Data Acquisition Portal (DAP) Web: Web Based Data Collection Application

Christina Carty, Elizabeth Spence, Norman Oals, Linda Linzy, and Reuben Richards
VA Cooperative Studies Program Coordinating Center, Perry Point, Maryland
and the Public Sector Group, SAS Institute, Rockville, Maryland

ABSTRACT

In our continuing effort to provide quality services for clinical data collection, warehousing, and analysis, the Department of Veterans Affairs (VA) Cooperative Studies Program (CSP), in conjunction with SAS, is developing and beta-testing a secure web based data collection application.

The Data Acquisition Portal (DAP) system utilizes relational databases that contain meta-data about questions, forms, and protocol properties for a clinical trial (study). The application is scalable as it enables the creation and management of an unlimited number of clinical trials (studies) regardless of complexity. Its interactive graphical interface is flexible, user-friendly, and offers a reusable and repeatable method for creating, storing, and managing data collected via the web.

The application is divided into three models: Administrative, Study Editor, and Study Viewer. The Administrative Model allows administrators to setup and maintain application security, create and manage users and accounts, and organize portal content. The Study Editor provides the tools that allow developers to create and modify the questions, forms, protocols, and studies that will be deployed for live data collection. The Study Viewer is the end-user interface used for data entry functions.

In addition to securely collecting data over the Internet, the application provides auditing, monitoring, and reporting options often required for maintaining data accuracy throughout the course of a clinical trial.

INTRODUCTION

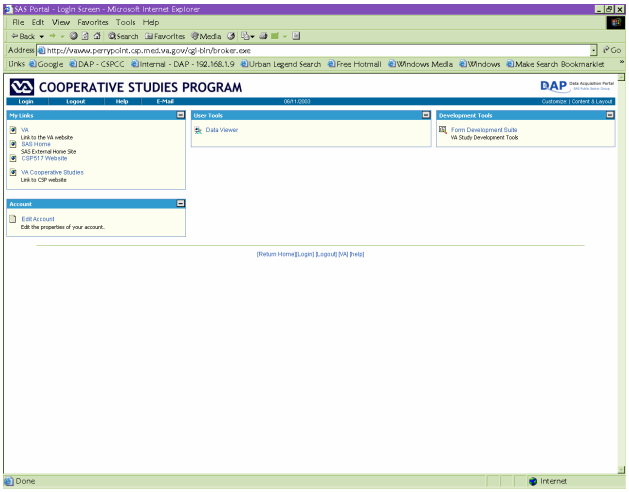
The Department of Veterans Affairs Cooperative Studies Program Coordinating Center (CSPCC) at the Perry Point, Maryland VA Medical Center is an administrative, data management, and statistical coordinating center for both VA and non-VA medical research clinical trials (studies). A primary challenge is the management of data generated by large multi-center clinical trials.

Our current process requires the collection of paper case report forms (CRF's) from over 250 medical centers for clinical trial research. Each CRF is received via snail mail and manually logged in using a data-mailing checklist. The data is then key entered and re-keyed for verification. New data is combined with existing master file data on a monthly basis. Through this process, reports are generated for review of data collection statistics and for clarification of data queries. Throughout the course of a clinical trial the data sets are regularly extracted for monitoring of safety issues, interim analysis, and reporting of drug efficacy. Ultimately, this data becomes the source for manuscript writing.

Although this process is effective, it has become increasingly more antiquated as technology progresses. The turnaround time of data query processing, auditing, the manual labor required to open, log in, double key enter, and file an average of 95,000 CRF's a year, hinders this method. The dependence on snail mail not only slows the process but calls into question security concerns in dealing with sensitive personal information. We have been challenged with developing an automated system to maintain our competitiveness within the field of clinical trials research. In order to accomplish this task within the stringent guidelines of the Code of Federal Regulations (CFR), we are currently collaborating with SAS to develop a secure web based data collection and reporting application-the CSP On-line Research Data Exchange System (CORDES).

OVERVIEW

The SAS Public Sector group has developed the DAP application for use with web based data entry. At the core of the DAP application is a form writing engine and business rule engine driven by a relational model of databases that stores the properties and rules of a study. The DAP application is undergoing customization of CORDES to adhere to current process requirements of 21 CFR Part 11 and the Good Clinical Practice (GCP) Guidelines for conducting clinical trial research.



CORDES is a user-friendly interactive graphical user interface (GUI) system. The collaborative environment within CORDES houses all libraries for questions, forms, studies, and protocols, which acts as a developmental area prior to deployment of a study. Once deployed, study specific databases are removed from the collaborative area and are ready for live collection of study data. When the study becomes live, the dynamic features of the application come into play. The screens that are displayed are based on the user type of the individual accessing the system and are referred to as the portal view. An important aspect in the conduction of a study is the process by which changes are logged and tracked. CORDES maintains an audit trail of all changes made to the data.

Another feature available within the application is an Xplore tool. The tool is used within the Administrative Model and can be made available to end-users. This interface permits users to select libraries and variables to query for generating reports and exporting results into a spreadsheet.

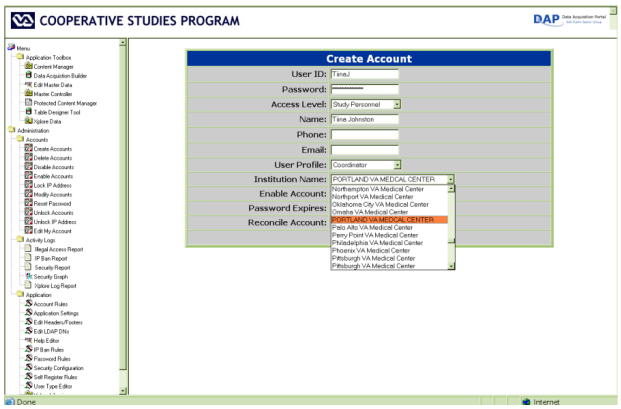
ADMINISTRATIVE MODEL

The Administrative Model is an interface management tool utilized by the application administrator to manage users, account access, security, and functionality. To accomplish these tasks,

the application administrator uses the four management functions within this model. In addition, the Administrative Model records usage documentation for monitoring purposes. New Health Insurance Portability and Accountability Act (HIPAA) regulations have raised the bar of data security. The administrative model successfully addresses these requirements.

ACCOUNT ADMINISTRATION

Account Administration allows the administrator the ability to create, modify, and delete user accounts. The administrator also has the ability to control access to users accounts by enabling or disabling accounts, as well as resetting or unlocking account passwords. Another security enhancement is the ability to block and unblock IP addresses.

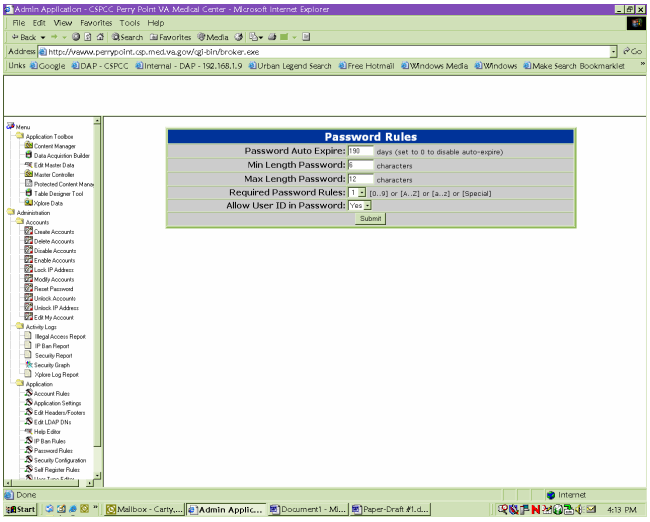


APPLICATION TOOLBOX

The Application Toolbox houses the security tools used to manage the content of the portal. The Content Manager is organized by topic and the user type dictates access to contents. To specify portal content using the Content Manager, the administrator must have a basic understanding of the dot notation syntax used to identify SAS libnames, catalogs, and SCL programs. The Protected Content Manager is used to pre-define portal views based on user type. This utility is also available for all users to customize the layout of their portal view at any time.

APPLICATION

The Application Management device is where settings for password rules and account rules are defined. Password policy options include forced periodic password changes, minimum and maximum length of passwords, and required password rules. The account rules settings provide four levels of security to control



login failures. This device also allows the administrator to setup the application for self-registration of new users for public surveys or other needs where the end user is given account creation privileges. A user type editor is available to create and delete user types. The Xplore library tool is used to make libraries accessible for the Content Manager.

ACTIVITY LOGS

The final management utility of the Administrative Model pertains to Activity Logs. By default the application retains multiple SAS datasets containing information on users accessing the system. There are three types of reports available within the application: user access reports, security reports, and illegal access reports. Using the Xplore tool, these reports allow the administrator to monitor data access and generate customized spreadsheets. Additionally, a graph may be generated to display login attempts over time.

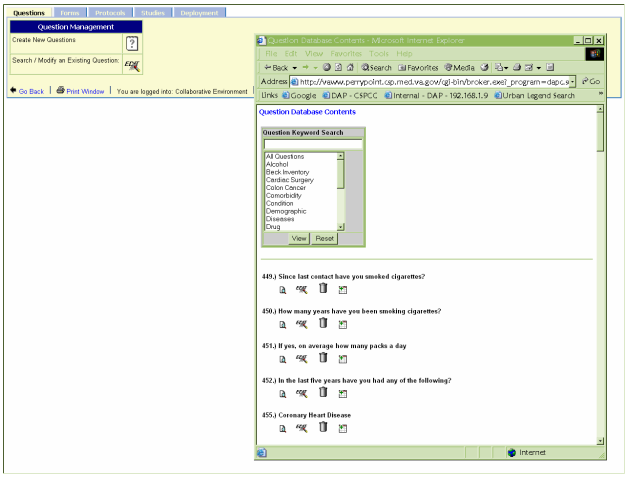
STUDY EDITOR MODEL

The Study Editor Model is used by developers to create and modify questions, CRF's, protocols, and studies that will be deployed for data collection in real time. To accomplish these tasks, the developer uses the five tool sets within this model. Four of the tools are geared towards building and maintaining the elements of a study. The fifth management tool is the study deployment tool, which is used to copy study specific meta-data to a predefined area on the application server.

The Question Builder is the core component of the Study Editor Model. The question database becomes the foundation for developing forms. Forms database becomes the resource for developing a study.

QUESTION BUILDER

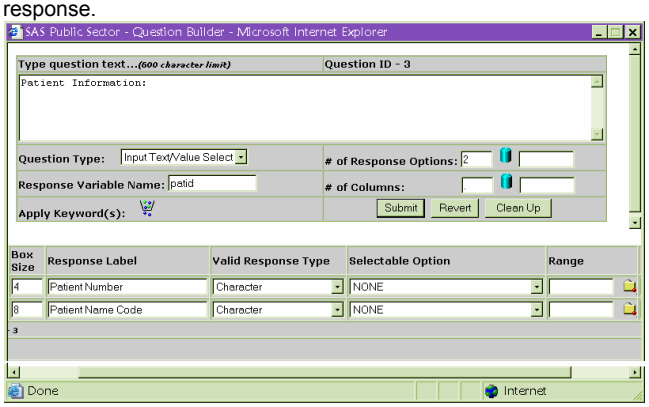
The first management tool of the Study Editor Model is the Question Builder. It provides the developer the ability to establish a library of questions.



Each question is created using a GUI interface. The Question Builder is comprised of properties within each question. Several question types are available including: select only one (radio button), select all that apply (checkbox), select drop box (drop down menu), text input supporting up to 4,000 characters, and look-up lists which can be applied as values of other questions.

Questions can be categorized by applying keywords, which allow the developer to easily search the questions database. The tool permits the use of SAS formats as a method to validate data entry, such as creating valid variable ranges. Response variable names can be assigned as well as the stored values for each

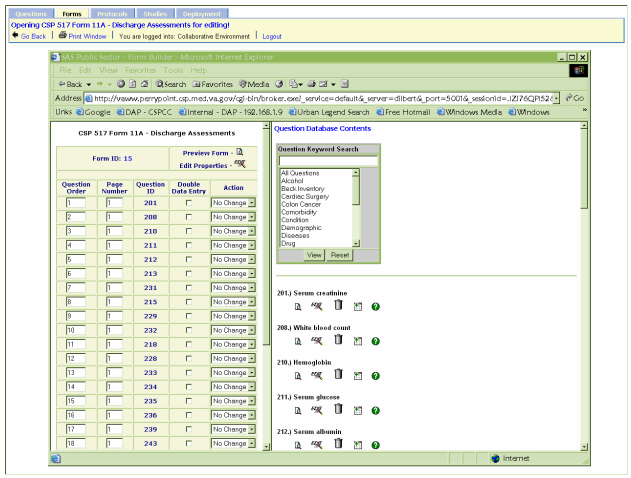
response.



In addition, questions can be classified as required and HTML tags can be added to enhance the visual display of questions. The application also provides the developer with the ability to copy, modify, and delete questions, which lends itself to efficiency for future resources.

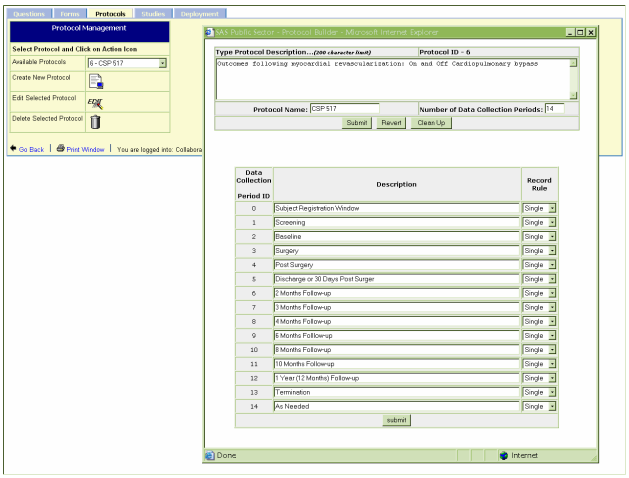
FORM BUILDER

The Form Management tool is used to create, copy, modify, and delete CRF's. The same GUI interface management tool used to create questions is used to apply questions to forms. Form properties that can be assigned include the numerical order of questions as they appear on a form, page numbering for multiple page forms (screens), and double data entry for validation purposes. Other attributes such as form description, instructions, and display options can be defined through the use of an additional Properties tool within this model. Another feature of the form builder is the ability to view a data dictionary report that lists form and question meta-data including variable names, assigned values, and question type. Lastly, the form builder provides a means for viewing collected form data, where the developer can create customized queries for viewing and exporting the results to other applications such as spreadsheets.



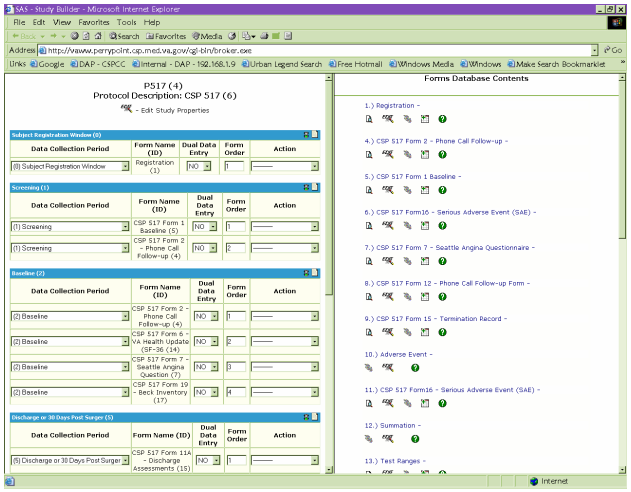
PROTOCOL BUILDER

The Protocol Management tool enables the developer to create and delete protocols, which define the data collection periods of a study. Protocols can be edited and collection periods can be modified as needed. Protocol properties include definitions of the data collection period. The application, by default, provides a predefined collection period for subject registration. As protocols are developed, they automatically become available for selection in the study builder tool. When a protocol is selected within the study builder, it essentially establishes the structure of data collection periods within a given study.



STUDY BUILDER

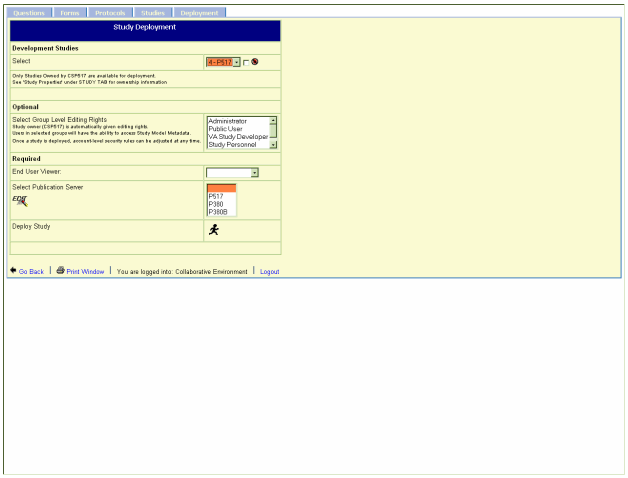
The Study Management tool is used to create and edit studies and specify study properties. A study is comprised of a protocol and CRF's. The CRF's are assigned to the predefined data collection periods of the protocol, and may be assigned to multiple collection periods. Within each collection period, form order can be defined and double data entry of a form can be turned on. The developer can also disable individual forms within a specific collection period, as well as disable an entire collection period.



In addition, the Study Builder contributes to the overall security of a study by allowing the developer to specify intra-study access. This option offers three levels of access: off, account level, and organization level.

STUDY DEPLOYMENT TOOL

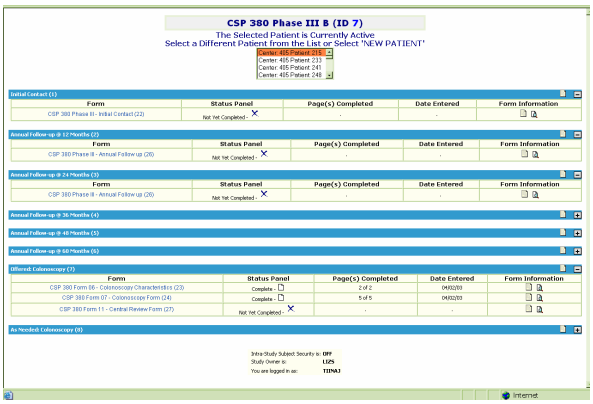
The final process for developing a study within CORDES is to deploy the study. This process copies meta-data for a study into a designated area on the application server. Segregating the meta-data eliminates the possibility of other users modifying the data. Once a study is deployed, the study owner still possesses the ability to modify the data. Any changes made to the deployed study have no effect to the meta-data within the collaborative environment.



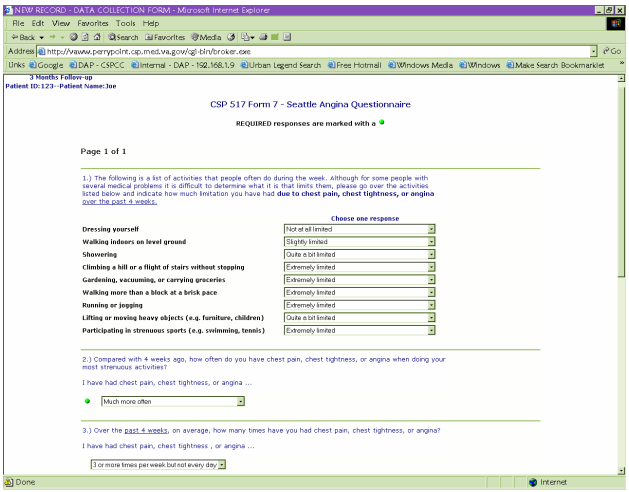
As part of the deployment process, the developer must select security parameters. These parameters include the group level editing rights, the end user viewer, and the selection of the application server. In addition to the study owners unlimited access, other users may be granted group level editing rights for the study. The end user viewer selection defines the layout of the user's screen. The selection of the application server defines the predetermined library for study specific meta-data and collected data to be written.

STUDY VIEWER

The Study Viewer is an end user interface used for enrolling patients and performing the data entry and editing functions of the data collection process. The viewer organizes and displays the CRF's by each of the enrolled study subjects across the data collection periods.



The status of the CRF is indicated by one of three possible conditions, not yet completed, completed, and signed off. The window also displays the number of pages completed and when they were completed. It allows the user to access and record notes for each data collection period, as well as each form within the data collection period.



The viewer provides the user with a link to drill directly into the CRF to be completed.

CONCLUSION

Although CORDES is a fully functional application, it is still in the beta testing phase. Early indications show that the application is an efficient and secure interactive product. It will bring our center to the forefront of data collection for clinical trials within the VA. The application will decrease the amount of man-hours spent in the production of a study and provide our center with a new standard for accomplishing this task. It is flexible in that it offers a reusable and repeatable method for developing studies and permits planning and conducting of an increased volume of studies regardless of complexity. More importantly, the application is being developed to adhere to the stringent guidelines for collecting clinical trial data in regards to HIPAA, 21 CFR Part 11, and GCP.

CONTACT INFORMATION

Your comments and questions are valued and encouraged. Contact the author at:

Author Name: Elizabeth Spence
Company: CSPCC (151E)
Address: VA Medical Center, P.O. Box 1010
City, State, Zip: Perry Point, MD 21902
Work Phone: 410-642-2411, ext. 5308
Fax: 410-642-1156
Email: Elizabeth.Spence@med.va.gov

Author Name: Christina Carty
Company: CSPCC (151E)
Address: VA Medical Center, P.O. Box 1010
City, State, Zip: Perry Point, MD 21902
Work Phone: 410-642-2411, ext. 5354
Fax: 410-642-1156
Email: Tina.Carty@med.va.gov