Category: Clinical Research Operations – Work in Progress

Reducing Overhead During Study Startup with System Integrations

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1. Background

NCI centers rely on a diversity of software systems to aid their clinical operations. Unfortunately, these systems create redundant tasks for research teams. For example, the process of adding a user in one system may have to be repeated in another.

In this research project, the Jefferson and Florence technical teams combined traditionally disparate systems (CTMS and eReg) for an integrated process. Examples of administrative study setup tasks include creating a virtual trial binder workspace, inviting users to that workspace and configuring their permissions.

This abstract describes a work in progress, shares preliminary results, and explores how this first effort can pave the way for future research.

2. Goals

The primary goal was to connect a popular oncology CTMS system to the Florence eBinders eRegulatory system in order to reduce administrative workload.

Within that context, the teams held two goals:

1. Could the systems "talk" to one another? Could we automate study setup in the eBinders trial binder system by initiating the study in the CTMS?
   Metric: Completion of workspace setup to spec.
2. Did this integration actually save the study or administration team time?
   Metric: Time spent on key configuration tasks

3. Solutions and Methods

Solution:

The team sought to integrate CTMS and eRegulatory systems in order to automate six setup tasks

1. Create regulatory binder structure—deploy the workspace
2. Create roles—identify categories of users
3. Assign permissions—decide which categories may do which things
4. Assign users to roles—assign users those capabilities
5. Register and activate users—onboard users onto the system
6. Validation—ensure the setup was completed correctly

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The result is that when a Study is created or modified in the CTMS the attributes of that study are sent to a middleware solution, configured programmatically, and are then established in the eRegulatory system. This results in a new set of binder structures, roles, and permissions that are immediately ready for use by the study team.

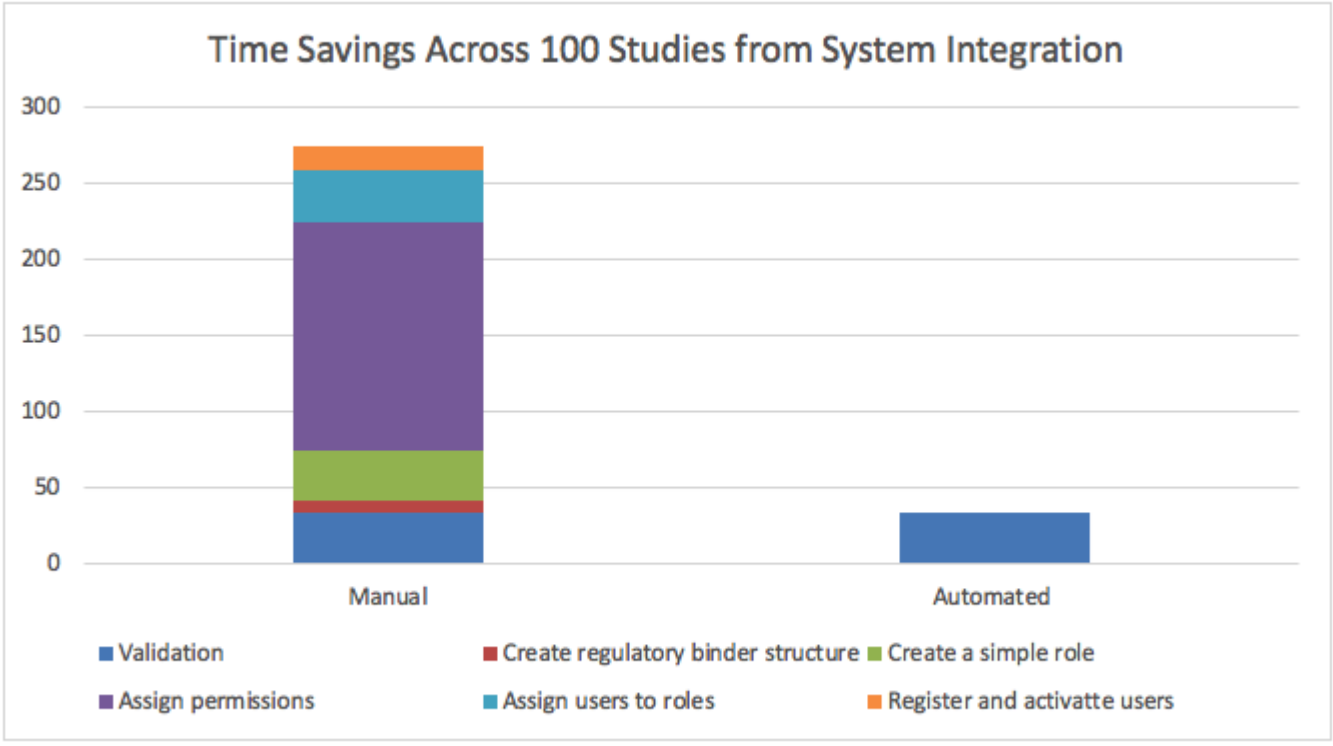
Methods:

Two categories of testing were used to measure performance of the solution against goals

1. Basic functionality: Would the system perform as desired against the specification developed?
2. Performance: Would this new integrated approach save time?

4. Outcomes and Future Directions

1. Basic functionality: The system ultimately satisfied the first functional goal. All six steps described above worked as designed when launched from the CTMS.
2. Performance: Our temporal analysis showed a reduction in system setup effort when eRegulatory workflows are initiated from the CTMS.



As the existing integrations free up resources from the most basic but critical activities, we are next exploring the possibilities of more complex workflows. These could include elaborate decision trees, as well as other systems such as IRB portals and electronic medical records. Ultimately, we seek to gain

more efficiencies, reduce dependencies on scarce resources, and improve quality through technical integrations.