tapestry NETWORKS

Advancing good practices and future approaches for use of local test options in clinical trials

Initiative Fact Sheet

Background and Goals

Today, oncology clinical trials aim to deliver cutting-edge treatments and high-quality outcomes for patients while being as operationally efficient and effective as possible. Trial sponsors, together with site investigator partners, are increasingly interested in using pre-existing local test results from a patient's medical record and/or biomarker testing by local laboratories during a trial to enroll patients. This may occur in parallel to central testing and the development of a companion diagnostic assay for simultaneous regulatory submissions for the drug and device.[1] Use of pre-existing results or local testing can promote faster test turnaround times and availability of samples for testing, thus enabling timelier access to trials for more patients and faster overall trial progress to expedite development for promising treatments. That said, using either test option—pre-existing results or local testing—can present complexities for a trial's implementation and regulatory approval of the treatment.

Against this backdrop, a select group of industry leaders are collaboratively seeking to address the use of local test options in trials. Specifically, the Local Test/ing in Clinical Trials Working Group will:

- Create a collaborative platform to identify and share good practices in using a local test option in oncology clinical trials to support the overarching goal of increasing patient access to investigational therapies
- Provide a trial sponsor view on the effective, pragmatic use of a local test option in oncology clinical trials to inform future thinking for regulators, the laboratory community, and other stakeholders

This effort builds from various regulatory initiatives, including those focused on increasing trial accessibility for patients and streamlining the use and oversight of diagnostics in clinical trials, such as the 2023 "Oncology Drug Products Used with Certain In Vitro Diagnostic Tests: Pilot Program" by the US Food and Drug Administration.[2] It also extends from prior multistakeholder initiatives on diagnostic quality and in silico reference files convened by Tapestry Networks.

Key Activities and Outputs

The initiative will engage in a series of individual and group conversations with select trial sponsors to identify benefits and elements for success, risks to mitigate, and additional considerations and approaches in using local test options during clinical trials. These experiences will be synthesized into a framework for consideration and incorporated into a public report that also highlights sponsor good practices. This initiative will outline opportunities for future action that might better enable practical use of local test options in clinical trials. Participants will focus on oncology, given the specialty's prevalent use of diagnostics in clinical decisions, but the effort may have relevance for other diseases. While the report will highlight trial sponsor experiences and recommendations, diverse stakeholders will be engaged in candid discussions to ensure a variety of views, expertise, and experiences are acknowledged.

Benefits and Rules of Engagement

All participants in this effort will engage in individual and multistakeholder conversations about the framework as it is drafted and refined, presenting an opportunity to be at the forefront of conversations on use of diagnostics in clinical research and the broader diagnostics policy landscape. Tapestry uses a modified version of the Chatham House Rule (i.e., attendee lists are public, but comments are not attributed) to enable candor in all discussions and public written outputs.

Current Participants

Amgen, AstraZeneca, Eli Lilly, and Gilead Sciences are sponsors of this initiative. This effort will collaborate with the Medical Device Innovation Consortium's Somatic Reference Sample effort, Friends of Cancer Research, and other stakeholders in diagnostics and drug development to elicit diverse views on these topics. Tapestry will provide staff support and a platform to advance this initiative in 2025.

About Tapestry Networks

Since 2004, Tapestry has been the premier firm for building collaboration platforms with leaders of the world's foremost organizations. Tapestry Networks brings senior leaders together to learn and to shape solutions to today's most pressing challenges. We are a trusted convener of board directors, executives, policymakers, and other stakeholders, connecting them with information, insight, and each other. Top experts join our discussions to learn from the leaders we convene and to share their knowledge. Our platforms help educate the market, identify good practices, and develop shared solutions. We call this the power of connected thinking.

[1] Imein Bousnina et al., *Expedited Development of Diagnostics for Therapies Targeting Rare Biomarkers or Indications* (Friends of Cancer Research, 2022).
[2] US Food and Drug Administration, "Oncology Drug Products Used with Certain In Vitro Diagnostic Tests: Pilot Program Guidance for Industry, Clinical Laboratories, and Food and Drug Administration Staff," June 20, 2023.