

Case Study: The Diagnostic Quality Assurance Pilot

Challenge:

From 2013-2015, Tapestry convened the Sustainable Predictive Oncology Therapeutics and Diagnostics (SPOT/Dx) working group to address the readiness of the US regulatory, reimbursement, and delivery system to meaningfully realize the promise of precision medicine. During SPOT/Dx meetings, participants underscored the challenges presented by the two-tiered regulatory structure governing advanced molecular diagnostics. How can laboratory developed tests (LDTs) demonstrate comparable performance to companion diagnostics (CDx) that undergo rigorous FDA review—and do so in a way that is pragmatic, efficient, and sustainable for all stakeholders?

Response:

Tapestry engaged closely with numerous public and private stakeholders to understand potential solutions to this challenge. Given the complexity of the topic and interests involved, this effort required several meetings throughout the course of 2015 to finalize the design of a pilot that would address the LDT-CDx gap and meet the interests of all stakeholders. Specifically, we:

- Conducted discrete conversations with regulators, public and private payers, patient advocates, providers, pathologists, clinicians, industry, and other subject matter experts to understand the concerns and positions of all parties
- Prepared relevant stakeholders for face-to-face working meetings through briefing documents and additional discussions, helping each understand the perspective of others and encouraging candor while upholding confidentiality
- Worked closely with all participants to develop meeting agendas, initial pilot concept materials, and a well-crafted meeting experience and format to foster progress and trust across participants
- Facilitated all working meeting discussions
- Finalized the pilot design and concept note with participants
- Consulted with the broader healthcare community to test the pilot's feasibility and understand stakeholders' concerns and questions

The solution:

Following the above process, Tapestry, together with a subset of SPOT/Dx participants, including the College of American Pathologists, Palmetto GBA, Blue Cross Blue Shield Association, Amgen, Illumina, Friends of Cancer Research, the American Society of Clinical Oncology, laboratories and liaisons from the National Cancer Institute, the US Food and Drug Administration, and the Center for Medicare and Medicaid Services launched the Diagnostic Quality Assurance Pilot in 2016. The pilot designs and equips select molecular pathology labs with traceable reference samples to assess whether participating labs' appropriately validated LDTs can achieve diagnostic performance comparable to a CDx for targeted cancer therapy. A next-generation-sequencing panel that is a CDx to a targeted therapy serves as the current test candidate in the pilot.

Tapestry continues to support ongoing execution of the pilot through project management, strategic communications, and outcomes-sharing, as well as ensuring effective alignment of the pilot with related efforts across the diagnostics and oncology communities. Tapestry advises the pilot's multistakeholder steering committee, its independent chair, and Amgen, the project's sponsor, and serves as the secretariat of the pilot.

When the pilot is finalized in early 2019, Tapestry will continue to help communicate its results and their implications and explore the sustainability and scalability of the pilot's approach. Regardless of the technical results of the pilot, the participatory, multistakeholder process Tapestry designed has helped facilitate the pilot's execution and build long-term relationships among the stakeholders involved: *"This process has revealed to me that such efforts need people and resources that can drive the process over the long term once it's started."*