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

A New Enrollment Barrier: Data Entry

M. DiMeglio, K. Senter

Sidney Kimmel Comprehensive Cancer Center at Jefferson

1. Background

A new trend among industry-sponsored cancer trials requires Case Report Form (CRF) completion prior to sponsor approval for enrollment and/or randomization. Even though this requirement increases the burden of data management at screening significantly, it is rarely well-communicated by the sponsor. This added step also creates an enrollment barrier, as data entry time narrows the screening window, and delays could result in treatment delays or screen failures.

2. Goals

This analysis examines the scope and impact of requiring data entry prior to enrollment and provides recommendations for engaging sponsors pre-and post-activation.

3. Solutions and Methods

Four studies with this added data entry requirement were initially selected and reviewed to determine:

- How and when this expectation was communicated
- Logistical impacts
- Effects on patient enrollment

Subsequent review will include conducting a cancer-center-wide analysis to assess the prevalence of this trend for the initiating sponsors and engaging sponsors in post-award budget modifications.

4. Outcomes

None of the trials reviewed mentioned the upfront data entry requirement in the protocol or CRF completion guidelines (CCGs), with two CCGs specifically recommending data entry after eligibility confirmation. One study mentioned the requirement in the Site Initiation Visit (SIV) slides – the others only once the first patient was identified or already consented *(summarized in Figure 1)*. Impacts of this new process include:

- Functional shortening of the screening window to allow for data entry and sponsor review
- Wasted data entry effort (for screen fails)
- Increased data entry effort
- Increased need for staff availability during screening
- Complications due to CRF database design
- Issues with existing site workflows

No patient screen failed due to this requirement, but one nearly required a treatment delay until the sponsor agreed to accept de-identified source instead of CRF completion. Meeting deadlines for other

patients often meant deferring other responsibilities or requiring site staff to assist with data entry outside of their normal responsibilities.

Initial findings from one disease group will be compared with other studies across the institution for sponsors who have added these requirements to determine whether the trend is predominately study or sponsor-specific. Outcomes will include sponsor engagement impact, including potential post-activation budget amendments to support staffing requirements for this added data burden.

5. 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 also be examined, as reviewing data entry prior to source data verification is an inefficient method of eligibility determination.

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