Confidential - Darryl Draper

		Page 170			Page 172
1	you print out the results of a search?	1 uge 1/0	1	MR. TORREGROSSA: I'm sorry,	raye 1/2
2	A. I don't know.		2	I missed that. Could I have that	
3	Q. Can you produce the results		3	repeated? I didn't get it.	
4	of a search? It doesn't have to be in a		4		
5	printed, hard copy, but in some		5	(The court reporter read the	
6	electronic format?		6	pertinent part of the record.)	
7	A. I don't know.		7		
8	MR. TORREGROSSA: Just		8	MR. TORREGROSSA: Objection,	
9	telling you to wait until he		9	form.	
10	finishes his question. That's		10	THE WITNESS: No.	
11	all.		11	BY MR. SMITH:	
12	BY MR. SMITH:				
13			12	Q. Is it a database of all the	
	<u> </u>		13	literature in the public domain that	
14	system?		14	discusses AstraZeneca products of which	
15	A. Okay.		15	AstraZeneca is aware?	
16	Q. Are you responsible for that		16	A. Yes.	
17	system?		17	Q. Does it contain the full	
18	A. No.		18	articles?	
19	Q. Is your department		19	A. No.	
20	responsible for that system?		20	Q. Does it contain abstracts?	
21	A. Yes.		21	A. Yes.	
22	Q. And what does your		22	Q. Are the abstracts in what	
23	department do with regards to that		23	format are they maintained in?	
24	system?		24	A. Text.	
		Page 171			Page 173
1	A. We provide the service and		1	Q. From within AstraZeneca, can	-
2	support.		2	anyone access it?	
3	Q. Is it used by drug safety?		3	A. Yes.	
4	A. Yes.		4	Q. Do you know whether search	
5	Q. What type of data is in the		5	history of users is saved in the system?	
6	PLANET system?		6	A. No. I'm sorry. Can I hear	
7	A. Published literature.		7		
8			l .	the question again, because I make	
9	- · · · · · · · · · · · · · · · · · · ·		8	sure I answered it correctly.	
10	about AstraZeneca products? A. Yes.		_	(The court reporter read the	
			10	(The court reporter read the	
11	Q. Is it about any other		11	pertinent part of the record.)	
12	products?		12	THE WITNESS: Y	
13	A. I think you're asking me		13	THE WITNESS: Yes.	
14	questions that relate to, again,		14	BY MR. SMITH:	
1			l	-	
ı	·		l		
ı	·		l .	• •	
ı				· ·	
ı			1		
ł .			I		
	contain other nonAstraZeneca products.		21	need to make a correction with regard to	
22	Q. Is there a database of all		22	unpublished articles.	
23	literature in the public domain		23	I believe that if a you	
24	discussing AstraZeneca products?		24	asked me questions about the actual	
23	Q. Is there a database of all literature in the public domain		22 23	need to make a correction with regard to unpublished articles. I believe that if a you	

44 (Pages 170 to 173)

i				
		Page 174		Page 17
1	content. And, you know, I'm not I		1	Q. Let's back up.
2	can't answer those questions on behalf		2	What departments in
3	of, you know, the people who the		3	AstraZeneca does your department provide
4	business owners of PLANET, so I want		4	IS services to?
5	to I feel like I need to correct that		5	A. Drug development.
6	answer, because again, I can answer the		6	Q. Is that it, drug
7	technical questions with regard to, you		7	development?
8	know, the architecture of the application		8	 A. The whole gamut of drug
9	PLANET.		9	development.
10	Q. Are you or someone in your		10	Q. Does that include drug
11	department responsible for shared drives,		11	safety?
12	where information is stored for clinical		12	A. Yes.
13	studies, other than in the databases that		13	Q. And it includes clinical
14	we've discussed?		14	studies?
15	A. I'm not sure I understand		15	A. Yes.
16	the question.		16	Q. It includes research and
17	Q. Does your department provide		17	development?
18	any services with regard to information		18	A. Yes.
19	that's contained on shared drives within		19	
l				Q. Does it include regulatory
20	the clinical studies department?		20	compliance?
21	A. Again, I really don't		21	A. Yes.
22	understand what you're trying to ask.		22	Q. Is there a list somewhere of
23	Q. Are you aware of any place		23	all of the systems that your department
24	on AstraZeneca's computers where		24	supports?
		Page 175		Page 17
		ruge 175		rage 17
l 1	unnublished articles are stored?		l 1	Δ I don't helieve there is a
1 2	unpublished articles are stored?		1	A. I don't believe there is a
2	A. Again, I think that's a		2	single list.
2 3	A. Again, I think that's a business process question.		2	single list. Q. Would there be more than one
2 3 4	A. Again, I think that's a business process question. What I know and can answer		2 3 4	single list. Q. Would there be more than one list?
2 3 4 5	A. Again, I think that's a business process question. What I know and can answer are in respect to these databases.		2 3 4 5	single list. Q. Would there be more than one list? A. Yes.
2 3 4 5 6	A. Again, I think that's a business process question. What I know and can answer are in respect to these databases. Q. Do your duties include		2 3 4 5 6	single list. Q. Would there be more than one list? A. Yes. Q. Do you know of some lists?
2 3 4 5 6 7	A. Again, I think that's a business process question. What I know and can answer are in respect to these databases. Q. Do your duties include providing IS services relating to systems		2 3 4 5 6 7	single list. Q. Would there be more than one list? A. Yes. Q. Do you know of some lists? A. Can you
2 3 4 5 6 7 8	A. Again, I think that's a business process question. What I know and can answer are in respect to these databases. Q. Do your duties include providing IS services relating to systems or applications that are not necessarily		2 3 4 5 6 7 8	single list. Q. Would there be more than one list? A. Yes. Q. Do you know of some lists? A. Can you Q. Do you know of the
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2 3 4 5 6 7 8 9 10	A. Again, I think that's a business process question. What I know and can answer are in respect to these databases. Q. Do your duties include providing IS services relating to systems or applications that are not necessarily databases? A. That would require some		2 3 4 5 6 7 8 9	single list. Q. Would there be more than one list? A. Yes. Q. Do you know of some lists? A. Can you Q. Do you know of the existence? A. Can you just describe for me
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	Dage :	70		D=== 100
1	Page : department or team, how many are there?	/° 1	A. Can you read that question	Page 180
2	A. I don't have an exact	2	back, please?	
3	number. It's a few hundred.	3		
4	MR. TORREGROSSA: When you	4	(The court reporter read the	
5	get to a convenient time, Mr.	5	pertinent part of the record.)	
6	Smith, if you would, we can take a	6		
7	break? We've been going for an	7	THE WITNESS: Yes.	
8	hour and 15 minutes.	8	BY MR. SMITH:	
9	MR. SMITH: Okay.	9	Q. Can you describe that?	
10	BY MR. SMITH:	10	A. You can assemble certain key	
11	Q. Is PLANET broken down by	11	words in PLANET for an individual to	
12	therapy areas?	12	receive notification that there is an	
13	A. Yes.	13	abstract relating to those particular key	
14	Q. Who's the third-party vendor	14	words.	
15	who sends data to AstraZeneca for the	15	Q. If I understand you	
16	PLANET system?	16	correctly, does that mean that if I were	i
17	A. Thompson Scientific.	17	a user if you were a user of PLANET	
18	Q. What can people download to	18	and you wanted to be notified if anything	
19	a laptop from the system?	19	appeared in an abstract relating to the	
20	A. You mean from PLANET?	20	search term "atypical," that you would	
21	Q. Yes.	21	automatically be sent a notification that	
22	A. I believe it's the abstract.	22	an abstract relating to or containing the	
23	Q. Is there any way to make and	23	word "atypical" had been received?	
24	store comments pertaining to items that	24	A. If atypical appeared in the	
		 		
	Page	70		D 101
	. 490	./9		Page 181
1	are contained in PLANET?	1	abstract or any of the other key index	Page 181
2	are contained in PLANET? A. Can you restate the		attributes, yes.	Page 181
1	are contained in PLANET?	1	attributes, yes. Q. Would there be a way that	Page 181
2	are contained in PLANET? A. Can you restate the question, please? I'm not sure Q. Is there any way that a user	1 2	attributes, yes. Q. Would there be a way that you could, if you were a user of PLANET,	Page 181
2 3 4 5	are contained in PLANET? A. Can you restate the question, please? I'm not sure Q. Is there any way that a user could make a comment regarding an	1 2 3	attributes, yes. Q. Would there be a way that you could, if you were a user of PLANET, order the full article?	rage 181
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2 3 4 5 6 7	are contained in PLANET? A. Can you restate the question, please? I'm not sure Q. Is there any way that a user could make a comment regarding an abstract that he or she found on PLANET? A. When you refer to user,	1 2 3 4 5 6 7	attributes, yes. Q. Would there be a way that you could, if you were a user of PLANET, order the full article? A. Yes. Q. How would you do that?	rage 181
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	Page 182			Page 184
1	page, a button that you can click on,	1	day-to-day involvement.	
2	that allows you to request the full	2	Q. What are your	İ
3	article?	3	responsibilities with regard to AZ	
4	A. Not that I'm aware of.	4	IMPACT?	
5	Q. Does it go via some separate	5	A. I don't have any direct	
6	system?	6	day-to-day responsibilities.	
7	A. I think I just described the	7	Q. Is there a data map or	
8	process.	8	schema for AZ IMPACT?	
9	Q. I don't understand your	9	A. I believe what the the	
10	answer.	10	vendor does provide information that you	
11		11	would consider relevant to what would be	
	Do you mean do you send an			
12	e-mail to somebody and say, get me this	12	in a data map.	
13	article?	13	Q. Could you produce that to	5
14	A. It would be an e-mail, yes.	14	me?	
15	MR. TORREGROSSA: Is now	15	MR. TORREGROSSA: Objection.	
16	good?	16	Lawyers produce things, not	
17	MR. SMITH: Sure.	17	witnesses.	
18	MR. TORREGROSSA: Thank you,	18	You can answer.	
19	sir.	19	THE WITNESS: I believe so,	
20		20	yeah.	
21	(A recess occurred.)	21	BY MR. SMITH:	
22	·	22	Q. Is there a system map?	
23	BY MR. SMITH:	23	A. I'm not aware of any system	
24	Q. I'd like to ask you some	24	map.	
	Page 183			Page 185
1	_	1	Q. What other systems does it	Page 185
1 2	Page 183 questions about AZ IMPACT. What is AZ IMPACT?	1 2	Q. What other systems does it interface with?	Page 185
2	questions about AZ IMPACT. What is AZ IMPACT?	l		Page 185
2 3	questions about AZ IMPACT. What is AZ IMPACT? A. It is a study management	2	interface with? A. I don't believe it has	Page 185
2 3 4	questions about AZ IMPACT. What is AZ IMPACT? A. It is a study management system.	2 3 4	interface with? A. I don't believe it has interfaces with any other systems.	Page 185
2 3 4 5	questions about AZ IMPACT. What is AZ IMPACT? A. It is a study management system. Q. Clinical studies?	2 3 4 5	interface with? A. I don't believe it has interfaces with any other systems. Q. Is it a validated system?	Page 185
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2 3 4 5 6 7 8	questions about AZ IMPACT. What is AZ IMPACT? A. It is a study management system. Q. Clinical studies? A. Yes. Q. When was it put into use? A. It was put into use at	2 3 4 5 6 7 8	interface with? A. I don't believe it has interfaces with any other systems. Q. Is it a validated system? A. Yes. Q. Who's the database manager? A. I believe it's Tor Limberg.	Page 185
2 3 4 5 6 7 8 9	questions about AZ IMPACT. What is AZ IMPACT? A. It is a study management system. Q. Clinical studies? A. Yes. Q. When was it put into use? A. It was put into use at AstraZeneca 2000 I believe it was	2 3 4 5 6 7 8 9	interface with? A. I don't believe it has interfaces with any other systems. Q. Is it a validated system? A. Yes. Q. Who's the database manager? A. I believe it's Tor Limberg. Q. Who's the business analyst?	Page 185
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	O Burnhama	Page 186			Page 188
1	Q. By whom?		1	missing. The agreement is what it	
2	A. By the Fowkes in study		2	is, which is foreign databases and	
3	delivery.		3	foreign information in databases	
4	Q. Is any of the data entered		4	are off the table for now. That's	
5	by outside people?		5	my position.	
6	MR. TORREGROSSA: Objection		6	Instruct the witness not to	
7	to form.		7	answer.	
8	THE WITNESS: No.		8	BY MR. SMITH:	
9	BY MR. SMITH:		9	Q. You're going to follow your	
10	Q. How's the data organized?		10	counsel's advice?	
11	A. It's organized by study.		11	A. Yes.	
12	_ , ,				
1	Q. Could you give me a list of		12	Q. Could you get me a copy of	
13	the fields?		13	training documentation?	
14	MR. TORREGROSSA: Objection.		14	MR. TORREGROSSA: Objection	
15	I'm sorry, were you		15	to form.	
16	finished?		16	You can answer.	
17	MR. SMITH: Uh-huh.		17	THE WITNESS: Could you be	
18	MR. TORREGROSSA: Objection		18	more specific?	
19	to form.		19	BY MR. SMITH:	
20	THE WITNESS: I believe		20	Q. Could you get me a user	
21	since it's a vendor product, that		21	guide?	
22	there would be lists of fields.		22	MR. TORREGROSSA: Same	
23	BY MR. SMITH:		23		
1				objection. I'm sorry.	
24	Q. Who's the vendor?		24	THE WITNESS: Yes.	
					
		Dago 107			Daga 100
1	A Percentive Informatics	Page 187	1	RV MD CMITH:	Page 189
1	A. Perceptive Informatics.	Page 187	1	BY MR. SMITH:	Page 189
2	Q. And where are they located?	Page 187	2	Q. Is training on how to	Page 189
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		Page 190			Page 192
1	BY MR. SMITH:		1	Q. Was there any data in Trial	
2	Q. What other types of		2	Manager that was lost or destroyed?	
3	documentation are available?		3	A. No.	
4	 A. Vendor documentation. 		4	MR. TORREGROSSA: I'm sorry.	
5	Q. And could you produce a copy		5	Objection to form. Go ahead.	
6	of that?		6	THE WITNESS: Sorry.	
7	MR. TORREGROSSA: Same		7	BY MR. SMITH:	
8	objection.		8	Q. When was Trial Manager put	
9	THE WITNESS: Yes.		9	into service?	
10	BY MR. SMITH:		10	A. 1998.	
11	Q. What type of database is it?		11	Q. Who was the database	
12	 A. It is an Oracle database. 		12	manager?	
13	Q. Who maintains the servers?		13	A. The database manager for AZ	
14	A. IBM.		14	IMPACT, I believe I answered that	
15	Q. Could you produce a list of		15	question.	
16	the authorized users?		16	Did I	
17	MR. TORREGROSSA: Same		17	Q. I'm sorry, was AZ IMPACT put	
18	objection. Same objection. I		18	into service in 1998?	
19	object to the extent you suggest		19	A. It was first used by	
20	we will produce it.		20	AstraZeneca in 2000.	
21	But you can answer the		21	Q. In 2000. Okay.	
22	question.		22	And so you only have two	
23	THE WITNESS: Yes.		23		
24	BY MR. SMITH:		24	1998 to approximately 2000?	
L .					
		Page 191	!		Page 193
	O. What system preceded A7	Page 191	1	MR TORREGROSSA: Objection	Page 193
1 2	Q. What system preceded AZ IMPACT?	Page 191	1 2	MR. TORREGROSSA: Objection	Page 193
2	IMPACT?	Page 191	2	to form.	Page 193
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	Page 194			Page 196
1	which there was data in CITS would have	1	A. I would expect that if	
2	been migrated to Trial Manager?	2	the there would be information there	
3	A. To answer your question, I'd	3	for the studies, yes.	
4	have to go back and look at the	4	Q. Would a data map be	
5	information regarding Trial Manager and	5	available for CITS?	
6	how it was decommissioned and what was	6	A. Possibly.	
7	migrated to the system that we use today.	7	Q. Would a system map be	
8	Q. Where would the closed	8	available?	
9	studies be archived?	9	A. Possibly.	
10	MR. TORREGROSSA: I didn't	10	Q. Who is the vendor for CITS?	
11	catch one of those words, where	11	A. I believe it was	
12	was the	12	AstraZeneca, but I would need to, again,	
13	MR. SMITH: Closed studies.	13	refer to the decommissioning and system	
14	MR. TORREGROSSA: Thank you,	14	documentation to acquire that specific	
15	sir.	15	vendor.	
16	THE WITNESS: I believe that	16	Q. Could you provide copies of	
17	information is goes into I'd	17	the system documentation for CITS?	
18	have to do a bit more research. I	18	MR. TORREGROSSA: Same	
19	don't recall exactly how	19	objection.	
20	information gets out of AZ	20	THE WITNESS: Didn't I	
21	IMPACT or I'm sorry, this CITS,	21	answer that question already?	
22	once a study is complete.	22	BY MR. SMITH:	
23	BY MR. SMITH:	23	Q. Could you provide system	
24	Q. Who would know the answer to	24	documentation for CITS?	
1				
	Page 195		A Assis I believe I previous	Page 197
1	that question?	1	A. Again, I believe I answered	Page 197
2	that question? A. Well, I would get that	2	that question already.	Page 197
2 3	that question? A. Well, I would get that answer by going to probably documentation	2 3	that question already. Q. Well, that was with regard	Page 197
2 3 4	that question? A. Well, I would get that answer by going to probably documentation in material that is in our archive.	2 3 4	that question already. Q. Well, that was with regard to data maps or system maps.	Page 197
2 3 4 5	that question? A. Well, I would get that answer by going to probably documentation in material that is in our archive. Q. Could you produce a copy of	2 3 4 5	that question already. Q. Well, that was with regard to data maps or system maps. Do you believe there would	Page 197
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1	Page 198	1		Page 200
1	Q. Well, would you have been	1	A. To manage investigator initiated	
2	able to export data from CITS and then	2 3		
	import it into Trial Manager?	3	Q. The reason for managing that?	
4	A. If a migration program was	5		
5 6	written, then yes.		A. I think that's a question	
7	Q. Do you know if there was a	6 7	more appropriate for a business	
8	migration program? A. Again, I think I already	8	representative. Q. How's the information	
9	,	9	•	
10	answered that question. Q. What was your answer?	10	managed? A. In a database, by	
11		11	·	
		1	Q. What type of database?	
12	the reporter's notes, please.	12	A. Sorry?	
13	Q. We talked about closed	13	Q. I'm sorry, what type of	
14	studies and open studies?	14	database?	
15	A. Yes.	15	A. An Oracle database.	
16	Q. Could the data for the	16	Q. And within the Oracle	
17	closed studies be exported today?	17	database, how's the data managed?	
18	A. No.	18	A. I'm not sure I understand	
19	Q. Is it stored somewhere?	19	your question.	
20	A. Not not to my knowledge.	20	Q. Take the data from the input	
21	It's not stored.	21	to the output and tell me what happens to	
22	Q. Does the data still exist?	22	it in between.	
23	A. Again, I would have to refer	23	A. How the data is managed is	
24	to the decommissioning documentation for	24	the business responsibility. It's not an	
	Page 19	,		Page 201
1	Page 19 that system to answer the question.			Page 201
1 2	that system to answer the question.	1	IT responsibility.	Page 201
2	that system to answer the question. Q. Pardon me if I asked you		IT responsibility. So I can answer your	Page 201
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	1:65	Page 202		define what was seen by	Page 204
1	different way, and you would figure out a		1	define what you mean by	
2	way to do that if it could be done.		2	application?	X
3	Right?		3	BY MR. SMITH:	
4	A. Yes.		4	Q. If an investigator submits	
5	Q. So how is the data handled		5	the organization his or her	
6	then? That's a system thing. How does		6	organization to conduct clinical research	
7	the system handle the data from the time		7	relating to an AstraZeneca product, I	
8	that it's inputted to the time that it's		8	assume there's a process for evaluating	
9	outputted?		9	and acting upon that application.	
10	A. The data is stored to the		10	Correct?	
11	database.		11	A. Yes.	
12	Q. Let me stop you here and ask		12	MR. TORREGROSSA: Objection.	
13	you, where does it come from? What are		13	BY MR. SMITH:	
14	the sources?		14	Q. Now, how does the IIRIS	
15	A. It would come from		15	system play a part in that?	
16	investigators' correspondence to initiate		16	A. That correspondence would	
17	· ·		17	be if it's electronic, it would be	
	a study.		18	stored in IIRIS.	
18	Q. And I apologize for				
19	interrupting you.		19	Q. What sorts of fields would	
20	Is the system, does it		20	be used to identify or define that	
21	interface with other systems on the input		21	request, that application?	
22	side?		22	A. Investigator's name,	
23	A. No.		23	document title, product.	
24	Q. It doesn't obtain any data		24	Q. Could you get me a field	
		Page 203			Page 205
1	through an interface with another system	Page 203	1	list?	Page 205
1 2	through an interface with another system	Page 203	1 2	list? MR. TORREGROSSA: Objection	Page 205
2	then?	Page 203	2	MR. TORREGROSSA: Objection	Page 205
2 3	then? A. No.	Page 203	2	MR. TORREGROSSA: Objection to form.	Page 205
2 3 4	then? A. No. Q. So the data comes in and	Page 203	2 3 4	MR. TORREGROSSA: Objection to form. THE WITNESS: Yes. I	Page 205
2 3 4 5	then? A. No. Q. So the data comes in and it's stored.	Page 203	2 3 4 5	MR. TORREGROSSA: Objection to form. THE WITNESS: Yes. I believe a simple screen shot of	Page 205
2 3 4 5 6	then? A. No. Q. So the data comes in and it's stored. Then what happens to it?	Page 203	2 3 4 5 6	MR. TORREGROSSA: Objection to form. THE WITNESS: Yes. I believe a simple screen shot of the data entry fields would	Page 205
2 3 4 5 6 7	then? A. No. Q. So the data comes in and it's stored. Then what happens to it? A. It can be updated. It can	Page 203	2 3 4 5 6 7	MR. TORREGROSSA: Objection to form. THE WITNESS: Yes. I believe a simple screen shot of the data entry fields would provide your list.	Page 205
2 3 4 5 6 7 8	then? A. No. Q. So the data comes in and it's stored. Then what happens to it? A. It can be updated. It can be reviewed.	Page 203	2 3 4 5 6 7 8	MR. TORREGROSSA: Objection to form. THE WITNESS: Yes. I believe a simple screen shot of the data entry fields would provide your list. BY MR. SMITH:	Page 205
2 3 4 5 6 7 8 9	then? A. No. Q. So the data comes in and it's stored. Then what happens to it? A. It can be updated. It can be reviewed. Q. Are applications to initiate	Page 203	2 3 4 5 6 7 8	MR. TORREGROSSA: Objection to form. THE WITNESS: Yes. I believe a simple screen shot of the data entry fields would provide your list. BY MR. SMITH: Q. Could you get me system	Page 205
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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	then? A. No. Q. So the data comes in and it's stored. Then what happens to it? A. It can be updated. It can be reviewed. Q. Are applications to initiate research put into IIRIS? MR. TORREGROSSA: Objection to form. THE WITNESS: Could you BY MR. SMITH: Q. Do investigators make applications to conduct research strike that. Are investigators' applications to do research processed through IIRIS? MR. TORREGROSSA: I'm sorry. Withdraw my objection.	Page 203	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	MR. TORREGROSSA: Objection to form. THE WITNESS: Yes. I believe a simple screen shot of the data entry fields would provide your list. BY MR. SMITH: Q. Could you get me system documentation for IIRIS? MR. TORREGROSSA: Objection to form. THE WITNESS: Yes. BY MR. SMITH: Q. Would that include a data map? A. No. Q. System map? A. No. Q. Training materials? A. No. Q. Descriptions of tables?	Page 205

tables? A. Yes. 3 Q. Relationships to other 4 systems? 5 MR. TORREGROSSA: Objection to form. 6 to form. 7 THE WITNESS: No. 8 PY MR. Systems? 9 Q. User guides? 11 Q. Sure. 12 A. There are no interfaces with 12 rejected. 13 question, there would be a status of whether or not that was accepted or rejected? 14 find such interfaces. That's why I've 13 answered no. 15 q. Ves. 16 q. Visit a validated system? 17 A. Yes. 18 q. Would discussions regarding 19 an application be stored in the system? 20 MR. TORREGROSSA: Objection to form. 21 THE WITNESS: Depends on what you mean by discussion. 22 THE WITNESS: Depends on what you mean by discussion. 23 What you mean by discussion. 24 BY MR. SMITH: 25 q. Discussions among 2 AstraZeneca personnel regarding the application? 26 A. Yes. 27 THE WITNESS: And the objection was? 39 MR. TORREGROSSA: Same objection. Specition Swore of the research? 4 MR. TORREGROSSA: To form. You can answer. THE WITNESS: And the objection was? 4 MR. TORREGROSSA: To form. You can answer. THE WITNESS: No. The world the records? 16 q. Would it contain resumes for the investigator or the record.) 17 THE WITNESS: No. The westigator or the organization? 18 THE WITNESS: No. The vestigator or the organization? 19 BY MR. SMITH: 10 Q. Would it contain a decision 24 as to whether the application was application generate status reports, no.		······································			•	
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,	O Con status variants ha	Page 210		mut in place in 2000. I thought you said	Page 212
1	Q. Can status reports be		1	put in place in 2000. I thought you said	
2	generated by the system?		2	that in our prior meeting, and I may be	
3	A. Yes.		3	wrong.	
4	Q. Was there a prior system		4	Does that ring any bells or	
5	that did this?		5	is it your recollection that IIRIS was	
6	MR. TORREGROSSA: You mean		6	put into place in 1996?	
7	the management in general, not		7	MR. TORREGROSSA: Take your	
8	MR. SMITH: Management of		8	time.	
9	the research applications.		9	THE WITNESS: No, I did want	
10	MR. TORREGROSSA: Yes, sir.		10	to correct that.	
11	Thank you.		11	It was implemented in 2000.	9
12	THE WITNESS: I don't		12	BY MR. SMITH:	
13	believe there was a system prior		13	Q. Was there another system	
14	to IIRIS, a computer system.		14	that was in place in 1996 that was	
15	BY MR. SMITH:		15	similar?	
16	Q. Were active research		16	A. No.	
17	projects put into the system after it was		17	Q. Why were you thinking 1996,	
18	initiated? In other words, ones that had		18	if there's any reason?	
19	been begun before the system was		19	A. Because there is information	
20	acquired		20	in IIRIS for investigator-initiated	
21	A. Yes.		21	research around the time in 1996.	
22	Q but were still active?		22	Q. That goes back to 1996?	
23	Okay.		23	A. Correct.	
24	A. Sorry.		24	Q. So that would be what we	
1 4	O My foult	Page 211	,	talked about earlier, when we said that	Page 213
1	Q. My fault.	raye 211	1	talked about earlier, when we said that	Page 213
2	And how are finances	rage 211	2	if there were pending projects, then they	Page 213
2 3	And how are finances pertaining to this research handled in	raye 211	2	if there were pending projects, then they were put into IIRIS when IIRIS was	Page 213
2 3 4	And how are finances pertaining to this research handled in IIRIS? How are they managed?	raye 211	2 3 4	if there were pending projects, then they were put into IIRIS when IIRIS was implemented? Is that what we're talking	Page 213
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1	during the break?		1	Q. Was that a Zeneca or an	
2	MR. TORREGROSSA: You can		2	Astra system?	
3	answer that yes or no.		3	You said it was put in place	
4	THE WITNESS: Yes.		4	around 2000 or 2001. Right? Strike that	
5	BY MR. SMITH:		5	question.	
6	Q. Now, what did you want to		6	MR. TORREGROSSA: He doesn't	
7	clarify?		7	get to strike things either.	
8	A. Earlier statement with		8	MR. SMITH: I can do that;	
9	regard to training materials. That was		9	you can't.	
10	an incorrect answer. There are		10	BY MR. SMITH:	
11	procedures, procedural documents for		11	Q. What does SAMSON do?	
12	managing the information that you would		12	A. It manages investigator	
13	put into IIRIS.		13	safety letter packages.	
14	Q. Okay. You could provide		14	Q. And how does it do that?	
15	those to us. Right?		15	 A. A safety report's entered 	
16	MR. TORREGROSSA: Objection		16	into the system and assembled with other	
17	to form.		17	documents into a package.	
18	THE WITNESS: Yes.		18	Q. All right. Let me break	
19	BY MR. SMITH:		19	that I'm sorry. Go ahead.	
20	Q. Okay, thanks.		20	A. That's it.	
21	Let's talk about SAMSON.		21	Q. All right. A safety report?	
22	What does SAMSON stand for?		22	Did you say a safety report is who	
23	A. Safety adverse management		23	prepares the safety report?	
24	I'm sorry. Apologies. Can I withdraw		24	A. Drug safety.	
Į		Page 215			Page 217
1	that, if it's possible?	Page 215	1	O. Is that done through the	Page 217
1 2	that, if it's possible? MR. TORREGROSSA: It's not.	Page 215	1 2	Q. Is that done through the SAMSON system?	Page 217
2	MR. TORREGROSSA: It's not,	Page 215	2	SAMSON system?	Page 217
2 3	MR. TORREGROSSA: It's not, but state what you want to state.	Page 215	2 3	SAMSON system? A. No.	Page 217
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