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Introduction

The proposed short paper presentation will describe recent efforts to help authors develop more effective documents in clinical study settings. Part of this work involves helping authors and project participants rethink their work from a rhetorical perspective by using a logic called MIRRS (Message, Issues, Response, Rationale, and Support) that characterizes current practices in clinical research. Additional work involves developing habitable technology using XML to support authoring and review that takes advantage of the MIRRS framework for knowledge elicitation, capture, and reuse.

Justification

A need for our work is demonstrated through examples like our recent survey of review practices, and the recent US Department of Health and Human Services (HHS) audit of the US Food and Drug Administration (FDA) review practices. These studies revealed that much of an organization's technology investment goes unused, and that poor document quality lead to major delays in New Drug Application (NDA) reviews. Presentations at industry association meetings on these issues, and the communication quality of documentation submitted to FDA demonstrate that documents are of insufficient quality to support FDA reviewers' needs.

The HHS report cited disorganized or missing information in NDAs as a major reason for delays and FDA requests for sponsor amendments. Ninety percent of FDA reviewers responding to a survey indicated that they spend too much review time searching or reorganizing data in NDAs. Common concerns expressed by reviewers describe information that was:

- Missing
- Irrelevant
- Difficult to locate
- Improperly formatted

The Technology Myth & Habitability

The technology myth gives us a view of technology that is powerful and can solve our problems. Organizations have invested in technology that supports

- Authoring
- Document/content management
- Review

While this technology could be used for knowledge elicitation, capture, and reuse, much of it goes unused. Usable technology often fails to solve the problems that those investing in it hoped for because it isn't habitable: It doesn't support the work people do in ways they expect it to, and may not reflect the logic of the work being done.

Habitable Technology

In the context of clinical studies, habitable technology

- Supports current ways of working
- Is technology people want to use for their work
- Reflects the logic of the work being done
- Links ideas to overarching goals
- Is truly collaborative
- Enables effective repurposing of information
- Can be validated

Habitable solutions must accommodate the information needs and expectations of all stakeholders, and must provide an environment for effective knowledge elicitation, capture, and reuse. Habitable solutions must provide authors with a familiar environment for doing this work using tools they want to use.

In our technology model, documents become visualization tools for knowledge elicitation, capture and reuse. XML allows us to manage content as information elements rather than documents, and store information that is more effectively organized, shared, reused, and validated.

Conclusion

The rhetorical solution is effective because it helps authors situate their work in the context of a project and project goals, and readers' information needs. The technology design is likely to be habitable because it takes advantage of current technology, practices, and ways of working to provide authors with a familiar but richer environment for producing their work (their use of XML is transparent) without imposing new technology or practices.