Breckenridge Institute

HARNESSING THE POWER OF CULTURE™

Independent Verification and Validation of AERS II Requirements Process

approved
Pgm 67

CONFIDENTIAL

Conducted by:
Breckenridge Institute
PO Box 5050
Breckenridge, CO 80424
www.breckenridgeinstitute.com

November 2006

TABLE OF CONTENTS

1.0 Executive Summary

The self assessment that is summarized in this report was conducted by the Breckenridge Institute™ and is an independent verification and validation of the AERS II Requirements Process. It describes AERS-related activities that are currently on-going as of October 2006 and is the final step in a process initiated in 2003 by [redacted] to replace the dysfunctional AERS system. The work that resulted in this report was initiated by the AERS Program Office prior to its being disbanded, and prior to the reorganization of the Office of Pharmacoepidemiology and Statistical Science (OPaSS) into the current Office of Surveillance and Epidemiology (OSE). Based on the information and data evaluated, the Breckenridge Institute assessment team has identified one root-cause finding (shown below) and 12 supporting observations that are found in Section 2.0. The assessment team has included three recommendations for corrective action.

Root Cause Finding: CDER's culture can be characterized as one in which managers at all organizational levels fail to move from the *awareness* of organizational problems, to the kind of *action* that will produce positive change. When some CDER managers do attempt to make positive change as with the AERS II system described in this report, their attempts are frustrated and undermined by an "invisible bureaucracy" that they don't really understand. In the case covered in this report, the AERS II system could have been completed in 2005, but was delayed and ultimately shelved, by: a) a change in project scope from replacing the dysfunctional AERS system to building an FDA-wide adverse event reporting system, and b) unilateral decisions and questionable procurement practices on the part of CDER's Office of Information Technology (OIT). These actions were taken despite the documented needs of AERS users, and the documented objections of CDER managers and scientists. The consequences of these actions include:

- Conducting an AERS II requirements process led by CDER OIT that: a) was unnecessary and cost $1,500,000; b) did not follow proper IT methodology; c) selected and utilized contractors that have a known and documented track record of inadequate or poor performance; d) ineffectively utilized the time of dozens of AERS users in requirements development meetings because OIT lacked personnel who could execute the Business Systems Analyst function; and e) culminated in a High-Level Requirements Document, a Technical Alternatives Analysis Document, and a Detailed Requirements document that makes FDA less prepared today to replace the dysfunctional AERS system than it was in 2004.
- A total estimated cost of $25,000,000 and a four-to-five year delay in replacing the AERS system, which will not be operational until 2009 or 2010.
- The frustrating and undermining of the post-marketing drug safety work of Safety Evaluators, epidemiologists, and personnel in the Offices of Compliance and FOI because they lack some of the basic tools they need to perform their jobs, e.g. a computing system that meets their requirements.

One of the most difficult tasks of characterizing the culture in an organization like CDER is to tease apart the difference between: a) the beliefs, assumptions, and ways of working of individual managers and key personnel, and b) beliefs, assumptions, and ways of working that are held collectively by the organization as a social phenomenon, e.g. culture. Perhaps the key indicator that an issue is "cultural" is the existence of long-term patterns of organizational behavior that span long-periods of time. In the case of AERS, this study documents a pattern of organizational behavior on the part of CDER's OIT that spans ten years, two Center Directors, at least two different configurations of CDER's organizational structure, and multiple Directors of CDER's OIT. Given the data presented in this report, the Breckenridge Institute assessment team is convinced that the root cause of the problems associated with the AERS II requirements processes is cultural and can only be addressed by a significant change in CDER's culture.

Recommendation 1: In an atmosphere in which IT management and contracting practices are coming under increased scrutiny, and in the wake of the recent report from the Institute of Medicine (IOM) that identifies organizational culture as a root cause of issues in FDA, the senior managers in CDER should conduct a thorough investigation into the leadership, management, and contracting practices of OIT.[1] In addition to characterizing the tacit, underlying patterns of organizational beliefs and behavior in CDER's organizational culture, they should investigate: a) how effectively CDER's portfolio of IT projects is being led and managed; b) the selection criteria by which contractors like the one mentioned above are screened and selected; c) and the way in which financial resources are being combined into larger and larger categories in CDER's OMB Exhibit 300. This *increases* the extent to which OIT can reprogram the IT funds of CDER's science-technical units like OSE, award those funds to contractors they select without the approval of science-technical managers, and *decreases* the level of traceability and overall accountability for doing so.[2]

Recommendation 2: The senior managers in CDER should take immediate action to correct the problems in CDER's OIT as described in this report. In addition, under the auspices of the IT consolidation, organizations such as OSE that contain AERS users should have the opportunity to select a team of IT professionals from the consolidated FDA IT organization that have a proven track record of technical performance and providing outstanding service to end users like the Safety Evaluators who use AERS.

Recommendation 3: FDA should execute an updated version of the software acquisition plan that was developed by the CDER OIT AERS II Project Manager and AERS Program Manager in 2004 and begin the process of acquiring a replacement for AERS I immediately. The AERS II system has been absorbed into an FDA-wide IT system that includes multiple FDA Centers. This is a much more complex and daunting task than simply replacing the AERS system, and consequently making such a system functional is probably four-to-five years away – minimum. This forces Safety Evaluators in CDER and CBER and other FDA units such as the Offices of Compliance and FOI, to work with the dysfunction AERS I system for yet another extended period of time, thus further undermining their ability to effectively carry out FDA's mission of post-marking surveillance and drug safety. Based on the information contained in this report, a replacement for AERS could be operational in less than two years at a cost of about $5 million dollars. More importantly, this fully functioning AERS II system could then be used as a solid foundation for an FDA-wide system. It is important to note, that recently in the wake of the IOM report, there seems to be a renewed interest on the part of CDER's OIT and OSE in replacing the dysfunctional AERS I system as a necessary first step in developing an Agency wide system, despite the fact that funding for AERS II has been zeroed out in FY 2006 and FY 2007.

---

[1] See the Institute of Medicine's report entitled, *The Future of Drug Safety: Promoting and Protecting the Health of the Public*, published on Sept 26, 2006.

[2] For example, see the audit and investigation into the $170 million IT system developed for the FBI that was unusable. See, "The FBI's Upgrade That Wasn't," by Dan Eggen and Griff Witte in, *The Washington Post*, August 18, 2006 (http://www.washingtonpost.com/wp-dyn/content/article/2006/08/17/AR2006081701485.html).

2.0 Summary of Observations

The conclusions that emerged from the research and analysis process conducted by the Breckenridge Institute have been codified into twelve observations. The supporting evidence for each observation in the text is linked to the observations below by reference in the text.

OB 1-2006: There has been a pattern of unilateral decision-making about the AERS II system on the part of CDER OIT despite the documented needs of AERS users, and the documented objections of CDER managers and scientists. This pattern of unilateral decision-making has been evidenced by the Directors of OIT since 2003 (see supporting data in the text below).

OB 2-2006: The requirements activity from 2005 on was unnecessary, did not add value to what had already been done, cost $1,500,000, and did not follow proper IT methodology as defined by FDA and industry standards such as Oracle – the FDA standard for IT systems. More specifically, no new information on user requirements emerged from the HL Requirements Document that would have supported taking a different direction, yet this was used as the basis for a second "technical" alternatives analysis and a Detailed Requirement's Document that took the AERS II project in an entirely different direction than the one established prior to July 2004. In addition, the AERS II requirements process violated procedures specific in the FDA's Life Cycle Systems Document (LCSD) and standard industry methodologies like those developed by Oracle – the FDA standard for IT systems (see supporting data in the text below).

OB 3-2006: Over the three years covered by this assessment, the Directors of OIT have demonstrated a lack of effective leadership and management of AERS II as evidenced by continued turnover of AERS II Project Managers - there were five Project Managers during the three year period. On November 8th 2006, another former AERS Project Manager resigned his position with OIT and the government (see supporting data in the text below).

OB 4-2006: Over the period of time covered by this assessment, CDER's OIT has been combining the Center's IT financial resources into larger and larger pools in the OMB Exhibit 300, making it increasingly difficult to have accountability for the spending of large amounts of money. This increases the extent to which OIT can: a) reprogram the IT funds of CDER's science-technical units like OSE, b) award those funds to contractors OIT selects without the approval of science-technical managers, and c) decrease the level of traceability and overall accountability for doing so (see supporting data in the text below).

OB 5-2006: The original AERS system was released on November 1, 1997, taken off-line because it was largely unusable by AERS users, and then re-released on 1998. Despite known and documented inadequacies in their performance, this same contractor was hired by CDER's OIT to do the High-Level Requirements Document that is methodologically flawed and makes FDA less able to replace the dysfunctional AERS system now than it was in 2004. When the hiring of the contractor was questioned by senior FDA managers and AERS users, OIT obfuscated the situation and did not justify their decision based on the contractor's previous performance (see supporting data in the text below).

OB 6-2006: The AERS II requirements process and CDER's OIT and OIM lacked an effective *liaison* between: a) AERS users, b) the working level technical people within OIT who functioned as AERS Project Managers, and c) the IT designers in the AERS software maintenance contractor organization. This liaison function is normally described as a business systems analyst (BSA). Until recently, the AERS Program Manager tried to fulfill this role, but this position has been abolished (see supporting data in the text below).

OB 7-2006: Neither the 2004 High-Level Requirements Document, nor the 2006 Detailed Requirements Document specifies what methodology and/or tools were used to manage the AERS II requirements process or to produce the models in the final documents, e.g. a requirements repository like Oracle Designer. Standard IT methodology requires that such methods and tools be used as the basis of a requirements process and that they be clearly documented in the final requirements document. In the case of the AERS II requirements process, it appears that lists of requirements that were available prior to July 2004 were edited, and then cut and pasted into the two documents using MS Word or Excel rather than using a requirements repository/tool to manage the overall requirements process. In 2003, FDA paid Oracle over $300,000 to reverse engineer the AERS I system into Oracle Designer, an automated tool widely used by Oracle customers and consultants to design new systems and document existing systems.[3] It appears that this information was ignored by CDER's OIT and its contractors during the AERS II requirements process (see supporting data in the text below).

OB 8-2006: Neither the 2004 High-Level Requirements Document, nor the 2006 Detailed Requirements Document took a "top down" Business Process Analysis approach to the AERS II requirements process, e.g. the AERS II requirements process was not linked to CDER's mission and goals in any meaningful way. More specifically, CDER mission and goals were not incorporated in the 2004 High-Level Requirements Document. Although the document contains a section entitled, *Business Vision and Objectives,* this contains a cursory discussion of the objectives for the AERS II system, but does not tie AERS II back to CDER's mission or goals. In addition, the 2004 High-Level Requirements Document does not contain (or reference) a properly conducted Business Process Analysis using methods such as workflow analysis, Swimlane diagrams, or IDEF0 process analysis. There is no "as-is" or "to-be" analysis of CDER's enterprise-wide business process of Drug Safety, or its enabling processes, e.g. conducting safety analyses, epidemiological studies, or the tasks performed by the Offices of Compliance and FOI. The form of analysis that was included in the document was inappropriate for a high level requirements phase, e.g. using Use Cases that would typically be used at the Presentation-User Interface to break down CDER's enterprise-wide business process and enabling processes, both of which should reside at the higher-level Enterprise-Wide Business Processes (see supporting data in the text below).

OB 9-2006: The back-engineering of the AERS I system using Oracle Designer in 2003 provided a solid foundation upon which to build AERS II in terms of an Entity Relationship (ER) model and underlying data structure. The 1996 AERS I document contained a Data Requirements section, complete with a dictionary report. Although this information is stored in the Oracle Designer container maintained by CDER's OIT, it appears to have been ignored by OIT and its contractors in the AERS II requirements work conducted from July 2004 on, resulting in a *very serious* lack of definition at the most fundamental level of Data Management. If, by leaving the Data Management tier out of both the 2004 HLR Document and the 2006 SRS Document, the intention was to rely on the ER Model and Data Management

---

[3] Oracle Designer, formerly called Oracle CASE (Computer Aided Systems Engineering), is a tool that can be used from day one of the systems development life cycle to document and analyze system requirements. Richard Barker's book, *Case Method: Tasks and Deliverables*, describes how to use the tool for every step of the life cycle. The Designer repository captures increasingly detailed information obtained during the life cycle, without the need for re-entry of requirements. For example, during the Strategy (High Level Requirements) phase, information about conceptual data entities is stored. During the Analysis (Detailed Requirements) phase, these same entities are documented in more detail, and a complete Entity Relationship model is completed. Then during the Design phase, a utility within the repository can be run to generate a default database design, which subsequently can be used to automatically generate SQL syntax and create the necessary tables in Oracle.

tier in AERS I, then serious deficiencies in AERS II functionality will be unavoidable, as indicated by the comments and data gathered in the 2005 AERS Users Satisfaction Survey. This also indicates that a higher priority was placed on the ER Model and Data Management Tier ten years ago than today. The lack of an ER Model and well-defined underlying data structure presents a *serious risk* to the potential success of AERS II because without these elements, user needs will not be met again as was the case with the AERS I system. Without an ER Model and underlying data structure, it is not possible to evaluate the degree to which the Presentation and Application Logic levels of the design actually contain complete functionality. Regardless of whether one is developing a custom software application where information deliverables are used to build a sound database structure, or evaluating the extent to which a COTS or COTS integration package will meet user needs, a well-defined foundation of an ER Model and information deliverables is required by standard industry practice (see supporting data in the text below).

OB 10-2006: The unilateral decision by CDER's OIT Director to begin the AERS II requirements process all over again post-July 2004 had an enormous negative impact on AERS users by delaying the replacement of the dysfunctional AERS I system by at least five years. This decision was made despite the objections of: a) technical staff in CDER's OIT, b) CDER's OIT AERS II Project Manager, c) AERS users in multiple FDA Centers, d) the OPaSS AERS Program Manager, and e) numerous CDER managers and scientists. But this unilateral decision also had an enormous financial impact that will ultimately cost FDA more that $25,000,000 in a time when funding for computing is increasingly scarce. In other words, had FDA moved forward on the CDER OIT-OPaSS approved plan in July-2004 rather than unilaterally changing direction, FDA would have: a) had a functioning AERS II system in 2005, and b) avoided spending more than $25,000,000 in contracts and services - many of which were not value-added to FDA or its mission (see supporting data in the text below).

OB 11-2006: The AERS users in CDER, CBER and other organizational units throughout the FDA have been forced to use the dysfunctional AERS I system for more than 10 years which has frustrated and undermined their ability to perform their jobs effectively (see User Survey comments). The additional 4-5 year delay caused by the AERS II requirements process being unnecessarily repeated have perpetuated and exacerbated the functionality problems identified in the AERS User Satisfaction Survey conducted in 2005 (see supporting data in the text below).

OB 12-2006: An analysis of the 2003 Requirements Traceability Matrix (RTM) that used the 1996 and 1998 Requirements Documents as a baseline revealed that almost 48% of the functionality of the AERS I system was removed from the original AERS system requirements (381 out of 795 requirements).[4] Even after discussions with CDER's OIT, it was unclear *why* these pieces of functionality were removed, *when* they had been removed, or *who* authorized their removal, yet many of the problems faced by users today in FY07 are *directly caused* by these missing pieces of functionality.[5] Further analysis has shown that at least 150 (40%) of the requirements that were removed from AERS I were *added back in* to the Detailed Requirements Document delivered by BAH in June of 2006, indicating that FDA will have to pay for this functionality a second time (see supporting data in the text below).

---

[4] See the Booz Allen Hamilton, *FDA Center for Drug Evaluation and Research, AERS Requirements Traceability Matrix*, Task No. T06 – Contract No. 223-97-5513, September 8, 2003.

[5] See Booz Allen Hamilton, *AERS II System Requirements Specification*, Version 1.1, April 6, 2006, and Booz Allen Hamilton, *AERS II Safety Evaluator, FOI, & Compliance Requirements (with Changes Tracked Based on Input from Safety Evaluators Received on May 17, 2006)*, June 2006.

3.0 Organizational Culture and Background

The purpose of this section is to establish the overall historical context for the Independent Verification and Validation of the AERS II Requirements Process, and to evaluate the rationale and consequences of critical decisions that were made by CDER's OIT, AERS users, and CDER managers and scientists that have brought the AERS II project to the point it is today in FY07. It is meant to answer two fundamental questions.

- How did the project scope for AERS II get radically shifted from replacing the dysfunctional AERS I system, to building an Agency-wide adverse event report system?[6]

- What are the end-effects and consequences for taking this path on FDA's and CDER's ability to carry out its mission of protecting and promoting public health through safety evaluations, epidemiological studies, and the functions executed by the Offices of Compliance and FOI.

The long-term patterns of decision-making and organizational behavior described in this section of the report are strong indicators that CDER's culture is one in which managers at all organizational levels fail to move from the *awareness* of organizational problems, to the kind of *action* that will produce positive change. When some CDER managers do attempt to make positive change as with the AERS II system, their attempts are frustrated and undermined by an "invisible bureaucracy" that they don't really understand. An example of an attempt to make positive change described in this section was [redacted] plan to create an "essential tension" (interdependency) between the scientific-technical elements within OPaSS and CDER's IT function, where OIT would be *accountable* for giving AERS users what they needed to do their jobs by replacing the dysfunctional AERS I system. As the evidence presented below indicates, this move was counter-cultural and created a deep-seated power-struggle between OPaSS and CDER's OIT for control of the AERS system because it meant that the IT-tail would no longer be able to wag the dog of FDA's scientific, programmatic and business needs. The fact that senior FDA managers have known about the ineffective performance of CDER's OIT for over ten years and have not corrected this situation is an example of CDER's failure to move from *awareness* of these organizational problems, to the kind of *action* that would have produced positive change.

As mentioned previously, one of the most difficult tasks of characterizing the culture in an organization like CDER is to tease apart the difference between: a) the beliefs, assumptions, and ways of working of individual managers and key personnel, and b) beliefs, assumptions, and ways of working that are held collectively by the organization as a social phenomenon, e.g. culture. Perhaps the key indicator that an issue is "cultural" is the existence of long-term patterns of organizational behavior that span long-periods of time. In the case of AERS, this study documents a pattern of organizational behavior on the part of CDER's OIT that spans ten years, two Center Directors, at least two different configurations of CDER's organizational structure, and multiple Directors of CDER's OIT. Given the data presented in this report, the Breckenridge Institute assessment team is convinced that the root cause of the problems associated with the AERS II requirements processes is cultural and can only be addressed by a significant change in CDER's culture.

---

[6] It is important to note, that recently in the wake of the IOM report, there seems to be a renewed interest on the part of CDER's OIT and OSE in replacing the dysfunctional AERS I system as a necessary first step in developing an Agency wide system, despite the fact that funding for AERS II has been zeroed out in FY2006 and FY 2007.

3.1 Background

The FDA is responsible for pre-market and post-marketing safety and efficacy assessments of human drugs and certain biologics through its Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER), respectively. Clinical trials, which represent the pre-market process that leads to formal marketing approval, only begin to quantify the safety and efficacy of a given pharmaceutical compound or biological product. The post-market assessment of safety and efficacy is conducted largely by means of reviewing and monitoring of adverse event reports.

An adverse event is any undesirable event associated with the use of a drug or biologic in humans. Given the approach of spontaneous or "passive" surveillance, the collection and analysis of adverse event data must be reported to FDA in order for the agency to carry out its mission of performing post-marketing drug safety (PMDS) throughout the entire life cycle of the product. The Adverse Event Reporting System (AERS) is a computing system that FDA staff uses to carry out the PMDS function. The Office of Pharmacoepidemiology and Statistical Science (OPaSS) AERS Program Office is the organizational unit in FDA that *orchestrates* the needs of users in all FDA Centers who perform the PMDS function and the technical support of CDER's Office of Information Technology (OIT) and Office of Information Management (OIM).

The genesis of the FDA spontaneous reporting system for drugs dates to the 1962 Kefauver-Harris Amendment to the Food, Drug, and Cosmetic Act that required drug manufacturers to report all adverse reactions for any product marketed under an approved New Drug Application (NDA). FDA began computerizing adverse drug reaction reports in the mid-1960s. The automated Spontaneous Reporting System (SRS) was initially designed in 1969 to serve as a means for FDA to detect rare, unexpected adverse drug and biologics reactions, where biologics included blood, allergenics, cellular tissue and gene products and therapies. In 1986, prescription drugs on the market without an approved application (i.e., those drugs and biologics marketed before 1938) became subject to adverse event reporting requirements. In 1993, the FDA initiated the MedWatch program to increase public awareness about the importance of reporting adverse reactions, to educate health professionals on reporting requirements, to standardize reporting formats, and to provide an agency-wide single point of entry for adverse reaction reports submitted by the public and health professionals.

The SRS worked well when CDER and CBER were receiving a total of 10,000 reports a year. But by the mid-1990s, the increasing scope of FDA's requirements for spontaneous reporting of adverse events combined with the agency's desire to increase public awareness about reporting adverse events increased the number of reports to over 150,000 per year. The enormous volume of reports pushed the SRS to its operational and technical limits. It also hampered the agency's ability to effectively perform PMDS. The Adverse Events Reporting System (AERS I) replaced the SRS in 1997 and became the primary post-marketing spontaneous reporting system for human drugs and biologic therapeutics. It was designed to utilize state-of-the art technology to facilitate the collection, analysis, and dissemination of post-marketing spontaneous reporting information.

Since that time the number of adverse event reports has grown to over 400,000 per year, and the FDA's commitment to gathering larger data samples, communicating risks to the public and encouraging reporting of adverse events will drive this number even higher. While FDA's efforts were successful in increasing the amount of data that the agency could use to protect public health and safety, this success has created an enormous IT challenge that the current AERS I computer system can no longer handle. The OPaSS AERS Program Office tried to *orchestrate* the needs of

users in all FDA Centers and the technical support of CDER's OIT and OIM to ensure that a new AERS computer system (AERS II) served the needs of users who carry out FDA's PMDS mission.[7]

3.2 From the SRS to AERS

The contract for AERS was established in September 1995, and the original AERS system requirements document was issued in 1996.[8] The development of AERS was part of a larger re-engineering project to revitalize the human drug post-marketing surveillance program and AERS was described as being a vital component of FDA's comprehensive Pharmacovigilance Program. The contractor who was designing the AERS system described it as being the "gold standard" of adverse event reporting systems that would implement international agreements and increase FDA's operational efficiency.[9] More specifically, they claimed that the AERS system would:

- Build an adverse event reporting system capable of supporting a revitalized Pharmacovigilance Program at FDA
- Improve the operational efficiency, effectiveness, and quality control of the processes for handling adverse events reports
- Improve the accessibility of adverse event information
- Integrate AERS with other agency information system
- Implement and maintain compatibility with ICH standards
- Build the capability to receive electronic submissions of adverse event reports
- Provide automated signal generation capabilities and improved tools for the efficient and effective analysis of adverse event signals

The AERS system was designed to address specific problems that FDA was having at that time, more specifically the process flow for handling adverse events was problematic. There was redundant effort, with multiple organizations performing the same reviews. There was also fragmentation of systems and data, making it difficult to integrate data for effective risk assessment and monitoring drug safety. The time required to process individual safety reports was lengthy sometimes taking several months before a report was fully accessible to risk assessors.

In addition, the system that was in use prior to the advent of AERS, the Spontaneous Reporting System (SRS), provided only limited automated support for processing and assessing drug safety risk. Designed in 1969 when information technology was much less sophisticated, the SRS consisted of on-line data entry screens, a database of all reports submitted since 1969, approximately 20 canned reports, and an ad hoc query facility. Only a few of the data elements on a typical adverse reaction report were entered into the database because the SRS was viewed as a system that would signal potentially serious and unexpected reactions, rather than as a full-text

---

[7] Since that time, FDA has formed the Office of Surveillance and Epidemiology (OSE) that has replaced many of the functions that OPaSS performed.

[8] See the overheads from [redacted] presentation at the ODP Session entitled, *Adverse Event Reporting System Configuration Control Board Process (CCB) Overview*, July 15, 2003, and Booze-Allen & Hamilton, *Adverse Event Reporting System (AERS) Requirements Document, Draft Version II*, Contract No: 223-94-5528/F01), September 23, 1996.

[9] See Booze-Allen & Hamilton, *AERS Requirements Document*, (1996), p. 1-5.

retrieval system. At that time, if reviewers needed the full text of the report to confirm a potential signal, they had to go back to the original paper form or to an image retrieval system. Although the SRS was migrated to an Oracle relational database in 1983, its core functions were largely untouched. At the time AERS was being designed, there were over one million records stored in the SRS database that included over 25 years of spontaneous reporting.

The contractor who was designing AERS promised to remedy many or all of these problems and provide a system that was a quantum advance over the SRS system and would equip FDA Safety Evaluators to better protect the public health. But the AERS system described in the 1996 Requirements Document that was released on November 1, 1997 was so flawed by a non-normalized database that created data integrity, functionality, and user problems that FDA's AERS Project Manager [redacted] aborted the release and he and the former Director of CDER's Office of Information Technology (OIT), [redacted] *demanded* that the contractor fix the system and deliver what they had promised in the 1996 requirements documents.[10] In the mean time, the CDER and CBER Safety Evaluators along with other FDA units like FOI and the Office of Compliance continued using the antiquated SRS to conduct their work. A revised AERS Requirements document was issued in August 1998 and the AERS system was also re-released, but the system was still plagued by data integrity, functionality, and user problems as evidenced by the fact that there were over 1,000 Change Control Requests (CCRs) for fixes to the AERS system.[11]

As this report indicates, one of the root causes of the *confusion* and *delay* surrounding the AERS II system from 2003 onward is a lack of effective leadership and management on the part of CDER's Office of Information Technology (OIT), despite the on-going protests of FDA's Office of Pharmacoepidemeology and Statistical Science (OPaSS) and OPaSS' on-going efforts to make AERS II functional as quickly as possible. More specifically, given the documented ineffective performance of this contractor and their inability to provide the deliverables of the original AERS system, it's unclear why CDER's OIT continued to use them to produced the detailed requirements for the AERS II system well into 2006. As this report shows, the work that this contractor is currently conducting on AERS II is even more methodologically flawed than the work that culminated in the original AERS system.[12]

3.3 The Initial Assessment in March 2003

User frustration with work-arounds, lack of functionality, data integrity and the overall ineffectiveness of the AERS system had reached an all time high when [redacted] Director of CDER's Office of Pharmacoepidemeology and Statistical Science (OPaSS), first contacted the Breckenridge Institute in February, 2003.[13] [redacted] told the Breckenridge Institute staff that most users were very unhappy with the performance of the AERS system and he identified three primary issues that needed to be addressed.

- Making better public health use of AERS data
- Improving the AERS database and its performance
- Better management of the AERS program

---

[10] Based on an interview conducted by the Breckenridge Institute with [redacted] on March 12, 2003.

[11] See Booze-Allen & Hamilton, *The Adverse Event Reporting System (AERS) Draft Version 2*, Contract No: 223-97-5513, August 14, 1998.

[12] See the Methodology Matrix in Section 4.0 that shows that the 1996 requirements document used more standard methodology than the current document dated June 2006.

[13] The Breckenridge Institute was formally called the Breckenridge Consulting Group, which conducted this work for FDA.

[redacted] said that some kind of "strategic planning" might be needed to sort out the issues involved and to develop a path forward toward improving the AERS situation once and for all. [redacted] three issues were used as the focus of an initial set of exploratory interviews of users and other FDA personnel conducted on March 11 and 12, 2003. About 25 people were interviewed from ODS, DSRCS, DMETS, CBER, DDRE, OB, CDER OIT, CDER OIM. In addition to [redacted] observations on AERS, the current version of the CDER OIT/OIM Strategic Plan (February 2003), provided to the Breckenridge Institute by [redacted] current Director of CDER's OIT, was used as a guide for what the FDA needed from the AERS system.[14]

The purpose of the exploratory interviews was: a) to determine what the salient issues were, and b) whether "strategic planning" or some other form of organization development activity might remedy the situation. The data that resulted from the interviews resulted in eleven Initial Observations for Improvement. The list of these observations (shown below) helped focus the subsequent Organizational Design and Planning process undertaken by [redacted] and the OPaSS organization.

- ***Observation 1 (Description and Purpose)***: The issues associated with AERS cannot be addressed by a "strategic planning" effort because strategic planning assumes that there is an organization that is doing the planning. The organizational flux of OIT, OIM, a temporary home for the AERS system in OPaSS, and the move to its eventual home in OIM is more like a business process reengineering project (BPR) combined with a strategic planning effort.[15]

- ***Observation 2 (Project Management)***: The management oversight of the software maintenance contract has been frustrating to OIT and users alike.[16] This needs to be corrected. OIT is taking many positive steps to do what can be done now by moving the contractor's people on-site so they will be more accountable and OIT can download information that they now have sole possession of. OIT is also having Oracle come in and back-engineer the existing AERS system to get as much documentation as is possible. The consensus of the people interviewed was that the structure of this contract, the CCB, and the CCR systems all need to be reengineered.

- ***Observation 3 (Communication)***: As is so often the case, the IT people and the users have different professional paradigms and talk past each other. Although the OIM plans to hire business analysts to "mediate" between these groups, this is a function that has been and continues to be missing, thus complicating communications.

- ***Observation 4: Poor System Design***: The discussions with technical people in OIT and in OPaSS indicated that the back-end of the AERS system built by the existing software maintenance contractor was not designed properly and would not be a suitable foundation for a future system. For example, the data were not normalized and many data tables were designed using embedded information. In addition, the system is extremely complicated (much more than it needs to be) with a multiplicity of tables that were kludged together without an overall guiding data model. This probably eliminates the possibility of just putting a new front end on the existing AERS system to increase functionality, but one of the initial tasks is for an OIT/OIM working group to determine. Interviews from technical people in OIT and OPaSS indicated that what was presented by the contractor as being a

[14] See the *CDER OIT/OIM Strategic Plan*, February 2003.

[15] These Observations also appear as a follow-up baseline in the AERS User's Satisfaction Survey conducted in 2005. See Appendix E for details.

[16] The software maintenance contractor for this work was Booz Allen Hamilton (BAH).

well-designed relational database, became a kind of two-dimensional flat file system that produces lists of information and lacks even the analytical capabilities of an Excel spread sheet. While systems like the Data Mart, CBEAR, etc have been able to increase analytical capabilities on a user-group, by user-group basis, and while the data-mining project appears to be a more complete solution, these are expensive and time consuming work-arounds that would not have been necessary if the contractor had delivered the system described in the 1996 and 1998 AERS Requirements Documents.

- ***Observation 5 (Lack of Documentation and Training)***: The difficulties of back-engineering the AERS system because of a lack of documentation, pale in the light of trying to reconstruct the history of what the original specifications and system functionality were and developing up-to-date user documentation and training. This is important because it defines a) what functionality was promised but not delivered, from b) "functionality creep" where users want more and more bells and whistles after the fact - beyond the scope of the original system. The documentation on how to use the system that does exist is badly out of date and currently there is no formal training on how to use the system.

- ***Observation 6 (Electronic Submissions)***: Electronic submissions will increasingly become a serious problem (especially given the requirement in the recent rulemaking). Interviews suggest that the main problem with increasing the number of electronic submission from its current rate of about 25% is on FDA's end. If everyone went to electronic submissions tomorrow (let's say as a result of rule making), the IT structure at the agency could not handle it because of limitations of the gateway (data lines) into the central IT structure (mainly due to attachments). Interviews also indicated that this limiting aperture could be eliminated with about a $200K upgrade to FDA systems. Of the $8M per year spent on AERS, about $6M goes to data input. One approach might be to invest the $200K in enlarging the capacity of the gateway and encourage electronic input from submitters to radically reduce the amount of data input needed, then leverage up to $5M out of $6M per year by using it to pay for the design and construction of a new AERS system.[17]

- ***Observation 7 (AERS Ownership)***: Ownership of the AERS system is a problem. If everyone is responsible, then no one is responsible (see comments below for Observation 9 on IT Consolidation).

- ***Observation 8 (AERS Activity)***: Estimates of the "usability" of the system by users range from 60-90% depending on who was asked. What seemed clear was that the system is useable, but there are multiple work-arounds that users must do in order to make it usable (cleaning up data, depending on their memory and knowledge for heuristics and analysis, etc). Given this level of usability, all revisions might be frozen, and this time and energy could be invested in looking toward a new system.

- ***Observation 9 (IT Consolidation)***: The role of the IT consolidation effort within FDA needs to be taken into consideration regardless of whatever path is taken, especially if this results in a 3-5 year strategic plan. The centralization of IT/IM resources and line management responsibility to the CIO must be factored into any future AERS system.

- ***Observation 10 (System Interfaces)***: The possibility of interfacing with other systems inside the FDA (Drug Quality Reporting System, Clinical Trials system), and outside the FDA (AHRQ safety net, etc) needs to be seriously considered.

---

[17] This Gateway finally became operational three years later in April 2006 with a delay cost of about $15 million related to the cost of having to re-key data into the AERS I system.

- ***Observation 11 (Identify All Users)***: All users' needs and requirements must be taken into account including, safety evaluators in OPSS, biologics, medical errors, epidemiologists, compliance people, FOI, and the 15 Review Divisions. The consensus on system requirements must be part of the written documentation of the next AERS system so that the baseline of functionality and user requirements can be teased apart from the normal course of functionality creep of systems of this size.

In addition to the above observations, information gathered during the March 2003 interviews revealed that there were three Change Control Boards (CCBs) overseeing AERS, with one dedicated to electronic submissions, a second focused on data entry issues, and a third CCB related to issues effecting CDER and CBER Safety Evaluators, and over 220 outstanding CCRs - many of which were long-standing. In addition, problems that FDA users had with functionality, downtime, or peripheral parts of the system (for example batch printing) were sent directly to the BAH AERS help desk, where BAH added to or deleted from the CCR list, with little or no oversight from CDER OIT personnel.[18]

3.4 Conflict between OIT Managers, Working Level Technical Staff, and Contractors

Another key issue that was revealed in the exploratory interviews conducted in March 2003 was serious organizational problems within the CDER OIT organization itself. [redacted] had only been Director of OIT for about six months and had inherited a problematic situation where the previous OIT management, OIT's technical people at the working level, and the AERS software maintenance contractor (BAH) were seriously misaligned.[19] Shortly after becoming the Director of CDER's OIT in the fall of 2002, [redacted] undertook an internal assessment of the projects being conducted by OIT staff. On January 24, 2003 [redacted] made a presentation to OIT staff entitled, "OIT Findings" and laid out [redacted] observations about the status of what was called the Big Four effort. Some of these issues included in the slides of that presentation are included below.[20]

- Lack of good budget and resource planning
- Insufficient resources
- Management must commit resources to projects by being realistic about workloads
- Hire additional project managers, security experts, software engineers, and database personnel
- Significant issues do not reach resolution
- No significant system success in about three years
- No clear lines of authority
- Lack of closure on management positions causing confusion
- Staff has good technical skills
- Lack of permanent project management causing confusion
- Lack of resources dedicated to systems engineering
- Lack of clarity on user requirements

---

[18] See the overheads from [redacted] presentation at the ODP Session entitled, *Adverse Event Reporting System Configuration Control Board Process (CCB) Overview*, July 15, 2003,

[19] Based on interviews with [redacted] and CCB members on March 12-13, 2003.

[20] The issues discussed during the March 12, 2003 interview with [redacted] were later documented in detail in the *Report of Findings on CDER-OIT, Tasks One through Four*, by [redacted] October, 2003.

From an historical perspective, these issues had plagued CDER's OIT for at least five years prior to [redacted] coming, e.g. back to the initial November 1, 1997 release of the AERS system. However, the presentation had a profoundly negative effect on the working level technical staff and project managers in OIT.

At the time of Breckenridge Institute's March 2003 exploratory interviews, [redacted] explained how [redacted] was attempting to address this long history of miscommunication; interpersonal conflicts; misalignment about roles, responsibilities, and authorities; missed goals and objectives; and a dysfunctional AERS system – all within a climate of interpersonal conflict, a lack of trust, and fear of retribution. This on-going conflict between OIT management and the working level technical people has manifested itself over the timeframe covered by this report as a continual turnover of AERS Project Managers. More specifically, there have been five different AERS Project Managers between 2003 and 2006, with the recent resignation of [redacted] creating a sixth vacancy.[21] [redacted] was aware of the negative impact that this lack of project management continuity had had on AERS and was trying to establish a long-term direction for CDER's OIT and AERS in the *CDER OIT/OIM Strategic Plan* document, given the realignment of all IT functions under CDER's Chief Information Officer, [redacted].[22]

Subsequently, in an OIT all-hands meeting on April 1, 2003 [redacted] announced a unilateral decision to simply ***halt*** all work on the Big Four effort pending a reevaluation. Although many of the people involved in the Big Four effort expressed admiration for [redacted] courage in trying to set clear direction, a number of working level technical people were devastated by the surprise announcement. As was later recounted, senior CDER management felt overwhelmingly that the way in which the project was halted was insensitive, uninformed, had seriously damaged morale, and was indicative of making snap decisions and acting on them without time for reflection and consensus building.[23] What is important to note, is that there has been a *pattern* of this type of unilateral decision-making by OIT management in regard to their staff and despite the protests of senior CDER management about AERS II and the affect of delays on the Safety Evaluators' ability to conduct effective post-marking surveillance, questions from pharmaceutical companies about the status of AERS II, and interest on the part of the Institute of Medicine in using AERS as an example of a data-driven approach to patient safety (OB 1-2006).[24]

As noted above in Observation 3 of the exploratory interviews conducted in March 2003, one of the most problematic issues with AERS was the lack of an effective *liaison* between: a) AERS users, b) the working level technical people within OIT who functioned as AERS Project Managers, and c) the IT designers in the AERS software maintenance contractor organization. This liaison function is normally described as a business systems analyst (OB 6-2006). More specifically, working level IT professionals with computing backgrounds and end users who are Safety Evaluators have different professional paradigms and often talk past each other with different professional languages. During [redacted] March 12, 2003 interview with the Breckenridge Institute, [redacted] recognized this problem and described how this missing function was going to be performed by CDER's new OIM organization that was being headed by [redacted] - also described in the *CDER OIT/OIM Strategic Plan*. The plan was for OIM to hire business analysts to "mediate" between AERS users, the OIT's AERS Project Manager, and the AERS software maintenance contractors for the development of AERS II. Our research showed no evidence for the fact that these business systems analysts were ever hired by OIM or that OIT or OIM provided this function during the AERS II requirements development

[21] The five different AERS Project Managers were [redacted]

[22] See the *CDER OIT/OIM Strategic Plan*, February 2003.

[23] See *Report of Findings on CDER-OIT, Tasks One through Four*, by [redacted] October, 2003, p. 6.

[24] See http://www.strategy-business.com/press/enewsarticle/22314.

process. As a result, over the three-year period covered by this report AERS users were forced into a role where they repetitively listed and described IT system functionality at the application logic and data management levels in meetings, rather than simply mapping out the day-to-day work process of conducting post-marketing surveillance for drug safety.

In early 2003, [redacted] was the acting OIT AERS Project Manager because the permanent OIT AERS Project Manager, [redacted] was on leave. [redacted] and [redacted] were the latest in a series of AERS Project Managers to inherit AERS and their biggest challenge was finding a way to get a handle on (and fix) the methodologically flawed AERS system when the same contractor that built it still had the AERS software maintenance contract. As working level technical people, both [redacted] and [redacted] were very concerned that this contractor: a) had sole possession of the vast majority of AERS information, b) had moved off of the FDA site, making them much less accessible, c) had only produced ten AERS releases between the years 1997-2003, and d) OIT management seemed unable to correct these problems.[25]

This misalignment between OIT management, the working level technical staff in OIT who functioned as AERS Project Managers, and the AERS software maintenance contractor is an on-going *theme* that runs throughout the entire period reviewed by this report, and is a *root cause* of the delays and unnecessary costs incurred to the AERS II project. More specifically, information from interviews and written documents seem to indicate that the working level technical people in OIT have been committed to satisfying the needs of AERS users as quickly as possible and working effectively with the "business" side of FDA. It's not clear what the objectives or goals of CDER's OIT management have been during this time period, but the documented result of their decisions as described below have resulted in: a) a four-five year delay in the replacement of the dysfunctional AERS I system released in 1997 which has (and will continue to) negatively impact the ability of Safety Evaluators to effectively conduct post-marketing surveillance, b) the unnecessary maintenance and operating cost of about $25 million for not replacing AERS I in FY 2005, and c) the risk of trying to develop an agency-wide adverse events reporting system without a fully functioning AERS II system as a foundation (see section entitled, *The Impact of Not Having AERS II Operational in 2005* for details).[26]

After returning as AERS Project Manager in the summer of 2003, [redacted] decided to take five steps to remedy the situation.

- First [redacted] planned to move the contractor people back onto the FDA site so they could be more accountable.
- Second, [redacted] planned to begin the process of downloading information about the AERS system from the contractor to OIT developers.[27]
- Third, [redacted] arranged for [redacted] (an [redacted] who was under contract to OIT) to back-engineer the AERS system and try to gather as much information as possible about the structure, design, and operation of the AERS system.[28]

---

[25] As a point of comparison, between 2003-2006 there have been over 20 releases, along with substantial reduction in software maintenance costs.

[26] Based on interviews with [redacted] and CCB members on March 12-13, 2003, and a subsequent interview with [redacted] on April 18, 2006. The cost to back-engineer the system was about $300K.

[27] See June 27, 2003 email from [redacted] to [redacted] on this topic.

[28] Interview with [redacted] on April 18, 2006 revealed that the AERS project personnel from Booz Allen Hamilton person refused to give [redacted] access to the forms for the AERS system, despite being directed to do

- Fourth, she had the information from the back-engineered AERS system placed into the CDER Oracle Designer/2000 Repository so it could be used as a CDER-wide resource on the structure, design, and operation of the AERS system, but subsequent analysis shows that this valuable resource was never used by any of contractors that worked on the AERS II requirements process under study in this report. More importantly, the failure to use a data repository as the basis of the process of developing detailed requirements is a *root cause* of the methodologically flawed approach used in the entire process.

- Fifth, [redacted] conducted some preliminary analysis of a Commercially Off The Shelf (COTS) adverse event reporting software package that was available from Oracle and had done some initial exploration of this option.

In the August 13, 2003 OMB 300, [redacted] reported that CDER's OIT staff had conducted two meetings with Oracle Representatives. The focus of the first meeting was to discuss the investment scope, while the second meeting focused on a Demo of the COTS. The estimate was based on an individual license cost of $15,000 and $3,000 per seat for about 500 users for a total of $1,515,000 for a new AERS system.[29] Given the pressing needs of the AERS users and the existence of a fully back-engineered AERS I system in the CDER Oracle Designer/2000 Repository, [redacted] viewed the Oracle AERS COTS option as the most cost-effective solution to quickly remedying the ineffectiveness of the AERS system.[30]

3.5 Creating an Essential Tension between OPaSS and OIT

As mentioned above, user frustration with the overall ineffectiveness of the AERS system had reached an all time high when [redacted] first contacted the Breckenridge Institute in February 2003. [redacted] knew that the contractor that designed and built the original AERS system had submitted a "white paper" to FDA proposing that the AERS system be "consolidated" with other adverse event reporting systems across the agency.[31] [redacted] also knew that AERS was too *mission critical* to be delegated to IT professionals in CDER's OIT who lacked the clinical, pharmaceutical, and epidemiological expertise required to understand FDA's overall purpose and goals. More importantly, the lack of project management continuity for AERS on the part of CDER's OIT was of great concern, as evidenced by the continuing turnover of AERS project managers. [redacted] decided to remedy these situations by bringing responsibility for OPaSS-related AERS activity within [redacted] organization – a move that was counter to FDA's culture.

[redacted] *first* step toward accomplishing this was to conduct a series of Organizational Design and Planning (ODP) meetings that began in June 2003. [redacted] *second* step was to create an organizational unit within OPaSS and direct it to give all AERS users the computing resources needed to effectively perform their jobs. Just prior to the first ODP meeting, [redacted] brought [redacted] into OPaSS on a detail as the AERS Program Manager and tasked [redacted] a) to assume responsibility

---

so by CDER OIT. This forced [redacted] to use the data repository (Oracle Designer) to try to reconstruct the forms.

[29] See the *OMB Exhibit 300* prepared by [redacted] August 13, 2003, p. 14. The cost estimate of $3,000 per seat was discussed with Breckenridge Institute staff during the interviews with [redacted] and [redacted]

[30] Almost two years later, forty percent of the vendors that proposed a total solution to the RFI issued in February 2005 included Oracle AERS as a part of their solution. They also said it would take about 30 months and over $10 million – over twice the estimated cost identified only months earlier. See CDER Drug Safety Team, *AERS II Alternatives Analysis Report*, version 1.3, June 2005, p. 19-20.

[31] Booz Allen Hamilton, *FDA Adverse Event Consolidation*, January 29, 2003.

for all OPaSS-related AERS activity, and b) to build an AERS Program Office.[32] The new AERS Program Office within OPaSS created an "essential tension" between the programmatic and IT functions within CDER that had long been missing – the kind of interdependency and accountability that is a *signature* for how IT infrastructure is designed in high-performing organizations.[33] [redacted] plan to make OIT *accountable* for giving AERS users what they needed to do their jobs, created a deep-seated power-struggle between OPaSS and CDER's OIT for control of the AERS system because it meant that the IT-tail would no longer be able to wag the dog of FDA's scientific, programmatic and business needs.

The ODP sessions that began in June 2003 were formed and operated around a written charter and involved people from OPaSS, OIT, OIM, ODS, DSRCS, DMETS, DDRE, OND, OC, CBER, CFSAN, CDRH, CVM, FOI, DRLS, FURLS, OTC and others. [redacted] and other personnel from CDER's OIT and OIM actively participated in these meetings, with [redacted] making a detailed presentation on AERS at most of the five meetings. Five working groups were formed to address the issues that had plagued the AERS system since its first release in November 1997. The five working groups covered the following issues:

- Data Input
- Data Structure
- Data Queries and Retrieval
- Contract Management
- Training

There were five ODP sessions in which the issues associated with AERS and many of the requirements and missing functionality were discussed and documented.[34] [redacted] actively participated in every session, and helped guide the new AERS Program Manager ([redacted]) in the direction [redacted] wanted the initiative and the AERS Program Office in OPaSS to take.

Under direction from [redacted] to move forward, [redacted] formalized the strengths and areas for improvement that emerged from the ODP sessions into the first *OPaSS AERS Program Strategic Plan* that outlined a path forward for AERS II.[35] This document described how the OPaSS AERS Program Office that was newly formed by [redacted] would be an organizational unit internal OPaSS that would be the "voice of the user." As such it would *orchestrate* the needs of users and the technical support of CDER's OIT and OIM to ensure that AERS II would enable OPaSS to operate an effective post marketing surveillance program. In the wake of the failed AERS I system, [redacted] charged the OPaSS AERS Program Office with ensuring that the new AERS II be designed to serve the needs of all users.

[redacted] began to work closely with [redacted] in OIT to improve communications between OIT and AERS users and to develop a path forward for what had become AERS II. As a follow-up to [redacted] meeting with Oracle in August 2003, [redacted] and [redacted] attended a second meeting in September with representatives of Oracle who offered to conduct a pilot program with an AERS COTS package that would take four weeks to conduct and would include a requirements analysis, a database migration, and ten pilot user licenses for a cost of $84,000. As a result, CDER's OIT recommended this approach as a path forward for AERS II in the August 2003 OMB Exhibit 300

---

[32] A preliminary outline of what the new AERS Program Office organizational structure would look like is found in the first *AERS Program Strategic Plan* document issued in December 2003.

[33] The Clinger-Cohen Act of 1996 requires federal agencies to follow corporate America's best practices for managing IT, see Alan Holmes, "Federal IT Flunks Out" in, *CIO Magazine*, May 15, 2006.

[34] The June 24-25, 2003, July 15-16, 2003, August 5-6, 2003, September 15-17, 2003, December 2003.

[35] See the *CDER OPaSS AERS Program Strategic Plan (FY 2003-2008)*, issued on December 9, 2003.

prepared by [redacted] and CDER's OIT began the process of planning a formal alternatives analysis for the new AERS II system.[36]

What is important to note is that the information produced by the back engineering of the AERS system that was (and still is) stored in CDER's Oracle Designer Case tool was more than sufficient to have AERS II up and running in FY 2004. More specifically, the information about AERS that OIT possessed since October of 2003 included:

- A Requirements Document Updated by the Back Engineering of the Oracle Designer CASE Tool and a Strategy/Vision Document[37]
- Entity Relationship Models and Definitions
- Physical Data Model and Definitions
- Module Definitions (for screens, XML, C++, JAVA, Webscreens, etc)
- Requirements Traceability

The above list of information would have been sufficient to enable CDER's OIT to: a) conduct a gap/fit analysis between AERS and COTS products like Oracle AERS to determine how well they map to the FDA Technical Reference Model, b) define the degree of customization of a COTS package, c) determine the degree to which a COTS fits with the overall Application Architecture of the agency, e.g. Net, J2EE, d) define whether a COTS is 2-tier, n-tier and whether it supported the overall architecture objectives of the agency, including moving to Service Orientated Architecture (SOA), e) define the extent to which a COTS supported a concept of services that fit within the overall FDA architecture, f) develop a work break down structure for actually customizing the COTS, data migration, and initializing the new system and finally g) providing the basis for developing a firm fixed price contract for the new AERS system.[38]

In other words, the AERS II system that was envisioned during the ODP sessions and was subsequently recommended by [redacted] in the August 2003 OMB Exhibit 300 could have been in operation and being used by FDA personnel sometime in FY 2005 had OIT management accepted the recommendations of the AERS Project Manager and [redacted] and [redacted] in OPaSS. As a result of decisions by CDER's OIT, the AERS users in CDER, CBER and other organizational units throughout the FDA have been forced to use the dysfunctional AERS I system for more than 10 years which has frustrated and undermined their ability to perform their jobs effectively as identified in the 2005 Users Satisfaction Survey found in Appendix E (OB 11-2006). The additional 4-5 year delay caused by the AERS II requirements process being unnecessarily repeated have perpetuated and exacerbated the functionality problems identified in the AERS User Satisfaction Survey conducted in 2005.

3.6 The AERS Project Manager Is Unilaterally Reassigned

From April 21 through June 17, 2003 [redacted] continued to conduct interviews with over 30 OIT employees about the halting of the Big Four effort, and [redacted] final report was issued in October

[36] See *OMB Exhibit 300*, August 13, 2004, completed by [redacted], p. 14. [redacted] took over for Valencia as AERS Project Manager in November 2003.

[37] See Booze-Allen & Hamilton, *The Adverse Event Reporting System (AERS) Draft Version 2*, Contract No: 223-97-5513, August 14, 1998, October 7, 2003 revision.

[38] The notion of "agility" (the ability to change IT quickly to fit business needs) and the latest strategy for doing this called Service Oriented Architecture (SOA) is described in, Christopher Koch, "The Truth about SOA" in, *CIO Magazine*, June 15, 2006, volume 19, number 17, p. 49-60. The key to SOA is to mirror chunks of business processes in modules of technology that can be mixed and matched to create automated business processes.

2003.[39] The view of the OIT staff described in [redacted] report was that OIT management could not be relied upon to review issues factually and make decisions based on objective technical criteria and user needs. Rather, decisions were made in a forum called *Senior Staff* without the input of working level technical people, organizations like OPaSS, or AERS users. Staff indicated that OIT management made decisions in a vacuum based on personality and favoritism, rather than with an openness to new ideas, new technologies, listening to the advice of OIT's technical people, or the voice of users in OPaSS and across the agency. When "action" meetings were held within OIT, no minutes were kept or distributed, and every participant came away with a different view of what had happened, and then proceeded to act based on their own views of what they thought had been decided.

The report by [redacted] also stated that OIT staff viewed OIT management as trying to create the *perception* that they required high standards of performance and held people accountable when "dealing up" to senior CDER management. But in terms of "managing down" within the OIT organization, staff viewed OIT management as arrogant, making constant references to the "absolute trust and freedom" granted them by senior CDER management to do as *they* saw fit regarding CDER-related IT decisions.[40] From the perspective of many of the thirty-three people who were interviewed by Rule, OIT management acted as if they had a "license" to run over the Staff's ideas and needs as well as the ideas and needs of the end users of CDER's IT systems. More specifically, interviews with senior CDER managers like [redacted] CCB members, Safety Evaluators, and other FDA scientists revealed that when [redacted] and [redacted] were questioned about the negative impacts on users of a unilateral decision they had made, the "business" side was told, "Just trust us – this is a 'technical' matter. We're the IT experts."

This pattern of creating the *perception* that OIT was working closely with senior CDER management and AERS users while acting *unilaterally* without building consensus with: a) OIT staff like [redacted] b) AERS users and the CCBs, c) OPaSS' AERS Program Manager [redacted] or even d) senior CDER management is a root cause of the four-five year delay in AERS II and unnecessary costs totaling $25 million (see section entitled, *Financial Impact and Value-Added of OIT Activities Post-July 2004* for details (OB 10-2006).

[redacted] joined the FDA as Deputy Director of CDER's OIT on August 11, 2003 at a time when the AERS II project was making great progress and was in the final stages of obtaining the AERS II system.[41] A fully back-engineered AERS I system existed in the CDER Oracle Designer/2000 Repository, the Oracle AERS COTS option had been proposed as a cost-effective solution to quickly remedying the ineffectiveness of the AERS I system, and [redacted] was planning on conducting an alternatives analysis. Consequently, [redacted] and [redacted] were seriously concerned that the project would lose momentum when OIT management suddenly announced in September 2003 that [redacted] was going to be "reassigned" to another project.

[redacted] and [redacted] questioned [redacted] and [redacted] decision to reassign [redacted] given the fact that OIT was ready to move forward on AERS II, with the final step being the completion of an alternatives analysis. But OIT management assured [redacted] and [redacted] that the project would stay on track because [redacted] would remain involved at some reduced level until October 31, 2003 and [redacted] would be acting AERS Project Manager until [redacted] replacement, [redacted] arrived in December of that year. OIT management assured [redacted] and [redacted] that one of [redacted]

---

[39] See *Report of Findings on CDER-OIT, Tasks One through Four*, by [redacted] October, 2003, p. 11-13 and 20-21.

[40] See *Report of Findings on CDER-OIT, Tasks One through Four*, by [redacted] October, 2003, p. 24.

[41] [redacted] prior position was as a network administrator for the State of Maryland where [redacted] worked with [redacted] who was formerly the CIO of the State of Maryland.

first tasks would be to conduct the alternatives analysis so that AERS II would not be delayed. As follow-up to these discussions [redacted] emailed a draft DHHS policy on alternatives analysis to [redacted] that stated that it was not necessary to spend a lot of time gathering detailed requirements prior to conducting an alternative analysis.[42]

Given the pressing needs of the AERS users, the existence of a fully back-engineered AERS I system in the CDER Oracle Designer/2000 Repository, and OIT's endorsement of the Oracle AERS COTS option in the August 13, 2003 OMB Exhibit 300 as the most cost-effective solution to quickly remedying the ineffectiveness of the AERS system, [redacted] informed [redacted] in an email in January 2004 that all she needed to proceed with the alternatives analysis was a set of high-level requirements. It appears that no one in CDER's OIT organization informed [redacted] or [redacted] that the information produced by back engineering the AERS system six months earlier would have been more than sufficient to conduct an alternatives analysis of various COTS, and then purchase the new AERS II system. Had they known about the existence of a complete set of requirements for the AERS I system, they could have proceeded down the path of obtaining an AERS II system even more quickly.

This lack of communication about valuable information that FDA had purchased at a cost of $300,000 was symptomatic of the deeply troubled situation within the OIT organization where the left-hand did not know what the right hand was doing. So in the absence of this information, two months later on March 12, 2004 [redacted] delivered a high-level requirements document to [redacted] Our analysis shows that the set of requirements produced by [redacted] was taken from the AERS I 1996 Detailed Requirements document and the RTM that he requested in 2003 and was more than enough information to conduct an alternatives analysis because it contained all (100%) of the requirements listed in the AERS I Detailed Requirement Document and new user requirements contained in the 2003 Requirements Traceability Matrix

The AERS II proposal was *reviewed* and *approved* by [redacted], [redacted] and the CDER IMSC on March 26, 2004. With the IMSC approval in hand, [redacted] began the alternatives analysis and stated in the March 2004 OMB Exhibit 300 that although detailed requirements would have to be developed, that the requirements found in [redacted] March 2004 document were sufficient to evaluate COTS packages like Oracle AERS as viable alternatives for AERS II. The OMB Exhibit also stated that given all the progress made, that *the new AERS II system would probably be up and running in FY2005.*[43] [redacted] also noted in the OMB 300 that despite the fact that there was a lack of *new* funding for AERS II, that the system could be brought on-line using the cost savings from the AERS maintenance contract, plus savings from reducing the cost of AERS I data entry. More specifically, the OPaSS AERS Program Office had instituted improvements and efficiencies that: a) reduced the AERS maintenance contract from $2.5 to $1.9 million per year, then ultimately to $1.2 million per year, plus b) AERS II would reduce the cost of data entry by another $500K per year. This was more than enough to have AERS II up and running in FY 2005 as was indicated two years earlier in Observation 6 of the initial report developed by the Breckenridge Institute staff.

OIT's [redacted] arranged a presentation by Oracle on May 4, 2004 so users could make a preliminary evaluation about whether the functionality provided by a COTS product like Oracle AERS was worthwhile pursuing from the perspective of AERS users. The following people attended the presentation:

- [redacted] (OPaSS)
- [redacted] (CDER OIT)

---

[42] See the *HHS IRM Policy for Conducting Information Technology Alternatives Analysis*, HHS-IRM-2003-0002.002, October, 2003.

[43] See *OMB Exhibit 300*, March 24, 2004, completed by [redacted] p. 16-17.

- [redacted] (CDER OIT)
- [redacted] (DSRCS)
- [redacted] (DDRE)
- [redacted]
- [redacted] (DMETS-IT)
- [redacted] (DDRE)
- [redacted] (CBER)
- [redacted] (CDER OIT)
- [redacted]
- [redacted] DER OIT)
- [redacted] (CBER)
- [redacted] (DSRCS)
- [redacted] (DMETS-IT)
- [redacted] (OPaSS)
- [redacted] (OC)
- [redacted] (DDRE)
- [redacted] (OC)

Because it was an initial demonstration, AERS users who attended were instructed not to reveal their requirements to Oracle, so as not to give them an unfair advantage. The general consensus of the attendees was that the Oracle AERS product would meet almost all of the AERS users' needs. As a follow-up to the meeting, Oracle sent a proposal to [redacted] on July 12, 2004 to conduct an Oracle AERS Pilot that would answer any lingering questions that the Safety Evaluators had about whether the Oracle AERS product was a viable alternative to AERS I and would provide functionality they were missing. The five phase pilot program would include: a) requirements gathering and scope definition, b) setup of initial AERS pilot instance, c) design and setup of data capture of final AERS pilot instance, d) user training and implementation of pilot, and e) complete documentation. The total cost of the pilot program with Oracle's 80% DHHS-wide discount was about $85,000.[44] As a follow on to the pilot, Oracle gave [redacted] a fixed-price proposal that would turn the Oracle AERS COTS package into a fully functioning AERS II system for $4.5 million. As a final step, [redacted] completed the AERS II alternatives analysis on June 3, 2004.

The AERS II system had past one of the last hurdles and was on it's way to becoming a reality. But over the next few months, a complicated series of events and *unilateral* decisions on the part of OIT management would: a) *slow down* and ultimately *shelve* the AERS II project, b) change the project scope from replacing the dysfunctional AERS system to an agency-wide adverse event reporting system championed by [redacted] and the [redacted] and c) create the perception that this radical change of project scope would have little or no negative impact on AERS users in CDER and across the agency (OB 1-2006).

- On April 30, 2004 [redacted] became the Director of CDER's Office of Information Management (OIM) and [redacted] became the Director of CDER's OIT.

- On June 30, [redacted] began to champion the idea of a consolidated, FDA-wide adverse event reporting system (FAERS) like the one proposed by BAH in a white paper they issued in January 2003.[45]

---

[44] For details on Oracle's 80% discount to Federal agencies see, John More, *Feds Get Smart with Oracle*, April 26, 2005, (http://www.fcw.com/article88699-04-26-05-Web).

[45] Booz Allen Hamilton, *FDA Adverse Event Consolidation*, January 29, 2003.

- Originally systems such as AERS had their own OMB Exhibit 300, but these documents started to be combined into more and more generic packages of budget and work (from AERS, to Drug Safety, to Post-Marketing, etc.) with the result that it became increasingly difficult to identify the exact budget allocation for a system like AERS II, which gave OIT much less accountability and traceability for how money was spent or "reprogrammed."

- The OMB Exhibit 300 issued on July 6, 2004 with [redacted] as the new Director of OIT stated that the AERS system would not be replaced until 2007 - two full years later than the date [redacted] recorded just three months earlier in the March 2004 OMB Exhibit 300. The only explanation given was that OIT had conducted a market research study that had showed that there were several other AERS COTS packages on the market other than the Oracle AERS package and that these packages would be investigated. This decision was not based on changes in user needs.

- [redacted] July 30, 2004 email to [redacted] and [redacted] about [redacted] AERS II meeting with [redacted] (CDER's CIO), [redacted] and [redacted] in Business Process Planning Office (BPP), and [redacted] interest in using the AERS II, Oracle AERS system as a basis for the next generation of FDA-wide adverse events reporting system (FAERS) and [redacted] willingness to present this concept to FDA's management council indicates gathering support for an agency-wide system at the very highest levels of FDA. This was the beginning of the change in project scope from replacing AERS I to building an Agency-wide adverse event reporting system.

As mentioned previously, these actions have resulted in: a) a four-five year delay in the replacement of the dysfunctional AERS I system released in 1997 which has (and will continue to) negatively impact the ability of Safety Evaluators to effectively conduct Drug Safety surveillance, b) the unnecessary maintenance and operating cost of about $25 million for not replacing AERS I in FY 2005, and c) the risk of trying to develop an agency-wide adverse events reporting system without a fully functioning AERS II system as a foundation (see section entitled, *The Impact of Not Having AERS II Operational in 2005* for details).

3.7 The Turning Point for AERS II Despite the Protest of OPaSS

[redacted], [redacted] and the community of AERS users were shocked when AERS II took a sudden change in direction under [redacted] leadership as [redacted] *unilaterally* informed them that they would have to begin the process of gathering requirements and conducting an alternatives analysis *all over again* (OB 1-2006). More specifically, OIT would: a) produce yet another high-requirements document, b) conduct a second alternatives analysis, c) issue a Request for Information (RFI), and d) produce another set of detailed requirements. These activities would cost $778,769 and not be completed until April 2006 - almost two years later.[46] Other than having conducted a market research study that identified potential COTS packages other than the Oracle AERS system, OIT management gave no reason for this abrupt change in direction. Not only were there no changes in user requirements that would have necessitated this change, OIT had more than enough information to evaluate these other COTS packages and/or COTS integration solutions for AERS without going through another requirements gathering process, including the ability to:

- Conduct a gap/fit analysis between AERS and the newly identified COTS products to determine how well they map to the FDA Technical Reference Model.
- Define the degree of customization of a given COTS package, e.g. 20%, 50% or more

[46] See *OMB Exhibit 300*, July 6, 2004, completed by [redacted] p. 16.

- Determine the degree to which a given COTS package fit with the overall Application Architecture of the agency, e.g. Net, J2EE
- Define whether a given COTS package is 2-tier, n-tier and whether it supported the overall architecture objectives of the agency, including moving to Service Orientated Architecture (SOA)
- Define the extent to which a given COTS package supported a concept of services that fit within the overall FDA architecture
- Develop a work break down structure for actually customizing a given COTS package, data migration, and initializing the new system and finally
- Providing the basis for developing a firm fixed price contract for the new AERS system

In an email dated August 26, 2004, [redacted] and [redacted] told OIT management that OPaSS and the broader community of AERS users across FDA *could not wait* two more years and spend almost $800,000 to repeat the process they had just completed because OIT already had all the information they needed to move ahead on AERS II. The email also noted that the Oracle proposal of $85,000 to conduct the pilot program within four weeks looked a lot better than the prospect of slowing down the AERS II project by more than two years. [redacted] also reminded [redacted] that he had a written fixed price from Oracle for the entire AERS II with a total cost of $4.5 million. [redacted] questioned the value-added of what she had decided and instead wanted to leverage the existing documentation and have the final requirements completed prior to the Presidential election and they specifically asked OIT not to obligate any funds or move forward on this plan. Those funds were obligated despite the objections of [redacted] and [redacted]

On August 27, 2004 [redacted] replied to [redacted] in an email stating, "Oracle is selling you a bill of goods – it's called low-balling." [redacted] also reminded [redacted], and the AERS users that, "As you well know, the business side of FDA isn't to be building IT systems."[47] But given the time delays and unnecessary costs incurred over the course of the next two years it would become clear that it was OIT that was selling OPaSS and the AERS users "a bill of goods" about how long it would take to replace the dysfunctional AERS I system while telling them - "Just trust us – this is a 'technical' matter. We're the IT experts" (OB 1-2006).

The September 2004 OMB Exhibit 300 issued by CDER's OIT stated that OIT was now going to conduct a "technical" alternatives analysis and consequently that AERS II had been pushed off until 2007. Given the fact that there had been no changes or additions to the AERS user requirements, this was a serious departure from what [redacted] had recorded in the OMB Exhibit 300 just a few months earlier. To the surprise of [redacted], [redacted] left OIT in September 2004 after staying only nine months and [redacted] became the next AERS II Project Manager on October 18, 2004. The new HL-Requirements Document started after [redacted] departure was delivered to OIT on December 15, 2004 at a cost of $169,910.[48] As discussed in the section of this report entitled, *Use of Appropriate IT Methodology*, analysis of this document revealed that it only partially followed appropriate IT methodology and the resulting document actually contains *less* "technical" information about AERS user requirements than the baseline that existed in July 2004.

OIT published a Request for Information (RFI) about the AERS II system in February 2005 using a base of user requirements that included the 1996 and 1998 AERS Requirements Documents developed by BAH; the 2003 RTM requested by [redacted] and two later versions of the RTM; and the High-Level Requirements Document that was completed in June 2005 by ISSA at a cost of $210,000.[49] There were 43 responses and the top eleven stated that it would take 24-30 months

[47] See August 27, 2004 e-mail from [redacted] to Stone.

[48] See *FDA CDER Adverse Event Reporting System II (AERS II) High Level Requirements (HLR)*, Version 1.03, by ISSA, December 15, 2004.

[49] See *Request for Information, OSS/OAGS/DSCI/ITCT RFI Number: FDA2005-001*, February 2005.

from this time and cost between 5-10 million dollars.[50] [redacted] presentation on the Alternatives Analysis states, "It can now be stated that the AERS II development effort should be a COTS integration effort. While it is possible that a significant portion of the AERS core functionality can be supplied by a COTS Adverse Events product, other major functionality must be supplied by other best-of-breed COTS products."[51]

But it is important to note that this change in direction means that new information should have emerged as part of the HL-Requirements and RFI processes, because in [redacted] summary presentation on the Alternatives Analysis presented on August 4, 2005 he stated that the *user requirements could not be satisfied* by a single COTS package so consequently AERS II would require a systems integrator or software developer to oversee a COTS integration process.[52] This was a very different conclusion than OIT's [redacted] and [redacted] and OPaSS' [redacted] had reached only a few months earlier following the June 2004 completion of [redacted] alternatives analysis. In fact, the Breckenridge Institute's evaluation of the HL-Requirements Document indicates that the level of detail of the AERS user requirements included in the December 2004 HL-Requirements Document *is substantially less* than the level of detail of the requirements used to complete [redacted] June 2004 alternatives analysis (OB 2-2006). This indicates OIT's decision to change directions on AERS II must have been predicated on something other than changes in AERS user requirements or other technical details (see section entitled, *Use of Appropriate IT Methodology*.

More specifically, the following things remain unchanged from [redacted] alternatives analysis following the issuance of the HL-Requirements, RFI results, and OIT's conclusions about the alternatives analysis. *First*, as described above, a gap/fit analysis would have had to been conducted on any COTS package or COTS integration package to identify the percent of customization because it's almost never the case that a COTS fully satisfies user needs. *Second*, the user requirements remained unchanged and our analysis shows that there is a many-to-one relationship where multiple requirements were rolled up into a single high-level summary requirement that provided *substantially less* information about AERS user requirements than the body of requirements used by [redacted] In fact, even things like moving away from a client server approach toward a web application for AERS II and interfacing with other FDA and government-wide systems were included in the requirements used by [redacted] and the Strategic Plan developed by [redacted] in 2003. *Third*, Oracle was still the accepted FDA standard in terms of computing applications and 80% of the respondents to the RFI specified that they would use Oracle products, with a number specifying that they would use Oracle AERS (OB 2-2006).

What does appear to have changed is the following:

- Who was leading the effort, e.g. the "essential tension" that [redacted] had established between CDER's OIT and AERS users in OPaSS and across the agency was dismantled
- A technological shift towards a Service-Oriented-Architecture (SOA) that: a) *was not* driven by user requirements, and b) was unilaterally decided in the absence of the detailed CDER-CBER business process mappings needed to create the components of an SOA architecture.[53]

---

[50] See CDER Drug Safety Team, *AERS II Alternatives Analysis Report*, version 1.3, June 2005

[51] See *FDA Adverse Events Reporting System (AERS) II Alternatives Analysis Report*, Version 1.3, June, 2005, p. 3

[52] See [redacted] presentation, *Adverse Events Reporting System (AERS) II Alternative Analysis Report*, August 4, 2005.

[53] The notion of "agility" (the ability to change IT quickly to fit business needs) and the latest strategy for doing this called Service Oriented Architecture (SOA) is described in, [redacted] "The Truth about

- A radical shift in project scope from replacing the dysfunctional AERS I system to an agency-wide adverse event reporting systems that would take on a number of different names, e.g. FAERS, MedWatch Plus, etc.

3.8 The 2005 AERS Users Satisfaction Survey

Had OIT management moved forward on the plan developed by [redacted] and [redacted] the AERS II system would have probably been up and running by the fall of 2005. Instead, the AERS II system was far from even beginning and AERS users were more unhappy than ever about the dysfunctional AERS I system, as evidenced in the June 2005 users survey – summarized below. Using the 11 Observations for Improvement identified in the 2003 interviews as a baseline, users were asked to evaluate performance of AERS related activities over the last 18 months (see Appendix E for the complete result of the AERS Users Survey).

- *Project Management*: BAH is no longer the contractor and interviews and other data show that the current contractor (SAIC/PSI) is doing a great job. In addition, the AERS Program Office is doing an excellent job providing oversight for all contractors working on the AERS Program by holding them to task and closely monitoring the number of tasks being completed and the contractor's performance on those tasks. The three CCBs have been combined into a single, more effective entity, the number of outstanding CCRs has been substantially reduced, CCRs for organizations such as DMETS and CBER that were outstanding for years have been completed, and the number of CCRs addressed per new release of AERS I has increased dramatically.

- *Communication*: Interviews and other data indicate that the AERS Program Office has effectively filled the role of liaison (business systems analyst) between CDER's OIT/OIM organizations and the spectrum of users in OPaSS, CBER and throughout the Agency. The level, kind, frequency, and quality of communication provided to AERS I users about the system has improved substantially over the last 18 months.

- *AERS Ownership*: Prior to [redacted] establishment of the AERS Program Office, organizational responsibility for the AERS I system was unclear. According to [redacted] and AERS users, the AERS Program Office owns and is responsible for the effective operation of the AERS Program. But this is increasingly difficult because the AERS Program Office has the *responsibility* for effectively running the program, without the funding *authority* needed to make this happen.

- *Identify All AERS Users*: Over the last 18 months, the AERS Program Office has systematically included and tried to meet the needs of all AERS users including other safety evaluators in OPaSS (DMETS), CBER, epidemiologists, Office of Compliance, FOI, and the Review Divisions in the Office of New Drugs (OND).

The data from the AERS User's Satisfaction Survey also showed the following issues remain extremely problematic.

- *Poor System Design*: [redacted] and the AERS Program Office have made a conscious decision not to invest resources in fixing problems in AERS I that would be fixed by AERS II and instead spent their time and resources trying to get AERS II into production.

SOA" in, *CIO Magazine*, June 15, 2006, volume 19, number 17, p. 49-60. The key to SOA is to mirror chunks of business processes in modules of technology that can be mixed and matched to create automated business processes.

Interviews with AERS users indicated, that if the AERS II system is substantially delayed, resources *must* be dedicated to increasing the functionality of the AERS I system. Analysis showed that AERS I users spent on average about 3/4 of an hour per day on AERS I-related inefficiencies, with some users spending as much as four hours per day on such inefficiencies. For the 75 users who participated in the survey, spending 3/4 of an hour per day amounted to about $700,000 per year in lost salary and is the equivalent of about 6 FTEs (see Appendix E for details).

- *Lack of Documentation and Training*: The documentation and User's Manual for the AERS I system that exists is badly out of date and was originally written in 1999, with none of the system upgrades or enhancements up through 2005 being included in this 1999 version. In addition, there was no regularly offered formal training on how to use the AERS system provided to existing or even new users. Increased change in AERS I and employee turnover among Safety Evaluators has made the training and documentation problems worse over the last 18 months.

- *Electronic Submissions*: This issue was scheduled to be completed as part of the AERS II process as listed in the AERS Program Office Strategic Plan but had not been acted upon as of June 2005 (Note: This was actually completed in April 2006).

- *IT Consolidation*: The "essential tension" consciously established by [redacted] when [redacted] established the AERS Program Office placed OPaSS in direct conflict with CDER's OIT because OPaSS has the *responsibility* for effectively running the AERS program, without the funding *authority* needed to make this happen. For example, in May 2005 CDER's OIT informed the AERS Program Manager that AERS I would have to take a 25% cut in funding. What is most problematic was that the Director of OIT [redacted] knew about this reduction in funding since January 2005, but failed to inform the AERS Program Manager until five months later when options for dealing with the cut were far fewer.

- *System Interfaces*: The need for interfacing with other systems inside the FDA (Drug Quality Reporting System, Clinical Trials system), and outside the FDA (AHRQ safety net, etc) was slated for completion as part of the AERS II process but had not been addressed at the time of the survey.

3.9 OIT Unilaterally Sets IT Direction Despite the Protests of AERS Users

In an email to [redacted] on June 16, 2005, [redacted] described how [redacted] and representatives from the CIO's Office and IT representatives from CBER, ORA, and CFSAN had met on the FAERS project and had decided to initiate the FAERS project as a formal Agency-wide project, with the first phase being AERS II. The group had also agreed that CDER's OIT and BPP group, not the AERS Program Office in OPaSS, would lead the initiative.[54] In effect the "essential tension" that [redacted] had created with the AERS Program Office to make OIT accountable to AERS users would no longer exist and the liaison (business systems analyst) function that [redacted] had provided would erode, as technically oriented OIT staff and consultants would once again interact directly with AERS users. [redacted] email was to inform [redacted] about this unilateral decision and to ask [redacted] for [redacted] support and concurrence in dismantling what he had created in OPaSS (OB 1-2006). In addition, other senior level FDA managers like [redacted] and [redacted] also gave their support and concurrence to the FAERS project with the stipulation that it did not negatively impact AERS II and/or CDER – a condition to which [redacted] agreed.

[54] See June 16, 2005 e-mail from [redacted] to [redacted]

On November 22, 2005, FEDSIM announced that BAH had been awarded the AERS II Detailed Requirements (SRS) contract at a price of $389,000 and two weeks later on December 8, 2005 [redacted] began a 120 day detail to CDER's BPP group, with [redacted] becoming acting Director of CDER's OIT. It is important to note that the pattern of *unilateral* decision-making on the part of OIT management described by [redacted] Report continued even after [redacted] joined the BPP group and [redacted] became acting Director of CDER's OIT. More specifically, interviews and evidence from documents and emails indicate a pattern of [redacted] and OIT: a) *telling* senior FDA and CDER management that the FAERS project would not negatively impact AERS II or AERS users, but b) making decisions that in fact resulted in a negative impact on the timely replacement of the dysfunctional AERS I system and the ability of AERS II users to adequately do their jobs of protecting the public health.

For example, during a FAERS meeting in December 2005, FDA's Deputy Commissioner [redacted] began to question why BAH had been hired to do the Detailed Requirements Document for AERS II given their track record on AERS I – a project that was done while [redacted] was Center Director of the CDER. [redacted] specifically asked that *BAH make a presentation to* [redacted] and the FAERS Executive Committee describing their current strategy for developing the detailed requirements, and to specifically describe what they were going to do differently now than they did for AERS I. The presentation by BAH was never given because of unilateral decision-making on the part of CDER's OIT, now led by [redacted] (OB 1-2006).

- First, on January 10, 2006 [redacted] sent an email to [redacted] and [redacted] informing them that the FAERS Executive Committee, and [redacted] in particular, wanted BAH to make a 20 minute presentation on January 18, 2006 covering: a) their approach to data gathering and documenting the detailed requirements for AERS II, and b) what they plan on doing differently this time.

- Second, on January 12, 2006, [redacted] sent an email to [redacted], [redacted], [redacted] and [redacted] stating, "I've talked with some of you individually, but (if time permits) it would be good for us to talk together so that OIT CDER and BAH can be best prepared to present how the AERS II requirements are being done. The underlying purpose behind [redacted] request is that the Executive Committee has a degree of distrust in BAH. You will be able to show (1) you made a valid selection, and (2) what is different this time in the methodology, structure and management involved.

- Third, on January 12, 2006, [redacted] sent an email to [redacted] and [redacted] stating, "[redacted] I don't think BAH should be giving a presentation; it should be us (OIT-CDER). I think we should propose to [redacted] that he recommend a presentation like this..."

- Fourth, on January 13, 2006 [redacted] sent an email to [redacted], and [redacted] stating, "I agree also. [redacted] – can you grease the skids with the committee? We should have a quick dry run before the brief."

[redacted] never got what she asked for, but instead, [redacted], [redacted] and [redacted] from OIT gave the presentation on February 15, 2006 and defended their decision to hire BAH once again. They also reiterated to [redacted] and what had become the MedWatch Plus Executive Committee (formerly FAERS) that the newly expanded scope of the FAERS project *would have no negative impact on AERS II or CDER.*

Consequently, [redacted] and [redacted] were shocked to learn on February 23, 2006 that the AERS II project schedule had gone from green to yellow on the CDER OIT status report, where a "green" status meant that the project was on track, and a "yellow" status means that there are definite

concerns about funding, cost, and schedule (OB 1-2006). In response to [redacted] inquiry about the change to yellow status, [redacted] replied in [redacted] February 24, 2006 email,

> "Actually [redacted] I'm the one who changed the status for the schedule from green to yellow. This is a report coming from OIT-CDER and my opinion is that this report was intended to convey risks as we perceive them. I feel that by changing this schedule area to yellow it shows that the AERS II schedule *will be* impacted by a change in scope to accommodate MedWatch Plus. In all of the discussions we've had about expanding the scope I have always taken the position that scope change would, in fact, impact our plans. The schedule, contract and cost will change. So to me this is a risk to the current AERS II project schedule. This status change was vetted through the OIT-CDER management chain.
>
> "With respect to cost we collectively (OIT-CDER) decided to change the status to yellow. This is intended to reflect the simple fact that it's almost March and there is still no FY06 budget for AERS II development. I've already lost a team member and am in danger of losing another in a week or so. Also, not knowing if there will be enough funds to move into the next phase represents a huge risk to the schedule. Actually when I think about it I believe I could make a case for the cost area being red, but at the very least it seems to me that this area should be yellow. Others in OIT-CDER agree."

Where had the funding for AERS II gone and why hadn't [redacted] and the AERS users been consulted about it? Who reprogrammed the money and to where had it been moved? These are questions that could not be determined within the scope of our study but need to be further explored (OB 1-2006).

The gathering of the detailed requirements had been underway since November 2005, and representatives from OIT and BAH had formed five working groups for AERS users to participate in:

- Data Input
- Dictionaries
- Interfaces
- Security
- User Needs

As the Safety Evaluators and other users participated in meeting after meeting with the CDER OIT staff and BAH contractors, the AERS users became more and more frustrated and eventually called an emergency meeting of the largest user group (User Needs) on February 21, 2006. The following is a summary of the major concerns expressed by AERS users that were captured in an email by AERS Program Office personnel.

- The contractor and OIT are not prepared; they don't understand our needs.
- We spend ours completing tables; to what end?
- The contractor and OIT should help us better understand features available in other AE system
- The contractor and OIT should use the existing AERS requirements, AERS II high level requirements, list of CCRs, and ODP session notes as a baseline (those that existed as of July 2004)
- We are very uncomfortable with the process of one contractor gathering requirements, and another contractor doing design and build

- The process of splitting the project into requirements and design/build means we will need to spend more time to train the next contractor
- We want to see other AE products so we know what is already available to other and to help stimulate better ways of doing our jobs
- What happens between the draft copy on March 21, 2006 and the final document on April 12, 2006?
- What happens if the final detailed requirements document delivered on April 12, 2006 is unsatisfactory? Who fixes? Will it cost more? Who pays?
- Why don't we have representatives from FOI; why don't we have Medical Officers and Epidemiologists attending? What about their requirements?

The AERS users suggested that OIT *stop work* on the requirements gathering process until they could be sure that the process would be done correctly, but OIT seemed to ignore their request. Had the AERS II process gone forward in July 2004 rather than being delayed by OIT management, the AERS II system would have been up and running for six months to a year.

Oblivious to the needs of AERS users to replace the dysfunctional AERS I system, [redacted] and the Business Process Planning group continued pushing toward the new project scope of building an FDA-wide system and contracted with IBM to conduct a high-level business process analysis. Given the scale and complexity of FDA and its Centers, and the fact that the scope of the IBM project was only $43,000, it's unclear what BPP was expecting to accomplish with this project other than to create more support for accelerating the FDA-wide system at the expense of an AERS I replacement by revealing the obvious, e.g. that there was a large degree of commonality of processes across the agency in the areas listed below.

- Developing instructions and guidance for adverse event reporter use
- Methods for collecting adverse event information (i.e., phone, fax, mail)
- Activities for registering a received adverse event (i.e., logging, sorting)
- Data Entry
- Identifying importance to address adverse event, typically termed "Triage"
- Steps for coding
- Quality control (data entry, coding, other handling)
- Conducting archiving (paper and electronic)
- Privacy Act Redaction
- Reviewer Notification
- Obtaining additional information, typically termed "Follow-up"

The IBM study in combination with an increasing pressure for an agency-wide adverse events reporting system propelled the MedWatch Plus project to the forefront and increasingly slowed the AERS II project. In an email dated March 13, 2006, Burnette transmitted a copy of the draft Addendum to the AERS II Boundary Document that incorporated FDA-wide needs to [redacted] and [redacted][55] [redacted] stated that CDER's OIT was preparing a high level analysis of the impact that these changes would have on the CDER/CBER AERS II initiative, when in fact OIT already knew the extent of the negative impact as would be indicated by [redacted] changing of the AERS II status from green to yellow.

[55] See Addendum AERS II Boundary Document, March 13, 2006.

In [redacted] March 15, 2006 email to [redacted] stated that the MedWatch Plus Executive Committee had reviewed the proposed addendum to the AERS II Boundary Document and had agreed on it subject to two key points:

- [redacted] stated and it was agreed/endorsed by all that any changes to AERS II scope to include agency-wide functions *could not negatively impact CDER*
- It was unanimously accepted that additional functionality would be phased in

This was another example of the pattern of *saying* that there would be no negative impact on AERS users or CDER, when in fact the project was (and would continue to be) negatively impacted (OB 1-2006). [redacted] learned that [redacted] was also worried about the negative impact that an agency-wide system would have on AERS users and CDER, so she sent [redacted] an email on March 15, 2006 trying to ease [redacted] concerns and smooth the situation over. In the email [redacted] states,

> "[redacted] I expect you have some concern about whether the MedWatch plus activities might negatively impact AERS II. I just want to let you know that it was specifically mentioned by [redacted] and agreed and endorsed by all at the MedWatch Plus Executive Committee meeting that any changes to AERS II scope to include agency wide functions could not negatively impact CDER. OIT-CDER has some good suggestions for how to proceed from a technical perspective.
>
> "You'll see some meeting notices in the next week or so (I expect) that talks about changes to the AERS II boundary document. What we've done is made the changes as an addendum, so basically AERS II continues as planned, and the agency wide components will be "add ons." This is similar to what we did with SPL, where the first phase was CDER only, but there were options in the contract to do additional components. There will have to be agreement to the 'add ons,' so it will be important to have the right people from CDER there to have the official CDER voice."

But it became increasingly difficult to see how CDER and AERS users *would not* be negatively impacted by an agency-wide system, given the fact that its funding for AERS II for FY 2006 had been zeroed out and reprogrammed to OIT (OB 1-2006). In fact, in the March 23, 2006 ODS Budget Sheet, AERS II funding for FY 2006 was listed as being $1.528 million and two weeks later in the April 10, 2006 ODS Budget Sheet the funding for AERS II had been zeroed out and reprogrammed from the "business side" in ODS to OIT. The current funding for AERS II in FY07 has also been zeroed out. Based on the information available to the assessment team, it is unclear exactly who reprogrammed the AERS II funding to OIT. But what is clear is that reprogramming AERS II funding to OIT *almost guaranteed* an enormous negative impact on AERS users and CDER by even more delays in replacing the dysfunctional AERS I system and unnecessary costs incurred by not moving on the AERS II system two years earlier in July 2004. More specifically, reprogramming AERS II funding to MedWatch Plus activities would give BIB and CDER's OIT a one year lead over the financially stalled AERS II project, allowing them to "leap frog" the MedWatch Plus project over AERS II, then argue that the AERS II project had been overcome by events, e.g. it had simply been absorbed into the yet to be developed agency-wide system, without ever becoming an operational IT system. Given the performance of OIT on AERS I and throughout the time period covered by this study, this is an enormous risk to FDA and AERS users in all Centers.

3.10 Unanswered Questions

What is most confusing about the current status of the AERS II project is that the COTS and/or COTS Integration solution that was shown in July 2004 to be the preferred solution for replacing

the dysfunctional AERS I system is still one of the solutions currently being considered, yet FDA has not acted on this plan. More specifically, on May 18, 2006 sent an email to OIT staff members and stating that she had just seen a presentation by a company that specializes in adverse event case management business processes that indicated there were only a few products that were widely used as adverse events reporting systems.[56] asked OIT to conduct *yet another* alternative analysis on the following four products mentioned in the presentation:

- Phase Forward – Clintrace
- Relsys – Argus
- Aris Global – ARISg
- Oracle – Oracle AERS

The fourth option, Oracle AERS, is the same system that was recommended by OIT's AERS Project Managers in the July 2004 OMB Exhibit 300. Had this proposal been implemented in 2004, the AERS II system would have been fully operational in FY 2005 at a cost of about $4.5 million, most of which would have been paid for by cost efficiencies from the existing AERS I system.

As mentioned above, the purpose of this section is to establish the overall historical context for the Independent Verification and Validation of the AERS II Requirements Process, and to evaluate the rationale and consequences of critical decisions that were made by CDER's OIT, AERS users, and CDER managers and scientists that have brought the AERS II project to the point it is today in FY07. It is meant to answer two fundamental questions.

- How did the project scope for AERS II get radically shifted from replacing the dysfunctional AERS I system, to building an Agency-wide adverse event report system?

- What are the end-effects and consequences for taking this path on FDA's and CDER's ability to carry out its mission of protecting and promoting public health through safety evaluations, epidemiological studies, and the functions executed by the Offices of Compliance and FOI?

But a close examination of the events surrounding the AERS II requirements development process raises as many questions as it answers, especially about the pattern of questionable decisions and practices used by CDER's OIT. For example, July 7, 2006 was last day as CDER's OIT AERS II Project Manager because accepted a job at - one of the four adverse event reporting companies that asked to evaluate only two months earlier in May 16, 2006 e-mail. During the last week of September 2006, made a presentation about adverse event reporting at the FDA sponsored meeting as the Director of Strategic Initiatives for On October 4, 2006 e-mailed FDA's apologizing for missing presentation at the meeting and asking for a copy of presentation slides. When questioned this as a conflict of interest, OIT's responded by e-mail, "I told had to talk to FDA Ethics about it."[57]

In an atmosphere in which IT management and contracting practices are coming under increased scrutiny, and in the wake of the recent report from the Institute of Medicine (IOM), the senior managers in CDER should conduct a thorough investigation into the leadership, management, and

[56] See May 18, 2006 e-mail from to and

[57] See e-mail from to with copies to and

contracting practices of OIT.[58] More specifically, they should investigate: a) how effectively CDER's portfolio of IT projects is being led and managed; b) the selection criteria by which contractors like the one mentioned above are screened and selected; and c) the way in which financial resources are being combined into larger and larger categories in CDER's OMB Exhibit 300 which *increases* the extent to which OIT can reprogram the IT funds of CDER's science-technical units like OSE, award those funds to contractors they select without the approval of science-technical managers, and *decreases* the level of traceability and overall accountability for doing so.

[58] For example, see the audit and investigation into the $170 million IT system developed for the FBI that was unusable. See, "The FBI's Upgrade That Wasn't," by Dan Eggen and Griff Witte in, *The Washington Post*, August 18, 2006 (http://www.washingtonpost.com/wp-dyn/content/article/2006/08/17/AR2006081701485.html). Also see the Institute of Medicine's report entitled, *The Future of Drug Safety: Promoting and Protecting the Health of the Public*, published on Sept 26, 2006.

4.0 Use of Appropriate IT Methodology[59]

This section of the report evaluates whether standard IT Methodology was used for the AERS II system's design and requirements development process. By way of general introduction, enterprise-wide knowledge management requires that leaders and managers put their organization's "whole brain" to work. This means viewing "knowledge-as-knowledge" whether it is stored and manipulated in a silicon-based system like a computer, or a carbon-based system like an FDA Safety Evaluator's brain. In today's information intensive environment, FDA's human and computing resources need to work together like a cross-functional work team to achieve the Agency's objectives and goals. A mission-oriented approach to the AERS II system that embodies an effective IT infrastructure should have four high-level functionalities:

- Move information about adverse events from the *external environment* outside FDA to the correct place in the organization so it can be analyzed, digested and acted on.
- Move information from *internal processes* within FDA to the correct place in the organization so it can be analyzed, digested and acted on, for example from OSE to the appropriate review divisions in OND.
- Move information about the *status* of goals, milestones, deliverables, and budgets in operations plans to the correct place within FDA so it can be analyzed, digested and acted on.
- *Structure* and *manage data storage* so it is a resource that's available to AERS II users in all FDA Centers, e.g. data isn't isolated in data silos or shadow systems.

All too often, an organization's IT infrastructure is designed and maintained by IT professionals who give line managers what they think is needed to operate the business. This is one of the root causes in the derailed development of the AERS II system. Savvy senior managers know that a high-performing IT infrastructure is a key element of accomplishing their purpose, mission and goals, and consequently systems like AERS II are much too mission-critical to be delegated to IT professionals who often lack an intimate knowledge of an organization's purpose, goals, structures, systems, and organizational culture.

Whether an organization is designing custom software like AERS I, or piecing together a COTS integration package like AERS II, there are specific foundational principles and IT methodologies that must be included. This section of the report compares the processes used in the development of the AERS II High-Level Requirements Document and Detailed Requirements Document

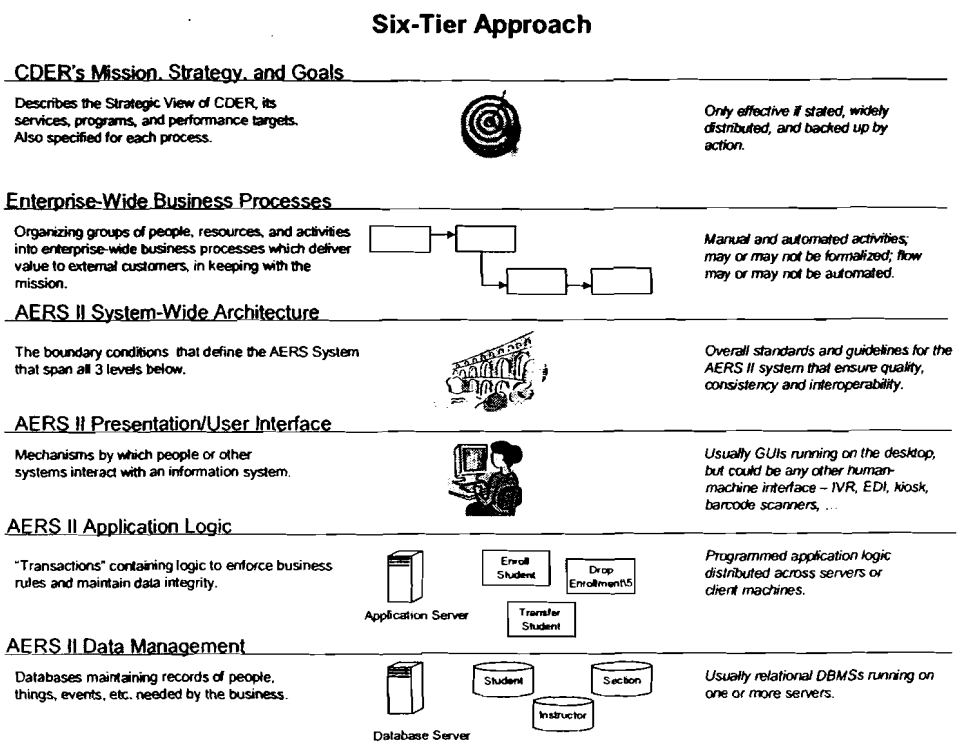
---

[59] The following references were used to define our assumptions of what constitutes an appropriate IT Methodology: a) Alec Sharp & Patrick McDermott, *Workflow Modeling,* (Boston: Artech House Inc., 2001). Sharp and McDermott provide proven techniques for identifying, modeling, and redesigning business processes, implementing workflow improvement, and developing software that effectively implements business processes. The techniques described enable requirements definition for either systems development or acquisition. The techniques include Workflow Modeling (Swimlane diagrams), Use Cases, and Entity Relationship Diagrams; and b) Richard Barker, *CASE*Method Tasks and Deliverables,* (New York: Oracle – Addison-Wesley, 1991). This is the gold-standard text that defines the structured development methodology used by Oracle Corporation for either systems development or acquisition. It describes how to utilize Oracle's repository system, Oracle Designer (formerly Oracle CASE), to document and automate the software development process. The CASE methodology may be used either to custom-build an application or to evaluate the suitability of off-the-shelf "COTS" applications or "COTS" integration.

(SRS) to IT software development methodology and practices that are commonly accepted in industry.[60]

4.1 The Six Tiered Method

A commonly used framework in the world of business process automation and information Technology is the six tiered framework.[61] The six tired framework clearly defines all of the layers that are essential to building successful IT systems. The six tiers are shown in the diagram below:



Adapted from Alec Sharp and Patrick McDermott, *Workflow Modeling: Tools for Process Improvement and Application Development*, (Boston, MA: Artech House, 2001), p. 43

The Six Tiered Method is a common sense approach to understanding the interdependent layers (tiers) that constitute an IT development project and how those tiers should interact over the course of an entire project. The Breckenridge Institute used this framework to evaluate the AERS II requirements process conducted by OIT and its contractors. A more detailed description of each of the six tiers appears below along with commentary on how the AERS II process either did or did not address these areas.

Tier One: CDER's Mission, Strategy, and Goals

---

[60] The Clinger-Cohen Act of 1996 requires federal agencies to follow corporate America's best practices for managing IT, see Alan Holmes, "Federal IT Flunks Out" in, *CIO Magazine*, May 15, 2006.

[61] The bulk of the information in this section was taken from Alec Sharp and Patrick McDermott, *Workflow Modeling: Tools for Process Improvement and Application Development*, (Boston, MA: Artech House, 2001), p. 39 ff.

An organization's Mission, Strategy, and Goals are the driving force behind everything that it does, including its IT systems – business processes and IT systems do not exist in isolation. With clear mission, strategy, and goals in place, the business processes that support them can be described and analyzed. It is at this level that senior CDER managers must ensure that the lifecycle phases and the activities therein are kept in alignment with the organization's mission. FDA's overall mission is to protect and promote the public health and safety and organizational units like CDER and CBER contribute to this mission in various ways. The following kinds of documentation for Tier 1 should have been kept in the forefront of IT development by CDER's OIT and its contractors throughout the AERS II requirements process:

- Mission for FDA, Centers, and Organizational Units like the Office of Surveillance and Epidemiology (OSE)
- Strategic Plan for FDA, Centers, and Organizational Units like OSE
- Goals and Objectives for FDA, Centers, and Organizational Units like OSE

The assessment team found no evidence that the AERS II requirements process meaningfully analyzed FDA's or CDER's mission, strategy, and goals, or the mission, strategy, or goals of any of the organizational units that utilize the AERS system in CDER, CBER, or elsewhere across the Agency. Neither the 2004 High-Level Requirements Document, nor the 2006 Detailed Requirements Document took a "top down" approach to the AERS II requirements process, e.g. the AERS II requirements process was not linked to CDER's mission and goals in any meaningful way (OB 8-2006). More specifically, CDER mission and goals (Tier One) were not incorporated in the 2004 High-Level Requirements Document. Although the document contains a section entitled, *Business Vision and Objectives,* this contains a cursory discussion of the objectives for the AERS II system, but does not tie AERS II back to CDER's mission or goals at Tier One.

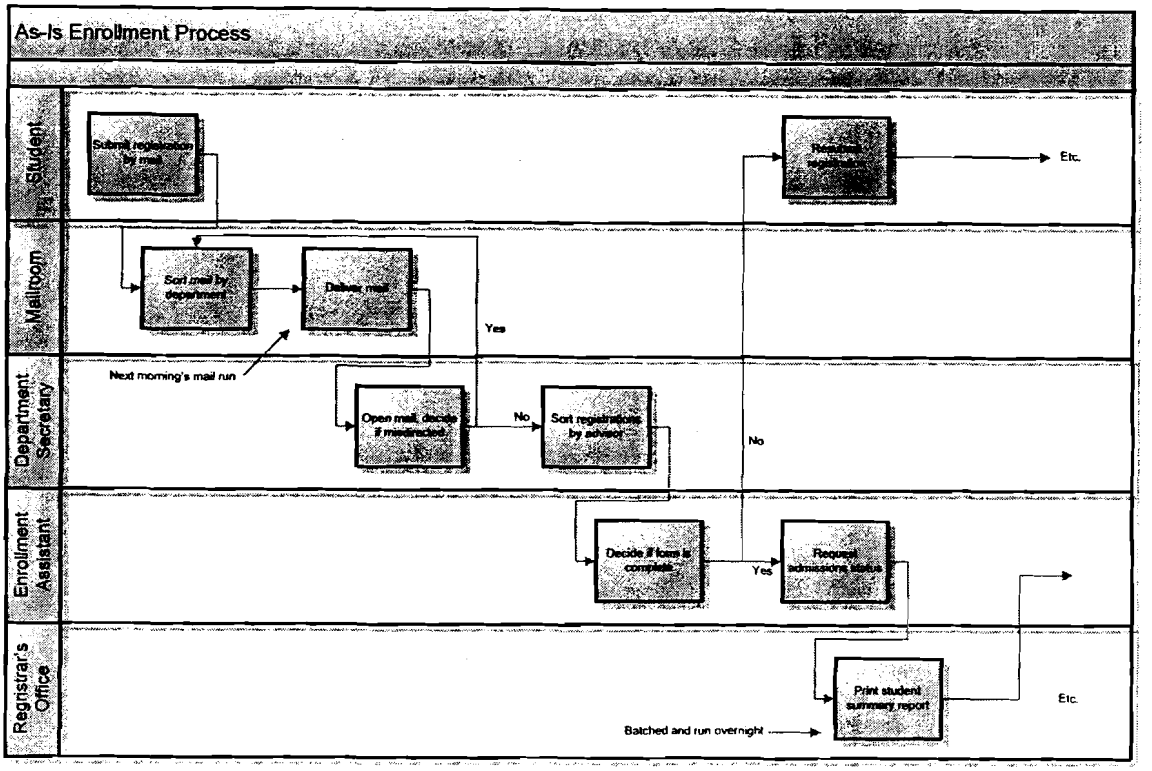
Tier Two: Enterprise-Wide Business Processes

The Business Process tier analyzes the enterprise-wide business processes and enabling processes (manual and automated) that allow an organization to conduct its business. Tier Two analysis typically occurs during the High-Level Requirements phase of a software development or COTS integration project. With respect to AERS II, this tier would consist of the end-to-end process of drug safety and enabling processes such as conducting safety evaluations, epidemiological studies, and the tasks associated with the Offices of Compliance and FOI.

When analyzing an organization's enterprise-wide business processes and enabling processes as part of software development, it is important to lay the groundwork by first analyzing the processes "as-is", or as they occur "today". This provides the perspective that is necessary for looking for process improvement and designing the "to-be" workflow. When designing software or evaluating the components of a COTS integration package, the "as-is" and "to-be" processes can be developed and analyzed using a repository tool like Oracle Designer. A diagramming technique frequently used for documenting the workflows is called a swimlane diagram. This diagram demonstrates both the process flow as well as the handoffs from one user or organization to another. The following kinds of documentation should be included in Tier 2:

- Overall Process Map
- As-is workflow (swimlane diagrams)
- To-be workflow (swimlane diagrams)

The following diagram demonstrates a sample swimlane diagram, and it can be seen from this diagram how easily a workflow can be understood by using this technique:



As mentioned above, the assessment team found no evidence that the AERS II requirements process analyzed either CDER's enterprise-wide process of drug safety, or any of the enabling process like conducting safety evaluations and epidemiological studies or the tasks associated with the Offices of Compliance or FOI. As mentioned earlier in the report, CDER's Office of Business Process Planning contracted with IBM to conduct a high-level business process analysis after the AERS II requirements process was almost complete. Given the scale and complexity of FDA and its Centers, and the fact that the scope of the IBM project was only $43,000, it's unclear what BPP was expecting to accomplish with this project other than to create more support for accelerating the FDA-wide system at the expense of an AERS I replacement by revealing the obvious, e.g. that there was a large degree of commonality of processes across the agency (see Section 3.9 of this report for details).

Neither the 2004 High-Level Requirements Document, nor the 2006 Detailed Requirements Document took a "top down" Business Process Analysis approach to the AERS II requirements process (OB 8-2006). The 2004 High-Level Requirements Document does not contain (or reference) a properly conducted Tier Two Business Process Analysis using methods such as workflow analysis, swimlane diagrams, or IDEF0 process analysis, e.g. there is no "as-is" or "to-be" analysis of CDER's enterprise-wide business process of Drug Safety, or its enabling processes, e.g. conducting safety analyses, epidemiological studies, or the tasks performed by the Offices of Compliance and FOI. The form of analysis that was included in the document (Use Cases) was inappropriate for a high level requirements phase. More specifically, the detailed levels of swimlane diagrams of CDER's Tier Two enterprise-wide business processes and enabling processes (safety evaluations and epidemiological studies) should have been linked to the Presentation-User Interface at Tier Four (functionality that AERS users see on the screen),

and then Use Cases should have been used to link the Presentation-User Interface to Tier Five (Application Logic). The assessment team found that *there is no meaningful connection between the High-Level Requirements Document and the Detailed Requirements Document (SRS).* Alec Sharp comments on the incorrect application of Use Cases in IT system design:

> "Whenever a technique is successful, someone will try to take it too far, and use cases are no exception. A notable example: they have been proposed as the core technique of a process reengineering methodology in which a process is viewed as a use case – a very large use case – that is progressively decomposed until it arrives at task-level use cases. This approach simply hasn't taken off, so if you're considering it, don't bother. Process framing and swimlane diagramming are better for dealing with complete business processes, just as use cases are better for determining how actors and systems will interact to complete tasks."[62]

The 2004 High-Level Requirements Document appears to assume that the CDER's current business and enabling processes (that are currently in operation and undefined) would remain unchanged, and simply summarized available lists of requirements that existed prior to 2004 and added some new features primarily in the area of technology (for example web-based interface). As operating experience with the dysfunctional AERS I system has painfully shown, the effect of functionality problems on users tends to magnify, the further into the IT systems development life cycle one progresses. More specifically, it is inexpensive and relatively easy to identify and analyze missing or incorrect Business Process functionality early on in the process, but very expensive and time consuming to add or fix functionality in the later stages of the development process (for example, while programming or integrating multiple COTS packages).

Tier Three: AERS System-Wide Architecture

The System-Wide Architecture Tier defines the overarching framework within which the AERS II system should be developed and operated. It spans the 3 tiers below it, and is necessary in order to define, build, and maintain a consistent, quality technical solution. The following kinds of documentation should be included in Tier 3:

- Project Schedule and Work Breakdown Structure
- Technical Architecture – Hardware platform, Operating system, Database Management System, etc.
- Standards – Naming, coding, look and feel
- Test Plan
- User Acceptance Criteria
- Migration Plan
- Constraints and Assumptions
- Quality Assurance Plan
- Security Plan
- Configuration Management Plan
- User Documentation
- User Training

Although some of these areas were mentioned in the requirements documents, they were not addressed in the depth required for a system of the scope and complexity of AERS II. For

---

[62] Alec Sharp, *Workflow Modeling: Tools for Process Improvement and Application Development,* (Artech House, Inc., 2001), p. 299

example, there were requirements that stated that data would be migrated from AERS I, but how could a Migration Plan be included when there was no Data Model included?

Tier Four: AERS Presentation/User Interface Level

The Presentation/User Interface Tier can be considered the "gateway" into and out of the AERS system. It represents the mechanisms by which people or other systems interact with the system and is the appropriate place for Use Cases to be used to model these interfaces. For end-users, this tier appears as the Presentation-User Interface, e.g. what they see on their desktop computer screen, Blackberry, reporting facilities, or other media/devices. Also included in this tier are other types of interfaces into and out of the system such as electronic data submission, bar code scanners, and public web sites. Some examples of documentation that should be generated at this tier include:

- Screen designs and specifications for their behavior
- Report layouts and specifications for their search capabilities
- Interface specifications
- Reporting tool requirements for specialized tools and advanced analytics (e.g. SAS, SPSS, Excel, etc.)
- Download/Upload requirements

Although over 50% of the requirements in the 2006 SRS are geared to defining this tier, they do so primarily through lists of requirement text, most of which existed prior to 2004, and some Use Cases that are *unconnected* to the other tiers, especially the Data Management tier. There are only a few sample screen designs and no report layouts contained in the 2006 AERS II SRS developed by BAH. These incomplete and/or disconnected requirements were interspersed throughout the document, making the 2006 AERS II SRS of questionable value.

In addition, the assessment team found that neither the 2004 High-Level Requirements Document, nor the 2006 Detailed Requirements Document specifies what methodology and/or tools were used to manage the AERS II requirements process or to produce the models in the final documents, e.g. a requirements repository like Oracle Designer (OB 7-2006). Standard IT methodology requires that such methods and tools be used as the basis of a requirements process and that they be clearly documented in the final requirements document.

In the case of the AERS II requirements process, it appears that lists of requirements that were available prior to July 2004 were edited, and then cut and pasted into the two documents using MS Word or Excel rather than using a requirements repository/tool to manage the overall requirements process. In 2003, FDA paid the Oracle Corporation over $300,000 to reverse engineer the AERS I system into Oracle Designer, an automated tool widely used by Oracle customers and consultants to design new systems and document existing systems.[63] This information appears to have been ignored by CDER's OIT and its contractors during the AERS II

[63] Oracle Designer, formerly called Oracle CASE (Computer Aided Systems Engineering), is a tool that can be used from day one of the systems development life cycle to document and analyze system requirements. Richard Barker's book describes how to use the tool for every step of the life cycle. The Designer repository captures increasingly detailed information obtained during the life cycle, without the need for re-entry of requirements. For example, during the Strategy (High Level Requirements) phase, information about conceptual data entities is stored. During the Analysis (Detailed Requirements) phase, these same entities are documented in more detail, and a complete Entity Relationship model is completed. Then during the Design phase, a utility within the repository can be run to generate a default database design, which subsequently can be used to automatically generate SQL syntax and create the necessary tables in Oracle.

requirements process. The existing AERS I data model was completely reverse engineered (loaded into the Designer repository using an Oracle utility that captures all information about the existing database), with additional documentation added regarding the description and size of every table in the database. This "physical" database design was then further analyzed and reversed engineered into a logical Entity Relationship model. Although BAH would not allow Oracle access to reverse engineer the Oracle programs (forms, reports, etc.), Oracle manually input information into the repository regarding the functional design of AERS I as well. This repository could have saved enormous amounts of time and money had it been used for the following purposes:

- Understanding and further documenting the "as-is" business processes during the High Level Requirements phase.
- Automating the analysis of the "to-be" processes, building upon the wealth of information already in the repository.
- Understanding the current AERS I Entity Relationship model.
- Based on the analysis of "to-be" processes, modifying and enhancing the AERS I Entity Relationship model to represent the data requirements for AERS II.
- Tracking the evolution of requirements from AERS I (1996) to the present day, without having to re-analyze, re-number, and re-document these requirements.
- Manage the current AERS I environment by having a single place for complete documentation needed for the maintenance of the system. This can include training new OIT (or contractor) employees on AERS I and doing impact analysis of changes.
- During the future COTS integration process, the Repository could be used for automated generation of any components of the system that must be custom developed, whether it be database components, such as database tables, or application components.

As a result of not using the appropriate methodology or tool, the requirement numbering schemes from the 1996 document to the 2006 requirements document changed multiple times, with very little traceability of requirements from one document to the next. For example, in the 2006 SRS document there is a column indicating the source of a requirement. In some cases, this source may indicate a specific requirement in the RTM. In many other cases, it may indicate a Work Group or another document, but that requirement still mapped back exactly to a requirement in the RTM. Because these requirements were not controlled and tracked in a data repository that recorded a given requirement's change history, users were forced to discuss the same requirements over and over again. What is even more problematic is that CDER's OIT actually owns and maintains CDER's Oracle Designer repository that contains a full back-engineered AERS I system, but failed to use it for the AERS II requirements process despite the fact that AERS is situated on an Oracle platform. The OIT did use an IBM-based repository called RequisitePro *after-the-fact* to generate a requirements traceability matrix. But the cost and work associated with this entire step would have been unnecessary had OIT and its contractors used Oracle Designer from the beginning of the process.

Tier Five: AERS Application Logic

The Application Logic Tier contains the business rules and process logic that must be implemented in order for the Presentation/User Interface Tier to interact with the Data

Management Tier. This application logic is programmed into the application, and may exist at any layer of the system (e.g. database server, web server, etc.). In addition to automating the logic of the application, it ensures that the application data can be maintained. Some examples of documentation that should be contained at this tier include:

- Use Case Diagrams with associated logic
- Life-cycle logic for maintenance of data entities (create, update, delete)
- Logic to support searching and analysis requirements

Tier Five is the most complex of the Six Tiers to analyze and requires a number of well established techniques: a) event identification, b) state transition modeling, and c) transaction specification, none of which were found in the 2006 AERS II SRS document produced by BAH.

There are numerous requirements associated with Tier Five in the 2006 AERS II SRS in the form of lists of requirements that existed prior to 2004 and Use Cases. However, it is difficult to assess their completeness and whether the requirements of AERS users have actually been included in the SRS because of: a) the aforementioned lack of a top-down approach that connects all six tiers, and b) the complete lack of a data model at Tier Six which is described below.

Tier Six: AERS Data Management

The Data Management Tier is the foundation of the system – the ability to store and retrieve data. Building a software system without a well-designed data management structure is like building a house without a foundation. As has been painfully evident with AERS I, without a quality database design and database management system, the quality and usefulness of the information provided to the users via the Application Logic and User Interface is of questionable value. The Data Management Tier must take into account both the day-to-day operational data as well as the data warehouse where the data will be used for analysis and reporting. Some examples of documentation that should be included at this tier include:

- Entity Relationship Model (ER Model). The ER Model starts out at a very high level during the High-Level Requirements phase, is refined to greater levels of detail during Detailed Requirements phase, and should be described in detail in the High-Level Requirements and Detailed Requirements Documents. Typically, this documentation would be comprised of:
  - The *things* that the organization must record information about (entities) – for example, the data contained in an adverse event report.
  - The connections or associations between one entity and another (relationships). For example, *one or more adverse events* about a specific drug.
  - The facts that describe an entity (attributes) – for example, drug ingredients, labeling information, etc.
- ER Model Dictionary Report – Contains definitions of entities and attributes as well as other detailed information about them.
- Entity usages – function/entity matrices and business unit/entity matrices.
- Data volumes – projected quantities of entities (e.g. there will be 10,000 customers).

- Detailed Database Design – takes the detailed ER Model and defines how it will be implemented in the database management system of choice (defined in Tier Three, Architecture). This is accomplished during the Design/Build phase, taking into account both the operational (transaction processing) needs and the data warehousing (reporting and analysis) needs of the application and its users.
- Data quality and data integrity logic.

The assessment team found this tier to be seriously deficient due to the complete lack of *all* of the components mentioned above – no ER model or dictionary, entity usages, detailed database design, or data quality and data integrity logic. The only Tier Six requirements contained in the HLR or SRS were lists of statements regarding types of data that needed to be included in the database, e.g., dictionaries.

In addition, it is important to note that the back-engineering of the AERS I system using Oracle Designer in 2003 would have provided a solid foundation upon which to build AERS II in terms of an Entity Relationship (ER) model and underlying data structure (OB 9-2006). The 1996 AERS I document contained a Data Requirements section, complete with a dictionary report. Although this information is stored in the Oracle Designer container maintained by CDER's OIT, it was ignored by OIT and its contractors in the AERS II requirements work conducted from July 2004 on, resulting in a *very serious* lack of definition in Tier Six, Data Management. If, by leaving the Data Management tier out of the 2006 SRS Document, the intention was to rely on the ER Model and Data Management tier in AERS I, then serious deficiencies in AERS II functionality will be unavoidable, as indicated by the comments and data gathered in the 2005 AERS Users Satisfaction Survey. This also indicates that a higher priority was placed on the ER Model and Data Management Tier ten years ago than today.

The lack of an ER Model and well-defined underlying data structure presents a *serious risk* to the potential success of AERS II because without these elements, user needs will not be met again as was the case with the AERS I system. Without an ER Model and underlying data structure, it is not possible to evaluate the degree to which Tier Four (Presentation) and Tier Five (Application Logic) actually contain complete functionality. One of the techniques for cross-checking that these requirements are complete is to evaluate each data entity in the ER Model to see if its complete life cycle is represented in them. For example, is there a Use Case for the creation, maintenance, and deletion of each entity, and is there a user interface (e.g. screen) or imbedded application logic to perform this function? Since there is no ER Model and no definition of entities, there is also most likely *a large hole* in the application logic requirements of the 2006 SRS document. Regardless of whether one is developing a custom software application where information deliverables are used to build a sound database structure or evaluating the extent to which a COTS or COTS integration package will meet user needs, a well-defined foundation of an ER Model underlying data structure and information deliverables is required.

4.2 OIT's People Design

There are a number of roles that must be filled in order to ensure that an organization like CDER's OIT can deliver a system that meets the needs of AERS II users. A close assessment of the AERS II requirements process conducted by OIT reveals that OIT did not have the appropriate "people design" to carry out the AERS II requirements process and that AERS users and CDER managers were not involved in appropriate roles. In addition, proper guidance for requirements gathering was not provided to AERS users by OIT or its contractors.

More specifically, the AERS II requirements process lacked an effective *liaison* between: a) AERS users, b) the working level technical people within OIT who functioned as AERS Project

Managers, and c) the IT designers in the AERS software maintenance contractor organization. This liaison function is normally described as a Business Analyst. Until recently, the AERS Program Manager tried to fulfill this role, but this position has since been abolished (OB 6-2006).

The roles listed below detail the roles that would typically be involved in the early stages (high level requirements, detailed requirements) of an IT project like AERS II. Some commentary related to the approach taken by OIT for AERS II is provided with each bullet, with more detailed descriptions presented below.

- *Sponsoring User*: The senior manager in the users' organization who is responsible for ensuring the quality of user input to the project, for resolving scientific and technical issues, and for signing off at the end of each phase. For AERS II, this role is filled by senior CDER managers who understand the scientific and medical issues involved in carrying out CDER's post-marketing Drug Safety function. It is important to note that this role should not be delegated to the OIT organization or to a staff-support organization like CDER's Business Process Planning Office (BPP).

- *User Management*: This role should be fulfilled by a formal steering committee to oversee the project to ensure that the new software system will meet users' needs, is cost-justified, and well run from a project management perspective. For AERS II, this function was carried out by the OPaSS AERS Program Office, the Change Control Board (CCB), and the AERS Project Manager in the OIT organization.

- *Business Analyst*: This is a key role, responsible for straddling the boundary between the OIT organization and the scientific and technical aspects of the processes used to conduct safety evaluations and epidemiological studies. The Business Analyst is the interface between the working level technical people/project managers in OIT, and the users and should be involved in all phases of development (2004 HLR and 2006 SRS). In this case, they must be able to speak the language of IT systems, *and* the language of Safety Evaluators, Epidemiology, and the Offices of Compliance and FOI. This function was, and remains, missing in CDER's OIT and OIM which forced AERS users to focus on issues of IT functionality rather than the processes involved in conducting safety evaluations and epidemiological studies.

- *User*: A person who will be the eventual user of a system. Users should provide input during all stages of a development project. They may be interviewed, participate in feedback sessions, work together with Business Analysts and designers, participate in the system acceptance tests, etc. In this case, Safety Evaluators, Epidemiologists and the Offices of Compliance and FOI are the primary users of AERS II.

- *Designers*: Responsible for producing the program specifications and database design, or *how* the requirement is to be met, as well as identifying and resolving design issues at any stage in the project. This role was filled by OIT who outsourced this work to contractors, e.g. High Performance Technologies Inc. for the High Level Requirements Document, and BAH for the Detailed Requirements Document. Although they outsourced the work, OIT remains responsible for this role throughout the life of the project. As the data presented in this report show, OIT selected contractors that had a known and documented history of marginal performance and then failed to exercise adequate oversight over their performance.

- *Project Manager*: The OIT person who was responsible for all application work, project planning and control, putting the plan into action, keeping all parties informed of plans,

progress, and issues, managing the project team, and ensuring the quality of the deliverables. There were six different project managers over the three year time period covered by this study.

- *Data Administrator*: Responsible for monitoring business models, advising on data issues, defining standards for data security and naming conventions, and accepting the data models. This is typically a senior person with extensive knowledge of the business. It is not clear to what extent a Data Administrator role was filled for AERS II by OIT personnel.

The absence of the role of the Business Analyst in the AERS II process left a gap between the technical working level and project staff in OIT, the Program Office staff in OPaSS, and the users in CDER, CBER and other FDA units. As a result, AERS users were forced to fill the vacuum of the Business Analyst role by attending myriad requirements gathering meetings where they were asked to list and re-list their requirements at an overly detailed level, rather than focusing on the process-oriented aspects of conducting safety evaluations and epidemiological studies. Many of these meetings would have been unnecessary had OIT provided staff members to function in the Business Analyst role. An even more serious problem is that it is unclear to AERS user who participated in these meeting and CDER managers and scientists whether the requirements need to replace the dysfunctional AERS I system are actually contained in the SRS delivered to FDA by BAH in June 2006.

4.3 Analysis of the High-Level Requirements Document

The High-Level Requirements (HLR) Document dated December 14, 2004, was reviewed and compared to standard Life Cycle Development Methodologies for completeness. The 2004 High Level Requirements document contains *almost nothing* regarding Data Management. There is no conceptual ER Model or documentation, only a few requirements in list format that refers to the dictionaries needed (OB 8-2006). This lack of an ER Model violates *FDA's own System Development Life Cycle*, as can be seen in the Methodology Summary – Detailed Requirements table below.

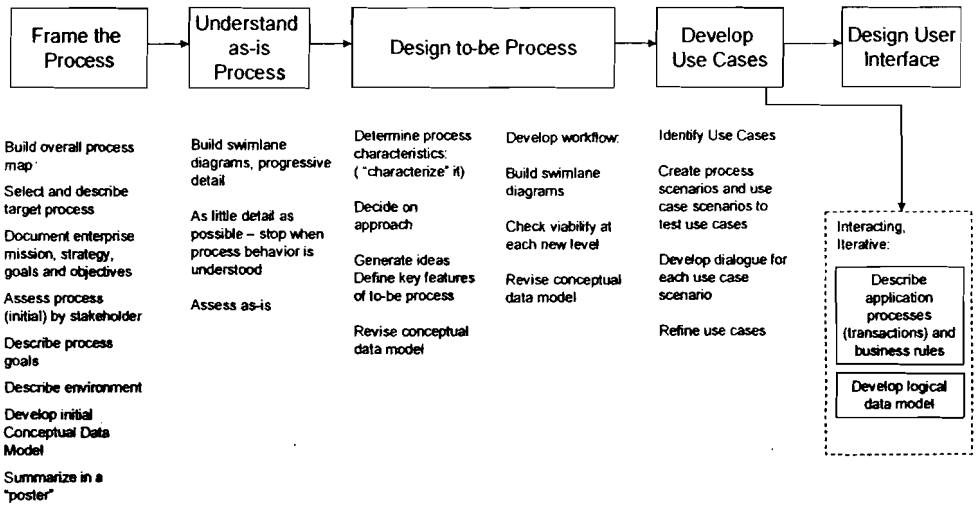
METHODOLOGY SUMMARY - STRATEGY (HIGH LEVEL) PHASE					
Doc Type	Document Content	AERS II HLR 12/15/04	Barker	Sharp	Comments
System-Wide	Statement of Organization mission, strategy, goals, objectives, and vision	P	X	X	Brief vision and objectives for system, not at organizational level.
	Organizational, technology, or other issues		X		
	System Boundary definition	P	X		As defined by Functionality Domains
	Phased development plan		X		
	Optional feasibility reports and vendor proposals		X		
	Glossary of terms	P	X		List of acronyms, but not a complete glossary of terms
	Proposed system architecture/approach (recommended and alternative system architectures, by application system area, with priorities, dependencies, assumptions, etc.)	P	X	X	Contains some diagrams showing architecture and interfaces; no alternatives presented.
Functional	Function Hierarchy (high level)		X		There are 2 workflow diagrams, covering only a very small part of the functionality. The rest of the functional requirements are depicted by Use Case Diagrams.
	As-Is Work Process - Swimlane diagrams			X	
	To-Be Work Processes - Swimlane diagrams	P		X	
Data	Entity Relationship Model (high level)		X	X	

This matrix shows expected components of a high level requirements document in green, as compared to the actual AERS II HLR contents in red. An "X" would indicate that the component is fairly completely represented, while a "P" indicates that it is only partially represented.

The FDA SDLC requires a Logical Data Model (ER Model), Logical Model Dictionary Report, and Data Volumes to be included with the Requirements Phase, comparable to the 2006 SRS document. None of these are included in this document. The three methodologies reviewed in this document, FDA's SDLC, Richard Barker, and Alec Sharp, are consistent in their approach to Tier 6 Data Management – they all require an ER Model. It would be difficult, if not impossible to find a sound IT development methodology that does not require data modeling and a solid Tier 6 foundation and specification. As mentioned in the above section on the Six Tier Approach, the HLR is the phase when "as-is" and "to-be" business processes should be analyzed. The standard technique is as shown in the diagram above and is incorporated in a repository tool like Oracle Designer.

The High-Level Requirements phase should cover the first 3 steps of the Business Process Analysis model shown below – Frame the Process, Understand the "as-is" Process, and Design the "to-be" Process. The framing step clearly sets the expectations and boundaries from the start regarding the target processes to be improved by developing an overall process map. It also ties the business processes to the organization's mission, strategy and goals. Understanding the "as-is" process provides a starting point for determining what needs to be "fixed" in AERS I and why it needs to be fixed. Then the designing of the to-be process takes a fresh look the businesses processes, identifying areas for improvement. The matrix summarizes the documentation that typically would be included in a High-Level Requirements Document and compares this to the December 15, 2004 AERS II HLR that was delivered to CDER's OIT.

Business Process Analysis



As mentioned above, the assessment team found the 2004 HLR to be seriously lacking in terms of a) having a top-down business process analysis approach and b) the data requirements specification. By not including an ER Model or performing "as-is" and "to-be" business process analysis, the stage for AERS II is not set upon a firm foundation, and the value of the entire HLR document is questionable.

4.4 Analysis of the Detailed Requirements Document and User Needs

The AERS II System Requirements Specification (SRS) dated April 6, 2006 and amended May 17, 2006 was also reviewed and compared to standard Life Cycle Development Methodologies for completeness (see chart below).[64] With reference to the Six-Tier Approach, this detailed requirements phase is when all four bottom tiers should be addressed from a business (not technical) perspective: System-Wide Architecture, Presentation/User Interface, Application Logic, and Data Management.

METHODOLOGY SUMMARY - ANALYSIS (DETAILED) PHASE							
Doc Type	**Document Content**	**AERS I SDD 8/14/98 (1)**	**AERS II SRS 5/17/06 (2)**	**FDA SDLC**	**Barker**	**Sharp**	
System-Wide	Current System Analysis Document		X	X			2 - Appendices include 1996 reqts and subsequent RTMs
	Project Management Plan			X			
	Project Schedule			X			
	Purchase Request/Request for Proposal			X			
	Function/Entity Matrices				X		
	Function/Business Unit Matrices				X		
	Entity/Business Unit Matrices				X		
	Models for Dataflow, Funct. Dependency, & State Transition				X		
	Outline of Manual Procedures				X		
	User Acceptance Criteria				X		
	Constraints and Assumptions	X	X		X		
	Methodology	X					1 - Describes methodology used, which is similar to Barker
Functional	Software Development Plan			X	X		
	Software Preliminary Design Document			X			
	Software Quality Assurance Plan			X			
	System Requirements Specification		X	X			
	Functional Hierarchy with Function Detail	X			X		
	Function Frequencies				X		
	To-Be Process Workflows (Swimlane Diagrams)	P				X	1 - Contains some process flows (not in the format of swimlane diagrams, don't show user hand-offs)
	Use Case Scenarios (dev. from Detailed Swimlane Diagrams)		P			X	2 - Use Cases with no Workflows
Data	Logical Data Model (Entity Relationship Diagram)	X		X	X	X	
	Logical Model Dictionary Report	X		X			
	Database Preliminary Design Document			X			
	Data Volumes	X			X		2 - Extremely high level volumes, not entity level
Architecture	Database Naming Standards			X			
	Software Coding Standards			X			
	Technical Architecture	X					1 - High-level diagram of systems architecture
	Software Configuration Management Plan			X			
	System Quality Assurance Plan			X			
	System Security Plan	X	P	X			2 - List of security requriements, not a plan
	User Performance Expectations		X		X		
	Working Style Definition				X		

The AERS II SRS, the matrix shown above evaluates the 1998 AERS System and Design document, against standard components of a detailed requirements document, including the standard process and criteria for developing software found in FDA's System Development Life Cycle document (SDLC). This matrix shows expected components of a detailed level requirements document in green, as compared to the actual AERS II HLR contents in red. An

[64] Although the AERS II document is entitled "System Requirements Specification", matching the name of one line item from the FDA SDLC, the purpose as defined in section 1.1 found on p. 6 is "The purpose of this document is to capture detailed requirements regarding the Adverse Event Reporting System (AERS) II and to communicate these requirements to the CDER business community who will review and validate the requirements prior to the system design and development phase of this project." This purpose implies that the document addresses the broader scope of the SDLC Requirements Analysis Phase. In fact, a System Requirements Specification as defined by the SDLC would not be sufficient to enter the system design and development phase for the project.

"X" would indicate that the component is fairly completely represented, while a "P" indicates that it is only partially represented. The comments are labeled to indicate which document they refer to – AERS I SDD (1) or AERS II SRS (2).

The 2006 System Requirements Specification document also contains almost nothing regarding Tier Six (Data Management). There is no detailed ER Model or documentation other than a list of the dictionaries needed (OB 8-2006). This lack of an ER Model violates *FDA's own System Development Life Cycle*, as can be seen in the Methodology Summary – Detailed Requirements table below. The FDA SDLC requires a Logical Data Model (ER Model), Logical Model Dictionary Report, and Data Volumes to be included with the Requirements Phase, comparable to the 2006 SRS document. None of these are included in this document. The three methods used as the basis of this assessment report (FDA's SDLC, [redacted] and [redacted]) are consistent in their approach to Tier Six Data Management – they all require an ER Model. It would be difficult, if not impossible to find a sound IT development methodology that does not require data modeling and a solid Tier Six foundation and specification. Building a software application or COTS integration package without a well-defined data model at Tier Six is like building a house without a foundation.

As mentioned previously, the assessment team found the 2006 SRS to be seriously lacking in both: a) a follow through of the top-down process that should have been started in the HLR (but wasn't) – there was no apparent connection between the HLR and the SRS and b) the complete lack of data requirements specification. The SRS even created a new nomenclature for the grouping of requirements that didn't match any previous document, which makes it difficult to assess the completeness of the requirements that are there. As can be seen from the Methodology Summary chart, there are so many components missing from this document that it is not possible to proceed to a Build phase.

In addition to the fact that the 2006 AERS II SRS does not follow standard IT methodology, it does not adequately address the long-standing needs of AERS users. In June of 2005, the Breckenridge Institute performed a User Satisfaction Survey of the AERS I system across all users of the system (see Appendix E). This report was presented to CDER managers upon completion in June 2005 and again to CDER managers and to the Quality Management Office in CDER's Business Process Planning (BPP) Office on May 13, 2006.[65] In addition to numeric rating questions, the survey contained written questions where users could provide specific comments regarding their level of satisfaction-dissatisfaction with AERS I. The comments received for two of the written questions regarding AERS Inefficiencies and AERS Weaknesses provided valuable input from the users with respect to missing, incomplete, and non-functioning areas of AERS I that were negatively impacting them on a day-to-day basis. The data from the survey indicated that AERS users were faced with day-to-day work-arounds, re-work, down-time, and inadequate functionality issues that cost FDA more than $700,000 per year in squandered time and energy (see Appendix E for details).

Despite the number of meetings attended by AERS users during the AERS II requirements process, a comparison between the written comments in the survey and the contents of the SRS document shows that the long-time concerns of users about missing or inadequate functionality were not adequately addressed in the SRS document. The assessment team uploaded the comments from the 2005 AERS Users Survey and the requirements from the 2006 SRS document into the analysis database described in Appendix A, analyzed both sets of data, and then binned both sets of data into the Six Tiers. The results of this analysis process are shown in the chart

[65] See e-mail from [redacted] to [redacted] and [redacted]

below. The issues identified by the AERS 2005 Survey in the first column should have been given high priority by CDER's OIT and its contractors in the AERS II requirements process because they represented the "voice of the user" but they were not. In fact, the 2005 Users Survey is not even referenced in the 2006 AERS II SRS Document.

Tier	AERS 2005 Survey		AERS II SRS	
	#	%	#	%
Tier 1: CDER's Mission, Strategy, and Goals				
Tier 2: Post-Marketing Surveillance Business Processes				
Tier 3: AERS System-Wide Architecture	29	21%	80	8%
Tier 4: AERS Presentation/User Interface	44	32%	543	53%
Tier 5: AERS Application Logic	24	17%	273	27%
Tier 6: AERS Data Management	41	30%	119	12%

Tier Three represented 21% of the issues identified by users and only 8% of the requirements in the SRS covered this area. User concerns included items such as inadequate training for new and more experienced AERS users, help systems, and user documentation that is either non-existent or seriously out of date. For example, the only AERS User Manual that currently exists is from 1999 and contains none of the updates up through 2006. At the time the Users Survey was conducted, some OSE divisions like DMETS did not even have a single copy of the 1999 AERS User Manual to give new Safety Evaluators and training for new employees was conducted using the "oral tradition." The 2006 AERS II SRS only contains eight requirements on training, help systems, and documentation that are listed under the Supplemental Requirements section entitled "On-Line User Documentation and Help System Requirements." There is no further elaboration on these eight requirements. User problems with inadequate training, help systems, and documentation will become more and more problematic over time, especially if the turnover increases among AERS users.

The chart above also shows that 30% of the users' concerns with AERS I fell into the Data Management tier – an area that was largely ignored in the AERS II SRS. This included: a) Drug Dictionary (mostly data quality and lack of functionality with respect to the Drug Dictionary issues), and b) Data Quality and Data Integrity issues (lack of clean, consistent, timely, quality data). It is *not possible* to address these areas of concern without spending the time and effort to develop a quality data model and the associated application logic, neither of which were done as part of the AERS II requirements process. Even the 12% shown in the chart at Tier Six were simply lists of statements regarding types of data that needed to be included in the database, e.g., dictionaries. As mentioned previously, the documentation that should have been included was:

- Entity Relationship Model (ER Model). The ER Model starts out at a very high level during the High-Level Requirements phase, is refined to greater levels of detail during Detailed Requirements phase, and should be described in detail in the High-Level Requirements and Detailed Requirements Documents. Typically, this documentation would be comprised of:
  - The *things* that the organization must record information about (entities) – for example, the data contained in an adverse event report.
  - The connections or associations between one entity and another (relationships). For example, *one or more adverse events* about a specific drug.
  - The facts that describe an entity (attributes) – for example, drug ingredients, labeling information, etc.

- ER Model Dictionary Report – Contains definitions of entities and attributes as well as other detailed information about them.
- Entity usages – function/entity matrices and business unit/entity matrices.
- Data volumes – projected quantities of entities (e.g. there will be 10,000 customers).
- Data quality and data integrity logic.

The assessment team found Tier Six (Data Management) to be seriously deficient due to the complete lack of *all* of the components mentioned above – no ER model or dictionary, entity usages, detailed database design, or data quality and data integrity logic.

4.5 A Quantitative Analysis of the AERS Requirements Process

The assessment team found that the requirements activity from 2005 on was unnecessary, did not add any value to what had already been done, cost $1,500,000, and did not follow proper IT methodology as defined by FDA and industry standards such as Oracle – the FDA standard for IT systems (OB 2-2006). More specifically, no new information on user requirements emerged from the HL Requirements Document that would have supported taking a different direction, yet this was used as the basis for a second "technical" alternatives analysis and a Detailed Requirement's Document that took the AERS II project in an entirely different direction then the one established prior to July 2004. In addition, the AERS II requirements process violated procedures specific in the FDA's Life Cycle Systems Document (LCSD) and standard industry methodologies like those developed by Oracle – the FDA standard for IT systems. In fact, the High-Level Requirements Document contains less information for purchasing a COTS than the information that was available in July 2004.

An analysis of the 2003 Requirements Traceability Matrix (RTM) that used the 1996 and 1998 Requirements Documents as a baseline revealed that almost 48% of the functionality of the AERS I system was removed from the original AERS system requirements, e.g. 381 out of 795 requirements (OB 12-2006).[66] Even after discussions with CDER's OIT, it was unclear *why* these pieces of functionality were removed, *when* they had been removed, or *who* authorized their removal, yet many of the problems faced by users today in FY07 are *directly caused* by these missing pieces of functionality.[67] Further analysis has shown that at least 150 (40%) of the requirements that were removed from AERS I were *added back in* to the Detailed Requirements Document delivered by BAH in June of 2006, indicating that FDA will have to pay for this functionality a second time

The users did not get almost 50% of the functionality in AERS I that they were expecting from the 1996 Requirements Document, functionality that they paid for and needed. This is evidenced by the following:

- When the RTM was produced in 2003, 6 years after the initial delivery of AERS I, 48% (381 out of 795) of the requirements that were contained in the AERS I Requirements Document, and thus expected to be in the AERS I system, had a status of "Removed".

---

[66] See the Booz Allen Hamilton, *FDA Center for Drug Evaluation and Research, AERS Requirements Traceability Matrix*, Task No. T06 – Contract No. 223-97-5513, September 8, 2003.

[67] See Booz Allen Hamilton, *AERS II System Requirements Specification*, Version 1.1, April 6, 2006, and Booz Allen Hamilton, *AERS II Safety Evaluator, FOI, & Compliance Requirements (with Changes Tracked Based on Input from Safety Evaluators Received on May 17, 2006)*, June 2006.

These 381 requirements span Tier 3 through Tier 6, with a large portion of them falling in Tier 4, Presentation/User Interface. The following chart demonstrates the distribution of AERS I "Removed" requirements by Tier:

Tier	Qty
3	17
4	293
5	61
6	10

This distribution is consistent with the 2005 AERS User Satisfaction Survey, as mentioned previously in this report. The users simply did not get what they wanted, or needed in AERS I.

- At least 148 or 15% of the requirements contained in the 2006 AERS II SRS are these same "Removed" requirements from the 1996 document. The users *still need* the functionality that they were supposed to get (but didn't) in AERS I.

There were inconsequential changes to the requirement wording, for example the wording of hundreds of requirements were changed from the "The system will" to "The system shall" with little or no other changes to the requirement.

- Time and effort was spent to adjust/readjust the wording of these requirements – in 1996 many of them were stated "The system must...", and by 2006 they were stated "The system shall". Even the requirements with more than one simple word change described the *exact same* functionality, implying that this functionality was analyzed, reanalyzed, and reworded, but *the needs of the users did not change.*

- Not only is FDA paying for the same functionality to be *implemented* in AERS II that they paid for but didn't get in AERS I, but the Agency has paid for this functionality to be *analyzed and reanalyzed* multiple times with no value-added.

The Breckenridge Institute has performed an analysis of several AERS requirements documents in order to identify the value that has been added by these documents. The documents that have been evaluated include:

1. AERS Requirements Document (AERS I RD) dated September 23, 1996
2. AERS Requirements Traceability Matrix (RTM) dated September 8, 2003
3. Basic Requirements for Conducting the AERS II Alternatives Analysis dated March 12, 2004
4. AERS II High Level Requirements (HLR) dated December 15, 2004
5. AERS II System Requirements Specification dated April 6, 2006 and amended May 17, 2006

The lists of requirements that were contained in tables in these documents were loaded into the assessment team's Microsoft Access database so that they could be compared and cross-referenced. This database provided powerful analysis abilities, and is described further in Appendix A. A summary of the mapping results is contained in the table below.

Document	Total Reqts	Mapped to RTM	% Mapped	Tier 3 Not Mapped	Tier 4 Not Mapped	Tier 5 Not Mapped	Tier 6 Not Mapped
1996 AERS I	795	704	89%	1	88	2	
2003 RTM	1550						
2004 AERS II Alternative Analysis	993	899	91%	1	90	2	1
2004 AERS II High Level Reqts & App	396						
2006 AERS II Detailed Requirements	1015	468	46%	57	294	108	88

AERS 2003 RTM

The AERS 2003 RTM was used as a "baseline" against which to compare the other requirements documents, since this document contained a "superset" of the original 1996 document. In addition to the requirements from 1996, the RTM also contained bug fixes and new requirements. Of the 1550 requirements listed in the 2003 RTM, 444 had a status of "Removed" (431) or "Not Implemented" (13). It is not known how or why these requirements attained this status.

AERS I Requirements Document

In order to establish a baseline of AERS I requirements, the AERS I Requirements Document and the AERS RTM were compared to each other, and the requirements from AERS I were mapped to the requirements in the RTM. As can be seen in the table above, 89% of the requirements from the AERS I document were found in the RTM. Of the 91 that could not be mapped, 80 were specific reports from the section labeled "Current and Desired Reports". The remaining 11 requirements were from various other sections of the document.

In conclusion, it appears that almost half of the RTM was taken directly from the AERS I RD, with slight wording changes to the requirements that didn't change the meaning. Other than not listing specific reporting requirements, the AERS I requirements that were missing from the RTM were a very small percentage and probably left out by error. They were mostly from the Presentation/User Interface Tier.

It also should be noted that, of the 795 requirements in the 1996 document, 381 or 48% of these requirements had a status of "Removed" in the 2003 RTM.

2004 Alternatives Analysis Document

This document was created by the OPaSS AERS Program Office for OIT's Kathleen Keats in preparation for the Alternatives Analysis that was completed in 2004. Since it was derived to a great extent from user requirements in the 1996 AERS I design document, as well as the new requirements in the RTM, the requirements in this document also mapped well to the RTM. Of the 94 requirements that didn't map to the RTM, 80 of them were the same specific reports in the AERS I document that weren't listed in the RTM.

2004 High Level Requirements Document

The 2004 High Level Requirements document was completed at the end of 2004, after the Alternatives Analysis. Although the assessment team initially attempted to map these requirements to the 2003 RTM, a single requirement in the HLR was frequently a summarized statement of 20 or more requirements from the RTM, and thus this mapping was not of value to the process.

2006 Systems Requirements Specification

When compared to the RTM, almost 50% of the requirements contained in this document mapped, many of them with almost the exact same wording. Of the requirements that did map, 148 (15% of the requirements in this document) mapped to requirements that had a status of "Removed" in the RTM. These were all requirements from the 1996 AERS I Requirements Document.

In summary, the 2004 High Level Requirements document provided little or no value to the AERS II systems design life cycle. More specifically,

- From the perspective of prior documents, the 2004 HLR appears to have rolled detailed requirements from the 2003 RTM and/or the 2004 Alternatives Analysis document into summary level requirements. These requirements are grouped into the same "critical business processes" as previous documents, including the 1996 AERS I Requirements Document.

- Much of the additional functionality that was incorporated in this document, such as a new web-based technology and more sophisticated data searching and analysis capabilities, was standard capability in COTS packages at that time.

- From the perspective of the next step in the requirements process, the 2006 SRS, it is unclear how the information gained from performing the 2004 HLR analysis benefited or was used by the 2006 SRS analysis process. This is evidenced by the following:

    - Once again, numbering schemes were changed from the 2004 HLR to the 2006 SRS.
    - The seven domains of functionality described on Page 11 of the 2004 HLR (Manage Adverse Event Details, Manage Requests for Information and Services, Manage Dictionaries and Other Reference Information, Manage Drug Safety: Manage Risk Assessment, Perform Application Administration, Administer Web Site, and Utilize Public Web Site), which served as the primary groupings by business process in this and previous documents, were not used in the 2006 SRS document. Since the systems analysis process is supposed to be a "top-down" process where high level requirements (HLR) are broken down into more detailed requirements (SRS), a completely new taxonomy in the 2006 SRS document makes it difficult to understand the connection between the HLR and SRS.
    - There appears to be no relationship between the Use Cases and other Figures contained in the 2004 HLR and those contained in the 2006 SRS. As mentioned previously, Process Flow analysis (swimlane diagrams) should have been used to break processes down into increasing levels of detail, with Use Cases only at the most detailed level. This is a continuous process, whereby the high-level work done at the Strategy (HLR) phase feeds into the Analysis (SRS) phase. Instead, with the 2004 HLR and the 2006 SRS there appears to be a *complete disconnect*, to the extent that it appears that the SRS "started from scratch" and didn't follow the path started by the HLR.
    - The only connections documented between the 2004 HLR and the 2006 SRS are that the HLR is mentioned as a reference document in the SRS, and some of the requirements listed in the SRS are cross-referenced back to a requirement in the HLR.

In addition, the 2006 Systems Requirements Specification document was an unnecessary and inappropriate step to take when proceeding down the path of a COTS integration project.

- When describing what is necessary for a COTS integration process, Richard Barker states the following: "In some cases it is very sensible to implement one, or perhaps several parts of a system using proprietary software packages. Typically these would cover general topics such as financials, human or physical resource management; or in vertical industries specialized packages such as manufacturing. How are these integrated and where do they fit within the life-cycle? The optimum solution for an organization will be found by conducting a strategy study in the normal manner to ensure the enterprise requirement and business direction are fully understood. With this framework in place, alternative implementation vehicles may then be accurately assessed for their specific applicability and their ability to fit in with the wider picture. In particular, the entity relationship model and its back-up attribute definitions can be used to check whether a package addresses the appropriate data..."[68] Barker's reference to a "strategy study" equates to the high level requirements phase, as previously discussed in the methodology section of this report. The detailed requirements listed in the SRS do not advance AERS II into a better position to select COTS package(s), and in fact, without a data model being completed for the 2004 HLR, the FDA is still unable to evaluate COTS packages for suitability.

- At least half of the requirements listed in the 2006 SRS existed in previous documents dating back to 1996. Of those requirements that did not map directly to the 2003 RTM, most belonged to functional areas that are either new (e.g. Public Web Site, Manufacturer Online, Data Mining with WebVDME) or areas that are described in significantly more detail (e.g. FOI, Medical Terms Dictionary, Product Dictionary, MedWatch Batch, Online, and Paper Receipt of ISRs, Inbox capabilities, Searching capabilities). Defining the business requirements properly during the Strategy/High Level Requirements phase would have addressed new requirements to an appropriate level.

[68] Richard Barker, *CASE*Method Tasks and Deliverables,* (Oracle – Addison-Wesley, 1991), p. 10-18

5.0 Impact of Not Having AERS II Operational in 2005

This section of the report evaluates the overall impact of not replacing the dysfunctional AERS I system with AERS II in 2005, and instead changing the project scope to building an FDA-wide adverse event reporting system which pushes a replacement for AERS I off until at least 2010. The key issue discussed below is the financial impact of not having replaced AERS I with AERS II in 2005. An equally important issue is the impact that it will have on CDER's ability to effectively conduct post-marking surveillance and Drug Safety through safety evaluations, epidemiological studies, and the functions carried out by the Offices of Compliance and FOI. These are discussed in the 2005 Users Satisfaction Survey in Appendix E.

5.1 Financial Impact of Not Having AERS II Operational in 2005

The assessment team found that the unilateral decision by CDER's OIT Director to begin the AERS II requirements process all over again post-July 2004 had an enormous negative impact on AERS users by delaying the replacement of the dysfunctional AERS I system by at least five years (OB 10-2006). This decision was made despite the objections of: a) technical staff in CDER's OIT, b) CDER's OIT AERS II Project Manager, c) AERS users in multiple FDA Centers, d) the OPaSS AERS Program Manager, and e) numerous CDER managers and scientists.

But this decision also had an enormous financial impact that will ultimately cost FDA more than $25,000,000 at a time when funding for computing is increasingly scarce. In other words, had FDA moved forward on the CDER OIT-OPaSS approved plan in July-2004 to replace AERS I rather than unilaterally changing direction, FDA would have: a) had a functioning AERS II system in 2005, and b) avoided spending more than $25,000,000 in contracts and services - many of which were not value-added to FDA or its mission. The breakdown of these costs is shown in the chart below.

Item	FY 05	FY 06	FY 07	FY 08	FY 09	FY 10	Total
AERS Maintenance Contract	$1,007,200	$896,800	$1,016,000	$1,056,800	$1,098,400		$5,075,200
AERS Users Work-arounds	$700,000	$700,000	$700,000	$700,000	$700,000		$3,500,000
TOTAL for AERS	**$1,707,200**	**$1,596,800**	**$1,716,000**	**$1,756,800**	**$1,798,400**	**$0**	**$8,575,200**
Data Entry, MedDRA Coding Contract	$1,597,000	$5,581,000	$4,522,956	$2,870,553	$1,183,382		$15,754,891
TOTAL Not Saved for DE, MedDRA	**$1,197,750**	**$4,185,750**	**$3,844,513**	**$2,439,970**	**$1,005,875**	**$0**	**$12,673,857**
Oracle AERS Reverse Engineering	**$300,000**	$0	$0	$0	$0		**$300,000**
Escalation Cost of AERS II Product	**$4,500,000**	**$225,000**	**$461,250**	**$945,563**	**$1,938,403**	**$0**	**$3,570,216**
TOTAL for NOT Doing AERS II in 2005	**$2,904,950**	**$6,007,550**	**$6,021,763**	**$5,142,333**	**$4,742,678**	**$0**	**$25,119,273**
Post-July 2004 OMB Exibit 300 Costs							
Alternatives Analysis	$0						$0
High Level Requirements Analysis	$210,100						$210,100
High Level Alternatives Analysis	$169,900						$169,900
Detailed Requirements Analysis	$398,769						$398,769
Acquisition (RFP & Phase One)	$578,000		$578,000				$1,156,000
Project Support for OIT		$140,000					$140,000
Acquisition (RFP & Phase One)							$0
TOTAL for AERS II	**$1,356,769**	**$140,000**	**$578,000**	**$0**	**$0**	**$0**	**$2,074,769**
TOTAL for NOT Doing AERS II in 2005 plus AERS II non-value added costs (HL Reqts, HL AA, and FEDSIM fee)							**$26,077,273**

AERS Maintenance Contract: The figures in this line from FY05 to FY09 reflect what FDA agreed to pay SAIC/PSI under the AERS maintenance contract minus an estimated amount for somewhat similar maintenance that FDA would have been paying for AERS II maintenance had we implemented AERS II in FY 2005. In other words, because FDA did not implement AERS II in FY 2005, the Agency is spending about 80% of its AERS funds to maintain the system that FDA plans to replace.

AERS Users Workarounds: These figures are the estimated costs identified in the 2005 Users Satisfaction Survey (see Appendix E). A key factor is that this estimate does not include inflation-escalation costs. For example, using the most recent OIT example from their AERS II budget spreadsheet, the cost in FY 2005 would be $700,000; followed by 5% in FY 2006 for $735,000; followed by 10% in FY 2007 for $808,500; followed by 10% in FY 2008 for $889,350; and followed by 10% in FY 2009 for $978,285. The total difference between the numbers in the spreadsheet versus the above inflation-adjusted numbers is $3.5 million to $4.1 million, e.g. $600,000.

AERS Data Entry, MedDRA Coding Contract: These are the exact costs shown in the present contract with PSI International. See the next item for the impact of not having AERS II.

TOTAL Not Saved for AERS DE, MedDRA: The number shown represent the costs for not implementing AERS II in 2005 and thus, staying with CDER's present AE reporting environment. If FDA had AERS II operational in 2005, the PSI costs would be less. An estimate is that FDA would have saved at least 35% in efficiencies via eSub interface, coding MedDRA at LLT, and using a Thesaurus Mgmt Sys similar to CFSAN. Also FDA would have also had better dictionary management for data entry QA/QC and safety evaluator searching/reporting. In FY 2005 and FY 2006 FDA, would have been taking 75% of the present contract value. In FY 2007 through FY 2009, FDA would have been taking 80% of the present contract value as costs that could have been saved if the Agency had had AERS II operational in 2005.

TOTAL for Oracle AERS Reverse Engineering: The CDER OIT had a contract with Oracle to conduct AERS reverse engineering efforts to document the AERS system and make recommendations. This is the cost that OIT paid to Oracle Corporation for the reverse engineering effort that apparently OIT never used. Not only is the failure to use this data repository an obvious waste of money that could have gone to help in the AERS II process, it is also a root cause of why the requirements process had little or no value-added.

TOTAL Escalation Cost of AERS II Product: The cost for the AERS product assumes a COTS or COTS integration package requiring additional enhancements unique to FDA. The initial cost in 2004 was a discount price of $4.5 million, which would have been less that the lowest value shown by OIT in the RFI analysis. The FY06-FY09 values show only a minimal 5% escalation on the original FY 2005 amount. If the recent OIT inflation percentages of 5% initial plus 10% for FY 2007 through FY 2009 are used, the total cost would be $5,463,225. This is $1,893,009 more than the value in the above spreadsheet.

TOTAL for NOT Doing AERS II in 2005: In FY 2005 this line is simply the total of AERS Maintenance Contract + AERS Users Work-arounds + TOTAL Not Saved for AERS DE, MedDRA. In FY 2006 through FY 2009 the totals are from FY 2005 (AERS Maintenance Contract + AERS Users Work-arounds + TOTAL Not Saved for AERS DE, MedDRA) + TOTAL Escalation Cost of AERS II Product. The spreadsheet shows a trend in which the total costs for not doing AERS II peaks in FY 2007, then tapers off. This is because of the reduced PSI International figures, which are the cost of *not* having AERS II operational in FY 2005.

AERS II Alternatives Analysis: The cost of the initial 2004 AERS II Alternatives Analysis is $0 because OIT's [redacted] conducted the analysis.

AERS II High Level Requirements Analysis and AERS II High Level Alternatives Analysis: The High Level Requirements and Technical Alternatives Analysis were performed by OIT's contractor, ISSA/HPTI.

AERS II Detailed Requirements Analysis: The funds for AERS II Detailed Requirements Analysis were given to FEDSIM to award the RFP/RFQ. OIT originally planned to use SETA, but the FEDSIM contracting process selected Booz*Allen & Hamilton.

AERS II Acquisition (RFP & Phase One): The funds for AERS II Acquisition (RFP & Phase One) were given to FEDSIM to award the RFP for AERS II design and initial build. Also, because of project delays, OIT needed to "obligate the funds or lose them. CDER OIT reported that FY06 funding delays caused FEDSIM to consider the $578,000 as a fee; thus, FDA will need another $578,000 for development.

AERS II Project Support for OIT: In addition to hiring [redacted] full time, plus FEDSIM, plus BAH OIT hired a contractor to support [redacted] in FY 2006, even though CDER management had decided not to fund AERS II in FY 2006 and there was no money to conduct work in FY 2006.

6.0 The Path Forward

Based on the data and analysis presented in this report, the Breckenridge Institute proposes three recommendations that will begin the process of correcting the issues described in this report.

Recommendation 1: In an atmosphere in which IT management and contracting practices are coming under increased scrutiny, and in the wake of the recent report from the Institute of Medicine (IOM) that identifies organizational culture as a root cause of issues in FDA, the senior managers in CDER should conduct a thorough investigation into the leadership, management, and contracting practices of OIT.[69] In addition to characterizing the tacit, underlying patterns of organizational beliefs and behavior in CDER's organizational culture, they should investigate: a) how effectively CDER's portfolio of IT projects is being led and managed; b) the selection criteria by which contractors like the one mentioned above are screened and selected; c) and the way in which financial resources are being combined into larger and larger categories in CDER's OMB Exhibit 300. This *increases* the extent to which OIT can reprogram the IT funds of CDER's science-technical units like OSE, award those funds to contractors they select without the approval of science-technical managers, and *decreases* the level of traceability and overall accountability for doing so.[70]

Recommendation 2: The senior managers in CDER should take immediate action to correct the problems in CDER's OIT as described in this report. In addition, under the auspices of the IT consolidation, organizations such as OSE that contain AERS users should have the opportunity to select a team of IT professionals from the consolidated FDA IT organization that have a proven track record of technical performance and providing outstanding service to end users like the Safety Evaluators who use AERS.

Recommendation 3: FDA should execute an updated version of the software acquisition plan that was developed by the CDER OIT AERS II Project Manager and AERS Program Manager in 2004 and begin the process of acquiring a replacement for AERS I immediately. The AERS II system has been absorbed into an FDA-wide IT system that includes multiple FDA Centers. This is a much more complex and daunting task than simply replacing the AERS system, and consequently making such a system functional is probably four-to-five years away – minimum. This forces Safety Evaluators in CDER and CBER and other FDA units such as the Offices of Compliance and FOI, to work with the dysfunction AERS I system for yet another extended period of time, thus further undermining their ability to effectively carry out FDA's mission of post-marking surveillance and drug safety. Based on the information contained in this report, a replacement for AERS could be operational in less than two years at a cost of about $5 million dollars. More importantly, this fully functioning AERS II system could then be used as a solid foundation for an FDA-wide system. It is important to note, that in the wake of the IOM report, there seems to be a renewed interest on the part of OSE in replacing the dysfunctional AERS I system as a necessary first step in developing an Agency wide system, despite the fact that funding for AERS II has been zeroed out in FY 2007.

---

[69] See the Institute of Medicine's report entitled, *The Future of Drug Safety: Promoting and Protecting the Health of the Public*, published on Sept 26, 2006.

[70] For example, see the audit and investigation into the $170 million IT system developed for the FBI that was unusable. See, "The FBI's Upgrade That Wasn't," by Dan Eggen and Griff Witte in, *The Washington Post*, August 18, 2006 (http://www.washingtonpost.com/wp-dyn/content/article/2006/08/17/AR2006081701485.html).

APPENDIX A
Requirements Analysis Database and Method

This section describes the process that the Breckenridge Institute used to analyze AERS requirements documents. The following documents were analyzed:

- AERS I Requirements Document, dated September 23, 1996
- AERS RTM dated September 2003
- AERS II Systems Requirements Specification, dated April 6, 2006 and revised May 17, 2006

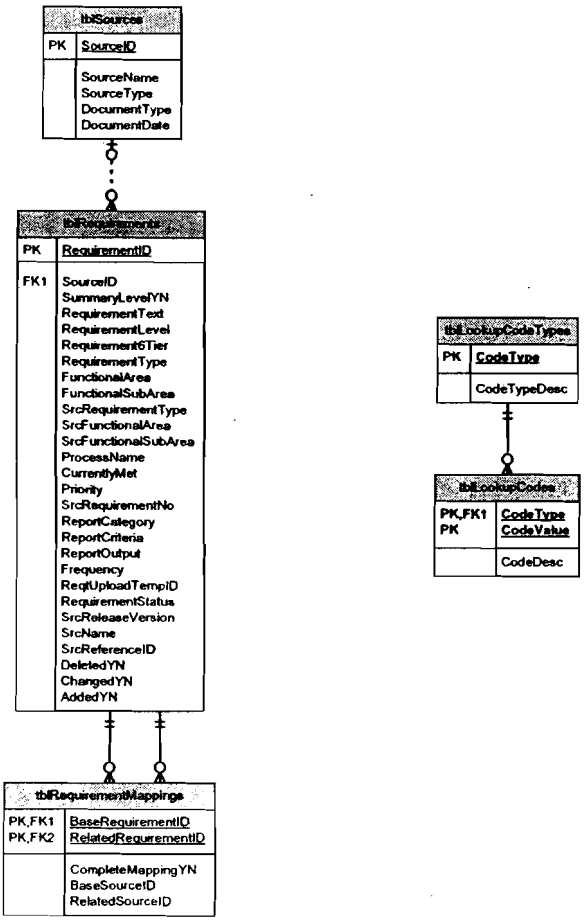
In order to perform the analysis, the Breckenridge Institute assessment team built a Microsoft Access 2003 database into which the requirements from the documents were uploaded. This provided the capability to perform text searches and other analysis of the requirements. It is important to note that this entire process would not have been necessary had CDER's OIT and its contractors utilized the back-engineered AERS I system in Oracle Designer, or some similar data repository system. The assessment team's database and methodology are further described below.

Database Design and Structure

The database structure that was used for the requirements analysis process consisted of 3 main tables, with 2 supporting tables for lookup purposes. The following ER Model below shows the tables and their relationships to each other.

Following are the descriptions of the 3 main tables:

- tblSources – contains basic information about the source documents
- tblRequirements – contains the text and additional information about each requirement; it connects the requirement back to the source document that it originated from through the SourceID field. This table also contains many other fields which are used to categorize the requirements. For example, the field Requirement6Tier describes which of the 6 Tiers that particular requirement fits into.
- tblRequirementMappings – this is the table that shows mappings between requirements from one document to another. For example, most of the requirements in the AERS I Requirement could be found in the AERS RTM with almost the exact same text. This table is where the AERS I requirement would be tied to the AERS RTM requirement.



Data Loading Methodology

The requirements that were loaded into the database from the AERS requirements documents all originally existed in Microsoft Word tables in these documents. The contents of the tables were first copied into a Microsoft Excel file for ease of uploading into Access. They were then imported into a temporary Access table from Excel, where any uploading errors (blank rows, etc.) were corrected. Subsequently they were appended to the tblRequirements table. No changes were made to the text of the requirements or other data that was included with the requirements.

Data Analysis Methodology

The analysis of the AERS requirements from the various documents consisted of three steps which are described in more detail below.

1. Comparing requirements from one document to another and mapping the same/similar requirements to each other.
2. Binning the requirements into the 6 Tiers described earlier in this document.
3. Analyzing the results of the mapping and binning processes in order to make observations.

During the mapping step the assessment team used text search techniques to compare requirements from one document to another. We started with the 1996 AERS I Requirements