

Case Study: Multistakeholder Drug Development Pilots

“From a public sector perspective, the process felt well-paced and safe ... Tapestry was a critical filter for stakeholder inputs and exploring comfort levels. There are lots of multistakeholder meetings now, but not everyone can do it and deliver both a high-quality level of content and type of interaction.”

Challenge:

From 2006 through 2012, Tapestry convened the European Healthcare Innovation Leadership Network (EHILN) to generate insights and develop solutions to advance European healthcare innovation and support patient access to valuable treatments during an era of severe budgetary pressures. The network comprised a focused group of high-level decision-makers from government ministries covering health, industry and finance, the pharmaceutical industry, and other key constituencies from eight European nations.

In this context, network participants and EHILN-affiliated multistakeholder working groups identified several challenges in the drug development process that limit health systems’ ability to deliver the right medicines to the right patients at the right time. The group agreed that multistakeholder consultations in early-stage drug development could help reduce the high costs of bringing innovative new medicines to market. These consultations would educate and align stakeholders on the factors that constitute a medicine’s value and the evidence needed to demonstrate that value, as well as focus development programs on the medicines that constrained health systems needed most.

Key questions remained: How would the multistakeholder consultations be structured? How could diverse participants—who are sometimes at odds with one another—work effectively together? What level of risk did such consultations pose to participants? What questions would be most appropriate for these consultations? What would be a sustainable resourcing and operating model? Presuming success and value in the pilot process, how could participants scale this approach over time?

Response:

From 2010-2012, Tapestry, working together with industry representatives AstraZeneca, GlaxoSmithKline, Bristol-Myers Squibb, Roche, and Janssen; participants and liaisons from the European Medicines Agency and the European Network for Health Technology Assessment; individual European health technology assessment bodies, budget-holders, and regulators in France, Germany, Italy, the Netherlands, Spain, Sweden, and the UK; as well as patient advocacy groups and other experts, designed and led the implementation of six multistakeholder drug development pilots in cancer, diabetes, anti-infectives, and Alzheimer's Disease. Specifically, Tapestry:

- Worked with EHILN participants and other stakeholders to refine the pilots' initial concept
- Engaged with relevant stakeholders to obtain initial support from their institutions
- Synthesized those inputs to identify an initial set of high-priority treatment areas including cancer, diabetes, Alzheimer's and dementia, and anti-infectives
- Designed and facilitated a series of meetings to further clarify the pilots' principles, processes, rules of engagement, and measures of success
- Managed the pilots' implementation, including:
 - Working with pharmaceutical innovators to identify appropriate assets, frame strategic questions, and develop briefing documents
 - Recruiting institutional representatives, experts, and patient advocates
 - Identifying and supporting joint consultation co-chairs
 - Briefing all participants and ensuring that a transparent and equitable scheme for resourcing was available
 - Leading clarification calls and producing summaries of feedback
 - Understanding and communicating the skills required for effective co-chairing of consultations
 - Co-developing an agenda for the consultation meeting with the development team and co-chairs
 - Managing logistics and scheduling for each consultation meeting
 - Debriefing participants and developing an informal consultation summary
 - Continuously improving the pilot process based on participant feedback
- Synthesized the pilots' results and findings into public reports
- Supported key stakeholders in eventually [institutionalizing the approach in Europe](#)

Outcomes:

The pilots provided a forum for medicine developers to receive integrated feedback on the expected value of a medicine in the pipeline and how best to demonstrate that value. They yielded several outcomes:

- Reduced risks of drug development
- Improved focus in drug development programs, including reaffirming or terminating development programs based on the feedback regarding the drug's potential value
- Increased clarity regarding the value of new treatments
- An opportunity for regulators and health technology assessment officials to influence the type and quality of evidence generated
- Mutual education across institutions

The pilots also brought forth several intangible benefits to participants, including enhanced trust, cooperation, and candor. Many praised the process as providing both a safe, neutral forum and a disciplined, thoughtful approach that acknowledged the key issues and positions of participants. *“What I found unique is that [everyone] made an investment in the briefing package and that led to broader adoption of the advice received ... Instead of the market access folks beating the drum of payer value, that value was internalized ... It helped the program to be more oriented not just toward regulatory approval,”* one industry participant commented. Another elaborated: *“I have plenty of experience attending [other advice] meetings. They are very formal, the atmosphere is more inquisitorial and the industry [participants] may feel sometimes to be on the defensive. This was not what we experienced in the pilots. We felt relaxed and that genuinely people were engaged and interested in understanding others' points of view.”*