

## Confidential - Darryl Draper

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1 Q. How about types of adverse  
2 events, is there some field for that?  
3 A. I think -- did I just  
4 describe the types? I mean --  
5 Q. Sorry?  
6 A. I think I just described the  
7 types, spontaneous, sponsored study,  
8 literature.  
9 Q. I meant like diabetes, heart  
10 attack, death, you know, event types.  
11 MR. TORREGROSSA: Objection  
12 to form, scope.  
13 BY MR. SMITH:  
14 Q. There's a field for that?  
15 A. Yes.  
16 Q. Could you print a list of  
17 the fields for CLINTRACE?  
18 A. The fields are listed in the  
19 vendor documentation.  
20 Q. Are there training materials  
21 for CLINTRACE?  
22 A. Yes.  
23 Q. User guides?  
24 A. Yes.

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1 Q. IS documentation?  
2 A. Yes.  
3 Q. Could you print copies of  
4 those?  
5 A. Yes.  
6 Q. Are there standard operating  
7 procedures pertaining to CLINTRACE?  
8 A. Yes.  
9 Q. Where are those located?  
10 A. They're located in the  
11 system documentation.  
12 Q. What type of database is  
13 CLINTRACE?  
14 A. Oracle.  
15 Q. Where is the server located?  
16 A. It's in England.  
17 Q. Could you print out a user  
18 list for CLINTRACE?  
19 A. Yes, I believe it's  
20 possible.  
21 Q. What was the predecessor for  
22 CLINTRACE?  
23 A. Predecessor for CLINTRACE.  
24 There are two systems, SECURE and RADAR.

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1 Q. SECURE and RADAR?  
2 A. Yes.  
3 Q. And what was SECURE?  
4 A. I'm sorry, what was the  
5 question again?  
6 Q. I'll come back to that  
7 later.  
8 A. It isn't that I couldn't  
9 answer it; I just forgot what the  
10 question was.  
11 Q. Was all of the data from  
12 SECURE migrated into CLINTRACE?  
13 A. Yes, it was.  
14 Q. Was all of the data from  
15 RADAR migrated into CLINTRACE?  
16 A. Not all data was migrated  
17 from RADAR.  
18 Q. Was all Seroquel data  
19 migrated from RADAR?  
20 A. All Seroquel data was  
21 migrated to CLINTRACE.  
22 Q. Has there been any loss or  
23 corruption of data from CLINTRACE that  
24 you're aware of?

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1 A. No.  
2 Q. Any loss or corruption of  
3 data from SECURE?  
4 A. No.  
5 Q. Any loss or corruption of  
6 data pertaining to Seroquel for RADAR?  
7 A. No.  
8 MR. SMITH: Let's take two  
9 minutes.  
10 - - -  
11 (A recess occurred.)  
12 - - -  
13 BY MR. SMITH:  
14 Q. Other than CLINTRACE, Mr.  
15 Draper, adverse event reports are logged  
16 into or by what other systems?  
17 A. As far as I'm aware, the  
18 CLINTRACE system is the system we use to  
19 track those adverse events.  
20 Q. Are there other systems that  
21 can access the -- that interface with  
22 CLINTRACE?  
23 A. Yes.  
24 Q. What other systems interface

24 (Pages 353 to 356)

1 with CLINTRACE?  
 2 A. I guess an example would  
 3 be -- I mentioned GES, which is a system  
 4 where the electronic case reports are  
 5 stored. Also refer to that as GESISS.  
 6 We talked yesterday about that.  
 7 Q. I'm sorry, I didn't  
 8 understand. GES what?  
 9 A. ISS.  
 10 Q. GESISS?  
 11 A. I use those terms very  
 12 loosely. Global electronic submission.  
 13 Q. Oh, okay. Fine. So GES is  
 14 not something -- GES and GESISS is the  
 15 same thing.  
 16 A. The system is GESISS.  
 17 Q. Great. That saves about 20  
 18 questions.  
 19 A. GES -- source documents are  
 20 stored into SAM. They are indexed based  
 21 on case ID. That case ID would be  
 22 validated against CLINTRACE.  
 23 Q. Where are investigator  
 24 brochures stored, do you know?

1 to form.  
 2 THE WITNESS: No. Again,  
 3 CANDAs would be the electronic NDA,  
 4 a tool used to view an electronic  
 5 NDA.  
 6 MR. TORREGROSSA: I'm sorry,  
 7 scope, too.  
 8 Go ahead.  
 9 BY MR. SMITH:  
 10 Q. But CANDAs itself does not  
 11 contain any documents. Right? It's a  
 12 tool that's used to navigate the NDA?  
 13 A. That's correct.  
 14 Yes. I'm sorry, I didn't  
 15 mean to answer --  
 16 Q. So CANDAs is simply a tool  
 17 that's used to navigate the NDA; is that  
 18 correct?  
 19 A. Yes.  
 20 Q. We're going to save some  
 21 trees and just do some pages.  
 22 I want to mark this as  
 23 Exhibit 4. Let me show it to counsel  
 24 first.

1 A. GEL.  
 2 Q. Is all the information  
 3 submitted to the FDA located in GEL?  
 4 MR. TORREGROSSA: Objection  
 5 to the form, scope.  
 6 THE WITNESS: That is the  
 7 repository for AstraZeneca for  
 8 correspondence with regulatory --  
 9 with the regulatory agency, yes.  
 10 BY MR. SMITH:  
 11 Q. Are there any other  
 12 applications or systems that contain  
 13 information submitted to FDA?  
 14 A. Well, I thought I just  
 15 explained GES.  
 16 Q. Any other systems besides  
 17 GEL and GES?  
 18 A. No.  
 19 Q. Are documents stored in  
 20 CANDAs?  
 21 A. No.  
 22 Q. So case report forms would  
 23 not be found in CANDAs?  
 24 MR. TORREGROSSA: Objection

1 MR. TORREGROSSA: We're not  
 2 giving him the whole document  
 3 because --  
 4 MR. SMITH: You can have it  
 5 if you want, but it's similar.  
 6 MR. TORREGROSSA: It's just  
 7 the list of investigators?  
 8 MR. SMITH: It goes on.  
 9 Right. If you want to look at it,  
 10 I have it here.  
 11 MR. TORREGROSSA: If you  
 12 wouldn't mind, while he looks at  
 13 that. Thank you, sir.  
 14 MR. SMITH: Let me have the  
 15 court reporter mark that as  
 16 Exhibit 4.  
 17 - - -  
 18 (Deposition Exhibit No.  
 19 Draper-4, Seroquel International  
 20 Approval Form, Bates stamped  
 21 AZ/SER 0834196 through AZ/SER  
 22 0834198, was marked for  
 23 identification.)  
 24 - - -

1 BY MR. SMITH:  
 2 Q. Would you take a look at  
 3 Exhibit 4, Mr. Draper.  
 4 Mr. Draper, have you had an  
 5 opportunity to look at Exhibit 4?  
 6 A. Yes. But --  
 7 Q. Yes.  
 8 A. But didn't you refer to this  
 9 as Exhibit 5?  
 10 Q. No.  
 11 You've had a chance to  
 12 review that?  
 13 A. Yes.  
 14 Q. This is a listing of what  
 15 type of information?  
 16 MR. TORREGROSSA: I object  
 17 to the form and scope. I think  
 18 this is way outside the bounds of  
 19 this deposition.  
 20 BY MR. SMITH:  
 21 Q. You can answer.  
 22 A. I'm sorry, the question  
 23 again was?  
 24 Q. This is a listing of what

1 MR. SMITH: All the pages  
 2 are the same lists.  
 3 MR. TORREGROSSA: I  
 4 understand. I'm just -- I thought  
 5 you were referring to the first  
 6 two pages. I'm sorry.  
 7 You're referring to this  
 8 page?  
 9 MR. SMITH: Right. To the  
 10 list.  
 11 THE WITNESS: Your question  
 12 again was?  
 13 BY MR. SMITH:  
 14 Q. For each of the  
 15 investigators listed there following  
 16 across the row, does it indicate the  
 17 location in the application of the case  
 18 report forms?  
 19 MR. TORREGROSSA: Same  
 20 objections as we have for the  
 21 balance of the testimony, but go  
 22 ahead.  
 23 THE WITNESS: I'm sorry. I  
 24 just simply need to hear the

1 type of information?  
 2 MR. TORREGROSSA: Same  
 3 objections.  
 4 THE WITNESS: Well,  
 5 according to the document, the  
 6 initial approval form, the title,  
 7 list of investigators.  
 8 BY MR. SMITH:  
 9 Q. Would this document be  
 10 maintained in GEL?  
 11 MR. TORREGROSSA: Same  
 12 objections.  
 13 THE WITNESS: I would expect  
 14 this document to be in GEL, yes.  
 15 BY MR. SMITH:  
 16 Q. And for each of the  
 17 investigators listed, if you follow  
 18 across the row, does it indicate the  
 19 location of the case report forms in the  
 20 applications?  
 21 MR. TORREGROSSA: Same  
 22 objections.  
 23 I assume you're talking  
 24 about page -- I guess it's 4.

1 question again, because I want to  
 2 make sure I'm giving a correct  
 3 answer.  
 4 BY MR. SMITH:  
 5 Q. No problem. For each  
 6 investigator listed --  
 7 A. Yes.  
 8 Q. -- if you follow across the  
 9 row, does it indicate location in the  
 10 application and case report forms?  
 11 MR. TORREGROSSA: Same  
 12 objections.  
 13 THE WITNESS: It does have a  
 14 column and a heading location in  
 15 application. And there's a column  
 16 that says case report forms with  
 17 an asterisk.  
 18 BY MR. SMITH:  
 19 Q. And in the case report forms  
 20 asterisk, the last column to the right,  
 21 does it show listings for CANDA and CT  
 22 Report?  
 23 MR. TORREGROSSA: Same  
 24 objections.

1 THE WITNESS: Yes.  
 2 BY MR. SMITH:  
 3 Q. Now, if I understood your  
 4 testimony earlier, the case report forms  
 5 would not physically be located in CANDA;  
 6 is that correct?  
 7 A. That is correct.  
 8 Q. Would the case report forms  
 9 be physically located in a system listed  
 10 here as CT Report?  
 11 A. I honestly don't know  
 12 whether or not that is a report or an  
 13 application. I don't recognize it as an  
 14 application.  
 15 MR. TORREGROSSA: Objection  
 16 to form and scope.  
 17 I'm sorry, Mr. Smith. Go  
 18 ahead.  
 19 BY MR. SMITH:  
 20 Q. Are you saying that you  
 21 don't recognize CT Report as an  
 22 application? Is that what you were  
 23 saying?  
 24 A. That's correct.

1 Q. And at the top of the page  
 2 it says Location In Application.  
 3 Do you know if that's  
 4 referring to the IND or the NDA?  
 5 MR. TORREGROSSA: Form and  
 6 scope.  
 7 THE WITNESS: Can I have the  
 8 question again, please.  
 9 BY MR. SMITH:  
 10 Q. I said, do you know whether  
 11 application refers to IND or NDA?  
 12 MR. TORREGROSSA: Form and  
 13 scope.  
 14 THE WITNESS: NDA.  
 15 MR. SMITH: I'd like to mark  
 16 this as Exhibit 5, please.  
 17 - - -  
 18 (Deposition Exhibit No.  
 19 Draper-5, Sources of Reporters,  
 20 Bates stamped AZ/SER 2288019, was  
 21 marked for identification.)  
 22 - - -  
 23 MR. SMITH: Please show that  
 24 to your counsel first, which I'm

1 Q. Do you recognize it as  
 2 anything? Do you know what it is? Do  
 3 you know what a CT Report is?  
 4 MR. TORREGROSSA: Form and  
 5 scope.  
 6 THE WITNESS: I don't. I  
 7 can make assumptions.  
 8 MR. TORREGROSSA: Don't make  
 9 assumptions.  
 10 BY MR. SMITH:  
 11 Q. What assumptions would you  
 12 make about CT Report?  
 13 MR. TORREGROSSA: Objection  
 14 to form and scope.  
 15 THE WITNESS: The column  
 16 would suggest that it's a case  
 17 report form.  
 18 BY MR. SMITH:  
 19 Q. That CT Report is a case  
 20 report form?  
 21 MR. TORREGROSSA: Form and  
 22 scope.  
 23 THE WITNESS: Yes.  
 24 BY MR. SMITH:

1 sure you will do anyway.  
 2 BY MR. SMITH:  
 3 Q. Would you look at Exhibit 5  
 4 for me, please, Mr. Draper.  
 5 Have you finished reviewing  
 6 Exhibit 5, sir?  
 7 A. Yes.  
 8 Q. Would you agree that it  
 9 depicts systems that can be sources of  
 10 information for drug safety?  
 11 MR. TORREGROSSA: Object to  
 12 the form as well as the scope.  
 13 THE WITNESS: No.  
 14 BY MR. SMITH:  
 15 Q. How would you interpret that  
 16 diagram?  
 17 MR. TORREGROSSA: Form and  
 18 scope.  
 19 THE WITNESS: I interpret  
 20 this diagram as sources of adverse  
 21 events.  
 22 BY MR. SMITH:  
 23 Q. Are you aware of any systems  
 24 that would contain sources of adverse

1 events other than the ones listed on that  
2 Exhibit 5?

3 MR. TORREGROSSA: Objection  
4 to form and mischaracterizes his  
5 testimony.

6 You can answer the question.

7 THE WITNESS: Can I have the  
8 question repeated from the court  
9 reporter, please.

10 - - -

11 (The court reporter read the  
12 pertinent part of the record.)

13 - - -

14 MR. TORREGROSSA: Same  
15 objections.

16 THE WITNESS: They are not  
17 listed on that document.

18 BY MR. SMITH:

19 Q. There are other sources that  
20 are not listed of which you're aware?

21 MR. TORREGROSSA: Objection  
22 to form.

23 THE WITNESS: There are no  
24 systems listed on that document.

1 for identification.)

2 - - -

3 BY MR. SMITH:

4 Q. Would you review Exhibit 6  
5 for me, please, Mr. Draper.

6 A. Yes.

7 Q. And let me know when you're  
8 finished.

9 Finished?

10 A. Yes.

11 Q. Exhibit Number 6 is an SOP  
12 for Drug Safety Adverse Event Report  
13 Training; is that correct?

14 MR. TORREGROSSA: Objection,  
15 scope.

16 THE WITNESS: No. It's a  
17 training template with references  
18 to an SOP on adverse event  
19 reporting.

20 BY MR. SMITH:

21 Q. Is there a system that  
22 contains these templates such as this?

23 A. Could be on the file system.

24 Q. What file system would that

1 BY MR. SMITH:

2 Q. Okay. I see what you're  
3 saying.

4 Are there any systems of  
5 which you are aware that we have not  
6 discussed in this deposition so far that  
7 contain information pertaining to those  
8 sources of adverse event reports?

9 A. No.

10 Q. Can I see that, please?  
11 Thank you.

12 MR. TORREGROSSA: Sir, I  
13 object to that last question to  
14 the extent it calls for foreign  
15 systems, but go ahead.

16 MR. SMITH: Mark this as  
17 Exhibit 6, please.

18 - - -

19 (Deposition Exhibit No.  
20 Draper-6, Welcome to AstraZeneca  
21 SOP No. 2 version 2 Drug Safety  
22 Adverse Event Report Training,  
23 Bates stamped AZ/SER 2288012  
24 through AZ/SER 2288018, was marked

1 be?

2 A. On file share, such as, you  
3 know, a Windows -- Windows 2000 file  
4 server.

5 Q. So this template would be  
6 used for training on drug safety, adverse  
7 event reports. Correct?

8 MR. TORREGROSSA: Hold on.  
9 Hold on a moment. Mr. Smith, we  
10 are so far out of the bounds that  
11 I fail to see how you can ask our  
12 IT person about this type of  
13 training. This is our IT person.  
14 You're in the wrong deposition.

15 MR. SMITH: Can you answer  
16 the question?

17 MR. TORREGROSSA: No, he  
18 cannot. Unless you give me some  
19 basis for why you can ask our IT  
20 person about drug safety training,  
21 I cannot allow him to answer that  
22 question on the scope of this  
23 deposition.

24 MR. SMITH: Are you

1 directing him not to answer?  
 2 MR. TORREGROSSA: I am,  
 3 unless you give me a basis.  
 4 You're asking our IT person  
 5 about drug safety training.  
 6 BY MR. SMITH:  
 7 Q. Do you provide training to  
 8 the drug safety personnel regarding the  
 9 systems that are used for adverse event  
 10 reports?  
 11 A. No.  
 12 Q. Does your department provide  
 13 any training in the use of those systems  
 14 for drug safety adverse event reports?  
 15 A. Yes.  
 16 Could I just have the last  
 17 question repeated by the court reporter,  
 18 please. I want to make sure that I  
 19 accurately answered that question.  
 20 - - -  
 21 (The court reporter read the  
 22 pertinent part of the record.)  
 23 - - -  
 24 THE WITNESS: Thank you.

1 content are maintained by the business.  
 2 And the server is simply there provided  
 3 as a technical platform for those  
 4 business activities.  
 5 So where IT support those  
 6 kind of Web sites, we would ensure that  
 7 the server is available, that it's, you  
 8 know, accessible such that people in the  
 9 business can get to it related to their  
 10 day-to-day needs and desires.  
 11 Q. Do people in your department  
 12 work with the developers of these Web  
 13 sites?  
 14 A. There may often be technical  
 15 questions beyond the capability of a  
 16 content owner, yes.  
 17 Q. Who would be the best person  
 18 in your organization to ask about Web  
 19 site content?  
 20 MR. TORREGROSSA: Content?  
 21 MR. SMITH: Content.  
 22 MR. TORREGROSSA: Thank you.  
 23 THE WITNESS: No one.  
 24 Content is owned by the business,

1 BY MR. SMITH:  
 2 Q. Was your answer accurate?  
 3 A. Yes.  
 4 Q. Are you familiar with the  
 5 electronic process manual?  
 6 A. No. But I think I've heard  
 7 that term used before, and I'm not sure  
 8 whether it was within AstraZeneca or  
 9 somewhere else.  
 10 Q. Are you familiar with the  
 11 clinical development SOP Web site?  
 12 A. No. That sounds like a  
 13 business kind of a Web site.  
 14 Q. Clinical development is a  
 15 department that your department provides  
 16 technical support for; is that correct?  
 17 A. Yes.  
 18 Q. Are you familiar with the  
 19 clinical GEL Web site?  
 20 A. Just let me clarify that  
 21 while we in GDDIS are the support  
 22 organization for many IT systems, Web  
 23 sites are often assembled for the use by  
 24 a business and are maintained, the

1 not by IT.  
 2 BY MR. SMITH:  
 3 Q. Are there applications that  
 4 are accessed through Web sites that your  
 5 organization or department supports?  
 6 A. The answer is yes. And I'm  
 7 going to clarify that by articulating  
 8 that Web sites often have links to --  
 9 what I mean by a link is a -- kind of  
 10 like an icon on your desktop. So if you  
 11 were to click that, it would facilitate  
 12 launch of an application, not necessarily  
 13 direct access.  
 14 So does that help?  
 15 Q. Sure. Where would drafts of  
 16 labels be kept?  
 17 A. I think that's a business  
 18 question.  
 19 MR. TORREGROSSA: Objection,  
 20 scope.  
 21 BY MR. SMITH:  
 22 Q. Do you provide service to  
 23 any system that is used to store or  
 24 review or submit drug product labeling?

1 A. That's GEL.  
 2 Q. Is there any other system  
 3 that would contain drafts or notes or  
 4 discussions pertaining to the labels,  
 5 drafting of labels?  
 6 MR. TORREGROSSA: Objection  
 7 to form, compound.  
 8 THE WITNESS: What's  
 9 submitted and approved is in GEL.  
 10 So GEL, I would go to GEL to seek  
 11 labeling information.  
 12 BY MR. SMITH:  
 13 Q. Would working drafts of  
 14 labeling be outside of GEL and then the  
 15 finished document would be imported into  
 16 GEL?  
 17 A. Now, the business -- it's my  
 18 understanding the business are trained to  
 19 create and author those documents in GEL.  
 20 And once they are approved, that is, the  
 21 approved version is the -- that's the  
 22 information that's submitted and --  
 23 Q. Does GEL have the capability  
 24 of importing a labeling document from

1 another source or system and then  
 2 submitting that as opposed to creating it  
 3 within GEL?  
 4 A. Yes. You can scan a  
 5 document. You can scan a physical  
 6 document and put that into GEL, so that's  
 7 a way of importing.  
 8 Q. Sure. What type of process  
 9 is involved in creating a document within  
 10 GEL? I mean, I assume it's not a Word  
 11 document.  
 12 What type of document is it  
 13 within GEL? Let's say a labeling  
 14 document, what do you use to create that  
 15 document?  
 16 A. If you were creating that in  
 17 GEL, you would use the typical Microsoft  
 18 Office products, Word being one of those.  
 19 And then that document is then rendered  
 20 to a .pdf. .pdf is the submitted  
 21 version --  
 22 Q. That's how you submit it,  
 23 electronically?  
 24 A. Electronically.

1 Q. You don't submit a Word  
 2 document. You submit a .pdf form of that  
 3 document. Right?  
 4 A. The final approved document  
 5 in its native form, Word, is rendered to  
 6 .pdf.  
 7 Q. Does -- I'm sorry?  
 8 A. And that's what is submitted  
 9 to the authority.  
 10 Q. Does GEL actually use Adobe  
 11 Acrobat to do that or some proprietary  
 12 means of converting it to a .pdf?  
 13 A. I believe with documenting  
 14 there's a rendition component. You know,  
 15 there are technical products on the  
 16 market such as kPublisher. It's a way to  
 17 convert documents. I mean, Adobe  
 18 Professional, you know, is another tool.  
 19 MR. SMITH: Would you mark  
 20 this as Exhibit 7, please.  
 21 - - -  
 22 (Deposition Exhibit No.  
 23 Draper-7, IND Annual Report Call  
 24 for Information Contributors List

1 for Seroquel (quetiapine fumarate)  
 2 IND Number 32,132, Bates stamped  
 3 AZ/SER 0535899, was marked for  
 4 identification.)  
 5 - - -  
 6 MR. SMITH: Please show that  
 7 to Mr. Draper or his counsel  
 8 first.  
 9 BY MR. SMITH:  
 10 Q. Would you look at that,  
 11 Exhibit 7, Mr. Draper, and let me know  
 12 when you've finished reviewing it.  
 13 A. Okay.  
 14 I'm finished.  
 15 Q. Are each of the persons and  
 16 departments on this list in Exhibit 7  
 17 supported by systems that GDDIS manages?  
 18 MR. TORREGROSSA: Take your  
 19 time.  
 20 THE WITNESS: Can I just  
 21 have the question read one more  
 22 time by the court reporter.  
 23 MR. SMITH: Sure.  
 24 - - -

1 (The court reporter read the  
2 pertinent part of the record.)

3 - - -  
4 THE WITNESS: You have to do  
5 it again, please.

6 - - -  
7 (The court reporter read the  
8 pertinent part of the record.)

9 - - -  
10 THE WITNESS: I'm going to  
11 ask again, please, for you to read  
12 it.

13 - - -  
14 (The court reporter read the  
15 pertinent part of the record.)

16 - - -  
17 THE WITNESS: I'm going to  
18 answer this, and I believe I'm  
19 going to also ask for some  
20 clarification in that you're  
21 asking me to make assumptions that  
22 these individuals work for a  
23 particular department, because  
24 there are no departments

1 don't you identify the title or position.

2 Why don't you do it that way.

3 A. US project physician. I'm

4 sorry, you want the name as well?

5 Q. You can just give me the  
6 position because we can look at the list  
7 later and match it up.

8 A. US project physician,  
9 clinical trial management, technical  
10 regulatory affairs, drug safety  
11 operations -- I'm sorry, right, drug  
12 safety operations, global RAD and RAM,  
13 experimental medicine, US project  
14 statistical. That's not necessarily a  
15 department there, just a statistical  
16 program.

17 Q. Does your department support  
18 statistical programming?

19 A. We support software, SAS,  
20 used by statistical programmers.

21 Q. Okay.

22 A. Clinical data management,  
23 clinical development, information  
24 sciences, regulatory affairs, clinical

1 necessarily listed on this list.

2 There are what I see as job  
3 titles, affairs representative,  
4 team leader, scientist,  
5 biostatistician, programmer,  
6 manager, director.

7 While I do recognize some  
8 names on here as being users --  
9 BY MR. SMITH:

10 Q. Why don't we start with  
11 that.

12 Why don't you identify the  
13 users, please.

14 A. Ronald Leong, Mark Blake,  
15 Jack Schwartz. Those are it.

16 Q. Okay. Are there any titles  
17 listed there that you believe you  
18 probably support but you don't  
19 necessarily recognize the name?

20 A. Yes.

21 Q. Could you identify those,  
22 please.

23 A. The names?

24 Q. Yes. If you want to -- why

1 development, reg ops, QAAS, and that's  
2 it.

3 Q. Can you think of any systems  
4 or applications that you provide support  
5 for that would be used by these persons  
6 or these positions that we haven't  
7 already discussed in this deposition?

8 MR. TORREGROSSA: Objection  
9 to form.

10 THE WITNESS: I'm sorry,  
11 that was a very complex question.  
12 Could I --

13 BY MR. SMITH:

14 Q. Are there any other systems  
15 or applications that your department  
16 supports, GDDIS, that we have not  
17 discussed that would be used by these  
18 people or positions?

19 A. Right.

20 MR. TORREGROSSA: Objection  
21 to form.

22 THE WITNESS: No. The  
23 individuals I identified, no.

24 BY MR. SMITH:



1 Q. Great. Thank you.  
 2 Does GDDIS support external  
 3 scientific affairs?  
 4 A. The title suggests that it's  
 5 an external -- would be an external  
 6 organization, so that's a difficult --  
 7 you're asking me, you know, based on that  
 8 title, I think you're asking me something  
 9 that really probably best be asked of the  
 10 business.  
 11 Q. Does GDDIS support the  
 12 Wilmington clinical information science  
 13 leadership team?  
 14 A. No. We -- I mean, the team  
 15 directly, I would have to say no.  
 16 However, if they use systems that we  
 17 provide, then the answer would be yes.  
 18 Q. You don't know which systems  
 19 they use?  
 20 A. I don't know who's on the  
 21 leadership team.  
 22 Q. I'll show you an  
 23 organizational chart. You can take a  
 24 look at that and see if that helps you.

1 chart, and based on that, there  
 2 are probably systems used by  
 3 personnel or persons reporting to  
 4 those individuals that we support,  
 5 we provide systems to.  
 6 BY MR. SMITH:  
 7 Q. Do you know what systems  
 8 they would use?  
 9 MR. TORREGROSSA: Objection  
 10 to form and scope.  
 11 THE WITNESS: Data  
 12 management. We're talking about  
 13 Wilmington clinical, so I'd have  
 14 to say the data management  
 15 systems, the clinical data  
 16 management systems.  
 17 BY MR. SMITH:  
 18 Q. All right. Does GDDIS have  
 19 any connection with CIS programming?  
 20 MR. TORREGROSSA: Objection  
 21 to form.  
 22 THE WITNESS: If the  
 23 question was, do we have any --  
 24 BY MR. SMITH:

1 MR. TORREGROSSA: Mark that.  
 2 MR. SMITH: We might want to  
 3 mark that as Exhibit 8.  
 4 - - -  
 5 (Deposition Exhibit No.  
 6 Draper-8, US Clinical Information  
 7 Science Organizational Chart,  
 8 Wilmington Clinical Information  
 9 Science Leadership Team, was  
 10 marked for identification.)  
 11 - - -  
 12 MR. TORREGROSSA: Have you  
 13 reviewed it?  
 14 THE WITNESS: Yes, I have.  
 15 BY MR. SMITH:  
 16 Q. Does that help?  
 17 A. Can I have the question  
 18 again.  
 19 - - -  
 20 (The court reporter read the  
 21 pertinent part of the record.)  
 22 - - -  
 23 THE WITNESS: I recognize  
 24 names on this organizational

1 Q. Relationship. Do you have  
 2 any relationship with CIS programming?  
 3 MR. TORREGROSSA: Same  
 4 objection.  
 5 THE WITNESS: Yes.  
 6 BY MR. SMITH:  
 7 Q. What is that?  
 8 A. I believe we provide systems  
 9 that support their business functions.  
 10 Q. Do you know what CIS stands  
 11 for?  
 12 A. Clinical information  
 13 systems.  
 14 Q. And how do you support their  
 15 business systems?  
 16 A. We develop, we deliver and  
 17 we support IT technologies and systems.  
 18 Q. Can you tell me what  
 19 business systems they use?  
 20 A. Business systems would be  
 21 things like Microsoft Office, Excel,  
 22 PowerPoint.  
 23 Q. You would do that for  
 24 clinical development as well, right,

1 GDDIS?  
 2 A. I'm not sure I understand  
 3 the question.  
 4 Q. Would you support business  
 5 services for clinical development?  
 6 A. No.  
 7 Q. Who would do that?  
 8 A. I believe that's IT  
 9 services.  
 10 Q. How about drug safety, do  
 11 you provide any business services to drug  
 12 safety?  
 13 A. I'm not sure I understand  
 14 your use of the word "business services."  
 15 Q. As you defined them as  
 16 servicing products like Microsoft Office.  
 17 A. No. Again, that's provided  
 18 by IT services.  
 19 Q. Does GDDIS provide any  
 20 services to medical communications and  
 21 document management?  
 22 A. Yes.  
 23 Q. What type of services?  
 24 A. Document management

1 pertinent part of the record.)  
 2 - - -  
 3 THE WITNESS: Let me go back  
 4 and correct a statement that I  
 5 said that GDDIS support these  
 6 applications used by medical  
 7 communication and document  
 8 management. The answer is no.  
 9 BY MR. SMITH:  
 10 Q. Do you know who would  
 11 provide IS services to medical  
 12 communications and document management?  
 13 A. That is the commercial IS or  
 14 BIS, medical affairs IS. They're  
 15 referred to a number of different ways,  
 16 but the way I understand and know them,  
 17 it's called business IS.  
 18 MR. SMITH: Mark this as  
 19 number 10, please.  
 20 MR. TORREGROSSA: Is it fair  
 21 to say these are organization  
 22 charts that are coming from  
 23 productions provided by us, sir?  
 24 MR. SMITH: No.

1 services.  
 2 Q. Would PIRs come within that?  
 3 MR. TORREGROSSA: Objection,  
 4 scope.  
 5 THE WITNESS: I'd have to  
 6 look at what document you're  
 7 looking at to help answer that  
 8 question.  
 9 MR. SMITH: Can you mark  
 10 that as Exhibit 9, please.  
 11 THE WITNESS: To know what  
 12 individuals you're referring to,  
 13 what functions.  
 14 - - -  
 15 (Deposition Exhibit No.  
 16 Draper-9, Medical Communications &  
 17 Document Management, was marked  
 18 for identification.)  
 19 - - -  
 20 THE WITNESS: Can I have the  
 21 court reporter read that question  
 22 back to me, please.  
 23 - - -  
 24 (The court reporter read the

1 - - -  
 2 (Deposition Exhibit No.  
 3 Draper-10, Data Management  
 4 Technology, was marked for  
 5 identification.)  
 6 - - -  
 7 THE WITNESS: Can I have the  
 8 question.  
 9 MR. TORREGROSSA: I don't  
 10 think there was one.  
 11 MR. SMITH: No.  
 12 BY MR. SMITH:  
 13 Q. For Exhibit Number 10, is  
 14 data management technology a group or  
 15 team within AstraZeneca that you are  
 16 familiar with?  
 17 A. Yes.  
 18 Q. What is it? What do they  
 19 do?  
 20 A. Well, I'm familiar with  
 21 certain names on here, knowing that we  
 22 provide systems that they and/or their  
 23 personnel may use.  
 24 Q. What systems do you provide?