But That’s the Way We’ve Always Done It!
Changing Culture in Medical Research R&D

Free Webinar
Wednesday, March 29
2 pm - 3 pm EST
Margaret Anderson

Executive Director
FasterCures

MODERATOR
10,000 DISEASES.
ONLY 500 TREATMENTS.
WE HAVE WORK TO DO.
### R&D policy

**FasterCures’ 21st Century Cures Act Tracker (P.L. 114-255)**

<table>
<thead>
<tr>
<th>Status</th>
<th>Title</th>
<th>Subtitle</th>
<th>Section</th>
<th>Tracked Deadlines and Requirements</th>
<th>Update</th>
<th>Date of Update</th>
<th>Tags</th>
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<tr>
<td></td>
<td>Title I — Innovation Projects and State Responses to Opioid Abuse</td>
<td>-</td>
<td>Sec. 1001. Beau Biden Cancer Moonshot and NIH Innovation projects.</td>
<td>Annual appropriation of funds into the NIH Innovation Account (FY17-26), and subsequent allocation to specific initiatives: PHi (FY17-26), BRAIN (FY17-26), Cancer Moonshot (FY17-23), and regenerative medicine (FY17-26). In addition, required NIH to submit a work plan to Congress by June 12, 2017 for the NIH Innovation Projects and to solicit input from the public prior to submitting the work plan. Further directs NIH to submit an annual report to Congress by October 1st of each fiscal year 2016–2027 outlining the amount of money obligated as well as a description of the projects and how they are advancing.</td>
<td>On March 26, 2017, the Advisory Committee to the Director of NIH held a conference call to discuss the draft work plans outlined in this section. The meeting was announced in a federal register notice. It provided an overview of implementation and provided an update on work plans for each of the following: Cancer Moonshot Initiative, Regenerative Medicine, Precision Medicine Initiative, BRAIN Initiative.</td>
<td>03/28/2017</td>
<td>Funding, NIH, Regenerative Medicine</td>
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<td>Title I — Innovation Projects and State Responses to Opioid Abuse</td>
<td>-</td>
<td>Sec. 1002. FDA Innovation projects</td>
<td>Annual appropriation of funds into the FDA Innovation Account (FY17-25).</td>
<td>FasterCures will periodically assess this item as appropriate.</td>
<td>12/13/2015</td>
<td>FDA, Funding, Regulatory Affairs</td>
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<td>Title I — Innovation Projects and State Responses to Opioid Abuse</td>
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<td>Sec. 1003. Account for the state response to the opioid abuse crisis.</td>
<td>Annual appropriations into the “Account for the State Response to the Opioid Abuse Crisis” (FY17-18)</td>
<td>FasterCures will periodically assess this item as appropriate.</td>
<td>12/13/2015</td>
<td>Funding</td>
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<td>Title I — Innovation Projects and State Responses to Opioid Abuse</td>
<td>-</td>
<td>Sec. 1004. Budgetary treatment</td>
<td>Provision in effect upon enactment. Further tracking not required.</td>
<td>Complete.</td>
<td>12/13/2015</td>
<td>FDA, Funding, NIH</td>
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### Find consortia

Select Disease Category  
Select Consortium Status  
Select Type of Research

Search by keyword, company...  
Update Results  
Clear Filters

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<tr>
<th>Consortium title &amp; disease focus</th>
<th>Tool Development</th>
<th>Biomarker Research</th>
<th>Basic Research</th>
<th>Data-Sharing Enabler</th>
<th>Product Development</th>
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<td>A GABRIEL Consortium Large-Scale Genome-Wide Association Study of Asthma</td>
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<td>A quantitative model of thrombosis in intracranial aneurysms (Thrombus)</td>
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<td>Thrombus</td>
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<td>Academic Drug Discovery Consortium</td>
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<td>Accelerating Medicines Partnership - Alzheimer's</td>
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<td>Alzheimer's Disease</td>
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<td>Accelerating Medicines Partnership—Autoimmune Diseases (Rheumatoid Arthritis &amp; Lupus)</td>
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What we’ve seen in the R&D space

- Culture was *slowing progress*
- Information sharing is *vital*
“No one said it would be easy”

- There is a high cost to doing business as usual
- It will take new business models to accelerate research
What’s on the agenda for today?

• How does change happen
• What incentives are needed
• What is the next generation doing
Richard Hamermesh
Senior Fellow
Harvard Business School
Kraft Precision Medicine Accelerator

But That’s the Way We’ve Always Done It

Richard Hamermesh
Senior Fellow
Faculty Co-Chair, Kraft Precision Medicine Accelerator
DATA SHARING

• Today genomic and clinical information is hoarded in academic medical centers and big pharma, with community hospitals and non-profits as accessories
• Genomic insights – the key to Precision Therapies – are only possible via large, robust datasets
• No one institution or company will ever have enough data, making data sharing a necessity


Website: http://www.hbs.edu/healthcare/faculty/kraft-accelerator/Pages/default.aspx
Today, medical research is conducted within the walls of the lab, school, or company.

The crowd can consistently outperform these closed institutions at a fraction of the cost.

Large open data sets with the right questions posed to the crowd can dramatically reduce the cost and time to develop new therapies.
PATIENT’S ROLE

• Today, most people would say that the owner of their health data is their physician or hospital
• HIPAA allows the patient to have their data sent to whoever and wherever they choose
• The patient is the owner and can contribute to the greater good and also benefit individually: It Will Take All of Us to Cure Each of Us.

STAT Article: https://www.statnews.com/2017/02/23/cancer-genome-multiple-myeloma/?mc_cid=2d63475ad9&mc_eid=5b74b720d3
RICHARD’S CONJECTURE

• How many years will it be until 90% of cancers will be cured/contained in the same sense that HIV is today?

• What will that be if the prior three items are implemented with speed and persistence?
  • One third less time
SOME THOUGHTS ON CHANGE

• Start small
  • Facebook
  • Uber
• Identify and publicize early successes
• Build quickly from those successes
Lyric Jorgenson
Deputy Director,
Office of Science Policy
National Institutes of Health
What elements of the culture of medical R&D need to change to accelerate progress?

- Reimagined incentive structures for researchers
- Mechanisms for supporting collaborative activities
- Innovative & flexible clinical trial infrastructure
What do we know about how change happens in organizations?

• Ideal - Push from the masses and pull from a champion

• Crises can effectively motivate change, but still require leadership to navigate the waters for a desirable outcome
What solutions could help change the culture of R&D?

- **Implement new training paradigms** (*some cultural values aren’t inherent to the system, break the cycle*)
- **Highlight and promulgate successes** (*demonstrate proof of concept, not everyone can innovate*)
- **Empower non-traditional partnerships** (*new ways of looking at old problems*)
- **Reward data quality and methodological rigor** (*encourage people to do what they are good at for everyone’s benefit*)
What would success look like?

**Easy answer**

- Getting effective treatments to patients faster

**Steps forward**

- Faster (smooth and seamless) transitions across the “pipeline”
- Systems that reward sharing high-quality data, algorithms, methods, etc.
- Mutual respect for and understanding of each sector’s unique challenges
Riley Ennis

Co-Founder and Chief Operating Officer
Freenome
What elements of the culture of medical R&D need to change to accelerate progress?

- Data access
  - Example: Many partners we engage with still send data through external drives
- Early partnership engagement
  - With all stakeholders from payer advisory boards to the FDA
  - Shorter iteration cycles / independent validation studies
- Patient reported outcomes (PROs) and closed system feedback loops to improve data quality

Case Study – Cancer Classifier

PRO feedback loop improves diagnostic performance

R&D Data
What do we know about how change happens in organizations?

- **Culture** (real-time feedback, unlearn and internalize that failure catalyzes growth)
  - *Example: Freenome’s real-time feedback system live snapshot (right)*
- **Multi-disciplinary teams and diversity**
  - *Individuals who speak multiple languages and were trained in parallel industries*
  - *Diversity of age, gender, sexual orientation, race etc.*
What solutions could help change the culture of R&D?
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Median Feature Freenome Profiles

Healthy

Cancer

Deep Learning Classifier

Mock Data
What would success look like?

- Actionability of health data from genomics to other biometric data
- R&D shift towards disease prevention
- Software and machine learning engineers are excited to work in healthcare
- Users feel like people NOT patients
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01/23/2017

Top Medical Research Issues and Trends to Watch in 2017

Peering into the crystal ball, the trajectory for medical R&D over the next year may seem a bit hazy. But never fear – FasterCures has analyzed trends and determined some of the issues critical to the future of medical innovation that we’ll be tracking over the coming year and that we think you should as well.

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12/08/2016

Opportunities for the Next Administration to Advance Biomedical Innovation

Biomedical innovation is vital to America’s health and economic well-being. President-elect Donald Trump has the opportunity to lead in this area and construct policies to maintain the system’s strength and productivity. FasterCures engaged our unique network of stakeholders across the R&D ecosystem to interview more than 150 thought leaders across eight sectors.

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fastercures.org/events/webinars/
Top Ten Medical Research Issues and Trends to Watch in 2017

by Margaret Anderson, Executive Director

As seen in the Huffington Post

"FDA needs strong allies and partners to ensure they are ready for the innovation and challenges ahead."

2016 will go down as a year that taught us to question our assumptions. The election of...
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This year, FasterCures is excited to convene Partnering for Cures in two biomedical innovation hubs.