

Confidential - Darryl Draper

<p style="text-align: right;">Page 34</p> <p>1 position with AstraZeneca and what your 2 duties are? 3 A. My position at AstraZeneca 4 is service performance manager. And 5 while that job title, essentially all 6 that is, has some roles and 7 responsibilities of which are ensuring 8 the delivery and support for services 9 used by AstraZeneca business areas. 10 Q. Let me see if I can read 11 that. 12 AstraZeneca business areas, 13 is that what your answer was? 14 A. Yes. 15 Q. Can you explain what you 16 mean by business areas, AstraZeneca 17 business areas? 18 A. There are departments within 19 AstraZeneca, and those departments 20 represent certain business processes or 21 own certain business processes. 22 Q. Which areas are you 23 concerned with? 24 A. I'm not sure I understand</p>	<p style="text-align: right;">Page 36</p> <p>1 A. Study delivery enablement. 2 Q. What does that mean? 3 A. That's an area of the 4 business that has a responsibility for 5 the delivery of studies. 6 Q. From whom and to whom? 7 Delivery suggests that it's from somebody 8 to somebody else. 9 A. Delivery on behalf of drug 10 projects. So therapeutic areas receive a 11 compound, and it is -- I mean, they 12 decide they want to study that particular 13 compound. The study team or study 14 delivery would be involved with the 15 set-up, I guess agreeing or involving 16 centers and sites and investigators to 17 perform certain activities of the trial 18 or the study. 19 Q. Would that include 20 laboratory and animal trials? 21 A. No. 22 Q. Would it include human 23 clinical trials? 24 A. Yes.</p>
<p style="text-align: right;">Page 35</p> <p>1 the question. 2 Q. Okay. Are you concerned 3 with all of the areas of AstraZeneca's 4 business in the US? 5 A. Do you mean do I have a 6 responsibility? 7 Q. Yes. 8 A. I do not have a 9 responsibility for all AstraZeneca 10 business areas. 11 Q. Which business areas do you 12 have a responsibility for? 13 A. The clinical drug 14 development area. 15 Q. That's the only business 16 area that you have responsibility for? 17 A. As I said, there are, how 18 can I say, departments, functions within 19 global clinical drug development. An 20 example would be drug safety. 21 Q. What are some of the other 22 divisions of clinical drug development 23 that you're responsible for, divisions or 24 departments?</p>	<p style="text-align: right;">Page 37</p> <p>1 Q. And what is your involvement 2 with the human clinical trials, as far as 3 the services you provide? 4 A. These -- a number of these 5 databases support that area of the 6 business. And I'm here to answer 7 questions, technical questions, with 8 regard to those databases. 9 Does that answer the 10 question? 11 Q. Not really. 12 Which databases are you 13 responsible for that support the human 14 clinical trials? 15 A. I'm assuming that you're 16 referring to the databases listed here. 17 Q. No. It's an open-ended 18 question. 19 A. SAM, SAMSON. That's all I 20 see at the moment from the list. 21 Q. Okay. Are there any other 22 databases that you're responsible for 23 that support human clinical trials that 24 are not on the list?</p>

10 (Pages 34 to 37)

1 A. Databases that support human
2 clinical trials?

3 Q. Yes, sir.

4 A. I don't believe that there
5 are any others.

6 Q. Aside from databases, are
7 there any software applications that you
8 are responsible for that support clinical
9 trials?

10 A. Can I -- I would like to go
11 back to my earlier statement about
12 databases --

13 Q. Sure.

14 A. -- other databases.

15 Could I just -- could you
16 ask me the question again, the previous
17 question, because I want to make sure
18 that I've...

19 MR. SMITH: Let me ask the
20 court reporter to find it. She's
21 probably better at it than I am.

22 - - -

23 (The court reporter read the
24 pertinent part of the record.)

1 Q. Did you e-mail anyone at
2 AstraZeneca concerning the software
3 systems that you're responsible for in
4 preparation for today's deposition?

5 A. Could you ask the question
6 again? I want to make sure I understand.

7 Q. Did you e-mail anyone at
8 AstraZeneca concerning the software
9 systems that you're responsible for in
10 preparation for today's deposition?

11 A. I sent meeting requests to
12 individuals from the business areas that
13 use the systems, certain systems, the
14 systems I have a responsibility for.

15 Q. Was any information
16 concerning the systems or their use of
17 the systems sent to you by way of e-mail?

18 A. I did receive confirmations
19 for the individuals that I had asked to
20 attend the face-to-face meeting.

21 Q. Did anybody provide any
22 information to you other than to confirm
23 the meetings?

24 A. In the meeting request, I

1 - - -

2 THE WITNESS: There is a
3 medical dictionary database that I
4 have a responsibility for.

5 BY MR. SMITH:

6 Q. Any other databases that you
7 can think of?

8 A. There is a database which
9 is a -- it's also part of the dictionary.
10 It's a database, but it's related to
11 medical dictionary management.

12 Q. Is there a name for that?

13 A. Yes.

14 Q. What?

15 A. GDMRS.

16 Q. GDMRS?

17 A. Correct.

18 Q. And what does that stand
19 for?

20 A. Global dictionary management
21 request system.

22 Q. And you're responsible for
23 the operation of that?

24 A. Yes.

1 specifically asked --

2 MR. TORREGROSSA: Don't
3 discuss what was asked to the
4 extent it was by direction of
5 counsel. Just state what was the
6 general nature of the request.

7 THE WITNESS: I'm sorry,
8 could you ask the question again,
9 please?

10 BY MR. SMITH:

11 Q. Did anybody provide any
12 information to you other than to confirm
13 the meetings?

14 A. Yes.

15 Q. What type of information?

16 A. Information such as --
17 actually, I'm -- could you ask the
18 question again, because I'm not sure I --

19 Q. Did anybody provide any
20 information to you other than to confirm
21 the meetings?

22 MR. TORREGROSSA: My
23 objection is to the extent it
24 calls for privileged information.

1 You can answer and say whether you
2 did or not, but don't disclose any
3 communications that were made
4 between us to counsel.

5 THE WITNESS: Yes, I did
6 receive information.

7 BY MR. SMITH:

8 Q. What type of information?

9 MR. TORREGROSSA: Again,
10 same instruction. You can
11 describe it generally, but don't
12 describe the communications to the
13 extent they were privileged.

14 THE WITNESS: Information,
15 general technical information or
16 business process information.

17 BY MR. SMITH:

18 Q. And that was information
19 that you felt that you needed to be able
20 to discuss these areas today?

21 A. Not necessarily, no.

22 Q. Why would you ask for it
23 then?

24 A. I didn't -- what do you

1 e-mail?

2 A. Yes.

3 Q. In some cases, did they
4 attach materials to their replies?

5 A. Yes.

6 Q. Is there any reason why you
7 couldn't produce those to me?

8 MR. TORREGROSSA: Objection
9 to the extent you're saying we
10 will produce them.

11 THE WITNESS: I did not
12 review any of the information that
13 was sent to me.

14 BY MR. SMITH:

15 Q. So if somebody sent you an
16 attachment regarding the technical
17 information that would be relevant on how
18 the system is designed or architected,
19 you didn't open the attachments?

20 A. That's correct.

21 Q. Can you give me an example
22 of -- name somebody that you corresponded
23 with via e-mail regarding the technical
24 information or architecture for one of

1 mean, ask for?

2 Q. I assume that if somebody
3 sent you some information, it was because
4 you asked for it.

5 A. I asked the -- I sent a
6 meeting request to discuss certain
7 aspects of the systems, their use, and
8 any technical information that would be
9 relevant on how the system is designed or
10 architected.

11 Q. And did they respond by
12 providing you with technical information
13 relevant to how the system is designed or
14 architected?

15 A. What I asked for -- what I
16 asked for was to have a discussion so
17 that I could speak about -- technically
18 about these systems.

19 Q. And in response, did they
20 provide you with some information that
21 would enable you to speak technically
22 about these systems?

23 A. Yes.

24 Q. And they did that via

1 your systems?

2 A. I'm sorry, can you state the
3 question again?

4 Q. Can you give me an example
5 of -- can you name somebody that you
6 corresponded with via e-mail regarding
7 the technical information or architecture
8 for one of your systems?

9 A. Are you asking me to name a
10 person?

11 Q. Yes.

12 A. Okay. Robert Lane.

13 Q. And who is Robert Lane?

14 A. He is the director of
15 networking -- I'm sorry, it's voice and
16 network communications.

17 Q. And what technical
18 information did you want to get from Mr.
19 Lane?

20 MR. TORREGROSSA: Again, you
21 can discuss this generally, but do
22 not give specific communications
23 that were made by and between us.

24 BY MR. SMITH:

1 Q. I'm not asking for
 2 communications between you and your
 3 lawyer. I'm asking for communications
 4 between you and Mr. Lane.
 5 Is that clear?
 6 MR. TORREGROSSA: Directly.
 7 And I'm objecting to the extent it
 8 calls for me -- or for discussion
 9 of what I directed him to do.
 10 But you're correct, any
 11 one-on-one communications that you
 12 had with him, you can discuss.
 13 MR. SMITH: Well, I didn't
 14 ask him if somebody told him to do
 15 it. I hadn't even mentioned
 16 anything like that.
 17 It's interfering with the
 18 purpose of the deposition to tell
 19 him that that's privileged because
 20 it's not privileged.
 21 MR. TORREGROSSA: Well, if
 22 you are asking what kinds of
 23 information did he seek out from
 24 Mr. Lane, I agree with you. He

1 Robert Lane. Paul Seymour.
 2 Q. Who is Paul Seymour?
 3 A. Paul Seymour is an
 4 AstraZeneca employee. His job role is
 5 similar to mine. He's a service
 6 performance manager.
 7 Q. And what systems is he
 8 responsible for?
 9 A. He has a responsibility for
 10 CLINTRACE.
 11 Q. Would he be a better person
 12 to ask about the systems for CLINTRACE
 13 than yourself?
 14 MR. TORREGROSSA: Objection
 15 to form.
 16 Go ahead. You can answer.
 17 THE WITNESS: No.
 18 BY MR. SMITH:
 19 Q. Did he provide any
 20 documentation to you regarding CLINTRACE?
 21 A. No.
 22 Q. Or any technical
 23 information, by e-mail or otherwise, that
 24 was in writing?

1 can answer that question.
 2 THE WITNESS: Phone and
 3 voicemail systems.
 4 BY MR. SMITH:
 5 Q. What did you want to know
 6 about the phone and voicemail systems?
 7 A. How they're used, their
 8 technical components and the
 9 architecture.
 10 Q. Did he send you any
 11 documentation regarding the phone and
 12 voicemail systems?
 13 A. No.
 14 Q. Who else did you correspond
 15 with via e-mail in preparation for
 16 today's deposition?
 17 A. There are many others that I
 18 sent meeting requests to.
 19 Do you want to go through
 20 the entire list?
 21 Q. If you would, please.
 22 A. I'm going to try to do it.
 23 I mean, I don't recall -- I may not
 24 recall every individual.

1 A. I'm not sure -- can you
 2 restate the question, please?
 3 Q. Yes, let me rephrase it.
 4 Did he provide -- what
 5 information, what types of information,
 6 did Mr. Seymour provide to you regarding
 7 CLINTRACE?
 8 A. I don't recall. I mean, I
 9 didn't -- any information that was sent
 10 to me, I did not review, I did not look
 11 at. I --
 12 MR. TORREGROSSA: I think
 13 the question was, what information
 14 did you inquire about to Mr.
 15 Seymour.
 16 Was that the question?
 17 MR. SMITH: No. The court
 18 reporter can read the question
 19 back if that's necessary.
 20 MR. TORREGROSSA: I
 21 apologize.
 22 - - -
 23 (The court reporter read the
 24 pertinent part of the record.)

1 - - -

2 MR. TORREGROSSA: Thank you,

3 Mr. Smith.

4 THE WITNESS: Paul provided,

5 during the interview, he provided

6 information about database size.

7 MR. TORREGROSSA: Don't

8 discuss the communications during

9 our meeting, but you can describe

10 the type -- you can answer his

11 question with respect to types of

12 information he provided with

13 regard to CLINTRACE.

14 THE WITNESS: The types of

15 information were of a technical

16 nature.

17 BY MR. SMITH:

18 Q. Was counsel present at this

19 meeting?

20 A. Yes.

21 Q. I need to know more about

22 the type of information that he gave to

23 you.

24 A. Can you be more specific?

1 Q. Would you have a job

2 description or performance record that

3 would outline all of the systems and

4 applications that you manage?

5 A. No.

6 Q. What is Mr. Seymour's title,

7 if you can recall?

8 A. He was a -- I'm sorry. His

9 title is service performance manager.

10 Q. Is he responsible for just

11 CLINTRACE or for other applications?

12 A. I believe he has a

13 responsibility for some other

14 applications.

15 Q. Does he work for you or is

16 he over you? What's the organizational

17 relationship?

18 A. He's a peer.

19 Q. He's a peer.

20 Who is your boss?

21 A. I'm sorry, can you be a bit

22 clearer on what you mean?

23 Q. Who is your supervisor?

24 A. Who is my supervisor? Mary

1 Q. I assume that wasn't

2 everything that he gave to you.

3 How long did the meeting

4 last?

5 A. Approximately an hour.

6 Q. And during that hour, what

7 did you talk about?

8 MR. TORREGROSSA: Objection.

9 Don't answer that. That's

10 privileged.

11 MR. SMITH: Not what your

12 lawyer talked about, what did you

13 talk about.

14 MR. TORREGROSSA: No.

15 That's privileged. We were all

16 meeting to prepare for this

17 deposition. That is sacrosanct.

18 You cannot get into that.

19 BY MR. SMITH:

20 Q. Did you discuss any of the

21 systems for which you're testifying today

22 with anyone at AstraZeneca when your

23 counsel was not present?

24 A. No.

1 Gabie.

2 Q. Could you spell that last

3 name, please?

4 A. G-A-B-I-E.

5 Q. And who is Mr. Seymour's

6 supervisor?

7 A. I would check with Sophia

8 Parker, who is the person that could give

9 me that information.

10 Q. And who is she?

11 A. She's a -- she has a

12 responsibility for the, what we call

13 resource managers within our

14 organization.

15 Q. Are you a resource manager?

16 A. I'm a service performance

17 manager.

18 Q. What's a resource manager?

19 A. They manage resources within

20 an IS or IT function.

21 Q. Do you mean human resources?

22 A. Yes.

23 Q. Personnel?

24 A. Personnel.

1 Q. Okay. What is your
 2 responsibility for CLINTRACE?
 3 A. I'm not sure I understand
 4 your question.
 5 With regard to the
 6 deposition?
 7 Q. With regard to your position
 8 at AstraZeneca.
 9 A. I don't have a day-to-day
 10 responsibility for CLINTRACE.
 11 Q. Did you ever have a
 12 day-to-day responsibility for CLINTRACE?
 13 A. Yes.
 14 Q. When was that?
 15 A. From 1999 to about 2003.
 16 Q. And what were your
 17 responsibilities for CLINTRACE during
 18 that period of time?
 19 A. Incident management, problem
 20 management, change management and release
 21 management.
 22 Q. Can you define each of those
 23 terms for me?
 24 A. Yes. Incident management is

1 - - -
 2 (A recess occurred.)
 3 - - -
 4 BY MR. SMITH:
 5 Q. I'm sure it's not necessary
 6 to remind you, but you're still under
 7 oath.
 8 Welcome back. And you have
 9 before you Exhibit Number 2.
 10 Can you identify that for
 11 me, please?
 12 A. That's my resume.
 13 Q. Is it current and accurate?
 14 A. Yes.
 15 Q. I'd like to shift gears a
 16 little bit here.
 17 Let's talk about AMOS,
 18 A-M-O-S.
 19 Is that a system for which
 20 you're responsible?
 21 A. No, but it's a system that
 22 I'm here to talk about today.
 23 Q. What does AMOS stand for?
 24 A. It no longer really has

1 the response to issues, technical issues
 2 and/or questions on how to use a system.
 3 Q. An incident is not an
 4 occasion where the system breaks down or
 5 malfunctions?
 6 A. An incident is the system
 7 not responding or behaving the way that a
 8 user would expect it to.
 9 Q. That sounds pretty good.
 10 That's an incident then?
 11 A. That's an incident.
 12 Q. When it's not behaving.
 13 A. Can I just clarify?
 14 Q. Yes.
 15 A. I mean that incident may
 16 simply be the result of not understanding
 17 how to use the system.
 18 MR. SMITH: With that, why
 19 don't we take a break. It's been
 20 about an hour.
 21 - - -
 22 (Deposition Exhibit No.
 23 Draper-2, Resume, was marked for
 24 identification.)

1 relevance to AstraZeneca. It stood for
 2 Astra Monitoring, I believe it's
 3 Operating System.
 4 Q. And what was its purpose?
 5 A. It is -- its purpose is to
 6 collect data from case report forms.
 7 Q. And what are the case report
 8 forms?
 9 A. The case report forms are a
 10 paper document used to collect patient
 11 information during a visit.
 12 Q. And how do these case report
 13 forms get to AstraZeneca? In other
 14 words, are you talking about clinical
 15 trials, or are you talking about
 16 spontaneous reports? What do you mean by
 17 case report forms?
 18 A. A case report form is a
 19 method whereby, during a trial, a patient
 20 would visit and provide information about
 21 their health and --
 22 Q. Just so I -- I'm sorry. I
 23 didn't mean to interrupt you.
 24 A. It's all right. Go ahead.

1 Q. Just so we're clear then,
 2 we're not talking about spontaneous
 3 post-marketing adverse event reports.
 4 We're talking about clinical
 5 trials. Right?
 6 A. The CRF is not a method for
 7 spontaneous adverse events, no.
 8 Q. Who are the users of AMOS?
 9 A. It's the clinical data
 10 management organization.
 11 Q. Is it currently in use?
 12 A. Yes.
 13 Q. Is it used by any other
 14 groups?
 15 A. It is also -- I believe that
 16 it's also used by the study teams.
 17 Q. Is it used for drug products
 18 other than Seroquel?
 19 A. Yes.
 20 Q. And it's used for Seroquel;
 21 is that correct?
 22 A. It can be used for Seroquel.
 23 Q. Is it used for Seroquel?
 24 A. You're asking me a question

1 with regard to whether -- when and how
 2 the business decide to use AMOS, so I
 3 think that's more of a business process
 4 question more so than a technical
 5 question.
 6 Q. Who should that question be
 7 put to, in your opinion?
 8 A. It probably should be posed
 9 to someone within the CNS study team.
 10 Q. Anyone in particular?
 11 A. I don't know the names of
 12 individuals on the -- in the CNS
 13 therapeutic area study teams.
 14 Q. When was AMOS first put into
 15 use?
 16 A. Is your question when was it
 17 first used in AstraZeneca?
 18 Q. Yes.
 19 A. In 2000.
 20 Q. Who maintains the servers?
 21 A. IBM.
 22 Q. What platform is AMOS based
 23 on?
 24 A. If your question is with

1 regard to the database, it is on a Sun
 2 Microsystem Unix server.
 3 Q. Is the software on a
 4 different server?
 5 A. Yes.
 6 Q. Where is the software?
 7 A. I just want to restate that
 8 answer.
 9 Software for the system
 10 encompasses all components. And so any
 11 hardware, software for the system would
 12 be on multiple components to the
 13 hardware.
 14 Q. And what software runs for
 15 AMOS?
 16 A. What is the software?
 17 Q. What software is used for --
 18 what is the software?
 19 A. If you're referring to the
 20 programming language, is it, I believe it
 21 is VB.net.
 22 Q. Who are the vendors --
 23 A. I'm sorry, I'm sorry.
 24 Q. I'm sorry. Go ahead.

1 A. It's not. It's Java. It's
 2 written in a language called Java.
 3 Q. Can you describe the front
 4 end?
 5 A. A series of screens whereby
 6 you would find particular patients'
 7 related information that was designed for
 8 the study, used -- that would be used to
 9 enter the data. It's a data entry
 10 system.
 11 Q. Who are the vendors for the
 12 system?
 13 A. AstraZeneca.
 14 Q. It was developed in-house?
 15 A. Yes.
 16 Q. What are the data sources
 17 for AMOS?
 18 A. Case report forms.
 19 Q. Can you give me examples of
 20 the fields that are used?
 21 A. Patient ID, visit number,
 22 blood pressure. Those are some examples.
 23 Q. Product, I assume?
 24 A. No.

1 Q. Clinical investigator?
2 A. Yes.
3 Q. Any information about --
4 A. Study center.
5 Q. Study center.
6 Anything about institutional
7 review board?
8 A. Not that I can recall, no.
9 Q. Who would be the business
10 analyst or consultant in IS for the
11 system?
12 A. To answer that question, I
13 believe I would have to inquire with the
14 application service manager.
15 Q. Who is that?
16 A. That's Rita White.
17 Q. Are you familiar with the
18 term "client partner"?
19 A. I'm not sure I am, no.
20 Q. Would there be somebody in
21 IS who works closely with the business
22 owner? Wouldn't that be a client
23 partner?
24 A. I guess you could use the

1 struggling to recall the individual's
2 name. I would get that information from
3 talking again to Rita White.
4 It may come back to me.
5 Q. Who provides user training
6 on the system?
7 A. The business.
8 Q. Do you know whether there's
9 documentation for user training?
10 A. There should be
11 documentation for training users prior to
12 using the system.
13 Q. Is there separate training
14 for IS persons responsible for the
15 system?
16 A. Yes.
17 Q. Is there documentation for
18 that?
19 A. Yes.
20 Q. What type of documentation?
21 A. Training required to support
22 the system.
23 Q. Who conducts that training?
24 A. Much of it is the

1 term "client partner."
2 Q. If you don't use the term,
3 then that's okay.
4 A. I mean, we have what was
5 known as a business partner.
6 Q. Okay. What would be the
7 business partner? Who would be the
8 business partner?
9 A. Again, I would have to
10 inquire with the application service
11 manager to identify that individual.
12 Q. What does the business
13 partner do? What is his or her function?
14 A. To understand the
15 business -- the inquiries from a business
16 perspective. An example would be you go
17 to visit a car sales rep, and they're
18 going to ask you, do you want a sunroof,
19 do you want tilt steering, you know, what
20 do you need to meet your transportation
21 needs.
22 Q. Who is the business owner
23 for this system?
24 A. The business owner. I'm

1 responsibility of the individual to read
2 those materials. There is also
3 instructor-led training that's conducted
4 by the quality management organization.
5 So I think the answer to
6 your question is, it's both the
7 individual and the instructor.
8 Q. Is there somebody in quality
9 management who provides training for each
10 system?
11 A. No.
12 Q. There's somebody in quality
13 management who provides IS training,
14 though, for AMOS. Right?
15 A. Not specifically for AMOS.
16 Q. Who has access to AMOS and
17 how is that done?
18 A. I think I answered that
19 question earlier.
20 Q. Could you explain it to me
21 again?
22 A. Okay. If I recall
23 correctly, your question was who uses
24 AMOS.

1 Would that be similar to who
2 has access?
3 Q. Yes, it would.
4 Okay. How do they get
5 access?
6 A. They are required to go
7 through training. A request is sent to
8 the administrator of the application.
9 And they're given access. Their account
10 is created.
11 Q. Okay. How do they
12 physically access the information in
13 AMOS? What machines do they use?
14 A. Well, they would use their
15 computer that has been assigned to them,
16 and they would launch a shortcut to the
17 application. They'd enter their
18 credentials, and they would be in the
19 system.
20 Q. Can AMOS be accessed by
21 AstraZeneca employees overseas?
22 MR. TORREGROSSA: Objection
23 to form. Don't answer that
24 question.

1 a pushing of information to another
2 system, no.
3 Q. Does AMOS contain raw
4 clinical data that can be exported to SAS
5 data sets for analysis?
6 A. Yes.
7 Q. Are the results of those
8 analyses in GEL?
9 A. If they were part of the
10 NDA, they would be in GEL.
11 Q. Why did you say no when I
12 asked you earlier if the system could
13 feed other applications?
14 MR. TORREGROSSA: Objection.
15 Misstates the question, but go
16 ahead. You can answer.
17 THE WITNESS: What I said
18 was if what you mean is pushing
19 data, AMOS initiating push of data
20 to another system, it does not.
21 BY MR. SMITH:
22 Q. So for SAS, the data is not
23 pushed but the data is pulled?
24 A. Yes.

1 MR. SMITH: Are you going to
2 follow your counsel's advice?
3 THE WITNESS: Yes.
4 BY MR. SMITH:
5 Q. What kinds of reports can be
6 run in AMOS?
7 A. Patient summary visit.
8 Q. Anything else?
9 A. I'm certain there are
10 others. I don't have the specific
11 titles. It would be -- require some
12 additional analysis to list the reports,
13 provide a list of the reports.
14 Q. Who could provide that
15 information to you?
16 A. Probably the application
17 service manager.
18 Q. Did you talk to the
19 application service manager in
20 preparation for this deposition?
21 A. No.
22 Q. Does the AMOS system feed
23 other applications?
24 A. If what you mean by feed is

1 Q. What term would you use to
2 describe or how would you describe the
3 interaction between AMOS and other
4 applications?
5 A. I'm sorry, could I just --
6 could I make sure I understand the
7 question correctly?
8 MR. TORREGROSSA: Sure. We
9 can have the court reporter --
10 MR. SMITH: Can you read it
11 back, please.
12 - - -
13 (The court reporter read the
14 pertinent part of the record.)
15 - - -
16 THE WITNESS: I guess
17 integration.
18 BY MR. SMITH:
19 Q. So AMOS is integrated with
20 other applications or systems?
21 A. By virtue of sharing data,
22 yes.
23 Q. With what other systems does
24 AMOS share data?

1 A. SPOLA.
 2 Q. Can you make sure we have
 3 that spelling correct?
 4 MR. TORREGROSSA: Spell the
 5 acronym.
 6 THE WITNESS: S-P-O-L-A,
 7 SPOLA.
 8 BY MR. SMITH:
 9 Q. And what is SPOLA?
 10 A. SPOLA is an application
 11 that's used to analyze clinical study
 12 data.
 13 Q. Who are the users of SPOLA?
 14 A. They -- I believe it's the
 15 study teams.
 16 Q. We'll come back to SPOLA in
 17 a little bit then. Let me stay on AMOS
 18 for a while.
 19 What other systems share
 20 data with AMOS?
 21 A. I guess there's an
 22 application called COOL.
 23 Q. And just briefly, what is
 24 COOL?

1 A. COOL is a -- it's an
 2 electronic CRF or remote data capture
 3 application.
 4 Q. Is data shared in both
 5 directions between AMOS and COOL?
 6 A. No. In fact, COOL does not
 7 share data back and forth between AMOS.
 8 Q. How does COOL interface with
 9 AMOS?
 10 A. It's in -- AMOS is paper
 11 base case report forms. COOL is remote
 12 electronic case report forms.
 13 Q. Does COOL feed into the SAS
 14 data sets for analysis?
 15 A. Does COOL feed into -- if
 16 what you're referring to, does the --
 17 does the data that is captured in COOL
 18 end up in SAS data sets, yes.
 19 I just want to clarify that
 20 the resulting data is not a SAS data set
 21 by entering data into COOL. The
 22 resulting data is not -- it does not
 23 result -- does not directly result in a
 24 SAS data set.

1 Q. How does it get into a SAS
 2 data set?
 3 A. It gets extracted from the
 4 COOL data repository into a SAS data set.
 5 Q. By whom? Who does that?
 6 A. I'm sorry?
 7 Q. Who does that?
 8 A. I believe it's the study
 9 teams that build those SAS data sets when
 10 the trial is closed.
 11 Q. Was there a previous system
 12 that performed some of the same functions
 13 as AMOS?
 14 A. Yes.
 15 Q. And what was that system
 16 called?
 17 A. Is your question with regard
 18 to this litigation?
 19 Q. It's with regard to the
 20 database and the collection of those
 21 types of data.
 22 Was there another system
 23 prior to AMOS that did something like
 24 that?

1 A. Yes.
 2 Q. What was that?
 3 A. That was called DIPLOMAT.
 4 Q. And AMOS is a collection of
 5 documents.
 6 Is that what you said
 7 earlier?
 8 A. No.
 9 Q. No? I misunderstood you
 10 then.
 11 A. AMOS is a data entry system.
 12 Q. Okay. Was data from the
 13 DIPLOMAT system migrated into AMOS?
 14 A. Some data was migrated to
 15 AMOS.
 16 Q. Which data was migrated into
 17 AMOS?
 18 A. I'm sorry, I want to correct
 19 that.
 20 No, there was no migration
 21 to AMOS.
 22 Q. Is there access to AMOS by
 23 third parties?
 24 A. No.