

A Formulated Visit Tracker: Reducing Lost to Follow-up

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1. Background

Follow-up assessments are an important outcome in clinical trials to determine progression free survival (PFS) and overall survival (OS); these endpoints are often the primary outcome measures of many later phase (II/III) trials. Yet, research teams are most focused on the active treatment phase and follow-up is often less prioritized. Clinical trials vary in follow-up visit requirements including assessments like physical exams, lab collections, adverse events, and tumor response during a defined follow up period. Formulating comprehensive methods to document patient status during the follow up period is crucial for the integrity of the study and institutions accruing to clinical trials must prioritize this. Between 14 disease groups within the clinical trials office (CTO) at NYU, there is no standardized way to track patients' follow up visits. Some disease groups utilize email calendars to keep track of patient visits, however this method leads to inconsistencies such as visits occurring out of window, missed study visits or assessments, or complete loss to follow up.

2. Goals

Our goal was to develop an efficient and dependable way to track patients in follow up through integrated data processing spreadsheets in order to improve follow up data quality, reduce protocol deviations, and increase replicability among disease groups.

3. Solutions and Methods

In 2023, an online spreadsheet was created by the clinical team to include every patient in follow up for 23 oncology clinical trials within one disease group. The document was stored in a secure centralized location accessible to team members. Patients were organized by protocol number, cohort, and visit type (office visit, phone call, lab draw, or scan). For each protocol, expected visit dates were calculated using arithmetical formulas. Data input was simplified so that staff only enter the index event, and the rest is automatically populated. A color indicator was used to identify visit status (upcoming, past, or missed). When visit dates changed, a standardized approach was implemented to update the tracker. Narrative data was entered to individual cells for reporting purposes if needed.

4. Outcomes

We tracked roughly 50 patients over 18 unique study protocols using the revised data input method. Since implementation in late September 2023, 98 follow up assessments have been completed. This included 80 follow up visits and 18 scan time points. No follow up visits have been missed due to staff oversight. Only one scan was completed out of window that was attributable to staff error. Overall, staff have regarded the new interface as easier to use compared to email calendars, and the tool allows both staff and patients to appropriately plan for upcoming study events and follow-up.

5. Lessons Learned and Future Directions:

Storing the document in a centralized location ensures continued maintenance in the face of staff turnover. Centralization and automation have resulted in significant improvement in completion of timely CT scan follow-up and survival assessments. We hope to standardize workflows between disease groups to help increase consistency within the CTO and facilitate cross-covering. Lastly, broadening the

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use of spreadsheets to help increase efficiency through automation and reduce calculation errors has the potential to be utilized across other domains within clinical research.