Leveraging Innovation Ecosystems to Enhance Patient Empowerment

27 July 2020
Mary Quilty

With recent changes in law and regulation, consumer products that collect health data – and how they handle that data – are in the spotlight. For example, with the 21st Century Cures Act signed into law in December 2016 and the subsequent promulgation of two rules emphasizing patient access to health data (the Office of the National Coordinator for Health Information Technology (ONC) 21st Century Cures Act rule and U.S. Centers for Medicare & Medicaid Services (CMS) Interoperability and Patient Access rule), the need within industry for a flexible and scalable resource to support the increased emphasis on interoperability, information sharing, and patient data management emerged, and became a focus for MITRE research. In analyzing the health-tech ecosystem, a likely source of new consumer health tools, it became clear that innovation-driven enterprises were in a position to deliver on novel patient-focused solutions, however their rapid pace of 'develop and deploy' necessitated support for infrastructure, such as policies and procedures.

Leveraging MITRE's mission to conduct research in support of the federal government's evolving challenges, the work of Principal Investigator Katherine Mikk on an open-source model Patient Data Use Agreement (PDUA) was brought into a MITRE partnership with the accelerator MassChallenge Health Tech (MCHT). As a templated, modular legal document focused on 'plain language' text intending to simplify the complex issues of patient data management, the model PDUA provides organizations with a framework to aid new ways of thinking about patient data. Together, MITRE and MCHT identified startups from the MCHT 2020 cohort that would serve as strong pilot partners in the adoption of model PDUA elements. The pilot, led out of MITRE's Bridging Innovation initiative's Health Vertical, represents MITRE's aim to establish a network of integrated, programmatic partnerships by which additional MITRE and government-focused initiatives can enter a virtuous cycle with start-ups and strategic health innovation ecosystems to collectively drive impact in the health domain.

The pilot, which ran from January to June of 2020, had MITRE serving as an *MCHT Champion Partner* for five start-ups, i.e., Eleos, UDoTest, TemboHealth, WorkingWell, and Byteflies. While startups worked through baseline and endpoint assessments, as well as an adoption plan outlining how they could integrate model PDUA elements into their organizations, MITRE and MCHT leveraged their partnership to engage with other start-ups and innovation ecosystem Champions to share MITRE's health work program through community-wide educational sessions. While the pilot did not provide legal counsel, through working sessions each start-up reflected on elements of their patient data management strategy and began adopting aspects of the model PDUA in consultation with their attorneys.

MITRE believed it could add and receive value from the MCHT innovation ecosystem and considered the pilot a strong way to test this type of partnership model. Starting MITRE involvement in this community with a focus on patient empowerment and the power of health IT in supporting both patients and providers was a deliberate choice as was leveraging MITRE thought leadership funded through an internal research program. MITRE saw the power of technology and data to transform health and healthcare.

Through the pilot, Mikk gained real-time, real-world user feedback on the model PDUA that she will use to evolve the work and increase MITRE's ability to support organizations working with patient data in alignment with federal policy. Mikk shared, "The timing of this work is critical. Federal policy makers want to ensure adoption of these new data-related policies, ensuring patients have access to their health information, but individuals may need help identifying and evaluating services they can trust with their data. Through awareness of patient data needs, new businesses have an opportunity to embrace digital delivery and build the patient, or consumer, into their business, in alignment with best-practices and federal policy, from the beginning".

"Connecting MITRE's research work with the innovation community in Boston's health-tech space made complete sense" says Graves, who leads MITRE's Bridging Innovation initiative and has seen like partnerships work in the Defense space, where connecting the government with industry to discover,

accelerate, and deliver innovative solutions emerging from start-ups and other non-traditional sources has been a core MITRE strength. Graves further noted, "MITRE is developing new tools and approaches to benefit our federal sponsors across all branches of government, who in turn aim to support our broader community. Leveraging our approach in the health domain and building more connections with innovators in this space is key to our mission to solve problems for a safer world. Bringing MITRE research to our innovation ecosystem partners through a formal pilot to evolve the research and add value to industry is a clear win."

To learn more about this work, please contact Mary Quilty, Health Vertical Lead for MITRE [Bridging Innovation](#) at mary@mitre.org