PhRMA PRISM Forum

Converging the eHR with CDISC Standards

CDISC®

Setting the Global Standard for Clinical Data

CLINICAL DATA INTERCHANGE STANDARDS CONSORTIUM

Wayne R. Kubick
Sr. Vice President, Lincoln Technologies
CDISC Technical Director
SDS Team Lead

Lincoln TECHNOLOGIES, INC.

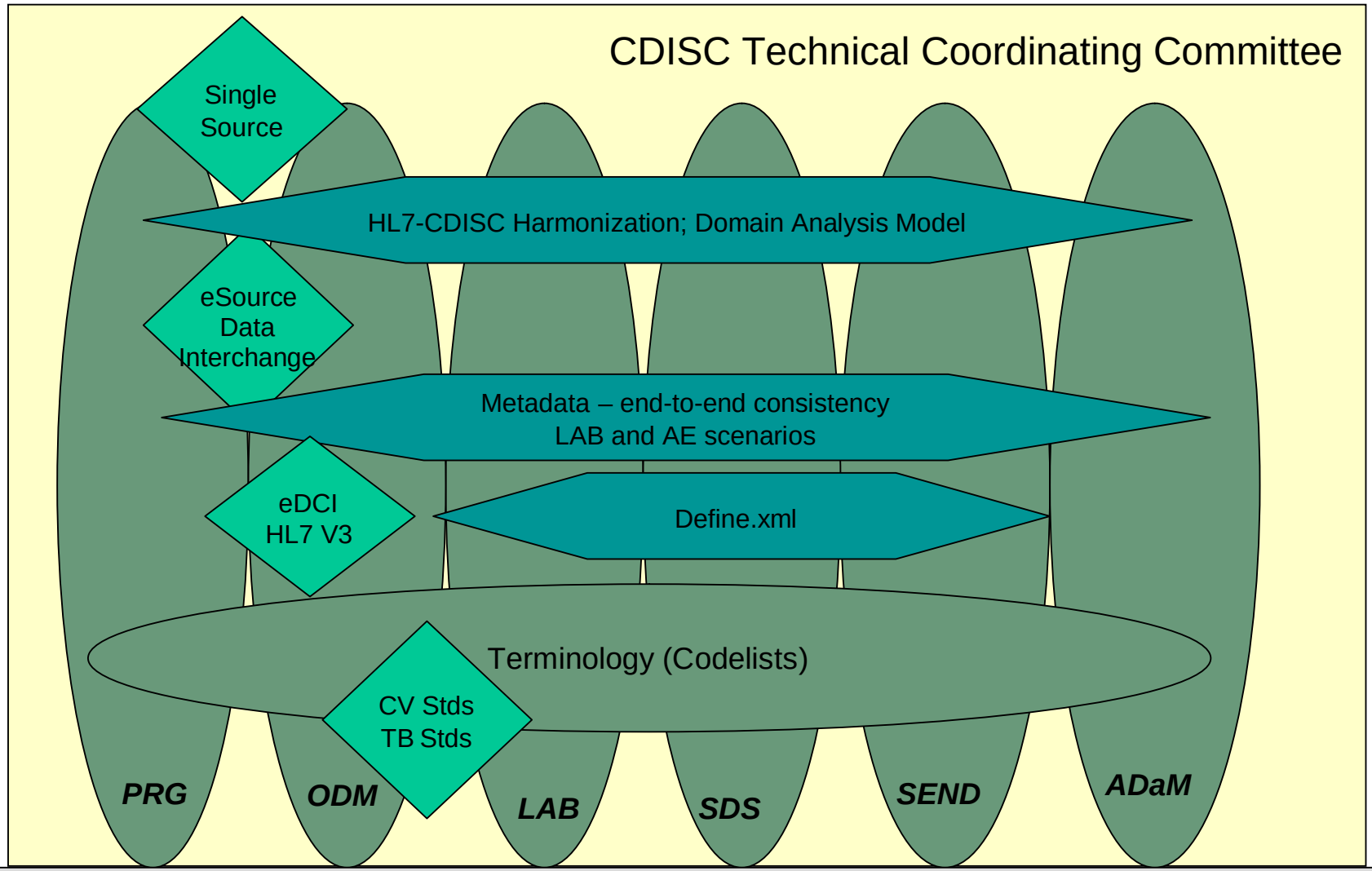
Acknowledgments & Disclaimers

- Notice: This presentation is composed partly of recycled materials
  - Material has been extended and modified for this purpose
- Many slides borrowed with permission of many colleagues: Rebecca Kush, Dave Iberson-Hurst
- Opinions expressed are not necessarily representative of CDISC, Lincoln Technologies, Phase Forward, or even the speaker (who is wont to change his mind)
- The speaker is not an expert on her, so there are unlikely to be any great “Patient Perspective” insights, despite the placement in the agenda.

Topics for Discussion

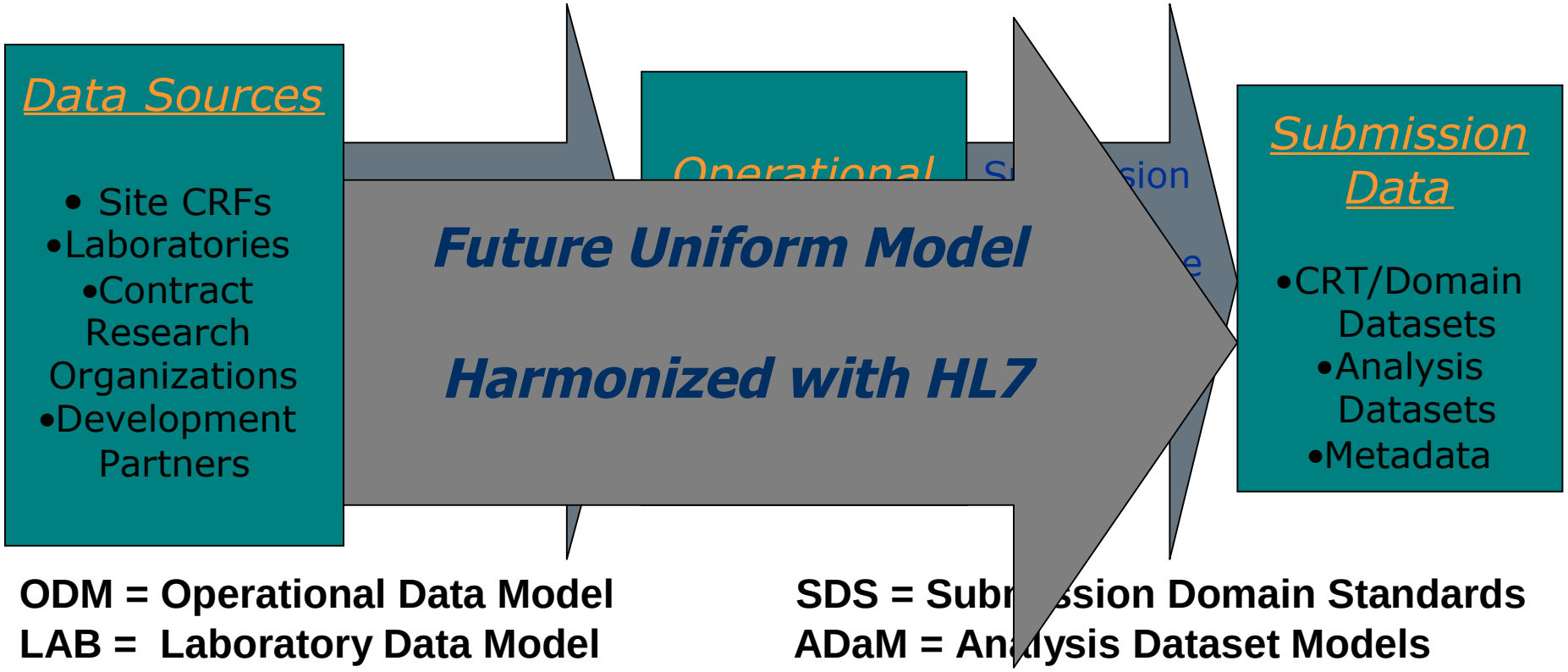
- eHRs and the CDISC Roadmap
- Opportunities to Apply Clinical Research Standards to eHRs
- Benefits and Challenges of Standards to eHR Implementation

CDISC Teams and Projects - 2005



Maintenance, Member Relations, Education and Implementation Groups, Glossary

Scope of CDISC Models



ODM = Operational Data Model
LAB = Laboratory Data Model
Protocol Representation

SDS = Submission Domain Standards
ADaM = Analysis Dataset Models
SEND = Std. Exch NonClin Data
Terminology

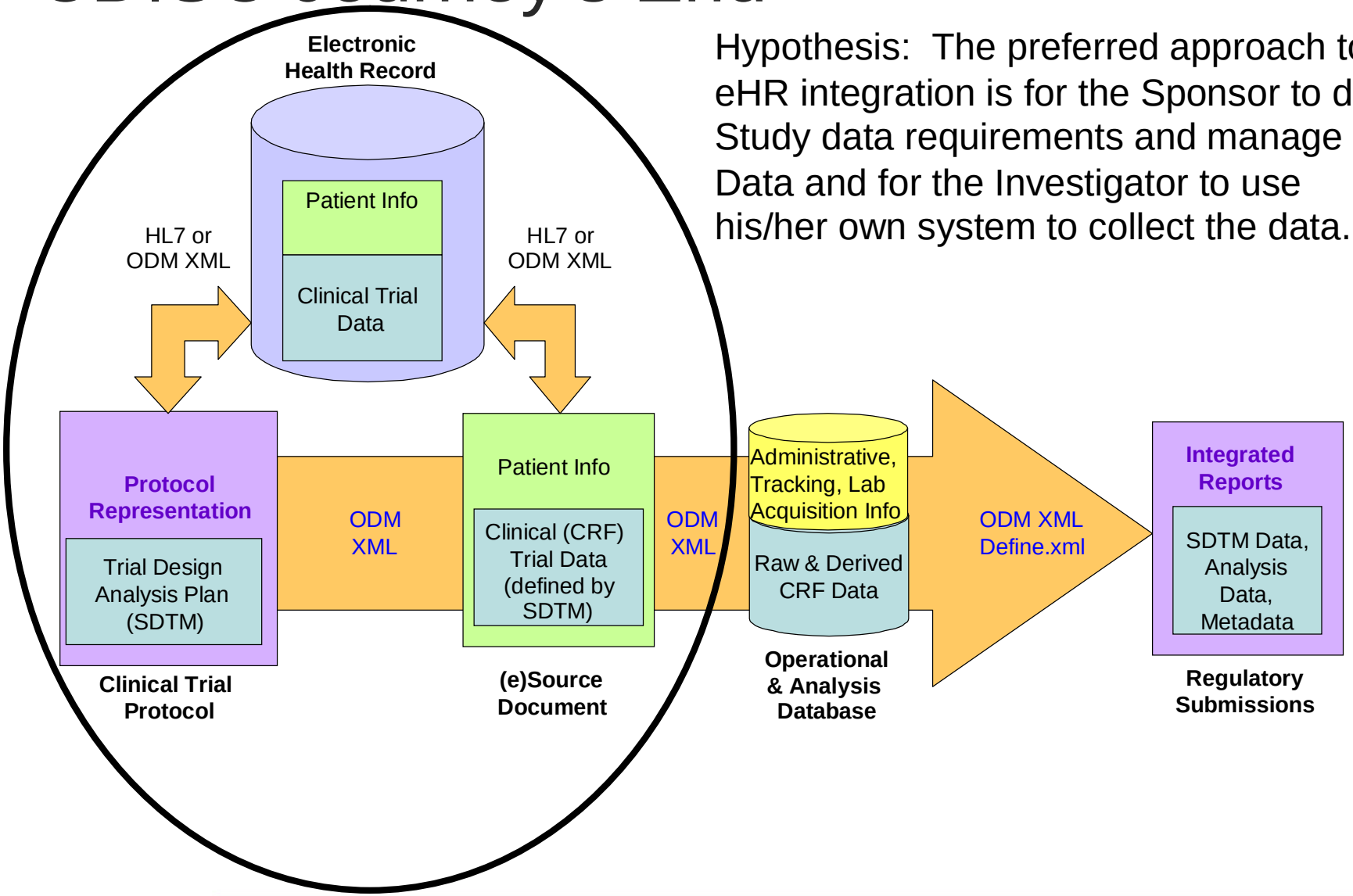
The CDISC Roadmap

- Purpose:
  - To provide a concise, common specification of all technical products to be developed by CDISC.
- Endpoint:
  - By 2008 (2010), there will be a **single CDISC standard** for the full life-cycle of a clinical trial or study from protocol representation through the capture of source data to submission and archive, comprising a set of fully integrated and consistent models which will form logically and organically from our current set.
- Success Criteria
  - **All submissions to the FDA** are being made using the CDISC standard;
  - The set of CDISC models in use across the **full life-cycle of clinical trials**; and
  - The CDISC standard being **globally adopted**.

Roadmap Guiding Principles

- Complete original mission, but focus on harmonization of CDISC models
- A single CDISC standard:
  - ODM XML defines format
    - Maintain Clinical Research scope while mapping to HL7
    - Remain platform-independent and platform-neutral
  - Define.xml describes common metadata
  - SDTM, LAB and AdaM define content
    - Standard ItemGroups and Items
    - Standard business rules and code lists
    - Metadata and information needed to support analysis
- **Alignment with the BRIDG model**
  - **HL7 as portal to healthcare**
- Leverage cross-functional teams
  - Fund projects not just teams, but assign teams as stewards and maintainers
  - Strive to achieve stability and maturity for current standards
- Prioritize processes over separate, individual models
- Support sites, sponsors and FDA as stakeholders.
- Expand Goals to include: Improving patient safety, process optimization, facilitating scientific and regulatory review.

CDISC Journey's End



Hypothesis: The preferred approach to eHR integration is for the Sponsor to define Study data requirements and manage the Data and for the Investigator to use his/her own system to collect the data.

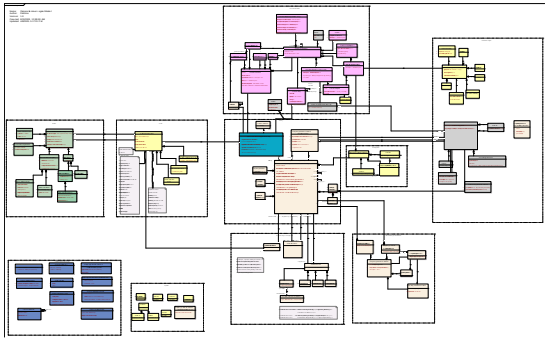
Topics for Discussion

- eHRs and the CDISC Roadmap
- Opportunities to Apply Clinical Research Standards to eHRs
- Benefits and Challenges of Standards to eHR Implementation

CDISC Initiatives Relevant to eHR

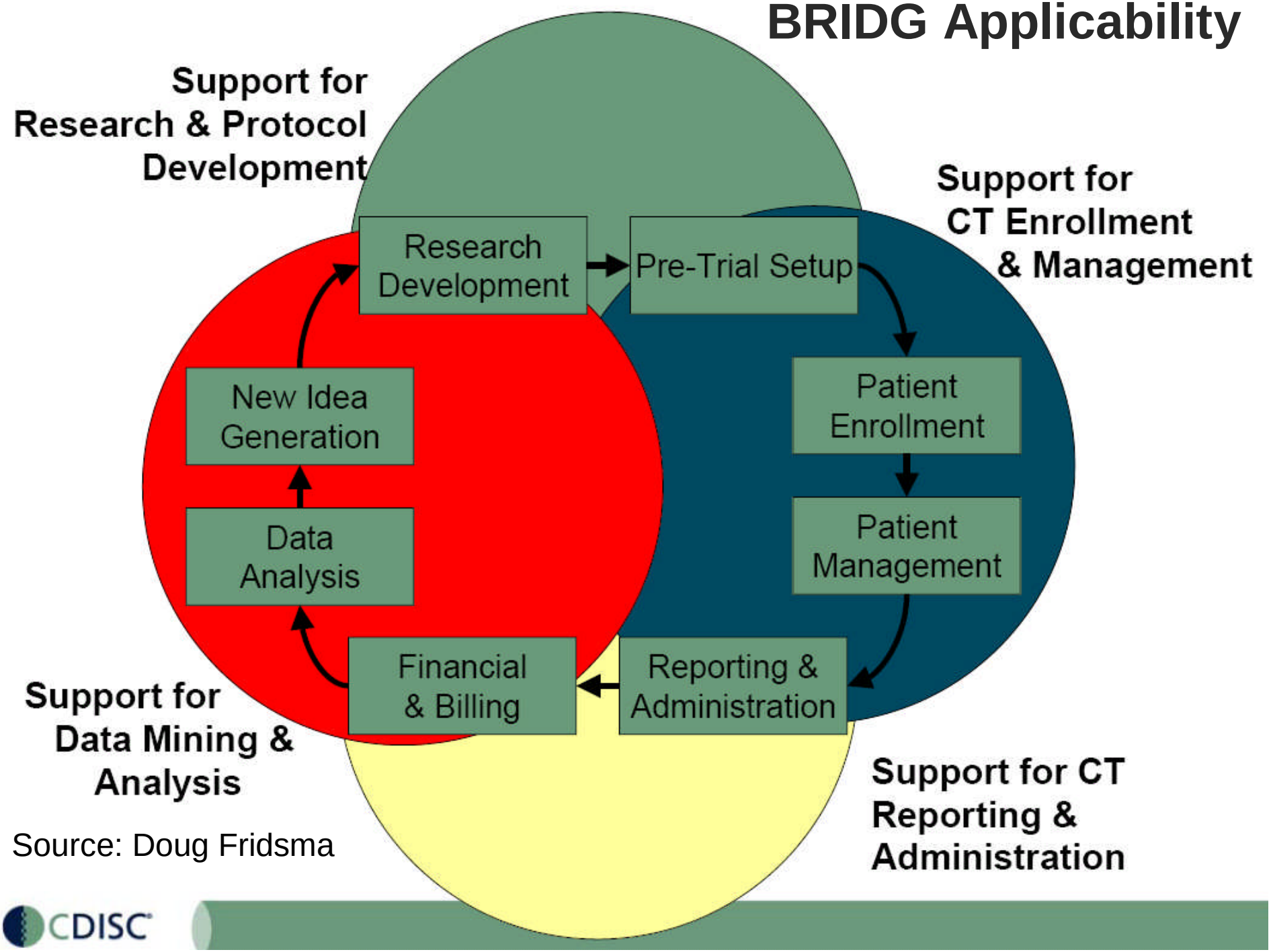
- BRIDG Model
- Trial Design Model and Structured Protocol
- Single Source Proof of Concept Project
- ODM and SDTM standards
- LAB Model/CT LAB HL7 Standard
- Terminology
- eSDI White Paper
- Various other HL7 RCRIM projects (eDCI, aECG, ICSR, etc.)

BRIDG Applicability



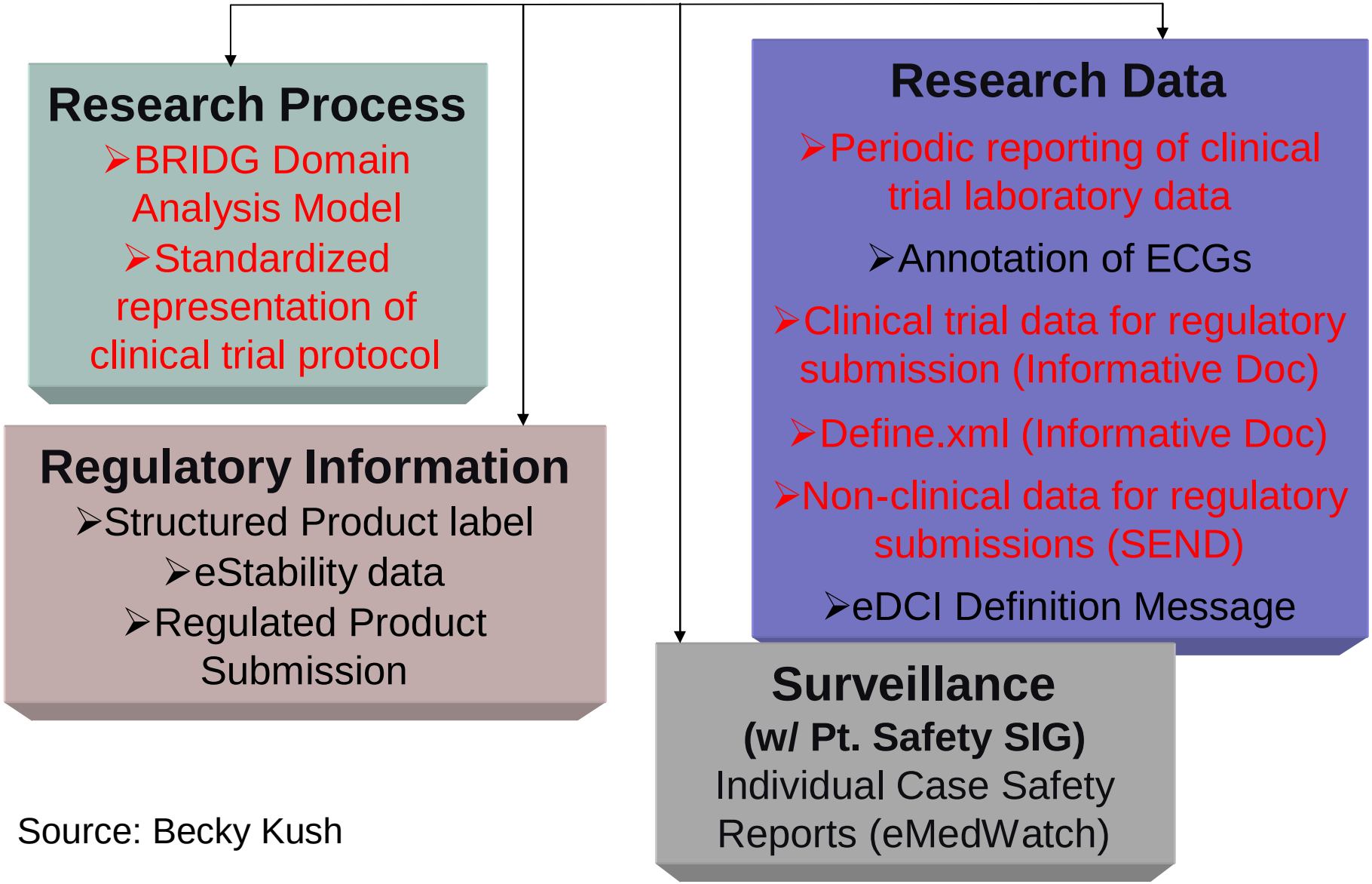
- Common model for Clinical Trial Standards used by CDISC, HL7, NCI
  - BRIDG Model provides context to healthcare world
  - Uses terminology familiar to clinical research in model form familiar to healthcare application providers
- Identifies semantic synergies and disconnects
- Can be used to generate messages and guide application development

BRIDG Applicability



Source: Doug Fridsma

RCRIM: Current Initiatives

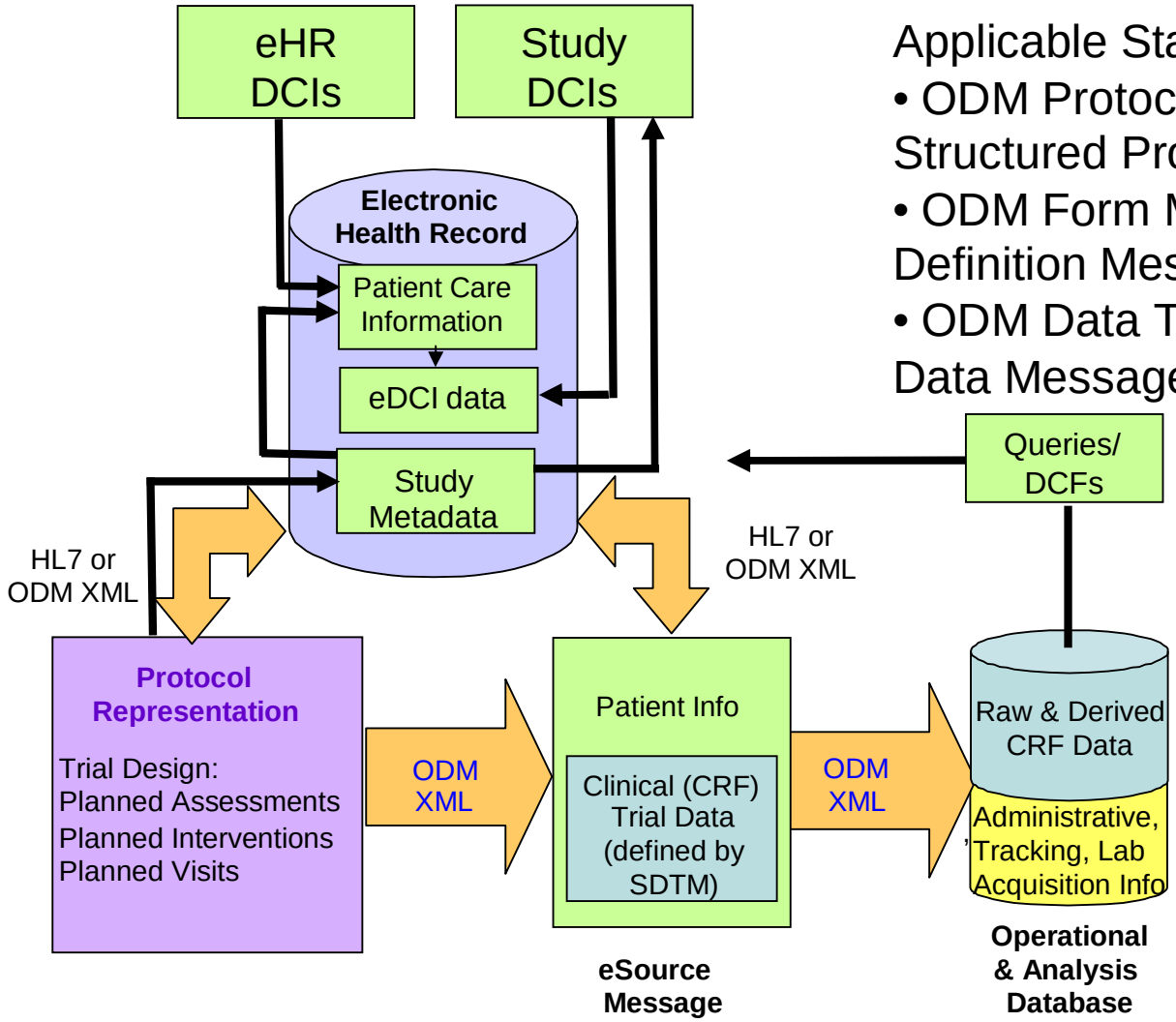


Source: Becky Kush

ODM/eDCI/SDTM Applicability

- ODM Metadata specification defines CDMS setup and data requirements
  - Enables communication of protocol requirements to site and enables validation of data returned
- eDCI will allow interchange of messages one CRF at a time
- ODM audit trail supports use of eSource and defines universal archival format for investigator records
- SDTM observational structure can be adapted to most CRF questions as a common syntax for individual data records
  - Also provides business rules, terminology, context.

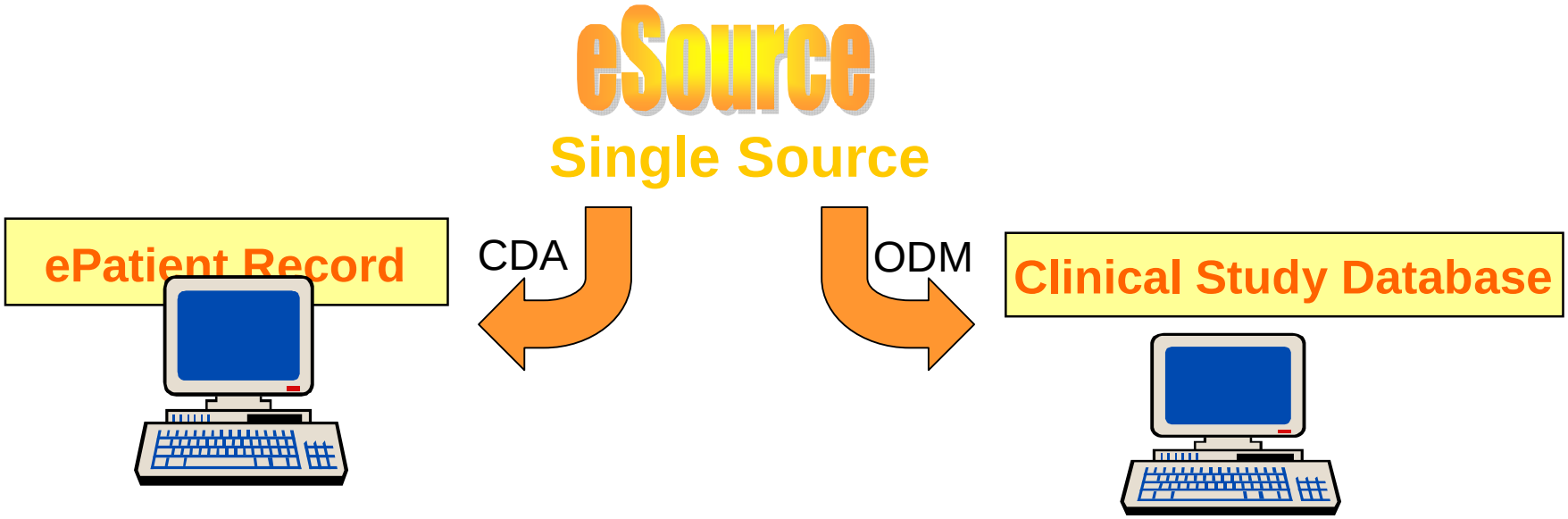
ODM-Centric eHR Scenario



Applicable Standards:

- ODM Protocol Metadata or Structured Protocol Equivalent
- ODM Form Metadata (or eDCI Definition Message)
- ODM Data Transfer or eDCI Data Message

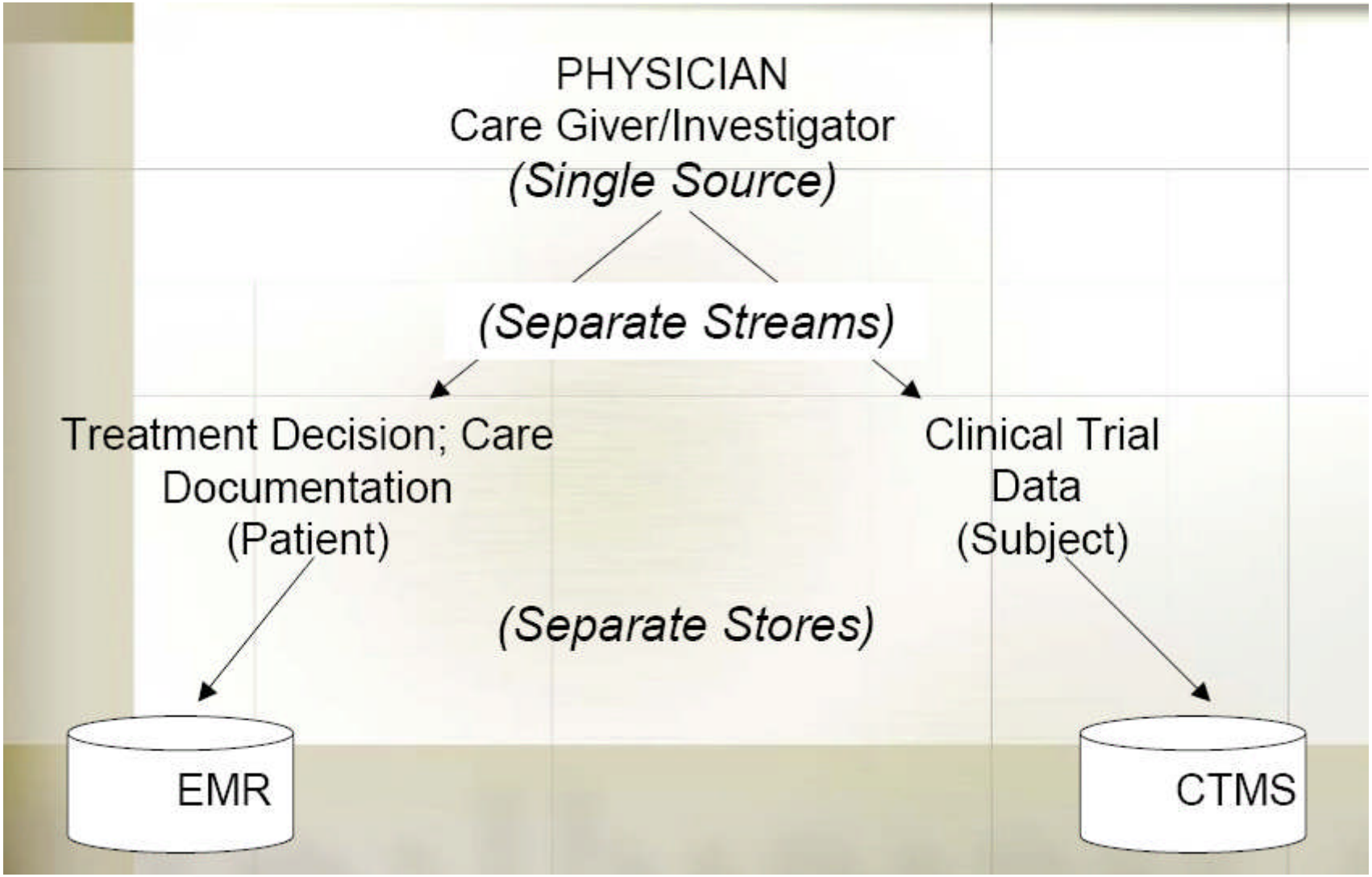
Single Source Proof-of-Concept



- Leverages healthcare (HL7) and research (CDISC) data interchange standards; tool interoperability
- Facilitates investigator workflow; eliminates transcription steps
- Compliance with 21CFR11 and HIPAA feasible
- Enables online monitoring

Source: Landen Bain

Single Source Remix (Landen Bain)



Other Potential Applications

- Improved utilization of recruiting databases
- Potential for automated investigator e-payments
- Potential access to standardized, large-scale, de-identified research databases
  - Common data representation standards will enable expanded data mining, analysis and use for simulation and modeling
- Improved post marketing data
  - Automatically generated ICSRs
  - Access to de-identified databases on prescribing practices and results
    - Reduced medication errors, improved compliance

Topics for Discussion

- eHRs and the CDISC Roadmap
- Opportunities to Apply Clinical Research Standards to eHRs
- Benefits and Challenges of Standards to eHR Implementation

Infrastructure Requirements

- Common technical services architecture
  - E.g., XML/web services -- the easy part
- Regulatory compliance at sites
  - E.g., authentication (SAFE), Part 11 audit trail and controls, validation
- Common agreement on more robust standards
  - Enhanced metadata for trial design and data collection plans
  - Metadata for form presentation
  - Expanded application functionality: edit check, skip logic, etc.
  - Common process requirements and workflow/business process modeling language
  - Common 2-way interchange standards (CDISC ODM and/or HL7)
  - CDMS functionality (study design, data management, clarification, aggregation)
- Common or fully translatable terminologies

Potential Benefits

- Relevant, high quality data could be harvested from eHR systems without transcription
  - Assuming cooperation/acceptance by eMR vendors
- Additional non-eHR CRF data could be collected using the Investigator's own system
  - Eliminate 1 laptop per study legacy perception
  - Maximize system learning curve; minimize disruptions and start-up challenges
- Reduce learning curve and ease of technology adoption
- Interoperability capabilities can unleash many more future synergies

Challenges

- Other eHR priorities are more likely to dominate
  - Clinical Research not a primary goal of health care
- Much clinical research data (AEs, efficacy, exposure) is not typically found in eHR systems
  - eHR data not likely to match overall protocol requirements
  - Incremental data specific to studies nearly always required
  - Regulated clinical research processes not integrated with health care processes
- What/who drives site provisioning and data reconciliation processes?
- Progress and agreement on standard terminologies
- Rollout and time to adoption
  - Many vendors with, staggered support for standards.

What Needs to Happen?

- Progress on many fronts:
  - Completion and adoption of pre-requisite standards:
    - CDISC Protocol/Trial Design, ODM, eDCI, Terminology
    - Messaging standards (HL7 or ODM)
- Agreement on approach within pharmaceutical research community (sponsors, regulatory, sites)
  - A cooperative consortium approach could accelerate progress
- Support from eMR and EDC vendors
  - EDC/CDMS vendors need to produce study design metadata in a consistent standard format and process external data interchange transactions
  - EMR vendors need to interpret incremental data requirements and collect, transmit and process protocol-driven research data in addition to primary care data
- Technology and process infrastructure to run this.