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

Daniela Delbeau Zagelbaum, MSN, APRN; Rashmi Unawane, MBBS, MS; Irene Chen, BS; Ekaterina Sepiashvili, BS; Therica Miller, MBA; Ruth Knecht, MSN, RN

Icahn School of Medicine at Mount Sinai

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 academic medical centers amid fast-growing portfolio of increasingly complex trials. To better characterize the trial activation landscape, an 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).

PURPOSE

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.[1]

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INTERVENTIONS

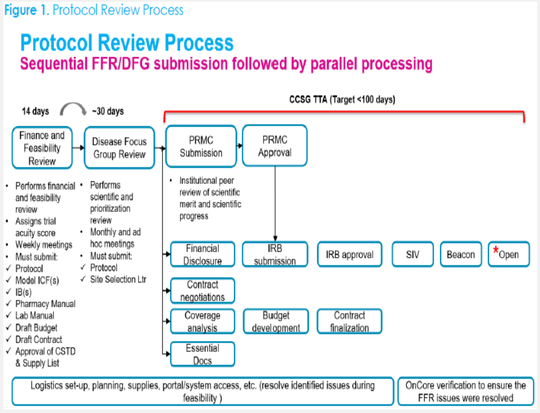
At TCI, the Finance and Feasibility review (FFR) committee evaluate trials REDCap[1] FFRv2.0 incorporates real-time correspondence, defined timeline throughput and a standardized study evaluation tool "study start-up packet (SSP)." SSP is described in Figure 1. It is available on Institutional Intranet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

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 1. Protocol Review Process



Study Start up Packet Aims
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.

TCI Sponsor Feasibility Survey

To Study Sponsors,

Thank you for your interest in opening your clinical research at Tisch Cancer Institute at Icahn School of Medicine at Mount Sinai. The first step in our study activation process is a comprehensive feasibility review by our Resource Allocation Evaluation (RAE) Committee. This review is conducted by a multi-disciplinary stakeholder group. In order to submit to this study to RAE, please complete the following survey.

Please complete our TCI Sponsor Feasibility Survey and email back to our study team.

1. Does study involve any of the following biological material:

☐ Yes(select all that apply below) ☐ No

- Recombinant/synthetic nucleic acid molecules, as covered by the NIH Guidelines
- Infectious agents (viruses, bacteria, fungi, parasites, prions, etc.) that can cause disease in healthy humans and/or significant environmental or agricultural impacts, as covered by the Biosafety in Microbiological and Biomedical Laboratories (BMBL) guidelines
- Select agents and select toxins, as covered by the Federal Select Agent regulations
- Human materials (including all fluids, tissues, excretions, secretions, or cell lines) as covered by the U.S. Occupational Safety and Health Administration (OSHA) Bloodborne Pathogens Standard
- Nonhuman primate materials (including live animals, all fluids, tissues, excretions, secretions, or cell lines) as covered by the BMBL and OSHA Bloodborne Pathogen Standard
- Genetically modified animals and whole plants, as covered by NIH guidelines
- Certain animals or animal specimens known to be reservoirs/vectors of zoonotic diseases
- Other (please specify):

2. Are genetically modified organisms (GMO) s, vaccines, and other viruses being utilized for this study?

☐ Yes ☐ No

3. Does your company have more than 50+ employees?

☐ Yes ☐ No

4. Please indicate the EDC vendor?

5. Please list any additional 3rd party technology required on this study where data or PHI is transmitted) (i.e. ipad devices, symptom management apps, holter monitors, Epic approved apps, etc.)

6. Please list any 3rd party e-payment solutions for patient reimbursement/stipends (i.e. Greenphire):

7. Please confirm the required equipment for this study:

☐ Sponsor will provide ECG machines

☐ Mount Sinai institutional supplied machines acceptable for use

**Please note that Mount Sinai has a preferred sponsor issued ECG machine: Eli Mortara **

8. Please indicate planned first patient in (FPI):

9. Please indicate planned last-patient out (LPO):

10. Please indicate the number of national/global sites participating:
    a. Please indicate the number of planned sites currently open to accrual

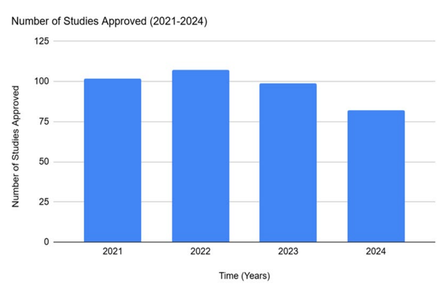
11. Please indicate the total enrollment to date:

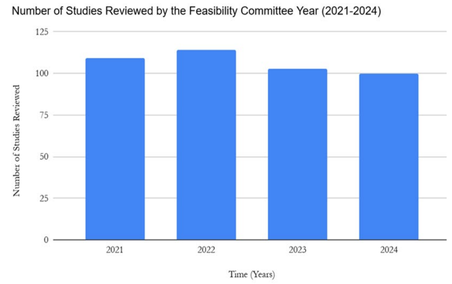
RESULTS

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:





We observed a 55.91% reduction (mean 34.80 days to 15.34 days) in FFR review times and overall TTA decreased by 16.80 % 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.[1] SSP has Closed System Transfer Device specific questions, prompting early conversations between 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 improving the trial activation process (50% somewhat effective, 25% 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% report spending less time in the feasibility process when the tools are used.[1]

LESSONS LEARNED AND FUTURE DIRECTIONS

The FFR v.2.0 with embedded SSP is a smart tool that accelerates review timelines by allowing site-specific customization and updates. The SSP feature increases staff satisfaction with study activation, sponsor communications, and expectation alignment. Furthermore, feedback from the TCI Feasibility survey is shared with sponsors and CROs, while information sessions with managers and sponsors help further tailor the tool for the best use.