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WESTERN DISTRICT OF LOUISIANA
LAFAYETTE, LOUISIANA

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF LOUISIANA

In Re: Actos (Pioglitazone) Products Liability Litigation	**MDL NO. 6:11-md-2299**
	JUDGE DOHERTY
This Document Applies to:	**MAGISTRATE JUDGE HANNA**
All Cases	

CASE MANAGEMENT ORDER:
PROTOCOL RELATING TO THE PRODUCTION OF ELECTRONICALLY STORED INFORMATION ("ESI")

Pursuant to the agreement reached between the Plaintiffs and Defendants herein, this Court enters the following Order concerning the production of electronically stored information in these proceedings:

A. Scope

1. General. The procedures and protocols outlined herein govern the production of electronically stored information ("ESI") by the Parties. Section E titled "Search Methodology Proof of Concept" applies only to the predictive coding and advanced analytics sampling procedure as outlined in that Section. Sections A through D and Sections F through J apply throughout the pendency of this litigation. This Order governs all parties to these proceedings, whether they currently are involved or become so in the future. The Parties to this protocol ("Protocol") will take reasonable steps to comply with this agreed-upon Protocol for the production of documents and information existing in electronic format. All disclosures and

productions made pursuant to this Protocol are subject to the Privilege Protocol and Protective Order entered in this matter.

2. Limitations and No-Waiver. The Parties and their attorneys do not intend by this Protocol to waive their rights to the attorney work-product privilege, except as specifically required herein, and any such waiver shall be strictly and narrowly construed and shall not extend to other matters or information not specifically described herein. All Parties preserve their attorney client privileges and other privileges and there is no intent by the protocol, or the production of documents pursuant to the protocol, to in any way waive or weaken these privileges. All documents produced hereunder are fully protected and covered by the Parties' confidentiality agreements, and order(s) of the United States District Court, as well as any clawback agreements, and protective order(s) of the United States District Court effectuating same.

B. ESI Preservation

1. The Parties have issued litigation notices to those identified as most likely to have discoverable information.

C. Sources

1. While Defendants' fact gathering is ongoing, the following are data sources identified to date that are most likely to contain discoverable information. Defendants agree to provide additional discovered data sources likely to contain relevant information. Defendants agree to provide information about the data sources to the extent applicable and known in addition to that found in the subparagraphs below, including the date range of information contained in the data source, the department(s) utilizing the data source, whether the data source is hosted internally or externally, and the database type.

a	ARISg	Adverse Event Database
b	BLUE	Labeling and promotional materials management system
c	Galaxy	Regulatory document management system
d	MEDIsource	Product information request database
e	T-Rx	Field sales call database
f	TSARS (or "S Drive")	Takeda Statistical Analysis and Repository System
g	T-Track	Clinical Science Liaison database
h	IRIS	Research grant management system
i	LARC	Clinical Science Liaison education resources database
j	Sample Guardian	Product sample management database
k	TEG	Takeda Educational Grant management system
l	PubBase	Publications management system
m	Records Management System	Records Operation Center ("ROC") information system

a. ARISg: ARISg is an adverse event database. It contains information that the Pharmacovigilance department at TRGD U.S. receives regarding adverse events related to Takeda drugs, including adverse event reports ("AERs") received from, without limitation, physicians, patients, clinical trials, medical literature, and foreign entities. ARISg is the software used for this database, which is sometimes called T-Gaea within Takeda. It has been in effect since 1999.

b. BLUE: This database is used by the Marketing department in the approval process for promotional materials. It contains a labeling module and a module for promotional pieces and marketing campaigns. BLUE has been active from April 2008 to present. The vendor is Schawk Blue.

c. Galaxy: Galaxy is a document repository system used by the Regulatory department containing components of regulatory submissions to the Food and Drug Administration. It went into production in 2009.

d. MEDIsource: This data system is used by the Medical Information and Quality Assurance departments to capture and respond to product information requests and non-medical product complaints. It has a Siebel component that documents the intake of requests for information from physicians and provides a response; a Documentum system with standard response and customer response letters; and Info Maestro which pulls information from the standard response letter and from the Sieble system to create the response letter to an individual physician.

e. T-Rx: This database contains information regarding U.S. commercial field sales calls.

f. TSARS (or "S Drive"): This is Takeda's Statistical Analysis and Repository System and is a Unix centralized repository used to manage Clinical and research data. It is used by the Analytical Science department. It contains clinical SAS data sets and programs used to analyze those data sets for purposes of final submission reports – tables, listings, and graphs.

g. T-Track: This database is a customized application of Seibel's Customer Relationship Management system for use by Takeda's field based Clinical Science Liaisons.

h. IRIS: This system is used by Takeda for the intake and processing of external research grant requests. It is a vendor hosted system (SteepRock is the vendor). It was implemented within the last five years.

i. LARC: This database includes articles, presentations, and publications related to Takeda products and the therapeutic areas they address. Quosa is the vender for this database. It is accessible by Clinical Science Liaisons in their respective therapeutic areas.

j. Sample Guardian: This database contains product sample management data regarding sample transactions and inventory reconciliations.

k. TEG: Takeda Educational Grant database is used for education grant request management.

l. PubBase: PubBase is a Documentum-based system used for the management and storage of publication documents.

m. Records Management System: This data source is used by the Records Operations Center ("ROC"), where physical records are maintained.

D. Custodians

1. The following are custodians who have been identified as most likely to have information relevant to this litigation. For these custodians, data is being pulled from e-mail, computer hard drives, and physical files that are in the possession, custody, and control of Takeda. Investigation is ongoing by both Parties as to potential additional custodians at Takeda (including potential Japanese custodians) and Eli Lilly and Company. Current key custodians include:

1.	Baron, David	Vice President, NonClinical Safety/Efficacy
2.	Spanheimer, Robert	Vice President, Medical and Scientific Affairs
3.	Greeby, Jennifer	Director, Marketing (Diabetes)
4.	Recker, David	Senior Vice President, Clinical Science
5.	Paris, Maria	Former Vice President, Pharmacovigilance
6.	Gerrits, Charles	Former Senior Director, Pharmacoepidemiology
7.	Johnston, Janet	Associate Director, Safety Surveillance
8.	Thom, Claire	Former Vice President, Research and Development
9.	Daly, Rich	Former Vice President, Marketing
10.	Perez, Alfonso	Vice President, Clinical Science Strategy

11.	Ortell, Una	Director, Promotion and Advertising
12.	Orlando, Dan	Former Vice President, Sales
13.	Lee, Jessie	Manager, Regulatory Affairs Strategy
14.	Cuomo, Maryann	Associate Director, Regulatory Labeling
15.	Weisbrich, Shay	Vice President, Franchise Leader (Former Director, Marketing)
16.	Kupfer, Stuart	Vice President, Clinical Science
17.	Ramstack, Mary	Sr. Director, Strategic Project Planning and Management
18.	Roebel, Mick	Sr. Director, Regulatory Affairs
19.	Lorenz, Janet	Associate Director, Regulatory Affairs, Promotion and Advertising
20.	Pritza, Mary Jo	Former Associate Director, Regulatory Affairs
21.	Caracci, Mike	Former Director, Marketing
22.	Tynan, Julie	Assistant Project Director, Strategic Project and Planning Management
23.	Hull, Andy	Vice President, Alliance Management (former Vice President, Marketing)
24.	Fusco, Gregory	Sr. Medical Director, Pharmacoepidemiology and Analysis
25.	Caggiano, Christopher	Sr. Product Manager, Diabetes Marketing
26.	Ryan, D'Arcy	Former Director, Marketing
27.	Khan, Mehmood	Former Sr. Vice President, Medical and Scientific Affairs
28.	Harris, Thomas	Vice President, Regulatory Affairs
29.	Trochanov, Anton	Associate Medical Director, Pharmacovigilance

E. Search Methodology Proof of Concept

1. General. The Parties have discussed the methodologies or protocols for the search and review of ESI collected from Takeda sources, including but not limited to e-mail, and the following is a summary of the Parties' agreement on the use of a search methodology proof of concept to evaluate the potential utility of advanced analytics as a document identification mechanism for the review and production of this data. The Parties agree to meet and confer regarding the use of advanced analytics for other data sources. While the Parties agree to explore the use of advanced analytics as a technique to ensure appropriate responses to discovery

requests, the Parties agree that Defendants retain the right to review documents after predictive coding but prior to production for relevance, confidentiality, and privilege. A sampling of documents withheld after such review will take place pursuant to Section E.10.

2. General Overview of Advanced Analytics/Predictive Coding Process. Takeda utilizes software provided by Epiq Systems ("Epiq") to search and review ESI for production in this case. Epiq uses Equivio's Relevance software for advanced analytics and predictive coding.

Epiq will collect e-mail documents from four key Takeda custodians, which will be combined to create the "sample collection population." The Parties will meet and confer to determine the names of the four custodians. Additionally, Takeda will add a set of regulatory documents which have already been collected to the "sample collection population." Takeda and Plaintiffs will each nominate three individuals ("the experts") to work collaboratively at the offices of Nelson Mullins, 1320 Main Street, Columbia, SC 29201 to train the Equivio Relevance system. Plaintiffs' experts will execute a Nondisclosure and Confidentiality Agreement in the form attached as Exhibit A hereto. To the extent that Plaintiffs' experts are exposed to information that would be subject to withholding or redaction under the Protective Order in this matter, Plaintiffs' experts agree not to disclose such information to co-counsel, client, any Party, or any third party without obtaining prior written consent of the other Party regarding the particular piece of information sought to be disclosed. Before the meeting, the Parties shall be provided a copy of the applicable Equivio training documents, handbook, or manual. The Parties' experts will receive technical training on the Equivio Relevance software and coding process and will work together to make one relevance decision for documents in the Control and Training sets, as described in more detail below.

The Parties will review a number of documents required by the Equivio Relevance system for the data to reach Stability as described below. Once Stability is reached, the Control and Training sets are then used to begin the predictive coding process. Using the Control and Training documents, the system calculates relevance scores for the entire sample collection population, with each document in the sample collection population receiving a relevance score of 0 through 100.

Attorneys representing Takeda will have access to the entire sample collection population to be searched and will lead the computer training, but they will work collaboratively with Plaintiffs' counsel during the Assessment and Training phases. Takeda's experts will conduct an initial review of documents presented by the Equivio Relevance system for privilege. The privileged documents will be either entirely withheld from viewing by Plaintiffs' experts or printed and redacted. A privilege log for such documents will be provided. The Parties, after review of the privilege log, reserve the right to require that such documents be deemed as "skip" (same as designation used for technical problem documents). Otherwise, these documents may still be used to train the system. Both Parties will then review all of the non-privileged documents during the training process (i.e., both documents coded as relevant and irrelevant). The Parties' experts will review the documents in collaboration and determine the coding to be applied to the documents. To the extent the Parties disagree regarding the coding of a particular document or designation of privilege, they will meet and confer in an effort to resolve the dispute prior to contacting the Court for resolution.

At the conclusion of the training process and upon calculation of relevance scores, the Parties will meet and confer regarding which relevance score will provide a cutoff for documents

to be manually reviewed by defense counsel for production. However, the Parties reserve the right to seek relief from the Court prior to the commencement of the final manual review.

At the recommendation of Epiq, no seeding will take place at this time. The Parties may meet and confer if it is determined that seeding may be applicable at a later date.

Plaintiffs' experts and counsel shall not remove any of the Control or Training documents from the offices of Nelson Mullins, nor shall they be allowed to copy such documents. The Parties agree that Defendants do not waive protection of trade secret or confidential information in allowing Plaintiffs to review documents under this sampling mechanism. All documents reviewed pursuant to this sampling protocol shall be done under the Protective Order in this matter as well as any Privilege Protocol or clawback agreement that shall be reduced to an order acceptable to the Court.

3. Relevance Tags. The Parties agree that as part of the Assessment and Training phases, all of the non-privileged and privilege-redacted documents reviewed by both parties' experts will be categorized as relevant, not relevant, or skip (to be used for documents with technical problems). The privileged-withheld documents will be categorized by Defendants' experts as relevant, not relevant, or skip, subject to the Parties' right to have any privileged-withheld documents categorized as a "skip." The Parties shall immediately discuss any disagreements on coding in good faith, so that the training may be improved accordingly, and may seek guidance from the Court or the Court appointed special masters if necessary.

4. Collection & Data Preparation. The Parties will meet and confer to agree upon the four custodians that will be selected for the sampling. E-mail and attachment documents will be collected from the four custodians and added to the collected regulatory documents, together

comprising the sample collection population. Documents may be removed from the sample collection population if they are:

a. Spam,

b. Commercial e-mail,

c. Files without text,

d. Exact duplicates within the custodians (see Section G.6 regarding production of information for duplicate documents), and

e. System files, etc. (*i.e.*, the documents that the samples will be selected from will be de-NISTED)

Epiq will extract the sample collection population documents' text and build an index.

5. Assessment Phase. The Equivio Relevance software generates an initial simple random sample of 500 documents from the sample collection population. Takeda's experts will initially review the documents for privilege. Any documents deemed privileged by Takeda's experts will be either entirely withheld from viewing by Plaintiffs' experts or printed and redacted prior to viewing by Plaintiffs' experts, and logged on a privilege log consistent with the Privilege Protocol in this matter. These documents may still be used to train the system. To the extent the Parties disagree regarding the privilege decision for a particular document, they will meet and confer in an effort to resolve the dispute prior to contacting the Court for resolution. The Parties' experts will then work collaboratively to determine the relevance of the non-privileged and privilege-redacted documents. The relevance of the privileged-withheld documents will be determined by Defendants' experts. The documents reviewed in the Assessment Phase make up the Control Set. The Control Set is used for estimating richness

(percentage of relevant documents in a population), and also serves as a reference point for calculating recall and precision.

a. The application's estimates of richness use a confidence level of 95%. The initial Control Set of 500 documents yields a confidence estimation of richness with an error margin of plus or minus 4.3%. This is a worst-case error margin assuming richness of 50%. For lower levels of richness, the error margin will also be lower. For example, for richness of 10%, the error margin would be plus or minus 2.6%, while for 5%, the error margin would be plus or minus 1.9%.

b. The Control Set also creates a basis for calculating recall and precision, which are then used for monitoring training progress and calculating results.

c. Equivio Relevance tracks the progress of the Assessment Phase to achieve the appropriate level of statistical validation. These levels of validation are referred to in the Equivio system as "Baseline," at the lowest level, through "Statistical," at the highest level. The terms "Baseline" and "Statistical" are used by Equivio Relevance as indicators to the user as to the progress of the Assessment Phase. The validation level achieved depends on the number of relevant documents found by the user in the Control Set. At the "Baseline" level, the number of relevant documents in the control set is too low to allow statistically valid estimates of recall and precision. The Parties will ensure that the number of Control Set documents reviewed will reach the "Statistical" level.

d. For informational purposes, the "Statistical" level of validation in Equivio requires the presence of at least 70 relevant documents in the Control Set. For document collections with richness of 14% and above, a Control Set of 500 documents is sufficient to reach

the "Statistical" level of validation. For lower levels of richness, additional documents will need to be reviewed in the Assessment Phase in order to reach the "Statistical" level.

e. Based on a confidence level of 95%, the Statistical level of validation yields an error margin on recall estimates of plus or minus 11.7%. This is a worst-case error margin assuming recall of 50%. The Parties will continue the Assessment Phase, beyond the "Statistical" level, until the Control Set contains at least 385 relevant documents. This sample will yield an error margin on recall estimates of plus or minus 5%.

6. Iterative Training Phase. Following the creation of the Control Set at the Statistical validation level, the Equivio Relevance system selects a random sample of forty documents. Takeda's experts will initially review the forty documents for privilege. Any documents deemed privileged by Takeda's experts will be either entirely withheld from viewing by Plaintiffs' experts or printed and redacted prior to viewing by Plaintiffs' experts, and logged on a privilege log consistent with the Privilege Protocol in this matter. These documents may still be used to train the system. The Parties' experts will then work collaboratively to determine the relevance of the non-privileged and privilege-redacted documents. The relevance of the privileged-withheld documents will be determined by Defendants' experts, subject to the Parties' right to have any privileged-withheld documents categorized as a "skip" and not included in the training. To the extent the Parties disagree regarding the relevance or privilege decision for a particular document, they will meet and confer in an effort to resolve the dispute prior to contacting the Court for resolution.

a. Once the experts have completed the first Training Set, the Equivio Relevance system calculates the Training Status. The three possible states are "Not Stable," "Nearly Stable," or "Stable."

b. The experts continue to review samples of forty documents each, using the process outlined in paragraph 6 above, until the Stable Training Status is reached.

c. The subsequent samples of forty documents are selected using an Active Learning approach. Active Learning means that each training sample is selected based on what has been learned from previous samples. The object is to maximize the sample's contribution to the training process. Therefore, the system chooses samples that provide comprehensive coverage of the population (reducing under-inclusiveness), while fine-tuning the concept of relevance that the Classifier is developing (reducing over-inclusiveness). The system reaches Stability when the marginal contribution of additional samples to the enhancement of the Classifier approaches zero, as determined by the Equivio software and which determination (Stability) is not configurable.

7. Calculation of Relevance Scores. Upon completion of the Training Phase once Stability is reached, and any related meet and confer sessions and agreed upon coding corrections, the Equivio Relevance system will run over the sample collection population and calculate relevance scores for each document in the sample collection population. Each document in the sample collection population receives a relevance score of 0 through 100, with 0 being least likely to be relevant and 100 being most likely.

8. Final Search, Review, and Production of Sample Collection Population Documents. The Parties will meet and confer regarding which relevance score will provide a cutoff that will yield a proportionate set of documents that will be manually reviewed by Takeda for production. All of the documents above the agreed upon relevance score in the sample collection population will be reviewed by Takeda. Documents found by Takeda's review to be relevant and non-privileged documents will be produced to Plaintiffs.

9. Quality Control by Random Sample of Irrelevant Documents. In addition, at the conclusion of the process described above, and prior to generating the review set, the Parties will collaboratively review at the offices of Nelson Mullins in Columbia, SC a random sample of documents in the sample collection population with relevance scores below the cut-off score set for establishing the review set (aka the "Rest"). These documents are flagged for culling, and will not be included in the review set. In Equivio Relevance, this test is referred to as "Test the Rest." The purpose for this phase is to verify that the Rest contains a low prevalence of relevant documents and that the proportionality assumptions underlying the cut-off decision are valid.

a. The Test the Rest sample is designed to provide a confidence level of 95%. The default sample size is 500 documents. The margin of error depends on the percentage of relevant documents in the Rest. For example, if 5% of the Rest documents are found to be relevant, the margin of error is 1.9%. If 1% are relevant, the margin of error is 0.8%.

b. Takeda's experts will initially review the Rest sample documents for privilege. Any documents deemed privileged by Takeda's experts will be either entirely withheld from viewing by Plaintiffs' experts or printed and redacted prior to viewing by Plaintiffs' experts, and logged on a privilege log consistent with the Privilege Protocol in this matter. The Parties' experts will then work collaboratively to determine the relevance of the non-privileged and privilege-redacted documents. The relevance of the privileged-withheld documents will be determined by Defendants' experts, subject to the Parties' rights to have any privilege-withheld document categorized as a "skip" for purposes of the Test the Rest sample. To the extent the Parties disagree regarding the relevance or privilege decision for a particular document, they will meet and confer in an effort to resolve the dispute prior to contacting the Court for resolution.

10. Sampling of Documents Not Produced After Predictive Coding. After the predictive coding process completes, and Takeda's counsel reviews and produces documents from the sample collection population consistent with paragraph 8, the Parties will collaboratively review at the offices of Nelson Mullins in Columbia, SC a random sample of documents above the agreed-upon cutoff relevance score that were withheld from production on relevance grounds. The Parties agree to meet and confer regarding an appropriate sample size.

a. Takeda's experts will initially review the sample documents for privilege. Any documents deemed privileged by Takeda's experts will be either entirely withheld from viewing by Plaintiffs' experts or printed and redacted prior to viewing by Plaintiffs' experts, and logged on a privilege log consistent with the Privilege Protocol in this matter. The Parties' experts will then work collaboratively to determine the relevance of the non-privileged and privilege-redacted documents. The relevance of the privileged-withheld documents will be determined by Defendants' experts, subject to the Parties' rights to have any privilege-withheld document categorized as a "skip" for this purpose. To the extent the Parties disagree regarding the relevance or privilege decision for a particular document, they will meet and confer in an effort to resolve the dispute prior to contacting the Court for resolution.

11. Post-Predictive Coding Sampling Meet and Confer. The Parties shall meet and confer in good faith to resolve any difficulties and finalize the method for searching documents on a going forward basis. To the extent that the Parties cannot agree, they shall apply to the Court for relief. Defendant shall not be required to proceed with the final search and review unless and until objections raised by either Party have been adjudicated by the Court or resolved by written agreement of the Parties. The Parties reserve the right to request a meet and confer

regarding the designation of any document as a "skip" for purposes of the control sample, training, or Test the Rest, if agreement cannot be reached.

F. Costs

1. Takeda reserves its right to seek relief from the Court (e.g., a cost shifting award and pursuant to the principles of proportionality). *See* Fed. R. Civ. P. 1, 26(b)(2)(C), 26(b)(2)(B), & 26(g); *Electronic Discovery*, 11 Sedona Conf. J. 289 (2010); *see also* Fed. R. Evid. 403 (inadmissibility of cumulative evidence).

2. Plaintiffs agree to bear all of the costs associated with their compliance with the terms of this protocol. Plaintiffs agree to bear all of the costs associated with the receipt and review of ESI produced hereunder including the costs associated with its ESI experts who will be involved with Plaintiffs in all aspects of this ESI protocol.

G. Format of Production For Documents Produced by Defendants

1. TIFF/Native File Format Production. Documents will be produced as single-page TIFF images with corresponding multi-page text, native file format document if applicable under paragraph G.2, and necessary load files. Native files, along with all corresponding metadata, will be preserved. TIFF images will be of 300 dpi quality or better. The load files will include an image load file as well as a metadata (.DAT) file with the metadata fields identified below on the document level to the extent available.

	Field	Summation Field (Florida)	Definition	Doc Type
1	SOURCE	SOURCE	Name of party producing the document	All
2	CUSTODIAN	CUSTODIAN	Name of person or non-human data source from where documents/files are produced. ***Where redundant names occur, individuals should be distinguished by an initial which is kept constant throughout productions (e.g., Smith, John A. and Smith, John B. Where data is collected from an archive, the archive will be listed as custodian.*	All
3	CUSTODIANAPPENDMULTI	CUSTODIANAPPENDMULTI	Name of Takeda person or non-human data source from where duplicate documents/files were suppressed. ***Where redundant names occur, individuals should be distinguished by an initial which is kept constant throughout productions (e.g., Smith, John A. and Smith, John B. Where data is collected from an archive, the archive will be listed as custodian.*	All
4	CUSTODIAN ID	CUSTODIAN ID	Each CUSTODIAN from #2 or 3 above will be assigned a unique numeric identifier that will be maintained throughout productions. Where data is collected from an archive, the archive will be listed as custodian.	All

	Field	Summation Field (Florida)	Definition	Doc Type
5	BEGBATES	BEGDOC#	Beginning Bates Number (production number)	All
6	ENDBATES	ENDDOC#	End Bates Number (production number)	All
7	PGCOUNT	PGCOUNT	Number of pages in the document	All
8	FILESIZE	FILESIZE	File Size	All
9	APPLICAT	APPLICAT	Commonly associated application for the specified file type.	All
10	FILEPATH	FILEPATH (for Edocs)	File source path for electronically collected documents other than emails, which includes location, file name, and file source extension.	Edocs
11	RELATIVE PATH APPEND	RELATIVE PATH APPEND (for Edocs)	File source path for duplicate electronically collected documents other than emails, which includes location, file name, and file source extension.	Edocs
12	NATIVEFILELINK	DOCLINK	For documents provided in native format only	All
13	TEXTPATH	LOGFILE or FULLTEXT	File path for OCR or Extracted Text files	All
14	MSGID	MSGID	Value extracted from parent message during processing	Email
15	FROM	FROM	Sender	Email
16	TO	TO	Recipient	Email
17	cc	cc	Additional Recipients	Email
18	BCC	BCC	Blind Additional Recipients	Email
19	SUBJECT	SUBJECT	Subject line of email	Email
20	PARENTBATES	PARENTID	BeginBates number for the parent email of a family (will not be populated for documents that are not part of a family)	Email

	Field	Summation Field (Florida)	Definition	Doc Type
21	ATTACHBATES	ATTACHID	Bates number from the first page of each attachment	Email
22	BEGATTACH	(will be provided from ATTRANGE)	First Bates number of family range (i.e. Bates number of the first page of the parent email)	Email
23	ENDATTACH	(will be provided from ATTRANGE)	Last Bates number of family range (i.e. Bates number of the last page of the last attachment)	Email
24	ATTACHCOUNT	ATTACHMENT COUNT	Number of attachments to an email	Email
25	ATTACHNAME	ATTACHMENT LIST	Name of each individual attachment	Email
26	DATESENT (mm/dd/yyyy hh:mm:ss AM)	DATESENT	Date Sent	Email
27	DATERCVD (mm/dd/yyyy hh:mm:ss AM)	DATERCVD	Date Received	Email
28	EMAILDATSORT (mrn/dd/yyyy hh:mm:ss AM)	DATESENT	Sent Date of the parent email (physically top email in a chain, I.e. immediate/direct parent email)	Email
29	Email Outlook Type	Email Outlook Type	Type of Outlook item, e.g.email, calendar item, contact, note, task	Email
30	HASHVALUE	MD5HASH	MD5 Hash Value	All
31	TITLE	DOCTITLE	Title provided by user within the document	Edocs
32	AUTHOR	AUTHOR	Creator of a document	Edocs
33	DATECRTD	DATECRTD	Creation Date	Edocs
34	MODIFIED BY	LAST EDITED BY	Person who has modified a document	Edocs
35	LASTMODD (mrn/dd/yyyy	LASTMODD (mrn/dd/yyyy hh:mm:ss	Last Modified Date	Edocs

	Field	Summation Field (Florida)	Definition	Doc Type
36	DocumentType	DocumentType	Descriptor for the type of document: **"E-document"** for electronic documents not attached to emails; **"Emails"** for all emails; **"E-attachments"** for files that were attachments to emails; and **"Physicals"** for hard copy physical documents that have been scanned and converted to an electronic image.	All
37	Importance	Importance	High Importance - indicates Priority Email message.	Email
38	Redacted	Redacted	Descriptor for documents that have been redacted. "Yes" for redacted documents; "No" for unredacted documents.	All
39	ProdVol	ProdVol	Name of media that data was produced on. Wave 00 I - Hard Drive	All
40	Confidentiality	Confidentiality	Indicates if the document has been designated as "Confidential" pursuant to any applicable Protective Order. "Yes" for Confidential documents; **"No"** for documents that are not so designated.	All
41	Email folder	Email folder	Folder in which non-archive collected email is stored within the custodians mailbox, such as "inbox", "sent", "deleted", "draft", or any custom folder.	Email

	Field	Summation Field (Florida)	Definition	Doc Type
42	Relevance score	Relevance score	Relevance score assigned by Equivio for documents that have been through the predictive coding process	All

a. This list of fields does not create any obligation to create or manually code fields that are not automatically generated by the processing of the ESI; that do not exist as part of the original Metadata of the document; or that would be burdensome or costly to obtain.

2. Defendants will produce spreadsheets (.xls/.xlsx files) and PowerPoint presentations (.ppt/.pptx files) in native form as well as audio and video files (e.g., mp3s, wavs, mpegs, etc.), except that spreadsheets and PowerPoint documents will be produced in TIFF format if redactions are applied. Audio and video files shall be edited if redactions are required, subject to appropriate identification of any such audio or video files having been edited. In addition, for any redacted documents that are produced, the documents' metadata fields will be redacted where required. The Parties will meet and confer regarding a request for the production of any other materials including documents in native file format.

3. The Parties agree to meet and confer regarding the format of production for structured databases.

4. Appearance. Subject to appropriate redaction, each document's electronic image will convey the same information and image as the original document, including formatting, such as bolding, highlighting, font size, italics. Documents will be produced in black and

white. After production, a Party may request that a document be produced in color at which time the Parties may meet and confer about such production. Documents that present imaging or formatting problems will be identified and the Parties will meet and confer in an attempt to resolve the problems.

5. Document Numbering. Each page of a produced document will have a legible, unique page identifier "Bates Number" electronically "burned" onto the image at a location that does not obliterate, conceal or interfere with any information from the source document. The Bates Number for each page of each document will be created so as to identify the producing Party and the document number. In the case of materials redacted in accordance with applicable law or confidential materials contemplated in any Protective Order or Confidentiality Stipulation entered into by the Parties, a designation may be "burned" onto the document's image at a location that does not obliterate or obscure any information from the source document.

6. De-NISTing and Deduplication. Electronic file collections will be De-NISTed, removing commercially available operating system and application file contained on the current NIST file list. Defendants will globally deduplicate identical ESI as follows:

a. Electronic Files: Duplicated electronic files will be identified based upon calculated MD5 Hash values for binary file content. File contents only will be used for MD5 Hash value calculation and will not include operating system metadata (filename, file dates) values. All files bearing an identical MD5 hash value are a duplicate group. The document reviewed by Defendants for privilege, relevance, or confidentiality shall be deemed the primary duplicate document within the group. Generally, the Defendants shall not remove any of the objective coding fields listed in paragraph G.1 above, in either primary or duplicate documents. If redactions are applied to the subject and/or text fields, however, Defendants may apply the

same redactions to all other documents within the duplicate group. Defendants shall only produce one document image or native file for duplicate ESI documents within the group. For Takeda sources, the following metadata fields as described in Section G.1 associated with the produced document will provide information for duplicate documents not produced: CustodianAppendMulti and RelativePathAppend.

b. Messaging Files: Duplicate messaging files will be identified based upon MD5 Hash values for the message family, including parent object and attachments. The following fields will be used to create the unique value for each message: To; From; CC; BCC; Date Sent; Subject; Body; and, MD5 Hash values for all attachments, in attachment order. Duplicate messaging materials will be identified at a family level, including message and attachment(s). All files bearing an identical MD5 Hash value are a duplicate group. The documents reviewed by Defendants for privilege, relevance, or confidentiality shall be deemed the primary duplicate document within the group. For identified duplicate ESI, the Defendants shall not remove any of the objective coding fields listed in paragraph G.1 above. If redactions have been applied to such fields, Defendants may substitute and replace the subject and text fields with those reviewed by Defendants' counsel for the primary duplicate ESI document for the other documents within the duplicate group. Defendants shall only produce one document image or native file for duplicate ESI documents within the group. For Takeda sources, the following metadata field as described in Section G.1 associated with the produced document will provide information for duplicate documents not produced: CustodianAppendMulti.

c. E-mail Threading: The producing Party may identify e-mail threads where all previous emails which make up the thread are present in the body of the final e-mail in the thread. Any party electing to use this procedure must notify all receiving parties that e-mail

thread suppression has been proposed to be performed on a specified production and the Parties agree to meet and confer regarding the format of this production, and reserve the right to seek Court guidance on the issue should agreement not be reached.

7. Production Media. The producing Party may produce documents via a secure file transfer mechanism and/or on readily accessible, computer or electronic media as the Parties may hereafter agree upon, including CD-ROM, DVD, external hard drive (with standard PC compatible interface), (the "Production Media"). Each piece of Production Media will be assigned a production number or other unique identifying label corresponding to the date of the production of documents on the Production Media (e.g., "Defendant Takeda Production April 1, 2012") as well as the sequence of the material in that production (e.g. "-001", "-002"). For example, if the production comprises document images on three DVDs, the producing Party may label each DVD in the following manner "Defendant Takeda Production April 1, 2012", "Defendant MSL Production April 1, 2012-002", "Defendant Takeda Production April 1, 2012-003." Additional information that will be identified on the physical Production Media includes: (1) text referencing that it was produced in *In re: Actos (Pioglitazone) Products Liability Litigation;* and (2) the Bates Number range of the materials contained on the Production Media. Further, any replacement Production Media will cross-reference the original Production Media and clearly identify that it is a replacement and cross-reference the Bates Number range that is being replaced.

8. Write Protection and Preservation. All computer media that is capable of write protection should be write-protected before production.

9. Inadvertent Disclosures. The terms of the Case Management Order: Assertions of Attorney-Client Privilege and Work Product Doctrine shall apply to this protocol.

10. Duplicate Production Not Required. The Parties shall meet and confer regarding any Party's request to produce identical paper copies of data already produced in electronic form.

H. Timing.

1. The Parties will use their reasonable efforts to produce ESI in a timely manner consistent with the Court's discovery schedule.

2. The Parties will produce ESI on a rolling basis.

I. General Provisions.

1. Any practice or procedure set forth herein may be varied by agreement of the Parties, and first will be confirmed in writing, where such variance is deemed appropriate to facilitate the timely and economical exchange of electronic data.

2. Should any Party subsequently determine it cannot in good faith proceed as required by this protocol; the Parties will meet and confer to resolve any dispute before seeking Court intervention.

3. The Parties agree that e-discovery will be conducted in phases and the Parties will meet and confer regarding discovery of data sources not listed herein.

4. Regardless of the foregoing, the Parties are under a continuing obligation to produce identified responsive, non-privileged documents and to identify sources of potentially discoverable materials consistent with their obligations under Federal Rules of Civil Procedure.

J. Items Requiring Meet and Confer.

1. The Parties agree to meet and confer regarding the following items in advance of impacted productions:

a. Whether the E-mail Property metadata field is able to be produced

b. Certain technical specifications for productions:

(1) Hard copy document unitization

(2) Microsoft "Auto" features or macros

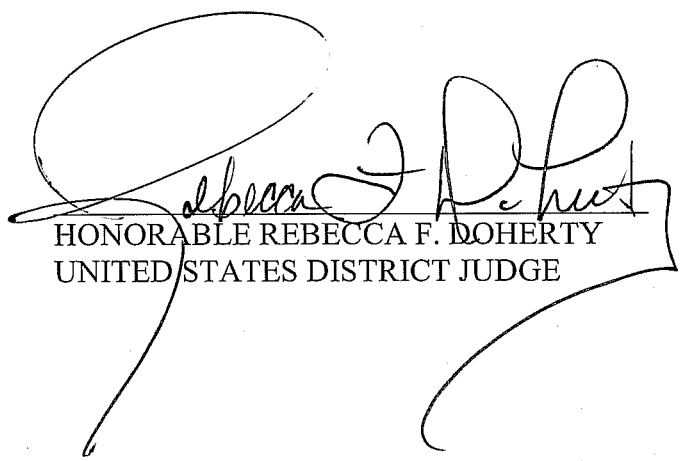
(3) Embedded objects

(4) Compressed Files

(5) Load file organization

IT IS SO ORDERED.

THUS DONE AND SIGNED in Lafayette, Louisiana, this 27 day of July, 2012.



HONORABLE REBECCA F. DOHERTY
UNITED STATES DISTRICT JUDGE