Category: Clinical Trial Operations (Trial Start-up, Regulatory, Finance, Data Management, IITs) - Work in progress

Fixing the Funnel: Strategies to Minimize Screen Failure Rates

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1. Background

Clinical trials offer access to newer therapies that are otherwise unavailable for oncology patients. The strict inclusion and exclusion criteria for these highly regulated trials may not allow all patients to have access to these newer agents despite their willingness to participate as indicated by signing an informed consent form (ICF) after which the study related procedures begin. Anyone that signs the ICF but is unable to start the protocol directed therapy is termed as a screen failure. By minimizing the screen failure rate, one may be able to provide the intended access to most patients. Understanding the reasons for screen failures might allow us to make adequate interventions for modifiable reasons. We hypothesize that disease and patient related factors such as inability to meet inclusion and exclusion criteria, travel and study specific logistics, system-based issues of operational inefficiencies such as delays in the screening procedures (imaging, biopsies etc.) might be the biggest contributors for screen failure rates. We have performed a retrospective chart review to identify reasons for screen failure among patients that have screen failed in 2025 at the Winship Cancer Institute of Emory University.

2. Goals

- Identify reasons for screen failure among all patients that signed ICF
- Identify modifiable reasons that led to screen failures to allow for optimal interventions
- Minimize the screen failure rates so that eligible patients can successfully initiate protocol directed therapy.

3. Solutions and Methods

We conducted a retrospective chart review of participants who signed ICFs to interventional therapeutic trials at the Winship Cancer Institute of Emory University in 2025. Data were manually extracted from institutional screening logs, electronic medical records, and research documentation to identify the reasons for screen failures.

4. Outcomes

A total of 1,228 participants signed ICFs to interventional therapeutic trials from 1/1/2025 until 12/31/2025. 845 patients started therapy as guided by the study. A total of 351 participants from 17 disease-based working groups (DBWG) were included in the analysis. The cohort consisted of 183 females (52.6 percent). 45.7 percent were white (n=159) and 40.2 percent were black (n=140). The mean Charlson Comorbidity Index (CCI) score was 9.34 (SD 4.18), with a median of 9 (IQR 7–11). The reasons for screen failure are listed in Table 1. Only 7.69 percent (n=27) of participants didn't have stated reasons in their charts regarding why screen failure occurred. The mean time from consent to

screen failure determination was 21.9 days (SD 19.2), with a median of 19 days (IQR 10–28). Screen failure rate is listed by disease group in Table 2.

5. Lessons Learned and Future Directions

We aim to conduct a structured quality improvement initiative using process mapping and root cause analysis to identify bottlenecks. Key interventions include:

- Implementation of a standardized pre-screening workflow that will identify patients that are not eligible prior to signing ICF. Real-time tracking of consented participants to ensure timely order entry and completion of screening procedures
- Development of an escalation process to the Clinical Trials Office to avoid delays in screening procedures
- Developing a task force to shorten the time to study treatment initiation to capture the patients that had clinical deterioration
- Participation in advocacy efforts to liberalize screening laboratory parameters

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Category	Reason for Discontinuation	N (%)
Non-Modifiable	Clinical deterioration due to comorbidity	22 (6.0)
	Clinical deterioration due to cancer progression	21 (5.98)
	Provider decision – prior therapy	5 (1.42)
	Provider decision – imaging findings (e.g., no MRD/measurable disease)	8 (2.28)
	Provider decision – lack of required biomarker	1 (0.28)
	Provider decision –laboratory abnormalities	15 (4.27)
	Provider decision –due to not meeting inclusion criteria for specific trial	164 (47.6)
Modifiable	Combined patient choice and operational delay	1 (0.28)
	Operational delay (no available slots, tissue not sent in time, internal operational issues)	27 (7.69)
	Provider decision – lack of adequate tissue	6 (1.71)
	Patient choice	33 (9.40)
	Sponsor/logistical reasons (including sponsor-determined ineligibility)	19 (5.41)

Table 1. Modifiable and non-modifiable factors for screen failure.

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Management Group	**N (%)**
BMT	6 (1.71)
Breast	41 (11.68)
Cellular Therapy	9 (2.56)
GI	34 (9.69)
GU	21 (5.98)
GYN	12 (3.42)
Head and Neck	23 (6.55)
Leukemia	24 (6.84)
Lymphoma	12 (3.42)
Melanoma	15 (4.27)
Multiple Myeloma	40 (11.4)
Neurology	6 (1.71)
Phase I	44 (12.54)
Proton Therapy	2 (0.57)
Sarcoma	1 (0.28)
Thoracic	47 (13.39)
RAD/ONC	14 (3.99)

Table 2. Screen failure rate by disease group.