

## Confidential - Darryl Draper

<p style="text-align: right;">Page 74</p> <p>1 Q. The people who are 2 conducting clinical trials, do they have 3 access to AMOS? 4 A. No. 5 I'm just -- can you just 6 clarify what you mean by conducting 7 clinical trials? 8 Q. Investigators. 9 A. The answer is no. 10 Q. How is the clinical data 11 from investigators managed in AMOS? 12 A. I'm not sure I understand 13 the question. 14 Q. How does the system work? 15 How does it manage the data? 16 A. It's a data collection tool. 17 I'm not certain I understand what you 18 mean by manage the data. 19 Q. Okay. Let's start with 20 that. 21 How is the data collected? 22 A. The patient data? 23 Q. Yes. 24 A. The patient data is</p>	<p style="text-align: right;">Page 76</p> <p>1 entered into AMOS, yes. 2 Q. Would you refer to that as 3 an ERD? 4 A. No. 5 Q. Are you familiar with the 6 acronym ERD? 7 A. Entity relationship diagram. 8 MR. TORREGROSSA: Mr. 9 Draper, I think you need to speak 10 up just a bit. 11 THE WITNESS: I'm sorry. 12 I'm a very low key person. 13 BY MR. SMITH: 14 Q. Would there be an ERD for 15 AMOS? 16 A. No, I don't believe there is 17 an ERD for AMOS. 18 Q. Would there be anything like 19 that, any sort of diagram that shows the 20 relationships? 21 A. I mean, generally speaking, 22 you would -- if you're designing a 23 system, you would build a diagram of 24 sort; but a database in itself, you know,</p>
<p style="text-align: right;">Page 75</p> <p>1 collected on a case report form. 2 Q. Is there any other data that 3 goes into AMOS? 4 A. Not that I'm aware of. 5 Q. So the only source for AMOS 6 is the CRFs; is that correct? 7 A. Correct. 8 Q. And who actually puts the 9 data into AMOS? 10 A. That would be AstraZeneca 11 personnel. 12 Q. Did you play any role in the 13 development of AMOS? 14 A. No. 15 Q. Would there be a schema for 16 AMOS? 17 A. Can you define schema? I 18 mean, what do you mean? 19 Q. Is that a term that you 20 would use in talking about how a database 21 operates? 22 A. If what you mean by schema 23 in terms of a relational database, there 24 is a schema to support the data that's</p>	<p style="text-align: right;">Page 77</p> <p>1 is the -- are the technical components 2 that would otherwise make up what you 3 would see in a visual diagram. 4 Q. You're not aware of any 5 visual diagram? 6 A. I'm not aware of any visual 7 diagram, no. 8 Q. Are you aware of a 9 description that would take the place of 10 a visual diagram? 11 A. Yes. 12 Q. So there's documentation for 13 the system that contains those 14 relationships? 15 A. Yeah, there's documentation. 16 Q. And you could provide a copy 17 of that documentation to us? 18 MR. TORREGROSSA: Objection 19 to the form. Objection to the 20 extent you suggest we will produce 21 it to you. 22 But you can answer if you 23 understand. You can answer the 24 question if you understand.</p>

20 (Pages 74 to 77)

1 THE WITNESS: I mean, if I  
 2 could put my hands on the  
 3 document, I could produce it.  
 4 BY MR. SMITH:  
 5 Q. Can you get your hands on  
 6 the document?  
 7 A. That would require, you  
 8 know, some investigation. I'm certain  
 9 that I could, yes.  
 10 Q. Do you think there would be  
 11 a diagram or flow chart that would show  
 12 the data sources and outputs or  
 13 interfaces with other systems for AMOS?  
 14 A. Could you simply -- I think  
 15 I understood the question. I'm just  
 16 asking if you could just simply  
 17 restate -- read.  
 18 Q. Read it back?  
 19 A. Read it back, please.  
 20 MR. SMITH: If you would,  
 21 please.  
 22 - - -  
 23 (The court reporter read the  
 24 pertinent part of the record.)

1 Thank you.  
 2 - - -  
 3 (Deposition Exhibit No.  
 4 Draper-3, Sketch of a System Map,  
 5 was marked for identification.)  
 6 - - -  
 7 (A recess occurred.)  
 8 - - -  
 9 BY MR. SMITH:  
 10 Q. Mr. Draper, would you do me  
 11 a favor and go through your diagram for  
 12 us audibly and then we can make copies at  
 13 lunchtime and look at it, but just in  
 14 case we have trouble reading your  
 15 writing.  
 16 A. All right.  
 17 Q. I appreciate it.  
 18 A. This is a system map of AMOS  
 19 and the kind of relationships.  
 20 What I have in the center is  
 21 a database server housing a database with  
 22 an AMOS and COOL schema, as you referred  
 23 to them.  
 24 Connected to that database

1 - - -  
 2 THE WITNESS: In my personal  
 3 opinion, I think there probably  
 4 could be a diagram.  
 5 BY MR. SMITH:  
 6 Q. If I handed you a blank  
 7 sheet of paper, could you draw a diagram  
 8 of the relationships?  
 9 A. Sure. Yes.  
 10 Q. Is there a term that you  
 11 would call for such a diagram? What  
 12 would you call such a diagram?  
 13 A. Maybe like a system map.  
 14 Q. All right. Could we mark  
 15 this as Exhibit Number 3 and ask Mr.  
 16 Draper to draw a system map for me for  
 17 AMOS.  
 18 MR. TORREGROSSA: Mr. Smith,  
 19 while he draws, can we take a  
 20 break, a quick break --  
 21 MR. SMITH: Sure,  
 22 absolutely.  
 23 MR. TORREGROSSA: -- while  
 24 he does that?

1 server, I have two, three boxes. And  
 2 those represent the SPOLA application  
 3 server, the AMOS application server and  
 4 an external nonAstraZeneca computer.  
 5 Let's see. Connected to  
 6 the -- the two application servers within  
 7 the AstraZeneca intranet is an  
 8 AstraZeneca client machine used to access  
 9 the systems.  
 10 Then outside of the  
 11 intranet, I also drew a box which is also  
 12 an AstraZeneca client representing the  
 13 device that a user, an AstraZeneca member  
 14 or person, personnel, would use to enter  
 15 data.  
 16 The COOL client, which is  
 17 outside of the AstraZeneca intranet, is  
 18 used -- typically used by a  
 19 nonAstraZeneca person, such as a CRO.  
 20 And I have it listed that way or  
 21 identified that way on this diagram.  
 22 Q. And a CRO is what?  
 23 A. Clinical research  
 24 organization.

1 Q. Can I see that for a second?  
 2 A. Sure.  
 3 Q. Is there a service level  
 4 agreement for AMOS?  
 5 A. Yes.  
 6 Q. And who would have that?  
 7 A. Application service manager.  
 8 Q. Has any of the data  
 9 maintained in the AMOS system been lost  
 10 or destroyed?  
 11 MR. TORREGROSSA: Objection  
 12 to form.  
 13 You can answer.  
 14 THE WITNESS: No.  
 15 BY MR. SMITH:  
 16 Q. Have there been any  
 17 incidents to your knowledge which would  
 18 affect the reliability of the data in the  
 19 system?  
 20 MR. TORREGROSSA: Same  
 21 objection.  
 22 THE WITNESS: No.  
 23 BY MR. SMITH:  
 24 Q. Let's turn to the DIPLOMAT

1 A. Minus the application names,  
 2 obviously.  
 3 Q. Sure.  
 4 A. So if you remove the names,  
 5 I think that probably would correctly  
 6 represent DIPLOMAT.  
 7 Q. What were the dates for  
 8 DIPLOMAT, the date that it was put into  
 9 service and the date it was retired?  
 10 A. It was retired in 2004. I  
 11 believe it was brought into service in  
 12 the 1990s.  
 13 Q. Who was the database  
 14 manager?  
 15 A. I could answer that question  
 16 by probably looking at the system  
 17 documentation materials. I would highly  
 18 doubt that that individual is still at  
 19 AstraZeneca.  
 20 Q. Could you provide us with a  
 21 copy of the documentation?  
 22 MR. TORREGROSSA: Same  
 23 objection.  
 24 You can answer if you

1 system now and go through that, if you  
 2 will.  
 3 Is the DIPLOMAT system one  
 4 for which you were responsible?  
 5 A. No.  
 6 Q. Are you familiar with it?  
 7 A. Yes.  
 8 Q. What was the DIPLOMAT  
 9 system?  
 10 A. Similar to AMOS.  
 11 Q. Would you be able to draw a  
 12 system map for DIPLOMAT like you did for  
 13 AMOS?  
 14 A. I'm not sure that I can in  
 15 that the system was decommissioned.  
 16 Q. Can you look at the system  
 17 map for AMOS and tell me if you can  
 18 recall how DIPLOMAT was different, if it  
 19 was?  
 20 A. I don't believe it would  
 21 have differed much at all from the  
 22 diagram that I provided for AMOS.  
 23 Can I just clarify?  
 24 Q. Yes.

1 understand the question.  
 2 THE WITNESS: Provided I was  
 3 able to locate the materials, I  
 4 believe I could produce it.  
 5 BY MR. SMITH:  
 6 Q. Do you know whether they  
 7 exist or not?  
 8 A. I don't have firsthand  
 9 knowledge that they exist. In principle,  
 10 we try to maintain and keep all  
 11 appropriate materials relating to  
 12 validate systems.  
 13 Q. Would you have a file where  
 14 you would have hard copies or a book, a  
 15 notebook, some sort of collection of  
 16 documentation for each system for which  
 17 you're responsible?  
 18 A. Yes.  
 19 Q. Could you make copies of  
 20 that information for each of those  
 21 systems and provide it to us through your  
 22 counsel?  
 23 MR. TORREGROSSA: Again,  
 24 same objection to the extent

1 you're asking him to produce it to  
2 you. We of course will work with  
3 you, but he's not here to say what  
4 he will or won't produce.

5 But you can answer the  
6 question, if you understand.

7 THE WITNESS: It will  
8 require considerable effort to  
9 collect all of the information  
10 related to DIPLOMAT that would  
11 otherwise be in paper archives.

12 BY MR. SMITH:

13 Q. I'm not sure if I followed  
14 your answer.

15 A. I'm answering the question  
16 by stating that it's doable, however,  
17 those materials aren't sitting in an  
18 office somewhere where I can simply walk  
19 up and pick up the binder and make  
20 copies. It would require, as I said,  
21 considerable time and effort to search  
22 and locate those materials from our paper  
23 archives.

24 Q. So those materials would be

1 Q. Is IMPACT a current system  
2 in use at AstraZeneca?

3 A. IMPACT or DIPLOMAT?

4 Q. No, you mentioned IMPACT.  
5 I'm asking, is that a system  
6 that's currently in use at AstraZeneca?

7 A. Yes.

8 Q. Are you prepared to discuss  
9 IMPACT today?

10 A. Yes.

11 Q. We're still on DIPLOMAT  
12 then.

13 A. Yes.

14 Q. Do you know who the business  
15 analyst is for DIPLOMAT?

16 A. The business analyst.  
17 The name escapes me at this  
18 moment. I would need to talk to the  
19 service manager.

20 Q. Do you know who the business  
21 partner is?

22 A. The business partner is -- I  
23 believe it's Mark Harrison. I may be  
24 confusing that with the application

1 stored someplace. They would be archived  
2 somewhere in paper form.

3 Is that what you're saying?

4 A. Yes.

5 Q. Would they also be archived  
6 somewhere in electronic format?

7 A. I think our method of system  
8 documentation for an application such as  
9 IMPACT --

10 MR. TORREGROSSA: Wrong  
11 system.

12 THE WITNESS: I'm sorry.  
13 DIPLOMAT.

14 MR. TORREGROSSA: It's okay.  
15 Go ahead.

16 THE WITNESS: DIPLOMAT is a  
17 very old system used for a long  
18 period of time. I would expect  
19 there to be material in an  
20 archive.

21 BY MR. SMITH:

22 Q. Is IMPACT a system which is  
23 a current system for AstraZeneca?

24 A. I'm sorry, can you --

1 service manager. But Mark Harrison is  
2 the person I would go to to inquire  
3 information -- further information on  
4 DIPLOMAT.

5 Q. And what were the data  
6 sources for DIPLOMAT?

7 A. I think I answered that  
8 question earlier in that DIPLOMAT, the  
9 information being like AMOS, would come  
10 from a case report form, physical case  
11 report form.

12 Q. Was there a vendor for AMOS?  
13 I mean DIPLOMAT?

14 A. Yes. It's AstraZeneca.

15 Q. Did you ever do any  
16 programming or developmental work with  
17 DIPLOMAT?

18 A. No; but I worked very  
19 closely with individuals who supported  
20 DIPLOMAT.

21 Q. And who were those  
22 individuals?

23 A. The person that comes to  
24 mind is no longer at AstraZeneca.

1 Q. Who is that?  
2 A. A gentleman by the name of  
3 Ken McKeown.  
4 Q. Do you know where he is now?  
5 A. I'm uncertain. I think he  
6 might be privately employed.  
7 Q. Do you know where he lives?  
8 A. He lives in Delaware.  
9 Q. In Wilmington?  
10 A. I don't think so, no.  
11 Q. Was DIPLOMAT archived on  
12 file shares?  
13 A. Is DIPLOMAT archived on file  
14 shares?  
15 If what you mean was data  
16 extracted from DIPLOMAT to support an NDA  
17 such as a SAS data set, I would expect  
18 that it would have been assembled in a  
19 SAS data set, yes.  
20 Q. I mean, it's not online now;  
21 is that correct?  
22 A. That's correct.  
23 Q. So is there a paper request  
24 system to request data from DIPLOMAT?

1 A. Being that DIPLOMAT, the  
2 data from DIPLOMAT was entered from case  
3 report forms, you could acquire the paper  
4 for that data from archive.  
5 Q. Who would be the person in  
6 charge of that or the department?  
7 A. I would expect somebody from  
8 the records management would assist in  
9 acquiring physical case report forms from  
10 archive.  
11 Q. And those report forms would  
12 be in electronic format as well as paper?  
13 A. The physical paper.  
14 Q. Are they still in -- when  
15 DIPLOMAT was operational, were they  
16 available in electronic format?  
17 A. DIPLOMAT was not -- was not  
18 electronic case report forms. It was a  
19 data collection -- data management  
20 database whereby you would take  
21 information off the case report form and  
22 enter that into DIPLOMAT.  
23 Q. So the data that was on the  
24 CRFs was put into DIPLOMAT?

1 A. Correct.  
2 Q. And that data still exists  
3 in a shared file someplace. Right?  
4 A. I would expect if it was  
5 extracted to SAS data sets, that it would  
6 be available on a file share.  
7 Q. Would that be the only form  
8 in which it would exist other than the  
9 actual paper forms would be in a SAS data  
10 set?  
11 A. No. Prior to  
12 decommissioning, the data was assembled  
13 into flat text files.  
14 Q. And where do those exist?  
15 A. They exist on a -- a file  
16 server.  
17 Q. And whose file server is  
18 that?  
19 A. Whose file server? I mean,  
20 it's AstraZeneca.  
21 Q. What department?  
22 A. I believe it's drug  
23 development IS.  
24 Q. Is there any sort of audit

1 for what was input into DIPLOMAT?  
2 A. Yes.  
3 Q. Is it a validated system?  
4 A. Yes. Was.  
5 Q. Was.  
6 Was there a service level  
7 agreement for DIPLOMAT?  
8 A. I'm not aware of any  
9 specific service level agreement. That's  
10 a relatively new term used in the IT  
11 industry.  
12 Q. What does that term mean to  
13 you?  
14 A. It's an agreement for the  
15 IS/IT organization to provide a certain  
16 level of service around an application.  
17 Q. What type of database was  
18 DIPLOMAT?  
19 A. It was a focus database.  
20 Q. Would you be able to obtain  
21 a user list for that database?  
22 A. I'm uncertain that there was  
23 so-called user lists assembled prior to  
24 decommissioning.

1 Q. What were the query or  
 2 search capabilities for DIPLOMAT?  
 3 A. Similar to what you would  
 4 have in AMOS.  
 5 Q. How about exportability,  
 6 exporting data?  
 7 A. As I said earlier, SAS data  
 8 sets was the general form of getting  
 9 clinical data out for analysis.  
 10 Q. Let's talk about the COOL  
 11 system, because that's a system which you  
 12 support. Is that a system you support?  
 13 A. There's two questions there.  
 14 Q. Is that a system?  
 15 A. Is it, yes.  
 16 Q. Do you support it?  
 17 A. No.  
 18 Q. Does somebody in your group  
 19 or team support it?  
 20 A. Somebody within our  
 21 organization supports it, and I'm here to  
 22 speak about it today.  
 23 Q. Who supports it?  
 24 A. Global drug development IS.

1 Q. What is it?  
 2 A. It's an application used to  
 3 collect information on an electronic case  
 4 report form.  
 5 Q. And when was it initiated?  
 6 A. If your question is, when  
 7 did AstraZeneca start to use COOL?  
 8 Q. Yes.  
 9 A. Around 2000-2001.  
 10 Q. What did they use to perform  
 11 that function before that?  
 12 A. Well, prior to remote data  
 13 capture, the data was entered -- there  
 14 was a -- we had case report forms. And  
 15 the information would have been collected  
 16 on the case report form and entered into  
 17 DIPLOMAT.  
 18 Q. Who is the database manager  
 19 for COOL?  
 20 A. I don't have the -- I mean,  
 21 the individual's name is not coming to me  
 22 right at this minute. I do know that the  
 23 database is managed by GDDIS, global drug  
 24 development IS.

1 Q. Did you contact anyone  
 2 regarding --  
 3 A. I'm sorry, can I just back  
 4 up and correct?  
 5 Q. Yeah.  
 6 A. Because I'm trying to draw  
 7 this --  
 8 MR. TORREGROSSA: You can.  
 9 THE WITNESS: I'm trying to  
 10 get this information assembled in  
 11 my mind.  
 12 The database is managed by a  
 13 gentleman by the name of Sam  
 14 Fitzpatrick.  
 15 BY MR. SMITH:  
 16 Q. Who is the business analyst  
 17 for COOL?  
 18 A. I would probably go to Rita  
 19 White to identify who the business  
 20 analyst is.  
 21 Q. And the business owner?  
 22 A. It's not -- I can't recall  
 23 the person's name. Again, I would speak  
 24 to -- probably speak to Rita White.

1 Q. And the business partner?  
 2 A. Again, I'd have to speak to  
 3 Rita White.  
 4 Q. Do you know who the vendor  
 5 is?  
 6 A. Vendor is AstraZeneca.  
 7 Q. What type of database is it?  
 8 A. It's an Oracle database.  
 9 Q. What information is in COOL?  
 10 A. I think I answered that  
 11 question already.  
 12 Q. Is COOL Web-based?  
 13 A. Yes.  
 14 Q. Can investigators enter  
 15 comments into COOL?  
 16 MR. TORREGROSSA: Objection  
 17 to form.  
 18 You can answer.  
 19 THE WITNESS: To the best of  
 20 my knowledge, there is no form for  
 21 entering comments.  
 22 BY MR. SMITH:  
 23 Q. Is there a comment field  
 24 within COOL?

1 A. Again, I don't believe  
 2 there's any comment field in COOL.  
 3 Q. Do persons outside of  
 4 AstraZeneca have access to COOL?  
 5 A. Yes.  
 6 Q. Can an investigator choose  
 7 to put a study in COOL or AMOS?  
 8 A. No.  
 9 Q. Are they required to put a  
 10 study in one or the other?  
 11 A. No.  
 12 Q. Do they put studies in COOL?  
 13 A. No.  
 14 Q. Do they put studies in AMOS?  
 15 A. No.  
 16 Q. How about if we say data  
 17 from studies, would that help?  
 18 A. Yes.  
 19 Q. Bingo. All right. Let's go  
 20 back through the questions.  
 21 A. Sorry.  
 22 Q. All right. Okay. Can  
 23 investigators put data from the studies  
 24 into COOL?

1 don't make that decision.  
 2 Q. Who does make that decision?  
 3 A. The study team makes the  
 4 decision of whether or not to use AMOS or  
 5 a remote data capture application, such  
 6 as COOL.  
 7 Q. And does the team do that?  
 8 They sometimes use one or the other?  
 9 A. I'm going to have to say  
 10 that that's a business process decision.  
 11 I mean --  
 12 MR. TORREGROSSA: Objection  
 13 to scope.  
 14 Go ahead.  
 15 THE WITNESS: Technically,  
 16 we support both with these  
 17 databases. I can't speak to what  
 18 the business rules or decisions  
 19 are on how to choose one or the  
 20 other.  
 21 BY MR. SMITH:  
 22 Q. We're talking about data  
 23 from patient visits. Right?  
 24 A. Correct.

1 A. No.  
 2 Q. Does data from the studies  
 3 get into COOL?  
 4 A. Information that is  
 5 collected during a patient visit is  
 6 entered into COOL.  
 7 Q. By whom?  
 8 A. By a clinical research  
 9 organization.  
 10 Q. An outside group?  
 11 A. An outside contracted  
 12 organization.  
 13 Q. And is that done via the  
 14 Web? Is it Web-based?  
 15 A. Yes.  
 16 Q. At this point in time do  
 17 they have a choice of entering the data  
 18 via paper forms in AMOS?  
 19 A. No.  
 20 Q. Was there a time when  
 21 investigators could choose between using  
 22 COOL or AMOS to enter their data?  
 23 A. The users don't make that  
 24 decision. The people that enter data

1 Q. And you could have data from  
 2 patient visits in COOL, which would be in  
 3 electronic format because it's Web-based.  
 4 Correct?  
 5 A. Yes.  
 6 Q. And you could have it in  
 7 paper CRFs, which would go into the AMOS  
 8 system then. Right?  
 9 A. You're referring to the  
 10 data?  
 11 Q. Yes. Data from the patient  
 12 visits.  
 13 A. Yes.  
 14 Q. Is there any interface  
 15 between the COOL and AMOS systems?  
 16 A. No.  
 17 Q. Is there any way to combine  
 18 patient visit data from the COOL system  
 19 with patient visit data from the AMOS  
 20 system?  
 21 MR. TORREGROSSA: Objection  
 22 to form and also scope. I think  
 23 this is outside the notice.  
 24 Go ahead. You can answer.

1 THE WITNESS: I mean, just  
2 purely from my personal technical  
3 perspective, if I had two data  
4 sets, I could certainly add them  
5 together.

6 BY MR. SMITH:

7 Q. Now, are you involved on a  
8 day-to-day basis with either COOL or  
9 AMOS?

10 A. No.

11 Q. Do you know whether any  
12 attempt has been made to interface or  
13 merge the patient visit data from COOL  
14 with that from AMOS?

15 A. I'm sorry, could you just  
16 read the question back, please?

17 - - -

18 (The court reporter read the  
19 pertinent part of the record.)

20 - - -

21 THE WITNESS: No.

22 BY MR. SMITH:

23 Q. And there are Seroquel  
24 studies, data from Seroquel studies in

1 A. I don't.

2 Q. Does COOL stand for clinical  
3 online?

4 A. Yes.

5 Can I just make a  
6 correction? It's clinical operation  
7 online.

8 Q. Thank you.

9 A. Yeah.

10 MR. TORREGROSSA: If you  
11 need to correct something else, go  
12 ahead.

13 THE WITNESS: Yeah,  
14 actually, just two -- two things.

15 One with regard to this  
16 Exhibit 3, this diagram. I have a  
17 line there that shows a COOL  
18 client connected to the  
19 AstraZeneca database server. It's  
20 actually a data file exchanged.

21 BY MR. SMITH:

22 Q. Do you need to amend your  
23 diagram to indicate that?

24 A. I would simply add a data

1 COOL?

2 A. I would assume that if the  
3 business made a decision to run a study  
4 via a CRO, that they could use COOL to  
5 collect patient information.

6 Q. You don't know whether  
7 they've done that for Seroquel or not; is  
8 that correct?

9 A. There may be Seroquel study  
10 data in COOL.

11 Q. Does that mean there is or  
12 isn't? I hate to be pushing you on it,  
13 but I'm --

14 A. The business -- the business  
15 make the decision. I would expect if  
16 they decided to use -- if it was a large  
17 enough study and they decided to use a  
18 clinical research organization, that --  
19 and involving Seroquel, that that  
20 information would have been collected and  
21 stored in the COOL database.

22 Q. Do you know whether they  
23 have ever made that business decision to  
24 do that?

1 store representing a file is produced  
2 that contains the patient information.  
3 And then that is imported into the COOL  
4 database.

5 Q. Do you want to use a red pen  
6 to make that change?

7 A. Yeah.

8 MR. TORREGROSSA: Can we go  
9 off for a second?

10 - - -

11 (A discussion off the record  
12 occurred.)

13 - - -

14 BY MR. SMITH:

15 Q. Did you want to say  
16 something?

17 A. The other correction. I  
18 have two corrections.

19 AstraZeneca had recently --  
20 your question about what other systems  
21 and applications are related to AMOS.  
22 And AstraZeneca have started to use  
23 another product called Rave, which is  
24 just a vendor product as opposed to a



1 AstraZeneca product, to do remote data  
2 capture.  
3 So the diagram is accurate  
4 in that, you know, the function of remote  
5 data capture comes into AMOS, but, you  
6 know, we have started to use another  
7 application called Rave.  
8 Q. Now, is Rave an acronym or  
9 is that the name of the vendor?  
10 A. That's the name of the  
11 product.  
12 Q. The name of the product.  
13 A. Right.  
14 Q. Do you know what that stands  
15 for?  
16 A. I would simply be guessing.  
17 I don't know the -- it may not be  
18 representing anything. It just may be,  
19 you know, a name.  
20 Q. Now, do you know who the  
21 administrator would be for Rave?  
22 A. Probably the similar  
23 resources that support remote data  
24 capture systems such as COOL.

1 Q. When did AstraZeneca begin  
2 using Rave?  
3 A. Probably 2006.  
4 Q. Now, I believe you indicated  
5 that they had started using it. That  
6 suggests that it's not fully implemented  
7 maybe.  
8 Can you explain that?  
9 A. I know that there was --  
10 typically when we look at -- when  
11 AstraZeneca look at different  
12 technologies and systems, we'll do sort  
13 of an evaluation or a nonproduction  
14 review or pilot. So we'll assemble a  
15 team and we'll look at, you know, does  
16 this vendor product meet our business  
17 requirements and our needs. So starting  
18 to use, what I meant was we started to,  
19 you know, assemble some information on  
20 whether or not that would be a suitable  
21 and adequate replacement for our  
22 internal, in-house built application.  
23 Q. Who's the vendor for the  
24 Rave system?

1 A. Medidata.  
2 Q. Where are they located, if  
3 you know?  
4 A. I don't recall.  
5 Q. And how would you compare  
6 Rave with COOL?  
7 A. Like for like?  
8 Homegrown/vendor built?  
9 Q. Does it have the same  
10 purpose and the same function, the same  
11 users as COOL?  
12 A. Yes.  
13 Q. Would searches and reports  
14 be similar?  
15 A. I can't say for certain  
16 whether or not they would be similar.  
17 Again, they typically support a very  
18 similar function. I would have to do  
19 some research with the -- on that  
20 particular vendor and that particular  
21 product and some comparison with our COOL  
22 application to say that we had identical  
23 reporting capability.  
24 Q. Would the sources be the

1 same as for COOL, the data sources?  
2 A. Yes.  
3 Q. How about if we go to  
4 CRF/DEN now.  
5 Can you describe that system  
6 for me?  
7 A. It is a case report form  
8 imaging system.  
9 Q. Is it searchable?  
10 A. Yes.  
11 Q. How do you search it?  
12 A. Study, center, patient.  
13 Q. And the output is going to  
14 be in the form of images?  
15 A. No. The output would be in  
16 the form of items displayed on the  
17 screen.  
18 Q. These items displayed on the  
19 screen, are they some type of document?  
20 A. No. It's simply information  
21 about the document.  
22 Q. So it's more like a report?  
23 A. It's simply an on-screen  
24 listing of document images.

1 Q. Does it relate in any way to  
2 AMOS?  
3 A. Yes.  
4 Q. Is it on our diagram?  
5 A. No.  
6 Q. Could it be added to the  
7 diagram?  
8 A. Yes.  
9 Q. Would it facilitate an  
10 understanding of how these systems  
11 interface?  
12 A. I don't believe so, no.  
13 Q. Is it just something that  
14 you didn't think about when you were  
15 drawing this diagram?  
16 MR. TORREGROSSA: Objection  
17 to form.  
18 THE WITNESS: No.  
19 MR. TORREGROSSA: Go ahead.  
20 BY MR. SMITH:  
21 Q. Or is it something that  
22 doesn't really belong on this diagram?  
23 A. Correct.  
24 Q. Why is it something that

1 doesn't belong on this diagram which is  
2 Exhibit 3?  
3 A. Because it has to do with  
4 the storage of physical -- I'm sorry, it  
5 has to do with the imaging of a physical  
6 document.  
7 Q. How does it interface with  
8 AMOS?  
9 A. It doesn't interface with  
10 AMOS.  
11 Q. How does it interface with  
12 COOL?  
13 A. It doesn't. COOL's  
14 electronic case report forms. There's no  
15 physical document.  
16 Q. AMOS is based on paper CRFs?  
17 A. Correct.  
18 Q. And is CRF/DEN based on  
19 paper CRFs?  
20 A. Yes.  
21 Q. Can you explain how they're  
22 similar or different?  
23 A. Can I explain how AMOS and  
24 CRF/DEN are different?

1 Q. Yes, please.  
2 A. Okay. They're different in  
3 that AMOS is used to take information off  
4 of the case report form and then turned  
5 into a database.  
6 CRF/DEN is a system whereby  
7 we scan that CRF as the source document  
8 for that data and we put that -- we take  
9 that scan, which is an image of the  
10 physical paper, and we store that in a  
11 storage data source.  
12 Q. And who's the business owner  
13 for CRF/DEN?  
14 A. Wendy Ramsey.  
15 Q. And the users would be?  
16 A. The users would be the --  
17 what we referred to as study delivery  
18 enablement.  
19 Q. Are these the same people  
20 who use AMOS?  
21 A. No.  
22 Q. If AstraZeneca receives a  
23 paper CRF from a study, who gets it?  
24 MR. TORREGROSSA: Objection

1 to form.  
2 Go ahead.  
3 BY MR. SMITH:  
4 Q. The next question will be,  
5 what do they do with it?  
6 A. When the company -- I'm  
7 sorry.  
8 Q. No, I was interrupting you.  
9 I just said, the next question will be  
10 what will they do with it, to put that in  
11 some sort of perspective.  
12 A. The first question was?  
13 Q. The first question is, who  
14 gets it?  
15 MR. TORREGROSSA: Same  
16 objection.  
17 BY MR. SMITH:  
18 Q. Who gets the paper CRF form?  
19 A. If I understand your  
20 question correctly, you said when  
21 AstraZeneca receives it, who gets it.  
22 It would be the clinical  
23 data management group.  
24 Q. And what do they do with it?

1 A. They enter the data into  
2 AMOS.  
3 Q. Do they also scan it into  
4 CRF/DEN?  
5 A. No. They send the paper to  
6 be scanned into CRF/DEN.  
7 Q. So the data from the form  
8 ends up in AMOS, and the image of the  
9 form itself ends up being scanned into  
10 CRF/DEN. Right?  
11 A. That's correct.  
12 Q. And neither one of these  
13 relate to COOL, right, or interface with  
14 COOL. Right?  
15 A. Correct.  
16 Q. Okay. Is CRF/DEN a  
17 validated system?  
18 A. Yes.  
19 Q. And when was CRF/DEN put  
20 into place?  
21 A. CRF/DEN was implemented in  
22 1995.  
23 Q. Was that an Astra or a  
24 Zeneca system?

1 A. That was a Zeneca system.  
2 Q. What platform is it built  
3 on?  
4 A. You mean the --  
5 Q. Is it Oracle?  
6 A. You mean the database? I'm  
7 sorry.  
8 Q. Is it an Oracle database?  
9 A. It is an Oracle database.  
10 Q. What is FileNet?  
11 A. FileNet is the technology  
12 used to actually house the images.  
13 Q. Can you annotate the images  
14 in some way in CRF/DEN?  
15 MR. TORREGROSSA: Objection  
16 to form.  
17 THE WITNESS: No.  
18 BY MR. SMITH:  
19 Q. Are there fields used to  
20 identify the CRFs?  
21 A. Yes.  
22 Q. What types of fields  
23 identify the CRFs?  
24 A. Study, center, patient,

1 visit.  
2 Q. Can you search it by  
3 patient?  
4 MR. TORREGROSSA: Objection  
5 to form.  
6 Go ahead.  
7 THE WITNESS: It's very  
8 difficult to search based strictly  
9 on a patient. You have to have  
10 some idea of what study that  
11 patient is participating in.  
12 BY MR. SMITH:  
13 Q. Otherwise, you cannot find a  
14 patient in the CRF/DEN database; is that  
15 correct?  
16 A. The general business use is  
17 to start with the study that you're  
18 investigating.  
19 MR. TORREGROSSA: Would now  
20 be a good time for lunch or later?  
21 MR. SMITH: Yes. I'll just  
22 finish up on this topic.  
23 MR. TORREGROSSA: Yes, sir.  
24 BY MR. SMITH:

1 Q. Do the CRF forms get  
2 forwarded to safety in some cases?  
3 MR. TORREGROSSA: Objection,  
4 scope.  
5 THE WITNESS: You're asking  
6 me a business process question. I  
7 mean, I can try to answer your  
8 questions related to technologies  
9 and the architecture.  
10 BY MR. SMITH:  
11 Q. Is there a technology to  
12 output adverse events from the CRF/DEN  
13 system to somebody in safety.  
14 MR. TORREGROSSA: Objection  
15 to form. Objection to form.  
16 You can answer.  
17 THE WITNESS: I'm sorry,  
18 could you repeat the question,  
19 please?  
20 - - -  
21 (The court reporter read the  
22 pertinent part of the record.)  
23 - - -  
24 THE WITNESS: Is that a