A New Enrollment Barrier: Data Entry

Martina DiMeglio, BA, and Katherine Senter, MPH
Sidney Kimmel Comprehensive Cancer Center at Jefferson

Thomas Jefferson University

Drexel University

SIDNEY KIMMEL COMPREHENSIVE CANCER CENTER RESEARCH CONSORTIUM

Background

- Pre-enrollment or pre-randomization data entry is a new and growing trend in Industry sponsored trials
- Rationale for this change is unclear
- This expectation is under-communicated and under-documented despite creating barriers to patient enrollment

Goals

Examine the scope and impact of pre-enrollment data entry on a trial

Provide recommendations for engaging with sponsor pre- and post-activation

Solutions and Methods

Studies Reviewed

- 4 interventional treatment trials in 1 disease team
- 3 additional studies identified via cancer center-wide inquiry

Assessment Criteria

- Sponsor type and study phase
- How and when the expectation was communicated
- Logistical impacts and effects on patient enrollment

Outcomes

Key Findings

- None of the studies reviewed included this requirement in the protocol or CRF completion guidelines
- Only 1 study included the requirement in the SIV slides
- Sponsor type varied from Big Pharma to biotech and study phase from Phase 1 to Phase 3
- Study team often not informed of enrollment data entry requirement until 1st patient in screening
- Guidance on required CRFs for enrollment and review turnaround often only provided upon request

Figure 1: Summary of communication and details of pre-enrollment data entry requirements across four studies

	Protocol	CRF Completion Guidelines	SIV Slides	Required CRFs Specified	Screening Period	Review After Data Entry	Requirement Notification
Study A	Not included	Not included	Included	No	28 Days	3- 5 Days	SIV
Study B	Not included	Instructs not to enter	Not included	Yes (All Forms)	28 Days	Not specified	1st patient screening
Study C	Not included	Instructs not to enter	Not included	Conflicting answers	28 Days	Not specified	1st patient screening
Study D	Not included	Not included	Not included	Yes (All Forms)	21 Days	72 - 48 Hrs	1st patient consent

Impacts

- Functional shortening of the screening window
- Wasted data entry effort for screen failures
- Increased data entry effort
- Increased need for staff availability during screening
- Complications due to EDC design
- Friction with existing site workflows

No patients screen failed due to this requirement, but 1 nearly required a treatment delay until the sponsor agreed to accept de-identified source in lieu of data entry. Meeting these data entry deadlines often meant deferring other responsibilities or requiring site staff to assist with data entry outside of their normal responsibilities.

Lessons Learned and Future Directions

- Lack of documentation and communication further complicates a situation already resulting in increased workload and logistical challenges
- A more proactive approach will be needed during study start up to prompt sponsors to share information and to ensure the study effort analysis is accurate
- The rationale behind this requirement should be examined with industry partners, as reviewing data entry prior to source data verification is an inefficient method of eligibility determination
- Sponsor engagement in post-award budget modification

@ResearchAtJeff

NCI Comprehensive Cancer Center
A Cancer Center Designated by the National Cancer Institute