Enhancing Data Analysis in Clinical Trials

Utilizing Internal Use Only Forms for Comprehensive Data Capture in the TAPUR Study

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Disclosures and Disclaimers

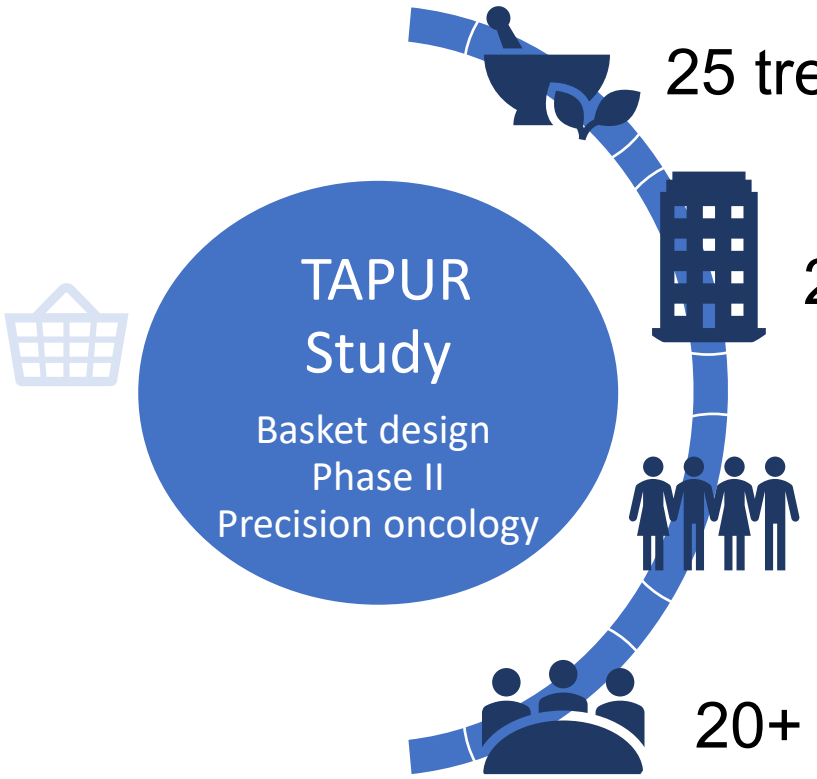
- I am an employee of the American Society of Clinical Oncology (ASCO).
  - ASCO receives funding from the following pharmaceutical companies to support the TAPUR Study: AstraZeneca, Bayer, Boehringer Ingelheim, Bristol Myers Squibb, Eli Lilly and Co., Genentech, Merck, Pfizer, Seagen, a wholly owned subsidiary of Pfizer Inc, and Taiho Oncology.

- All opinions expressed here are my own and not necessarily those of ASCO.

Statement of Purpose

- The aim of this presentation is to describe:
  - The utilization of internal use only forms in a large, complex, pragmatic basket study;
  - The benefits of incorporating data from internal use only forms into data analysis and presentation for the TAPUR Study

Overview of the Targeted Agent and Profiling Utilization Registry (TAPUR) Study



25 treatment arms total, 14 currently enrolling

260+ clinical sites, 28 states

180 enrolling cohorts, 2800+ patients enrolled

20+ published cohort manuscripts to date

As of April 22, 2024

Primary Objective and Endpoints

Primary Objective

- To describe the anti-tumor activity (efficacy) and toxicity (safety) of commercially available, targeted anti-cancer drugs
- Treating participants with advanced solid tumors with a genomic variant known (i) to be a target of an FDA-approved anti-cancer drug or (ii) to predict sensitivity to an FDA-approved anti-cancer drug

Primary endpoint: Disease control defined as objective response or stable disease at 16 weeks, per RECIST v.1.1

Other endpoints: Objective response rate, progression free survival, overall survival, time on treatment, duration of response, adverse events

Challenges That Led To Current Process

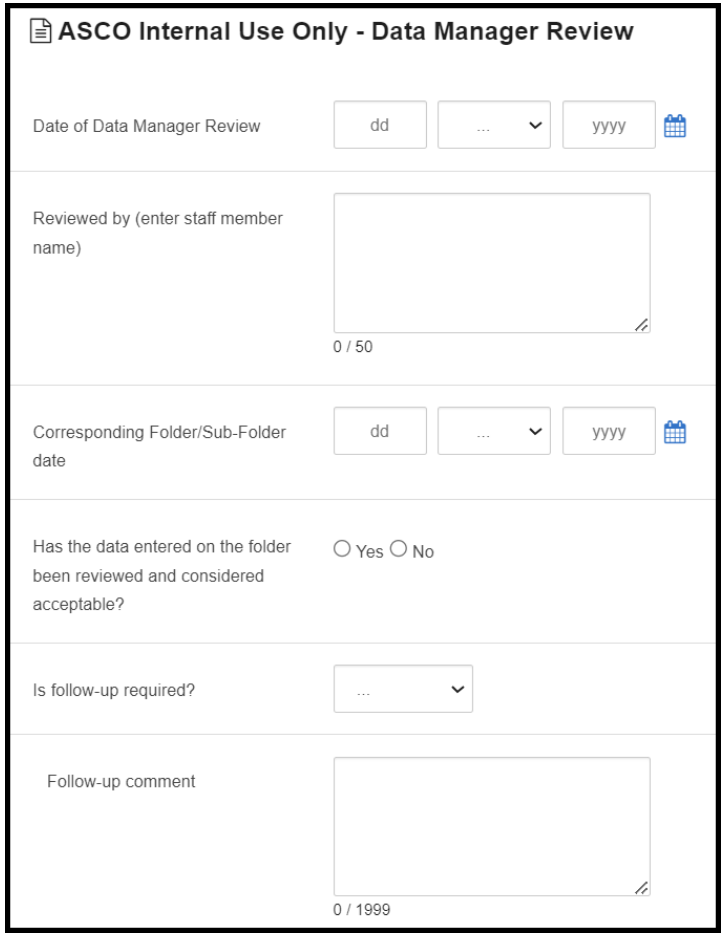
- Pragmatic data collection with broad eligibility criteria
  - Limiting clinical data capture can lead to insufficient level of detail in recorded information and can create additional work for data coordinating center
- Relying on details recorded by clinical site staff which may lack uniformity and have variability in the level of detail
- Information captured in disparate sources (Excel, Smartsheet, email repositories) will need to be integrated with clinical trial data by programmer

Internal Use Only Forms in EDC System

- Built into electronic data capture system (Medidata Rave) case report forms
  - Pre-populates as a blank form in pre-defined folders
  - Several types of internal use only forms
- Role based permissions prevent clinical sites are viewing and/or editing forms
- Captured by ASCO/TAPUR staff

Internal Use Only Forms (General)

- Forms are used to supplement data entered by clinical site staff
  - Data is not changed during this process
- Streamlines capture of study team notes
- Include structured fields that can be incorporated into SAS programs and supplemental data management reports, as well as free text fields to capture internal discussion, considerations, and decisions

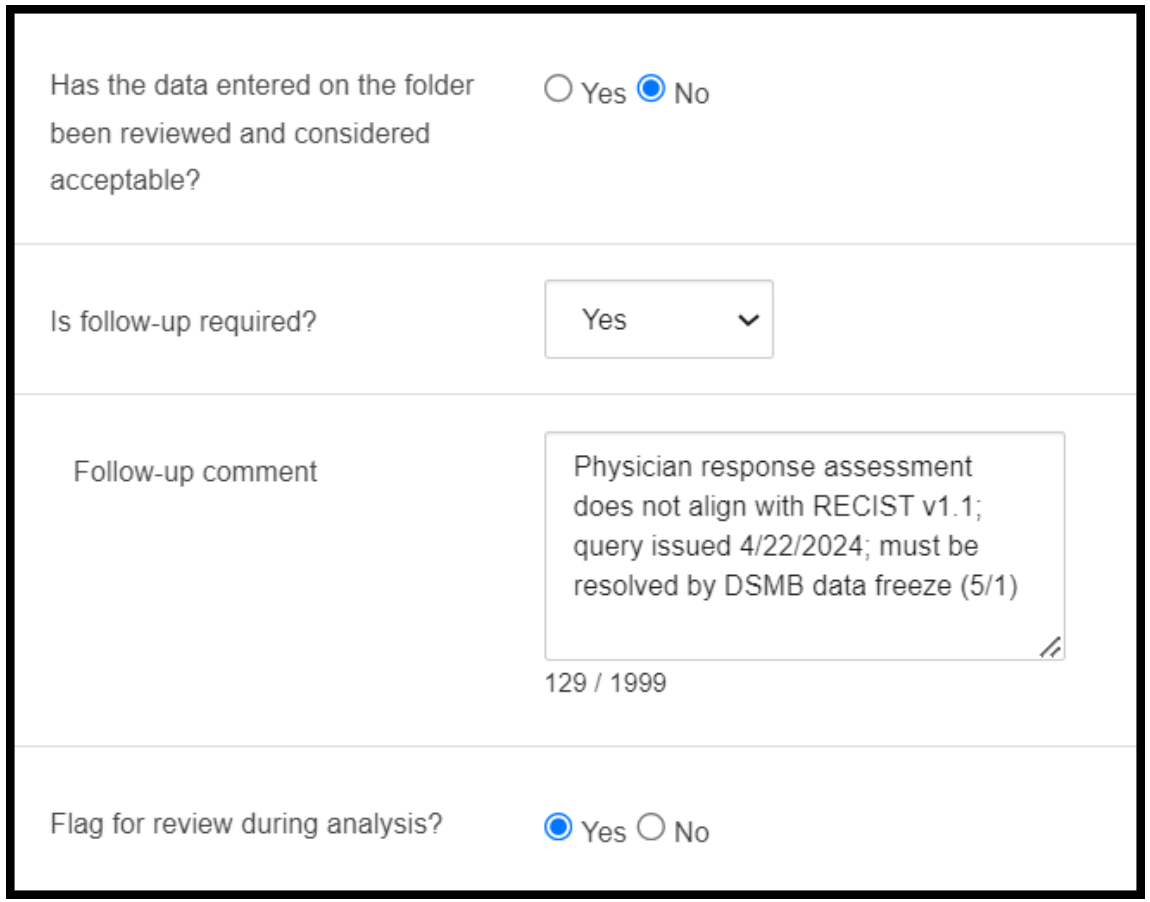


Pathology Report Reviews

Has the pathology report been reviewed for this participant?	Yes
Are there additional comments to be recorded from the pathology review?	Yes
If yes, enter comments from pathology review	Pathologist noted that the final diagnosis was adenocarcinoma involving fibrous tissue. Pathologist let additional note saying that the primary tumor site of the tumor is unknown despite extensive immuno workup. FMI notes unknown primary adenocarcinoma.
Histology term determined via pathology report review available for reporting	

- Most study arms include a tumor type based on primary site (ICD10 codes)
- When primary site is unknown, histology information can be extracted from pathology report to provide additional context

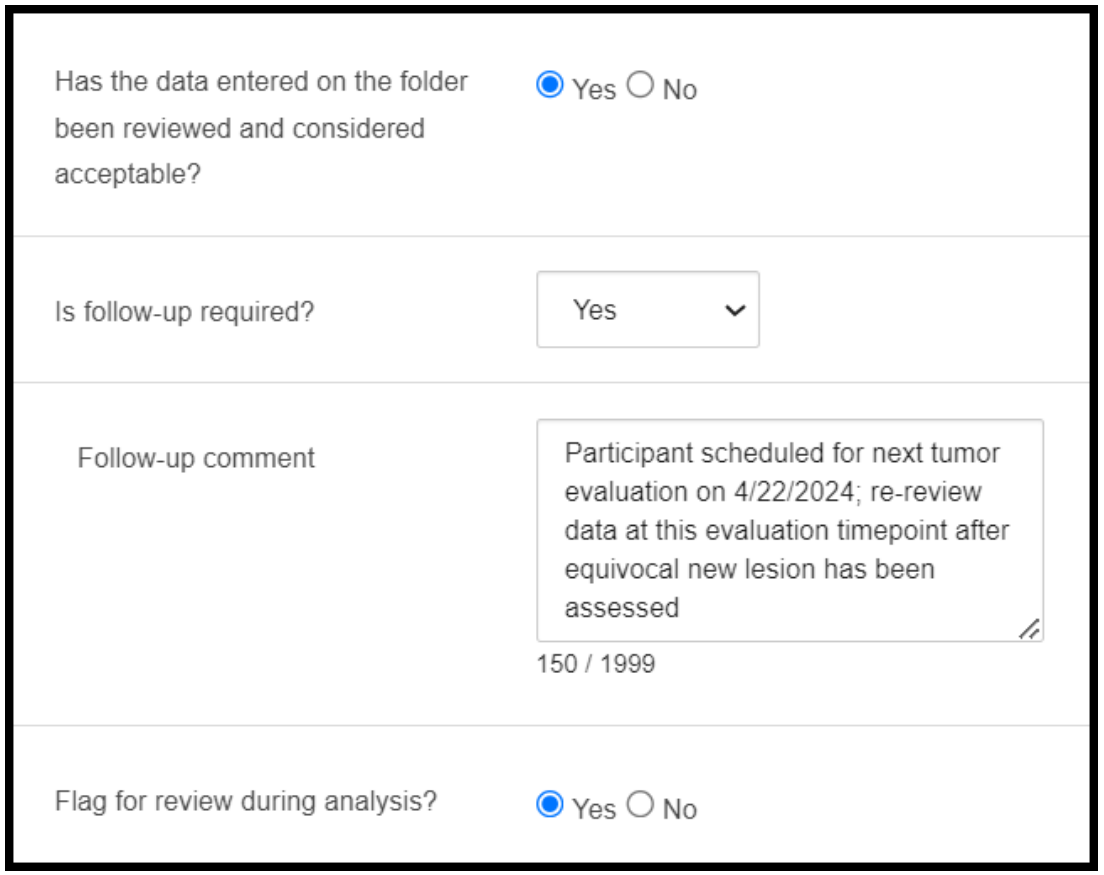
Query Tracking High Priority Data Quality Issues



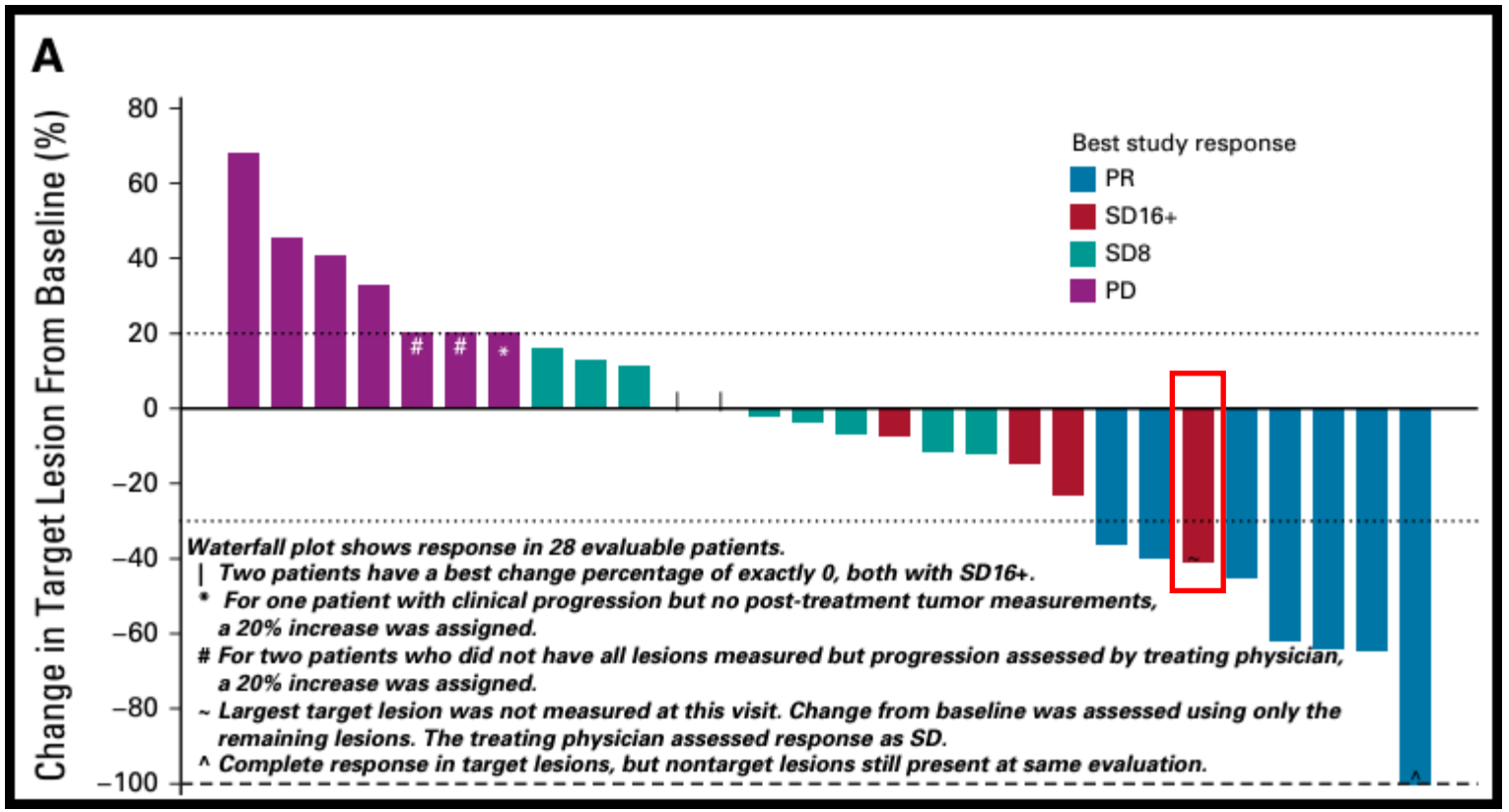
- Follow-up required dropdown includes Yes, No, Resolved options
- Follow-up comment field allows ASCO/TAPUR staff to record detailed information about scenarios, expectations, and deadlines

Pseudoprogression or Equivocal Progression

- Contextualize why participants remained on treatment until it's confirmed they have reached the study endpoint
- Participant response data being misinterpreted could have a significant impact on the cohort signal (positive versus negative)



Response Assessment in Waterfall Plot



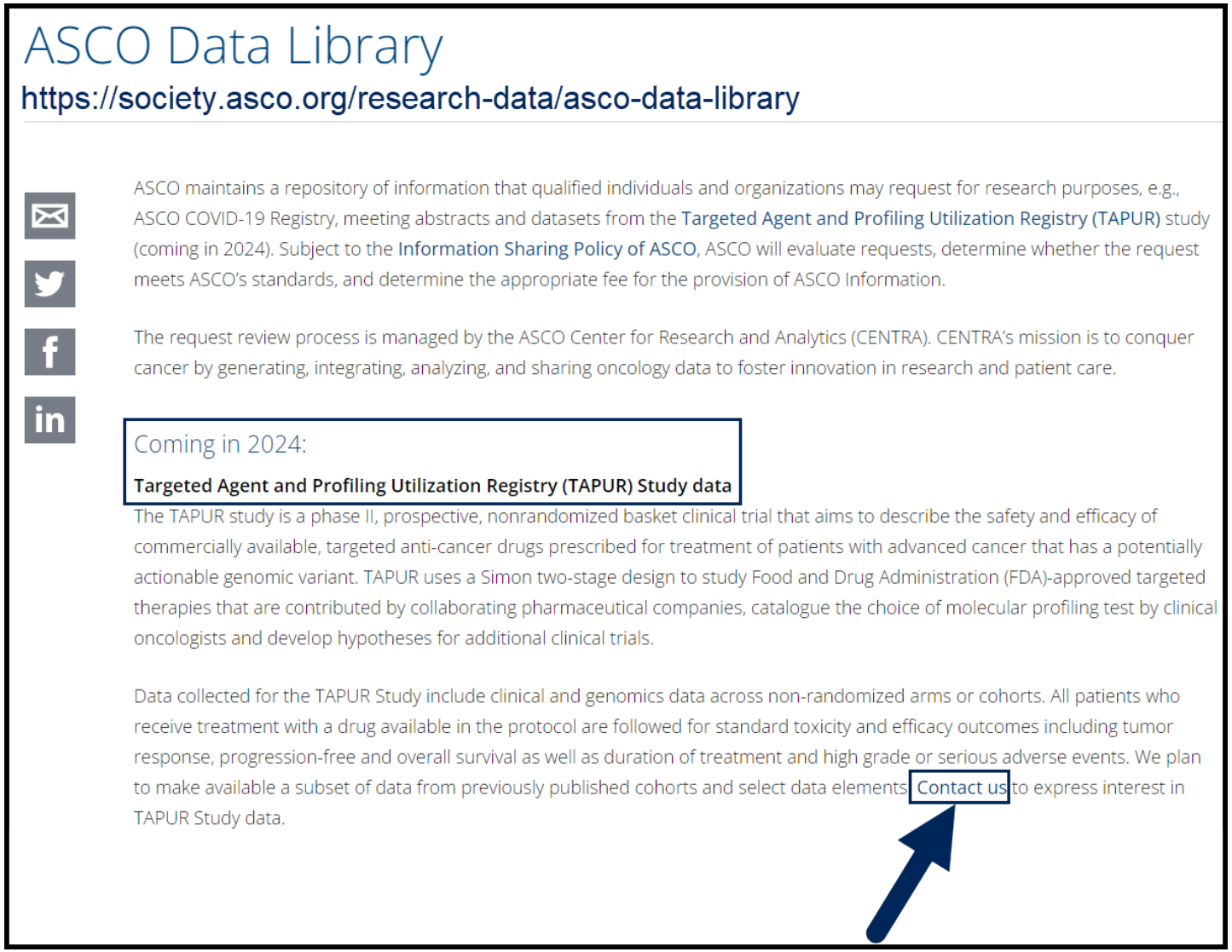
- Physician response assessment did not align with RECIST v1.1
- Largest lesion was not measured at 52-week visit
- Rationale for SD response assessment recorded in internal use only form

Conclusion

- Implementation of internal use only forms for capturing study team notes in the TAPUR Study has significantly enhanced data analysis and reporting
- These forms will be used in the analysis of hundreds of cohorts throughout the lifetime of the study which makes them invaluable
- By utilizing this approach, the TAPUR Study has strengthened its ability to provide valuable real-world data and address unique scenarios in the realm of clinical research

Thank you!

- Questions? Please contact TAPUR@asco.org
- The authors thank the patients who participated, the clinical centers, staff, and the TAPUR Study Team for study conduct and support
- Published TAPUR cohorts are being added to ASCO Data Library this year



ASCO Data Library

https://society.asco.org/research-data/asco-data-library

ASCO maintains a repository of information that qualified individuals and organizations may request for research purposes, e.g., ASCO COVID-19 Registry, meeting abstracts and datasets from the Targeted Agent and Profiling Utilization Registry (TAPUR) study (coming in 2024). Subject to the Information Sharing Policy of ASCO, ASCO will evaluate requests, determine whether the request meets ASCO's standards, and determine the appropriate fee for the provision of ASCO Information.

The request review process is managed by the ASCO Center for Research and Analytics (CENTRA). CENTRA's mission is to conquer cancer by generating, integrating, analyzing, and sharing oncology data to foster innovation in research and patient care.

Coming in 2024:

Targeted Agent and Profiling Utilization Registry (TAPUR) Study data

The TAPUR study is a phase II, prospective, nonrandomized basket clinical trial that aims to describe the safety and efficacy of commercially available, targeted anti-cancer drugs prescribed for treatment of patients with advanced cancer that has a potentially actionable genomic variant. TAPUR uses a Simon two-stage design to study Food and Drug Administration (FDA)-approved targeted therapies that are contributed by collaborating pharmaceutical companies, catalogue the choice of molecular profiling test by clinical oncologists and develop hypotheses for additional clinical trials.

Data collected for the TAPUR Study include clinical and genomics data across non-randomized arms or cohorts. All patients who receive treatment with a drug available in the protocol are followed for standard toxicity and efficacy outcomes including tumor response, progression-free and overall survival as well as duration of treatment and high grade or serious adverse events. We plan to make available a subset of data from previously published cohorts and select data elements. Contact us to express interest in TAPUR Study data.