Clinical Research Administrative Data from the Extramural Community

Proposal to Define Clinical Research Administrative Data Standards, Develop and Deploy Tools to Support Reporting, and Coordinate Sharing of Data Among Federal Agencies

Background: The successful implementation of clinical research/clinical trials information exchange between the research community and the NIH must begin with data standards. Unless a common set of data standards is defined and recognized by both the originating and recipient parties, it is not possible to guarantee any validity or benefit in the exchange.

A valuable approach to define a common data standard is to put forward a straw man that can be tested by all parties. The strength of such straw men is determined by the extent to which the putative standard meets the breadth of information requirements for all parties.

The majority of clinical research-related information that involves the NIH originates out of extramural research grants, cooperative agreements and contracts. For example, in FY2002 the NIH awarded 17,743 grant awards that involved human subjects. Each of these funded projects must include clinical protocols, IRB reviews and related event reporting.

This magnitude of extramural clinical research has resulted in efforts in the extramural community and private sector to define a common clinical research/IRB dataset and develop tools to affect electronic transactions. Prominent among the straw men is a standard developed by a consortium of 10 institutions working with MIT to introduce an IRB module for the COEUS® grants administration software. COEUS® has been developed by MIT and licensed to over 100 institutions. The IRB module that includes data related to creation and maintenance of protocols and IRB committees is a tool that is currently in testing by the 10 institutions with deployment to the other 100+ licensed institutions by the end of 2003. Another influential group working toward the same end is the Federal Demonstration Partnership (FDP). The FDP is a group of 100+ research institutions and federal agencies whose purpose is to reduce the administrative burdens of performing research. Preliminary indications from the eIRB Task Force of the FDP (http://thefdp.org) are that the consensus data dictionary being used in the COEUS® IRB module will form the basis of evaluation by the FDP affiliated institutions and federal agencies. Other tools also exist. As part of the proposed work, a needs assessment will be conducted to identify a broad consensus for data standards and tools across the extramural community.

The entire NIH agency can gain much from leveraging and perfecting such a broadly adopted data standard. Further, since a significant number of the same extramural partners are communicating clinical research-related data to other federal agencies, the proposal will also seek to coordinate with other federal agencies. This will ensure that the adopted data standards and tools will be broadly supported across the government.

We propose to work initially with MIT and the FDP to test a standard against NIH administrative, regulatory, and event-driven reporting requirements. To prove concept and gain acceptance among grantees and other agencies, a phased, multi-year approach will be undertaken wherein the dataset and corresponding tools will be defined, designed, developed, and piloted. The approach will recognize the need to adapt and refine the data standards and tools to support electronic transactions between federal agencies and our extramural partners.

Proposed Tasks: **The first year of the project** will be devoted to the data standard relating to the clinical protocol. Adverse event reporting is seen as a well-defined research activity by which the data standard could be tested. Working with MIT and the FDP, a tool will be developed to support this specific administrative transaction. A parallel effort during the first year will be to conduct a needs assessment involving the broad extramural community. The outcome of this study will ensure that the data and tool will be well received beyond the FDP.

In year two of the project additional protocol management activities will be incorporated, including protocol amendments, revisions, and terminations. A second area of concentration in the second year will be IRB committee management. The addition of such activities will involve an expansion of the dataset to effectively include a consensus definition of the entire protocol. In this activity the outcome of the needs assessment conducted in year one will prove crucial to know that the expanded dataset is complementary to user and data requirements across the extramural community. In parallel to the expansion of the data standard will be the design and development of further tools. As tools are conceived, they will be piloted to prospective users as a way to validate data and user requirements.

With the full protocol data defined and significant portion of the administrative processes being supported through the use of software tools, **the third year** will be devoted primarily to refining the exchange/sharing of data with other federal agencies and the private sector. As mandated in Public Law 106-107, we must work with other agencies toward streamlining grants administration processes. The exchange/sharing of clinical research-related information is primed for this type of streamlining. Interactions and consensus standards discussed with other agencies in the first and second years will be emphasized. Pilots will be undertaken to share data defined according to consensus standards. A parallel effort will be to involve the private sector. It is known that major pharmaceutical companies and healthcare providers, for example, are well on their way to defining versions of clinical research standards and tools, especially in the area of clinical care. Interactions in year three will encourage an expansion of private sector involvement in administrative data standards and tools. Working with other federal agencies and the private sector toward a common dataset and toolkit will guarantee a common set of well-defined, well-adopted electronic interactions between research organizations, federal agencies and our private sector partners.