Category: Trial Start-up and Activation – Work in Progress

Implementation of a Feasibility Committee – University of Cincinnati Cancer Center (UCCC) Study Operations & Administrative Review (SOAR)

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1. Background

The University of Cincinnati Cancer Center (UCCC) clinical trials office (CTO) looked critically at the study start-up process, identifying several inefficiencies:

1) initiating the start-up process with an incomplete packet of information from the sponsor created re-work as new details arose
2) delays in the hospital ancillary services (investigational drug service pharmacy, radiology, lab/pathology) approval of protocols during the required hospital approval process
3) an assumption of site feasibility when site selection occurred

There was no committee critically looking at the operational requirements of each protocol early in the process. Late feasibility issues caused wasted time, effort, and resources.

2. Goals

Institute operational review of all new protocols that will be managed by the UCCC CTO without increasing time-to-activation. Evaluate the committee impact by measuring the time from site selection to receipt of full protocol packet inclusive of disease group review; decreasing the time required for ancillary hospital reviews during study activation process; and earlier determination of a protocol that should not move forward in start-up.

3. Solutions and Methods

SOAR Committee reviews all protocols utilizing UCCC CTO resources prior to scientific committee review. The committee meets weekly and is comprised of CTO staff, laboratory manager, infusion suite manager, pharmacy, radiology, pathology, inpatient manager, and others based upon the protocol. A complete protocol packet inclusive of the disease group review is required for a trial to be placed on the SOAR agenda. Reviews are recorded in a REDCap form designed to facilitate documentation of key information by committee members in advance, during, and for resolution after the meeting of any action items. Each study is reviewed for accrual period, adequate funding, operations support, laboratory needs, staffing, imaging/radiation safety review requirements, clinical/hospital integration and locations, and pharmacy requirements at a minimum. The REDCap form is provided to the scientific review committee, regulatory staff, coordinator staff, and budget staff to facilitate start-up operations.

4. Outcomes

After review of 128 new studies median time from site selection to receipt of a full packet for SOAR review is 12 days, inclusive of UCCC disease group review and approval.

There is no data to support a decrease in time required for ancillary hospital reviews, as the hospital approval process also requires IRB approval and fully executed clinical trial agreement.

A total of 14 studies were identified as not feasible to move forward early in the start-up process as a result of SOAR demonstrating valuable impact to institutional resources.

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5. Lessons Learned and Future Directions

Although unable to show a decrease in hospital approval turnaround time as the result of improved efficiencies in the ancillary review, hospital ancillary services have embraced the improved workflow after the implementation of SOAR such that there are discussions to change the hospital approval process at the institutional level by integrating it into SOAR.

Large institutional changes in the trial activation process involving budgeting and contracting were instituted mid-year have impacted the ability to assess the true impact of SOAR on time to activation, so this goal metric will be evaluated in the future.

Figure: