

# UCL – Yale Meeting

## Facilitating Data Access to Non-Industry Funded Research

Friday, 9 October 2015

# UCL – Yale Meeting

## Welcome and Introductions

## Yale University

### Former names

Collegiate School (1701–1718)

Yale College (1718–1887)

Named after benefactor Elihu Yale

### Motto:

Lux et veritas (Light and truth )

### Established

October 9, 1701 (314 years old – today!)

## University College London (UCL)

Founded on 11 February  
1826 under the name  
London University

Bentham (1748-1832) is  
today commonly regarded  
as the "spiritual father" of  
UCL

## Yale-UCL Collaborative Event

### *Main themes:*

1. Access to quality, detailed data regarding “standard of care”. To be used for generating hypotheses and creating accurate sample size calculations for RCT proposals.
2. Collecting person-specific data on patients who have given consent to participate in a study (RCT, prospective cohort, etc.). To run the studies efficiently and inexpensively, while maintaining research and data security governance.
3. Long-term follow-up on patients in clinical studies.
4. Management of secure and responsible access to study data sets.

### *Special projects:*

- Independent analysis of data sets of studies that are in progress.
- Maintaining a knowledge base of precise data definitions for studies.
- Working with funders to ensure long-term responsible access to data.
- Working with publishers to link journal articles with data sets.

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## University/Trial Collaborative Perspectives & Policies for Data Sharing

## From: Finding the Missing Link for Big Biomedical Data

JAMA. 2014;311(24):2479-2480. doi:10.1001/jama.2014.4228

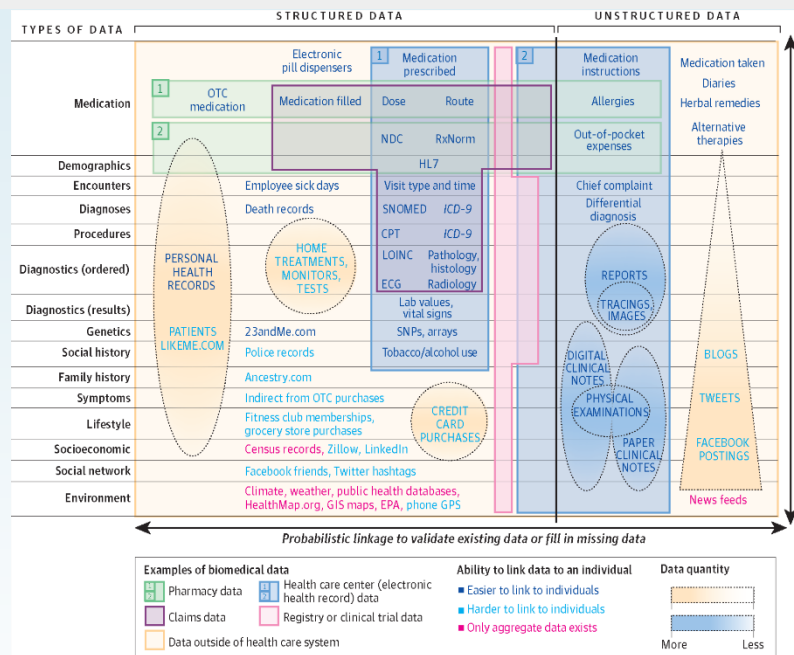
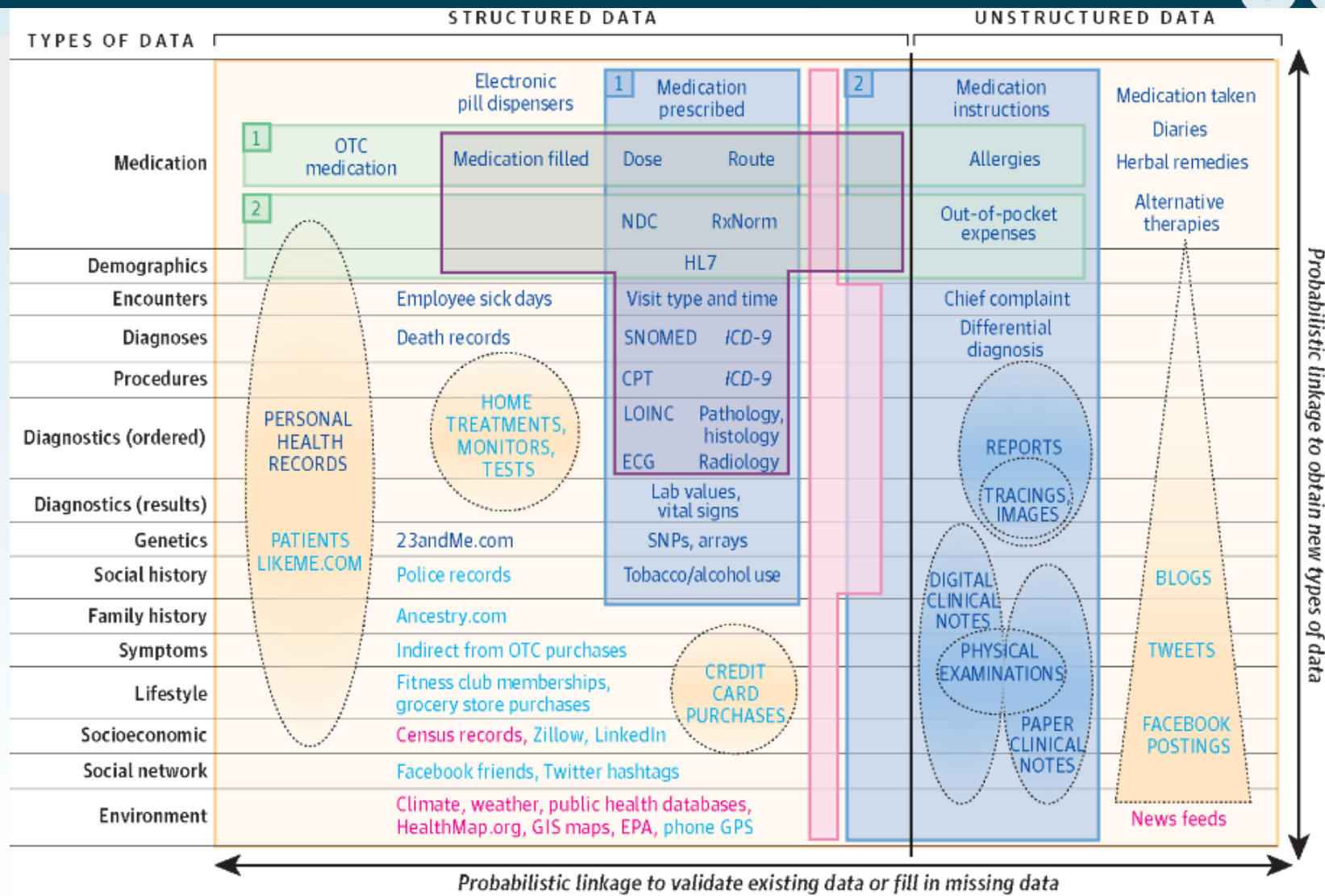
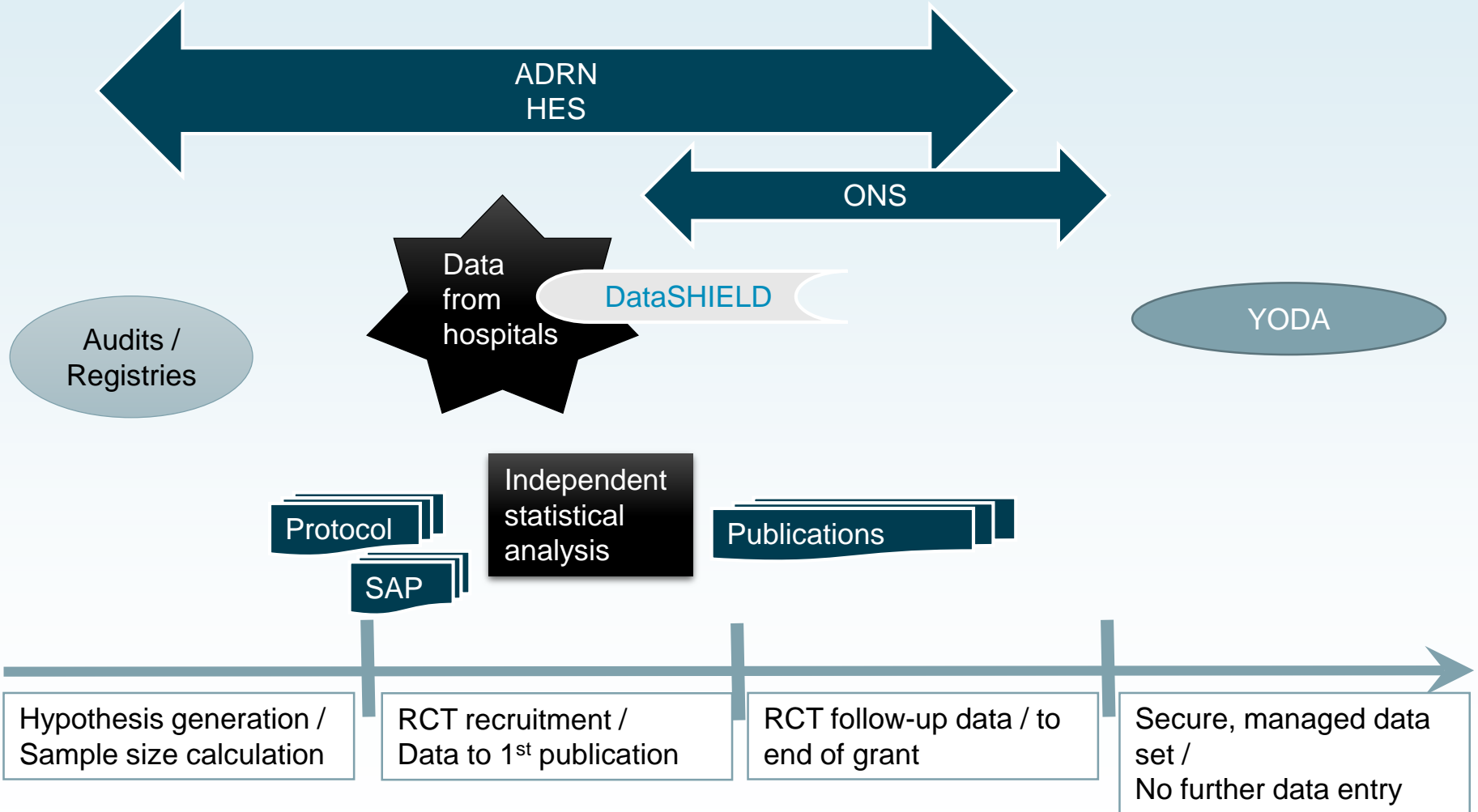


Figure Legend:

The Tapestry of Potentially High-Value Information Sources That May be Linked to an Individual for Use in Health Care CPT indicates current procedural terminology; ECG, electrocardiography; EPA, US Environmental Protection Agency; GIS, geographic information systems; GPS, global positioning system; HL7, Health Level 7 coding standard; ICD-9, Institutional Classification of Diseases, Ninth Revision; LOINC, Logical Observation Identifiers Names and Codes; NDC, National Drug Code; OTC, over-the-counter; SNOMED, Systematized Nomenclature of Medicine; SNP, single-nucleotide polymorphism.



<b>Examples of biomedical data</b>		<b>Ability to link data to an individual</b>	<b>Data quantity</b>
Pharmacy data	Health care center (electronic health record) data	Easier to link to individuals	More
Claims data	Registry or clinical trial data	Harder to link to individuals	Less
Data outside of health care system		Only aggregate data exists	





# Legislation

Currently applicable legislation:

EU legislation applying to Clinical Trials of Investigational Medicinal Products (CTIMPs) currently includes:

- EU Clinical Trials Directive (“EUCTD”; Directive 2001/20/EC)
- EU Directive relating to medicinal products for human use 2001/83/EC
- EU Good Clinical Practice (GCP) Directive 2005/28/EC.
- Note also European Advanced Therapy Medicinal Products (ATMP) Regulation EC 1394/2007

EU Directives are transposed into legislation in Member States. In the UK this gave rise to the UK’s Clinical Trials Regulations.

Future legislative environment:

EU Clinical Trials Regulation (EU Regulation No 536/2014):

EU Regulation No 536/2014 on clinical trials on medicinal products published in Official Journal of the European Union on 27 May 2014. The Regulation will streamline the authorisation process and harmonise requirements for clinical trials of medicines in Europe while maintaining safety for participants.

# Information Commissioner's Office

<https://ico.org.uk/>

The UK's independent authority set up to uphold information rights in the public interest, promoting openness by public bodies and data privacy for individuals.

# Examples of Sharing Data

Publishing CCTV images in the media to “catch criminals” – or those simply wanted for questioning.

Capturing the results of routine eye examinations performed in retail chain opticians.