

## Confidential - Darryl Draper

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1 A. Can you import documents  
2 from Market Pro into eStar? No.  
3 Can I --  
4 Q. Please.  
5 A. EStar is where you review  
6 and approve. You review and approve  
7 those documents. That's simply a  
8 repository of that material.  
9 Market Pro, it's my  
10 understanding, pulls those active  
11 marketing materials into Market Pro.  
12 Q. I'm sorry, your answer was  
13 that Market Pro pulls those materials  
14 into Market Pro? I think you may have  
15 misspoken or that doesn't make sense to  
16 me.  
17 Is that what you meant to  
18 say?  
19 A. Materials that you find in  
20 Market Pro are retrieved by a process, an  
21 automated process, from Market Pro.  
22 That's my understanding.  
23 Q. From Market Pro to Market  
24 Pro?

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1 MR. TORREGROSSA: You're  
2 right. That last one -- why don't  
3 you start over, because you said  
4 Market Pro twice. Go ahead.  
5 THE WITNESS: Market Pro  
6 acquires the active promotional  
7 marketing materials from eStar.  
8 So I may have been using the  
9 word "Market Pro" incorrectly.  
10 BY MR. SMITH:  
11 Q. So the direction is that  
12 materials go from eStar to Market Pro,  
13 not the other way around?  
14 A. Yes.  
15 Q. And do you know what happens  
16 to them in Market Pro?  
17 MR. TORREGROSSA: Let me  
18 interpose an objection on scope  
19 here. This was an area that  
20 should have been inquired into in  
21 Mr. John Dowling's deposition.  
22 You're free to ask this  
23 witness what he knows based on his  
24 personal knowledge.

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1 THE WITNESS: I don't know.  
2 MR. SMITH: For the record,  
3 Market Pro was not listed by Mr.  
4 Pogust as databases that either  
5 one of these witnesses was going  
6 to discuss.  
7 MR. TORREGROSSA: For the  
8 record, Mr. Smith, that record  
9 came from you, not from us. And  
10 those are the ones you asked us to  
11 be prepared about. Just because  
12 you didn't name Market Pro is not  
13 our issue.  
14 MR. SMITH: It came from the  
15 Dechert law firm, which you're a  
16 part of.  
17 MR. TORREGROSSA: Mr. Smith,  
18 I was extensively involved in the  
19 negotiations. We pulled this list  
20 as part of those negotiations from  
21 your folks.  
22 So this list is yours.  
23 Market Pro is a sales and  
24 marketing database that you were

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1 free to inquire about with Mr.  
2 Dowling, and you chose not to.  
3 MR. SMITH: I didn't choose  
4 not to. You haven't disclosed it  
5 to us.  
6 BY MR. SMITH:  
7 Q. Can you export documents  
8 from eStar to anyplace other than Market  
9 Pro?  
10 A. Yes.  
11 Q. What other systems could you  
12 export the documents to?  
13 A. I wouldn't necessarily  
14 export it to a system. You could export  
15 a .pdf of that marketing material onto  
16 your C drive.  
17 Q. Is there a user list for  
18 Market Pro?  
19 MR. TORREGROSSA: For --  
20 hold on. For Market Pro?  
21 MR. SMITH: For Market Pro.  
22 MR. TORREGROSSA: Can I have  
23 a running objection, sir?  
24 MR. SMITH: Sure.

13 (Pages 309 to 312)

1 MR. TORREGROSSA: Thank you.  
2 THE WITNESS: I don't have  
3 knowledge, information,  
4 organization, technical components  
5 of Market Pro.

6 BY MR. SMITH:

7 Q. Has there been any  
8 corruption or loss of information from  
9 eStar, to your knowledge?

10 A. No.

11 Q. There was a system of some  
12 sort that was mentioned yesterday. We  
13 didn't go into it, and I don't know if  
14 the letters were even reported correctly  
15 by the court reporter, although she's  
16 doing a great job, but my reading is  
17 GDMRS.

18 Is that a system, an  
19 AstraZeneca system, to your knowledge?

20 A. Yes.

21 Q. Is GDMRS the correct name of  
22 the system?

23 A. Yes.

24 MR. TORREGROSSA: I think

1 Q. That's because all these  
2 systems we've been discussing are  
3 actually used globally; is that correct?

4 MR. TORREGROSSA: Objection  
5 to form.

6 THE WITNESS: No.

7 BY MR. SMITH:

8 Q. But some of them are?

9 MR. TORREGROSSA: You can  
10 answer that yes or no. That's it.

11 THE WITNESS: Yes.

12 MR. SMITH: Counsel, the  
13 only thing in that letter  
14 regarding foreign materials is  
15 that you weren't going to let us  
16 ask about foreign regulatory  
17 submissions. Everything else is  
18 on the table. I don't know where  
19 you got the idea that we couldn't  
20 talk about anything that was  
21 foreign. It's only foreign  
22 regulatory submissions. We can  
23 talk about foreign access to data,  
24 we can talk about foreign adverse

1 you owe an apology to the court  
2 reporter.

3 MR. SMITH: I owe an apology  
4 to the court reporter.

5 BY MR. SMITH:

6 Q. What does that stand for?

7 A. Global dictionary management  
8 request system.

9 Q. Is that a system that you  
10 support, your department?

11 A. Yes.

12 Q. What is your involvement, if  
13 any, with GDMRS?

14 A. I'm global application  
15 service manager.

16 Q. And what does global mean?

17 A. Sorry. I'm the application  
18 service manager.

19 Q. You're not the global  
20 application service manager?

21 A. I -- the global application  
22 service manager and service manager are  
23 synonymous. I'm sorry I used that word  
24 "global."

1 event reporting, we can talk about  
2 all of that under the terms of  
3 your letter.

4 MR. TORREGROSSA: It  
5 discusses events, is the first  
6 part of my response. And I  
7 believe it was clear from the  
8 negotiations that you were not a  
9 part of that anything foreign you  
10 could submit your own 30(b)6. You  
11 would have the right to do that,  
12 and we would have the right to  
13 object. No one in any of the  
14 other depositions, as far as I am  
15 aware, have violated that  
16 agreement except for you. I think  
17 it was crystal clear. My  
18 objection stands.

19 MR. SMITH: All right. The  
20 language of the letter really  
21 speaks for itself. And in  
22 addition, it includes a sentence  
23 which says, "This does not prevent  
24 questioning concerning the

1 witness' personal knowledge of  
 2 these topics that were reported to  
 3 the United States."  
 4 So we may pursue that a  
 5 little bit further, Mr. Draper.  
 6 BY MR. SMITH:  
 7 Q. So not talking about  
 8 regulatory affairs but talking about in  
 9 regard to GDMRS, if I understand your  
 10 testimony correctly, this is a global  
 11 system, which means it can be accessed by  
 12 related entities in the United Kingdom or  
 13 Sweden or elsewhere; is that correct?  
 14 MR. TORREGROSSA: You can  
 15 answer that yes or no.  
 16 THE WITNESS: Yes.  
 17 BY MR. SMITH:  
 18 Q. Is AMOS a global system?  
 19 MR. TORREGROSSA: You can  
 20 answer that yes or no.  
 21 THE WITNESS: Yes.  
 22 BY MR. SMITH:  
 23 Q. DIPLOMAT?  
 24 MR. TORREGROSSA: Same

1 BY MR. SMITH:  
 2 Q. Is PLANET a global system?  
 3 MR. TORREGROSSA: Same  
 4 instruction.  
 5 THE WITNESS: Yes.  
 6 BY MR. SMITH:  
 7 Q. S-A-M, SAM?  
 8 MR. TORREGROSSA: Same  
 9 instruction.  
 10 THE WITNESS: Yes.  
 11 BY MR. SMITH:  
 12 Q. GESISS?  
 13 MR. TORREGROSSA: Same  
 14 instruction.  
 15 THE WITNESS: Yes.  
 16 BY MR. SMITH:  
 17 Q. AZ IMPACT?  
 18 MR. TORREGROSSA: Same  
 19 instruction.  
 20 THE WITNESS: Yes.  
 21 BY MR. SMITH:  
 22 Q. IIRIS?  
 23 MR. TORREGROSSA: Same  
 24 instruction.

1 instruction.  
 2 THE WITNESS: Yes.  
 3 BY MR. SMITH:  
 4 Q. COOL?  
 5 MR. TORREGROSSA: Same  
 6 instruction.  
 7 THE WITNESS: Yes.  
 8 BY MR. SMITH:  
 9 Q. CRF/DEN?  
 10 MR. TORREGROSSA: Same  
 11 instruction.  
 12 THE WITNESS: No.  
 13 BY MR. SMITH:  
 14 Q. By the way, what did the DEN  
 15 stand for, the D-E-N, if you know?  
 16 A. Data edit notation.  
 17 Q. Can you repeat your answer  
 18 for the court reporter?  
 19 A. I'm sorry. Data edit  
 20 notation.  
 21 Q. Is DIRM a global system?  
 22 MR. TORREGROSSA: Same  
 23 instruction.  
 24 THE WITNESS: No.

1 THE WITNESS: No.  
 2 BY MR. SMITH:  
 3 Q. SAMSON?  
 4 MR. TORREGROSSA: Same  
 5 instruction.  
 6 THE WITNESS: No.  
 7 BY MR. SMITH:  
 8 Q. CLINTRACE?  
 9 MR. TORREGROSSA: Same  
 10 instruction.  
 11 THE WITNESS: Yes.  
 12 BY MR. SMITH:  
 13 Q. GEL?  
 14 MR. TORREGROSSA: Same  
 15 instruction.  
 16 THE WITNESS: Yes.  
 17 BY MR. SMITH:  
 18 Q. SPOLA?  
 19 MR. TORREGROSSA: Same  
 20 instruction.  
 21 THE WITNESS: Yes.  
 22 BY MR. SMITH:  
 23 Q. RAVE?  
 24 MR. TORREGROSSA: Same

1 instruction.  
 2 THE WITNESS: No.  
 3 BY MR. SMITH:  
 4 Q. Would it be if it's  
 5 implemented?  
 6 MR. TORREGROSSA: I'm sorry,  
 7 I didn't catch that.  
 8 Would it be --  
 9 MR. SMITH: If it is  
 10 implemented.  
 11 THE WITNESS: Yes.  
 12 BY MR. SMITH:  
 13 Q. Webster?  
 14 MR. TORREGROSSA: Same  
 15 instruction.  
 16 THE WITNESS: No.  
 17 BY MR. SMITH:  
 18 Q. EStar?  
 19 MR. TORREGROSSA: Same  
 20 instruction.  
 21 THE WITNESS: No.  
 22 Can I -- I just want to make  
 23 sure that I'm answering your  
 24 questions correctly.

1 BY MR. SMITH:  
 2 Q. You're not referring to that  
 3 question, are you?  
 4 A. I was referring to that  
 5 question, yes.  
 6 Q. But the question for all of  
 7 these systems was, are they global or  
 8 not.  
 9 A. Right.  
 10 Q. And the implementation  
 11 question only pertained to RAVE because I  
 12 understood that that's in a trial status.  
 13 Right?  
 14 A. Correct.  
 15 Q. Okay. And it's being  
 16 evaluated?  
 17 A. Just trying to make sure  
 18 that I'm answering your questions  
 19 correctly.  
 20 Q. All right. So that there's  
 21 no question then, Webster is or is not a  
 22 global system?  
 23 A. It is not.  
 24 Q. And eStar?

1 You changed your question a  
 2 few statements back.  
 3 So I just want to be sure  
 4 that the answers are to your  
 5 original question and not your  
 6 last question.  
 7 Can I have some  
 8 clarification?  
 9 MR. TORREGROSSA: You're  
 10 asking if all those answers were  
 11 whether they're global?  
 12 THE WITNESS: That's  
 13 correct.  
 14 MR. TORREGROSSA: Yes.  
 15 That's what he was asking. Right?  
 16 THE WITNESS: Well, he's  
 17 changed the question, so all my  
 18 answers, I just want to, you know,  
 19 for the record, I want to make --  
 20 MR. SMITH: The last  
 21 question was, would it, meaning  
 22 RAVE, be global if it's  
 23 implemented.  
 24 THE WITNESS: Okay.

1 A. No.  
 2 Q. And CTM is or was a global  
 3 system?  
 4 A. Was.  
 5 Q. And GDMRS is global. Right?  
 6 A. Yes.  
 7 Q. Was STEP 2000 global?  
 8 A. No.  
 9 MR. TORREGROSSA: When you  
 10 get to a good spot, if we could  
 11 take a break.  
 12 MR. SMITH: Yes. I just  
 13 want to finish this line and then  
 14 we'll --  
 15 MR. TORREGROSSA: Okay, sir.  
 16 MR. SMITH: Okay.  
 17 BY MR. SMITH:  
 18 Q. Is Market Pro global?  
 19 A. No.  
 20 MR. TORREGROSSA: Scope  
 21 objection.  
 22 THE WITNESS: To the best of  
 23 my knowledge, it is not global.  
 24 BY MR. SMITH:

1 Q. Is CANDAs global?  
 2 A. Sorry, I just want to -- to  
 3 the best of my personal knowledge, it's  
 4 not global.  
 5 Q. With regard to Market Pro?  
 6 A. Yes.  
 7 Q. Is CANDAs global?  
 8 A. I can't answer that yes or  
 9 no.  
 10 Q. Why?  
 11 A. Again, what I am able to  
 12 talk about are the technical aspects,  
 13 kind of what its purpose was. But  
 14 decisions by the business to use it for  
 15 globally as opposed to strictly US, that  
 16 would have been a business decision. And  
 17 IT/IS aren't always that aware of those  
 18 decisions.  
 19 MR. TORREGROSSA: Objection,  
 20 scope.  
 21 BY MR. SMITH:  
 22 Q. Is your answer with  
 23 reference to CANDAs only? Is that what  
 24 you're referring to?

1 A. No.  
 2 Q. Is it a database?  
 3 A. No.  
 4 Q. What type of system is it?  
 5 A. It's an application very  
 6 similar to what you -- such as Adobe  
 7 Acrobat, if that helps.  
 8 Q. What are the dates of use  
 9 for CANDAs?  
 10 A. I believe it was 19 -- early  
 11 '90s.  
 12 Q. Is it still in use today?  
 13 A. No.  
 14 Q. When was it retired?  
 15 A. 2000.  
 16 Q. What replaced it?  
 17 A. Well, ECTD.  
 18 Q. What is ECTD?  
 19 A. Electronic -- sorry.  
 20 Electronic -- ECDT. Electronic common --  
 21 sorry.  
 22 MR. TORREGROSSA: Take your  
 23 time. Take your time.  
 24 THE WITNESS: ECTD,

1 A. Yes.  
 2 Q. Did you or your department  
 3 provide or do you now provide support for  
 4 CANDAs, IS support?  
 5 A. We did.  
 6 Q. And what was your  
 7 involvement?  
 8 A. I did not have any direct  
 9 involvement.  
 10 Q. What does CANDAs stand for,  
 11 the name?  
 12 A. Computer assisted NDA.  
 13 Q. Can you describe CANDAs?  
 14 A. Yes. It's an application  
 15 used to navigate an NDA.  
 16 Q. Does it perform any tracking  
 17 function?  
 18 MR. TORREGROSSA: Objection  
 19 to the form.  
 20 THE WITNESS: Not to the  
 21 best of my knowledge, no.  
 22 BY MR. SMITH:  
 23 Q. Is it a repository for  
 24 documents?

1 electronic common technical  
 2 document.  
 3 MR. TORREGROSSA: You made  
 4 Mr. Smith wear his pencil down.  
 5 THE WITNESS: Apologies.  
 6 It's the world I live in, the  
 7 acronyms.  
 8 BY MR. SMITH:  
 9 Q. What is ECTD?  
 10 A. ECTD is a regulatory  
 11 standard or format.  
 12 Q. How is it used?  
 13 A. It's used for electronic  
 14 submissions.  
 15 Q. Is that an application  
 16 supported by you or your department?  
 17 A. It's not an application.  
 18 It's a format.  
 19 Q. A format.  
 20 Would that be used globally?  
 21 MR. TORREGROSSA: You can  
 22 answer that yes or no.  
 23 THE WITNESS: I'm sorry, can  
 24 I have the question again, please?

1 BY MR. SMITH:  
 2 Q. Would ECTD be used globally?  
 3 MR. TORREGROSSA: You can  
 4 answer that yes or no.  
 5 THE WITNESS: Yes.  
 6 MR. SMITH: Why don't we  
 7 take a break.  
 8 MR. TORREGROSSA: Thank you,  
 9 sir.  
 10 - - -  
 11 (A recess occurred.)  
 12 - - -  
 13 BY MR. SMITH:  
 14 Q. Who is the business owner  
 15 for Market Pro, if you know?  
 16 MR. TORREGROSSA: Same  
 17 running objection.  
 18 THE WITNESS: Well, I  
 19 thought we were talking about  
 20 CANDAs.  
 21 BY MR. SMITH:  
 22 Q. We're talking about lots of  
 23 things.  
 24 A. Okay. I don't know.

1 Q. Is there any reason why you  
 2 couldn't make copies of users guides or  
 3 IS documentation for CANDAs?  
 4 MR. TORREGROSSA: Objection  
 5 to form, scope.  
 6 You can answer.  
 7 THE WITNESS: Yes.  
 8 BY MR. SMITH:  
 9 Q. What would that reason be?  
 10 MR. TORREGROSSA: Would  
 11 there be any reason you couldn't?  
 12 THE WITNESS: I'm sorry.  
 13 I'm not sure I understood the  
 14 question.  
 15 MR. TORREGROSSA: Right.  
 16 Could you get the question back,  
 17 please?  
 18 MR. SMITH: We'll give you a  
 19 second bite at the apple.  
 20 Would there be any reason  
 21 why you couldn't make a copy of  
 22 the user guide or the IS  
 23 documentation for CANDAs?  
 24 MR. TORREGROSSA: Objection

1 Q. Do you know who the business  
 2 owner is for CANDAs? You anticipated my  
 3 next question.  
 4 A. I can't recall.  
 5 Q. And who would you ask to  
 6 find that out?  
 7 A. Probably Bob Keesler.  
 8 Q. Is there an application  
 9 service manager for CANDAs?  
 10 A. I think I would go to Bob  
 11 Keesler to identify who that individual  
 12 was.  
 13 Q. Is any information collected  
 14 in CANDAs or is it just a tool?  
 15 A. It's a tool. It's a tool,  
 16 yes.  
 17 Q. Do you know if there are  
 18 training materials for CANDAs?  
 19 A. I would expect there to be  
 20 training materials or user guides.  
 21 Q. Would there be any IS  
 22 documentation for CANDAs?  
 23 A. I would expect there to be  
 24 IS documentation.

1 to form, scope.  
 2 THE WITNESS: No.  
 3 BY MR. SMITH:  
 4 Q. Was there a predecessor to  
 5 CANDAs?  
 6 A. No.  
 7 Q. Is there any sort of search  
 8 or report capability in CANDAs?  
 9 A. In the sense that you can  
 10 navigate through the electronic NDA, and  
 11 there are, let's say, hyperlinks to  
 12 various sections, similar to what you'd  
 13 call a bookmark in, say, like Adobe  
 14 Reader.  
 15 Q. Thank you.  
 16 Who's the vendor for CANDAs?  
 17 A. AstraZeneca.  
 18 Q. Do you know who the vendor  
 19 is for Market Pro?  
 20 MR. TORREGROSSA: Scope.  
 21 THE WITNESS: No.  
 22 BY MR. SMITH:  
 23 Q. The ECTD, is there a vendor  
 24 for that?

1 A. I guess you could call them  
 2 a vendor.  
 3 Q. Is it the FDA?  
 4 A. Yes.  
 5 Q. Okay.  
 6 A. Regulatory authorities.  
 7 Q. Who's the vendor for GDMRS?  
 8 A. AstraZeneca.  
 9 Q. Is there a user list for  
 10 GDMRS?  
 11 A. If what you mean by a list  
 12 is are we able to identify the users of  
 13 GDMRS, yes.  
 14 Q. Can you make a copy of the  
 15 list of users for GDMRS?  
 16 A. Yes.  
 17 Q. Was there a predecessor to  
 18 GDMRS?  
 19 A. Not that I'm aware of.  
 20 Q. Can you describe that  
 21 system?  
 22 A. Yes. And I'm trying to  
 23 think of a way to come up with an  
 24 explanation to give you and help you

1 manager.  
 2 Q. Who's the business partner?  
 3 A. Nate Blevins.  
 4 Q. Business owner?  
 5 A. Hillary Vass.  
 6 Q. I didn't catch that last  
 7 name?  
 8 A. Vass, Hillary Vass.  
 9 Q. Can you spell that?  
 10 A. I believe it's V-A-S-S.  
 11 Q. What is the data source for  
 12 the GDMRS?  
 13 A. A user requesting -- making  
 14 a request.  
 15 Q. Would that be somebody on  
 16 the study team?  
 17 A. No. It could be an  
 18 individual on a study team. I think it's  
 19 primarily used by people who are entering  
 20 data into the clinical data management  
 21 system.  
 22 Q. Now, I'm not quite clear on  
 23 this, but let's say when development was  
 24 started on -- when did the system come

1 understand what GDMRS is.  
 2 So the answer is yes. It  
 3 allows folks to request additions to,  
 4 say, a drug dictionary. For instance, if  
 5 we were -- we have a product that's in  
 6 the clinical trial and we need to be able  
 7 to identify that somehow, a request would  
 8 be placed to add that to the drug  
 9 dictionary and/or the medical dictionary.  
 10 Q. I don't quite understand.  
 11 To add what to the medical  
 12 dictionary?  
 13 A. To add a term or a drug to a  
 14 medical dictionary or to a dictionary.  
 15 It's just a simple request system.  
 16 Q. And do you or your  
 17 department support that system?  
 18 A. Yes.  
 19 Q. Do you have any personal  
 20 involvement?  
 21 A. I have direct involvement.  
 22 Q. And what is your  
 23 involvement?  
 24 A. I'm the application service

1 into use? Let's start there.  
 2 A. I believe it was around  
 3 2000.  
 4 Q. Approximately how many terms  
 5 would be defined in the GDMRS?  
 6 A. You wouldn't define terms.  
 7 I don't believe you define terms in  
 8 GDMRS. You simply ask for something to  
 9 be added, say, to a dictionary.  
 10 Q. So what is added? If it's  
 11 not defined, is it a search term?  
 12 A. It may not appear in a  
 13 dictionary, or it may not be retrieved --  
 14 being retrieved appropriately during the  
 15 coding of data. So you might request a  
 16 synonym be added to the dictionary.  
 17 Q. Who uses the dictionary?  
 18 MR. TORREGROSSA: Objection  
 19 to form, scope.  
 20 THE WITNESS: Again, GDMRS  
 21 is not a dictionary. Dictionaries  
 22 in general are used by anybody who  
 23 wants to code medical information.  
 24 BY MR. SMITH:

1 Q. What other systems does the  
2 GDMRS interface with?  
3 A. It doesn't.  
4 Q. I'm having trouble  
5 understanding how the information that's  
6 put into GDMRS is used.  
7 Can you explain that for me?  
8 A. How the information is used.  
9 You're asking me a question that, if I  
10 was in the business, a business person  
11 coding medical information, I could  
12 explain to you how that was being used.  
13 It's like asking me, you know, how my  
14 mother uses her car. I mean, I'm  
15 assuming that she uses it to travel back  
16 and forth to work.  
17 Q. That's exactly what I mean,  
18 is think of it, it's like a car, and tell  
19 me what you would use this car for.  
20 MR. TORREGROSSA: Objection,  
21 scope.  
22 THE WITNESS: Again, it's to  
23 request changes to dictionaries,  
24 to medical dictionaries.

1 BY MR. SMITH:  
2 Q. To which dictionaries?  
3 A. MedRA drug dictionary.  
4 Q. And what is MedRA?  
5 A. MedRA is a medical coding  
6 dictionary. Precisely what it stands  
7 for, again, you're better off asking  
8 the -- you know, someone who uses the  
9 MedRA dictionary on a day-to-day basis.  
10 Q. Is MedRA, that is M-E-D-R-A?  
11 A. M-E-D -- I believe it's D,  
12 capital D, capital R, capital A. You can  
13 search on the Internet and find it quite  
14 easily.  
15 Q. I mean, that's not an  
16 AstraZeneca system, MedRA. Right?  
17 A. No, it's not a system. It's  
18 a dictionary.  
19 Q. It's not an AstraZeneca  
20 dictionary?  
21 A. No, it's not.  
22 Q. And the drug dictionary you  
23 mentioned, what is that?  
24 MR. TORREGROSSA: Objection,

1 form and scope.  
2 THE WITNESS: It's a  
3 dictionary of drugs on the -- on  
4 the market.  
5 BY MR. SMITH:  
6 Q. What is STEP 2000?  
7 A. It's the predecessor system  
8 to eStar.  
9 Q. What does Step stand for, do  
10 you know?  
11 A. I believe it's just a name.  
12 Q. What were the dates of use  
13 for STEP 2000?  
14 A. I would have to -- I'd have  
15 to speak directly to Dina O'Brien to  
16 understand when it was first used. It  
17 was --  
18 Q. And what's her connection  
19 with STEP 2000?  
20 A. Well, she is the now current  
21 system owner for the system that is used  
22 within AstraZeneca today, which is eStar.  
23 Q. Do you know who the  
24 application service manager was for STEP

1 2000?  
2 A. Again, I'd have to speak to  
3 Dina.  
4 Q. Same for the business  
5 partner?  
6 A. Yes.  
7 You know, the data was  
8 migrated into eStar, so I would expect  
9 any inquiries, the active data, the  
10 active marketing materials.  
11 Q. Were the data sources for  
12 STEP 2000 the study teams and the study  
13 centers?  
14 MR. TORREGROSSA: Objection  
15 to form. I think that confuses  
16 things.  
17 THE WITNESS: I'm sorry, I  
18 didn't understand the question.  
19 BY MR. SMITH:  
20 Q. Were the data sources for  
21 STEP 2000 the study teams and the study  
22 centers?  
23 MR. TORREGROSSA: Objection  
24 to form.



1 THE WITNESS: Again, I'd  
 2 speak to Dina, try to get a better  
 3 understanding of that.  
 4 MR. TORREGROSSA: Mr. Smith,  
 5 it was the legacy system to eStar.  
 6 MR. SMITH: Uh-huh.  
 7 MR. TORREGROSSA: Okay.  
 8 Yes, and if you direct certain  
 9 inquiries to me after this  
 10 deposition, I will inquire whether  
 11 some of this information is still  
 12 available for STEP 2000.  
 13 MR. SMITH: You'll answer my  
 14 20 questions on STEP 2000?  
 15 MR. TORREGROSSA: I will try  
 16 and get you information, yes, sir.  
 17 MR. SMITH: Okay.  
 18 BY MR. SMITH:  
 19 Q. Let's take a look at  
 20 CLINTRACE.  
 21 Can you tell me what the  
 22 name means?  
 23 A. It doesn't really -- as far  
 24 as I understand, it doesn't really have

1 any particular...  
 2 Q. That's fine.  
 3 Can you describe CLINTRACE  
 4 for me?  
 5 A. It is a data management  
 6 system used to enter, track and report  
 7 adverse events.  
 8 Q. Is it used to submit adverse  
 9 events?  
 10 A. It's used to produce output  
 11 that is ultimately the information  
 12 submitted to a regulatory authority, yes.  
 13 Q. Does it interface with  
 14 another system to submit adverse event  
 15 reports?  
 16 A. Yes.  
 17 Q. What system is that?  
 18 A. GES.  
 19 Q. Is GES different from GEL?  
 20 A. Yes.  
 21 Q. What is GES?  
 22 A. That's a system used to  
 23 submit electronic ICSRs to regulatory  
 24 bodies.

1 Q. What does GES stand for, if  
 2 you know?  
 3 A. Global electronic  
 4 submissions.  
 5 Q. What does ICSR stand for?  
 6 A. Individual case safety  
 7 report.  
 8 Q. What are the dates of use  
 9 for CLINTRACE?  
 10 A. March 31, 1998.  
 11 MR. TORREGROSSA: Is that  
 12 specific enough, or were you  
 13 looking for something more?  
 14 MR. SMITH: That's pretty  
 15 good.  
 16 BY MR. SMITH:  
 17 Q. And that system is currently  
 18 used today?  
 19 A. Yes.  
 20 Q. Is there a data map for  
 21 CLINTRACE?  
 22 A. I believe that the vendor  
 23 materials has information with regard to  
 24 a data map.

1 Q. Do you know if it's in a  
 2 diagram or schematic form?  
 3 A. I don't believe that that  
 4 material has actual -- there  
 5 are diagrams. There are diagrams. To  
 6 what detail level, I'm not recalling.  
 7 Q. What is your involvement  
 8 with CLINTRACE?  
 9 A. I was part of the  
 10 implementation team, as well as the  
 11 architect for AstraZeneca implementation.  
 12 Q. What are your current  
 13 responsibilities with regard to  
 14 CLINTRACE?  
 15 A. I don't have any day-to-day  
 16 direct responsibilities for CLINTRACE.  
 17 Q. Is there an ERD for  
 18 CLINTRACE?  
 19 A. Yes. I believe the vendor  
 20 documentation does have specific  
 21 information pertaining to relationships  
 22 of data.  
 23 Q. Is there a system map or  
 24 diagram?

1 A. Again, I recall diagrams in  
 2 that documentation, you know, the  
 3 complete picture of the data map.  
 4 There's various components to CLINTRACE,  
 5 and I believe those components are  
 6 detailed, either, you know, textually.  
 7 Again, I don't recall precisely whether  
 8 or not there was like a picture. But  
 9 that information would be available in  
 10 that material.  
 11 Q. Some form of written  
 12 documentation that would include that  
 13 information is available then?  
 14 A. Yes.  
 15 Q. Are there user guides for  
 16 CLINTRACE?  
 17 A. Yes, both AstraZeneca and  
 18 vendor.  
 19 Q. And there's IS documentation  
 20 for CLINTRACE?  
 21 A. Yes.  
 22 Q. Who's the application  
 23 service manager?  
 24 A. Paul Seymour.

1 Q. Is there both a US business  
 2 owner and a global business owner?  
 3 MR. TORREGROSSA: You can  
 4 answer that yes or no.  
 5 THE WITNESS: Yes.  
 6 BY MR. SMITH:  
 7 Q. Is that two different  
 8 people?  
 9 A. Can I go back to the  
 10 question, please, the question that I've  
 11 answered already?  
 12 Q. Is there both a US business  
 13 owner and a global business owner, and  
 14 you said yes. And now I'm asking, could  
 15 they be the same person.  
 16 Are they the same person, or  
 17 are they two different people?  
 18 A. Al Fowkes is the -- I'm  
 19 sorry, system owner. I'm confused now.  
 20 Q. Business owner?  
 21 A. Business owner. Okay.  
 22 No, there is a system owner.  
 23 There's not multiple owners.  
 24 Q. What types of information

1 Q. And he would be the global  
 2 application service manager. Correct?  
 3 A. Yes.  
 4 Q. Who's the business partner?  
 5 A. Business partner is Al  
 6 Fowkes.  
 7 Q. How do you spell Fowkes?  
 8 A. F-O-K-E-S, I believe.  
 9 Q. No L?  
 10 A. I believe it's F-O-W-K-E-S,  
 11 Fowkes.  
 12 Q. Thank you.  
 13 Business owner?  
 14 A. Business owner. Used to be  
 15 Barry Erdle, but I think it's -- I have  
 16 difficulty pronouncing the name, is it  
 17 Jacques, I'd have to look at the exact  
 18 spelling, but I have difficulty  
 19 pronouncing it. It's a difficult name to  
 20 pronounce.  
 21 MR. TORREGROSSA: We'll get  
 22 that for you.  
 23 THE WITNESS: Sorry.  
 24 BY MR. SMITH:

1 are in CLINTRACE?  
 2 A. Types of information would  
 3 be adverse events.  
 4 Q. And those would be as  
 5 documents?  
 6 MR. TORREGROSSA: Objection  
 7 to form, scope.  
 8 Go ahead.  
 9 THE WITNESS: The CLINTRACE  
 10 is a data entry system, so it's  
 11 very similar to AMOS in that you  
 12 enter data onto forms or screens.  
 13 So it's data, not document.  
 14 BY MR. SMITH:  
 15 Q. What's the difference  
 16 between AMOS and CLINTRACE?  
 17 A. Well, CLINTRACE is the  
 18 adverse events data management system,  
 19 and AMOS is the clinical data management  
 20 system.  
 21 Q. Thank you.  
 22 A. I'll just say, safety data,  
 23 clinical data. So we're required to  
 24 report things to regulatory authorities.

1 That data would be housed in CLINTRACE.  
 2 MR. TORREGROSSA: I think he  
 3 was making a technical comparison  
 4 versus a...  
 5 BY MR. SMITH:  
 6 Q. Can the same information be  
 7 entered into CLINTRACE and AMOS? Can an  
 8 adverse event report be entered into both  
 9 CLINTRACE and AMOS?  
 10 A. No. I think, again, I'm  
 11 going to -- this is more of a business  
 12 process question. However, I'll try to  
 13 give you a technical understanding  
 14 underneath CLINTRACE.  
 15 There are adverse events  
 16 experienced by the patient that are  
 17 recorded in the CLINTRACE database.  
 18 Q. Is that by a patient in a  
 19 clinical study or a patient anywhere?  
 20 MR. TORREGROSSA: Objection  
 21 to form, scope.  
 22 BY MR. SMITH:  
 23 Q. I'm trying to clarify your  
 24 answers.

1 Right?  
 2 A. Various categories in  
 3 CLINTRACE, the way to categorize records  
 4 would be spontaneous investigator study  
 5 literature.  
 6 Does that help?  
 7 Q. That does help.  
 8 MR. TORREGROSSA: Excuse me.  
 9 Let me interpose a form and scope  
 10 objection.  
 11 Go ahead, Mr. Smith.  
 12 BY MR. SMITH:  
 13 Q. Any other categories of  
 14 adverse events that you can think of?  
 15 MR. TORREGROSSA: Same  
 16 objections.  
 17 THE WITNESS: Those are the  
 18 three very high level technical --  
 19 those are the -- what you call  
 20 them, like pick list items that  
 21 you find in the application.  
 22 BY MR. SMITH:  
 23 Q. Did you say pick list or  
 24 pink list?

1 Are you referring to a  
 2 patient in a clinical study or to any  
 3 patient?  
 4 MR. TORREGROSSA: Same  
 5 objections.  
 6 THE WITNESS: It's a -- it  
 7 could be a patient in a clinical  
 8 study. It could also be a  
 9 spontaneous.  
 10 BY MR. SMITH:  
 11 Q. With regard to CLINTRACE,  
 12 the source could be either from a  
 13 clinical study or a spontaneous report,  
 14 in CLINTRACE.  
 15 Is that your answer?  
 16 MR. TORREGROSSA: Same  
 17 objections.  
 18 THE WITNESS: My answer is  
 19 there are adverse event reports in  
 20 CLINTRACE.  
 21 BY MR. SMITH:  
 22 Q. Right. And the source could  
 23 be, a possible source could be a  
 24 spontaneous report not from a study.

1 A. Pick list.  
 2 Q. Pick list.  
 3 A. I'm trying to give you a  
 4 technical understanding of the database.  
 5 Q. So technically, if one  
 6 enters an adverse event into the  
 7 CLINTRACE database, I envision a pick list  
 8 to be like a dropdown list or perhaps  
 9 where you could check off whether it's  
 10 spontaneous, investigator study or  
 11 literature.  
 12 How accurate is that?  
 13 A. That's accurate.  
 14 Q. Do you believe there are  
 15 other choices on the pick list other than  
 16 those three?  
 17 A. I think those are the three.  
 18 Q. What other fields are there  
 19 in CLINTRACE?  
 20 A. Reporter, narrative, patient  
 21 initials, age group. I could probably  
 22 talk for a few hours on all of the  
 23 fields. There's quite extensive  
 24 information collected.