Leveraging Big Data in Drug Development: Toxicity Assessment & Signal Detection

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The views in this presentation do not necessarily represent the policies of FDA

Disclosures: None
What is big data?

- **Velocity**
  - Real time
  - Near-real time
  - Intermittent
- **Volume**
  - PB
  - GB
  - TB
- **Variety**
  - Internet of things
  - Social
  - Video
  - Sensors and wearables
  - Omics
  - Clinical trials
  - Electronic health records
  - Databases
  - Tables
  - Structured
  - Mostly structured
  - Mostly unstructured
  - Undefined
- **Veracity**

Reductionist centre
Holistic edge
Reductionist to holistic transformation
Current capacity (generalization)

Nature Reviews | Drug Discovery

What is big data?
Inflection point

Algorithmic analytics

Data 
Data 
Data 
Data 
Data 
Data 
Data 
Data 
Data 

Reductionist  → Holistic
Information Exchange and Data Transformation (INFORMED)

A holistic approach to oncology regulatory science

Clinical trials
• Aggregation
• Analysis

Novel pipelines
• Real world
• Sensors (IoT)
• Omics
Information Exchange and Data Transformation (INFORMED)

Algorithmic Analytics

Drug development tools
Algorithmic Analytics

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www.fda/OC
Ingredients for successful deployment of algorithmic analytics solutions for safety signal detection

• Leverage existing digital assets through *data sharing*
  • Imaging
  • ECGs
  • Clinical trial/EHRs

• Increase digital footprint

• Match innovation with need
Data sharing
Leveraging existing digital assets

Advantages of a Truly Open-Access Data-Sharing Model
Monica M. Bertagnolli, M.D., Oliver Sartor, M.D., Bruce A. Chabner, M.D.,
Mace L. Rothenberg, M.D., Sean Khozin, M.D., M.P.H., Charles Hugh-Jones, M.D.,
David M. Reese, M.D., and Martin J. Murphy, D.Med.Sc., Ph.D.

IBM Watson, FDA to explore blockchain for secure patient data exchange
The initial focus for blockchain will be oncology-related data exchange
Figure 3. Evaluated on the test set, the model outperforms the average cardiologist score on both the Sequence and the Set F1 metrics.
Increasing digital footprint

Paper in file cabinets ➔ PDF in “electronic” file cabinets

3D

2D

Missing
The fax of life

It’s 2017. Why does American medicine still run on fax machines?

Updated by Sarah Kliff | sarah@vox.com | Oct 30, 2017, 8:00am EDT
Increasing digital footprint

Regulatory watch: Evaluating the potential for digital submission of expedited premarket safety reports to the FDA

Sean Khozin, Meredith Chuk, Tamy Kim, Suranjan De, Sanjay Sahoo, Geoffrey Kim & Richard Pazdur

Published online  29 September 2016

Biometric monitoring devices for assessing end points in clinical trials: developing an ecosystem


Published online  22 September 2017
Matching innovation with need
Thank you