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

Loss to Follow-up: Policy Development and Formal Guidelines

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1. Background
Patients being followed for clinical trials provide critical data for long term efficacy and safety of investigational products. Successfully gathering survival data is an important aspect of clinical trials. However, patients are lost to follow up for a wide variety of reasons, and these data are not collected. Pressure from sponsoring agencies can put demands on research team time and effort or inadvertently create negative patient experiences if they are subject to bothersome communications. Sponsors may also utilize third party vendors to track and conduct survival checks on patients, requiring sites to share patient's identifiable information including social security number and date of birth. Patients may not have consented to have this information used in this way or entered into web searches or databases, and thus there would be no opportunity to collect any of the follow up data.

2. Goals
We determined that individual team policies and practices were insufficient and difficult to enforce. Instead, we developed a department-wide standard operating policy related to the number of communications a patient would receive, the timeline and types of communication, and language required in a consent form in order to use public searches. Formal guidelines ensure a compliant and consistent approach.

3. Solutions and Methods
The policy was developed to address the number and frequency of contact attempts that would be performed by study teams. With survival contacts stretching from one to six months apart, contact attempts, if the expectation is that they are ongoing until contact is made, can create undue burden for the team. The policy laid out clear limits to the number of contact attempts per timepoint and requires variation in method (e.g. phone call, mychart message, certified letter). The policy also clarifies that, in these instances, there will not be protocol deviations logged because the protocol was followed as expected though the patient did not respond, and data were not collected.

In collaboration with the privacy and security team, language was developed that will be required in the consent form if the sponsor wishes to use a third-party vendor or search service to find patients and confirm vital status. If a consent form does not include this specific language or sufficient language regarding use of public websites, databases, or search services, these cannot be used by the sponsor or their vendor. This, however, prevents collection of survival data, thus negatively impacting the endpoints for the trials.

4. Outcomes
This policy creates enforceable, consistent parameters for follow up across disease teams. It also strengthens the informed consent form with specific language around sharing identifiers and public searches. The policy ensures disease teams are not spending years and countless person hours contacting patients and that patients are not burdened or harassed.

5. Lessons Learned and Future Directions

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The consent form template has been updated to include the required language. We anticipate that, over the next two to three years, all consent forms will include this specific language, if desired by the sponsors, and fewer survival datapoints will be lost.