Category: Clinical Trial Operations – Completed Project

One Small Step: Eliminating Investigator Sign-offs on Individual Epic Lab Reports

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1. Background

Investigators have long been tasked with physically signing and dating study subject lab reports originating from the electronic medical record, along with indicating clinical significance for any out-of-range value. This has put an undue burden on study staff, as this is often duplicative effort. It is standard practice for the investigators to review patient labs in Epic prior to treatment. Often, it is not feasible for study staff to obtain a physical signature on printed labs prior to treatment, so signatures are often obtained days or weeks after treatment, providing little value to this process.

2. Goals

While experiencing rapid growth and limited budgets, like many U.S. cancer centers, the MCW Cancer Center Clinical Trials Office (CTO) has had to do more with less in many areas. The Cancer Center CTO needed to find a way to reduce the burden of these lab sign-offs, which had proved problematic for research nurses, coordinators, assistants, as well as investigators. The MCW Cancer Center CTO had to find a way to maximize productivity while still maintaining patient safety and proper study oversight. Signing off on laboratory reports that were days or weeks in the past was a hinderance to study staff and was taking time away from performing other meaningful safety-related tasks.

3. Solutions and Methods

In 2017, the MCW Cancer Center CTO implemented a Standard Operating Procedure that eliminated sign-offs on individual study subject laboratory reports, citing duplicative effort. As a standard practice, the study coordinator and the subject's clinical team review patient laboratory results prior to treatment. These values are examined alongside the protocol to check for any necessary dose modifications, sponsor reporting, or other necessary actions. The investigator then approves the subject for treatment by signing the treatment orders. The study coordinator or research nurse determines clinical significance by reviewing the clinic documentation and establishing if any action resulted from the lab value (treatment held, supplementation given, repeat lab draws, etc.). Only if a lab result is considered clinically significant, is it then reported as an adverse event.

4. Outcomes

The MCW Cancer Center CTO has not collected and analyzed formal time saving data around this issue. However, MCW Cancer Center CTO study staff anecdotally report considerable time savings by no longer having to obtain physician signatures on labs. This has been widely accepted by sponsors and auditors since the SOP's official approval in 2017.

5. Lessons Learned

Currently, staff are still obtaining physician signatures on lab reports that come from central labs, since they are not in the medical record. MCW Cancer Center CTO is exploring the need for these signatures,

since they are often received by sites in the days after treatment, and therefore, not being used for treatment-related decisions.