Targeted Agent and Profiling Utilization Registry

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Problem

- Patient with advanced cancer; no standard Rx options
- Genomic profile test performed
- Who pays for the testing? Is it “worth it”?  
- Potentially actionable variant detected
- How to get the drug?
- Who pays for the drug? Is it “worth it”?  
- How to learn from the treatment?
TAPUR Study Primary Objective

• To describe the anti-tumor activity and toxicity of commercially available, targeted anti-cancer drugs prescribed for treatment of patients with advanced solid tumors, B cell NHL or MM with a genomic variant known to be a drug target or to predict sensitivity to a drug.

Current Status

• 462 patients registered (5/31/17)
• 301 patients enrolled (5/31/17)
• 65 participating sites (15 states)
New Sites and Collaborations

- 8 new centers with 36 locations in coming months—will bring total to 101 sites in 20 states:
  - Fox Chase Cancer Center – Pennsylvania, 1 site
  - Inova Schar Cancer Institute, Inova Health System – Virginia, 6 sites
  - Sutter Cancer Research Consortium – Northern California, 9 sites
  - The Angeles Clinic and Research Institute, a Cedars Sinai Affiliate – Southern California, 3 sites
  - The University of Texas MD Anderson Cancer Center – Texas, 5 sites
  - The University of Alabama at Birmingham Comprehensive Cancer Center – Alabama, 1 site
  - Sylvester Comprehensive Cancer Center, University of Miami – Florida, 7 sites
  - Winship Cancer Institute of Emory University – Georgia, 4 sites

- Amendment approved to lower enrollment age to 12
Current + 2017 Expansion Sites (101)
New Sites and Collaborations (cont’d)

- **Cure-One™ (formerly MED-C, The Molecular Evidence Development Consortium)**
  “Patients Diagnosed with Advanced Malignancy or Myelodysplasia, Tested by Standardized Sequencing, and Treated by Physician-Determined Care Plan: A Cure-One Observational Registry (N1 Registry™)”: Through this collaboration, both ASCO and Cure-One will develop ways to identify and support patients who are eligible to participate in both initiatives.

- **Caris Life Sciences® and Foundation Medicine**: First to receive the new “optimized for TAPUR reporting” designation—their reports are organized to optimize identification of genomic alterations that match to TAPUR Study drugs.

- **Canadian Cancer Trials Group (CCTG) and WIN Consortium**: Have studies in development based on TAPUR; ASCO aims to collaborate with them to share study results to accelerate learning.
Variation of Genomic Aberrations in 8 Most Frequent Tumor Types

As of Tuesday, April 25, 2017
Who Benefits if TAPUR Succeeds?

- **Patients** receive targeted agent matched to tumor genomic profile; drugs at no cost
- **Physicians** receive guidance in interpretation of genomic test results and treatment options, access to drugs, clinical data on off-label use
- **Pharma** receives data on drug use and outcomes to inform R&D plans and life cycle management
- **Payers** receive data on test and drug use and outcomes to inform future coverage decisions
- **Regulators** receive data on extent and outcomes of off label drug and test use and real world safety data
For more information:
www.TAPUR.org
www.ClinicalTrials.gov/02693535

About the Study

The Targeted Agent and Profiling Utilization Registry (TAPUR) Study is a non-randomized clinical trial that aims to describe the performance (both safety and efficacy) of commercially available, targeted anticancer drugs prescribed for treatment of patients with advanced cancer that has a potentially actionable genomic variant. The study also aims to simplify patient access to approved targeted therapies that are contributed to the program by collaborating pharmaceutical companies, catalogue the choice of genomic profiling test by clinical oncologists and learn about the utility of registry data to develop hypotheses for additional clinical trials.

Who Benefits?