LEAPS transforms patient outcomes through planning, producing and using RWE to benefit all stakeholders.

MISSION
The NEWDIGS 'think and do' tank helps downstream (post-market) innovation match the upstream scientific innovation driving biopharmaceutical development. The mission is to drive more value faster to patients in ways that work for all stakeholders. NEWDIGS, launched in 2009, provides a proven safe haven environment for collaborative systems innovation, and structured methods and tools that enable high impact engagement by multi-stakeholder teams.5-11

Starting with Rheumatoid Arthritis, the ~150 LEAPS collaborators are designing regimen optimization learning systems grounded in real-world evidence (RWE) to enhance decision-making for drug therapy Selection, Sequencing, Switching, and Stopping along each patient’s journey to improve their outcomes AND ensure economic sustainability for the system.

LEAPS transforms how stakeholders collaboratively plan, produce and use RWE (see Fig 1) to optimize drug therapy regimens.

BEYOND EVIDENCE, INCENTIVES
Evidence alone is not enough, LEAPS addresses the misaligned incentives that inhibit RWE generation and use. Payers, prescribers and patients lead the conceptualization and piloting of new payment and access models with developers, policy makers and others alongside.

New models range from how we pay for drug therapies using “Precision Financing” to innovative contracting approaches for real-world federated data marketplaces and analytics.

PLAN & USE, NOT MERELY PRODUCE
The LEAPS Learning Lifecycle, explicitly targets RWE generation on uncertainties whose resolution will improve patient outcomes and be implemented by all stakeholders. These processes reshape stakeholder and disciplinary silos into a sustainable learning system with measurable impact.
LEAPS produces decision-quality RWE better, faster, and cheaper through the power of platforms in a collaborative learning eco-system. LEAPS is designing new evidence generation platforms to enhance the efficiency and scale of knowledge creation with minimal risk. Rheumatoid Arthritis demonstrations of these platforms are:

- **REAL WORLD DISCOVERY PLATFORM (RWDP):** An infrastructure of diverse federated (retrospective) data sets, advanced analytic capabilities, and partnerships focused on identifying insights with potential predictive value. Data sources include EHR, claims, registry, and patient-generated, among others. Target outputs include hypotheses related to sub-populations, patient journey “archetypes,” and predictive biomarkers.

- **ADAPTIVE POINT-OF-CARE PLATFORM (APOC):** A scalable comparative effectiveness study capability, guided by a Master or Core protocol that offers adaptive, multi-arm designs that continuously evaluate multiple treatments in the context of a single disease, both in parallel and sequentially over time. In effect, an APoC is a scalable pragmatic trial for evaluating drug therapy regimens, that is embedded at the point-of-care in clinical decision-making in ambulatory care settings.

- **CONNECTIONS ACROSS PLATFORMS:** Strong hypotheses generated from the retrospective observational studies within the RWDP could be prospectively validated through the APoC Platform, fueling further learning efficiency. Validated hypotheses, in turn, would be integrated into decision-support tools for each stakeholder.

**LEAP WITH US**

As LEAPS grows, we are receiving inquiries from senior level innovators from other diseases (e.g., Oncology, Immunology, CNS, and COVID-19) who are interested in applying evolving LEAPS design principles within their ecosystems. Translational road-mapping for diseases beyond Rheumatoid Arthritis will begin in 2021.

For further information on work currently underway in LEAPS for Rheumatoid Arthritis, or now being planned for other target diseases, please contact:

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**REFERENCES**

[1] NEWDIGS List of Members and Collaborators (partial list)


ABOUT NEWDIGS
MIT NEWDIGS (NEW Drug Development ParadIGmS) 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.

ABOUT LEAPS
The LEAPS Project (Learning Ecosystems Accelerator for PAtient-centered, Sustainable innovation) is advancing the mission of the MIT NEWDIGS consortium through a new collaborative systems approach to the planning, production, and use of RWE to “get the right treatment to the right patient at the right time.” Components of a model system for Rheumatoid Arthritis will be piloted in 2021, and will inform related efforts in other diseases. Success in LEAPS targets better patient outcomes while also reducing waste and inefficiency across the system.

ABOUT FoCUS
The MIT NEWDIGS consortium FoCUS Project (Financing and Reimbursement of Cures in the US) seeks to collaboratively address the need for new, innovative financing and reimbursement models for durable and potentially curable therapies that ensure patient access and sustainability for all stakeholders. Our mission is to deliver an understanding of financial challenges created by these therapies leading to system-wide, implementable precision financing models. This multi-stakeholder effort gathers developers, providers, regulators, patient advocacy groups, payers from all segments of the US healthcare system, and academics working in healthcare policy, financing, and reimbursement in this endeavor.

LEAPS Strategic Advisory Network

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