Speeding IRB Reliance using SMART IRB Collaboration Systems, Derived Metrics and Responsive Improvements

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Introduction

In the IRB reliance model, institutions develop networks in which each of the IRBs in a multisite study agrees to rely on a single involved IRB to review, approve and monitor the study. That IRB is designated as the “IRB of Record,” and it takes on most or all of the human subjects protection responsibilities for the study. The other IRBs agree to rely on the decision-making of the IRB of Record.

SMART IRB – a unique way to collect metrics and speed up IRB reliance

SMART IRB is a platform designed to ease common challenges associated with initiating multisite research and to provide a roadmap for institutions to implement the NIH Single IRB Review policy¹. Freely available for institutions and investigators, SMART IRB is an integrated, comprehensive platform that allows flexibility in the size and scope of collaboration to enable IRB reliance for multisite studies across the nation. Investigators and institutions use the SMART IRB ORS to request, track, and document reliance arrangements on a study-by-study basis. Since May 2017 we have captured metrics regarding achieving reliance using the ORS. These metrics have given us insight into the reliance process, barriers to achieving rapid reliance and the effectiveness of systematic support for the process. Usage of the ORS has steadily increased since its introduction. By tracking requests from inception to completion we have been able to determine the time to achieve reliance to be a rapid 4 weeks or less for 60% of the studies. Furthermore, using system metrics we have also been able to identify long running requests, identify the barriers involved and make systematic improvements to address these issues. These barriers have included: slow to respond institutions and the need for greater visibility across study teams and institutional officials. We will describe these barriers, their solutions and show how this has impacted the speed of achieving reliance.

Figure 1: Usage of the ORS over time (cumulative).

Conclusion

The systematic approach of the SMART IRB Online Reliance System provides detailed and reliable metrics about the overall process of achieving reliance that both informs stakeholders and provides the opportunity to identify barriers. The SMART IRB team has used this information in order to drive significant improvements to the system and speed achievement of reliance, supporting the overall research enterprise for NIH sponsored multi-site studies.

References


Funded by the NIH National Center for Advancing Translational Sciences through its Clinical and Translational Science Awards Program, grant number 3UL1TR002541-01S1.