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An Electronic Regulatory Document Management System for a Clinical Trial Network

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Introduction

Human subject protection is an important part of clinical trial management [1,2]. Institutions and individuals involved in human subject related clinical research activities must obtain approval from regulatory agencies such as the Food and Drug Administration (FDA) and from oversight bodies such as local Institutional Review Boards (IRB). Investigators must also

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institute, document, and maintain appropriate credentials, training, and safeguards in order to perform research involving human subjects. For a single clinical trial with a small number of participating clinical sites, regulatory documents could be managed manually with the help of Microsoft Excel spread sheet or relational database software such as Microsoft Access. On the other hand, a multicenter clinical trial or a clinical trial network, where a multitude of clinical sites may conduct multiple studies simultaneously, creates special challenges for regulatory document management including the large number of documents to be collected and maintained, the complexity associated with simultaneous multiple project operations, the need for document file sharing by multiple owners, and the dynamic nature caused by unavoidable changes in study protocols and site study teams.

The following presents a computerized regulatory document management (RDM) system that has been developed as a module in a comprehensive Clinical Trial Management System (CTMS) designed for an NIH-funded clinical trial network. The ultimate goal of using a computerized RDM system is to facilitate project and data management activities and to more efficiently manage and track regulatory compliance.

Materials and methods

The Neurological Emergencies Treatment Trials (NETT) Network was funded by the National Institute of Neurological Disorders and Stroke (NINDS) in Fall 2006 to conduct large Phase III trials in an effort to reduce the burden of very acute injuries and illnesses affecting the brain, spinal cord, and peripheral nervous system. The network includes a Clinical Coordinating Center (CCC) at the University of Michigan, a Statistical and Data Management Center (SDMC) at the Medical University of South Carolina, and 17 clinical hubs across the United States. Each clinical hub has an average of 12 potential spoke hospitals that act as patient recruitment centers [3]. Two clinical trials are currently in progress and additional trials are anticipated to begin in the next year. A Project Manager is staffed at the CCC to ensure compliance with Good Clinical Practice (GCP) Guidelines, government regulations, and the respective study protocols. The DMC is charged with providing a comprehensive web-based Clinical Trial Management System (CTMS), which supports data and project management for all the clinical trials conducted within the NETT Network.

Several systems using the sophisticated technology of the internet and electronic data-capturing (EDC) systems to meet the need to handle the complexities associated with capturing and managing clinical research data have been described in the literature [4–7]. However, the description of systems that additionally support the collection and management of regulatory documents is lacking. Specific to the NETT, there are challenges of regulatory document management and a certain level of complexity involved in managing the network's hub-and-spoke network structure. The challenges come not only from the collection and updating of valid regulatory documents, but also from the utilization of information on regulatory documents and their collection and management in the project and data management activities of each clinical trial in the Network. The Regulatory Document Management (RDM) system is one module within the developed CTMS.

The RDM system was developed based upon a unique database structural design. In this system, regulatory document requirements and document collection are treated as two independent entities. The document requirement entity is determined based upon the study protocol and site team members. It automatically adapts to changes in the study protocol and site team composition. The document collection entity is grounded to the owner of each document. Owner is defined as the person listed on the document, e.g., a medical license is owned by the person listed on the medical license. As a central management information system, data entities are designed based on relational database principles to protect data

integrity. Furthermore, all user activities are grouped into two actions: putting data into the system and pulling information out of the system. Generic user interfaces have been developed for these two activities, independent from the contents of the data entity. The generic user interface design provides a high level of system operation reliability and system development efficiency.

The enormity of required regulatory documents for the NETT Network trials

The NETT Network has a hub-and-spoke structure. Hubs are administrative units affiliated with academic medical centers that have resources and experience in trial operations. They operate as local coordination centers for their spokes. Hubs are individually supported by their own NIH grant awards, and were selected through a competitive peer review process. Spokes are hospital emergency departments where study subjects are actually enrolled. Spokes are generally located in geographic proximity to their hub, and the hub can add or remove individual spokes from a specific trial, or from their hub-spoke complex entirely. Currently, the NETT Network includes 17 hubs and up to 226 spokes. This organizational structure is aimed at minimizing trial management costs and maximizing subject recruitment capabilities. It also requires that an immense amount of regulatory documents be collected. Consider running a trial requiring 4 documents for each clinical site (e.g. Protocol IRB approval, Informed Consent Form IRB approval, Clinical Laboratory Improvement Amendments (CLIA) certification, College of American Pathologists (CAP) certification) and 6 documents for each investigator (e.g. curriculum vitae, medical license, human subjects training, protocol training certification, two outcome measures certifications). Assume that each clinical site has 10 investigators and each document has an average of 4 submissions during the course of the study due to annual renewals, protocol amendments and staff changes. The total number of documents to be collected would be $(4\text{submissions} \times 226\text{sites} \times (4\text{site documents} + (6\text{investigator documents} \times 10\text{invest/site}))) = 57\,856$. If five trials are to be conducted in the Network as conceived, and all documents are managed separately by trials, there could be 289 280 documents to be collected. This estimation shows that the scope of regulatory document collection and tracking in the NETT Network can be beyond the capacity of accurate and efficient manual management. A computerized RDM system is not an option, but is rather a prerequisite to the success of the Network.

Redundancy of regulatory document requirements due to multiple trials in the NETT

When institutions and investigators are involved in multiple clinical trials, they are requested to submit regulatory documents for each trial. One of the primary motivations of creating the NETT Network is to create an economy of scale and to eliminate duplication of effort by using a centralized regulatory management system for all trials within the Network. Some regulatory documents are trial specific, such as IRB approval of the study protocol, IRB approval of protocol amendments, investigator certifications of study specific procedures, and FDA 1572 forms for investigational new drug studies. Others are trial independent, such as the institution's IRB Federal Wide Assurance (FWA), CAP Certification, and CLIA Certification, a study investigator's professional (e.g., medical, nursing) license, curriculum vitae, Health Insurance Portability and Accountability Act (HIPAA) training certification, and NIH mandated human subject protection training certification. In general, each of these regulatory documents, whether trial dependent or independent, has only one owner, either a site such as an IRB approval or an investigator such as a medical license. However, in certain situations, a document file may be shared by several owners (sites and/or investigators). For example, the FDA Form 1572 lists all investigators at a site for a specific project and can be shared by several investigators at a site. A study protocol training log may list all investigators across all sites who are participating in the protocol training. In these scenarios, it is necessary to record the document collection for each investigator listed; however, the document file (i.e., 1572 or training log) should be uploaded no more than once. For example, the site's laboratory

certification or an investigator's medical license is uploaded once and can be linked to several studies. Revisit the 298 280 required documents, if 2 of the 4 site documents and 3 of the 6 people documents are project independent, by sharing across 5 projects, there will be a 40% reduction in the total number of documents to be collected. Further reduction can be obtained by sharing documents across sites. This is advantageous for all of the trial-independent documents to be shared across all trials within the Network since this reduces redundancy of effort at both the site and the coordinating center.

Dynamic nature of document requirements

Clinical trial regulatory document management is dynamic throughout the study. The content of documents can change for a variety of reasons during the course of the study. During the study period, site study team members may experience any number of modifications. For example, investigators must be added to or removed from the FDA Form 1572 when staff members join or leave the team. When such changes occur, document collection and renewal requirements for those who have left the study team must be archived and all relevant investigator-related documents need to be collected for each new site team member. Additionally, many regulatory documents have a limited valid lifespan. Renewal of these documents may be required periodically such as annually or biannually. Finally, the study protocol may experience modifications during the course of the study period. Each amendment to the study protocol requires IRB approval at all of the participating sites. Hence, to effectively manage the regulatory document requirements for a study, the Project Manager must be notified when any of the above changes occur to ensure that the study is in compliance with the GCP Guidelines at all times.

Utilization of regulatory document collection information

Collecting all of the required regulatory documents is not the only goal of regulatory management. The ultimate objective is to utilize regulatory information to ensure compliance with the study protocol, the GCP Guidelines, and government regulations in the trial execution. For example, a clinical site should be released for subject enrollment only after all required regulatory documents have been collected and approved for that site. Also, a missing or expired regulatory document, such as an IRB approval, may trigger a suspension in subject enrollment (or study termination) at the delinquent site. Other missing or expired documents, such as investigator certifications, may trigger protocol violation flags that can then be tracked and addressed by data managers and site monitors.

RDM system database structure design

The overall database structure of the RDM system and the relationship between tables within the system is illustrated in Figure 1.

The main frame of the RDM system is built based on the separation of two entities: "Required Document" and "Collected Document". The "Required Document" entity is defined by the study protocol, participating sites and the composition of site study team. The "Collected Document" entity records what has been collected in the database. The goal of this design is to address the dynamic nature of a study and its team members and to eliminate redundancies in document collection. As shown in Figure 1, the [Document] table lists all regulatory documents to be collected. All documents are divided into two types based on owners, "People Documents" and "Site Documents", and two classes based on relationship with projects, "Project Specific" and "Project Independent". For example, a curriculum vitae is a "Project Independent People Documents", the 1572 Form is a "Project Specific People Document", a lab certification is a "Project Independent Site Documentation", and protocol IRB approval is a "Project Specific Site Document". When a site joins several projects, project independent site documents can be shared across projects. When an investigator is involved in several

projects at several sites, project independent people documents can be shared across sites and projects.

For each project, regulatory document requirements are specified in [Project Required Site Document] table and [Project Required People Document] Table. When these two tables are merged with [Project Site] and [Project Site Team] respectively, we have [Required Site Document] view and [Required People Document] view. A database view is a virtual table containing the results of a query from one or several tables. Information in a database view is automatically changed when data in the relevant tables are changed. For example, when a new site joins a project, all required site documents for that project will be automatically populated in the [Required Site Document] view. When one document is added into the [Project Required Site Document] table, it will be automatically listed in [Required Site Document] view for all participating sites. When a person joins the site study team for a project, required documents for this person will be automatically posted based on the role of this person in the study team. When a team member leaves a project, all document requirements for this person will be dropped automatically. [Required Site Document] view and [Required People Document] view define “what is required” only. Information on collected documents is stored in the [Collected Site Document] table and the [Collected People Document] table. These two tables record “what have been collected”. By comparing this information to “what needs to be collected” defined in [Required Site Document] and [Required People Document], the Project Manager can see which requirement has been met and unmet by viewing [Site Document Collection Status] and [People Document Collection Status].

Another key design aspect is the separation of two key actions by the site: document collection and file upload. Uploaded documents are managed in the [Document File Upload] table. One record in this table can be linked to several records in the [Collected People Document] table, indicating that several people are sharing this document file; or linked to several records in the [Collected Site Document] table, indicating that several sites are sharing the same document file. This structure is a critical design aspect that avoids duplicate file uploads within and across projects. In the NETT network, investigators at a hub may be involved in trial operations at several of that hub’s spokes. These study team members can join multiple spoke (site) study teams without duplication of site independent document submission. In a setting where study team members are not at multiple participating sites, the reduction in file uploads can be seen in a case where multiple trials are being conducted by the study team member. This structure allows several document collection actions to share one physical file. For example, a FDA 1572 form lists several investigators from one site for a specific project. Because the 1572 form needs to be tracked for each individual investigator, it is considered as a [Project Specific People Document]. In other words, we need to collect the 1572 form for each investigator, but we do not need to physically upload the same PDF file several times.

User interfaces are provided to hub study coordinators in order for them to submit regulatory documents based upon information in the two [Document Collection Status] views. Submitted documents are reviewed by the Project Manager at CCC and either accepted or rejected. Rejected documents are sent back to the hub study coordinator with an automatic email notification. Accepted regulatory documents are stored on the web server for authorized users to view or download. Meanwhile, corresponding records are generated in the [Collected Document] table. This action triggers the update of the [Document Collection Status] view. The review process can be extended to third party reviewers if needed. Document version control is managed in two approaches. For documents requiring periodic renewal, such as investigator’s CV, an expiration date is entered for each collected document. This expiration date is monitored by the system and an automatic e-mail notification of an upcoming expiring document is sent to the Project Manager as well as to the site study coordinator and PI. For those documents with several versions during the study period, a version stamp is included in

the document name, and a flagging field is used to indicate if the document is the current version.

Integration of the RDM system with other CTMS components

The RDM system is just one component in the CTMS for the NETT Network. The integration of the RDM system with the entire CTMS begins at the system planning stage and is achieved on three levels: the database structure level, the web user interface level and the trial management level. Database tables [Project], [Site], [Project Site], [People], and [Project Site Team] are required by the CTMS for other purposes in addition to regulatory document management. Information in these tables is maintained in the Project Management Module (PMM) of the CTMS. The PMM houses the study specific documents such as the protocol, informed consent, manual of operations and amendments to these documents. The RDM houses the approvals of these documents as well as site and project specific documents. This is the structure for the NETT and allows us to link project management functions with regulatory document management functions. The RDM module is linked to the PMM tables as shown in Figure 1.

All computerized information systems deal with two fundamental tasks: input information into the system and access information from the system. Based on this concept, the NETT Network CTMS utilizes generic web user interfaces, including [Add/Edit Record], [List Record], and [View Record]. Each database action is defined based on a single data form, which is linked to a single database table/view. Data items on the individual data forms are defined in the database. These item definitions are used to compose the user interfaces and to process data reading and saving tasks. The RDM module uses the same generic user interfaces throughout the CTMS so no task specific user interfaces are programmed for a specific module. Adding a new regulatory document collection record is done in exactly the same way as adding a site in the PMM or adding a Case Report Form (CRF) in the Data Management Module. Using generic user interfaces provides a high level of performance reliability.

A key benefit of a central information system is that information on regulatory document collection can be used by the project and data management modules in the CTMS to strengthen compliance with the GCP Guidelines, government regulations and study protocols. For example, the site status in a clinical trial is affected by the regulatory document collection status. If a site is missing required regulatory documents or any collected document has expired, that site's status in the trial can be set to "subject enrollment suspended", and the subject enrollment permissions can be removed from that site in the project management module. Some trials require an investigator to maintain a valid certification in order to perform certain study treatments and assessments. For example, a protocol may require that a subject's severity on the NIH Stroke Scale (NIHSS) be assessed only by an investigator with a current NIHSS certification. In the DMM, the date of the assessment and the name of the person who did the assessment are recorded on the CRF and entered in to the study database. This information is cross checked with the collected regulatory documents to ensure that the assessor held a valid NIHSS certification on the date of the assessment. A violation of this requirement generates a protocol violation record and the data collected on that CRF may be excluded from data analysis.

Results

The NINDS-funded Albumin In Acute Stroke – Part 2 Trial (ALIAS2) and Rapid Anticonvulsant Medication Prior to Arrival Trial (RAMPART) are two large neurological emergency treatment clinical trials currently in progress within the NETT Network. The ALIAS2 trial is a multicenter, randomized, placebo controlled, double-blind, parallel two-arm phase III clinical trial conducted to ascertain whether high-dose human albumin therapy confers

neuroprotection in acute ischemic stroke over and above the standard of care in patients with acute ischemic stroke. The trial is structured as a large simple study, whereby eligible subjects are randomized 1:1 to either albumin or placebo (isotonic saline solution) and the primary outcome is assessed at a 3-month clinic visit using the Modified Raking Scale (MRS). The study is being conducted under an FDA Investigational New Drug (IND) application.

The RAMPART study is a non-inferiority study designed to determine whether intramuscular administration of midazolam is no less effective than intravenous lorazepam (by a predefined clinically unimportant margin) in stopping seizures in the prehospital setting in people having status epilepticus. Due to the emergent nature of status epilepticus and the unconscious state of the patient at the time of treatment, subject enrollment and treatment are performed using exception from informed consent (EFIC) for emergency research (21 CFR 50.24). The study is being conducted under an FDA IND application.

Strict compliance with federal regulations and underlying ethical principles are important to protect subjects enrolled into these studies. Figure 2 lists regulatory documents defined in the system. Some documents are project specific such as the ALIAS Part 2 Protocol Training, while some others can be applied for all projects such as the Normal Range of Lab Values Report. [Owner Type] indicates if the document is for a person or a spoke. [Spoke Specific] tells if the document allies to a specific spoke, e.g., 1572 Form, or can be applied to all spokes.

Figure 3 shows the document requirement for people. The list is filtered for [Project = ALIAS2] and [Role] = Principal Investigator. Data filtering and sorting tools are provided for users to query data. User specified data queries can be saved in the system for future use.

Figure 4 lists document collection activities for spokes. Each collected document links to a document file. When a site submits a document, the default status is set to “pending”. The Project Manager at the CCC reviews the document and decides to accept or reject. There are data validation rules programmed in the system to prevent data entry errors on [Effective Date] and [Expiration Date].

Figure 5 illustrates the [Spoke Document Collection Status] view. It lists the current status of all required documents for spokes, filtered by a specific spoke and project and allows the user to easily see what regulatory documents are missing, pending or expired.

Currently, a total of 13 722 regulatory document requirements have been created for ALIAS2, RAMPART and two other NETT projects that are housed within the system. By document sharing across projects and sites, the actual number of document requirements reduces to 5 634, showing a 59% reduction by document sharing. The RDM system recorded 9 914 document collection actions, including renewals. A total of 6 767 document files have been uploaded to the RDM system, a 32% reduction by file sharing. These numbers are changing as hubs are continuing to submit documents and as their spokes are being initiated for patient enrollment into various studies. It is anticipated that the benefit of using this RDM system will be expanded as more projects are added to the NETT network.

Discussion

The NETT is one example of a clinical trial network that is enhanced by the use of an electronic regulatory document module of a CTMS. The complexity of a network's structure, the vast amount of required regulatory document collection and maintenance that is repeated across studies and across study team members as well as the need for reporting in real-time indicates that the success of the overall network and each study is dependent upon a management system that offers secure, reliable data capturing and tracking methods. The RDM is one component of the CTMS and is accompanied by a Project Management Module and a Data Management

Module for efficient and accurate overall trial management. The system developed for the NETT network is not isolated to only a network with a hub/spoke structure. The generic structure of the designed system allows it to be adapted to any setting that is conducting multiple studies within a site or across multiple sites and where study team members are strictly within one site or are across sites. The overall goal of the RDM is to reduce the burden of regulatory document maintenance, to reduce the amount of duplicated paperwork when sites and study team members are involved with several trials and to maintain a real-time regulatory data collection system with automatic notification of expired documents and required submissions.

Internet-based clinical trial management systems offer time-saving, secure options for managing clinical trial data. However, it should be understood that any CTMS/EDC system is only as reliable as its developers. The developers should consist not only of sophisticated computer programmers but also of the users of the system including project managers, regulatory managers, data managers and site personnel. The input of the users is a critical step to ensuring a user-friendly system. For our system, the site personnel provided valuable input on document uploading processes, the project and regulatory managers provided input on document approval processes and how they foresaw managing document collection and renewals, and the data managers provided input on the generic user interfaces based on their familiarity with data collection and validation processes.

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Figure 1.
Database Structure of the RDM System

WebDCU™ NETT

Home Project Management + Project Setup + Regulatory Document +

List Records: Regulatory Documents [Log Out](#)

Page 3 of 3 Show 10 of 30 Remove Query Save Query

#	Document Name	Project Specific	Project	Owner Type	Spoke Specific	Expiration Window (days)	View
21	RAMPART Delegation of Authority Log	Yes	RAMPART	Spoke	No	0	
22	ALIAS IRB Approved Informed Consent Form v4	Yes	ALIAS2	Spoke	No	0	
23	ALIAS Protocol IRB Approval v4.01	Yes	ALIAS2	Spoke	No	0	
24	ALIAS Part 2 Protocol Training	Yes	ALIAS2	People	No	0	
25	RAMPART Protocol v2 IRB Approval	Yes	RAMPART	Spoke	No	0	
26	ALIAS Part 2 1572	Yes	ALIAS2	People	Yes	0	
27	ALIAS Part 2 PI Attestation Form	Yes	ALIAS2	Spoke	No	0	
28	ALIAS Part 2 Delegation of Authority Log	Yes	ALIAS2	Spoke	No	0	
29	ALIAS Part 2 Training Certification	Yes	ALIAS2	People	No	0	
30	Normal Ranges of Lab Values Report	No		Spoke	No	0	

Done Internet 100%

Figure 2.
List of Regulatory Documents

WebDCU™ NETT

Home Project Management + Project Setup + Regulatory Document +

List Records: People Required Documents [Log Out](#)

Page 1 of 1 Show 9 of 9 Remove Query Save Query

#	Project	Regulatory Document	Role	View
1	ALIAS2	ALIAS Part 2 1572	Principal Investigator*	
2	ALIAS2	Curriculum Vitae	Principal Investigator*	
3	ALIAS2	Medical License	Principal Investigator*	
4	ALIAS2	HIPAA Certification	Principal Investigator*	
5	ALIAS2	Human Subjects Protection Certification	Principal Investigator*	
6	ALIAS2	NIHSS Certification	Principal Investigator*	
7	ALIAS2	mRS Certification	Principal Investigator*	
8	ALIAS2	ALIAS Part 2 Protocol Training	Principal Investigator*	
9	ALIAS2	ALIAS Part 2 Training Certification	Principal Investigator*	

[Add to My Work Folder](#) Add New

Done Internet 100%

Figure 3.
List of Required Documents for People

WebDCU™ NETT

Home Project Management + Project Setup + Regulatory Document + Log Out

List Records: Spoke Document Collection

Page 1 of 116 Show 10 of 1156 Select Query

#	Hub	Spoke	Project Specific	Document	Waived	Effective Date	Expiration Date	Document File	Status	View
1	Cincinnati	Mercy Fairfield		CAP Certification	No	25-JUL-2007	16-MAR-2008	F2100.pdf	Accepted	
2	Cincinnati	Mercy Franciscan - Mt. Airy		CAP Certification	No	25-JUL-2007	16-MAR-2008	F2088.pdf	Accepted	
3	Cincinnati	Saint Elizabeth South		CAP Certification	No	25-JUL-2007	25-FEB-2008	F2092.pdf	Accepted	
4	Cincinnati	Jewish Kenwood		CAP Certification	No	25-JUL-2007	26-OCT-2007	F2084.pdf	Accepted	
5	Cincinnati	Jewish Kenwood		CAP Certification	No	25-JUL-2007	26-OCT-2007	F2085.pdf	Accepted	
6	Cincinnati	Christ Hospital		CAP Certification	No	25-JUL-2007	26-OCT-2007	F2095.pdf	Accepted	
7	Cincinnati	Christ Hospital		CAP Certification	No	25-JUL-2007	26-OCT-2007	F2096.pdf	Accepted	
8	Cincinnati	University Hospital		CAP Certification	No	25-JUL-2007	26-OCT-2007	F2117.pdf	Accepted	
9	Cincinnati	University Hospital		CAP Certification	No	25-JUL-2007	26-OCT-2007	F2118.pdf	Accepted	
10	Cincinnati	Mercy Fairfield		CLIA Certification	No	09-FEB-2007	08-FEB-2009	F2101.pdf	Accepted	

Done Internet 100%

Figure 4.
List of Required Documents for Spokes

WebDCU™ **NETT** List Records: Spoke Required Document Status [Log Out](#)

Page **1** of 1 Show **7** of 7 [Remove Query](#) [Save Query](#) [Select Query](#)

#	Hub	Spoke	Project	Document	Waived	Expire Date	Document File	Status	View
1	Cincinnati	Mercy Franciscan - Mt. Airy	ALIAS2	ALIAS Protocol IRB Approval v4.01					
2	Cincinnati	Mercy Franciscan - Mt. Airy	ALIAS2	ALIAS IRB Approved Informed Consent Form v4					
3	Cincinnati	Mercy Franciscan - Mt. Airy	ALIAS2	IRB Federalwide Assurance	No	06-DEC-2009	F2102.pdf	Accepted	
4	Cincinnati	Mercy Franciscan - Mt. Airy	ALIAS2	CAP Certification	No	05-MAR-2010	F4095.pdf	Accepted	
5	Cincinnati	Mercy Franciscan - Mt. Airy	ALIAS2	ALIAS Part 2 Delegation of Authority Log	No		F5434.pdf	Accepted	
6	Cincinnati	Mercy Franciscan - Mt. Airy	ALIAS2	ALIAS Part 2 PI Attestation Form	No		F5704.pdf	Pending	
7	Cincinnati	Mercy Franciscan - Mt. Airy	ALIAS2	CLIA Certification	No	08-FEB-2011	F6172.pdf	Accepted	

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Figure 5.
List of Spoke Required Document Collection Status

Legend for Figure 1: Definition of Database Design Diagram Symbols