UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE SUBOXONE (BUPRENORPHINE/NALOXONE) FILM PRODUCTS LIABILITY LITIGATION	)	Case No. 1:24-md-3092
	)	MDL No. 3092
	)	Judge J. Philip Calabrese
This Document Applies to All Cases	)	

CASE MANAGEMENT ORDER NO. 21
PROTOCOL REGARDING NON-CUSTODIAL DOCUMENT PRODUCTION

Based on the respective proposals of counsel, and with the Court being fully advised as to same, and for good cause shown, the Court **ORDERS** as follows as to the productions of Defendants Indivior Inc., Indivior Solutions Inc., (together, "Indivior"), and Aquestive Therapeutics, Inc. (collectively, the "Defendants"):

All document productions shall comply with Case Management Order No. 5, Case Management Order No. 6, and Case Management Order No. 11.

On September 18, 2024, the Indivior Defendants identified the following non-custodial data sources: Veeva RIM (regulatory documents), Argus (drug safety/adverse events), Veeva PromoMats (promotional materials), Veeva MedComms (medical communications), Veeva Quality Docs (written standards, e.g., policies, procedures, work instructions), Icertis (contracts), and IRMS MAX (Medical Information Unit) per the ESI protocol (Case Management Order No. 11). Also on September 18, 2024, Defendant Aquestive identified Master Control as its non-custodial data source (repository for product complaints). Plaintiffs have identified

additional non-custodial data sources in the productions to date, which are also included below.

I. Aquestive: MasterControl

Within 30 days of the entry of this Order, Aquestive will produce its MasterControl: Repository through September 30, 2025 for product complaints regarding Suboxone Film.

II. Indivior: Veeva Quality Docs

Within 60 days of the date of this Order, Indivior will produce documents maintained in its Veeva Quality Docs through September 30, 2025, regarding Suboxone Film, Suboxone Tablet, or Subutex Tablet relating to clinical trials, drug safety including safety reporting and monitoring, creation of regulatory reports, labeling, promotional materials, medical communications, and any other documents from these sources that Defendants intend to use at trial or in support of any motion or provide to a testifying expert, to the extent that such documents have not previously been produced in other non-custodial productions. To the extent such documents have been previously produced, Indivior will identify the production volume and Bates numbers of the previously produced documents from these databases at the time it provides the production.

III. Indivior: Argus Drug Safety Database[1]

Within 90 days of this Order, Indivior will produce the adverse events from the Argus database for all dental adverse events listed below, irrespective of whether

[1] Regarding the global safety database, Plaintiffs have agreed to forego requesting adverse-event reports for dental events related to Sublocade based on Defendants' agreement

(a) the adverse event was identified as the Preferred Term or (b) was supplied to FDA, (except for Plaintiffs in this litigation unless there is an event that pre-dates the filing of the Plaintiff's lawsuit) for Subutex, Suboxone Tablet, and Suboxone Film,[2] through September 30, 2025 to the extent that such documents have not previously been produced. The timing does not include production of source files due to the requirement of redaction of both patient and reporter identifying information pursuant to 21 C.F.R. § 20.63, and the parties will meet and confer on timing and/or undue burden within 21 days of this Order. To the extent such documents have been previously produced, Indivior will identify the production volume and Bates numbers of any previously produced documents (also within 90 days of the date of this Order). In producing documents from this database, the following dental terms will be produced:

Acquired enamel hypoplasia	Oral hemorrhage
Alveolar bone defect	Oral mucosa bleeding
Alveolar bone resection	Oral pain
Alveolar bone resorption	Periapical disease
Alveolar osteitis	Pericoronitis
Alveoloplasty	Peri-implantitis

to the following evidentiary stipulation: "Based on existing medical and scientific evidence, Sublocade, when administered as labeled, has not been to shown to increase the risk of dental adverse events."

[2] The parties agree that all adverse-event reports regarding any Plaintiff selected for bellwether discovery will be produced in case-specific discovery.

Apical granuloma

Apicectomy

Artificial crown procedure

Crown lengthening

Dental abfraction

Dental attrition

Dental bone graft

Dental care

Dental caries (tooth decay)

Dental cyst

Dental discomfort

Dental dysaesthesia

Dental fistula

Dental gangrene

Dental implantation

Dental leakage

Dental necrosis

Dental operation

Dental paraesthesia

Dental plaque

Dental prosthesis placement

Dental pulp disorder

Periodontal destruction

Periodontal disease

Periodontal flap surgery

Periodontal inflammation

Periodontal operation

Periodontic-endodontic disease

Periodontitis

Poor dental condition

Pulp capping

Pulpitis dental

Pulpless tooth

Root canal

Root canal infection

Sensitivity of teeth

Stomatitis

Teeth brittle

Tooth abscess

Tooth abscess drainage

Tooth avulsion

Tooth delamination

Tooth demineralization

Tooth deposit

Dental restoration failure	Tooth discolouration
Dental root perforation	Tooth dislocation
Dental sepsis	Tooth disorder
Dry mouth (xerostomia)	Tooth erosion
Endodontic procedure	Tooth extraction
Gingival pain	Tooth fracture
Glossodynia	Tooth impacted
Hemisection of tooth	Tooth infection
Hypercementosis	Tooth injury
Hyperaesthesia teeth	Tooth loss
Hypoaesthesia teeth	Tooth pulp hemorrhage
Impacted tooth exposure	Tooth repair
Loose tooth	Tooth resorption
Malocclusion	Tooth restoration
Mouth ulceration	Tooth socket haemorrhage
Necrotizing ulcerative periodontitis	Toothache
	Traumatic tooth displacement

IV. Indivior: Veeva RIM

Within 60 days of the date of this Order, Indivior will produce the regulatory submissions and correspondence to and from the FDA housed in its Veeva RIM

database for Subutex, Suboxone Tablet, and Suboxone Film,[3] through September 30, 2025 to the extent that such documents have not previously been produced.

With that production, Indivior will identify by Bates number any documents previously produced from that non-custodial source.

V. Indivior: Veeva PromoMats

Within 90 days of the date of this Order, Indivior will produce the draft and approved promotional materials contained in its Veeva PromoMats database from approval of Suboxone Film through September 30, 3025, to the extent that such documents have not previously been produced in past non-custodial productions.

With that production, Indivior will identify by Bates number any documents previously produced from that non-custodial source.

VI. Indivior: Ironclad

Within 90 days of the date of this Order, Indivior will produce contracts maintained in Ironclad[4] with third parties regarding Suboxone Film relating to manufacturing, packaging, marketing, sales, and promotion, and regarding Suboxone Film, Suboxone Tablets, and Subutex[5] regarding the handling of adverse-event reports, investigations of adverse-event reports, and quality assurance relating to

[3] Plaintiffs' agreement to forego Sublocade-related documents from this data source is contingent upon the stipulation detailed above.

[4] Defendants have represented that contracts maintained in Icertis were migrated to Ironclad in March 2025.

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[5] Plaintiffs' agreement to forego Sublocade-related documents from this data source is contingent upon the stipulation detailed above.

adverse events, through September 30, 2025 to the extent that such documents have not been previously produced in past non-custodial productions.

To the extent such documents have been previously produced, Indivior will identify them by production volume and Bates number.

VII. Veeva MedComms and IRMS MAX

Within 90 days of the date of this Order, Indivior will produce any additional communications (whether in draft form or final) maintained in Veeva MedComms relating to Suboxone Film, Suboxone Tablets, or Subutex Tablets,[6] through September 30, 2025 to the extent that such documents have not been previously produced in past non-custodial productions. With that production, Indivior will identify by Bates number any documents previously produced from that non-custodial source.

Within 90 days of the date of this Order, Indivior will produce contacts to Indivior Inc. in the United States through September 30, 2025, relating to Suboxone Film in IRMS MAX.

Within one week after the production deadline for each non-custodial source, the producing Defendant will supply the PLC with a written certification of substantial completion of which it is aware after reasonable inquiry and based upon reasonable efforts.

[6] Plaintiffs' agreement to forego Sublocade-related documents from these data sources is contingent upon the stipulation detailed above.

Defendants agree to advise the PLC if a Defendant discovers another non-custodial source that contains additional, non-duplicative relevant information. If Plaintiffs identify another non-custodial data source, Defendants will meet and confer with Plaintiffs within one week of receiving notification from Plaintiffs of the potential data source and will produce documents from that data source as soon as practicable subject to relevancy and undue burden objections.

VIII. Other Non-Custodial Data Sources Identified in Discovery

Reportum is non-custodial data source identified through the discovery process that is used in reporting adverse events. Defendants provided Plaintiffs an example of Reportum data on September 30, 2025. Plaintiffs are evaluating whether they will seek production of some or all of the Reportum data.

Entrust Hardcopy is a non-custodial data source where paper copies of older adverse event source files can be located some of which were previously produced based upon agreed search terms in October 2024. It was not included in the list of non-custodial sources Indivior provided the PLC in September 2024.

iLearn is non-custodial data source identified through the discovery process. It is used for internal training purposes for the Indivior Defendants.

VeevaGrants and **Veeva QMS** are additional non-custodial data sources identified through the discovery process.

Additional non-custodial data sources identified through the discovery process include the following SharePoint sites: **U.S. Richmond Files–PV Case Processing**, **U.S. Richmond Files–PV Signal Risk**, **U.S. Richmond Files–PV**

Compliance, **Global Files–Supply Sharepoint**, **Inspection Readiness**, and **Global R&D–Regulatory**. Plaintiffs have requested that the search terms used in custodial production be utilized, as well, on these SharePoint sites. Due to the length and syntactic complexity of the search terms, and the limitations of the software used to obtain documents from SharePoint, Defendants' position is that it is not technologically feasible to apply the search terms used in custodial productions to SharePoint sites; however, Defendants continue to investigate the feasibility of culling documents from the SharePoint sites using search terms.

The parties have agreed to continue to meet and confer as to these additional non-custodial data sources and will submit a revised protocol as needed.

SO ORDERED.

Dated: October 8, 2025

J. Philip Calabrese
United States District Judge
Northern District of Ohio