Impact of Data Standards on FDA Regulatory Decisions and Policies

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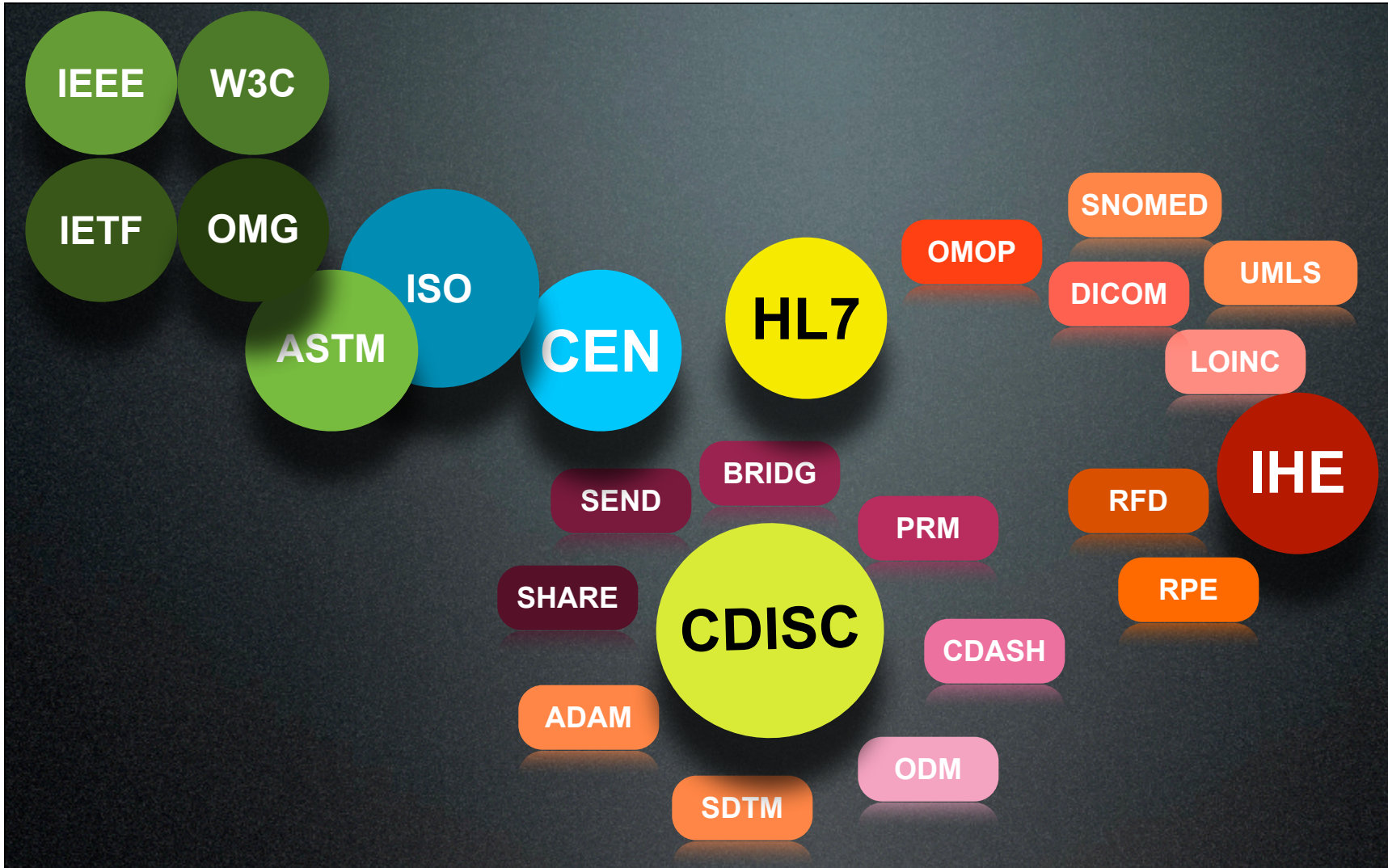
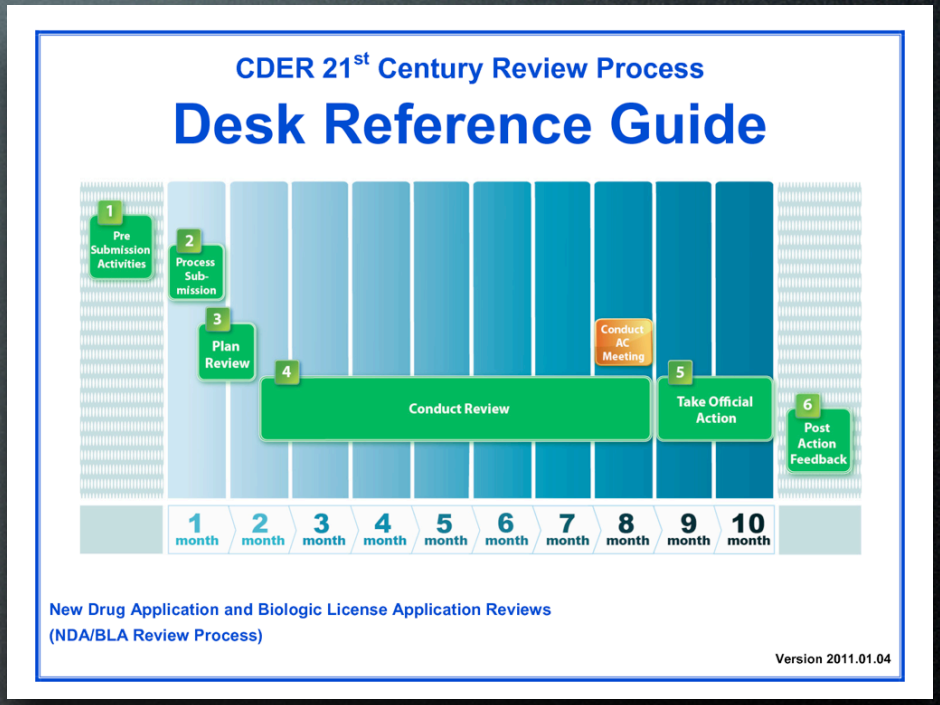


The Data Standards Landscape

Why Standards?

Impact of Interoperability

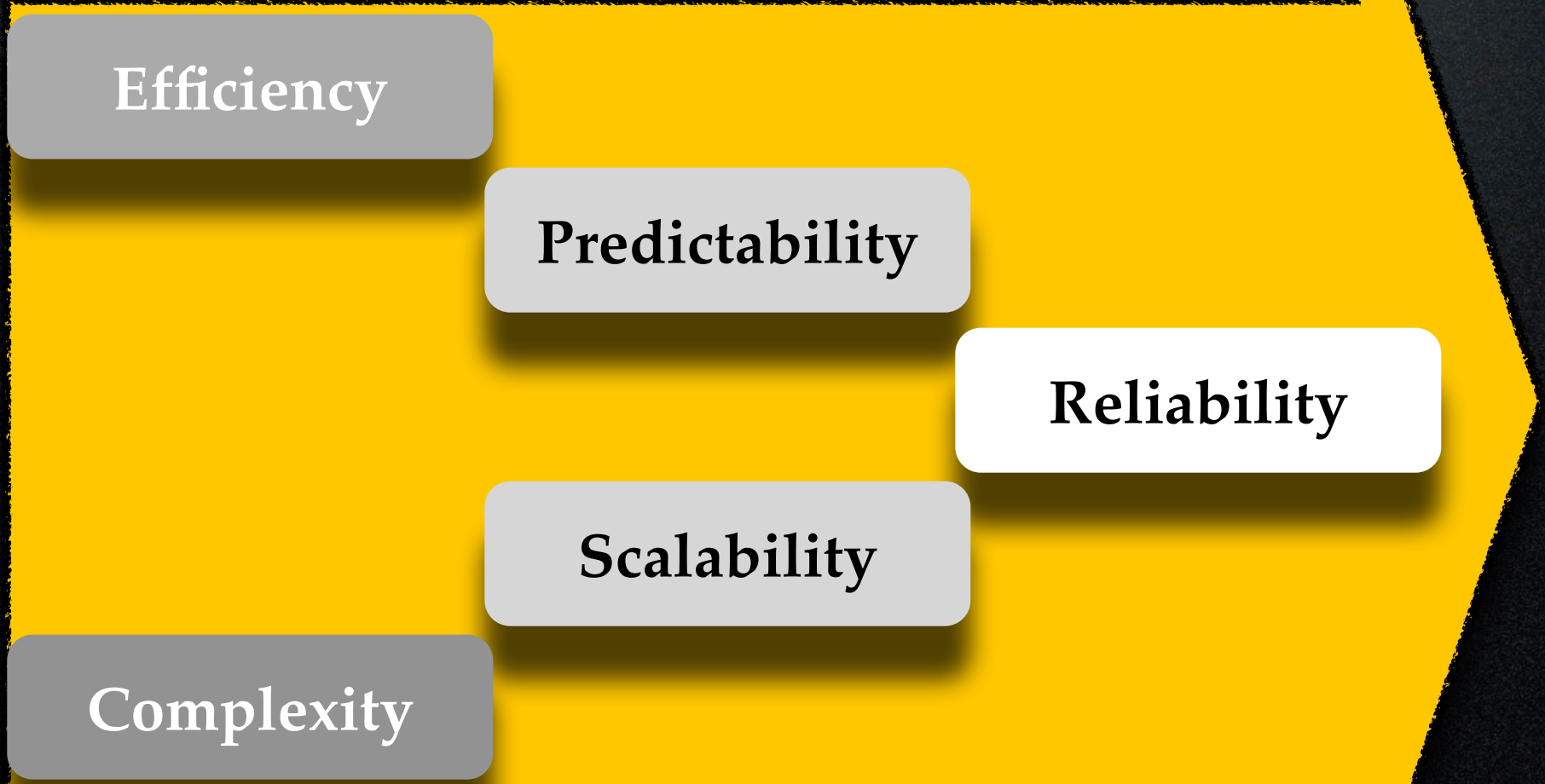
From PAPER to E-Submission



The logistical side of protecting the public health

Life of a Reviewer

Impact of Interoperability



Is there more to standards?

Regulatory Decisions and Policies

Take home

- Standards have **improved quality** of anti-Hepatitis C Virus (HCV) NDA review decisions
- Standards have impacted **policies** to keep up with **rapid changes** in HCV landscape

2008: Can we handle the onslaught of HCV INDs and NDAs?

- With our FTEs (2) for Anti-viral portfolio , it was clearly impossible
  - ✶ Can we automate certain tasks?
  - ✶ Can we get pharma industry to do certain tasks?
  - ✶ How can we learn from success and failures?

One minor problem

We didn't know systems, we didn't know standards

Antiviral Information Management System (AIMS)

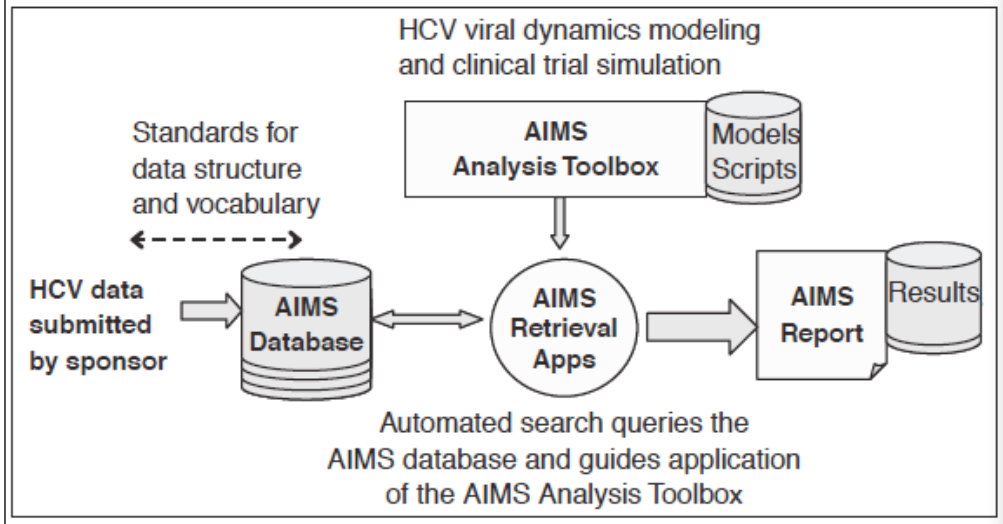
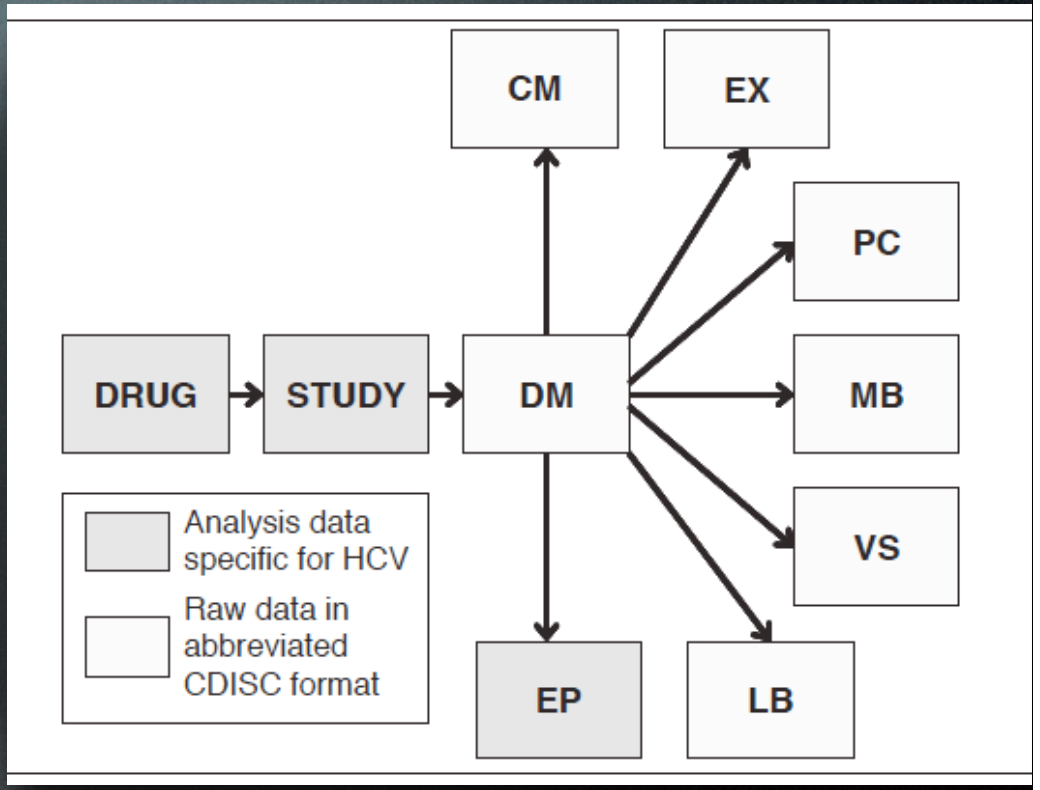


Figure 2. AIMS workflow.



Antiviral Information Management System (AIMS): A Prototype for Operational Innovation in Drug Development

Pravin R. Jadhav, PhD, FCP, Lauren Neal, PhD, Jeff Florian, PhD, Ying Chen, PhD, Lisa Naeger, PhD, Sarah Robertson, PharmD, Guoxing Soon, PhD, and Debra Birnkrant, MD

Journal of Clinical Pharmacology, 2010;50:50S-55S

2010: Developed and Published the Workflow and Standards

2011: Two new therapies were landmark developments

AIMS meaningfully contributed to regulatory decisions

2012: Three Publications in Major Clinical Journals

Interferon responsiveness does not change in treatment-experienced hepatitis C subjects: implications for drug development and clinical decisions.

Liu J, Florian J, Birnkrant D, Murray J, Jadhav PR.

Clin Infect Dis. 2012 Sep;55(5):639-44.

Boceprevir dosing for late responders and null responders: the role of bridging data between treatment-naïve and -experienced subjects.

Florian J, Jadhav PR, Amur S, Ayala R, Harrington P, Mishra P, O'Rear J, Pacanowski M, Robertson S, Singer M, Soon G, Zeng W, Murray J.

Hepatology. 2013 Mar;57(3):903-7

Response-guided telaprevir therapy in prior relapsers? The role of bridging data from treatment-naïve and experienced subjects.

Liu J, Jadhav PR, Amur S, Fleischer R, Hammerstrom T, Lewis L, Naeger L, O'Rear J, Pacanowski M, Robertson S, Seo S, Soon G, Birnkrant D.

Hepatology. 2013 Mar;57(3):897-902

2011: Data Mining, Regulatory Decisions and Public Health

Avoided the need for at least TWO NEW clinical studies

Streamlined Approval and Dosing Instructions

Estimated Sample Size for each New Study: 100 patients studied over 72 weeks

Impact on Healthcare Cost by streamlining dosing: 12 weeks of less therapy that costs $1100/week

2013: Impact of Standards on Regulatory Policies

Can we change the regulatory endpoint for HCV drug approvals?

Technical Question: What is the concordance between SVR12 and SVR24 for HCV trials?

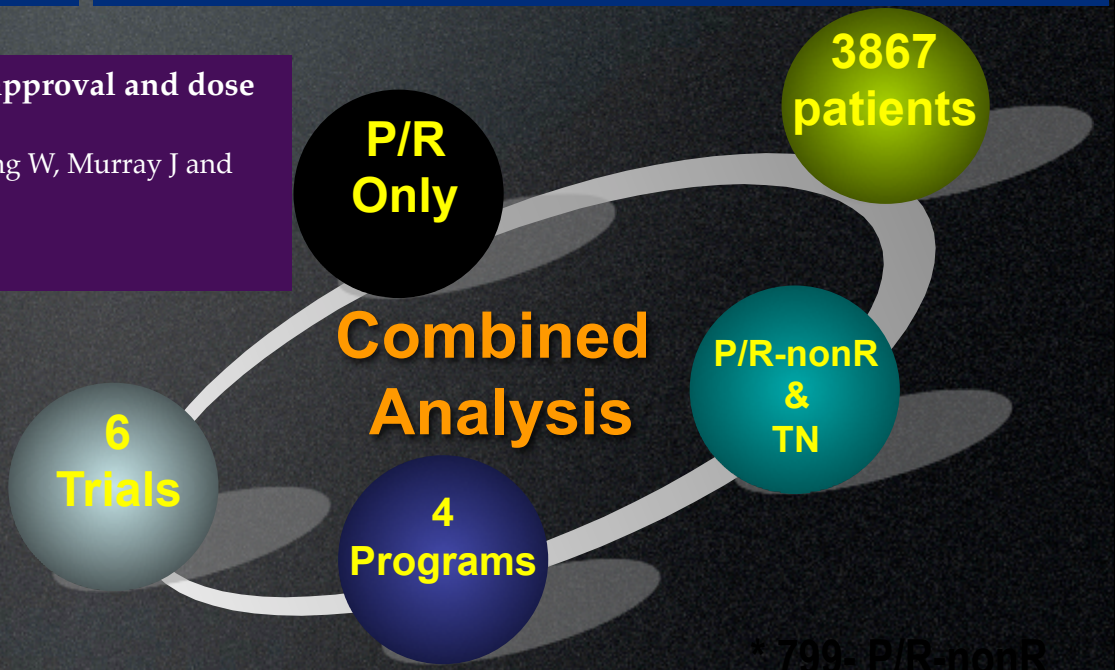
Genotype	PPV	NPV
I	98.3	98.8
II, III	91.1	98.3
Pediatric	100	100

Patients will be able to get
SVR12 vs SVR24
Early Access to Approved therapy

From Question to Answers
by genotype, by drugs, by dosing regimen etc
in ONE hour

Earlier sustained virologic response end points for regulatory approval and dose selection of hepatitis C therapies
Chen J, Florian J, Carter W, Fleischer RD, Hammerstrom T, Jadhav PR, Zeng W, Murray J and Birnkrant D

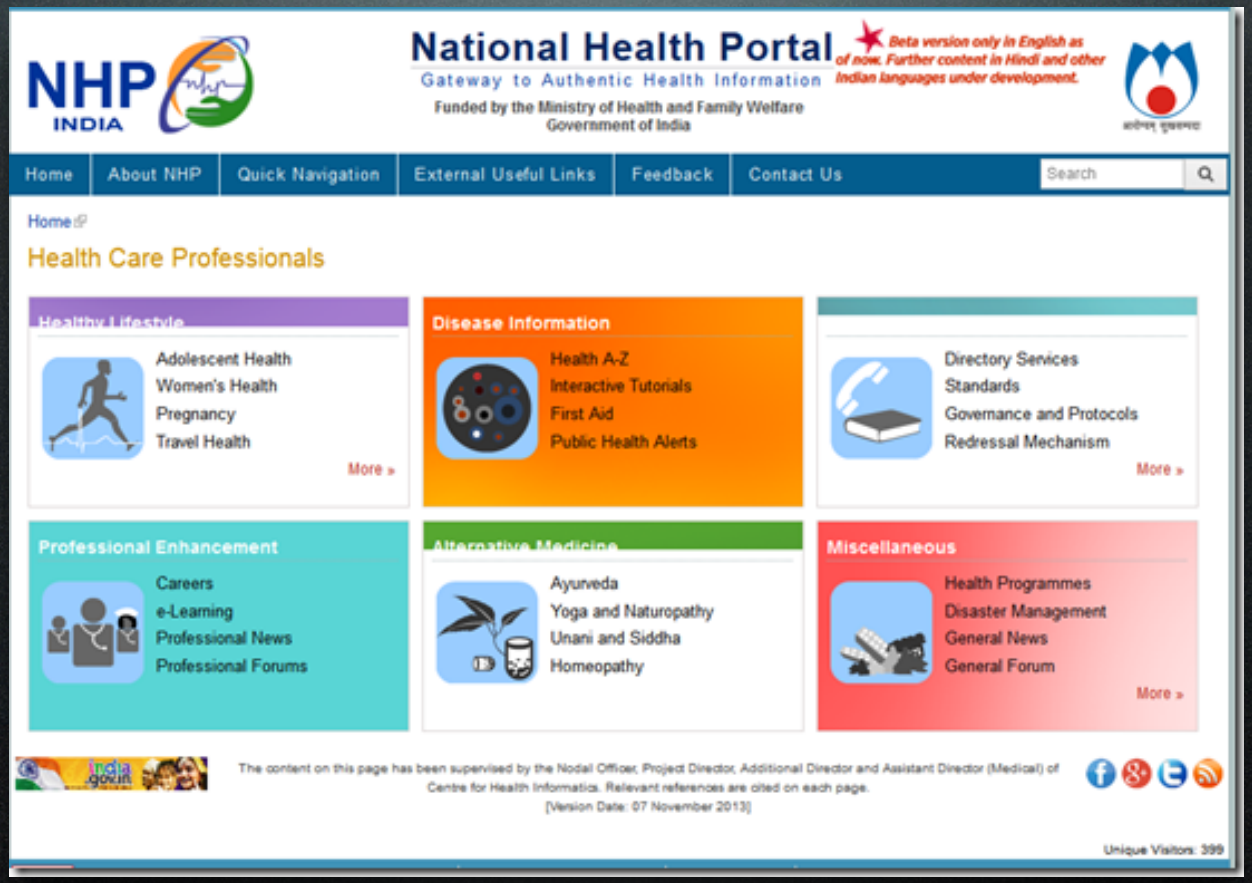
Gastroenterology. 2013 Jun;144(7):1450-1455.e2.



Opportunities: Clinical Data Standards

- Automation
- Integration
- Vision
- Certification
- Education

Opportunities: Healthcare Data Standards



If we thought, clinical trial data standards were complex.....

Acknowledgements

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