

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

IN RE: XARELTO (RIVAROXABAN)
PRODUCTS LIABILITY LITIGATION

MDL NO. 2592

SECTION L
JUDGE ELDON E FALLON
MAG. JUDGE NORTH

PRETRIAL ORDER NO. 20

CONSENT ORDER REGARDING THE FORMAT FOR PRODUCTION OF
HARDCOPY DOCUMENTS AND ELECTRONICALLY STORED INFORMATION

The Parties hereby agree to the following protocol for production of electronically stored information (“ESI”) and paper (“hardcopy”) documents. This protocol, subject to the Protective Order in this litigation, governs all production in this litigation. Nothing in this protocol shall limit a party’s right to seek or object to discovery as set out in applicable rules or to object to the authenticity or admissibility of any hardcopy document or ESI produced in accordance with this protocol. The Parties having conferred and agreed to entry of the within Consent Order, and good cause appearing therefore, it is hereby **ORDERED**, as follows.

A. GENERAL AGREEMENTS

1. Discovery Costs

This protocol does not address who will bear the expense associated with responding to discovery requests which a party believes are unduly burdensome. If a party believes that any discovery request is unduly burdensome, the parties will meet and confer concerning the potential expense, and if they cannot resolve the matter, then each party expressly reserves their rights to seek reimbursement.

2. Designated ESI Liaison

Each Party shall designate one or more individuals as Designated ESI Liaison(s) for purposes of meeting and conferring with the other Parties and of attending Court hearings on the subject of relevant ESI. The Designated ESI Liaison or their designee shall be reasonably prepared to speak about and explain the Party’s relevant electronic systems and capabilities and the technical aspects of the manner in which the Party has responded to e-discovery, including (as appropriate) relevant ESI retrieval technology and search methodology.

3. No Designation of Document Requests

Productions of hardcopy documents and ESI in the reasonably usable form set out in this protocol need not include any reference to the document requests to which a document may be

responsive. However, upon reasonable request and on a case-by-case basis, a Producing Party will provide a Bates range and/or source file where a particular set of materials can be found in their production.

4. Ongoing Cooperation among the Parties

The Parties agree to continue to consult and cooperate reasonably as productions occur, to discuss, as appropriate, legitimate questions that arise out of the productions, including issues (if any) pertaining to poor image quality or pages out of sequence; the existence of proprietary software or manuals, including third party software and manuals; and other issues.

5. Avoidance of Duplicate Production

A Producing Party shall take reasonable steps to de-duplicate ESI horizontally and/or globally. "Duplicate ESI" means files that are exact duplicates based on the files' MD5 or SHA-1 hash values. Entire document families may constitute Duplicate ESI. De-duplication shall not break apart families. A document within a family (such as an email attachment) shall not be considered a duplicate of a stand-alone document even if the hash values are the same, and a copy of both the document family and the stand-alone document will be produced. The Producing Party otherwise may produce only a single copy of responsive Duplicate ESI, and shall indicate the source files that contained the Duplicate ESI in the All Custodians field in the load file accompanying each production. The Producing Party shall provide an overlay file to allow the Receiving Party to update the All Custodians field. The overlay file will be provided at the time of each production and will identify all source files that contained a previously produced Duplicate ESI, including the identity of any new source files in the subject production that contained the previously produced Duplicate ESI. The Producing Party will not use e-mail threading as a method of de-duplication.

6. Non-Discoverable ESI.

The following categories of ESI are not subject to preservation and are not discoverable:

- i. Deleted, "slack," fragmented, or unallocated data on hard drives;
- ii. Random access memory (RAM) or other ephemeral data;
- iii. On-line access data such as (without limitation) temporary internet files, history files, cache files, and cookies;
- iv. System, network, server, or software application logs;
- v. Structural files not material to individual document contents (e.g. .CSS, .XSL, .XML, .DTD, etc.).

7. Test Load File.

The producing party will send a small test load file at the onset of the first document production to test parameters discussed within this format of production document.

B. ELECTRONICALLY STORED INFORMATION

1. Production in Native and TIFF-Image Format.

a. Electronic spreadsheets (*e.g.*, Excel), electronic presentations (*e.g.*, PowerPoint), desktop databases (*e.g.*, Access), audio/video multimedia and JPEG files that have been identified as responsive shall be produced in native format, unless they are authorized to be redacted in accordance with this Protocol and PTO No. 12. After such redactions, the Producing Party either shall produce the redacted file in TIFF format, with extracted or OCR text files and the associated metadata set out in Attachment A or shall produce the redacted copy in native format as agreed to by the Parties.

b. Word documents (*e.g.*, Microsoft Word) and PDF documents shall be produced in both native format (unless they are authorized to be redacted in accordance with this Protocol and PTO No. 12) and TIFF-image format, with extracted or OCR text files and the associated metadata set out in Attachment A, which is incorporated in full in this Protocol. Where available, extracted text will be provided for any electronic document that does not have redactions. Redacted files shall be produced in TIFF format with OCR text. TIFF-image Word and PDF documents endorsed with a Bates number and protected designation, if any, shall be used by all parties at depositions, at trial, or any other proceedings, and TIFF-image Word and PDF documents shall be provided to any consultants or experts. As to Word or PDF color documents, or Word documents with tracked changes in color, parties using such documents in depositions or other court proceedings may use the native format document, but must mark into the record both the TIFF-image format document with Bates number and protected designation, if any, as well as the native format document with attached slip sheet containing the Bates number and protected designation.

c. E-mails and other document types not identified above shall be produced in TIFF-image format with extracted or OCR text files and the associated metadata set out in Attachment A. Where available, extracted text will be provided for any electronic document that does not have redactions. OCR text will be provided for paper documents or electronic documents with redactions.

d. Except as otherwise stated in this Protocol, no other ESI need be produced in native format, unless the Receiving Party, for good cause explained in the request, seeks production of specifically identified ESI in native format and unless the Producing Party agrees to the request. The Producing Party shall respond reasonably and in good faith to any such request.

2. Additional Procedures for Native Format Files

Any Party seeking to use, in any proceeding in this litigation, files produced in native format shall do so subject to the following: The slip sheet provided by the producing party containing the Bates number and confidentiality designation, if any, must be prepended to an image of the native file used. Any party using native format files for any reason during the course of the litigation, for instance as an exhibit at a deposition or at trial, as an exhibit for a motion, or documents given to any experts or consultants, is responsible for ensuring that the slip

sheet associated with each native format file is prepended to the file prior to its use. Use of a file in native format, or use of a TIFF image or hardcopy document representing the original native-format file shall constitute a representation that the file being used is an accurate, unaltered and complete depiction of the original native-format file.

3. Redactions.

The Producing Party may redact, from any TIFF image, metadata field, or native file, information that is protected from disclosure by applicable privilege or immunity, that is governed by the European Data Privacy Directive, German Data Privacy Law¹ or other applicable privacy law or regulation, or that contains non-responsive information concerning products or matters unrelated to Xarelto® including:

- i. The names, street addresses, Social Security numbers, tax identification numbers, and any other personal identifying information of patients, health care providers or other voluntary reporters reporting specific adverse events, and individual patients participating in clinical studies or referenced in adverse event reports. Other general information that does not identify the person, however, such as patient or health care provider numbers, shall not be redacted unless required by state or federal law. To the extent a plaintiff's name is contained in any of these documents, a copy of the documents that have not had the plaintiff's information redacted may be produced directly to counsel for said plaintiff;
- ii. Business and proprietary information relating to products manufactured or marketed by the named Defendants other than Xarelto® that does not also relate to Xarelto®. For purposes of the preceding sentence, information concerning the following will be considered to relate to Xarelto® and shall not be redacted: (a) materials relating to any reversal agent or antidote for Xarelto (or for any product containing rivaroxaban); (b) materials relating to any other products containing rivaroxaban, whether currently on the market or in development; (c) materials within the custody or control of Defendants relating to any product, device, method and/or assay, that is manufactured, designed, developed and/or discussed by any entity, including, but not limited to the defendants, that is used, intended and/or designed to evaluate and/or measure (quantitatively and/or qualitatively) the concentration of rivaroxaban in a rivaroxaban treated patient and/or the anticoagulant effect(s) of rivaroxaban in a rivaroxaban treated patient; and (d) materials relating to market research, comparative or competitive research or

¹ Pursuant to Article 8 of the European Data Privacy Directive, "the processing of personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, trade-union membership, and the processing of data concerning health or sex life" is prohibited. This is different from production of information that has "personal data", defined in these laws as any document that identifies an individual or by recourse to other information could allow identification of an individual. An example is an email of a German employee because it identifies individuals. If produced as relevant and non-privileged, the content and "personal data" (e.g. sender and recipients) would not be redacted for the reason expressed above. Rather the document would be designated Protected under the Protective Order.

analysis, market or scientific comparison or market surveillance (including the tracking, review and analysis of medical or scientific literature) of dabigatran (Pradaxa), apixaban (Eliquis) or any other new oral anticoagulant (commonly referred to as “NOACs”) and/or their reversal agents, warfarin (Coumadin), fondaparinux (Arixlara) or enoxaparin sodium (Lovenox) to the extent such data was created or collected in connection with Xarelto or any potential reversal agent or antidote for Xarelto.

- iii. Social Security numbers, passwords, telephone conference line numbers, tax identification numbers and other private personal information of employees or other persons in any records.

To the extent that the Producing Party redacts documents or portions thereof, the redaction shall state on the face of the document a designation: “Redacted: Relevance” or “Redacted: Privilege” or a similar designation setting forth the general basis of the redaction. The Producing Party shall also provide a field in the load file that reflects whether a document has any redaction and, if so, the general type(s) of redaction on the document. Documents in families that would be entirely redacted consistent with these provisions will be replaced by a ship sheet containing a statement that the document has not been produced because it would be redacted in its entirety. To the extent practical, if information in a document is redacted because it does not relate to Xarelto®, the Producing Party will endeavor to leave in headings or similar non-substantive information concerning the redacted information to facilitate identification of the general nature of the non-relevant information.

The foregoing provisions concerning redactions are production guidelines designed to facilitate the prompt production of potentially relevant discovery material and to minimize pre-production disputes and motion practice concerning the treatment of discovery material. Nothing in the foregoing paragraph shall be construed as a waiver by the Receiving Party of any right to seek an order for good cause shown compelling production of information redacted pursuant to this Order nor restrict a Producing Party’s right to object or otherwise seek protection from the Court concerning any such request. The parties shall meet and confer before engaging in any motion practice with respect to this paragraph.

Further, nothing in this paragraph precludes the Receiving Party from challenging any redaction set out above pursuant to Paragraphs 13 and 14 of Pretrial Order No. 12.

4. Color Copies

Each Party may make requests, for good cause, for production of specifically identified documents in color.

5. Enterprise Databases and Database Management Systems

The Parties will meet and confer on the appropriate format to produce or to provide access to discoverable electronically stored information in an enterprise database or database management system (*e.g.*, Oracle, SQL server, DB2). It is expected that the Producing Party will produce such information in a manner that allows the Receiving Party to have the ability to search or review the data similar to that possessed by the Producing Party, such as an already

existing and reasonably available report, or an export from the original database of discoverable information in a format compatible with Microsoft Excel or Microsoft Access produced in native format. The Parties will also meet and confer regarding whether and in what format an appropriate export of responsive data depending on the database architecture will meet these objectives, or can seek appropriate relief from the Court if necessary.

6. Use of Search Filters

a. The Parties will meet and confer to discuss the use of reasonable search terms and date ranges. Defendants have provided a list to Plaintiffs' ESI Liaison of the search term filters that they have utilized to date to collect data from various sources. The Parties' ESI Liaisons will work on any revisions to search term filters understanding that this will be a collaborative process. During such discussions, the Producing Party shall retain the sole right and responsibility to manage and control searches of its data files.

b. The fact that any document has been identified in agreed-upon search term filters shall not prevent any Party from withholding such document from production on the grounds that the document is not responsive, that it is protected from disclosure by applicable privilege or immunity, that it is governed by the European Data Privacy Directive or other applicable privacy law or regulation, that it contains commercially sensitive or proprietary non-responsive information, or that the Protective Order entered in this Action allows the document to be withheld.

c. Nothing in this section shall limit a Party's right reasonably to seek agreement from the other Parties or a court ruling to modify previously agreed-upon search terms.

C. DOCUMENTS THAT EXIST ONLY IN HARDCOPY (PAPER) FORM

A Party may produce documents that exist in the normal course of business only in hardcopy form scanned and produced in accordance with the procedures set out below. Scanned hardcopy documents shall be produced in accordance with the Technical Specifications set out in Attachment A. The scanning of original hardcopy documents does not otherwise require that the scanned images be treated as ESI. If a Producing Party creates objective coding for hard-copy documents, the objective coding shall be provided to the Receiving Party when the objective coding is available. The Producing Party does not guarantee the accuracy of any provided objective coding.

ATTACHMENT A:

A.1. Image Files. Documents produced in *.tif image format will be single page black and white *.tif files at 300 DPI, Group IV compression. To the extent possible, original document orientation will be maintained (*i.e.*, portrait-to-portrait and landscape-to-landscape). Each *.tif file will be assigned a unique name matching the production number of the corresponding page. Such files will be grouped in folders of no more than 1,000 *.tif files each unless necessary to prevent a document from splitting across folders. Documents will not be split across folders and separate folders will not be created for each document. Document production (“Bates”) numbers shall be endorsed on the lower right corner of all images. This number shall be a unique, consistently formatted identifier that will:

- a) be consistent across the production;
- b) contain no special characters; and
- c) be numerically sequential within a given document.

Bates numbers should be a combination of an alpha prefix along with an 8 digit number (e.g. ABC00000001). The number of digits in the numeric portion of the Bates number format should not change in subsequent productions. Confidentiality designations, if any, will be endorsed on the lower left corner of all images and shall not obscure any portion of the original file.

A.2. Document Text. Except where ESI contains text that has been redacted under assertion of privilege or other protection from disclosure, full extracted text will be provided in the format of a single *.txt file for each document (*i.e.*, not one *.txt file per *.tif image). Where ESI contains text that has been redacted under assertion of privilege or other protection from disclosure, the redacted *.tif image will be OCR'd and document-level OCR text will be provided in lieu of extracted text. Searchable text will be produced as document-level multi-page UTF-8 text files with the text file named to match the beginning production number of the document. The full path of the text file must be provided in the *.dat data load file.

A.3. Word Processing Files. Word processing files, including without limitation Microsoft Word files (*.doc and *.docx), will be produced in the above format as well as native format with tracked changes and comments showing.

A.4. Presentation Files. To the extent that presentation files, including without limitation Microsoft PowerPoint files (*.ppt and *.pptx), are produced in *.tif image format, such *.tif images will display comments, hidden slides, speakers' notes, and similar data in such files.

A.5. Spreadsheet or Worksheet Files. To the extent that spreadsheet files, including without limitation Microsoft Excel files (*.xls or *.xlsx), are produced in *.tif image format, such *.tif images will display hidden rows, columns, and worksheets, if any, in such files.

- A.6. Parent-Child Relationships. Parent-child relationships (*e.g.*, the associations between emails and their attachments) will be preserved. Email and other ESI attachments will be produced as independent documents immediately following the parent email or ESI record. Parent-child relationships will be identified in the data load file pursuant to paragraph A.14 below.
- A.7. Dynamic Fields. Documents containing dynamic fields such as file names, dates, and times will be produced showing the field code (*e.g.*, “[FILENAME]” or “[AUTODATE]”), rather than the values for such fields existing at the time the file is processed.
- A.8. English Language. To the extent any data exists in more than one language, the data will be produced in English, if available. If no English version of a document is available, the Producing Party shall not have an obligation to produce an English translation of the data. However, any foreign language document will be so indicated in a metadata field.
- A.9. Embedded Objects. Some Microsoft Office and .RTF files may contain embedded objects. Such objects typically are the following file types: Microsoft Excel, Word, PowerPoint, Project, Outlook, and Access; and PDF. Subject to claims of privilege and immunity, as applicable, and to the extent reasonably available, objects with those identified file types shall be extracted as separate documents and shall be produced as attachments to the document in which they were embedded.
- A.10. Compressed Files. Compressed file types (*i.e.*, .CAB, .GZ, .TAR, .Z, .ZIP) shall be decompressed in a reiterative manner to ensure that a zip within a zip is decompressed into the lowest possible compression resulting in individual files.
- A.11. Encrypted Files. The Producing Party will take reasonable steps, prior to production, to unencrypt any discoverable electronically stored information that exists in encrypted format (*e.g.*, because password-protected) and that can be reasonably unencrypted.
- A.12. Scanned Documents
- a) In scanning hardcopy documents, multiple distinct documents should not be merged into a single record, and single documents should not be split into multiple records (*i.e.*, hard copy documents should be logically unitized).
 - b) Producing Party agrees to provide OCR text for scanned images of hard copy documents. OCR is to be performed on a document level and provided in document-level *.txt files named to match the production number of the first page of the document to which the OCR text corresponds. OCR text should not be delivered in the data load file or any other delimited text file.
 - c) In the case of an organized compilation of separate documents—for example, a binder containing several separate documents behind numbered tabs—the document behind each tab should be scanned separately, but the relationship among the documents in the binder should be reflected in proper coding of the family fields set out below.

A.13. Production Numbering. Each *.tif image file will be named according to the production number of the page it represents. Production numbers will:

- a) be consistent across the production;
- b) contain no special characters; and
- c) be numerically sequential within a given document.

The Producing Party shall take reasonable steps to ensure that attachments to documents are assigned production numbers that directly follow the production numbers on the documents to which they were attached. If a production number or set of production numbers is skipped, the skipped number or set of numbers will be noted. In addition, wherever possible, each *.tif image will have its assigned production number electronically “burned” onto the image.

A.14. Data and Image Load Files.

- a) Load Files Required. Unless otherwise agreed, each production will include a data load file in Concordance (*.dat) format and an image load file in Opticon (*.opt) format.
- b) Load File Formats.
 - i. Load file names should contain the volume name of the production media. Additional descriptive information may be provided after the volume name. For example, both ABC001.dat or ABC001_metadata.dat would be acceptable.
 - ii. Unless other delimiters are specified, any fielded data provided in a load file should use Concordance default delimiters. Semicolon (;) should be used as multi-entry separator.
 - iii. Any delimited text file containing fielded data should contain in the first line a list of the fields provided in the order in which they are organized in the file.
- c) Fields to be Included in Data Load File. For all documents produced, the following metadata fields will be provided in the data load file pursuant to subparagraph (a), above, for each document to the extent that such information is available at the time of collection and processing, except to the extent that a document has been produced with redactions. The term “Scanned Docs” refers to documents that are in hard copy form at the time of collection and have been scanned into *.tif images. The term “Email and E-Docs” refers to documents that are in electronic form at the time of their collection. All date fields should be produced as MM/DD/YYYY format, paying attention to European date formats. European dates should be produced in US format to assure sorting and usability along with US based documents.

d) The following metadata will be produced:

Field	Sample Data	Scanned Docs	Email and E-Docs	Comment
PRODBEG [Key Value]	ABC00000001	Yes	Yes	Beginning production number
PRODEND	ABC00000008	Yes	Yes	Ending production number
PRODBEGATT	ABC00000009	Yes	Yes	Beginning production number of parent document in a family
PRODENDATT	ABC00001005	Yes	Yes	Ending production number of last page of the last attachment in a family
CUSTODIAN(S)	Smith, John	Yes	Yes	Custodian(s) that possessed the document—multiple custodians separated by semicolon
NATIVEFILE	Natives\\ \00000001.xls	N/A	Yes	Path and file name for native file on production media
FILEDESC	Microsoft Office 2007 Document	N/A	Yes	Description of the type file for the produced record.
FOLDER	\My Documents\ Document1.doc	N/A	Yes	Original source folder for the record produced.
FILENAME	Document1.doc	N/A	Yes	Name of original electronic file as collected.
DOCEXT	DOC	N/A	Yes	File extension for email or e-doc
PAGES	2	Yes	Yes	Number of pages in the produced document (not applicable to native file productions).
AUTHOR	John Smith	N/A	Yes	Author information as derived from the properties of the document.
DATECREATED	10/09/2005	N/A	Yes	Date that non-email file was created as extracted from file system metadata
DATELASTMOD	10/09/2005	N/A	Yes	Date that non-email file was modified as extracted from file system metadata
SUBJECT	Changes to Access Database	N/A	Yes	“Subject” field extracted from email message or metadata properties of the document
FROM	John Beech	N/A	Yes	“From” field extracted from email message
TO	Janice Birch	N/A	Yes	“To” field extracted from email message
CC	Frank Maple	N/A	Yes	“Cc” or “carbon copy” field extracted from email message

Field	Sample Data	Scanned Docs	Email and E-Docs	Comment
BCC	John Oakwood	N/A	Yes	“Bcc” or “blind carbon copy” field extracted from email message
DATESENT	10/10/2005	N/A	Yes	Sent date of email message (mm/dd/yyyy format)
TIMESENT	10:33 am	N/A	Yes	Sent time of email message, time zone set to GMT
DATERCVD	10/10/2005	N/A	Yes	Received date of email message (mm/dd/yyyyformat)
TIMERCVD	10:33 am	N/A	Yes	Received time of email message, time zone set to GMT
CONFIDENTIALITY	HIGHLY CONFIDENTIAL	Yes	Yes	Text of confidentiality designation, if any
TEXTPATH	Text\\\.txt	Yes	Yes	Path to *.txt file containing extracted or OCR text
PRODVOL	VOL001	Yes	Yes	Name of the Production Volume
Redaction	Privilege	Yes	Yes	Field noting redactions applied to document
Foreign Language List	English: German	N/A	Yes	Field noting languages within document.
MD5 Hash Value	098f6bcd 4621d 373cade4e 832627b4f6	N/A	Yes	MD5 Hash value of document

- A.15. Files Produced in Native Format. Any file produced in native file format shall be given a file name consisting of a unique Bates number and, as applicable, a confidentiality designation; for example, “ABC00000002_Confidential.” For each native file produced, the production will include a *.tif image slipsheet indicating the production number of the native file and the confidentiality designation, and stating “File Provided Natively”. To the extent that it is available, the original document text shall be provided in a document-level multi-page UTF-8 text file with a text path provided in the *.dat file; otherwise the text contained on the slipsheet language shall be provided in the *.txt file with the text path provided in the *.dat file.
- A.16. Production Media. Unless otherwise agreed, documents and ESI will be produced on optical media (CD/DVD), external hard drive, secure FTP site, or similar electronic format. Such media should have an alphanumeric volume name; if a hard drive contains multiple volumes, each volume should be contained in an appropriately named folder at the root of the drive. Volumes should be numbered consecutively (ABC001, ABC002, etc.). Deliverable media should be labeled with the name of this action, the identity of the producing Party, and the following information: Volume name, production range(s), and date of delivery.
- A.17. Production Index. With each production, the Producing Party will provide, in native excel format, a complete production log detailing the source(s) produced with Bates

range identified. This log should also identify the number of documents produced in each set.

- A.18. Encryption of Production Media. To maximize the security of information in transit, any media on which documents are produced may be encrypted by the producing Party. In such cases, the producing Party shall transmit the encryption key or password to the requesting Party, under separate cover, contemporaneously with sending the encrypted media. The receiving parties in this matter are on notice that certain data produced may originate from custodians in the European Union and the receiving parties therefore agree to follow the strictest security standards in guarding access to said data.

New Orleans, Louisiana this 15th day of June, 2015.

A handwritten signature in black ink, reading "Eldon E. Fallon". The signature is written in a cursive style with a horizontal line underneath it.

Honorable Eldon E. Fallon
United States District Court