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

THIS DOCUMENT RELATES TO:
ALL CASES

PRE-TRIAL ORDER NO. 14C

The parties having agreed to amend Pre-Trial Order No. 14 (PTO 14) dated May 4, 2015, PTO 14 is hereby amended as follows:

1.   In Section IV and VII.5 of the Defendant's Fact Sheet ("DFS"), Defendants have agreed, without objection to answer certain questions and provide certain data relating to the dispensing and prescribing practices of Plaintiffs' Prescribing and Primary Treating Health Care Providers as it relates to Xarelto if such data is within their possession, custody or control.

2.   Defendants license information and data responsive to Section IV and VII.5 of the DFS from Source Healthcare Analytics LLC ("SHA"), a wholly-owned subsidiary of Symphony Health Solutions Corporation ("SHS"). SHA has authorized Defendants to provide a copy of the responsive data to the Plaintiffs, with no fee, upon execution of the Third Party Data Use Agreement attached hereto as Exhibit 1 by the individual Plaintiff's counsel to whom the data will be produced.

3. Defendants shall, upon receipt of an executed Third Party Data Use Agreement from Plaintiff's counsel (sent to each Defendants' counsel by E-mail to jennifer.lamont@dbr.com, julie.tersigni@dbr.com, and shane.oconnell@dbr.com):

 a) produce all responsive SHS data and documents pursuant to Section IV and VII.5 of the DFS in cases which have been designated to receive a DFS pursuant to CMO 6.

 b) supplement its response to Section IV and VII.5 of any DFS already provided to Plaintiff pursuant to CMO 6 and produce all responsive documents within ten (10) days of receiving the executed Third Party Data Use Agreement.

 c) all responsive data and documents will be produced in excel format.

4. All provisions of PTO 14 other than those amended herein shall remain unchanged and in full force and effect.

New Orleans, Louisiana this 23rd day of May, 2018

_____
ELDON E. FALLON
UNITED STATES DISTRICT JUDGE

EXHIBIT 1

THIRD PARTY DATA USE AGREEMENT (LITIGATION)

This **THIRD PARTY DATA USE AGREEMENT (LITIGATION)** ("**Agreement**") is by and among Source Healthcare Analytics, LLC, a Delaware corporation with its principal place of business at 2390 East Camelback Road, Phoenix, Arizona 85016 ("**SHA**"), **Janssen Pharmaceuticals, Inc., Janssen Research & Development, LLC, Janssen Ortho, LLC and Johnson & Johnson** (collectively, "**JANSSEN**"), Bayer Corporation, Bayer Healthcare, AG, Bayer Pharma, AG, Bayer, AG, Bayer Healthcare, LLC, and Bayer Healthcare Pharmaceuticals, Inc. (collectively, "BAYER") and **the PLAINTIFF and/or PLAINTIFF'S LAW FIRM identified on the signature page of this Agreement** ("**PLAINTIFF**") SHA, JANSSEN, BAYER and PLAINTIFF may be individually referred to herein as a "**party**" or may be collectively referred to herein as the "**parties**." PLAINTIFF and BAYER are collectively referred to herein as "Data Users".

THE PARTIES AGREE TO THE FOLLOWING:

1.   **Effective Date.** This Agreement shall only become effective as of the earlier of: (i) the date last signed by all parties, or (ii) the date that Data Users receive access to the SHA Data ("**Effective Date**").

2.   **Scope of this Agreement.** PLAINTIFF is currently involved in litigation with JANSSEN and BAYER in one or more of the consolidated lawsuits (the "**Litigation**") titled:

>   IN RE: XARELTO® PRODUCTS LIABILITY LITIGATION,
>   PHILADELPHIA COURT OF COMMON PLEAS

>   IN RE: XARELTO® (RIVAROXABAN) PRODUCTS LIABILITY LITIGATION
>   MDL 2592, as well as the various federal District Courts to which an MDL case may be remanded

As part of discovery in the Litigation, Data Users seek to receive, use and/or disclose (subject to the Court-approved Protective Orders) all or part of the following data product(s)/service(s) that JANSSEN previously licensed from SHA ("**SHA Data**" or "**Data**"):

SHA Data includes information or data licensed by JANSSEN from SHA relating to the number of new prescriptions and the number of total prescriptions for Xarelto® for 2011 to the present written by the prescribing healthcare providers and one primary treating healthcare provider identified by each PLAINTIFF in Section III.A.1(a) and Section III.B.1 of the Plaintiff Fact Sheet, along with the name and address of the healthcare provider.

SHA Data also includes any license agreement, or amendment thereto, pursuant to which JANSSEN licensed information or data from SHA, and any correspondence or communications relating to any such license agreement or amendment thereto.

SHA Data further includes any data or information derived from any SHA Data licensed by JANSSEN. By the signature below of an authorized representative of SHA, this Agreement constitutes SHA's prior written permission to JANSSEN to disclose such data to Data Users, subject to the terms and conditions contained in this Agreement.

3.   **Data Delivery.** JANSSEN will have sole responsibility for providing Data Users with access to the SHA Data. SHA has no obligation to deliver any SHA Data or provide support of any kind to JANSSEN or Data Users unless expressly provided in this Agreement.

4.   **Permitted Scope of Data Use.** The parties agree that the SHA Data may be used solely in accordance with this Agreement and for the purpose(s) and in the manner expressly described below ("**Permitted Use(s)**"):

SHA Data may be used in connection with discovery, motion practice, trial and appeal in the Litigation pursuant to the terms of the Protective Orders (as defined in Section 6(a) below). No report, document, or exhibit using SHA data will be represented as having been prepared by SHA. The Permitted Uses shall terminate at the conclusion of the Litigation identified in Section 2 on the last to occur of the following dates: (1) entry of a final order and judgment disposing of all claims; (2) exhaustion of all appellate rights relating to any final order and judgment; (3) expiration of the time to appeal any final order and judgment; or (4) final settlement of all claims.

SHA's consent is limited to disclosure of the SHA Data in connection with legally required production of information or documents in the Litigation. JANSSEN and Data Users each will not disclose the SHA Data to any other party or in any other legal proceeding without SHA's prior written consent. The American Medical Association ("AMA"), whose proprietary data is or may be included within the SHA Data that JANSSEN intends to disclose to Data Users, has consented to the disclosure of SHA data to Data Users, subject to the requirements that (1) the AMA information will be designated with the highest degree of confidentiality under the Protective Orders and (2) all other reasonable steps will be undertaken to maintain the confidentiality of the AMA information.

5. **Restrictions on Data Users' Use of SHA Data.** The Permitted Use(s) described in the preceding Section 4 are subject to all of the following restrictions:

a. SHA will only act as an objective service provider and not as an expert on behalf of a client or any party. SHA Data may only be used in accordance with this Agreement. SHA will not offer and will not be expected or required to provide expert testimony or other evidence regarding the interpretation of the results of the data provided by SHA or the services performed by SHA in connection with the Litigation on behalf of JANSSEN or Data Users. In addition, SHA will not provide any advice or engage in any advocacy with respect to witness testimony or expert analysis of any other party. Also, SHA will not provide any opinion as to the relative merits of the clients' or other party's positions in the Litigation.

b. SHA Data cannot be used to identify an individual patient or pharmacy or for any other unlawful purpose. SHA Data must be delivered to Data Users only in a format which does not identify an individual patient or pharmacy in compliance with the Health Insurance Portability and Accountability Act of 1996 and its implementing regulations. Data Users represent and warrant that they will not attempt, directly or indirectly, to re-identify any SHA Data to identify an individual or pharmacy. SHA may require JANSSEN to immediately suspend delivery of any SHA Data to Data Users in the event that SHA has a good faith reason to believe that identifiable data will be or is included with or in any SHA Data. Data Users shall ensure that the SHA Data will not be used by or on behalf of Data Users in any way to exhibit, reference, access or generate any individual, pharmacy or hospital level data. Data Users represent and warrant that they will not attempt to link, on an individual basis, any other information to the SHA Data. Data Users further represent and warrant that they maintain, and will continue to maintain, appropriate access controls to physically, technically, and administratively separate any SHA Data. Data Users agree to notify SHA immediately if any individual or pharmacy identifiable data is received by Data Users. Data Users agree that subject to SHA's direction, they will either: (1) promptly return to SHA any SHA Data that contains identifiable data, or (2) destroy such Data and copies thereof.

c. Except for the Permitted Use(s), Data Users may not use any SHA Data for Data Users' own benefit or for the benefit of any other person or entity. Further, Data Users may not resell, sublicense, copy, duplicate or otherwise distribute, disclose or permit access to SHA Data by any third party (including affiliates of Data Users).

d. Data Users acknowledge that SHA has an obligation to handle medical information in a legally appropriate and confidential manner. In addition to any other remedy or right hereunder, SHA shall have the right to obtain equitable relief in the event that Data Users breach any obligation herein.

6.   **Confidentiality.**

a. SHA's willingness to enter into this Agreement is expressly conditioned upon JANSSEN's and Data Users' willingness to treat SHA Data as confidential information subject to the terms of a valid, Court-approved Protective Orders. A copy of the applicable Protective Orders in the Litigation, Pre-Trial Order No. 12 (Stipulated Protective Order) [Rec. Doc. 894], filed 05/04/15 in MDL No. 2592, *In re: Xarelto (Rivaroxaban) Products Liability Litigation* attached hereto as Exhibit A and Case Management Order No. 5 (Stipulated Protective Order), filed 05/19/15, First Judicial District of Pennsylvania, Philadelphia Court of Common Pleas, *In re: Xarelto Products Liability Litigation* attached hereto as Exhibit B (collectively referred to within as "**Protective Orders**"). JANSSEN and Data Users each agree that they will not disclose any SHA Data during the Litigation unless such disclosure fully complies with the terms of the attached Protective Orders.

b. Data Users shall ensure that: (i) any employees or agents who receive any SHA Data is apprised of and appreciates the confidential and proprietary nature of the SHA Data; and (ii) each such employee or agent agrees to the confidentiality obligations herein and refrains from disclosing or discussing the SHA Data with anyone other than the Court or required employees of Data Users, JANSSEN or SHA. Data Users' employees shall only receive those portions of the SHA Data necessary to fulfill Data Users' requirements in connection with the Litigation and in accordance with the Permitted Use.

c. Data Users agree not to remove or alter any SHA confidentiality, protected designation, copyright or proprietary notice appearing on any SHA Data received from JANSSEN. In addition, any documents or materials prepared by Data Users which contain information derived from any SHA Data shall be marked or designated HIGHLY PROTECTED – SUBJECT TO PROTECTIVE ORDER pursuant to the terms and procedures set forth in the Protective Orders and without regard to whether such information may or will be disclosed to any other person or party. In addition, any documents or materials prepared by Data Users which contain information derived from any SHA Data shall be marked or designated HIGHLY PROTECTED – SUBJECT TO PROTECTIVE ORDER pursuant to the terms of this Agreement and without regard to whether such information may or will be disclosed to any other person or party.

d. Except in accordance with the terms of the Protective Orders referenced above, no part of the SHA Data shall be published, quoted or reproduced by Data Users. JANSSEN will credit SHA as a source of data only for the Litigation. JANSSEN's attribution of the SHA Data to SHA does not constitute and will in no way be characterized by JANSSEN or Data Users as SHA's endorsement of the data, views, opinions or findings expressed, shared or otherwise reported by JANSSEN or Data Users.

e. No part of the SHA Data shall be published, quoted, made or reproduced by Data Users for any business, competitive, personal, private, advertising, promotional or public relations purposes.

f. Data User accepts sole responsibility for ensuring that Data users' employees and agents comply with the terms of this Section of the Agreement and the Protective Orders.   Data Users agree that they are directly and separately liable for any breach of such terms by Data Users' employees and agents.

7.   **Ownership.** JANSSEN and Data Users acknowledge that the Data provided under this Agreement are proprietary and confidential to SHA and that JANSSEN and Data Users have the right only to use such Data in accordance with the terms of this Agreement. Except as otherwise provided for herein, SHA retains all right, title and interest in, to, and under the Data.

8. **Term and Termination.** The term of this Agreement shall begin on the Effective Date and shall end at the: (i) the expiration or termination of the Permitted Use(s); or (ii) any earlier termination as permitted under the Agreement. Upon the termination or expiration of this Agreement, Data Users shall at SHA's option destroy or return to JANSSEN or to SHA, all SHA Data, and if applicable, an authorized representative of Data Users shall certify in writing to SHA, with a copy to JANSSEN, that Data Users have destroyed or returned to JANSSEN or SHA all SHA Data.

9. **No Warranty.** ANY SHA DATA PROVIDED TO DATA USERS IN CONNECTION WITH THIS AGREEMENT IS PROVIDED TO DATA USERS "AS-IS" AND SHA MAKES NO REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, TO DATA USER SOR TO JANSSEN IN CONNECTION WITH THE SHA DATA, INCLUDING THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

10. **Limitation of Liability.** THE PARTIES ACKNOWLEDGE AND AGREE THAT SHA SHALL HAVE NO LIABILITY TO ANY OTHER PARTY UNDER THIS AGREEMENT, INCLUDING BUT NOT LIMITED TO, ANY LIABILITY ARISING FROM THE INACCURACY OR INCOMPLETENESS OF THE DATA. IN NO EVENT SHALL SHA BE LIABLE FOR ANY INCIDENTAL OR CONSEQUENTIAL DAMAGES INCLUDING BUT NOT LIMITED TO, LOST BUSINESS, LOST PROFITS OR THIRD PARTY CLAIMS, WHETHER FORESEEABLE OR NOT, EVEN IF SHA HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. The parties acknowledge and agree that a breach of Data Users or its employees of the provisions of this Agreement will cause SHA and/or its affiliates irreparable injury and damage which may not be compensable by money damages, and, therefore, Data Users agree that SHA and/or its affiliates shall be entitled to injunctive or other relief to prevent such a breach and to secure enforcement of the terms of this Agreement, in addition to any other remedies which may be available. Without limiting the availability to SHA of any other rights or remedies, if Data Users breach any of the terms of this Agreement, SHA reserve the right to immediately terminate this Agreement upon notice to JANSSEN and Data Users.

11. **Notices.** All notices, demands or other communications required hereunder shall be given or made in writing and shall be delivered personally or sent prepaid (a) by certified or registered first class mail with return receipt requested or (b) by a nationally-recognized common carrier's overnight courier service, addressed to the receiving party at the address first written above or such other address as the receiving party may advise in writing to use hereunder. Further, in the case of SHA, the notice must be sent to the attention of the "President & CEO" with a copy to the "Legal Department."

12. **Miscellaneous.** This Agreement sets forth the entire agreement between the parties and supersedes prior proposals, agreements and representations related to the subject matter of this Agreement, whether written or oral. No modifications, amendments or waiver of any of the provisions of this Agreement shall be binding upon the parties unless made in writing and duly executed by authorized representatives of all parties. No party may assign, transfer or sublicense any portion of this Agreement or the Data provided hereunder without the express prior written consent of SHA. Any attempt to assign, transfer or sublicense by Data Users or JANSSEN shall be void. This Agreement may be executed in one or more counterparts, each of which shall be deemed an original, and all of which together shall constitute one and the same document. The headings of the paragraphs hereof are used for convenience only and shall not affect the meaning or interpretation of the content thereof. This Agreement and the relationship of the parties in connection with the subject matter of this Agreement shall be governed by and determined in accordance with the laws of the State of Delaware. The failure to enforce at any time the provisions of this Agreement or to require at any time performance by the other parties of any of the provisions hereof shall in no way be construed to be a waiver of such provisions or to affect either the validity of this Agreement (or any part hereof), or the right of any of the parties thereafter to enforce each and every provision in accordance with the terms of this Agreement. If any provision of this Agreement is held to be invalid or unenforceable by any judgment of a tribunal of competent jurisdiction, the remainder of this Agreement shall not be affected by such judgment, and the Agreement shall be carried out as nearly as possible according to its original terms and intent. However, if the original intent of the parties cannot be preserved, this Agreement shall terminate upon the effective date of such judgment.

SHA, JANSSEN, BAYER and PLAINTIFF acknowledge their receipt and acceptance of the terms and conditions of this Agreement by the signature below of their respective authorized representatives.

PLAINTIFF:
By: _____
Printed Name: _____
Title: _____
Law Firm: _____
Address: _____
Address: _____
Telephone: _____
E-mail:_____
Date: _____

JANSSEN:
By: _____
Printed Name:_____
Title: _____
Law Firm: _____
Address: _____
Address: _____
Telephone: _____
E-mail:_____
Date: _____

SOURCE HEALTHCARE ANALYTICS, LLC
By: _____
Printed Name: _____
Title: _____
Date: _____

BAYER:
By: _____
Printed Name: _____
Title: _____
Law Firm: _____
Address: _____
Address: _____
Telephone: _____
E-mail:_____