A Formulated Visit Tracker: Reducing Lost to Follow Up

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BACKGROUND

Follow-up assessments are important for outcome measures 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, quality of life questionnaires 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; institutions accruing to clinical trials must prioritize this.

Between 14 disease groups within the CTO at NYU, there is no standardized method 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.

GOALS

To develop an efficient and dependable method 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.

OUTCOMES

- 333 total assessments from 69 patients were captured
- 187 visits/scans occurred prior to implementation of the spreadsheet
  - This included n= 148 visits and n= 39 scans
    - N= 20 (10.7%) of visits were missed completely
    - N= 8 (4.3%) were out of window
- 146 visits/scans occurred post implementation of the spreadsheet
  - This included n= 118 visits and n= 28 scans
  - Zero follow up visits have been missed completely
  - N= 2 (1.4 %) scans were completed out of window
- Benefits include ease of use, improved ability to retrospectively refer to prior visits compared to tracking visits via email calendars, and a decreased number of visits missed due to staff error
- Areas for improvement include more efficient ways to maintain spreadsheets as more patients enter into follow up

Table 1. Visits Missed and Out of Window- Prior to and Post Implementation of Spreadsheet

	Prior to Implementation Visits N (%)			Post- Implementation Visits N (%)		
	Visits (n= 148)	Scans (n=39)	Total (n = 187)	Visits (n= 118)	Scans (n=28)	Total (n= 146)
Missed	14 (9.5)	6 (15.4)	20 (10.7)	0 (0)	0 (0)	0 (0)
Out of Window	5 (3.4)	3 (7.7)	8 (4.3)	0 (0)	2 (7.1)	2 (1.4)

SOLUTIONS & METHODS

- In late 09/2023 an online spreadsheet was created by the clinical team to include every patient in follow up for 20 oncology clinical trials within one disease group
- The document was stored in a secure centralized location accessible to study team members
- Patients were organized by protocol number, cohort, and visit type (office visit, phone call, lab draw, or scan)
  - Expected visit dates were calculated using arithmetical formulas
  - Staff enter the index event and future dates are automatically populated
  - Color indicator was used to identify visit status (future, past, or missed)
  - Narrative data was entered to individual cells for reporting purposes if needed
- Total assessments were sub-divided into scans and visits - which including in-person clinical appointments and survival phone call assessments
- Assessments missed and completed out of window (OOW) attributable to staff oversight were captured
  - Those missed or completed OOW for other reasons were excluded.

Figure 1. Example of Formulated Spreadsheet Inputs and Outputs

FUTURE DIRECTIONS

Stage 2: Standardize workflows between disease groups to help increase consistency within the CTO and facilitate cross-covering

Stage 3: Broaden the use of spreadsheets across other domains within clinical research to help increase efficiency through automation and reduce calculation errors

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