

**DEVELOPMENT OF A RANDOMIZED CONTROLLED TRIAL METADATA
QUERY TOOL AND WEB SERVICE.**

by

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ABSTRACT

Collecting structured data on the results, design, and outcomes of randomized controlled trials (RCTs) can benefit the systematic review process. Generally, this process involves manual data abstraction from retrieved text articles in the many bibliographic databases. An effort to build a knowledge base of RCTs is currently underway, but has not been widely adopted by authors publishing in the literature. This development project was undertaken to explore other mechanisms that could be used to contribute to the collection of RCT metadata. The current model for the knowledge base is a centralized approach, whereby RCT data is submitted to the RCT Bank, the current face of the knowledge base. This project explored the option of using a distributed model, whereby each institution responsible for generating RCT data would also collect and distribute the data into a networked knowledge base. The advantage to this approach is that each institution could integrate an RCT metadata collection mechanism with the current workflow associated with the daily management and lifecycle of the RCT, as well as maintain ownership of their data. In order to build on the current data structure being used by the RCT Bank, the RCT Bank data schema was adopted in this development project. This data schema has its' origins in an RCT ontology that has been modeled on the systematic review process and is therefore most capable of benefiting the review process. A relational database was generated and populated with test data for twelve RCTs. Queries were then developed to extract the trial details. These queries were then integrated into a Web service, a collection of functional units that are exposed over the web using newer standards of interoperability. Publishing the Web service then has the

advantage of allowing a larger web application to consume this functionality, such as a search interface for a distributed knowledge base.

DEVELOPMENT OF A RANDOMIZED CONTROLLED TRIAL METADATA

QUERY TOOL AND WEB SERVICE

INTRODUCTION

Randomized controlled trials (RCTs) are the least biased source of information on the effectiveness of medical interventions and are the backbone of systematic reviews, the gold standard for the best scientific evidence. This evidence subsequently forms our evidence-based practice guidelines, such as those published in the National Guideline Clearinghouse, as well as provide a knowledge base for evidence-based clinical decision support systems. However, the time span between publication and the time when the evidence becomes incorporated into clinical practice has long been recognized as the rate-limiting step of evidence-based medicine. A typical practice guideline is the result of over ten years of data synthesis, interpretation and summarization. By the time it is published, a guideline may be close to expiration because of the accumulation of newer evidence. In addition, there are now over 10,000 RCT's indexed in Medline every year, further straining our current processes of evidence management [1].

Although there are many barriers to increasing the rate at which evidence becomes practice that may not be amenable to intervention, such as regulatory affairs, there are others that can be alleviated through automation [2]. For example, in the systematic review process, the reviewer typically gains access to the design, execution and results of an RCT through manual text-based literature searches of bibliographic databases such as Medline. The reviewer is then responsible for aggregating RCTs based

on study type, intervention, and other criteria in order to standardize data to be used for meta-analyses of the papers. This whole process is time-consuming and labor intensive, requiring individuals to take on various information processing roles including literature searcher, reference manager, document supplier, critical appraiser, data extractor, and data synthesizer[3].

In an attempt to make this process more efficient and to increase the quality in which RCT methodology is reported, efforts are being made to create a knowledge base of RCTs using a structured data representation of clinical trials[4]. A knowledge base of RCTs that could be consumed by both machines and humans has the potential to eliminate some of the burden spent on evidence collection and synthesis in systematic reviews.

In her landmark dissertation, Ida Sim proposed the idea of a knowledge base for RCTs in which investigators publish structured, electronic information about their study in conjunction with traditional journal publication[5]. This model of data/text publication can currently be found within the genomics community whereby researchers publish new gene sequences electronically into a centralized system called GenBank, as a requirement to journal publication. This massive collection of raw genetic data has had a tremendous positive impact on the advancement of genomic investigation.

Since her 1997 dissertation, Dr. Sim has successfully demonstrated proof-of-concept with the development of RCT Bank, an electronic knowledge base containing all the detailed metadata of a trial in a structured format. In the first phase of implementing RCT Bank, Dr. Sim invited researchers publishing RCTs in the Journal of the American Medical Association and the Annals of Internal Medicine to co-publish their studies

electronically in RCT Bank. The current second phase of implementation allows for direct author submission to RCT Bank, which is accessible through a web-based data-entry tool called Bank-a-Trial[6]. Any author publishing an RCT is encouraged to submit their data via this web-based tool.

Currently, the process of submitting a trial to RCT Bank is exhaustive and is based on an easily accessible web-based collection of forms. The web site contains over 135 dynamically generated web pages and takes an average of 8 hours to complete[7]. Efforts have been made in the past to allow for direct programmatic access to the RCT Bank with Java and Perl APIs, but unfortunately these have not been maintained with the evolution of the system[8]. This would allow for the direct transfer of data from an institution managing an RCT and collecting this structured data without having to go through the web forms.

Although submitting RCT metadata is not a requirement for journal publication or continued funding, future policy may help to influence the regulated submission of RCT metadata if the burden of submission could be reduced to a manageable limit and if the required information infrastructure was in place. Current policy initiatives targeting clinical trials are focused only on registering and identifying active trials in a central location such as the federally sponsored ClinicalTrials.gov.

In order to follow Dr. Sim's lead in contributing to a global RCT knowledge base, institutions implementing RCTs will need to target their publication strategy toward collecting RCT metadata either locally or depositing it via a central repository such as RCT Bank. Given the sheer amount of metadata that can possibly be collected from an RCT, there is an incentive to capture the data throughout the life cycle of the trial and either

deposit it in a centralized system or maintain ownership of the data and distribute it into a distributed or federated network of other RCT metadatabases. A good deal of structured RCT metadata could be captured electronically during the course of the trial if the proper mechanisms were in place. For example, many of the protocol and study design details are contained within the documentation sent to the Institutional Review Board and could easily be extracted to an RCT metadatabase. Other details may be contained within the study management software or statistical analyses packages. Other than small technical barriers, it would not be difficult to incorporate mechanisms to extract this data from its original location to a database for RCT metadata. However, in the effort to build an RCT knowledge base, either in a central or distributed model, it would be necessary for a standard RCT ontology to be adopted in order to ensure a unified collection process within and between institutions. A standard collection process would allow for the formation of a distributed knowledge base existing between individual institutions and their RCT databases and even between central efforts such as RCT Bank. This knowledge base would then serve as a gateway for systematic reviewers, whereby the elaborate process of filtering text-based journal articles could be replaced by more efficient electronic search mechanisms.

In this paper, the development of an interoperable electronic search mechanism that allows for RCT metadata retrieval is described. The development effort was focused on two tasks that would culminate in a working prototype of a query tool using the Web services model. The first was on adapting the foremost ontology of RCT metadata developed by Dr. Sim and instantiating a relational database to store test data. The scope of the project did not allow for exploring data entry mechanisms discussed above, but

rather assumes that the data is already collected. The second part of the development project focused on implementing newer World Wide Web Consortium (W3C) standards of programmatic access to data sources via Web services [9] to facilitate interoperability across computing platforms, a necessity for any distributed or federated knowledge base. The goals of the project were to demonstrate a fully operational system for performing a search query to extract RCT metadata on a given data set and to demonstrate how the technology implemented in this project facilitates the formation of a distributed knowledge base. With further refinement, this prototype system could potentially be integrated with other collection efforts, or nodes, to create a distributed knowledge base of RCT metadata. Furthermore, the system could be integrated into other software applications used in the workflow of systematic reviewing to facilitate the retrieval and synthesis of RCT metadata.

BACKGROUND

The systematic review process

A systematic review is a collaborative effort to methodically collect, validate, and summarize a number of published clinical trials given a particular health condition or treatment. The steps required for study selection and analysis in a proposed systematic review can be quite complex and can be biased by the reviewers' methodology. Prior studies on the retrieval process have shown that 30%-80% of all known published RCTs were identified during retrieval tasks, indicating significant variability in identifying relevant studies for inclusion in the review [10].

The Cochrane Collaboration, which publishes the Cochrane Reviews database, is generally recognized as the early authority in systematic review methodology and through

its publications and recommendations has increased the standardization of systematic review execution [11]. For example, the Cochrane highly sensitive search strategy for Medline is now the recommended approach to identifying RCTs for inclusion in a systematic review [12]. This strategy focuses on three main elements: 1) name of the health condition 2) intervention terms and 3) study design, which is typically ‘randomized trial’. The Cochrane Controlled Clinical Trials Register (CENTRAL) is a database built specifically for controlled trials and indexes all Medline citations meeting this requirement, therefore providing an auxiliary source for bibliographic references to RCTs [13].

The initial step taken by any systematic reviewer is to identify potential studies for inclusion using the search strategy and databases just discussed. After employing the search strategy, the reviewer compiles a list of citations that meet the search criteria and publishes it in a registry which is then distributed to the editing members of the systematic review team. It is at this step that the process of quality assessment (judging internal and external validity) and information abstraction (quantitative synthesis, and contextual interpretation) begins, done by manually reading each article. Once this step is complete, and studies not meeting the predefined inclusion requirements are excluded, abstracted study characteristics are collected in a structured format for meta-analysis across all the studies. Analysis is usually done with the aid of software such as RevMan developed, at the Nordic Cochrane Center.

In the process briefly described above, it is the task of quality assessment and information abstraction that is amenable to automation and which has been addressed by Dr. Sim in her development of the RCT Bank. Using a task-oriented, ontology content specification method called competency decomposition, Dr. Sim has generated a specific,

systematic review-based ontology for RCT's to aid in trial reporting and analysis [14]. The ontology shares some elements of study performance and execution found in other RCT ontologies, but as a whole is more complete and matched to the task of systematic reviewing. It specifically addresses many of the tasks that systematic reviewers undergo as mentioned earlier, including retrieval, judging internal validity, judging external validity, quantitative synthesis, and contextual interpretation [15]. For example, the task of judging internal validity is composed of eleven subtasks such as finding whether or not there was any intervention-related bias, which is then decomposed into more granular sub-subtasks, hence the ontology specification method name - competency decomposition. Just this one task alone of judging external validity can produce up to 112 unique data elements in the RCT metadata collection process.

The role of an RCT ontology and Consort Plus

Recognizably, formulating any RCT ontology is a large step towards standardizing the collection of RCT metadata. Efforts to promote the reporting of RCT metadata within the literature have primarily been from the CONSORT group, an international group of scientists and editors pushing to improve the reporting of RCT methodology [16-17]. The group has published a statement regarding the need for improved reporting and also lists required and recommended items to be submitted for publication by journals adhering to the CONSORT principle. There are currently over 80 journals who have agreed to participate in adopting this initiative [18]. However, despite its grand approach to improving RCT reporting, the current recommendation for journal publication is only 22 items out of the over 100 that have been identified by the group as necessary for the

systematic review process [19]. In a subsequent effort to promote the standardization of RCT metadata captured electronically, the CONSORT group has expanded its requirements to impose more data integrity. This initiative, termed CONSORT Plus, contains a required minimal data set in conjunction with a list of recommended and optional data elements.

The complete collection of CONSORT Plus elements [20] represents a thorough description of the RCT and is essentially the core of Dr. Sim's RCT ontology.

To date, the RCT ontology contains eight major concepts: Intervention, Administrative, Protocol, Outcome, Design, Treatment-assignment, Population, and Generic. Furthermore, each concept is subdivided into multiple sub-concepts as a result of the competency decomposition method (**Figure 1**). The breadth of the ontology is intentional and is meant to be flexible in order to accommodate the variability of RCT execution.

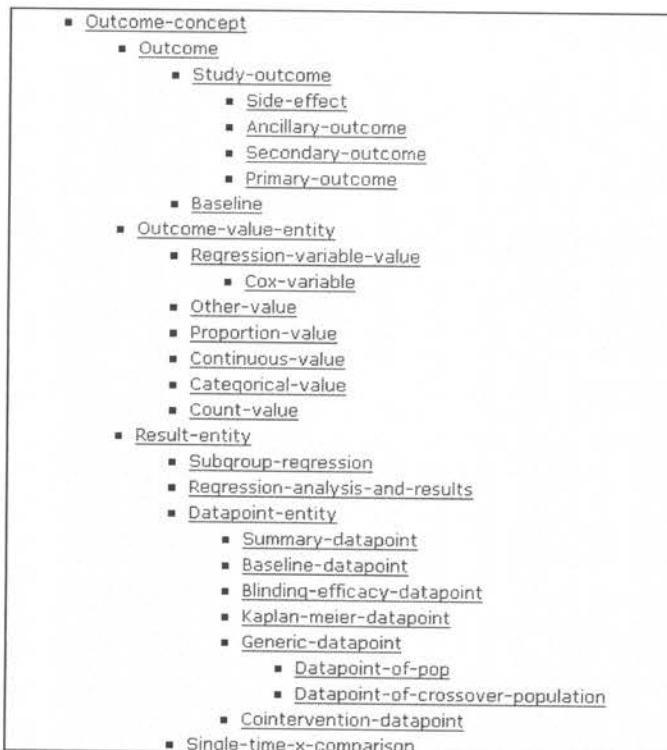


Figure 1. A portion of the RCT ontology hierarchy. Source <http://rctbank.ucsf.edu/ontology/index.html>. See Appendix I for the complete hierarchy.

RCT Bank and metadata collection

The RCT Bank project and RCT ontology are still works in progress as new idiosyncrasies are introduced with the addition of new studies [21]. RCT Bank currently holds fourteen trials, most of which have complete data. The data architecture supporting the knowledge base is quite unique and is implemented on the Unix operating system using software written in Lisp, called Ocelot [22]. Ocelot is based on a object-oriented framework of frames and slots which are akin to classes and attributes [23]. Currently, the system is supporting 188 frames and 601 unique slots [24].

The RCTs can be viewed or accessed via the web from the same site offering data submission [25]. The attempt to offer programmatic access to the database has been made, but is generally not supported, as mentioned earlier. It is this weakness of the trial bank that is partially addressed in this paper, using newer methods that facilitate interoperability, specifically Web services.

Description of Web services

There has been tremendous hype and press regarding the theory and application of Web services. In theory, Web services are essentially a newer standard for exposing functional units of business logic over the internet [26]. Web services can also be thought of as reusable objects, software components, remote procedures, or subroutines, just to name a few descriptors. There is no restriction on how small or big a Web service can be, but they are not typically full-blown applications. The best example of a Web service is the free Google search tool Web service. This tool, which you download in the form of code,

can be placed inside any web application needing content search functionality. Part of the code contains a link to the URL where the Web service, or subroutine, is being hosted. This link contains a document written in the Web Services Description Language (WSDL) that describes the Web service in terms of input, output, operating platform, port number, and communication protocol which can be programmatically consumed by the application using the service. All the functionality of the Web service is remotely executed outside of the application consuming it. The embedded Web service performs a function call to the Google server when the search tool is activated by the user. Activation simply means that the URL of the Web service has been requested and the required input parameters are available. The communication between the web application requesting a search and the Google server responding to a search request, is done via the Web service standard or Simple Object Access Protocol (SOAP), which is essentially a delivery envelope for the Web service request and response. SOAP is a messaging scheme that uses eXtensible Markup Language (XML), a lightweight, platform independent standard to exchange documents over the HTTP or TCP transport protocols. XML is nothing more than a markup language that describes the structure and content of a document. In the Google Web service example, the search parameter is converted to XML, packaged in SOAP, and delivered to the Google server. The output of the server is converted to XML, packaged in SOAP and sent back to the requestor which parses the returned XML and presents the results.

The advantage to adopting these Web service standards for developing applications that run over the web is that most of the business heavyweights – Microsoft, IBM, Sun, BEA, and Oracle as well as policy bodies, such as W3C and OASIS, have all rallied around

the involved technologies. At heart, Web services are truly a larger set of standards that encompass everything from registration, discovery, communication, access, security, scalability, and more for delivering platform independent computing across the web.

DEVELOPMENT

Pre-development

Because of the inherent limitations and complexities of redistributing the RCT Bank Ocelot architecture from one computing environment to another, this project included some preparation steps to allow for local instantiation of a database modeled from the RCT ontology. These few steps included the centralization of the RCT data dictionary, the building of a more user-friendly RCT Ontology Viewer, and the conversion of the object-oriented RCT schema to a relational model.

Data Dictionary

The first step was to acquire the data dictionary (**Figure 2**) for the RCT ontology which was accessed at: <http://rctbank.ucsf.edu/ontology/index.html>. This publicly-

Class STUDY-OUTCOME						
Parent class: Outcome						
Subclasses: Side-effect Ancillary-outcome Secondary-outcome Primary-outcome						
Template Slots						
Slot name	Documentation	Type	Allowed Values/Classes	Cardinality	Default	
<i>reason-for-post-hoc-definition</i>	"If this outcome was specified post-hoc, describe why this outcome was defined post-hoc."	STRING		0..1		
<i>survival-analyses-and-results</i>		Instance	Survival-analyses-and-results	0..1		
<i>regression-analyses-and-results</i>	"Details about the regression analysis done on this outcome."	Instance	Regression-analyses-and-results			
<i>specification-time</i>		SYMBOL	A-pron Post-hoc Not stated	0..1		
<i>timepoint-comments</i>	"Comments on the definition of timepoints, e.g., how 'hospital discharge' was defined."	STRING		0..1		
<i>unit</i>	"The unit of the outcome value, e.g., feet or mmHg. Should come from a controlled vocabulary."	STRING		0..1		

Figure 2. Data dictionary for the RCT ontology developed by Dr. Ida Sim. Source
<http://rctbank.ucsf.edu/ontology/Study-outcome.html>

available dictionary is reasonably descriptive of the task-oriented ontology for RCTs, but is not convenient for easy viewing because the dictionary spans 150 HTML pages. Each page originates from the underlying Ocelot framework and describes such detail as the element name, a description of the element, the specific data type, and more. In order to aggregate the data dictionary into one manageable page so that processing of the data dictionary could occur, each HTML page was “scraped” for data and put into a spreadsheet. The hierachal relationship between ontology concepts was maintained and grouped accordingly in the spreadsheet.

Next, SQL code was auto-generated that would allow for the creation of the tables and fields from the concept and data element names contained in the spreadsheet. The generated SQL script was then run in a MySQL (MySQL AB, Uppsala, Sweden) script executor to generate all the tables and fields without any referential integrity or relationships. This process created a database with 143 tables and over 1200 data elements which now serves as the database underlying the more user-friendly RCT Ontology Viewer.

RCT Ontology Viewer

Neither the spreadsheet nor the database were an ideal viewing format for the ontology, so the next step was to create a dynamically generated HTML document that would allow for easier navigation through the hierarchy of elements. The HTML document allows for the viewing of all data elements at each level in the hierarchy for any particular parent concept (**Figure 3**).

View	Name	Count			
		Parents	Children	SubChildren	Data Elements
C01	Intervention	8	16	3	169
C02	Administrative	8	6	2	163
C03	Outcome	6	22	13	268
C04	Design	9	2		81
C05	Protocol	8	11		226
C06	Treatment Assignment	2	2		22
C07	Population	5	4	12	163
C08	Generic	4	11	15	117

Figure 3. RCT Ontology Viewer showing the concepts for the ontology.

For example, clicking on the concept button for Protocol will display all the sub-concepts such as Protocol Change and Follow-up along with all the data elements associated with each sub-concept (**Figure 4**).

RCT Ontology Hierarchy							
RCT Data Elements							
Children	Parent Class	Element Name	Description	Data Type	Foreign Key	CONSORT Req	GCRC Name
2	Outcome	unit	"The unit of the outcome value, e.g., feet or mmHg. Should come from a controlled vocabulary."	STRING		No	
		comment-on-efficacy-results		STRING		No	
		outcome-assessment	"Details about the assessment of this outcome."	Instance	Outcome-assessment	No	
		term-information	"Pointer to a UMLS preferred term or terms, if available, that capture the major clinical concepts in this data class (e.g., diabetes mellitus)."	Instance	Term-information	No	
		special-variable-information	"Points to additional information relevant to special classes of variables (e.g., discount rate for cost variables)."	Instance	Special-variable-information	No	

Figure 4. RCT Ontology Viewer showing the top-level data elements for the Outcome concept.

There were two motivations for producing this RCT Ontology Viewer. The first was to become better acquainted with the ontology and its complexities, in order to facilitate the development of this projects' main component, the Web service. The second was to provide an interactive medium in which RCT data elements currently being collected locally by OHSU's General Clinical Research Center (GCRC) could be identified. This was done using a checkbox mechanism for each data element.

The GCRC is a clinical research support center that receives a majority of its funding from the NIH. The goal of this center is to provide a range of support, including informatics, to NIH-funded research trials. The informatics component that is in place within the center allows for trial protocol management and data entry. The initial intent of using the RCT Ontology Viewer in this project was to identify GCRC data elements matching the RCT ontology. However, it was found after some review of the GCRC data schema that the data collected by the GCRC differed significantly from the RCT metadata ontology. The GCRC data collection efforts are directed toward the daily management of the study protocol, a “micro” approach, and lacked any “macro” details of the actual trial which is the primary the scope of the RCT ontology. Because of this, the cataloging of data element overlap between the GCRC and RCT ontology did not occur. There is no doubt however that a sizable portion of the RCT metadata elements are being collected at some point in the life cycle of a trial. For example, many of the administrative details are presumably being collected by the Institutional Review Board (IRB) and a few of the study design details could be found in the study protocol and grant documentation, yet this information may not exist in electronic format to facilitate extraction. As IRBs migrate to electronic data submission, there is potential for this information to be captured locally and incorporated into an RCT metadata collection effort.

Converting the database to a relational model

The large database that was instantiated for the RCT Ontology Viewer was a strict mapping of the object-oriented RCT Bank. Many redundancies needed to be removed in order to produce a manageable relational structure for the Web service development component. Again, using the initial spreadsheet containing the data dictionary, any

redundancies that existed in the original object oriented schema were removed in order to be more compliant with the strict relational model. SQL code was then regenerated from this list and run through the script executor for a Firebird (IBPhoenix, Manchester, Massachusetts) database. The Firebird DBMS was chosen for its ease of management using the IBExpert management tool (H-K Software, Oldenburg, Germany) later used to generate the query syntax for the Web service. The new database structure was reduced to 102 tables and under 700 data elements.

The second step was to begin enforcing referential integrity in the database structure by creating primary and foreign key relationships. In order to do this more efficiently, the database structure was run through a reverse engineering function inside of an entity-relationship (ER) modeler, in this case ERWin Fusion Data Modeler (Computer Associates, Islandia, New York). This function generates an ER diagram from the database structure to allow for relationship building. This process proved to be quite complicated and time- intensive given the extreme nature of the decomposition within the ontology. At some point, the developer must decide how much integrity is enforced in the database of the application and how much is enforced by the user interface. Enforcing all the integrity in the database proved to be a complicated step when modeling the RCT ontology to a relational model. Since it was not a goal of this project to exhaustively enforce this integrity, nor develop a front-end data entry module, only the most general relationships were enforced.

Once the data model was complete (**Appendix II - III**), it was instantiated on a Firebird database server. Randomly generated data was used to populate the tables and certain descriptive fields used to display information in the Web service were filled with

non-random data simulating either an RCT on the use of amiodarone for atrial fibrillation or on the use of percutaneous transluminal coronary angioplasty (PCTA) in myocardial infarction. Between these two interventions, twelve mock studies were generated to be used for the Web service demonstration. In order to extract this simulated study data in ways meaningful to a person performing a search on either of these interventions, database queries had to then be generated.

Constructing the queries

With the database operational and a number of test trials entered, the next step in the process was to generate the queries needed to extract details of the trial, given a limited set of search parameters. Using the Cochrane highly sensitive search strategy as a starting point, various search criteria were identified that would be beneficial to systematic reviewers needing to identify studies for inclusion. The following list of search items would allow the user to filter the pool of RCTs to a more relevant set. They are:

- Outcome – Limit by the measured outcome, such as Chest pain.
- Intervention – Limit by treatment, such as the drug Amiodarone.
- Study size – Limit by the trial size, such as ≥ 900 patients.
- Population – Limit by the targeted population age, such as Adults 55-75 years old.

This list is just a small sample of the more important filtering options that could aid the systematic reviewer in the process of identifying RCTs to better match a given set of inclusion criteria. These search criteria are also being used by the RCT Bank in the online search tool and more are expected to be added in the future as development of the RCT Bank continues.

With these search parameters identified, the process of formulating queries to extract the details of studies matching these criteria was then begun. Query formation was primarily done using views that aggregated data based on the search parameters. For example, one query is written to get a list of RCT study identifiers matching the intervention specified in the search. Other queries that rely on the returned results from the database views were written with specific Web service functions. These queries perform higher level aggregation and sorting that would be more difficult to implement in the database alone. In all, the entire collection of queries and views used to extract the data are incorporated into the functions of the Web service.

RCT Web service functions

The theory behind Web services is more complicated than the actual application of those theories. Generating the specific requirements for a Web service is no longer a challenge given the widespread approval (although not necessarily of adoption) of this technology. Generally, it involves a simple conversion of language specific-syntax, such as C#, CFML, Java, or some other programming language, into a W3C Web service standard format called the Web services Description Language (WSDL). This ubiquitous WSDL file is typically auto-generated from within the software development environment (e.g. VB Studio, ColdFusion MX/Dreamweaver MX) and is essentially an XML document that conforms to the W3C XML Schema for describing a Web service. The WSDL file defines the Web service method signatures (the input arguments and return output), location, port numbers, SOAP communication and error handling of the language specific methods in a

format that can be interpreted by any computing platform enabled for XML-SOAP (**Figure 5**).

```
<?xml version="1.0" encoding="UTF-8" ?>
- <wsdl:definitions targetNamespace="http://ws_rct" xmlns:impl="http://ws_rct" xmlns:intf="http://ws_rct"
  xmlns:apachesoap="http://xml.apache.org/xml-soap" xmlns:wsdlsoap="http://schemas.xmlsoap.org/wsdl/soap/"
  xmlns:soapenc="http://schemas.xmlsoap.org/soap/encoding/" xmlns:xsd="http://www.w3.org/2001/XMLSchema"
  xmlns:rct="http://rpc.xml.coldfusion" xmlns:wsdl="http://schemas.xmlsoap.org/wsdl/"
  xmlns="http://schemas.xmlsoap.org/wsdl/">
- <wsdl:types>
- <schema xmlns="http://www.w3.org/2001/XMLSchema" targetNamespace="http://ws_rct">
  <import namespace="http://schemas.xmlsoap.org/soap/encoding/" />
- <complexType name="ArrayOf_xsd_string">
  - <complexContent>
    - <restriction base="soapenc:Array">
      <attribute ref="soapenc:arrayType" wsdl:arrayType="xsd:string[]" />
    </restriction>
  </complexContent>
</complexType>
- <complexType name="ArrayOfArrayOf_xsd_anyType">
  - <complexContent>
    - <restriction base="soapenc:Array">
      <attribute ref="soapenc:arrayType" wsdl:arrayType="xsd:anyType[][]," />
    </restriction>
  </complexContent>
</complexType>
</schema>
- <schema xmlns="http://www.w3.org/2001/XMLSchema" targetNamespace="http://rpc.xml.coldfusion">
  <import namespace="http://schemas.xmlsoap.org/soap/encoding/" />
- <complexType name="QueryBean">
  - <sequence>
    <element name="columnList" nullable="true" type="impl:ArrayOf_xsd_string" />
    <element name="data" nullable="true" type="impl:ArrayOfArrayOf_xsd_anyType" />
  </sequence>
</complexType>
```

Figure 5. WSDL example generated from the ColdFusion server.

Once the WSDL is generated, it is associated with a specific Uniform Resource Locator (URL) for its location on the application server. A web application developer may access the WSDL file directly and obtain a list of methods published by the Web service. These methods are then integrated into the developer's development environment, allowing them to be embedded into the application. The invocation of the methods within the application is actually a remote procedure call to the WSDL referenced in the URL.

The RCT Web service developed in this project is comprised of over 30 unique methods (**Appendix IV**) written originally in ColdFusion Markup Language (CFML) and saved as a ColdFusion Component (CFC), which is ColdFusion's attempt at object oriented programming (**Figure 6**).

```

<!--- *****
<!--- ***
<!--- ***
      FILTER BY INTERVENTION
      INPUT = name of intervention (ex PCTA)
      OUTPUT = List of RCT ID's
<cfunction name="filterByIntervention" access="remote" returnType="query" output="false">
    <!-- body -->
    <cfargument name="filterByInterventionArg" type="any">
    <cfquery name="filterByInterventionQuery" datasource="RCT_FBD" >
        SELECT RCTID FROM GET_MATCHING_INTERVENTIONS
        WHERE DISPLAY_NAME = '#filterByInterventionArg#'
        GROUP BY RCTID
    </cfquery>
    <cfreturn filterByInterventionQuery>
</cffunction>

```

Figure 6. A ColdFusion CFC function used in the Web service.

A CFC is then registered with the ColdFusion server as a source for a Web service. The CFC has a declaration that allows its methods to be exposed remotely and this subsequently allows the ColdFusion server to generate a WSDL file from the CFC code. Once the WSDL (**Appendix V**) is generated by the server and made public, via a given URL, the methods are exposed and can be consumed by an application. In this project, access to the RCT database queries are exposed and can then be incorporated into an application enabled for HTTP and XML-SOAP communication that performs the search.

RCT Web service invocation

As it exists now, the RCT Web service is a solo effort to expose a local relational database of RCT metadata. In order to be of some utility, the RCT Web service methods need to be invoked by an application which sends the search arguments and receives the query results. The application receiving the results can either display them for user review or could potentially store them in a database.

For the demonstration purposes of this project, a user interface was built to allow for searching and results-viewing such that it could facilitate the direct comparison of RCT metadata between studies, a feature not currently available within RCT Bank. The RCT Bank performs similar query functions, but is limited in how it displays the results. Each trial that is retrieved must be reviewed independent of the other returned trials and does not permit rapid review of multiple trials simultaneously.

The user interface to perform the search is a ColdFusion web page (**Appendix VI**) containing drop-down boxes (**Figure 7**) for each of the search criteria given earlier. This web application acts as a gateway to the RCT database and allows the user to select the necessary inclusion criteria from a limited list of items in each search category.

The screenshot shows a web-based search interface titled "RCT Meta-Data SEARCH". It contains four search fields:

Search Criteria	Selected Value
1. Intervention Type	Amiodarone
2. Outcome	% vessel blockage following MI
3. Population	Adult: 55-65 yrs
4. Sample Size	>= 510 Range from 510 to 980

Below the search fields is a "Submit" button.

Figure 7. Search interface for the Web service

When the selection of search criteria is complete, the user submits the search request and a limited set of RCTs matching the search criteria are presented with top order information visible, such as study name, intervention arms, outcomes, population, and design (**Figure 8**).

RCT Meta-Data					
SEARCH SUMMARY					
Intervention	Amiodarone		Population	Adult: 55-65 yrs	
Outcome	Recurrence of AF		Sample Size	510	
4 RESULTS					
Title	1 Amiodarone post-cardioversion		2 Amiodarone for rhythm control	3 Amiodarone post-cardioversion II	4 Amiodarone for paroxysmal atrial fibrillation
Intervention Arm	Show 300 mg/kg Amiodarone post cardioversion		Chemical conversion with high dosage loading of Amiodarone	Amiodarone loading 10 minutes following cardioversion	Use of amiodarone in paroxysmal cases
Comparison Arm	Show Placebo post cardioversion		Chemical conversion with Sotalol	Amiodarone loading upon discharge	Placebo in paroxysmal cases
Primary Outcomes	Liver enzymes	Recurrence of AF	Recurrence of AF	Liver enzymes	Recurrence of AF
Secondary Outcomes	Show Bleeding from High INR		Liver enzymes		Bleeding from High INR
Population	Show Adult: 55-65 yrs Sample Size = 520		Adult: 55-65 yrs Sample Size = 980	Adult: 55-65 yrs Sample Size = 650	Adult: 55-65 yrs Sample Size = 850

Figure 8. Results of the search.

Further details of the trial are hidden in an accordion-type page which expands upon clicking of a button. The information that is returned in the search page is essentially all the exhaustive details of the trial. Retrieved studies are presented side by side for easy visual comparison of data fields (**Figure 9**).

4 RESULTS					
Title	1 Amiodarone post-cardioversion	2 Amiodarone for rhythm control	3 Amiodarone post-cardioversion II	4 Amiodarone for paroxysmal atrial fibrillation	5 Amiodarone for atrial fibrillation
Intervention Arm	Show 300 mg/kg Amiodarone post cardioversion	Chemical conversion with high dosage loading of Amiodarone	Amiodarone loading 10 minutes following cardioversion	Use of amiodarone in paroxysmal cases	Placebo in paroxysmal cases
COMPLIANCE_DEFINITION	lecalaydiuionenmeggpuuleytonj	higjhskntbekul	ymnnyoedlpczjpqejujqpscwube	rtzowhowdeathgpmzuifgeczvviapae	azalaP@)
COMPLIANCE_DETAILS					ujjogezigtmsabl
COMPLIANCE_ENCOURAGEMENT_METHOD	euamwatuojijihfsuidztrhvniipegziqroou	ijhiutfgdemkthyakop			Amiodarone loading 10 minutes following cardioversion
COMPLIANCE_RESULTS					
DELAY_AFTER_RANDOMIZATION	edooqklyuycomuhotmxowthfk	jch alkjbevnuizewqg			
DESCRIPTION_OF_INTERVENTION_ARM	dobwe	miveoiuguyaibdkjwe			
DISPLAY_NAME	300 mg/kg Amiodarone post cardioversion	Chemical conversion with high dosage loading of Amiodarone			
INTERVENTIONS					
INTERVENTION_ARM_COMPLIANCE_CODE	nodmanokaltrnhzmodgluhnjkosbbadshbg	askijewemnnzorjqlwai			
INTERVENTION_ARM_EXECUTION_NOTE	yipse addzobzic	zozmnasenmbtnl			
INTERVENTION_ARM_ID	7	10			
JUSTIFICATION					
MULTIPLE_INTERVENTIONS_P	qffdgpyzutjbtsmeobmzlgqothwputiczy	ekitjolsdxconmamnrejkshdldj			
RCTID	0	1			
TERM_INFORMATION					

Figure 9. Trial details become visible after selecting a viewing category. Details of all returned trials are displayed side-by-side. Much of the data shown for this entry is randomly generated.

Although this method of information display is more efficient than skimming through multiple pages of journal text, incorporating even more granular search criteria would improve efficiency. It is possible to provide further filtering capability of the RCT search page, but at the cost of adding more complexity to the Web service, something beyond the scope of this project. Alternatively, the invocation of the Web service could theoretically occur from within a larger application that provides further filtering functionality. For example, this Web service could be incorporated into the RevMan systematic review software. Currently this software requires the user to enter in the metadata manually, but by building the Web service into the application, this could be performed automatically.

DISCUSSION

This development project grew out of a desire to extend prior work on an RCT knowledge base by exploring a new programmatic interface. The primary objective of this project was to use Web services technology to generate a query able prototype of an RCT metadata node. While in the course of the development, it was found that addressing the Web service development was the least technically challenging aspect given the widespread acceptance of Web services standards. The more technically demanding component of this project was adapting the robust RCT ontology to a relational model which could then be instantiated and incorporated into the development of the RCT Web service.

The Web service developed in this project is meant to satisfy the querying needs of one database, in this case a local and modified installation of the RCT Bank. Ideally,

however, this Web service model would be adopted by a centralized knowledge base such as RCT Bank to allow for direct programmatic access to the knowledge base.

Another alternative is to adopt this Web services model as the basic unit of functionality for a distributed or federated management system of an RCT knowledge base. In this scenario, multiple, individual Web services would be invoked by one web application acting as the interface to the knowledge base. A distributed system would allow for differing data schemas between participating institutions, but would require a more elaborate unification process by the managing web application. A federated approach would ensure that the same data schema is used between participating institutions, but requires more effort to coordinate. In either system, however, data management of the knowledge base is not centralized, but rather a shared responsibility.

The future of an RCT knowledge base is likely to be a combination of the various models (**Figure 10**), but integration issues can easily be addressed if the knowledge base were to be built on Web services platform. In addition to facilitating integration of multiple RCT collection nodes, the RCT knowledge base architecture must address access. Access is currently limited to a web-based query tool, but adoption of the Web services model can promote more access to the knowledge base from within common tools used in the systematic review process, such as the RevMan software package.

Other issues that were not explored in the project, and are obvious challenges, include the methodology used to collect the RCT metadata. In this project, random test data was generated. In a production mode, the RCT data collection effort must have a user interface that is either integrated with other data collection processes, such as the study management software typically used in the course of a trial, or built as a stand-alone

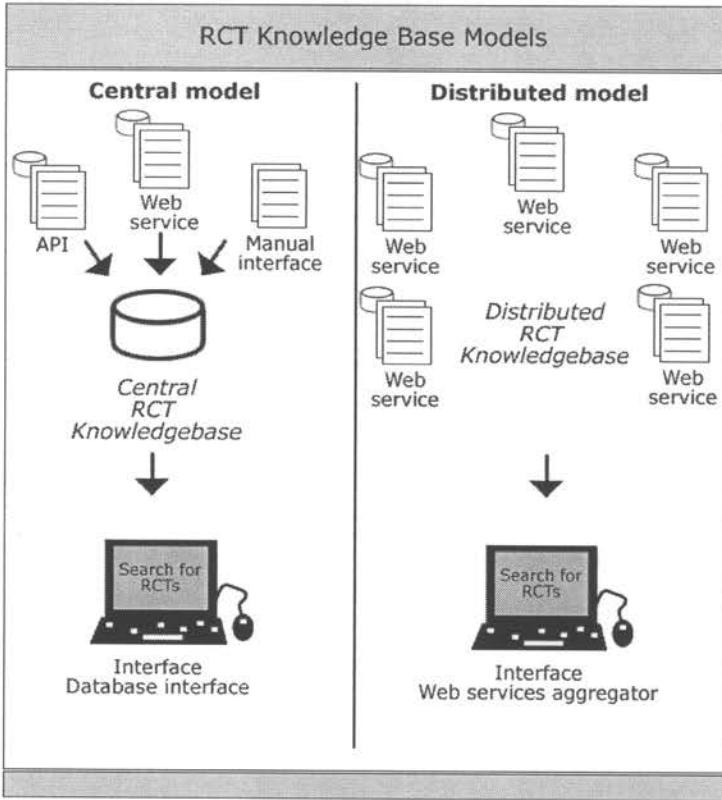


Figure 10. A diagram representing two storage and retrieval modalities. A central model can collect data from different sources, but will tend to enforce one particular methodology in the data collection process. A distributed model connects various sources and offers a central interface. In this example all Web service sources are represented, but not all sources need to agree on the data schema as in a federated approach.

application like the web-based interface to the RCT Bank. Ideally, any institution that is managing an RCT, whether it be a single or multi-site study, would have a mechanism to collect and load their RCT metadata into the RCT knowledge base. If an institution desires to participate in a distributed model of the knowledge base, then issues of data integration arise. Certain freedoms in data collection may need to be addressed so that data homogeneity is maintained within a distributed system. This would require some level of agreement in the initial development of a functional distributed knowledge base, specifically on the RCT ontology to be used. The RCT ontology developed by Dr. Sim is an exhaustive effort to collect RCT metadata most suitable for the systematic review process, but is far from a simple minimal data set. There is clearly a cost associated with

adopting this large ontology as a framework for the distributed RCT knowledge base, which is the amount of development needed for each participating institution. The breadth of the data schema and the fact that it is still attempting to accommodate various idiosyncrasies, may act as implementation barriers to a distributed RCT knowledge base model. However, with further development of this project, it would be possible to generate sharable software components. These shared components would relieve the burden of development between institutions and facilitate the formation of a distributed RCT knowledge base best suited to support the systematic review process.

CONCLUSION

Efforts to collect RCT metadata are currently ongoing and rely on a central model to store and distribute the data. The value of RCT metadata is realized in the systematic review process which will benefit from a structured representation of RCTs as opposed to relying on manual text abstraction of the literature. This project demonstrated that a local RCT metadata storage and distribution node could be created and that the Web services technology used in this development could promote the formation of a distributed RCT knowledge base. The distributed model allows for institutional ownership of data and assumes some level of workflow integration of the data collection process. In order to proceed towards this distributed model, a common RCT ontology must be used to build compatible data models from site to site. Given that the RCT ontology previously developed by Dr. Ida Sim and used in this project is most adept at facilitating the systematic review process, it is recommended that the ontology continued to be used in future developments of an RCT knowledge base.

REFERENCES

1. Sim I, Olasov B, Carini S. An ontology of randomized controlled trials for evidence-based practice: content specification and evaluation using the competency decomposition method. *Journal of Biomedical Informatics*. 2004; 37:108-119.
2. Haynes B, Haines A. Barriers and bridges to evidence based clinical practice. *British Medical Journal*. 1998; 317(7153):273-6.
3. Beverley CA, Booth A, Bath PA. The role of the information specialist in the systematic review process: a health information case study. *Health Information & Library Journal*. 2003; 20(2):65-74.
4. Sim I, Olasov B, Carini S. The Trial Bank system: capturing randomized trials for evidence-based medicine. *AMIA Annual Symposium Proceedings*. 2003; 1076.
5. Sim I. Trial Banks: An Informatics Foundation for Evidence-Based Medicine. Doctoral Dissertation. Stanford University. 1997. Accessed from: <http://rctbank.ucsf.edu/sim/dissertation.pdf>.
6. Sim I, Carini S, Olasov B, Jeng S. Trial bank publishing: phase I results. *Medinfo* 2004; 2004:1476-80.
7. Sim I, Olasov B, Carini S. The Trial Bank system: capturing randomized trials for evidence-based medicine. *AMIA Annual Symposium Proceedings*. 2003; 1076.
8. Olasov B. (Personal communication. Dec 6, 2004).
9. Web Services Activity. World Wide Web Consortium (W3C). Available from: <http://www.w3.org/2002/ws/>. Accessed 5/1/05.
10. Dickersin K, Scherer R, Lefebvre C. Identifying relevant studies for systematic reviews. *British Medical Journal*. 1994; 309:1286-1291.
11. The Cochrane Collaboration. Available from: <http://www.cochrane.org>. Accessed 5/1/05.
12. Alderson P, Green S, Higgins JPT, editors. Formulating the problem. *Cochrane Reviewers' Handbook 4.2.2 [updated December 2003]; Section 5*. In: The Cochrane Library, Issue 1, 2004. Chichester, UK: John Wiley & Sons, Ltd.
13. Cochrane CENTRAL. The Cochrane Collaboration. Available from: <http://www.cochrane.us/central.htm>. Accessed 5/1/05.

14. Sim I, Olasov B, Carini S. An ontology of randomized controlled trials for evidence-based practice: content specification and evaluation using the competency decomposition method. *Journal of Biomedical Informatics*. 2004. 37:108-119.
15. Task Analysis of Systematic Reviewing. RCT Bank. Available from: <http://rctbank.ucsf.edu/tasks/tasks.html>. Accessed 5/1/05.
16. CONSORT. Available from: <http://www.consort-statement.org/>. Accessed Mar 10, 2005.
17. Ioannidis JP, Evans S, Gotzsche PC, O'Neill RT, Altman DG, Schulz K, Moher D. Better Reporting of Harms in Randomized Trials: An Extension of the CONSORT Statement. *Annals of Internal Medicine*. 2004. 141:781-788.
18. CONSORT Journals. CONSORT. Available from: <http://www.consort-statement.org/endorsements/journals/journals.html>. Accessed 4/13/05.
19. Sim I, Olasov B, Carini S. An ontology of randomized controlled trials for evidence-based practice: content specification and evaluation using the competency decomposition method. *Journal of Biomedical Informatics*. 2004. 37:108-119.
20. Complete CONSORT Plus Guideline. RCT Bank. Available from: <http://rctbank.ucsf.edu/consort/full-list.html>. Accessed 5/1/05.
21. Sim I, Olasov B, Carini S. An ontology of randomized controlled trials for evidence-based practice: content specification and evaluation using the competency decomposition method. *Journal of Biomedical Informatics*. 2004. 37:108-119.
22. Ocelot User's Guide. SRI. Available from: <http://www.ai.sri.com/pkarp/ocelot/ocelot-guide.html>. Accessed 5/1/05.
23. Karp P, Gruber, T. The Generic Frame Protocol. Available from: <http://www.ai.sri.com/~gfp/spec/paper/paper.html>. Accessed 5/1/05.
24. Sim I, Hunter K. "RCT Trial Banks: Supporting Evidence-based Practice Through Informatics". October 2003. Available from: http://www.ehto.org/2004/RCT_Trial_Banks.htm. Accessed 5/1/05.
25. RCT Bank. Available from: <http://rctbank.ucsf.edu/>. Accessed 4/13/05.
26. Guruge, Anura. Web Services. Theory and Practice. London. Elsevier Digital Press, 2004.

APPENDICES

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APPENDIX A

RCT Ontology Heirarchy

This RCT ontology was adapted for use in this development project.

The RCT ontology author is Dr. Ida Sim and the link to the source is
at: <http://rctbank.ucsf.edu/ontology/index.htm>.

- Root
 - Concept
 - Intervention-concept
 - Intervention-logic
 - Conditional-logic
 - Simple-logic
 - Blocking-logic
 - Option-logic
 - Chain-logic
 - Compliance-result
 - Intervention
 - Placebo-or-sham
 - No-treatment
 - Usual-care
 - Drug
 - Device
 - Procedure
 - Other-intervention
 - Cointervention
 - Intervention-arm
 - Experimental-arm
 - Comparison-arm
 - Intervention-step
 - Non-drug-intervention-step
 - Drug-step
 - Compliance-details
 - Blinding-concept
 - Blinding-efficacy
 - Blinding-methods
 - Blinding
 - Administrative-concept
 - Registry-id
 - Institution
 - Funder
 - Study-committee
 - Ethics
 - Person
 - Investigator
 - Trial-subject
 - Study-site
 - Publication-concept
 - Publication
 - Journal-publication
 - Abstract
 - Text-subsection
 - Pub-uid
 - Authorship
 - Outcome-concept
 - Outcome
 - Study-outcome
 - Side-effect

- Ancillary-outcome
- Secondary-outcome
- Primary-outcome
- Baseline
- Outcome-value-entity
 - Regression-variable-value
 - Cox-variable
 - Other-value
 - Proportion-value
 - Continuous-value
 - Categorical-value
 - Count-value
- Result-entity
 - Subgroup-regression
 - Regression-analysis-and-results
 - Datapoint-entity
 - Summary-datapoint
 - Baseline-datapoint
 - Blinding-efficacy-datapoint
 - Kaplan-meier-datapoint
 - Generic-datapoint
 - Datapoint-of-pop
 - Datapoint-of-crossover-population
 - Cointervention-datapoint
 - Single-time-x-comparison
 - All-comparisons-at-time-x
 - Survival-analysis-and-results
 - Kaplan-meier-timepoint
 - Miscellaneous-outcome-entity
 - Range
 - Category
 - Outcome-assessment
 - Special-variable-information
 - Cost
 - Categorical
 - Scored-instrument
 - Life-year
 - Rate
 - Design-concept
 - Stopping-rule
 - Regression-analysis-and-results
 - Study-monitoring
 - Study-objective
 - Hypothesis-concept
 - Secondary-hypothesis
 - Primary-hypothesis
 - Trial-design
 - Sample-size-calculation
 - Statistical-analysis-and-results
 - Survival-analysis-and-results
 - Protocol-concept
 - Secondary-study-protocol
 - Executed-secondary-study-protocol

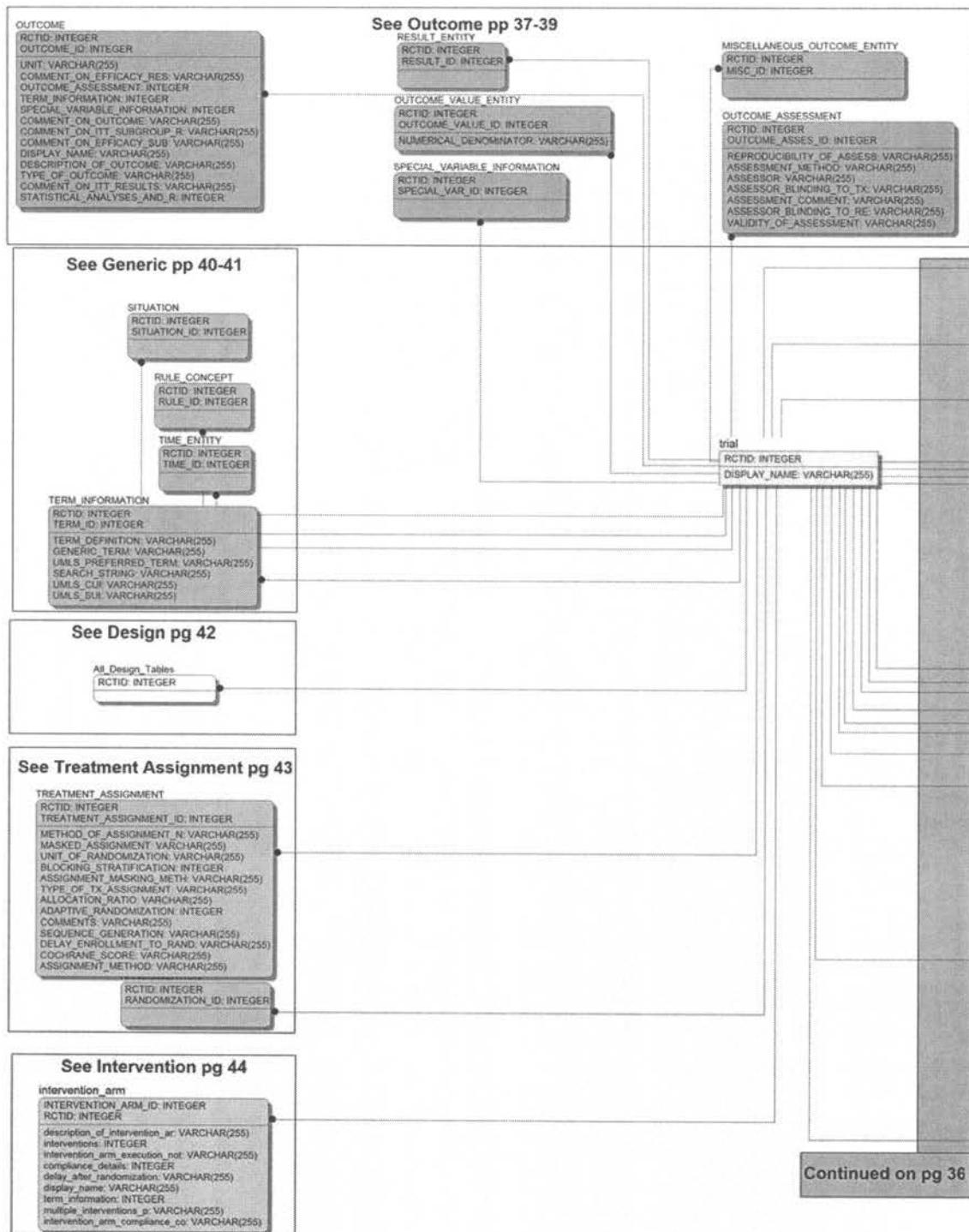
- Intended-secondary-study-protocol
- Outcomes-followup
- Reason
 - Withdrawal-reason
 - Reason-off-assigned-intervention
 - Reason-not-eligible
 - Reason-not-enrolled
 - Reason-not-randomized
 - Reason-excluded-postrand
 - Reason-outcome-not-assessed
- Protocol
 - Intended-protocol
 - Executed-protocol
- Protocol-change
- Follow-up
- Follow-up-activity
- Follow-up-compliance
- Treatment-assignment-concept
 - Treatment-assignment
 - Randomization
 - Fixed-randomization
 - Adaptive-randomization
- Population-concept
 - Site-enrollment
 - Recruitment
 - Population
 - Analyzed-population
 - Subgroup-population
 - Study-arm-population
 - Crossover-population
 - All-subjects
 - Excluded-population
 - Not-eligible-population
 - Not-enrolled-population
 - Not-randomized-population
 - Excluded-postrand-population
 - Recruited-population
 - Screened-population
 - Eligible-population
 - Enrolled-population
 - Randomized-population
 - Recruitment-flowchart
 - Primary-recruitment-flowchart
 - Subgroup
- Generic-concept
 - Situation
 - State
 - Non-concurrent-situations
 - Concurrent-situations
 - Event-entity
 - Regularly-recurring-event
 - Single-or-irregular-event
 - Rule-concept

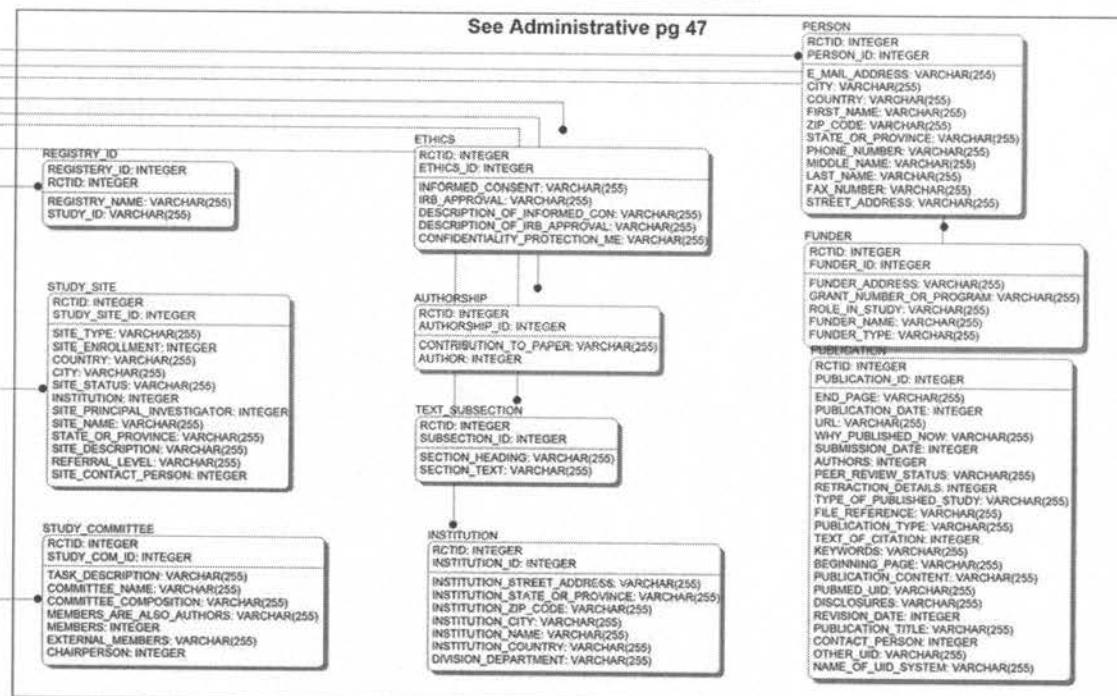
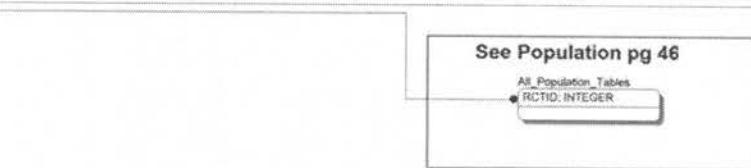
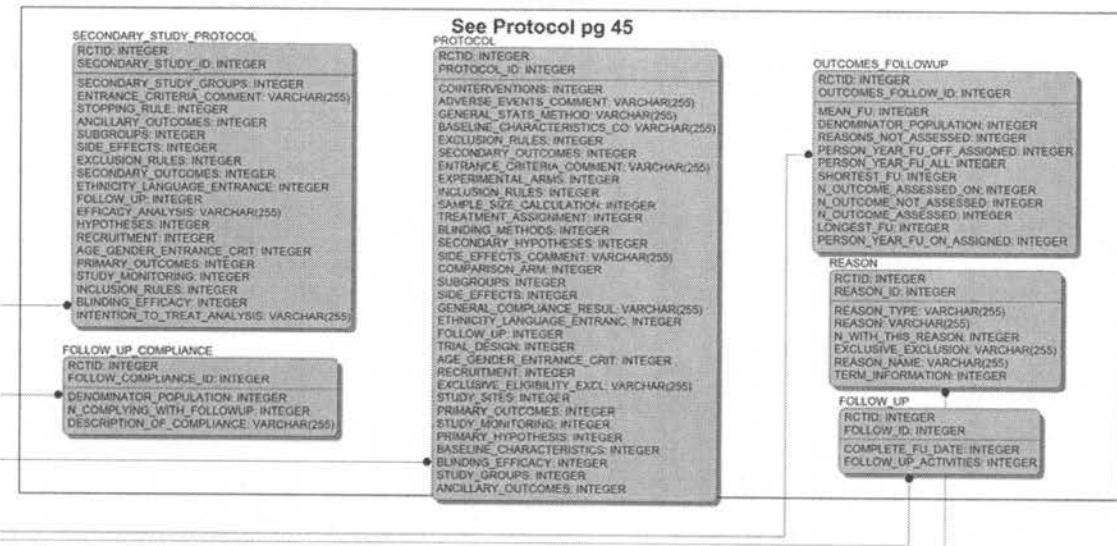
- Age-gender-rule
- Ethnicity-language-rule
- Rule-entity
 - Base-rule
 - Recursive-rule
- Clinical-rule
 - Inclusion-rule
 - Exclusion-rule
- Time-entity
 - Date
 - Time-range
 - Duration
 - Fuzzy-duration
 - Interval
 - Single-anchored-interval
 - Double-anchored-interval
 - Anchored-time
 - Timepoint
 - Interval
 - Single-anchored-interval
 - Double-anchored-interval
 - Term-information
- Trial
- Trial-details
 - Fraud-details
 - Correction-details
 - Retraction-details
 - Stopping-details
 - Background-details
 - Conclusion-details
 - Administrative-details
 - Primary-administrative-details
 - Secondary-administrative-details
 - Trial-entry-details
 - Publication-details
 - Erratum
- Secondary-study

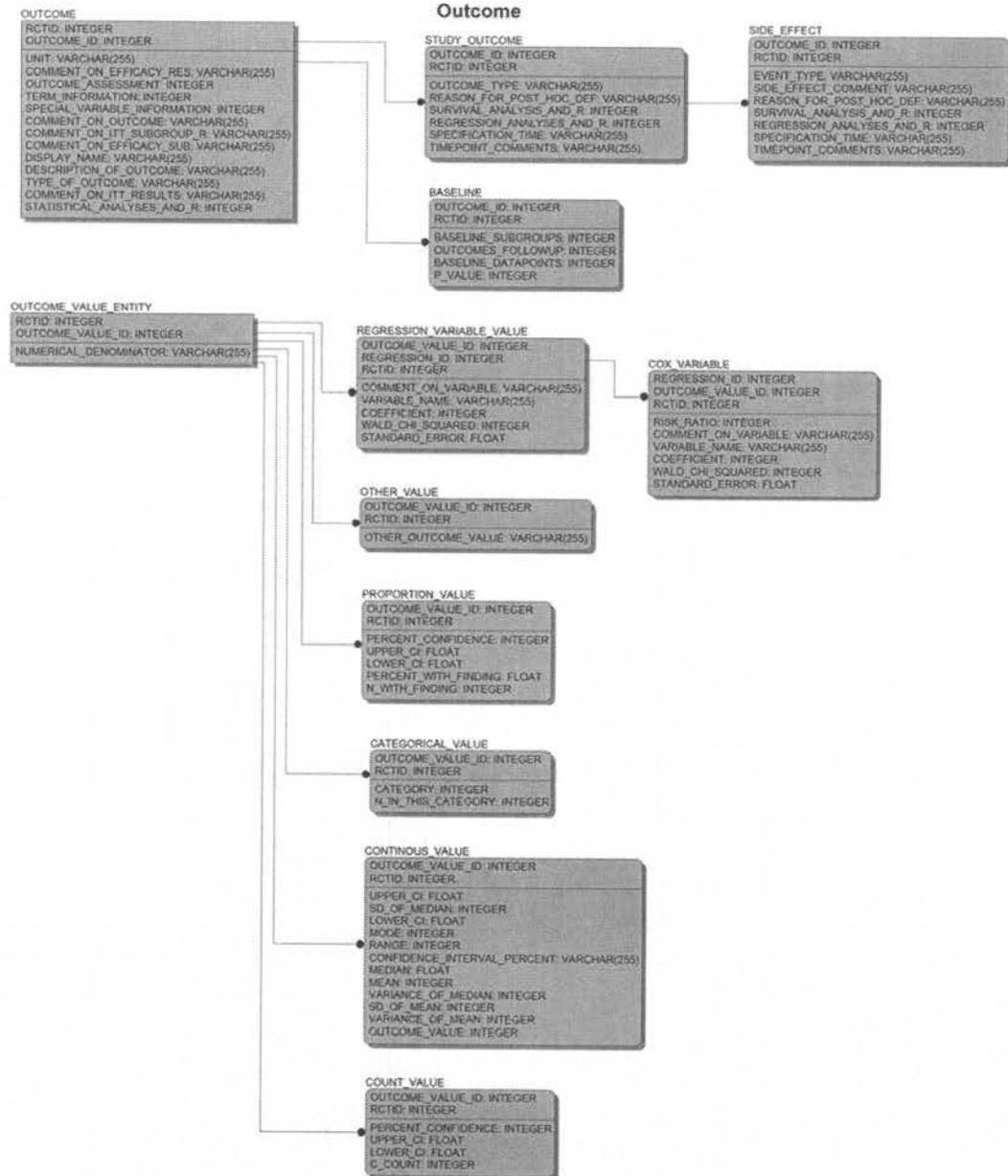
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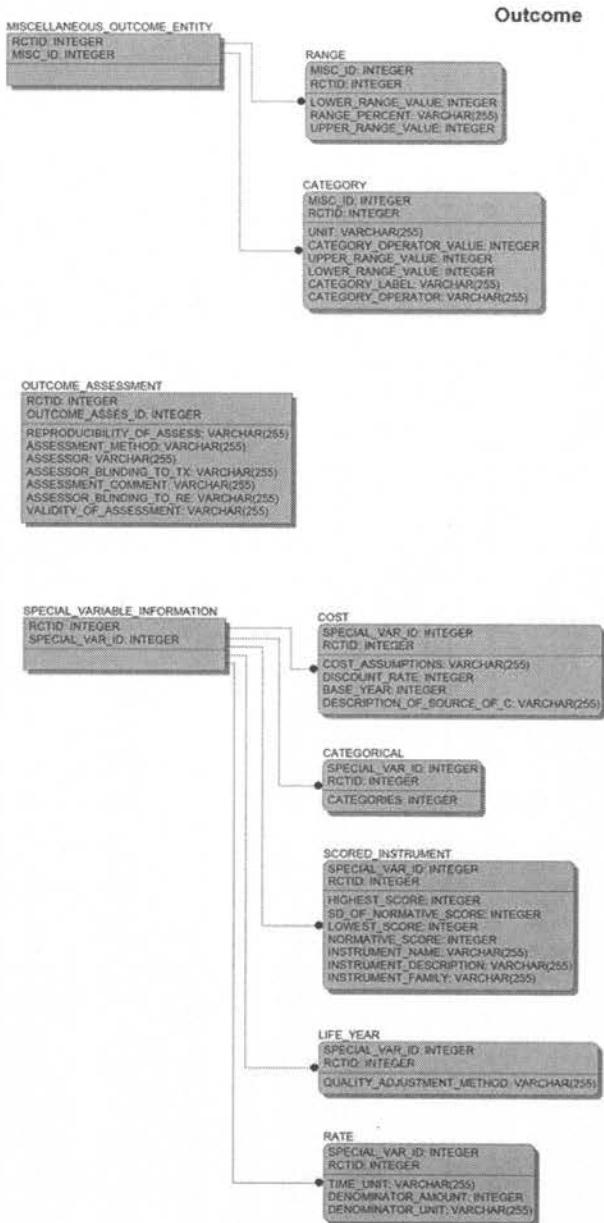
APPENDIX B**DATABASE SCHEMA**

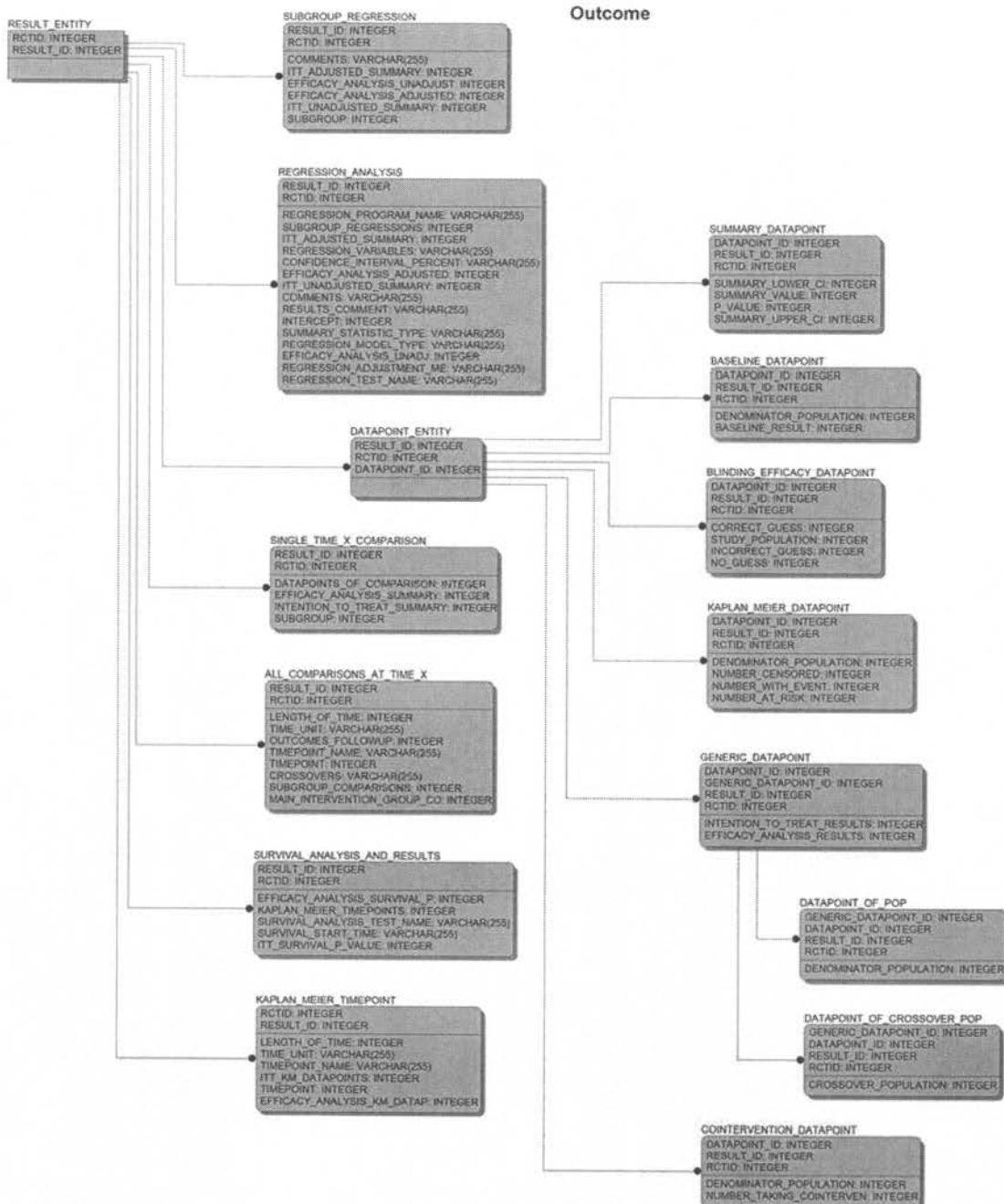
This schema was generated from the data dictionary found in Appendix C. It represents the data model used in the development of the Web service and is a modification of the original RCT ontology source in Appendix A.

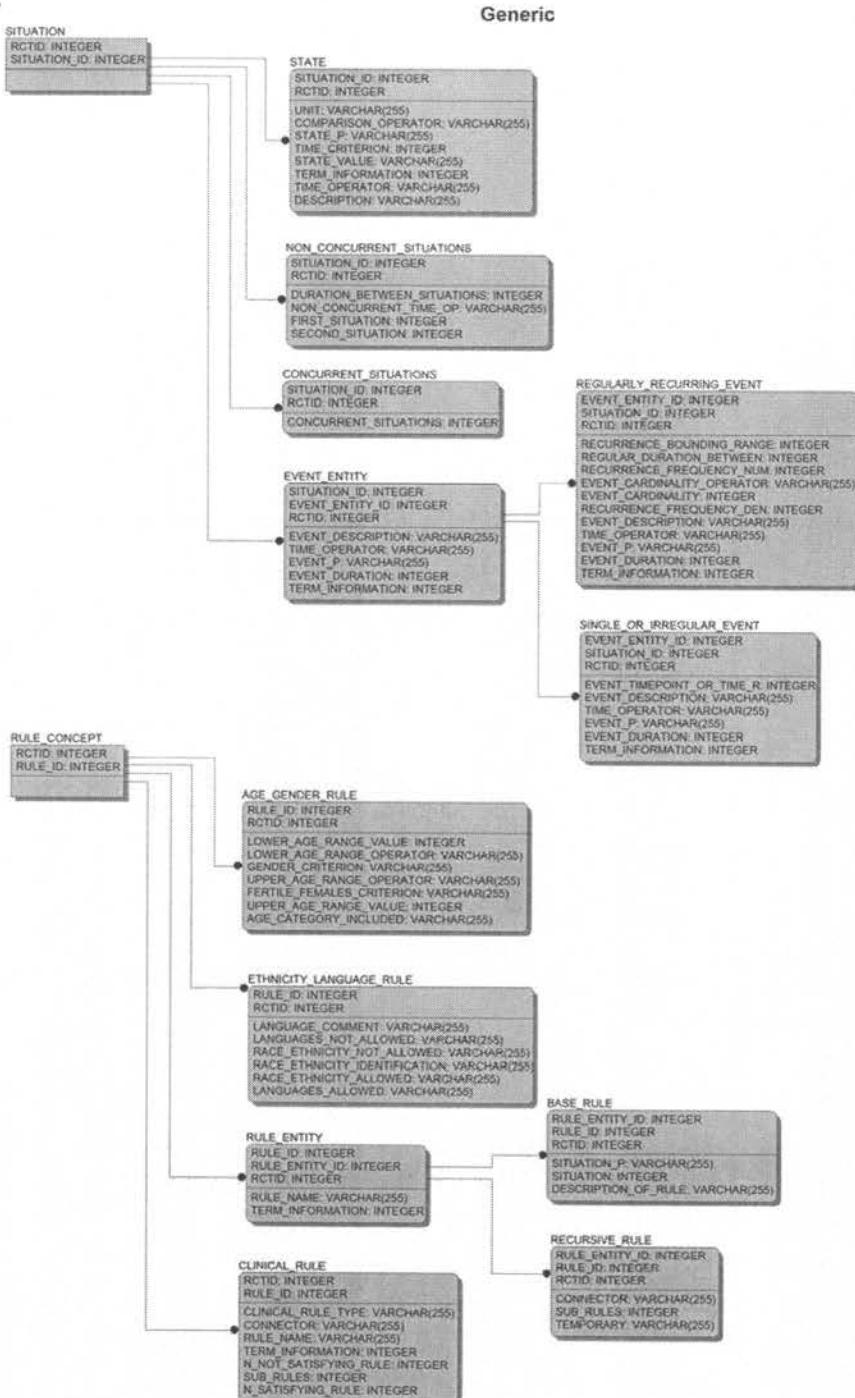


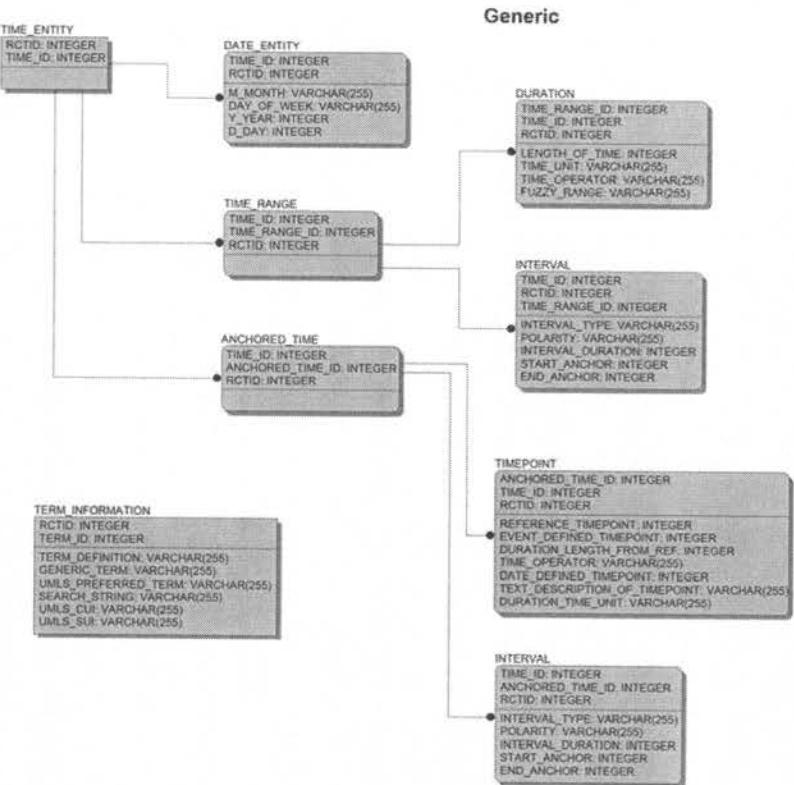






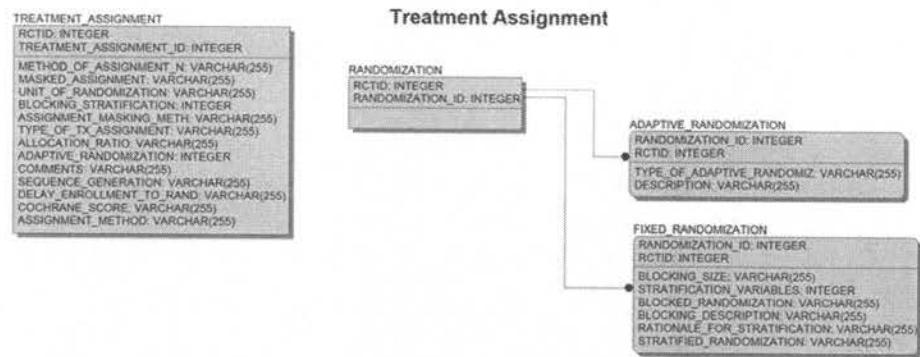


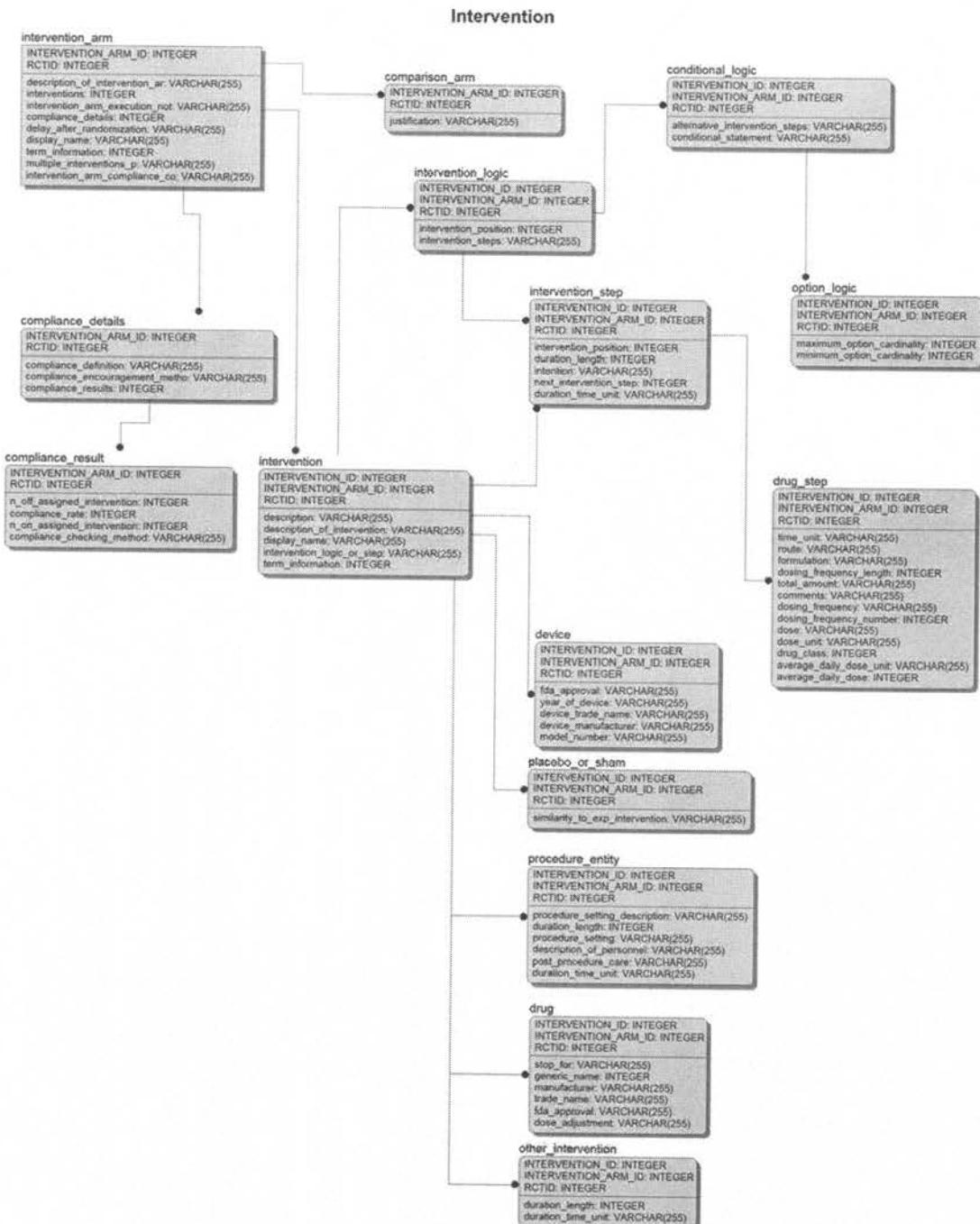


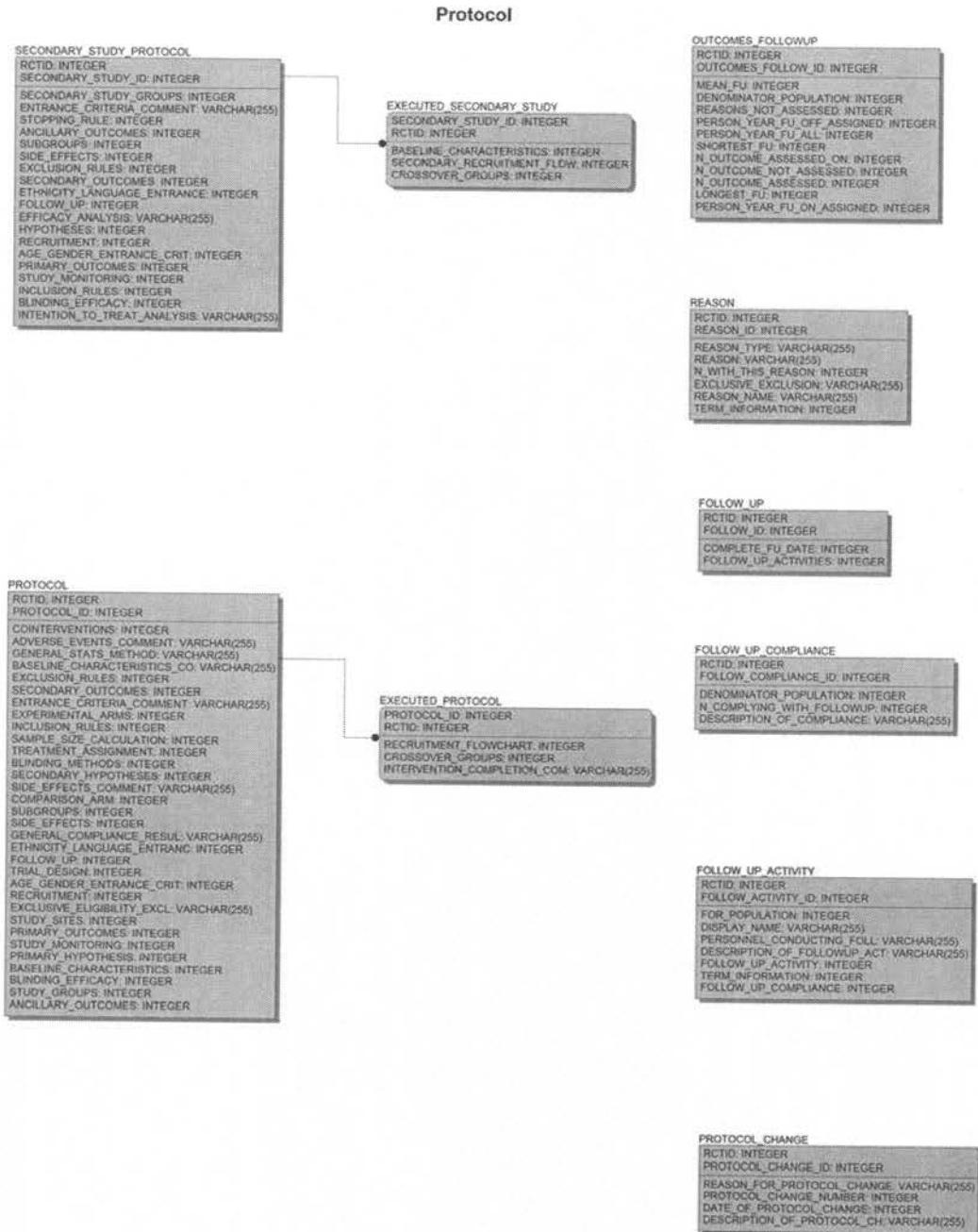


Design

<p>STOPPING_RULE</p> <pre>RCTID: INTEGER STOPPING_RULE_ID: INTEGER WHEN_STOPPING_RULE_DEFINED: VARCHAR(255) STOPPING_RULE_DESCRIPTION: VARCHAR(255)</pre>	<p>TRIAL DESIGN</p> <pre>RCTID: INTEGER DESIGN_ID: INTEGER LOSS_HANDLING: VARCHAR(255) DEFINITION_OF_INTENTION_TO_TREAT: VARCHAR(255) STOPPING_RULE: INTEGER BAYESIAN_OR_CLASSICAL: VARCHAR(255) NURSE_BLINDING: INTEGER PROVIDER_BLINDING: INTEGER DEFINITION_OF_EFFICACY_ANA: VARCHAR(255) INVESTIGATOR_BLINDING: INTEGER SUBJECT_BLINDING: INTEGER ALLOCATOR_BLINDING: INTEGER EFFICACY_ANALYSIS: VARCHAR(255) TYPE_OF_TRIAL_DESIGN: VARCHAR(255) INTENTION_TO_TREAT_ANALYSIS: VARCHAR(255)</pre>
<p>D_REGRESSION_ANALYSIS</p> <pre>RCTID: INTEGER DESIGN_REGRESSION_ID: INTEGER REGRESSION_PROGRAM_NAME: VARCHAR(255) SUBGROUP_REGRESSIONS: INTEGER ITT_ADJUSTED_SUMMARY: INTEGER REGRESSION_VARIABLES: VARCHAR(255) CONFIDENCE_INTERVAL_PERCENT: VARCHAR(255) EFFICACY_ANALYSIS_ADJUSTED: INTEGER ITT_UNADJUSTED_SUMMARY: INTEGER COMMENTS: VARCHAR(255) RESULTS_COMMENT: VARCHAR(255) INTERCEPT: INTEGER SUMMARY_STATISTIC_TYPE: VARCHAR(255) REGRESSION_MODEL_TYPE: VARCHAR(255) EFFICACY_ANALYSIS_UNADJUSTED: INTEGER REGRESSION_ADJUSTMENT_MET: VARCHAR(255) REGRESSION_TEST_NAME: VARCHAR(255)</pre>	<p>SAMPLE_SIZE_CALCULATION</p> <pre>RCTID: INTEGER SAMPLE_SIZE_ID: INTEGER JUSTIFICATION_FOR_ONE_TAILED: VARCHAR(255) ASSUMPTIONS_UNDERLYING_TAR: VARCHAR(255) THRESHOLD_RATE_RATIONALE: VARCHAR(255) REFERENT_OUTCOME: INTEGER SAMPLE_SIZE_CALCULATION_M: VARCHAR(255) COMMENTS: VARCHAR(255) ALPHA_TAILS: VARCHAR(255) ALPHA_VALUE: INTEGER P_POWER: INTEGER BASELINE_RATIONALE: VARCHAR(255) BASELINE_COMPARISON_GROUP: VARCHAR(255) THRESHOLD_EXP_GROUP_OUT: VARCHAR(255) TARGET_SAMPLE_SIZE: INTEGER TARGET_ENROLLMENT: INTEGER</pre>
<p>STUDY_MONITORING</p> <pre>RCTID: INTEGER STUDY_MONITORING_ID: INTEGER RECOMMENDATIONS_PROCEDURE: VARCHAR(255) MONITORING_SCHEDULE: VARCHAR(255) MONITORING_METHOD: VARCHAR(255) MONITORING_BLINDING: VARCHAR(255)</pre>	<p>D_STATISTICAL_ANALYSIS</p> <pre>RCTID: INTEGER DESIGN_STATISTICAL_ID: INTEGER JUSTIFICATION_FOR_ONE_TAILED: VARCHAR(255) NUMBER_OF_TAILS: VARCHAR(255) WHETHER_TEST_ASSUMPTIONS: VARCHAR(255) PROGRAM_NAME: VARCHAR(255) STATISTICIAN_TEST_NAME: VARCHAR(255) OTHER_NOTES: VARCHAR(255) PARAMETRIC_WILCOXON: INTEGER CONFIDENCE_INTERVAL_PERCENT: VARCHAR(255) JUSTIFICATION_FOR_STATISTICAL: VARCHAR(255) CENSORING_APPROACH: VARCHAR(255) SUMMARY_STATISTIC_TYPE: VARCHAR(255) JUSTIFICATION_FOR_TRANSFORMA: VARCHAR(255) REPEATED_MEASURES_ADJUST: VARCHAR(255) RESULTS: INTEGER P_LEVEL_THRESHOLD: INTEGER DIFFERENCE_SCORE: VARCHAR(255) DIFFERENCE_SCORE_RESULTS: INTEGER</pre>
<p>HYPOTHESIS_CONCEPT</p> <pre>RCTID: INTEGER HYPOTHESIS_ID: INTEGER HYPOTHESIS_TYPE: VARCHAR(255) HYPOTHESIS_VARIABLE: VARCHAR(255) SPECIFICATION_TIME: VARCHAR(255) STATEMENT_OF_HYPOTHESIS: VARCHAR(255)</pre>	<p>D_SURVIVAL_ANALYSIS</p> <pre>RCTID: INTEGER DESIGN_SURVIVAL_ID: INTEGER KAPLAN_MEIER_TIMEPOINTS: INTEGER SURVIVAL_ANALYSIS_TEST_NAME: VARCHAR(255) EFFICACY_ANALYSIS_SURVIVAL_P: INTEGER SURVIVAL_START_TIME: VARCHAR(255) ITTSURVIVAL_P_VALUE: INTEGER</pre>







Population

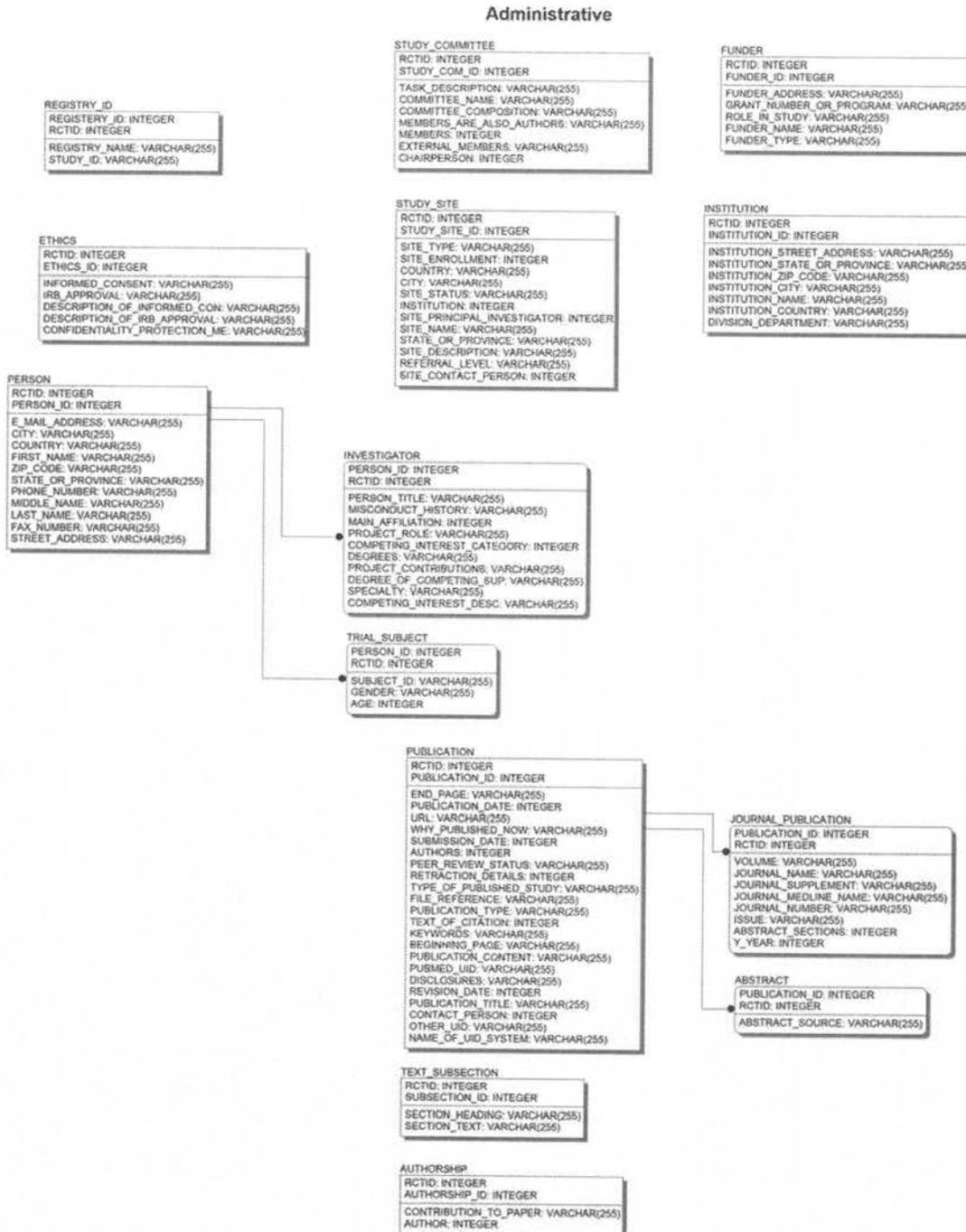
```
SITE_ENROLLMENT
RCTID: INTEGER
SITE_ENROLLMENT_ID: INTEGER
FOR_STUDY: INTEGER
ENROLLMENT_END_DATE: INTEGER
ENROLLMENT_START_DATE: INTEGER
TOTAL_ENROLLED: INTEGER
```

```
RECRUITMENT
RCTID: INTEGER
RECRUITMENT_ID: INTEGER
COMMENTS: VARCHAR(255)
METHOD_OF_RECRUITMENT: FLOAT
SOURCE_OF_REFERRAL: VARCHAR(255)
SOURCE_DESCRIPTION: VARCHAR(255)
METHOD_OF_RECRUITMENT: VARCHAR(255)
ENROLLMENT_END_DATE: INTEGER
ENROLLMENT_START_DATE: INTEGER
WHY_RECRUITMENT_GONE_NOT_VARCHAR(255)
```

```
PRIMARY RECRUITMENT_FLOWCHART
RCTID: INTEGER
RECRUITMENT_FLOW_ID: INTEGER
RANDOMIZED_POPULATION: INTEGER
NOT_ENROLLED_POPULATION: INTEGER
NOT_ELIGIBLE_POPULATION: INTEGER
EXCLUDED_POSTRAND_POP: INTEGER
ALL_SUBJECTS: INTEGER
SCREENED_POPULATION: INTEGER
ENROLLED_POPULATION: INTEGER
ELIGIBLE_POPULATION: INTEGER
```

```
POPULATION
RCTID: INTEGER
POPULATION_ID: INTEGER
POPULATION_TYPE: INTEGER
POPULATION_SUBTYPE: VARCHAR(255)
INDIVIDUAL_MEMBERS: INTEGER
POPULATION_DESCRIPTION: VARCHAR(255)
POPULATION_AGE: INTEGER
NUMBER_OF FEMALES: INTEGER
NUMBER_OF MALES: INTEGER
POPULATION_NAME: VARCHAR(255)
NUMBER_OF SUBJECTS: INTEGER
SUBGROUP_ID: INTEGER
STUDY_ASSIGNED_ARM: INTEGER
CROSSOVER_REFERENCE_TIMEP: INTEGER
CROSSOVER_FROM_WHICH_ARM: INTEGER
CROSSOVER_TO_WHICH_ARM: INTEGER
CROSSOVER_DURATION_SINCE_REF: INTEGER
ALL_P_OF_GENDER: INTEGER
ALL_P_OF_AGE: INTEGER
REASONS_EXCLUDED: VARCHAR(255)
EXCLUDED_POSTRAND_DENOM: INTEGER
```

```
SUBGROUP
RCTID: INTEGER
SUBGROUP_ID: INTEGER
SUBGROUP_POPULATIONS: INTEGER
SUBGROUP_CRITERION: INTEGER
DISPLAY_NAME: VARCHAR(255)
P_VALUE: INTEGER
RATIONALE_FOR_POST_HOC_DEF: VARCHAR(255)
TERM_INFORMATION: INTEGER
SUBGROUP_DEFINITION: VARCHAR(255)
SPECIFICATION_TIME: VARCHAR(255)
```



APPENDIX C
DATA DICTIONARY

This dictionary is a modification of the original RCT ontology dictionary found at <http://rctbank.ucsf.edu/ontology/index.htm>. These data elements were used in the development of the Web service.

Concept	Table	Data Element	Description	Data Type
Administrative	Registry_id	RCTID		INTEGER
Administrative	Registry_id	REGISTRY_ID		INT
Administrative	Registry_id	registry_name	"Name of the registry for which this study was registered with this study-id."	[undefined]
Administrative	Registry_id	study_id		STRING
Administrative	Institution	RCTID		INTEGER
Administrative	Institution	INSTITUTION_ID		INT
Administrative	Institution	institution_street_address		STRING
Administrative	Institution	institution_state_or_province		SYMBOL
Administrative	Institution	institution_zip_code		STRING
Administrative	Institution	institution_city		STRING
Administrative	Institution	institution_name		STRING
Administrative	Institution	institution_country		SYMBOL
Administrative	Institution	division_department	"A string describing the Division and/or Department affiliation(s) at this institution. e.g., -Division of General Internal Medicine, Department of Medicine, and the Institute for Health Policy Studies-"	STRING
Administrative	Funder	RCTID		INTEGER
Administrative	Funder	FUNDER_ID		INT
Administrative	Funder	funder_address		STRING
Administrative	Funder	grant_number_or_program	"The grant number or the name of the grant program funding this study."	STRING
Administrative	Funder	role_in_study	"The funder-s role in reviewing, interpreting, and reporting results."	STRING
Administrative	Funder	funder_name		STRING
Administrative	Funder	funder_type	"The type of funder."	SYMBOL
Administrative	Study_committee	RCTID		INTEGER
Administrative	Study_committ	STUDY_COM_ID		INT

	ee			
Administrative	Study_committ ee	task_description		STRING
Administrative	Study_committ ee	committee_name		STRING
Administrative	Study_committ ee	committee_composition		STRING
Administrative	Study_committ ee	members_are_also_authors	"Whether some members of this committee are also authors of the reporting paper(s)."	SYMBOL
Administrative	Study_committ ee	members		Instance
Administrative	Study_committ ee	external_members	"Names of committee members who are not investigators of this study."	STRING
Administrative	Study_committ ee	chairperson	"chairman of the steering committee"	Instance
Administrative	Ethics	RCTID		INTEGER
Administrative	Ethics	ETHICS_ID		INTEGER
Administrative	Ethics	informed_consent		SYMBOL
Administrative	Ethics	irb_approval		SYMBOL
Administrative	Ethics	description_of_informed_con		STRING
Administrative	Ethics	description_of_irb_approval	"Description of Institutional Review Board approval."	STRING
Administrative	Ethics	confidentiality_protection_me		STRING
Administrative	Person	RCTID		INTEGER
Administrative	Person	PERSON_ID		INT
Administrative	Person	e_mail_address		STRING
Administrative	Person	city		STRING
Administrative	Person	country		SYMBOL
Administrative	Person	first_name		STRING
Administrative	Person	zip_code		STRING
Administrative	Person	state_or_province		SYMBOL
Administrative	Person	phone_number		STRING
Administrative	Person	middle_name		STRING
Administrative	Person	last_name		STRING
Administrative	Person	fax_number		STRING
Administrative	Person	street_address		STRING
Administrative	Investigator	PERSON_ID		INT
Administrative	Investigator	person_title	"For example, Department Chair"	STRING

Administrative	Investigator	misconduct_history	"Details of any past findings of misconduct for this investigator."	STRING
Administrative	Investigator	main_affiliation	"The main institutional affiliation of this investigator."	Instance
Administrative	Investigator	project_role	"The one selection that best describes the role of this investigator for this study. Actual contributions are detailed under the slot [project-contributions]."	SYMBOL
Administrative	Investigator	competing_interest_category	"investigator has 1 = no relationship with the sponsor of the trial or with another company; 2 = has a personal financial relationship with the sponsor of the trial or with another company; 3 = receives research support for his or her laboratory from the sponsor of the trial or from another company; 4 = is a paid employee of a company or of a not-for-profit organization (from Alpert, JS et al. Arch Int Med 162(6))"	Instance
Administrative	Investigator	degrees	"Takes a single string value from the choice list below."	SYMBOL
Administrative	Investigator	project_contributions	"Contributions of this investigator to this study, categories taken from Instructions to Author of the	SYMBOL

			Annals of Internal Medicine. "	
Administrative	Investigator	degree_of_competing_sup	"For cash and/or stock options per year: minor <\$5000, moderate \$5001-\$25,000; major over \$25,000"	SYMBOL
Administrative	Investigator	specialty	"Specialty of investigator"	SYMBOL
Administrative	Investigator	competing_interest_desc	"Description of conflict of interest."	STRING
Administrative	Trial_subject	PERSON_ID		INT
Administrative	Trial_subject	subject_id		STRING
Administrative	Trial_subject	gender		SYMBOL
Administrative	Trial_subject	age	"Age of this trial subject"	[undefined]
Administrative	Study_site	RCTID		INTEGER
Administrative	Study_site	STUDY_SITE_ID		INT
Administrative	Study_site	site_type	"see health care facilities twistdown tree on MeSH browser at nlm.nih.gov"	SYMBOL
Administrative	Study_site	site_enrollment	"Start and end date, and numbers enrolled in this site."	Instance
Administrative	Study_site	country		SYMBOL
Administrative	Study_site	city		STRING
Administrative	Study_site	site_status		SYMBOL
Administrative	Study_site	institution		Instance
Administrative	Study_site	site_principal_investigator	"Only one principal investigator per site. This person must also be a study investigator."	Instance
Administrative	Study_site	site_name		STRING
Administrative	Study_site	state_or_province		SYMBOL
Administrative	Study_site	site_description	"Textual description of a site, its payment type, patient population, etc."	STRING
Administrative	Study_site	referral_level	"*** May have more than one referral level."	SYMBOL
Administrative	Study_site	site_contact_person	"Assumes the study site contact person is an	Instance

			investigator."	
Administrative	Publication	RCTID		INTEGER
Administrative	Publication	PUBLICATION_ID		INT
Administrative	Publication	end_page		STRING
Administrative	Publication	publication_date		Instance
Administrative	Publication	url	"The web address to a public version of this paper, e.g., to its abstract."	STRING
Administrative	Publication	why_published_now		STRING
Administrative	Publication	submission_date		Instance
Administrative	Publication	authors		Instance
Administrative	Publication	peer_review_status		SYMBOL
Administrative	Publication	retraction_details		Instance
Administrative	Publication	type_of_published_study	****Should be the same tags as for MeSH."	SYMBOL
Administrative	Publication	file_reference		STRING
Administrative	Publication	publication_type		SYMBOL
Administrative	Publication	text_of_citation		Instance
Administrative	Publication	keywords	"Keywords for topic of trial"	STRING
Administrative	Publication	beginning_page		STRING
Administrative	Publication	publication_content		SYMBOL
Administrative	Publication	pubmed_uid		STRING
Administrative	Publication	disclosures	"Financial or other conflicts of interests"	STRING
Administrative	Publication	revision_date		Instance
Administrative	Publication	publication_title		STRING
Administrative	Publication	contact_person		Instance
Administrative	Publication	other_uid		STRING
Administrative	Publication	name_of_uid_system		STRING
Administrative	Journal_publication	PUBLICATION_ID		INT
Administrative	Journal_publication	volume		STRING
Administrative	Journal_publication	journal_name		STRING
Administrative	Journal_publication	journal_supplement		STRING
Administrative	Journal_publication	journal_medline_name		SYMBOL
Administrative	Journal_publication	journal_number		STRING
Administrative	Journal_publication	issue		STRING
Administrative	Journal_publication	abstract_sections		Instance
Administrative	Journal_publication	y_year		INTEGER
Administrative	Abstract	PUBLICATION_ID		INT

Administrative	Abstract	abstract_source		STRING
Administrative	Text_subsection	RCTID		INTEGER
Administrative	Text_subsection	SUBSECTION_ID		INT
Administrative	Text_subsection	section_heading		STRING
Administrative	Text_subsection	section_text		STRING
Administrative	Authorship	RCTID		INTEGER
Administrative	Authorship	AUTHORSHIP_ID		INT
Administrative	Authorship	contribution_to_paper	"From Annals of Internal Medicine, Author Form (http://www.annals.org/shared/author_form.html)"	[undefined]
Administrative	Authorship	author		Instance
Outcome	Outcome	RCTID		INTEGER
Outcome	Outcome	OUTCOME_ID		INT
Outcome	Outcome	unit	"The unit of the outcome value, e.g., feet or mmHg. Should come from a controlled vocabulary."	STRING
Outcome	Outcome	comment_on_efficacy_res		STRING
Outcome	Outcome	outcome_assessment	"Details about the assessment of this outcome."	Instance
Outcome	Outcome	term_information	"Pointer to a UMLS preferred term or terms, if available, that capture the major clinical concepts in this data class (e.g, diabetes mellitus)."	Instance
Outcome	Outcome	special_variable_information	"Points to additional information relevant to special classes of variables (e.g., discount rate for cost variables)"	Instance
Outcome	Outcome	comment_on_outcome	"Comment on selection, importance, etc. of outcome "	STRING
Outcome	Outcome	comment_on_itt_subgroup_r		STRING

Outcome	Outcome	comment_on_efficacy_sub		STRING
Outcome	Outcome	display_name	"A -pretty name-for referring to this intervention arm. May be - Anti-coagulation- or -Control-, for example. This name may or may not be identical to the UMLS term for the intervention. "	STRING
Outcome	Outcome	description_of_outcome	"Text definition of this outcome."	STRING
Outcome	Outcome	type_of_outcome	Study, baseline, side-effect	SYMBOL
Outcome	Outcome	comment_on_itt_results		STRING
Outcome	Outcome	statistical_analyses_and_r	"Pointer to the description of how this outcome will be statistically analyzed."	Instance
Outcome	Study_outcome	OUTCOME_ID		INT
Outcome	Study_outcome	outcome_type	Primary, Secondary, Ancillary	STRING
Outcome	Study_outcome	reason_for_post_hoc_def	"If this outcome was specified post-hoc, describe why this outcome was defined post-hoc."	STRING
Outcome	Study_outcome	survival_analysis_and_r		Instance
Outcome	Study_outcome	regression_analyses_and_r	"Details about the regression analysis done on this outcome."	Instance
Outcome	Study_outcome	specification_time		SYMBOL
Outcome	Study_outcome	timepoint_comments	"Comments on the definition of timepoints, e.g., how -hospital discharge- was defined. "	STRING
Outcome	Side_effect	OUTCOME_ID		INT
Outcome	Side_effect	event_type	"Side effects are known problems that some subjects encounter from the intervention. Adverse events	SYMBOL

			are unexpected events or effects."	
Outcome	Side_effect	side_effect_comment	"Any comments on this side effect or adverse event."	STRING
Outcome	Side_effect	reason_for_post_hoc_def	"If this outcome was specified post-hoc, describe why this outcome was defined post-hoc."	STRING
Outcome	Side_effect	survival_analysis_and_r		Instance
Outcome	Side_effect	regression_analyses_and_r	"Details about the regression analysis done on this outcome."	Instance
Outcome	Side_effect	specification_time		SYMBOL
Outcome	Side_effect	timepoint_comments	"Comments on the definition of timepoints, e.g., how -hospital discharge- was defined."	STRING
Outcome	Baseline	OUTCOME_ID		INT
Outcome	Baseline	baseline_subgroups	"Points to subgroups within this baseline characteristic. e.g., of those with CHF, those with EF <35% and those with EF >35%."	Instance
Outcome	Baseline	outcomes_followup	"Points to class with number of subjects off their assigned intervention at this timepoint, for each study-arm-population, with the reasons for their withdrawal."	Instance
Outcome	Baseline	baseline_datapoints	"The value of this baseline characteristic among different study populations."	Instance
Outcome	Baseline	p_value	"Enter as (--- 0.975-)"	INTEGER

Outcome	Outcome_value_entity	RCTID		INTEGER
Outcome	Outcome_value_entity	OUTCOME_VALUE_ID		INT
Outcome	Outcome_value_entity	numerical_denominator	"States the number of subjects to which this outcome value applies to. In many cases, this number is the denominator to be used for this result, and may refer to actual numbers of persons or person-years of followup for e.g., assessed subjects on intervention. The actual value of the denominator is in the DATAPPOINT instance of which this instance is a slot value. For rate values, this number is the number of subjects in whom the rate was determined (e.g., the slot value is 572 for -a death rate of 0.5 per 100 person years assesed in 572 subjects who had death assesed at this timepoint and were on their assigned intervention-)."	SYMBOL
Outcome	Regression_variable_value	OUTCOME_VALUE_ID		INTEGER
Outcome	Regression_variable_value	REGRESSION_ID		INTEGER
Outcome	Regression_variable_value	comment_on_variable		STRING
Outcome	Regression_variable_value	variable_name	"The (UMLS) name of this regression variable. "	STRING

Outcome	Regression_variable_value	coefficient		[undefined]
Outcome	Regression_variable_value	wald_chi_squared		[undefined]
Outcome	Regression_variable_value	standard_error		FLOAT
Outcome	Cox_variable	REGRESSION_ID		INTEGER
Outcome	Cox_variable	risk_ratio		[undefined]
Outcome	Cox_variable	comment_on_variable		STRING
Outcome	Cox_variable	variable_name	"The (UMLS) name of this regression variable."	STRING
Outcome	Cox_variable	coefficient		[undefined]
Outcome	Cox_variable	wald_chi_squared		[undefined]
Outcome	Cox_variable	standard_error		FLOAT
Outcome	Other_value	OUTCOME_VALUE_ID		INTEGER
Outcome	Other_value	other_outcome_value	"For any kind of datapoint value."	STRING
Outcome	Proportion_value	OUTCOME_VALUE_ID		INTEGER
Outcome	Proportion_value	percent_confidence		[undefined]
Outcome	Proportion_value	upper_ci		FLOAT
Outcome	Proportion_value	lower_ci		FLOAT
Outcome	Proportion_value	percent_with_finding		FLOAT
Outcome	Proportion_value	n_with_finding		INTEGER
Outcome	Continous_value	OUTCOME_VALUE_ID		INTEGER
Outcome	Continous_value	upper_ci		FLOAT
Outcome	Continous_value	sd_of_median		INTEGER
Outcome	Continous_value	lower_ci		FLOAT
Outcome	Continous_value	mode		INTEGER
Outcome	Continous_value	range		Instance
Outcome	Continous_value	confidence_interval_percent		SYMBOL
Outcome	Continous_value	median		FLOAT
Outcome	Continous_value	mean		INTEGER
Outcome	Continous_value	variance_of_median		INTEGER
Outcome	Continous_value	sd_of_mean		INTEGER
Outcome	Continous_value	variance_of_mean		INTEGER

	e			
Outcome	Continous_value	outcome_value	"The continuous value itself."	INTEGER
Outcome	Categorical_value	OUTCOME_VALUE_ID		INTEGER
Outcome	Categorical_value	category		Instance
Outcome	Categorical_value	n_in_this_category	"The number of subjects in the category CATEGORY for this population and timepoint."	INTEGER
Outcome	Count_value	OUTCOME_VALUE_ID		INTEGER
Outcome	Count_value	percent_confidence		[undefined]
Outcome	Count_value	upper_ci		FLOAT
Outcome	Count_value	lower_ci		FLOAT
Outcome	Count_value	c_count		INTEGER
Outcome	Result_entity	RCTID		INTEGER
Outcome	Result_entity	RESULT_ID		INTEGER
Outcome	Subgroup_regression	RESULT_ID		INTEGER
Outcome	Subgroup_regression	comments		STRING
Outcome	Subgroup_regression	itt_adjusted_summary	"The adjusted intention-to-treat summary result of this regression."	Instance
Outcome	Subgroup_regression	efficacy_analysis_unadjusted	"The efficacy analysis summary result of the regression unadjusted for said variables."	Instance
Outcome	Subgroup_regression	efficacy_analysis_adjusted	"The efficacy analysis summary result of the regression adjusted for said variables."	Instance
Outcome	Subgroup_regression	itt_unadjusted_summary	"The unadjusted intention-to-treat summary result of this regression."	Instance
Outcome	Subgroup_regression	subgroup	"The subgroup for which this comparison stores data."	Instance
Outcome	Regression_analysis	RESULT_ID		INTEGER
Outcome	Regression_analysis	regression_program_name		STRING

Outcome	Regression_analysis	subgroup_regressions	"Results of this regression analysis in different subgroups."	Instance
Outcome	Regression_analysis	itt_adjusted_summary	"The adjusted intention-to-treat summary result of this regression."	Instance
Outcome	Regression_analysis	regression_variables	"List of the variables in the regression model. Could/should be UMLS terms in the future."	STRING
Outcome	Regression_analysis	confidence_interval_percent		SYMBOL
Outcome	Regression_analysis	efficacy_analysis_adjusted	"The efficacy analysis summary result of the regression adjusted for said variables."	Instance
Outcome	Regression_analysis	itt_unadjusted_summary	"The unadjusted intention-to-treat summary result of this regression."	Instance
Outcome	Regression_analysis	comments		STRING
Outcome	Regression_analysis	results_comment		STRING
Outcome	Regression_analysis	intercept		INTEGER
Outcome	Regression_analysis	summary_statistic_type	"Type of summary statistic. In STATISTICAL-ANALYSIS-AND-RESULTS and REGRESSION-ANALYSIS-AND-RESULTS, specifies the standard summary statistic used. In SUMMARY-DATAPOINT, other summary values (e.g., ARR in addition to OR) can also be provided."	SYMBOL

Outcome	Regression_analysis	regression_model_type		SYMBOL
Outcome	Regression_analysis	efficacy_analysis_unadj	"The efficacy analysis summary result of the regression unadjusted for said variables."	Instance
Outcome	Regression_analysis	regression_adjustment_me		[undefined]
Outcome	Regression_analysis	regression_test_name		SYMBOL
Outcome	Datapoint_entity	RESULT_ID		INTEGER
Outcome	Datapoint_entity	DATAPOINT_ID		INTEGER
Outcome	Summary_data_point	DATAPOINT_ID		INTEGER
Outcome	Summary_data_point	summary_lower_ci	"The lower confidence interval for this summary. The % interval is in confidence-interval-percent in STATISTICAL-ANALYSIS-AND-RESULTS for this outcome."	INTEGER
Outcome	Summary_data_point	summary_value	"The point estimate of the summary."	INTEGER
Outcome	Summary_data_point	p_value	"Enter as (--- 0.975-)"	INTEGER
Outcome	Summary_data_point	summary_upper_ci	"The upper confidence interval for this summary. The % interval is specified in slot [confidence-interval-percent] in STATISTICAL-ANALYSIS-AND-RESULTS."	INTEGER
Outcome	Baseline_datapoint	DATAPOINT_ID		INTEGER
Outcome	Baseline_datapoint	denominator_population	"The population on which this datapoint was assessed. E.g., the experimental group, or the subgroup of diabetics who were assigned	Instance

			the comparative intervention."	
Outcome	Baseline_datapoint	baseline_result	"The actual value of this baseline characteristic for this population."	Instance
Outcome	Blinding_efficacy_datapoint	DATAPOINT_ID		INTEGER
Outcome	Blinding_efficacy_datapoint	correct_guess	"Actual number of people in this blindee group who guessed the study population's assigned treatment correctly."	INTEGER
Outcome	Blinding_efficacy_datapoint	study_population	"The study population (experimental, control, overall, or subgroup) to which these data are applicable. If blank, assume it is for ALL-SUBJECTS."	Instance
Outcome	Blinding_efficacy_datapoint	incorrect_guess	"Actual number of people in this blindee group who guessed the study population's assigned treatment incorrectly."	INTEGER
Outcome	Blinding_efficacy_datapoint	no_guess	"The actual number of people in this blindee group who did not guess at the study population's assigned treatment."	INTEGER
Outcome	Kaplan_meier_datapoint	DATAPOINT_ID		INTEGER
Outcome	Kaplan_meier_datapoint	denominator_population	"The population on which this datapoint was assessed. E.g., the experimental group, or the subgroup of diabetics who were assigned the comparative intervention."	Instance
Outcome	Kaplan_meier_	number_censored	"Number of	INTEGER

	datapoint		patients censored at the beginning of the time interval; includes those who have been lost-to follow-up, who have died from causes other than that under study, or who were still alive at the end of the last interval."	
Outcome	Kaplan_meier_datapoint	number_with_event	"Number of people with the event, since the beginning of the time period until the end."	INTEGER
Outcome	Kaplan_meier_datapoint	number_at_risk	"Number of patients alive, and therefore at risk of the event, at the end of the time period"	INTEGER
Outcome	Generic_datapoint	DATAPOINT_ID		INTEGER
Outcome	Generic_datapoint	GENERIC_DATAPOINT_ID		INTEGER
Outcome	Generic_datapoint	intention_to_treat_results		Instance
Outcome	Generic_datapoint	efficacy_analysis_results		Instance
Outcome	Datapoint_of_pop	GENERIC_DATAPOINT_ID		INTEGER
Outcome	Datapoint_of_pop	denominator_population	"The population on which this datapoint was assessed. E.g., the experimental group, or the subgroup of diabetics who were assigned the comparative intervention. "	Instance
Outcome	Datapoint_of_crossover_pop	GENERIC_DATAPOINT_ID		INTEGER
Outcome	Datapoint_of_crossover_pop	crossover_population		Instance
Outcome	Cointervention_datapoint	DATAPOINT_ID		INTEGER
Outcome	Cointervention_datapoint	denominator_population	"The population on which this datapoint was	Instance

			assessed. E.g., the experimental group, or the subgroup of diabetics who were assigned the comparative intervention. "	
Outcome	Cointervention_datapoint	number_taking_cointerven	"The number of people in this population taking this cointervention."	INTEGER
Outcome	Single_time_x_comparison	RESULT_ID		INTEGER
Outcome	Single_time_x_comparison	datapoints_of_comparison	"Right now, does not handle kaplan-meier or crossover population datapoints."	Instance
Outcome	Single_time_x_comparison	efficacy_analysis_summary	"Pointers to summary statistics for this analysis. Could have more than one summary, e.g., an OR, an ARR."	Instance
Outcome	Single_time_x_comparison	intention_to_treat_summary	"Pointers to summary statistics for this analysis."	Instance
Outcome	Single_time_x_comparison	subgroup	"The subgroup for which this comparison stores data."	Instance
Outcome	All_comparisons_at_time_x	RESULT_ID		INTEGER
Outcome	All_comparisons_at_time_x	length_of_time		INTEGER
Outcome	All_comparisons_at_time_x	time_unit	"Unit of time for various uses. For DRUG-STEP, refers to time-unit of dosing frequency."	SYMBOL
Outcome	All_comparisons_at_time_x	outcomes_followup	"Points to class with number of subjects off their assigned intervention at this timepoint, for each study-arm-population, with the reasons for	Instance

			their withdrawal."	
Outcome	All_comparisons_at_time_x	timepoint_name	"Name of this timepoint, e.g., 6 months."	STRING
Outcome	All_comparisons_at_time_x	timepoint	"The machine-interpretable definition of when this comparison was assessed, expressed as a TIMEPOINT."	Instance
Outcome	All_comparisons_at_time_x	crossovers		[undefined]
Outcome	All_comparisons_at_time_x	subgroup_comparisons		Instance
Outcome	All_comparisons_at_time_x	main_intervention_group_co	"Comparisons at this timepoint for this outcome among the main intervention groups (experimental and comparison). This may be a two-way comparison, or ANOVA of 3 interventions, etc."	Instance
Outcome	Survival_analyses_and_results	RESULT_ID		INTEGER
Outcome	Survival_analyses_and_results	kaplan_meier_timepoints	kaplan_meier_timepoints	Instance
Outcome	Survival_analyses_and_results	survival_analysis_test_name	survival_analysis_test_name	SYMBOL
Outcome	Survival_analyses_and_results	efficacy_analysis_survival_p	efficacy_analysis_survival_p	[undefined]
Outcome	Survival_analyses_and_results	survival_start_time	survival_start_time	STRING
Outcome	Survival_analyses_and_results	itt_survival_p_value	itt_survival_p_value	[undefined]
Outcome	Kaplan_meier_timepoint	RESULT_ID		INTEGER
Outcome	Kaplan_meier_timepoint	length_of_time		INTEGER
Outcome	Kaplan_meier_timepoint	time_unit	"Unit of time for various uses. For DRUG-STEP, refers to time-unit of dosing frequency."	SYMBOL
Outcome	Kaplan_meier_timepoint	timepoint_name	"Name of this timepoint, e.g., 6 months."	STRING
Outcome	Kaplan_meier_timepoint	itt_km_datapoints		Instance

	imepoint			
Outcome	Kaplan_meier_t imepoint	timepoint	"The machine-interpretable definition of when this comparison was assessed, expressed as a TIMEPOINT."	Instance
Outcome	Kaplan_meier_t imepoint	efficacy_analysis_km_d atap		Instance
Outcome	Miscellaneous_ outcome_entity	RCTID		INTEGER
Outcome	Miscellaneous_ outcome_entity	MISC_ID		INTEGER
Outcome	Range	MISC_ID		INTEGER
Outcome	Range	lower_range_value	"The value of the lower end of the range, e.g, 20 in 95% range 20 to 80."	INTEGER
Outcome	Range	range_percent	"e.g. 25% for quartiles, etc."	SYMBOL
Outcome	Range	upper_range_value	[undefined]	
Outcome	Category	MISC_ID		INTEGER
Outcome	Category	unit	"The unit of the outcome value, e.g., feet or mmHg. Should come from a controlled vocabulary."	STRING
Outcome	Category	category_operator_val ue	"The value on which the operator operates, e.g., 200 in -< 200 cells/mm3-."	INTEGER
Outcome	Category	upper_range_value	[undefined]	
Outcome	Category	lower_range_value	"The value of the lower end of the range, e.g, 20 in 95% range 20 to 80."	INTEGER
Outcome	Category	category_label	"The name of each category, e.g, -+2-, --1-, - Fair-, etc. "	STRING
Outcome	Category	category_operator	"For specifying categories such as -< 200 cells/mm3-"	SYMBOL
Outcome	Outcome_assessment	RCTID		INTEGER
Outcome	Outcome_assessment	OUTCOME_ASSES_ID		INTEGER

Outcome	Outcome_assessment	reproducibility_of_assess		STRING
Outcome	Outcome_assessment	assessment_method		STRING
Outcome	Outcome_assessment	assessor		STRING
Outcome	Outcome_assessment	assessor_blinding_to_tx		SYMBOL
Outcome	Outcome_assessment	assessment_comment	"For general comments or for describing changes or qualifications to outcome assessment at conclusion of trial. "	STRING
Outcome	Outcome_assessment	assessor_blinding_to_re		SYMBOL
Outcome	Outcome_assessment	validity_of_assessment		STRING
Outcome	Special_variable_information	RCTID		INTEGER
Outcome	Special_variable_information	SPECIAL_VAR_ID		INTEGER
Outcome	Cost	SPECIAL_VAR_ID		INTEGER
Outcome	Cost	cost_assumptions		STRING
Outcome	Cost	discount_rate		INTEGER
Outcome	Cost	base_year		INTEGER
Outcome	Cost	description_of_source_of_c		STRING
Outcome	Categorical	SPECIAL_VAR_ID		INTEGER
Outcome	Categorical	categories	"The categories for the categorical variable, assumed to be in the order in which they were entered (as shown by the last number of the instance name)."	Instance
Outcome	Scored_instrument	SPECIAL_VAR_ID		INTEGER
Outcome	Scored_instrument	highest_score	"The upper range of scores allowed for this instrument. e.g., 90 for the Digit Symbol subscale of the Wechsler Adult Intelligence Scale-Revised. "	INTEGER
Outcome	Scored_instrument	sd_of_normative_score	"The standard	INTEGER

	ent		deviation of the normative scores of this instrument."	
Outcome	Scored_instrument	lowest_score	"The lower range for allowable scores for this instrument. e.g., 0 for the Digit Suymbol subscale of the Wechsler Adult Intelligence Subscale-Revised."	INTEGER
Outcome	Scored_instrument	normative_score	"The normative score for this instrument."	INTEGER
Outcome	Scored_instrument	instrument_name	"Name of instrument used."	STRING
Outcome	Scored_instrument	instrument_description	"Description of this instrument, including validation, verification, etc."	STRING
Outcome	Scored_instrument	instrument_family	"Family of instrument this one may be related to, e.g., a modification of the SF-12, from a selected list."	SYMBOL
Outcome	Life_year	SPECIAL_VAR_ID		INTEGER
Outcome	Life_year	quality_adjustment_method	"Method used to quality adjust life years, if applicable."	STRING
Outcome	Rate	SPECIAL_VAR_ID		INTEGER
Outcome	Rate	time_unit	"Unit of time for various uses. For DRUG-STEP, refers to time-unit of dosing frequency."	SYMBOL
Outcome	Rate	denominator_amount	"The amount of the unit for the rate denominator, e.g, -5- in survival/5 year."	INTEGER
Outcome	Rate	denominator_unit	"Unit for rate denominator, e.g. per fall, per person, per person-year , per month. Should	STRING

			ideally be controlled choices or a UMLS term. Can also use time-unit slot for time denominators. "	
Design	Stopping_rule	RCTID		INTEGER
Design	Stopping_rule	STOPPING_RULE_ID		INTEGER
Design	Stopping_rule	when_stopping_rule_defined	"If defined a priori, was defined before subject enrollment or randomization began."	SYMBOL
Design	Stopping_rule	stopping_rule_description	"Description of the rule (may be statistical) of when study may be stopped prematurely."	STRING
Design	D_Regression_analysis	RCTID		INTEGER
Design	D_Regression_analysis	DESIGN_REGRESSION_ID		INTEGER
Design	D_Regression_analysis	regression_program_name		STRING
Design	D_Regression_analysis	subgroup_regressions	"Results of this regression analysis in different subgroups."	Instance
Design	D_Regression_analysis	itt_adjusted_summary	"The adjusted intention-to-treat summary result of this regression."	Instance
Design	D_Regression_analysis	regression_variables	"List of the variables in the regression model. Could/should be UMLS terms in the future."	STRING
Design	D_Regression_analysis	confidence_interval_percent		SYMBOL
Design	D_Regression_analysis	efficacy_analysis_adjusted	"The efficacy analysis summary result of the regression adjusted for said variables."	Instance
Design	D_Regression_analysis	itt_unadjusted_summary	"The unadjusted intention-to-treat	Instance

			summary result of this regression."	
Design	D_Regression_analysis	comments		STRING
Design	D_Regression_analysis	results_comment		STRING
Design	D_Regression_analysis	intercept		INTEGER
Design	D_Regression_analysis	summary_statistic_type	"Type of summary statistic. In STATISTICAL-ANALYSIS-AND-RESULTS and REGRESSION-ANALYSIS-AND-RESULTS, specifies the standard summary statistic used. In SUMMARY-DATAPoint, other summary values (e.g., ARR in addition to OR) can also be provided."	SYMBOL
Design	D_Regression_analysis	regression_model_type		SYMBOL
Design	D_Regression_analysis	efficacy_analysis_unadjusted	"The efficacy analysis summary result of the regression unadjusted for said variables."	Instance
Design	D_Regression_analysis	regression_adjustment_met		[undefined]
Design	D_Regression_analysis	regression_test_name		SYMBOL
Design	Study_monitoring	RCTID		INTEGER
Design	Study_monitoring	STUDY_MONITORING_ID		INTEGER
Design	Study_monitoring	recommendations_procedure	"How recommendations arising from monitoring were communicated to the study investigators."	STRING
Design	Study_monitoring	monitoring_schedule	"The schedule of when monitoring is performed."	STRING

Design	Study_monitoring	monitoring_method	"How study monitoring was conducted, by whom."	STRING
Design	Study_monitoring	monitoring_blinding	"Whether monitors were blinded to subject assignment."	SYMBOL
Design	Study_objective	RCTID		INTEGER
Design	Study_objective	OBJECTIVE_ID		INTEGER
Design	Study_objective	rationale	"Rationale for this objective or hypothesis."	STRING
Design	Study_objective	statement_of_objective	"Text statement of study objective"	STRING
Design	Hypothesis_concept	RCTID		INTEGER
Design	Hypothesis_concept	HYPOTHESIS_ID		INTEGER
Design	Hypothesis_concept	HYPOTHESIS_TYPE	Primary, Secondary	STRING
Design	Hypothesis_concept	hypothesis_variable	"The variable to which this hypothesis refers."	STRING
Design	Hypothesis_concept	specification_time		SYMBOL
Design	Hypothesis_concept	statement_of_hypotheses		STRING
Design	Trial_design	RCTID		INTEGER
Design	Trial_design	DESIGN_ID		INTEGER
Design	Trial_design	loss_handling		STRING
Design	Trial_design	definition_of_intention_to_tr		STRING
Design	Trial_design	stopping_rule	"Description of the stopping rule used, if any."	Instance
Design	Trial_design	bayesian_or_classical		SYMBOL
Design	Trial_design	nurse_blinding	"Were the study nurses blinded to the subjects-assigned treatment and/or interim results? "	Instance
Design	Trial_design	provider_blinding	"Were care providers blinded to the subjects-assigned treatment and/or interim results? "	Instance
Design	Trial_design	definition_of_efficacy_annotation		STRING

Design	Trial_design	investigator_blinding	"Were investigators blinded to subjects-assigned treatment and/or interim results? "	Instance
Design	Trial_design	subject_blinding	"Were trial subjects blinded to their treatment assignment and/or interim results? "	Instance
Design	Trial_design	allocator_blinding	"Whether the allocator was blinded to the subjects assignment, or to interim results."	Instance
Design	Trial_design	efficacy_analysis	"Whether analyses were performed on the basis of actual intervention received, rather than intervention assigned. A study may have both efficacy and intention-to-treat analyses."	SYMBOL
Design	Trial_design	type_of_trial_design		SYMBOL
Design	Trial_design	intention_to_treat_analysis	"Whether analyses were performed on basis of participant-s assigned intervention. A study may include both intention-to-treat and efficacy analyses."	SYMBOL
Design	Sample_size_calculation	RCTID		INTEGER
Design	Sample_size_calculation	SAMPLE_SIZE_ID		INTEGER
Design	Sample_size_calculation	justification_for_one_tailed	"If the statistical test is one-tailed, it-s use must be explained."	STRING
Design	Sample_size_calculation	assumptions_underlying_target	"Describe assumptions that impact on target enrollment versus	STRING

			sample size. e.g., assumptions on proportion of eligible subjects who will agree, number who will stay in study, etc."	
Design	Sample_size_calculation	threshold_rate_rationale		STRING
Design	Sample_size_calculation	referent_outcome	"The outcome on which the sample size requirements for this study were calculated."	Instance
Design	Sample_size_calculation	sample_size_calculation_m		STRING
Design	Sample_size_calculation	comments		STRING
Design	Sample_size_calculation	alpha_tails	"also called -sides-"	SYMBOL
Design	Sample_size_calculation	alpha_value	"Acceptable probability of a false positive for rejecting the null hypothesis. Often 0.05."	INTEGER
Design	Sample_size_calculation	power	"1-the probability of a false negative. Is 1-beta, is a real number between 0 and 1, often 0.80."	INTEGER
Design	Sample_size_calculation	base_rate_rationale		STRING
Design	Sample_size_calculation	baseline_comparison_group		STRING
Design	Sample_size_calculation	threshold_exp_group_out		STRING
Design	Sample_size_calculation	target_sample_size		INTEGER
Design	Sample_size_calculation	target_enrollment		INTEGER
Design	D_Statistical_analysis	RCTID		INTEGER
Design	D_Statistical_analysis	DESIGN_STATISTICAL_ID		INTEGER
Design	D_Statistical_analysis	justification_for_one_tailed	"If the statistical test is one-tailed, its use must be explained."	STRING
Design	D_Statistical_analysis	number_of_tails	"Two-tailed tests consider and test for the possibility	SYMBOL

			of the effect being beneficial or harmful. One-tailed tests consider only one possibility. The use of one-tailed tests must be justified."	
Design	D_Statistical_analysis	whether_test_assumptions	"Description of whether the assumptions necessary for the test (e.g., normal distribution), were seen in the actual data analyzed."	STRING
Design	D_Statistical_analysis	program_name	"Name of the computer program used to run this analysis, e.g., STATA, SAS, SPSS, Minitab."	STRING
Design	D_Statistical_analysis	statistical_test_name	"The name of the statistical test for analysis of this outcome. e.g., paired-t-test, Kruskal-Wallis test, Wilcoxon rank-sum, etc. These test names are partially modelled in UMLS (mostly in PSY97). The list below is taken from Lang, Secic -How to Report Statistics in Medicine- p. 71."	SYMBOL
Design	D_Statistical_analysis	other_notes		STRING
Design	D_Statistical_analysis	parametric	"Whether the test is a parametric or non-parametric test."	SYMBOL
Design	D_Statistical_analysis	confidence_interval_percent		SYMBOL
Design	D_Statistical_analysis	justification_for_statistical	"Justification for why this statistical test was used."	STRING
Design	D_Statistical_analysis	censoring_approach	"The statistical approach taken	STRING

			"to dealing with censored observations."	
Design	D_Statistical_analysis	summary_statistic_type	"Type of summary statistic. In STATISTICAL-ANALYSIS-AND-RESULTS and REGRESSION-ANALYSIS-AND-RESULTS, specifies the standard summary statistic used. In SUMMARY-DATAPoint, other summary values (e.g., ARR in addition to OR) can also be provided."	SYMBOL
Design	D_Statistical_analysis	justification_for_transformation	"Justification for why the data is parameterized or transformed (e.g., log-transformed)."	STRING
Design	D_Statistical_analysis	repeated_measures_adjust		SYMBOL
Design	D_Statistical_analysis	results	"Points to collection of classes, grouped by all comparisons at a particular timepoint (e.g., 6 months). For study outcomes, the value of this slot are instances of ALL-COMPARISONS-AT-TIME-X (one instance for each timepoint). For BASELINEs, the value is BASELINE-COMPARISON."	Instance
Design	D_Statistical_analysis	p_level_threshold	"The p-level at which statistical - significance- is declared."	INTEGER
Design	D_Statistical_analysis	difference_score	"Whether	SYMBOL

	nalysis		analysis of intrasubject differences was performed, e.g., difference within a subject on repeated measures of a test."	
Design	D_Statistical_analysis	difference_score_results		Instance
Design	D_Survival_analysis	RCTID		INTEGER
Design	D_Survival_analysis	DESIGN_SURVIVAL_ID		INTEGER
Design	D_Survival_analysis	kaplan_meier_timepoints		Instance
Design	D_Survival_analysis	survival_analysis_test_name		SYMBOL
Design	D_Survival_analysis	efficacy_analysis_survival_p		[undefined]
Design	D_Survival_analysis	survival_start_time		STRING
Design	D_Survival_analysis	itt_survival_p_value		[undefined]
Protocol	Secondary_study_protocol	RCTID		INTEGER
Protocol	Secondary_study_protocol	SECONDARY_STUDY_ID		INTEGER
Protocol	Secondary_study_protocol	secondary_study_groups	"Study groups of secondary studies must be subgroups of the original study groups of the main trial."	Instance
Protocol	Secondary_study_protocol	entrance_criteria_comment	"General comments on the application or other aspects of subject selection."	STRING
Protocol	Secondary_study_protocol	stopping_rule	"Description of the stopping rule used, if any."	Instance
Protocol	Secondary_study_protocol	ancillary_outcomes		Instance
Protocol	Secondary_study_protocol	subgroups	"Pointers to both a priori and post-hoc subgroup definitions and thence to the actual subgroup populations."	Instance
Protocol	Secondary_stu	side_effects	"Clinical"	Instance

	dy_protocol		outcomes that are side effects. Details of assessment, statistical analysis, and results are at the object pointed to."	
Protocol	Secondary_study_protocol	exclusion_rules		Instance
Protocol	Secondary_study_protocol	secondary_outcomes		Instance
Protocol	Secondary_study_protocol	ethnicity_language_entrance		Instance
Protocol	Secondary_study_protocol	follow_up		Instance
Protocol	Secondary_study_protocol	efficacy_analysis	"Whether analyses were performed on the basis of actual intervention received, rather than intervention assigned. A study may have both efficacy and intention-to-treat analyses."	SYMBOL
Protocol	Secondary_study_protocol	hypotheses	"These cannot be primary hypotheses since that is the main hypothesis of the main trial. These are all technically secondary hypotheses."	Instance
Protocol	Secondary_study_protocol	recruitment		Instance
Protocol	Secondary_study_protocol	age_gender_entrance_crit		Instance
Protocol	Secondary_study_protocol	primary_outcomes		Instance
Protocol	Secondary_study_protocol	study_monitoring	"Description of how the study as a whole was monitored. Specific details of data monitoring are described in the relevant STUDY-COMMITTEEs."	Instance
Protocol	Secondary_study_protocol	inclusion_rules		Instance

Protocol	Secondary_study_protocol	blinding_efficacy	"Details about intervention binding , including blinding efficacy, of investigators, subjects, nurses, etc. "	Instance
Protocol	Secondary_study_protocol	intention_to_treat_analysis	"Whether analyses were performed on basis of participant-s assigned intervention. A study may include both intention-to-treat and efficacy analyses."	SYMBOL
Protocol	Executed_secondary_study	SECONDARY_STUDY_ID		INTEGER
Protocol	Executed_secondary_study	baseline_characteristics	"The clinical characteristics of this population at baseline. Modeled as comparisons of individual datapoints among populations. "	Instance
Protocol	Executed_secondary_study	secondary_recruitment_flow		Instance
Protocol	Executed_secondary_study	crossover_groups		Instance
Protocol	Outcomes_follo wup	RCTID		INTEGER
Protocol	Outcomes_follo wup	OUTCOMES_FOLLOW_ID		INTEGER
Protocol	Outcomes_follo wup	mean_fu		Instance
Protocol	Outcomes_follo wup	denominator_population	"The population on which this datapoint was assessed. E.g., the experimental group, or the subgroup of diabetics who were assigned the comparative intervention. "	Instance
Protocol	Outcomes_follo wup	reasons_not_assessed	"The reasons for dropout/withdrawals for this	Instance

			datapoint. The number of dropouts/withdrawals is the population denominator minus the n-had-outcome-assessed. Probably will only be supplied for the end-of-study datapoint, although there could be different reasons and numbers of subjects with these reasons for each datapoint."	
Protocol	Outcomes_follo wup	person_year_fu_off_as signed	"The number of person-years of follow-up for this datapoint in those who were off their assigned intervention."	INTEGER
Protocol	Outcomes_follo wup	person_year_fu_all	"The number of person-years of followup for this population at this datapoint."	INTEGER
Protocol	Outcomes_follo wup	shortest_fu		Instance
Protocol	Outcomes_follo wup	n_outcome_assessed_on	"The number of subjects who had this outcome assessed AND who were on their assigned intervention at the time of assessment."	INTEGER
Protocol	Outcomes_follo wup	n_outcome_not_assess ed	"Subjects who withdrew from the study entirely and did not have their outcomes assessed."	INTEGER
Protocol	Outcomes_follo wup	n_outcome_assessed		INTEGER
Protocol	Outcomes_follo wup	longest_fu		Instance
Protocol	Outcomes_follo wup	person_year_fu_on_as signed	"The number of years of followup at this datapoint"	INTEGER

			in those who were on their assigned intervention."	
Protocol	Reason	RCTID		INTEGER
Protocol	Reason	REASON_ID		INTEGER
Protocol	Reason	REASON_TYPE	Withdraw-reason,reason-off-assigned-intervention, reason-not-eligible,reason-not-enrolled, reason-not-randomized, reason-excluded-post-rand, reason-outcome-not-assessed	STRING
Protocol	Reason	reason		STRING
Protocol	Reason	n_with_this_reason		INTEGER
Protocol	Reason	exclusive_exclusion		SYMBOL
Protocol	Reason	reason_name		STRING
Protocol	Reason	term_information	"Pointer to a UMLS preferred term or terms, if available, that capture the major clinical concepts in this data class (e.g, diabetes mellitus)."	Instance
Protocol	Protocol	RCTID		INTEGER
Protocol	Protocol	PROTOCOL_ID		INTEGER
Protocol	Protocol	cointerventions		Instance
Protocol	Protocol	adverse_events_comment	"General comments on adverse events and/or their results."	STRING
Protocol	Protocol	general_stats_method	"General comments on statistical methods used, e.g., that continuous variables were tested using t-tests."	STRING
Protocol	Protocol	baseline_characteristics_co		STRING
Protocol	Protocol	exclusion_rules		Instance
Protocol	Protocol	secondary_outcomes		Instance
Protocol	Protocol	entrance_criteria_com	"General	STRING

		ment	comments on the application or other aspects of subject selection."	
Protocol	Protocol	experimental_arms		Instance
Protocol	Protocol	inclusion_rules		Instance
Protocol	Protocol	sample_size_calculation		Instance
Protocol	Protocol	treatment_assignment		Instance
Protocol	Protocol	blinding_methods	"Methods used to blind providers, subjects, study nurses, investigators to the subject-s assigned intervention."	Instance
Protocol	Protocol	secondary_hypotheses	"Hypotheses of the study that were not used to calculate sample size."	Instance
Protocol	Protocol	side_effects_comment	"General comments on side effects and/or their results."	STRING
Protocol	Protocol	comparison_arm		Instance
Protocol	Protocol	subgroups	"Pointers to both a priori and post-hoc subgroup definitions and thence to the actual subgroup populations. "	Instance
Protocol	Protocol	side_effects	"Clinical outcomes that are side effects. Details of assessment, statistical analysis, and results are at the object pointed to."	Instance
Protocol	Protocol	general_compliance_result		STRING
Protocol	Protocol	ethnicity_language_entrant		Instance
Protocol	Protocol	follow_up		Instance
Protocol	Protocol	trial_design		Instance
Protocol	Protocol	age_gender_entrance_crit		Instance
Protocol	Protocol	recruitment		Instance

Protocol	Protocol	exclusive_eligibility_exclusion	"Whether subjects excluded from eligibility are counted as meeting only a single exclusion criterion or more than one if applicable."	SYMBOL
Protocol	Protocol	study_sites		Instance
Protocol	Protocol	primary_outcomes		Instance
Protocol	Protocol	study_monitoring	"Description of how the study as a whole was monitored. Specific details of data monitoring are described in the relevant STUDY-COMMITTEEs."	Instance
Protocol	Protocol	primary_hypothesis	"The primary hypothesis of this study. As rigorously defined, should only refer to the primary outcome, and be the statistical context for calculating this study's sample size."	Instance
Protocol	Protocol	baseline_characteristics	"The clinical characteristics of this population at baseline. Modeled as comparisons of individual datapoints among populations."	Instance
Protocol	Protocol	blinding_efficacy	"Details about intervention blinding, including blinding efficacy, of investigators, subjects, nurses, etc."	Instance
Protocol	Protocol	study_groups		Instance
Protocol	Protocol	ancillary_outcomes		Instance
Protocol	Executed_proto	PROTOCOL_ID		INTEGER

	col			
Protocol	Executed_protocol	recruitment_flowchart		Instance
Protocol	Executed_protocol	crossover_groups	"Points to the groups of subjects that crossed from one to another arm."	Instance
Protocol	Executed_protocol	intervention_completion_com		STRING
Protocol	Protocol_change	RCTID		INTEGER
Protocol	Protocol_change	PROTOCOL_CHANGE_ID		INTEGER
Protocol	Protocol_change	reason_for_protocol_change		STRING
Protocol	Protocol_change	protocol_change_number	"The change number"	INTEGER
Protocol	Protocol_change	date_of_protocol_change		Instance
Protocol	Protocol_change	description_of_protocol_ch		STRING
Protocol	Follow_up	RCTID		INTEGER
Protocol	Follow_up	FOLLOW_ID		INTEGER
Protocol	Follow_up	complete_fu_date	"Date at which last participant was followed up."	Instance
Protocol	Follow_up	follow_up_activities	"Followup activities such as clinic visits, phone calls, etc. for each intervention and/or subgroup. Although most studies will have the same followup activity schedule for all participants, some studies may have different schedules for experimental and control groups for instance."	Instance
Protocol	Follow_up_activity	RCTID		INTEGER
Protocol	Follow_up_activity	FOLLOW_ACTIVITY_ID		INTEGER
Protocol	Follow_up_activity	for_population	"Followup activity for the stated populations. If this followup	Instance

			activity applied to all subjects, then the slot [for-population] should include instances of all STUDY-ARM-POPULATIONS. If only some populations had this followup activities, then the slot [for-population] will point only to those populations (e.g., a SUBGROUP-POPULATION) "	
Protocol	Follow_up_activity	display_name	"A -pretty name-for referring to this intervention arm. May be - Anti-coagulation- or -Control-, for example. This name may or may not be identical to the UMLS term for the intervention. "	STRING
Protocol	Follow_up_activity	personnel_conducting_follow	"Who performed the e.g., clinic visits, followup phone calls, etc."	STRING
Protocol	Follow_up_activity	description_of_followup_act		STRING
Protocol	Follow_up_activity	follow_up_activity	"Machine-interpretable description of this follow-up activity "	Instance
Protocol	Follow_up_activity	term_information	"Pointer to a UMLS preferred term or terms, if available, that capture the major clinical concepts in this data class (e.g, diabetes mellitus)."	Instance
Protocol	Follow_up_activity	follow_up_compliance	"Points to information on compliance with followup activities	Instance

			for relevant study populations."	
Protocol	Follow_up_compliance	RCTID		INTEGER
Protocol	Follow_up_compliance	FOLLOW_COMPLIANCE_ID		INTEGER
Protocol	Follow_up_compliance	denominator_population	"The population on which this datapoint was assessed. E.g., the experimental group, or the subgroup of diabetics who were assigned the comparative intervention."	Instance
Protocol	Follow_up_compliance	n_complying_with_followup	"For simple cases, the total number of subjects in the denominator population that was compliant with this followup activity."	INTEGER
Protocol	Follow_up_compliance	description_of_compliance	"For more complicated situations, narrative description of how many subjects in the denominator population complied with followup activities, eg at which times."	STRING
Treatment-assignment	Treatment_assignment	RCTID		INTEGER
Treatment-assignment	Treatment_assignment	TREATMENT_ASSIGNMENT_ID		INTEGER
Treatment-assignment	Treatment_assignment	method_of_assignment_n	"How assignment is communicated to the study staff"	SYMBOL
Treatment-assignment	Treatment_assignment	masked_assignment	"Whether the person assigning the participant to the intervention is masked to what the participant's assignment is."	SYMBOL
Treatment-assignment	Treatment_assignment	unit_of_randomization	"The entity that is subjected to randomization"	SYMBOL

			"and then treatment allocation."	
Treatment-assignment	Treatment_assignment	blocking_stratification	"Details of randomization blocking or stratification, which assumes that a fixed randomization scheme is being used."	Instance
Treatment-assignment	Treatment_assignment	assignment_masking_meth		STRING
Treatment-assignment	Treatment_assignment	type_of_tx_assignment		SYMBOL
Treatment-assignment	Treatment_assignment	allocation_ratio		SYMBOL
Treatment-assignment	Treatment_assignment	adaptive_randomization	"Can be either fixed or adaptive randomization."	Instance
Treatment-assignment	Treatment_assignment	comments		STRING
Treatment-assignment	Treatment_assignment	sequence_generation		STRING
Treatment-assignment	Treatment_assignment	delay_enrollment_to_rand		STRING
Treatment-assignment	Treatment_assignment	cochrane_score		SYMBOL
Treatment-assignment	Treatment_assignment	assignment_method		STRING
Treatment-assignment	Randomization	RCTID		INTEGER
Treatment-assignment	Randomization	RANDOMIZATION_ID		INTEGER
Treatment-assignment	Fixed_randomization	RANDOMIZATION_ID		INTEGER
Treatment-assignment	Fixed_randomization	blocking_size	"Whether the block sizes were variable (as preferred) or fixed."	SYMBOL
Treatment-assignment	Fixed_randomization	stratification_variables	"Variable(s) that is/are controlled for stratified randomization, ie when participants are assigned to interventions in such a way as to ensure that participants with this variable have the same distribution in all"	Instance

			intervention groups. "	
Treatment-assignment	Fixed_randomization	blocked_randomization		SYMBOL
Treatment-assignment	Fixed_randomization	blocking_description		STRING
Treatment-assignment	Fixed_randomization	rationale_for_stratification		STRING
Treatment-assignment	Fixed_randomization	stratified_randomization		SYMBOL
Treatment-assignment	Adaptive_randomization	RANDOMIZATION_ID		INTEGER
Treatment-assignment	Adaptive_randomization	type_of_adaptive_randomiz		SYMBOL
Treatment-assignment	Adaptive_randomization	description		STRING
Population	Site_enrollment	RCTID		INTEGER
Population	Site_enrollment	SITE_ENROLLMENT_ID		INTEGER
Population	Site_enrollment	for_study	"Which study this enrollment data is for, primary, secondary, or followup studies of this trial."	Instance
Population	Site_enrollment	enrollment_end_date	"The date that the last study subject was enrolled from this study site for the primary study."	Instance
Population	Site_enrollment	enrollment_start_date	"The date that enrollment started at this study site for the primary study."	Instance
Population	Site_enrollment	total_enrolled	"Total number of subjects enrolled in the study from this site. This may be the number randomized or in the analysis."	INTEGER
Population	Recruitment	RCTID		INTEGER
Population	Recruitment	RECRUITMENT_ID		INTEGER
Population	Recruitment	comments		STRING
Population	Recruitment	rate_of_recruitment	"Rate in percent"	FLOAT
Population	Recruitment	source_settings	"see health care facilities twistdown tree on MeSH browser at nlm.nih.gov"	SYMBOL
Population	Recruitment	source_description		STRING
Population	Recruitment	method_of_recruitment		STRING

Population	Recruitment	enrollment_end_date	"The date that the last study subject was enrolled from this study site for the primary study."	Instance
Population	Recruitment	enrollment_start_date	"The date that enrollment started at this study site for the primary study."	Instance
Population	Recruitment	why_recruitment_goal_not		STRING
Population	Population	RCTID		INTEGER
Population	Population	POPULATION_ID		INTEGER
Population	Population	POPULATION_TYPE	Analyzed, excluded, recruited	INTEGER
Population	Population	POPULATION_SUBTYPE	Subgroup, Study, Crossover, All, Not-eligible, Not-enrolled, Not-randomized, Excluded-postrand, Screened, Eligible, Enrolled, Randomized	STRING
Population	Population	individual_members		Instance
Population	Population	population_description		STRING
Population	Population	population_age	"Age information for this population (as a continuous variable). If age is to be described categorically(e.g., 25% under age 50), then it should be described like any other baseline characteristic using ALL-TIME-X-COMPARISONS, etc. "	Instance
Population	Population	number_of_females		INTEGER
Population	Population	number_of_males		INTEGER
Population	Population	population_name	"A label for referring to this population. E.g., -Control Group- or -Amiodarone- or whatever. "	STRING

Population	Population	number_of_subjects		INTEGER
Population	Population	subgroup_of	"Allows the recursive definition of subgroups in which the subgroup at each level can be have outcomes associated with it. e.g., separate outcomes for each of the subgroup of all males of the subgroup of all diabetics of the subgroup of all assigned to placebo. Alternatively, a single subgroup could be defined with all the criteria applied at once (e.g., the subgroup of male diabetics assigned to control)."	Instance
Population	Population	study_assigned_arm	"Points to the intervention arm that this population was assigned to. Allows arbitrary numbers of treatment populations to accommodate multi-armed trials. Each population can have more than one assigned treatment, to allow for factorial designs (e.g., treatment A and NOT B)."	Instance
Population	Population	crossover_reference_timep	"The timepoint from which timings are referenced. For outcomes, this is the time when the	Instance

			timing of the outcomes should start from. Often is -at enrollment- but may be something else. "	
Population	Population	crossover_from_which_arm	"The arm to which this population was originally assigned. "	Instance
Population	Population	crossover_to_which_arm	"The arm to which this population crossed over to."	Instance
Population	Population	crossover_duration_since_ref	"The amount of time since the reference timepoint, e.g., 6 months from enrollment. If no duration is specified, assumes that timepoint is coincident with reference-timepoint."	Instance
Population	Population	all_p_of_gender		INTEGER
Population	Population	all_p_of_age		INTEGER
Population	Population	reasons_excluded		SYMBOL
Population	Population	excluded_postrand_denom	"The population on which this datapoint was assessed. E.g., the experimental group, or the subgroup of diabetics who were assigned the comparative intervention. "	Instance
Population	Primary_recruitment_flowchart	RCTID		INTEGER
Population	Primary_recruitment_flowchart	RECRUITMENT_FLOW_ID		INTEGER
Population	Primary_recruitment_flowchart	randomized_population	"Number of eligible, enrolled subjects who were randomized."	Instance
Population	Primary_recruitment_flowchart	not_randomized_population	"Number of eligible, enrolled subjects who were not	Instance

			randomized."	
Population	Primary_recruitment_flowchart	not_enrolled_population	"Number of eligible subjects who were enrolled."	Instance
Population	Primary_recruitment_flowchart	not_eligible_population	"Number of subjects who were ineligible."	Instance
Population	Primary_recruitment_flowchart	excluded_postrand_pop	"Number of eligible,enrolled, and randomized subjects who were excluded post-randomization in each intervention arm."	Instance
Population	Primary_recruitment_flowchart	all_subjects	"Number of subjects who were included in the analysis group."	Instance
Population	Primary_recruitment_flowchart	screened_population	"Number of subjects in screened group."	Instance
Population	Primary_recruitment_flowchart	enrolled_population	"Number of eligible subjects who were enrolled."	Instance
Population	Primary_recruitment_flowchart	eligible_population	"Number of subjects who were eligible."	Instance
Population	Subgroup	RCTID		INTEGER
Population	Subgroup	SUBGROUP_ID		INTEGER
Population	Subgroup	subgroup_populations	"The actual subgroup populations defined using this definition, e.g., diabetics in the experimental group and in the control group. "	Instance
Population	Subgroup	subgroup_criterion	"State which defines this subgroup, e.g., diabetes , or hemoglobin greater than 10 mg/dL."	Instance
Population	Subgroup	display_name	"A -pretty name-for referring to this intervention arm. May be - Anti-coagulation-	STRING

			or -Control-, for example. This name may or may not be identical to the UMLS term for the intervention. "	
Population	Subgroup	p_value	"Enter as (--- 0.975-)"	INTEGER
Population	Subgroup	rationale_for_subgroup	"The reason this subgroup is being defined."	STRING
Population	Subgroup	rationale_for_post_hoc_def	"Why this subgroup was defined post-hoc and not a priori."	STRING
Population	Subgroup	term_information	"Pointer to a UMLS preferred term or terms, if available, that capture the major clinical concepts in this data class (e.g, diabetes mellitus)."	Instance
Population	Subgroup	subgroup_definition	"Text description of this subgroup"	STRING
Population	Subgroup	specification_time		SYMBOL
Generic	Situation	RCTID		INTEGER
Generic	Situation	SITUATION_ID		INTEGER
Generic	State	SITUATION_ID		INTEGER
Generic	State	unit	"The unit of the outcome value, e.g., feet or mmHg. Should come from a controlled vocabulary."	STRING
Generic	State	comparison_operator	"Comparison operator for the value of the criterion (e.g., the ->= in >= 10 mg/dL) . Not to be confused with the time-operator , which specifies when this condition exists in reference to the time-criterion ."	SYMBOL
Generic	State	state_p	"Whether it is the possession or the absence of this	SYMBOL

			state that is being specified."	
Generic	State	time_criterion	"Any temporal constraints on this state. E.g., Hgb <10 mg/dL at time of enrollment."	Instance
Generic	State	state_value		STRING
Generic	State	term_information	"Pointer to a UMLS preferred term or terms, if available, that capture the major clinical concepts in this data class (e.g, diabetes mellitus)."	Instance
Generic	State	time_operator	"Before, after, concurrent with or combinations thereof. Probably need more operators, e.g., coincident with but not extending outside of this time..."	SYMBOL
Generic	State	description		STRING
Generic	Non_concurrent_situations	SITUATION_ID		INTEGER
Generic	Non_concurrent_situations	duration_between_situations	"The amount of time between the two situations."	Instance
Generic	Non_concurrent_situations	non_concurrent_time_op	"States whether the first-situation is before or after, or overlapping, the second-situation."	SYMBOL
Generic	Non_concurrent_situations	first_situation	"Situation A in (situation A time-operator situation B)."	Instance
Generic	Non_concurrent_situations	second_situation	"Situation B in (Situation A time-operator Situation B)."	Instance
Generic	Concurrent_situations	SITUATION_ID		INTEGER
Generic	Concurrent_situations	concurrent_situations	"The situations that are concurrent."	Instance
Generic	Event_entity	SITUATION_ID		INTEGER
Generic	Event_entity	EVENT_ENTITY_ID		INTEGER

Generic	Event_entity	event_description		STRING
Generic	Event_entity	time_operator	"Before, after, concurrent with or combinations thereof. Probably need more operators, e.g., coincident with but not extending outside of this time..."	SYMBOL
Generic	Event_entity	event_p	"Whether having or not having this event is the criterion."	SYMBOL
Generic	Event_entity	event_duration	"No value implies either an instantaneous event, or unspecified, depending on the event."	Instance
Generic	Event_entity	term_information	"Pointer to a UMLS preferred term or terms, if available, that capture the major clinical concepts in this data class (e.g, diabetes mellitus)."	Instance
Generic	Regularly_recurring_event	EVENT_ENTITY_ID		INTEGER
Generic	Regularly_recurring_event	recurrence_bounding_range	"The time within which the recurrence takes place."	Instance
Generic	Regularly_recurring_event	regular_duration_between	"For regular recurring events, the duration of time between iterations. "	Instance
Generic	Regularly_recurring_event	recurrence_frequency_num	"To capture e.g., 3 times a week. "	INTEGER
Generic	Regularly_recurring_event	event_cardinality_operator	"e.g., 6 or more episodes of event."	SYMBOL
Generic	Regularly_recurring_event	event_cardinality	"Number of times this event occurs within the bounding duration"	INTEGER
Generic	Regularly_recurring_event	recurrence_frequency_den	"e.g., 1 week in I&D 3 times a week for 6	Instance

			"weeks"	
Generic	Regularly_recurring_event	event_description		STRING
Generic	Regularly_recurring_event	time_operator	"Before, after, concurrent with or combinations thereof. Probably need more operators, e.g., coincident with but not extending outside of this time..."	SYMBOL
Generic	Regularly_recurring_event	event_p	"Whether having or not having this event is the criterion."	SYMBOL
Generic	Regularly_recurring_event	event_duration	"No value implies either an instantaneous event, or unspecified, depending on the event."	Instance
Generic	Regularly_recurring_event	term_information	"Pointer to a UMLS preferred term or terms, if available, that capture the major clinical concepts in this data class (e.g, diabetes mellitus)."	Instance
Generic	Single_or_irregular_event	EVENT_ENTITY_ID		INTEGER
Generic	Single_or_irregular_event	event_timepoint_or_time_r	"When this event occurred or should occur, either by specifying a timepoint or an interval and its associated [time-operator]. Instantaneous events (e.g., death) are best described using a single timepoint (e.g., before Jan. 1, 2001). For events lasting a certain [event-duration], an interval could be specified and the	Instance

			time operator chosen to reflect whether the event should be before, after, or overlap in some way with the interval. (e.g., counselling entirely before 1990 (<1990) or counselling starting before 1990 and not lasting past 1995 (<=1990-1995))	
Generic	Single_or_irregular_event	event_description		STRING
Generic	Single_or_irregular_event	time_operator	"Before, after, concurrent with or combinations thereof. Probably need more operators, e.g., coincident with but not extending outside of this time..."	SYMBOL
Generic	Single_or_irregular_event	event_p	"Whether having or not having this event is the criterion."	SYMBOL
Generic	Single_or_irregular_event	event_duration	"No value implies either an instantaneous event, or unspecified, depending on the event."	Instance
Generic	Single_or_irregular_event	term_information	"Pointer to a UMLS preferred term or terms, if available, that capture the major clinical concepts in this data class (e.g, diabetes mellitus)."	Instance
Generic	Rule_concept	RCTID		INTEGER
Generic	Rule_concept	RULE_ID		INTEGER
Generic	Age_gender_rule	RULE_ID		INTEGER
Generic	Age_gender_rule	lower_age_range_value	"The value of the lowest age	INTEGER

			allowed in the study population."	
Generic	Age_gender_rule	lower_age_range_operator		SYMBOL
Generic	Age_gender_rule	gender_criterion		SYMBOL
Generic	Age_gender_rule	upper_age_range_operator		SYMBOL
Generic	Age_gender_rule	fertile_females_criterion	"Whether females of child-bearing potential are included or excluded from the study population."	SYMBOL
Generic	Age_gender_rule	upper_age_range_value	"The value of the highest age allowed in the study population."	INTEGER
Generic	Age_gender_rule	age_category_included	"Age category from MeSH that best describes the study population."	SYMBOL
Generic	Ethnicity_language_rule	RULE_ID		INTEGER
Generic	Ethnicity_language_rule	language_comment	"Description of whether language restrictions are for spoken and/or written language, or other relevant comments."	STRING
Generic	Ethnicity_language_rule	languages_not_allowed	"One of more languages excluded from study population."	SYMBOL
Generic	Ethnicity_language_rule	race_ethnicity_not_allowed	"The races or ethnicities excluded from this study population. Categories are from the Office of Management and Budget, year 2000."	SYMBOL
Generic	Ethnicity_language_rule	race_ethnicity_identification	"How a subject's ethnicity is identified."	SYMBOL
Generic	Ethnicity_language_rule	race_ethnicity_allowed	"Ethnicities allowed for eligibility. Categories are from the Office of	SYMBOL

			Management and Budget , 2000."	
Generic	Ethnicity_language_rule	languages_allowed	"The languages that subjects can use in the trial, e.g., English and Spanish. No distinction is made between reading or verbal comprehension."	SYMBOL
Generic	Rule_entity	RULE_ID		INTEGER
Generic	Rule_entity	RULE_ENTITY_ID		INTEGER
Generic	Rule_entity	rule_name	"An English string naming this criteron."	STRING
Generic	Rule_entity	term_information	"Pointer to a UMLS preferred term or terms, if available, that capture the major clinical concepts in this data class (e.g, diabetes mellitus)."	Instance
Generic	Base_rule	RULE_ENTITY_ID		INTEGER
Generic	Base_rule	situation_p	"Whether this situation is TRUE to satisfy this BASE-RULE, or NOT TRUE. e.g., value of this slot is NOT TRUE if rule is -Patient does not have SITUATION.-"	SYMBOL
Generic	Base_rule	situation	"Points to the situation/state/event that is the substance of this BASE-RULE."	Instance
Generic	Base_rule	description_of_rule	"Text description of this rule."	STRING
Generic	Recursive_rule	RULE_ENTITY_ID		INTEGER
Generic	Recursive_rule	connector	"The logical AND or OR that connects the sub-rules for this rule"	SYMBOL
Generic	Recursive_rule	sub_rules	"The rules that make up this rule. The base case is a single instance of BASE-RULE. "	Instance
Generic	Recursive_rule	temporary	"See for SPINAF, some criteria are	SYMBOL

			not permanent exclusions. Patients excluded on non-permanent exclusions may be rescreened later."	
Generic	Clinical_rule	RULE_ID		INTEGER
Generic	Clinical_rule	CLINICAL_RULE_TYPE	Inclusion, Exclusion	STRING
Generic	Clinical_rule	connector	"The logical AND or OR that connects the sub-rules for this rule"	SYMBOL
Generic	Clinical_rule	rule_name	"An English string naming this criterion."	STRING
Generic	Clinical_rule	term_information	"Pointer to a UMLS preferred term or terms, if available, that capture the major clinical concepts in this data class (e.g, diabetes mellitus)."	Instance
Generic	Clinical_rule	n_not_satisfying_rule	"The number of screened subjects who did not satisfy this rule."	INTEGER
Generic	Clinical_rule	sub_rules	"The rules that make up this rule. The base case is a single instance of BASE-RULE. "	Instance
Generic	Clinical_rule	n_satisfying_rule	"The number of screened subjects who satisfied this rule."	INTEGER
Generic	Time_entity	RCTID		INTEGER
Generic	Time_entity	TIME_ID		INTEGER
Generic	Date_entity	TIME_ID		INTEGER
Generic	Date_entity	m_month		SYMBOL
Generic	Date_entity	day_of_week		SYMBOL
Generic	Date_entity	y_year		INTEGER
Generic	Date_entity	d_day		INTEGER
Generic	Time_range	TIME_ID		INTEGER
Generic	Time_range	TIME_RANGE_ID		INTEGER
Generic	Duration	TIME_RANGE_ID		INTEGER
Generic	Duration	length_of_time		INTEGER
Generic	Duration	time_unit	"Unit of time for	SYMBOL

			various uses. For DRUG-STEP, refers to time-unit of dosing frequency."	
Generic	Duration	time_operator	"Before, after, concurrent with or combinations thereof. Probably need more operators, e.g., coincident with but not extending outside of this time..."	SYMBOL
Generic	Duration	fuzzy_range	"+/- this amount of time, assumed to be symmetric on the plus and minus sides."	STRING
Generic	Interval	TIME_RANGE_ID		INTEGER
Generic	Interval	INTERVAL_TYPE	Single-anchored, double-anchored	STRING
Generic	Interval	polarity	"Whether the duration occurs before or after the time anchor (ie whether the time anchor is at the beginning or the end of the interval)"	SYMBOL
Generic	Interval	interval_duration	"The duration of the interval, either fully defined (e.g., 3 months) or fuzzy (3 months +/- 1 week)."	Instance
Generic	Interval	start_anchor	"When this interval of this duration starts. Can start from an absolute or a relative timepoint (e.g., May 2, 1998 or -at enrollment-) . "	Instance
Generic	Interval	end_anchor	"When this interval of this duration ends. May end at an absolute or a relative timepoint (eg. May 2, 1995 or -end of trial.-)"	Instance

Generic	Anchored_time	TIME_ID		INTEGER
Generic	Anchored_time	ANCHORED_TIME_ID		INTEGER
Generic	Timepoint	ANCHORED_TIME_ID		INTEGER
Generic	Timepoint	reference_timepoint	"The timepoint from which timings are referenced. For outcomes, this is the time when the timing of the outcomes should start from. Often is -at enrollment- but may be something else. "	Instance
Generic	Timepoint	event_defined_timepoint	"May be used to specify a timepoint relative to a given event, as described elsewhere in the KB. e.g., ENROLLMENT-EVENT "	Instance
Generic	Timepoint	duration_length_from_ref	"The length of time from the reference timepoint."	INTEGER
Generic	Timepoint	time_operator	"Before, after, concurrent with or combinations thereof. Probably need more operators, e.g., coincident with but not extending outside of this time..."	SYMBOL
Generic	Timepoint	date_defined_timepoint	"A timepoint that is stated explicitly in some absolute scale (e.g., calendar time or system time). Right now, only takes calendar time."	Instance
Generic	Timepoint	text_description_of_timepoint	"A string description of a relative timepoint, e.g, -at enrollment- -now-. May be used to further describe an anchoring	STRING

			event that is the value of the anchor-event slot. "	
Generic	Timepoint	duration_time_unit	"The time unit for the duration before or after the reference timepoint."	SYMBOL
Generic	Term_informati on	RCTID		INTEGER
Generic	Term_informati on	TERM_ID		INTEGER
Generic	Term_informati on	term_definition	"Definition for this term."	STRING
Generic	Term_informati on	generic_term	"This string will be the user-s submission for terms that cannot be found in UMLS or other standard vocabulary. UMLS terms should be stored as instances of UMLS-TERM."	STRING
Generic	Term_informati on	umls_preferred_term		STRING
Generic	Term_informati on	search_string	"A string or a series of substrings originally used to locate the preferred term. "	STRING
Generic	Term_informati on	umls_cui	"Unique concept identifier"	STRING
Generic	Term_informati on	umls_sui	"Unique string identifier"	STRING

APPENDIX D

RCT WEB SERVICE CODE (ColdFusion Markup Language)

The ColdFusion Component used in the RCT Web service is written in ColdFusion Markup Language and contains over thirty SQL queries used by the RCT Query Tool.

```

<!--*****-->
<cffunction name="showInterventionsFunction" access="remote" returnType="query" output="false">
<!-- body --->
<cfquery name="showInterventionsQuery" datasource="RCT_FBD" >
SELECT DISPLAY_NAME FROM GET_INTERVENTION_DISPLAY
ORDER BY DISPLAY_NAME ASC
</cfquery>
<cfreturn showInterventionsQuery>
</cffunction>

<cffunction name="showOutcomesFunction" access="remote" returnType="query" output="false">
<!-- body --->
<cfquery name="showOutcomesQuery" datasource="RCT_FBD" >
SELECT DISPLAY_NAME FROM GET_OUTCOME_DISPLAY
ORDER BY DISPLAY_NAME ASC
</cfquery>
<cfreturn showOutcomesQuery>
</cffunction>

<cffunction name="showPopulationFunction" access="remote" returnType="query" output="false">
<!-- body --->
<cfquery name="showPopulationQuery" datasource="RCT_FBD" >
SELECT POPULATION_NAME FROM GET_POPULATION
ORDER BY POPULATION_NAME ASC
</cfquery>
<cfreturn showPopulationQuery>
</cffunction>

<cffunction name="showMaxSizeFunction" access="remote" returnType="query" output="false">
<!-- body --->
<cfquery name="showMaxSizeQuery" datasource="RCT_FBD" >
SELECT MAX_OF_NUMBER_OF_SUBJECTS FROM GET_POPULATION_MAX
</cfquery>
<cfreturn showMaxSizeQuery>
</cffunction>

<cffunction name="showMinSizeFunction" access="remote" returnType="query" output="false">
<!-- body --->
<cfquery name="showMinSizeQuery" datasource="RCT_FBD" >
SELECT MIN_OF_NUMBER_OF_SUBJECTS FROM GET_POPULATION_MIN
</cfquery>
<cfreturn showMinSizeQuery>
</cffunction>

<!--*****-->
<!--***** QUERIES TO MATCH SEARCH CRITERIA *****-->
<!--*****-->
<!--*****-->

<!--*****
          FILTER BY INTERVENTION
          INPUT = name of intervention (ex PCTA)
          OUTPUT = List of RCT ID's
          --->
<cffunction name="filterByIntervention" access="remote" returnType="query" output="false">

```

```

<!-- body -->
<cfargument name="filterByInterventionArg" type="any">
<cfquery name="filterByInterventionQuery" datasource="RCT_FBD" >
SELECT RCTID FROM GET_MATCHING_INTERVENTIONS
WHERE DISPLAY_NAME = '#filterByInterventionArg#'
GROUP BY RCTID
</cfquery>
<cfreturn filterByInterventionQuery>
</cffunction>

<!--***** FILTER BY OUTCOMES *****-->
<!--*** INPUT = Name of outcome (ex Stroke) --->
<!--*** OUTPUT = List of RCT ID's --->
--->
<cffunction name="filterByOutcomesFunction" access="remote" returnType="query" output="false">
<!-- body -->
<cfargument name="filterByOutcomesArg" type="string">
<cfquery name="filterByOutcomesQuery" datasource="RCT_FBD" >
SELECT RCTID FROM GET_OUTCOME_DETAILS
WHERE DISPLAY_NAME = '#filterByOutcomesArg#'
GROUP BY RCTID
</cfquery>
<cfreturn filterByOutcomesQuery>
</cffunction>

<!--***** FILTER BY POPULATION *****-->
<!--*** INPUT = Population name (ex Adult:55-65) --->
<!--*** OUTPUT = List of RCT ID's --->
--->
<cffunction name="filterByPopulationFunction" access="remote" returnType="query" output="false">
<!-- body -->
<cfargument name="filterByPopulationArg" type="string">
<cfquery name="filterByPopulationQuery" datasource="RCT_FBD" >
SELECT RCTID FROM GET_POPULATION_DETAILS
WHERE POPULATION_NAME = '#filterByPopulationArg#'
GROUP BY RCTID
</cfquery>
<cfreturn filterByPopulationQuery>
</cffunction>

<!--***** FILTER BY SAMPLE SIZE *****-->
<!--*** INPUT = Study size (ex >= 600) --->
<!--*** OUTPUT = List of RCT ID's --->
--->
<cffunction name="filterBySizeFunction" access="remote" returnType="query" output="false">
<!-- body -->
<cfargument name="filterBySizeArg" type="string">
<cfquery name="filterBySizeQuery" datasource="RCT_FBD" >
SELECT RCTID FROM GET_POPULATION_DETAILS
WHERE NUMBER_OF_SUBJECTS >= #filterBySizeArg#
GROUP BY RCTID
</cfquery>
<cfreturn filterBySizeQuery>
</cffunction>

<!--***** END OF MATCHING *****-->

```

```

<!--***** CREATE MASTER LIST OF RCTID'S *****-->
<!--***** COMBINE RCTID'S FROM ALL THE FILTERS *****-->
<!--***      INPUT = name of table (intervention type)    -->
<!--***      OUTPUT = List of RCT ID's                  -->

<cffunction name="getMatchingRCTIDs_1" access="remote" returnType="query" output="false">
<cfargument name="filterPopulationArg" type="query">
<cfargument name="filterSizeArg" type="query">
<cfquery name="getRCTIDsQuery_1" dbtype="query">
SELECT filterPopulationArg.RCTID
FROM filterPopulationArg, filterSizeArg
WHERE filterSizeArg.RCTID =
filterPopulationArg.RCTID
</cfquery>
<cfreturn getRCTIDsQuery_1>
</cffunction>

<cffunction name="getMatchingRCTIDs_2" access="remote" returnType="query" output="false">
<cfargument name="getRCTIDsQuery_1Arg" type="query">
<cfargument name="filterOutcomesArg" type="query">
<cfquery name="getRCTIDsQuery_2" dbtype="query">
SELECT getRCTIDsQuery_1Arg.RCTID
FROM getRCTIDsQuery_1Arg, filterOutcomesArg
WHERE filterOutcomesArg.RCTID=
getRCTIDsQuery_1Arg.RCTID
</cfquery>
<cfreturn getRCTIDsQuery_2>
</cffunction>

<cffunction name="compileMasterList" access="remote" returnType="query" output="false">
<!-- body -->
<cfargument name="filterInterventionsArg" type="query">
<cfargument name="getRCTIDsQuery_2Arg" type="query">
<cfquery name="getAllRCTIDsQuery" dbtype="query">
SELECT filterInterventionsArg.RCTID
FROM filterInterventionsArg, getRCTIDsQuery_2Arg
WHERE getRCTIDsQuery_2Arg.RCTID =
filterInterventionsArg.RCTID
</cfquery>
<cfreturn getAllRCTIDsQuery>
</cffunction>

<!--***** CREATE TEMPORARY TABLE TO HOLD RCTID'S *****-->
<cffunction name="truncateTempTable" access="remote" returnType="any" output="false">
<!-- body -->
<cfquery name="truncateTableQuery" datasource="RCT_FBD" >
CREATE TABLE TEMP_TABLE (
RCTID INTEGER)

```

```

</cfquery>
<cfset createSuccess = 1>
<cfreturn createSuccess>
</cffunction>
<!--***** POPULATE THE TEMP TABLE WITH THE MASTER LIST *****-->
<cffunction name="insertTempTable" access="remote" returnType="any" output="false">
<cfargument name="getAllRCTIDsArg" type="query">
<cfloop query="getAllRCTIDsArg">
<cfquery name="populateTempTableQuery" datasource="RCT_FBD" >
INSERT INTO TEMP_TABLE (RCTID) VALUES(#getAllRCTIDsArg.RCTID#)
</cfquery>
</cfloop>
<cfset populateSuccess = 1>
<cfreturn populateSuccess>
</cffunction>
<!--***** END OF MASTER LIST *****-->
<!--***** DETAILS *****-->
<!--***** 1. First step to extract arm details. *****-->
<!--*** INPUT = none --->
<!--*** OUTPUT = Query of intervention arm details --->

<cffunction name="getArmDetails" access="remote" returnType="query" output="false">
<cfquery name="getArmDetailsQuery" datasource="RCT_FBD" >
SELECT * FROM GET_ARM_DETAILS
WHERE RCTID IN
(SELECT RCTID FROM TEMP_TABLE)
ORDER BY RCTID
</cfquery>
<cfreturn getArmDetailsQuery>
</cffunction>
<!--** 2. Second step to get specific intervention type details. **-->
<!--*** INPUT = none --->
<!--*** OUTPUT = Query of intervention type details --->

<cffunction name="getDevice" access="remote" returnType="query" output="false">
<cfquery name="getDeviceQuery" datasource="RCT_FBD" >
SELECT * FROM GET_DEVICE
WHERE RCTID IN
(SELECT RCTID FROM TEMP_TABLE)
ORDER BY RCTID
</cfquery>
<cfreturn getDeviceQuery>
</cffunction>

<cffunction name="getDrug" access="remote" returnType="query" output="false">
<cfquery name="getDrugQuery" datasource="RCT_FBD" >
SELECT * FROM GET_DRUG
WHERE RCTID IN
(SELECT RCTID FROM TEMP_TABLE)

```

```

ORDER BY RCTID
</cfquery>
<cfreturn getDrugQuery>
</cffunction>

<cffunction name="getOtherInterv" access="remote" returnType="query" output="false">
<cfquery name="getOtherIntervQuery" datasource="RCT_FBD" >
SELECT * FROM GET_OTHER_INTERV
WHERE RCTID IN
(SELECT RCTID FROM TEMP_TABLE)
ORDER BY RCTID
</cfquery>
<cfreturn getOtherIntervQuery>
</cffunction>

<cffunction name="getPlacebo" access="remote" returnType="query" output="false">
<cfquery name="getPlaceboQuery" datasource="RCT_FBD" >
SELECT * FROM GET_PLACEBO
WHERE RCTID IN
(SELECT RCTID FROM TEMP_TABLE)
ORDER BY RCTID
</cfquery>
<cfreturn getPlaceboQuery>
</cffunction>

<cffunction name="getProcedure" access="remote" returnType="query" output="false">
<cfquery name="getProcedureQuery" datasource="RCT_FBD" >
SELECT * FROM GET_PROCEDURE
WHERE RCTID IN
(SELECT RCTID FROM TEMP_TABLE)
ORDER BY RCTID
</cfquery>
<cfreturn getProcedureQuery>
</cffunction>

```

```

<!--***** 3. Third step to get compliance details *****-->
<!--**      INPUT = none      -->
<!--***      OUTPUT = Query of intervention compliance details-->
<cffunction name="getCompResults" access="remote" returnType="query" output="false">
<cfquery name="getCompResultsQuery" datasource="RCT_FBD" >
SELECT * FROM GET_COMP_RESULTS
WHERE RCTID IN
(SELECT RCTID FROM TEMP_TABLE)
ORDER BY RCTID
</cfquery>
<cfreturn getCompResultsQuery>
</cffunction>

```

```

<!--*****4. Fourth step to get Intervention steps *****-->
<!--**      INPUT = none      -->
<!--***      OUTPUT = Query of intervention compliance details-->
<cffunction name="getInterventionSteps" access="remote" returnType="query" output="false">
<cfquery name="getInterventionStepsQuery" datasource="RCT_FBD" >
SELECT * FROM GET_STEPS

```

```

WHERE RCTID IN
(SELECT RCTID FROM TEMP_TABLE)
ORDER BY RCTID
</cfquery>
<cfreturn getInterventionStepsQuery>
</cffunction>

<!--***** 5. Fifth step to get Outcomes ****-->
<!--*** INPUT = none --->
<!--** OUTPUT = Query of intervention compliance details--->
<cffunction name="getOutcomeDetails" access="remote" returnType="query" output="false">
<cfquery name="getOutcomeDetailsQuery" datasource="RCT_FBD" >
SELECT * FROM GET_OUTCOME_DETAILS
WHERE RCTID IN
(SELECT RCTID FROM TEMP_TABLE)
ORDER BY RCTID
</cfquery>
<cfreturn getOutcomeDetailsQuery>
</cffunction>

<!--*****6. Get trial title ****-->
<!--*** INPUT = none --->
<!--** OUTPUT = Query of intervention compliance details--->
<cffunction name="getTrialTitle" access="remote" returnType="query" output="false">
<cfquery name="getTrialTitleQuery" datasource="RCT_FBD" >
SELECT * FROM TRIAL
WHERE RCTID IN
(SELECT RCTID FROM TEMP_TABLE)
ORDER BY RCTID
</cfquery>
<cfreturn getTrialTitleQuery>
</cffunction>

<!--***** 7. Get population details ****-->
<!--*** INPUT = none --->
<!--** OUTPUT = Query of intervention compliance details--->
<cffunction name="getPopulation" access="remote" returnType="query" output="false">
<cfquery name="getPopulationQuery" datasource="RCT_FBD" >
SELECT * FROM GET_POPULATION_DETAILS
WHERE RCTID IN
(SELECT RCTID FROM TEMP_TABLE)
ORDER BY RCTID
</cfquery>
<cfreturn getPopulationQuery>
</cffunction>

<!--*****8. Get design core details ****-->
<!--*** INPUT = none --->
<!--** OUTPUT = Query of intervention compliance details--->
<cffunction name="getDesign" access="remote" returnType="query" output="false">
<cfquery name="getDesignQuery" datasource="RCT_FBD" >
SELECT * FROM GET_STUDY DESIGN_CORE
WHERE RCTID IN
(SELECT RCTID FROM TEMP_TABLE)
ORDER BY RCTID
</cfquery>
```

```

<cffreturn getDesignQuery>
</cffunction>

<cffunction name="getDesignHyp" access="remote" returnType="query" output="false">
<cfquery name="getDesignHypQuery" datasource="RCT_FBD" >
SELECT * FROM GET_DESIGN_HYP
WHERE RCTID IN
(SELECT RCTID FROM TEMP_TABLE)
ORDER BY RCTID
</cfquery>
<cffreturn getDesignHypQuery>
</cffunction>

<cffunction name="getDesignHyp2" access="remote" returnType="query" output="false">
<cfquery name="getDesignHyp2Query" datasource="RCT_FBD" >
SELECT * FROM GET_DESIGN_HYP2
WHERE RCTID IN
(SELECT RCTID FROM TEMP_TABLE)
ORDER BY RCTID
</cfquery>
<cffreturn getDesignHyp2Query>
</cffunction>

<cffunction name="getSizeCalc" access="remote" returnType="query" output="false">
<cfquery name="getSizeCalcQuery" datasource="RCT_FBD" >
SELECT * FROM GET_SAMPLE_SIZE_CALC
WHERE RCTID IN
(SELECT RCTID FROM TEMP_TABLE)
ORDER BY RCTID
</cfquery>
<cffreturn getSizeCalcQuery>
</cffunction>

<cffunction name="getStatistical" access="remote" returnType="query" output="false">
<cfquery name="getStatisticalQuery" datasource="RCT_FBD" >
SELECT * FROM GET_DESIGN_STATISTICAL
WHERE RCTID IN
(SELECT RCTID FROM TEMP_TABLE)
ORDER BY RCTID
</cfquery>
<cffreturn getStatisticalQuery>
</cffunction>

<cffunction name="getRegression" access="remote" returnType="query" output="false">
<cfquery name="getRegressionQuery" datasource="RCT_FBD" >
SELECT * FROM GET_DESIGN_REGRESSION
WHERE RCTID IN
(SELECT RCTID FROM TEMP_TABLE)
ORDER BY RCTID
</cfquery>
<cffreturn getRegressionQuery>
</cffunction>

<cffunction name="getSurvival" access="remote" returnType="query" output="false">
<cfquery name="getSurvivalQuery" datasource="RCT_FBD" >
SELECT * FROM GET_DESIGN_SURVIVAL

```

```
WHERE RCTID IN
(SELECT RCTID FROM TEMP_TABLE)
ORDER BY RCTID
</cfquery>
<cfreturn getSurvivalQuery>
</cffunction>

<!--***** Drop master table of RCT's *****-->
<cffunction name="dropTempTable" access="remote" returnType="any" output="false">
<cfquery name="dropTempTableQuery" datasource="RCT_FBD" >
DROP TABLE TEMP_TABLE
</cfquery>
<cfset dropSuccess = 1>
<cfreturn dropSuccess>
</cffunction>

</cfcomponent>
```

APPENDIX E

RCT WEB SERVICES DESCRIPTION LANGUAGE (WSDL)

This code is generated by the ColdFusion server and is the Web services API for the RCT Query Tool.

```

<?xml version="1.0" encoding="UTF-8" ?>
- <wsdl:definitions targetNamespace="http://ws_rct"
  xmlns:impl="http://ws_rct" xmlns:intf="http://ws_rct"
  xmlns:apachesoap="http://xml.apache.org/xml-soap"
  xmlns:wsdlsoap="http://schemas.xmlsoap.org/wsdl/soap/"
  xmlns:soapenc="http://schemas.xmlsoap.org/soap/encoding/"
  xmlns:xsd="http://www.w3.org/2001/XMLSchema"
  xmlns:tns1="http://rpc.xml.coldfusion"
  xmlns:wsdl="http://schemas.xmlsoap.org/wsdl/"
  xmlns="http://schemas.xmlsoap.org/wsdl/">
- <wsdl:types>
- <schema xmlns="http://www.w3.org/2001/XMLSchema"
  targetNamespace="http://ws_rct">
    <import namespace="http://schemas.xmlsoap.org/soap/encoding/" />
- <complexType name="ArrayOf_xsd_string">
- <complexContent>
- <restriction base="soapenc:Array">
    <attribute ref="soapenc:arrayType" wsdl:arrayType="xsd:string[]" />
  </restriction>
</complexContent>
</complexType>
- <complexType name="ArrayOfArrayOf_xsd_anyType">
- <complexContent>
- <restriction base="soapenc:Array">
    <attribute ref="soapenc:arrayType" wsdl:arrayType="xsd:anyType[][]" />
  </restriction>
</complexContent>
</complexType>
</schema>
- <schema xmlns="http://www.w3.org/2001/XMLSchema"
  targetNamespace="http://rpc.xml.coldfusion">
    <import namespace="http://schemas.xmlsoap.org/soap/encoding/" />
- <complexType name="QueryBean">
- <sequence>
    <element name="columnList" nillable="true" type="impl:ArrayOf_xsd_string" />
    <element name="data" nillable="true" type="impl:ArrayOfArrayOf_xsd_anyType" />
  </sequence>
</complexType>
- <complexType name="CFCInvocationException">
  <sequence />
</complexType>
</schema>
</wsdl:types>
- <wsdl:message name="getMatchingRCTIDs_1Request">
  <wsdl:part name="filterPopulationArg" type="tns1:QueryBean" />
  <wsdl:part name="filterSizeArg" type="tns1:QueryBean" />
</wsdl:message>
<wsdl:message name="getSurvivalRequest" />

```

```

<wsdl:message name="showPopulationFunctionRequest" />
_- <wsdl:message name="CFCInvocationException">
  <wsdl:part name="fault" type="tns1:CFCInvocationException" />
</wsdl:message>
<wsdl:message name="getPlaceboRequest" />
_- <wsdl:message name="getOtherIntervResponse">
  <wsdl:part name="getOtherIntervReturn" type="tns1:QueryBean" />
</wsdl:message>
<wsdl:message name="getSizeCalcRequest" />
_- <wsdl:message name="getDeviceResponse">
  <wsdl:part name="getDeviceReturn" type="tns1:QueryBean" />
</wsdl:message>
<wsdl:message name="truncateTempTableRequest" />
<wsdl:message name="dropTempTableRequest" />
_- <wsdl:message name="getStatisticalResponse">
  <wsdl:part name="getStatisticalReturn" type="tns1:QueryBean" />
</wsdl:message>
<wsdl:message name="getInterventionStepsRequest" />
_- <wsdl:message name="insertTempTableResponse">
  <wsdl:part name="insertTempTableReturn" type="xsd:anyType" />
</wsdl:message>
_- <wsdl:message name="getMatchingRCTIDs_2Response">
  <wsdl:part name="getMatchingRCTIDs_2Return" type="tns1:QueryBean" />
</wsdl:message>
_- <wsdl:message name="getProcedureResponse">
  <wsdl:part name="getProcedureReturn" type="tns1:QueryBean" />
</wsdl:message>
<wsdl:message name="getDeviceRequest" />
<wsdl:message name="showInterventionsFunctionRequest" />
_- <wsdl:message name="filterByOutcomesFunctionRequest">
  <wsdl:part name="filterByOutcomesArg" type="xsd:string" />
</wsdl:message>
_- <wsdl:message name="getSizeCalcResponse">
  <wsdl:part name="getSizeCalcReturn" type="tns1:QueryBean" />
</wsdl:message>
<wsdl:message name="getOutcomeDetailsRequest" />
<wsdl:message name="getDrugRequest" />
_- <wsdl:message name="filterBySizeFunctionResponse">
  <wsdl:part name="filterBySizeFunctionReturn" type="tns1:QueryBean" />
</wsdl:message>
_- <wsdl:message name="filterBySizeFunctionRequest">
  <wsdl:part name="filterBySizeArg" type="xsd:string" />
</wsdl:message>
<wsdl:message name="getDesignRequest" />
_- <wsdl:message name="compileMasterListRequest">
  <wsdl:part name="filterInterventionsArg" type="tns1:QueryBean" />
  <wsdl:part name="getRCTIDsQuery_2Arg" type="tns1:QueryBean" />
</wsdl:message>
<wsdl:message name="getOtherIntervRequest" />

```

```

_= <wsdl:message name="showMinSizeFunctionResponse">
  <wsdl:part name="showMinSizeFunctionReturn" type="tns1:QueryBean" />
</wsdl:message>
<wsdl:message name="getDesignHyp2Request" />
_= <wsdl:message name="showInterventionsFunctionResponse">
  <wsdl:part name="showInterventionsFunctionReturn"
type="tns1:QueryBean" />
</wsdl:message>
_= <wsdl:message name="filterByPopulationFunctionResponse">
  <wsdl:part name="filterByPopulationFunctionReturn"
type="tns1:QueryBean" />
</wsdl:message>
_= <wsdl:message name="getDrugResponse">
  <wsdl:part name="getDrugReturn" type="tns1:QueryBean" />
</wsdl:message>
_= <wsdl:message name="getMatchingRCTIDs_1Response">
  <wsdl:part name="getMatchingRCTIDs_1Return" type="tns1:QueryBean" />
</wsdl:message>
<wsdl:message name="getRegressionRequest" />
_= <wsdl:message name="showPopulationFunctionResponse">
  <wsdl:part name="showPopulationFunctionReturn" type="tns1:QueryBean" />
</wsdl:message>
</wsdl:message>
_= <wsdl:message name="filterByOutcomesFunctionResponse">
  <wsdl:part name="filterByOutcomesFunctionReturn" type="tns1:QueryBean" />
</wsdl:message>
</wsdl:message>
_= <wsdl:message name="getCompResultsResponse">
  <wsdl:part name="getCompResultsReturn" type="tns1:QueryBean" />
</wsdl:message>
<wsdl:message name="showMaxSizeFunctionRequest" />
_= <wsdl:message name="getTrialTitleResponse">
  <wsdl:part name="getTrialTitleReturn" type="tns1:QueryBean" />
</wsdl:message>
<wsdl:message name="getStatisticalRequest" />
_= <wsdl:message name="truncateTempTableResponse">
  <wsdl:part name="truncateTempTableReturn" type="xsd:anyType" />
</wsdl:message>
_= <wsdl:message name="showOutcomesFunctionResponse">
  <wsdl:part name="showOutcomesFunctionReturn" type="tns1:QueryBean" />
</wsdl:message>
</wsdl:message>
_= <wsdl:message name="getPopulationResponse">
  <wsdl:part name="getPopulationReturn" type="tns1:QueryBean" />
</wsdl:message>
<wsdl:message name="getDesignHypRequest" />
_= <wsdl:message name="compileMasterListResponse">
  <wsdl:part name="compileMasterListReturn" type="tns1:QueryBean" />
</wsdl:message>

```

```

<wsdl:message name="showMinSizeFunctionRequest" />
<wsdl:message name="getProcedureRequest" />
_- <wsdl:message name="dropTempTableResponse">
  <wsdl:part name="dropTempTableReturn" type="xsd:anyType" />
</wsdl:message>
<wsdl:message name="getTrialTitleRequest" />
_- <wsdl:message name="filterByInterventionResponse">
  <wsdl:part name="filterByInterventionReturn" type="tns1:QueryBean" />
</wsdl:message>
_- <wsdl:message name="getDesignHypResponse">
  <wsdl:part name="getDesignHypReturn" type="tns1:QueryBean" />
</wsdl:message>
_- <wsdl:message name="insertTempTableRequest">
  <wsdl:part name="getAllRCTIDsArg" type="tns1:QueryBean" />
</wsdl:message>
_- <wsdl:message name="filterByInterventionRequest">
  <wsdl:part name="filterByInterventionArg" type="xsd:anyType" />
</wsdl:message>
<wsdl:message name="getArmDetailsRequest" />
_- <wsdl:message name="getInterventionStepsResponse">
  <wsdl:part name="getInterventionStepsReturn" type="tns1:QueryBean" />
</wsdl:message>
<wsdl:message name="getPopulationRequest" />
_- <wsdl:message name="getMatchingRCTIDs_2Request">
  <wsdl:part name="getRCTIDsQuery_1Arg" type="tns1:QueryBean" />
  <wsdl:part name="filterOutcomesArg" type="tns1:QueryBean" />
</wsdl:message>
_- <wsdl:message name="filterByPopulationFunctionRequest">
  <wsdl:part name="filterByPopulationArg" type="xsd:string" />
</wsdl:message>
_- <wsdl:message name="getOutcomeDetailsResponse">
  <wsdl:part name="getOutcomeDetailsReturn" type="tns1:QueryBean" />
</wsdl:message>
_- <wsdl:message name="showMaxSizeFunctionResponse">
  <wsdl:part name="showMaxSizeFunctionReturn" type="tns1:QueryBean" />
</wsdl:message>
_- <wsdl:message name="getSurvivalResponse">
  <wsdl:part name="getSurvivalReturn" type="tns1:QueryBean" />
</wsdl:message>
_- <wsdl:message name="getDesignResponse">
  <wsdl:part name="getDesignReturn" type="tns1:QueryBean" />
</wsdl:message>
<wsdl:message name="getCompResultsRequest" />
_- <wsdl:message name="getDesignHyp2Response">
  <wsdl:part name="getDesignHyp2Return" type="tns1:QueryBean" />
</wsdl:message>
<wsdl:message name="showOutcomesFunctionRequest" />
_- <wsdl:message name="getRegressionResponse">
  <wsdl:part name="getRegressionReturn" type="tns1:QueryBean" />

```

```

    </wsdl:message>
  - <wsdl:message name="getArmDetailsResponse">
    <wsdl:part name="getArmDetailsReturn" type="tns1:QueryBean" />
  </wsdl:message>
  - <wsdl:message name="getPlaceboResponse">
    <wsdl:part name="getPlaceboReturn" type="tns1:QueryBean" />
  </wsdl:message>
  - <wsdl:portType name="j_ws_rct">
    - <wsdl:operation name="insertTempTable"
parameterOrder="getAllRCTIDsArg">
      <wsdl:input name="insertTempTableRequest"
message="impl:insertTempTableRequest" />
      <wsdl:output name="insertTempTableResponse"
message="impl:insertTempTableResponse" />
      <wsdl:fault name="CFCInvocationException"
message="impl:CFCInvocationException" />
    </wsdl:operation>
    - <wsdl:operation name="filterByIntervention"
parameterOrder="filterByInterventionArg">
      <wsdl:input name="filterByInterventionRequest"
message="impl:filterByInterventionRequest" />
      <wsdl:output name="filterByInterventionResponse"
message="impl:filterByInterventionResponse" />
      <wsdl:fault name="CFCInvocationException"
message="impl:CFCInvocationException" />
    </wsdl:operation>
    - <wsdl:operation name="showInterventionsFunction">
      <wsdl:input name="showInterventionsFunctionRequest"
message="impl:showInterventionsFunctionRequest" />
      <wsdl:output name="showInterventionsFunctionResponse"
message="impl:showInterventionsFunctionResponse" />
      <wsdl:fault name="CFCInvocationException"
message="impl:CFCInvocationException" />
    </wsdl:operation>
    - <wsdl:operation name="showMaxSizeFunction">
      <wsdl:input name="showMaxSizeFunctionRequest"
message="impl:showMaxSizeFunctionRequest" />
      <wsdl:output name="showMaxSizeFunctionResponse"
message="impl:showMaxSizeFunctionResponse" />
      <wsdl:fault name="CFCInvocationException"
message="impl:CFCInvocationException" />
    </wsdl:operation>
    - <wsdl:operation name="getDesign">
      <wsdl:input name="getDesignRequest" message="impl:getDesignRequest" />
      <wsdl:output name="getDesignResponse"
message="impl:getDesignResponse" />
      <wsdl:fault name="CFCInvocationException"
message="impl:CFCInvocationException" />
    </wsdl:operation>
  </wsdl:portType>

```

```

_ <wsdl:operation name="getOtherInterv">
  <wsdl:input name="getOtherIntervRequest"
message="impl:getOtherIntervRequest" />
  <wsdl:output name="getOtherIntervResponse"
message="impl:getOtherIntervResponse" />
  <wsdl:fault name="CFCInvocationException"
message="impl:CFCInvocationException" />
</wsdl:operation>
_ <wsdl:operation name="filterBySizeFunction"
parameterOrder="filterBySizeArg">
  <wsdl:input name="filterBySizeFunctionRequest"
message="impl:filterBySizeFunctionRequest" />
  <wsdl:output name="filterBySizeFunctionResponse"
message="impl:filterBySizeFunctionResponse" />
  <wsdl:fault name="CFCInvocationException"
message="impl:CFCInvocationException" />
</wsdl:operation>
_ <wsdl:operation name="getTrialTitle">
  <wsdl:input name="getTrialTitleRequest"
message="impl:getTrialTitleRequest" />
  <wsdl:output name="getTrialTitleResponse"
message="impl:getTrialTitleResponse" />
  <wsdl:fault name="CFCInvocationException"
message="impl:CFCInvocationException" />
</wsdl:operation>
_ <wsdl:operation name="dropTempTable">
  <wsdl:input name="dropTempTableRequest"
message="impl:dropTempTableRequest" />
  <wsdl:output name="dropTempTableResponse"
message="impl:dropTempTableResponse" />
  <wsdl:fault name="CFCInvocationException"
message="impl:CFCInvocationException" />
</wsdl:operation>
_ <wsdl:operation name="truncateTempTable">
  <wsdl:input name="truncateTempTableRequest"
message="impl:truncateTempTableRequest" />
  <wsdl:output name="truncateTempTableResponse"
message="impl:truncateTempTableResponse" />
  <wsdl:fault name="CFCInvocationException"
message="impl:CFCInvocationException" />
</wsdl:operation>
_ <wsdl:operation name="getDevice">
  <wsdl:input name="getDeviceRequest" message="impl:getDeviceRequest" />
  <wsdl:output name="getDeviceResponse"
message="impl:getDeviceResponse" />
  <wsdl:fault name="CFCInvocationException"
message="impl:CFCInvocationException" />
</wsdl:operation>
_ <wsdl:operation name="filterByPopulationFunction"
parameterOrder="filterByPopulationArg">

```

```

<wsdl:input name="filterByPopulationFunctionRequest"
message="impl:filterByPopulationFunctionRequest" />
<wsdl:output name="filterByPopulationFunctionResponse"
message="impl:filterByPopulationFunctionResponse" />
<wsdl:fault name="CFCInvocationException"
message="impl:CFCInvocationException" />
</wsdl:operation>
_ <wsdl:operation name="getSurvival">
  <wsdl:input name="getSurvivalRequest" message="impl:getSurvivalRequest" />
  <wsdl:output name="getSurvivalResponse"
message="impl:getSurvivalResponse" />
  <wsdl:fault name="CFCInvocationException"
message="impl:CFCInvocationException" />
</wsdl:operation>
_ <wsdl:operation name="getDesignHyp2">
  <wsdl:input name="getDesignHyp2Request"
message="impl:getDesignHyp2Request" />
  <wsdl:output name="getDesignHyp2Response"
message="impl:getDesignHyp2Response" />
  <wsdl:fault name="CFCInvocationException"
message="impl:CFCInvocationException" />
</wsdl:operation>
_ <wsdl:operation name="getPopulation">
  <wsdl:input name="getPopulationRequest"
message="impl:getPopulationRequest" />
  <wsdl:output name="getPopulationResponse"
message="impl:getPopulationResponse" />
  <wsdl:fault name="CFCInvocationException"
message="impl:CFCInvocationException" />
</wsdl:operation>
_ <wsdl:operation name="getCompResults">
  <wsdl:input name="getCompResultsRequest"
message="impl:getCompResultsRequest" />
  <wsdl:output name="getCompResultsResponse"
message="impl:getCompResultsResponse" />
  <wsdl:fault name="CFCInvocationException"
message="impl:CFCInvocationException" />
</wsdl:operation>
_ <wsdl:operation name="filterByOutcomesFunction"
parameterOrder="filterByOutcomesArg">
  <wsdl:input name="filterByOutcomesFunctionRequest"
message="impl:filterByOutcomesFunctionRequest" />
  <wsdl:output name="filterByOutcomesFunctionResponse"
message="impl:filterByOutcomesFunctionResponse" />
  <wsdl:fault name="CFCInvocationException"
message="impl:CFCInvocationException" />
</wsdl:operation>
_ <wsdl:operation name="getSizeCalc">
  <wsdl:input name="getSizeCalcRequest"
message="impl:getSizeCalcRequest" />

```

```

    <wsdl:output name="getSizeCalcResponse"
message="impl:getSizeCalcResponse" />
    <wsdl:fault name="CFCInvocationException"
message="impl:CFCInvocationException" />
</wsdl:operation>
_ <wsdl:operation name="getPlacebo">
    <wsdl:input name="getPlaceboRequest" message="impl:getPlaceboRequest"
/>
    <wsdl:output name="getPlaceboResponse"
message="impl:getPlaceboResponse" />
    <wsdl:fault name="CFCInvocationException"
message="impl:CFCInvocationException" />
</wsdl:operation>
_ <wsdl:operation name="compileMasterList"
parameterOrder="filterInterventionsArg getRCTIDsQuery_2Arg">
    <wsdl:input name="compileMasterListRequest"
message="impl:compileMasterListRequest" />
    <wsdl:output name="compileMasterListResponse"
message="impl:compileMasterListResponse" />
    <wsdl:fault name="CFCInvocationException"
message="impl:CFCInvocationException" />
</wsdl:operation>
_ <wsdl:operation name="getStatistical">
    <wsdl:input name="getStatisticalRequest"
message="impl:getStatisticalRequest" />
    <wsdl:output name="getStatisticalResponse"
message="impl:getStatisticalResponse" />
    <wsdl:fault name="CFCInvocationException"
message="impl:CFCInvocationException" />
</wsdl:operation>
_ <wsdl:operation name="getDesignHyp">
    <wsdl:input name="getDesignHypRequest"
message="impl:getDesignHypRequest" />
    <wsdl:output name="getDesignHypResponse"
message="impl:getDesignHypResponse" />
    <wsdl:fault name="CFCInvocationException"
message="impl:CFCInvocationException" />
</wsdl:operation>
_ <wsdl:operation name="getRegression">
    <wsdl:input name="getRegressionRequest"
message="impl:getRegressionRequest" />
    <wsdl:output name="getRegressionResponse"
message="impl:getRegressionResponse" />
    <wsdl:fault name="CFCInvocationException"
message="impl:CFCInvocationException" />
</wsdl:operation>
_ <wsdl:operation name="getInterventionSteps">
    <wsdl:input name="getInterventionStepsRequest"
message="impl:getInterventionStepsRequest" />
    <wsdl:output name="getInterventionStepsResponse"
message="impl:getInterventionStepsResponse" />

```

```

<wsdl:fault name="CFCInvocationException"
message="impl:CFCInvocationException" />
</wsdl:operation>
_ <wsdl:operation name="showOutcomesFunction">
  <wsdl:input name="showOutcomesFunctionRequest"
message="impl:showOutcomesFunctionRequest" />
  <wsdl:output name="showOutcomesFunctionResponse"
message="impl:showOutcomesFunctionResponse" />
  <wsdl:fault name="CFCInvocationException"
message="impl:CFCInvocationException" />
</wsdl:operation>
_ <wsdl:operation name="showMinSizeFunction">
  <wsdl:input name="showMinSizeFunctionRequest"
message="impl:showMinSizeFunctionRequest" />
  <wsdl:output name="showMinSizeFunctionResponse"
message="impl:showMinSizeFunctionResponse" />
  <wsdl:fault name="CFCInvocationException"
message="impl:CFCInvocationException" />
</wsdl:operation>
_ <wsdl:operation name="getMatchingRCTIDs_2"
parameterOrder="getRCTIDsQuery_1Arg filterOutcomesArg">
  <wsdl:input name="getMatchingRCTIDs_2Request"
message="impl:getMatchingRCTIDs_2Request" />
  <wsdl:output name="getMatchingRCTIDs_2Response"
message="impl:getMatchingRCTIDs_2Response" />
  <wsdl:fault name="CFCInvocationException"
message="impl:CFCInvocationException" />
</wsdl:operation>
_ <wsdl:operation name="getProcedure">
  <wsdl:input name="getProcedureRequest"
message="impl:getProcedureRequest" />
  <wsdl:output name="getProcedureResponse"
message="impl:getProcedureResponse" />
  <wsdl:fault name="CFCInvocationException"
message="impl:CFCInvocationException" />
</wsdl:operation>
_ <wsdl:operation name="getMatchingRCTIDs_1"
parameterOrder="filterPopulationArg filterSizeArg">
  <wsdl:input name="getMatchingRCTIDs_1Request"
message="impl:getMatchingRCTIDs_1Request" />
  <wsdl:output name="getMatchingRCTIDs_1Response"
message="impl:getMatchingRCTIDs_1Response" />
  <wsdl:fault name="CFCInvocationException"
message="impl:CFCInvocationException" />
</wsdl:operation>
_ <wsdl:operation name="getArmDetails">
  <wsdl:input name="getArmDetailsRequest"
message="impl:getArmDetailsRequest" />
  <wsdl:output name="getArmDetailsResponse"
message="impl:getArmDetailsResponse" />

```

```

<wsdl:fault name="CFCInvocationException"
message="impl:CFCInvocationException" />
</wsdl:operation>
_ <wsdl:operation name="getDrug">
  <wsdl:input name="getDrugRequest" message="impl:getDrugRequest" />
  <wsdl:output name="getDrugResponse" message="impl:getDrugResponse" />
/>
  <wsdl:fault name="CFCInvocationException"
message="impl:CFCInvocationException" />
</wsdl:operation>
_ <wsdl:operation name="showPopulationFunction">
  <wsdl:input name="showPopulationFunctionRequest"
message="impl:showPopulationFunctionRequest" />
  <wsdl:output name="showPopulationFunctionResponse"
message="impl:showPopulationFunctionResponse" />
  <wsdl:fault name="CFCInvocationException"
message="impl:CFCInvocationException" />
</wsdl:operation>
_ <wsdl:operation name="getOutcomeDetails">
  <wsdl:input name="getOutcomeDetailsRequest"
message="impl:getOutcomeDetailsRequest" />
  <wsdl:output name="getOutcomeDetailsResponse"
message="impl:getOutcomeDetailsResponse" />
  <wsdl:fault name="CFCInvocationException"
message="impl:CFCInvocationException" />
</wsdl:operation>
</wsdl:portType>
_ <wsdl:binding name="j_ws_rct.cfcSoapBinding" type="impl:j_ws_rct">
  <wsdlsoap:binding style="rpc"
transport="http://schemas.xmlsoap.org/soap/http" />
_ <wsdl:operation name="insertTempTable">
  <wsdlsoap:operation soapAction="" />
_ <wsdl:input name="insertTempTableRequest">
  <wsdlsoap:body use="encoded"
encodingStyle="http://schemas.xmlsoap.org/soap/encoding/"
namespace="http://ws_rct" />
</wsdl:input>
_ <wsdl:output name="insertTempTableResponse">
  <wsdlsoap:body use="encoded"
encodingStyle="http://schemas.xmlsoap.org/soap/encoding/"
namespace="http://ws_rct" />
</wsdl:output>
_ <wsdl:fault name="CFCInvocationException">
  <wsdlsoap:fault use="encoded"
encodingStyle="http://schemas.xmlsoap.org/soap/encoding/"
namespace="http://ws_rct" />
</wsdl:fault>
</wsdl:operation>
_ <wsdl:operation name="filterByIntervention">
  <wsdlsoap:operation soapAction="" />

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```
_= <wsdl:input name="filterByInterventionRequest">
  <wsdlsoap:body use="encoded"
encodingStyle="http://schemas.xmlsoap.org/soap/encoding/"
namespace="http://ws_rct" />
</wsdl:input>
_= <wsdl:output name="filterByInterventionResponse">
  <wsdlsoap:body use="encoded"
encodingStyle="http://schemas.xmlsoap.org/soap/encoding/"
namespace="http://ws_rct" />
</wsdl:output>
_= <wsdl:fault name="CFCInvocationException">
  <wsdlsoap:fault use="encoded"
encodingStyle="http://schemas.xmlsoap.org/soap/encoding/"
namespace="http://ws_rct" />
</wsdl:fault>
</wsdl:operation>
_= <wsdl:operation name="showInterventionsFunction">
  <wsdlsoap:operation soapAction="" />
_= <wsdl:input name="showInterventionsFunctionRequest">
  <wsdlsoap:body use="encoded"
encodingStyle="http://schemas.xmlsoap.org/soap/encoding/"
namespace="http://ws_rct" />
</wsdl:input>
_= <wsdl:output name="showInterventionsFunctionResponse">
  <wsdlsoap:body use="encoded"
encodingStyle="http://schemas.xmlsoap.org/soap/encoding/"
namespace="http://ws_rct" />
</wsdl:output>
_= <wsdl:fault name="CFCInvocationException">
  <wsdlsoap:fault use="encoded"
encodingStyle="http://schemas.xmlsoap.org/soap/encoding/"
namespace="http://ws_rct" />
</wsdl:fault>
</wsdl:operation>
_= <wsdl:operation name="showMaxSizeFunction">
  <wsdlsoap:operation soapAction="" />
_= <wsdl:input name="showMaxSizeFunctionRequest">
  <wsdlsoap:body use="encoded"
encodingStyle="http://schemas.xmlsoap.org/soap/encoding/"
namespace="http://ws_rct" />
</wsdl:input>
_= <wsdl:output name="showMaxSizeFunctionResponse">
  <wsdlsoap:body use="encoded"
encodingStyle="http://schemas.xmlsoap.org/soap/encoding/"
namespace="http://ws_rct" />
</wsdl:output>
_= <wsdl:fault name="CFCInvocationException">
  <wsdlsoap:fault use="encoded"
encodingStyle="http://schemas.xmlsoap.org/soap/encoding/"
namespace="http://ws_rct" />
```

```

    </wsdl:fault>
    </wsdl:operation>
    -<wsdl:operation name="getDesign">
        <wsdlsoap:operation soapAction="" />
    -<wsdl:input name="getDesignRequest">
        <wsdlsoap:body use="encoded">
            encodingStyle="http://schemas.xmlsoap.org/soap/encoding/"
            namespace="http://ws_rct" />
        </wsdl:input>
    -<wsdl:output name="getDesignResponse">
        <wsdlsoap:body use="encoded">
            encodingStyle="http://schemas.xmlsoap.org/soap/encoding/"
            namespace="http://ws_rct" />
        </wsdl:output>
    -<wsdl:fault name="CFCInvocationException">
        <wsdlsoap:fault use="encoded">
            encodingStyle="http://schemas.xmlsoap.org/soap/encoding/"
            namespace="http://ws_rct" />
        </wsdl:fault>
    </wsdl:operation>
    -<wsdl:operation name="getOtherInterv">
        <wsdlsoap:operation soapAction="" />
    -<wsdl:input name="getOtherIntervRequest">
        <wsdlsoap:body use="encoded">
            encodingStyle="http://schemas.xmlsoap.org/soap/encoding/"
            namespace="http://ws_rct" />
        </wsdl:input>
    -<wsdl:output name="getOtherIntervResponse">
        <wsdlsoap:body use="encoded">
            encodingStyle="http://schemas.xmlsoap.org/soap/encoding/"
            namespace="http://ws_rct" />
        </wsdl:output>
    -<wsdl:fault name="CFCInvocationException">
        <wsdlsoap:fault use="encoded">
            encodingStyle="http://schemas.xmlsoap.org/soap/encoding/"
            namespace="http://ws_rct" />
        </wsdl:fault>
    </wsdl:operation>
    -<wsdl:operation name="filterBySizeFunction">
        <wsdlsoap:operation soapAction="" />
    -<wsdl:input name="filterBySizeFunctionRequest">
        <wsdlsoap:body use="encoded">
            encodingStyle="http://schemas.xmlsoap.org/soap/encoding/"
            namespace="http://ws_rct" />
        </wsdl:input>
    -<wsdl:output name="filterBySizeFunctionResponse">
        <wsdlsoap:body use="encoded">
            encodingStyle="http://schemas.xmlsoap.org/soap/encoding/"
            namespace="http://ws_rct" />
        </wsdl:output>

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```
_= <wsdl:fault name="CFCInvocationException">
  <wsdlsoap:fault use="encoded"
encodingStyle="http://schemas.xmlsoap.org/soap/encoding/"
namespace="http://ws_rct" />
  </wsdl:fault>
</wsdl:operation>
_= <wsdl:operation name="getTrialTitle">
  <wsdlsoap:operation soapAction="" />
_= <wsdl:input name="getTrialTitleRequest">
  <wsdlsoap:body use="encoded"
encodingStyle="http://schemas.xmlsoap.org/soap/encoding/"
namespace="http://ws_rct" />
  </wsdl:input>
_= <wsdl:output name="getTrialTitleResponse">
  <wsdlsoap:body use="encoded"
encodingStyle="http://schemas.xmlsoap.org/soap/encoding/"
namespace="http://ws_rct" />
  </wsdl:output>
_= <wsdl:fault name="CFCInvocationException">
  <wsdlsoap:fault use="encoded"
encodingStyle="http://schemas.xmlsoap.org/soap/encoding/"
namespace="http://ws_rct" />
  </wsdl:fault>
</wsdl:operation>
_= <wsdl:operation name="dropTempTable">
  <wsdlsoap:operation soapAction="" />
_= <wsdl:input name="dropTempTableRequest">
  <wsdlsoap:body use="encoded"
encodingStyle="http://schemas.xmlsoap.org/soap/encoding/"
namespace="http://ws_rct" />
  </wsdl:input>
_= <wsdl:output name="dropTempTableResponse">
  <wsdlsoap:body use="encoded"
encodingStyle="http://schemas.xmlsoap.org/soap/encoding/"
namespace="http://ws_rct" />
  </wsdl:output>
_= <wsdl:fault name="CFCInvocationException">
  <wsdlsoap:fault use="encoded"
encodingStyle="http://schemas.xmlsoap.org/soap/encoding/"
namespace="http://ws_rct" />
  </wsdl:fault>
</wsdl:operation>
_= <wsdl:operation name="truncateTempTable">
  <wsdlsoap:operation soapAction="" />
_= <wsdl:input name="truncateTempTableRequest">
  <wsdlsoap:body use="encoded"
encodingStyle="http://schemas.xmlsoap.org/soap/encoding/"
namespace="http://ws_rct" />
  </wsdl:input>
_= <wsdl:output name="truncateTempTableResponse">
```

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<wsdlsoap:body use="encoded"
encodingStyle="http://schemas.xmlsoap.org/soap/encoding/"
namespace="http://ws_rct" />
</wsdl:output>
- <wsdl:fault name="CFCInvocationException">
  <wsdlsoap:fault use="encoded"
encodingStyle="http://schemas.xmlsoap.org/soap/encoding/"
namespace="http://ws_rct" />
  </wsdl:fault>
</wsdl:operation>
- <wsdl:operation name="getDevice">
  <wsdlsoap:operation soapAction="" />
- <wsdl:input name="getDeviceRequest">
  <wsdlsoap:body use="encoded"
encodingStyle="http://schemas.xmlsoap.org/soap/encoding/"
namespace="http://ws_rct" />
  </wsdl:input>
- <wsdl:output name="getDeviceResponse">
  <wsdlsoap:body use="encoded"
encodingStyle="http://schemas.xmlsoap.org/soap/encoding/"
namespace="http://ws_rct" />
  </wsdl:output>
- <wsdl:fault name="CFCInvocationException">
  <wsdlsoap:fault use="encoded"
encodingStyle="http://schemas.xmlsoap.org/soap/encoding/"
namespace="http://ws_rct" />
  </wsdl:fault>
</wsdl:operation>
- <wsdl:operation name="filterByPopulationFunction">
  <wsdlsoap:operation soapAction="" />
- <wsdl:input name="filterByPopulationFunctionRequest">
  <wsdlsoap:body use="encoded"
encodingStyle="http://schemas.xmlsoap.org/soap/encoding/"
namespace="http://ws_rct" />
  </wsdl:input>
- <wsdl:output name="filterByPopulationFunctionResponse">
  <wsdlsoap:body use="encoded"
encodingStyle="http://schemas.xmlsoap.org/soap/encoding/"
namespace="http://ws_rct" />
  </wsdl:output>
- <wsdl:fault name="CFCInvocationException">
  <wsdlsoap:fault use="encoded"
encodingStyle="http://schemas.xmlsoap.org/soap/encoding/"
namespace="http://ws_rct" />
  </wsdl:fault>
</wsdl:operation>
- <wsdl:operation name="getSurvival">
  <wsdlsoap:operation soapAction="" />
- <wsdl:input name="getSurvivalRequest">

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<wsdlsoap:body use="encoded"
encodingStyle="http://schemas.xmlsoap.org/soap/encoding/"
namespace="http://ws_rct" />
</wsdl:input>
- <wsdl:output name="getSurvivalResponse">
  <wsdlsoap:body use="encoded"
encodingStyle="http://schemas.xmlsoap.org/soap/encoding/"
namespace="http://ws_rct" />
</wsdl:output>
- <wsdl:fault name="CFCInvocationException">
  <wsdlsoap:fault use="encoded"
encodingStyle="http://schemas.xmlsoap.org/soap/encoding/"
namespace="http://ws_rct" />
</wsdl:fault>
</wsdl:operation>
- <wsdl:operation name="getDesignHyp2">
  <wsdlsoap:operation soapAction="" />
- <wsdl:input name="getDesignHyp2Request">
  <wsdlsoap:body use="encoded"
encodingStyle="http://schemas.xmlsoap.org/soap/encoding/"
namespace="http://ws_rct" />
</wsdl:input>
- <wsdl:output name="getDesignHyp2Response">
  <wsdlsoap:body use="encoded"
encodingStyle="http://schemas.xmlsoap.org/soap/encoding/"
namespace="http://ws_rct" />
</wsdl:output>
- <wsdl:fault name="CFCInvocationException">
  <wsdlsoap:fault use="encoded"
encodingStyle="http://schemas.xmlsoap.org/soap/encoding/"
namespace="http://ws_rct" />
</wsdl:fault>
</wsdl:operation>
- <wsdl:operation name="getPopulation">
  <wsdlsoap:operation soapAction="" />
- <wsdl:input name="getPopulationRequest">
  <wsdlsoap:body use="encoded"
encodingStyle="http://schemas.xmlsoap.org/soap/encoding/"
namespace="http://ws_rct" />
</wsdl:input>
- <wsdl:output name="getPopulationResponse">
  <wsdlsoap:body use="encoded"
encodingStyle="http://schemas.xmlsoap.org/soap/encoding/"
namespace="http://ws_rct" />
</wsdl:output>
- <wsdl:fault name="CFCInvocationException">
  <wsdlsoap:fault use="encoded"
encodingStyle="http://schemas.xmlsoap.org/soap/encoding/"
namespace="http://ws_rct" />
</wsdl:fault>
```

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        </wsdl:operation>
    - <wsdl:operation name="getCompResults">
        <wsdlsoap:operation soapAction="" />
    - <wsdl:input name="getCompResultsRequest">
        <wsdlsoap:body use="encoded"
encodingStyle="http://schemas.xmlsoap.org/soap/encoding/"
namespace="http://ws_rct" />
        </wsdl:input>
    - <wsdl:output name="getCompResultsResponse">
        <wsdlsoap:body use="encoded"
encodingStyle="http://schemas.xmlsoap.org/soap/encoding/"
namespace="http://ws_rct" />
        </wsdl:output>
    - <wsdl:fault name="CFCInvocationException">
        <wsdlsoap:fault use="encoded"
encodingStyle="http://schemas.xmlsoap.org/soap/encoding/"
namespace="http://ws_rct" />
        </wsdl:fault>
    </wsdl:operation>
- <wsdl:operation name="filterByOutcomesFunction">
    <wsdlsoap:operation soapAction="" />
- <wsdl:input name="filterByOutcomesFunctionRequest">
    <wsdlsoap:body use="encoded"
encodingStyle="http://schemas.xmlsoap.org/soap/encoding/"
namespace="http://ws_rct" />
    </wsdl:input>
- <wsdl:output name="filterByOutcomesFunctionResponse">
    <wsdlsoap:body use="encoded"
encodingStyle="http://schemas.xmlsoap.org/soap/encoding/"
namespace="http://ws_rct" />
    </wsdl:output>
- <wsdl:fault name="CFCInvocationException">
    <wsdlsoap:fault use="encoded"
encodingStyle="http://schemas.xmlsoap.org/soap/encoding/"
namespace="http://ws_rct" />
    </wsdl:fault>
    </wsdl:operation>
- <wsdl:operation name="getSizeCalc">
    <wsdlsoap:operation soapAction="" />
- <wsdl:input name="getSizeCalcRequest">
    <wsdlsoap:body use="encoded"
encodingStyle="http://schemas.xmlsoap.org/soap/encoding/"
namespace="http://ws_rct" />
    </wsdl:input>
- <wsdl:output name="getSizeCalcResponse">
    <wsdlsoap:body use="encoded"
encodingStyle="http://schemas.xmlsoap.org/soap/encoding/"
namespace="http://ws_rct" />
    </wsdl:output>
- <wsdl:fault name="CFCInvocationException">

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<wsdlsoap:fault use="encoded"
encodingStyle="http://schemas.xmlsoap.org/soap/encoding/"
namespace="http://ws_rct" />
</wsdl:fault>
</wsdl:operation>
_- <wsdl:operation name="getPlacebo">
  <wsdlsoap:operation soapAction="" />
_- <wsdl:input name="getPlaceboRequest">
  <wsdlsoap:body use="encoded"
encodingStyle="http://schemas.xmlsoap.org/soap/encoding/"
namespace="http://ws_rct" />
</wsdl:input>
_- <wsdl:output name="getPlaceboResponse">
  <wsdlsoap:body use="encoded"
encodingStyle="http://schemas.xmlsoap.org/soap/encoding/"
namespace="http://ws_rct" />
</wsdl:output>
_- <wsdl:fault name="CFCInvocationException">
  <wsdlsoap:fault use="encoded"
encodingStyle="http://schemas.xmlsoap.org/soap/encoding/"
namespace="http://ws_rct" />
</wsdl:fault>
</wsdl:operation>
_- <wsdl:operation name="compileMasterList">
  <wsdlsoap:operation soapAction="" />
_- <wsdl:input name="compileMasterListRequest">
  <wsdlsoap:body use="encoded"
encodingStyle="http://schemas.xmlsoap.org/soap/encoding/"
namespace="http://ws_rct" />
</wsdl:input>
_- <wsdl:output name="compileMasterListResponse">
  <wsdlsoap:body use="encoded"
encodingStyle="http://schemas.xmlsoap.org/soap/encoding/"
namespace="http://ws_rct" />
</wsdl:output>
_- <wsdl:fault name="CFCInvocationException">
  <wsdlsoap:fault use="encoded"
encodingStyle="http://schemas.xmlsoap.org/soap/encoding/"
namespace="http://ws_rct" />
</wsdl:fault>
</wsdl:operation>
_- <wsdl:operation name="getStatistical">
  <wsdlsoap:operation soapAction="" />
_- <wsdl:input name="getStatisticalRequest">
  <wsdlsoap:body use="encoded"
encodingStyle="http://schemas.xmlsoap.org/soap/encoding/"
namespace="http://ws_rct" />
</wsdl:input>
_- <wsdl:output name="getStatisticalResponse">

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<wsdlsoap:body use="encoded"
encodingStyle="http://schemas.xmlsoap.org/soap/encoding/"
namespace="http://ws_rct" />
</wsdl:output>
- <wsdl:fault name="CFCInvocationException">
  <wsdlsoap:fault use="encoded"
encodingStyle="http://schemas.xmlsoap.org/soap/encoding/"
namespace="http://ws_rct" />
  </wsdl:fault>
</wsdl:operation>
- <wsdl:operation name="getDesignHyp">
  <wsdlsoap:operation soapAction="" />
- <wsdl:input name="getDesignHypRequest">
  <wsdlsoap:body use="encoded"
encodingStyle="http://schemas.xmlsoap.org/soap/encoding/"
namespace="http://ws_rct" />
  </wsdl:input>
- <wsdl:output name="getDesignHypResponse">
  <wsdlsoap:body use="encoded"
encodingStyle="http://schemas.xmlsoap.org/soap/encoding/"
namespace="http://ws_rct" />
  </wsdl:output>
- <wsdl:fault name="CFCInvocationException">
  <wsdlsoap:fault use="encoded"
encodingStyle="http://schemas.xmlsoap.org/soap/encoding/"
namespace="http://ws_rct" />
  </wsdl:fault>
</wsdl:operation>
- <wsdl:operation name="getRegression">
  <wsdlsoap:operation soapAction="" />
- <wsdl:input name="getRegressionRequest">
  <wsdlsoap:body use="encoded"
encodingStyle="http://schemas.xmlsoap.org/soap/encoding/"
namespace="http://ws_rct" />
  </wsdl:input>
- <wsdl:output name="getRegressionResponse">
  <wsdlsoap:body use="encoded"
encodingStyle="http://schemas.xmlsoap.org/soap/encoding/"
namespace="http://ws_rct" />
  </wsdl:output>
- <wsdl:fault name="CFCInvocationException">
  <wsdlsoap:fault use="encoded"
encodingStyle="http://schemas.xmlsoap.org/soap/encoding/"
namespace="http://ws_rct" />
  </wsdl:fault>
</wsdl:operation>
- <wsdl:operation name="getInterventionSteps">
  <wsdlsoap:operation soapAction="" />
- <wsdl:input name="getInterventionStepsRequest">

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<wsdlsoap:body use="encoded"
encodingStyle="http://schemas.xmlsoap.org/soap/encoding/"
namespace="http://ws_rct" />
</wsdl:input>
_ <wsdl:output name="getInterventionStepsResponse">
  <wsdlsoap:body use="encoded"
encodingStyle="http://schemas.xmlsoap.org/soap/encoding/"
namespace="http://ws_rct" />
</wsdl:output>
_ <wsdl:fault name="CFCInvocationException">
  <wsdlsoap:fault use="encoded"
encodingStyle="http://schemas.xmlsoap.org/soap/encoding/"
namespace="http://ws_rct" />
</wsdl:fault>
</wsdl:operation>
_ <wsdl:operation name="showOutcomesFunction">
  <wsdlsoap:operation soapAction="" />
_ <wsdl:input name="showOutcomesFunctionRequest">
  <wsdlsoap:body use="encoded"
encodingStyle="http://schemas.xmlsoap.org/soap/encoding/"
namespace="http://ws_rct" />
</wsdl:input>
_ <wsdl:output name="showOutcomesFunctionResponse">
  <wsdlsoap:body use="encoded"
encodingStyle="http://schemas.xmlsoap.org/soap/encoding/"
namespace="http://ws_rct" />
</wsdl:output>
_ <wsdl:fault name="CFCInvocationException">
  <wsdlsoap:fault use="encoded"
encodingStyle="http://schemas.xmlsoap.org/soap/encoding/"
namespace="http://ws_rct" />
</wsdl:fault>
</wsdl:operation>
_ <wsdl:operation name="showMinSizeFunction">
  <wsdlsoap:operation soapAction="" />
_ <wsdl:input name="showMinSizeFunctionRequest">
  <wsdlsoap:body use="encoded"
encodingStyle="http://schemas.xmlsoap.org/soap/encoding/"
namespace="http://ws_rct" />
</wsdl:input>
_ <wsdl:output name="showMinSizeFunctionResponse">
  <wsdlsoap:body use="encoded"
encodingStyle="http://schemas.xmlsoap.org/soap/encoding/"
namespace="http://ws_rct" />
</wsdl:output>
_ <wsdl:fault name="CFCInvocationException">
  <wsdlsoap:fault use="encoded"
encodingStyle="http://schemas.xmlsoap.org/soap/encoding/"
namespace="http://ws_rct" />
</wsdl:fault>
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    </wsdl:operation>
  - <wsdl:operation name="getMatchingRCTIDs_2">
    <wsdlsoap:operation soapAction="" />
  - <wsdl:input name="getMatchingRCTIDs_2Request">
    <wsdlsoap:body use="encoded"
encodingStyle="http://schemas.xmlsoap.org/soap/encoding/"
namespace="http://ws_rct" />
    </wsdl:input>
  - <wsdl:output name="getMatchingRCTIDs_2Response">
    <wsdlsoap:body use="encoded"
encodingStyle="http://schemas.xmlsoap.org/soap/encoding/"
namespace="http://ws_rct" />
    </wsdl:output>
  - <wsdl:fault name="CFCInvocationException">
    <wsdlsoap:fault use="encoded"
encodingStyle="http://schemas.xmlsoap.org/soap/encoding/"
namespace="http://ws_rct" />
    </wsdl:fault>
  </wsdl:operation>
  - <wsdl:operation name="getProcedure">
    <wsdlsoap:operation soapAction="" />
  - <wsdl:input name="getProcedureRequest">
    <wsdlsoap:body use="encoded"
encodingStyle="http://schemas.xmlsoap.org/soap/encoding/"
namespace="http://ws_rct" />
    </wsdl:input>
  - <wsdl:output name="getProcedureResponse">
    <wsdlsoap:body use="encoded"
encodingStyle="http://schemas.xmlsoap.org/soap/encoding/"
namespace="http://ws_rct" />
    </wsdl:output>
  - <wsdl:fault name="CFCInvocationException">
    <wsdlsoap:fault use="encoded"
encodingStyle="http://schemas.xmlsoap.org/soap/encoding/"
namespace="http://ws_rct" />
    </wsdl:fault>
  </wsdl:operation>
  - <wsdl:operation name="getMatchingRCTIDs_1">
    <wsdlsoap:operation soapAction="" />
  - <wsdl:input name="getMatchingRCTIDs_1Request">
    <wsdlsoap:body use="encoded"
encodingStyle="http://schemas.xmlsoap.org/soap/encoding/"
namespace="http://ws_rct" />
    </wsdl:input>
  - <wsdl:output name="getMatchingRCTIDs_1Response">
    <wsdlsoap:body use="encoded"
encodingStyle="http://schemas.xmlsoap.org/soap/encoding/"
namespace="http://ws_rct" />
    </wsdl:output>
  - <wsdl:fault name="CFCInvocationException">

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<wsdlsoap:fault use="encoded"
encodingStyle="http://schemas.xmlsoap.org/soap/encoding/"
namespace="http://ws_rct" />
</wsdl:fault>
</wsdl:operation>
- <wsdl:operation name="getArmDetails">
  <wsdlsoap:operation soapAction="" />
- <wsdl:input name="getArmDetailsRequest">
  <wsdlsoap:body use="encoded"
encodingStyle="http://schemas.xmlsoap.org/soap/encoding/"
namespace="http://ws_rct" />
</wsdl:input>
- <wsdl:output name="getArmDetailsResponse">
  <wsdlsoap:body use="encoded"
encodingStyle="http://schemas.xmlsoap.org/soap/encoding/"
namespace="http://ws_rct" />
</wsdl:output>
- <wsdl:fault name="CFCInvocationException">
  <wsdlsoap:fault use="encoded"
encodingStyle="http://schemas.xmlsoap.org/soap/encoding/"
namespace="http://ws_rct" />
</wsdl:fault>
</wsdl:operation>
- <wsdl:operation name="getDrug">
  <wsdlsoap:operation soapAction="" />
- <wsdl:input name="getDrugRequest">
  <wsdlsoap:body use="encoded"
encodingStyle="http://schemas.xmlsoap.org/soap/encoding/"
namespace="http://ws_rct" />
</wsdl:input>
- <wsdl:output name="getDrugResponse">
  <wsdlsoap:body use="encoded"
encodingStyle="http://schemas.xmlsoap.org/soap/encoding/"
namespace="http://ws_rct" />
</wsdl:output>
- <wsdl:fault name="CFCInvocationException">
  <wsdlsoap:fault use="encoded"
encodingStyle="http://schemas.xmlsoap.org/soap/encoding/"
namespace="http://ws_rct" />
</wsdl:fault>
</wsdl:operation>
- <wsdl:operation name="showPopulationFunction">
  <wsdlsoap:operation soapAction="" />
- <wsdl:input name="showPopulationFunctionRequest">
  <wsdlsoap:body use="encoded"
encodingStyle="http://schemas.xmlsoap.org/soap/encoding/"
namespace="http://ws_rct" />
</wsdl:input>
- <wsdl:output name="showPopulationFunctionResponse">
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<wsdl:soap:body use="encoded"
encodingStyle="http://schemas.xmlsoap.org/soap/encoding/"
namespace="http://ws_rct" />
</wsdl:output>
_ <wsdl:fault name="CFCInvocationException">
  <wsdl:soap:fault use="encoded"
encodingStyle="http://schemas.xmlsoap.org/soap/encoding/"
namespace="http://ws_rct" />
  </wsdl:fault>
</wsdl:operation>
_ <wsdl:operation name="getOutcomeDetails">
  <wsdl:soap:operation soapAction="" />
_ <wsdl:input name="getOutcomeDetailsRequest">
  <wsdl:soap:body use="encoded"
encodingStyle="http://schemas.xmlsoap.org/soap/encoding/"
namespace="http://ws_rct" />
  </wsdl:input>
_ <wsdl:output name="getOutcomeDetailsResponse">
  <wsdl:soap:body use="encoded"
encodingStyle="http://schemas.xmlsoap.org/soap/encoding/"
namespace="http://ws_rct" />
  </wsdl:output>
</wsdl:operation>
_ <wsdl:fault name="CFCInvocationException">
  <wsdl:soap:fault use="encoded"
encodingStyle="http://schemas.xmlsoap.org/soap/encoding/"
namespace="http://ws_rct" />
  </wsdl:fault>
</wsdl:operation>
</wsdl:binding>
_ <wsdl:service name="j_ws_rctService">
_ <wsdl:port name="j_ws_rct.cfc" binding="impl:j_ws_rct.cfcSoapBinding">
  <wsdl:soap:address location="http://localhost:8501/ws_rct/j_ws_rct.cfc" />
</wsdl:port>
</wsdl:service>
</wsdl:definitions>
```

APPENDIX F

RCT QUERY TOOL CODE (ColdFusion Markup Language & HTML)

This code represents the web interface of the RCT Query Tool and RCT Web service. The code is a combination of server-side ColdFusion Markup Language and HTML. There are two components to this interface: the search page and the results page. The code for both is given in this appendix.

SEARCH PAGE

```

<cfif IsDefined("Session.searched")>
<cfset StructDelete(Session, "searched")>
</cfif>

<!-- Invoke queries to create drop-down lists ****=>
<!-- Get Interventions for a drop-down list --->
<cfinvoke
webservice="j_ws_rct"
method="showInterventionsFunction"
returnvariable="showInterventionsQuery">
</cfinvoke>

<!-- Get Outcomes for a drop-down list --->
<cfinvoke
webservice="j_ws_rct"
method="showOutcomesFunction"
returnvariable="showOutcomesQuery">
</cfinvoke>

<!-- Get Population for a drop-down list --->
<cfinvoke
webservice="j_ws_rct"
method="showPopulationFunction"
returnvariable="showPopulationQuery">
</cfinvoke>

<!-- Get Max Size for a drop-down list --->
<cfinvoke
webservice="j_ws_rct"
method="showMaxSizeFunction"
returnvariable="showMaxSizeQuery">
</cfinvoke>

<!-- Get Min Size for a drop-down list --->
<cfinvoke
webservice="j_ws_rct"
method="showMinSizeFunction"
returnvariable="showMinSizeQuery">
</cfinvoke>

<!-- END queries for drop-down lists ****=>

<html>
<head>
<title>RCT Meta-Search</title>
<meta http-equiv="Content-Type" content="text/html; charset=iso-8859-1">
<link href="css/rctstyle.css" rel="stylesheet" type="text/css">
</head>

<body bgcolor="#E7CBA0">
<p class="topheading">RCT Meta-Data SEARCH</p>
<form action="j_action.cfm" method="post">
<table width="400" border="0" align="center" cellpadding="6" cellspacing="0">
<tr>
<td colspan="4" nowrap class="heading">&ampnbsp</td>

```

```

</tr>
<tr>
<td nowrap class="side">1.</td>
<td nowrap class="side">Intervention Type</td>
<td colspan="2" class="list1"> <div align="left">
<select name="filterByInterventionArg">
<cfoutput query="showInterventionsQuery">
<option value="#DISPLAY_NAME#">#DISPLAY_NAME#</option>
</cfoutput>
</select>
</div></td>
</tr>
<tr>
<td nowrap class="side">2.</td>
<td nowrap class="side">Outcome</td>
<td colspan="2" class="list1"> <div align="left">
<select name="filterByOutcomeArg">
<cfoutput query="showOutcomesQuery">
<option value="#DISPLAY_NAME#">#DISPLAY_NAME#</option>
</cfoutput>
</select>
</div></td>
</tr>
<tr>
<td nowrap class="side">3.</td>
<td nowrap class="side">Population</td>
<td colspan="2" class="list1"> <div align="left">
<select name="filterByPopulationArg">
<cfoutput query="showPopulationQuery">
<option value="#POPULATION_NAME#">#POPULATION_NAME#</option>
</cfoutput>
</select>
</div></td>
</tr>
<tr>
<td nowrap class="side">4.</td>
<td nowrap class="side">Sample Size</td>
<td colspan="2" nowrap class="list1"> <div align="left">&nbsp;>=&nbsp;
<input name="filterBySizeArg" type="text" value="510" size="10" maxlength="4">
&nbsp;
Range from
<cfoutput>#showMinSizeQuery.MIN_OF_NUMBER_OF_SUBJECTS#</cfoutput>
to
<cfoutput>#showMaxSizeQuery.MAX_OF_NUMBER_OF_SUBJECTS#</cfoutput></div></td>
</tr>
<tr>
<td colspan="4" nowrap class="heading"> <div align="center">
<input name="submitFilter" type="submit" value="Submit">
</div></td>
</tr>
<tr>
<td colspan="2">&nbsp;</td>
<td>&nbsp;</td>
<td width="100%">&nbsp; </td>
</tr>

```

```
</table>
</form>
</body>
</html>
```

RESULTS PAGE

```
<cfset currentPage=GetFileFromPath(GetTemplatePath())>

<cfif IsDefined ("form.filterBySizeArg") AND #form.filterBySizeArg# NEQ "" AND Not
IsDefined("Session.searched")>
<cfset Session.searched = #form.filterByInterventionArg#>
<!--*****-->
<!--***** FILTERS *****-->
<!--*****-->
<!-- 1. Intervention Filter -->
<!-- Returns = query of RCTID's and INTERVENTION_ARM_ID'S for the intervention type -->
<cfinvoke
webservice="j_ws_rct"
method="filterByIntervention"
returnvariable="filterByInterventionQuery">
<cfinvokeargument name="filterByInterventionArg" value="#form.filterByInterventionArg#"/>
</cfinvoke>

<!--2. Outcomes Filter-->
<cfinvoke
webservice="j_ws_rct"
method="filterByOutcomesFunction"
returnvariable="filterByOutcomesQuery">
<cfinvokeargument name="filterByOutcomesArg" value="#form.filterByOutcomeArg#"/>
</cfinvoke>
<!-- 3. X Filter-->
<cfinvoke
webservice="j_ws_rct"
method="filterByPopulationFunction"
returnvariable="filterByPopulationQuery">
<cfinvokeargument name="filterByPopulationArg" value="#form.filterByPopulationArg#"/>
</cfinvoke>
<!-- 4. X Filter-->
<cfinvoke
webservice="j_ws_rct"
method="filterBySizeFunction"
returnvariable="filterBySizeQuery">
<cfinvokeargument name="filterBySizeArg" value="#form.filterBySizeArg#"/>
</cfinvoke>
<!--*****-->
<!--***** COMPILE *****-->
<!--*****-->
<!--1. Compile master list of RCTs meeting all above criteria-->

<cfinvoke
webservice="j_ws_rct"
method="getMatchingRCTIDs_1"
returnvariable="getRCTIDsQuery_1">
<cfinvokeargument name="filterPopulationArg" value="#filterByPopulationQuery#"/>
<cfinvokeargument name="filterSizeArg" value="#filterBySizeQuery#"/>
```

```

</cfinvoke>

<cfinvoke
webservice="j_ws_rct"
method="getMatchingRCTIDs_2"
returnvariable="getRCTIDsQuery_2">
<cfinvokeargument name="getRCTIDsQuery_1Arg" value="#getRCTIDsQuery_1#" />
<cfinvokeargument name="filterOutcomesArg" value="#filterByOutcomesQuery#" />
</cfinvoke>

<cfinvoke
webservice="j_ws_rct"
method="compileMasterList"
returnvariable="getAllRCTIDsQuery">
<cfinvokeargument name="filterInterventionsArg" value="#filterByInterventionQuery#" />
<cfinvokeargument name="getRCTIDsQuery_2Arg" value="#getRCTIDsQuery_2#" />
</cfinvoke>

<!-- 2. Make a temp table to hold RCTIDs -->
<cfinvoke
webservice="j_ws_rct"
method="truncateTempTable"
returnvariable="createSuccess">
</cfinvoke>
<!-- 3. Make a temp table to hold RCTIDs -->
<cfinvoke
webservice="j_ws_rct"
method="insertTempTable"
returnvariable="populateTempTableQuery">
<cfinvokeargument name="getAllRCTIDsArg" value="#getAllRCTIDsQuery#" />
</cfinvoke>

<!----*****-->
<!----*****--> DETAILS <!----*****-->
<!----*****-->
<!----* Extract study details. --->

<cfinvoke
webservice="j_ws_rct"
method="getArmDetails"
returnvariable="getArmDetailsQuery">
</cfinvoke>

<cfinvoke
webservice="j_ws_rct"
method="getDevice"
returnvariable="getDeviceQuery">
</cfinvoke>

<cfinvoke
webservice="j_ws_rct"

```

```
method="getDrug"
returnvariable="getDrugQuery">
</cfinvoke>

<cfinvoke
webservice="j_ws_rct"
method="getOtherInterv"
returnvariable="getOtherIntervQuery">
</cfinvoke>

<cfinvoke
webservice="j_ws_rct"
method="getPlacebo"
returnvariable="getPlaceboQuery">
</cfinvoke>

<cfinvoke
webservice="j_ws_rct"
method="getProcedure"
returnvariable="getProcedureQuery">
</cfinvoke>

<cfinvoke
webservice="j_ws_rct"
method="getCompResults"
returnvariable="getCompResultsQuery">
</cfinvoke>

<cfinvoke
webservice="j_ws_rct"
method="getInterventionSteps"
returnvariable="getInterventionStepsQuery">
</cfinvoke>

<cfinvoke
webservice="j_ws_rct"
method="getOutcomeDetails"
returnvariable="getOutcomeDetailsQuery">
</cfinvoke>

<cfinvoke
webservice="j_ws_rct"
method="getTrialTitle"
returnvariable="getTrialTitleQuery">
</cfinvoke>

<cfinvoke
webservice="j_ws_rct"
method="getPopulation"
returnvariable="getPopulationQuery">
</cfinvoke>

<cfinvoke
webservice="j_ws_rct"
method="getDesign"
```

```

returnvariable="getDesignQuery">
</cfinvoke>

<cfinvoke
webservice="j_ws_rct"
method="getDesignHyp"
returnvariable="getDesignHypQuery">
</cfinvoke>

<cfinvoke
webservice="j_ws_rct"
method="getDesignHyp2"
returnvariable="getDesignHyp2Query">
</cfinvoke>

<cfinvoke
webservice="j_ws_rct"
method="getStatistical"
returnvariable="getStatisticalQuery">
</cfinvoke>

<cfinvoke
webservice="j_ws_rct"
method="getRegression"
returnvariable="getRegressionQuery">
</cfinvoke>

<cfinvoke
webservice="j_ws_rct"
method="getSurvival"
returnvariable="getSurvivalQuery">
</cfinvoke>

<cfinvoke
webservice="j_ws_rct"
method="getSizeCalc"
returnvariable="getSizeCalcQuery">
</cfinvoke>

<cfinvoke
webservice="j_ws_rct"
method="dropTempTable"
returnvariable="dropSuccess">
</cfinvoke>

<cfelseif Not IsDefined("form.filterBySizeArg") AND #form.filterBySizeArg# EQ "" AND Not
IsDefined("Session.searched")>
<cflocation url="j_portal.cfm">
</cfif>

<html>
<head>
<title>RCT Meta-Data RESULTS</title>
<meta http-equiv="Content-Type" content="text/html; charset=iso-8859-1">

```

```

<script language="JavaScript" src="toggle.js" type="text/javascript"></script>
<link href="css/rctstyle.css" rel="stylesheet" type="text/css">
</head>

<body bgcolor="#E7CBA0">
<form action="j_action.cfm" method="post">
<!-- Display page heading --->
<table width="100%" border="0" cellspacing="0" cellpadding="0">
<tr><td class="topheading">RCT Meta-Data</td></tr>
<tr><td class="topheading2">SEARCH SUMMARY</td></tr>
</table>

<!-- Search result table --->

<table width="100%" border="0" cellspacing="0" cellpadding="8">
<tr>
<td nowrap class="list1">Intervention</td>
<td width="50%" nowrap class="intervention"> <cfoutput>#form.filterByInterventionArg#</cfoutput>
</td>
<td nowrap class="list1">Population</td>
<td width="50%" class="intervention"> <cfoutput>#form.filterByPopulationArg#</cfoutput> </td>
</tr>
<tr></tr>
<tr>
<td nowrap class="list1">Outcome</td>
<td width="50%" nowrap class="intervention"><cfoutput>#form.filterByOutcomeArg#</cfoutput></td>
<td nowrap class="list1">Sample Size</td>
<td width="50%" class="intervention"><cfoutput>#form.filterBySizeArg#</cfoutput></td>
</tr>
<tr></tr>
</table>
<br>

<!-- Show results if there are any --->
<cfif #getTrialTitleQuery.RecordCount# NEQ 0>
<table width="100%" border="0" cellspacing="0" cellpadding="0">
<tr><td class="topheading2"><cfoutput>#getTrialTitleQuery.RecordCount#</cfoutput>
RESULTS</td></tr>
</table>

<!-- Start of main content table --->
<table width="100%" border="0" cellspacing="0" cellpadding="4">
<tr class="intervention"><td class="list1">Title</td>

<!-- 1st Row - Display Title--->

<!-- Main loop over all returned trials --->
<cfset x = 1>
<cfloop query="getTrialTitleQuery">
<!-- Show the title--->
<td class="interventionCell">

```

```

<table width="100%" height="50" border="0" cellpadding="4" cellspacing="0">
<tr>
<td class="title"><div align="center"><cfoutput>#x#</cfoutput><br>
<cfoutput>#getTrialTitleQuery.DESCRIPTION#</cfoutput></div></td>
</tr>
</table>
</td>
<cfset x = x+1>
</cfloop>
</tr>
<tr></tr>

<!--***** 2nd Row - Display Interventions *****-->
<!--1. Display Heading-->
<tr class="intervention">
<td class="list1" nowrap>Intervention Arm <br>
<input name="displayInt2" type="button" value="Show" onClick="toggle('showInterventionRow')"></td>

<!-- Main loop over all returned trials -->

<cfloop query="getTrialTitleQuery">
<td class="interventionCell">
<table width="100%" height="50" border="0" cellpadding="4" cellspacing="0">
<!-- Show the interventions-->
<cfset id = #getTrialTitleQuery.RCTID#>
<!-- 2nd loop -->
<!-- Display study arm details-->
<tr>
<cfloop query="getArmDetailsQuery">
<cfif getArmDetailsQuery.RCTID EQ id AND getArmDetailsQuery.JUSTIFICATION EQ "">
<td class="newSubheading">
<cfoutput>#getArmDetailsQuery.DISPLAY_NAME#</cfoutput>
</td>
</cfif>
</cfloop>
</tr>
</table>
</td>
</cfloop>
</tr>

<!--2. Display Details-->
<tr class="intervention" id="showInterventionRow" style = display:none>
<!-- In the first cell, display a table of column names -->
<td class="interventionCell">
<table width="100%" border="0" cellspacing="0" cellpadding="4">
<!-- Initialize Counter -->
<cfset int1 = 1>
<!-- Loop over the list of column names from the Query -->
<cfloop index="ColumnName" list="#getArmDetailsQuery.columnlist#">
<cfoutput><tr></tr><tr><td class="subheading">#ColumnName#</td></tr>
</cfoutput>
<!-- Increment Counter -->
<cfset int1 = int1 + 1>

```

```

</cfloop>
</table>
</td>

<!-- Main loop over all returned trials -->
<cfloop query="getTrialTitleQuery">
<td class="interventionCell">
<table width="100%" border="0" cellspacing="0" cellpadding="4">
<!-- Show the interventions-->
<cfset id = #getTrialTitleQuery.RCTID#>
<!-- 2nd loop -->
<!-- Display study arm details-->

<cfloop query="getArmDetailsQuery">
<cfif getArmDetailsQuery.RCTID EQ id AND getArmDetailsQuery.JUSTIFICATION EQ "">

<CFSET zz = 1>

<!-- Loop over the list of column names from the Query -->

<CFLOOP INDEX="ColumnName" LIST="#getArmDetailsQuery.columnlist#">

<!-- Create a temporary variable with the column name -->
<CFSET Variables.TEMPNAME = "getArmDetailsQuery.#ColumnName#">
<!-- Create a session variable with the value of the column name -->
<CFSET TEMP = SetVariable("Session.#ColumnName#", "#evaluate(Variables.TEMPNAME)")>
<cfif #TEMP# EQ "">
<CFOUTPUT><tr></tr><tr><td nowrap class="subheading">&nbsp;</td></tr></CFOUTPUT>
<cfelse>
<CFOUTPUT><tr></tr><tr><td nowrap class="subheading">#TEMP#</td></tr></CFOUTPUT>
</cfif>
<!-- Increment Counter -->
<CFSET zz= zz + 1>
</CFLOOP>

</cfif>

</cfloop>

</table>
</td>
<!-- End Main loop over all returned trials -->
</cfloop>

</tr>
<tr></tr>
<!--***** End of 2nd Row ***** -->
      End of 2nd Row      ****>

<!--***** 3rd Row - Display Comparisons ***** -->
<!-- 1. Display heading -->
<tr class="intervention">
<td class="list1" nowrap>Comparison Arm<br>
<input name="displayInt" type="button" value="Show" onClick="toggle('showComparisonRow')"></td>

```

```

<!-- Main loop over all returned trials -->

<cfloop query="getTrialTitleQuery">
<td class="interventionCell">
<table width="100%" height="50" border="0" cellpadding="4" cellspacing="0">
<!-- Show the interventions-->
<cfset id = #getTrialTitleQuery.RCTID#>
<!-- 2nd loop --->
<!-- Display study arm details--->
<tr>
<cfloop query="getArmDetailsQuery">
<cfif getArmDetailsQuery.RCTID EQ id AND getArmDetailsQuery.JUSTIFICATION NEQ "">
<td class="newSubheading2">
<cfoutput>#getArmDetailsQuery.DISPLAY_NAME#</cfoutput>
</td>
</cfif>
</cfloop>
</tr>

</table>
</td>

</cfloop>
</tr>
<!--2. Display Details-->
<!-- Create hidden row of details-->
<tr class="intervention" id="showComparisonRow" style = display:none>
<!-- In the first cell, display a table of column names -->
<td class="interventionCell">
<table width="100%" border="0" cellspacing="0" cellpadding="4">
<!-- Initialize Counter --->
<cfset int1 = 1>
<!-- Loop over the list of column names from the Query --->
<cfloop index="ColumnName" list="#getArmDetailsQuery.columnlist#">
<cfoutput><tr></tr><tr><td class="subheading">#ColumnName#</td></tr></cfoutput>
<!-- Increment Counter --->
<cfset int1= int1 + 1>
</cfloop>
</table>
</td>

<!-- Main loop over all returned trials -->
<cfloop query="getTrialTitleQuery">
<td class="interventionCell">
<table width="100%" border="0" cellspacing="0" cellpadding="4">
<!-- Show the interventions-->
<cfset id = #getTrialTitleQuery.RCTID#>
<!-- 2nd loop --->
<!-- Display study arm details--->

<cfloop query="getArmDetailsQuery">
<cfif getArmDetailsQuery.RCTID EQ id AND getArmDetailsQuery.JUSTIFICATION NEQ "">
<CFSET zz = 1>

```

```

<!-- Loop over the list of column names from the Query -->
<CFLOOP INDEX="ColumnName" LIST="#getArmDetailsQuery.columnlist#">

<!-- Create a temporary variable with the column name -->
<CFSET Variables.TEMPNAME = "getArmDetailsQuery.#ColumnName#">
<!-- Create a session variable with the value of the column name -->
<CFSET TEMP = SetVariable("Session.#ColumnName#",
"#evaluate(Variables.TEMPNAME)#")>
<cfif #TEMP# EQ "">
<CFOUTPUT><tr></tr><tr><td nowrap class="subheading">&nbsp;</td></tr></CFOUTPUT>
<cfelse>
<CFOUTPUT><tr></tr><tr><td nowrap class="subheading">#TEMP#</td></tr></CFOUTPUT>
</cfif>
<!-- Increment Counter -->
<CFSET zz= zz + 1>
</CFLOOP>

</cfif>
</cfloop>

</table>
</td>
<!-- End Main loop over all returned trials -->
</cfloop>

</tr>
<tr></tr>
<!--***** End of 3rd Row *****-->

<!--***** 4th Row - Display Outcomes *****-->
<!-- 1. Display heading -->
<tr class="intervention">
<td class="list1" nowrap>Primary Outcomes<br>
<input name="displayInt" type="button" value="Show" onClick="toggle('showOutcomesRow')"/></td>

<!-- Main loop over all returned trials -->

<cfloop query="getTrialTitleQuery">
<td class="interventionCell">
<table width="100%" height="50" border="0" cellpadding="4" cellspacing="0">
<!-- Show the interventions-->
<cfset id = #getTrialTitleQuery.RCTID#>
<!-- 2nd loop -->
<!-- Display study arm details-->
<tr>
<cfloop query="getOutcomeDetailsQuery">
<cfif getOutcomeDetailsQuery.RCTID EQ id AND getOutcomeDetailsQuery.OUTCOME_TYPE EQ
"Primary">
<td class="newSubheading3">
<cfoutput>#getOutcomeDetailsQuery.DISPLAY_NAME#</cfoutput>
</td>
</cfif>
</cfloop>

```

```

</tr>
</table>
</td>

</cfloop>
</tr>
<!--2. Display Details-->
<!-- Create hidden row of details-->
<tr class="intervention" id="showOutcomesRow" style = display:none>
<!-- In the first cell, display a table of column names -->
<td class="interventionCell">
<table width="100%" border="0" cellspacing="0" cellpadding="4">
<!-- Initialize Counter -->
<cfset int1 = 1>
<!-- Loop over the list of column names from the Query -->
<cfloop index="ColumnName" list="#getOutcomeDetailsQuery.columnlist#">
<cfoutput><tr></tr><tr><td class="subheading">#ColumnName#</td></tr></cfoutput>
<!-- Increment Counter -->
<cfset int1= int1 + 1>
</cfloop>
</table>
</td>

<!-- Main loop over all returned trials -->
<!-- Display content -->
<cfloop query="getTrialTitleQuery">
<td class="interventionCell">
<table width="100%" border="0" cellspacing="0" cellpadding="4">
<tr>
<!-- Show the interventions-->
<cfset id = #getTrialTitleQuery.RCTID#>
<!-- 2nd loop -->
<!-- Display study arm details-->

<cfloop query="getOutcomeDetailsQuery">
<cfif getOutcomeDetailsQuery.RCTID EQ id AND getOutcomeDetailsQuery.OUTCOME_TYPE EQ
"Primary">
<td>
<CFSET zz = 1>

<!-- Loop over the list of column names from the Query -->
<table width="100%" border="0" cellspacing="0" cellpadding="4">
<CFLOOP INDEX="ColumnName" LIST="#getOutcomeDetailsQuery.columnlist#">

<!-- Create a temporary variable with the column name -->
<CFSET Variables.TEMPNAME = "getOutcomeDetailsQuery.#ColumnName#">
<!-- Create a session variable with the value of the column name -->
<CFSET TEMP = SetVariable("Session.#ColumnName#", "#evaluate(Variables.TEMPNAME)#")>
<cfif #TEMP# EQ "">
<CFOUTPUT><tr></tr><tr><td nowrap class="subheading">&nbsp;</td></tr></CFOUTPUT>
<cfelse>
<CFOUTPUT><tr></tr><tr><td nowrap class="subheading">#TEMP#</td></tr></CFOUTPUT>
</cfif>

```

```

<!-- Increment Counter -->
<CFSET zz= zz + 1>
</CFLOOP>
</table>
</td>
</cfif>

</cfloop>
</tr>
</table>
</td>
<!-- End Main loop over all returned trials -->
</cfloop>

</tr>
<tr></tr>
<!--***** End of 4th Row *****-->
<!--***** 5th Row - Display Secondary Outcomes *****-->
>
<!-- 1. Display heading -->
<tr class="intervention">
<td class="list1" nowrap>Secondary Outcomes<br>
<input name="displayInt" type="button" value="Show" onClick="toggle('showOutcomesSecRow')"></td>

<!-- Main loop over all returned trials -->

<cfloop query="getTrialTitleQuery">
<td class="interventionCell">
<table width="100%" height="50" border="0" cellpadding="4" cellspacing="0">
<!-- Show the interventions-->
<cfset id = #getTrialTitleQuery.RCTID#>
<!-- 2nd loop -->
<!-- Display study arm details-->
<tr>
<cfloop query="getOutcomeDetailsQuery">
<cfif getOutcomeDetailsQuery.RCTID EQ id AND getOutcomeDetailsQuery.OUTCOME_TYPE EQ
"Secondary">
<td class="newSubheading4">
<cfoutput>#getOutcomeDetailsQuery.DISPLAY_NAME#</cfoutput>
</td>
</cfif>
</cfloop>
</tr>

</table>
</td>

</cfloop>
</tr>
<!--2. Display Details-->
<!-- Create hiden row of details-->
<tr class="intervention" id="showOutcomesSecRow" style = display:none>
<!-- In the first cell, display a table of column names -->
<td class="interventionCell">
<table width="100%" border="0" cellspacing="0" cellpadding="4">
<!-- Initialize Counter -->

```

```

<cfset int1 = 1>
<!-- Loop over the list of column names from the Query -->
<cfloop index="ColumnName" list="#getOutcomeDetailsQuery.columnlist#">
<cfoutput><tr></tr><tr><td class="subheading">#ColumnName#</td></tr></cfoutput>
<!-- Increment Counter -->
<cfset int1= int1 + 1>
</cfloop>
</table>
</td>

<!-- Main loop over all returned trials -->
<cfloop query="getTrialTitleQuery">
<td class="interventionCell">
<table width="100%" border="0" cellspacing="0" cellpadding="4">
<!-- Show the interventions-->
<cfset id = #getTrialTitleQuery.RCTID#>
<!-- 2nd loop -->
<!-- Display study arm details-->

<cfloop query="getOutcomeDetailsQuery">
<cfif getOutcomeDetailsQuery.RCTID EQ id AND getOutcomeDetailsQuery.OUTCOME_TYPE EQ
"Secondary">

<CFSET zz = 1>

<!-- Loop over the list of column names from the Query -->
<CFLOOP INDEX="ColumnName" LIST="#getOutcomeDetailsQuery.columnlist#">

<!-- Create a temporary variable with the column name -->
<CFSET Variables.TEMPNAME = "getOutcomeDetailsQuery.#ColumnName#">
<!-- Create a session variable with the value of the column name -->
<CFSET TEMP = SetVariable("Session.#ColumnName#", 
"#evaluate(Variables.TEMPNAME)#")>
<cfif #TEMP# EQ "">
<CFOUTPUT><tr></tr><tr><td nowrap class="subheading">&nbsp;</td></tr></CFOUTPUT>
<cfelse>
<CFOUTPUT><tr></tr><tr><td nowrap class="subheading">#TEMP#</td></tr></CFOUTPUT>
</cfif>
<!-- Increment Counter -->
<CFSET zz= zz + 1>
</CFLOOP>

</cfif>
</cfloop>

</table>
</td>
<!-- End Main loop over all returned trials -->
</cfloop>

</tr>
<tr></tr>
<!--***** End of 5th Row *****-->

```

```

<!--*****6th Row - Display Population*****-->
<!-- 1. Display heading --->
<tr class="intervention">
<td class="list1" nowrap>Population<br>
<input name="displayInt" type="button" value="Show" onClick="toggle('showPopulationRow')"/></td>

<!-- Main loop over all returned trials --->

<cfloop query="getTrialTitleQuery">
<td class="interventionCell">
<table width="100%" height="50" border="0" cellpadding="4" cellspacing="0">
<!-- Show the interventions--->
<cfset id = #getTrialTitleQuery.RCTID#>
<!-- 2nd loop --->
<!-- Display study arm details--->
<tr>
<cfloop query="getPopulationQuery">
<cfif getPopulationQuery.RCTID EQ id>
<td class="newSubheading">
<cfoutput>#getPopulationQuery.POPULATION_NAME#</cfoutput>
<br>
Sample Size = <cfoutput>#getPopulationQuery.NUMBER_OF_SUBJECTS#</cfoutput>
</td>
</cfif>
</cfloop>
</tr>

</table>
</td>

</cfloop>
</tr>
<!--2. Display Details--->
<!-- Create hiden row of details--->
<tr class="intervention" id="showPopulationRow" style = display:none>
<!-- In the first cell, display a table of column names --->
<td class="interventionCell">
<table width="100%" border="0" cellspacing="0" cellpadding="4">
<!-- Initialize Counter --->
<cfset int1 = 1>
<!-- Loop over the list of column names from the Query --->
<cfloop index="ColumnName" list="#getPopulationQuery.columnlist#">
<cfoutput><tr></tr><tr><td class="subheading">#ColumnName#</td></tr></cfoutput>
<!-- Increment Counter --->
<cfset int1= int1 + 1>
</cfloop>
</table>
</td>

<!-- Main loop over all returned trials --->
<cfloop query="getTrialTitleQuery">
<td class="interventionCell">
<table width="100%" border="0" cellspacing="0" cellpadding="4">
<!-- Show the interventions--->
<cfset id = #getTrialTitleQuery.RCTID#>

```

```

<!-- 2nd loop -->
<!-- Display study arm details-->

<cfloop query="getPopulationQuery">
<cfif getPopulationQuery.RCTID EQ id>

<CFSET zz = 1>

<!-- Loop over the list of column names from the Query -->

<CFLOOP INDEX="ColumnName" LIST="#getPopulationQuery.columnlist#">

<!-- Create a temporary variable with the column name -->
<CFSET Variables.TEMPNAME = "getPopulationQuery.#ColumnName#">
<!-- Create a session variable with the value of the column name -->
<CFSET TEMP = SetVariable("Session.#ColumnName#", "#evaluate(Variables.TEMPNAME)#")>
<cfif #TEMP# EQ "">
<CFOUTPUT><tr></tr><tr><td nowrap class="subheading">&nbsp;</td></tr></CFOUTPUT>
<cfelse>
<CFOUTPUT><tr></tr><tr><td nowrap class="subheading">#TEMP#</td></tr></CFOUTPUT>
</cfif>
<!-- Increment Counter -->
<CFSET zz= zz + 1>
</CFLOOP>

</cfif>

</cfloop>

</table>
</td>
<!-- End Main loop over all returned trials -->
</cfloop>

</tr>
<tr></tr>
<!--***** End of 7th Row ***** -->
<!--***** 8th Row - Display Design ***** -->
<!-- 1. Display heading -->
<tr class="intervention">
<td class="list1" nowrap>Design<br>
<input name="displayInt" type="button" value="Show" onClick="toggle('showDesignRow'); toggle('showDesignRowHyp1'); toggle('showDesignRowPrim'); toggle('showDesignRowHyp2'); toggle('showDesignRowSec'); toggle('showRowSizeCalc'); toggle('showRowSizeCalc1'); toggle('showRowStatistical'); toggle('showRowStatistical1'); toggle('showRowSurvival'); toggle('showRowSurvival1'); toggle('showRowRegression'); toggle('showRowRegression1')"></td>

<!-- Main loop over all returned trials -->

<cfloop query="getTrialTitleQuery">
<td class="interventionCell">
<table width="100%" height="50" border="0" cellpadding="4" cellspacing="0">
<!-- Show the interventions-->
<cfset id = #getTrialTitleQuery.RCTID#>
<!-- 2nd loop -->

```

```

<!-- Display study arm details-->
<tr>
<cfloop query="getDesignHypQuery">
<cfif getDesignHypQuery.RCTID EQ id>
<td class="newSubheading2">
<cfoutput>#getDesignHypQuery.STATEMENT_OF_HYPOTHESIS#</cfoutput>
</td>
</cfif>
</cfloop>
</tr>

</table>
</td>

</cfloop>
</tr>
<!--2. Display Details-->
<!-- Create hiden row of details-->
<tr class="intervention" id="showDesignRow" style = display:none>
<!-- In the first cell, display a table of column names -->
<td class="interventionCell">
<table width="100%" border="0" cellspacing="0" cellpadding="4">
<!-- Initialize Counter -->
<cfset int1 = 1>
<!-- Loop over the list of column names from the Query -->
<cfloop index="ColumnName" list="#getDesignQuery.columnlist#">
<cfoutput><tr></tr><tr><td class="subheading">#ColumnName#</td></tr></cfoutput>
<!-- Increment Counter -->
<cfset int1= int1 + 1>
</cfloop>
</table>
</td>

<!-- Main loop over all returned trials -->
<cfloop query="getTrialTitleQuery">
<td class="interventionCell">
<table width="100%" border="0" cellspacing="0" cellpadding="4">
<!-- Show the interventions-->
<cfset id = #getTrialTitleQuery.RCTID#>
<!-- 2nd loop -->
<!-- Display study arm details-->

<cfloop query="getDesignQuery">
<cfif getDesignQuery.RCTID EQ id>

<CFSET zz = 1>

<!-- Loop over the list of column names from the Query -->

<CFLOOP INDEX="ColumnName" LIST="#getDesignQuery.columnlist#">
<!-- Create a temporary variable with the column name -->
<CFSET Variables.TEMPNAME = "getDesignQuery.#ColumnName#">
<!-- Create a session variable with the value of the column ame -->
<CFSET TEMP = SetVariable("Session.#ColumnName#", ,

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"#evaluate(Variables.TEMPNAME#">
<cfif #TEMP# EQ "">
<CFOUTPUT><tr></tr><tr><td nowrap class="subheading">&nbsp;</td></tr></CFOUTPUT>
<cfelse>
<CFOUTPUT><tr></tr><tr><td nowrap class="subheading">#TEMP#</td></tr></CFOUTPUT>
</cfif>
<!-- Increment Counter --->
<CFSET zz= zz + 1>
</CFLoop>

</cfif>
</cfloop>

</table>
</td>
<!-- End Main loop over all returned trials --->
</cfloop>
</tr>

<!-- More hidden info; Show primary hypothesis --->

<tr class="intervention" id="showDesignRowHyp1" style = display:none><td>Primary Hypothesis
</td></tr>
<tr class="intervention" id="showDesignRowPrim" style = display:none>
<!-- In the first cell, display a table of column names --->
<td class="interventionCell">
<table width="100%" border="0" cellspacing="0" cellpadding="4">
<!-- Initialize Counter --->
<cfset int1 = 1>
<!-- Loop over the list of column names from the Query --->
<cfloop index="ColumnName" list="#getDesignHypQuery.columnlist#">
<cfoutput><tr></tr><tr><td class="subheading">#ColumnName#</td></tr></cfoutput>
<!-- Increment Counter --->
<cfset int1= int1 + 1>
</cfloop>
</table>
</td>
<!-- Main loop over all returned trials --->
<cfloop query="getTrialTitleQuery">
<td class="interventionCell">
<table width="100%" border="0" cellspacing="0" cellpadding="4">
<!-- Show the interventions--->
<cfset id = #getTrialTitleQuery.RCTID#>
<!-- 2nd loop --->
<!-- Display study arm details--->

<cfloop query="getDesignHypQuery">
<cfif getDesignHypQuery.RCTID EQ id>

<CFSET zz = 1>

<!-- Loop over the list of column names from the Query --->

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```

<CFLOOP INDEX="ColumnName" LIST="#getDesignHypQuery.columnlist#">

    <!-- Create a temporary variable with the column name -->
    <CFSET Variables.TEMPNAME = "getDesignHypQuery.#ColumnName#">
    <!-- Create a session variable with the value of the column name -->
    <CFSET TEMP = SetVariable("Session.#ColumnName#", "#evaluate(Variables.TEMPNAME)#")>
    <cfif #TEMP# EQ "">
        <CFOUTPUT><tr></tr><tr><td nowrap class="subheading">&nbsp;</td></tr></CFOUTPUT>
    <cfelse>
        <CFOUTPUT><tr></tr><tr><td nowrap class="subheading">#TEMP#</td></tr></CFOUTPUT>
    </cfif>
    <!-- Increment Counter -->
    <CFSET zz= zz + 1>
</CFLOOP>

</cfif>
</cfloop>

</table>
</td>
<!-- End Main loop over all returned trials -->
</cfloop>
</tr>

<!-- More hidden info; Show secondary hypothesis -->

<tr class="intervention" id="showDesignRowHyp2" style = display:none><td>Secondary Hypothesis
</td></tr>
<tr class="intervention" id="showDesignRowSec" style = display:none>
    <!-- In the first cell, display a table of column names -->
    <td class="interventionCell">
        <table width="100%" border="0" cellspacing="0" cellpadding="4">
            <!-- Initialize Counter -->
            <cfset int1 = 1>
            <!-- Loop over the list of column names from the Query -->
            <cfloop index="ColumnName" list="#getDesignHyp2Query.columnlist#">
                <cfoutput><tr></tr><tr><td class="subheading">#ColumnName#</td></tr></cfoutput>
            <!-- Increment Counter -->
            <cfset int1= int1 + 1>
        </cfloop>
    </td>
    <!-- Main loop over all returned trials -->
    <cfloop query="getTrialTitleQuery">
        <td class="interventionCell">
            <table width="100%" border="0" cellspacing="0" cellpadding="4">
                <!-- Show the interventions-->
                <cfset id = #getTrialTitleQuery.RCTID#>
                <!-- 2nd loop -->
                <!-- Display study arm details-->

                <cfloop query="getDesignHyp2Query">
                    <cfif getDesignHyp2Query.RCTID EQ id>

```

```

<CFSET zz = 1>

<!--- Loop over the list of column names from the Query --->

<CFLOOP INDEX="ColumnName" LIST="#getDesignHyp2Query.columnlist#">

<!--- Create a temporary variable with the column name --->
<CFSET Variables.TEMPNAME = "getDesignHyp2Query.#ColumnName#">
<!--- Create a session variable with the value of the column name --->
<CFSET TEMP = SetVariable("Session.#ColumnName#",
"#evaluate(Variabes.TEMPNAME)#")>
<cfif #TEMP# EQ "">
<CFOUTPUT><tr></tr><tr><td nowrap class="subheading">&nbsp;</td></tr></CFOUTPUT>
<cfelse>
<CFOUTPUT><tr></tr><tr><td nowrap class="subheading">#TEMP#</td></tr></CFOUTPUT>
</cfif>
<!--- Increment Counter --->
<CFSET zz= zz + 1>
</CFLOOP>

</cfif>

</cfloop>

</table>
</td>
<!--- End Main loop over all returned trials --->
</cfloop>
</tr>
<tr></tr>

<!--- More hidden info; Show sample size calculation info --->

<tr class="intervention" id="showRowSizeCalc" style = display:none><td>Sample Size Calculation
</td></tr>
<tr class="intervention" id="showRowSizeCalc1" style = display:none>
<!--- In the first cell, display a table of column names --->
<td class="interventionCell">
<table width="100%" border="0" cellspacing="0" cellpadding="4">
<!--- Initialize Counter --->
<cfset int1 = 1>
<!--- Loop over the list of column names from the Query --->
<cfloop index="ColumnName" list="#getSizeCalcQuery.columnlist#">
<cfoutput><tr></tr><tr><td class="subheading">#ColumnName#</td></tr></cfoutput>
<!--- Increment Counter --->
<cfset int1= int1 + 1>
</cfloop>
</table>
</td>
<!--- Main loop over all returned trials --->
<cfloop query="getTrialTitleQuery">
<td class="interventionCell">
<table width="100%" border="0" cellspacing="0" cellpadding="4">
<!--- Show the interventions--->
<cfset id = #getTrialTitleQuery.RCTID#>

```

```

<!-- 2nd loop -->
<!-- Display study arm details-->

<cfloop query="getSizeCalcQuery">
<cfif getSizeCalcQuery.RCTID EQ id>

<CFSET zz = 1>

<!-- Loop over the list of column names from the Query -->

<CFLOOP INDEX="ColumnName" LIST="#getSizeCalcQuery.columnlist#">

<!-- Create a temporary variable with the column name -->
<CFSET Variables.TEMPNAME = "getSizeCalcQuery.#ColumnName#">
<!-- Create a session variable with the value of the column name -->
<CFSET TEMP = SetVariable("Session.#ColumnName#", "#evaluate(Variables.TEMPNAME)")>
<cfif #TEMP# EQ "">
<CFOUTPUT><tr></tr><tr><td nowrap class="subheading">&nbsp;</td></tr></CFOUTPUT>
<cfelse>
<CFOUTPUT><tr></tr><tr><td nowrap class="subheading">#TEMP#</td></tr></CFOUTPUT>
</cfif>
<!-- Increment Counter -->
<CFSET zz= zz + 1>
</CFLOOP>

</cfif>

</cfloop>

</table>
</td>
<!-- End Main loop over all returned trials -->
</cfloop>
</tr>
<tr></tr>

<!-- More hidden info; Show statistical analysis and results design info -->

<tr class="intervention" id="showRowStatistical" style = display:none><td>Statistical Analysis
</td></tr>
<tr class="intervention" id="showRowStatistical1" style = display:none>
<!-- In the first cell, display a table of column names -->
<td class="interventionCell">
<table width="100%" border="0" cellspacing="0" cellpadding="4">
<!-- Initialize Counter -->
<cfset int1 = 1>
<!-- Loop over the list of column names from the Query -->
<cfloop index="ColumnName" list="#getStatisticalQuery.columnlist#">
<cfoutput><tr></tr><tr><td class="subheading">#ColumnName#</td></tr></cfoutput>
<!-- Increment Counter -->
<cfset int1= int1 + 1>
</cfloop>
</table>
</td>
<!-- Main loop over all returned trials -->

```

```

<cfloop query="getTrialTitleQuery">
<td class="interventionCell">
<table width="100%" border="0" cellspacing="0" cellpadding="4">
<!-- Show the interventions--->
<cfset id = #getTrialTitleQuery.RCTID#>
<!-- 2nd loop --->
<!-- Display study arm details--->

<cfloop query="getStatisticalQuery">
<cfif getStatisticalQuery.RCTID EQ id>

<CFSET zz = 1>

<!-- Loop over the list of column names from the Query --->

<CFLOOP INDEX="ColumnName" LIST="#getStatisticalQuery.columnlist#">

<!-- Create a temporary variable with the column name --->
<CFSET Variables.TEMPNAME = "getStatisticalQuery.#ColumnName#">
<!-- Create a session variable with the value of the column name --->
<CFSET TEMP = SetVariable("Session.#ColumnName#", "#evaluate(Variables.TEMPNAME)#")>
<cfif #TEMP# EQ "">
<CFOUTPUT><tr></tr><tr><td nowrap class="subheading">&nbsp;</td></tr></CFOUTPUT>
<cfelse>
<CFOUTPUT><tr></tr><tr><td nowrap class="subheading">#TEMP#</td></tr></CFOUTPUT>
</cfif>
<!-- Increment Counter --->
<CFSET zz= zz + 1>
</CFLOOP>

</cfif>

</cfloop>

</table>
</td>
<!-- End Main loop over all returned trials --->
</cfloop>
</tr>
<tr></tr>

<!-- More hidden info; Show survival analysis and results design info --->

<tr class="intervention" id="showRowSurvival" style = display:none><td>Survival Analysis
</td></tr>
<tr class="intervention" id="showRowSurvival1" style = display:none>
<!-- In the first cell, display a table of column names --->
<td class="interventionCell">
<table width="100%" border="0" cellspacing="0" cellpadding="4">
<!-- Initialize Counter --->
<cfset int1 = 1>
<!-- Loop over the list of column names from the Query --->
<cfloop index="ColumnName" list="#getSurvivalQuery.columnlist#">
<cfoutput><tr></tr><tr><td class="subheading">#ColumnName#</td></tr></cfoutput>
<!-- Increment Counter --->

```

```

<cfset int1= int1 + 1>
</cfloop>
</table>
</td>
<!-- Main loop over all returned trials -->
<cfloop query="getTrialTitleQuery">
<td class="interventionCell">
<table width="100%" border="0" cellspacing="0" cellpadding="4">
<!-- Show the interventions-->
<cfset id = #getTrialTitleQuery.RCTID#>
<!-- 2nd loop --->
<!-- Display study arm details-->

<cfloop query="getSurvivalQuery">
<cfif getSurvivalQuery.RCTID EQ id>

<CFSET zz = 1>

<!-- Loop over the list of column names from the Query -->

<CFLOOP INDEX="ColumnName" LIST="#getSurvivalQuery.columnlist#">

<!-- Create a temporary variable with the column name -->
<CFSET Variables.TEMPNAME = "getSurvivalQuery.#ColumnName#">
<!-- Create a session variable with the value of the column name -->
<CFSET TEMP = SetVariable("Session.#ColumnName#", "#evaluate(Variables.TEMPNAME)#")>
<cfif #TEMP# EQ "">
<CFOUTPUT><tr></tr><tr><td nowrap class="subheading">&nbsp;</td></tr></CFOUTPUT>
<cfelse>
<CFOUTPUT><tr></tr><tr><td nowrap class="subheading">#TEMP#</td></tr></CFOUTPUT>
</cfif>
<!-- Increment Counter -->
<CFSET zz= zz + 1>
</CFLOOP>

</cfif>

</cfloop>

</table>
</td>
<!-- End Main loop over all returned trials -->
</cfloop>
</tr>
<tr></tr>

<!-- More hidden info; Show regression analysis and results design info -->

<tr class="intervention" id="showRowRegression" style = display:none><td>Regression Analysis
</td></tr>
<tr class="intervention" id="showRowRegression1" style = display:none>
<!-- In the first cell, display a table of column names -->
<td class="interventionCell">
<table width="100%" border="0" cellspacing="0" cellpadding="4">
<!-- Initialize Counter -->

```

```

<cfset int1 = 1>
<!-- Loop over the list of column names from the Query -->
<cfloop index="ColumnName" list="#getRegressionQuery.columnlist#">
<cfoutput><tr></tr><tr><td class="subheading">#ColumnName#</td></tr></cfoutput>
<!-- Increment Counter -->
<cfset int1= int1 + 1>
</cfloop>
</table>
</td>
<!-- Main loop over all returned trials -->
<cfloop query="getTrialTitleQuery">
<td class="interventionCell">
<table width="100%" border="0" cellspacing="0" cellpadding="4">
<!-- Show the interventions-->
<cfset id = #getTrialTitleQuery.RCTID#>
<!-- 2nd loop -->
<!-- Display study arm details-->

<cfloop query="getRegressionQuery">
<cfif getRegressionQuery.RCTID EQ id>

<CFSET zz = 1>

<!-- Loop over the list of column names from the Query -->

<CFLOOP INDEX="ColumnName" LIST="#getRegressionQuery.columnlist#">

<!-- Create a temporary variable with the column name -->
<CFSET Variables.TEMPNAME = "getRegressionQuery.#ColumnName#">
<!-- Create a session variable with the value of the column name -->
<CFSET TEMP = SetVariable("Session.#ColumnName#", "#evaluate(Variables.TEMPNAME)#")>
<cfif #TEMP# EQ "">
<CFOUTPUT><tr></tr><tr><td nowrap class="subheading">&nbsp;</td></tr></CFOUTPUT>
<cfelse>
<CFOUTPUT><tr></tr><tr><td nowrap class="subheading">#TEMP#</td></tr></CFOUTPUT>
</cfif>
<!-- Increment Counter -->
<CFSET zz= zz + 1>
</CFLOOP>

</cfif>

</cfloop>

</table>
</td>
<!-- End Main loop over all returned trials -->
</cfloop>
</tr>
<tr></tr>
<!--***** End of 8th Row *****-->
<cfelse>
<table width="100%" border="0" cellspacing="0" cellpadding="4">
<tr><td class="topheading2">No matching results</td></tr>
</cfif>

```

```
<!-- Close main table -->
</table>
</form>

</body>
</html>
```