Perceived Impact of Investigator Toolkit

JK Perez[1], LM Baez-Mari[1], GN Grantham[1], PK Mangat[1]
[1]American Society of Clinical Oncology, Alexandria, VA
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Background

- The Targeted Agent and Profiling Utilization Registry (TAPUR) Study is a phase II, precision oncology, multi-basket clinical trial that evaluates the antitumor activity of FDA-approved drugs outside of their approved indication(s) in patients with advanced cancers with specific genomic alterations (Mangat et al., 2018).
- The TAPUR Study has over 260 academic and community clinical sites across 28 states in the United States which currently utilize 14 treatment arms.
- The study consists of approximately 170 cohorts, defined as drug/tumor type/genomic alteration which may open or close as the enrollment goal is reached using the Simon-two stage study design.
- Study resources are stored on a private website that is accessible by TAPUR Clinical Site Staff. There are 8 modules that contain resources (Figure 1). Treating physicians must review TAPUR resources daily to identify available treatment arms.
- In 2023 as part of study recruitment initiatives, the study team surveyed TAPUR Investigators to determine which resources were accessed the most. These resources were then compiled to create a new “Investigator Toolkit” module (Figure 2).

Initial Survey and Results

- An online panel survey was administered to the 49 TAPUR Study site Investigators in April 2023 with a 91.8% response rate (45/49 responses).
- We aimed to determine how often Investigators used the private website and which tools were accessed the most during patient pre-screening, screening, or treatment for the study.
- Results showed that 51.1% of Investigators accessed the private website once or less per week.
- The most accessed resources were the cohort status report (60%) and the matching rules (27%).
- In response to the results, the study team launched a new “Investigator Toolkit” module within the private website on May 9th, 2023.

Scan the QR code to learn more about the TAPUR Study

Figure 1. Investigator Toolkit Module

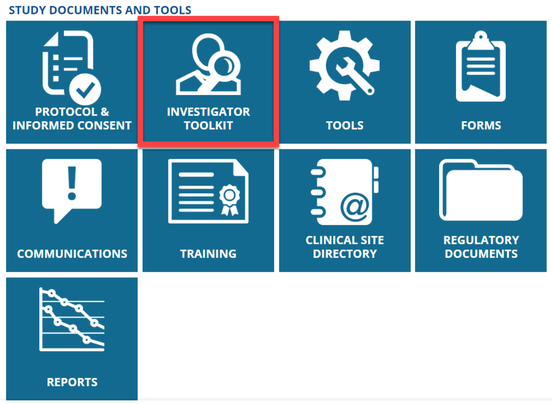

Figure 2. Investigator Toolkit

Investigator Toolkit

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This page is aimed to assist TAPUR clinicians navigate screening, and post enrollment visits.

Pre-Screening Guides/Resources*

- Cohort Status Report
- Table 7-1: List of Available Drugs and Acceptable Genomic Targets in the TAPUR Study v1 **(Protocol Version 6.0)**
- Drug-Specific Eligibility Assessment Reference Guide v7 **(Protocol Version 6.0)**
- General Eligibility Assessment Reference Guide v6 **(Protocol Version 6.0)**
- Table 13-1: Study Schedule of Assessments **v1 (Protocol Version 6.0)**
- How to Identify Available TAPUR Study Cohort(s) For Participant Enrollment Workflow

Molecular Tumor Board (MTB) Resources

- Schedule of MTB Meetings & Review Submission Cutoff Times March - May 2024
- Schedule of MTB Meeting & Review Submission Cutoff Times June - August 2024
- How to Navigate the TAPUR Molecular Tumor Board Process

Post-enrollment Guides/Resources*

- TAPUR Guide to Adverse Event and Serious Adverse Event Reporting v7 **(Protocol Version 6.0)**
- TAPUR Study Guide for Reporting Protocol and Operational Deviations v5 **(Protocol Version 6.0)**
- TAPUR Brain Mets Flowchart **v1**

EDC Workflow Guide

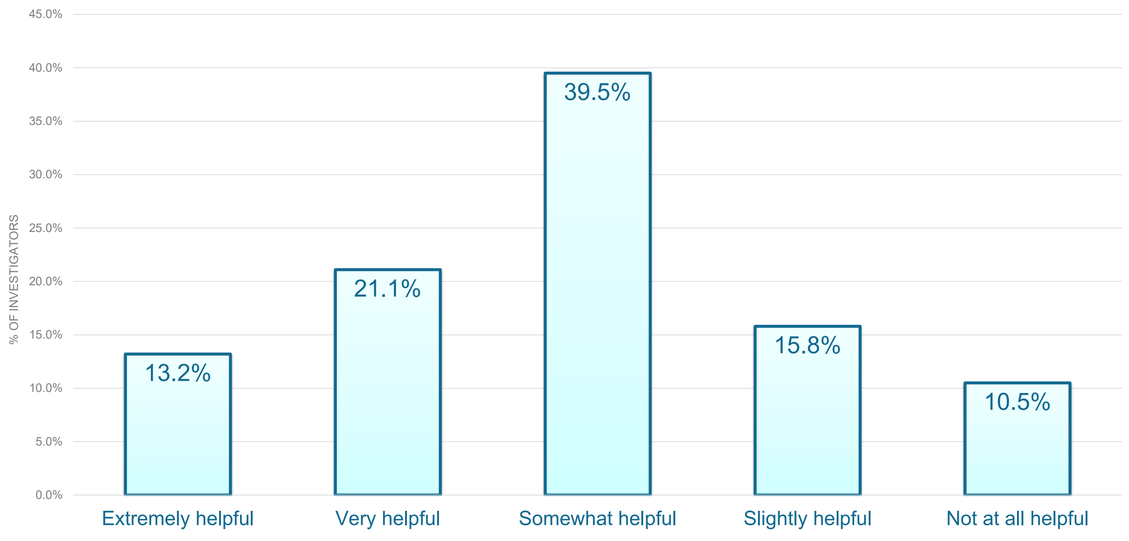
- TAPUR Study EDC Workflow and Forms

TAPUR Overview Presentation*

(*Investigators may use this presentation to promote the TAPUR Study within their organization/community)

- TAPUR Overview **(May 2024)**

Figure 3. Investigator Assessment of Toolkit Utility



Post Investigator Toolkit Survey Results

- In November 2023, TAPUR conducted a 6-month follow-up survey to assess the use of the Investigator Toolkit module. The response rate was 77.6% (38/49 responses).
- Results demonstrated that most Investigators (89.6%) found the Investigator Toolkit module to be helpful and accessed the new module at least once per week (76.3%).
- When asked to rank how often they accessed each resource, the results were consistent across the board with the initial survey.
- Further analysis showed that 39.5% of Investigators found it somewhat helpful, 21.1% very helpful, 15.8% slightly helpful, 13.2% extremely helpful, while only 10.5% found it not at all helpful.

Conclusions

- Of the multiple resources available in the module, there were two resources which TAPUR Investigators seem to access most of the time or all the time: cohort status report and matching rules table.
- The entire module did not prove to be effective for the TAPUR Study. However, there has been other research depicting the success in creating and using an investigator toolkit (Higgins et al., 2022).
- We recommend Sponsors focus on enhancing the existing tools that are perceived most valuable to investigators and creating a toolkit aimed at recruitment and marketing.

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