## Confidential - Darryl Draper

		Page 309			Page 311
1	A. Can you import documents		1	THE WITNESS: I don't know.	
2	from Market Pro into eStar? No.		2	MR. SMITH: For the record,	
3	Can I		3	Market Pro was not listed by Mr.	
4	Q. Please.		4	Pogust as databases that either	
5	A. EStar is where you review		5	one of these witnesses was going	
6	and approve. You review and approve		6	to discuss.	
7	those documents. That's simply a		7	MR. TORREGROSSA: For the	
8					
	repository of that material.		8	record, Mr. Smith, that record	
9	Market Pro, it's my		9	came from you, not from us. And	
10	understanding, pulls those active		10	those are the ones you asked us to	
11	marketing materials into Market Pro.		11	be prepared about. Just because	
12	Q. I'm sorry, your answer was		12	you didn't name Market Pro is not	
13	that Market Pro pulls those materials		13	our issue.	
14	into Market Pro? I think you may have		14	MR. SMITH: It came from the	
15	misspoken or that doesn't make sense to		15	Dechert law firm, which you're a	
16	me.		16	part of.	
17	Is that what you meant to		17	MR. TORREGROSSA: Mr. Smith,	
18	say?		18	I was extensively involved in the	
19	A. Materials that you find in		19	negotiations. We pulled this list	
20	Market Pro are retrieved by a process, an		20	as part of those negotiations from	
21	automated process, from Market Pro.		21	your folks.	
22	That's my understanding.		22	So this list is yours.	
23	Q. From Market Pro to Market		23	Market Pro is a sales and	
24	Pro?		24	marketing database that you were	
			- 1	marketing database that you were	
		Page 310			Page 312
1	MR. TORREGROSSA: You're	Page 310	1	free to inquire about with Mr.	Page 312
1		Page 310	1 2	free to inquire about with Mr. Dowling, and you chose not to.	Page 312
2	right. That last one why don't	Page 310	2	Dowling, and you chose not to.	Page 312
2	right. That last one why don't you start over, because you said	Page 310	2 3	Dowling, and you chose not to.  MR. SMITH: I didn't choose	Page 312
2 3 4	right. That last one why don't you start over, because you said Market Pro twice. Go ahead.	Page 310	2 3 4	Dowling, and you chose not to.  MR. SMITH: I didn't choose not to. You haven't disclosed it	Page 312
2 3 4 5	right. That last one why don't you start over, because you said Market Pro twice. Go ahead. THE WITNESS: Market Pro	Page 310	2 3 4 5	Dowling, and you chose not to.  MR. SMITH: I didn't choose not to. You haven't disclosed it to us.	Page 312
2 3 4 5 6	right. That last one why don't you start over, because you said Market Pro twice. Go ahead. THE WITNESS: Market Pro acquires the active promotional	Page 310	2 3 4 5 6	Dowling, and you chose not to.  MR. SMITH: I didn't choose not to. You haven't disclosed it to us.  BY MR. SMITH:	Page 312
2 3 4 5 6 7	right. That last one why don't you start over, because you said Market Pro twice. Go ahead. THE WITNESS: Market Pro acquires the active promotional marketing materials from eStar.	Page 310	2 3 4 5 6 7	Dowling, and you chose not to.  MR. SMITH: I didn't choose not to. You haven't disclosed it to us.  BY MR. SMITH: Q. Can you export documents	Page 312
2 3 4 5 6 7 8	right. That last one why don't you start over, because you said Market Pro twice. Go ahead.  THE WITNESS: Market Pro acquires the active promotional marketing materials from eStar.  So I may have been using the	Page 310	2 3 4 5 6 7 8	Dowling, and you chose not to.  MR. SMITH: I didn't choose not to. You haven't disclosed it to us.  BY MR. SMITH: Q. Can you export documents from eStar to anyplace other than Market	Page 312
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13 (Pages 309 to 312)

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		Page 313			Page 315
1	MR. TORREGROSSA: Thank you.		1	Q. That's because all these	
2	THE WITNESS: I don't have		2	systems we've been discussing are	
3	knowledge, information,		3	actually used globally; is that correct?	
4	organization, technical components		4	MR. TORREGROSSA: Objection	
5	of Market Pro.		5	to form.	
6	BY MR. SMITH:		6	THE WITNESS: No.	
7	Q. Has there been any		7	BY MR. SMITH:	
8	corruption or loss of information from		8	Q. But some of them are?	
9	eStar, to your knowledge?		9	MR. TORREGROSSA: You can	
10	A. No.		10	answer that yes or no. That's it.	
11	Q. There was a system of some		11	THE WITNESS: Yes.	
12	sort that was mentioned yesterday. We		12	MR. SMITH: Counsel, the	
13	didn't go into it, and I don't know if		13	only thing in that letter	
14	the letters were even reported correctly		14	regarding foreign materials is	
15	by the court reporter, although she's		15	that you weren't going to let us	
16	doing a great job, but my reading is		16	ask about foreign regulatory	
17	GDMRS.		17	submissions. Everything else is	
18	Is that a system, an		18	on the table. I don't know where	
19	AstraZeneca system, to your knowledge?		19	you got the idea that we couldn't	
20	A. Yes.		20	talk about anything that was	
21	Q. Is GDMRS the correct name of		21	foreign. It's only foreign	
22	the system?		22	regulatory submissions. We can	
23	A. Yes.		23	talk about foreign access to data,	
24	MR. TORREGROSSA: I think		24	we can talk about foreign adverse	
		Page 314			Page 316
1	you owe an apology to the court	Page 314	1	event reporting, we can talk about	Page 316
2	you owe an apology to the court reporter.	Page 314	1 2	event reporting, we can talk about all of that under the terms of	Page 316
	·	Page 314		all of that under the terms of your letter.	Page 316
2 3 4	reporter.  MR. SMITH: I owe an apology to the court reporter.	Page 314	2	all of that under the terms of	Page 316
2 3	reporter.  MR. SMITH: I owe an apology	Page 314	2 3	all of that under the terms of your letter.	Page 316
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2 3 4 5	reporter.  MR. SMITH: I owe an apology to the court reporter.  BY MR. SMITH:	Page 314	2 3 4 5	all of that under the terms of your letter.  MR. TORREGROSSA: It discusses events, is the first	Page 316
2 3 4 5 6	reporter.  MR. SMITH: I owe an apology to the court reporter.  BY MR. SMITH:  Q. What does that stand for?	Page 314	2 3 4 5 6	all of that under the terms of your letter.  MR. TORREGROSSA: It discusses events, is the first part of my response. And I	Page 316
2 3 4 5 6 7	reporter.  MR. SMITH: I owe an apology to the court reporter.  BY MR. SMITH:  Q. What does that stand for?  A. Global dictionary management	Page 314	2 3 4 5 6 7	all of that under the terms of your letter.  MR. TORREGROSSA: It discusses events, is the first part of my response. And I believe it was clear from the	Page 316
2 3 4 5 6 7 8	reporter.  MR. SMITH: I owe an apology to the court reporter.  BY MR. SMITH:  Q. What does that stand for?  A. Global dictionary management request system.	Page 314	2 3 4 5 6 7 8	all of that under the terms of your letter.  MR. TORREGROSSA: It discusses events, is the first part of my response. And I believe it was clear from the negotiations that you were not a	Page 316
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2 3 4 5 6 7 8 9 10 11 12	reporter.  MR. SMITH: I owe an apology to the court reporter.  BY MR. SMITH: Q. What does that stand for? A. Global dictionary management request system. Q. Is that a system that you support, your department? A. Yes. Q. What is your involvement, if	Page 314	2 3 4 5 6 7 8 9 10 11 12	all of that under the terms of your letter.  MR. TORREGROSSA: It discusses events, is the first part of my response. And I believe it was clear from the negotiations that you were not a part of that anything foreign you could submit your own 30(b)6. You would have the right to do that, and we would have the right to	Page 316
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	Page 317			Page 319
1	witness' personal knowledge of	1	BY MR. SMITH:	
2	these topics that were reported to	2	Q. Is PLANET a global system?	
3	the United States."	3	MR. TORREGROSSA: Same	
4	So we may pursue that a	4	instruction.	
5	little bit further, Mr. Draper.	5	THE WITNESS: Yes.	
6	BY MR. SMITH:	6	BY MR. SMITH:	
7	Q. So not talking about	7	Q. S-A-M, SAM?	
8	regulatory affairs but talking about in	8	MR. TORREGROSSA: Same	
9	regard to GDMRS, if I understand your	9	instruction.	
10	testimony correctly, this is a global	10	THE WITNESS: Yes.	
11	system, which means it can be accessed by	11	BY MR. SMITH:	
12	related entities in the United Kingdom or	12	Q. GESISS?	
13	Sweden or elsewhere; is that correct?	13	MR. TORREGROSSA: Same	
14	MR. TORREGROSSA: You can	14	instruction.	
15		15	THE WITNESS: Yes.	
	answer that yes or no. THE WITNESS: Yes.	16	BY MR. SMITH:	
16 17	BY MR. SMITH:	17		
18			Q. AZ IMPACT?	
19	Q. Is AMOS a global system? MR. TORREGROSSA: You can	18 19	MR. TORREGROSSA: Same	
1		20	instruction.	
20	answer that yes or no.		THE WITNESS: Yes.	
21	THE WITNESS: Yes.	21	BY MR. SMITH:	
22	BY MR. SMITH:	22	Q. IIRIS?	
23	Q. DIPLOMAT?	23 24	MR. TORREGROSSA: Same instruction.	
24	MR. TORREGROSSA: Same	24	Instruction.	
	Page 318			Page 320
	Page 318 instruction.	1	THE WITNESS: No.	Page 320
1 2	instruction.	1 2	THE WITNESS: No. BY MR. SMITH:	Page 320
2	instruction. THE WITNESS: Yes.	2	BY MR. SMITH:	Page 320
2 3	instruction.  THE WITNESS: Yes.  BY MR. SMITH:	2 3	BY MR. SMITH: Q. SAMSON?	Page 320
2 3 4	instruction. THE WITNESS: Yes. BY MR. SMITH: Q. COOL?	2 3 4	BY MR. SMITH: Q. SAMSON? MR. TORREGROSSA: Same	Page 320
2 3 4 5	instruction. THE WITNESS: Yes. BY MR. SMITH: Q. COOL? MR. TORREGROSSA: Same	2 3 4 5	BY MR. SMITH: Q. SAMSON? MR. TORREGROSSA: Same instruction.	Page 320
2 3 4 5 6	instruction. THE WITNESS: Yes. BY MR. SMITH: Q. COOL? MR. TORREGROSSA: Same instruction.	2 3 4 5 6	BY MR. SMITH: Q. SAMSON? MR. TORREGROSSA: Same instruction. THE WITNESS: No.	Page 320
2 3 4 5 6 7	instruction. THE WITNESS: Yes. BY MR. SMITH: Q. COOL? MR. TORREGROSSA: Same instruction. THE WITNESS: Yes.	2 3 4 5 6 7	BY MR. SMITH: Q. SAMSON? MR. TORREGROSSA: Same instruction. THE WITNESS: No. BY MR. SMITH:	Page 320
2 3 4 5 6 7 8	instruction. THE WITNESS: Yes. BY MR. SMITH: Q. COOL? MR. TORREGROSSA: Same instruction. THE WITNESS: Yes. BY MR. SMITH:	2 3 4 5 6 7 8	BY MR. SMITH: Q. SAMSON? MR. TORREGROSSA: Same instruction. THE WITNESS: No. BY MR. SMITH: Q. CLINTRACE?	Page 320
2 3 4 5 6 7 8 9	instruction. THE WITNESS: Yes. BY MR. SMITH: Q. COOL? MR. TORREGROSSA: Same instruction. THE WITNESS: Yes. BY MR. SMITH: Q. CRF/DEN?	2 3 4 5 6 7 8 9	BY MR. SMITH: Q. SAMSON? MR. TORREGROSSA: Same instruction. THE WITNESS: No. BY MR. SMITH: Q. CLINTRACE? MR. TORREGROSSA: Same	Page 320
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		Page 321			Page 323
1	instruction.		1	BY MR. SMITH:	
2	THE WITNESS: No.		2	Q. You're not referring to that	
3	BY MR. SMITH:		3	question, are you?	
1					
4	Q. Would it be if it's		4	A. I was referring to that	
5	implemented?		5	question, yes.	
6	MR. TORREGROSSA: I'm sorry,		6	Q. But the question for all of	
7	I didn't catch that.		7	these systems was, are they global or	
8	Would it be		8	not.	
9	MR. SMITH: If it is		9	A. Right.	
10	implemented.		10	Q. And the implementation	
11	THE WITNESS: Yes.		11	question only pertained to RAVE because I	
12	BY MR. SMITH:		12	understood that that's in a trial status.	
13	Q. Webster?		13	Right?	
14	MR. TORREGROSSA: Same		14	A. Correct.	
15	instruction.		15	Q. Okay. And it's being	
16	THE WITNESS: No.		16	evaluated?	
17	BY MR. SMITH:		17	A. Just trying to make sure	
18	Q. EStar?		18	· · · · · · · · · · · · · · · · · · ·	
				that I'm answering your questions	
19	MR. TORREGROSSA: Same		19	correctly.	
20	instruction.		20	Q. All right. So that there's	
21	THE WITNESS: No.		21	no question then, Webster is or is not a	
22	Can I I just want to make		22	global system?	
23	sure that I'm answering your		23	A. It is not.	
24	questions correctly.		24	Q. And eStar?	
1	questions con couly			Q. And Coda.	
1					1
		Page 322			Page 324
	You changed your question a	Page 322	1	A No.	Page 324
1 2	You changed your question a	Page 322	1	A. No.	Page 324
2	few statements back.	Page 322	2	Q. And CTM is or was a global	Page 324
2 3	few statements back. So I just want to be sure	Page 322	2 3	Q. And CTM is or was a global system?	Page 324
2 3 4	few statements back. So I just want to be sure that the answers are to your	Page 322	2 3 4	Q. And CTM is or was a global system? A. Was.	Page 324
2 3	few statements back. So I just want to be sure that the answers are to your original question and not your	Page 322	2 3 4 5	Q. And CTM is or was a global system? A. Was. Q. And GDMRS is global. Right?	Page 324
2 3 4	few statements back. So I just want to be sure that the answers are to your	Page 322	2 3 4	Q. And CTM is or was a global system? A. Was.	Page 324
2 3 4 5	few statements back. So I just want to be sure that the answers are to your original question and not your	Page 322	2 3 4 5	Q. And CTM is or was a global system? A. Was. Q. And GDMRS is global. Right? A. Yes.	Page 324
2 3 4 5 6 7	few statements back. So I just want to be sure that the answers are to your original question and not your last question. Can I have some	Page 322	2 3 4 5 6 7	Q. And CTM is or was a global system? A. Was. Q. And GDMRS is global. Right? A. Yes. Q. Was STEP 2000 global?	Page 324
2 3 4 5 6 7 8	few statements back. So I just want to be sure that the answers are to your original question and not your last question. Can I have some clarification?	Page 322	2 3 4 5 6 7 8	Q. And CTM is or was a global system? A. Was. Q. And GDMRS is global. Right? A. Yes. Q. Was STEP 2000 global? A. No.	Page 324
2 3 4 5 6 7 8 9	few statements back. So I just want to be sure that the answers are to your original question and not your last question. Can I have some clarification? MR. TORREGROSSA: You're	Page 322	2 3 4 5 6 7 8 9	Q. And CTM is or was a global system? A. Was. Q. And GDMRS is global. Right? A. Yes. Q. Was STEP 2000 global? A. No. MR. TORREGROSSA: When you	Page 324
2 3 4 5 6 7 8 9	few statements back. So I just want to be sure that the answers are to your original question and not your last question. Can I have some clarification? MR. TORREGROSSA: You're asking if all those answers were	Page 322	2 3 4 5 6 7 8 9	Q. And CTM is or was a global system?  A. Was. Q. And GDMRS is global. Right? A. Yes. Q. Was STEP 2000 global? A. No. MR. TORREGROSSA: When you get to a good spot, if we could	Page 324
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Page 325  1 Q. Is CANDA 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.  Page 325  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 Adol	Page 327
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? 2 Q. Is it a database? 3 A. No. 4 Q. What type of system is it	
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5 Q. With regard to Market Pro? 5 A. It's an application very	<b>.</b> .
	L.f
I b cimilar to what voil == eiich ae bho	h
· · · · · · · · · · · · · · · · · · ·	be
7 Q. Is CANDA global? 7 Acrobat, if that helps.	
8 A. I can't answer that yes or 8 Q. What are the dates of us	se
9 no. 9 for CANDA?	
10 Q. Why? 10 A. I believe it was 19 ear	ly
11 A. Again, what I am able to 11 '90s.	
12 talk about are the technical aspects, 12 Q. Is it still in use today?	
13 kind of what its purpose was. But 13 A. No.	
14 decisions by the business to use it for 14 Q. When was it retired?	
15 globally as opposed to strictly US, that 15 A. 2000.	
16 would have been a business decision. And 16 Q. What replaced it?	
17 IT/IS aren't always that aware of those 17 A. Well, ECTD.	
18 decisions. 18 Q. What is ECTD?	
19 MR. TORREGROSSA: Objection, 19 A. Electronic sorry.	
20 scope. 20 Electronic ECDT. Electronic com	nmon
21 BY MR. SMITH: 21 sorry.	
22 Q. Is your answer with 22 MR. TORREGROSSA: Tal	ke your
23 reference to CANDA only? Is that what 23 time. Take your time.	·
24 you're referring to? 24 THE WITNESS: ECTD,	
Page 326	Page 328
1 A. Yes. 1 electronic common technical	
2 Q. Did you or your department 2 document.	
3 provide or do you now provide support for 3 MR. TORREGROSSA: You	u made
4 CANDA, IS support? 4 Mr. Smith wear his pencil dov	
5 A. We did. 5 THE WITNESS: Apologie	
6 Q. And what was your 6 It's the world I live in, the	
7 involvement? 7 acronyms.	
8 A. I did not have any direct 8 BY MR. SMITH:	
TO DITILLIFE	
9 involvement. 9 Q. What is ECTD?	
9 involvement. 9 Q. What is ECTD? 10 Q. What does CANDA stand for, 10 A. ECTD is a regulatory	
9 involvement. 9 Q. What is ECTD? 10 Q. What does CANDA stand for, 11 the name? 11 standard or format.	
9 Q. What is ECTD? 10 Q. What does CANDA stand for, 11 the name? 12 A. Computer assisted NDA. 9 Q. What is ECTD? 10 A. ECTD is a regulatory 11 standard or format. 12 Q. How is it used?	
9 involvement. 9 Q. What is ECTD? 10 Q. What does CANDA stand for, 11 the name? 11 standard or format. 12 A. Computer assisted NDA. 12 Q. How is it used? 13 Q. Can you describe CANDA? 13 A. It's used for electronic	
9 involvement. 9 Q. What is ECTD? 10 Q. What does CANDA stand for, 10 A. ECTD is a regulatory 11 the name? 11 standard or format. 12 A. Computer assisted NDA. 12 Q. How is it used? 13 Q. Can you describe CANDA? 13 A. It's used for electronic 14 submissions.	
9 involvement. 10 Q. What does CANDA stand for, 11 the name? 12 A. Computer assisted NDA. 13 Q. Can you describe CANDA? 14 A. Yes. It's an application 15 used to navigate an NDA.  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	ont?
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		Page 329			Page 331
1	BY MR. SMITH:		1	Q. Is there any reason why you	
2	Q. Would ECTD be used globally?		2	couldn't make copies of users guides or	
3	MR. TORREGROSSA: You can		3	IS documentation for CANDA?	
4	answer that yes or no.		4	MR. TORREGROSSA: Objection	
5	THE WITNESS: Yes.		5	to form, scope.	
6	MR. SMITH: Why don't we		6	You can answer.	
7	take a break.		7	THE WITNESS: Yes.	
8	MR. TORREGROSSA: Thank you,		8	BY MR. SMITH:	
9	sir.		9	Q. What would that reason be?	
10			10	MR. TORREGROSSA: Would	
11	(A recess occurred.)		11	there be any reason you couldn't?	
12	(A recess occurred.)		12		
	DV MD CMITTLE			THE WITNESS: I'm sorry.	
13	BY MR. SMITH:		13	I'm not sure I understood the	
14	Q. Who is the business owner		14	question.	
15	for Market Pro, if you know?		15	MR. TORREGROSSA: Right.	
16	MR. TORREGROSSA: Same		16	Could you get the question back,	
17	running objection.	!	17	please?	
18	THE WITNESS: Well, I		18	MR. SMITH: We'll give you a	
19	thought we were talking about		19	second bite at the apple.	
20	CANDA.		20		
				Would there be any reason	
21	BY MR. SMITH:		21	why you couldn't make a copy of	
22	Q. We're talking about lots of		22	the user guide or the IS	
23	things.		23	documentation for CANDA?	
24	A. Okay. I don't know.		24	MR. TORREGROSSA: Objection	
		Page 330			Page 332
1	Q. Do you know who the business	Page 330	1	to form, scope.	Page 332
1	•	Page 330	1 2	to form, scope.  THE WITNESS: No.	Page 332
2	owner is for CANDA? You anticipated my	Page 330	2	THE WITNESS: No.	Page 332
2 3	owner is for CANDA? You anticipated my next question.	Page 330	2 3	THE WITNESS: No. BY MR. SMITH:	Page 332
2 3 4	owner is for CANDA? You anticipated my next question.  A. I can't recall.	Page 330	2 3 4	THE WITNESS: No. BY MR. SMITH: Q. Was there a predecessor to	Page 332
2 3 4 5	owner is for CANDA? You anticipated my next question.  A. I can't recall.  Q. And who would you ask to	Page 330	2 3 4 5	THE WITNESS: No. BY MR. SMITH: Q. Was there a predecessor to CANDA?	Page 332
2 3 4 5 6	owner is for CANDA? You anticipated my next question.  A. I can't recall. Q. And who would you ask to find that out?	Page 330	2 3 4 5 6	THE WITNESS: No. BY MR. SMITH: Q. Was there a predecessor to CANDA? A. No.	Page 332
2 3 4 5 6 7	owner is for CANDA? You anticipated my next question.  A. I can't recall. Q. And who would you ask to find that out? A. Probably Bob Keesler.	Page 330	2 3 4 5 6 7	THE WITNESS: No.  BY MR. SMITH: Q. Was there a predecessor to  CANDA? A. No. Q. Is there any sort of search	Page 332
2 3 4 5 6 7 8	owner is for CANDA? You anticipated my next question.  A. I can't recall. Q. And who would you ask to find that out? A. Probably Bob Keesler. Q. Is there an application	Page 330	2 3 4 5 6 7 8	THE WITNESS: No.  BY MR. SMITH: Q. Was there a predecessor to  CANDA? A. No. Q. Is there any sort of search or report capability in CANDA?	Page 332
2 3 4 5 6 7 8 9	owner is for CANDA? You anticipated my next question.  A. I can't recall. Q. And who would you ask to find that out? A. Probably Bob Keesler. Q. Is there an application service manager for CANDA?	Page 330	2 3 4 5 6 7 8 9	THE WITNESS: No.  BY MR. SMITH: Q. Was there a predecessor to  CANDA? A. No. Q. Is there any sort of search or report capability in CANDA? A. In the sense that you can	Page 332
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		Page 333			Page 335
1	A. I guess you could call them		1	manager.	
2	a vendor.		2	Q. Who's the business partner?	
3	Q. Is it the FDA?		3	A. Nate Blevins.	
4	A. Yes.		4	Q. Business owner?	
5	Q. Okay.		5	A. Hillary Vass.	
6	A. Regulatory authorities.		6	Q. I didn't catch that last	
7	Q. Who's the vendor for GDMRS?		7	name?	
8	A. AstraZeneca.		8	A. Vass, Hillary Vass.	
9	Q. Is there a user list for		9	Q. Can you spell that?	
10	GDMRS?		10	A. I believe it's V-A-S-S.	
11	A. If what you mean by a list		11	Q. What is the data source for	
12	, ,			•	
	is are we able to identify the users of		12	the GDMRS?	
13	GDMRS, yes.		13	A. A user requesting making	
14	Q. Can you make a copy of the		14	a request.	
15	list of users for GDMRS?		15	<ul><li>Q. Would that be somebody on</li></ul>	
16	A. Yes.	i	16	the study team?	
17	<ul><li>Q. Was there a predecessor to</li></ul>	•	17	A. No. It could be an	
18	GDMRS?		18	individual on a study team. I think it's	
19	<ul> <li>A. Not that I'm aware of.</li> </ul>		19	primarily used by people who are entering	
20	Q. Can you describe that		20	data into the clinical data management	
21	system?		21	system.	j
22	A. Yes. And I'm trying to		22	Q. Now, I'm not quite clear on	
23	think of a way to come up with an		23	this, but let's say when development was	Ì
24	explanation to give you and help you		24	started on when did the system come	
	explanation to give you and help you		27	started on when did the system come	
		Page 334			Page 336
1	understand what GDMRS is	Page 334	1	into use? Let's start there	Page 336
1 2	understand what GDMRS is.	Page 334	1	into use? Let's start there.	Page 336
2	So the answer is yes. It	Page 334	2	A. I believe it was around	Page 336
2	So the answer is yes. It allows folks to request additions to,	Page 334	2	A. I believe it was around 2000.	Page 336
2 3 4	So the answer is yes. It allows folks to request additions to, say, a drug dictionary. For instance, if	Page 334	2 3 4	<ul><li>A. I believe it was around</li><li>2000.</li><li>Q. Approximately how many terms</li></ul>	Page 336
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		Page 337			Page 339
1	<ul><li>Q. What other systems does the</li></ul>		1	form and scope.	
2	GDMRS interface with?		2	THE WITNESS: It's a	
3	A. It doesn't.		3	dictionary of drugs on the on	
4	Q. I'm having trouble		4	the market.	
5	understanding how the information that's	,	5	BY MR. SMITH:	
6	put into GDMRS is used.		6	Q. What is STEP 2000?	
7	Can you explain that for me?		7	A. It's the predecessor system	
8	A. How the information is used.		8	to eStar.	
9	You're asking me a question that, if I		9	Q. What does Step stand for, do	
10	was in the business, a business person			• •	
1	· · · · · · · · · · · · · · · · · · ·		10	you know?	
11	coding medical information, I could		11	A. I believe it's just a name.	
12	explain to you how that was being used.		12	Q. What were the dates of use	
13	It's like asking me, you know, how my		13	for STEP 2000?	
14	mother uses her car. I mean, I'm		14	A. I would have to I'd have	
15	assuming that she uses it to travel back		15	to speak directly to Dina O'Brien to	
16	and forth to work.		16	understand when it was first used. It	
17	<ul><li>Q. That's exactly what I mean,</li></ul>		17	was	I
18	is think of it, it's like a car, and tell		18	Q. And what's her connection	
19	me what you would use this car for.		19	with STEP 2000?	
20	MR. TORREGROSSA: Objection,		20	A. Well, she is the now current	
21	scope.		21	system owner for the system that is used	
22	THE WITNESS: Again, it's to		22	within AstraZeneca today, which is eStar.	
23					
1	request changes to dictionaries,		23	Q. Do you know who the	
24	to medical dictionaries.		24	application service manager was for STEP	
		Page 338			Page 340
1	BY MR. SMITH:	Page 338	1	2000?	Page 340
1 2	BY MR. SMITH:  O To which dictionaries?	Page 338	1 2	2000?  A Again I'd have to speak to	Page 340
2	Q. To which dictionaries?	Page 338	2	A. Again, I'd have to speak to	Page 340
2 3	<ul><li>Q. To which dictionaries?</li><li>A. MedRA drug dictionary.</li></ul>	Page 338	2 3	A. Again, I'd have to speak to Dina.	Page 340
2 3 4	<ul><li>Q. To which dictionaries?</li><li>A. MedRA drug dictionary.</li><li>Q. And what is MedRA?</li></ul>	Page 338	2 3 4	A. Again, I'd have to speak to Dina. Q. Same for the business	Page 340
2 3 4 5	<ul><li>Q. To which dictionaries?</li><li>A. MedRA drug dictionary.</li><li>Q. And what is MedRA?</li><li>A. MedRA is a medical coding</li></ul>	Page 338	2 3 4 5	A. Again, I'd have to speak to Dina. Q. Same for the business partner?	Page 340
2 3 4 5 6	<ul> <li>Q. To which dictionaries?</li> <li>A. MedRA drug dictionary.</li> <li>Q. And what is MedRA?</li> <li>A. MedRA is a medical coding dictionary. Precisely what it stands</li> </ul>	Page 338	2 3 4 5 6	A. Again, I'd have to speak to Dina. Q. Same for the business partner? A. Yes.	Page 340
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	THE MATTHEOG A STATE	Page 341		0 141 1 1 0 0 1 1 7	Page 343
1	THE WITNESS: Again, I'd		1	Q. What does GES stand for, if	
2	speak to Dina, try to get a better		2	you know?	
3	understanding of that.		3	A. Global electronic	
4	MR. TORREGROSSA: Mr. Smith,		4	submissions.	
5	it was the legacy system to eStar.		5	Q. What does ICSR stand for?	
6	MR. SMITH: Uh-huh.		6	<ul> <li>A. Individual case safety</li> </ul>	
7	MR. TORREGROSSA: Okay.		7	report.	
8	Yes, and if you direct certain		8	Q. What are the dates of use	
9	inquiries to me after this		9	for CLINTRACE?	
10	deposition, I will inquire whether		10	A. March 31, 1998.	
11	some of this information is still		11	MR. TORREGROSSA: Is that	
12	available for STEP 2000.		12	specific enough, or were you	
13	MR. SMITH: You'll answer my		13	looking for something more?	
14	20 questions on STEP 2000?		14	MR. SMITH: That's pretty	
15	MR. TORREGROSSA: I will try		15	good.	
16	and get you information, yes, sir.		16	BY MR. SMITH:	
17	MR. SMITH: Okay.		17	Q. And that system is currently	
18	BY MR. SMITH: ORay.		18	used today?	
19	Q. Let's take a look at		19	A. Yes.	
20	CLINTRACE.		20		
21			21	Q. Is there a data map for CLINTRACE?	
22	Can you tell me what the name means?		22		
23				A. I believe that the vendor	
	A. It doesn't really as far		23	materials has information with regard to	
24	as I understand, it doesn't really have		24	a data map.	
		Page 342			Page 344
1	any particular	Page 342	1	O. Do you know if it's in a	Page 344
1 2	any particular O. That's fine.	Page 342	1 2	Q. Do you know if it's in a	Page 344
2	Q. That's fine.	Page 342	2	diagram or schematic form?	Page 344
2 3	Q. That's fine. Can you describe CLINTRACE	Page 342	2 3	diagram or schematic form?  A. I don't believe that that	Page 344
2 3 4	Q. That's fine. Can you describe CLINTRACE for me?	Page 342	2 3 4	diagram or schematic form?  A. I don't believe that that material has actual there	Page 344
2 3 4 5	Q. That's fine. Can you describe CLINTRACE for me? A. It is a data management	Page 342	2 3 4 5	diagram or schematic form?  A. I don't believe that that material has actual there are diagrams. To	Page 344
2 3 4 5 6	Q. That's fine. Can you describe CLINTRACE for me? A. It is a data management system used to enter, track and report	Page 342	2 3 4 5 6	diagram or schematic form?  A. I don't believe that that material has actual there are diagrams. There are diagrams. To what detail level, I'm not recalling.	Page 344
2 3 4 5 6 7	Q. That's fine. Can you describe CLINTRACE for me? A. It is a data management system used to enter, track and report adverse events.	Page 342	2 3 4 5 6 7	diagram or schematic form?  A. I don't believe that that material has actual there are diagrams. There are diagrams. To what detail level, I'm not recalling.  Q. What is your involvement	Page 344
2 3 4 5 6 7 8	Q. That's fine. Can you describe CLINTRACE for me? A. It is a data management system used to enter, track and report adverse events. Q. Is it used to submit adverse	Page 342	2 3 4 5 6 7 8	diagram or schematic form?  A. I don't believe that that material has actual there are diagrams. There are diagrams. To what detail level, I'm not recalling.  Q. What is your involvement with CLINTRACE?	Page 344
2 3 4 5 6 7 8 9	Q. That's fine. Can you describe CLINTRACE for me? A. It is a data management system used to enter, track and report adverse events. Q. Is it used to submit adverse events?	Page 342	2 3 4 5 6 7 8 9	diagram or schematic form?  A. I don't believe that that material has actual there are diagrams. There are diagrams. To what detail level, I'm not recalling.  Q. What is your involvement with CLINTRACE?  A. I was part of the	Page 344
2 3 4 5 6 7 8 9	Q. That's fine. Can you describe CLINTRACE for me? A. It is a data management system used to enter, track and report adverse events. Q. Is it used to submit adverse events? A. It's used to produce output	Page 342	2 3 4 5 6 7 8 9	diagram or schematic form?  A. I don't believe that that material has actual there are diagrams. There are diagrams. To what detail level, I'm not recalling.  Q. What is your involvement with CLINTRACE?  A. I was part of the implementation team, as well as the	Page 344
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q. That's fine. Can you describe CLINTRACE for me? A. It is a data management system used to enter, track and report adverse events. Q. Is it used to submit adverse events? A. It's used to produce output that is ultimately the information submitted to a regulatory authority, yes. Q. Does it interface with another system to submit adverse event reports? A. Yes. Q. What system is that? A. GES. Q. Is GES different from GEL? A. Yes. Q. What is GES? A. That's a system used to	Page 342	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	diagram or schematic form?  A. I don't believe that that material has actual there are diagrams. There are diagrams. To what detail level, I'm not recalling.  Q. What is your involvement with CLINTRACE?  A. I was part of the implementation team, as well as the architect for AstraZeneca implementation.  Q. What are your current responsibilities with regard to CLINTRACE?  A. I don't have any day-to-day direct responsibilities for CLINTRACE.  Q. Is there an ERD for CLINTRACE.  A. Yes. I believe the vendor documentation does have specific information pertaining to relationships of data.	Page 344

		<u> </u>		
١.	Page 34	Ι.		Page 347
1	A. Again, I recall diagrams in	1	Q. Is there both a US business	
2	that documentation, you know, the	2	owner and a global business owner?	
3	complete picture of the data map.	3	MR. TORREGROSSA: You can	
4	There's various components to CLINTRACE,	4	answer that yes or no.	
5	and I believe those components are	5	THE WITNESS: Yes.	
6	detailed, either, you know, textually.	6	BY MR. SMITH:	
7	Again, I don't recall precisely whether	7	Q. Is that two different	
8	or not there was like a picture. But	8	people?	
9	that information would be available in	9	A. Can I go back to the	
10	that material.	10	question, please, the question that I've	
11	Q. Some form of written	11	answered already?	
12	documentation that would include that	12	Q. Is there both a US business	
13	information is available then?	13	owner and a global business owner, and	
14	A. Yes.	14	you said yes. And now I'm asking, could	
15	Q. Are there user guides for	15	they be the same person.	
16	CLINTRACE?	16	Are they the same person, or	
17	A. Yes, both AstraZeneca and	17	are they two different people?	
18	vendor.	18	A. Al Fowkes is the I'm	
19	Q. And there's IS documentation	19	sorry, system owner. I'm confused now.	
20	for CLINTRACE?	20	Q. Business owner?	
21	A. Yes.	21	A. Business owner. Okay.	
22	Q. Who's the application	22	No, there is a system owner.	
23	service manager?	23	There's not multiple owners.	
24	A. Paul Seymour.	24	Q. What types of information	
	Page 34	5		Page 348
1	Page 34 O. And he would be the global		are in CLINTRACE?	Page 348
1 2	Q. And he would be the global	1	are in CLINTRACE?  A. Types of information would	Page 348
1 2 3	· · · · · · · · · · · · · · · · · · ·			Page 348
2	Q. And he would be the global application service manager. Correct? A. Yes.	1 2 3	A. Types of information would be adverse events.	Page 348
2 3	Q. And he would be the global application service manager. Correct? A. Yes. Q. Who's the business partner?	1 2	A. Types of information would be adverse events.     Q. And those would be as	Page 348
2 3 4	<ul><li>Q. And he would be the global application service manager. Correct?</li><li>A. Yes.</li><li>Q. Who's the business partner?</li></ul>	1 2 3 4	<ul><li>A. Types of information would be adverse events.</li><li>Q. And those would be as documents?</li></ul>	Page 348
2 3 4 5	Q. And he would be the global application service manager. Correct? A. Yes. Q. Who's the business partner? A. Business partner is Al Fowkes.	1 2 3 4 5	A. Types of information would be adverse events. Q. And those would be as documents? MR. TORREGROSSA: Objection	Page 348
2 3 4 5 6	Q. And he would be the global application service manager. Correct? A. Yes. Q. Who's the business partner? A. Business partner is Al Fowkes.	1 2 3 4 5 6	<ul><li>A. Types of information would be adverse events.</li><li>Q. And those would be as documents?</li></ul>	Page 348
2 3 4 5 6 7	Q. And he would be the global application service manager. Correct? A. Yes. Q. Who's the business partner? A. Business partner is Al Fowkes. Q. How do you spell Fowkes?	1 2 3 4 5 6 7	A. Types of information would be adverse events. Q. And those would be as documents? MR. TORREGROSSA: Objection to form, scope.	Page 348
2 3 4 5 6 7 8	Q. And he would be the global application service manager. Correct? A. Yes. Q. Who's the business partner? A. Business partner is Al Fowkes. Q. How do you spell Fowkes? A. F-O-K-E-S, I believe.	1 2 3 4 5 6 7 8	A. Types of information would be adverse events. Q. And those would be as documents? MR. TORREGROSSA: Objection to form, scope. Go ahead.	Page 348
2 3 4 5 6 7 8 9	Q. And he would be the global application service manager. Correct? A. Yes. Q. Who's the business partner? A. Business partner is Al Fowkes. Q. How do you spell Fowkes? A. F-O-K-E-S, I believe. Q. No L?	1 2 3 4 5 6 7 8 9	A. Types of information would be adverse events. Q. And those would be as documents? MR. TORREGROSSA: Objection to form, scope. Go ahead. THE WITNESS: The CLINTRACE	Page 348
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	Page 349			Page 351
1	That data would be housed in CLINTRACE.	1	Right?	
2	MR. TORREGROSSA: I think he	2	<ul> <li>A. Various categories in</li> </ul>	
3	was making a technical comparison	3	CLINTRACE, the way to categorize records	
4	versus a	4	would be spontaneous investigator study	
5	BY MR. SMITH:	5	literature.	
6	<ul><li>Q. Can the same information be</li></ul>	6	Does that help?	
7	entered into CLINTRACE and AMOS? Can an	7	Q. That does help.	
8	adverse event report be entered into both	8	MR. TORREGROSSA: Excuse me.	
9	CLINTRACE and AMOS?	9	Let me interpose a form and scope	
10	A. No. I think, again, I'm	10	objection.	
11	going to this is more of a business	11	Go ahead, Mr. Smith.	
12	process question. However, I'll try to	12	BY MR. SMITH:	
13	give you a technical understanding	13	Q. Any other categories of	
14	underneath CLINTRACE.	14	adverse events that you can think of?	
15	There are adverse events	15	MR. TORREGROSSA: Same	
16	experienced by the patient that are	16	objections.	
17	recorded in the CLINTRACE database.	17	THE WITNESS: Those are the	
18	Q. Is that by a patient in a	18	three very high level technical	
19	clinical study or a patient anywhere?	19	those are the what you call	
20	MR. TORREGROSSA: Objection	20	them, like pick list items that	
21	to form, scope.	21	you find in the application.	
22	BY MR. SMITH:	22	BY MR. SMITH:	
23	Q. I'm trying to clarify your	23	Q. Did you say pick list or	
24	answers.	24	pink list?	
- '	dilovers.	~ '	pirik iist:	
	Page 350			Page 352
1	Page 350 Are you referring to a	1	A Pick list	Page 352
1 2	Are you referring to a	1 2	A. Pick list.	Page 352
2	Are you referring to a patient in a clinical study or to any	2	Q. Pick list.	Page 352
2 3	Are you referring to a patient in a clinical study or to any patient?	2	<ul><li>Q. Pick list.</li><li>A. I'm trying to give you a</li></ul>	Page 352
2 3 4	Are you referring to a patient in a clinical study or to any patient?  MR. TORREGROSSA: Same	2 3 4	<ul><li>Q. Pick list.</li><li>A. I'm trying to give you a technical understanding of the database.</li></ul>	Page 352
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