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

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Background of the problem:

UCCC CTO identified several inefficiencies in the study start up process:

1. Initiating the startup 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, and
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.

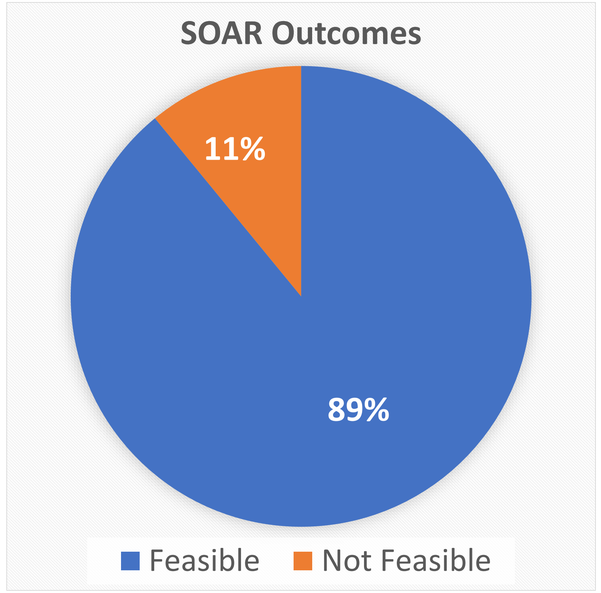
Metrics or goals to be achieved:

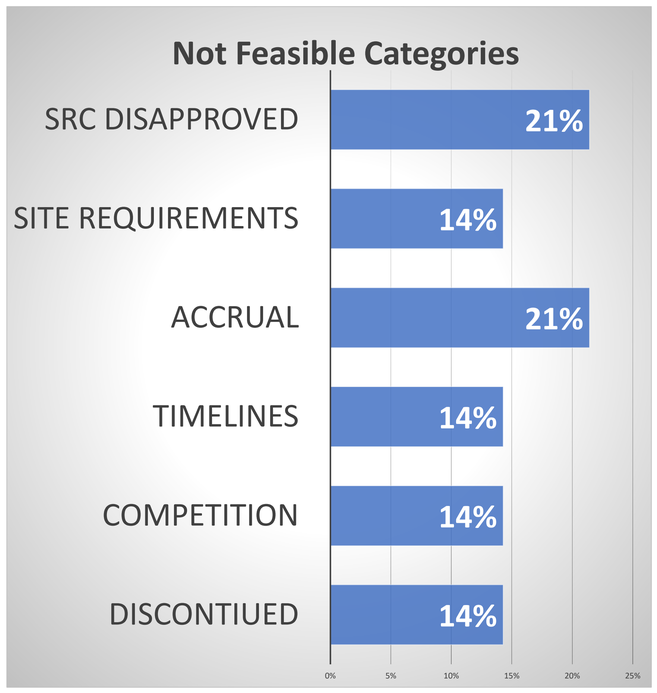
Institute operational review of all new protocols that will be managed by the UCCC CTO without increasing time-to-activation. Impact was measured by:

1. Measuring the time from site selection to receipt of full protocol packet inclusive of disease group review,
2. Decreasing the time required for ancillary hospital reviews during study activation process, and
3. Earlier determination of a protocol that should not move forward in start-up.

Solutions of methods implemented:

- SOAR Committee meets weekly to review all protocols utilizing UCCC CTO resources prior to scientific review
  - Comprised of several stake holders (e.g., CTO staff) based on protocol
- Complete protocol packet is required for a trial to be placed on the SOAR agenda





Solutions of methods implemented (cont'd):

- 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.

Outcome:

- 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 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.

Lessons Learned & Future Directions

- Ongoing discussions to change the hospital approval process at the institutional level to integrate 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.

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