

NEW DIGS

LEAPS

Learning Ecosystems Accelerator for
Patient-centered, Sustainable innovation



Successfully delivering on the promise of biomedical innovation, in the world of value-based healthcare, means advancing from “trial-and-error” to “precision” medicine, where patients are confident that they are receiving the right treatments at the right time for their situation.

Getting there requires that we transform our current approach to evidence generation.

The LEAPS Project is advancing the mission of the MIT NEWDIGS consortium - *to deliver more value from biomedical innovation faster to patients, in ways that work for all stakeholders* - through a new collaborative systems approach to the planning, production, and use of real world evidence across R&D and healthcare delivery. A model system for Rheumatoid Arthritis (RA) will be piloted in Massachusetts (2020 launch), and will inform related efforts in other diseases and geographies. Success in LEAPS targets better patient outcomes while also reducing waste and inefficiency across the system. Core to LEAPS is the creation of new evidence generation infrastructures (platforms) designed for patient-level impact, scale and sustainability.

KEY FEATURES OF LEAPS

System Innovation: Demonstrate a powerful new approach to reducing critical uncertainties in drug development, access, and use that undermine patient outcomes, and fuel unsustainable inefficiencies.

One Disease at a Time: Design and pilot a model system (processes, policies, technologies, and infrastructures) for one target disease (RA) within a geographically defined testbed (Massachusetts).

Proven Approach: Structure system redesign activities with real world cases, multi-stakeholder Design Labs, interactive game theory exercises, and rigorous team-based modeling/simulation.

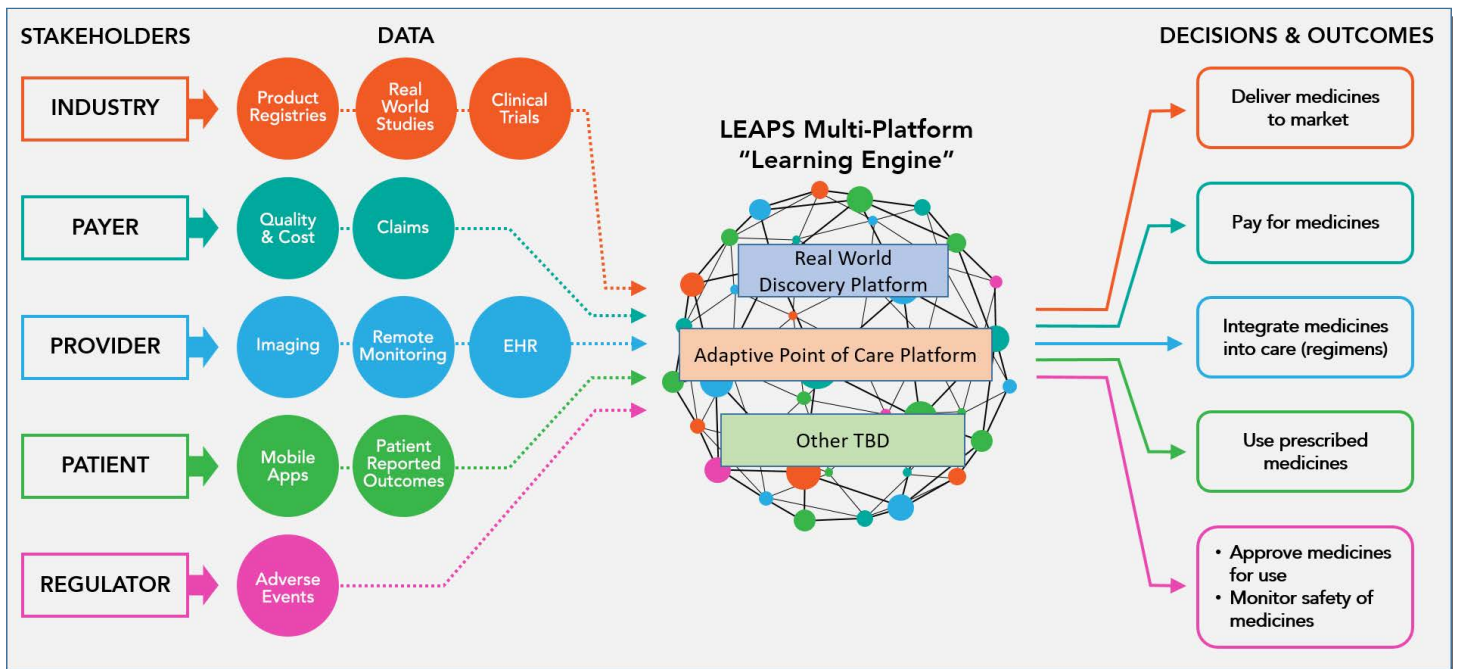
Build on What We Have: Harness the transformational power of emergent, but fragmented, innovations, such as:

- Platform strategies/architectures¹⁻⁴
- Digital health technologies and advanced analytics
- Disruptive collaboration models (e.g., open source, pre-competitive governance, patient-centered and multi-stakeholder-driven processes)

Broadly Applicable Insights: Synthesize and disseminate generalizable insights and tools from the pilot to accelerate innovation in other geographies and diseases.

REFERENCES

1. Woodcock J and LaVange L. *Master Protocols to Study Multiple Drugs, Multiple Diseases, or Both*. N Engl J Med 2017; 377:62-70.
2. Trusheim MR, Shrier AA, Antonijevic Z, Beckman A, Campbell RK, Chen C, Flaherty KT, Lowey J, Lacombe D, Madhavan S, Selker HP, and Esserman LJ. *PIPELINES: Creating Comparable Clinical Knowledge Efficiently by Linking Trial Platforms*. Clin Pharm & Therap, December 2016.
3. Angus D. *Fusing Randomized Trials With Big Data: The Key to Self-learning Health Care Systems*. JAMA 2015;314:767-8.
4. I-SPY: <https://www.ispytrials.org/>



The centerpiece of the LEAPS RA pilot in MA is a coordinated network of real-world evidence generation platforms (“Learning Engine”) designed for efficiency, patient impact, scale, and sustainability. Success targets both improved patient outcomes and financial sustainability for all stakeholders in the system.

About MIT NEWDIGS

MIT NEW Drug Development ParadIGmS (NEWDIGS) is an international “think and do tank” dedicated to delivering more value faster to patients, in ways that work for all stakeholders. NEWDIGS designs, evaluates, and initiates advancements that are too complex and cross-cutting to be addressed by a single organization or market sector. Its members include global leaders from patient advocacy, payer organizations, biopharmaceutical companies, regulatory agencies, clinical care, academic research, and investment firms. For more information, visit <http://newdigs.mit.edu>.

Join LEAPS!

Success in the LEAPS Project requires hands-on participation by diverse partners. To learn more about how to participate, please contact us.

More information on NEWDIGS projects can be found at: <https://newdigs.mit.edu>

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