Category: Clinical Trial Operations – Work in Progress

Harness the Power of Automation for Clinical Research Management

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1. Background

Managing a successful clinical trials office (CTO) requires leveraging data for various reasons including reporting to the National Cancer Institute, grants, tracking accrual, patient safety such as re-consent, and portfolio management. Data is spread across many systems and is entered by many users. Real-time and accessible data is essential for efficient and effective management of the clinical research enterprise. Quality control measures must be in place to ensure the accuracy of the data. The Huntsman Cancer Institute (HCI) CTO has 13 separate clinical trials research groups, 454 active interventional treatment trials, and 282 individual users actively entering data. Automating reports and safety checks ensures that the data entered is constantly being monitored and that reports are readily available with the most accurate and up-to-date information; and creates efficiency and availability from strained resources.

2. Goals

The HCI CTO's four primary goals of automating reports and quality checks are:

1. Provide our investigators and CTO leadership the ability to access presentable and up-to-date data for their trials and patients instantly
2. Increase the efficiency of the quality assurance and oversight processes
3. Provide coordination staff with automated emails to monitor patients/trials they are managing
4. Free up strained resources within our business systems team

3. Solutions and Methods

To accomplish these goals, several software platforms are used, including SQL Management Studio, SQL Developer, JasperSoft, SQL Server Reporting Services, and OnCore.

1. Analyze the desired output and data
2. Determine if automation is the right fit
3. Identify tools and level of automation required such as lists, graphs, system-generated emails, etc.
4. Develop code to be as fluid as possible to account for variable changes
5. Test and make enhancements as they are requested

4. Outcomes

The HCI CTO System Administrator automated 66 individual reports containing charts and graphs. Previous to automation, this required 11.6 hours of work. After automation, this can be completed in 16 minutes and is done weekly rather than ad hoc. These reports can also be run at any point using a web link. The leadership in each research group utilizes this to prepare for monthly meetings and provide metrics to investigators whenever requested. Key data points are monitored weekly for all patients and

trials in our systems for quality assurance. An average of 1,411 new patients and 269 new protocols are entered yearly. Automated reports were created to ensure that all associated data points are accurate. Patient and protocol records are reviewed weekly and automatic emails are sent to the responsible users with a list of errors. This has led to improved data quality. Automating the creation of routine reports has greatly increased efficiency in business systems operations.

5. Lessons Learned

We have noted that it is not possible to automate some reports due to complexity of the data and desired format. Software has the possibility of adjusting the name/structure of the database, which can lead to required code adjustments. We plan to continue to expand our reports to further cover additional areas of interest and get rid of the need for any manual oversite.

Figure: