NEWDIGS: New Drug Development ParadIGmS

Applying MIT systems expertise to transform healthcare innovation
Introduction

- Thank you for this opportunity to contribute to this important discussion

- My perspectives are drawn from MIT’s New Drug Development Paradigms (NEWDIGS) initiative, a real time collaborative process design experiment that may offer useful ideas and insights for approaches to strengthening a workforce for innovative regulatory science in therapeutics development

- I am grateful to the remarkably talented and committed community of collaborators within NEWDIGS who have contributed enormous time, passion, and intellectual capital to our effort
Current Healthcare Innovation Ecosystem is Broken

FAILURE TO CAPTURE FULL VALUE OF INNOVATION FOR ALL STAKEHOLDERS

PATIENTS
Unmet Medical Needs

“Of the 7,000 human diseases, fewer than 300 are of interest to the biopharmaceutical industry, due to limited prevalence and/or commercial potential.”
Office of Rare Diseases Research, NIH

PHARMAS
Usustainable cost of innovation

PROVIDERS
Need better benefit/risk information

“I rarely prescribe a new drug during the first 2 years it has been on the market. There is too much uncertainty about safety during this time.”
Neurologist, Boston

REGULATORS
Competing Demands: Innovation & Safety

“Our current regulatory model sets unrealistic expectations for the public that it is possible to eliminate all uncertainty about product safety prior to market approval.”
Senior Official, FDA

PAYORS
Skyrocketing costs

Healthcare spending to reach 25% of GDP by 2025. Reimbursement coverage decisions should be driven by evidence of clinical value.
NEWDIGS Concept Overview

- Unique collaborative innovation and learning environment
- Goal is to ensure the sustainability of innovation
  - Requires that we enhance the value of innovation for all stakeholders
- All key stakeholders participate with MIT as neutral intermediary
- Systems approach to transforming process, technology, and policy elements of innovation
- Tight coordination between real world pilot projects and academic research in engineering, science, management & clinical medicine
Test Beds Enable Rapid Cycle Learning

NEWDIGS Ecosystem
Multi-stakeholder Collaboration, Safe Haven Environment

Rapid Cycle Learning

Real World Demonstration Projects
Policy Technologies Process

Academic Research
Science Engineering Management
# Roadmap Shaped by Broad Stakeholder\* Input

## NEWDIGS

### Pharma/Biotech
- AstraZeneca
- BMS
- GSK
- J&J
- Merck Serono
- Novartis
- Pfizer
- Quintiles
- Sanofi

### Regulators
- FDA
- EMA
- HSA (Singapore)
- HealthCanada
- SwissMedic

### Academia
- MIT
- Harvard
- Sloan –Kettering
- MGH/Partners
- Dana Farber

### Payors
- Aetna
- Medco
- Wellpoint

### Other
- Friends of Cancer Research
- Life Technologies
- NICE

* Sponsors in bold

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**MIT STRATEGIC ADVISORS**

- **Charles Cooney, PhD**, Robert T. Haslam Professor of Chemical Engineering;
- **Elazer Edelman, MD, PhD**, Thomas D & Virginia W Cabot Professor of Health Sciences & Technology
- **Phillip Sharp, PhD**, Institute Professor, MIT; Nobel Laureate
- **Ram Sasisekharan, PhD**, Director and E.H. Taplin Professor, Harvard-MIT Division of Health Sciences and Technology
- **Anthony Sinskey, ScD**, Professor of Biology & Health Sciences & Technology
MODULE 1
Regulatory Science
“Historically, regulatory change happens when there is a crisis. Reactive solutions are developed, and the unintended consequences are not apparent until changes become law.

NEWDIGS offers the opportunity for proactive, strategic design of policy with broad stakeholder input, followed by the empiric evaluation of these designs to inform our discussions about change.”

Participant in NEWDIGS workshop
Former regulator and academic researcher
MODULE 1 (Regulatory Science): Snapshot

Initial Focus: Adaptive Licensing (AL)

Participants* from:

- Regulatory agencies (US, EU, Singapore, and Canada)
  - Senior official from EMA is Visiting Scholar at CBI through December 2011
- Bristol-Myers Squibb, GlaxoSmithKline, Pfizer, Johnson & Johnson, Quintiles
- Aetna, NICE
- MIT & Harvard

Initial demonstration projects being designed for implementation in Singapore, in close collaboration with Singapore Health Sciences Authority (H.S.A.)

*Participants in NEWDIGS forums do not speak on behalf of their employer organizations
Module 1: Current Activities

NEWDIGS Ecosystem
- Strategic planning and implementation
- Formal & informal information sharing
- Outreach & dissemination
- Building bridges to Modules 2 & 3

Real World Demonstration Projects
Evaluating assets & “system readiness” in Singapore for 2 potential demonstration projects, each involving anti-infectives:
1) Gram positives/MRSA (GSK)
2) TB (Pfizer)

Academic Research
- Monthly research seminar with growing cross-campus attendance
- Portfolio of adaptive licensing simulations across range of situations
- Economic implications of AL
- Artificial Intelligence/predictive technologies
- “Intelligent” data sharing models
- Other projects TBD...

Center for Biomedical Innovation
Design & Implementation Considerations
Key Collaborative Capabilities of the Workforce

- Innovate
- Learn
- Execute
Establishing a “safe haven” environment through explicit Ground Rules for workshops has been critical for enabling learning & innovative thinking:

- No decisions made in workshops
- Encourage broad exploration of possibilities before narrowing to recommended solution
- Individual participants do not speak officially on behalf of their organizations
- Confidentiality about proprietary information is respected
- Transparency about processes and generalizeable learnings is ensured (without attribution to individuals or their affiliated organizations)
Observations from NEWDIGS: Systems Thinking

Systems approaches to design & problem-solving are critical but very challenging!

- Enormous complex interdependencies across disciplines, functional silos, organizations, market sectors, & society

- There is little experience in applying systems engineering methods for process improvement & change management beyond functional silos or a single enterprise, to industry-wide challenges

- Diversity of expertise & perspectives is extremely valuable but difficult to harness due to cultural barriers, misaligned incentives, & resource constraints

- There is an important role for a test bed for enabling systems-level change
The ability to demonstrate that the learning and innovation activities fuel continuous improvement in execution is central to the sustainability of NEWDIGS

“Consortium fatigue” in healthcare highlights the need for a more disciplined approach to understanding and managing the “science” of collaboration

• Leverage learnings from past/current initiatives
• Define shared goals, milestones, & productivity metrics
• Define new models of work
• Develop greater precision in managing human capital
  • Innovative team structures
  • Align internal & external roles & responsibilities
  • Psychosocial segmentation of individuals to guide deployment strategies into virtual team environment
Thank you.

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