Updating case report forms using a cross-functional team approach

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Background

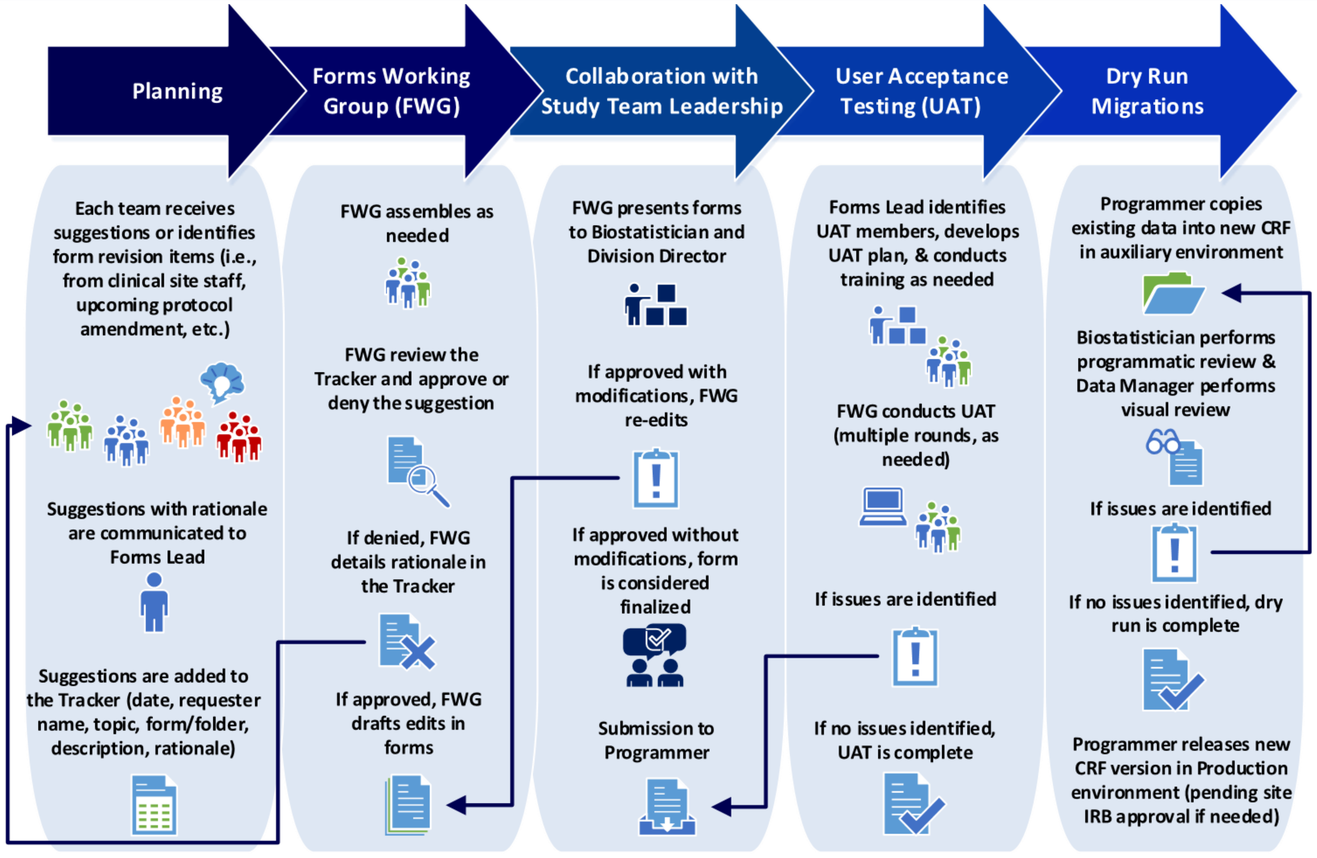
- The Targeted Agent and Profiling Utilization Registry (TAPUR) Study is a precision oncology phase II basket trial that evaluates the antitumor activity of commercially available targeted agents in patients with advanced cancers with specific genomic alterations outside of their approved use.
- TAPUR has regular protocol amendments as treatments are added to/removed from the study and utilizes a complex workflow to screen, enroll, match and follow-up with participants at >250 clinical sites across the United States.
- An adaptable approach to data collection and a cross-functional team approach to form revision is required.

Suggestion Tracker

Date	Requester Name	Topic	Form	Description	Rationale	Status	Review Date	FWG Comments
1/1/2023	Data Manager	New Dropdown Option	Patient's Cancer Type for Automated Matching Rules Engine	Add new FDA approved indications for TAPUR study drugs or additional tumor type exclusions per drug specific criteria	Adding these cancer types to the dropdown will prevent participants from being matched to study drugs they aren't eligible for	Approved	2/15/2023	Suggestion approved and will be incorporated into next round of CRF revisions
2/1/2023	Protocol Team Manager	New Data Element	Drug Eligibility - Exclusion Criteria	Add new drug eligibility folder with new exclusion criteria form. If any question is answered "No" the participant is ineligible	Need new folder added to make new study drug available on TAPUR	Approved	2/15/2023	Suggestion approved and will be incorporated into next round of CRF revisions
2/1/2023	Data Team Member	New Dropdown Option	Operational Deviation Information	Add "Misplaced study drug" to the operational deviation type dropdown	The clinical site wasn't sure how to record this deviation type so it could be added as a structured option to avoid it being recorded as "Other"	Denied	2/15/2023	CRF update was not needed to address this one time occurrence. The clinical site was instructed to record this as an applicable deviation type that is already available on the CRF.
3/1/2023	Clinical Site 123	Revision	Adverse Event Information	Update instructions to explain all of the fields that need to be updated in order to consider an AEFWU complete	Updating instructions will cut down on site follow-up and streamline reporting	Pending		

TAPUR's Approach

- The TAPUR Forms Working Group (FWG) is a cross-functional team consisting of study team members with a variety of expertise (protocol, data, biostatistics) that meet to review and implement revisions.
- The FWG is involved in the entire case report form (CRF) update process which includes, updating printable CRFs, edit check spreadsheets and data dictionaries; collaborating with study builders to modify electronic CRFs (architects); conducting user acceptance testing (UAT); and reviewing dry run migrations.
- The goal is to think through the process, anticipate downstream/upstream implications, identify dependencies, and understand potential impacts of CRF revision decisions.



*Workflow above is intended to be read from left column to right column and top to bottom.

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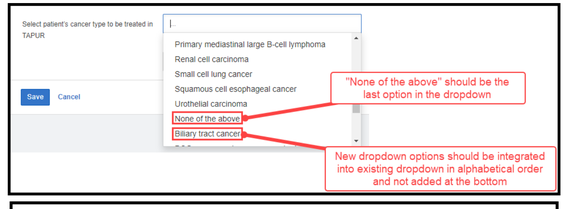
Conclusions

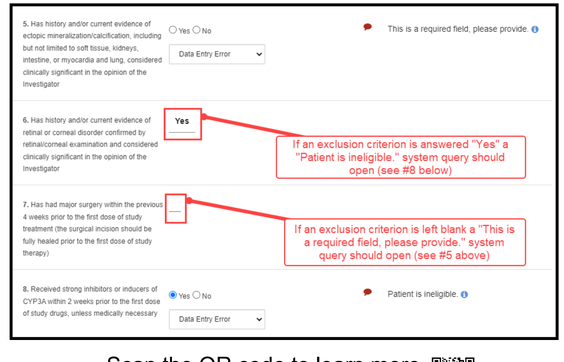
- TAPUR has found that using cross-functional teams is an advantageous approach to implement CRF revisions.
- This approach avoids rework and creates an open dialogue about the optimal way to collect new data elements, modify existing data elements, improve data quality, and streamline the workflow for study coordinators at clinical sites.
- A cross-functional team approach is ideal as it engages content and technical expertise and supports effective change management.

UAT Plan

- A UAT plan is a comprehensive set of use cases that is tested to ensure the EDC system can handle real-world tasks and perform up to development specifications.
- A UAT plan is developed by identifying test cases, thinking through logic and workflows, defining acceptance criteria, and assigning each expected outcome to at least one tester. Role based permissions may also need to be tested.
- It is best practice to hyperlink supplemental documentation (e.g., CRFs, edit check spreadsheets) within the plan for easy access.
- The number of rounds of UAT depends on the scope of the changes. On average, 2-5 rounds of UAT are required for a protocol amendment.
- Types of findings during UAT can include typos, forms not loading based on the defined workflow, and system queries opening unexpectedly.
- Findings can be captured in a separate document with an explanation for each issue that the programmer needs to fix.

UAT Findings





Scan the QR code to learn more about the TAPUR Study