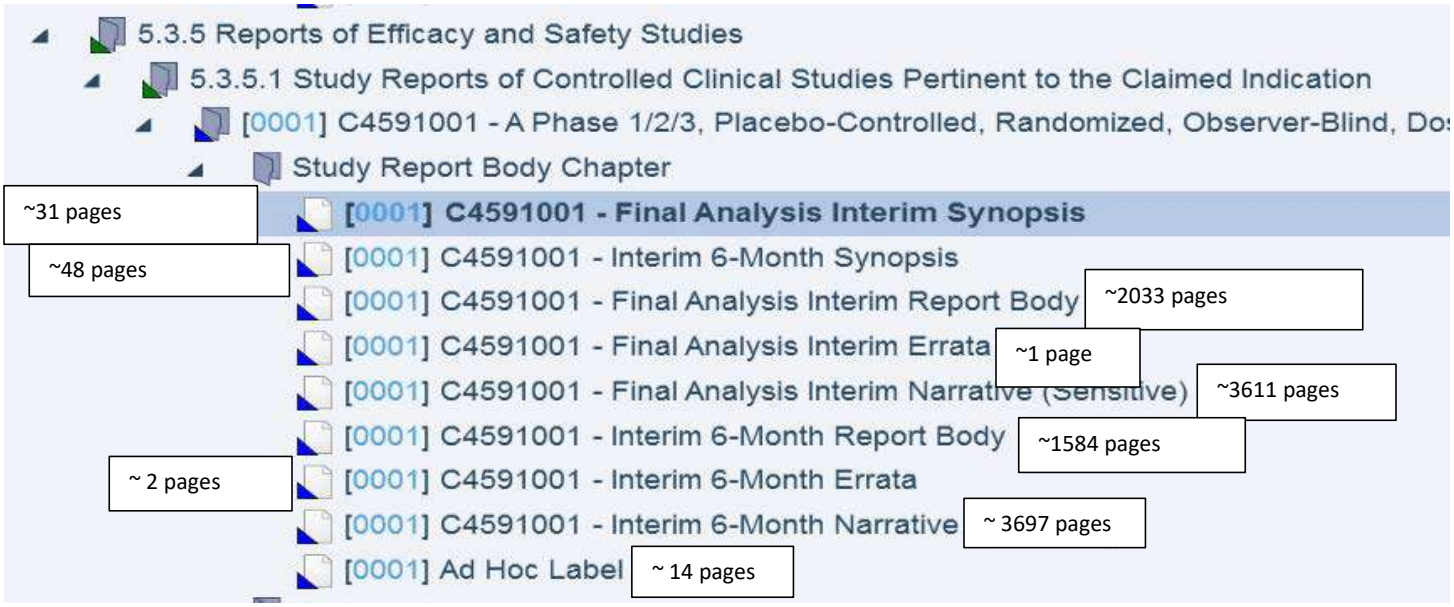
0001 --> 125742/0.0 (Original Application) - Recd 2021-05-06 - DATS# 1067058
1 Administrative Information and Prescribing Information
2 Common Technical Document Summaries
4 Nonclinical Study Reports
5 Clinical Study Reports
5.2 Tabular Listing of all Clinical Studies
5.3 Clinical Study Reports
5.4 Literature 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

5.3.5



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



- 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)
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- 16.1.8 Audit Certificates or similar documentation
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- 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
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- 16.2. Patient Data Listings
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  - 16.2.2 Protocol Deviation Listing
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  - 16.2.3 Patients Excluded from Efficacy Analysis Listing

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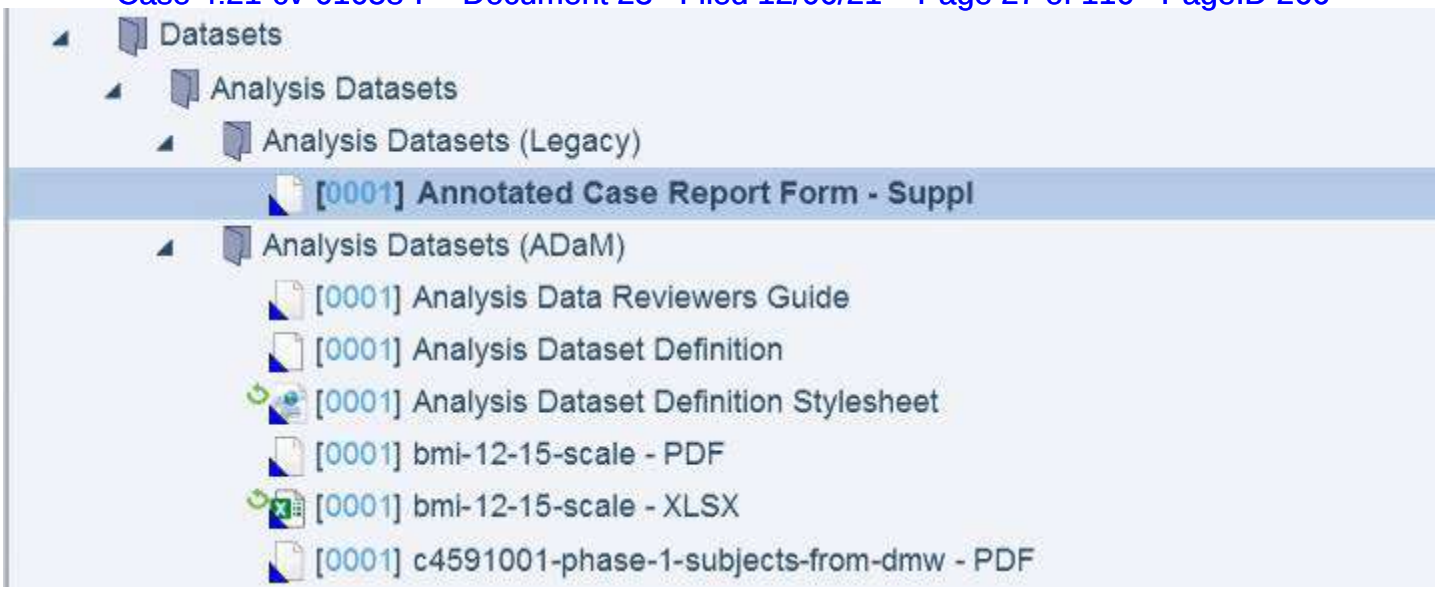
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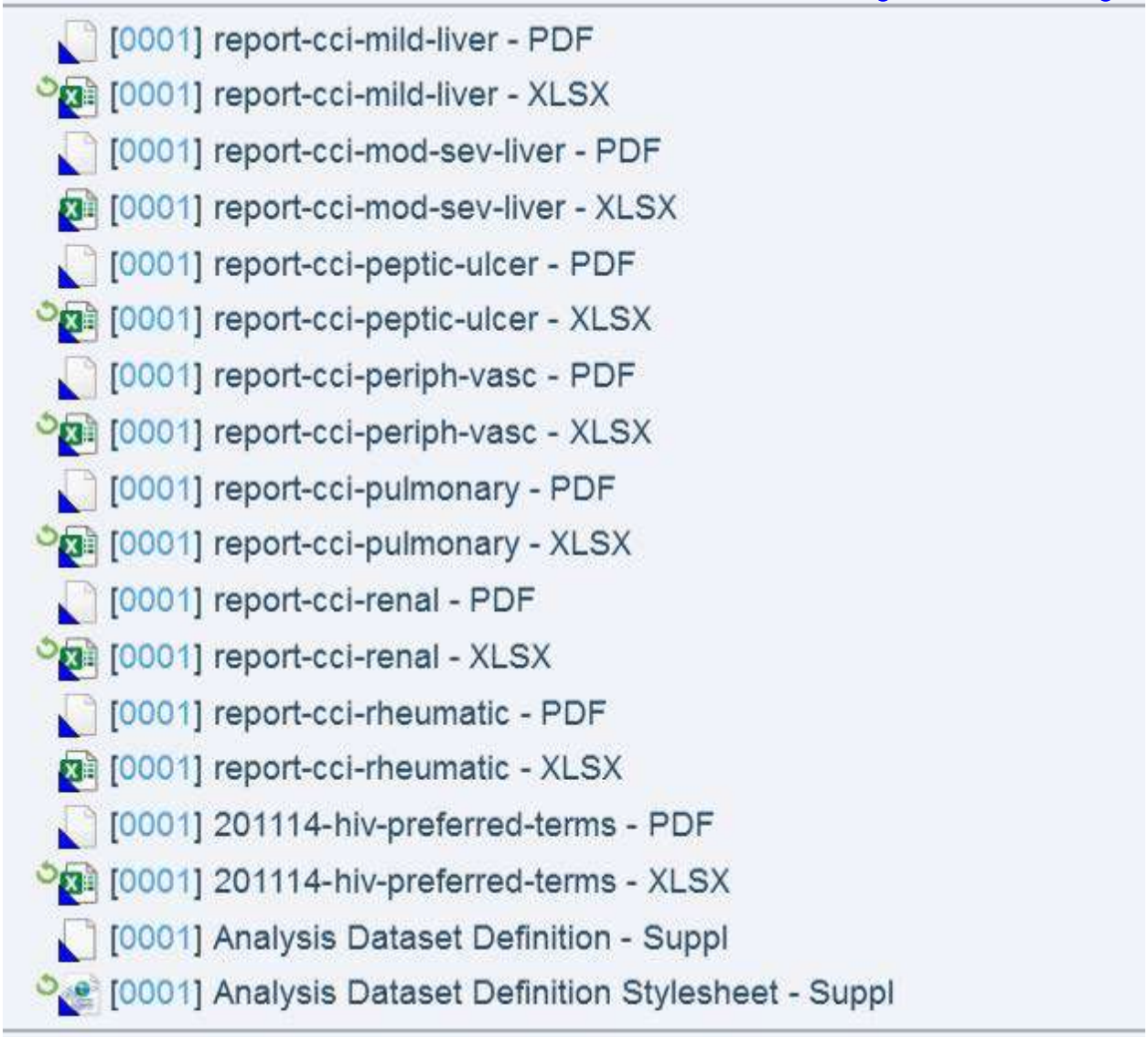
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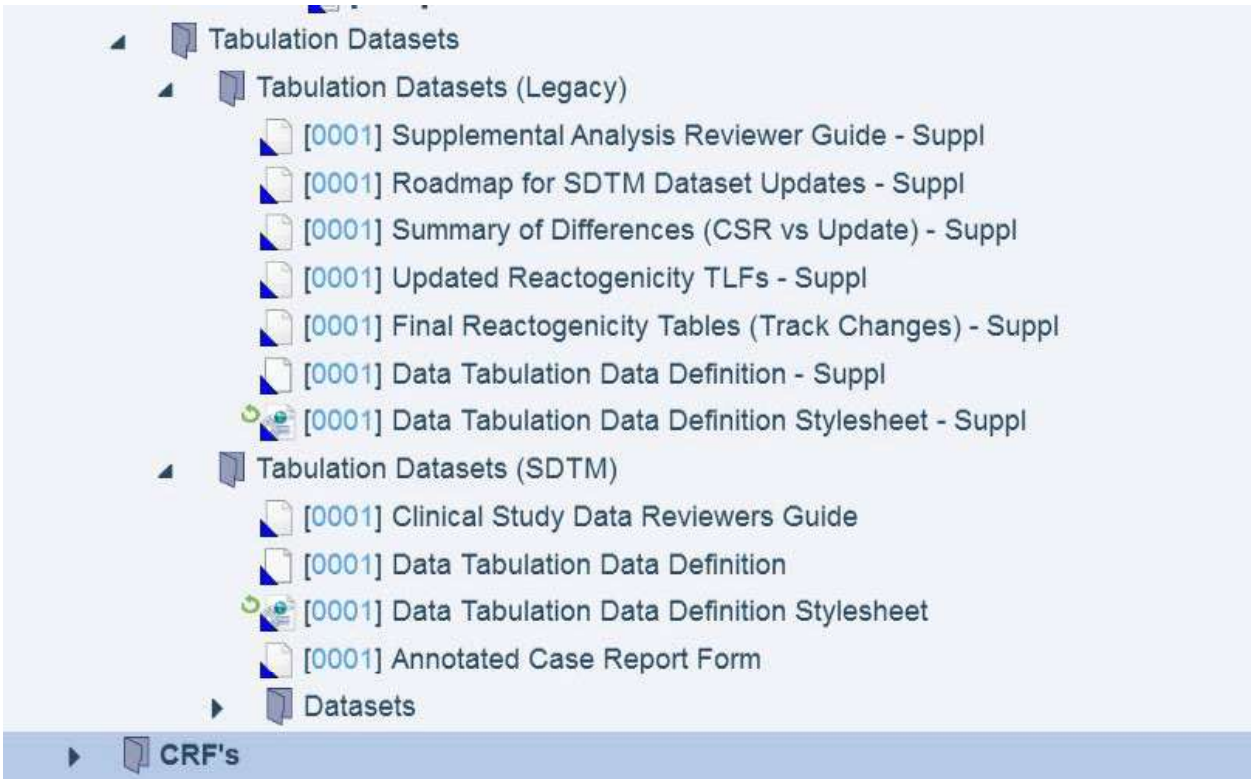
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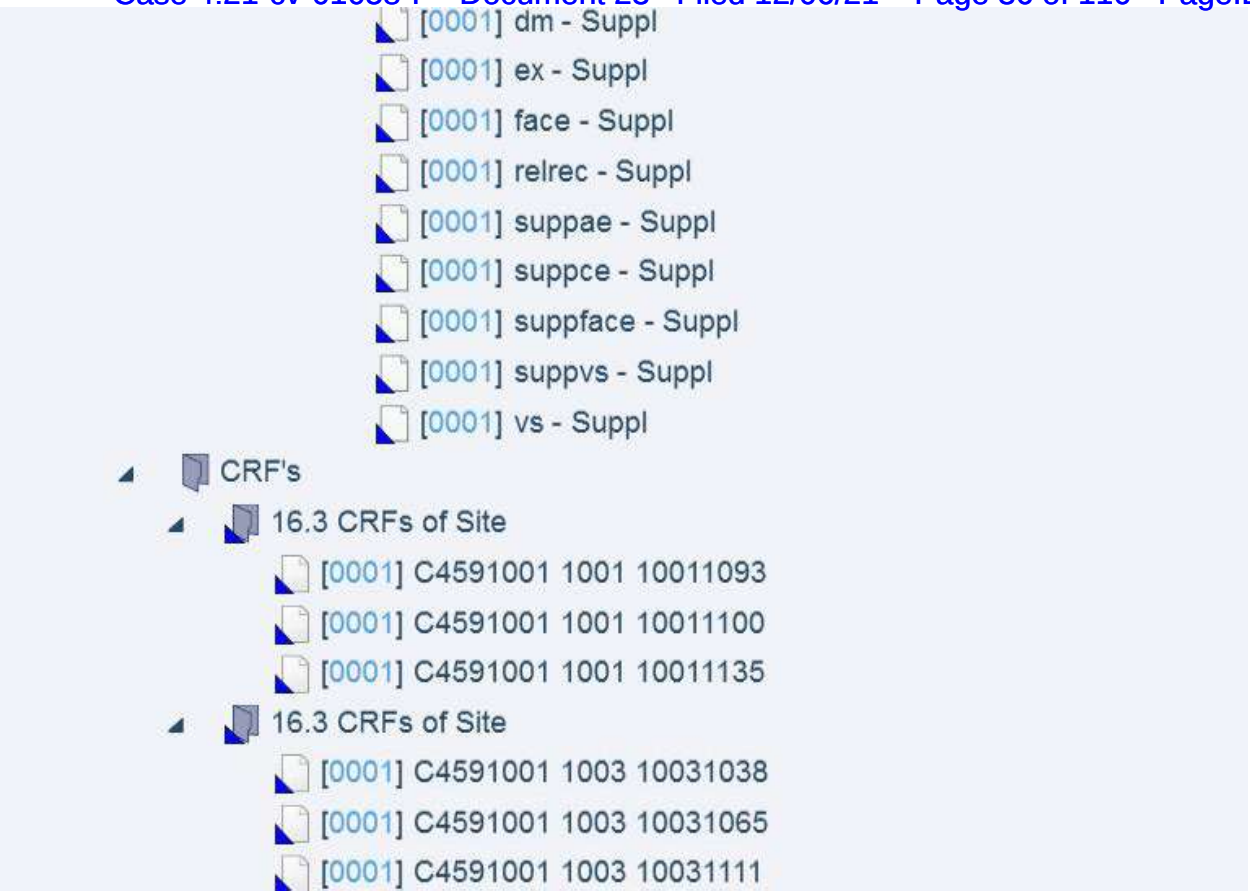
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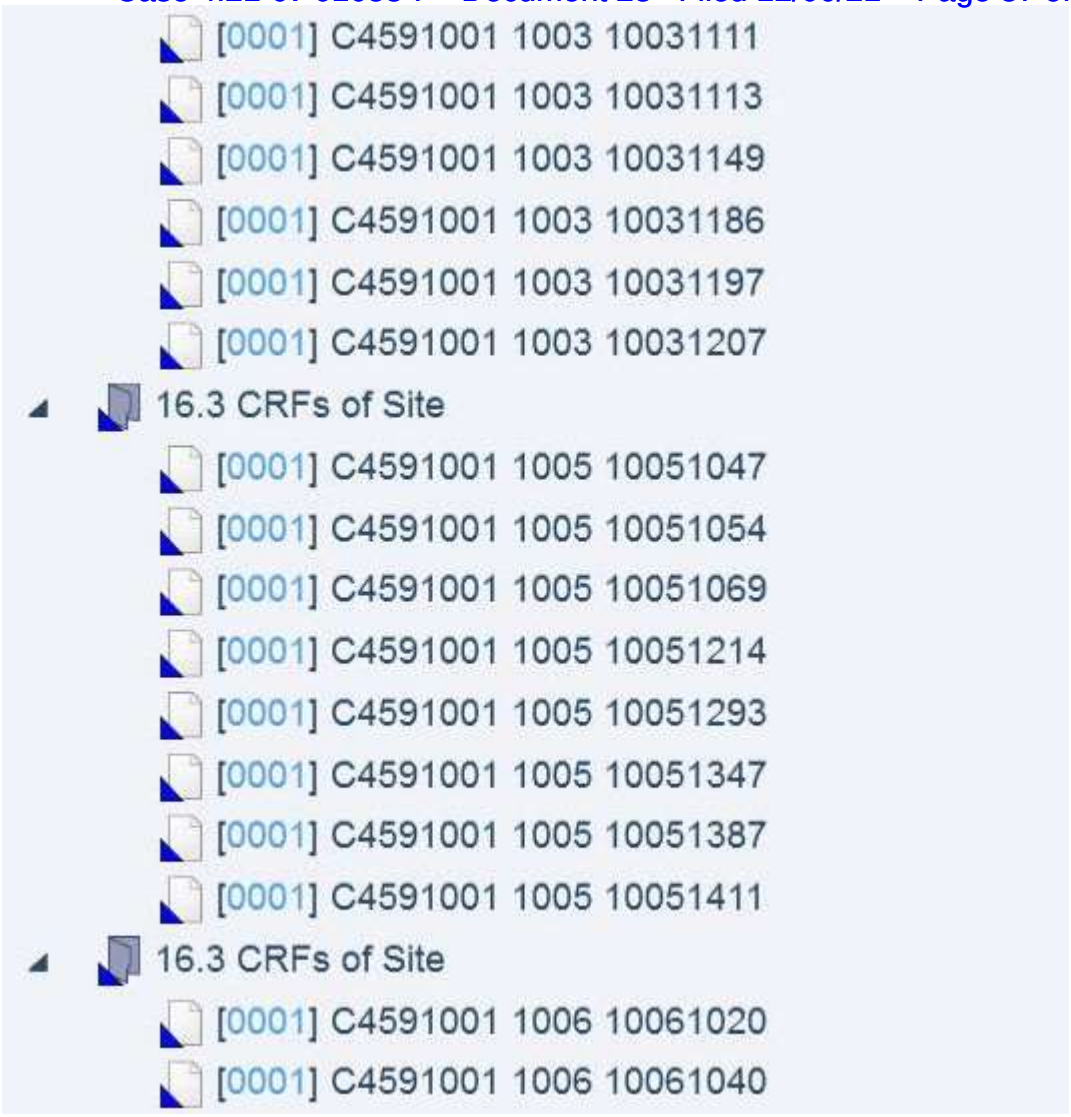
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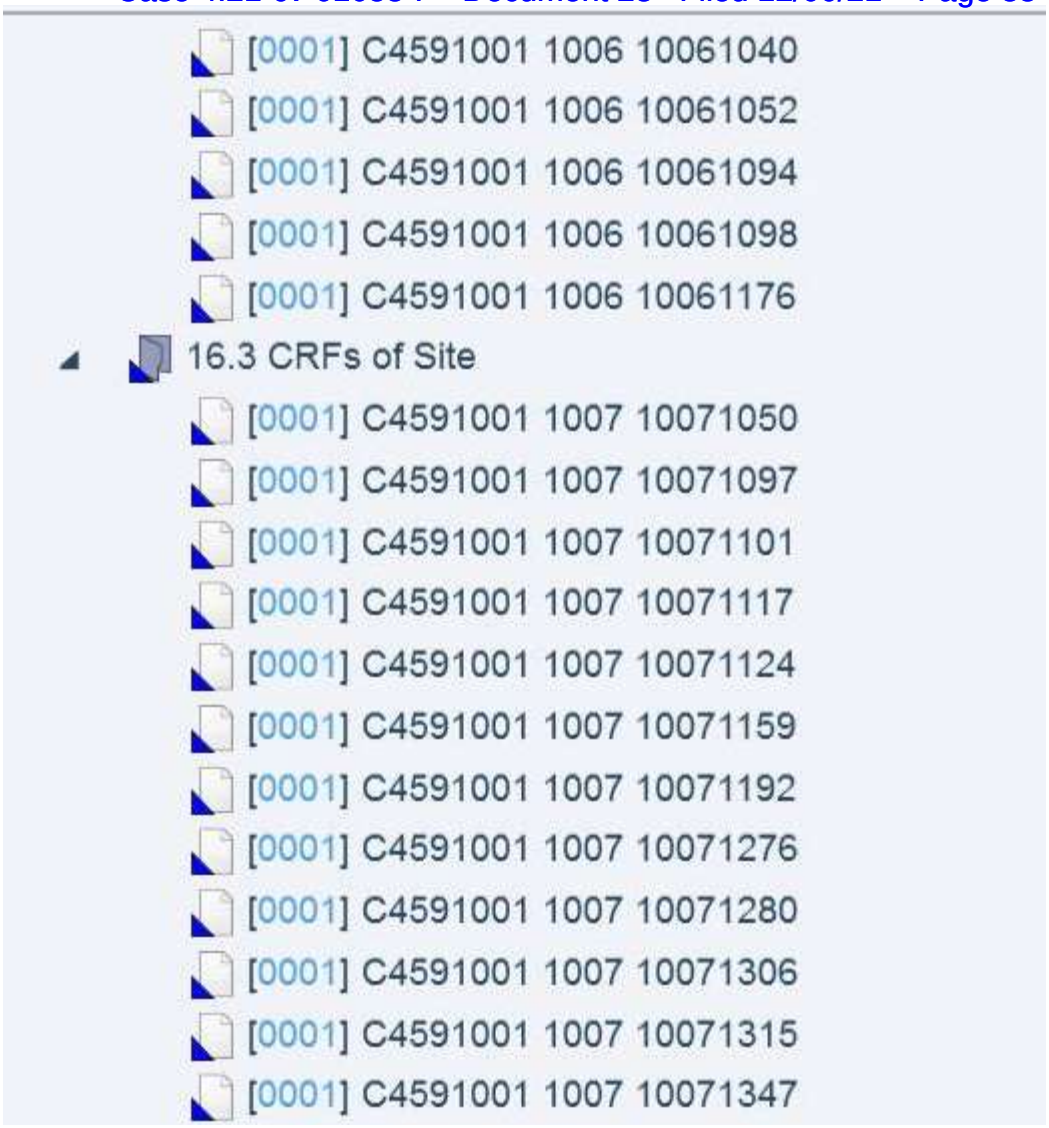
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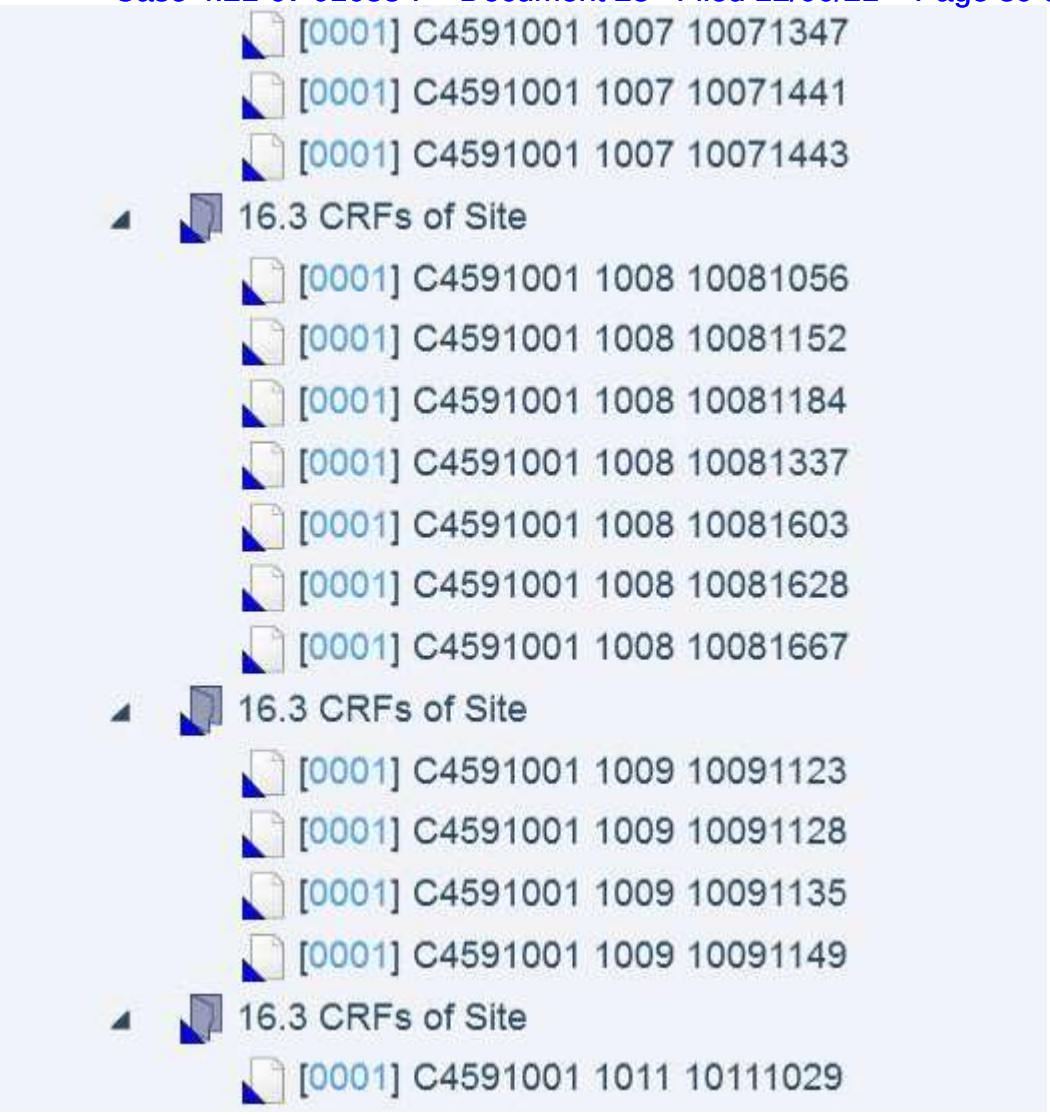
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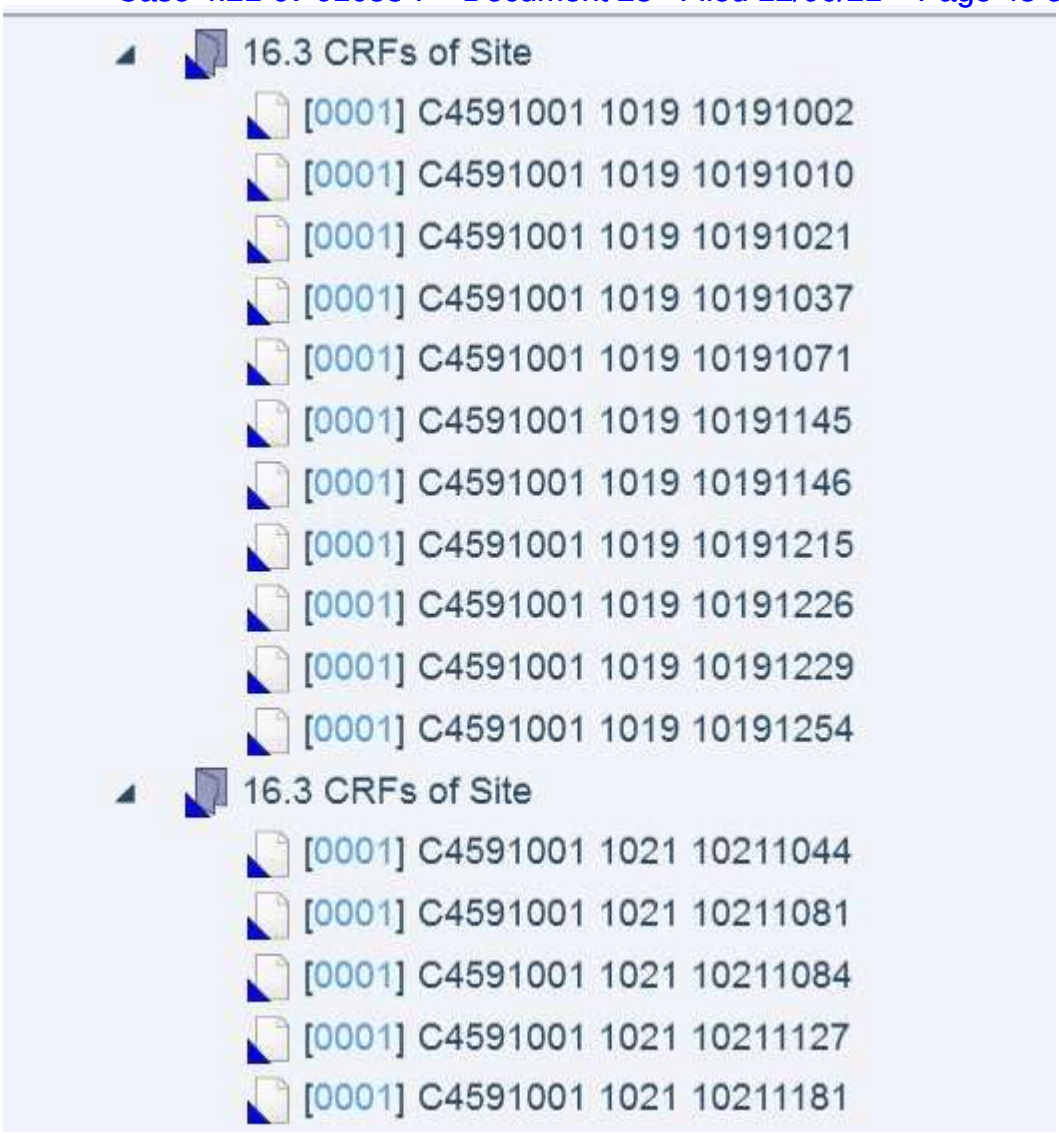
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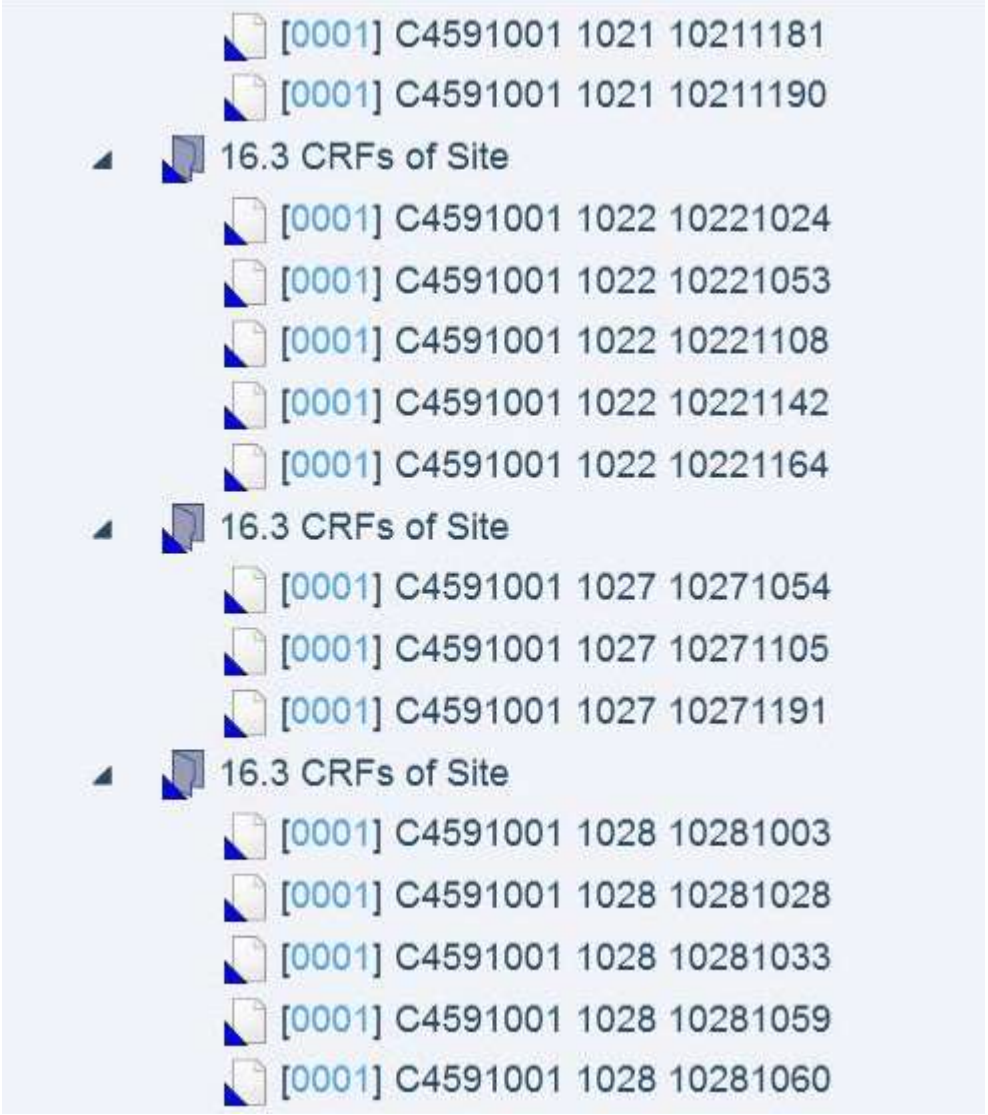
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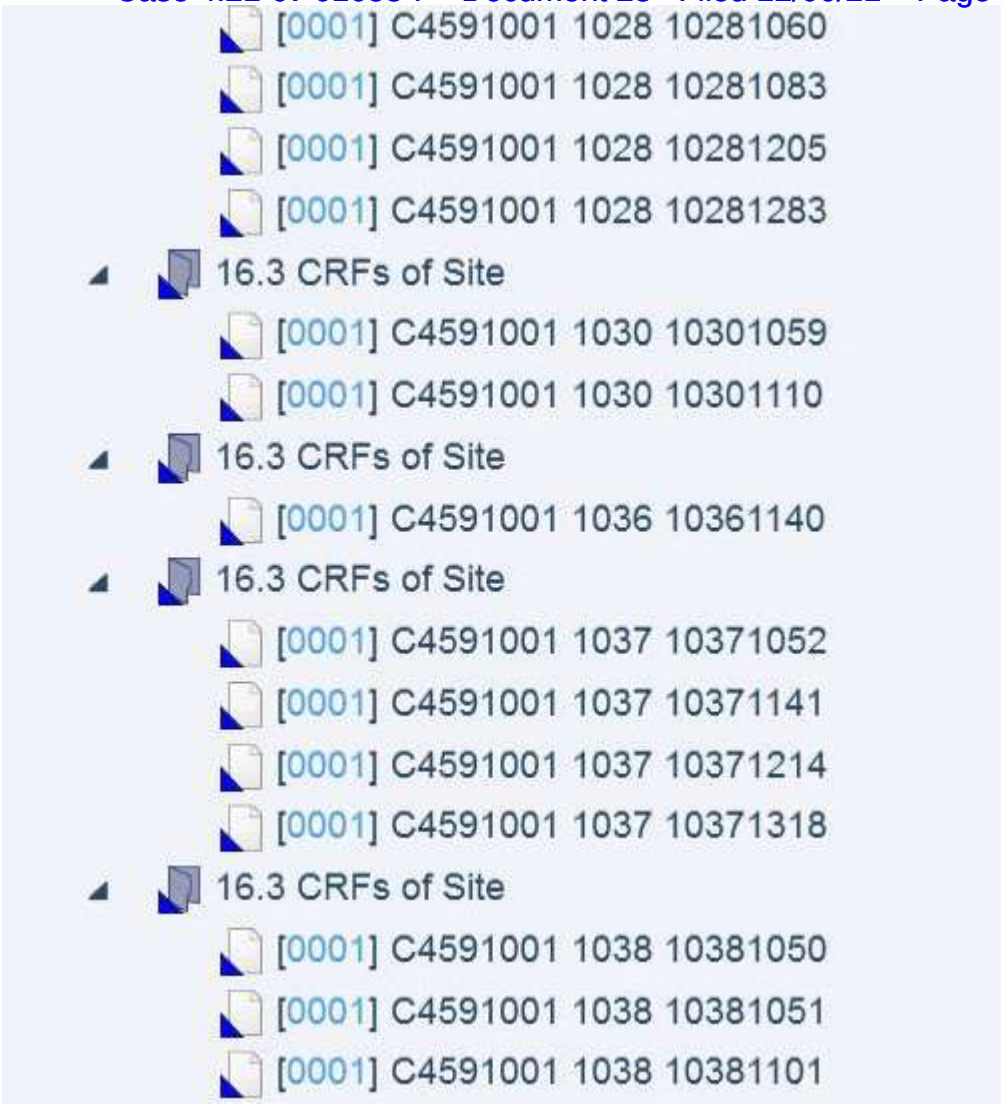
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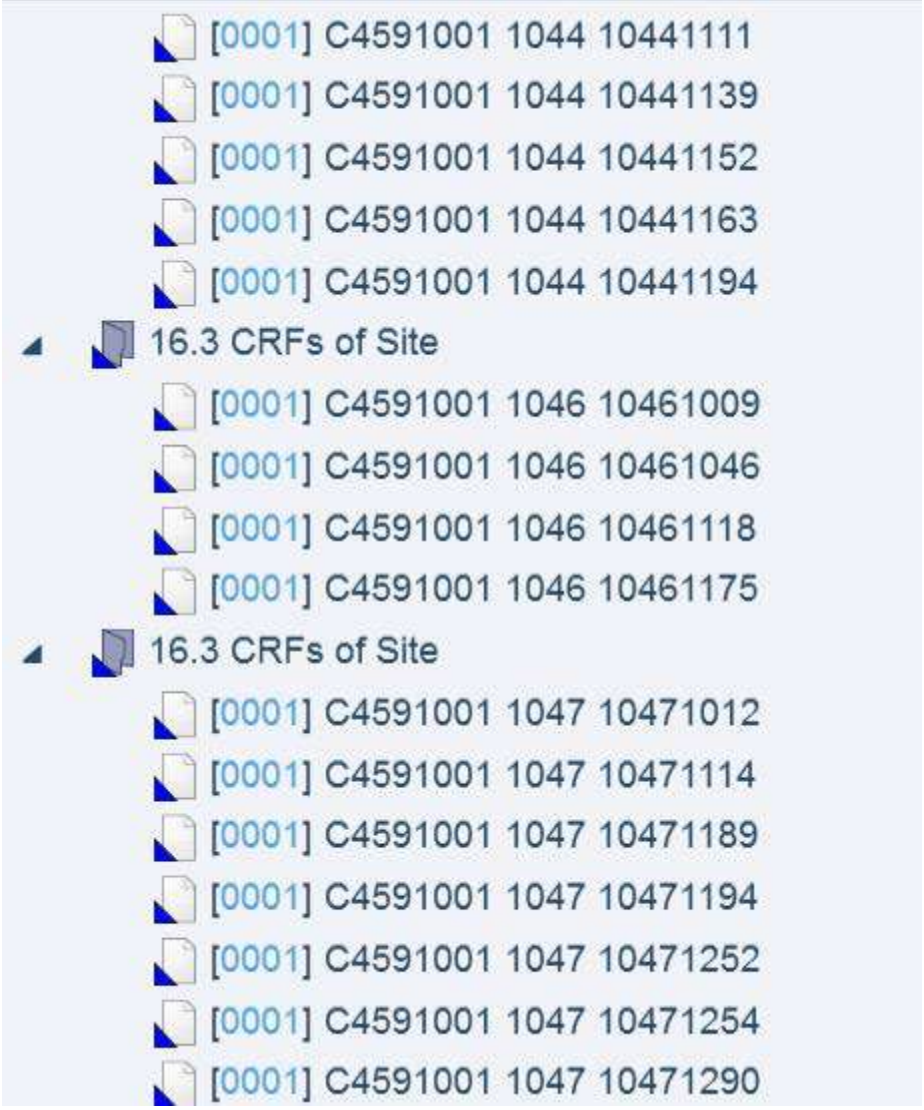
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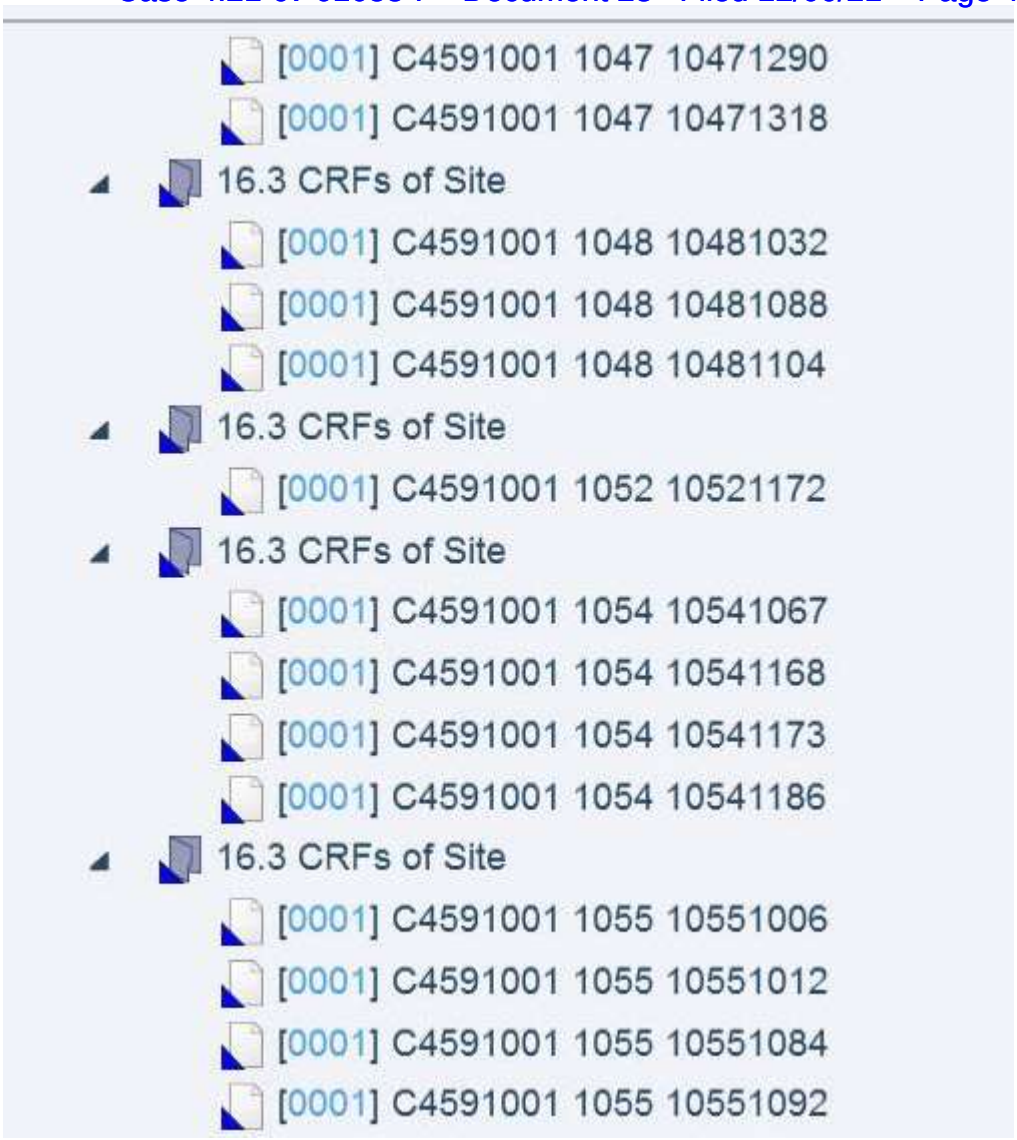
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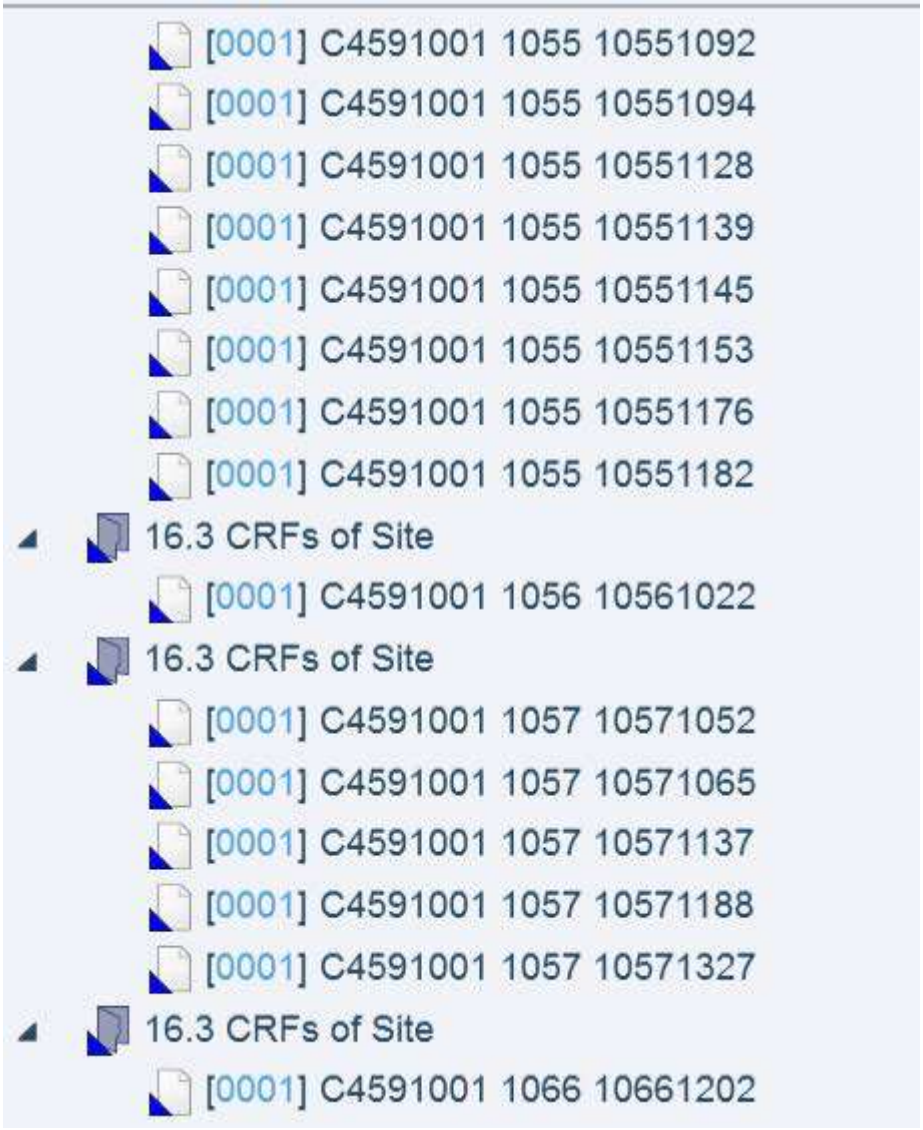
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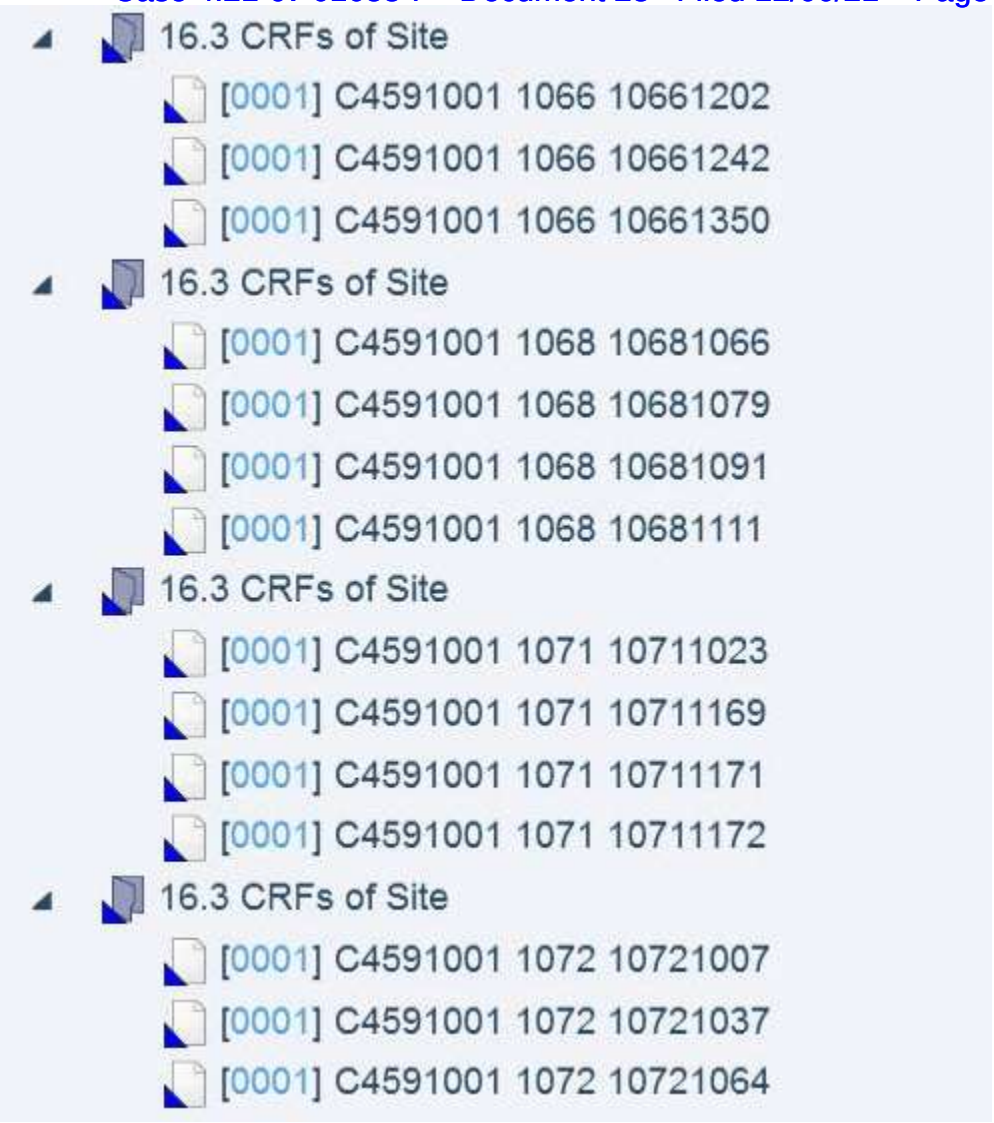
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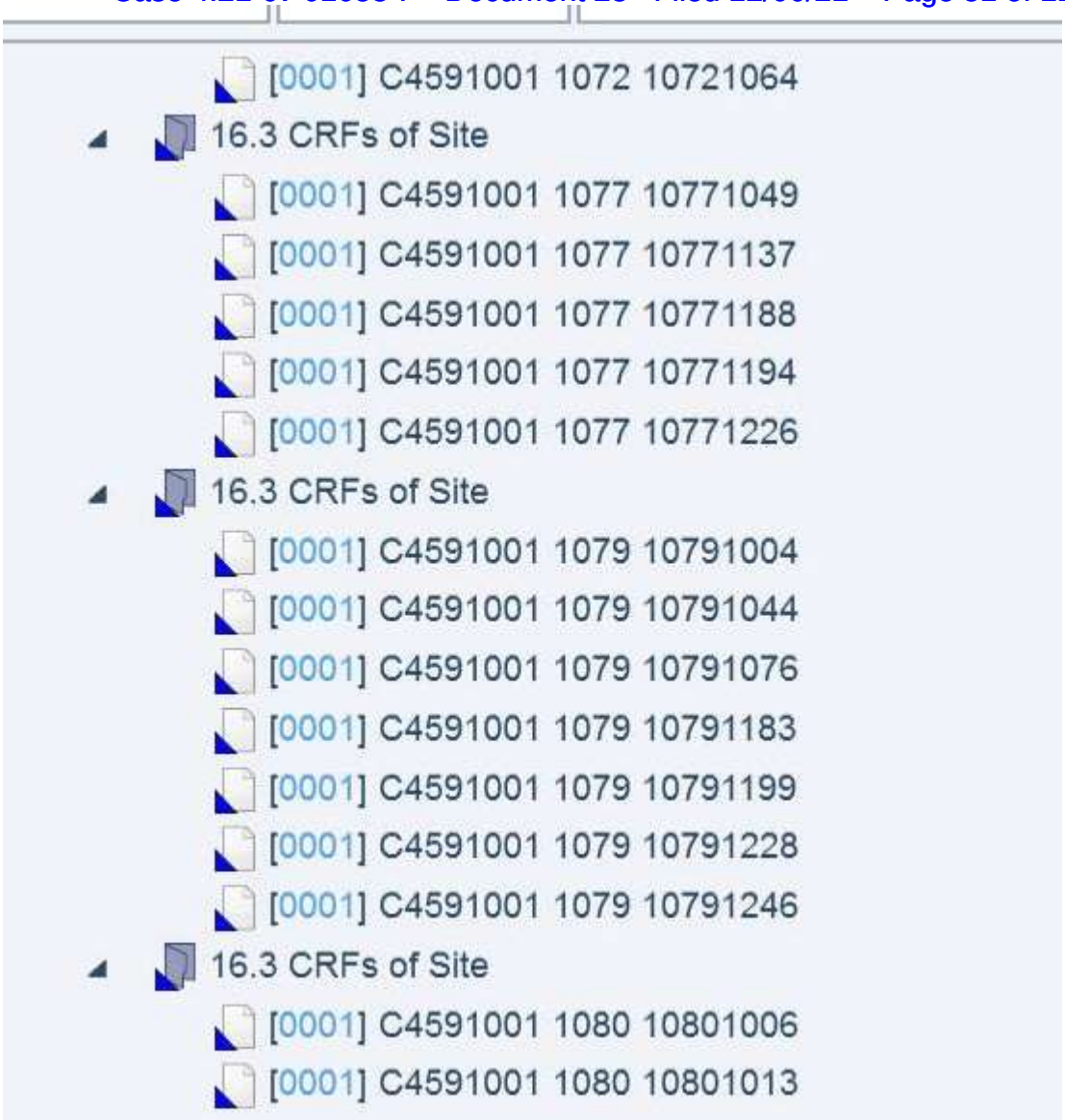
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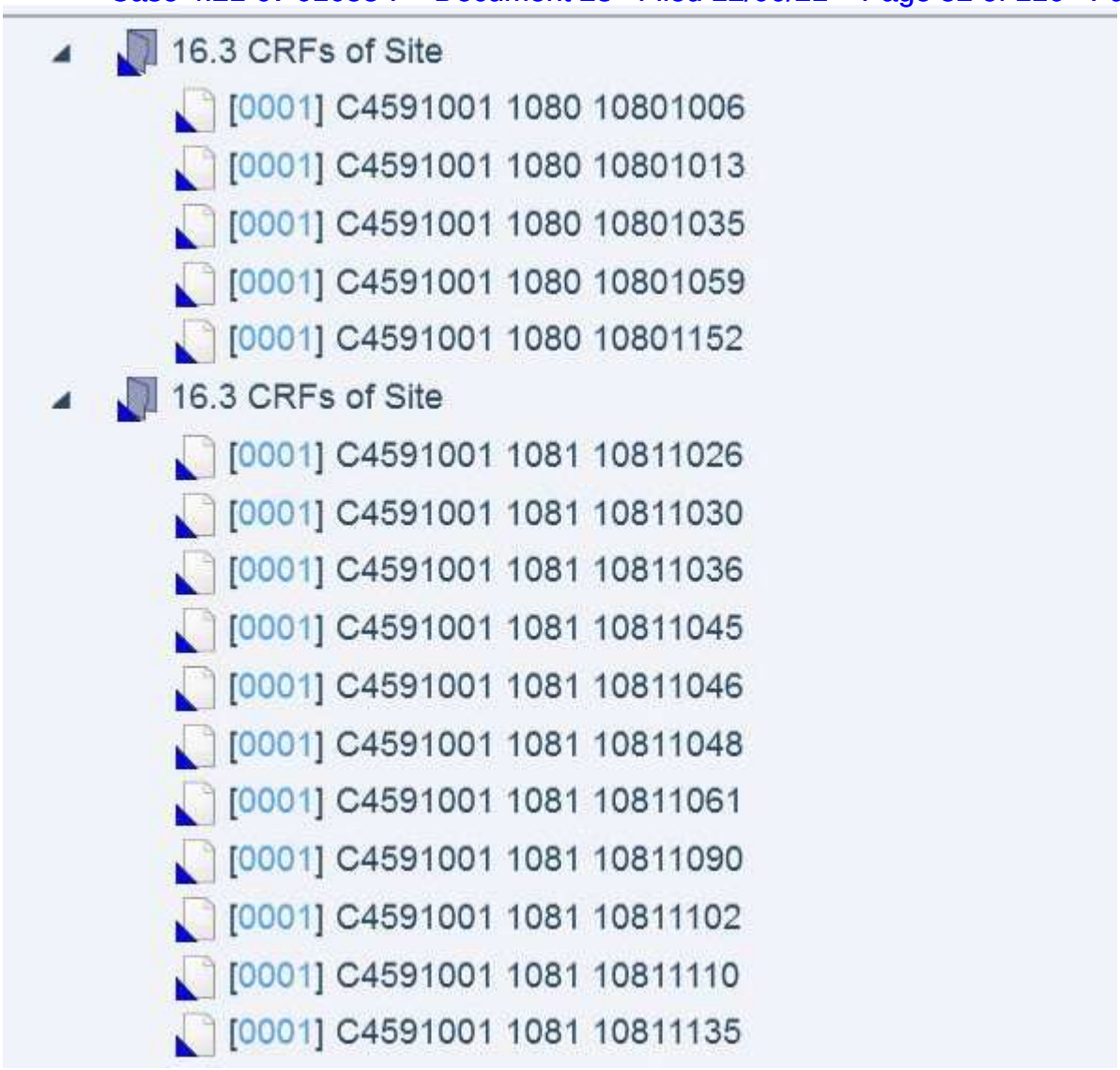
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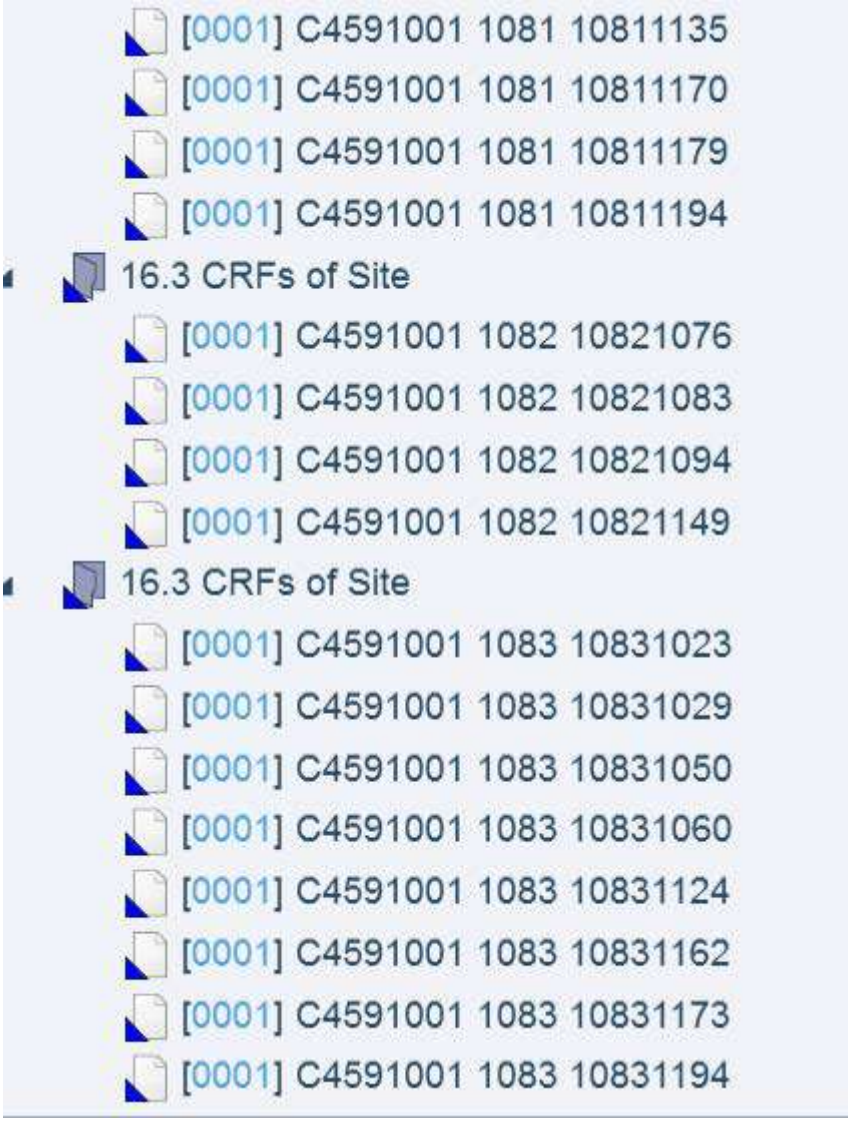
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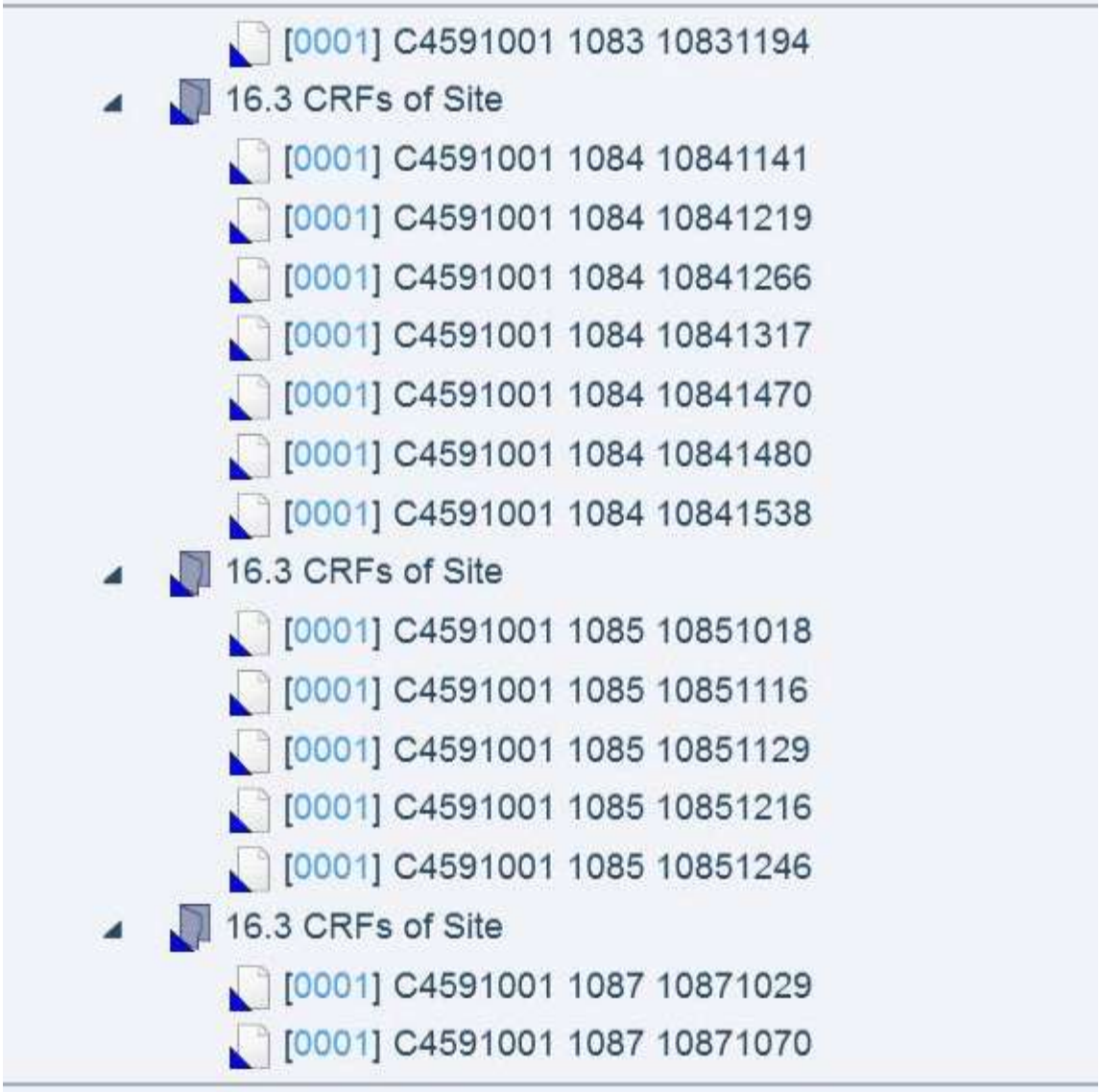
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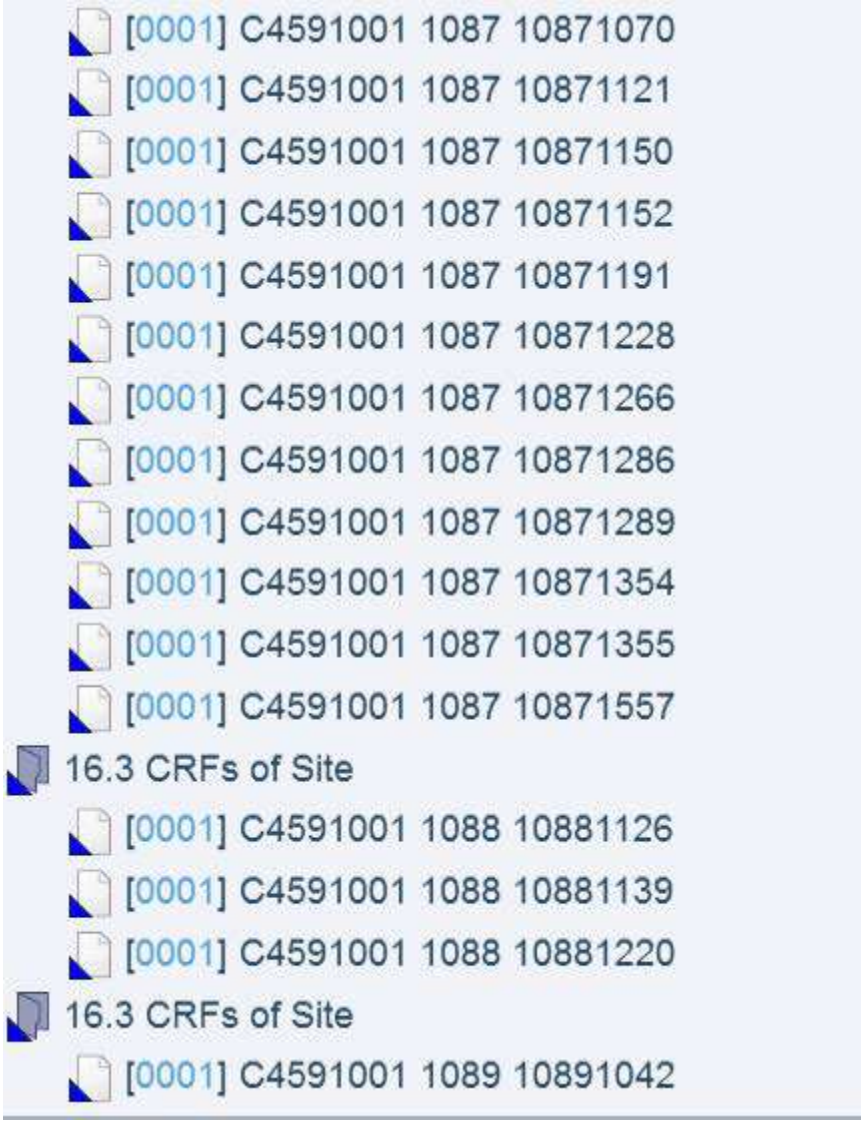
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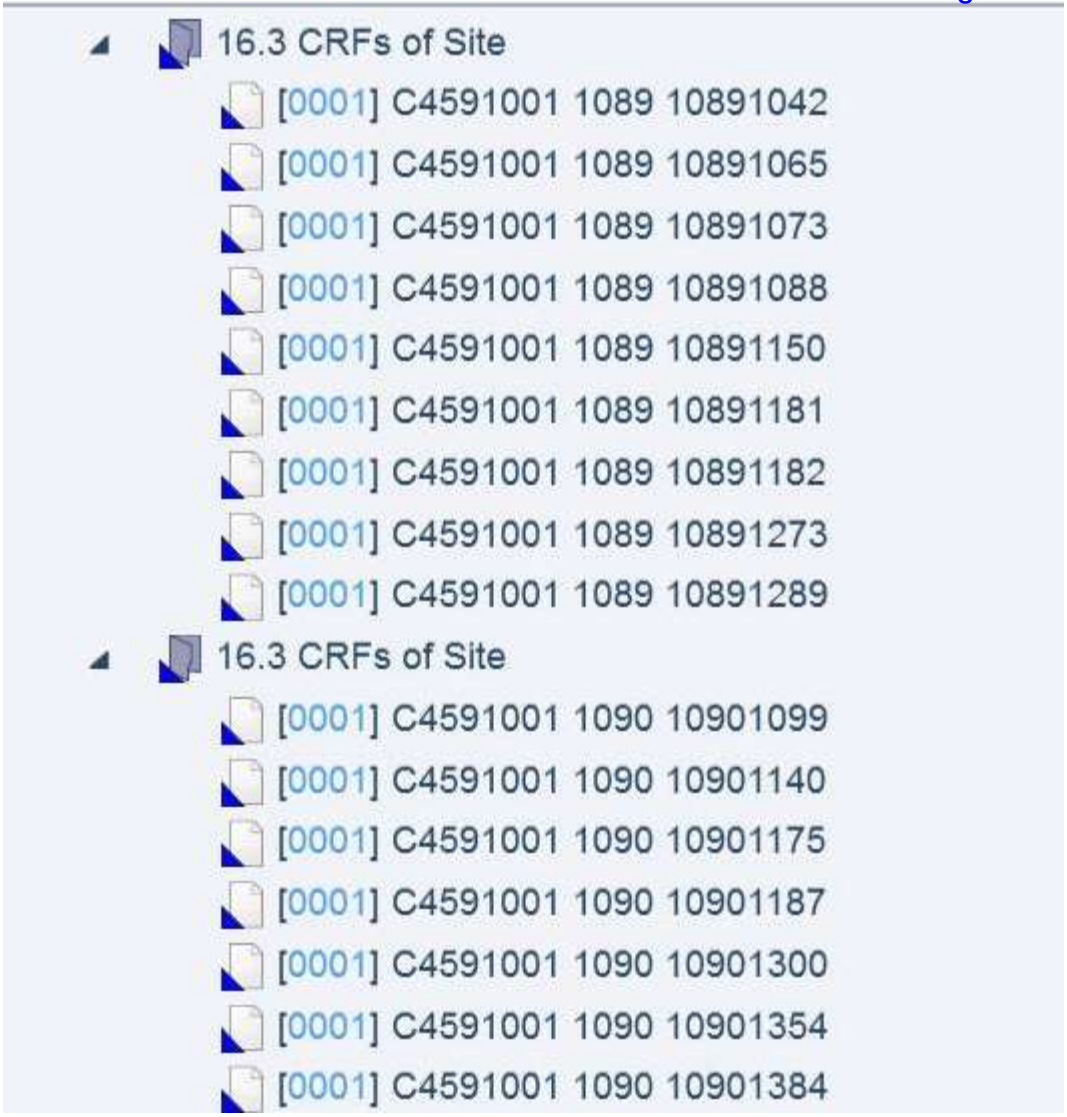
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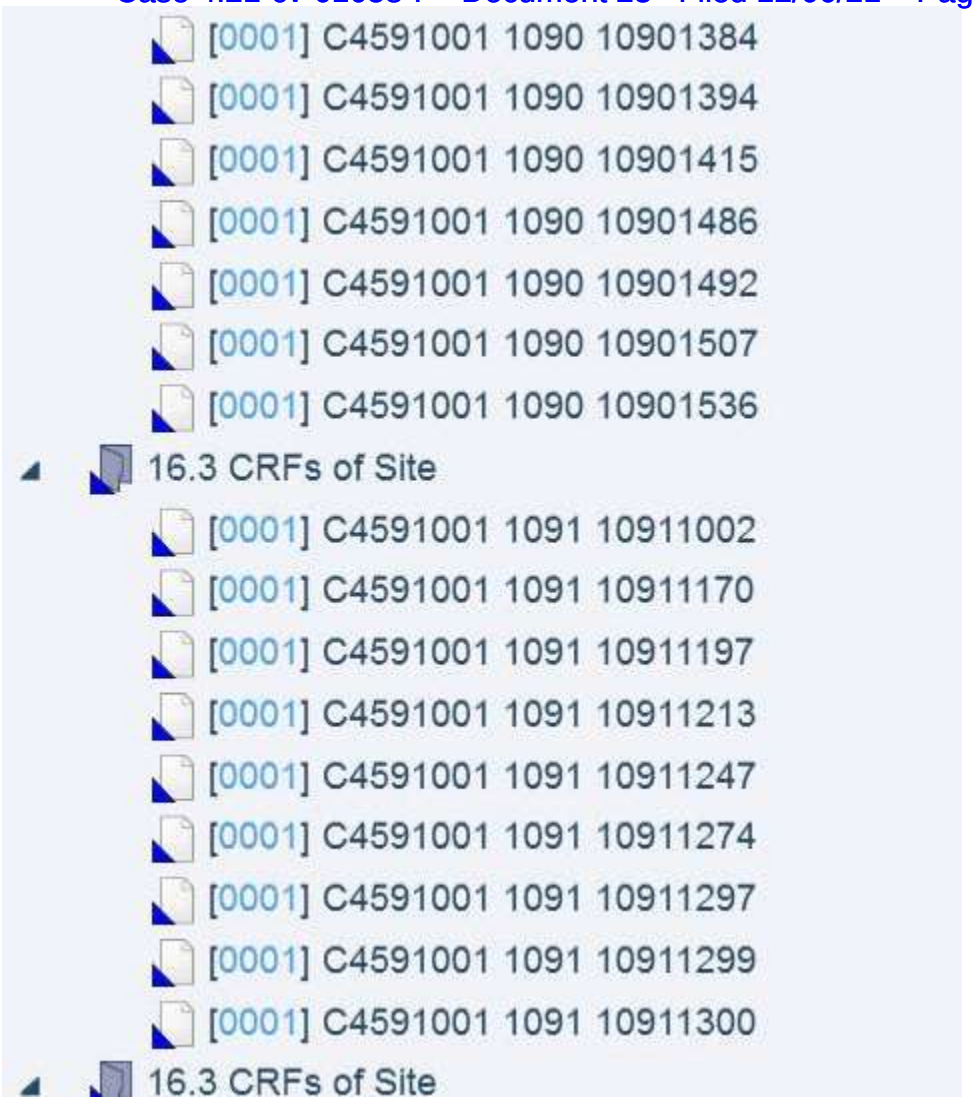
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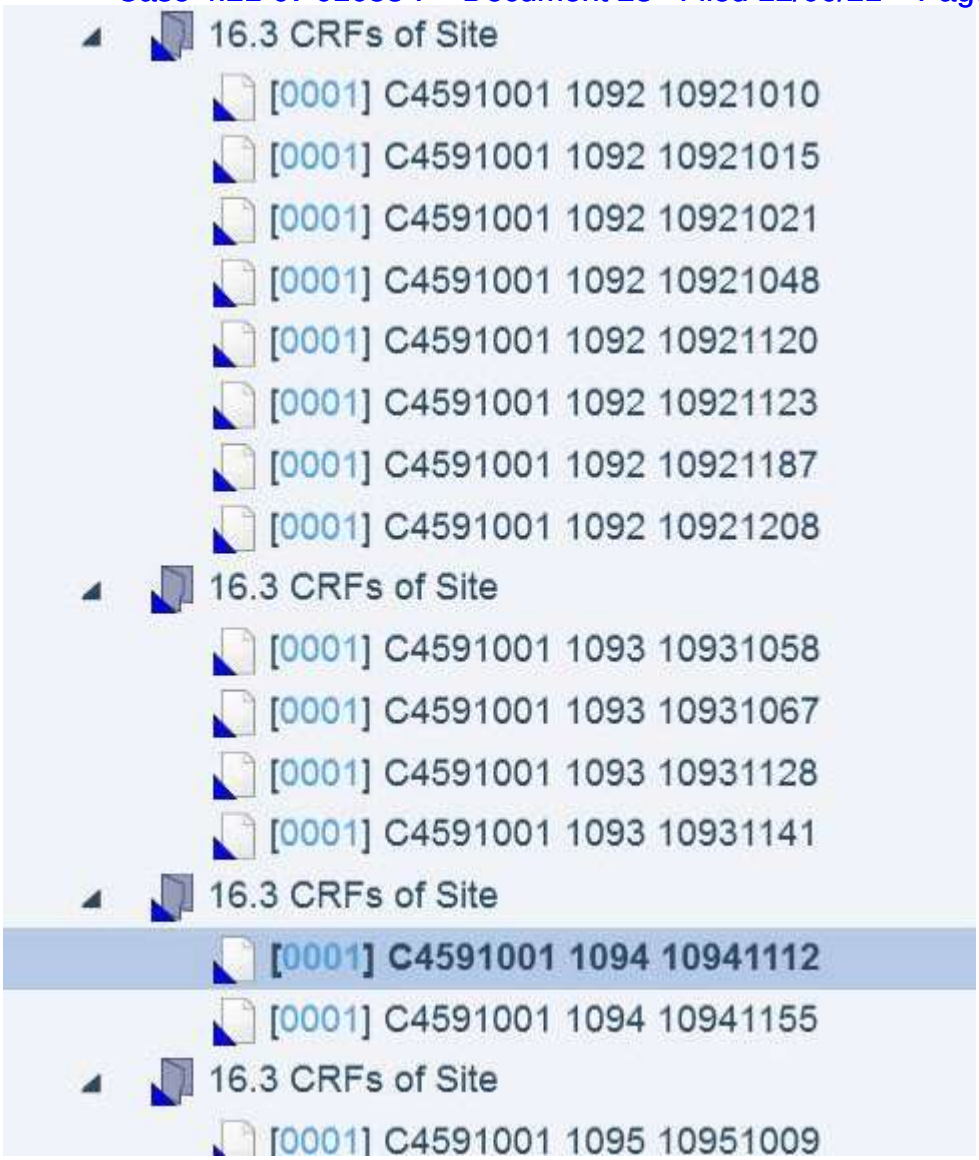
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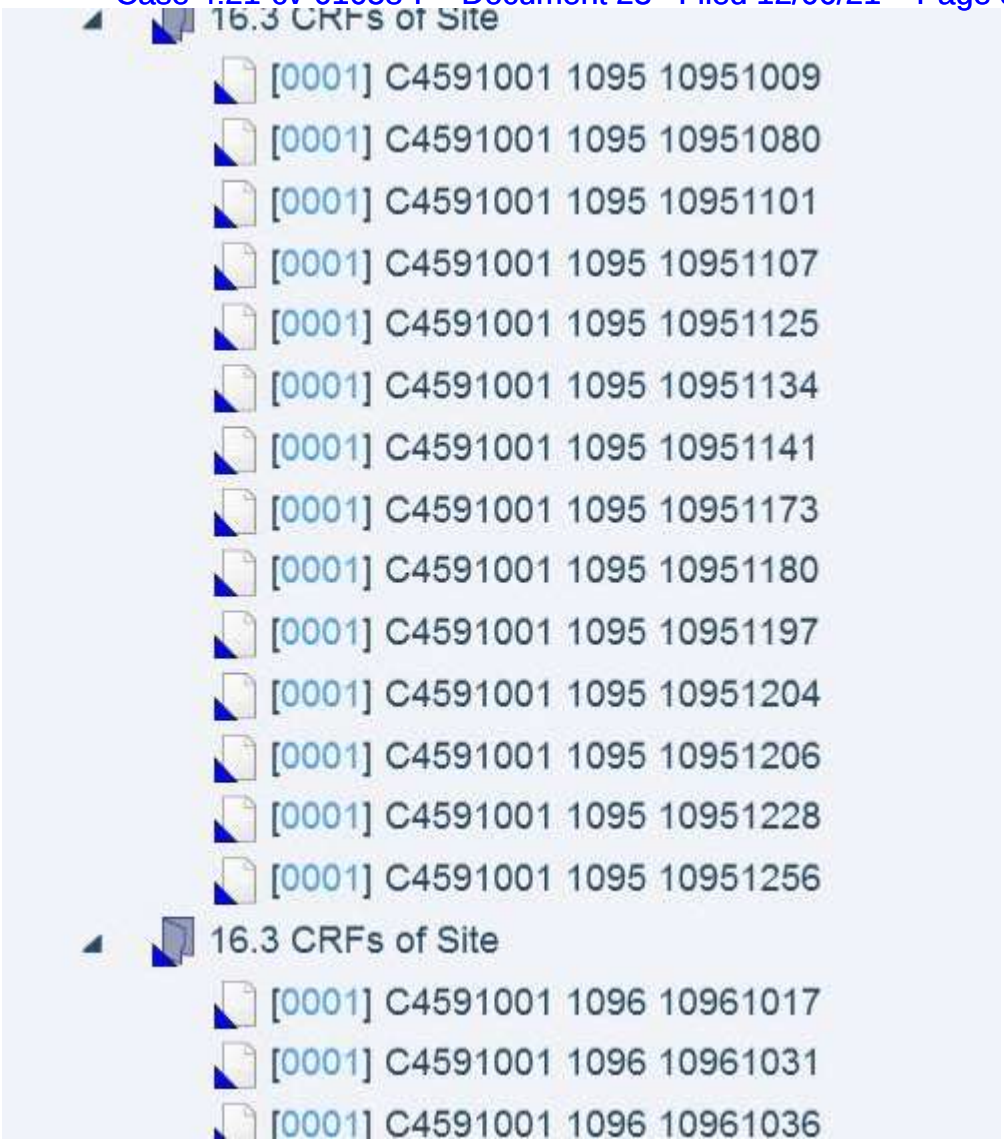
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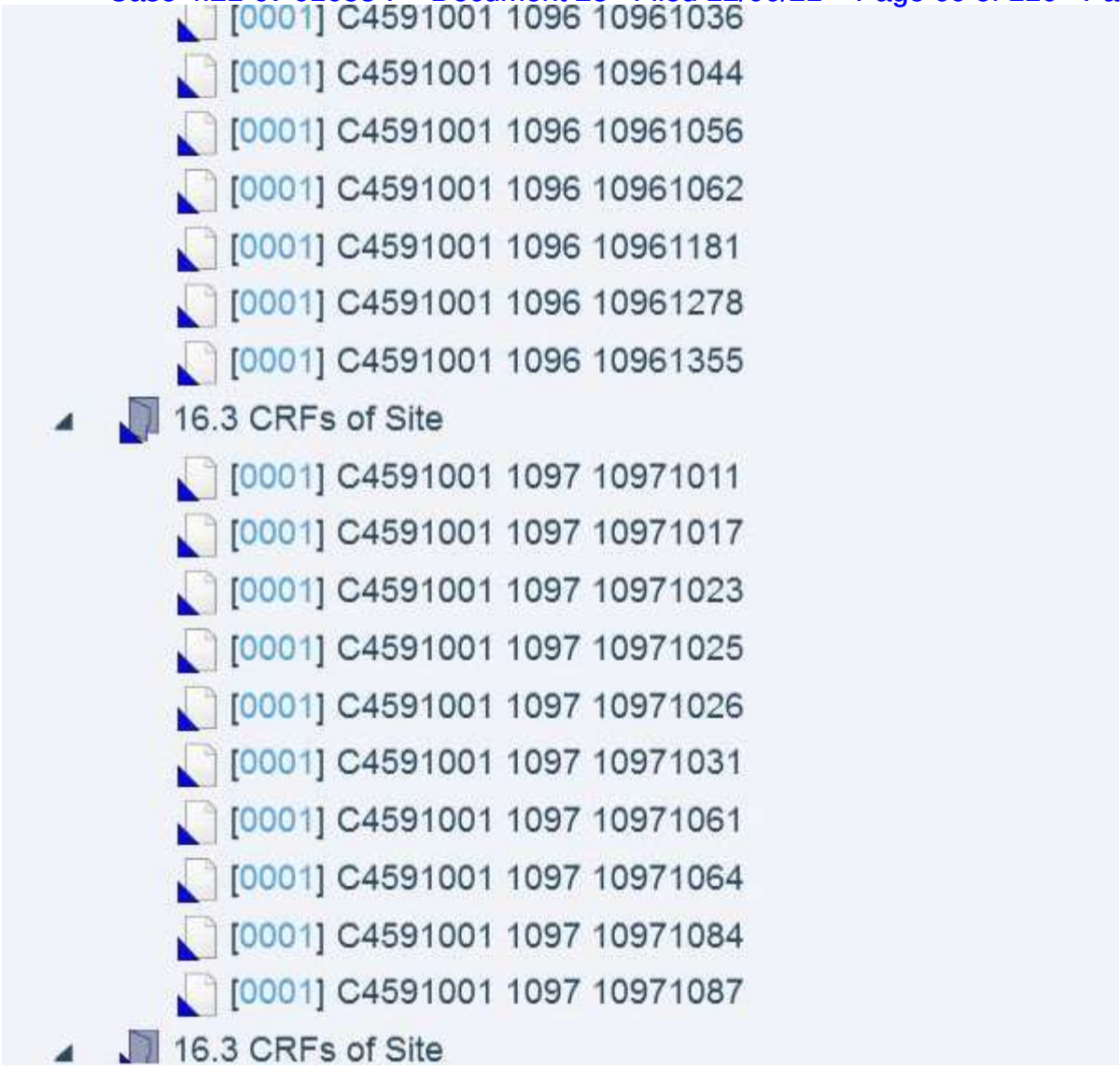
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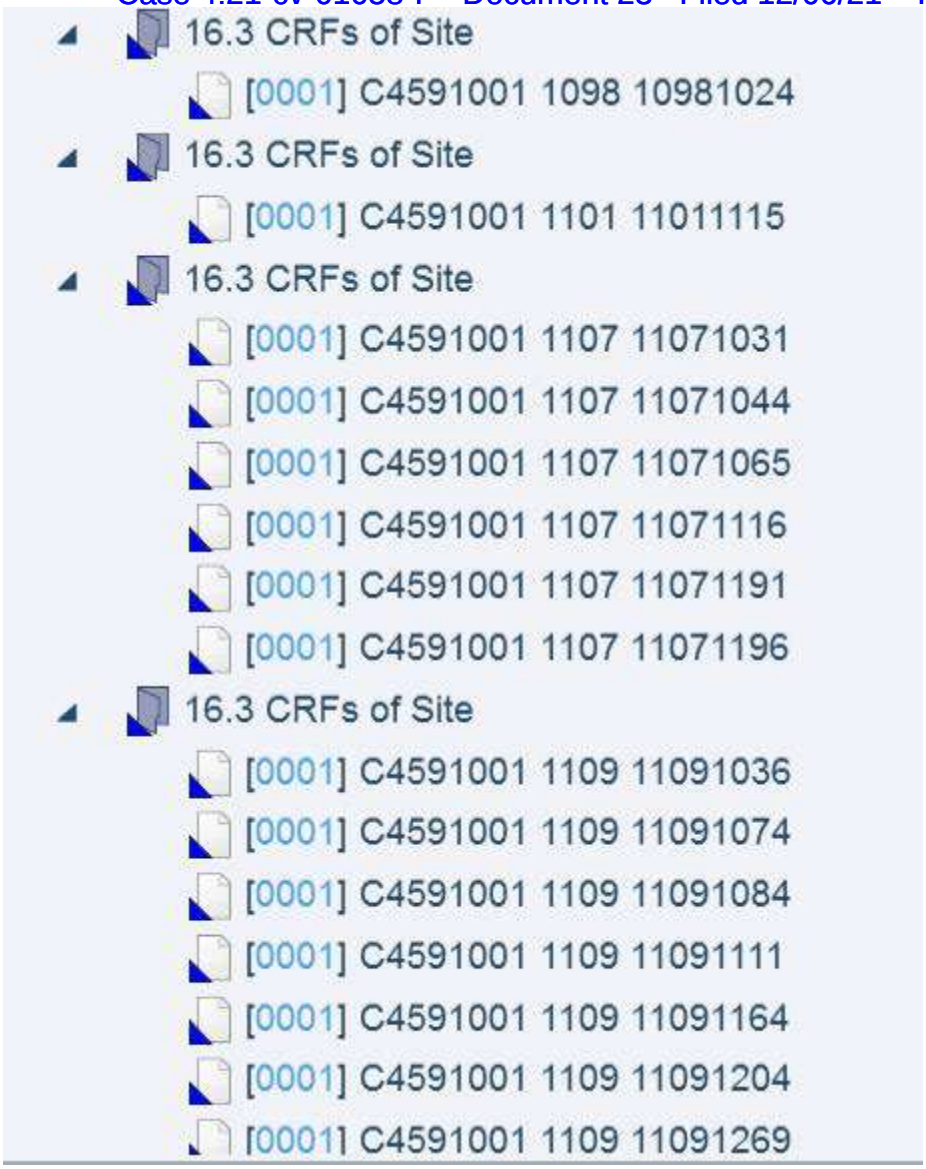
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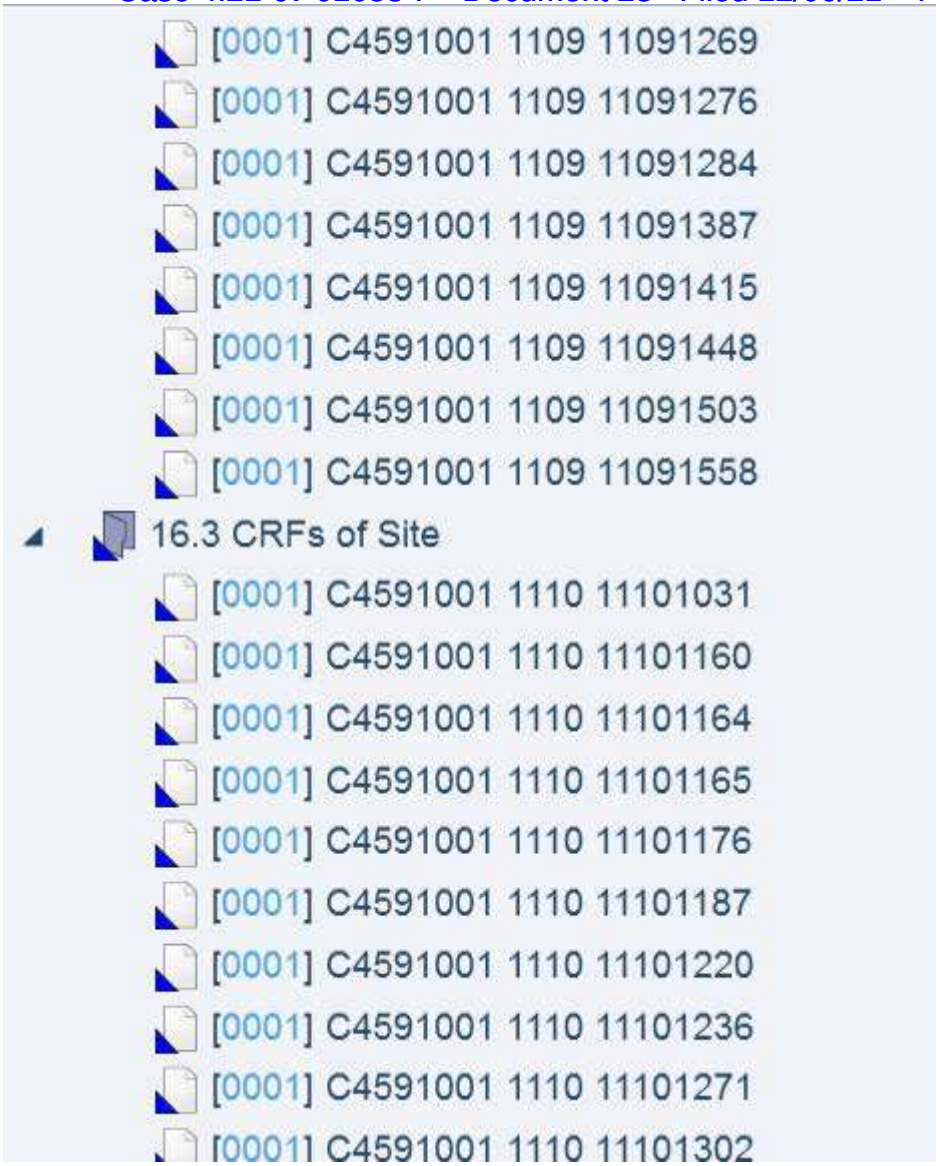
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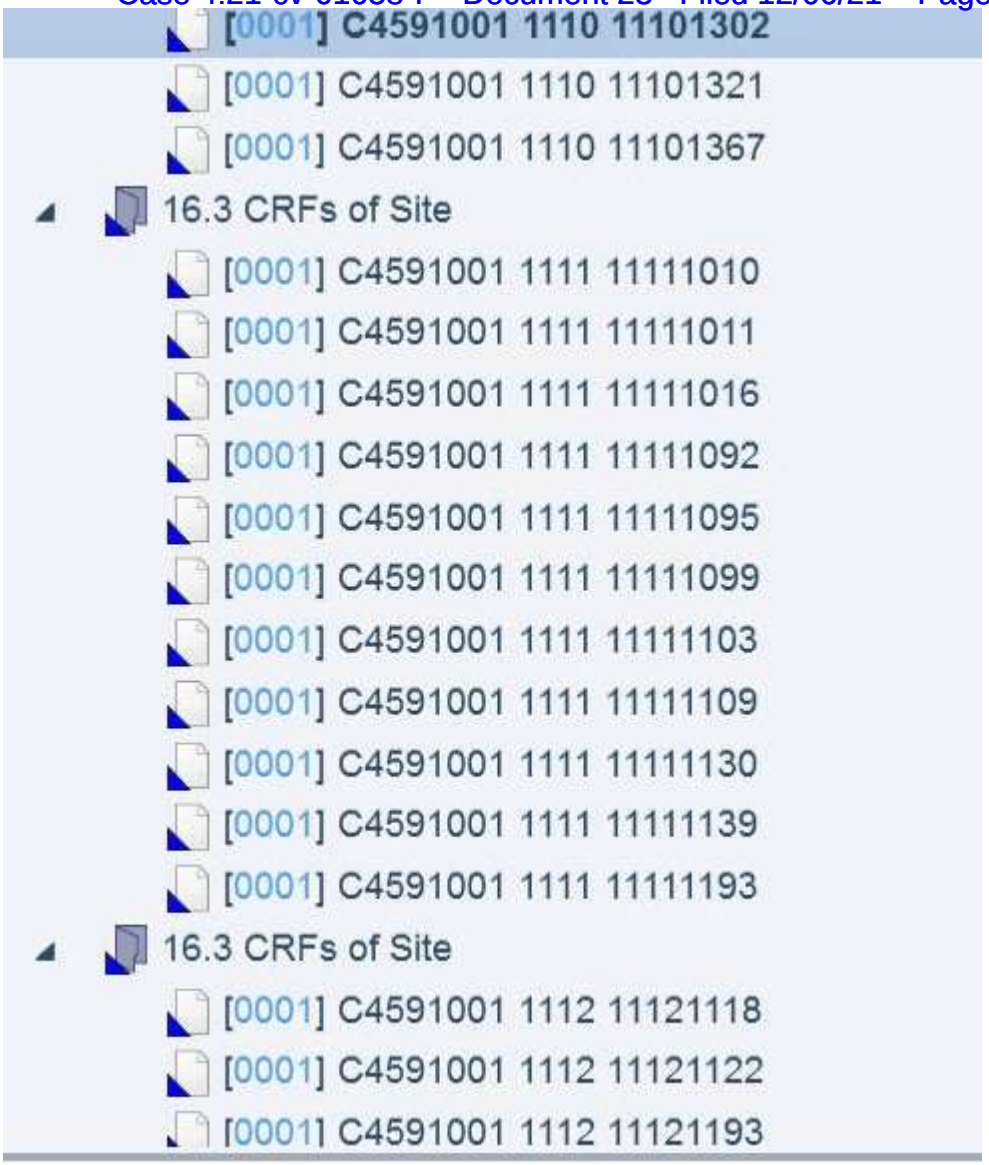
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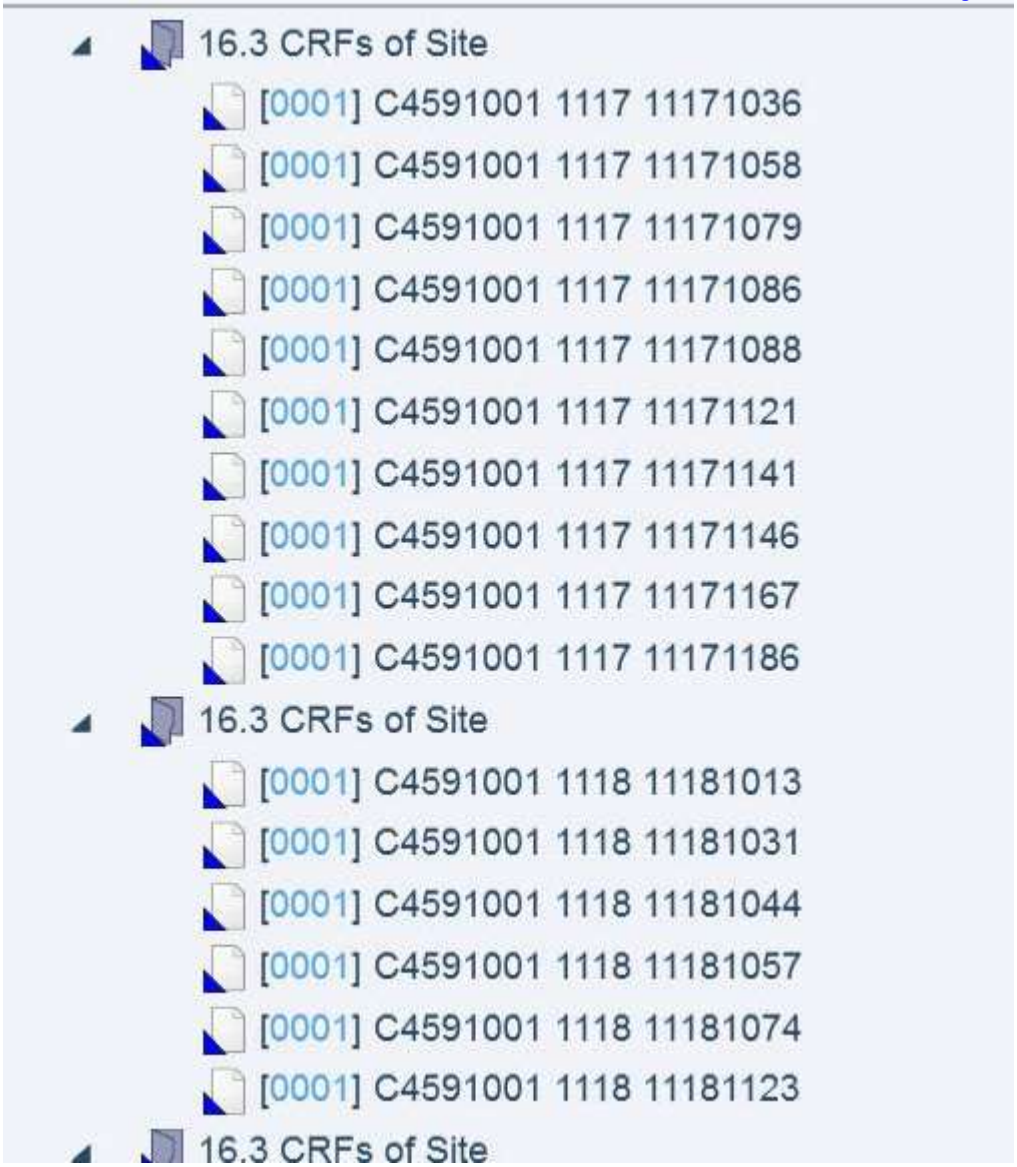
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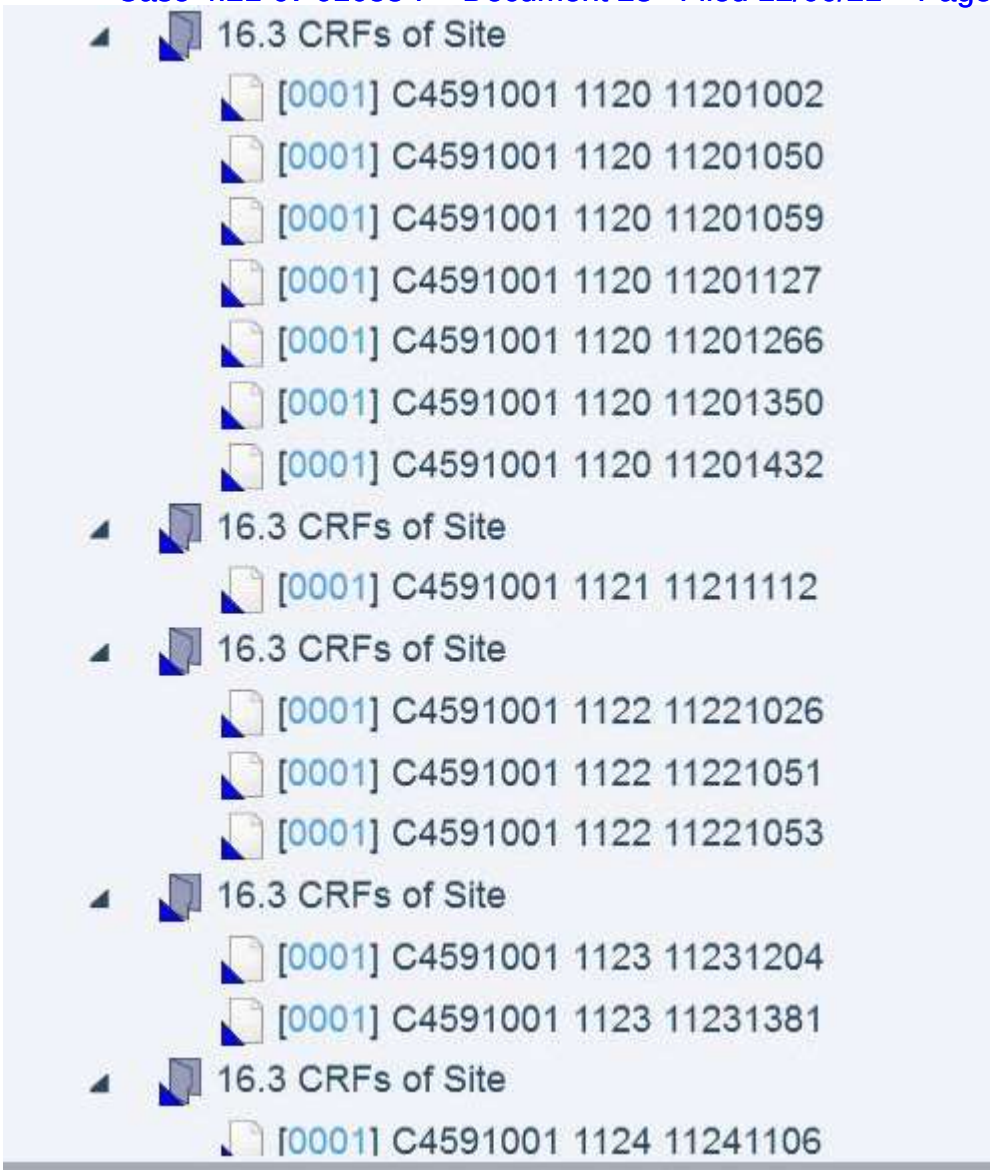
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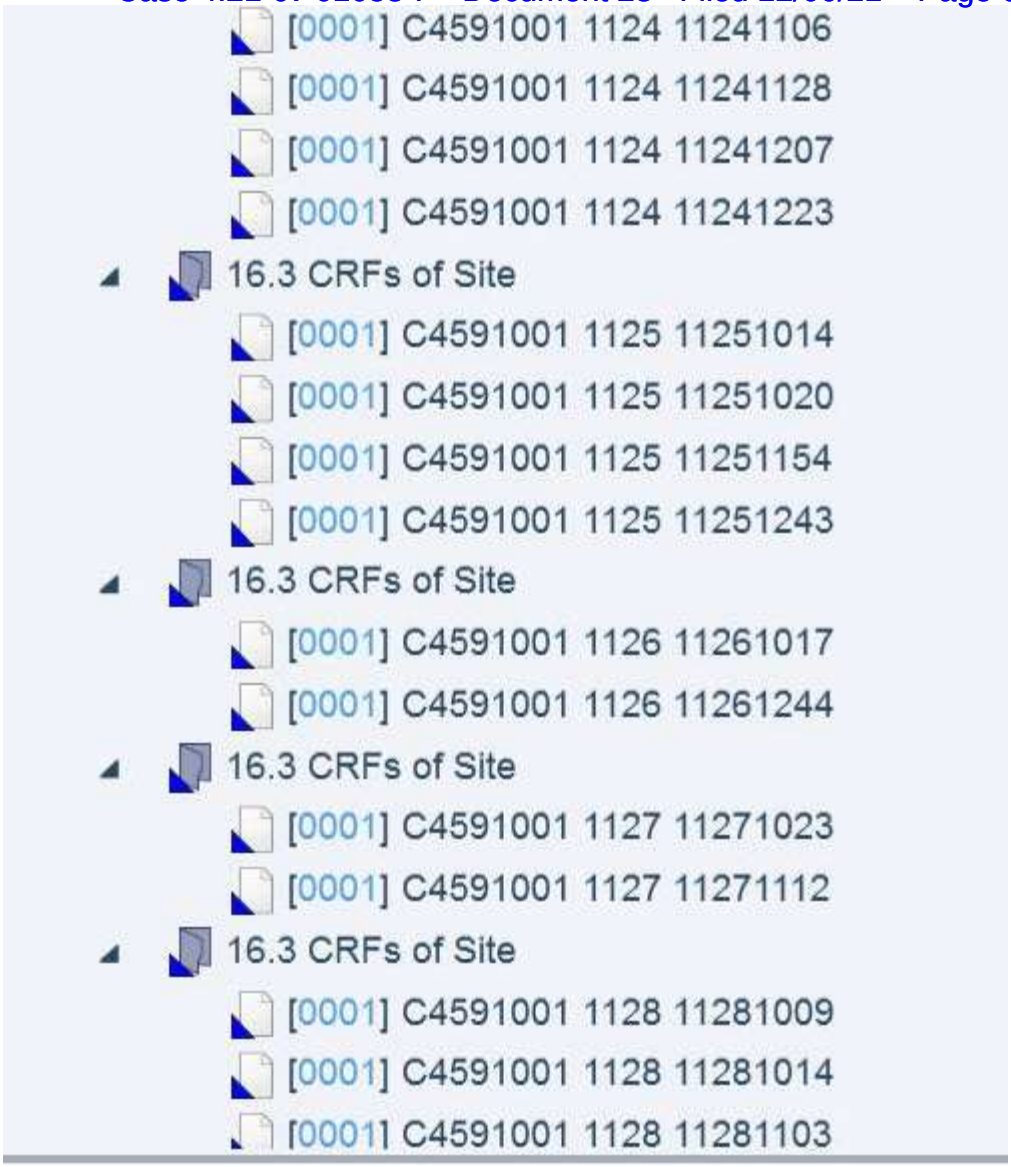
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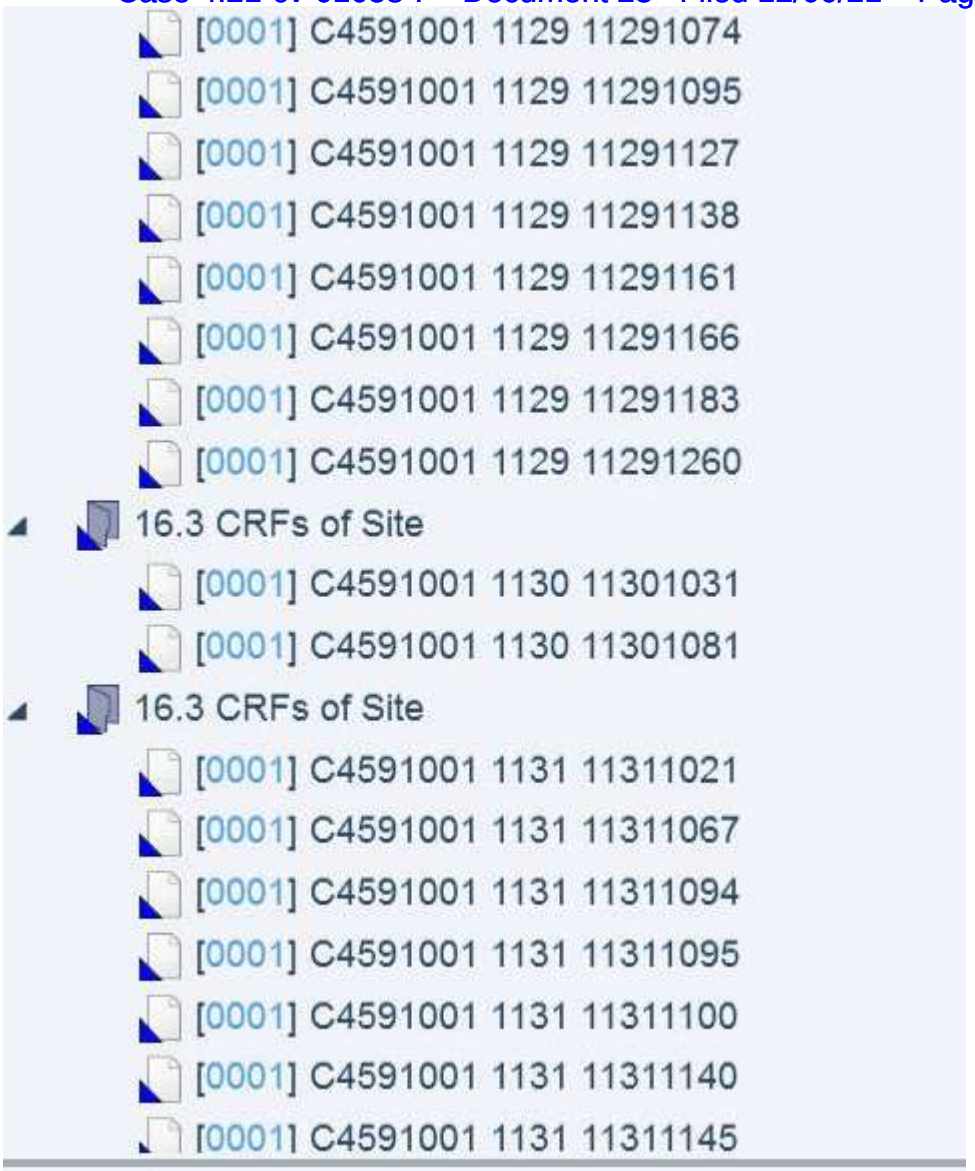
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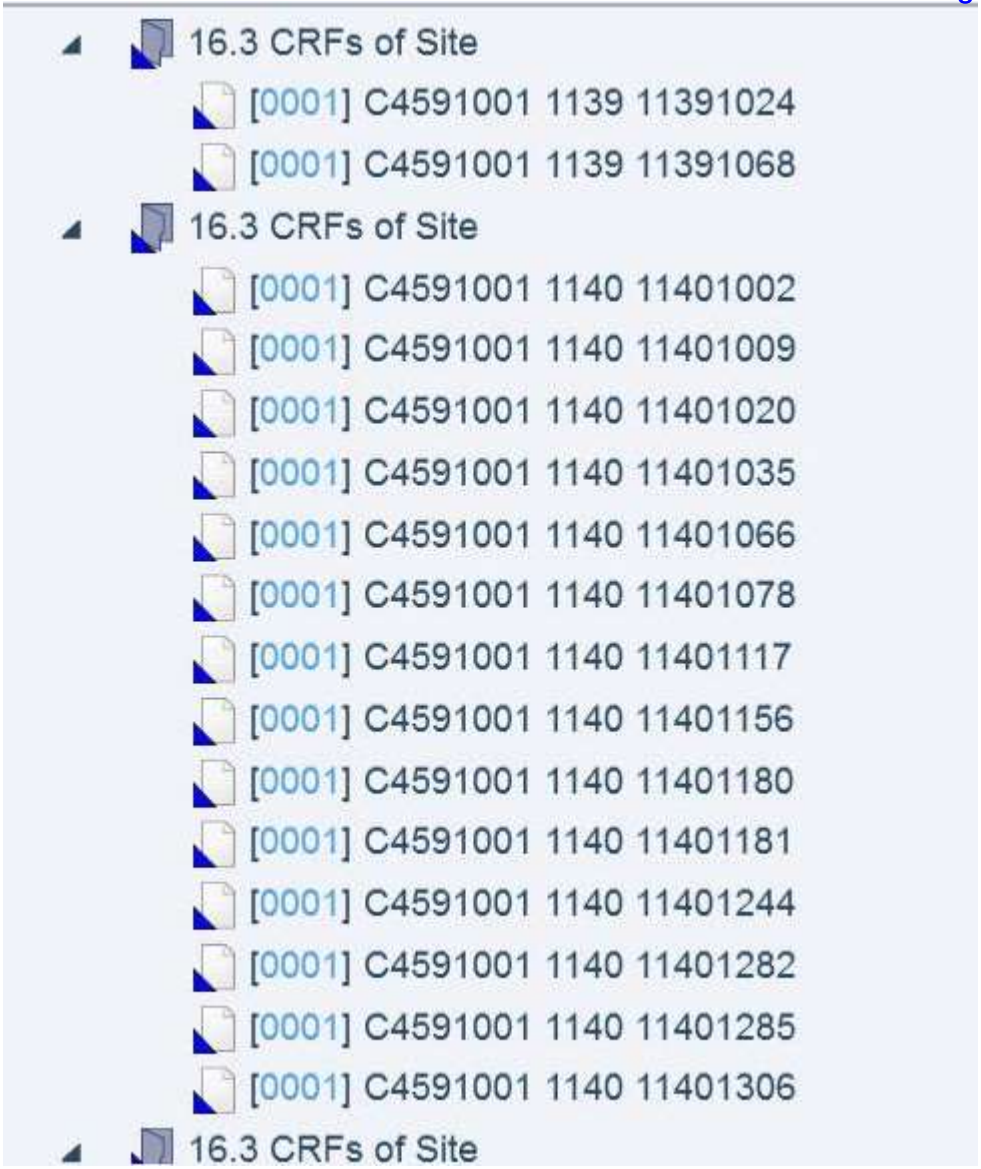
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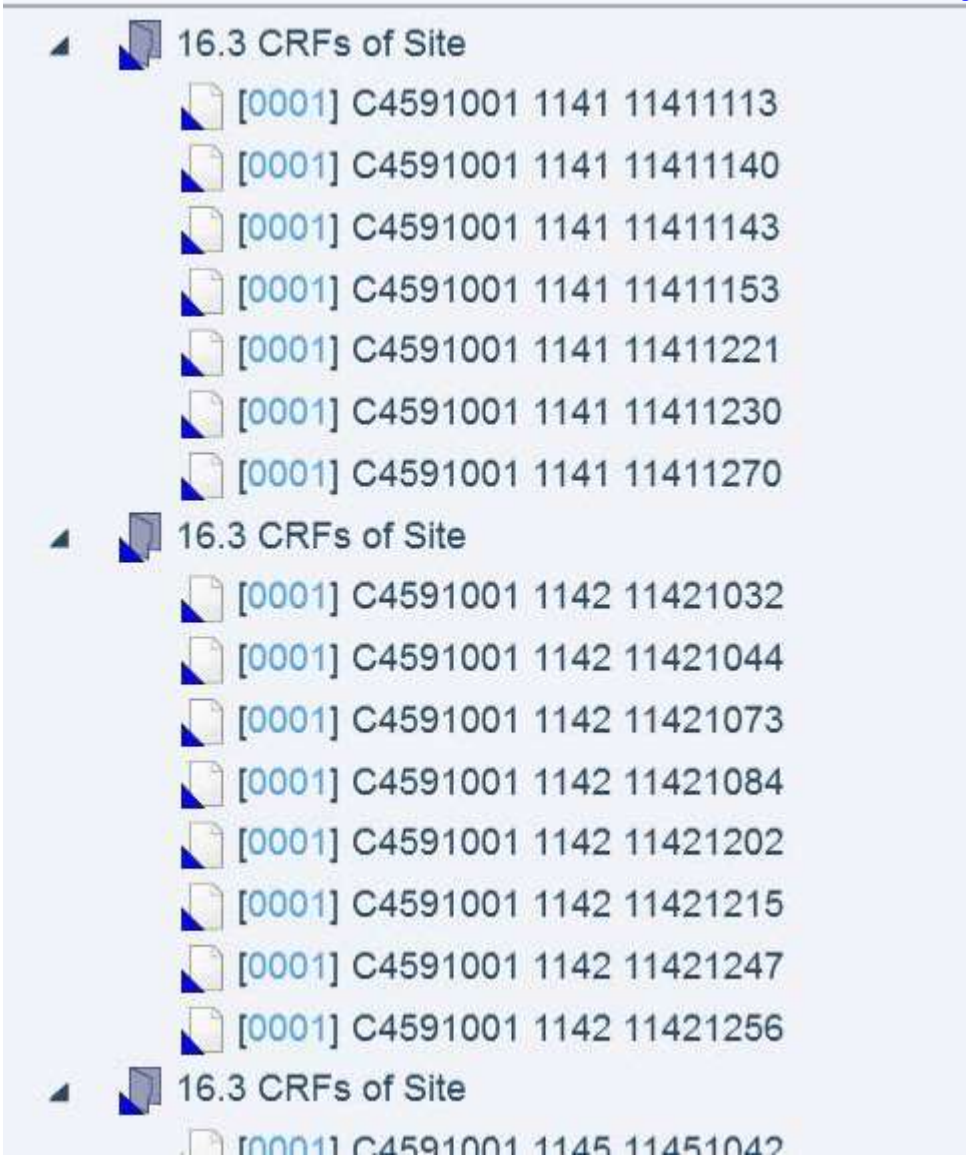
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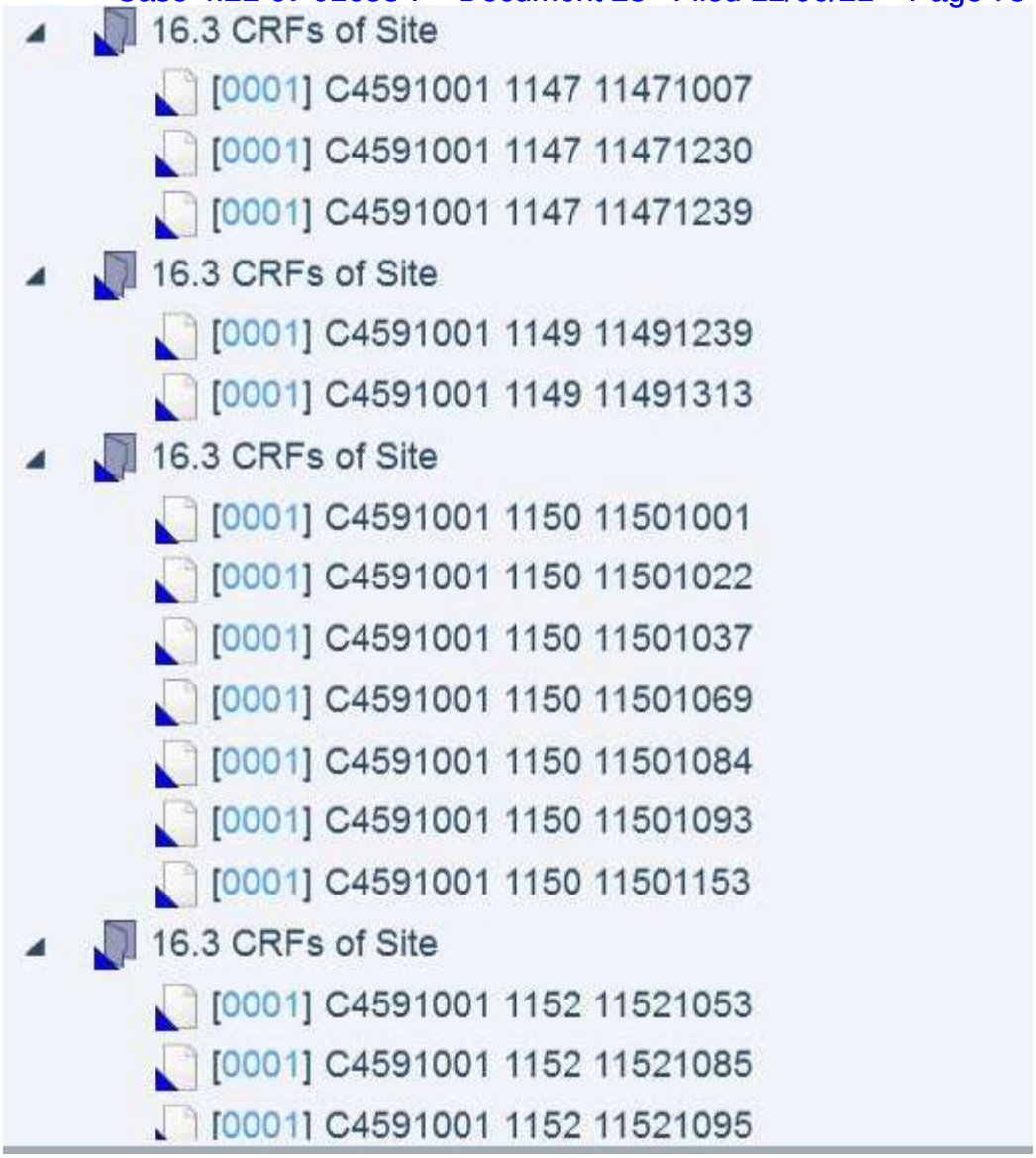
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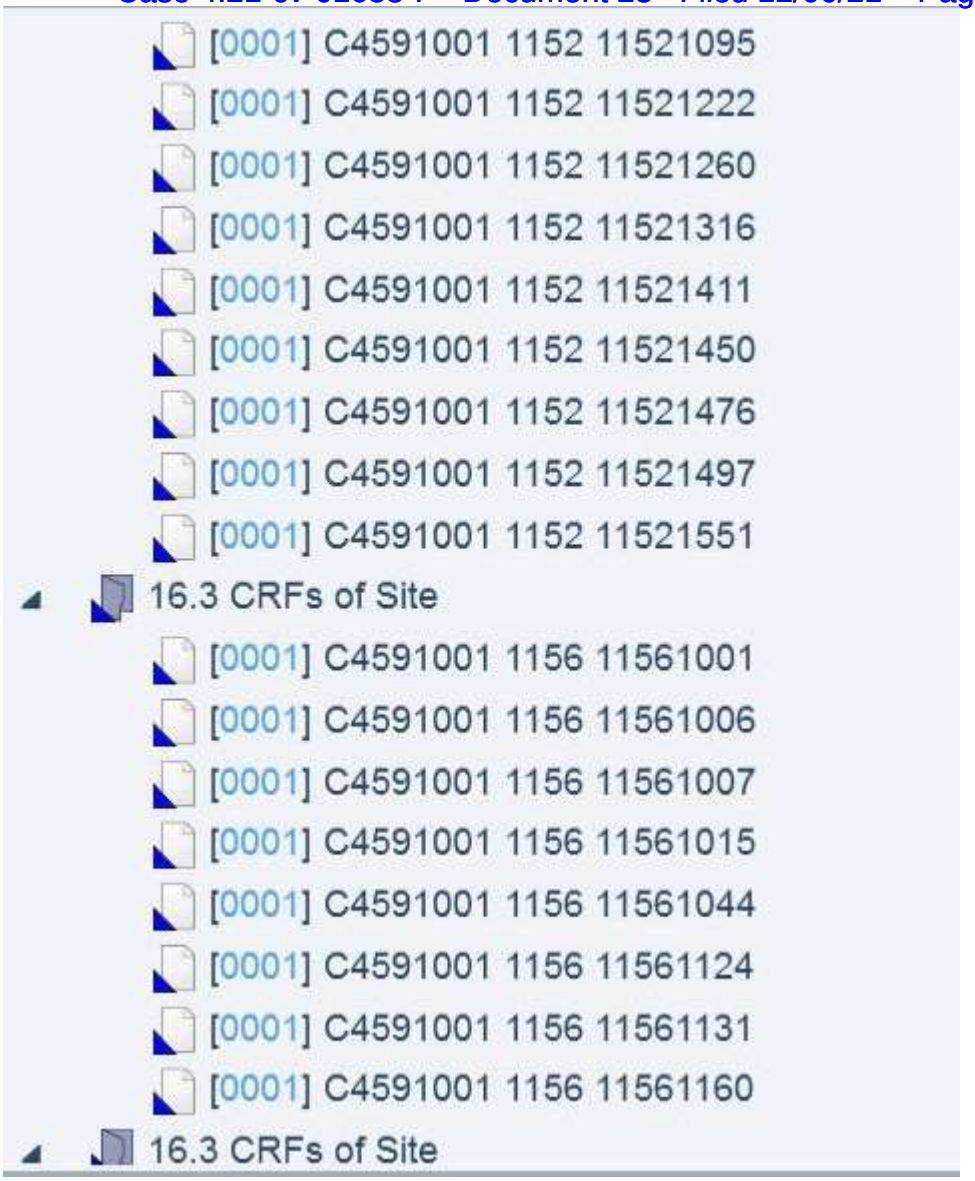
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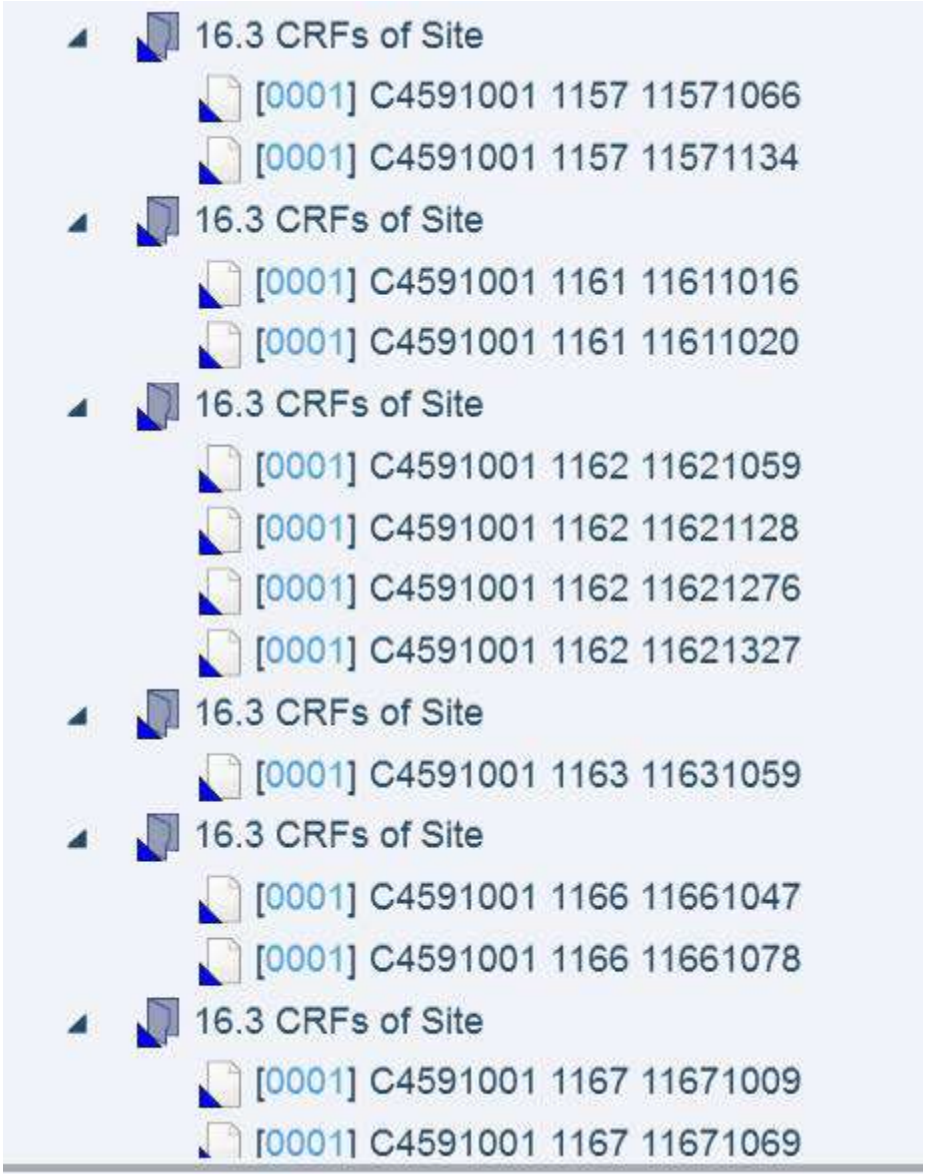
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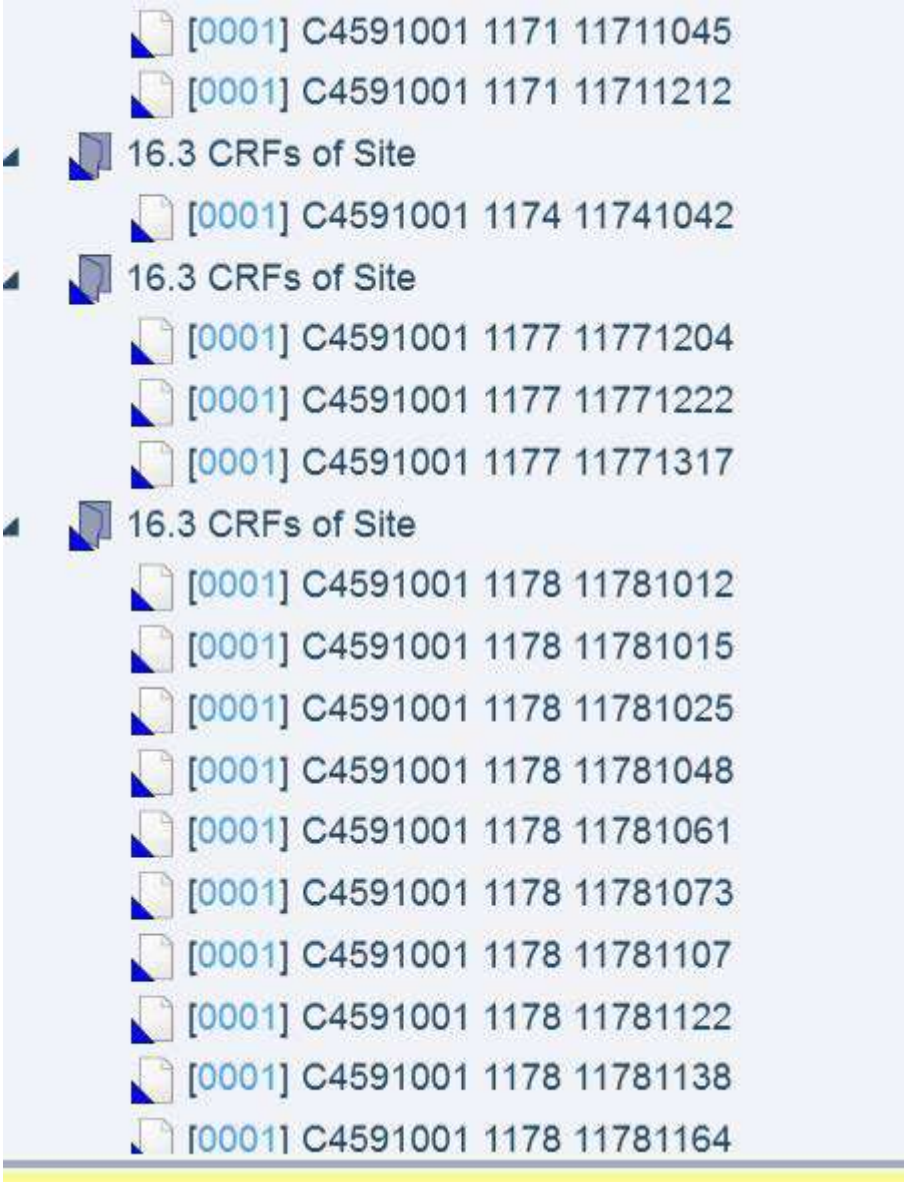
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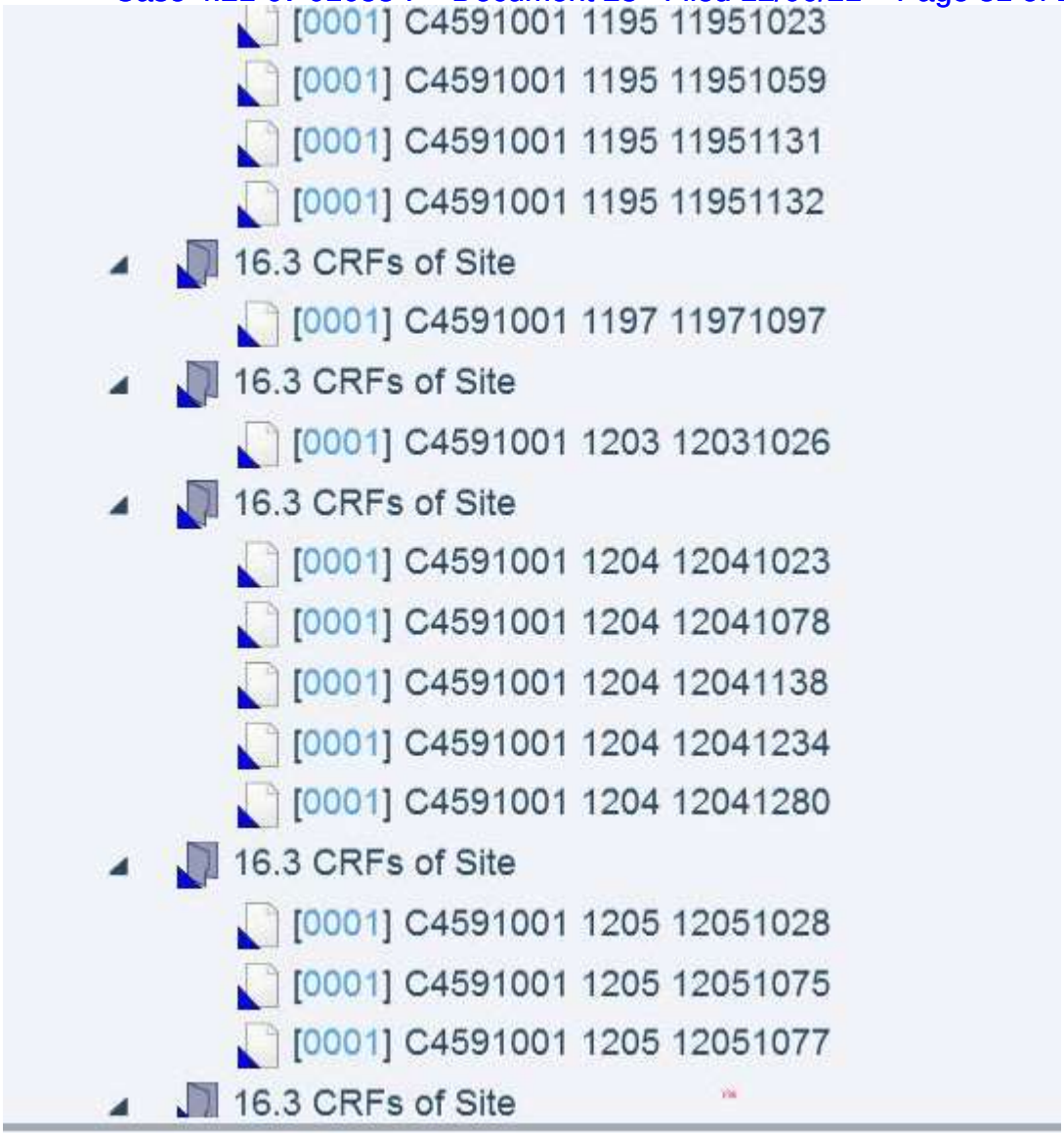
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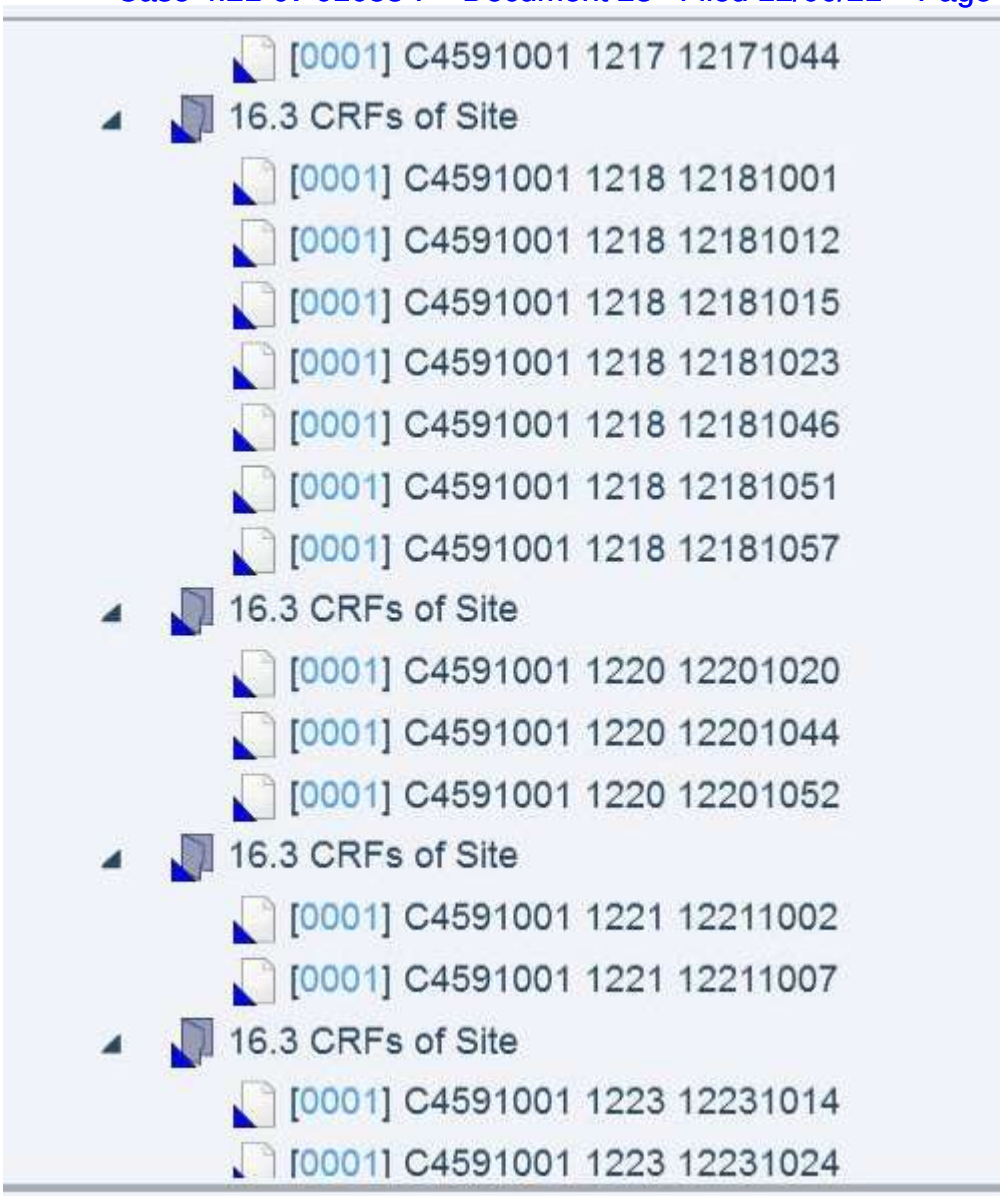
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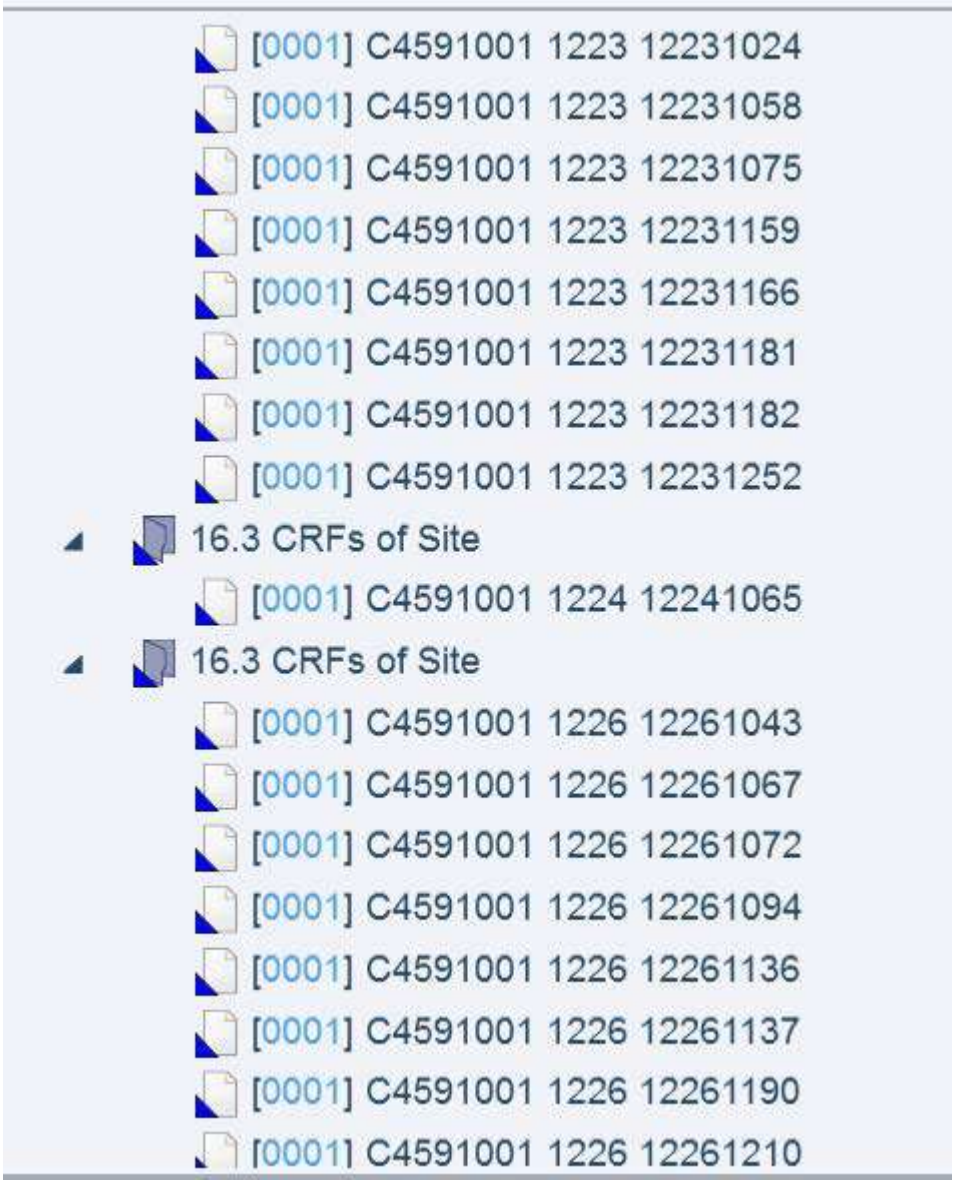
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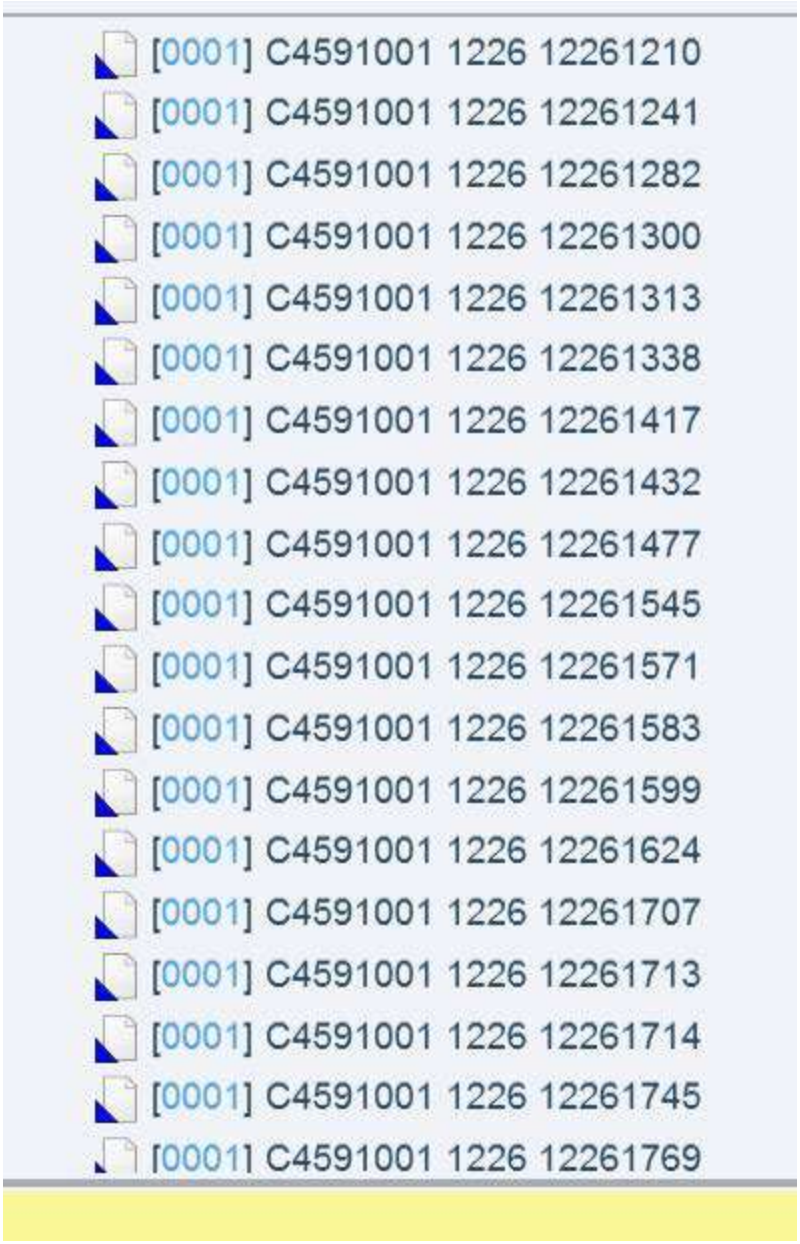
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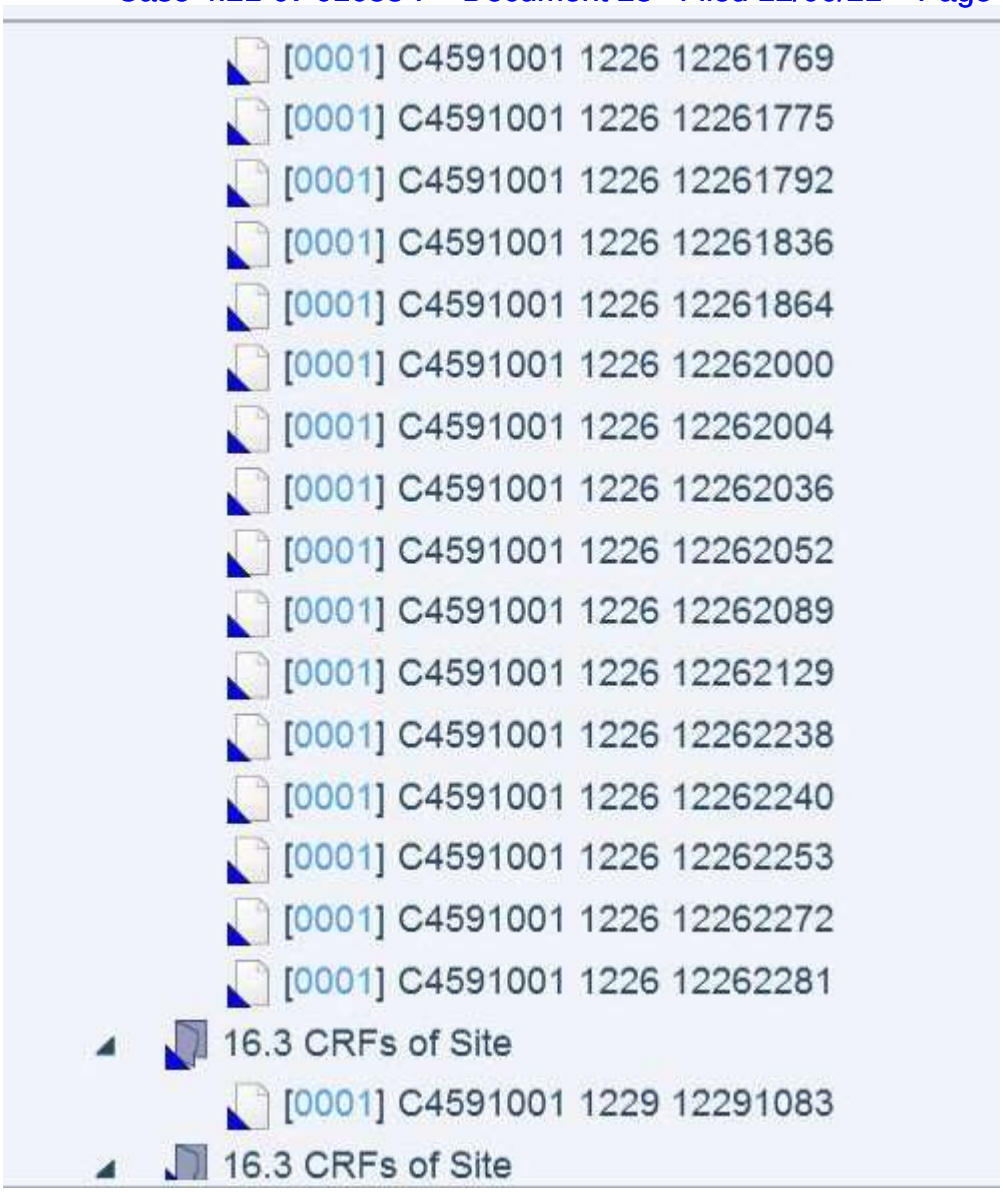
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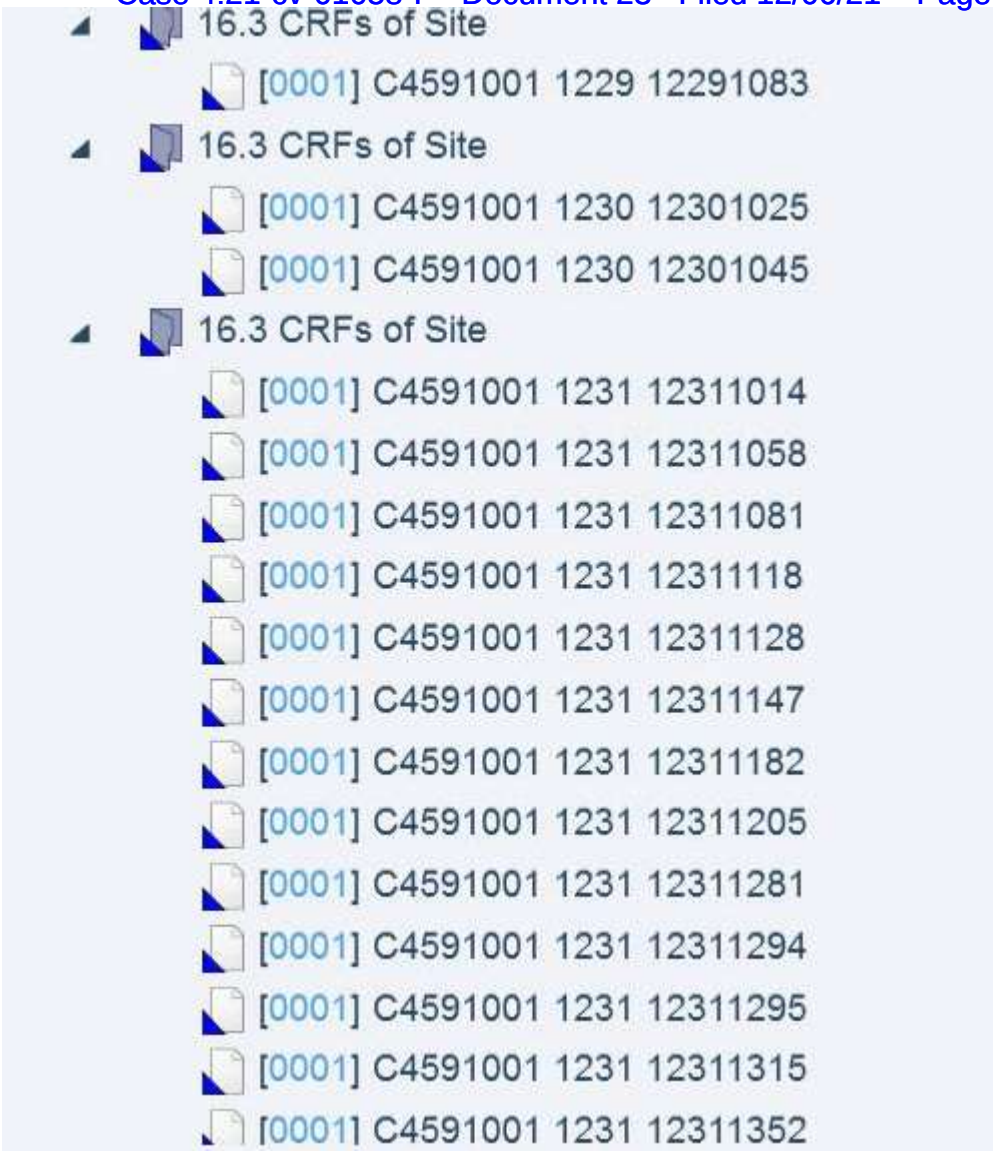
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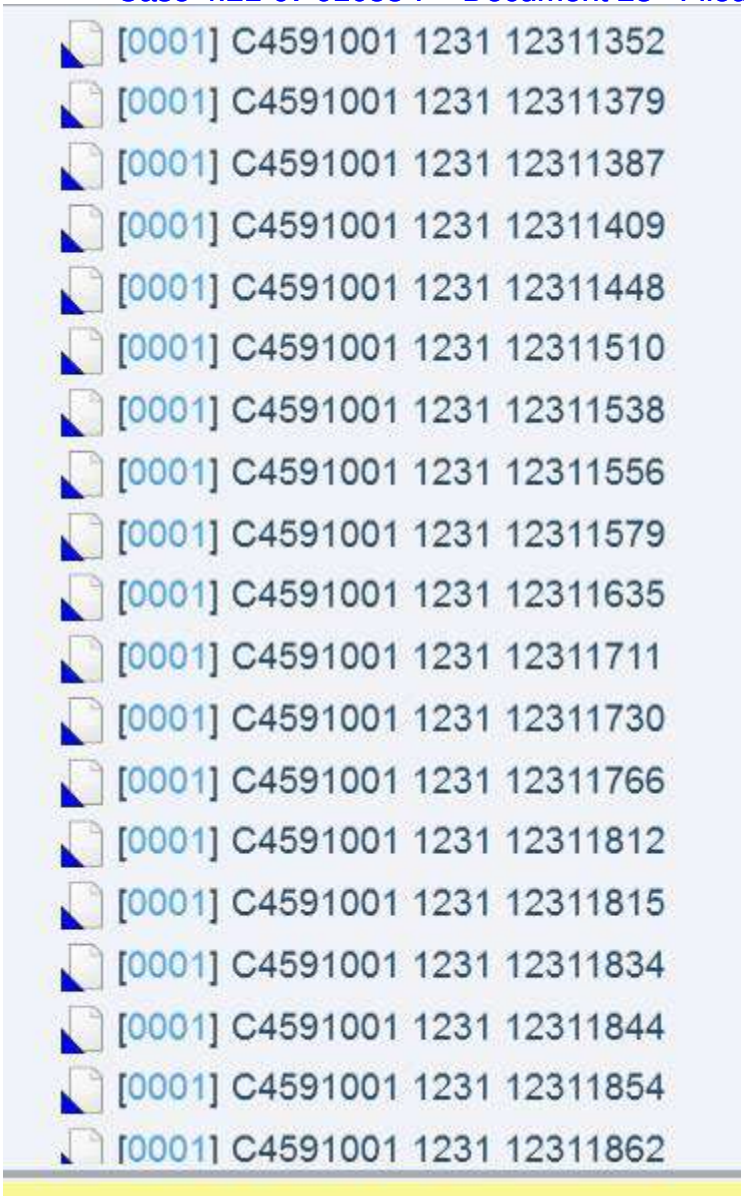
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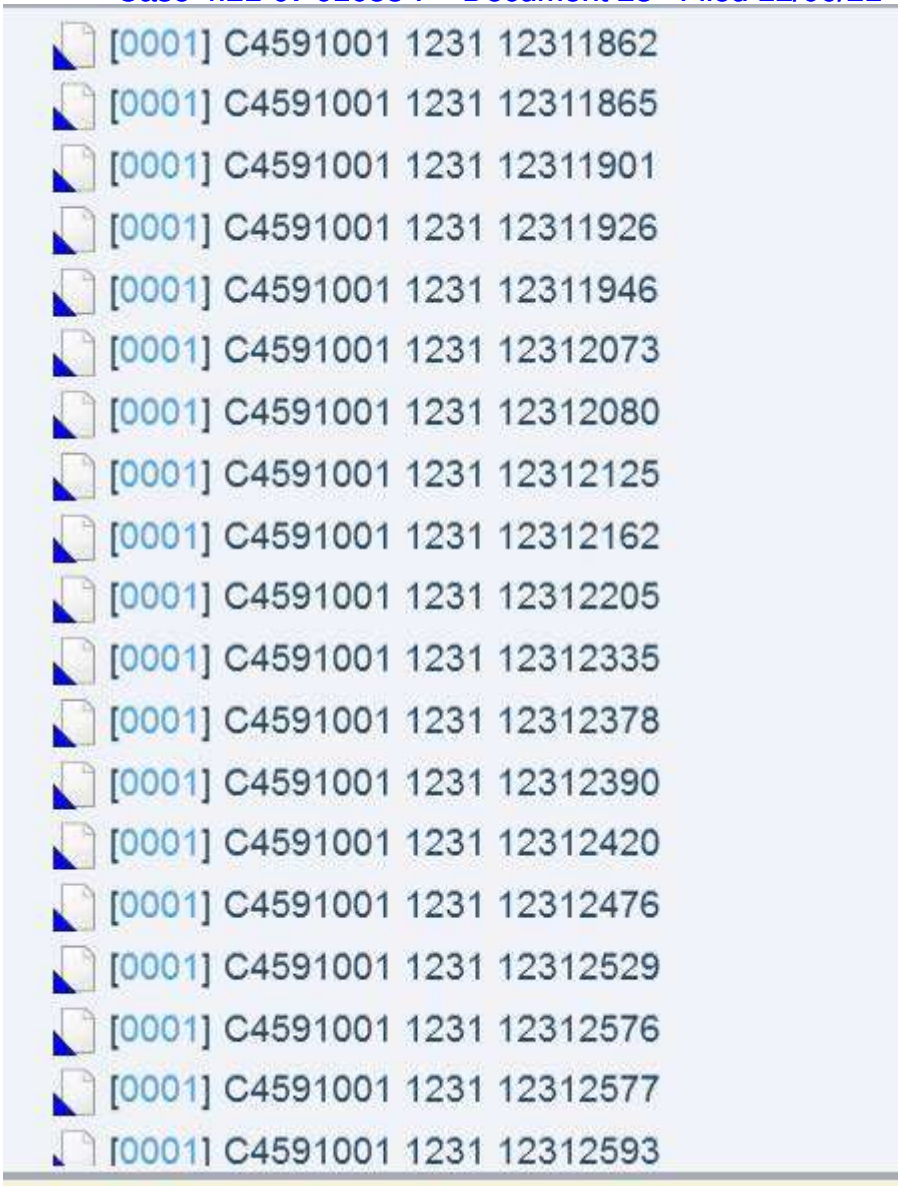
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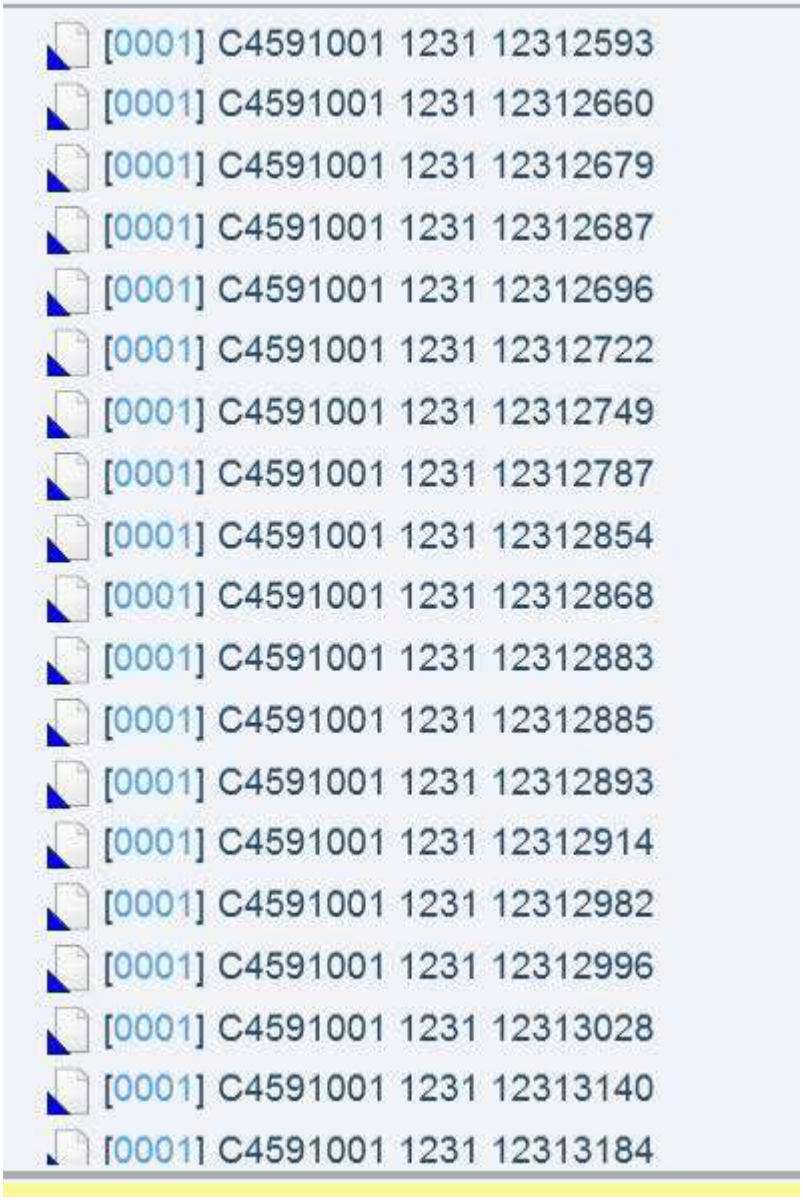
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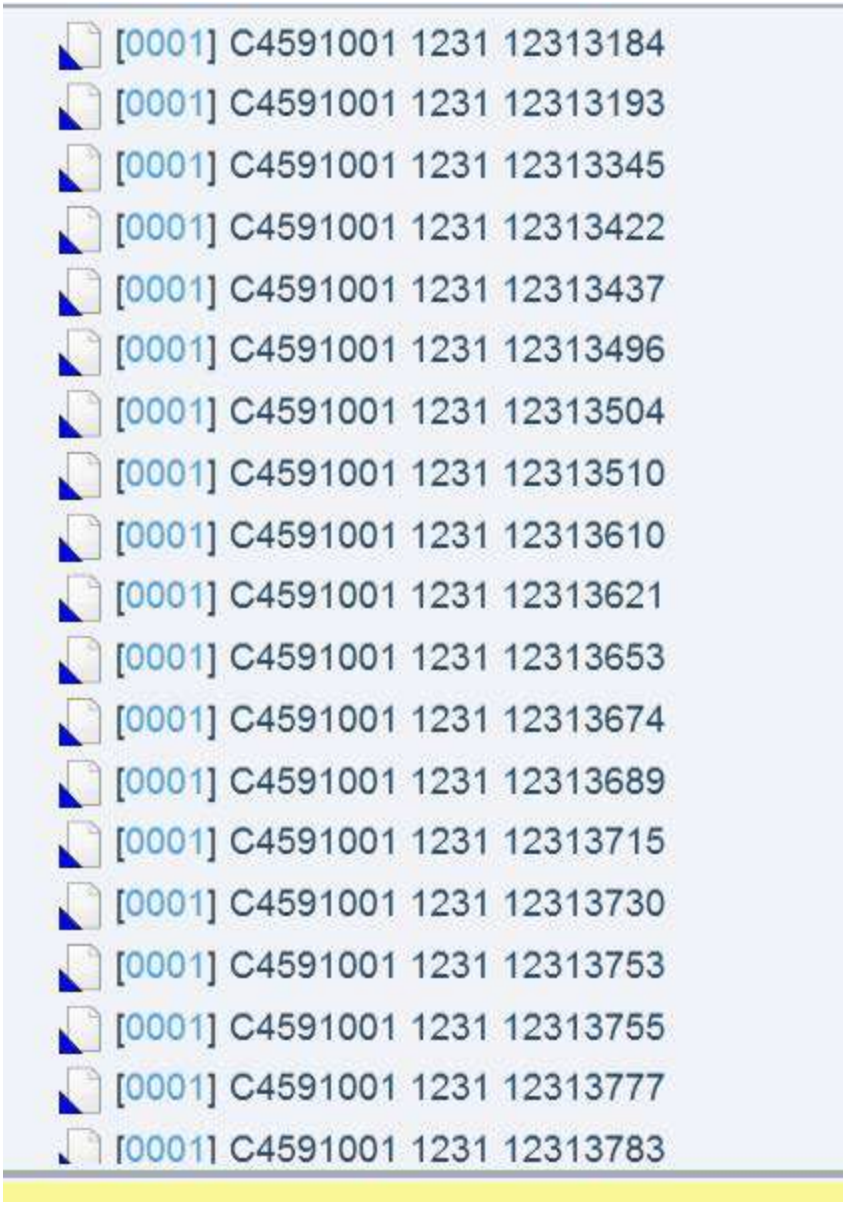
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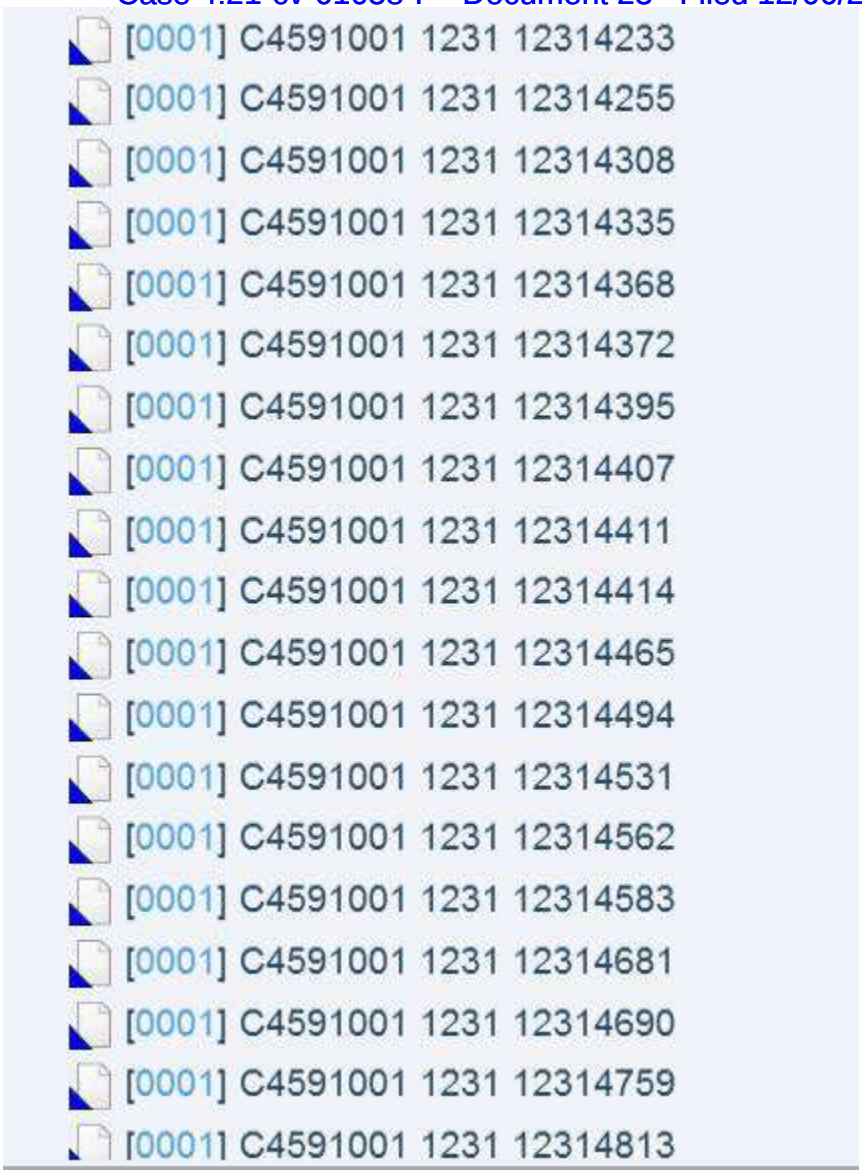
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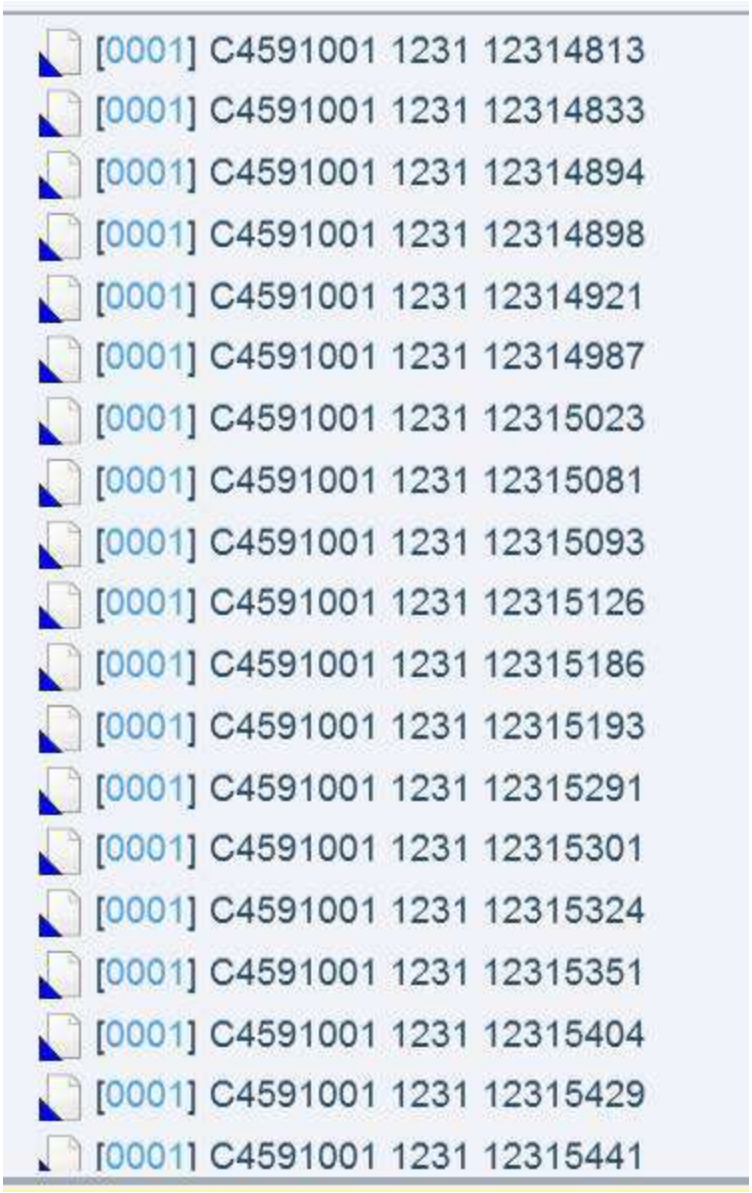
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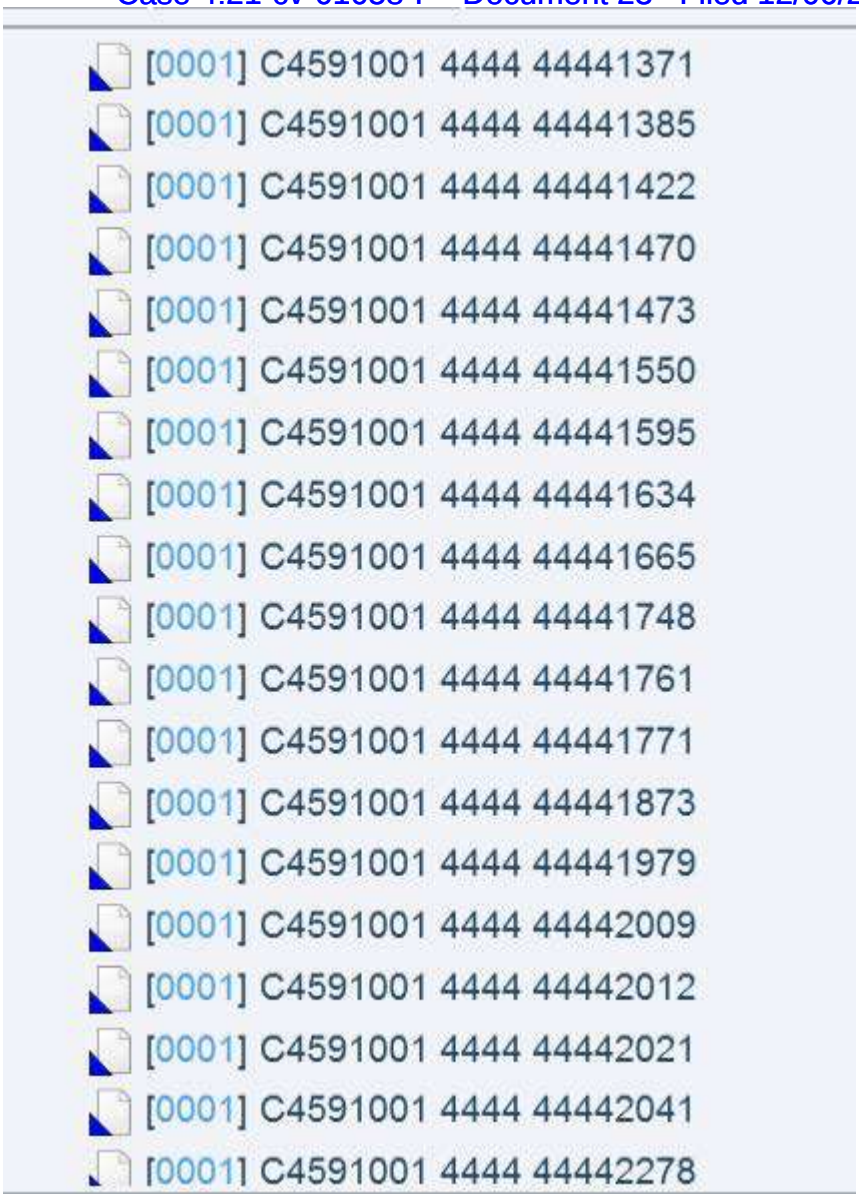
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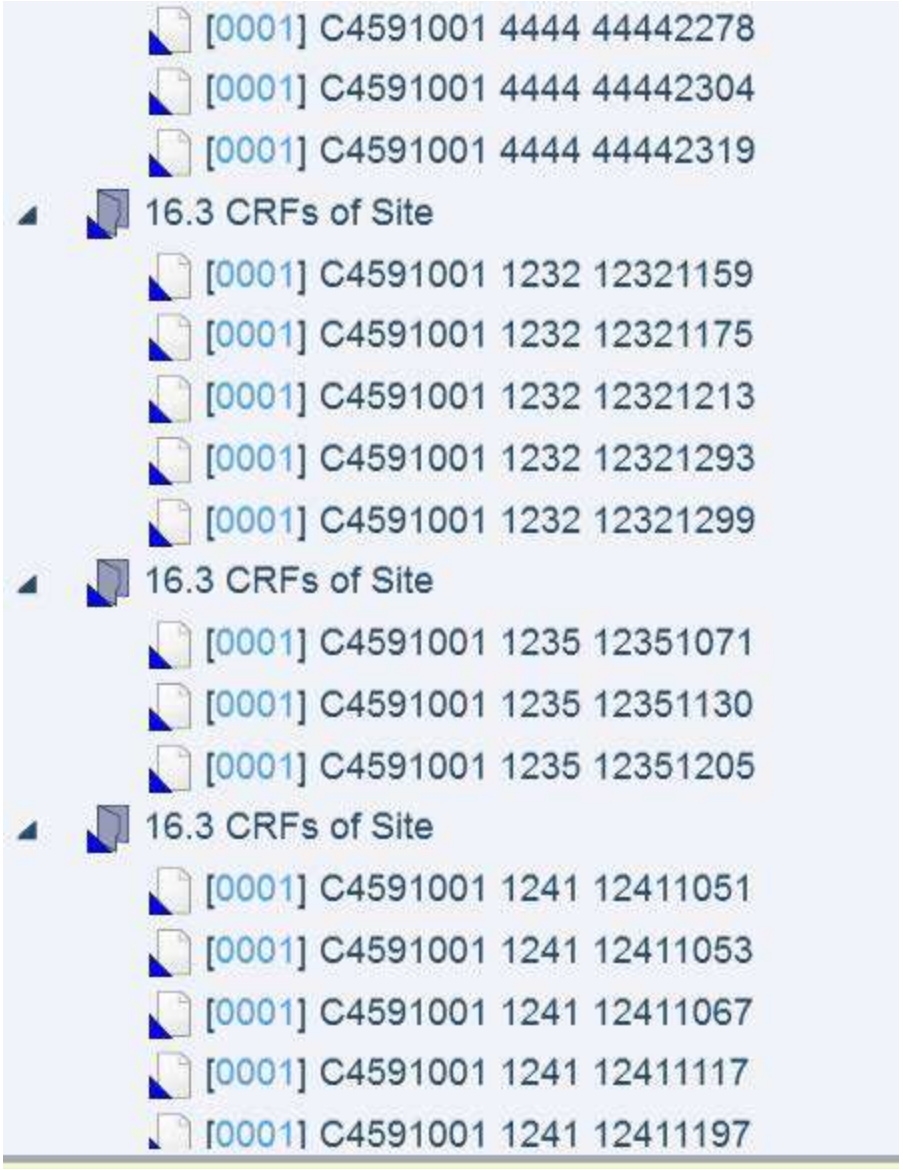
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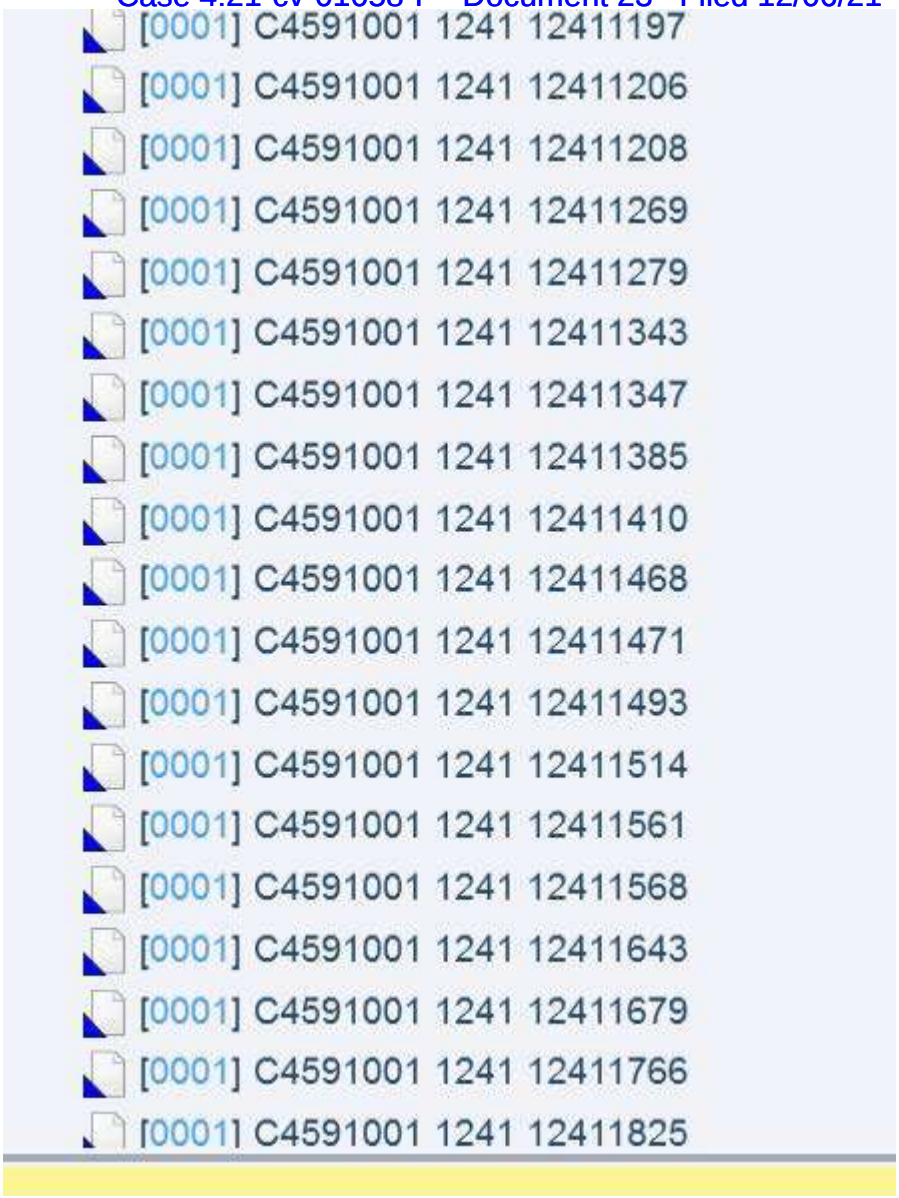
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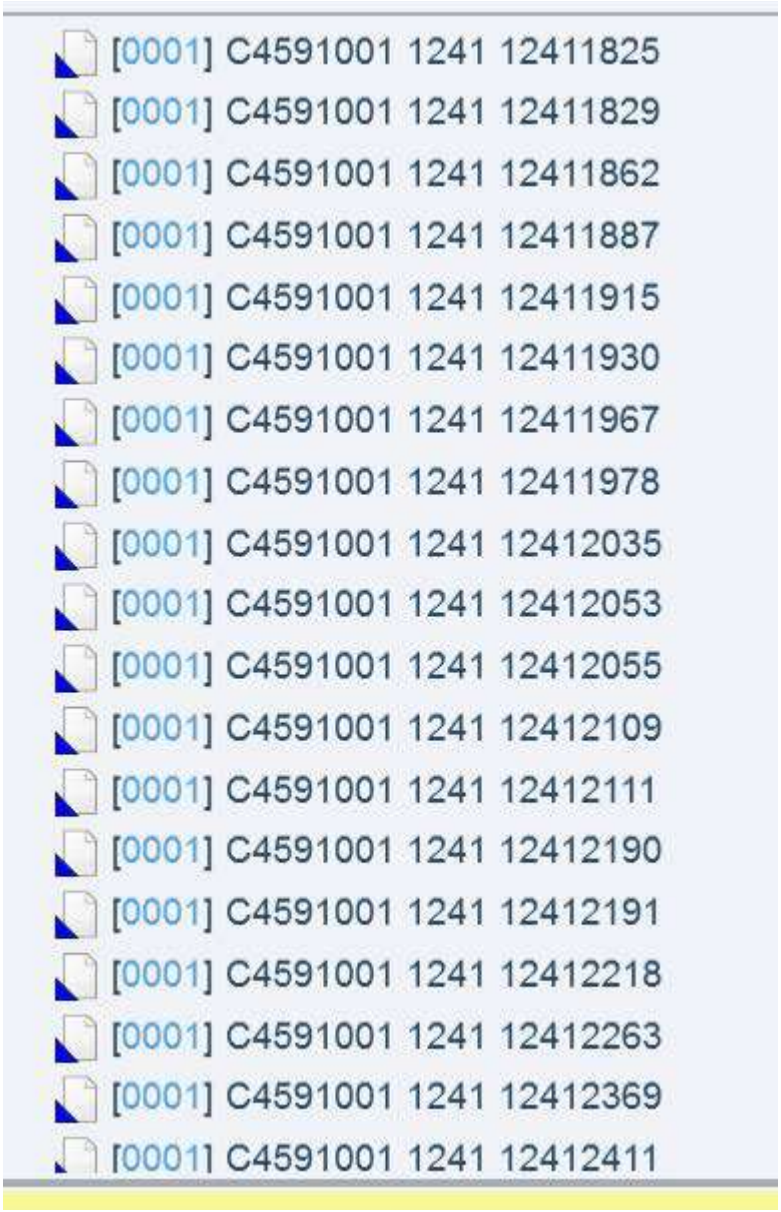
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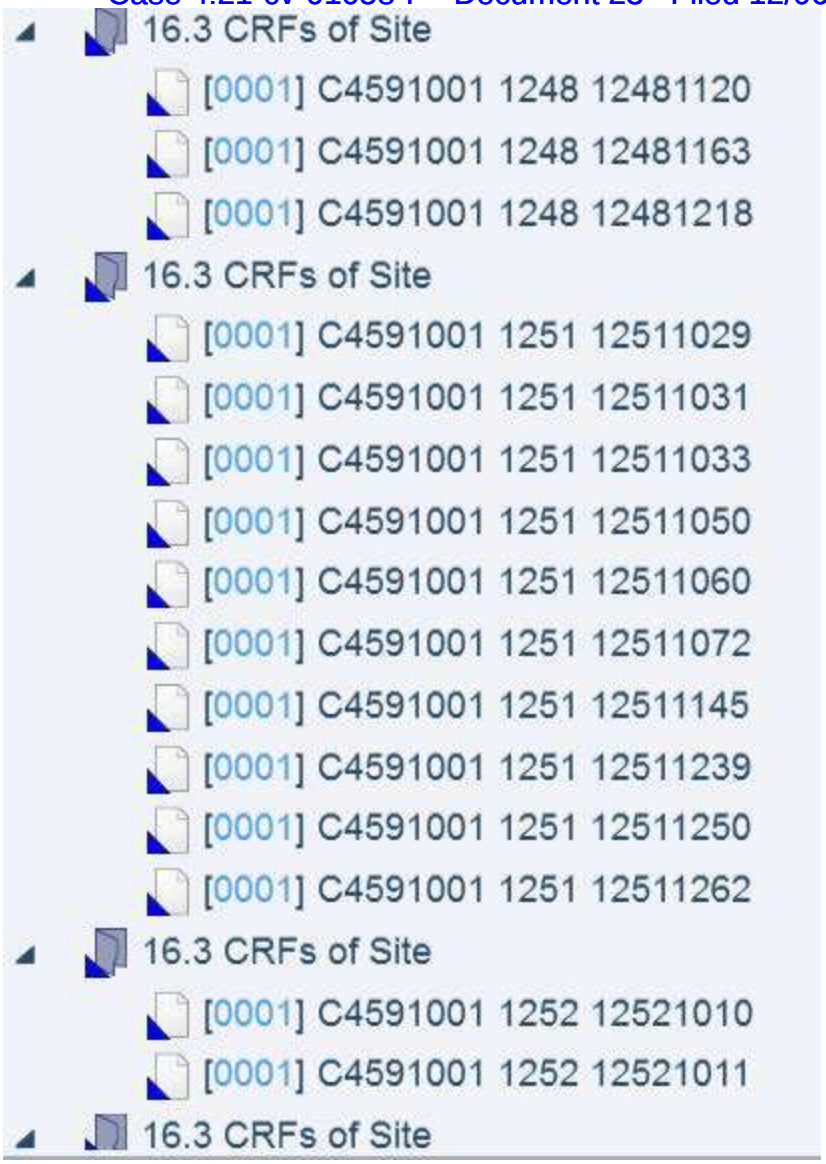
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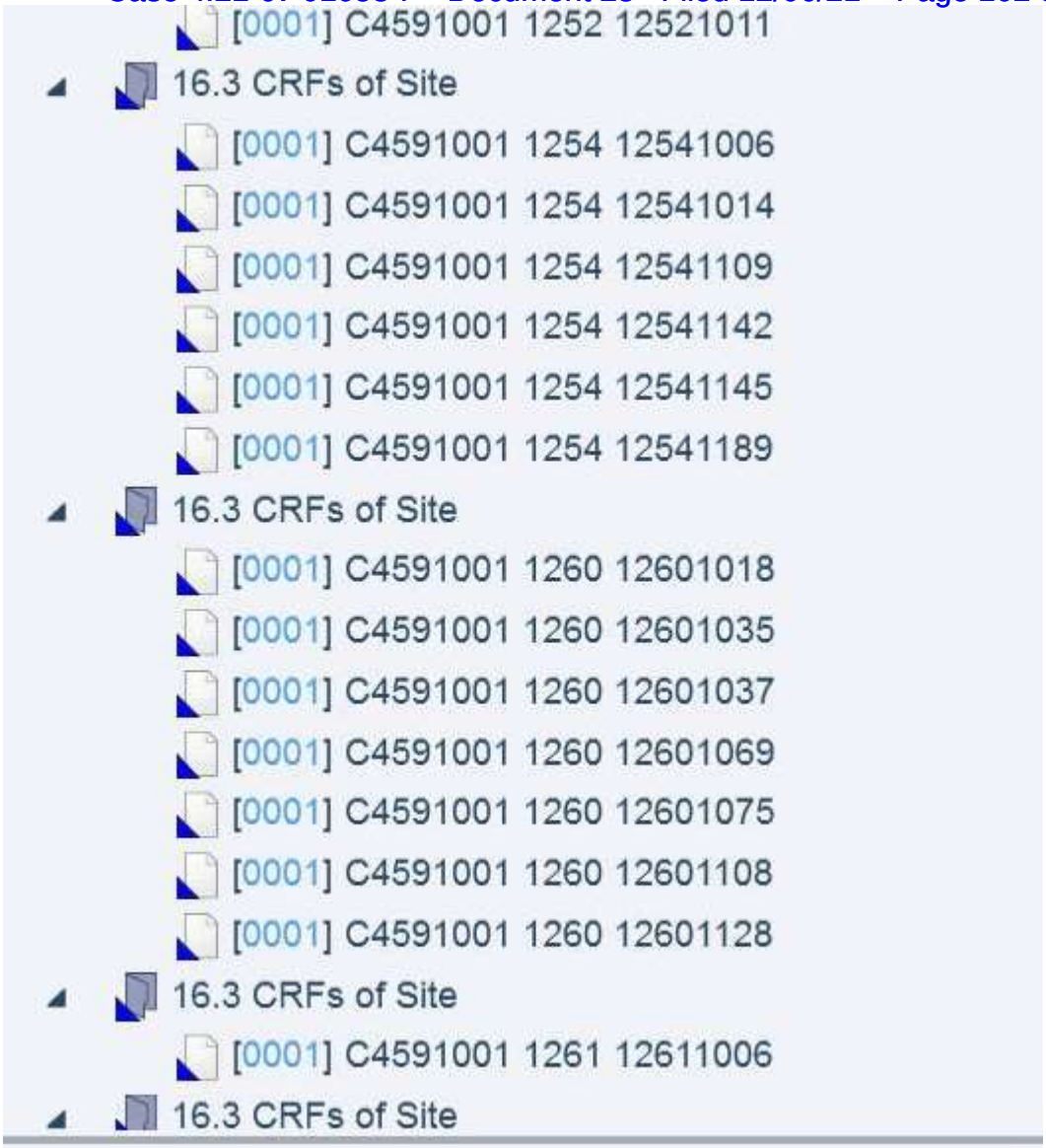
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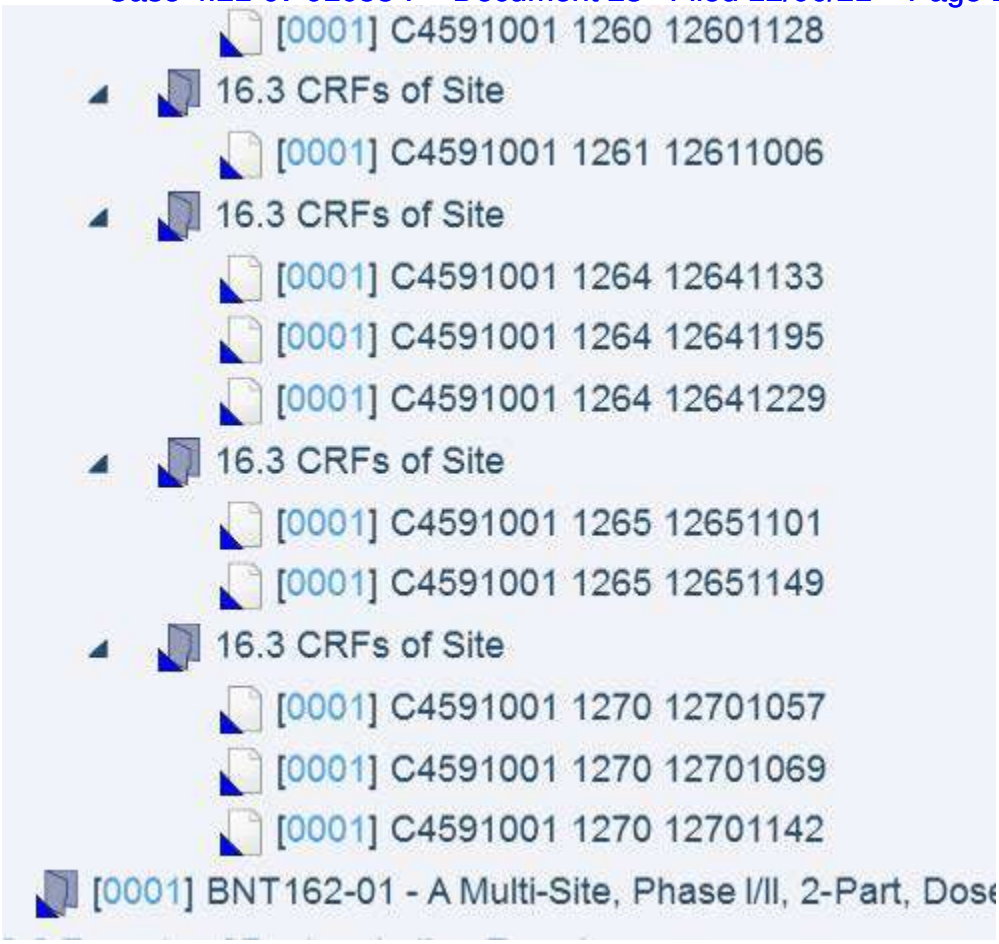
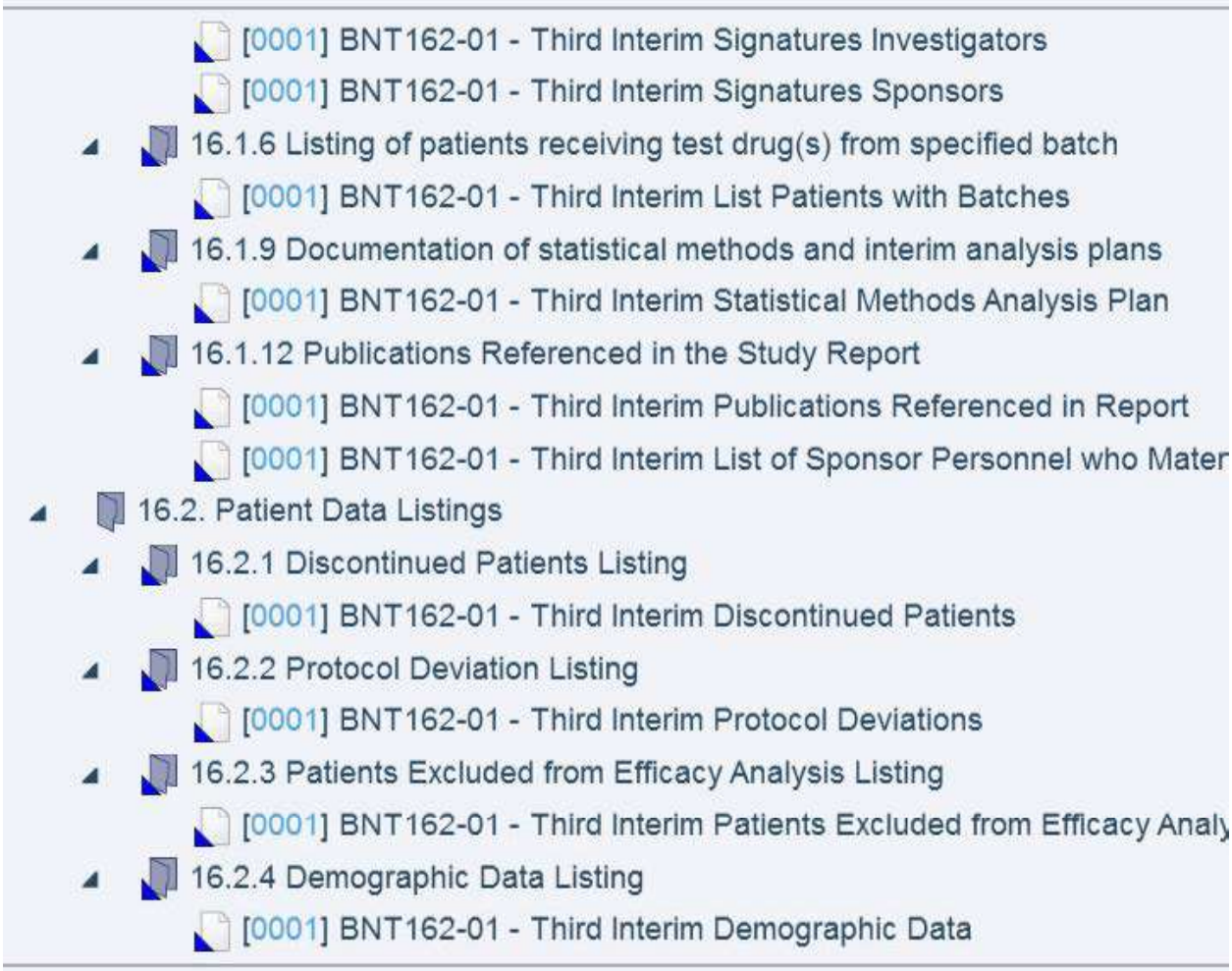


That is the end of the first study

See below for the Phase I/II study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16.1.6 Listing of patients receiving test drug(s) from specified batch
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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
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16.2.3 Patients Excluded from Efficacy Analysis Listing
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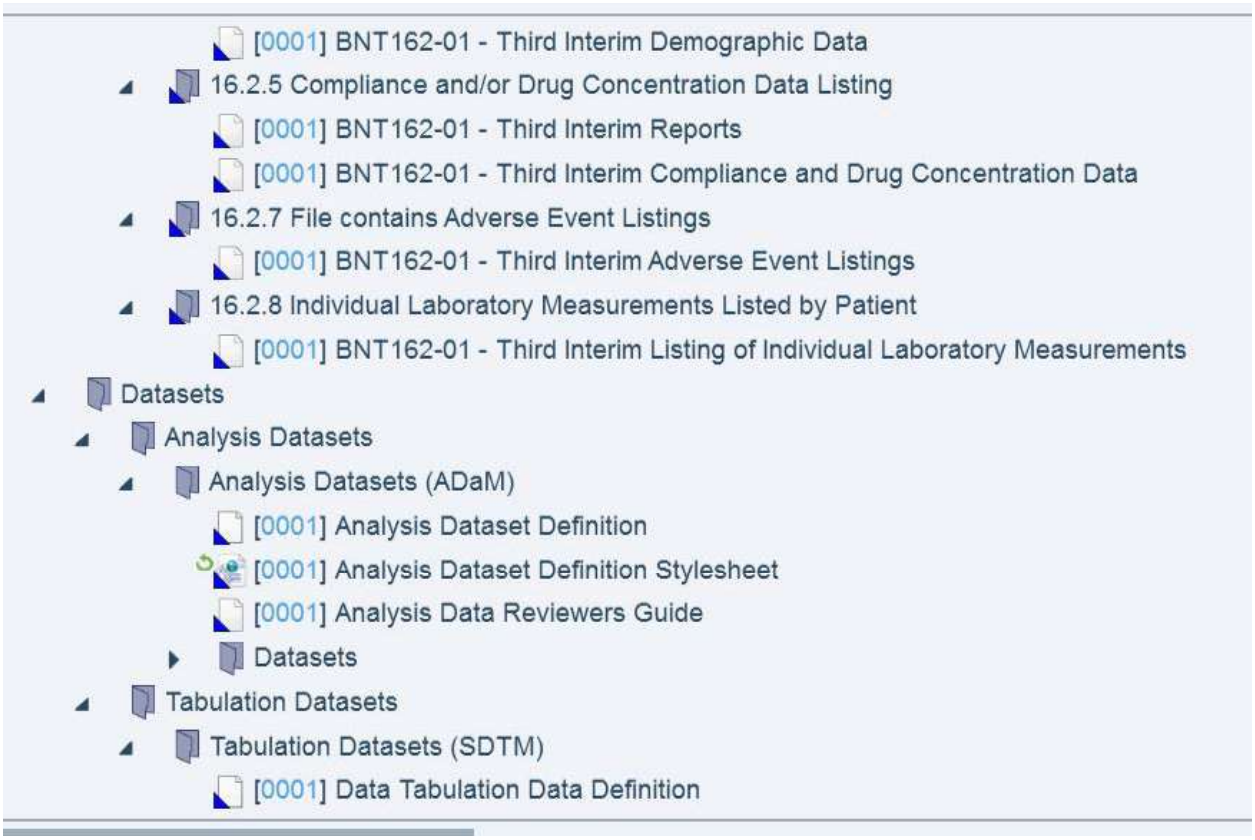
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16.2.5 Compliance and/or Drug Concentration Data Listing
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16.2.7 File contains Adverse Event Listings
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16.2.8 Individual Laboratory Measurements Listed by Patient
[0001] BNT162-01 - Third Interim Listing of Individual Laboratory Measurements
Datasets
Analysis Datasets
Analysis Datasets (ADaM)
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Datasets
Tabulation Datasets
Tabulation Datasets (SDTM)
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Tabulation Datasets
Tabulation Datasets (SDTM)
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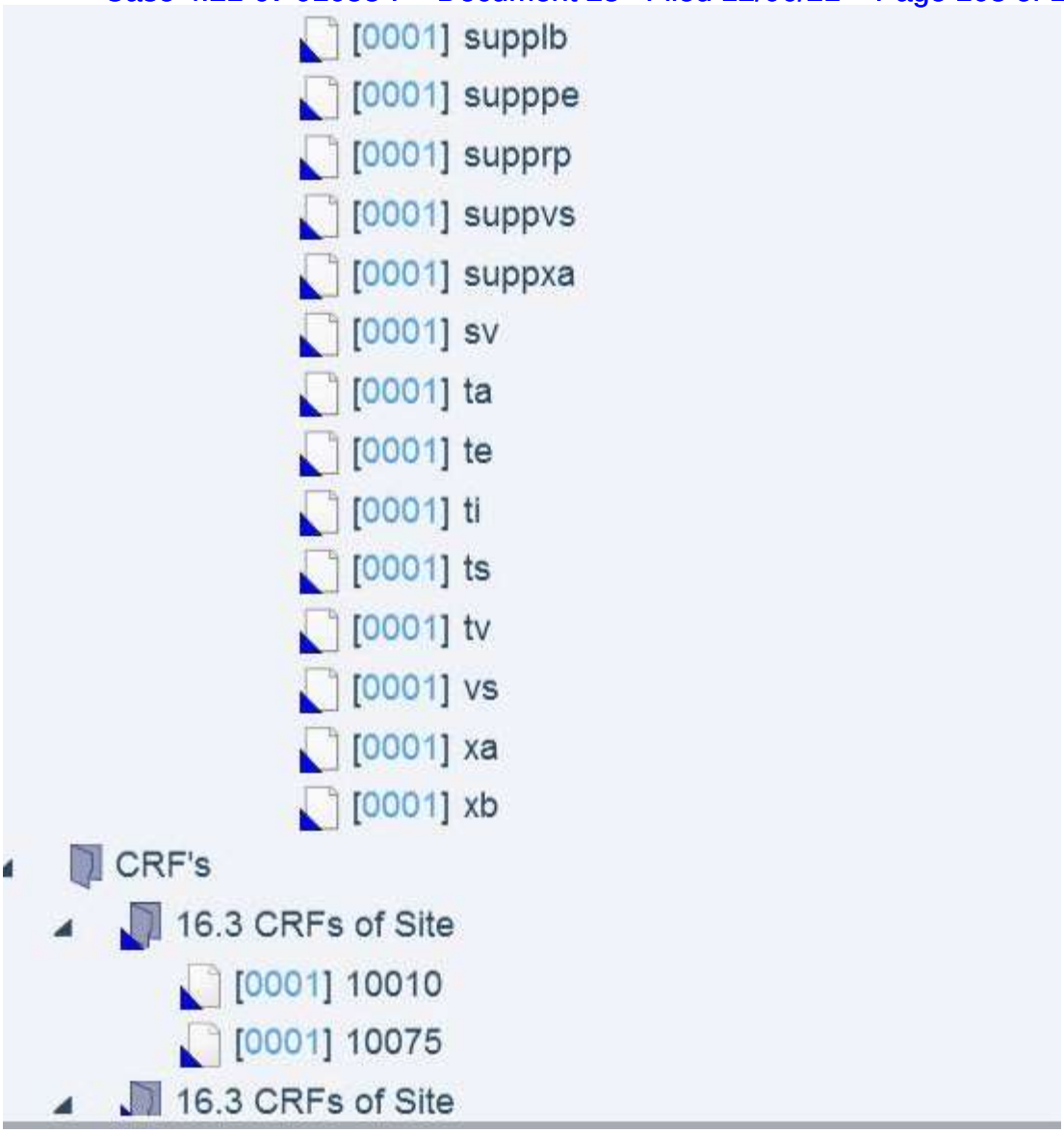
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CRF's
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16.3 CRFs of Site

16.3 CRFs of Site
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5.3.6 Reports of Postmarketing Experience
5.4 Literature References

Exhibit C

From:	Aaron Siri
To:	Enlow, Courtney D. (CIV)
Cc:	Elizabeth Brehm; Gabrielle Palmer
Subject:	[EXTERNAL] RE: Public Health and Medical Professionals for Transparency v. FDA,, 4:41-cv-01058-P (N.D. Tex. 2021)
Date:	Thursday, November 04, 2021 4:06:13 PM
Attachments:	image001.png image002.png image003.png image004.png

Also, CFRs for site 1085 which is on page 33 of the PDF.

From: Aaron Siri
Sent: Thursday, November 4, 2021 12:58 PM
To: Enlow, Courtney D. (CIV) <Courtney.D.Enlow@usdoj.gov>
Cc: Elizabeth Brehm <ebrehm@sirillp.com>; Gabrielle Palmer <gpalmer@sirillp.com>
Subject: RE: Public Health and Medical Professionals for Transparency v. FDA,, 4:41-cv-01058-P (N.D. Tex. 2021)

Hi Courtney,

Nice meeting yesterday. Based on our follow-up preliminary discussion with our client earlier today, they would like to know if the FDA will produce the following items by November 17:

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

If we can get agreement on producing these limited items as noted, we can advise as much in our joint letter and that we are continuing to discuss a production schedule for the remaining data and information.

Please let us know if the FDA will agree to their proposal.

Thanks,

Aaron

From: Enlow, Courtney D. (CIV) <Courtney.D.Enlow@usdoj.gov>
Sent: Thursday, November 4, 2021 11:07 AM
To: Gabrielle Palmer <gpalmer@sirillp.com>
Cc: Aaron Siri <aaron@sirillp.com>; Elizabeth Brehm <ebrehm@sirillp.com>
Subject: RE: Public Health and Medical Professionals for Transparency v. FDA,, 4:41-cv-01058-P (N.D. Tex. 2021)