Accelerating Data-Driven Drug Development

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September 18, 2019

OVERVIEW

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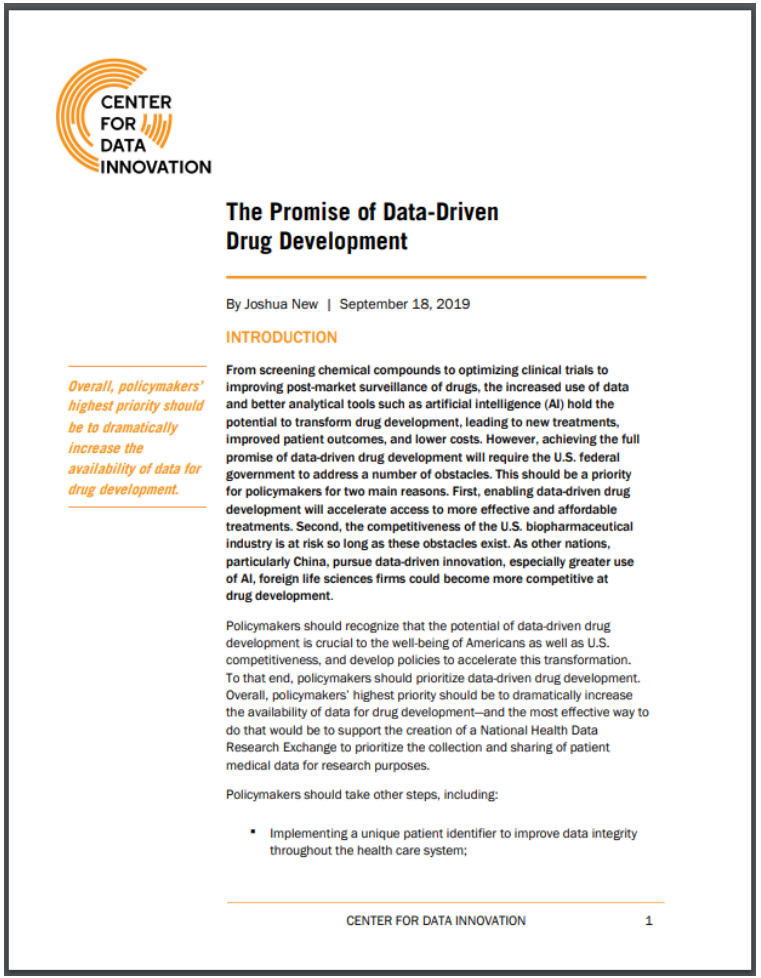
2. Creating a National Health Research Data Exchange
3. Other Ways to Accelerate Drug Development with Data



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The Promise of Data-Driven Drug Development

By Joshua New | September 18, 2019

INTRODUCTION

Overall, policymakers' highest priority should be to dramatically increase the availability of data for drug development.

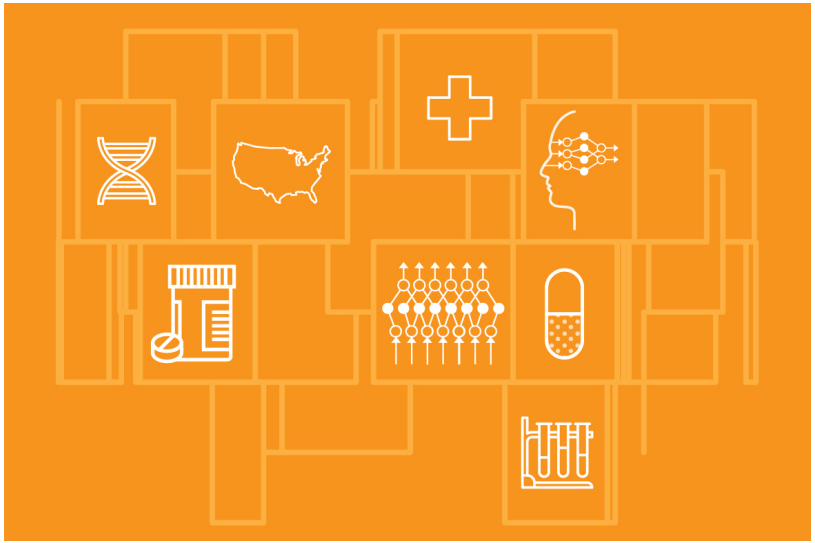
From screening chemical compounds to optimizing clinical trials to improving post-market surveillance of drugs, the increased use of data and better analytical tools such as artificial intelligence (AI) hold the potential to transform drug development, leading to new treatments, improved patient outcomes, and lower costs. However, achieving the full promise of data-driven drug development will require the U.S. federal government to address a number of obstacles. This should be a priority for policymakers for two main reasons. First, enabling data-driven drug development will accelerate access to more effective and affordable treatments. Second, the competitiveness of the U.S. biopharmaceutical industry is at risk so long as these obstacles exist. As other nations, particularly China, pursue data-driven innovation, especially greater use of AI, foreign life sciences firms could become more competitive at drug development.

Policymakers should recognize that the potential of data-driven drug development is crucial to the well-being of Americans as well as U.S. competitiveness, and develop policies to accelerate this transformation. To that end, policymakers should prioritize data-driven drug development. Overall, policymakers' highest priority should be to dramatically increase the availability of data for drug development—and the most effective way to do that would be to support the creation of a National Health Data Research Exchange to prioritize the collection and sharing of patient medical data for research purposes.

Policymakers should take other steps, including:

- Implementing a unique patient identifier to improve data integrity throughout the health care system;

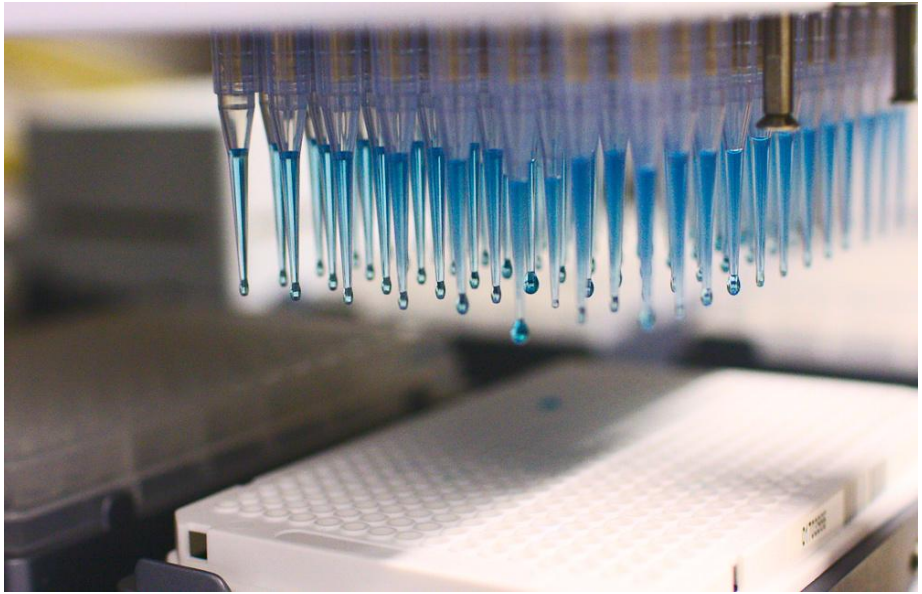
THE PROMISE OF DATA-DRIVEN DRUG DEVELOPMENT



Data-driven innovation is transforming every stage of the drug development lifecycle: discovery, clinical research, FDA review, and FDA post-market safety monitoring.

THE PROMISE OF DATA-DRIVEN DRUG DEVELOPMENT - DISCOVERY

- Moving from analysis of existing remedies and serendipitous discovery to target-based discovery and high-throughput screening (HTS).
- Making phenotypic screening more viable at scale.
- Enabling i*n silico* screening.



HTS assays. Source: University of Bergen

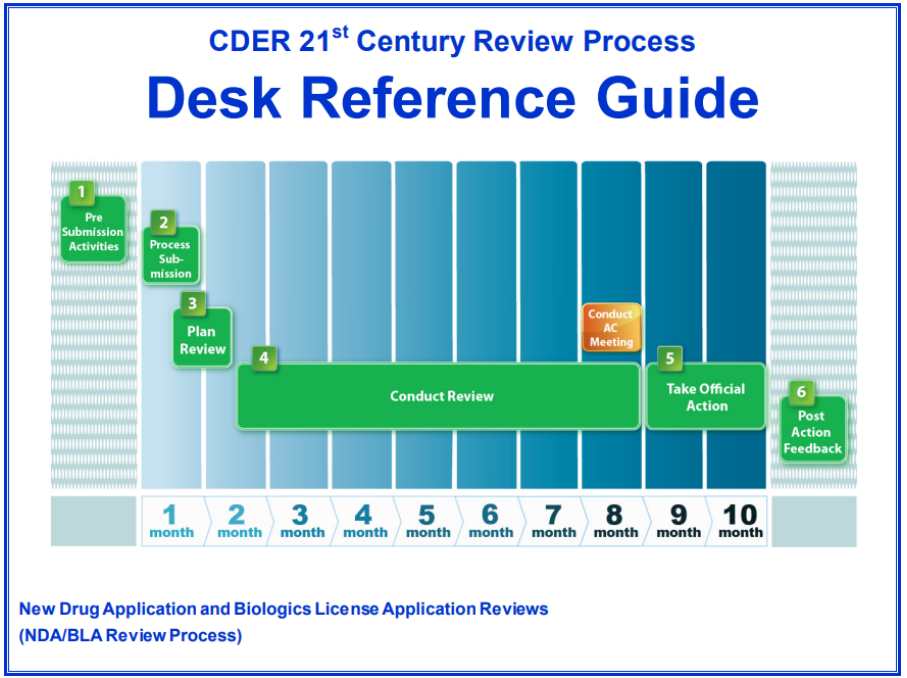
THE PROMISE OF DATA-DRIVEN DRUG DEVELOPMENT – CLINICAL RESEARCH

Source: U.S. Air Force

- Improving patient recruitment with machine learning.
- Ensuring patients stay engaged and complete trials successfully.
- Reducing side effects that cause patients to exit a trial.
- Decentralized and virtual trials.

THE PROMISE OF DATA-DRIVEN DRUG DEVELOPMENT – FDA REVIEW

- Bringing drugs to market faster with real-time data analysis.
- The FDA's Real-Time Oncology Review program approved breast cancer drug Kisqali just one month after submission.



Source: FDA

THE PROMISE OF DATA-DRIVEN DRUG DEVELOPMENT – FDA POST-MARKET SAFETY MONITORING

Source: WebMD

- FDA begins work on the Sentinel Initiative in 2007, launches the Sentinel System to cover hundreds of millions of patients in 2016.
- Analyzing data from EHRs, insurance claims, and partners to monitor drug safety.
- Using real-world data (RWD) to support drug development.

CREATING A NATIONAL HEATLH RESEARCH DATA EXCHANGE

- Access to data is a major barrier to data-driven drug development.
- Patients want to share data, but often do not have the opportunity.
- A National Health Research Data Exchange would solve these issues and be a boon to drug development, health care research, and public health.

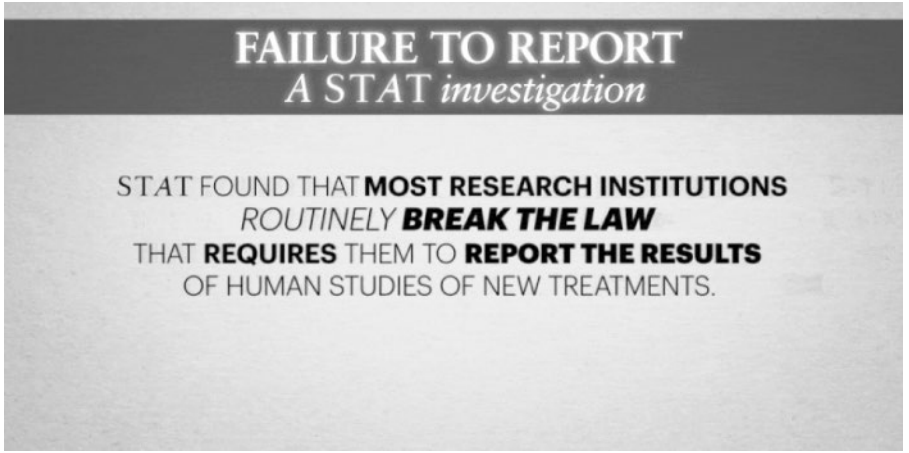
CREATING A NATIONAL HEATLH RESEARCH DATA EXCHANGE

Source: Johns Hopkins University

- EHR integration
  - Require National Health Research Data Exchange API integration for EHR system eligibility for ONC certification.
- Patient participation
  - Opt-out, rather than opt-in.
  - Option to donate data after death.
- Data access
  - Governed by a contractual model to guard against misuse.
- Unique identifiers
  - Implemented as originally recommended in HIPAA to ensure data integrity.

OTHER WAYS TO ACCELERATE DRUG DEVELOPMENT WITH DATA

- Expanding access to institutional data
- Expanding access to nontraditional data
- Modernizing regulatory processes
- Promoting equity
  - "It's hard to tailor treatments for people's unique needs, if the people who are suffering from those diseases aren't included in the studies."
- Developing AI skills



Source: STAT

THANK YOU

- Reports: “The Promise of Data-Driven Drug Development”
  - http://www2.datainnovation.org/2019-data-driven-drug-development.pdf
- Email me: jnew@datainnovation.org

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