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Data Standards Panel Discussion
November 30, 2011

Creating Consensus Science: New Tools and Tactics for Next-Gen Drug Development

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FDA

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Data Standards Panel Discussion

Panel Members

- Chuck Cooper, MD, CDER, FDA
- Margaret Haber, National Cancer Institute, NIH
- Dana Pinchotti, American College of Cardiology
- Frank Rockhold, PhD, GlaxoSmithKline
  Chair, CDISC Board of Directors
- Mary Ann Slack, CDER, FDA

Session Co-Chairs

- Rebecca Kush, PhD,
  Clinical Data Interchange Standards Consortium
- Enrique Aviles, Critical Path Institute

Data Standards Overview Presentation

Rebecca Kush, PhD
President and CEO,
Clinical Data Interchange Standards Consortium

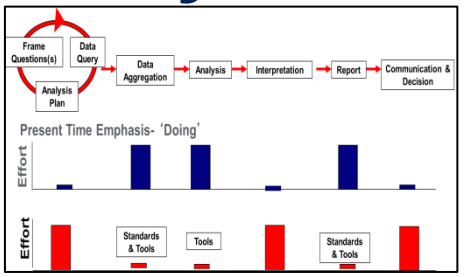
Enrique Avilés
Director, Data Standards and Management
Critical Path Institute

Why Standards ?

- More efficient collaboration

- Better science

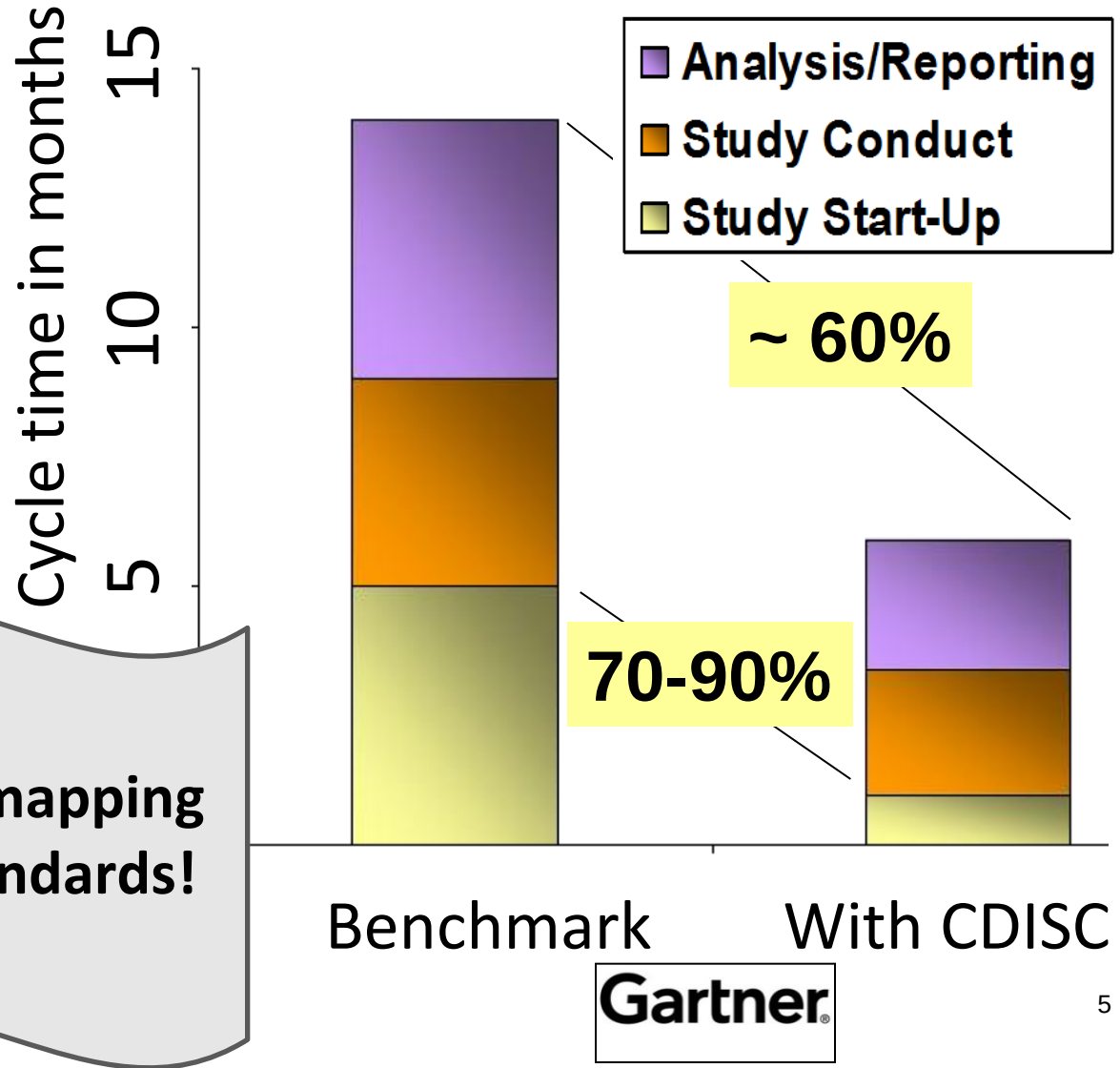
- Increased regulatory efficiency



Value Proposition

For new clinical trials, there is value in using standards

There is also value in remapping legacy data to CDISC standards!



Gartner

Data Standards Value Proposition

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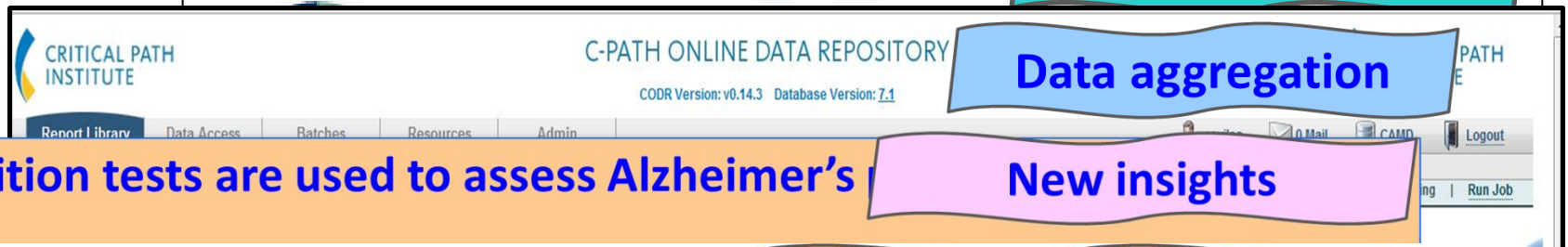
Better standards

Data aggregation

New insights

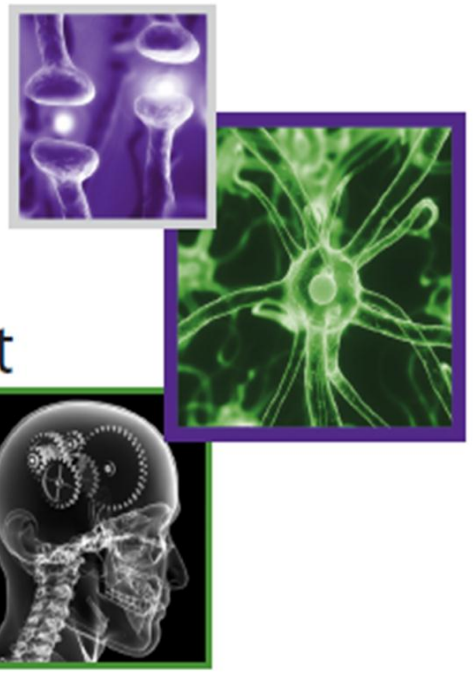
Better science

- **Cognition tests are used to assess Alzheimer's**



SPECIAL REPORT

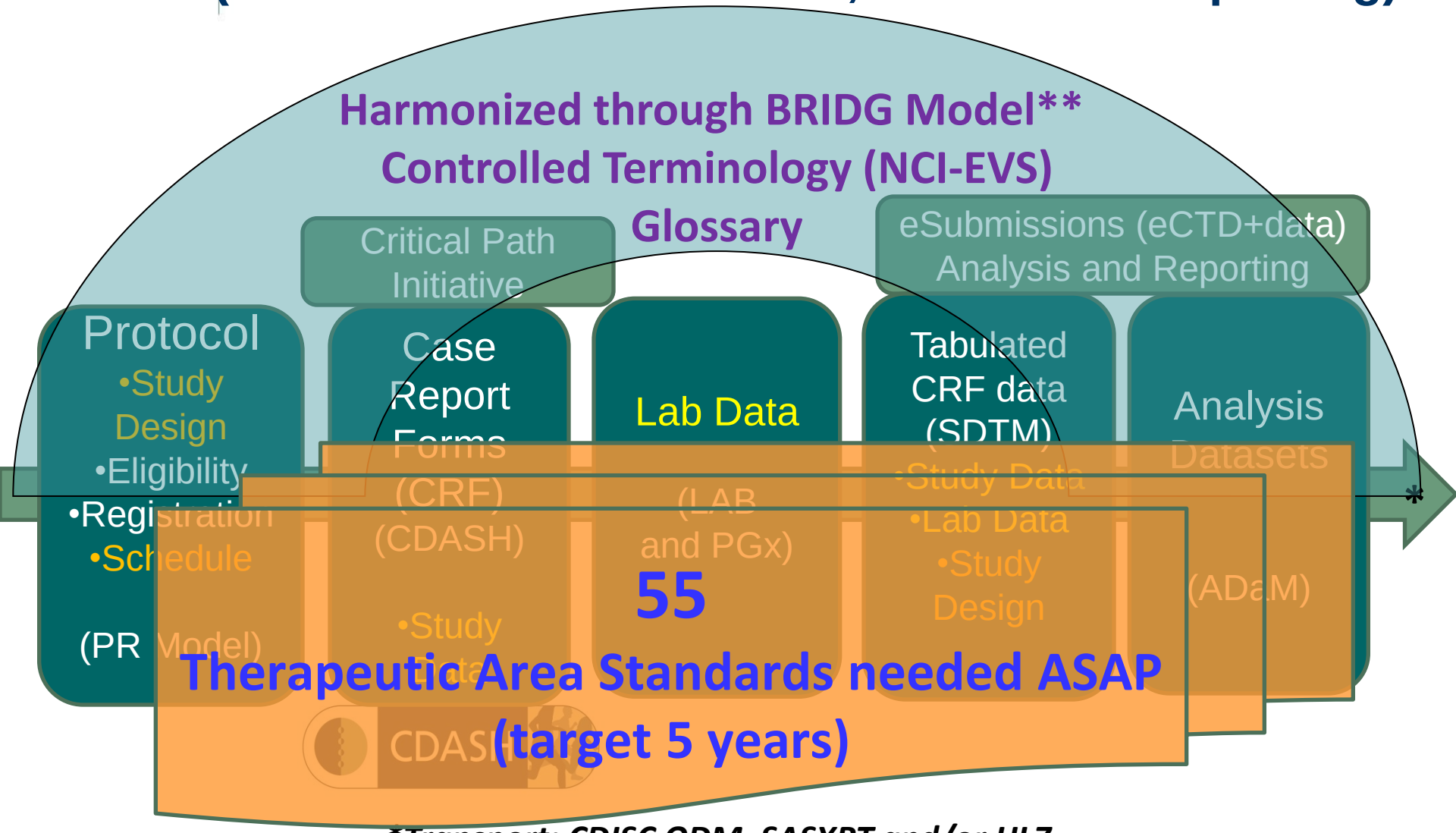
Striving for an integrated drug development process for neurodegeneration: the coalition against major diseases



Klaus Romero[1†], Brian Corrigan[2], Jon Neville[1], Steve Kopko[3] & Marc Cantillon[1]

Neurodegenerative Disease Management, October 2011, Vol. 1, No. 5, Pages 379-385.

Global Content Standards for Clinical Research (Protocol-driven Research; Protocol →Reporting)



*Transport: CDISC ODM, SASXPT and/or HL7

** CDISC, (ISO/CEN), HL7 Standard

Towards an Improved Process
Therapeutic Area (TA) Package Development

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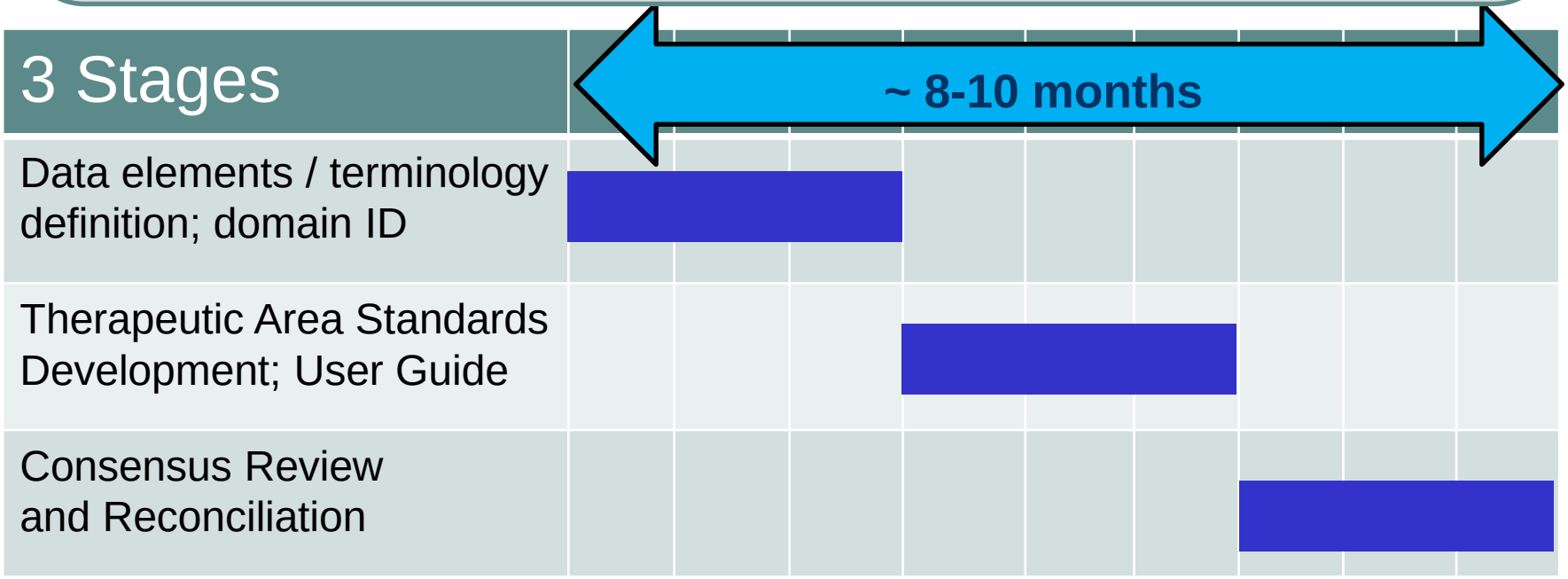
Advance Analyses

- Analyze TA areas/domains (**Scope**, relations, meaning);
- Gather **Samples** including definitions (CRFs, data samples, FDA/SME expert advice) from *Contributors*
- Address **Copyright** Issues
- Form **Multi-disciplinary Core Teams**



CFAST 55n5 Governance

CFAST = an Alliance of C-Path and CDISC:
Coalition ***F***or ***A***ccelerating ***S***tandards and ***T***herapies

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CFAST 55n5 Advisory Committee
(prioritizes work)

Expert Standards Review Council

55n5 Program Mgr

PM: 3 TA Multidisciplinary Teams

Ideal TA Pkg Multi-disciplinary Team

PM
CT Expert
Data Analyst
Stds Experts
Acad/FDA SME
Clin. SME
Tech Writer

Cross-Cutting TA Support for 55n5

Comms
IT
Admin

PDUFA V

FDA's draft Performance Goals for PDUFA V

- Clinical data standards needed for therapeutic areas
- Use of data standards indicated for future applications.

E. *Clinical Terminology Standards: …FDA shall develop standardized clinical data terminology through open standards development organizations (i.e., ….CDISC) with the goal of completing clinical data terminology and …. implementation guides by FY 2017.*

1. *FDA shall develop a project plan for distinct therapeutic indications…. FDA shall publish a proposed project plan for stakeholder review and comment by June 30, 2013…..*

G. *FDA shall periodically publish final guidance specifying the completed data standards, formats, and terminologies that sponsors must use to submit data in applications…..*

http://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM270412.pdf

Standards Development: Next Steps

Process Development

- Develop CDISC Operating Procedure for TA Standards
- Test New Process on new TA domain

CFAST Alliance

- Develop C-Path / CDISC Alliance Agreement & Bylaws
- Review and approval by C-Path & CDISC boards
- Activate CFAST
  (Coalition For Accelerating Standards and Therapies)

55n5

- Launch 55n5 as first project for CFAST
- Apply process improvements to 9 TA standards in progress
- Promote and obtain funding to develop the remaining TA standards

Growth of Data

Industry / Academia

RSNA Image Data Project

One Mind / TranSMART

A

In

Government

Clinical Trial Repository

Ca ular image data repository

.....

Patients

Public image data repositories

(share your CT scan..)

....

- 1 Bit = Binary Digit
- 4 Bits = 1 Nibble
- 8 Bits = 1 Byte
- 1000 Bytes = 1 Kilobyte
- 1000 Kilobytes = 1 Megabyte
- 1000 Megabytes = 1 Gigabyte
- 1000 Gigabytes = 1 Terabyte
- 1000 Terabytes = 1 Petabyte
- 1000 Petabytes = 1 Exabyte
- 1000 Exabytes = 1 Zettabyte
- 1000 Zettabytes = 1 Yottabyte
- 1000 Yottabytes = 1 Brontobyte

CD/DVD era

2010

Revisited: The Rapid Growth in Unstructured Data

Posted by David Vellante in Cloud Computing, Storage, Wikibon on August 17, 2010

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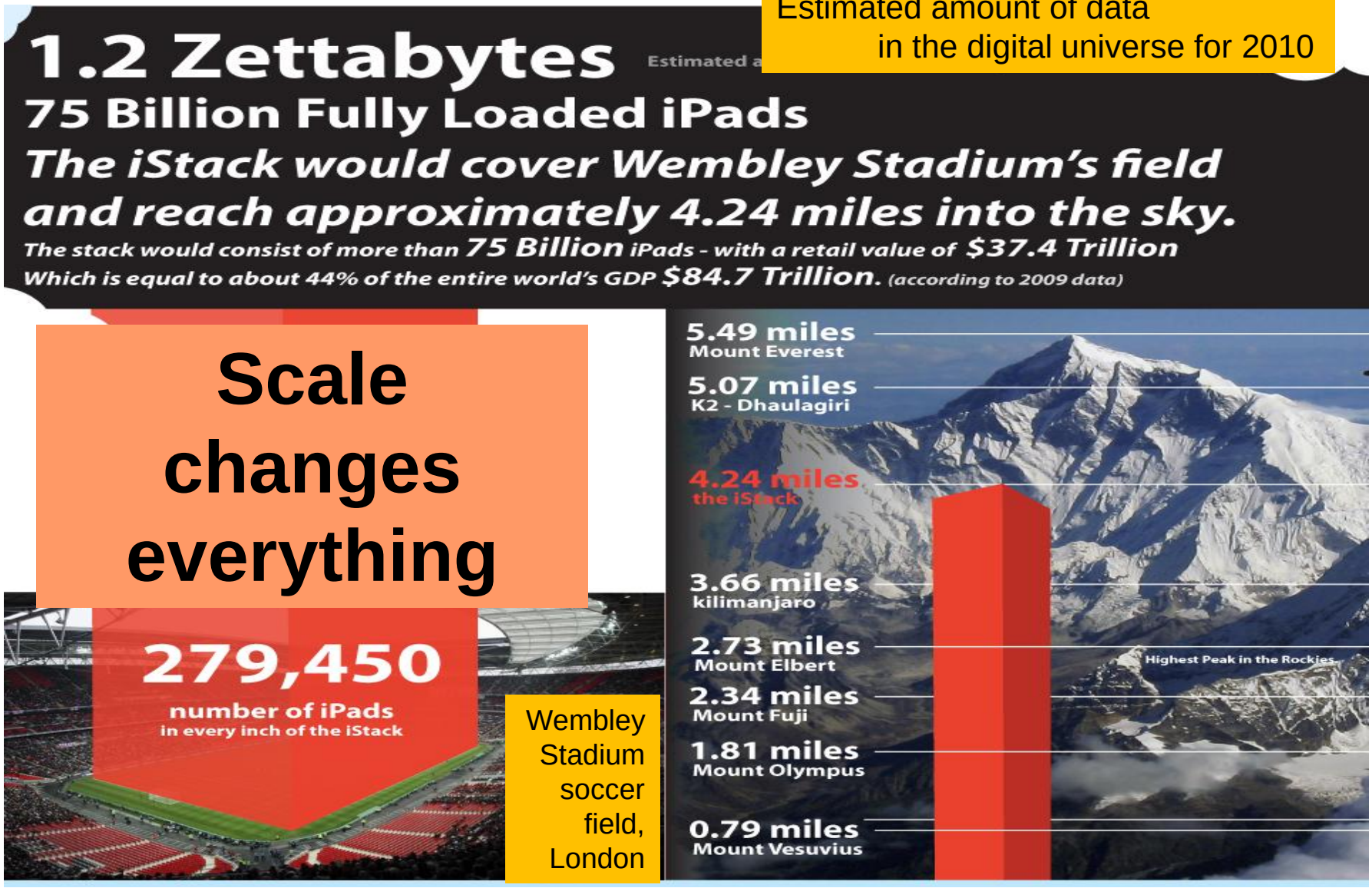
Estimated amount of data in the digital universe for 2010



Initial Topics for Discussion:

- The Data Standards Initiative: 55n5 - a proposed five-year program to develop clinical data standards for a set of therapeutic areas posted by the FDA
- The explosion of clinical data repositories – meeting the challenge to integrate and harmonize data repositories using standards.
- What are the rate-limiting steps in developing and implementing data standards?