

HIMSS[®]19

CHAMPIONS OF HEALTH UNITE

Global Conference & Exhibition
FEB 11-15, 2019 | ORLANDO



interoperability
showcase™

Required Infrastructure for the Research Moonshot

ISED22, February 14, 2019 2:30PM-3:30PM EST

Lisa Simpson, Prez & CEO, AcademyHealth

Wayne Kubick, Chief Technology Officer, HL7

Sam Hume, VP Data Science, CDISC

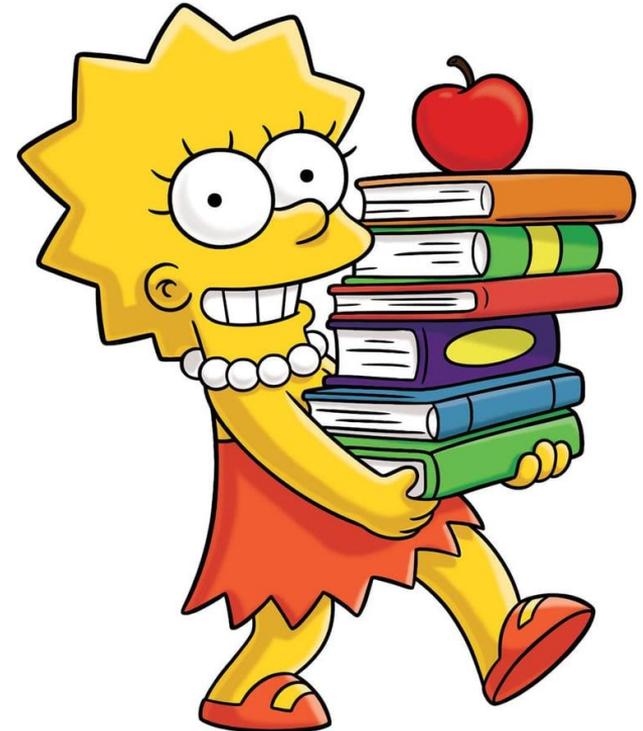
Speaker Introduction

Lisa Simpson MB, BCh, MPH, FAAP

President & CEO
AcademyHealth
@DrSimpsonHSR

Pediatrician and health services
researcher, passionate about
translating evidence into action

Former #academic, AHRQ Deputy
Director



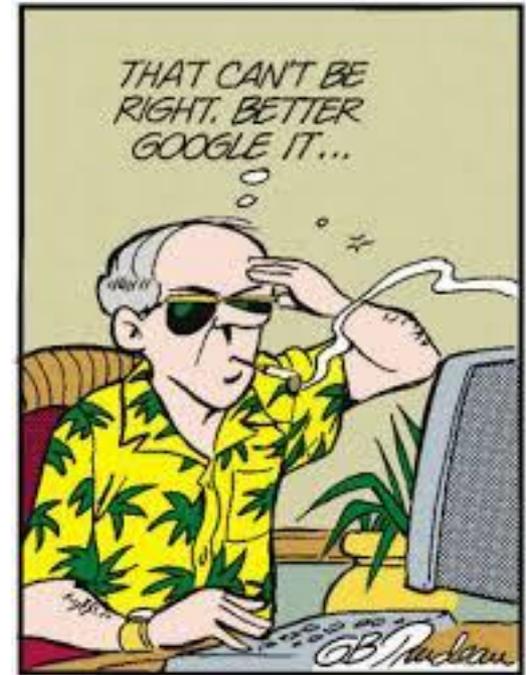
Speaker Introduction

Wayne R. Kubick, BA, MBA

Chief Technology Officer
Health Level Seven International
@WayneKubick

Sr. Executive with more than 25 years
of experience in pharmaceutical
clinical research standards, processes
and technologies.

Former CTO, CDISC, Oracle, Phase
Forward, Parexel...



Speaker Introduction

Sam Hume, D.Sc.

VP, Data Science
CDISC

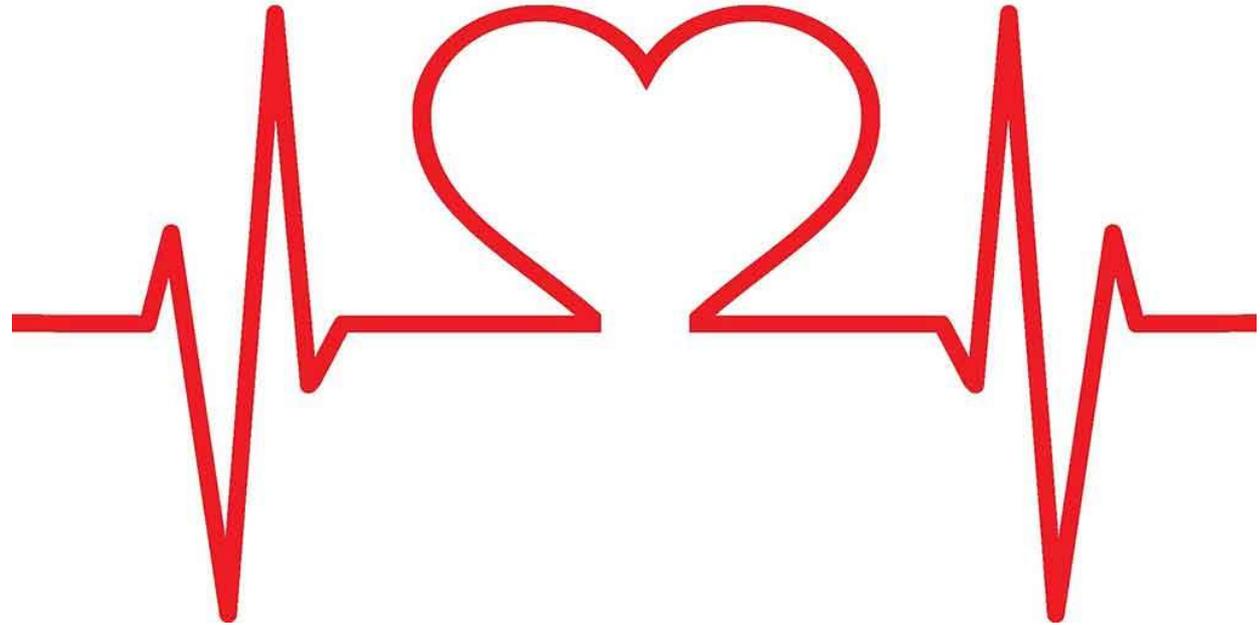
@swhume

shume@cdisc.org

I specialize in clinical research and healthcare informatics including data science, data exchange, data integration, software development, and related research projects.



Data is the lifeblood of research



AcademyHealth

- Mission: *to improve health and the performance of the health system with **data** and **evidence***
- 4,000+ evidence producers and users across ecosystem
- Committed to
 - Community building
 - Translation
 - Policy context
 - Fed AND state
- Health Datapalooza
 - HIMSS is partner



What works?



About Health Level 7 International

- ANSI-accredited healthcare standards development organization with >2500 members in >50 countries
 - >300 standards products
 - Major product families: v2, v3, CDA, FHIR
 - Regulated Research products: SPL, ICSR, IDMP
- HL7 Vision: *A world in which everyone can securely access and use the right health data when and where they need it*
- HL7 Mission: *To provide standards that empower global health data interoperability*



The Fundamentals of FHIR

Fast Healthcare Interoperability Resources

- A next generation **standards framework & platform**, built on 30 years of HL7 experience, designed for simplicity and implementation
 - R4, with normative content now available
- Built on REST, a pattern for using web technologies to manage information (the platform used by Facebook, Twitter...) and APIs
 - Availability of APIs required by 21st Century Cures
- Content based on Resources: essential, portable modular information building blocks easily assembled into working systems
 - Like web pages directed toward computers; fast and scalable
- Flexible outputs: web, messages, documents, services
- A *technology*, a *data model*, and an active, global *community*

“The Web, for Healthcare” – Grahame Grieve



Some Talking Points

- The increased availability of digital health data, more accessible, consistent and reliable via FHIR APIs under 21st Century Cures, can provide significant opportunities for advancing Biopharma research
- Research would benefit by adapting to data as represented via FHIR resources, minimizing transformations, terminology conversions and mapping
- CDISC standards such as CDASH and SDTM are still significant, and required for the near future for regulatory submissions, but can also likely be adapted as views on FHIR resources in the future
- The vast power, potential and widespread acceptance of the FHIR platform standard will likely catalyze many new opportunities to improve healthcare treatment and outcomes
- A significant dialogue is needed on how to best adapt to this changing landscape for pharma and broader research.



About CDISC

- Global Standards Development Organization (SDO)
- Founded in 1997 (all volunteers)
- >450 organizational members
- Standards for clinical & translational research
- Required for FDA and PMDA regulatory submissions

Mission: To develop and support global, platform-independent data standards that enable information system interoperability to improve medical research and related areas of healthcare

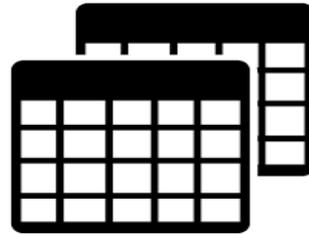


Support Common Functions for All Research

Providing Common Content, Structure, & Terminology for:



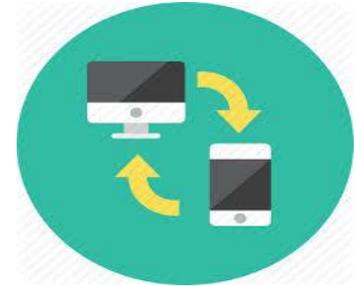
Data Collection



Data Aggregation
(Tabulation)



Data Analysis

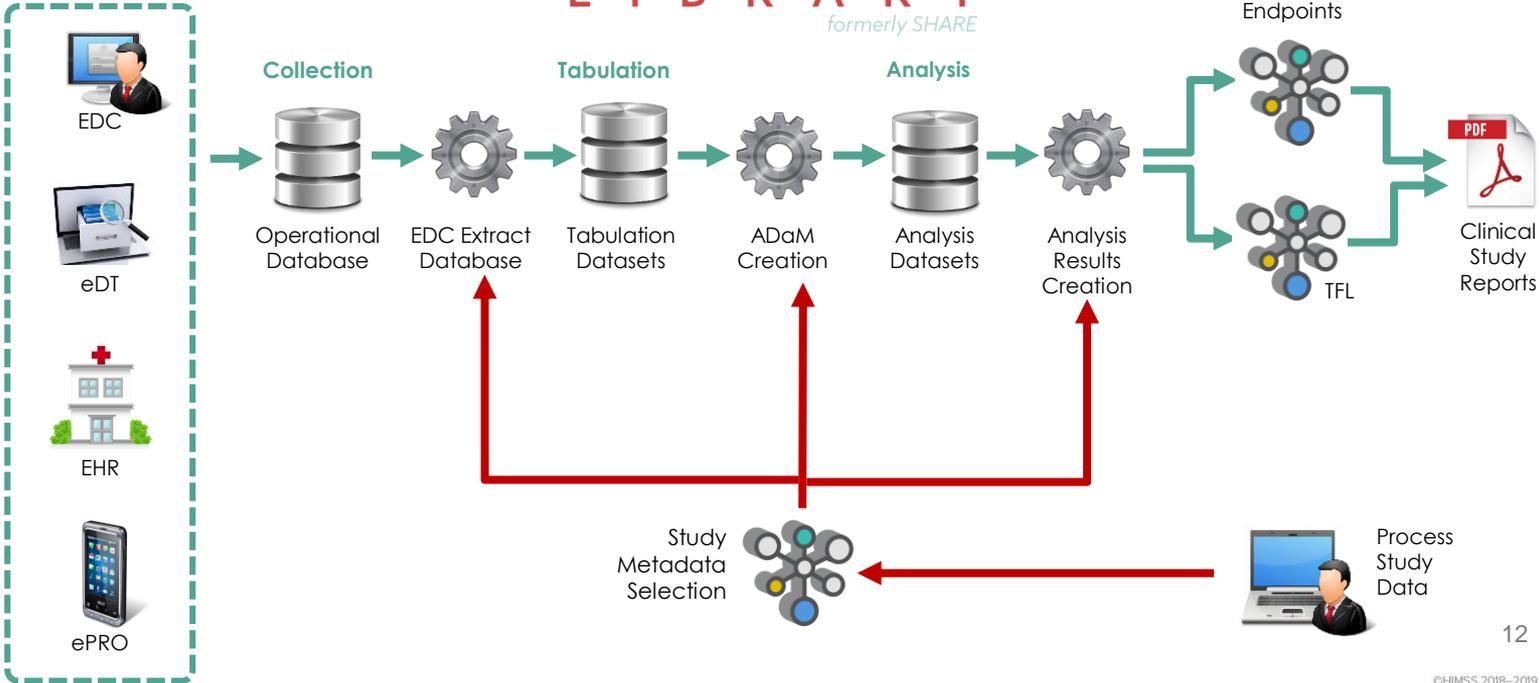


Data Exchange

CDISC is:

- Working to connect EHRs to Research using FHIR
- Demonstrating the use of RWD with CDISC standards
- Continuing to support registries and pragmatic trials

CDISC 360 – A Research Data Moonshot



Dialogue

- What is most significant progress since #HIMSS18?
- Will the rule drop affect research?
- Can you comment on the impact of FDA's approach to regulating apps on the demand for research?
- How quickly do you see "traditional" research models embracing newer methods, etc...
- If you could make one thing happen to accelerate research – what would it be?

