Taming Clinical Research’s Paper Tigers

John I. Gallin

Several years ago, a prominent NIH intramural physician-scientist wanted to translate basic science observations to clinical medicine, but the paperwork involved in taking a protocol from concept to conduct was overwhelming. “It was easier to get a paper published in Nature, Science, or The New England Journal of Medicine than to get a protocol written and approved,” said the frustrated scientist. So began the journey by a group of intramural scientists, a quest dedicated to designing tools that could cut through the complex and often confusing paperwork associated with the development and implementation of clinical research projects. By taming the literal paper tiger of bureaucratic paperwork (or red tape), these tools can help create a clinical research enterprise that is safer, more efficient, and better managed.

The ultimate goal is a tool, ProtoType, which we are building from scratch. The vision is that ProtoType will facilitate protocol writing and review, filing of investigational new drug forms, patient recruitment, resource projections, and the informed consent process. It also will track protocol activity, generate early toxicity alerts, initiate adverse event reports, and automate milestone letters to referring physicians. Some portions of the tool are complete; others are under development or will be developed elsewhere.

The major completed component is protocol authoring. This component has a standard format that comprises a précis, an introduction, background, study design, patient enrollment, study analysis, adverse event/data safety monitoring plan, human subjects protection, pharmacologic and device information, references, and structured informed consent forms. Throughout the tool are learning portals for access to details on how to use the resource and links to historical and current references. Cassettes with the most up-to-date language recommended by institutional review boards can be dragged into the protocol and placed in appropriate sections, a feature particularly helpful when writing consent forms. It’s even possible to tailor a protocol to specific institutional review board requirements (there are 14 institutional review boards at the NIH).

Protocol authors can

• build a collection of images that can be stored and dragged into future protocols,
• integrate policy and regulatory updates into the protocol.

ProtoType’s reference manager enables easy connection to PubMed, automatically renumerates references, and facilitates migration of references from one protocol to another. An investigational new drug wizard allows the investigator to decide, based on questions developed with input from the Food and Drug Administration, on the necessity of filing an investigational new drug form.

Once the protocol is written, it is easy to send the document electronically to the required review groups. At the NIH, a protocol undergoes independent reviews by numerous bodies for scientific quality, ethics, and institutional review board and resource requirements. Electronic signatures by the reviewing officials are standard operating procedure.

Several NIH institutes now use ProtoType. Plans for expanding its capability include

• linking the précis and inclusion and exclusion criteria to the National Library of Medicine’s website (http://www.clinicaltrials.gov/),
• monitoring protocol activity for compliance with the study’s initial intent,
• sending toxicity alerts and milestone letters to referring physicians using predetermined rules.

Long-term goals include assisted writing of investigational new drug forms, automatic submission of investigational new drugs to the Food and Drug Administration, electronic bedside adverse-event writing, and electronic submission of adverse events to all required regulatory bodies.

If you find the bureaucracy surrounding clinical research suffocating, ProtoType may offer some relief. Because the software was created at the NIH using your tax dollars, the tool is available at no cost other than what will be required to adapt the system to specific institutional needs. Please contact me and I will put you in touch with the appropriate personnel at the NIH who can assist your implementation of ProtoType.
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