Accelerating Data-Driven Drug Development

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OVERVIEW

1. The Promise of Data-Driven Drug Development
2. Creating a National Health Research Data Exchange
3. Other Ways to Accelerate Drug Development with Data
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 in silico screening.
THE PROMISE OF DATA-DRIVEN DRUG DEVELOPMENT – CLINICAL RESEARCH

- 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.

Source: U.S. Air Force
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.
THE PROMISE OF DATA-DRIVEN DRUG DEVELOPMENT – FDA POST-MARKET SAFETY MONITORING

- 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.

Source: WebMD
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 HEALTH RESEARCH DATA EXCHANGE

- **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.

Source: Johns Hopkins University
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”
- Email me: jnew@datainnovation.org