

Confidential - Darryl Draper

Page 170

1 you print out the results of a search?
 2 A. I don't know.
 3 Q. Can you produce the results
 4 of a search? It doesn't have to be in a
 5 printed, hard copy, but in some
 6 electronic format?
 7 A. I don't know.
 8 MR. TORREGROSSA: Just
 9 telling you to wait until he
 10 finishes his question. That's
 11 all.
 12 BY MR. SMITH:
 13 Q. Can we talk about the PLANET
 14 system?
 15 A. Okay.
 16 Q. Are you responsible for that
 17 system?
 18 A. No.
 19 Q. Is your department
 20 responsible for that system?
 21 A. Yes.
 22 Q. And what does your
 23 department do with regards to that
 24 system?

Page 171

1 A. We provide the service and
 2 support.
 3 Q. Is it used by drug safety?
 4 A. Yes.
 5 Q. What type of data is in the
 6 PLANET system?
 7 A. Published literature.
 8 Q. Is that published literature
 9 about AstraZeneca products?
 10 A. Yes.
 11 Q. Is it about any other
 12 products?
 13 A. I think you're asking me
 14 questions that relate to, again,
 15 information that would be relevant to the
 16 content of those published materials.
 17 And while I can speak to the technical
 18 nature and aspects of the PLANET
 19 database, I don't know whether or not
 20 that literature would or would not
 21 contain other nonAstraZeneca products.
 22 Q. Is there a database of all
 23 literature in the public domain
 24 discussing AstraZeneca products?

Page 172

1 MR. TORREGROSSA: I'm sorry,
 2 I missed that. Could I have that
 3 repeated? I didn't get it.
 4 - - -
 5 (The court reporter read the
 6 pertinent part of the record.)
 7 - - -
 8 MR. TORREGROSSA: Objection,
 9 form.
 10 THE WITNESS: No.
 11 BY MR. SMITH:
 12 Q. Is it a database of all the
 13 literature in the public domain that
 14 discusses AstraZeneca products of which
 15 AstraZeneca is aware?
 16 A. Yes.
 17 Q. Does it contain the full
 18 articles?
 19 A. No.
 20 Q. Does it contain abstracts?
 21 A. Yes.
 22 Q. Are the abstracts -- in what
 23 format are they maintained in?
 24 A. Text.

Page 173

1 Q. From within AstraZeneca, can
 2 anyone access it?
 3 A. Yes.
 4 Q. Do you know whether search
 5 history of users is saved in the system?
 6 A. No. I'm sorry. Can I hear
 7 the question again, because I -- make
 8 sure I answered it correctly.
 9 - - -
 10 (The court reporter read the
 11 pertinent part of the record.)
 12 - - -
 13 THE WITNESS: Yes.
 14 BY MR. SMITH:
 15 Q. Is it?
 16 A. No.
 17 Q. Do you know where within
 18 AstraZeneca unpublished studies would be
 19 stored?
 20 A. Go back, because I think I
 21 need to make a correction with regard to
 22 unpublished articles.
 23 I believe that if a -- you
 24 asked me questions about the actual

44 (Pages 170 to 173)

1 content. And, you know, I'm not -- I
2 can't answer those questions on behalf
3 of, you know, the people who -- the
4 business owners of PLANET, so I want
5 to -- I feel like I need to correct that
6 answer, because again, I can answer the
7 technical questions with regard to, you
8 know, the architecture of the application
9 PLANET.

10 Q. Are you or someone in your
11 department responsible for shared drives,
12 where information is stored for clinical
13 studies, other than in the databases that
14 we've discussed?

15 A. I'm not sure I understand
16 the question.

17 Q. Does your department provide
18 any services with regard to information
19 that's contained on shared drives within
20 the clinical studies department?

21 A. Again, I really don't
22 understand what you're trying to ask.

23 Q. Are you aware of any place
24 on AstraZeneca's computers where

1 Q. Let's back up.

2 What departments in
3 AstraZeneca does your department provide
4 IS services to?

5 A. Drug development.

6 Q. Is that it, drug
7 development?

8 A. The whole gamut of drug
9 development.

10 Q. Does that include drug
11 safety?

12 A. Yes.

13 Q. And it includes clinical
14 studies?

15 A. Yes.

16 Q. It includes research and
17 development?

18 A. Yes.

19 Q. Does it include regulatory
20 compliance?

21 A. Yes.

22 Q. Is there a list somewhere of
23 all of the systems that your department
24 supports?

1 unpublished articles are stored?

2 A. Again, I think that's a
3 business process question.

4 What I know and can answer
5 are in respect to these databases.

6 Q. Do your duties include
7 providing IS services relating to systems
8 or applications that are not necessarily
9 databases?

10 A. That would require some
11 additional research to answer that
12 question.

13 Q. What type of research?

14 A. Looking at all of the
15 systems across the entire organization, I
16 would imagine.

17 Q. You only provide support to
18 drug safety and clinical studies?

19 A. We -- I'm sorry. You're
20 referring to me specifically?

21 Q. Your department, the IS
22 department.

23 A. The department, just in the
24 two departments you described were --

1 A. I don't believe there is a
2 single list.

3 Q. Would there be more than one
4 list?

5 A. Yes.

6 Q. Do you know of some lists?

7 A. Can you --

8 Q. Do you know of the
9 existence?

10 A. Can you just describe for me
11 what you mean by list?

12 Q. Lists of systems for which
13 your department provides IS services.

14 A. Yes.

15 Q. Could you produce those
16 lists?

17 MR. TORREGROSSA: Objection.
18 Object to the extent that you're
19 suggesting we will.

20 But you can answer if you
21 understand.

22 THE WITNESS: Yes.

23 BY MR. SMITH:

24 Q. How many members of your

1 department or team, how many are there?
 2 A. I don't have an exact
 3 number. It's a few hundred.
 4 MR. TORREGROSSA: When you
 5 get to a convenient time, Mr.
 6 Smith, if you would, we can take a
 7 break? We've been going for an
 8 hour and 15 minutes.
 9 MR. SMITH: Okay.
 10 BY MR. SMITH:
 11 Q. Is PLANET broken down by
 12 therapy areas?
 13 A. Yes.
 14 Q. Who's the third-party vendor
 15 who sends data to AstraZeneca for the
 16 PLANET system?
 17 A. Thompson Scientific.
 18 Q. What can people download to
 19 a laptop from the system?
 20 A. You mean from PLANET?
 21 Q. Yes.
 22 A. I believe it's the abstract.
 23 Q. Is there any way to make and
 24 store comments pertaining to items that

1 A. Can you read that question
 2 back, please?
 3 - - -
 4 (The court reporter read the
 5 pertinent part of the record.)
 6 - - -
 7 THE WITNESS: Yes.
 8 BY MR. SMITH:
 9 Q. Can you describe that?
 10 A. You can assemble certain key
 11 words in PLANET for an individual to
 12 receive notification that there is an
 13 abstract relating to those particular key
 14 words.
 15 Q. If I understand you
 16 correctly, does that mean that if I were
 17 a user -- if you were a user of PLANET
 18 and you wanted to be notified if anything
 19 appeared in an abstract relating to the
 20 search term "atypical," that you would
 21 automatically be sent a notification that
 22 an abstract relating to or containing the
 23 word "atypical" had been received?
 24 A. If atypical appeared in the

1 are contained in PLANET?
 2 A. Can you restate the
 3 question, please? I'm not sure --
 4 Q. Is there any way that a user
 5 could make a comment regarding an
 6 abstract that he or she found on PLANET?
 7 A. When you refer to user,
 8 what? Somebody who has --
 9 Q. Anybody who has access.
 10 A. I cannot make comments, no.
 11 Q. Are there other people who
 12 would have permission to make comments?
 13 A. Yes.
 14 Q. What department or team or
 15 persons would those be?
 16 A. I believe it's the
 17 information services.
 18 Q. Is there a way to share
 19 comments relating to these articles among
 20 users?
 21 A. No.
 22 Q. Is information regarding the
 23 acquisition of a new abstract
 24 disseminated in some way to users?

1 abstract or any of the other key index
 2 attributes, yes.
 3 Q. Would there be a way that
 4 you could, if you were a user of PLANET,
 5 order the full article?
 6 A. Yes.
 7 Q. How would you do that?
 8 A. You would submit a request.
 9 Q. Would you submit a request
 10 through PLANET?
 11 A. No.
 12 Q. How would you do it? How
 13 does the system work for requesting a
 14 full article?
 15 A. You submit a request to the
 16 information -- sorry, the scientific
 17 information library. They would seek to
 18 acquire that article.
 19 Q. Is there a link to the
 20 library within PLANET?
 21 A. I don't recall precisely
 22 whether or not there's a link to a
 23 physical article, no.
 24 Q. Is there something on the

1 page, a button that you can click on,
 2 that allows you to request the full
 3 article?
 4 A. Not that I'm aware of.
 5 Q. Does it go via some separate
 6 system?
 7 A. I think I just described the
 8 process.
 9 Q. I don't understand your
 10 answer.
 11 Do you mean do you send an
 12 e-mail to somebody and say, get me this
 13 article?
 14 A. It would be an e-mail, yes.
 15 MR. TORREGROSSA: Is now
 16 good?
 17 MR. SMITH: Sure.
 18 MR. TORREGROSSA: Thank you,
 19 sir.
 20 - - -
 21 (A recess occurred.)
 22 - - -
 23 BY MR. SMITH:
 24 Q. I'd like to ask you some

1 day-to-day involvement.
 2 Q. What are your
 3 responsibilities with regard to AZ
 4 IMPACT?
 5 A. I don't have any direct
 6 day-to-day responsibilities.
 7 Q. Is there a data map or
 8 schema for AZ IMPACT?
 9 A. I believe what the -- the
 10 vendor does provide information that you
 11 would consider relevant to what would be
 12 in a data map.
 13 Q. Could you produce that to
 14 me?
 15 MR. TORREGROSSA: Objection.
 16 Lawyers produce things, not
 17 witnesses.
 18 You can answer.
 19 THE WITNESS: I believe so,
 20 yeah.
 21 BY MR. SMITH:
 22 Q. Is there a system map?
 23 A. I'm not aware of any system
 24 map.

1 questions about AZ IMPACT.
 2 What is AZ IMPACT?
 3 A. It is a study management
 4 system.
 5 Q. Clinical studies?
 6 A. Yes.
 7 Q. When was it put into use?
 8 A. It was put into use at
 9 AstraZeneca 2000 -- I believe it was
 10 2001.
 11 Q. Is it still in use today?
 12 A. Yes.
 13 Q. What is your involvement
 14 with or your responsibilities with regard
 15 to AZ IMPACT?
 16 A. You mean for today?
 17 Q. What is your involvement
 18 with or your responsibilities with regard
 19 to AZ IMPACT? I can break that down into
 20 two questions, if you'd like.
 21 A. Please.
 22 Q. What is your involvement
 23 with AZ IMPACT?
 24 A. I don't have any direct,

1 Q. What other systems does it
 2 interface with?
 3 A. I don't believe it has
 4 interfaces with any other systems.
 5 Q. Is it a validated system?
 6 A. Yes.
 7 Q. Who's the database manager?
 8 A. I believe it's Tor Limberg.
 9 Q. Who's the business analyst?
 10 A. I believe it's Jasper
 11 Hennington.
 12 Q. Who's the business owner?
 13 A. I'm sorry, can I make a
 14 correction?
 15 I believe Jasper Hennington
 16 is the business owner, and it's Eva
 17 Petterson who's the business analyst. I
 18 believe that's correct.
 19 Q. What are the data sources?
 20 A. Information that would be
 21 part of the study protocol.
 22 Q. How is that put into the
 23 system?
 24 A. It's entered on screens.

1 Q. By whom?
 2 A. By the Fowkes in study
 3 delivery.
 4 Q. Is any of the data entered
 5 by outside people?
 6 MR. TORREGROSSA: Objection
 7 to form.
 8 THE WITNESS: No.
 9 BY MR. SMITH:
 10 Q. How's the data organized?
 11 A. It's organized by study.
 12 Q. Could you give me a list of
 13 the fields?
 14 MR. TORREGROSSA: Objection.
 15 I'm sorry, were you
 16 finished?
 17 MR. SMITH: Uh-huh.
 18 MR. TORREGROSSA: Objection
 19 to form.
 20 THE WITNESS: I believe
 21 since it's a vendor product, that
 22 there would be lists of fields.
 23 BY MR. SMITH:
 24 Q. Who's the vendor?

1 missing. The agreement is what it
 2 is, which is foreign databases and
 3 foreign information in databases
 4 are off the table for now. That's
 5 my position.
 6 Instruct the witness not to
 7 answer.
 8 BY MR. SMITH:
 9 Q. You're going to follow your
 10 counsel's advice?
 11 A. Yes.
 12 Q. Could you get me a copy of
 13 training documentation?
 14 MR. TORREGROSSA: Objection
 15 to form.
 16 You can answer.
 17 THE WITNESS: Could you be
 18 more specific?
 19 BY MR. SMITH:
 20 Q. Could you get me a user
 21 guide?
 22 MR. TORREGROSSA: Same
 23 objection. I'm sorry.
 24 THE WITNESS: Yes.

1 A. Perceptive Informatics.
 2 Q. And where are they located?
 3 A. Birmingham, England.
 4 Q. Do you know whether foreign
 5 studies are entered into the system or
 6 not?
 7 MR. TORREGROSSA: You can
 8 answer that limited question yes
 9 or no.
 10 THE WITNESS: Yes.
 11 BY MR. SMITH:
 12 Q. By whom?
 13 MR. TORREGROSSA: The rest,
 14 Mr. Smith, I have to object for
 15 the same reasons, paragraph G.
 16 MR. SMITH: Paragraph G
 17 states that this does not
 18 preventing questioning concerning
 19 the witness's personal knowledge
 20 of these topics that were reported
 21 to the United States.
 22 MR. TORREGROSSA: But were
 23 reported to the United States.
 24 That's the distinction that you're

1 BY MR. SMITH:
 2 Q. Is training on how to
 3 operate the system conducted?
 4 A. Yes.
 5 Q. Is it conducted by
 6 AstraZeneca personnel or by the vendor or
 7 both?
 8 A. By AstraZeneca.
 9 Q. Is IS training regarding the
 10 system performed by AstraZeneca?
 11 A. Yes.
 12 Q. Are there training materials
 13 that are available?
 14 A. Yes.
 15 Q. Could you get me those?
 16 MR. TORREGROSSA: Objection
 17 to form.
 18 THE WITNESS: It would take
 19 some work to get those materials.
 20 BY MR. SMITH:
 21 Q. But it could be done?
 22 MR. TORREGROSSA: Same
 23 objection.
 24 THE WITNESS: Yes.

1 BY MR. SMITH:
 2 Q. What other types of
 3 documentation are available?
 4 A. Vendor documentation.
 5 Q. And could you produce a copy
 6 of that?
 7 MR. TORREGROSSA: Same
 8 objection.
 9 THE WITNESS: Yes.
 10 BY MR. SMITH:
 11 Q. What type of database is it?
 12 A. It is an Oracle database.
 13 Q. Who maintains the servers?
 14 A. IBM.
 15 Q. Could you produce a list of
 16 the authorized users?
 17 MR. TORREGROSSA: Same
 18 objection. Same objection. I
 19 object to the extent you suggest
 20 we will produce it.
 21 But you can answer the
 22 question.
 23 THE WITNESS: Yes.
 24 BY MR. SMITH:

1 Q. Was there any data in Trial
 2 Manager that was lost or destroyed?
 3 A. No.
 4 MR. TORREGROSSA: I'm sorry.
 5 Objection to form. Go ahead.
 6 THE WITNESS: Sorry.
 7 BY MR. SMITH:
 8 Q. When was Trial Manager put
 9 into service?
 10 A. 1998.
 11 Q. Who was the database
 12 manager?
 13 A. The database manager for AZ
 14 IMPACT, I believe I answered that
 15 question.
 16 Did I --
 17 Q. I'm sorry, was AZ IMPACT put
 18 into service in 1998?
 19 A. It was first used by
 20 AstraZeneca in 2000.
 21 Q. In 2000. Okay.
 22 And so you only have two
 23 years of data from Trial Manager, from
 24 1998 to approximately 2000?

1 Q. What system preceded AZ
 2 IMPACT?
 3 A. There was a system called
 4 Trial Manager.
 5 Q. Is that system still in use?
 6 A. No.
 7 Q. Was data from Trial Manager
 8 migrated to AZ IMPACT?
 9 A. Yes.
 10 Q. Was there any data in Trial
 11 Manager that was not migrated to AZ
 12 IMPACT?
 13 A. I don't believe that there
 14 was anything that was not migrated.
 15 Q. Was there any data in Trial
 16 Manager that was --
 17 A. I'm sorry, can I hear the
 18 question again, please?
 19 - - -
 20 (The court reporter read the
 21 pertinent part of the record.)
 22 - - -
 23 THE WITNESS: No.
 24 BY MR. SMITH:

1 MR. TORREGROSSA: Objection
 2 to form.
 3 THE WITNESS: That's
 4 correct.
 5 BY MR. SMITH:
 6 Q. What system was used prior
 7 to Trial Manager?
 8 A. I believe it was a system
 9 called the Clinical Information Trial
 10 System, CITS.
 11 Q. And when was that system put
 12 into place?
 13 A. I believe it was in the
 14 early 1990s.
 15 Q. Is that system still in use?
 16 A. No.
 17 Q. Was the data in CITS
 18 migrated into another system when it was
 19 retired?
 20 A. I don't believe once the
 21 study was completed that that information
 22 would have been migrated. It would have
 23 only been active studies.
 24 Q. So any active studies for

1 which there was data in CITS would have
2 been migrated to Trial Manager?
3 A. To answer your question, I'd
4 have to go back and look at the
5 information regarding Trial Manager and
6 how it was decommissioned and what was
7 migrated to the system that we use today.
8 Q. Where would the closed
9 studies be archived?
10 MR. TORREGROSSA: I didn't
11 catch one of those words, where
12 was the --
13 MR. SMITH: Closed studies.
14 MR. TORREGROSSA: Thank you,
15 sir.
16 THE WITNESS: I believe that
17 information is -- goes into -- I'd
18 have to do a bit more research. I
19 don't recall exactly how
20 information gets out of AZ
21 IMPACT -- or I'm sorry, this CITS,
22 once a study is complete.
23 BY MR. SMITH:
24 Q. Who would know the answer to

1 A. I would expect that if
2 the -- there would be information there
3 for the studies, yes.
4 Q. Would a data map be
5 available for CITS?
6 A. Possibly.
7 Q. Would a system map be
8 available?
9 A. Possibly.
10 Q. Who is the vendor for CITS?
11 A. I believe it was
12 AstraZeneca, but I would need to, again,
13 refer to the decommissioning and system
14 documentation to acquire that specific
15 vendor.
16 Q. Could you provide copies of
17 the system documentation for CITS?
18 MR. TORREGROSSA: Same
19 objection.
20 THE WITNESS: Didn't I
21 answer that question already?
22 BY MR. SMITH:
23 Q. Could you provide system
24 documentation for CITS?

1 that question?
2 A. Well, I would get that
3 answer by going to probably documentation
4 in material that is in our archive.
5 Q. Could you produce a copy of
6 the documentation material that's in your
7 archives?
8 MR. TORREGROSSA: Objection.
9 THE WITNESS: Yes.
10 BY MR. SMITH:
11 Q. Could you do that for Trial
12 Manager as well?
13 MR. TORREGROSSA: Same
14 objection.
15 THE WITNESS: Yes.
16 BY MR. SMITH:
17 Q. Do you know who the database
18 manager was for CITS?
19 A. I -- again, I would have to
20 go look at those decommissioning
21 materials to identify who the database
22 administrator was.
23 Q. Does CITS contain data
24 pertaining to Seroquel?

1 A. Again, I believe I answered
2 that question already.
3 Q. Well, that was with regard
4 to data maps or system maps.
5 Do you believe there would
6 be other types of system documentation?
7 A. Yes.
8 Q. And you could provide that?
9 MR. TORREGROSSA: Same
10 objection.
11 THE WITNESS: Yes.
12 BY MR. SMITH:
13 Q. Who were the users of that
14 system?
15 A. Study delivery.
16 Q. Did it have query and search
17 capabilities?
18 A. Yes.
19 Q. Could you export data?
20 A. I'm struggling to understand
21 what relevance exporting data from a
22 decommissioned system has with the
23 current systems that we use at
24 AstraZeneca.

1 Q. Well, would you have been
 2 able to export data from CITS and then
 3 import it into Trial Manager?
 4 A. If a migration program was
 5 written, then yes.
 6 Q. Do you know if there was a
 7 migration program?
 8 A. Again, I think I already
 9 answered that question.
 10 Q. What was your answer?
 11 A. I'll have to refer back to
 12 the reporter's notes, please.
 13 Q. We talked about closed
 14 studies and open studies?
 15 A. Yes.
 16 Q. Could the data for the
 17 closed studies be exported today?
 18 A. No.
 19 Q. Is it stored somewhere?
 20 A. Not -- not to my knowledge.
 21 It's not stored.
 22 Q. Does the data still exist?
 23 A. Again, I would have to refer
 24 to the decommissioning documentation for

1 A. To manage investigator
 2 initiated --
 3 Q. The reason for managing
 4 that?
 5 A. I think that's a question
 6 more appropriate for a business
 7 representative.
 8 Q. How's the information
 9 managed?
 10 A. In a database, by --
 11 Q. What type of database?
 12 A. Sorry?
 13 Q. I'm sorry, what type of
 14 database?
 15 A. An Oracle database.
 16 Q. And within the Oracle
 17 database, how's the data managed?
 18 A. I'm not sure I understand
 19 your question.
 20 Q. Take the data from the input
 21 to the output and tell me what happens to
 22 it in between.
 23 A. How the data is managed is
 24 the business responsibility. It's not an

1 that system to answer the question.
 2 Q. Pardon me if I asked you
 3 before, can you provide system
 4 documentation for Trial Manager?
 5 MR. TORREGROSSA: Objection
 6 to form.
 7 THE WITNESS: Yes.
 8 BY MR. SMITH:
 9 Q. What is IIRIS?
 10 A. A system for managing
 11 investigator-sponsored studies.
 12 Q. What do you mean by
 13 managing?
 14 A. Managing the details, the
 15 particulars of a request by an
 16 investigator.
 17 Q. What is the purpose of the
 18 system?
 19 A. Isn't that very similar to
 20 the answer I just gave or the question
 21 that was --
 22 Q. Similar. Different enough.
 23 What is the business purpose
 24 of the IIRIS system?

1 IT responsibility.
 2 So I can answer your
 3 questions with regard to technology. But
 4 again, I think that management of that
 5 information is not my responsibility.
 6 Q. Don't they work with IS to
 7 come up with a system to help them do
 8 their work?
 9 A. Yes.
 10 Q. And so you have to discuss
 11 their needs and how to meet them with a
 12 system. Right? And you come up with a
 13 system between you. Right?
 14 A. Yes.
 15 Q. If the system needs to be
 16 modified in some way, you work it out.
 17 Right?
 18 A. What do you mean by work it
 19 out?
 20 Q. If they want the system to
 21 do something differently or to do it in a
 22 different way, they would come to you and
 23 say, I want it to do something
 24 differently or I want it to be done in a

1 different way, and you would figure out a
2 way to do that if it could be done.
3 Right?

4 A. Yes.

5 Q. So how is the data handled
6 then? That's a system thing. How does
7 the system handle the data from the time
8 that it's inputted to the time that it's
9 outputted?

10 A. The data is stored to the
11 database.

12 Q. Let me stop you here and ask
13 you, where does it come from? What are
14 the sources?

15 A. It would come from
16 investigators' correspondence to initiate
17 a study.

18 Q. And I apologize for
19 interrupting you.

20 Is the system, does it
21 interface with other systems on the input
22 side?

23 A. No.

24 Q. It doesn't obtain any data

1 define what you mean by
2 application?

3 BY MR. SMITH:

4 Q. If an investigator submits
5 the organization -- his or her
6 organization to conduct clinical research
7 relating to an AstraZeneca product, I
8 assume there's a process for evaluating
9 and acting upon that application.

10 Correct?

11 A. Yes.

12 MR. TORREGROSSA: Objection.

13 BY MR. SMITH:

14 Q. Now, how does the IIRIS
15 system play a part in that?

16 A. That correspondence would
17 be -- if it's electronic, it would be
18 stored in IIRIS.

19 Q. What sorts of fields would
20 be used to identify or define that
21 request, that application?

22 A. Investigator's name,
23 document title, product.

24 Q. Could you get me a field

1 through an interface with another system
2 then?

3 A. No.

4 Q. So the data comes in and
5 it's stored.

6 Then what happens to it?

7 A. It can be updated. It can
8 be reviewed.

9 Q. Are applications to initiate
10 research put into IIRIS?

11 MR. TORREGROSSA: Objection
12 to form.

13 THE WITNESS: Could you --

14 BY MR. SMITH:

15 Q. Do investigators make
16 applications to conduct research --
17 strike that.

18 Are investigators'
19 applications to do research processed
20 through IIRIS?

21 MR. TORREGROSSA: I'm sorry.

22 Withdraw my objection.

23 Go ahead.

24 THE WITNESS: Could you

1 list?

2 MR. TORREGROSSA: Objection
3 to form.

4 THE WITNESS: Yes. I
5 believe a simple screen shot of
6 the data entry fields would
7 provide your list.

8 BY MR. SMITH:

9 Q. Could you get me system
10 documentation for IIRIS?

11 MR. TORREGROSSA: Objection
12 to form.

13 THE WITNESS: Yes.

14 BY MR. SMITH:

15 Q. Would that include a data
16 map?

17 A. No.

18 Q. System map?

19 A. No.

20 Q. Training materials?

21 A. No.

22 Q. Descriptions of tables?

23 A. Yes.

24 Q. Relationships between

1 tables?
 2 A. Yes.
 3 Q. Relationships to other
 4 systems?
 5 MR. TORREGROSSA: Objection
 6 to form.
 7 THE WITNESS: No.
 8 BY MR. SMITH:
 9 Q. User guides?
 10 A. I mean, can I just clarify?
 11 Q. Sure.
 12 A. There are no interfaces with
 13 other systems. Therefore, you would not
 14 find such interfaces. That's why I've
 15 answered no.
 16 Q. Is it a validated system?
 17 A. Yes.
 18 Q. Would discussions regarding
 19 an application be stored in the system?
 20 MR. TORREGROSSA: Objection
 21 to form.
 22 THE WITNESS: Depends on
 23 what you mean by discussion.
 24 BY MR. SMITH:

1 accepted or rejected?
 2 A. I'm not sure I understand
 3 what you mean by decision.
 4 Q. Somebody approves or
 5 disapproves the application. Right?
 6 A. Yes.
 7 Q. Would that determination be
 8 indicated somewhere in the system?
 9 A. Yes. To answer your
 10 question, there would be a status of
 11 whether or not that was accepted or
 12 rejected.
 13 Q. So the applications, if
 14 there's a status, then the applications
 15 would be tracked in the system from their
 16 receipt to the point at which they're
 17 acted upon. Correct?
 18 A. That is the purpose of
 19 IIRIS.
 20 Q. If the request is approved,
 21 then does IIRIS track the progress of the
 22 research?
 23 A. That's a business process
 24 question.

1 Q. Discussions among
 2 AstraZeneca personnel regarding the
 3 application?
 4 MR. TORREGROSSA: Same
 5 objection. Same objection.
 6 You can answer.
 7 THE WITNESS: And the
 8 objection was?
 9 MR. TORREGROSSA: To form.
 10 You can answer.
 11 THE WITNESS: Sorry, can I
 12 have the court reporter provide
 13 that question again, please?
 14 - - -
 15 (The court reporter read the
 16 pertinent part of the record.)
 17 - - -
 18 THE WITNESS: No.
 19 BY MR. SMITH:
 20 Q. Would it contain resumes for
 21 the investigator or the organization?
 22 A. Yes.
 23 Q. Would it contain a decision
 24 as to whether the application was

1 Q. No.
 2 Can the system track the
 3 progress of the research?
 4 A. The system -- yes.
 5 Q. If the contract for the
 6 research contains goals or milestones,
 7 can the system track whether those goals
 8 or milestones are met?
 9 A. Yes.
 10 Q. Are documents attached to
 11 the records?
 12 MR. TORREGROSSA: To the
 13 records?
 14 Go ahead.
 15 THE WITNESS: Yes.
 16 BY MR. SMITH:
 17 Q. There's a record for any
 18 research application, is there not?
 19 A. There would be a database
 20 record, yes.
 21 Q. Are status reports
 22 generated?
 23 A. If what you mean, does the
 24 application generate status reports, no.

1 Q. Can status reports be
 2 generated by the system?
 3 A. Yes.
 4 Q. Was there a prior system
 5 that did this?
 6 MR. TORREGROSSA: You mean
 7 the management in general, not --
 8 MR. SMITH: Management of
 9 the research applications.
 10 MR. TORREGROSSA: Yes, sir.
 11 Thank you.
 12 THE WITNESS: I don't
 13 believe there was a system prior
 14 to IIRIS, a computer system.
 15 BY MR. SMITH:
 16 Q. Were active research
 17 projects put into the system after it was
 18 initiated? In other words, ones that had
 19 been begun before the system was
 20 acquired --
 21 A. Yes.
 22 Q. -- but were still active?
 23 Okay.
 24 A. Sorry.

1 put in place in 2000. I thought you said
 2 that in our prior meeting, and I may be
 3 wrong.
 4 Does that ring any bells or
 5 is it your recollection that IIRIS was
 6 put into place in 1996?
 7 MR. TORREGROSSA: Take your
 8 time.
 9 THE WITNESS: No, I did want
 10 to correct that.
 11 It was implemented in 2000.
 12 BY MR. SMITH:
 13 Q. Was there another system
 14 that was in place in 1996 that was
 15 similar?
 16 A. No.
 17 Q. Why were you thinking 1996,
 18 if there's any reason?
 19 A. Because there is information
 20 in IIRIS for investigator-initiated
 21 research around the time in 1996.
 22 Q. That goes back to 1996?
 23 A. Correct.
 24 Q. So that would be what we

1 Q. My fault.
 2 And how are finances
 3 pertaining to this research handled in
 4 IIRIS? How are they managed?
 5 A. There is some information in
 6 IIRIS that gets entered.
 7 Q. Pertaining to payments to
 8 the investigators?
 9 A. Yes.
 10 Q. Pertaining to sample
 11 drugs that are -- not sample drugs, but
 12 drugs for the clinical study, are those
 13 tracked in the system?
 14 A. No.
 15 And I'm going to qualify
 16 that in that we don't track shipment.
 17 There's a status of whether or not an
 18 investigator received or will receive
 19 product.
 20 Q. When was the system put in
 21 place?
 22 A. 1996.
 23 Q. For some reason, I thought
 24 it was put into -- the IIRIS system was

1 talked about earlier, when we said that
 2 if there were pending projects, then they
 3 were put into IIRIS when IIRIS was
 4 implemented? Is that what we're talking
 5 about?
 6 A. Yes, I believe my earlier
 7 answer to that, yes.
 8 MR. SMITH: That's fine.
 9 Why don't we take a break.
 10 MR. TORREGROSSA: Yes, sir.
 11 - - -
 12 (A recess occurred.)
 13 - - -
 14 BY MR. SMITH:
 15 Q. Let me just ask you first,
 16 Mr. Draper, if you conferred with your
 17 counsel during the break?
 18 MR. TORREGROSSA: You can
 19 answer that yes or no.
 20 THE WITNESS: I'm sorry,
 21 confirmed --
 22 BY MR. SMITH:
 23 Q. Conferred with your counsel
 24 concerning the subject of the deposition

1 during the break?
 2 MR. TORREGROSSA: You can
 3 answer that yes or no.
 4 THE WITNESS: Yes.
 5 BY MR. SMITH:
 6 Q. Now, what did you want to
 7 clarify?
 8 A. Earlier statement with
 9 regard to training materials. That was
 10 an incorrect answer. There are
 11 procedures, procedural documents for
 12 managing the information that you would
 13 put into IIRIS.
 14 Q. Okay. You could provide
 15 those to us. Right?
 16 MR. TORREGROSSA: Objection
 17 to form.
 18 THE WITNESS: Yes.
 19 BY MR. SMITH:
 20 Q. Okay, thanks.
 21 Let's talk about SAMSON.
 22 What does SAMSON stand for?
 23 A. Safety adverse management --
 24 I'm sorry. Apologies. Can I withdraw

1 that, if it's possible?
 2 MR. TORREGROSSA: It's not,
 3 but state what you want to state.
 4 THE WITNESS: It really has
 5 no meaning whatsoever, other than
 6 it was a very similar technology
 7 and application of SAM.
 8 BY MR. SMITH:
 9 Q. Which came first?
 10 A. SAM.
 11 Q. What is your involvement
 12 with SAMSON?
 13 A. I'm the application service
 14 manager.
 15 Q. And as an application
 16 service manager, what do you do for
 17 SAMSON?
 18 A. I ensure the delivery of
 19 that service and all its support.
 20 Q. When was SAMSON put in
 21 place?
 22 A. Around 2000-2001.
 23 Q. Is that an Oracle system?
 24 A. Yes.

1 Q. Was that a Zeneca or an
 2 Astra system?
 3 You said it was put in place
 4 around 2000 or 2001. Right? Strike that
 5 question.
 6 MR. TORREGROSSA: He doesn't
 7 get to strike things either.
 8 MR. SMITH: I can do that;
 9 you can't.
 10 BY MR. SMITH:
 11 Q. What does SAMSON do?
 12 A. It manages investigator
 13 safety letter packages.
 14 Q. And how does it do that?
 15 A. A safety report's entered
 16 into the system and assembled with other
 17 documents into a package.
 18 Q. All right. Let me break
 19 that -- I'm sorry. Go ahead.
 20 A. That's it.
 21 Q. All right. A safety report?
 22 Did you say a safety report is -- who
 23 prepares the safety report?
 24 A. Drug safety.

1 Q. Is that done through the
 2 SAMSON system?
 3 A. No.
 4 Q. Is it transmitted to the
 5 investigator through the SAMSON system?
 6 A. No.
 7 Q. How does SAMSON enter a
 8 safety report into the system?
 9 A. It's imported.
 10 Q. From where?
 11 A. From a file system.
 12 Q. I'm sorry?
 13 A. From a file system.
 14 Q. What file system?
 15 A. Where you would store the
 16 investigator safety letter.
 17 Q. Where is the investigator
 18 safety letter stored?
 19 A. The investigator safety
 20 letter is imported into SAMSON and then
 21 stored in SAMSON.
 22 Q. Okay. Who prepares the
 23 investigator safety letter?
 24 A. Drug safety. I'm sorry.