NEWDIGS

LEAPS

Learning Ecosystems Accelerator for Patient-centered, Sustainable innovation

Design Lab

July 17, 2018 – Day 1

Introduction

MIT CENTER FOR BIOMEDICAL INNOVATION

Welcome!

This Design Lab
is hosted by the
MIT NEWDIGS
LEAPS Project

LEAPS: Launched January 2018

Massachusetts Institute of Technology

MIT News

ON CAMPUS AND AROUND THE WORLD

Massachusetts to Pioneer Next Generation Healthcare Innovation Ecosystem to Better Serve Patients

December 2017

NEWDIGS Initiative at MIT leads multi-stakeholder collaboration to design and pilot a sustainable, patient-centered innovation ecosystem for a target disease

NEWDIGS

STRATEGIC ADVISORY NETWORK

Anna Barker, PhD
Director, National Biomarker Development Alliance
Former Deputy Director, National Cancer Institute
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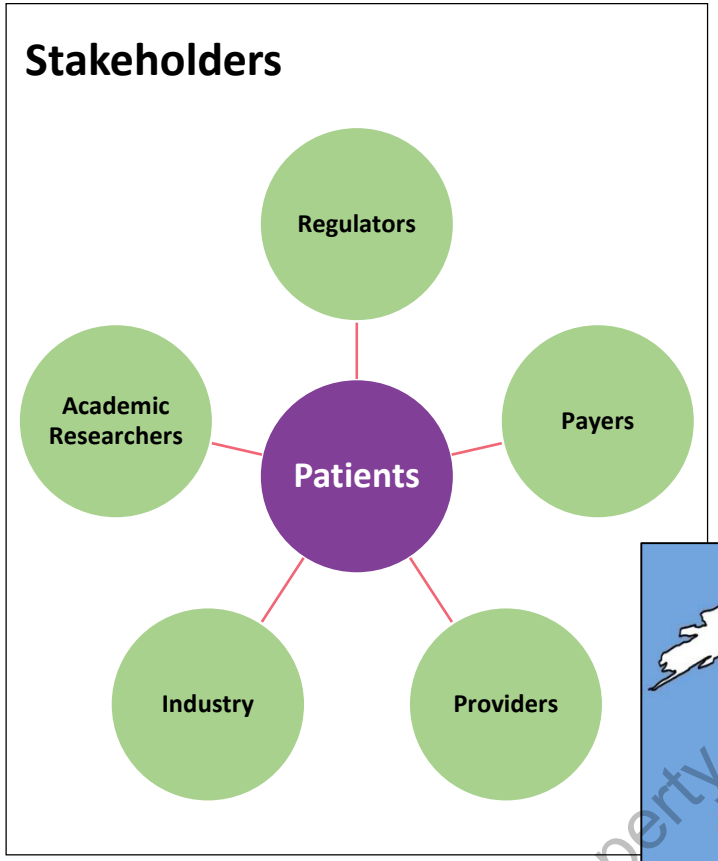
Former CEO, MA Life Sciences Center

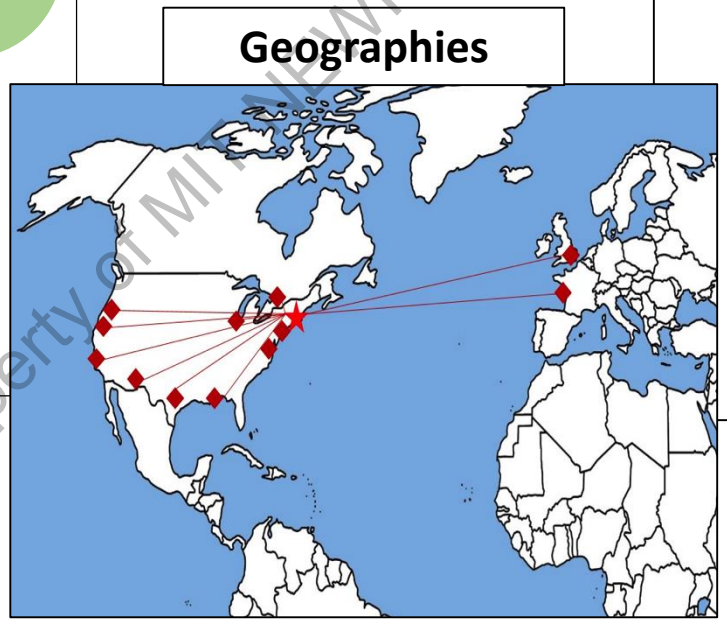
Marylou Sudders, MS, Hon. DSc
Secretary of Health & Human Services
Commonwealth of Massachusetts

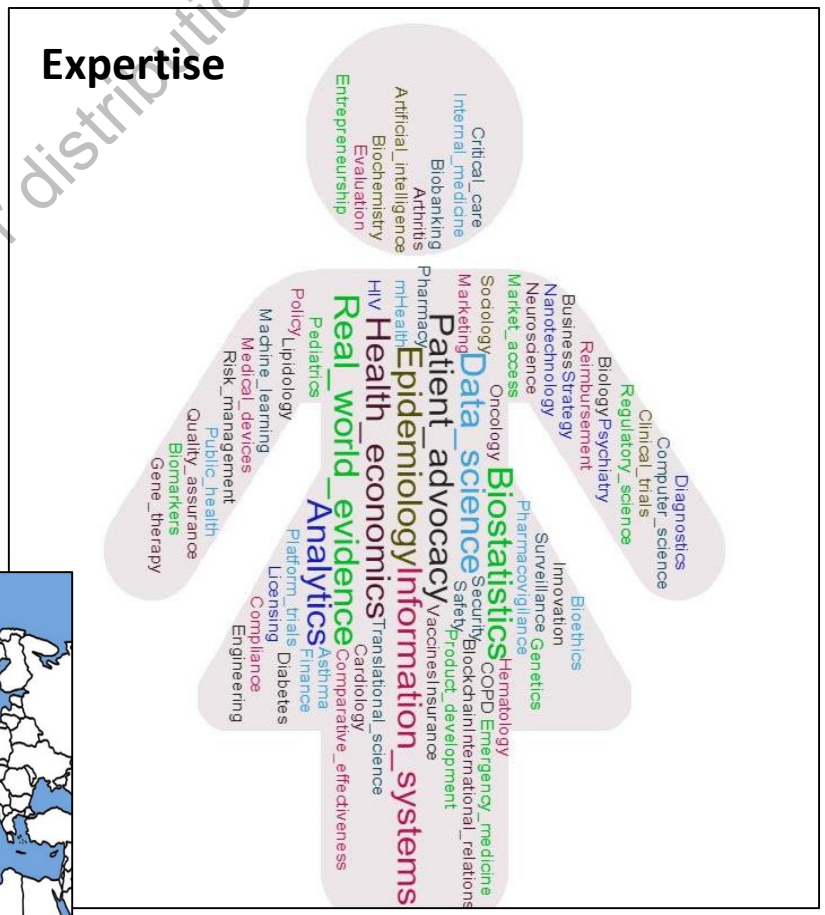
Janet Woodcock, MD
Director, Center for Drug Evaluation & Research
US Food & Drug Administration

Others TBA.....

It takes an ecosystem! Who's here today?







NEWDIGS: Innovating how we innovate

- Work together across silos to help the system catch up with the science—faster, smarter, & better.
- Advance **sustainable, patient-centered innovation.**

MISSION

Deliver more value faster to patients,

in ways that work for all stakeholders.

What is MIT NEWDIGS?

- Safe haven “think & do” tank
- Neutral intermediary convening all stakeholder groups
- Utilize tools for collaboration and systems innovation
- Record of effective stewardship & real world impact

NEWDIGS "Adaptive Licensing" Project fueled timely action & impact in Europe

March 2012:
NEWDIGS Concept Prototyping

STATE OF THE ART

nature publishing group

Open

See COMMENTARY page 378

Adaptive Licensing: Taking the Next Step in the Evolution of Drug Approval

H-G Eichler[1,2], K Oye[2,3,4], LG Baird[2], E Abadie[5], J Brown[6], CL Drum[2], J Ferguson[7], S Garner[8,9], P Honig[10], M Hukkelhoven[11], JCW Lim[12], R Lim[13], MM Lumpkin[14], G Neil[15], B O'Rourke[16], E Pezalla[17], D Shoda[18], V Seyfert-Margolis[14], EV Sigal[19], J Sobotka[20], D Tan[12], TF Unger[18] and G Hirsch[2]

Traditional drug licensing approaches are based on binary decisions. At the moment of licensing, an experimental therapy is presumptively transformed into a fully vetted, safe, efficacious therapy. By contrast, adaptive licensing (AL) approaches are based on stepwise learning under conditions of acknowledged uncertainty, with iterative phases of data gathering and regulatory evaluation. This approach allows approval to align more closely with patient needs for timely access to new technologies and for data to inform medical decisions. The concept of AL embraces a range of perspectives. Some see AL as an evolutionary step, extending elements that are now in place. Others envision a transformative framework that may require legislative action before implementation. This article summarizes recent AL proposals; discusses how proposals might be translated into practice, with illustrations in different therapeutic areas; and identifies unresolved issues to inform decisions on the design and implementation of AL.

Clinical Pharmacology & Therapeutics (2012);
91 3, 426–437. doi:10.1038/clpt.2011.345

March 2014:
EMA Pilot Program

Home ▸ News and Events ▸ News and press release archive

European Medicines Agency launches adaptive licensing pilot project

Press release

19/03/2014

European Medicines Agency launches adaptive licensing pilot project

Improving timely access for patients to new medicines: pilot explores adaptive licensing approach with real medicines in development

The European Medicines Agency (EMA) is inviting companies to participate in its adaptive licensing pilot project. Companies who are interested in participating in the pilot are requested to submit ongoing medicine development programmes for consideration as prospective pilot cases.

A framework to guide discussions of individual pilot studies has been published.

The adaptive licensing approach, sometimes called staggered approval or progressive licensing, is part of the Agency's efforts to improve timely access for patients to new medicines. It is a prospectively planned process, starting with the early authorisation of a medicine in a restricted patient population, followed by iterative phases of evidence gathering and adaptations of the marketing authorisation to expand access to the medicine to broader patient populations.

From Adaptive Licensing to Adaptive Biomedical Innovation: Generalizable Learnings (from individual products)

- **Patient-centered innovation can not be achieved one silo at a time.**
  - Requires stakeholders to work together in fundamentally different ways to optimize tradeoffs and enhance “collective impact” for patients.

- **Decisions made in one silo have implications for other silos.**
  - Managing risk & reducing uncertainty are iterative processes managed through ongoing stakeholder interactions across life span of products.

- **Science evolves from left to right.**
  Evidence should be planned from right to left
  - Value (as defined by patients, clinicians, and payers) must be considered earlier in drug development.

Evidence is the centerpiece of LEAPS

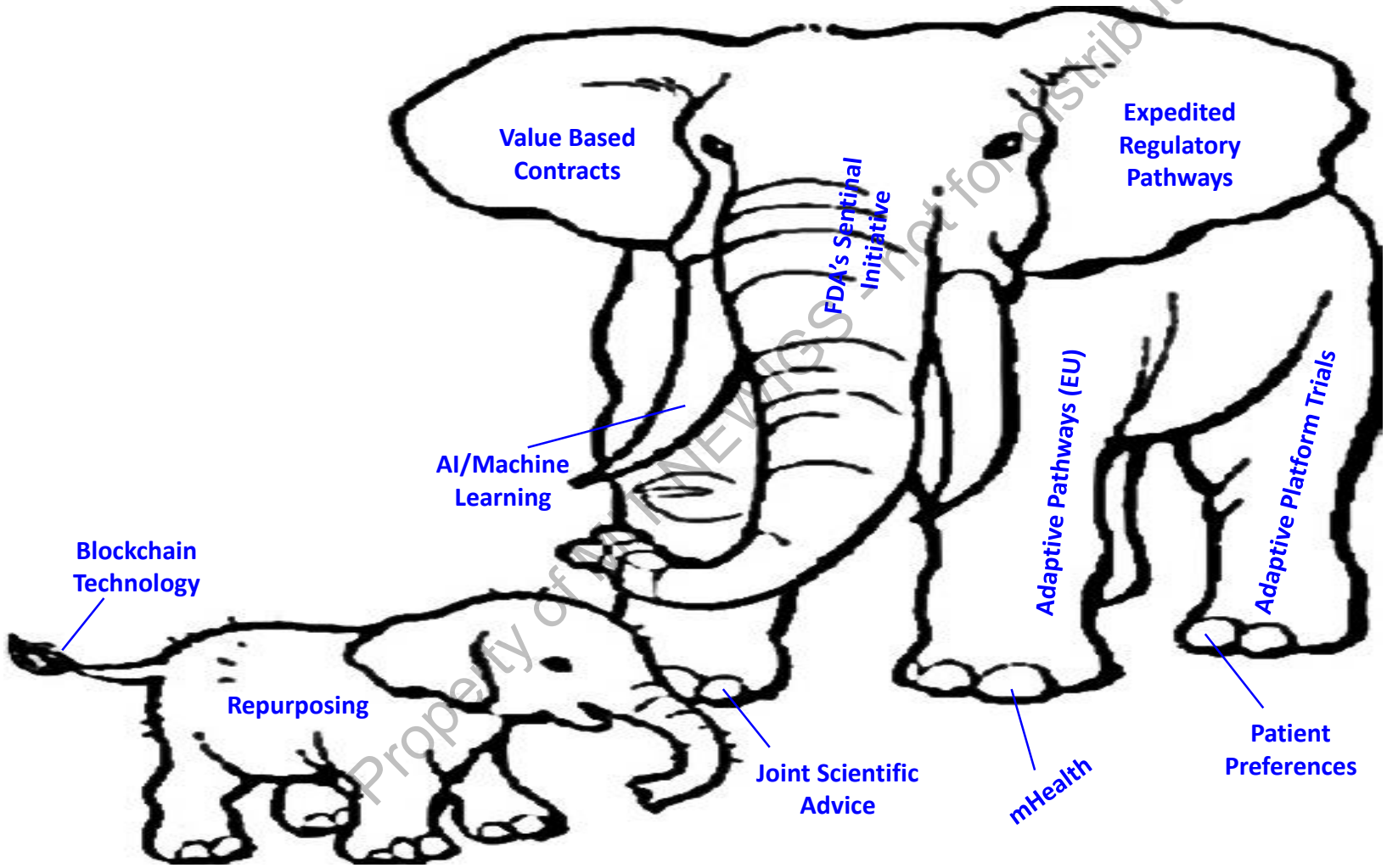
From

- Left-to-right planning
- R&D/Healthcare Delivery disconnected
- Fit for Purpose for regulators only
- Systematic learning stops at regulatory approval
- 1 stakeholder at a time
- 1 product at a time
- 1 study at a time
- One and done studies
- Excessive time, cost

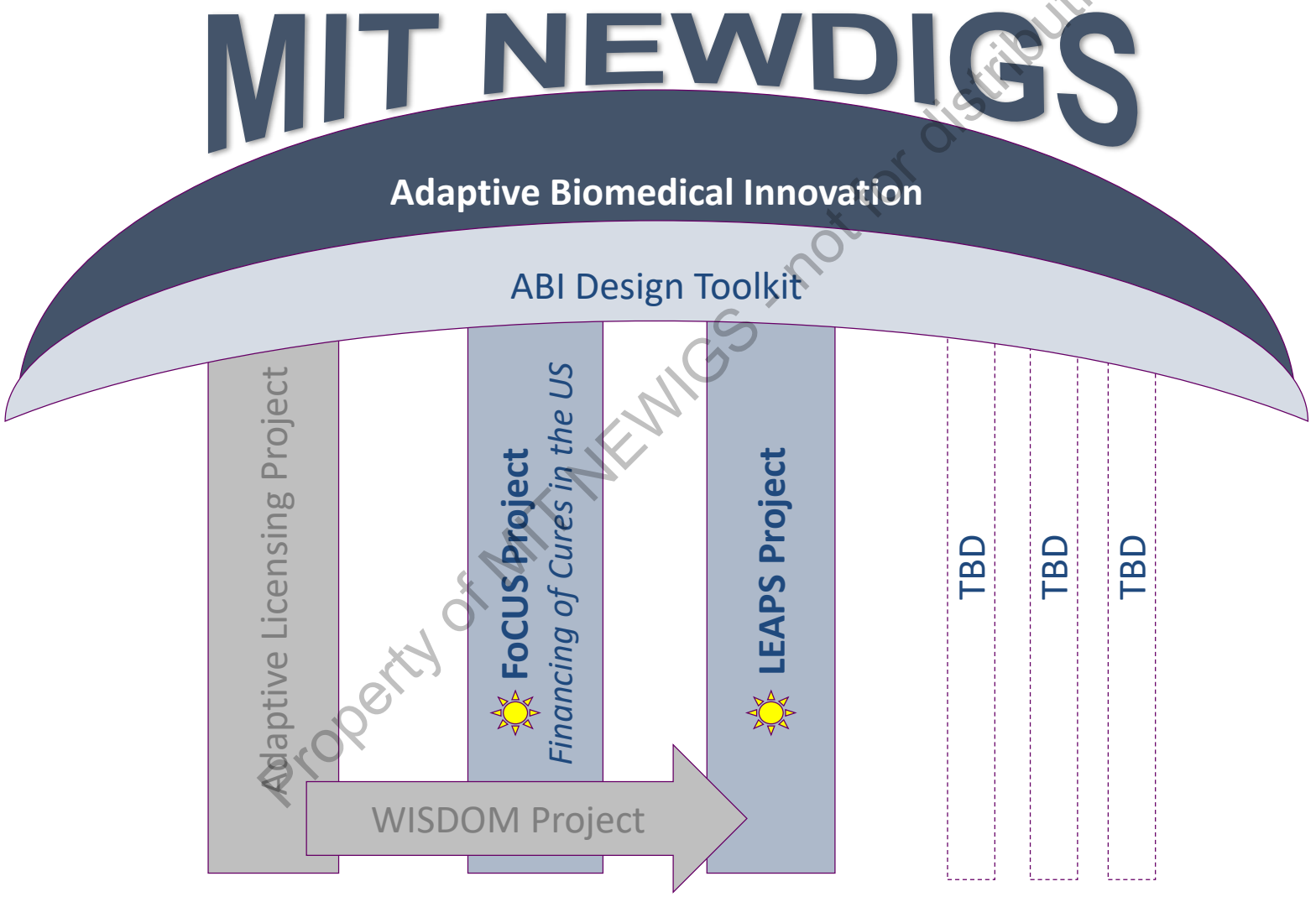
To

- Right-to-left planning
- R&D/Healthcare Delivery connected
- Fit for Purpose for all stakeholders
- Continuous learning, feedback, & improvement
- Multi-stakeholder, coordinated
- Portfolio of products for a disease
- Integrated evidence plan, prospective, iterative
- Multi-use, scalable, sustainable infrastructures
- Minimize waste, inefficiency

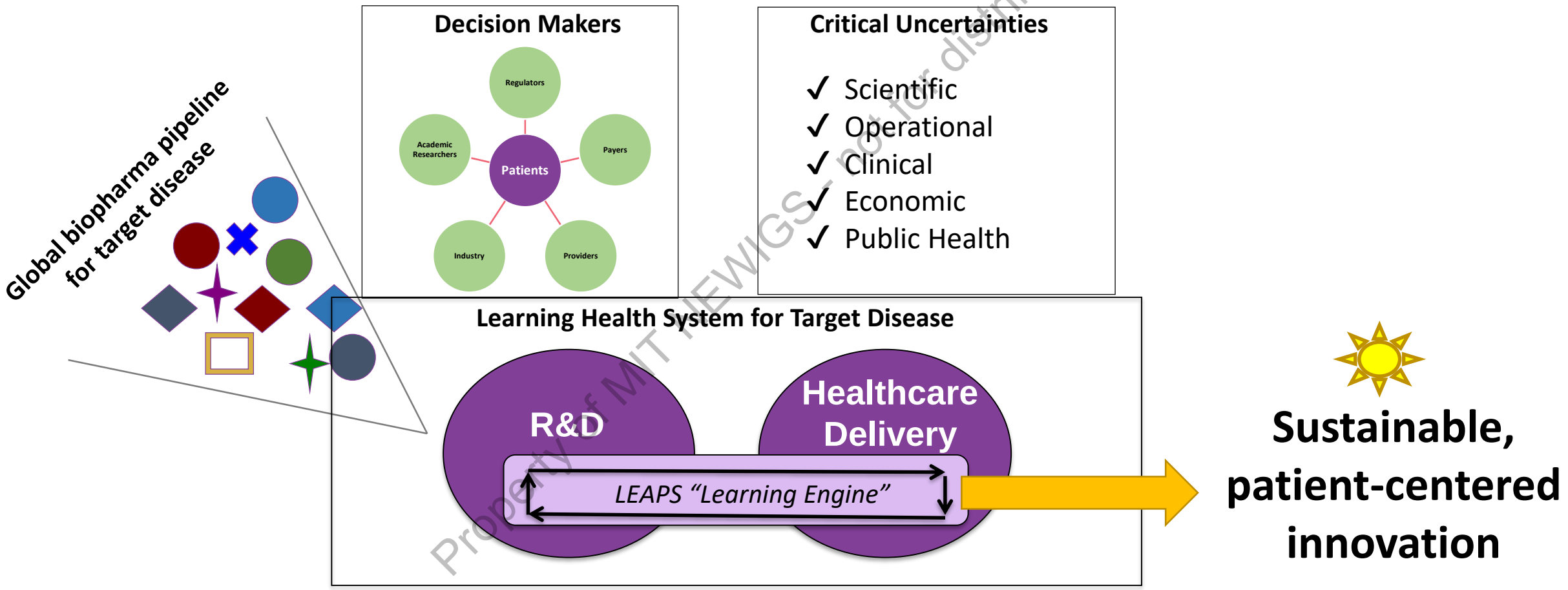
Important, relevant innovations are emerging, but in fragmented ways



ABI Provides a framework for connecting innovations - within LEAPS/NEWDIGS, and globally



LEAPS: Apply ABI Principles, at scale, to demonstrate sustainable patient-centered innovation for one disease



A foundational principle for engagement in LEAPS

All key stakeholders generate relevant data

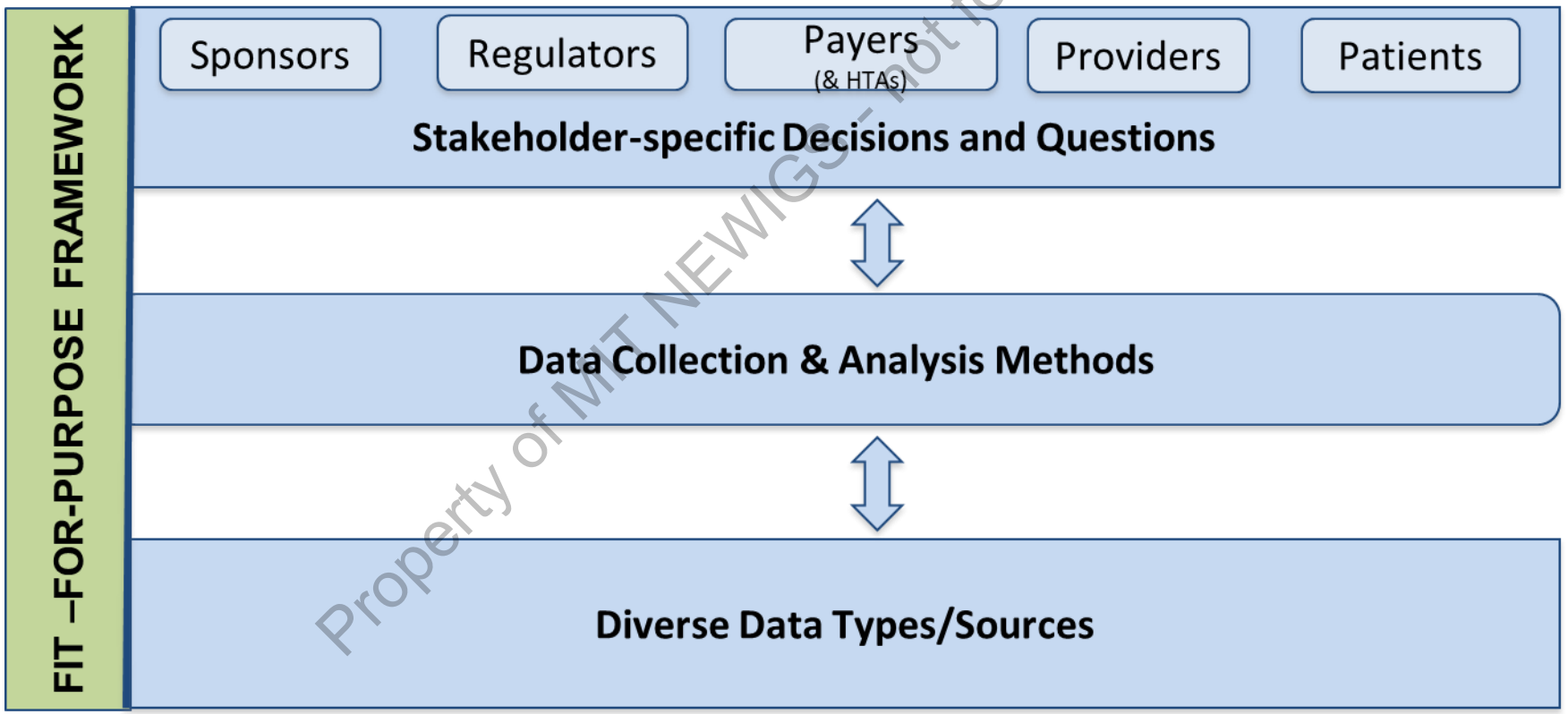
in our daily lives/work,

but we need more than just our own data

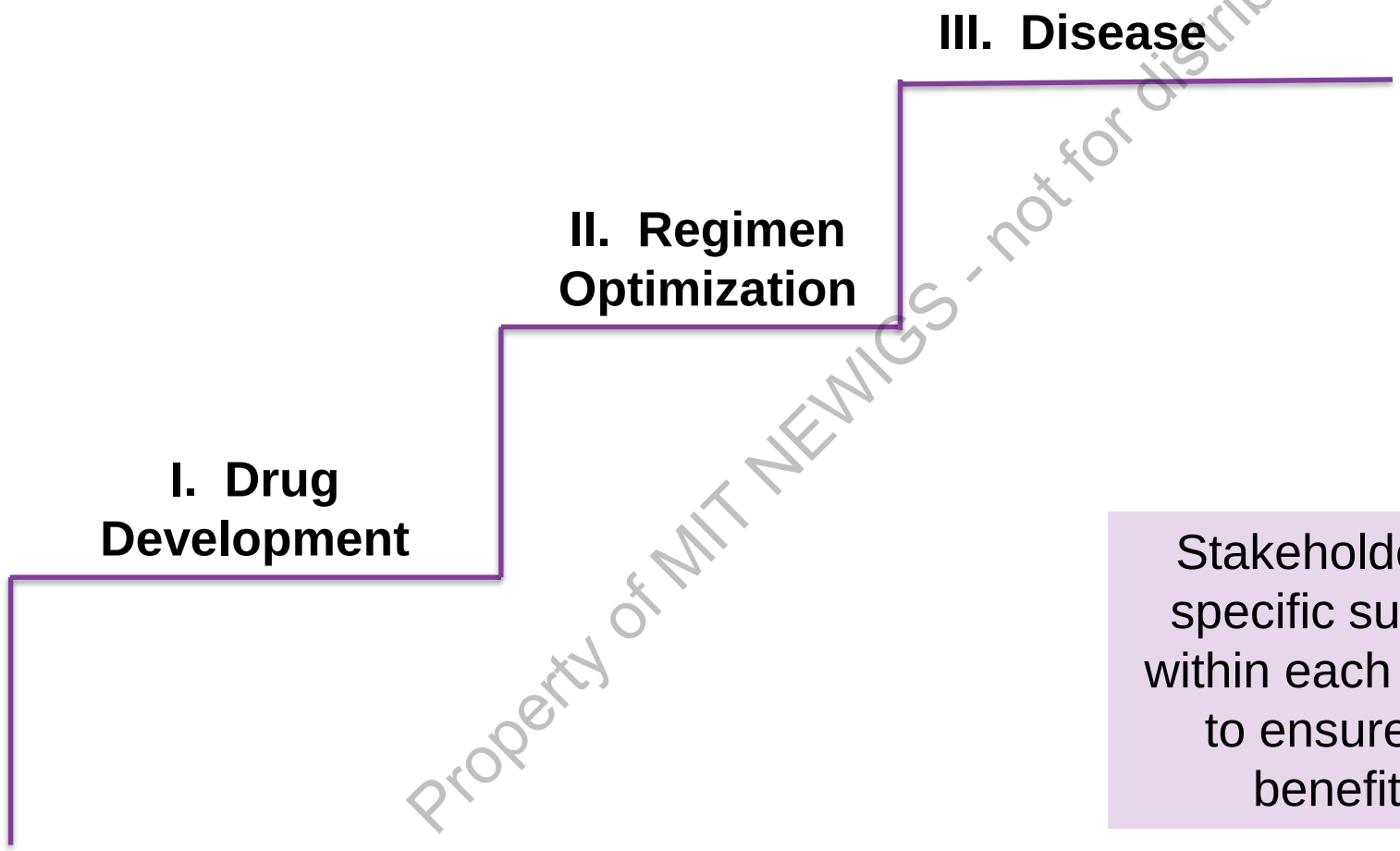
to make good decisions.

We are not starting from scratch!
LEAPS will leverage existing NEWDIGS Frameworks & Tools

NEWDIGS "3 Layer Cake": Supports multi-stakeholder planning of evidence that is "fit-for-purpose" for decisions across product life span



LEAPS will benefit all stakeholders across 3 impact domains



Stakeholders will define specific success metrics within each impact domain to ensure meaningful benefits to them.

Initial modeling will focus on a MA Pilot Project

Massachusetts is the ideal place to pilot this solution

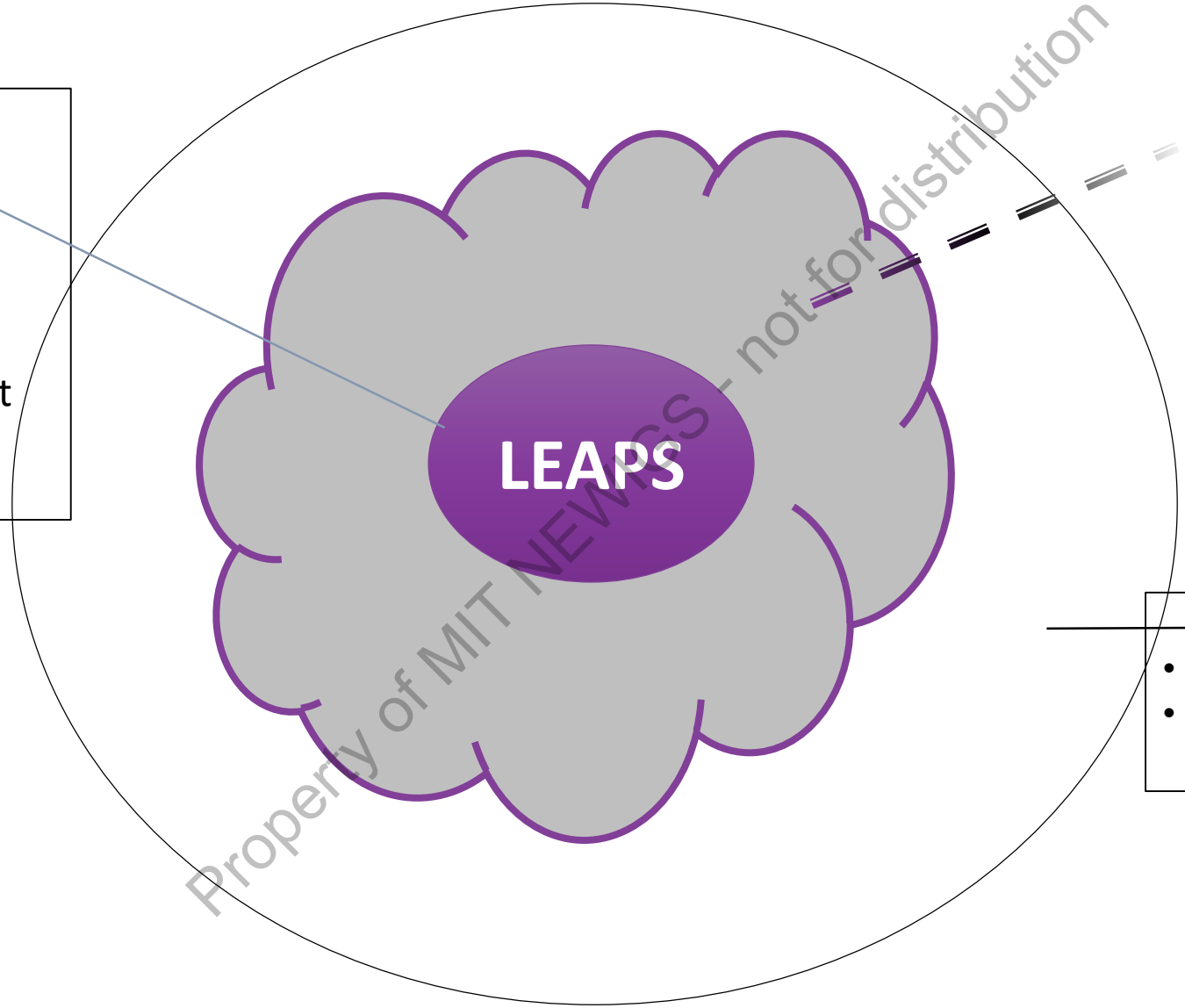
- Super biopharma-cluster, envied by all globally
- World class healthcare provider systems
- 97% of population with health insurance coverage
- One of 18 states with an all-payer claims database

An opportunity to increase healthcare value in MA and maintain state's desired position as the global biomedical innovation hub

LEAPS Scope: What's In, What's Out?

In

- Therapeutics
  - Development
  - Access
  - Use
- Data, evidence, & decision-making about therapeutics



Shape as We Go….

OUT

- Fix healthcare delivery system
- Jenny Craig weight loss program