Category: Clinical Trial Operations (Trial Start-up, Regulatory, Data Management, IITs) – Completed Project

The Impact of Feasibility Tools on Study Start-Up and Activation Timeline

D. Delbeau-Zagelbaum, R. Unawane, I. Chen, E. Sepiashvili, T. Miller, R. Knecht

Tisch Cancer Institute at Mount Sinai Hospital

1. Background

Laborious trial activation workflows have shown to contribute to the diminishing clinical trial workforce[1]. Developing an adaptive trial activation system to shorten time to activation (TTA) remains challenging at aca-demic medical centers amid fast-growing portfolio of increasingly complex trials. To better characterize the trial activation landscape, an Association of American Cancer Institutes (AACI) Benchmarking survey was conducted in 2024. Key insights on staffing, labor division, unified intake-process, centralized protocol-activation models, parallel processing, and effective communication with stakeholders were incorporated in revised trial activation process at the Tisch Cancer Institute (TCI).

2. Goals

Goals of the revised trial activation process at TCI were 1) establishment of a standardized intake process across disease teams 2) implementing electronic system to streamline trial feasibility assessments, both being critical to determine trials fit for patients, aligning with institutional goals, financial sustainability, and efficient resources utilization[2,5].

3. Solutions and Methods

At TCI, the Finance and Feasibility review (FFR) committee evaluate trials REDCap[3] FFRv2.0 incorporates real-time correspondence, defined timeline throughput and a standardized study evaluation tool "study start-up packet (SSP)." SSP is described in Figure 1. It is available on Institutional Intranet and intends to provide consistent information to all stakeholders.

SSP aims to 1) identify major impediments to trial activation and conduct 2) provide investigators with decisional support ensuring adequate assessment of institutional resources 3) improve turnaround time for feasibility review (date of submission to date of decision) 4) reduce TTA 5) streamline resources and 6) reduce redundancy during trial activation.

4. Outcomes

We observed a 55.91 percent reduction (mean 34.80 days to 15.34 days) in FFR review times and overall TTA de-creased by 16.80 percent from 2021 to 178 days. FFR vs FFRv2.0 performance is summarized in Figure 2. Implementing FFRv2.0-SSP has enabled investigators to pinpoint and resolve feasibility barriers quickly and improve overall TTA[4]. SSP has Closed System Transfer Device specific questions, prompting early conversations be-tween sponsors and site-staff regarding drug-administration logistics, reducing compatibility issues and shorten timelines. Pre-award finance review upfront demonstrated improvement in accuracy of budgets and increased dollars negotiated, further reducing TTA, with added financial gains while flagging studies with budgetary shortfalls.

Survey data: End users of the FFR-v2.0-SSP were surveyed (n=23) and reported the tools were effective in im-proving the trial activation process (50% somewhat effective, 25 percent extremely effective), had a moderate or greater effect on TTA (30%), view the tools as "important" (30%), agree the tools align sponsor/site expectations (35% strongly agree, 30% agree), helps easily identify feasibility issues (35%) and 35 percent report spending less time in the feasibility process when the tools are used[5].

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5. Lessons Learned and Future Directions

- FFR v2.0 with embedded SSP is a proven smart tool that shortens review timelines, with the ability to customize/update the SSP with pertinent information specific to the site.
- The SSP functionality improved staff satisfaction with study activation, sponsor-site communications, and sponsor/site expectation alignment.
- Provide and collect feedback to sponsors and contract research organizations CROs based on findings from the TCI Feasibility Survey.
- Conduct information sessions with managers and sponsors to further tailor FFR v2.0 with SSP.

Figure

Figure 1:

Tisch Cancer Institute Study Start-up Process (TCI-SSP) Packet Contents

Overview of internal review process for industry fund studies

- Site Management Plan
- Information about Site Initiation Visits (SIVs), full site Activation and remote monitoring.
  - Safety IND Reporting SOP
  - PPHS SOP regarding reporting
  - Commonly referenced Industry Fixed Fees Memo
  - Fast Track Fee Memo (if applicable)
- Information about institutional facilities, equipment and research capabilities.
  - Investigational Drug services
  - Confirmation of Closed system Transfer Devices Form
  - List of approved research Ancillary supplies
  - Laboratory Information

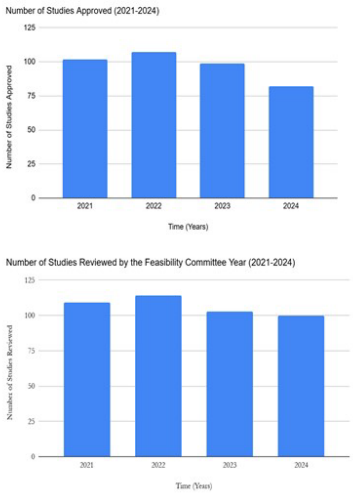
Fillable TCI Feasibility Survey and commonly asked questions for study activation.

- Biosafety
- Cybersecurity
- EDC Vendors
- 3rd part technology
- 3rd party e-payment solutions
- Closed system transfer device and Research ancillary supply list agreement

Figure 2:

Year	Studies Reviewed	Studies Deferred/ Denied	Studies Approved	Studies Withdrawn	Average time from Submission to Decision	Studies Abandoned	Time to Activation (All Trials)
2021	109	6	102	1	37.64		214
2022	114	3	107	3	34.79	1	211
2023	103	2	99	2	31.97		200
2024	100	7	82	11 studies total not proceeded with	15.35	2 (part of 11 not proceeded with)	178

Figure 3:



Citations:

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