

Confidential - Darryl Draper

<p style="text-align: right;">Page 118</p> <p>1 question about the business 2 process of communicating adverse 3 events to safety? 4 BY MR. SMITH: 5 Q. It's about whether there's a 6 system in place to transmit information 7 concerning an adverse event from a CRF 8 form to somebody in safety? 9 A. Yes. 10 Q. Okay. Can you describe how 11 that would be done? 12 A. The system is COOL. 13 Q. If the CRF form is put into 14 AMOS, if the information from the CRF 15 form is put into AMOS, I thought it was 16 not put into COOL; is that inaccurate? 17 I thought it was an 18 either/or situation? 19 A. It is an either/or. 20 Q. So safety's access to 21 adverse event information in the CRF 22 forms is only through COOL, or is it 23 through other systems such as AMOS or 24 CRF/DEN?</p>	<p style="text-align: right;">Page 120</p> <p>1 adverse -- or a known event 2 occurs, that that be communicated 3 to drug safety. 4 BY MR. SMITH: 5 Q. So is there a process by 6 which information regarding an adverse 7 event reported on a CRF form is 8 transferred to an adverse event report 9 form? 10 MR. TORREGROSSA: Again, I 11 object to the extent it calls for 12 a business process, but you can 13 answer it on a technological 14 basis. 15 THE WITNESS: COOL -- you're 16 referring to the paper case report 17 form; is that correct? 18 BY MR. SMITH: 19 Q. I'm referring to the 20 information on the paper CRF or the 21 information gathered electronically 22 through COOL. Either way it could come 23 into the system, as I understand it, two 24 ways, either by paper or electronically.</p>
<p style="text-align: right;">Page 119</p> <p>1 MR. TORREGROSSA: I object 2 on scope to the extent it calls 3 for business process, but he can 4 answer from a technological 5 standpoint. 6 THE WITNESS: COOL -- that 7 was a very long question. 8 Can I ask the court reporter 9 to just read the question, please? 10 - - - 11 (The court reporter read the 12 pertinent part of the record.) 13 - - - 14 MR. TORREGROSSA: And I 15 objected to the extent it calls 16 for business process, but you can 17 answer it on a technological 18 basis. 19 THE WITNESS: Yeah. Drug 20 safety don't seek -- they don't go 21 around and ask people to collect 22 information on adverse event 23 reports. The company has a policy 24 whereby when it's a known</p>	<p style="text-align: right;">Page 121</p> <p>1 So maybe we'd better break them up and 2 take them one at a time. Let me do this. 3 Does drug safety have access 4 to the CRF/DEN system? In other words, 5 are they authorized users of the CRF/DEN 6 system? 7 A. They are -- generally 8 speaking, the users of CRF/DEN are not 9 folks in drug safety. However, they may 10 inquire on the -- inquire or review an 11 image of a case report form, as that may 12 be the source for an adverse event. 13 Q. Suppose somebody in drug 14 safety gets an adverse event report and 15 they want to look at the original data, 16 either on the image of the form or in 17 COOL. 18 Do they have access to those 19 systems to go and look at that online? 20 A. Again, you're asking a 21 question more aligned with, you know, 22 business process. And I -- 23 MR. TORREGROSSA: Objection, 24 scope.</p>

1 THE WITNESS: Again, I'm
2 struggling to -- to really know
3 what the business process is. I
4 know about the architecture and
5 the technology for these
6 databases. And that's what I'm
7 most capable and skilled to talk
8 about.
9 BY MR. SMITH:
10 Q. Isn't access to a system
11 part of the architecture and technology,
12 who has access to it, who can use it?
13 A. No, not necessarily.
14 Q. Wouldn't you know for most
15 of the systems that you are responsible
16 for who the authorized users are?
17 A. Right, yes.
18 Q. Would authorized users for
19 the CRF/DEN system include people in drug
20 safety?
21 A. I don't believe so, no.
22 Q. Would people in drug safety
23 be authorized users of the AMOS system?
24 A. No.

1 Q. Would they be authorized
2 users of the COOL system?
3 A. No.
4 Q. Now, those we're kind of
5 talking about looking back from drug
6 safety to CRF. Okay?
7 Now let's talk in a -- take
8 a different aspect of that and talk about
9 whether there's something in the system
10 that you know about that allows the
11 information, from either a paper or an
12 electronically gathered clinical report
13 form, or CRF, to be transferred by
14 somebody in CRF -- and you can correct me
15 on the -- you can tell me what the name
16 of that team is, it's probably not CRF,
17 but, you know, the people who are
18 collecting that information, when they
19 see an adverse event, is there an
20 electronic method or system in which they
21 take that information and transfer it to
22 an adverse event report form?
23 And it's a horribly long
24 question, but let me explain it and then

1 we'll break it up probably.
2 But let me ask another
3 question. Let's just stop here and ask
4 you another question.
5 Would it be possible
6 electronically to take the information
7 from the data or information from the CRF
8 form and transfer it to an adverse event
9 report form?
10 MR. TORREGROSSA: Let me
11 interpose a scope objection there.
12 I think we're really starting to
13 get into business process and drug
14 safety questions. But I will
15 allow him to answer to the extent
16 of his knowledge about the systems
17 and whether that's a possibility.
18 MR. SMITH: The pending
19 question is whether it's
20 technically possible,
21 technologically possible to take
22 the information from one form and
23 transfer it to the other form.
24 MR. TORREGROSSA: Same

1 objection.
2 You can answer.
3 THE WITNESS: It's
4 technologically possible, yes.
5 BY MR. SMITH:
6 Q. Do they do that?
7 MR. TORREGROSSA: Same
8 objection, same instruction.
9 BY MR. SMITH:
10 Q. To your knowledge?
11 A. They being?
12 Q. The people who collect the
13 CRF forms, and transfer it to --
14 A. I guess -- well, the people
15 don't do it. The systems would do -- is
16 the technology. And the technology --
17 but you keep going back to people.
18 Q. Okay.
19 A. So I'm struggling to answer
20 your question.
21 Q. Let's put it in that
22 framework, because we're talking about
23 technology here.
24 Does the system take the

1 information gathered from the CRFs and
 2 transfer it to an adverse report form?
 3 A. Which system?
 4 Q. Any system that you're
 5 familiar with.
 6 A. Yes.
 7 Q. Which system?
 8 A. COOL.
 9 Q. And that information then is
 10 transmitted to somebody in drug safety.
 11 Right?
 12 A. It's not transmitted to
 13 someone in drug safety, no.
 14 Q. Where does the
 15 information on the -- where does the
 16 adverse report form go?
 17 MR. TORREGROSSA: Objection
 18 to form.
 19 THE WITNESS: It's sent to
 20 the drug safety system.
 21 BY MR. SMITH:
 22 Q. Okay. People is the problem
 23 we're running into here. Right? We want
 24 to talk about systems, is that what

1 the processes around the transfer
 2 of information from CRFs to drug
 3 safety, and I mean, and how that's
 4 developed, that's all protocol
 5 that's developed by the study
 6 teams, as well the people perhaps
 7 in drug safety. So I think you're
 8 really crossing the line into
 9 business process on drug safety.
 10 MR. SMITH: Let's just
 11 restrict the objections to
 12 objection to form here.
 13 MR. TORREGROSSA: No.
 14 Because I'm allowed to, because I
 15 can't allow my witness -- this is
 16 not a drug safety deposition.
 17 This is an IT deposition. And
 18 we're getting into drug safety way
 19 more than we should be.
 20 BY MR. SMITH:
 21 Q. Mr. Draper, you're here
 22 today to talk about the IS systems as
 23 they relate to drug safety. Correct?
 24 A. Yes.

1 you're saying?
 2 A. Yes.
 3 Q. So you don't know who's
 4 using the system over there, but to your
 5 knowledge, to the best of your knowledge,
 6 the information from the CRF form gets
 7 transferred through COOL to the drug
 8 safety system; is that accurate?
 9 A. Certain studies can be
 10 configured to transmit adverse event
 11 information from an electronic case
 12 report form into the safety system.
 13 Q. And the name of the safety
 14 system?
 15 A. CLINTRACE.
 16 Q. CLINTRACE.
 17 Are you personally aware of
 18 studies where that is done at AstraZeneca
 19 for Seroquel?
 20 MR. TORREGROSSA: Hold on.
 21 Objection there. Mr. Smith, I
 22 think we're really getting into
 23 business process here. How the
 24 study is developed and what are

1 Q. All right. And you said
 2 it's possible, and that it happens with
 3 some studies, that the data gets
 4 transferred from the CRFs to the drug
 5 safety system through COOL; is that
 6 correct?
 7 A. Yes.
 8 Q. Okay. And then my question
 9 to follow up on that was, you know,
 10 because your answer suggests that that's
 11 not done all the time, I'm asking you,
 12 are you aware of cases where that
 13 actually is done?
 14 MR. TORREGROSSA: I object
 15 to what you suggested his answer
 16 was, but go ahead.
 17 THE WITNESS: I mean, I wish
 18 I could answer that question, but
 19 those are decisions that are made
 20 by the business. And what I'm
 21 trying to explain to you is that
 22 the technology allows the business
 23 to make those decisions, and the
 24 system perform those functions.

1 If they choose to do it
2 electronically, the system will do
3 it. If they don't, then the
4 system won't.

5 BY MR. SMITH:

6 Q. I think I understand what
7 you're saying.

8 The technology exists. It's
9 in place. Whether they use it or not is
10 not your decision. Right?

11 A. Correct.

12 MR. SMITH: Why don't we
13 take a break for lunch.

14 - - -

15 (A luncheon recess
16 occurred.)

17 - - -

18 MR. TORREGROSSA: If you
19 want to start there, we have some
20 names of people that we did not
21 have before, if you like.

22 BY MR. SMITH:

23 Q. Mr. Draper, you had some
24 names of people that we didn't have

1 on --

2 THE WITNESS: For CRF/DEN?

3 MR. TORREGROSSA: AMOS we
4 were on. I'm sorry, did you
5 intentionally go there or were you
6 meaning to follow down the line?

7 We gave AMOS --

8 MR. SMITH: We were actually
9 going through CRF/DEN. It's just
10 that it was related to AMOS and
11 COOL.

12 MR. TORREGROSSA: I
13 apologize, sir. Go ahead.

14 THE WITNESS: I answered the
15 question with regard to --

16 BY MR. SMITH:

17 Q. With regard to AMOS.

18 Mr. --

19 A. Brian Bryzniski.

20 Q. -- Bryzniski is with regard
21 to AMOS. Right?

22 A. Right.

23 Q. And who would be the
24 business owner for CRF/DEN?

1 before?

2 A. Yes. You had questions with
3 regard to certain systems, the system
4 owners, business analysts.

5 I, actually, have written
6 down -- the system owner for AMOS is
7 Brian Bryzniski.

8 Q. What's his position?

9 A. He's a system owner.

10 Q. I'm sorry, I can't hear you?

11 A. System owner. You asked --
12 the question was a system owner.

13 Q. Is that a business owner?

14 A. Yes.

15 Q. So he's on the business
16 side?

17 A. Correct.

18 Q. And that's for AMOS.
19 And did you spell his last
20 name?

21 A. B-R-Y-Z-N-I-S-K-I.

22 Q. And who's the business
23 analyst then for CRF/DEN?

24 MR. TORREGROSSA: We were

1 A. I gave that earlier.

2 That's --

3 Q. Who would be, with regard to
4 AMOS, let's go back to AMOS then.

5 Who would be the business
6 analyst?

7 A. Nate Blevins.

8 Q. And the database manager for
9 AMOS?

10 A. I gave that earlier.

11 Q. So those were the only two
12 names that you had there?

13 A. Yeah. The two names I was
14 unable to recall.

15 Q. So there's still some names
16 that you can't recall?

17 MR. TORREGROSSA: We have
18 some more information.

19 THE WITNESS: I have other
20 names. The other, I believe you
21 had asked who the system owner was
22 for COOL.

23 BY MR. SMITH:

24 Q. Okay.

1 A. That's Mohammad Kazemi.
 2 Q. Can you spell these names,
 3 please, for the court reporter?
 4 A. M-O-H-A-M-M-A-D, last name
 5 Kazemi, K-A-Z-E-M-I.
 6 Q. Who else did you have?
 7 A. The business analyst, Maria
 8 Bjorkqvist.
 9 Q. For COOL. Correct?
 10 A. COOL.
 11 Q. Can you spell her name,
 12 please?
 13 A. Maria, M-A-R-I-A,
 14 B-J-O-R-K-Q-V-I-S-T.
 15 You also asked about SPOLA.
 16 The system owner for SPOLA is Susan
 17 Gutschmuth. And do you want the spelling
 18 of the full name or the last name?
 19 Q. We can spell Susan.
 20 A. G-U-T-S-M-U-T-H.
 21 Q. Who else?
 22 A. The business analyst is
 23 Maria Bjorkqvist.
 24 Q. Who else?

1 That's A-N-N-A S-J-O-O.
 2 Q. The identities of these
 3 people for the COOL system, would those
 4 be contained in a writing or some sort of
 5 documentation for the system someplace?
 6 A. Yes.
 7 Q. And where would they be
 8 located?
 9 A. It would be -- those names
 10 would be located on materials such as
 11 change requests.
 12 So if we were to attempt
 13 to -- if business asked to change the
 14 system, those people in those roles would
 15 sign off. So they would be listed on
 16 that document.
 17 Q. Is the only way you could
 18 identify those people would be by going
 19 through change requests?
 20 A. No.
 21 Q. Is there a list somewhere of
 22 the people who hold these positions with
 23 regard to the COOL database?
 24 A. Certain individuals would

1 A. And you had asked about
 2 DIPLOMAT. The system owner at the time
 3 DIPLOMAT was in use was David Cartwright,
 4 C-A-R-T-W-R-I-G-H-T.
 5 Q. And just go ahead and give
 6 us all the people that you have on your
 7 list, if you would.
 8 A. I'm sorry, you want me to go
 9 through the list -- the names again?
 10 Q. Yes. These are people whose
 11 names you couldn't remember in response
 12 to questions that were asked this
 13 morning. Right?
 14 MR. TORREGROSSA: Right.
 15 And he wants to know, I think, if
 16 there's any more. That's all.
 17 THE WITNESS: There are no
 18 more.
 19 BY MR. SMITH:
 20 Q. Okay.
 21 A. I'm sorry. The application
 22 service manager, my peer who I would go
 23 to to get answers for specific things
 24 relating to COOL, would be Anna Sjoo.

1 probably be listed in a service level
 2 agreement.
 3 Q. Now, would that be true for
 4 the other databases with regard to which
 5 you're speaking today?
 6 MR. TORREGROSSA: Can we
 7 have Exhibit 1, please, so he can
 8 see the list of databases? Thank
 9 you.
 10 THE WITNESS: Yes, but there
 11 are exceptions. Just DIPLOMAT,
 12 which I mentioned earlier.
 13 BY MR. SMITH:
 14 Q. What is GERM?
 15 A. Can you spell it, please?
 16 Q. I'm giving it to you
 17 phonetically. It was one that your
 18 counsel said that you would be speaking
 19 on today.
 20 MR. TORREGROSSA: I'm sorry.
 21 DIRM.
 22 MR. SMITH: DIRM?
 23 MR. TORREGROSSA: Yes.
 24 MR. SMITH: Oh, we

1 misunderstood.
 2 MR. TORREGROSSA: I
 3 apologize.
 4 MR. SMITH: Thanks.
 5 D-I-R-M. Thank you.
 6 BY MR. SMITH:
 7 Q. What is DIRM?
 8 A. What is DIRM? DIRM is a
 9 document imaging database.
 10 Q. Is D-I-R-M how you spell the
 11 name of this database?
 12 A. Yes, D-I-R-M.
 13 Q. And what does that stand
 14 for?
 15 A. Document imaging repository
 16 management system.
 17 Q. Is there a system map for
 18 DIRM?
 19 A. A system map with -- such as
 20 I drew for AMOS?
 21 Q. Yes.
 22 A. I'm uncertain whether or not
 23 there is a system map for DIRM. I
 24 would -- that would -- I would probably

1 scanner.
 2 Q. What kind of documents?
 3 A. Contracts. I believe study
 4 master files, images of study master
 5 files.
 6 Q. What kinds of contracts?
 7 A. Contracts with clinical
 8 research organizations, contracts with
 9 investigators.
 10 Q. Where are the study master
 11 files maintained?
 12 A. I believe the study master
 13 files are maintained in GEL.
 14 Q. Would study protocols be
 15 maintained in DIRM?
 16 A. I'm sorry, could you --
 17 Q. Would study protocols be
 18 maintained in DIRM?
 19 A. Study protocols maintained
 20 in DIRM.
 21 I don't think the study
 22 protocols are maintained in DIRM.
 23 Q. Do you know where the study
 24 protocols are maintained?

1 go to Rita White. I'm sorry, not Rita,
 2 but Paula George, and seek her assistance
 3 in identifying whether or not there's a
 4 system map.
 5 Q. Is there a data map for
 6 DIRM?
 7 A. Yes.
 8 Q. Could you print that out?
 9 A. Yeah, I believe it could be
 10 printed. I'd have to -- again, it
 11 probably would take some work to obtain
 12 where that data map is and...
 13 Q. Who's the database manager?
 14 A. Sam Fitzpatrick.
 15 Q. The business analyst?
 16 A. Paula George.
 17 Q. The business owner?
 18 A. Susan Lamhorn.
 19 Q. Do you have -- excuse me.
 20 Can you tell me what the
 21 data sources are for DIRM?
 22 A. They're paper documents.
 23 Q. How do they get into DIRM?
 24 A. They would be scanned on a

1 MR. TORREGROSSA: Objection,
 2 scope.
 3 You can answer if you have
 4 any individual knowledge.
 5 THE WITNESS: I believe that
 6 they are maintained in -- I'm not
 7 certain.
 8 BY MR. SMITH:
 9 Q. What systems interface with
 10 DIRM?
 11 A. I don't believe DIRM has
 12 system interfaces with other systems.
 13 Q. Are there any data feeds --
 14 are there no data feeds into or out of
 15 DIRM?
 16 A. Can you describe what you
 17 mean by data feed?
 18 Q. Well, can you put data into
 19 the system via a link with another
 20 system?
 21 A. No.
 22 Q. Can you output data from
 23 DIRM to any other system?
 24 MR. TORREGROSSA: Objection

1 to form.
 2 THE WITNESS: I believe I
 3 just answered that question.
 4 BY MR. SMITH:
 5 Q. I think that was in relation
 6 to an automatic feed.
 7 A. Can I ask how the second
 8 question differs from the first?
 9 Q. Is there any way to send
 10 data from DIRM to another system?
 11 A. Could you --
 12 MR. TORREGROSSA: Wait. We
 13 may have another question.
 14 MR. SMITH: No, I'd like to
 15 him to answer this question.
 16 MR. TORREGROSSA: Go ahead.
 17 THE WITNESS: Can I answer
 18 the question again, please?
 19 - - -
 20 (The court reporter read the
 21 pertinent part of the record.)
 22 - - -
 23 BY MR. SMITH:
 24 Q. Actually, is there any way

1 DIRM?
 2 A. Yes.
 3 Q. How would you do that?
 4 A. You would identify the
 5 object image that you desire to export,
 6 and you would choose the export function.
 7 Q. Is the metadata stored in
 8 relation to the .tifs in the system?
 9 A. Yes.
 10 Q. Is the metadata searchable?
 11 A. Yes.
 12 Q. Is that data used by anyone
 13 in AstraZeneca outside of the DIRM
 14 system?
 15 A. Could I hear the question
 16 again, please?
 17 - - -
 18 (The court reporter read the
 19 pertinent part of the record.)
 20 - - -
 21 THE WITNESS: I think you're
 22 asking me a question with regard
 23 to business-related processes.
 24 If I heard you correctly,

1 to send data from DIRM to another system?
 2 MR. TORREGROSSA: Objection,
 3 form.
 4 THE WITNESS: I get the
 5 sense of what you're asking me is
 6 a business-related question. I
 7 mean, I thought I answered the
 8 question earlier by simply stating
 9 that there is no interface,
 10 there's no -- again, I thought I
 11 answered that question earlier.
 12 I'm struggling to understand the
 13 difference between the questions.
 14 BY MR. SMITH:
 15 Q. Is it a standalone
 16 repository?
 17 A. Yes.
 18 Q. There's no access or
 19 connection with any other system?
 20 MR. TORREGROSSA: Objection
 21 to the form, compound.
 22 THE WITNESS: No.
 23 BY MR. SMITH:
 24 Q. Can you export data from

1 you're asking me does the business
 2 use metadata somewhere else. I
 3 can't answer that question.
 4 BY MR. SMITH:
 5 Q. Can you print a list of the
 6 users who have access to DIRM?
 7 A. Can I print a list of the
 8 users? We don't generally print lists of
 9 users.
 10 Q. Can you do so?
 11 A. I suppose I could create a
 12 list.
 13 Q. What are the document types
 14 in DIRM?
 15 A. Contracts, I'm sorry,
 16 what --
 17 Q. Okay. You answered that one
 18 earlier.
 19 How would people be
 20 permitted to input data into the free
 21 form text fields?
 22 A. I'm not certain there are
 23 free form text fields to enter data into.
 24 Q. Can people make changes to

1 the data in any field in DIRM?
 2 A. Yes.
 3 Q. Which team or teams are able
 4 to do that, have permission to do that?
 5 A. Fowkes in -- is what you're
 6 asking me, who has access to the system?
 7 Q. Yes, another way of putting
 8 it.
 9 A. The Fowkes that have access
 10 are in the study delivery.
 11 Q. And those people who have
 12 access, can they make changes to the
 13 data?
 14 A. There are certain
 15 individuals who can change the indexing
 16 attributes for those images.
 17 Q. How are the images indexed?
 18 A. Author, title, investigator.
 19 Q. Who's the vendor for DIRM?
 20 A. AstraZeneca.
 21 Q. And when was it put into
 22 use?
 23 A. In 1997.
 24 Q. Is it still in use?

1 we met before back in January, I believe
 2 you said that there was a field for
 3 country in CRF/DEN.
 4 Does that refresh your
 5 recollection?
 6 MR. TORREGROSSA: Objection
 7 to form.
 8 THE WITNESS: I don't recall
 9 what I stated back in January.
 10 I'm trying to explain to you what
 11 I understand and recall about
 12 CRF/DEN and DIRM.
 13 BY MR. SMITH:
 14 Q. Can you print out a list of
 15 the fields in CRF/DEN?
 16 A. Print out a list of fields
 17 in CRF/DEN.
 18 It's technically possible, I
 19 believe, to possibly do a screen shot.
 20 Would that --
 21 Q. Could you export the
 22 metadata to an Excel spreadsheet?
 23 MR. TORREGROSSA: Do you
 24 need the question again?

1 A. Yes.
 2 Q. What system was used for
 3 this purpose prior to 1997?
 4 A. I believe it was a system
 5 called SAS.
 6 Q. One of the fields -- strike
 7 that.
 8 Is there a field in DIRM for
 9 country?
 10 A. I don't believe there's a
 11 field in there for country, no.
 12 Q. How about in CRF/DEN, is
 13 there a field in CRF/DEN for country?
 14 MR. CAMP BAILEY: What was
 15 that last question?
 16 - - -
 17 (The court reporter read the
 18 pertinent part of the record.)
 19 - - -
 20 THE WITNESS: I cannot
 21 visualize a country field in
 22 CRF/DEN.
 23 BY MR. SMITH:
 24 Q. To be honest with you, when

1 THE WITNESS: Yes. Could I
 2 have the question again, please?
 3 - - -
 4 (The court reporter read the
 5 pertinent part of the record.)
 6 - - -
 7 THE WITNESS: We currently
 8 don't have a method for exporting
 9 to Excel spreadsheets.
 10 BY MR. SMITH:
 11 Q. Can you export the data in
 12 any format?
 13 A. The metadata?
 14 Q. Yes.
 15 A. I believe it could be
 16 exported into some form, although it -- I
 17 cannot think -- well, the answer still
 18 stands I guess yes, that it could be
 19 exported in some form.
 20 I'm not going to say that
 21 all the metadata, but certain elements
 22 that are relevant to that image as it
 23 would relate to a -- going into a
 24 submission.

1 Q. Is DIRM built on Oracle?
 2 A. Yes.
 3 Q. Does it use FileNet?
 4 A. Yes.
 5 Q. Does it contain data from
 6 any non-US sources?
 7 MR. TORREGROSSA: Can I get
 8 that question again?
 9 - - -
 10 (The court reporter read the
 11 pertinent part of the record.)
 12 - - -
 13 MR. TORREGROSSA: You can
 14 answer that limited question.
 15 THE WITNESS: I'm sorry?
 16 MR. TORREGROSSA: You can
 17 answer that limited question. You
 18 can answer whether it has data
 19 from non-US sources.
 20 THE WITNESS: No.
 21 BY MR. SMITH:
 22 Q. Can you provide a list of
 23 document types that are in DIRM?
 24 MR. TORREGROSSA: Objection,

1 storing the type of images that are in
 2 DIRM for those that were acquired prior
 3 to the start of DIRM?
 4 A. If you're referring to the
 5 paper, which was the form that they would
 6 have been in, there is a storage facility
 7 for paper documents.
 8 Q. Do you have an electronic
 9 storage system?
 10 A. I'm not sure I understand
 11 the question.
 12 Q. For the types of files that
 13 are imaged in DIRM that were acquired
 14 prior to DIRM, where and how are they
 15 stored?
 16 A. There was no -- paper
 17 documents were sent to archive. And they
 18 are indexed so that they can be retrieved
 19 at a later time.
 20 Q. Okay. So if I understand
 21 you correctly, prior to DIRM, the
 22 documents were in paper form only?
 23 A. Yes.
 24 Q. And they're archived in

1 form.
 2 You can answer.
 3 THE WITNESS: Yes.
 4 BY MR. SMITH:
 5 Q. Was data prior to the
 6 initiation of DIRM migrated into DIRM?
 7 A. Can I hear the question
 8 again, please?
 9 - - -
 10 (The court reporter read the
 11 pertinent part of the record.)
 12 - - -
 13 THE WITNESS: No.
 14 BY MR. SMITH:
 15 Q. Was data prior to DIRM
 16 stored someplace?
 17 A. I'm sorry, can I -- I'm
 18 struggling to understand -- I'm
 19 struggling to understand whether or not
 20 you're asking me technical questions or
 21 business process questions.
 22 Can I have the question
 23 asked again?
 24 Q. Do you have a system for

1 paper form, and no place are they
 2 archived in electronic format?
 3 A. Can I just back up a little
 4 bit?
 5 What -- DIRM is an imaging
 6 system. There's always a paper document
 7 for the image. I'm not aware of any
 8 electronic images being stored in DIRM.
 9 Q. DIRM contains electronic
 10 images of documents. Right?
 11 A. Yes.
 12 Q. And for documents prior to
 13 DIRM, they weren't migrated into DIRM.
 14 Right?
 15 A. I think I answered this
 16 question before. You asked if there was
 17 a system.
 18 Can I go back to the
 19 question that was asked before about the
 20 legacy system or prior system?
 21 Q. Let's do it this way.
 22 DIRM was started in 1997.
 23 Right?
 24 A. Correct.

1 Q. Prior to 1997, those
2 documents only existed in paper form, not
3 in electronic format. Right?
4 A. Yes.
5 Q. And they are stored today
6 not in electronic format but as paper
7 documents only. Correct?
8 A. Yes.
9 Q. But there is an electronic
10 system, an index, for those documents.
11 Correct?
12 A. Yes.
13 Q. Where is that electronic
14 index and in what form and who has it or
15 what system has it?
16 MR. TORREGROSSA: Objection
17 to the four questions.
18 THE WITNESS: That's four
19 questions.
20 BY MR. SMITH:
21 Q. We'll do one at a time.
22 A. Okay.
23 Q. Where is the electronic form
24 of the index maintained?

1 A. It's in a system called
2 TRIM.
3 Q. What is TRIM? That has
4 never been identified before. What is
5 TRIM?
6 A. It's an index of paper
7 documents in an archive.
8 Q. Who maintains that TRIM
9 system?
10 A. I believe it's records
11 management.
12 Q. Who's the business owner?
13 MR. TORREGROSSA: Objection
14 to form.
15 THE WITNESS: I don't know.
16 BY MR. SMITH:
17 Q. Who's the --
18 MR. TORREGROSSA: I'm sorry,
19 go ahead.
20 BY MR. SMITH:
21 Q. Who is the database
22 administrator?
23 MR. TORREGROSSA: Objection
24 to form. It doesn't make sense.

1 But go ahead.
2 THE WITNESS: I don't know.
3 BY MR. SMITH:
4 Q. Is TRIM a database?
5 A. I'm sorry?
6 Q. Let's break this down.
7 Is TRIM a database? We'll
8 be here all day if it takes it.
9 Is TRIM a database?
10 A. Yes.
11 Q. All right. There's some
12 sort of operating software that is used
13 to maintain this database?
14 A. Yes.
15 Q. What type of software is it?
16 A. This system is beyond my
17 technical expertise. I don't have all
18 the technical knowledge with regard to
19 TRIM.
20 MR. TORREGROSSA: This is a
21 record management system. It's
22 not particular to any one issue.
23 It's sort of outside the scope of
24 this deposition, because it's a

1 record management issue. I'm just
2 letting you know that, but go
3 ahead.
4 BY MR. SMITH:
5 Q. Your job, one of your
6 functions is to manage records
7 electronically, is it not?
8 A. No.
9 Q. No, that's not your job at
10 all?
11 A. No.
12 Q. You don't do any document
13 management electronically?
14 A. No.
15 Q. You mean -- well, CRF/DEN,
16 isn't that an electronic document
17 management system?
18 A. It's an imaging system.
19 Q. Isn't it a management
20 system?
21 A. It's -- they're images in
22 the system.
23 Q. What is the purpose of a
24 document imaging system?

1 A. To image physical documents.
 2 Q. Why would anybody want to
 3 image physical documents?
 4 A. I think you're asking me a
 5 question that is a -- related to a
 6 business process.
 7 Q. Business owners come to your
 8 department, and they work with you on
 9 requirements for their business in the IS
 10 realm. Correct?
 11 A. That's correct.
 12 Q. Your job is to provide IS
 13 support to the certain business
 14 departments at AstraZeneca. Correct?
 15 A. Yes.
 16 Q. Business departments
 17 relating to drug safety. Correct?
 18 A. Yes.
 19 Q. Business departments
 20 relating to clinical studies. Correct?
 21 A. Yes.
 22 Q. What other departments? Any
 23 other departments?
 24 A. The ones that I mentioned

1 imaging systems. TRIM is
 2 completely different. That's my
 3 only point.
 4 And it is outside the scope
 5 of this. If you want to issue a
 6 record management 30(b)6 under our
 7 agreement, you're welcome to do
 8 that and we're welcome to object
 9 to it. My only point to you is,
 10 sir, is you can ask this question
 11 as much as you want about TRIM and
 12 what he knows about it, but it's
 13 not the purpose of this 30(b)6.
 14 It's outside the scope. That's
 15 all I'm telling you.
 16 I'm sorry, I apologize. If
 17 you would like to follow up on
 18 TRIM, I will follow up for you and
 19 we will consider your request.
 20 That's my only point, Mr. Smith.
 21 BY MR. SMITH:
 22 Q. If you have documents in
 23 an -- if you have images of documents in
 24 a system, you're going to have tools to

1 earlier.
 2 Q. If you have a document
 3 imaging system, would you ever, as an IS
 4 person, have a document imaging system
 5 that didn't have some sort of index?
 6 A. No.
 7 Q. Have you ever heard of such
 8 a system?
 9 A. No.
 10 Q. I think we're playing word
 11 games here, to be honest with you.
 12 MR. TORREGROSSA: Mr. Smith,
 13 that's just inappropriate. All
 14 I'm saying to you is you guys
 15 issued a notice that was about
 16 record management, okay, of
 17 physical paper documents. That's
 18 not here what we're talking about
 19 today.
 20 So my only point to you is
 21 that he's prepared to talk about
 22 the databases that manage some of
 23 these systems, and some of them,
 24 you're correct, are document

1 manage those documents. Correct?
 2 A. I'm not sure if you're
 3 asking me from a technical perspective.
 4 Q. Sir, what does document
 5 management mean to you as an IS person?
 6 A. Management of documents.
 7 Q. What do you mean,
 8 management?
 9 A. That could mean --
 10 Q. Not could mean. I'd like
 11 you to tell me what it does mean to you.
 12 A. Managing documents to me
 13 means the ability to author a document
 14 and then manage it through its life
 15 cycle, i.e., I create it, I send it out
 16 for review, I approve it, I retire it.
 17 That's what a document management system
 18 is.
 19 Q. You don't think you were
 20 managing documents that were created by
 21 somebody else?
 22 MR. TORREGROSSA: Objection
 23 to form.
 24 THE WITNESS: I don't

1 understand the question.
 2 BY MR. SMITH:
 3 Q. In your view, document
 4 management means you're only dealing with
 5 documents that are authored by the people
 6 you're working for. Correct?
 7 MR. TORREGROSSA: Objection
 8 to form.
 9 THE WITNESS: Can I hear the
 10 question again, please?
 11 - - -
 12 (The court reporter read the
 13 pertinent part of the record.)
 14 - - -
 15 THE WITNESS: Not
 16 necessarily. They could be
 17 documents that are created by
 18 someone else.
 19 BY MR. SMITH:
 20 Q. Okay. Well, I was confused
 21 by your definition of document management
 22 when you said that it only dealt with
 23 documents that were authored by you and
 24 tracked through their life cycle.

1 A. I thought you asked my
 2 personal description.
 3 Q. Well, is your personal
 4 description different from people in the
 5 industry, the definition the people in
 6 the IS industry would use for document
 7 management?
 8 A. I don't know that answer.
 9 Q. Can we agree that
 10 information management means storing a
 11 document and having it organized in some
 12 fashion so that it's accessible
 13 electronically?
 14 A. Information management?
 15 Q. Yes. Electronic information
 16 management.
 17 A. No.
 18 Q. What is your definition of
 19 electronic information management?
 20 A. It's the management of data,
 21 electronic data.
 22 Q. Can data be an image?
 23 A. Data can be an image.
 24 Q. And when you manage it, you

1 organize it in some fashion. Correct?
 2 A. When you -- I'm sorry, the
 3 question was, when you manage it --
 4 Q. When you manage data, you
 5 organize it in some fashion. Correct?
 6 A. You can organize it, yes.
 7 Q. If it's not organized, what
 8 use is it to you?
 9 A. It becomes simply a
 10 repository, an archive.
 11 Q. Is TRIM an archive?
 12 MR. TORREGROSSA: Again,
 13 objection, scope.
 14 You can answer on your
 15 individual knowledge.
 16 THE WITNESS: It's a system
 17 for managing physical paper
 18 documents.
 19 BY MR. SMITH:
 20 Q. Is it searchable?
 21 MR. TORREGROSSA: Same
 22 objection.
 23 THE WITNESS: Yes.
 24 BY MR. SMITH:

1 Q. Can you print out the data
 2 in the system?
 3 MR. TORREGROSSA: Same
 4 objection.
 5 THE WITNESS: I believe you
 6 can.
 7 BY MR. SMITH:
 8 Q. Can you provide a data map
 9 or schema for the system?
 10 MR. TORREGROSSA: Same
 11 objection, scope. Same objection,
 12 scope.
 13 You can answer based on your
 14 personal knowledge.
 15 THE WITNESS: I don't know.
 16 BY MR. SMITH:
 17 Q. You don't know?
 18 A. I don't know.
 19 Q. Who would know?
 20 MR. TORREGROSSA: Same
 21 objection.
 22 You can answer.
 23 THE WITNESS: Someone in
 24 records management.

1 BY MR. SMITH:
 2 Q. Do you know who the users of
 3 TRIM are?
 4 MR. TORREGROSSA: Same
 5 objection.
 6 You can answer.
 7 THE WITNESS: I don't know
 8 all the users.
 9 BY MR. SMITH:
 10 Q. Do you know any users?
 11 A. Yes.
 12 Q. Who?
 13 A. Study -- I'm sorry, clinical
 14 data management.
 15 Q. Do you know how they access
 16 it?
 17 MR. TORREGROSSA: Same
 18 objection.
 19 You can answer.
 20 THE WITNESS: They put a
 21 request in for an account.
 22 BY MR. SMITH:
 23 Q. Do you know what the fields
 24 are in the indexing system?

1 maintenance for the TRIM system?
 2 A. I don't know.
 3 Q. I may have asked you this
 4 before, but is there a database manager
 5 for TRIM?
 6 A. I don't know.
 7 Q. Do you know if there's a
 8 business analyst for TRIM?
 9 A. No.
 10 Q. Do you know what other
 11 systems TRIM interfaces with?
 12 A. No.
 13 Q. Do you know who the vendor
 14 is for TRIM?
 15 A. AstraZeneca.
 16 Q. Do you know when the system
 17 was implemented?
 18 A. No.
 19 Q. What type of system is it,
 20 can you describe it for me?
 21 A. It's a client server system,
 22 client server.
 23 Q. Is it Oracle based?
 24 A. I don't know.

1 MR. TORREGROSSA: Can I just
 2 get a running objection here?
 3 MR. SMITH: To any question
 4 about TRIM?
 5 MR. TORREGROSSA: Yes.
 6 MR. SMITH: Sure.
 7 MR. TORREGROSSA: Thank you,
 8 sir.
 9 THE WITNESS: Can I just get
 10 some clarity then?
 11 MR. TORREGROSSA: You can
 12 answer the question based on your
 13 personal knowledge.
 14 BY MR. SMITH:
 15 Q. Is the TRIM system used by
 16 the drug safety department or system in
 17 some fashion?
 18 A. Could be.
 19 Q. Do you know whether it is or
 20 is not?
 21 A. No.
 22 Q. Who would know?
 23 A. Somebody in drug safety.
 24 Q. Who in IS provides

1 Q. Could you print out a list
 2 of the images in the TRIM system?
 3 MR. TORREGROSSA: Objection
 4 to form, images.
 5 THE WITNESS: I'm sorry, the
 6 question again?
 7 BY MR. SMITH:
 8 Q. Could you print out an index
 9 of the images in the TRIM system?
 10 A. No.
 11 Q. The index is a form of data,
 12 isn't it?
 13 A. Yes.
 14 Q. And if there's data in a
 15 system, you can get to it. Right?
 16 MR. TORREGROSSA: Objection
 17 to form.
 18 THE WITNESS: I think I
 19 answered that question earlier.
 20 BY MR. SMITH:
 21 Q. I don't recall the answer.
 22 A. You asked if it was
 23 searchable.
 24 Q. So if it's searchable, can