

#3. The TEMPO database and the associated images for all draft material related to Pradaxa shall be produced to the PSC on or before **January 14, 2013**.

- b. BIPI does not have to produce the “Task” feature from the TEMPO database. BIPI shall produce all items in the Digital Asset Library that relate to Pradaxa on or before **January 14, 2013**.
- c. Both Drafts and Final versions of all responsive and non-privileged material contained in TEMPO shall be produced. The parties are directed to meet-and-confer about a schedule for updates of the TEMPO database and materials and advise the Court about the status of the same on **January 14, 2013**.

4. VISTA Database

- a. BIPI shall produce all of the data from the following “tabs” within the VISTA database as it relates to Pradaxa to the PSC on or before **December 17th** (this production shall include all entries through December 1st and shall be produced all at one time):
 - i. Activities;
 - ii. Service Request;
 - iii. Managed Market; and
 - iv. SFX.
- b. BIPI shall produce full incremental updates of these four “tabs” from VISTA database as it relates to Pradaxa on a quarterly basis beginning on **April 1, 2013** for all new data entered into the database through thirty (30) days before the production deadline.

5. Defendants’ Adverse Events Database (ARISg5)

- a. BIPI and BII shall produce to the PSC a virtual machine loaded with the full worldwide Pradaxa case data from the ARISg5 database on or before **January 14, 2013** (this production shall include all entries through December 1, 2012 and shall be produced all at one time). The virtual machine produced by BIPI and BII shall provide the PSC with the same general capabilities that Defendants have with regard to the ARISg database (*e.g.*, the ability to search the database, sort the data, save searches and results, view case history, print search results, and extract data from the database). Notwithstanding the above, the ARISg5 database is being produced with the understanding that the PSC will not be receiving the proprietary ARISg5 application program and any corresponding or associated user interface capabilities. BIPI

and BII shall be permitted to withhold or redact the production of any patient or reporter identifying information (name, street address (but not city or state), phone number, e-mail address, and social security number) in order to comply with federal and European regulations, and in particular, the German Data Protection Act. BII and BIPI need not produce tables that do not contain any data, but are merely database inter-relational tables, however, if such tables are required in order for the PSC to access, analyze (*e.g.*, search, sort, etc.), save and/or extract all data related to Pradaxa adverse event cases in ARISg, then they shall be produced (*e.g.*, if the tables are needed to create or view the case history).

- b. The parties shall continue to meet and confer regarding the production of incremental updates of the ARISg database, and the production of source files for adverse events. The parties will update the Court regarding the status of these matters, as needed.
- c. The virtual machine produced by BII and BIPI shall be maintained by the PSC in a secure environment and shall not be made available for access via the Internet.
- d. Pursuant to and in accordance with the timing set forth in paragraph 16 of CMO #2 (Confidentiality Order [Dkt #5]), the PSC shall return the virtual machine to BII and BIPI, and to the extent that the PSC has made any copies of the data, the PSC shall delete or destroy all copies that have been created. Pursuant to paragraph 16 of CMO #2 (Confidentiality Order [Dkt #5]), at the end of the litigation, the PSC shall certify that all copies of the adverse event data have been destroyed and that the virtual machine is returned to BII and BIPI.
- e. Pursuant to CMO #2, the adverse event data produced shall only be used for purposes of this litigation.

6. IDEA for Submission and Z-Drive (Storage Area for Regulatory Submissions):
 - a. BIPI shall produce all data and documents from the Z-Drive related to Pradaxa (with working hyperlinks) on or before **January 14, 2013**. Production of native versions of the documents that comprise the INDs or NDAs for Pradaxa from IDEA for Submission, which have already been produced to the PSC from BIPI's PDF version of the same or will be produced as part of the Z-Drive production, shall be deferred until a subsequent Order of the Court, and the parties shall continue to meet-and-confer about this issue after production of the Z-Drive.
 - b. The parties will update the Court regarding the status of these matters, as needed.
 - c. Any documents from IDEA for Submission that are going to be produced by BII shall be produced on the schedule set forth in CMO #18. The parties shall meet and confer about the format for production for this data source and advise the Court of any issues as needed. BII's productions of Idea for Submission shall include data from both the "work in progress" and the "archive" part of IDEA for Submission as testified to by Ms. Peacock on November 15, 2012.

7. IDEA for General and IDEA for Controlled Documents
 - a. BIPI shall produce all responsive and non-privileged data within IDEA for Controlled Documents by **January 14, 2013**.
 - b. With respect to IDEA for General, BIPI and BII shall produce all Pradaxa-related documents retrieved by applying the agreed-upon search terms. The parties understand that the extraction of relevant information from IDEA for General will likely result in the loss of the functionality of hyperlinks between documents. The documents themselves will remain intact.
 - c. BIPI and BII shall produce all responsive and non-privileged data (both final versions and drafts) from IDEA for General as follows:
 - i. R-Gen-bus side of Idea for General: by **February 15, 2013**.
 - ii. I-Gen-bus side of Idea for General: by **March 15, 2013**.

8. Oracle Clinical
 - a. BIPI shall produce all raw data for all clinical trials related to Pradaxa and/or Dabigatran Etxilate by **December 17th**. The

production shall be made in such a manner to permit the PSC to determine what study or test the data is related to.

- b. In addition to all raw data related to Pradaxa, BIPI shall produce any data set that was provided to the FDA or other regulatory agency, and such data shall be provided to the PSC as a complete data set, just as it was submitted to the FDA or other regulatory agency, by **January 14, 2013**.

9. BRAIN and CERBERUS

- a. BIPI shall produce all raw data for all pre-clinical studies related to Pradaxa and/or Dabigatran Etxilate by **January 14, 2013**. The production shall be made in such a manner to permit the PSC to determine what study or test the data is related to.
- b. In addition to all raw data related to Pradaxa, BIPI shall produce any data set that was provided to the FDA or other regulatory agency, and such data shall be provided to the PSC as a complete data set, just as it was submitted to the FDA or other regulatory agency, by **January 14, 2013**.

10. SAS Data

- a. BIPI shall produce all SAS data for all pre-clinical studies and clinical trials related to Pradaxa and/or Dabigatran Etxilate by **January 14, 2013**. The production shall be made in such a manner to permit the PSC to determine what study or test the data is related to.
- b. In addition to all SAS data related to Pradaxa, BIPI shall produce any data set that was provided to the FDA or other regulatory agency, and such data shall be provided to the PSC as a complete data set, just as it was submitted to the FDA or other regulatory agency, by **January 14, 2013**.

11. Materials Responsive to Boston Request for Production or PSC's First Request for Production that will be Produced from Sources Other than those Sources Identified herein

- a. Any such responsive materials shall be produced **January 14, 2013**.

12. Responses to PSC's Second Request for Production and Second Set of Interrogatories (Served on November 8, 2012)

- a. BIPI shall file a motion for a protective order on **December 21, 2012**; the PSC shall file an opposition to such motion on **January 7, 2013**; BIPI may file a response on **January 11,**

2013. The motion shall be addressed at the **January 14, 2013** Status Conference.

13. Paper and Electronic Custodial Files for the five (5) BII Category "C" Custodians Identified by the PSC on December 1, 2012:
 - a. Shall be produced by **March 15, 2013.**

14. G-Drive (a BIPI common shared drive):
 - a. BIPI shall produce all Pradaxa-related materials stored on the G-Drive, retrieved by applying the agreed-upon search terms, on or before **January 30, 2013.**

So Ordered:


Digitally signed by
David R. Herndon
Date: 2013.01.02
11:06:43 -06'00'

**Chief Judge
United States District Court**

Date: January 2, 2013