Developing effective clinical research tools requires exceptional coordination between a variety of stakeholders: investigators, software developers, testers, user interface designers, IRBs, information technology support departments and research administrators. User-centered design methodologies have proven to be effective at improving software quality and producing software that is both accessible and highly appropriate to task, but the training and manpower requirements of this approach has made adoption in healthcare research environments difficult. At the same time, development of clinical applications in hospitals and elsewhere traditionally proves expensive - the testing and quality assurance requirements of HIPAA, 21 CFR Part 11 and related regulations require development teams to accept substantial risk and expense.

The Clickframes platform, an open source development process toolkit developed by the Informatics Solutions Group at Children's Hospital Boston, was designed to address all of these issues, allowing research groups and hospital IT shops to develop higher quality, better tested, more reliable software faster, and at lower cost. Clickframes provides a collaborative requirements model that supports a user centered design process, allowing principal investigators, developers, testers, designers and other stakeholders to collaboratively develop an interactive specification for an application. Once the specification is complete, the Clickframes tools automate code generation and maintenance across multiple platforms, provide developers with up-to-date and easy to use documentation of additional requirements, and accelerate testing through automated script generation and execution. The result is both a better software design and working code that actually looks like the design.

This talk will introduce the Clickframes toolset, and describe how ISG has used Clickframes in conjunction with a user-centered design process to develop a range of applications, including a grant management system for the Harvard Catalyst CTSC, a novel patient reported outcomes tool for clinical trials, and a major clinical application for Children's Hospital.