Information Exchange and Data Transformation (INFORMED)

An integrated approach to big data analytics

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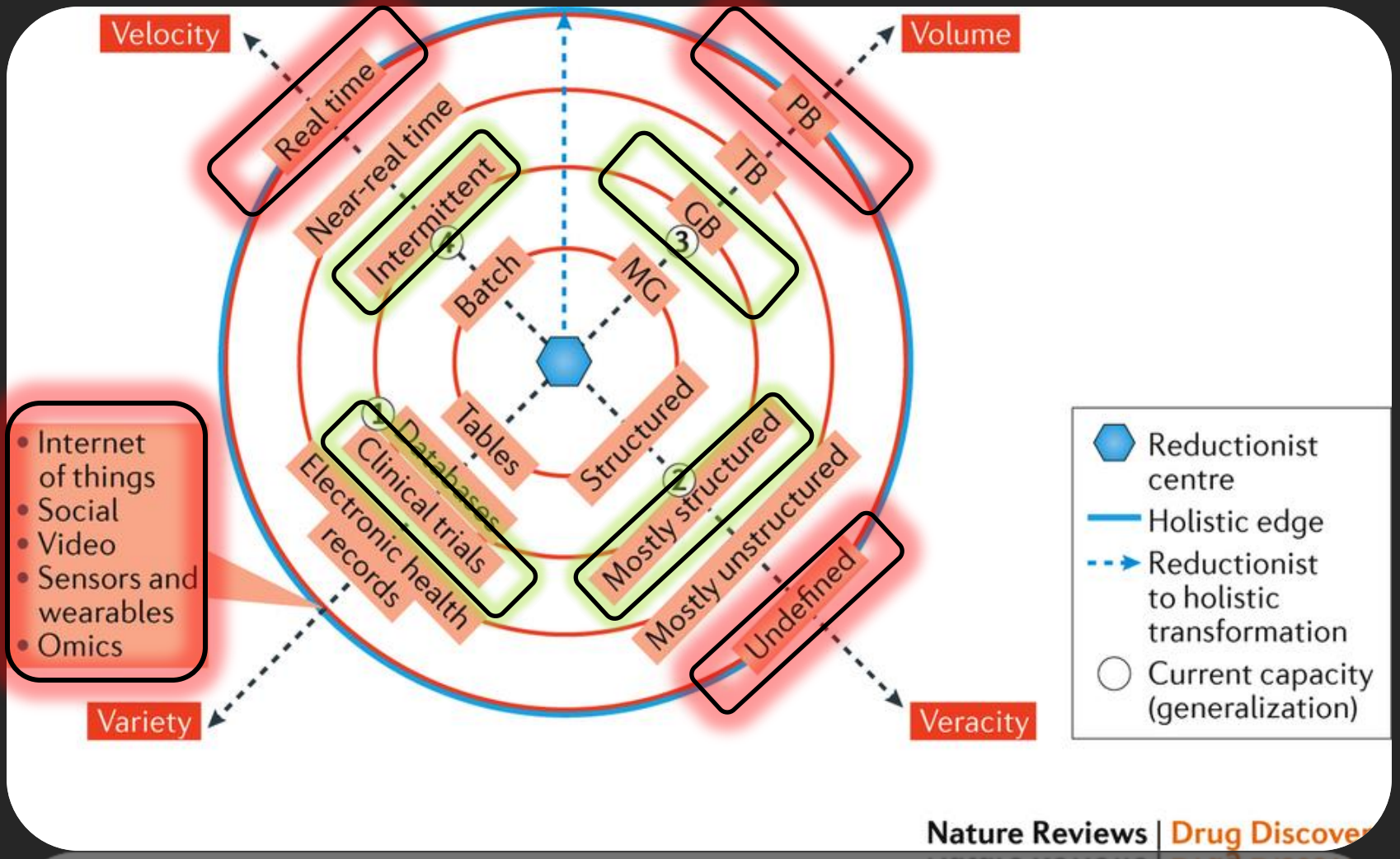
Disclosures: None

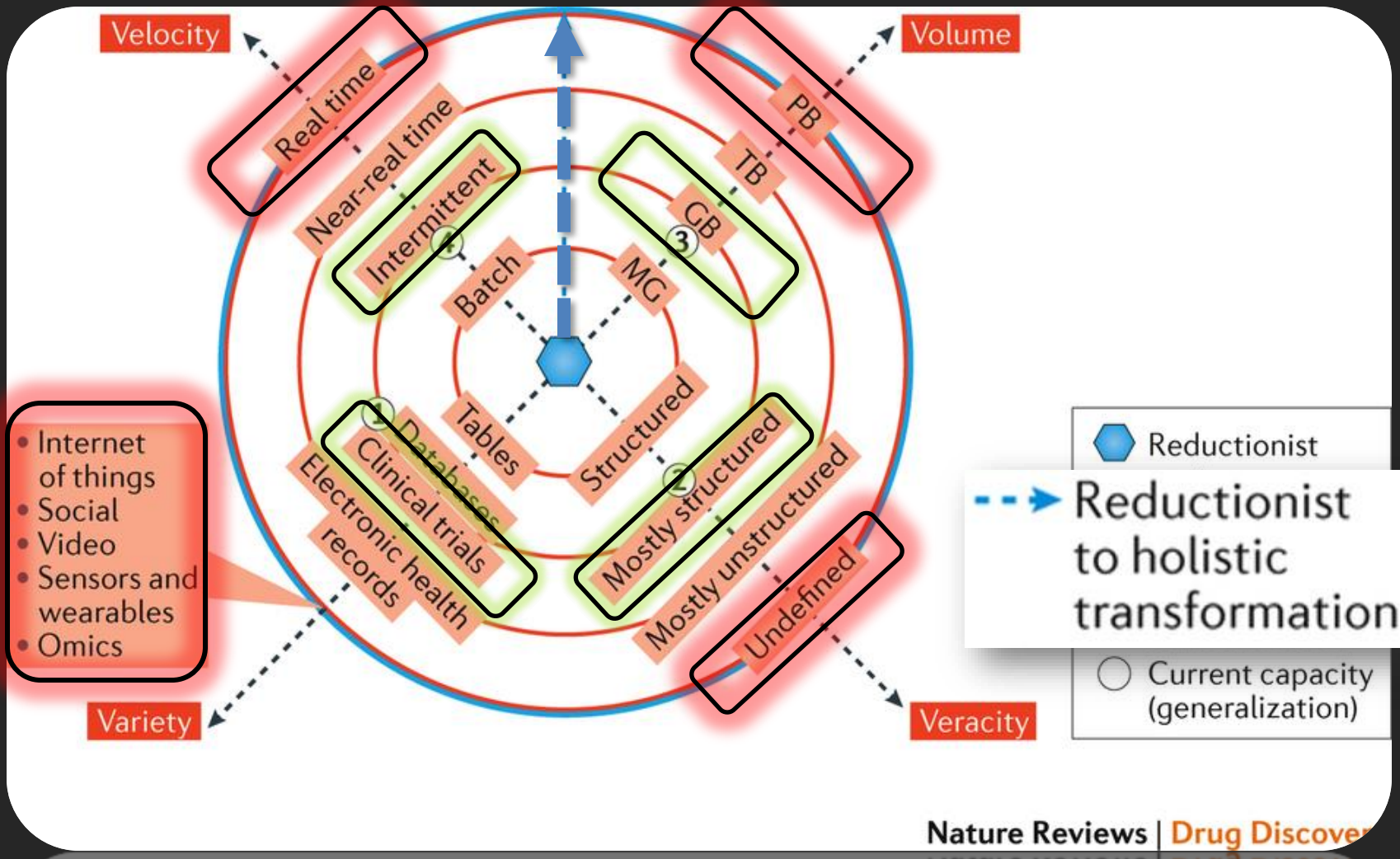
The views in this presentation are my own and do not necessarily reflect the policies of FDA

Expanding universe of big data



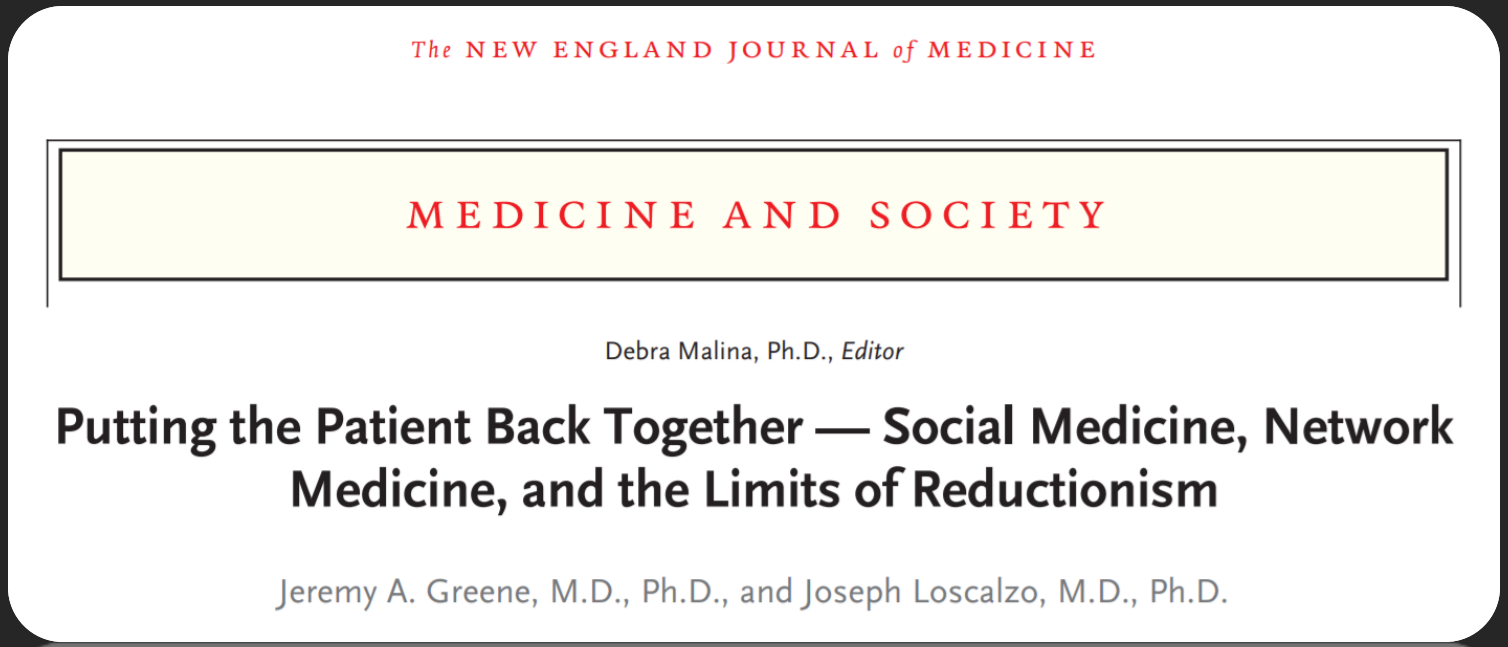
Khozin S, et al. Nat Rev Drug Discov 2017

Expanding universe of big data



Khozin S, et al. Nat Rev Drug Discov 2017

Putting the patient back together



The NEW ENGLAND JOURNAL of MEDICINE

MEDICINE AND SOCIETY

Debra Malina, Ph.D., *Editor*

Putting the Patient Back Together — Social Medicine, Network Medicine, and the Limits of Reductionism

Jeremy A. Greene, M.D., Ph.D., and Joseph Loscalzo, M.D., Ph.D.

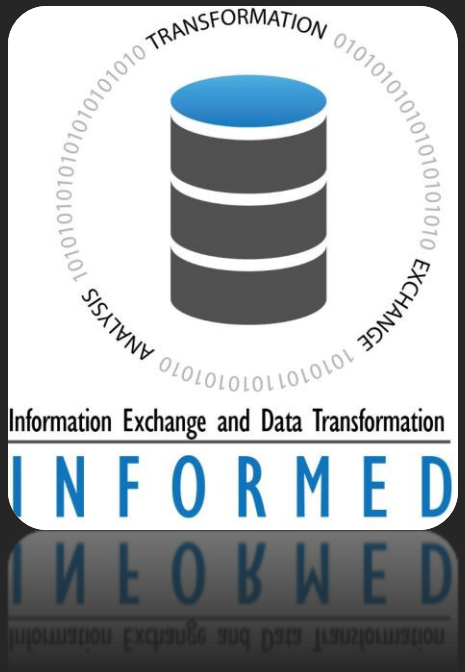
December 2017

Information Exchange and Data Transformation (INFORMED)

A holistic approach to oncology regulatory science

Clinical trials

- Aggregation
- Analysis



Novel pipelines

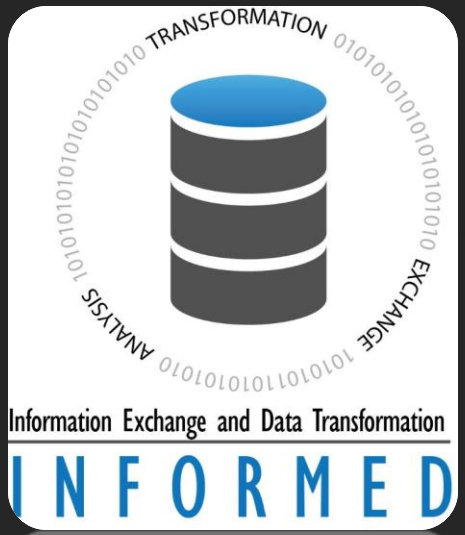
- Real world
- Sensors (IoT)
- Omics

Information Exchange and Data Transformation (INFORMED)

A holistic approach to oncology regulatory science

Input

- Clinical trial
- Electronic health records
- Digital premarket safety
- Biometrics
- Apps



Output

Information Exchange and Data Transformation (INFORMED)

A holistic approach to oncology regulatory science

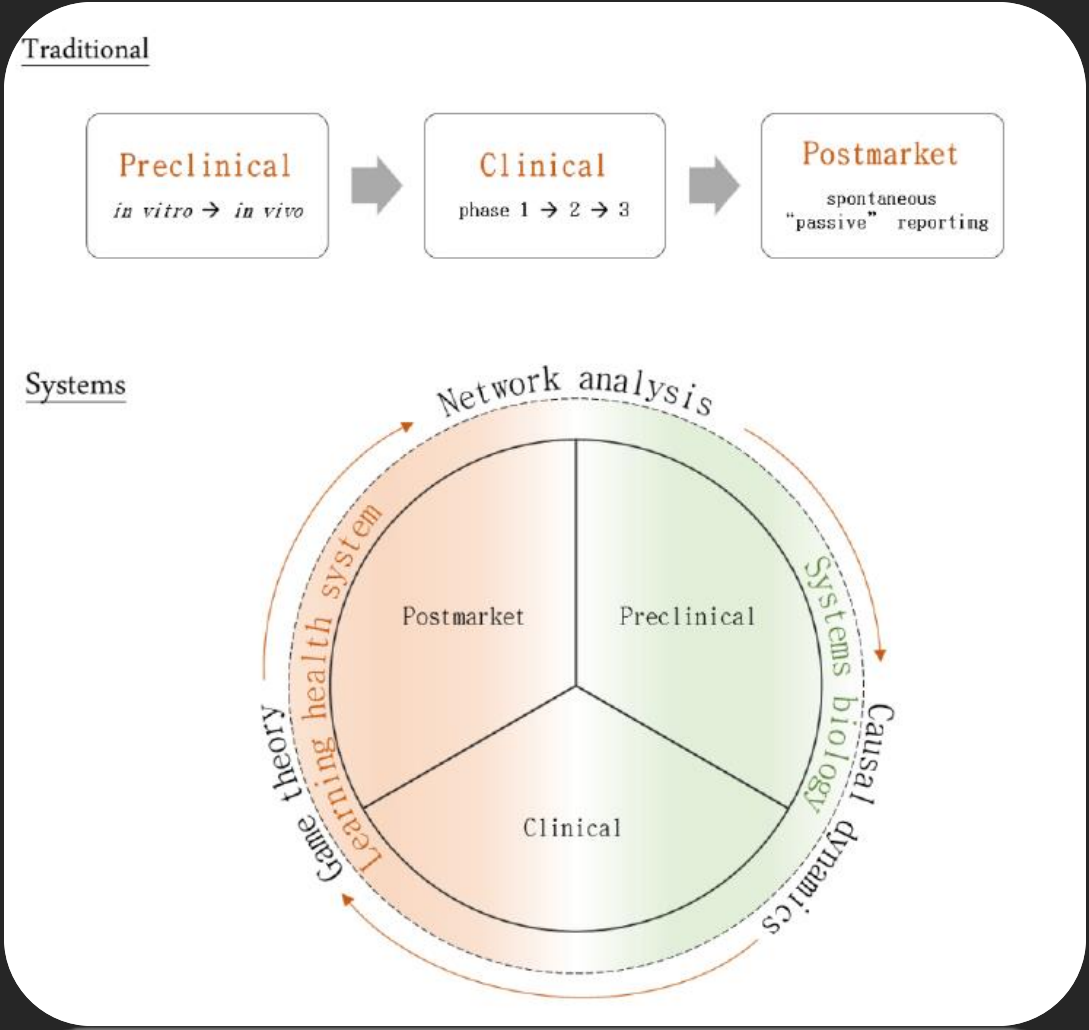
Launch of FDA's New Digital Health Incubator

… **to support the integration of data analytics into regulatory decision making**, we're taking another new step with the creation of an internal data science incubator called the Information Exchange and Data Transformation; or INFORMED

Remarks by Scott Gottlieb, M.D.
Commissioner of Food and Drugs
Academy Health's 2018 Health Datapalooza
Washington, DC
April 26, 2018

https://www.fda.gov/NewsEvents/Speeches/ucm605697.htm

System theory



Khozin S, Pazdur R, Shah A. Nat Rev Drug Discov. 2018 Apr 6. doi: 10.1038/nrd.2018.34. [Epub ahead of print]

Additional Readings & References

INFORMED

Comment | Published: 06 April 2018

nature REVIEWS DRUG DISCOVERY

INFORMED: an incubator at the US FDA for driving innovations in data science and agile technology

Sean Khozin ✉, Richard Pazdur & Anand Shah

Nature Reviews Drug Discovery | Download Citation ⬇

Information Exchange and Data Transformation (INFORMED), a multidisciplinary initiative anchored in the FDA Oncology Center of Excellence, is a decentralized science and technology incubator designed to harness the power of big data and advanced analytics to improve disease outcomes.

Regulatory watch: From big data to smart data: FDA's INFORMED initiative

Sean Khozin ✉, Geoffrey Kim & Richard Pazdur

Nature Reviews Drug Discovery **16**, 306 (2017) | Download Citation ⬇

nature REVIEWS DRUG DISCOVERY

Real-world evidence

OXFORD

JNCI J Natl Cancer Inst (2017) 109(11): djx187

doi: 10.1093/jnci/djx187
First published online September 13, 2017
Commentary

COMMENTARY

Real-world Data for Clinical Evidence Generation in Oncology

Sean Khozin, Gideon M. Blumenthal, Richard Pazdur

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Abstract

Conventional cancer clinical trials can be slow and costly, often produce results with limited external validity, and are difficult for patients to participate in. Recent technological advances and a dynamic policy landscape in the United States have created a fertile ground for the use of real-world data (RWD) to improve current methods of clinical evidence generation. Sources of RWD include electronic health records, insurance claims, patient registries, and digital health solutions outside of conventional clinical trials. A definition focused on the original intent of data collected at the point of care can distinguish RWD from conventional clinical trial data. When the intent of data collection at the point of care is research, RWD can be generated using experimental designs similar to those employed in conventional clinical trials, but with several advantages that include gains in efficient execution of studies with an appropriate balance between internal and external validity. RWD can support active pharmacovigilance, insights into the natural history of disease, and the development of external control arms. Prospective collection of RWD can enable evidence generation based on pragmatic clinical trials (PCTs) that support randomized study designs and expand clinical research to the point of care. PCTs may help address the growing demands for access to experimental therapies while increasing patient participation in cancer clinical trials. Conducting valid real-world studies requires data quality assurance through auditable data abstraction methods and new incentives to drive electronic capture of clinically relevant data at the point of care.

Additional Readings & References

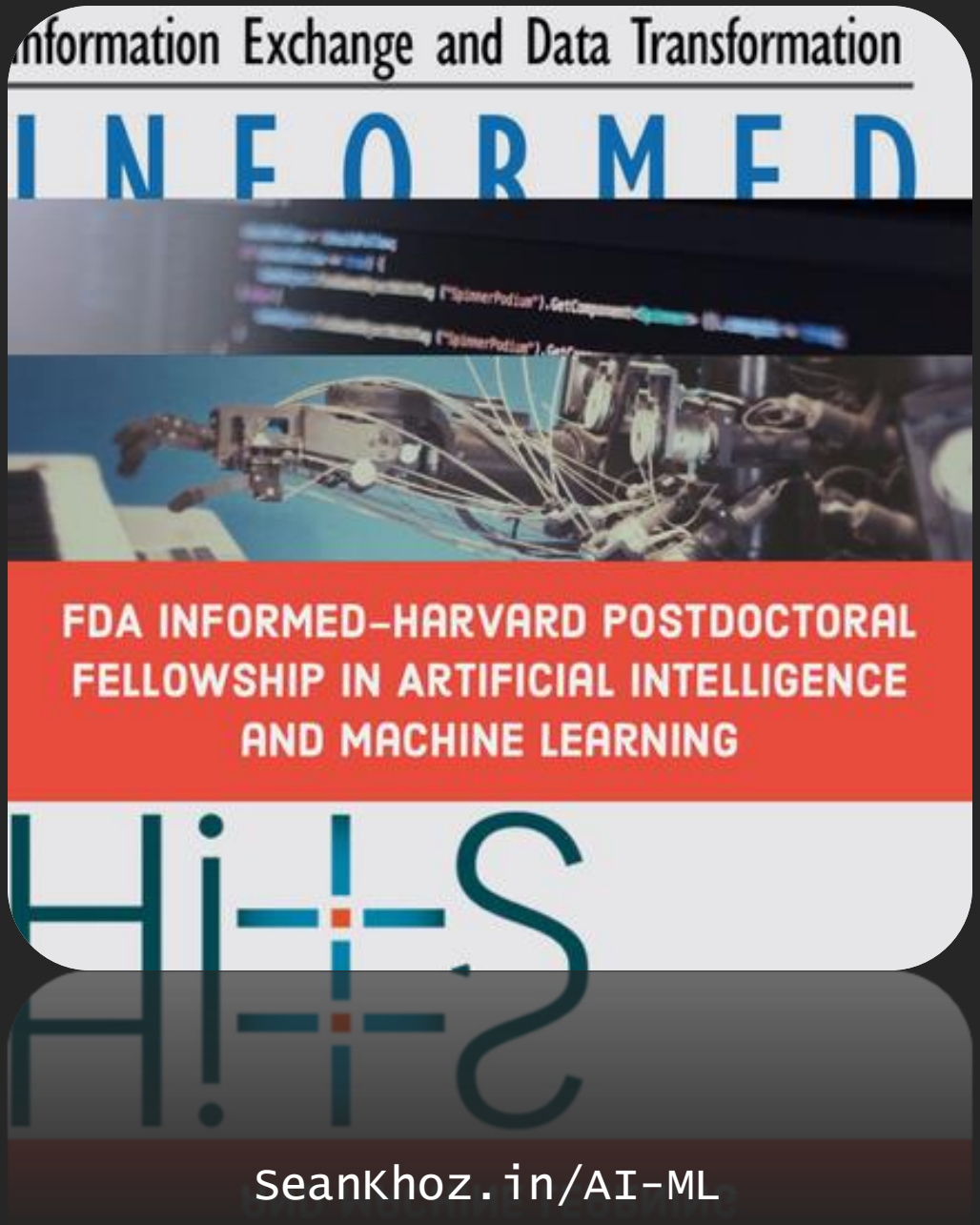
Big Data And The FDA: To Mine The Value, First Mind The Gaps

INFORMED is a new initiative at the FDA to incubate new ideas in applying big data to boost the scientific, economic and social returns from the regulation of drugs and medical devices, with a particular focus on cancer.

InVivo

May 2018

FDA's INFORMED incubator seeks to emulate the entrepreneurial mind-set of a Silicon Valley start-up, applying data science approaches to drug development and regulatory decisions. Page 24



SeanKhoz.in/AI-ML

Thank you

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