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The investigator safety letter is created -- generated by the system.
Q. Which system?
A. SAMSON.
Q. How?
A. There's a template in the system. And when you select the product for that safety report, it assembles the appropriate drug information into the cover letter.
Q. What is the source of that appropriate drug information?
A. A list of drugs. I'm not sure I understand the question.
Q. I'm not sure I understand what you mean by the investigator safety letter.
Can you try that again? Can you tell me what an investigator safety letter is?
A. An investigator safety letter is a report of an adverse event.
Q. By an investigator?

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A. It could be by an investigator.
Q. Who else could initiate an investigator safety letter other than the investigator?
MR. TORREGROSSA: I'm going to object on scope. I think this is way out of bounds, but I'll let him answer on his personal knowledge, if he has any.
THE WITNESS: A consumer can call AstraZeneca and report an adverse event.
BY MR. SMITH:
Q. Would SAMSON handle an adverse event outside of a clinical study?
A. SAMSON is not used to manage adverse events. It's used to manage investigator safety letters.
Q. And the investigator safety letters, are they prepared by the system using a template?
A. Not by SAMSON, no.

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Q. Where are they prepared, the investigator safety letters?
A. By drug safety.
Q. Where is the data about the adverse event that is the basis of the letter?
A. In the safety -- in the safety database.
Q. SAMSON or another database?
A. Another database.
Q. Which database?
A. CLINTRACE.
Q. And is SAMSON sending a notification of adverse events to the investigator?
MR. TORREGROSSA: Objection to form, scope.
THE WITNESS: No.
BY MR. SMITH:
Q. Is it sending a notification of an adverse event reported by an investigator?
MR. TORREGROSSA: Same objections.

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THE WITNESS: It could be.
BY MR. SMITH:
Q. The adverse event report forms are prepared by drug safety. Right?
A. I'm sorry, can you just restate the question?
Q. The adverse event report forms, are they prepared by drug safety?
A. Yes.
Q. And then the SAMSON system somehow sucks that information and puts it into the investigator safety letter?
A. As I stated earlier, they're imported into SAMSON. There's no sucking of ISLs.
Q. The adverse event reports, are they in CLINTRACE?
A. Yes.
Q. And do they get from CLINTRACE into SAMSON?
A. Can I ask you to clarify what you mean by an adverse event report?
Q. Well, you mentioned the

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adverse event report. And you say that SAMSON is sending I believe a notification of adverse events to the investigator. Right?

A. I'm sorry, could you say that again?

Q. Did you not say that SAMSON is sending a notification of an adverse event to the investigator?

A. In describing the process of how SAMSON is used, that is what I said, yes.

Q. And when you said adverse event report, what did you mean by that?

A. The adverse event report appears in what we call an investigator safety letter.

Q. And the letter is going to the investigator, not from the investigator. Right?

A. A letter -- the investigator safety letter, its ultimate destination is in the hands of an investigator.

Q. All right. And that adverse

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event report might have come from somebody in his study or it might have come from somebody in another study?

A. You're asking me questions about -- you know, that aren't technical in nature. I'm struggling to understand.

Q. Okay.

A. It would be more appropriate to ask me questions of a technical.

Q. Sure. I'm sorry to talk over you.

How does the system work to import the adverse event information, the SAMSON system? How does it work? How does it acquire the adverse event information?

A. An investigator letter administrator will take the adverse event report that is in the ISL format and import that into SAMSON.

Q. In what format?

A. It's a -- I believe it's a .pdf.

Q. Did you say ISL?

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A. The investigator safety letter. It's a format for the adverse event report.

Q. It takes the adverse event report and merges it into the investigator safety letter?

A. Investigator safety letter is a format.

Q. And then it generates the investigator safety letter.

And how is it sent to the investigator?

A. It is sent to the investigator by being assembled into -- printed out -- it's sent to all investigators by simply being printed out, stuffed into envelopes, postage placed on it and then sent through the -- a postal service.

Q. So if you have a Seroquel adverse event report, that goes into CLINTRACE. The data goes from CLINTRACE to SAMSON. And SAMSON sends that information in the form of an ISL to all

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of the Seroquel investigators; is that accurate?

A. No.

Q. Okay. Where is it not accurate?

A. It's not accurate with respect to data.

Q. In what regard? What happens to the data coming from CLINTRACE to SAMSON?

A. The -- if you're referring to data as the ISL, there's no adverse event data. The data is assembled into an ISL, which is investigator safety letter. That describes what the adverse event is. That format is imported into SAMSON as an object, as a document.

Q. Where is the ISL letter prepared, in what system?

A. CLINTRACE.

Q. Okay. We're making some progress.

And the data that goes into the ISL letter, where does that data come

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from?
A. CLINTRACE.
Q. It comes from the AER form?
A. It comes from the data entry system CLINTRACE.
Q. Okay. Is that the same data that goes into the AER form?
A. Can you describe to me what you mean by AER form?
Q. The MedWatch form, MedWatch reporting form.
A. Oh. Yes.
Q. Is an ISL letter, a separate ISL letter, generated for each Seroquel adverse event report?
A. Yes.
Q. Does the investigator receive in some format a listing of adverse event reports, of all adverse event reports pertaining to the drug product that they're investigating?
MR. TORREGROSSA: Objection to the extent it's way outside the scope of this deposition.

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You can answer if you have personal knowledge.
THE WITNESS: Could I just have the question again?
BY MR. SMITH:
Q. Is there a system that sends a line listing of adverse event reports to the clinical investigators for a drug?
A. No.
Q. So they just get letter after letter, but they don't get an assemblage of that information into some sort of line listing; is that correct?
In other words -- let me just rephrase the question.
In other words, they're not going to get a line listing that lists 50 adverse event reports. You're going to get 50 ISLs that each report a separate event; is that correct?
A. You're asking me a question that has to do with I believe business process. I can tell you what the system does with respect to ISLs.

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Q. I think we're talking about managing the information.
In the SAMSON system, what does it do besides create ISLs?
Excuse me. What does it do besides send out ISLs to the investigators? That's what it does, right, sends out ISLs to the investigators. Right?
A. Yes.
Q. Does it do anything besides that?
A. No.
Q. Is it a database?
A. Yes.
Q. And what are the data?
A. The data are information describing the packet.
Q. And besides the letter, what's in the packet?
A. The list of investigators, a summary of the number of ISLs in that packet and the number of investigators that it will be sent to.

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Q. And does SAMSON generate the list of investigators?
A. Yes.
Q. What is the source of the list?
A. It's a database of investigators.
Q. What database?
A. Well, sorry. When I say database, what I mean is there's a table in SAMSON that houses the investigator addresses.
Q. Where do the investigator addresses come from?
A. They come from another database.
Q. What database?
A. AZ IMPACT.
Q. A summary of the number of ISLs in the packet, where is that generated, that summary?
A. It's generated by SAMSON.
Q. What is the source of that information?

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A. The number of investigators that are assembled for that AE product.
Q. Where are they listed? Where's that data -- where's that data reside?
A. I'm not sure I understand your question.
Q. The summary of the number of ISLs in that packet, what do you mean by a summary of the number of ISLs? I guess I don't understand that terminology.
A. There is a total. If there are 10 investigators that that ISL needs to be sent to, and there's one ISL, there will be a count of 10 letters. So the summary is 10. It's a count of the investigators times the number of documents in the packet.
Q. Okay. And if a user wanted a report of the ISLs that went to a particular investigator, could they get that report from SAMSON?
A. Not very easily.
Q. Why?

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A. Well, the information is not really part of the metadata for that packet. It's actually contained within the ISL packet.
Q. Is it in CLINTRACE?
A. No.
Q. Is there anyplace where you could obtain information regarding communications to a clinical investigator, any one place where you could go to get a look at all of the communications with that investigator?
A. The investigator site.
Q. Would that be a different database or a Web site?
MR. TORREGROSSA: Objection to form.
THE WITNESS: It's at the physical site. The investigator would have the ISLs.
BY MR. SMITH:
Q. But AstraZeneca wouldn't have any way of obtaining or producing a report that showed what communications

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went to that investigative site.
Is that what you're saying?
A. I don't believe that there's a report that would give you that information.
Q. Is SAMSON -- I'm sorry. I didn't mean to interrupt you.
A. It's a business process to ensure that the investigators have the ISLs on site.
Q. It's also a system that uses software to perform this function. Right?
A. I'm having difficulty trying to answer that question, because you've made a statement based on your interpretation of what a system should do. And I can describe what the system does based on the AstraZeneca requirements of what the system is required to do.
Q. Well, to recap then, let's state as succinctly as possible, what is a SAMSON system, what requirements is the

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SAMSON system designed to meet, and how does it do it?
MR. TORREGROSSA: Objection. Multiple questions.
BY MR. SMITH:
Q. All right. What are the requirements it's designed to meet? We'll break it down.
A. The requirements are to assemble and track the -- rather, demonstrate that we are mailing or distributing SAEs to investigators.
Q. Is that a validated system?
A. Yes.
Q. So you can prove that you sent the ISLs to the investigators.
What are SAEs?
A. It's a terminology that's frequently used to describe a serious adverse event.
Q. So is that the same as the ISLs, or are we talking about something different now?
MR. TORREGROSSA: Objection

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to form.
BY MR. SMITH:
Q. Let me rephrase that.
Are the ISLs the tool that is used to mail or distribute the SAEs to investigators?
A. The ISL is a document that contains the adverse event information that needs to be communicated to investigators.
Q. Is that only serious adverse events?
MR. TORREGROSSA: Objection. I think this is way outside the scope of this deposition.
BY MR. SMITH:
Q. You used the term, so I just wanted to follow up on that, Mr. Draper.
A. I may have inappropriately used that term "serious." The adverse event I'm trying to speak to is, we have an investigator safety letter. And the criteria for why that needs to be communicated to an investigator are

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federal regulations interpreted by the business.
What I'm trying to stick to and explain to you are the technical aspects for managing those documents in the database called SAMSON.
Q. And because you have to track those mailings, it's a validated system. Right?
A. Well, if what you mean in the term of "track," we need to demonstrate that we have mailed those event reports to investigators or those ISLs, as we call them, to investigators.
Q. Earlier didn't you tell me that there was no way to tell which ISLs went to which investigators?
MR. TORREGROSSA: Objection, mischaracterizes his testimony.
You can answer.
BY MR. SMITH:
Q. You can answer that yes or no or explain -- and explain your answer, if you want to, like any question.

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A. Can I have the question again, please, from the court reporter?
- - -
(The court reporter read the pertinent part of the record.)
- - -
MR. TORREGROSSA: Objection, mischaracterizes his testimony.
MR. SMITH: Just object to form, please.
MR. TORREGROSSA: No.
MR. SMITH: If I need to know what the basis of your objection is, I'll ask you for details.
MR. TORREGROSSA: No.
MR. SMITH: No, that's the rule. The only objection you're allowed to make is to form or privilege, and that's it.
MR. TORREGROSSA: No. First of all, that's incorrect under the agreement of the parties.
Second of all, I am allowed

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to state if I think you've mischaracterized his testimony. That is an objection to form.
MR. SMITH: No. That is coaching the witness, and please don't do it.
MR. TORREGROSSA: I'm not coaching the witness. You're accusing him of saying something he didn't.
MR. SMITH: Just say objection to form.
MR. TORREGROSSA: I'll state my objections.
THE WITNESS: Can I have --
MR. SMITH: You can have it again.
THE WITNESS: Can I go back to the question again, please?
- - -
(The court reporter read the pertinent part of the record.)
- - -
THE WITNESS: No.

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BY MR. SMITH:
Q. Could you generate a report showing which ISLs went to which investigators?
A. I don't believe that we have a report to do that.
Q. Well, how would you prove you sent them if you couldn't generate a report?
A. You're asking me questions that, again, are purely business process related. That is a responsibility of the business, to use the information in the database for those purposes.
Q. But does the system contain information that will allow you to produce a report showing what ISLs went to which investigators? I am not talking about a business decision.
I'm talking about will the system do this? Does it have the capability of doing this?
A. You can identify, by going into the actual packet, you can identify

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the investigators that were intended to receive that ISL.
Q. Okay. That's for a particular ISL?
A. That's correct.
Q. Now, if I asked you with regard to a particular investigator, would the system allow you to identify all the packets that went to that investigator?
A. That would be an extremely burdensome and laborious process, to drive down into every single ISL packet, search through, you know, extensive lists of investigators that received that packet to identify a particular investigator.
Q. Can you search by investigator?
A. No.
Q. What types of search are available in SAMSON?
A. Drug, date range.
Q. Is there a table of

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information on the investigator?
MR. TORREGROSSA: Objection to form.
You can answer.
THE WITNESS: I think I answered that earlier.
And the earlier --
BY MR. SMITH:
Q. And there is?
A. -- answer I gave, yes.
Q. Was information from SAMSON migrated into SAM? Was data from SAMSON migrated into SAM?
A. No.
Q. SAMSON was a pred -- SAMSON was the predecessor of SAM. Correct?
A. No.
Q. Oh, I misunderstood your testimony then.
What is SAM?
A. It's a document -- source document management system.
Q. And what is your involvement with SAM?

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A. I'm the application service manager.
Q. And when was SAM put in place?
A. 2000, approximately 2000 -- actually, excuse me. Let me correct that. 2001.
Q. Does SAM interface with CLINTRACE?
A. No.
Q. Does it contain the underlying documentation for adverse events?
A. Can you please describe -- just clarify what you mean by that term?
Q. Does it contain the data that would go into adverse event reports?
A. If what you mean by data is information reported to AstraZeneca that would otherwise be an adverse event, yes.
Q. What does SAM stand for? Is it an acronym?
A. It's the safety adverse event -- or sorry, it's the safety

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adverse management system.
Q. And is there a vendor for SAM?
A. Yes.
Q. Who is that?
A. AstraZeneca.
Q. Who's the database manager?
A. When you say database manager, I've been assuming that you mean the database administrator.
Q. Database administrator. That's acceptable.
A. Okay. Sam Fitzpatrick.
Q. Okay. I want to use whatever term you use. I mean, people could use different terms. So the database administrator.
Who's the business analyst?
A. Mark Barsume.
Q. Business owner?
A. Nancy Wolpert.
Q. Is there a data map or schema?
A. No.

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Q. Is there a system map or diagram?
A. Yes.
Q. Could you produce a copy?
MR. TORREGROSSA: Objection to form.
THE WITNESS: Yes.
BY MR. SMITH:
Q. What other documentation is there for SAM?
A. Training materials, user guide, typical validation materials.
Q. Could you provide that information?
MR. TORREGROSSA: Objection to form.
THE WITNESS: Yes.
BY MR. SMITH:
Q. What type of database is it?
A. It's an Oracle database.
Q. What information does it contain?
A. Again, if by information -- earlier you referred to data and now

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you're referring to information?
Q. Data. No, I'm sorry, I mean data, data.
A. They're two very, very different terms in the IT world.
Q. Yeah. Well, data. I misspoke.
A. Okay. Data being a form of metadata.
Q. Well, data being -- all right. We're back to information then.
Does SAM contain information? Is it a collection of information?
A. Yes.
Q. Does it contain metadata regarding the information?
A. Yes.
Q. Is the information organized in tables?
A. Parts of it are organized in tables.
Q. What parts?
A. The metadata.

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Q. What is the purpose of the system?
A. I think I answered that question already. I'll state it again. That it's used to manage source documents.
Q. For the adverse event reports. Right?
A. Yes.
Q. And what departments or teams use SAM?
A. Drug safety.
Q. Anyone else?
A. No.
Q. And what are the sources of the information?
A. They're adverse event reports received by drug safety.
Q. Are we talking about global adverse event reports?
MR. TORREGROSSA: You can answer that yes or no.
THE WITNESS: Yes.
BY MR. SMITH:

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Q. When was the system put into use?
A. I answered that question already.
Q. I apologize.
MR. TORREGROSSA: Just --
THE WITNESS: 2001.
MR. TORREGROSSA: I know it's frustrating, but just give it to him if you could.
THE WITNESS: 2001.
BY MR. SMITH:
Q. Was there a system that preceded it?
A. No.
Q. Does it have query and search capabilities?
A. Yes.
Q. Can you export information from the system?
MR. TORREGROSSA: Objection to form.
THE WITNESS: There is a function whereby you can, on an

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individual basis, export.
BY MR. SMITH:
Q. Can you export the metadata?
A. No.
Q. Are you aware of any information being lost or destroyed from the system?
MR. TORREGROSSA: Objection to form.
THE WITNESS: I'm sorry, I didn't get the first -- could you just restate that?
BY MR. SMITH:
Q. Sure.
Are you aware of any data -- excuse me.
Are you aware of any information being lost or destroyed from the system?
MR. TORREGROSSA: Objection to form.
THE WITNESS: No.
BY MR. SMITH:
Q. Are you aware of any data

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corruption that would affect reliability?
A. No.
Q. What systems does SAM interface with?
A. I think I answered that question already.
MR. TORREGROSSA: Answer again.
BY MR. SMITH:
Q. I don't think so, but if you would, please.
A. SAM itself does not interface. The information that comes into SAM is imported or scanned.
Q. How about on the output side, does it link to any other systems or interface with them?
A. No.
Q. I believe you said the adverse event information was scanned.
Do you know where that information is obtained or by whom?
MR. TORREGROSSA: Objection, scope. It's outside the scope.

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THE WITNESS: Am I to answer that question?
MR. TORREGROSSA: Yes. You can answer to your personal knowledge.
THE WITNESS: Drug safety entered these documents into the system. Where they come from or how they're received, I'm sure -- I guess I could speak a little bit to what I understand the business --
BY MR. SMITH:
Q. Sure.
A. You get a document and you scan that document in, and it's indexed into the database.
Q. Are you familiar with medical affairs outlook forms?
A. Could you be more specific?
Q. Do you know what the medical affairs outlook forms refers to, what the term refers to?
A. I have a general technical

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understanding of what an outlook form is. But your reference to medical affairs, I can't say that I do.

Q. Are you aware of whether medical affairs provides any information that is used in this system?

MR. TORREGROSSA: Used in --

MR. SMITH: That is inputted into this system.

MR. TORREGROSSA: And what system are we talking about? I'm sorry.

MR. SMITH: SAM.

MR. TORREGROSSA: SAM, okay. Thank you.

THE WITNESS: Can I just have the question again so I understand?

- - -

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

- - -

THE WITNESS: Again, I can't speak to the source of where this

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information comes from. That's the business -- the businesses are going to understand where the source of that information is better than I am.

BY MR. SMITH:

Q. Does your department provide IS services to medical affairs?

A. No.

Q. Are any systems that you manage used by medical affairs?

A. Could you please clarify what you mean by systems I manage?

Q. Systems -- IS systems that you're responsible for, or your team, when I say you.

A. Pardon?

Q. When I say you, I don't mean you personally, I mean your team.

A. No.

Q. Who would provide IS services to medical affairs?

A. I think primarily commercial -- what we refer to as

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commercial IS or business IS, as well as GDDIS.

Q. What is the GESISS system, if I'm pronouncing that correctly?

A. It's GESISS. It's just a letter pronunciation.

Q. What is that?

A. It is an archive of electronic adverse event reports.

Q. When was it put into place?

A. I believe it was implemented in 2003, and the business subsequently began using it in 2005.

Q. I thought you had indicated when we met a couple -- a few months ago that it was begun sometime in 1998.

Was I mistaken?

A. Yes.

Q. And what is your involvement with GESISS? I guess start with you personally.

Do you have any involvement?

A. Present day?

Q. Yes.

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A. No.

Q. Does your department have responsibility for GESISS?

A. Yes.

Q. Did you in the past have any involvement with GESISS?

A. Yes.

Q. Could you describe your involvement?

A. I developed or architected or designed, architected and developed, was part of the development team for that application.

Q. What type of platform is it?

A. Can you just --

Q. What kind of platform does it use?

A. You mean the database. It's an Oracle database.

Q. It's an archive, it's a repository, that's where the images of the documents reside; is that correct?

A. There's no images of documents in GESISS.

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Q. How --
A. I'm sorry, can I --
Q. Yes.
A. There are electronic documents, but there are no images, so...
Q. So there can be an electronic document, like in Word or Excel or something like that?
A. Not those kinds of documents.
Q. What kinds of documents?
A. .pdf.
Q. What is ICSR?
A. An ICSR simply means an individual case safety report.
Q. And does GESISS store those reports?
A. Yes.
Q. Does it track those reports?
A. It's an archive. I don't know how to describe it other than an archive.
Q. I assume it's searchable?
A. Yes.

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Q. What metadata is there with the .pdf files?
A. CLINTRACE case ID, drug, maybe data entry site.
Q. Does it have any information pertaining to date of submission to the FDA?
A. Yes.
Q. Does it have a way to associate it with any changes or supplements to the report?
A. Again, it's an archive. It's a read only. You wouldn't make changes to these reports.
Q. No. I meant, if you see a report in GESISS, can you find out whether there were any subsequent, any supplements to the report?
A. If what you mean by supplement, the follow-up information about the adverse event report entered into CLINTRACE, the answer is yes.
Q. How would you locate the follow-up information? Would you do that

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using GESISS?
A. No. You would use CLINTRACE.
Q. What was the predecessor to this system?
A. There was no system. The reports were submitted in paper.
Q. Okay. Were the prior reports imported into GESISS when it was implemented?
A. No.
Q. Where would the prior reports be -- previous reports be maintained?
A. In the paper archives.
Can I just --
Q. Uh-huh.
A. I'll just -- never mind.
Q. Can you search by case ID number?
A. I think I answered that. Yes.
Q. Can you search by manufacturer control number?

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A. Yes.
Q. Who's the database administrator?
A. Sam Fitzpatrick.
Q. And the business analyst?
A. Al Fowkes.
Q. Business owner?
A. Sorry. I -- names are clouding a bit.
I believe Al Fowkes is the system owner. The -- I believe he's also the business analyst. And I'm struggling to recall the names.
Q. Could you provide copies of system documentation?
MR. TORREGROSSA: Objection to form.
THE WITNESS: Such as user guide and training manuals? Yes.
BY MR. SMITH:
Q. Yes.
Also data maps, system maps?
MR. TORREGROSSA: Objection to form.

THE WITNESS: If they are available, they could be, yes.
BY MR. SMITH:
Q. I take it you don't know whether they're available or not?
A. There is a system map.
Q. Okay. And you could provide that to me. Right?
MR. TORREGROSSA: Objection to form.
THE WITNESS: Yes.
BY MR. SMITH:
Q. Could you provide me with a user list?
MR. TORREGROSSA: Same objection.
THE WITNESS: Yes.
MR. SMITH: Okay. Why don't we adjourn until tomorrow morning.
(Deposition adjourned at approximately 5:37 p.m.)

CERTIFICATE

I HEREBY CERTIFY that the witness was duly sworn by me and that the deposition is a true record of the testimony given by the witness.

____________________ ______________
ANN MARIE MITCHELL, a Federally Approved Certified Realtime Reporter, Registered Diplomate Reporter and Notary Public
Dated: May 21, 2007

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ERRATA
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PAGE	LINE	CHANGE

ACKNOWLEDGMENT OF DEPONENT

I,____________________, do hereby certify that I have read the foregoing pages, 1 - 263, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

____
DARRYL DRAPER DATE

Subscribed and sworn to before me this _____ day of _______________, 20____.

My commission expires:______________

____
Notary Public

LAWYER'S NOTES

PAGE LINE