

Background

Precision medicine testing is becoming more affordable and widely used. Numerous companies now offer next-generation sequence (NGS) testing. Consequently, targeted therapy options are rapidly changing. However, there is currently not a mechanism to review this testing to determine which treatment options are best. Many clinical trials incorporate basket or umbrella study designs, focus on numerous cancers and use many treatments. This adds significant difficulty in identifying patients for these studies. The EAY131-Match protocol is an example of the complexity that a molecular-based trial with a basket design poses. A systematic approach to manage the broad scope and range of studies that are similar to Match is needed to be successful.

Goals

- 1) Establish a committee with adequate representation from medical oncology, genetics and the Clinical Trials Office to review all patients who undergo molecular testing for trial eligibility, germline testing and/or didactic value for the Molecular Tumor Board.
- 2) Efficiently identify and screen patients for molecular-targeted trials and germline testing through centralized screening, using a lead molecular research coordinator on the Cancer Center Genomic Review Committee (CCGRC).
- 3) Develop a notification structure that allows geneticists and the coordinator to alert providers of qualifying patients.
- 4) Create a central Clinical Trials Office contact whom providers can reach out to regarding molecular testing.
- 5) Provide cases and expertise to the MCW Molecular Tumor Board to increase visibility of trial and treatment options, based on precision medicine testing.

Solutions

The Medical College of Wisconsin adopted a centralized approach to reviewing precision medicine testing. First, the Cancer Center Genomic Review Committee (CCGRC) was created to assess genomic data on all adult cancer patients who undergo comprehensive somatic mutation profiling. Committee members include medical oncologists, geneticists and clinical trial coordinators. The committee's central goal is to identify candidates for biomarker-enriched clinical trials and patients who may benefit from germline testing, based on somatic analysis. The CCGRC meets every two weeks to evaluate all molecular testing.

A representative notifies providers that a patient needs germline testing or has a finding that qualifies him or her for a clinical trial. 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.

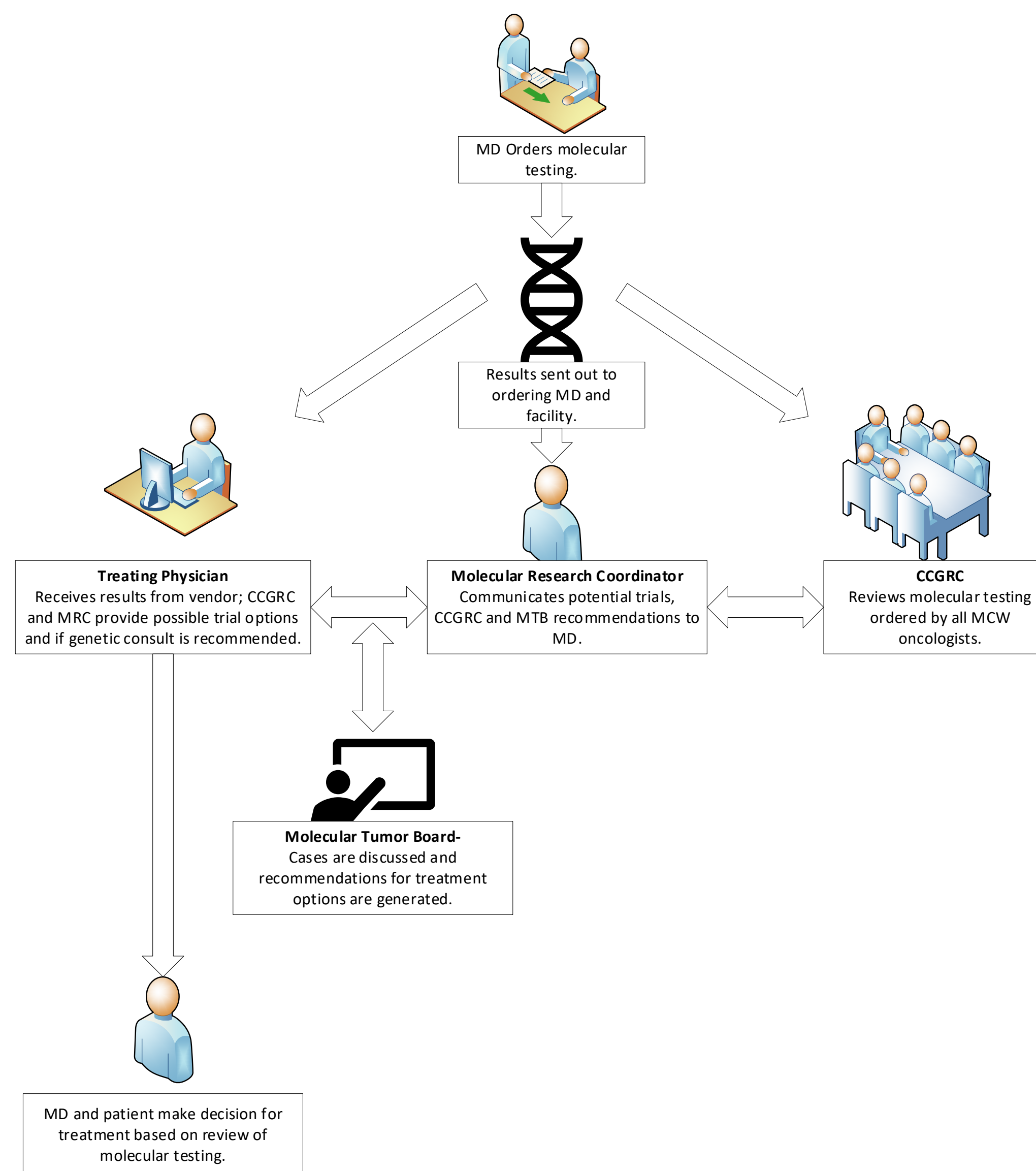


Figure 1. This illustrates the process the MCW Cancer Center uses to review molecular testing. The treating physician, molecular research coordinator (MRC) and Cancer Center Genomic Review Committee (CCGRC) review results. The patients are screened for molecular-targeted clinical trials that match their results. Then, treating physicians are notified.

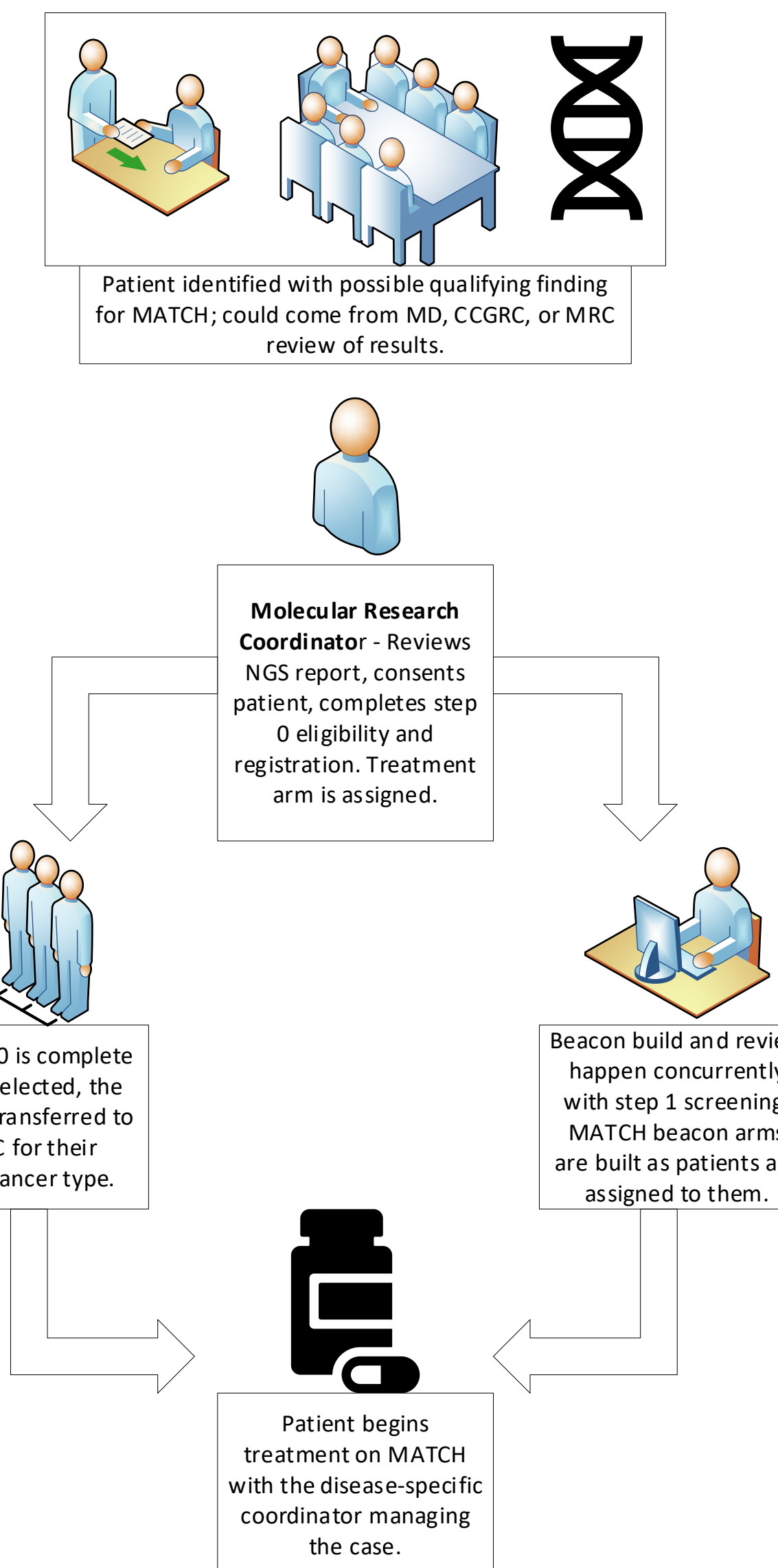


Figure 2. This outlines the MATCH screening process. The molecular research coordinator screens and completes Step 0. After the treatment arm is determined, the case is referred to the coordinator responsible for the patient's cancer type.

Outcomes

The CCGRC was established last year and meets every two weeks. Since October 2018, the committee reviewed more than 300 cases. More than 120 molecular findings met eligibility for a trial. The committee is investigating novel technology solutions to improve efficiency.

A lead molecular research coordinator is a CCGRC member and a resource for providers for eligibility and screening. This individual, who is a central point of contact for physicians, handles all Match screening cases. If patients are eligible, they are referred.

The monthly Molecular Tumor Board often reviews cases from community-based hospitals. This provides an opportunity for patients outside the area to be identified for trials.

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