

A web-based solution for clinical study management

Spreadsheets, simple databases and paper forms no longer can meet the complex data management requirements of clinical studies, especially those spanning multiple sites. Accordingly, Cincinnati Children's Hospital Medical Center has developed Protocol Manager, a web-based application that enables researchers to control the scope and accuracy of data collection for single- and multi-site clinical studies. From enrollment to physical exams to specimen collection to lab reports, Protocol Manager covers key aspects of data collection while ensuring complete security and adherence to regulatory guidelines.

Conveniently control multiple protocols at multiple sites

As a web-based application, Protocol Manager enables you to create and customize multiple protocols from any computer with Internet access, eliminating paperwork pileups and geographical barriers. PIs and other designated users get complete control over protocol parameters including enrollment dates, consent/assent requirements and inclusion/exclusion criteria. In addition, you can define time points and stages for organizing study data. You also can enable and disable system modules so that only data relevant to your study is captured.

For multi-site studies, investigators can create an unlimited number of remote sites. Remote site personnel can view protocol settings, but they cannot modify them. However, they can customize enrollment dates and contact information, which differ at each site.

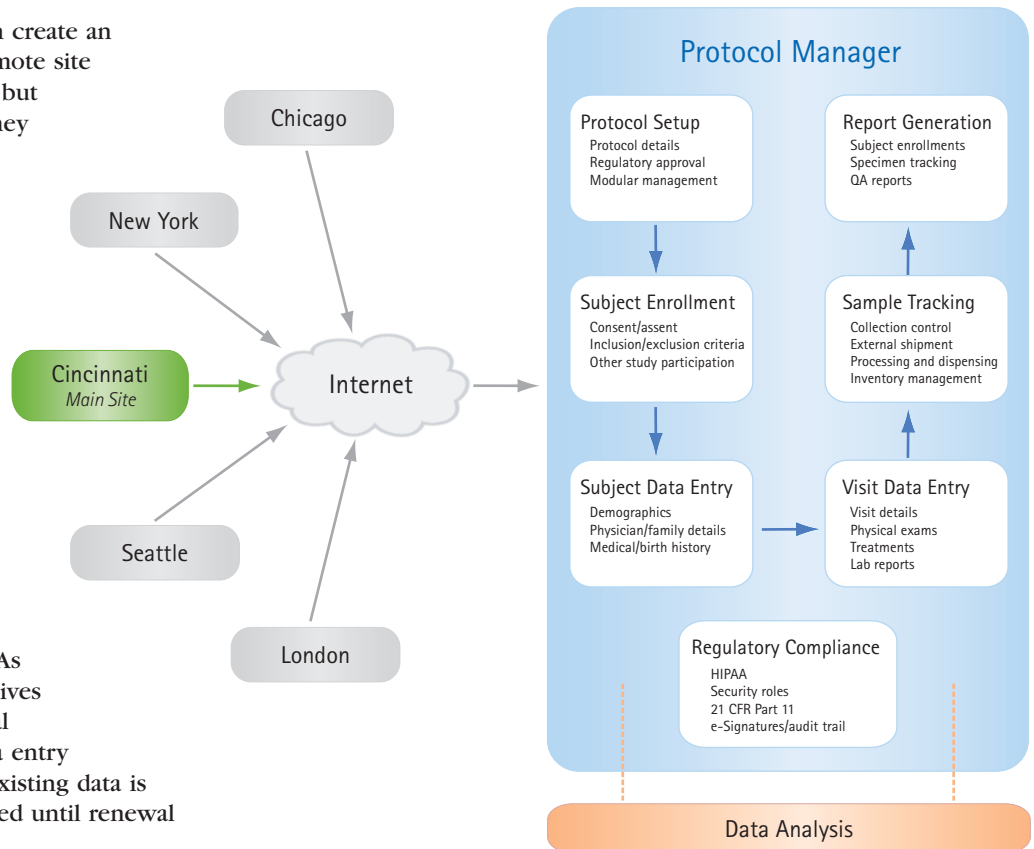
Track regulatory approvals

To meet increasing standards for transparency and regulatory compliance, Protocol Manager enables you to track approvals and renewals from both internal and external regulatory bodies.

For each study or site, IRB approval is required before data entry can begin. As expiration dates approach, the PI receives automatic email warnings that renewal information must be recorded for data entry to continue. If IRB approval expires, existing data is locked, and no new data can be entered until renewal details have been entered.

Ensure security and HIPAA compliance

All data is protected by a network firewall, and all users are assigned security roles that control which data they can view and modify, ensuring full compliance with HIPAA guidelines for protected health information (PHI). To access patient-sensitive information, for example, users must be assigned a special role. Users also are required to enter e-Signatures when performing tasks such as subject enrollment or data verification. This ongoing verification of user identity ensures compliance with 21 CFR Part 11.



Record consent details and apply custom inclusion/exclusion criteria

Before each subject is saved to the system, consent and/or assent details must be entered. Before any data can be entered for a subject, the study's customized inclusion and exclusion criteria must be applied. This two-step process ensures that no subject data is collected without permission and that no subjects are enrolled outside the protocol's parameters. During both steps, you can scan and upload associated paper forms.

Store complete subject data including birth and medical histories

By navigating a few simple screens, you can store basic data such as addresses, phone numbers and email addresses for subjects as well as family members and physicians. Via the Medical History module, you can store a range of information including developmental milestones, diagnoses and hospitalizations.

Store visit data including physical exams, treatments and lab reports

With Protocol Manager, case report forms (CRFs) successfully make the complicated transition from print to screen. For each subject visit, physical exam details and treatments such as medications, transfusions and transplants can be recorded. In addition, results of more than 50 general and specialized labs currently can be stored, with more to be added on an ongoing basis. At the same time, you can customize which labs are to be used with each protocol so that screens do not become overwhelming and options do not become unmanageable.

Data can be graphed according to pre-established time points to assess a subject's clinical progress. You also can upload digital image files and other outputs from medical diagnostic equipment.



Interested in learning more?

To view an animated tour of Protocol Manager and other clinical research software developed by the Division of Biomedical Informatics, visit <http://info.cchmc.org/software>.

To request a more detailed demonstration or to inquire about using Protocol Manager for your studies, contact:

Charlotte Andersen
Project Manager, Biomedical Informatics
513-636-2112
charlotte.andersen@cchmc.org

Track biological samples and prepare orders for batch processing

Since so many studies in the post-genomic era rely on tissue collection and analysis, Protocol Manager includes tools to aid researchers in managing biological samples. Once collected, samples are barcoded – either at your workstation or through a handheld device equipped with software that synchronizes with the central database. All samples, including aliquots, are associated with a subject, including those taken from family members. However, subject identifiers are visible only to users who have been assigned a special security role.

When samples are ready for processing by an external lab, you can batch and dispense them. At any time, you also can monitor samples entering and exiting your repository by running inventory and dispense reports.

Quickly generate data summaries and quality assurance reports

Using Protocol Manager's built-in query engine, you can generate a series of reports. Quality assurance reports, for example, can be run on a monthly, quarterly and annual basis to monitor enrollments, adverse events and other study details. In addition, demographic data can be searched to create subject summaries and mailing lists.

Directly query the database to create custom reports

Protocol Manager enables third-party reporting tools to link to the central database for generating ad hoc and periodic reports. This added flexibility enables you to customize reports as your studies progress and reporting needs change. It also eliminates the need for expensive technical support each time a new report is needed.