Category: Clinical Research Operations – Work in Progress

Development of a systematic review of molecular testing increases precision medicine based clinical trial screening and awareness

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1. Background

Precision medicine testing is becoming more affordable and more widely used. Target therapy is rapidly changing as a result. But there is currently not a mechanism to review this testing to determine what treatment options are best, whether that is on or off clinical trials. Trial design has also shifted to basket or umbrella study design incorporating numerous cancers into one trial. This adds complexities and difficulties in identifying patients for these studies. The EAY131-Match protocol is an example of the complexity that the basket molecular based trial pose to sites. A systematic approach to manage the broad scope and range of studies like Match is needed to be successful.

2. Goals

1) Establish committee with adequate representation from medical oncology, geneticists, and clinical trial office to review all patients who undergo molecular testing for: trial eligibility, germline testing, and/or didactic value for Molecular Tumor Board.

2) Efficiently identify and screen patients for molecular targeted trials and germline testing through centralized screening with a lead coordinator at CCGRC

3) Develop a notification structure that allows for geneticists and coordinator to notify providers of qualifying patients.

4) Create a central clinical trial office contact that providers can reach out to regarding molecular testing. This contact can screen the molecular testing

4) Provide cases and expertise to the MCW Molecular Tumor Board to increase visibility of trial and treatment options based on precision medicine testing.

3. Solutions and Methods

The Medical College of Wisconsin has adopted a centralized approach to reviewing precision medicine testing. The first step was to establish the Cancer Center Genomic Review Committee (CCGRC) to review genomic data on all adult cancer patients who undergo comprehensive somatic mutation profiling. The membership of the committee includes medical oncologists, geneticists, and clinical trial coordinators. The goal is to identify candidates for biomarker enriched clinical trials and patients who may benefit from germ line testing based on somatic analysis. The CCGRC meets every 2 weeks and reviews all molecular testing.

Notifications are generated to providers to inform them a patient has a qualifying finding for a clinical trial or need germline testing. Coordinators of the targeted trials are also included on the notification to facilitate the communication between the Clinical Trials Office (CTO) and providers.

The CTO representative on CCGRC is the primary contact for questions regarding molecular testing eligibility for targeted trials such as Match. Providers only need to know one contact to inquire about eligibility.

4. Outcomes and Future Directions

The CCGRC was established in 2018 and meets every 2 weeks. Since October 2018, 236 cases have been reviewed by the CCGRC. 109 molecular findings potentially met eligibility for a trial.

A lead coordinator is a representative on the CCGRC and a resource for providers for eligibility and screening. All Match screening cases run through this single person and then referred out if they match to a treatment.

The Molecular Tumor Board meets monthly, often including cases from community-based hospitals. This provides an opportunity for patient's outside of our area to be identified for trials and have the opportunity to enroll.