Individual Patient Records and the Critical Path

Steve Wilson, DrPH (Biostatistics), CAPT, USPHS

Acting Director, Office of Business Process Support (OBPS), CDER/FDA

Deputy Director, Division of Biometrics II, CDER/FDA

PRISM

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Disclaimer

Views expressed in this presentation are those of the speaker and not, necessarily, of the Food and Drug Administration

My New Disclaimer

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- Norm Stockbridge, *CDER, FDA*
- Stan Woolen, *OC, FDA*

Outline

- FDA Mission
- White Oak and OBPS
- Critical Path
- Standards Development and the FDA
  - Data Standards Council
  - CDISC/HL7/RCRIM
- Review of Safety
  - Patient Profile Viewer
  - Do-It-Yourself SDTM
- Updates/Opportunities
  - NCI Janus/CRIX
  - CDISC eSDI
  - Academic Consortia

The Critical Path to New Medical Products

- "… a new focus on updating the tools currently used to assess the safety and efficacy of new medical products"
- "… develop this list through extensive consultation with private and public stakeholders…"
- Directly references CDISC SDTM as a "Critical Path" initiative

http://www.fda.gov/oc/initiatives/criticalpath/

FDA's Mission & Innovation

- "protecting the public health"
  - Organization
  - Electronic submissions and review
  - Study design, data quality and analysis
- "advancing the public health by helping to speed innovations"
  - Improvements: collection, review & submission processes
  - Standards
  - Shared repositories
  - Registries
  - Electronic data capture
  - Individual patient records

White Oak, MD: CDER's New "Home"

Office of Business Process Support -- OBPS

(the Office formerly known as OIM)

- Immediate Office (IO)
- Project Development Staff (PDS)
- Business Analysis and Reporting Staff (BARS)
- Regulatory Review Support Staff (RRSS)
- Division of Records Management (DRM)

OBPS: Some of It's Responsibilities

- Develops tools for access to and analysis of data used to support regulatory decisions
- Business process changes and/or implementation of information technology
- Standardizes information management processes
- Publishes regulations, guidance documents and MaPPs to support electronic submissions
- Develops information management project proposals
- Coordinates IT systems development projects
- Standardizes information management processes
- Develops and maintains business and data layers of the enterprise architecture
- Operates and manages the document rooms

Standards Development and the FDA

FDA's Motivation for Standards

Improve time to market for safe and effective treatments (increased patient safety and reduced costs) by…

- Improving efficiency of evaluation of safety and efficacy of investigational treatments
  - Facilitates communication between regulatory authority and applicant
  - Facilitates development of efficient review environment (e.g., training, analysis tools)
- Improving efficiency for clinical research
  - Facilitates design and conduct of clinical trials
  - Facilitates communication between researchers and study sponsor (e.g., between CRO and drug company)

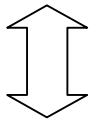
FDA Data Standards Council

- Coordinates the evaluation, development, maintenance, and adoption of health and regulatory data standards
- Ensures that common data standards are used throughout the agency
- Ensures that these standards are consistent with those used outside the FDA.
- Accomplished through
  - strategically focused and systematic analysis of health and regulatory data standards requirements; and
  - evaluation of existing standards and adoption or development and maintenance of standards.
- http://www.fda.gov/oc/datacouncil/

FDA Data Standards Council
Procedures

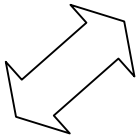
Business Process Planning

Identify data or terminology standard need

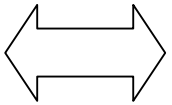


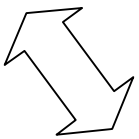
FDA Data Standards Council

Coordinate adoption or development



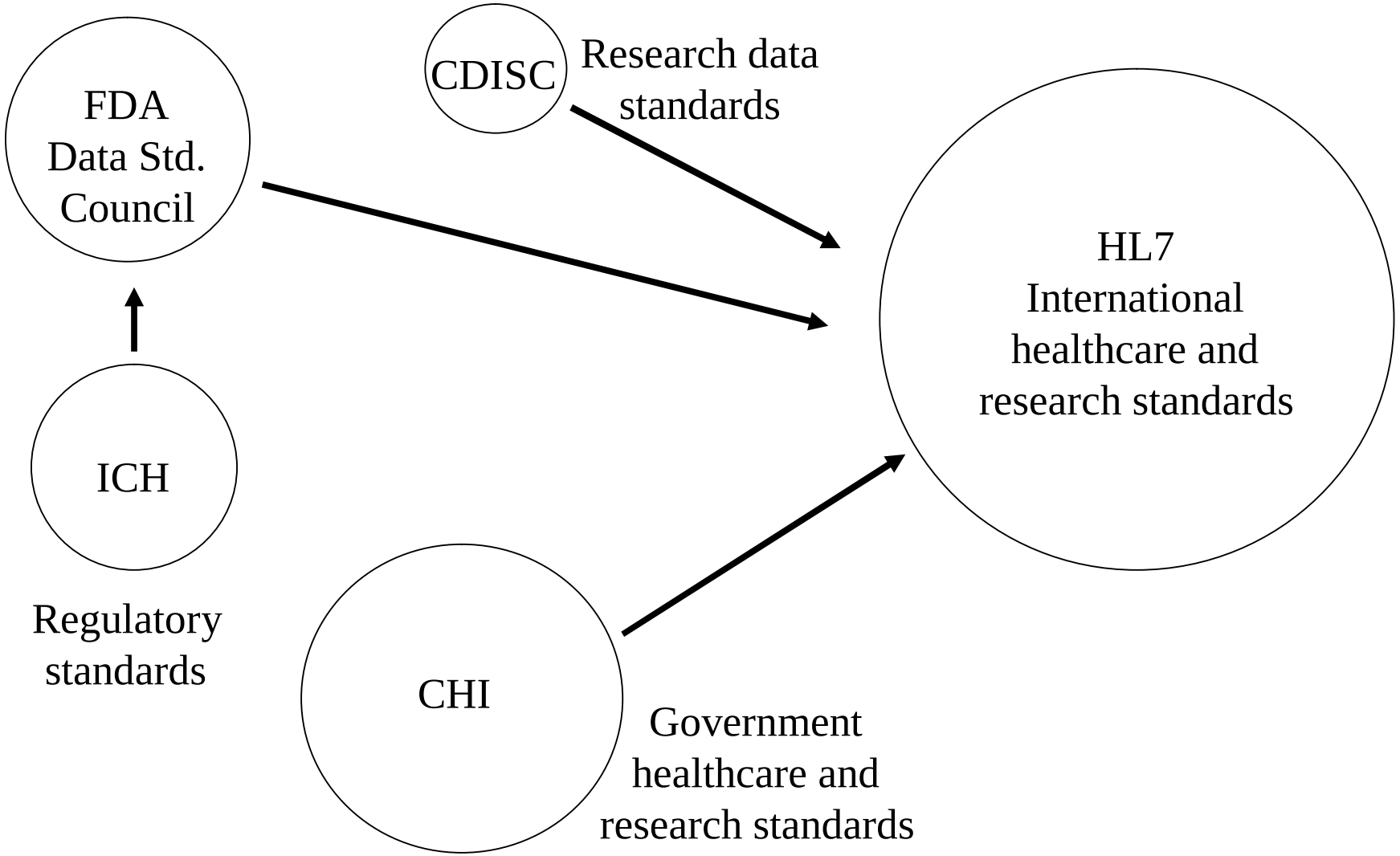
Working group of FDA experts





Standard Development Organization

Standards Organization

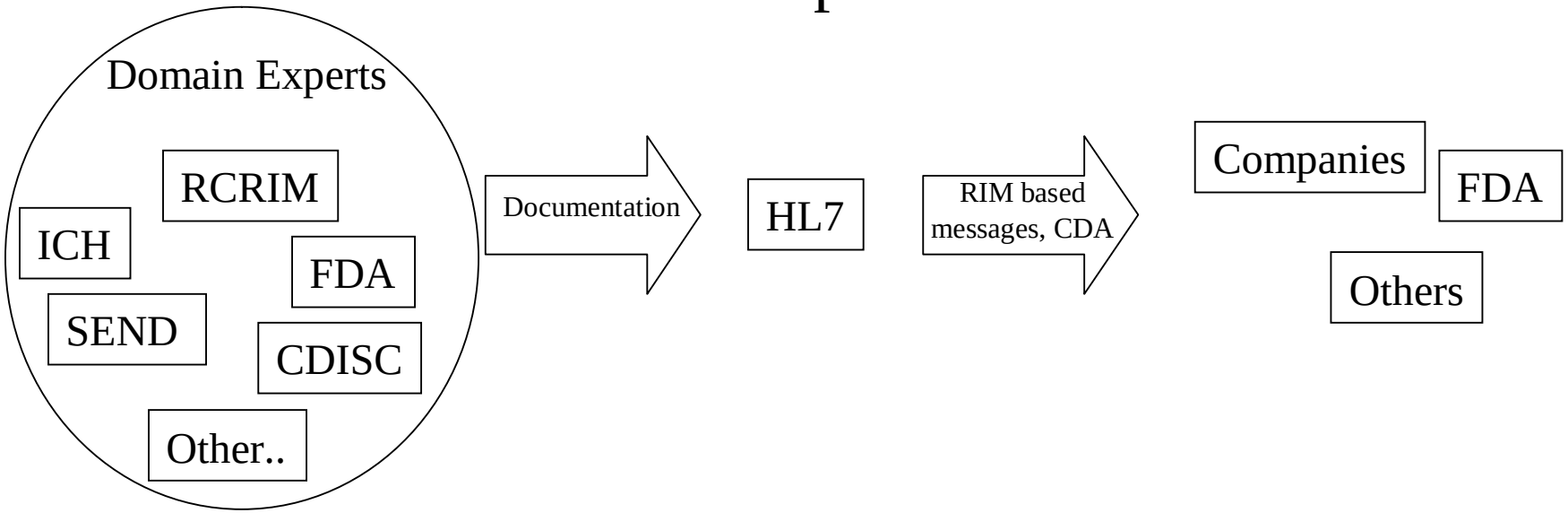


Standards Development

Requirements

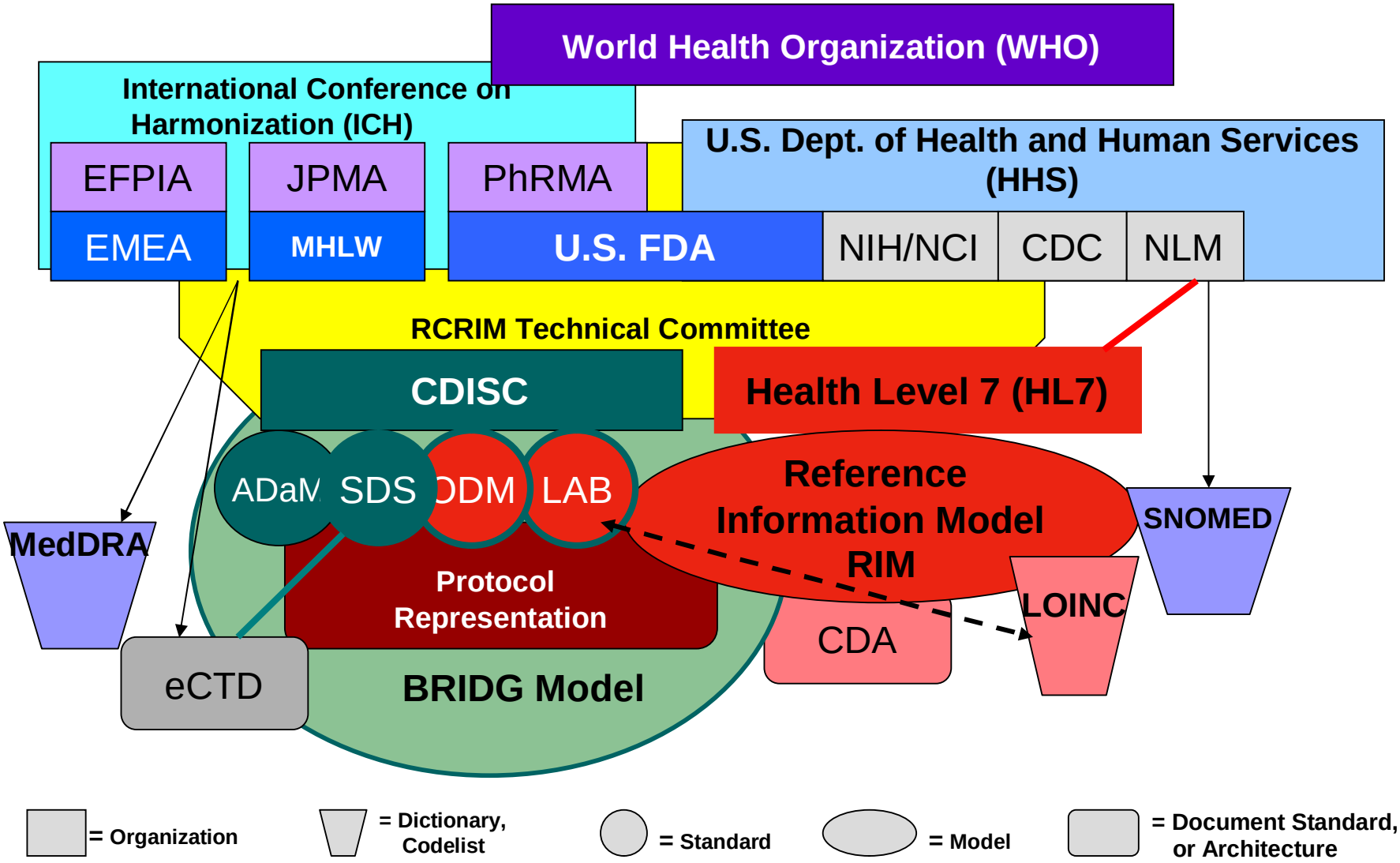
Specification Development

Implementation



"World of Standards" 2005

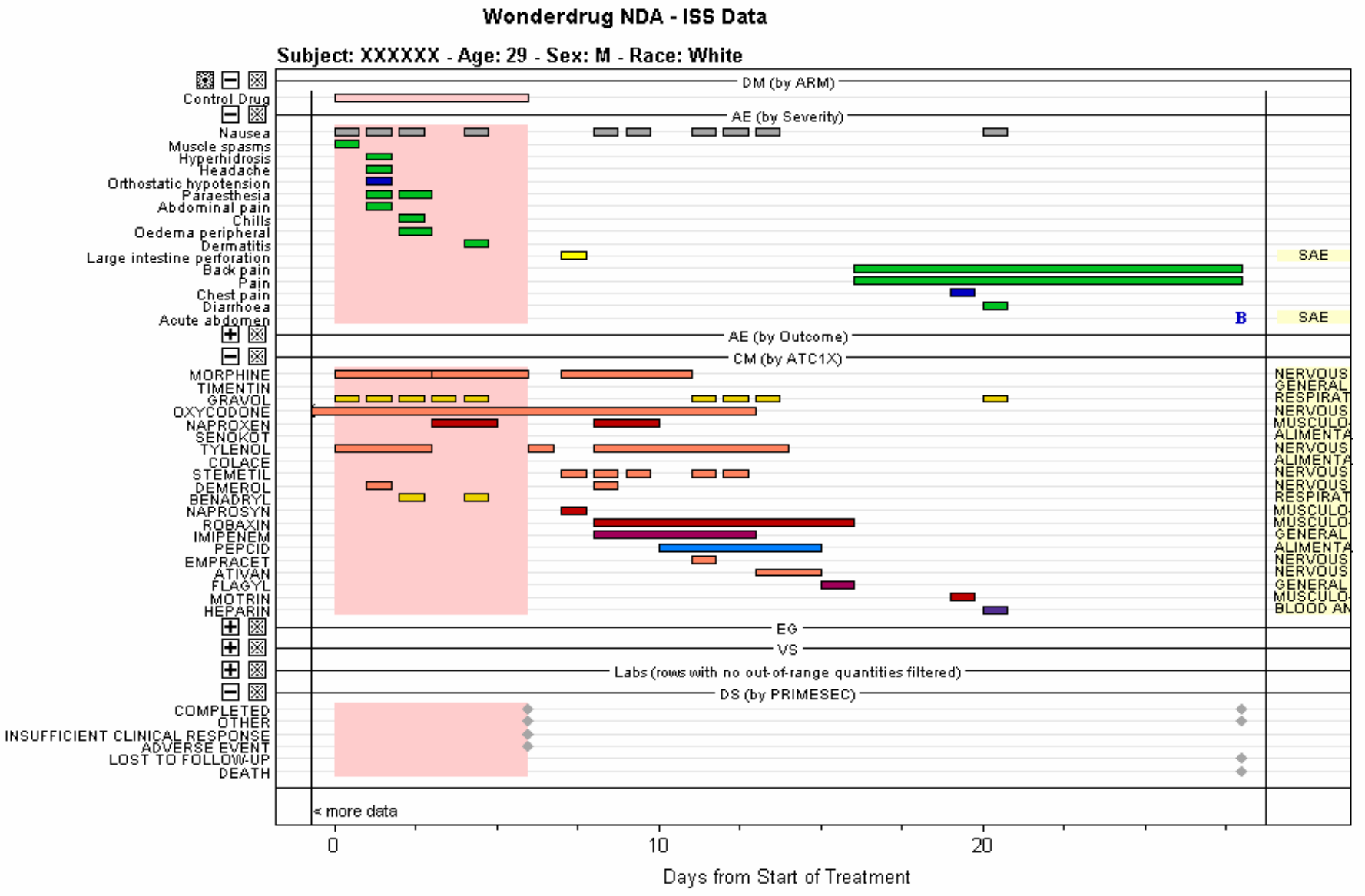
Becky Kush/CDISC Interchange, 2005



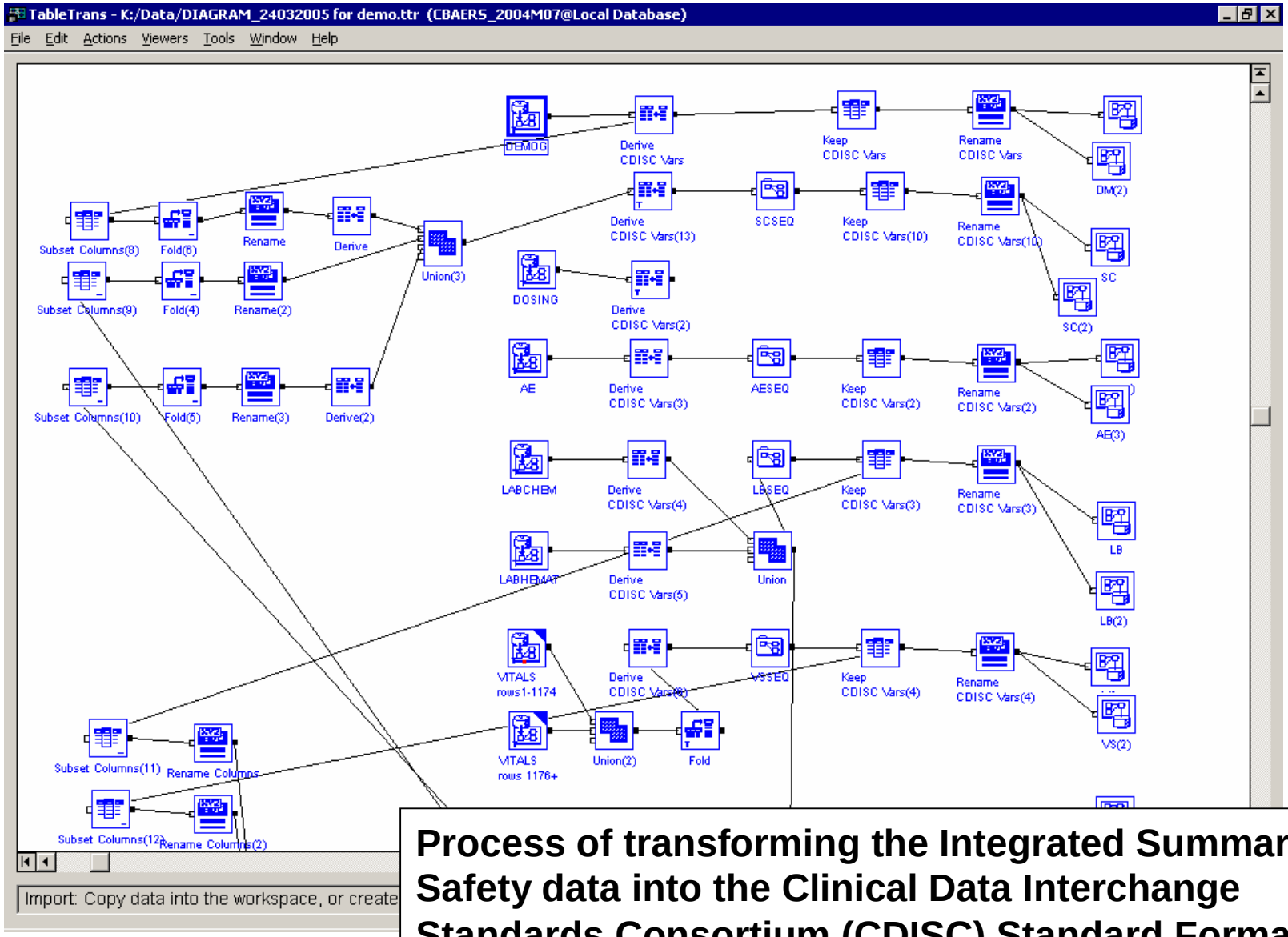
Safety Review & Individual Patient Records

- Patient Profile Viewer
- Do-It-Yourself SDTM

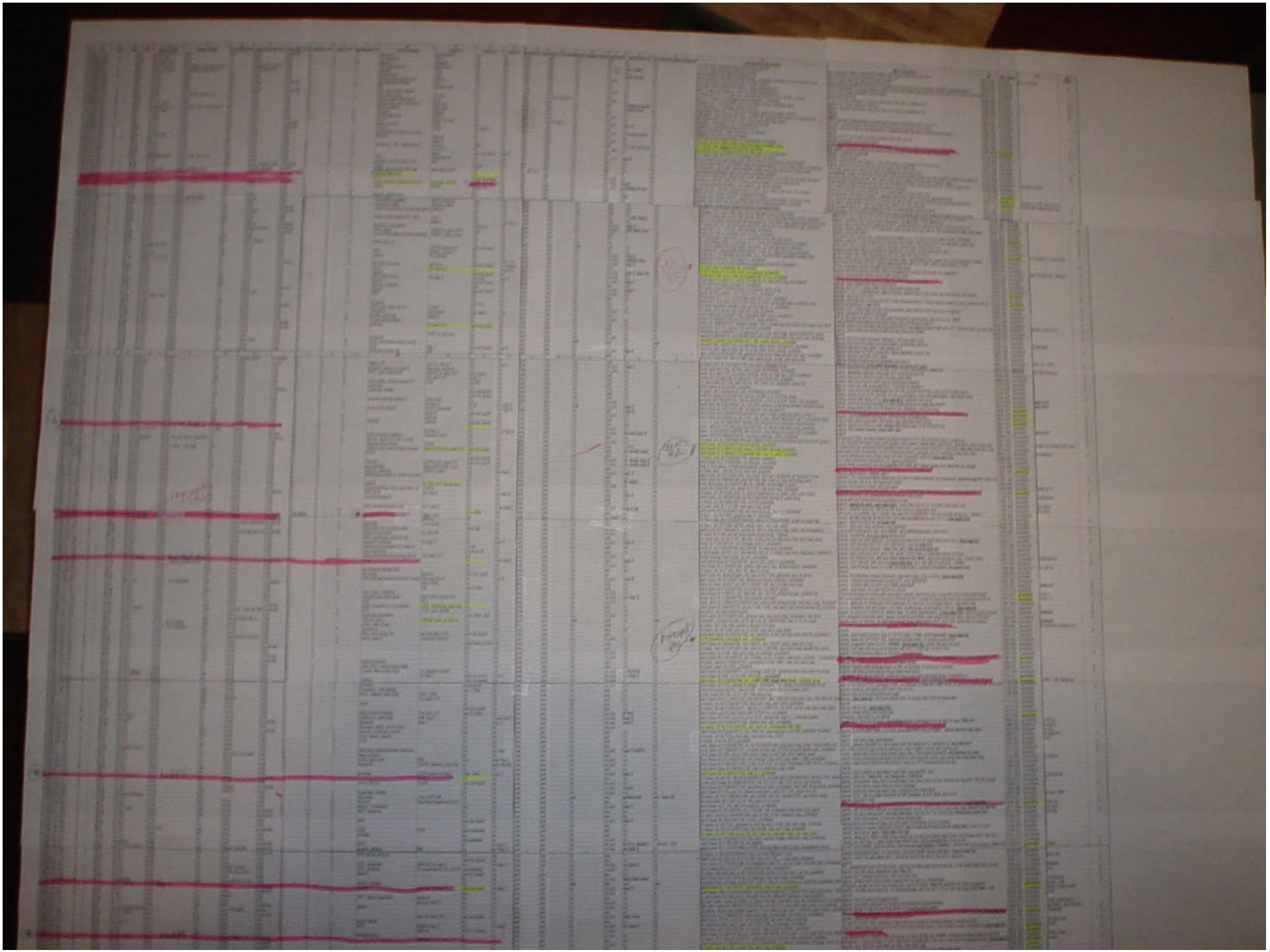
Patient Profile Viewer

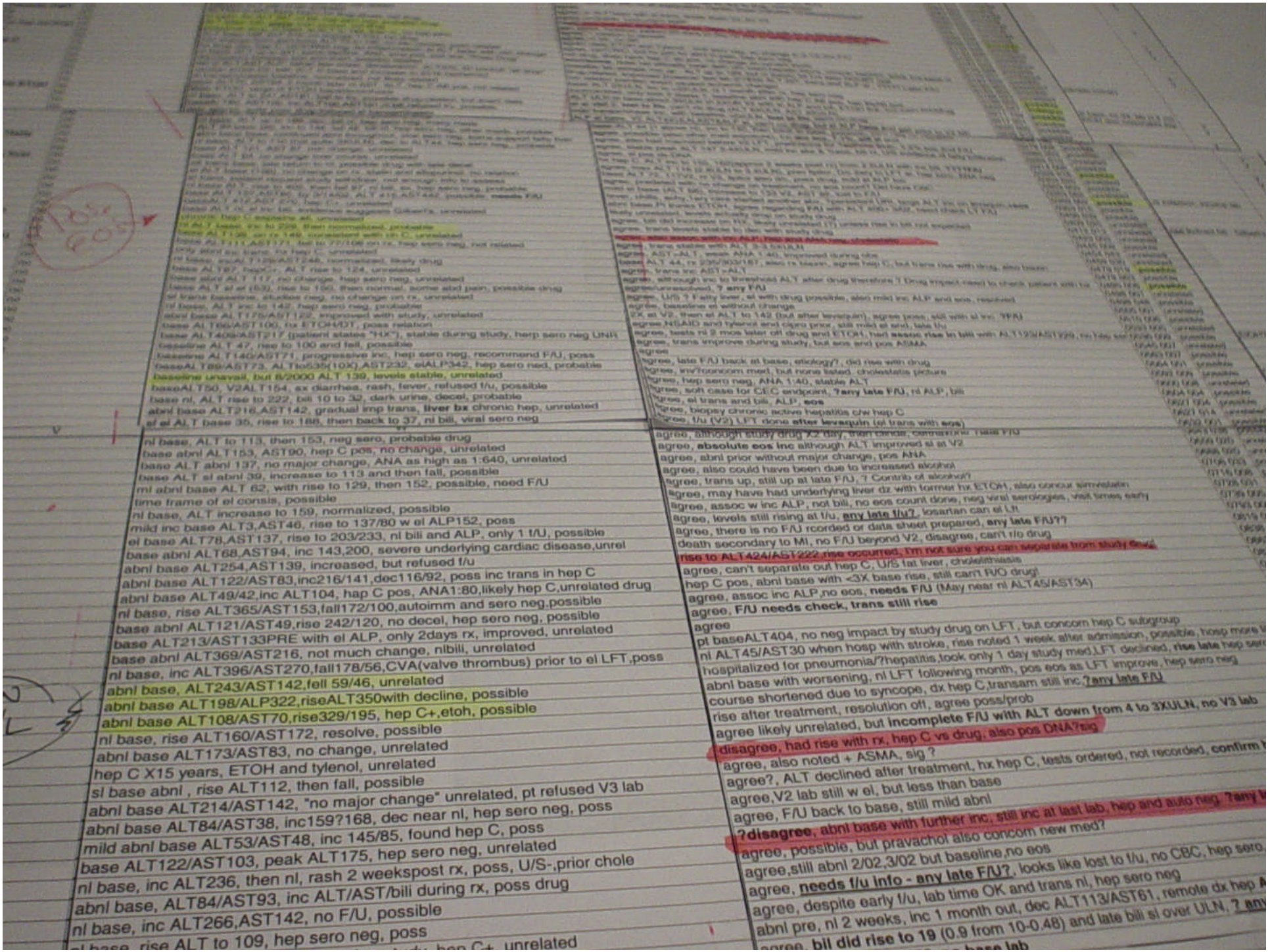


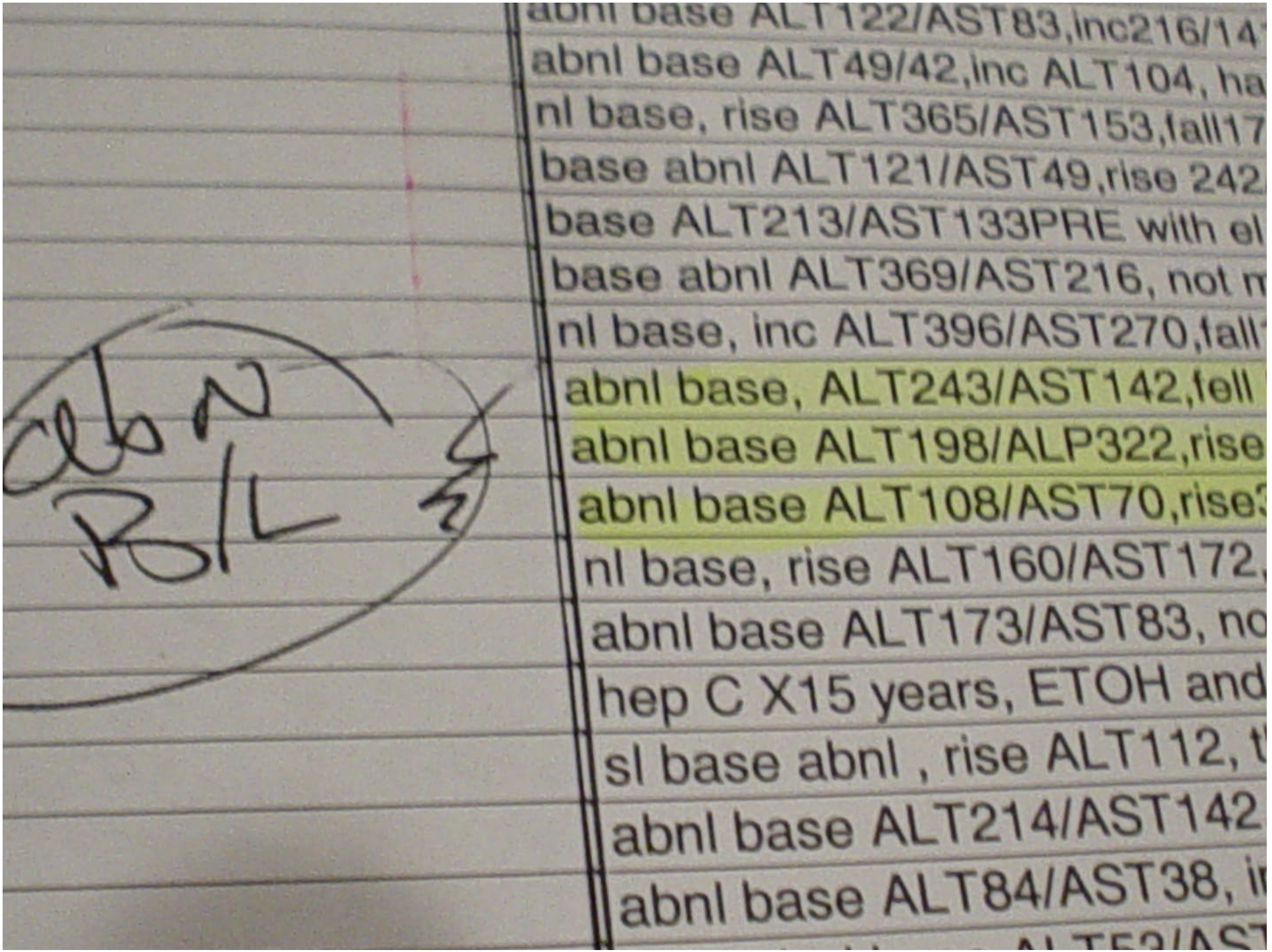
Do-It-Yourself SDTM



Process of transforming the Integrated Summary of Safety data into the Clinical Data Interchange Standards Consortium (CDISC) Standard Format



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base ALT213/AST133PRE with el
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nl base, inc ALT396/AST270,fall
abnl base, ALT243/AST142,fell
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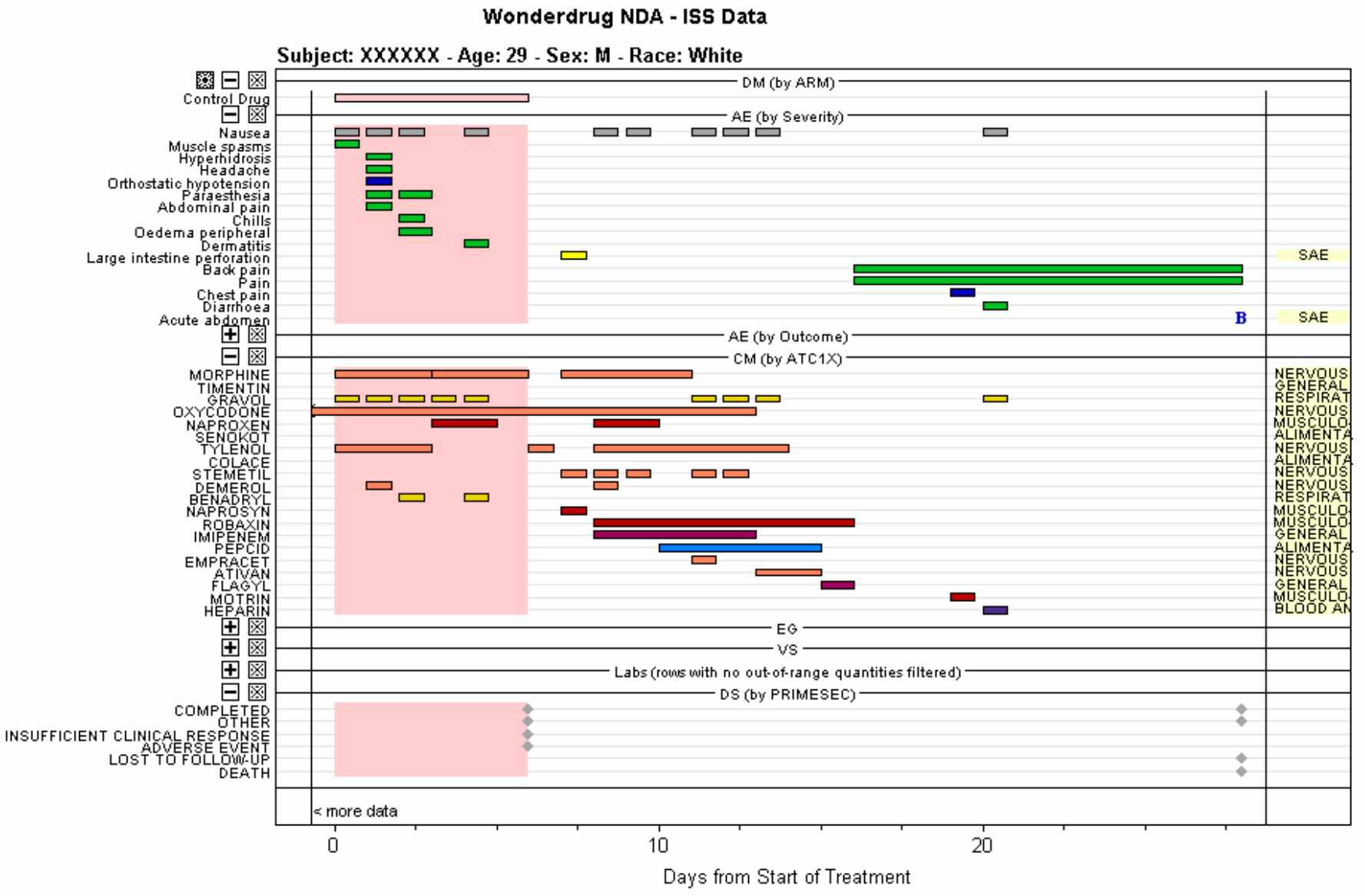
Patient Profile Viewer



Updates/Opportunities

- NCI Janus/CRIX
- CDISC eSDI
- Academic Consortia

JANUS and the Evolution of Data Management

Data

General Purpose Tools

Std Data

Smart Tools

Std Data

Database

Controlled vocabulary

Smart Tools

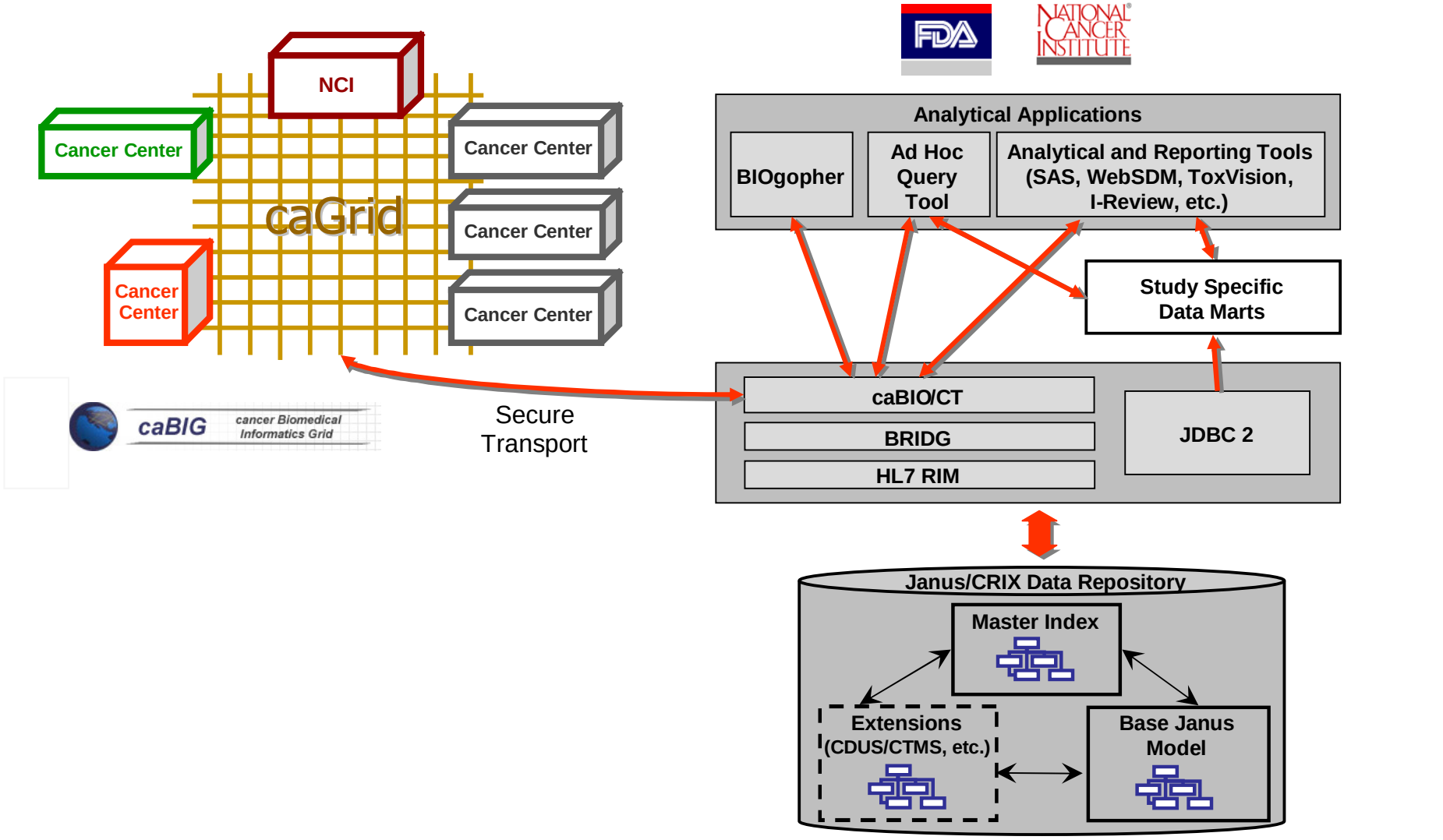
Stockbridge, 2005

Cross-study analyses

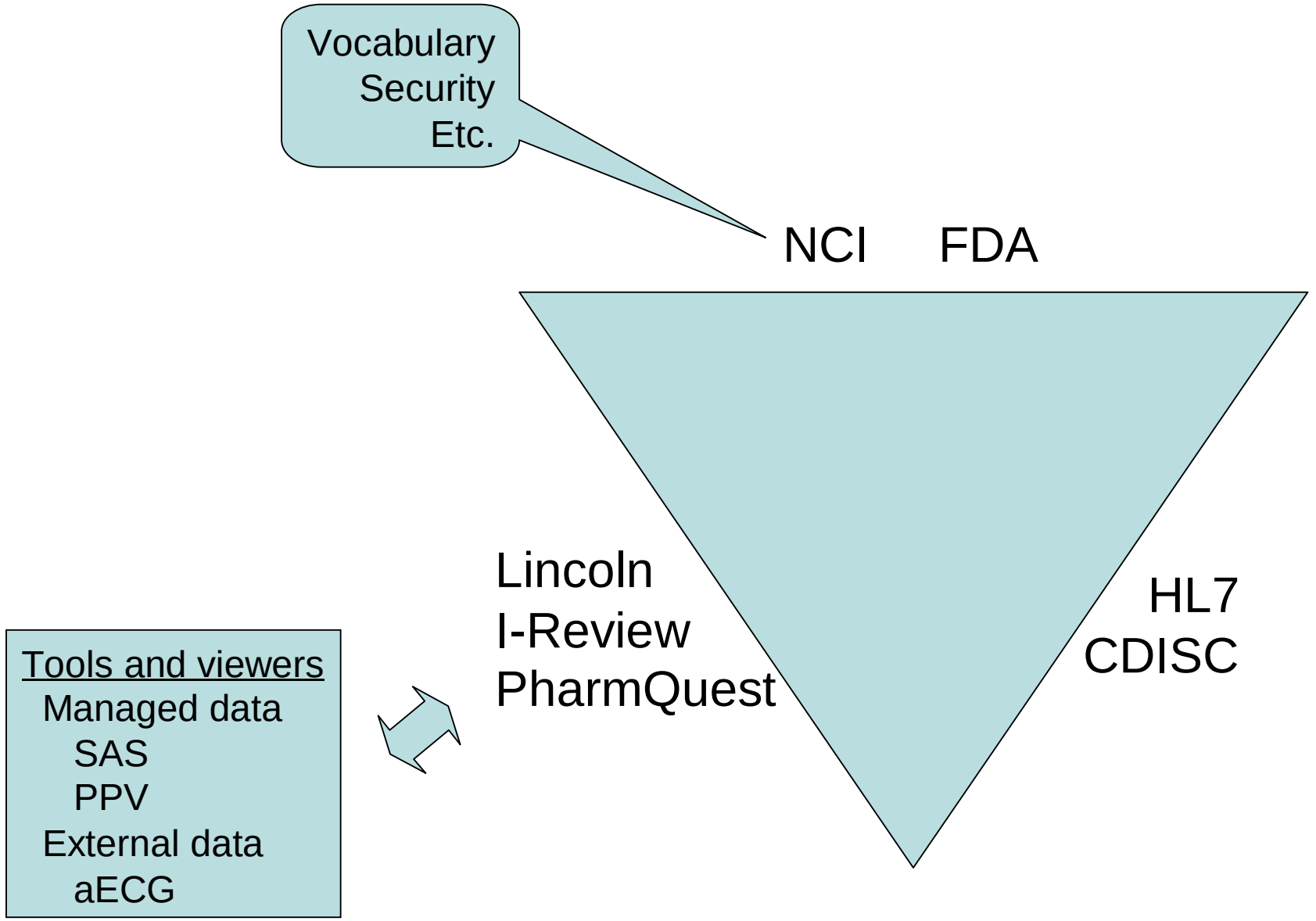
- Integrated demographics
- Integrated safety review
- Historical controls
- Drug class-wide trends
- Disease modeling and other Critical Path Initiative activities

Stockbridge, 2005

CRIX Data Access Vision



Common Security Module (CSM) | Enterprise Vocabulary Service (EVS) | Data Standards Repository (caDSR)


Vocabulary
Security
Etc.
NCI
FDA
Lincoln
I-Review
PharmQuest
HL7
CDISC
Tools and viewers
Managed data
SAS
PPV
External data
aECG

eSource* Data Interchange (eSDI)

- **Purpose of eSDI Initiative**
  - to facilitate the use of electronic technology in the context of existing regulations for the collection of source data in clinical trials for regulatory submission by leveraging the power of the CDISC standards, in particular the Operational Data Model (ODM).
  - "Pave the path towards the vision of 'research at the point of care and care at the point of research' and ultimately to enable information system interoperability to improve medical research and related areas of healthcare, which is at the core of the CDISC mission."
- **Document Posted** for Open Public Review and Comment by 17 October

**Note*: *eSource pertains to eDiaries, ePRO, eDCI, Electronic Health Record*

Requirements

PAPER

- **Requirement 1:** An instrument used to capture source data shall be an accurate representation of the protocol ensuring that the data as specified within the protocol is captured correctly.
- **Requirement 2:** Source data shall be Accurate, Legible, Contemporaneous, Original, Attributable, Complete and Consistent.
- **Requirement 3:** An audit trail shall be maintained as part of the source documents for the original creation and subsequent modification of all source data..

Requirements

- **Requirement 4:** The storage of source documents shall provide for their ready retrieval.
- **Requirement 5:** The investigator shall maintain the original source document or a certified copy.
- **Requirement 6:** The mechanism used to maintain source documents shall ensure that source data cannot be modified without the knowledge or approval of the investigator.
- **Requirement 7:** Source documents and data shall be protected from destruction.

Requirements

- **Requirement 8:** The source document shall allow for accurate copies to be made.
- **Requirement 9:** Source documents shall be protected against unauthorized access.

Electronic

- **Requirement 10:** The sponsor shall not have exclusive control of a source document.

The Critical Path and MIT's Center for Biomedical Innovation

- The **MIT Center for Biomedical Innovation (CBI)** is a new Institute-wide collaboration of faculty from the MIT Schools of Engineering, Management, and Science, the Harvard-MIT Division of Health Sciences & Technology (HST), and their counterparts from government and industry.
- CBI is identifying, researching and enabling the implementation of innovative methodologies and approaches which will transform the discovery, development and distribution of accessible therapeutics, diagnostics and medical devices.
- http://cbi.mit.edu/

CBI Planning Workshop Participants,

June 16-17, 2005

Abbott (Rx)
ALTANA
Amgen
AstraZeneca
Biogen Idec
Boehringer Ingelheim
Bristol-Myers Squibb
Centers for Medicare & Medicaid Services (CMS)
Corning Life Sciences
Food and Drug Administration (FDA)
GE Heathcare
Genzyme
Gene Logic
GlaxoSmithKline (GSK)
Guidant (J&J)
IBM
IMS Health
International Society for Pharmaceutical Engineering (ISPE)
Jackson Laboratory
Johnson & Johnson
Lehman Brothers
Eli Lilly
Massachusetts State Government
Mayo Clinic
Merck
Millennium
National Cancer Institute (NIH)
Novartis
Pfizer
Roche
Schering-Plough
Stryker
Wyeth

THANK YOU

wilsons@cder.fda.gov