CLINICAL DATA INTERCHANGE STANDARDS CONSORTIUM

Setting the Global Standard for Medical Research

Strength *through Collaboration*

CDISC: A Global Approach to Accelerating Medical Research

Overview

- Enabling Collaboration
- What is CDISC?
- Business case for using CDISC standards
- Brief (non-technical) Introduction to the CDISC Standards/Models
- Example: End-to-end use of CDISC Standards
- The Future -
  - SHARE
  - Healthcare Link

Enabling Collaboration

Broad Definition of Clinical or Medical Research

Patient-oriented research is research conducted with human subjects (or on material of human origin such as tissues, specimens, and cognitive phenomena) in which a researcher directly interacts with human subjects.

- epidemiologic and behavioral studies
- outcomes research
- health services research
- research on mechanisms of human disease, therapeutic interventions, clinical trials, and development of new technologies
- does not include in vitro studies using human tissues not linked to a living individual.

For the purpose of this course, studies with animals are also addressed.

Information from healthcare (private, aggregated) to enable research

Healthcare

- Quality healthcare
- Informed decisions
- Personalized medicine
- Patient safety and privacy
- Public health
- Improved therapies
- Efficiencies/reduced costs

Research

- Discovery of new therapies
- Understanding diseases
- Testing/comparing therapies (CER)
- Assessing efficacy
- Monitoring safety
- Understanding responses (genomics, biomarkers)
- Public health/quality evaluations
- Post-marketing surveillance

Research findings to inform healthcare decisions

A Learning Health Care System

Medical Research

- Research informs health care decisions
- Approximately $100B spent annually on medical research in the U.S. alone and significantly more on a global basis.
- Data requirements for clinical research overlap substantially with clinical quality, safety and efficacy use cases.
- Health care and clinical research need to have consistent standards.
- Medical research needs a process transformation

Clinical Care Decisions

Clinical Research Today

- ~ 40-50% of trials - data collected on paper and are entered, re-entered or transcribed 4-7 times total, 2-3 times by the clinicians
- ~50-60% of data are collected by electronic systems
- An average active study site has 3 disparate solutions; many have up to a dozen or more

Implications:

- Lag (~ 17 years!) between research results and translation into clinical practice
- Clinicians may not participate in research due to administrative burden
- Insurance companies may be first to spot safety issues

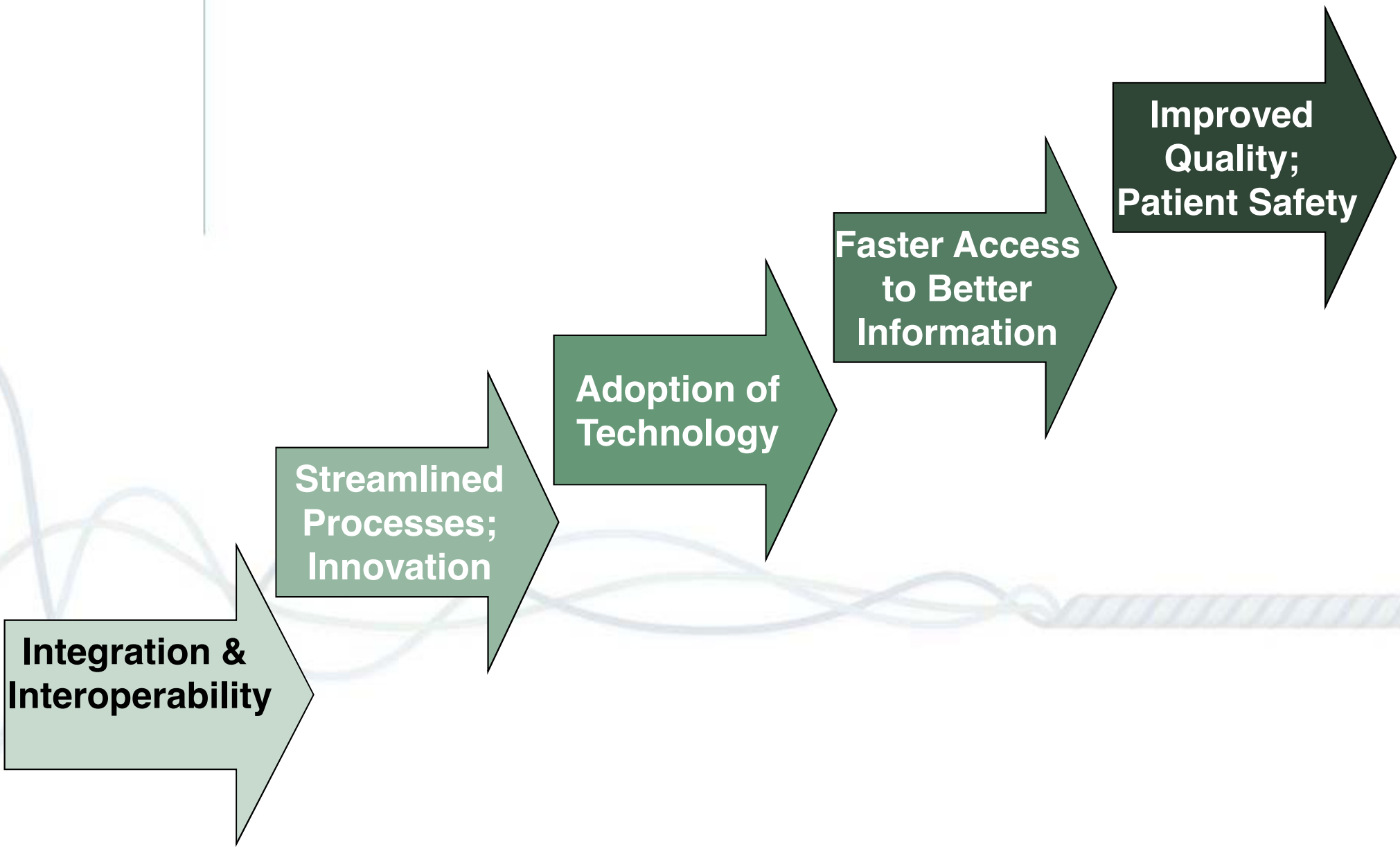
The "Road" to Quality Clinical Data

- Build quality into the system – up front
- Train and educate
  - site personnel, project team and reviewers/auditors
- Decrease the amount of data collected
- Define the data set needed and specify requirements
- Standardize formats and procedures
- Also plan for data quality during post-marketing
- Decrease the number of times data are 'handled'

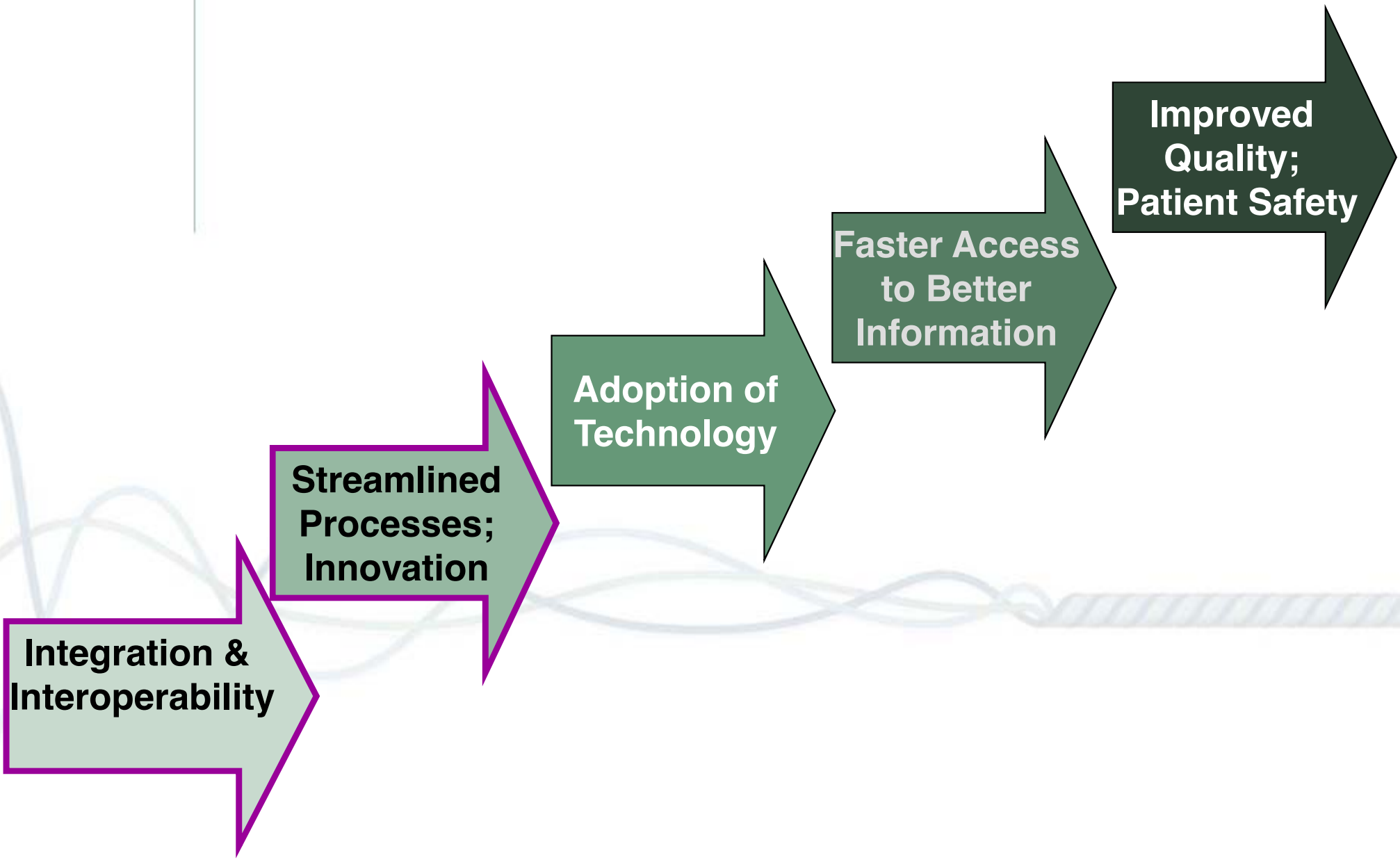
(Note: Anticipated 'by-products' of these steps to improve quality are increased efficiency and lower costs.)

Source: Assuring Data Quality and Validity in Clinical Trials for Regulatory Decision Making: Workshop Report, 2000

Ultimate Goal for Medical Research



What Can Standards do Towards this Goal?



What is CDISC?

Quality Improvement

Enablers

CDISC is more than Standards!

Speed

Process Redesign

Workflow Integration

Standards-inspired Innovation

Resource Savings

Strength through collaboration

The CDISC Mission

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

As of 2004

CDISC®

Strength *through collaboration*

Vision – Medical Innovation

Subject Data – Enter Once for Multiple Purposes

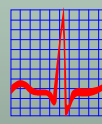
"Rolling" Warehousing, Reporting and Submissions

Data Sources

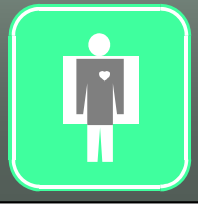
EDC

EHR

ECG



X-RAY

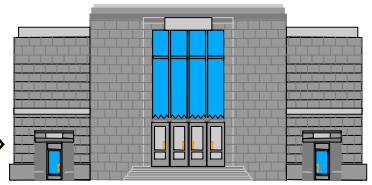


LAB

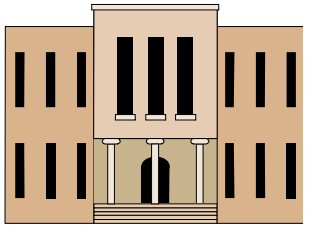
Regulatory Authority

Public Registries and IRBs

CDISC Standards Real-time Integration



Sponsor



CRO or Partner

Payer

CDISC

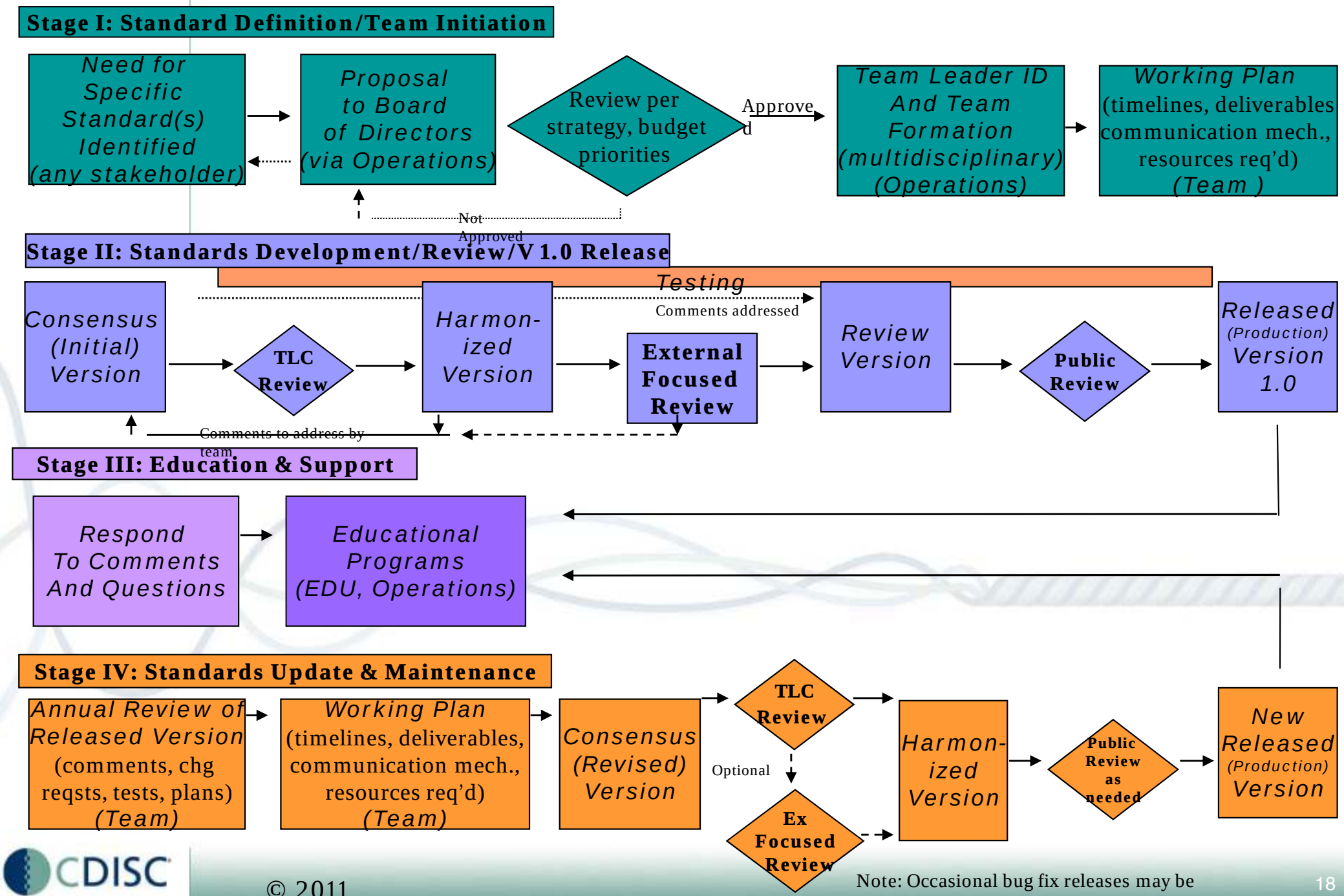
- **Global, open, multi-disciplinary, vendor-neutral non-profit standards developing organization (SDO)**
  - Founded in 1997; incorporated in 2000
  - > 260 organizational members (academia, biopharma, service and technology providers, etc)
  - Liaison A Status with ISO TC 215
  - Charter agreement with HL7 since 2001
  - Member of Joint Initiative Council for Global Harmonization of Standards
  - Member of ANSI-led ISO TAG
  - Active Coordinating Committees
    - Europe, Japan, China, Korea
  - Over 60 countries in participant database

www.cdisc.org

- Through a consensus-based approach (COP-001), CDISC has established worldwide industry standards to support the electronic acquisition, exchange, submission and archiving of clinical research data and metadata to improve data quality and streamline medical and biopharmaceutical product development and research processes.

- Standards are freely available on the CDISC website (www.cdisc.org); IP Policy to ensure open standards

CDISC Standards Development Process (COP-001)



Note: Occasional bug fix releases may be issued as needed with team review only.

COP-001 CDISC
Stages of Standards Development Process

Stage I: Standard Definition/Team Initiation

Stage II: Standards Development/Review/V 1.0 Release

Stage III: Education & Support

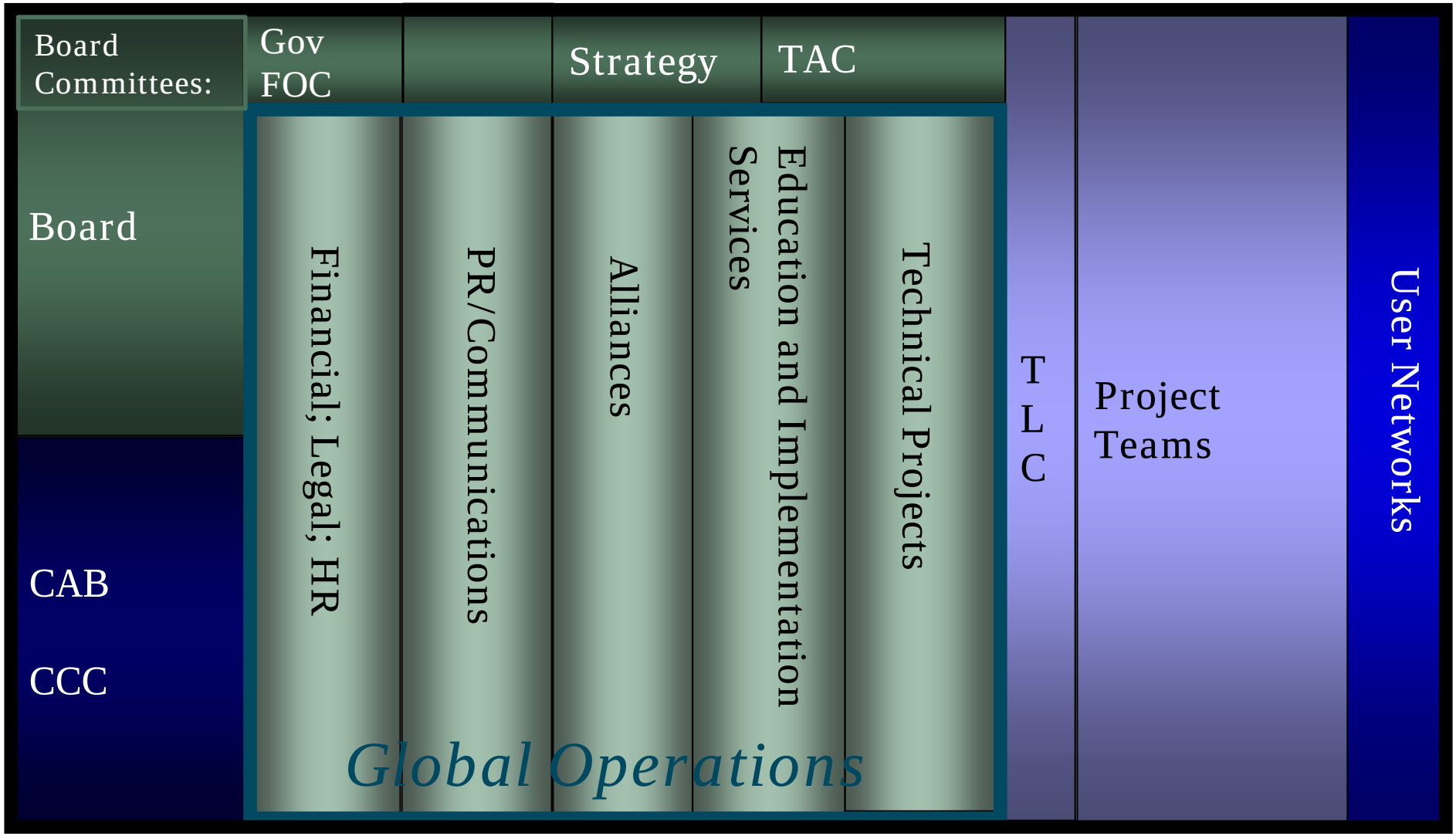
Stage IV: Standards Update & Maintenance

CDISC Organization

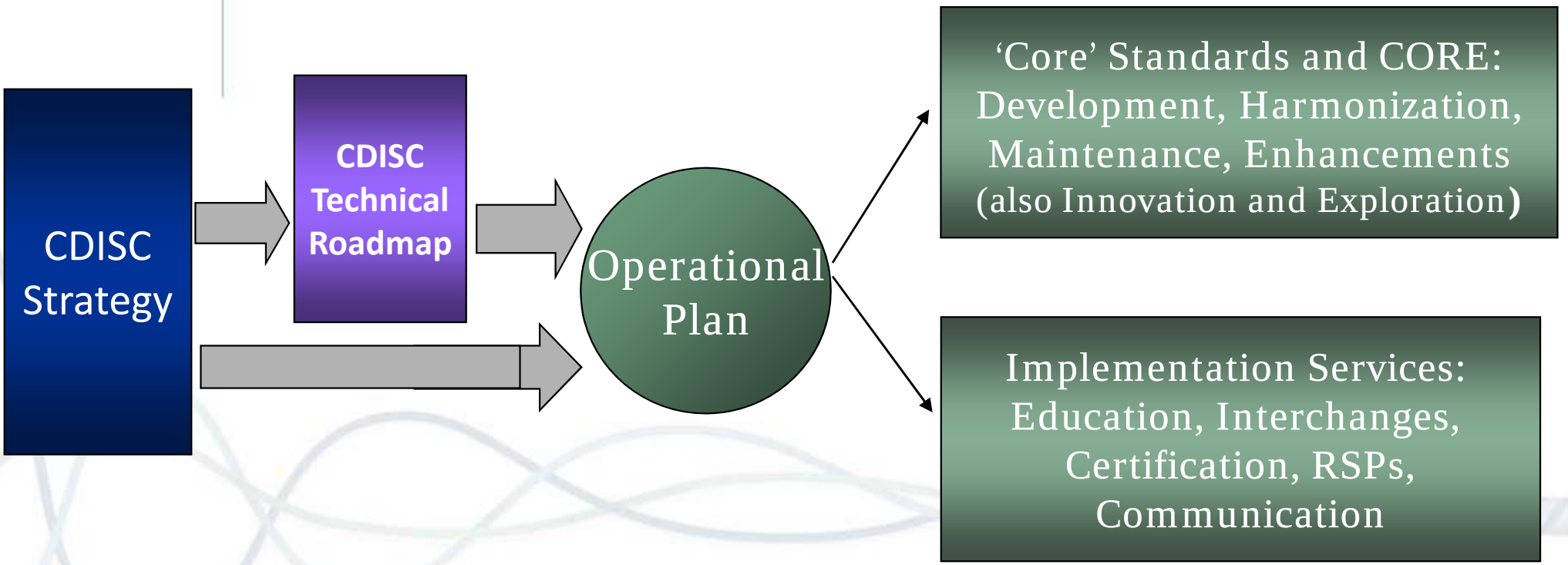
- Volunteer participants and team members
  - CDISC Teams: Anyone can participate
  - 3 Cs (CDISC Coordinating Committees)
  - User Networks (regional, often language-centered)

- Technical Leadership Committee
  - Team leaders and co-leads
  - Oversees the standards development and implementation across Focus Areas and project teams

Organizational Structure to Support CDISC Operational Plan



CDISC Strategy to Implementation/Support



Strategy 2010 (+5y) Document

Technical Roadmap Document

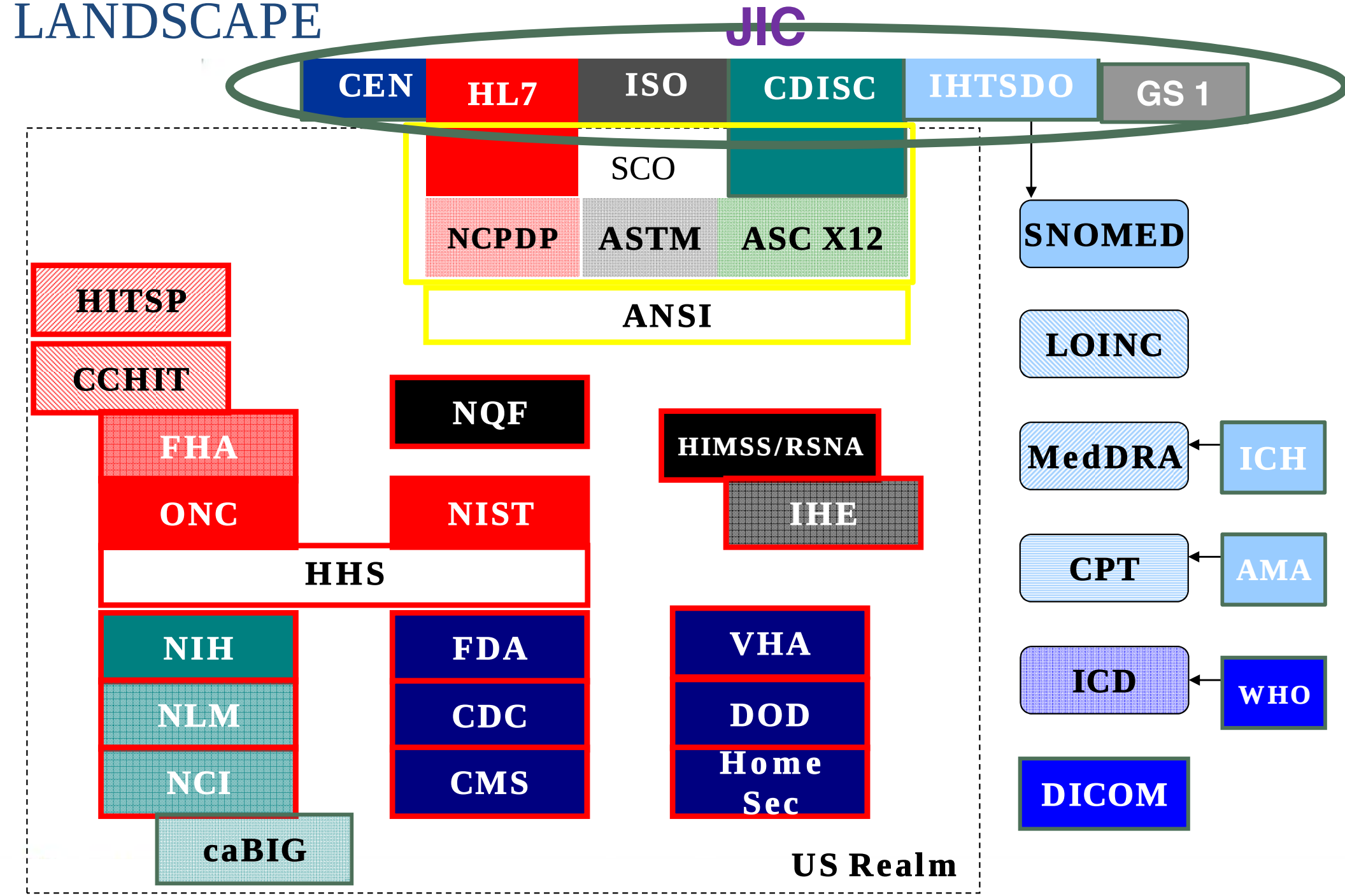
Operational Goals 2010

See CDISC Website for more Information:
– Standards, Education, Events, Procedure for Standards Development, Registered Solution Providers (RSP), ODM Certification, Publications.....

Strategic Themes 2011

1) Ensure the existence, harmonization, acceptance and support of standards for medical research
2) Promote and provide education on the use and benefits of standards
3) Facilitate the integration with Electronic Health Record (EHR) / Health Information Technology (HIT)
4) Use CDISC standards to support data collection and reporting with a focus on data aggregation for the purposes of scientific investigation and comparative effectiveness
5) Leverage our global, nonprofit, vendor neutral, independent status to forge productive collaborations with other Standards Development Organizations (SDOs) and key stakeholder communities including regulators and health agencies

INTERNATIONAL HEALTHCARE STANDARDS LANDSCAPE




CDISC

CDISC is YOU!

What does CDISC mean to you?

The Business Case for Using CDISC Standards

Speaking of health benefits/opportunities to be realized from making more effective use of IT....

"I think that CDISC will be a big part of moving FDA onto an electronic information architecture where we can realize all of these opportunities. I think this will have a profound and positive impact on our drug review process, allowing us to design trials that can be less expensive and still tell us more about the risks and benefits of a new medical product. And I think that the most significant and perhaps enduring legacy to your efforts could be the very immediate and significant impact it has on improving the lives of patients."

-Mark McClellan, MD, PhD, FDA
Commissioner, September 2003

"Testimonies"

- I had half a day to review data from a company we were considering acquiring to provide input into the decision; fortunately, it was in CDISC format and easy to review.
- My company was asked by FDA to aggregate data across several studies so that they could better do their review; the therapy was never approved because we could not aggregate the data.
- Academic investigators do not want to use standards (thinking it will inhibit innovation and creativity), but afterwards they want to use the data and want to get it out of a database...and they don't realize that they are actually asking for standards.
- Standards are foundational to modernizing the FDA review process.
- If you cannot find/use the data from clinical trials afterwards, you have broken your contract with the participating patients/subjects.

CDISC Value by Profession

Profession	Why CDISC?
CEO, Study Sponsor, Program/Project Manager Ask yourself, do you want:	a) To initiate your study quickly and economically? b) Have your CRFs easily understood and completed by investigative site personnel? c) Receive high quality data that will readily fit into the format requested by FDA? d) To have a protocol with sections that can be re-used (without re-entry) for trial registration, IRBs, generating study reports, publication, eSubmissions e) Your data to readily integrate with that of other studies? f) To be able to find your data later? g) Have your data ready in case of a merger or acquisition? h) Be able to use data from past research to improve current/future research?

CDISC Value by Profession

Profession	Why CDISC?
Medical Writer Ask yourself, do you want:	a) To write your protocols and study reports a bit faster? b) Re-use information from your protocols without re-entering information, e.g. trial registration, study reports, publications? c) To enable others on the team to auto-generate visit schedules and CRFs?
Data Manager Ask yourself, do you want:	a) To get your CRFs ready more quickly and economically? b) To create your data validation specifications more quickly and effectively? c) To build your databases more efficiently? d) To reduce training and improve communication with your CRAs and sites? e) To get cleaner data, faster? f) To reduce data problems and be able to focus more on the scientific content? g) To build more effective partnerships with the whole study team?

CDISC Value by Profession

Profession	Why CDISC?
Vendor or Information Technologist Ask yourself, do you want:	a) To ensure that your system will be able to readily exchange information with another system the sponsor may wish to use? b) To be able to provide a system based on industry standards? c) To be able to quickly respond to sponsor requests by using standard libraries?
Statistician Ask yourself, do you want:	a) To be able to create tables, listings and figures more efficiently? b) To be able to integrate data from multiple studies more easily? c) To be able to standardize your safety analysis programming?
Others?	What do you want from standards?

Do You Need CDISC?

1. Do you do protocol-based clinical research?
2. Do you do annotate, acquire, aggregate, analyze, archive?
3. Do you want high quality data?
4. Do you want to save time?
5. Do you have limited resources?
6. Do you have limited time to complete your clinical programs?
7. Do you ever have to go back and look at old data for knowledge extraction?
8. Do you need patients and investigators?
9. Do you want to get information from EHRs?
10. Do you track and report safety data?
11. Do you submit to FDA?
12. Do you intend to or have you acquired another company?
13. Do you need to be transparent and compliant?
14. Do you use partners (CROs, tech vendors, development partners, labs)?

If you responded 'yes' to any of 1-7, you need standards.

If you responded 'yes' to any of 8-14, you need industry standards.

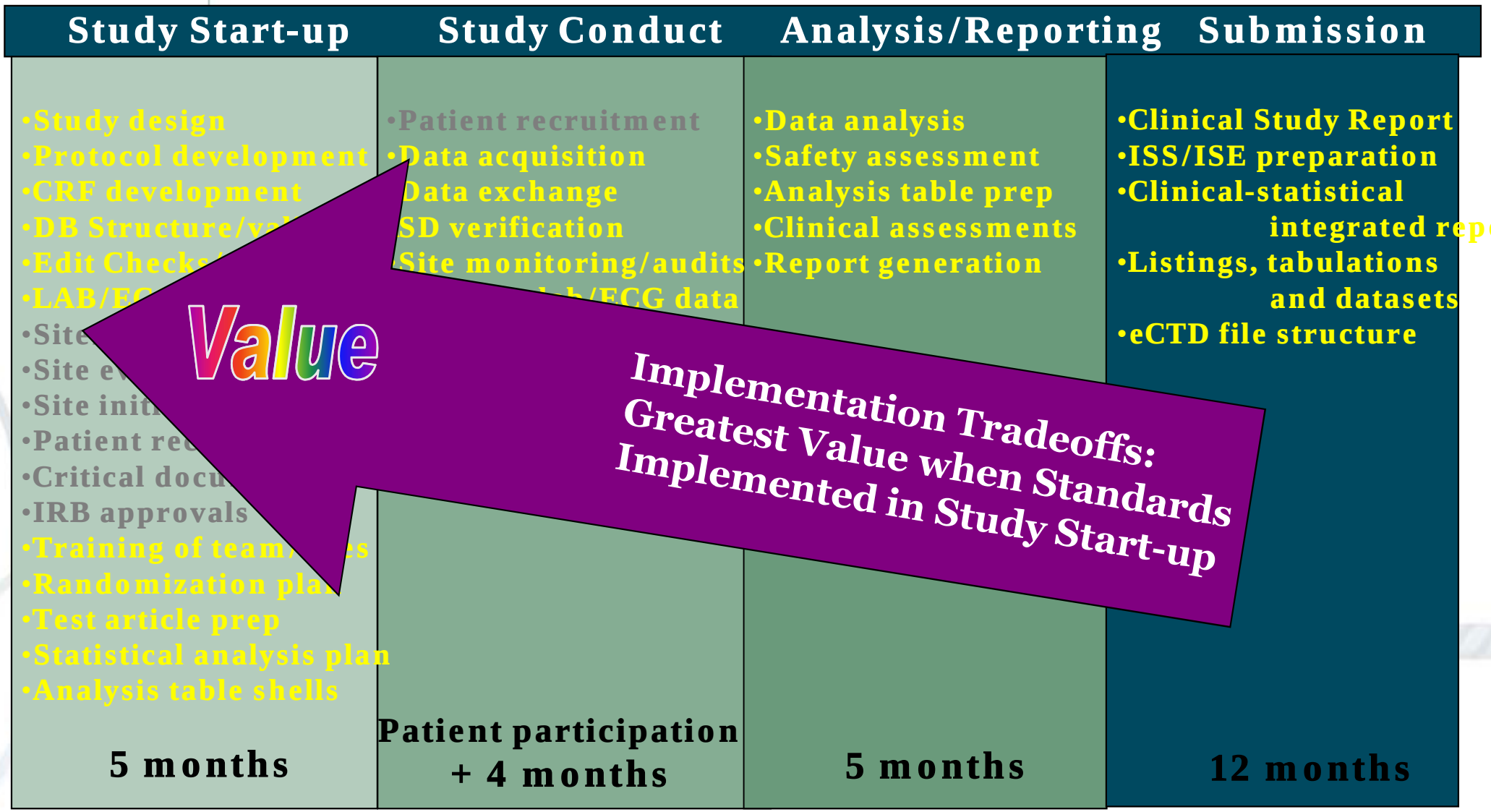
Quotes from the Business Case

- "Operationalized standards become your common language, helping processes by facilitating communication and clarifying study design and setup processes. This is important when working with outside partners. There is the need to clearly communicate what your expectations are."

- "We are convinced that clinical data standardization is critical to efficient and successful pharmaceutical product development and commercialization."

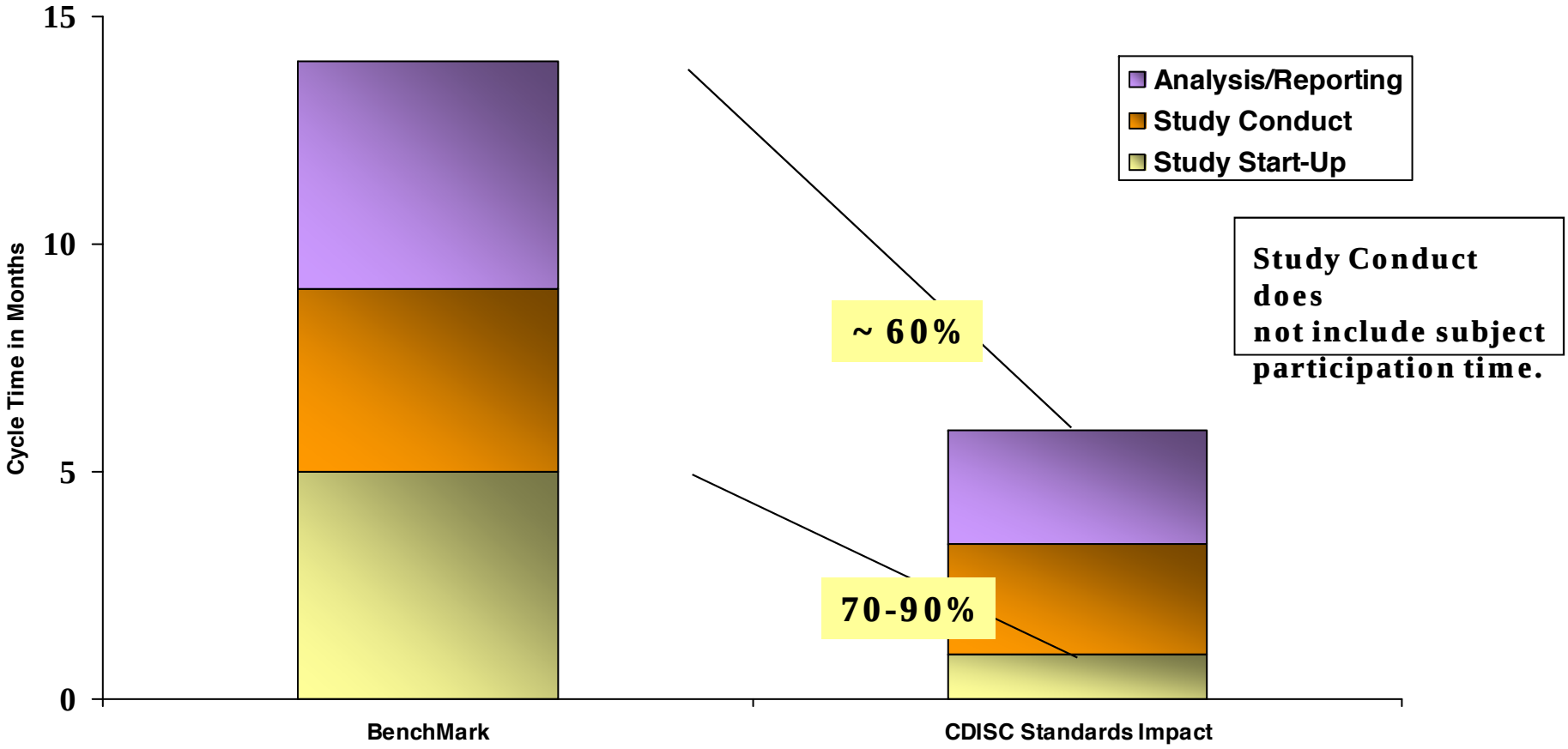
- "The initial costs related to defining data according to the CDISC structure and using the standardized formats will translate to a worthwhile investment in time, efficiency, accuracy of content, and optimization of use in analysis." (FDA interviewee)

Standards Impact On Clinical Study Activities



Quantifying the Value of Standards

- Cycle Time (and Cost) Savings -



Note: Figures are benchmarks based on aggregate data; study-specific cycle times and cost metrics will vary.

Figure: K. Getz, Tufts CSDD

Summary of Business Case Findings (Gartner-PhRMA-CDISC Project)

- CDISC standards ***can save significant time and cost, especially when implemented in the early stages of the study***
- CDISC standards have additional impact on clinical research to:
  - ***Increase data quality***
  - ***Enable data integration, enhancing re-usability in 'knowledge' warehouses***
    - ***improving science, marketing and safety surveillance***
  - ***Facilitate data interchange among partners***
  - ***Enable choice of tools that readily exchange data***
  - ***Improve communication among project teams***
  - ***Facilitate review of regulatory submissions, audits***

Sample Calculations When Standards are Implemented in the Study Start-up Stage
NOTE: Each company should use their own time and cost baselines.

Start-up Time (mos)	% Savings w/ Stds	Net mos saved	Conduct mos w/o *Subject participation time***	% Svngs w/ Stds	Net mos saved	Analysis & report(mos)	% Svngs w stds	Net mos saved	Total mos saved	Cost Savings	"Value" (Cost of Clinical Res per day)
5	(80%) x 0.8	4	4	(40%) x 0.4	1.6	5	(50%) X 0.5	2.5	**8.1**	Multiply time saved x actual cost of study/ month	X $37,000 (Tufts loaded cost per day) ~ $9M
4	x 0.8	3.2	3	x 0.4	1.2	3	X 0.5	1.5	**5.9**		
2	x 0.8	1.6	2	x 0.4	0.8	2	X 0.5	1.0	**3.4**		
12	x 0.8	9.6	7	x 0.4	2.8	7	X 0.5	3.5	**15.9**		
Your time	x 0.8	= A	Your non-subject participation time (LPO->DBL)	x 0.4	= B	Your time	X 0.5	= C	**A + B + C = Y**	Y x cost per month	Y x $37K per day

***Subject participation time is excluded.

Efficiencies and Effectiveness Not Considered in the Calculations

- Site personnel and monitoring efficiency during patient participation period
- Recruitment
- Source document validation and randomization
- Safety surveillance
- Reuse (e.g. protocol, disease population data, CRF/eCRF designs)
- Training
- Improved team communication

Opportunity value is doing more trials with the same number of people

from the PhRMA-Gartner-CDISC Project

- The value of standards extends far beyond process efficiency.
  - Higher quality data/information
  - Real time integrated data e.g. safety surveillance, marketing, submission, study design
  - Reusability of information to enhance science
  - Improved communication among project teams and business partners
  - Facilitated regulatory review process

- Standards save significant time and money, especially when implemented in the study startup stage.

Key Messages for Healthcare from the PhRMA-Gartner-CDISC Project

- Organizations are becoming proactively compliant with CDISC standards.
  - FDA's endorsement important; mandate still needed
- Harmonization of standards across clinical research and with healthcare is a core strategic goal.
  - Enter the data only once - at the site
  - Streamline investigator participation in research

How can Data Standards help you ?

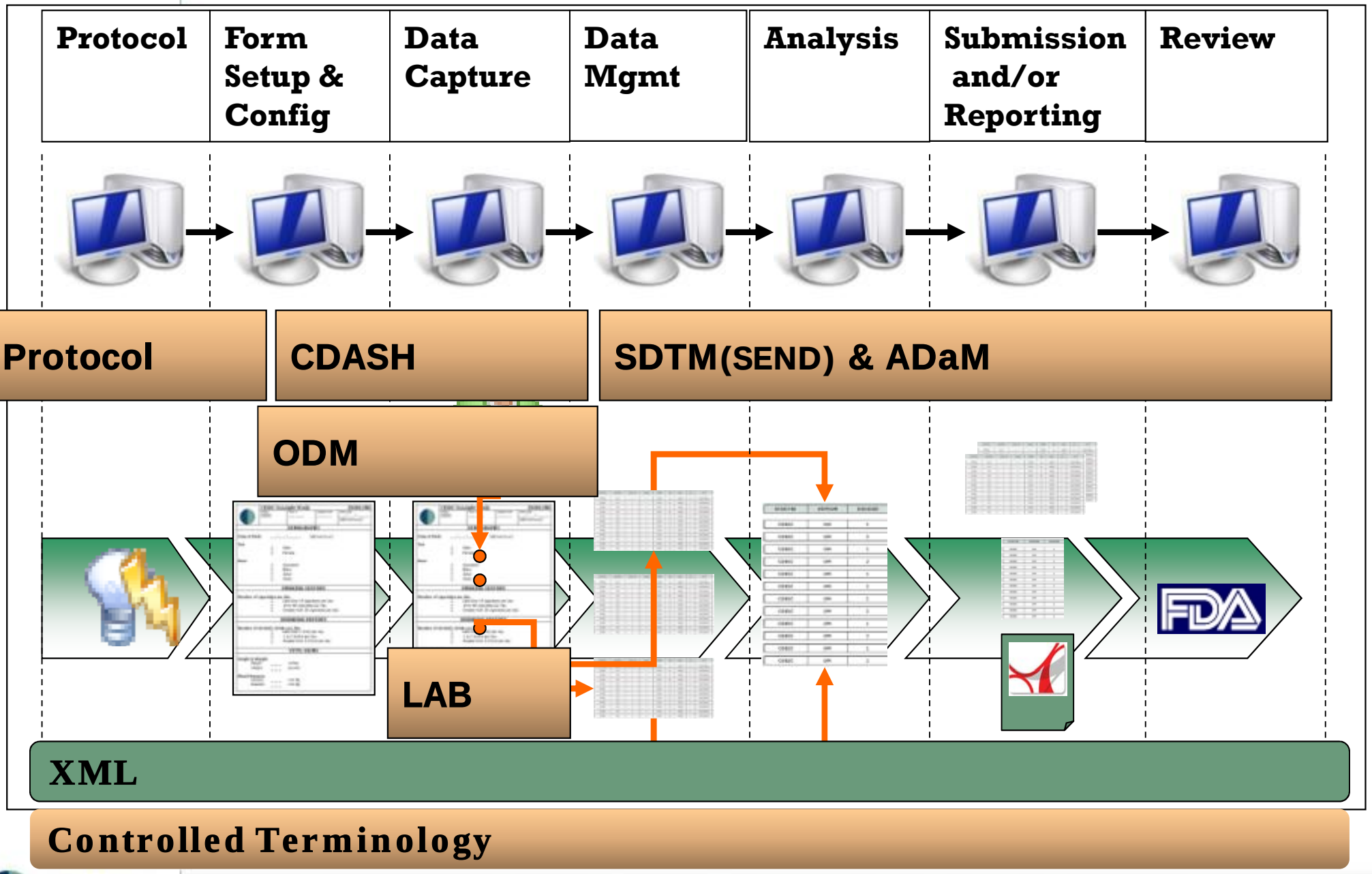
- What are the problems you are trying to solve?
- What benefits would standards bring?

- What are the potential challenges of implementing standards?

10 Minute Break

Brief (non-technical) Introduction to the CDISC Standards

CDISC Production Standards



Relevant Definitions

- Transport Standards (Amy Malla – CBER)
  - Provide a consistent way to exchange information between computer systems in various organizations
- Content Standards (adapted from Amy Malla – CBER)
  - Consistent presentation and description of individual data or concepts
- Data Model (CDISC Glossary)
  - Unambiguous, formally stated, expression of items, the relationship among items, and the structure of the data in a certain problem area or context of use. A data model uses symbolic conventions agreed to represent content so that content does not lose its intended meaning when communicated.

Relevant Definitions

- Data [FDA] (Synonym: Information)
  - representations of facts, concepts, or instructions in a manner suitable for communication, interpretation, or processing by humans or by automated means.
- Metadata (CDISC Glossary)
  - Data that describe other data

WHY Metadata? What value is it?

How Important is Metadata?

02/03/04

How Important is Metadata?

02 /MAR /2004

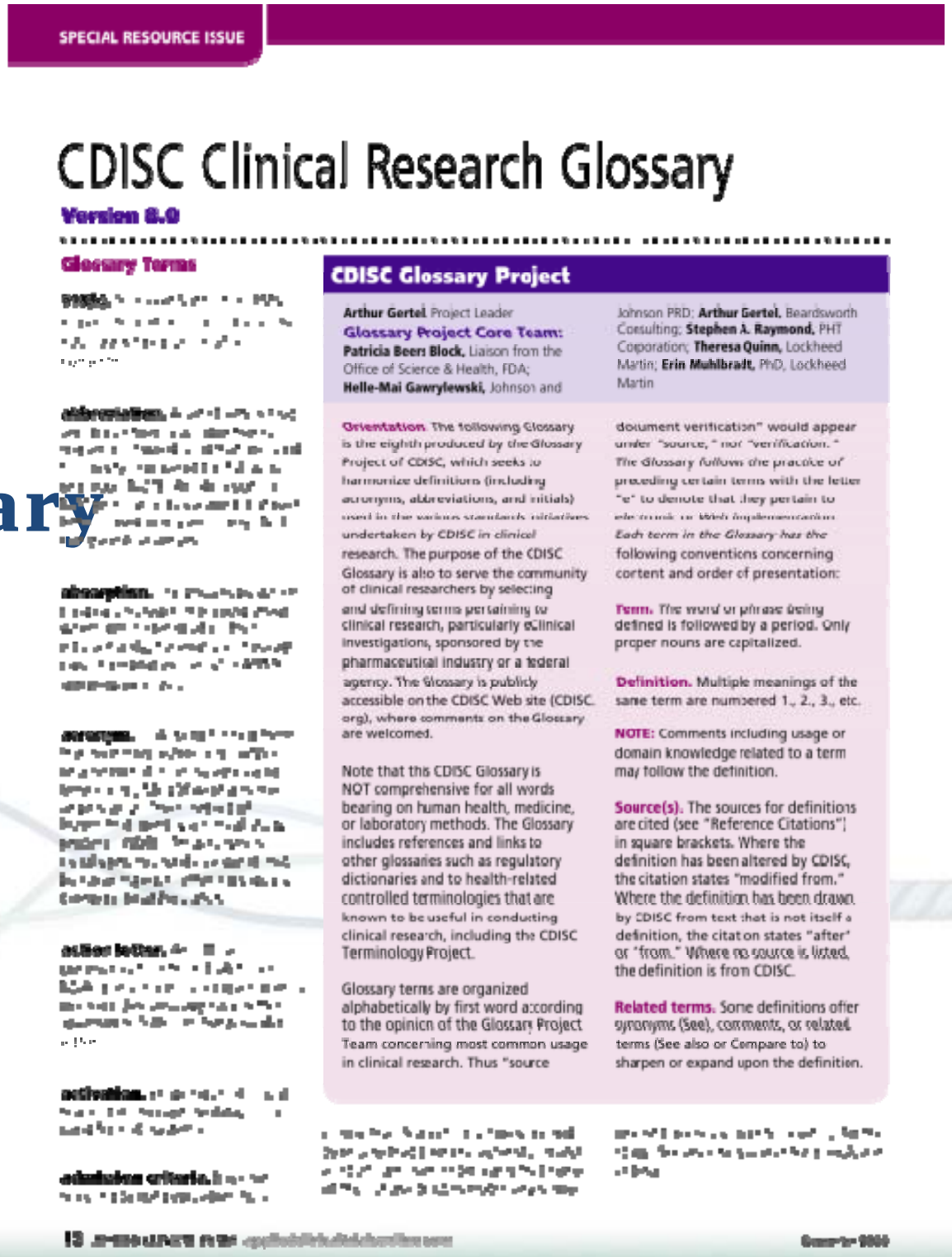
DD/MM/YY

GLOSSARY

CDISC GLOSSARY

- First CDISC team to establish a scope and achieve it: "Define every word in the CDISC mission statement."
- Mission statement in 1997: development of... standards to support the electronic acquisition, exchange, submission and archiving of clinical trials data...
- Glossary now updated each year and published in Applied Clinical Trials (December resource issue) and on the CDISC website
- Accompanying list of Acronyms included

Glossary



SPECIAL RESOURCE ISSUE

CDISC Clinical Research Glossary

Version 8.0

Glossary Terms

CDISC Glossary Project

Arthur Gertel, Project Leader
Glossary Project Core Team: **Patricia Beers Block**, Liaison from the Office of Science & Health, FDA; **Helle-Mai Gawrylewski**, Johnson and Johnson PRD; **Arthur Gertel**, Beardsworth Consulting; **Stephen A. Raymond**, PHT Corporation; **Theresa Quinn**, Lockheed Martin; **Erin Muhlbradt**, PhD, Lockheed Martin

Orientation. The following Glossary is the eighth produced by the Glossary Project of CDISC, which seeks to harmonize definitions (including acronyms, abbreviations, and initials) used in the various standards initiatives undertaken by CDISC in clinical research. The purpose of the CDISC Glossary is also to serve the community of clinical researchers by selecting and defining terms pertaining to clinical research, particularly eClinical investigations, sponsored by the pharmaceutical industry or a federal agency. The Glossary is publicly accessible on the CDISC Web site (CDISC.org), where comments on the Glossary are welcomed.

Note that this CDISC Glossary is NOT comprehensive for all words bearing on human health, medicine, or laboratory methods. The Glossary includes references and links to other glossaries such as regulatory dictionaries and to health-related controlled terminologies that are known to be useful in conducting clinical research, including the CDISC Terminology Project.

Glossary terms are organized alphabetically by first word according to the opinion of the Glossary Project Team concerning most common usage in clinical research. Thus "source document verification" would appear under "source," not "verification." The Glossary follows the practice of preceding certain terms with the letter "e" to denote that they pertain to electronic or Web implementation. Each term in the Glossary has the following conventions concerning content and order of presentation:

Term. The word or phrase being defined is followed by a period. Only proper nouns are capitalized.

Definition. Multiple meanings of the same term are numbered 1., 2., 3., etc.

NOTE: Comments including usage or domain knowledge related to a term may follow the definition.

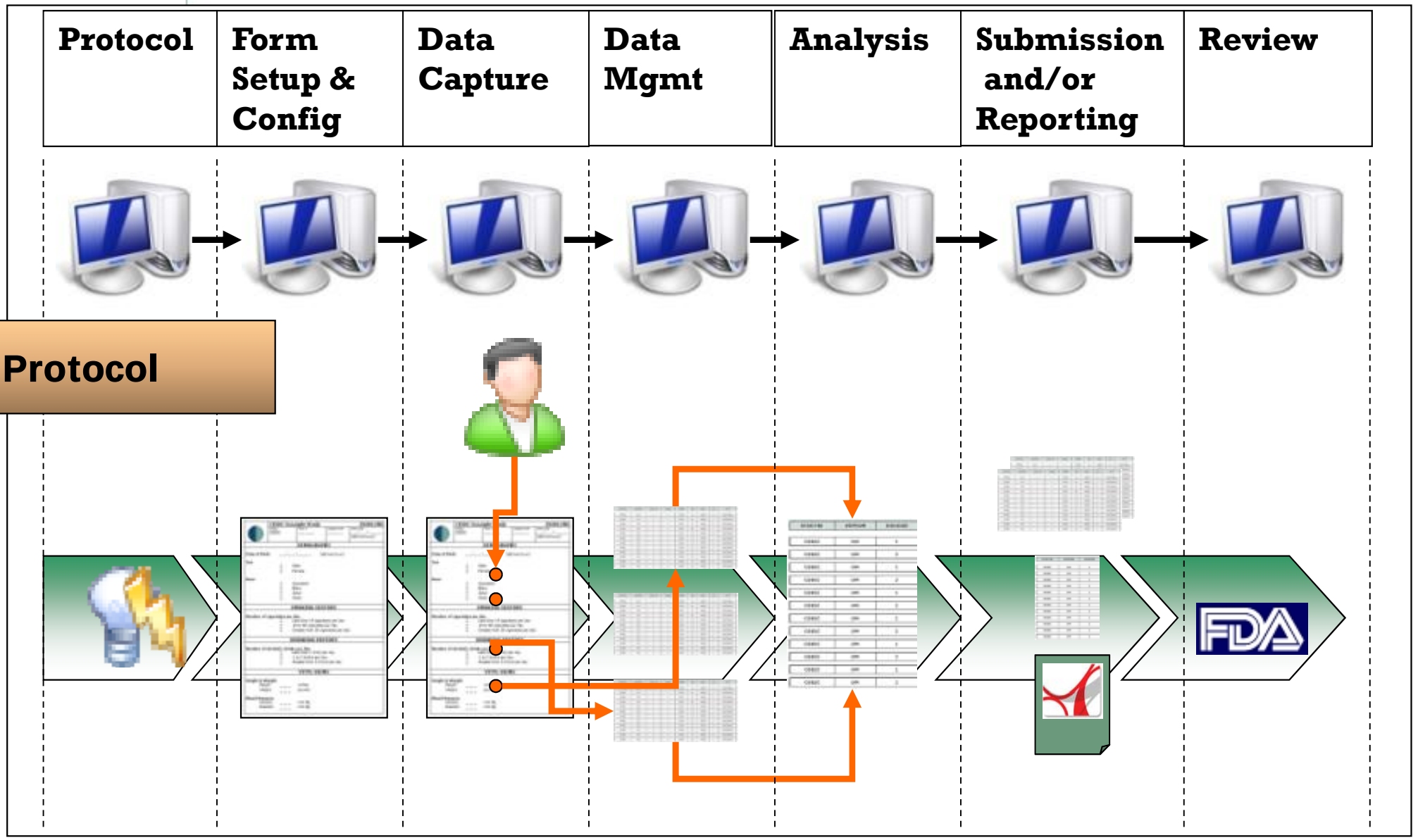
Source(s). The sources for definitions are cited (see "Reference Citations") in square brackets. Where the definition has been altered by CDISC, the citation states "modified from." Where the definition has been drawn by CDISC from text that is not itself a definition, the citation states "after" or "from." Where no source is listed, the definition is from CDISC.

Related terms. Some definitions offer synonyms (See), comments, or related terms (See also or Compare to) to sharpen or expand upon the definition.

Acronyms, Abbreviations, and Initials

PROTOCOL REPRESENTATION

CDISC Production Standards



Protocol Representation: Project Scope and Objectives

Protocol Representation will identify standard elements of a clinical study protocol that can be further elucidated and codified to facilitate study design, regulatory compliance, project management, trial conduct and data interchange among consumers and systems.

This work will be based upon the needs of protocol consumers, which may include regulatory authorities, IRBs, statisticians, project managers, site personnel and users of any downstream systems for the management of clinical research information.

Project Objective(s): Publication of a standard, machine-readable model for protocol representation that will enable interchange of this data among systems and stakeholders.

PR Group April 2002

Protocol Representation

3.1. Summary of Study Design

FORM: Bolded, Arial, 14pt, Heading Level 1

This is a prospective, randomized, double-blind, double-dummy, placebo controlled, forced-titration, multicenter, parallel group trial. Stage I or II hypertensive patients, age 18 years of age or older, who meet all other inclusion and exclusion criteria and successfully complete the placebo run-in period will be randomized at the site level.

FORM: Arial, 14 pt, Body text

Not very Useful!

Source: Cara Willoughby

A Document Example: Structuring Information by "Meta" Information

3.1. Summary of Study Design

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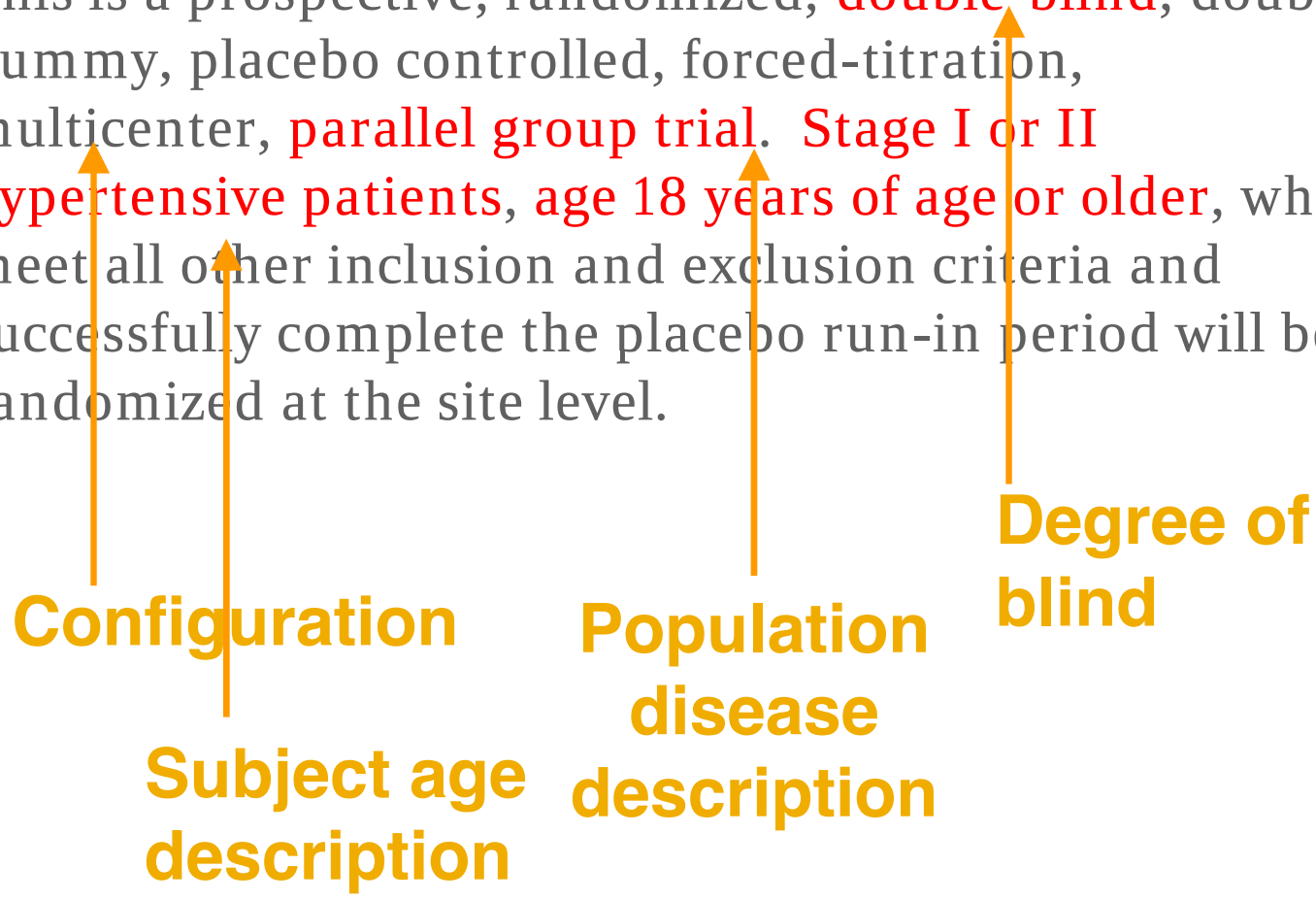


Source: Kristin O'Connor

A Document Example: Structuring Information by "Meta" Information

"Meta" Information about Content	Content
Subject age description	Age 18 years of age or older
Configuration	Parallel group trial
Population disease description	Stage I or II hypertensive patients
Degree of blind	Double-blind

Much More Useful!

Value of a Protocol Representation Standard

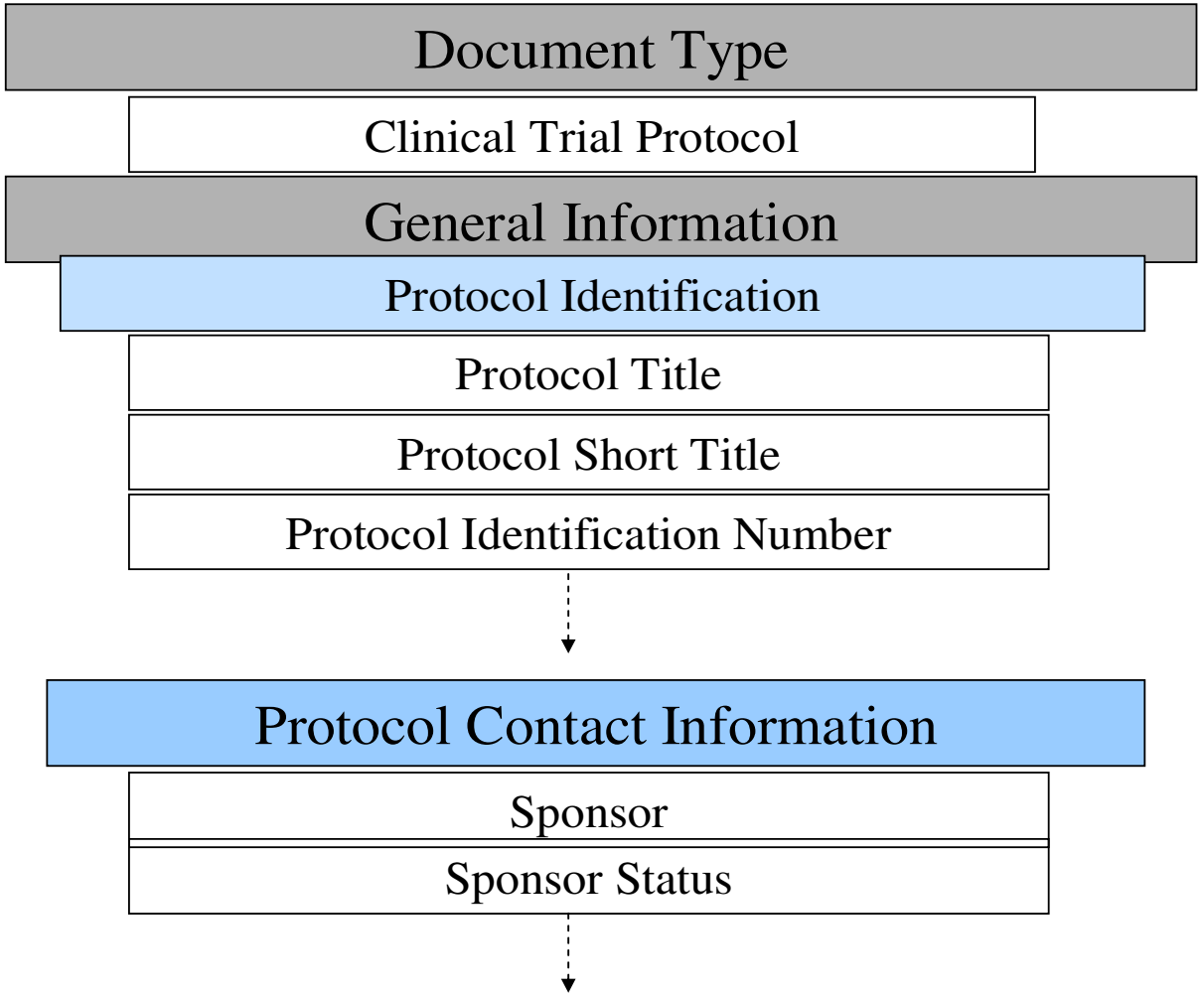
- Structured information to facilitate re-use (trial registries, study design, reporting)
- Ensure compliance with IRB requirements
- Facilitate study team comprehension of requirements
- Automation of CRF creation or EHR configuration to support clinical research

NOTE: NOT intended to inhibit creativity or innovation in study designs

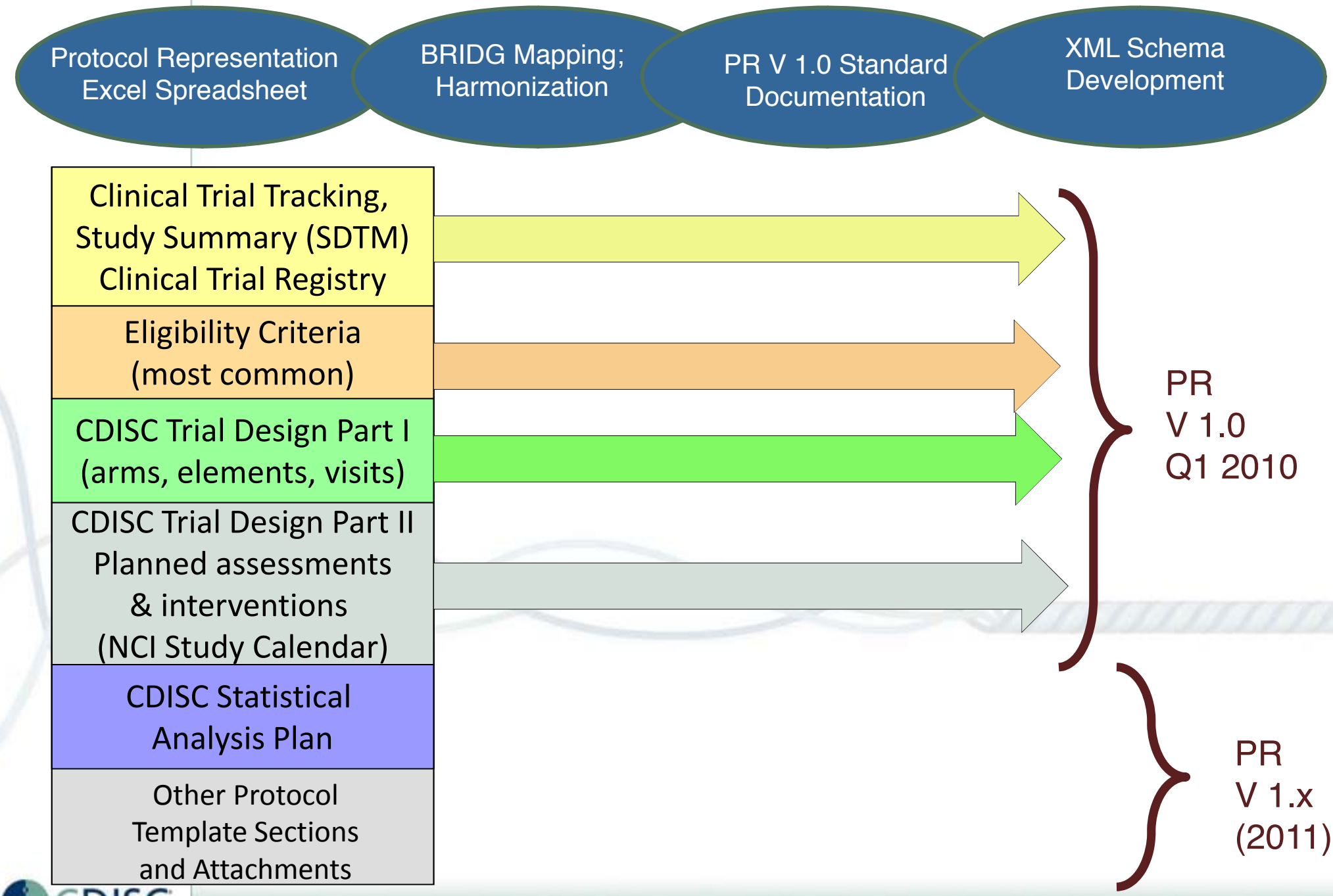
PRG Approach

- Development should concentrate on content first and implementation second
- Elements must be defined in a glossary, since the industry uses multiple definitions for the majority of protocol elements
  - CDISC Glossary, Applied Clinical Trials, published yearly
- Identify core set of elements initially, expand with further details as needed
- Initially based on
  - ICH E6 - Basis for the development and organization
  - ICH E3 - Terms & definitions
  - EudraCT (EMEA) - Key words and Protocol description
  - Specific topics (e.g. IRB, SAP-E9)
  - Clinicaltrials.gov and WHO ICTRP

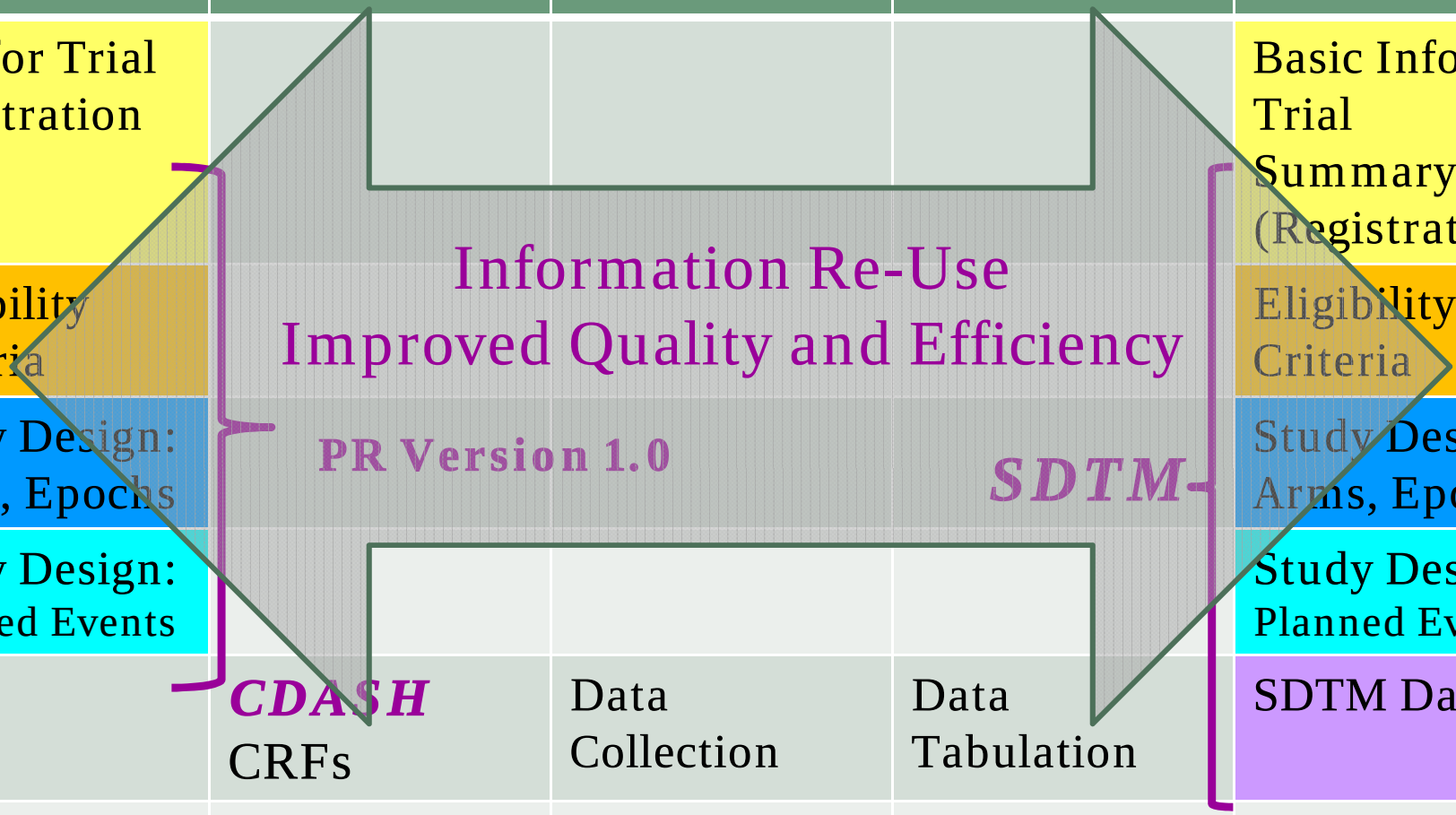
Protocol Representation – Hierarchy
Sample: *Sections, Sub-sections, Elements*



CDISC Protocol Representation Standard - Development

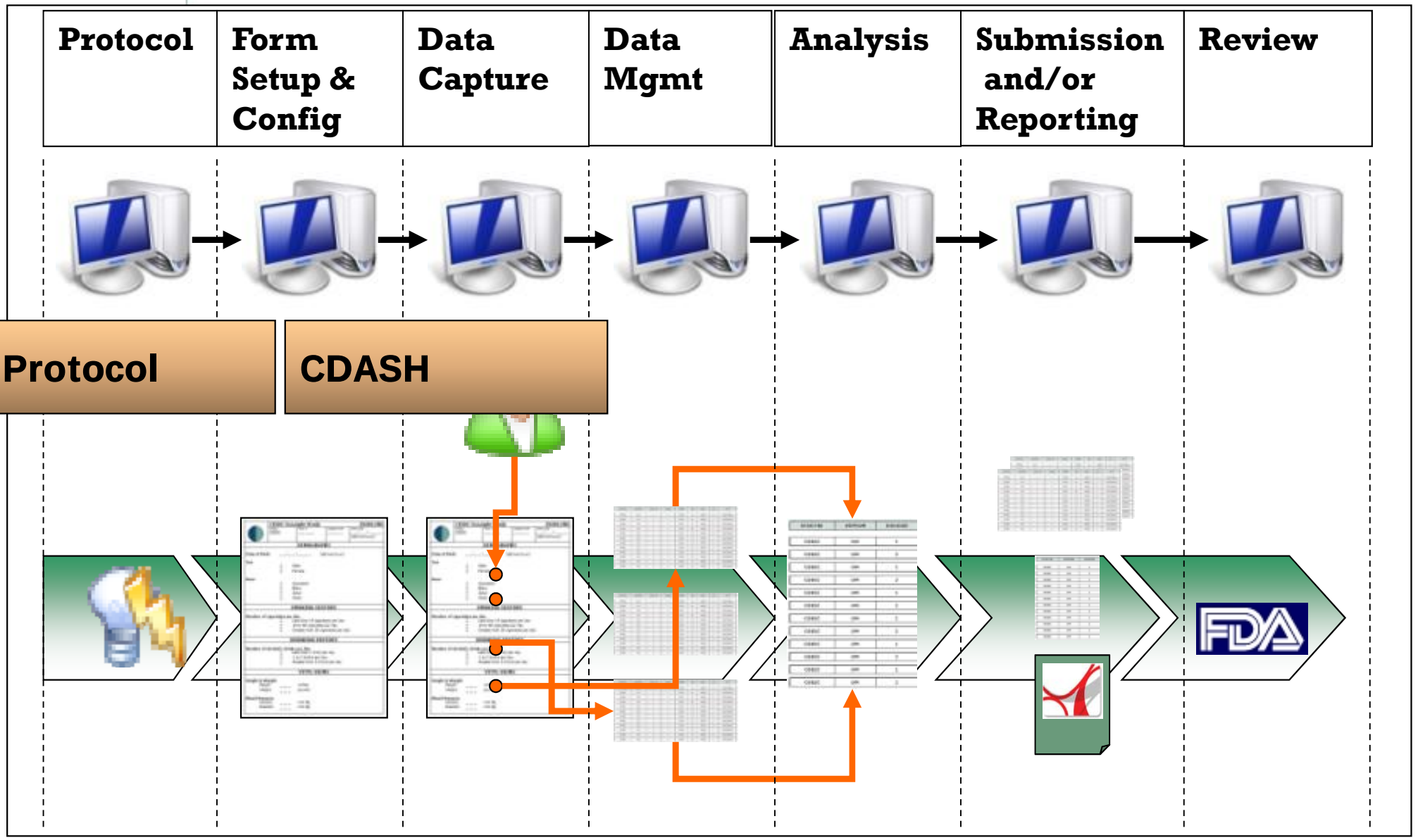


Protocol Section	CRF Development	Data Collection	Data Analysis	Report or eSubmission
Info for Trial Registration				Basic Info/ Trial Summary (Registration)
Eligibility Criteria				Eligibility Criteria
Study Design: Arms, Epochs				Study Design: Arms, Epochs
Study Design: Planned Events				Study Design: Planned Events
	CDASH CRFs	Data Collection	Data Tabulation	SDTM Data
Statistical Analysis Plan			Data Analysis	***ADaM*** Datasets
Appendices, etc.				Appendices, etc.



CLINICAL DATA ACQUISITION STANDARDS HARMONIZATION (CDASH)

CDISC Production Standards



CDASH

- **FDA CRITICAL PATH INITIATIVE: STREAMLINING CLINICAL TRIALS**
  - *Creating Innovative and Efficient Clinical Trials and Improved Clinical Endpoints*
  - 45. Consensus on Standards for Case Report Forms. Clinical trial data collection, analysis, and submission can be inefficient and unnecessarily expensive. A wide array of different forms and formats are used to collect clinical trial information, and most data are submitted to the FDA on paper. **Differences in case report forms across sponsors and trials creates opportunities for confusion and error.** Standardization of the look and feel of case report forms could reduce these inefficiencies and also help accelerate progress toward electronic data capture and submission.

"Innovation/Stagnation: Challenge and Opportunity on the Critical Path to New Medical Products", Critical Path Opportunities List, March 2006, page L-10.

CDASH Project Snapshot

- Streamlines data collection at investigative sites - addresses Critical Path Opportunity #45
- Continuation of ACRO's Initiative
- Started October 2006
- Supported by a collaborative group of 17 organizations
- Initial Core Team of 16 members managed
  - 11 working groups
  - Composed of between 8-40 volunteers
- Current Leadership Team of 11 manages a Core Team of ~50
- 16 (+2) Safety data domains developed
- Consolidated document posted for public review in May 2008
- Received over 1800 comments from 46 companies, institutions and agencies.
- All 3 ICH regions were represented in the public comment process
  - US
  - Europe
  - Japan

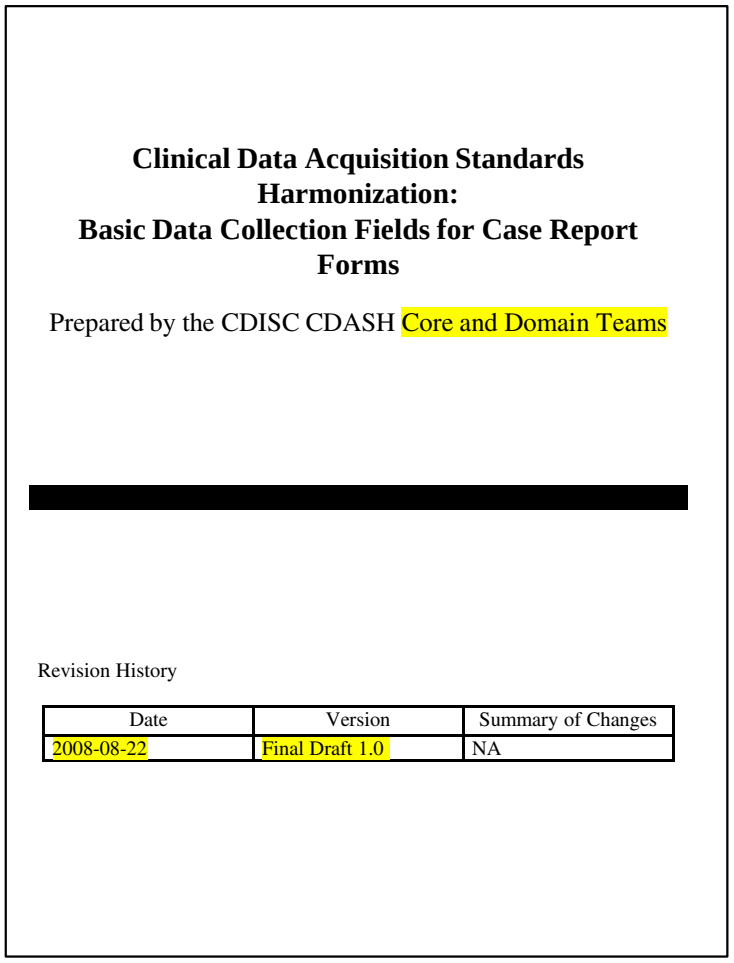
- Harmonized with analogous NCI CRFs

CDASH Standards

CDISC CDASH
V 1.1 2010

UG V1.0 in progress: due Q1 2011

ODM CRF examples: included in UG; available to members Q4 2010



Clinical Data Acquisition Standards Harmonization:
Basic Data Collection Fields for Case Report Forms

Prepared by the CDISC CDASH Core and Domain Teams

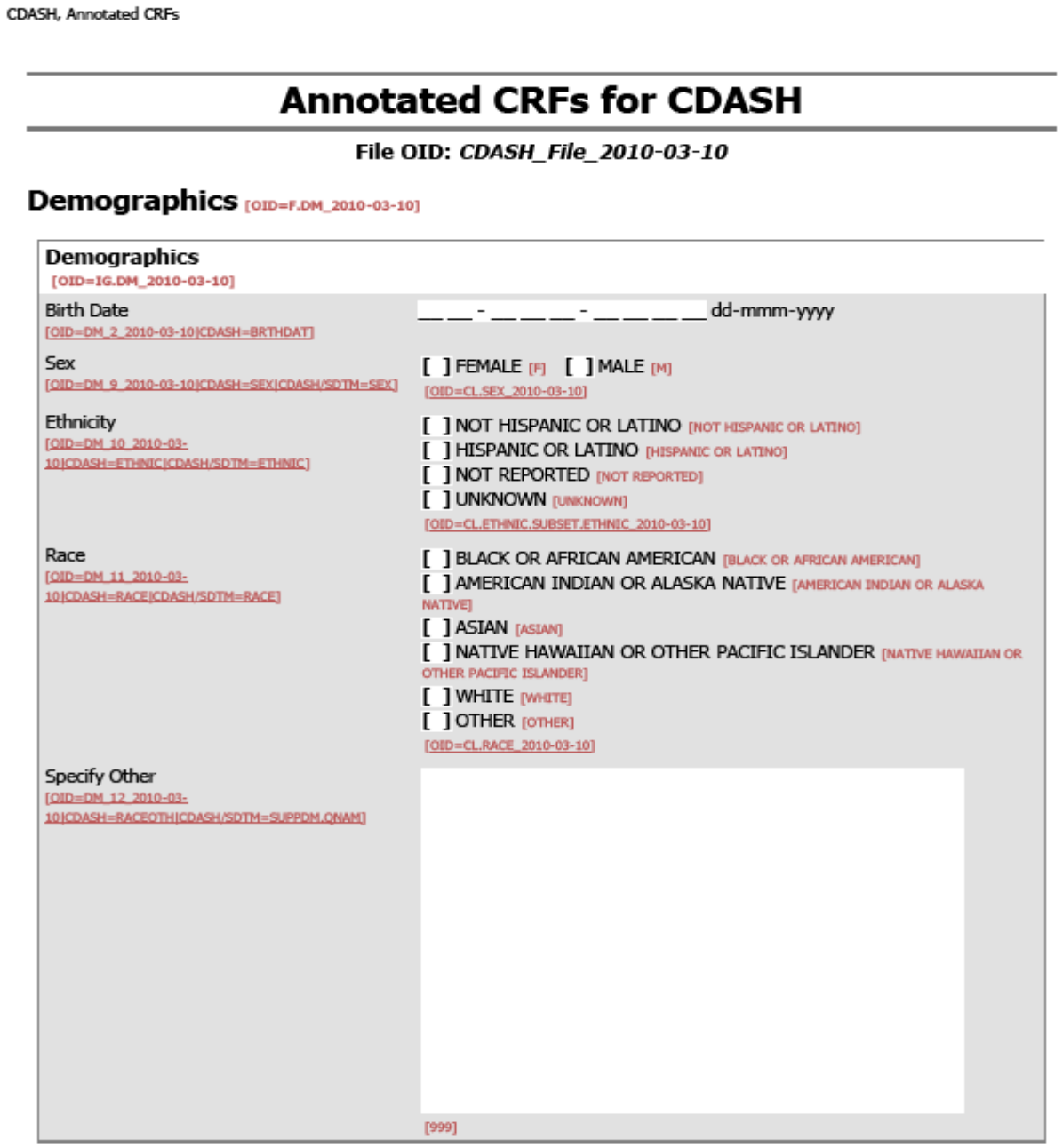
Revision History

Date	Version	Summary of Changes
2008-08-22	Final Draft 1.0	NA

CDASH CRFs

ODM Sample: Demographics

Conformant to CDASH rules



CDASH, Annotated CRFs

Annotated CRFs for CDASH

File OID: *CDASH_File_2010-03-10*

Demographics [OID=F.DM_2010-03-10]

Demographics
[OID=IG.DM_2010-03-10]

Birth Date [OID=DM_2_2010-03-10|CDASH=BRTHDAT]	__ __ - __ __ __ - __ __ __ __ dd-mmm-yyyy
Sex [OID=DM_9_2010-03-10|CDASH=SEX|CDASH/SDTM=SEX]	[ ] FEMALE [F] [ ] MALE [M] [OID=CL.SEX_2010-03-10]
Ethnicity [OID=DM_10_2010-03-10|CDASH=ETHNIC|CDASH/SDTM=ETHNIC]	[ ] NOT HISPANIC OR LATINO [NOT HISPANIC OR LATINO] [ ] HISPANIC OR LATINO [HISPANIC OR LATINO] [ ] NOT REPORTED [NOT REPORTED] [ ] UNKNOWN [UNKNOWN] [OID=CL.ETHNIC.SUBSET.ETHNIC_2010-03-10]
Race [OID=DM_11_2010-03-10|CDASH=RACE|CDASH/SDTM=RACE]	[ ] BLACK OR AFRICAN AMERICAN [BLACK OR AFRICAN AMERICAN] [ ] AMERICAN INDIAN OR ALASKA NATIVE [AMERICAN INDIAN OR ALASKA NATIVE] [ ] ASIAN [ASIAN] [ ] NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER [NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER] [ ] WHITE [WHITE] [ ] OTHER [OTHER] [OID=CL.RACE_2010-03-10]
Specify Other [OID=DM_12_2010-03-10|CDASH=RACEOTH|CDASH/SDTM=SUPPDM.QNAM]	[999]

file:///C|/...op/Temp/CDASH/ODM/cdash-team-files/2010-03-10/CDASH-ODM-2010-03-10/Form-F.DM_2010-03-10.CRF.html[2010-03-10 02:26:38 PM]

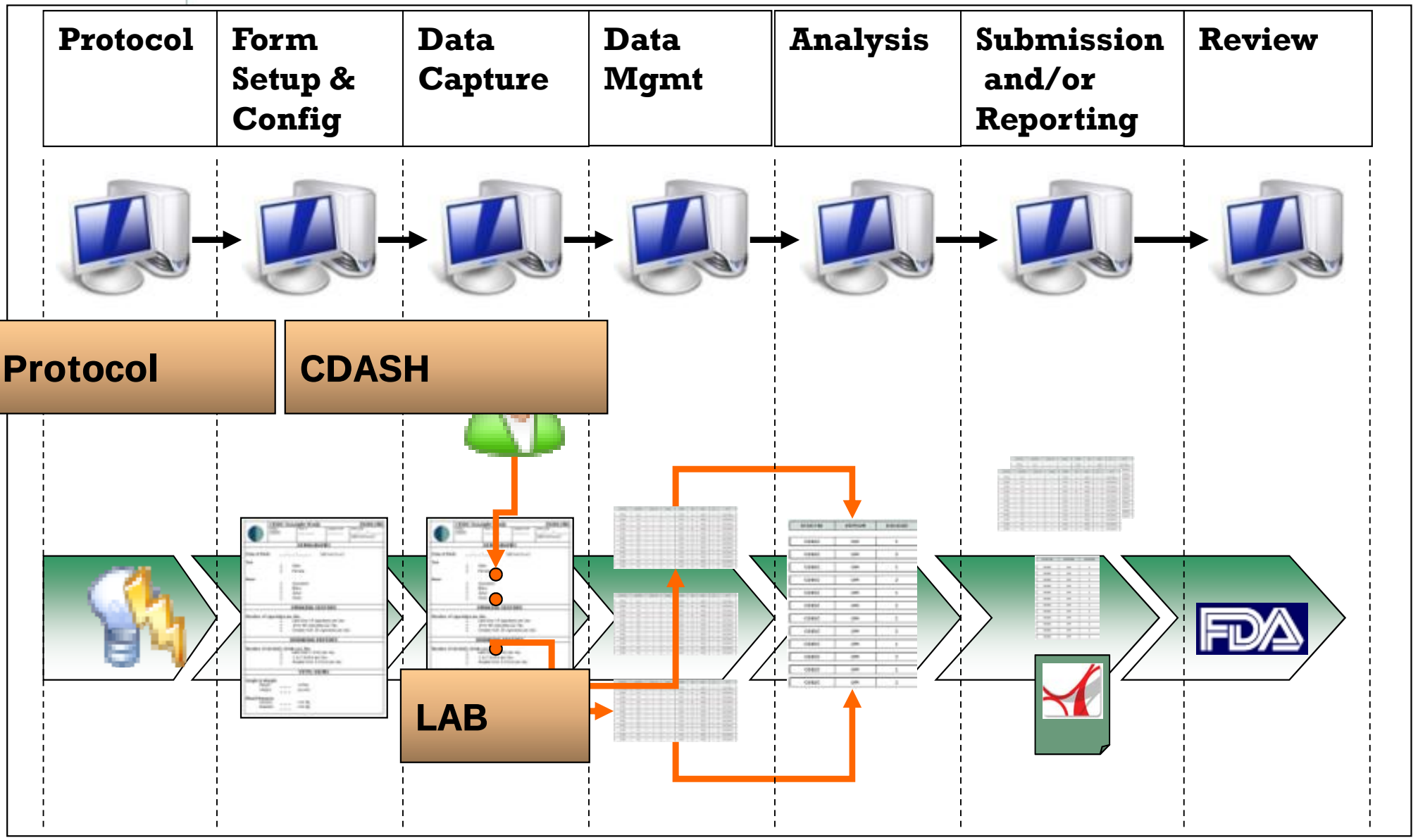
General Recommendations

Best Practice (General Recommendations and Observations Applicable to all Domains) TOC:

- Implementation of CDASH Recommendations
  - Mapping to SDTM and meeting regulatory requirements
  - Collecting data using CDISC Terminology
  - Collection of dates in unambiguous format
- Recommended Methodologies for Creating Data Collection Instruments
  - Methodologies
  - FAQs
  - Suggested CRF Development Process Flowchart
- Use Common Identifier Variables that map to SDTM

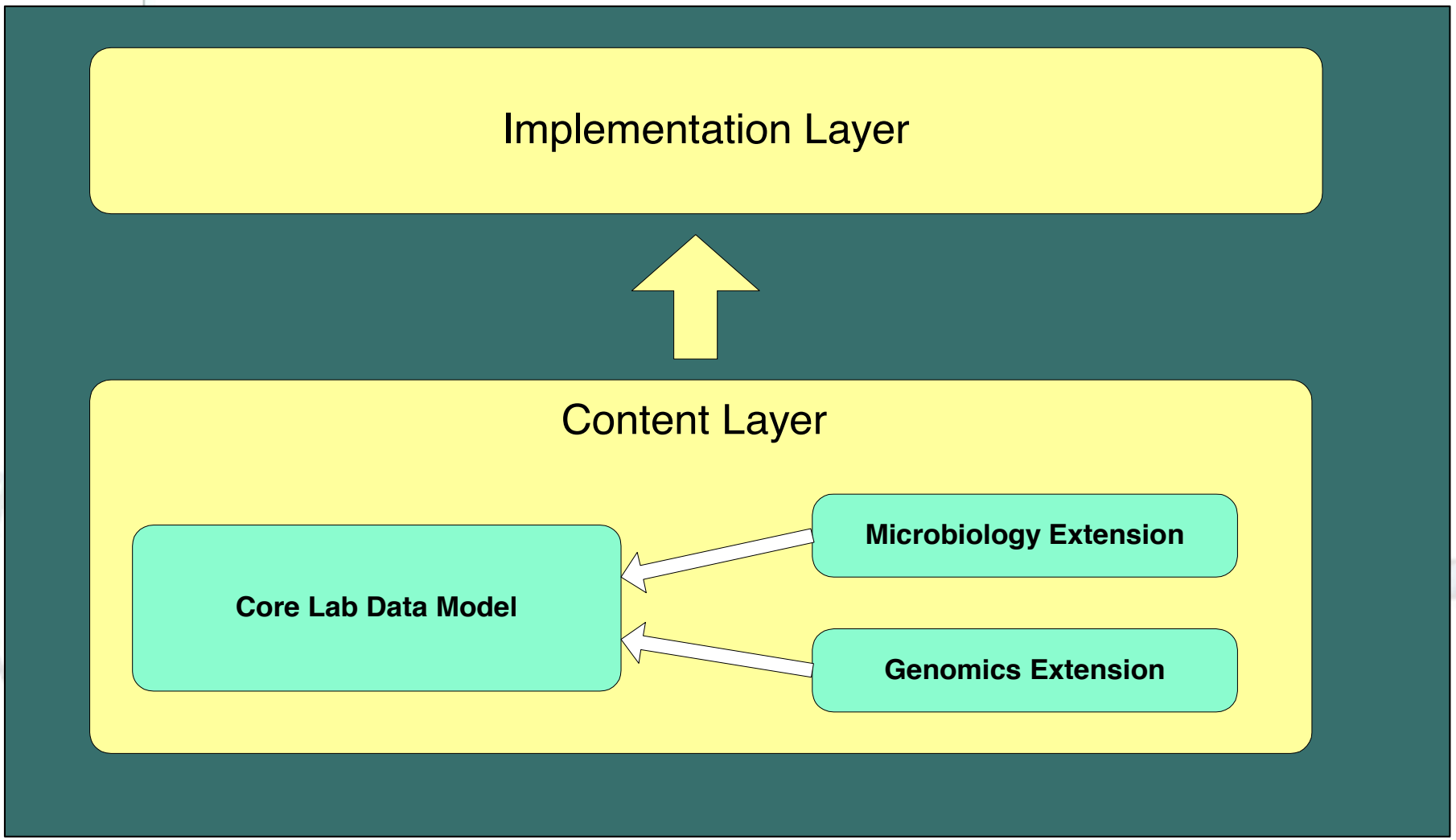
LABORATORY MODEL (LAB)

CDISC Production Standards



CDISC LAB Model (Lab)

- Primary AIMS
  - Interchange of test results & reference ranges
  - Incremental and cumulative data interchange
  - Full range of transaction types
  - Interchange data from 1+ studies in single file
  - Support the bulk transfer of laboratory data


Implementation Layer
Content Layer
Core Lab Data Model
Microbiology Extension
Genomics Extension

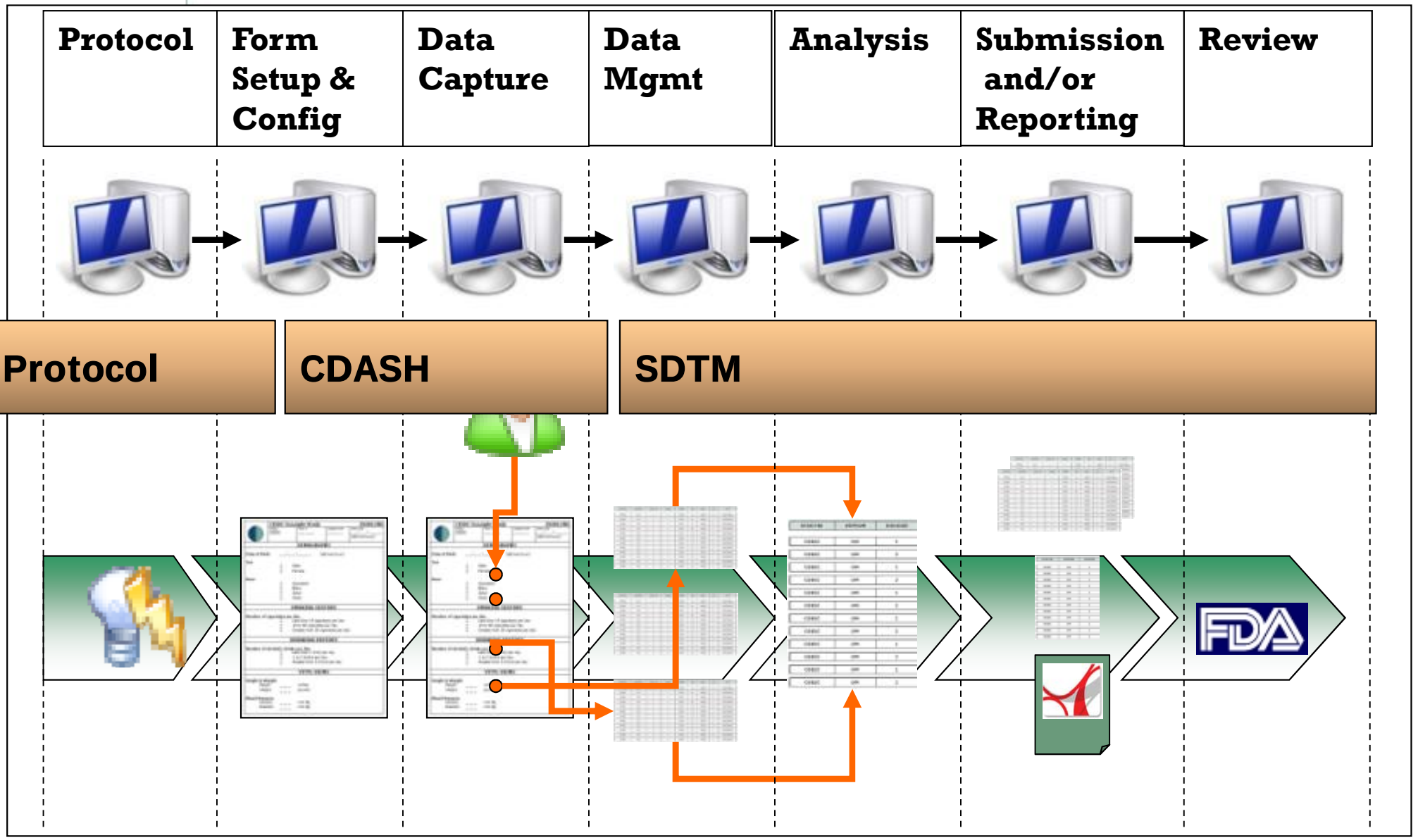
CDISC Lab Core Model Levels

1. GTP (Good Transmission Practice)
2. Study
3. Site/Investigator
4. Subject
5. Visit
6. Accession (Kit)
   Record Type
7. Specimen (Container)
8. Battery
9. Test
10. Result

LAB Standard Content/Information can be transported using CDISC ODM, HL7 V3, HL7 V2.5, ASCII, SAS...)

STUDY DATA TABULATION MODEL (SDTM)

CDISC Production Standards



Data without Standards

Name for Subject ID is never the same

Study #1 – demog.xpt

SUBJID	SEX
0001	M
0002	F
0003	F
0004	M
0005	F

Is Sex Male or Female, M or F, 1 or 2?

Study #2 – dmg.xpt

ID	GENDER
A1	Male
A2	Male
A3	Female
A4	Female
A5	Male

Study #4 – dmgph.xpt

PTID	GENDER
0001	1
0002	1
0003	2
0004	2
0005	1

Name for demography dataset is variable???

Study #3 – axd222.xpt

USUBID	SEX
00011	0
00012	1
00013	1
00014	0
00015	1

Gender or Sex, what will today's submission use?

vith Standards

Column Header (Variable) for Subject ID is always the same

Name for demography dataset always the same!

Study #1 – DM.xpt

USUBJID	SEX
ABC-0001	M
ABC-0002	F
ABC-0003	F
ABC-0004	M
ABC-0005	F

Study #2 – DM.xpt

USUBJID	SEX
DEF-001	M
DEF-002	M
ABC-001	F
DEF-004	F
DEF-005	M

Study #3 – DM.xpt

USUBJID	SEX
JKL-011	M
JKL-012	F
GHI-003	F
JKL-014	M
JKL-015	F

Study #4 – DM.xpt

USUBJID	SEX
GHI-001	M
GHI-002	M
GHI-003	F
GHI-004	F
GHI-005	M

Sex is always reported using the same terminology (codelist)

Sex is always reported using the same variable name.

Adapted from slide courtesy of Armando Oliva, M.D. and Amy Malla, FDA

SDTM Basics

Structures Based Upon General Observation Classes

Interventions:

- Investigational treatments, therapeutic treatments, and procedures administered to or taken by the subject
- One record per constant dosing/treatment interval
- Examples: study medications(EX), concomitant medications(CM)

Events:

- Occurrences or incidents independent of planned study evaluations occurring during the trial or prior to the trial
- One record per event
- Examples: medical history(MH), adverse events(AE)

Findings:

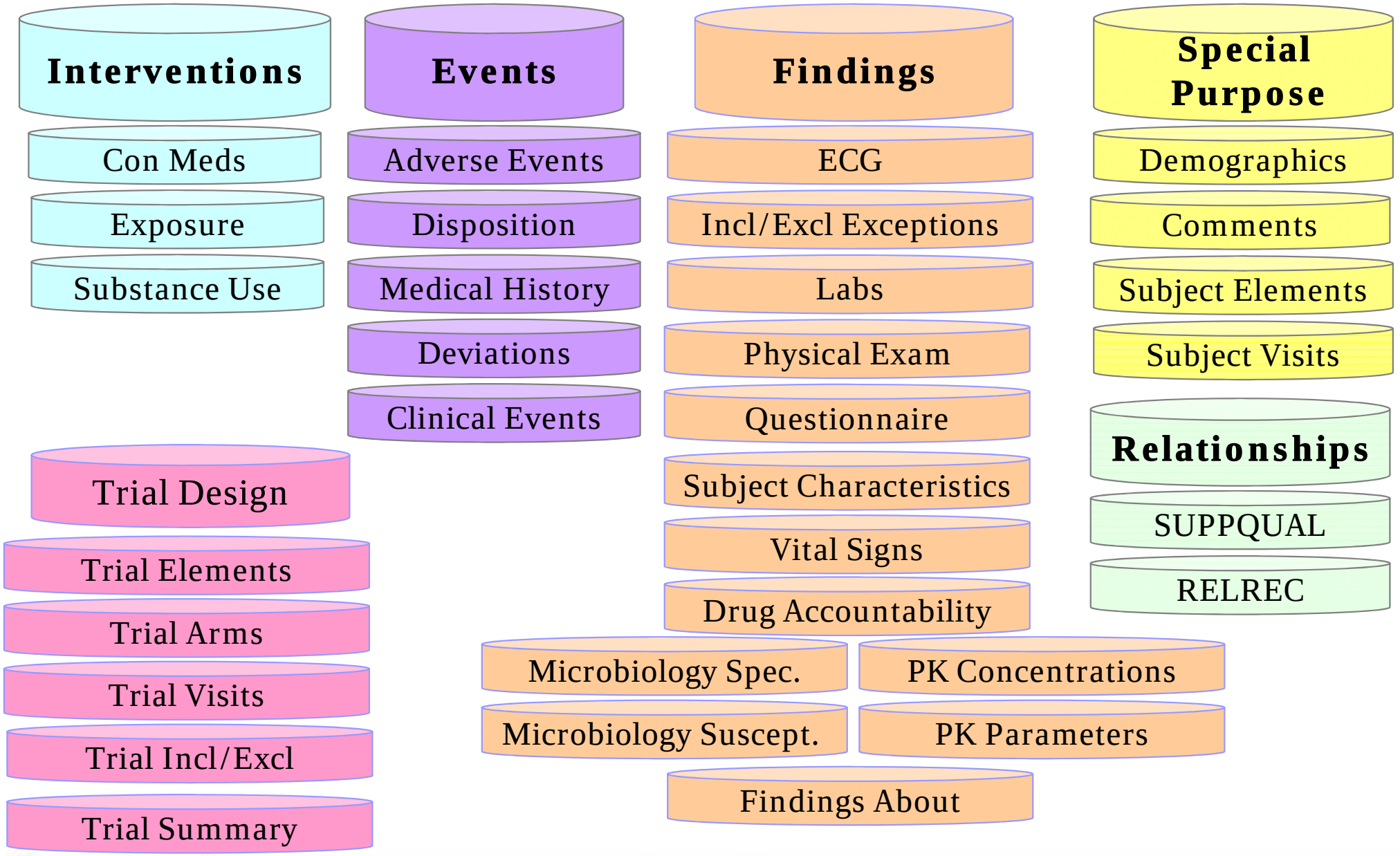
- Observations resulting from planned evaluations
- One record per finding result or measurement
- Examples: lab data(LB), vital signs(VS)

SDTM Basics

Special Purpose Domains, Trial Design and Relationships

- Not Classified as Interventions, Events, or Findings
- They Have Special Rules
  - Demographics(DM)
    - Subject data
  - Comments(CO)
    - Free-text comments
  - Supplemental Qualifiers
    - Used for data items not included in the SDTM standard
  - RELREC
    - Used for Relating records across datasets
  - Trial Design Tables
    - Planned treatments, planned visits
  - Subject Element and Visit tables
    - Subject actual experience

SDTMIG Standard Domains – v3.1.2

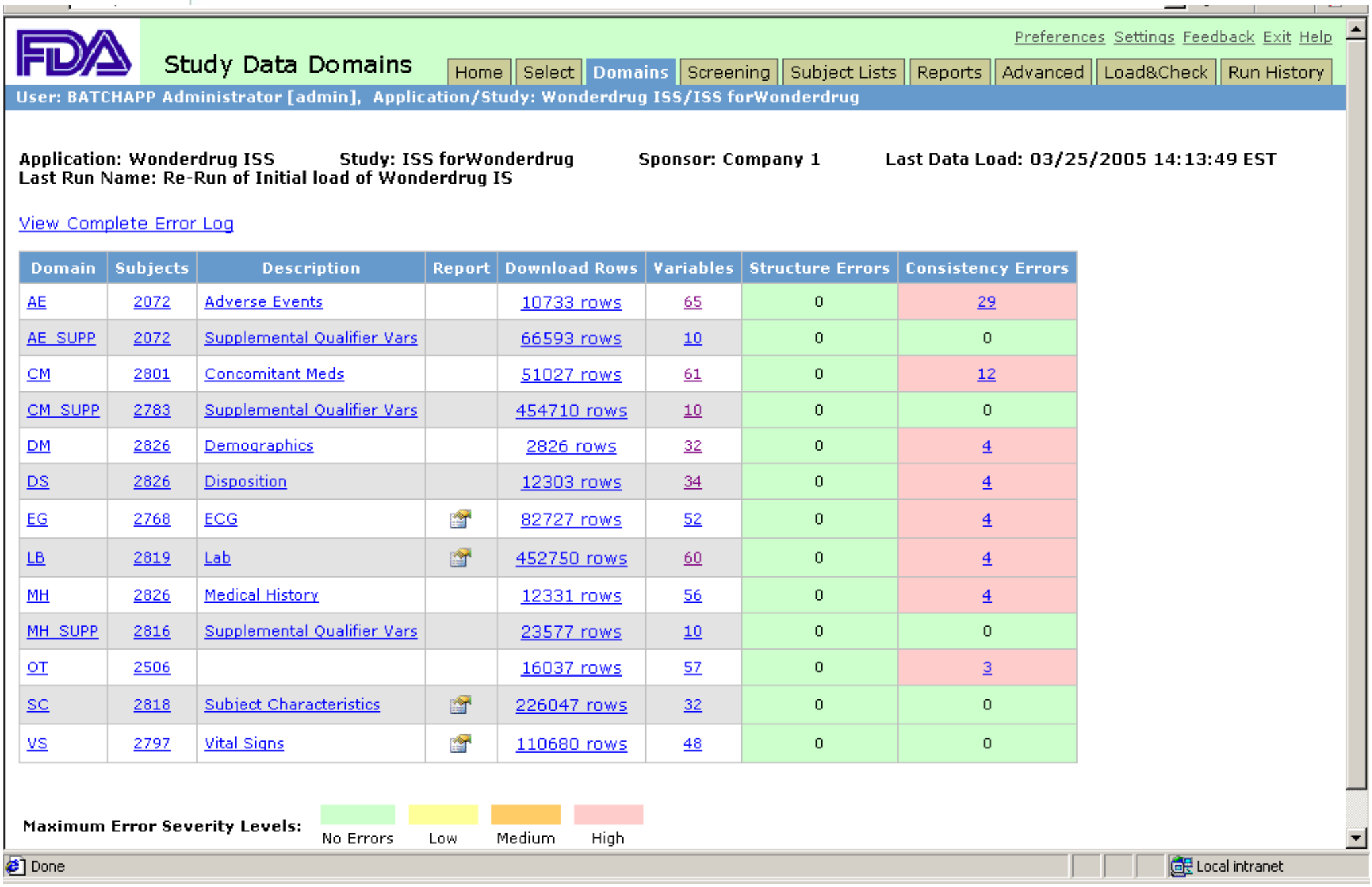


SDTM Example – Laboratory Data (LB) - Findings

	STUDYID	DOMAIN	USUBJID	LBSEQ	LBTESTCD	LBTEST	LBCAT	LBORRES	LBORRESU	LBORNRLO	LBORNRHI
Row 1	ABC	LB	ABC-001-001	1	GLUCOSE	Glucose	Urine	7	mg/dL	1	15
Row 2	ABC	LB	ABC-001-001	2	GLUCOSE	Glucose	Urine	11	mg/dL	1	15
Row 3	ABC	LB	ABC-001-001	3	GLUCOSE	Glucose	Urine	9	mg/dL	1	15

	LBSTRESC	LBSTRESN	LBSTRESU	LBSTNRLO	LBSTNRHI	VISIT	VISITNUM
Row 1 (cont)	0.38	0.38	mmol/L	0.1	0.8	BASELINE	1
Row 2 (cont)	0.61	0.61	mmol/L	0.1	0.8	BASELINE	1
Row 3 (cont)	0.5	0.5	mmol/L	0.1	0.8	BASELINE	1

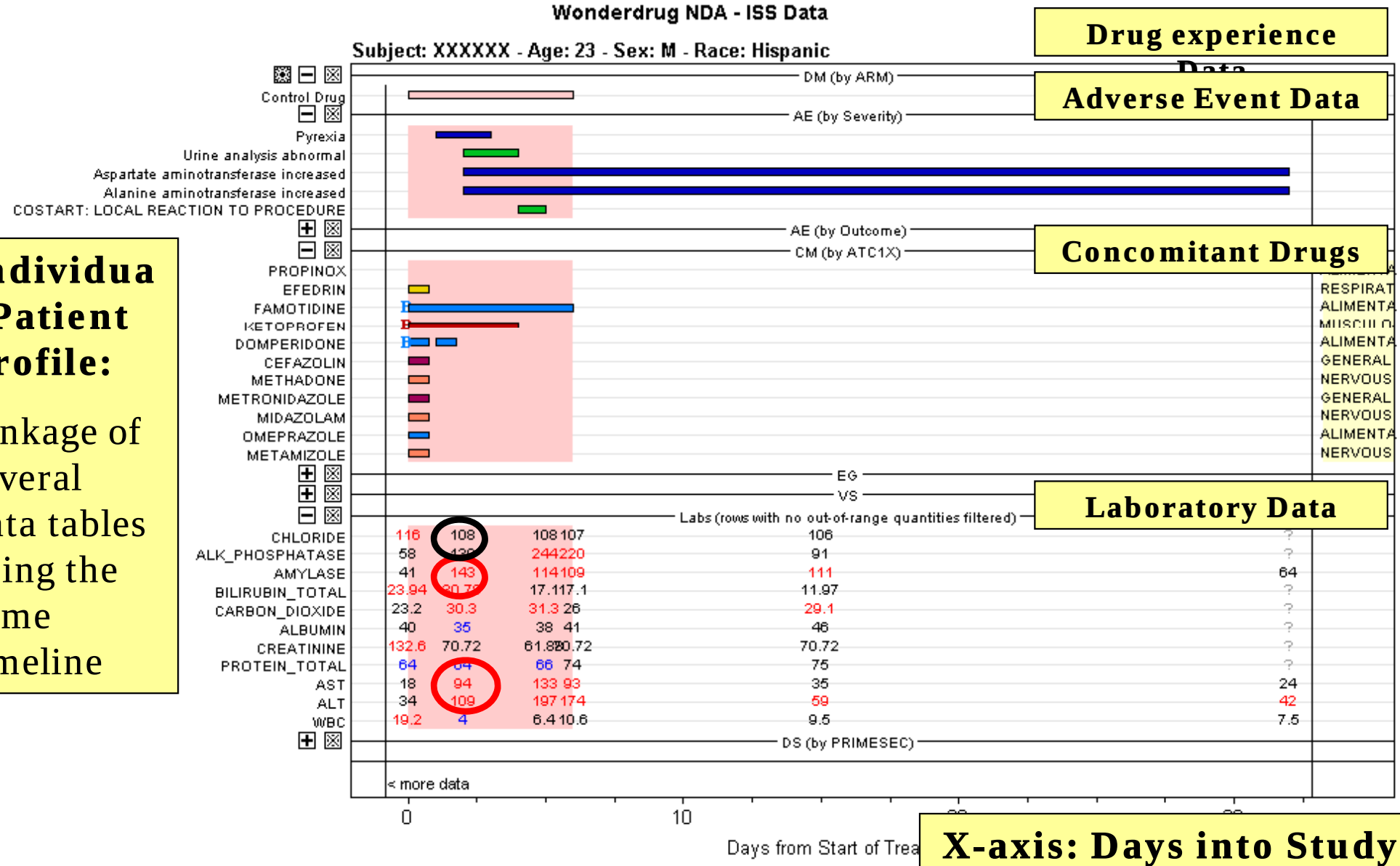
	LBDTC	LBENDTC	LBTPT	LBTPTNUM	LBELTM	LBTPTREF	LBRFTDTC
Row 1 (cont)	1999-06-19T04:00	1999-06-19T07:45	Pre-dose	1	-P15M	Dosing	1999-06-19T08:00
Row 2 (cont)	1999-06-19T08:00	1999-06-19T16:00	0-8 hours after dosing	2	P8H	Dosing	1999-06-19T08:00
Row 3 (cont)	1999-06-19T16:00	1999-06-20T00:00	8-16 hours after dosing	3	P16H	Dosing	1999-06-19T08:00


Study Data Domains
Preferences Settings Feedback Exit Help
Home Select Domains Screening Subject Lists Reports Advanced Load&Check Run History
User: BATCHAPP Administrator [admin], Application/Study: Wonderdrug ISS/ISS forWonderdrug
Application: Wonderdrug ISS Study: ISS forWonderdrug Sponsor: Company 1 Last Data Load: 03/25/2005 14:13:49 EST
Last Run Name: Re-Run of Initial load of Wonderdrug IS
View Complete Error Log
Domain | Subjects | Description | Report | Download Rows | Variables | Structure Errors | Consistency Errors
AE | 2072 | Adverse Events | | 10733 rows | 65 | 0 | 29
AE_SUPP | 2072 | Supplemental Qualifier Vars | | 66593 rows | 10 | 0 | 0
CM | 2801 | Concomitant Meds | | 51027 rows | 61 | 0 | 12
CM_SUPP | 2783 | Supplemental Qualifier Vars | | 454710 rows | 10 | 0 | 0
DM | 2826 | Demographics | | 2826 rows | 32 | 0 | 4
DS | 2826 | Disposition | | 12303 rows | 34 | 0 | 4
EG | 2768 | ECG | | 82727 rows | 52 | 0 | 4
LB | 2819 | Lab | | 452750 rows | 60 | 0 | 4
MH | 2826 | Medical History | | 12331 rows | 56 | 0 | 4
MH_SUPP | 2816 | Supplemental Qualifier Vars | | 23577 rows | 10 | 0 | 0
OT | 2506 | | | 16037 rows | 57 | 0 | 3
SC | 2818 | Subject Characteristics | | 226047 rows | 32 | 0 | 0
VS | 2797 | Vital Signs | | 110680 rows | 48 | 0 | 0
Maximum Error Severity Levels:
No Errors Low Medium High
Done
Local intranet

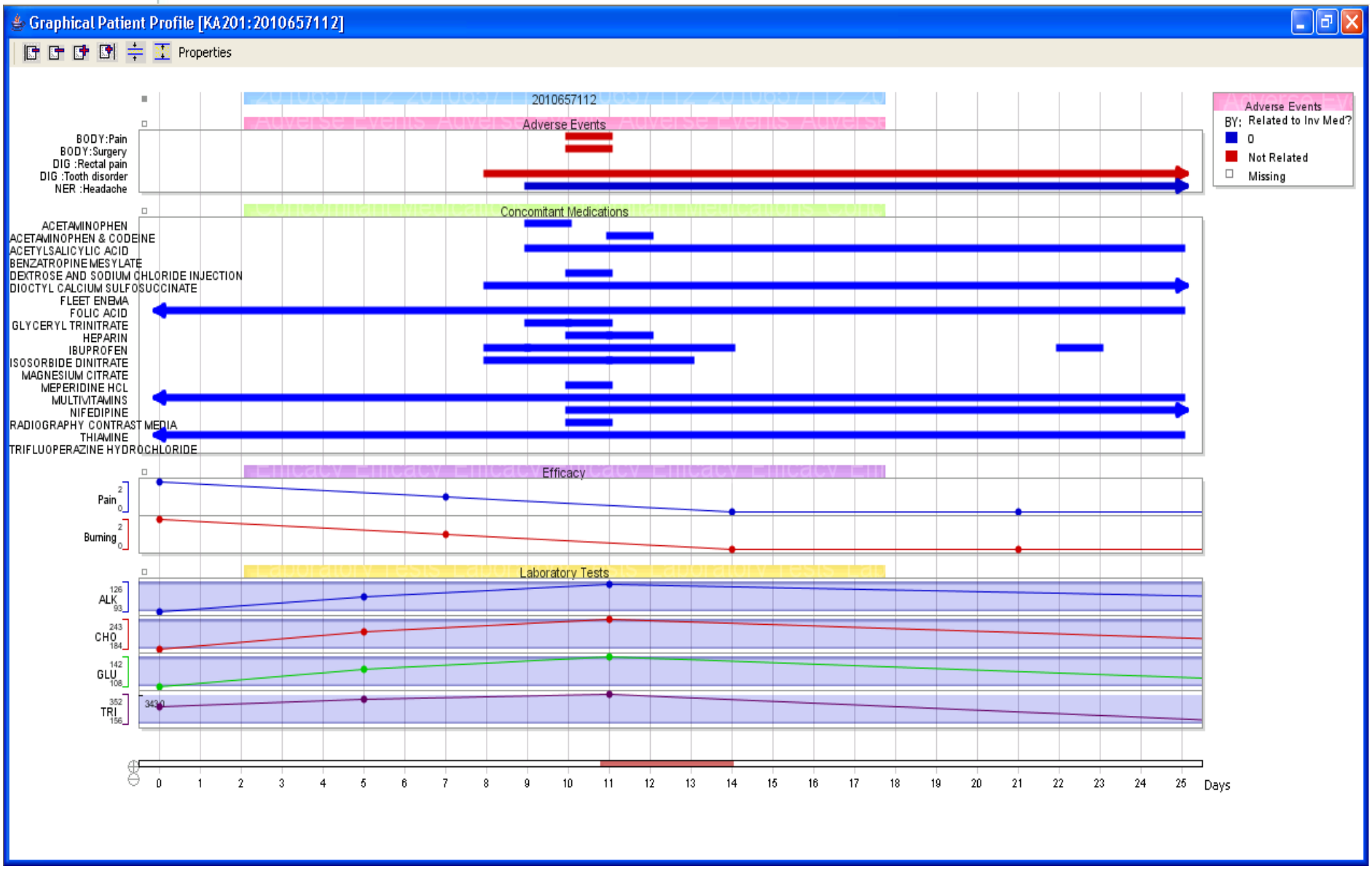
Assessing Potential Liver Injury by Analyzing Increases in Serum Alanine Aminotransferase (ALT) and Total Serum Bilirubin (TBILI) IN ONE STEP

Individual Patient Profile:

Linkage of several data tables using the same timeline

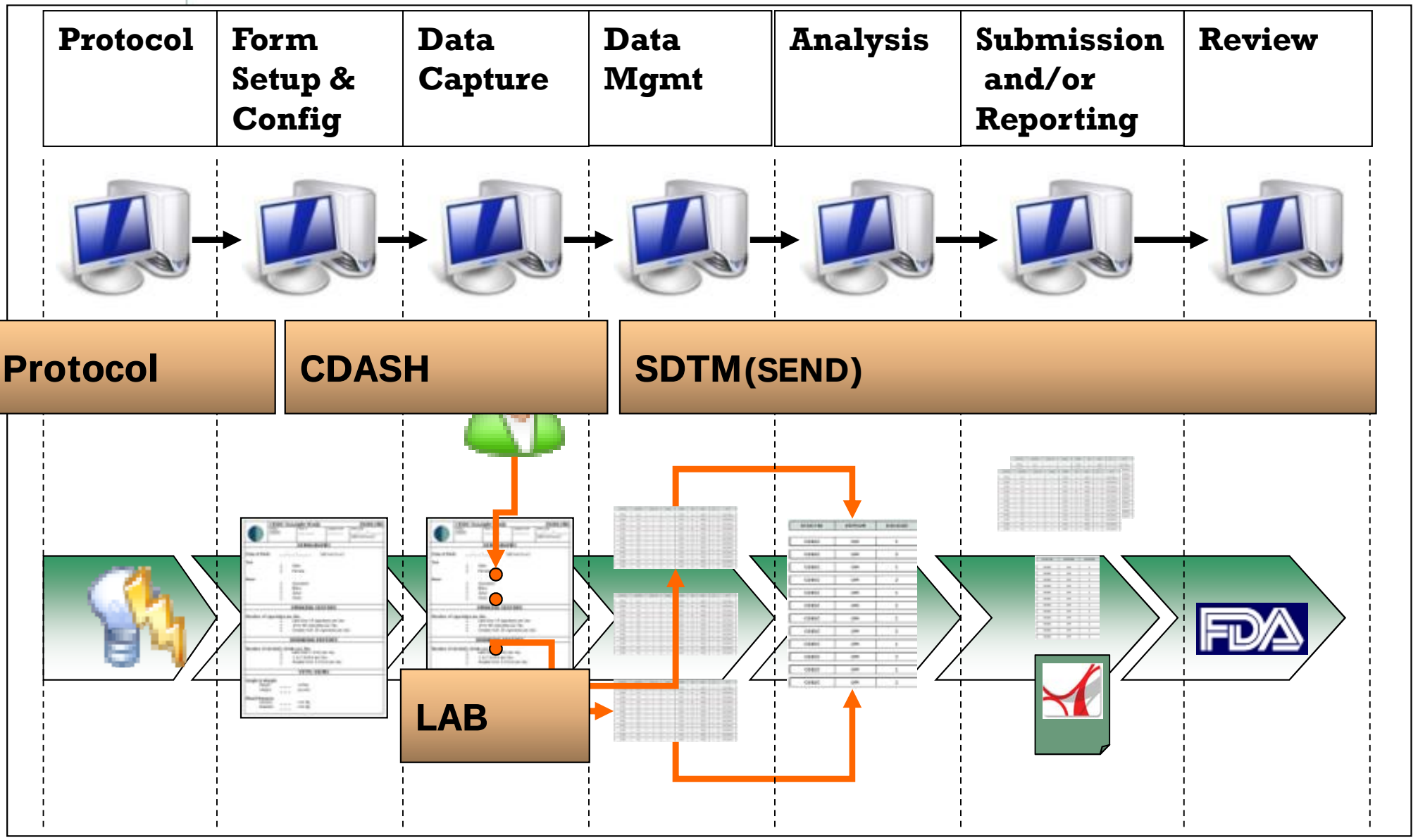


J Review


Graphical Patient Profile [KA201:2010657112]
Properties
2010657112
Adverse Events
BODY:Pain
BODY:Surgery
DIG :Rectal pain
DIG :Tooth disorder
NER :Headache
Adverse Events
BY: Related to Inv Med?
0
Not Related
Missing
Concomitant Medications
ACETAMINOPHEN
ACETAMINOPHEN & CODEINE
ACETYLSALICYLIC ACID
BENZATROPINE MESYLATE
DEXTROSE AND SODIUM CHLORIDE INJECTION
DIOCTYL CALCIUM SULFOSUCCINATE
FLEET ENEMA
FOLIC ACID
GLYCERYL TRINITRATE
HEPARIN
IBUPROFEN
ISOSORBIDE DINITRATE
MAGNESIUM CITRATE
MEPERIDINE HCL
MULTIVITAMINS
NIFEDIPINE
RADIOGRAPHY CONTRAST MEDIA
THIAMINE
TRIFLUOPERAZINE HYDROCHLORIDE
Efficacy
Pain
Burning
Laboratory Tests
ALK
CHO
GLU
TRI
0 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25
Days

STANDARD FOR EXCHANGE OF NONCLINICAL DATA (SEND)

CDISC Production Standards



SEND

- SEND is an implementation of SDTM for animal data
- SEND defines domains and variables for submitting all data generated from animal toxicity studies
  - Includes: single- and repeat-dose toxicity, carcinogenicity, reproductive toxicity, and rodent micronucleus
  - Does not include data generated from in vitro studies or as part of basic pharmacology or efficacy studies conducted in animals

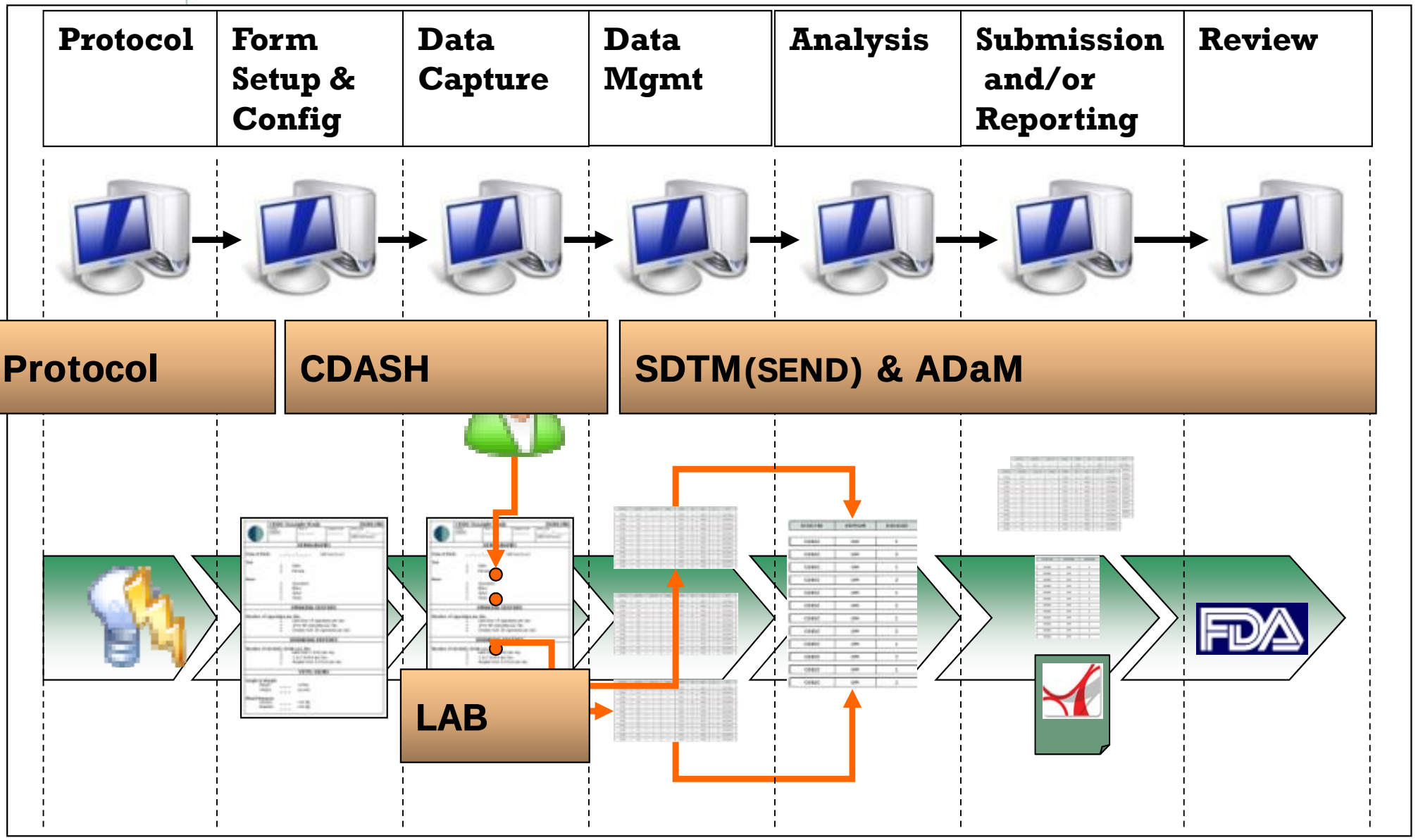
- CRADA (April 2002) between PharmQuest and CDER to develop and evaluate software tools for receiving, storing, viewing and analyzing nonclinical (i.e., animal toxicity) data based on SEND model

SEND v2.3 Findings Domains

- Animal Characteristics
- Water Consumption
- Clinical Signs
- Clinical Pathology
- Organ Weights
- Fetal Data
- Group Observations
- Drug/Metabolite Levels
- Tumor Analysis
- Vital Signs
- Food Consumption
- Body Weights
- Animal Disposition
- Macroscopic Findings
- Microscopic Findings
- Fertility
- Group Characteristics
- Study Summary
- Rodent Micronucleus

ANALYSIS DATA MODEL (ADaM)

CDISC Production Standards



Analysis Data Model: Version 2.1

- ADaM used for statistical analysis and reporting
- Describes
  - key principles
  - conventions for standard analysis variables
  - provides an example of a key subject-level analysis file

- Describes metadata specific for Analysis Datasets
  - Analysis dataset metadata
  - Analysis variable metadata
  - Analysis results metadata

} structured documentation of analysis datasets

Key Principles for Analysis Dataset Creation

Analysis datasets should:

- facilitate clear and unambiguous communication
- be useable by currently available tools
- be linked to machine-readable metadata
- be analysis-ready
- include subject-level analysis dataset named ADSL
- use the convention: ADxxxxxx for naming
- have optimum number of datasets so minor programming needed
- maintain SDTM variable attributes for same variables
- use SDTM naming fragments where feasible

Example: Analysis Dataset

An ADaM dataset should be named "ADxxxxxx"

SAMPLE DATASET FOR ADSL

Obs	STUDYID	USUBJID	SAFFL	ITTFL	PPROTFL	COMPLTFL	DSREAS	AGE	AGEGR1
1	XX0001	0001-1	Y	Y	Y	Y		30	21-35
2	XX0001	0001-2	Y	Y	N	N	ADVERSE EVENT	38	36-50

SAMPLE DATASET FOR ADSL (continued)

Obs	AGEGR1N	SEX	RACE	RACEN	TRT01P	TRT01PN	HEIGHTBL	WEIGHTBL	BMIBL
1	2	F	WHITE	1	DRUG A	1	170	63.5	21.97
2	3	M	ASIAN	4	PLACEBO	0	183	86.2	25.74

SDTM variable with no changes

ADaM Treatment Variable

Why both SDTM & ADaM Datasets?

SDTM Datasets:

- observations from a clinical trial
- useful in medical officer evaluation of safety
- how the data were collected

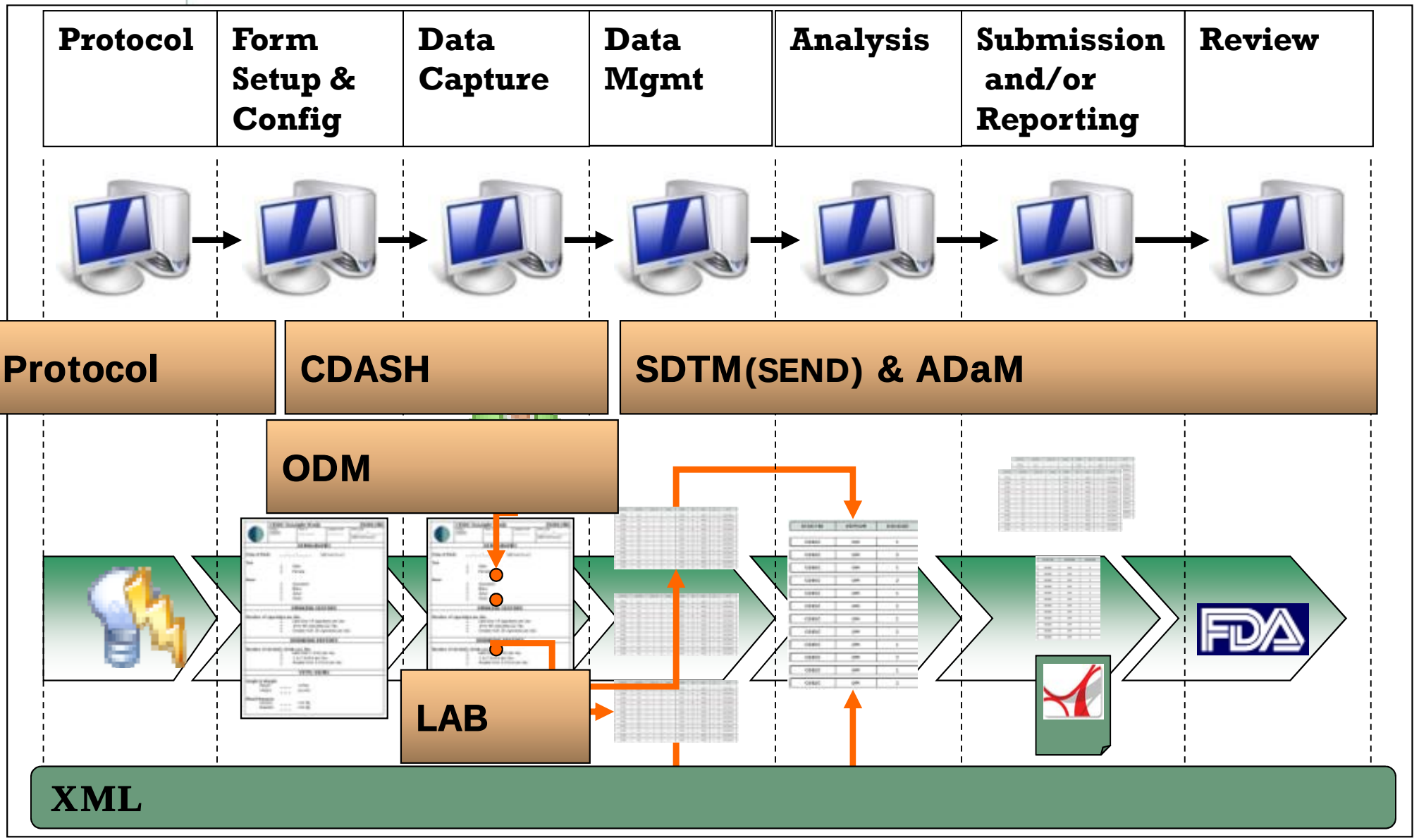
ADaM Datasets:

- restructured and contain additional information (derived variables, flags, comments, etc.)
- how the data were used in analysis

BOTH ARE NEEDED FOR FDA REVIEW !

OPERATIONAL DATA MODEL (ODM)

CDISC Production Standards



CDISC Operational Data Model

- Transport Standard (XML)
  - Developed to carry case report form data
  - Carries complete audit trail information (21CFR11)
  - Supports electronic signatures
  - Archives electronic data without need to archive original system at sites
  - Can automate generation of eCRFs
  - Enables remote monitoring or auditing
  - Facilitates exchange of data between different technologies that are ODM (supports features common to all CDM and EDC systems)

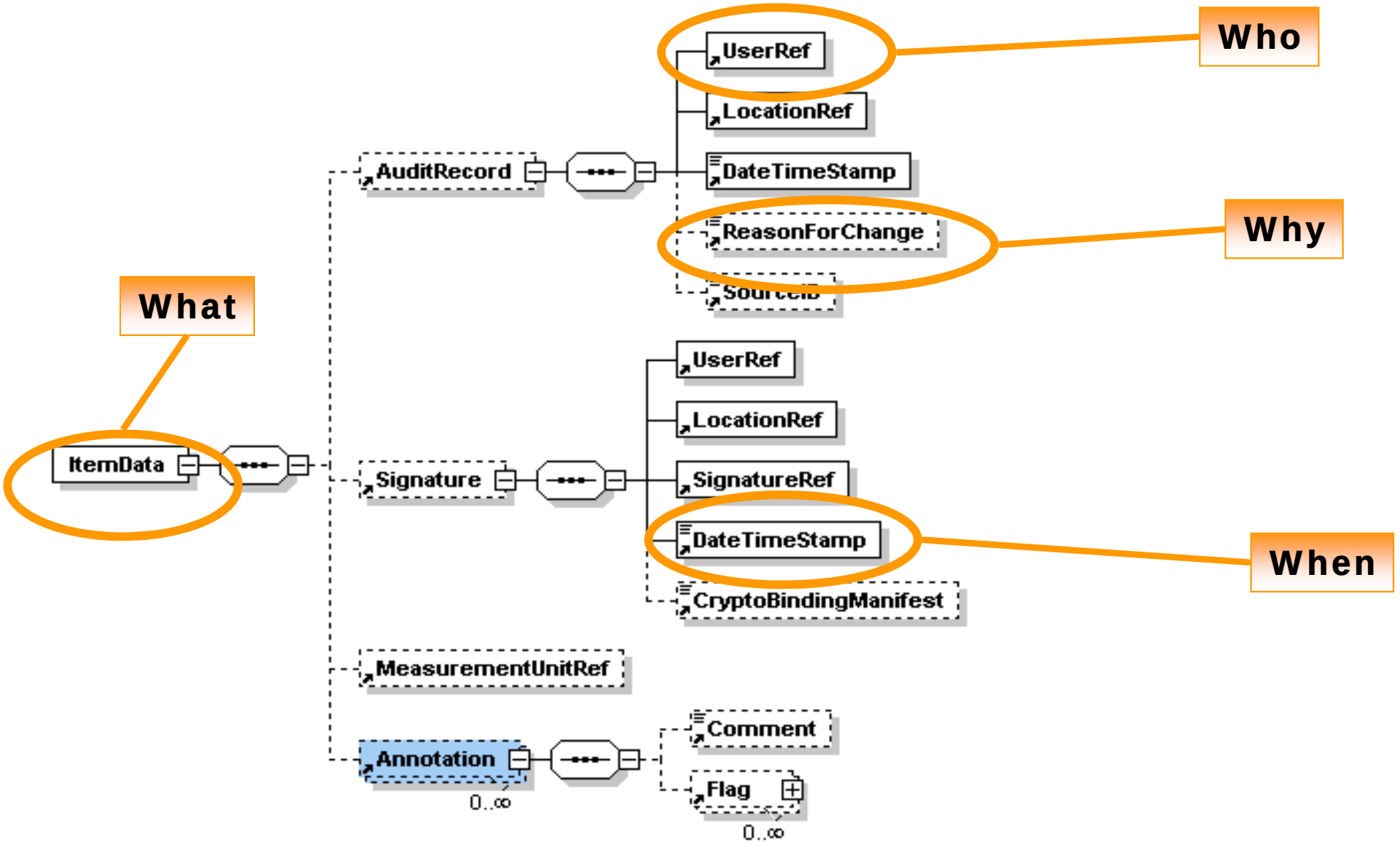
eXtensible Markup Language

- XML - method for putting structured data in a text file
- Looks similar to HTML
  - Tags “<“ “>”
  - Attributes name=“Value”
- Very flexible standard for data/metadata exchange
- Text based & readable by humans and machines
  - Vendor neutral
  - Computer system neutral

Glossary for ODM

- A **StudyEvent** corresponds to a patient visit
- A **Form** corresponds to a data-entry form
- An **ItemGroup** corresponds to a panel,relational table or SAS dataset. Related group of items.
- An **Item** corresponds to a dataset variable or SAS field
- A **CodeList** corresponds to an external lookup table or a SAS format

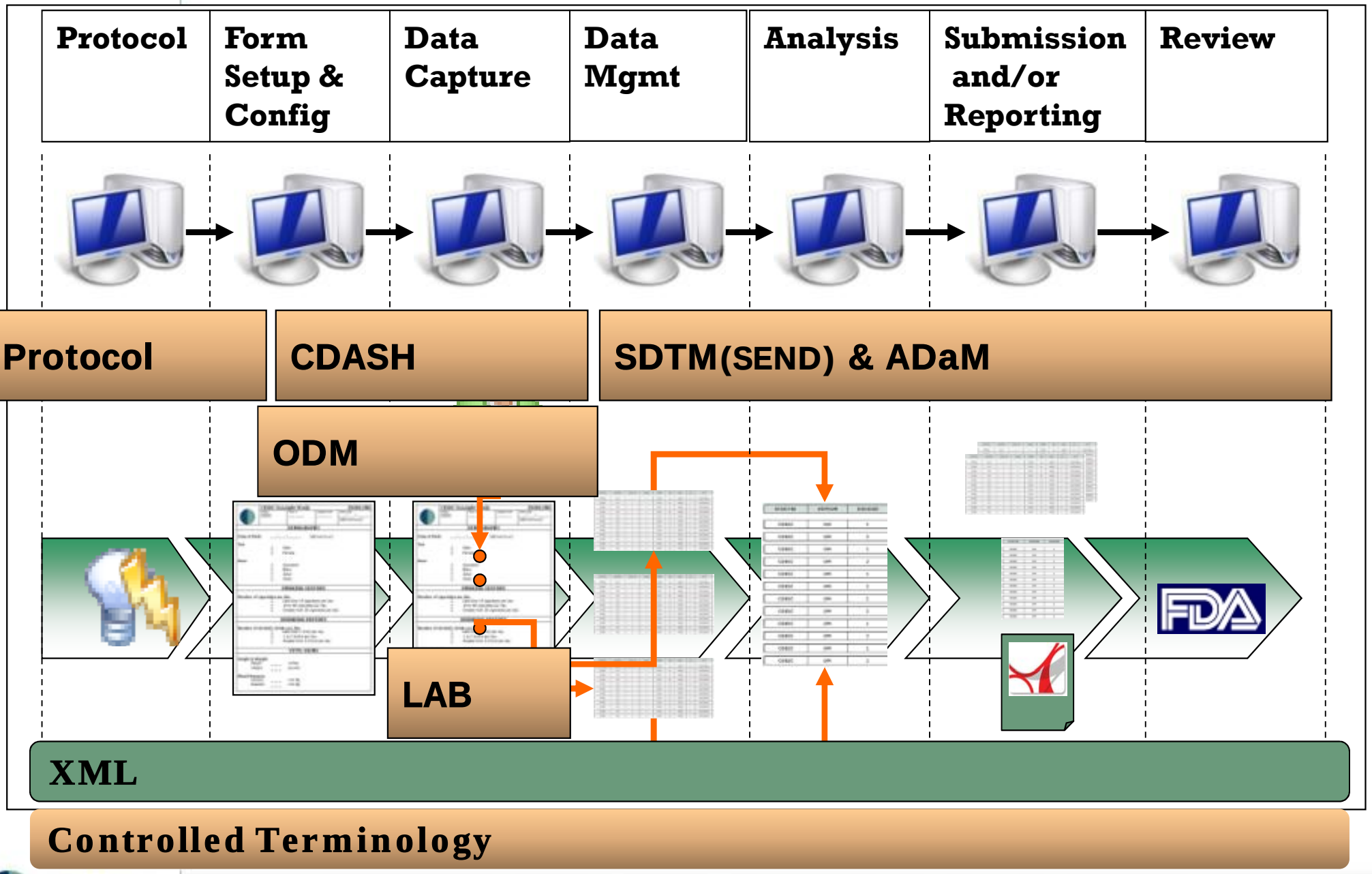
ODM & Audit Trail



Slide courtesy Dave Iberson-Hurst, Assero

CONTROLLED TERMINOLOGY

Clinical Information Flow the CDISC Way



CDISC Terminology

- Formalized CDISC Terminology Initiative in 2005
- Primary Objective: to define and support the terminology needs of the CDISC models across the clinical trial continuum (CDASH → SDTM), Focus on "standard" terminology codelist development and publication
- Terminology Initiative comprised of 45 team members (FDA, NCI, Global Sponsors & CROs, Academia) distributed across 4 project teams
- Key partnership with NCI Enterprise Vocabulary Services (NCI EVS) with dedicated CDISC / FDA resources

Collaboration with NCI EVS

NCI Enterprise Vocabulary Services (EVS) has committed expertise and significant resources in support of the CDISC Terminology Initiative...

Guiding Principles (1)

Adopt...Adapt...Develop philosophy

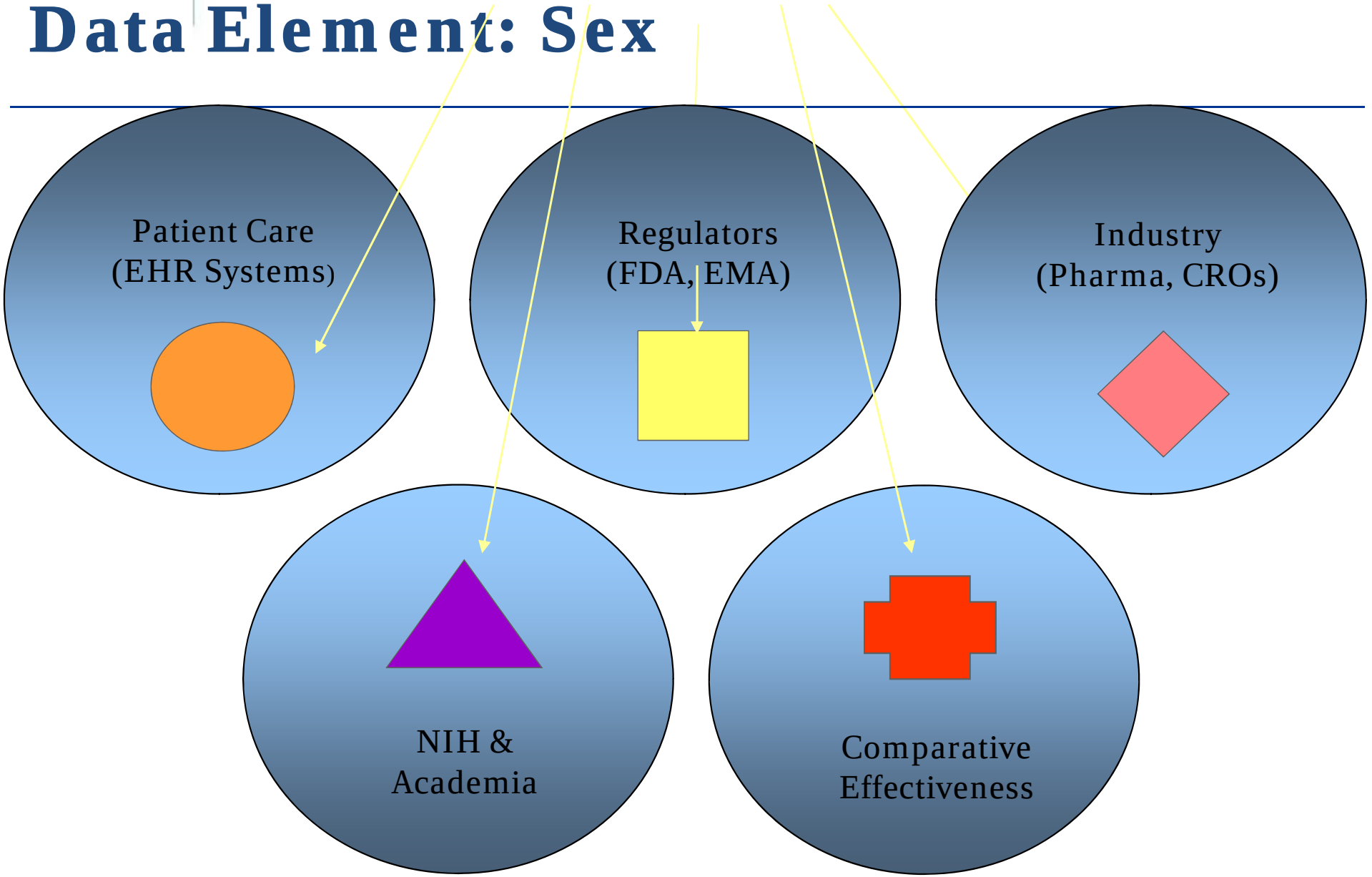
- Evaluate and/or utilize existing terminology first
- Expand existing vocabularies where incomplete, working with vocabulary developer / owner
- Harmonize across CDISC Models and with pre-existing vocabulary initiatives

Guiding Principles (2)

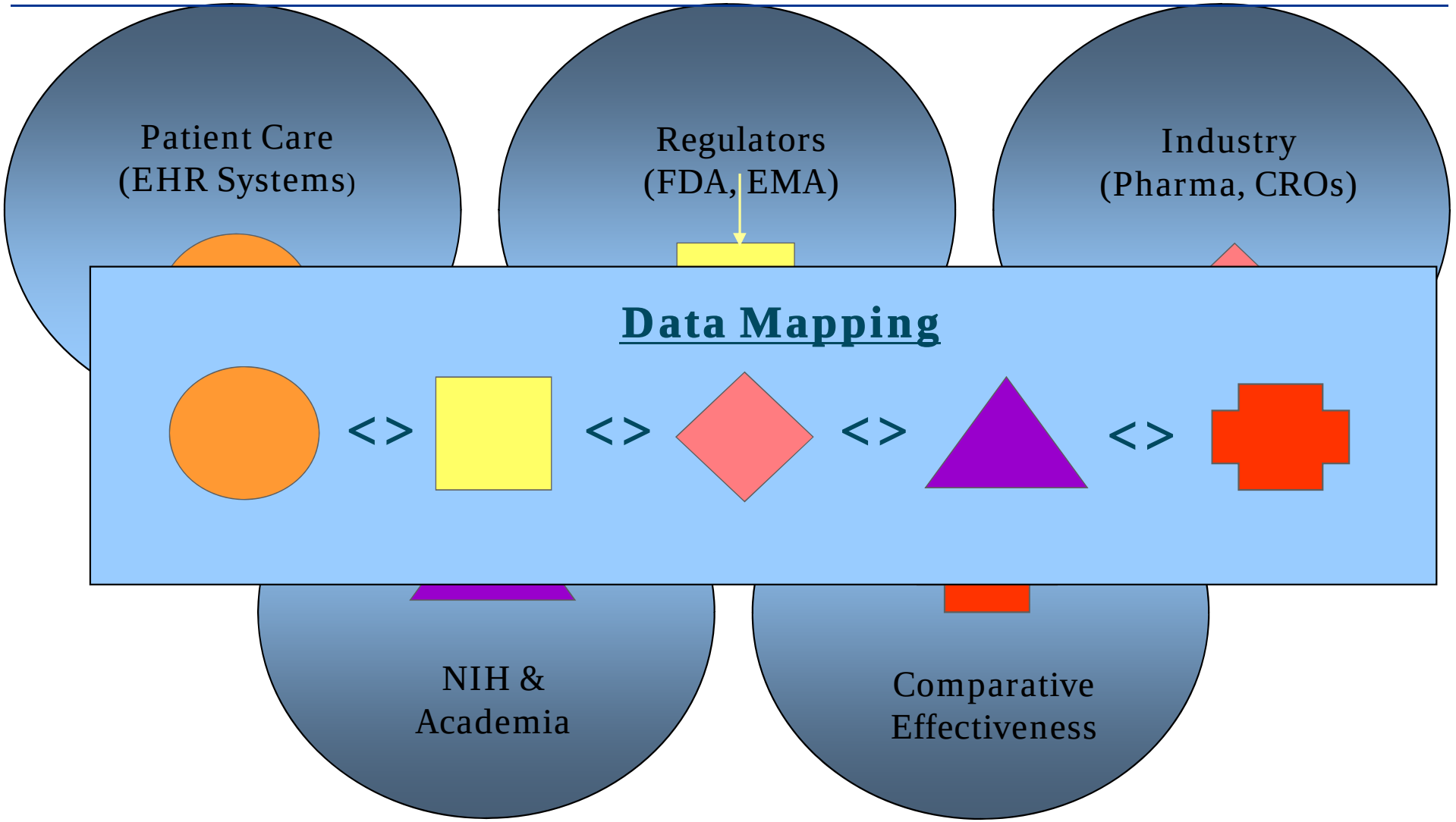
- Address international needs for global projects and organizations

- Ensure a sustainable “open source” environment and infrastructure for production terminology supporting terminology evolution

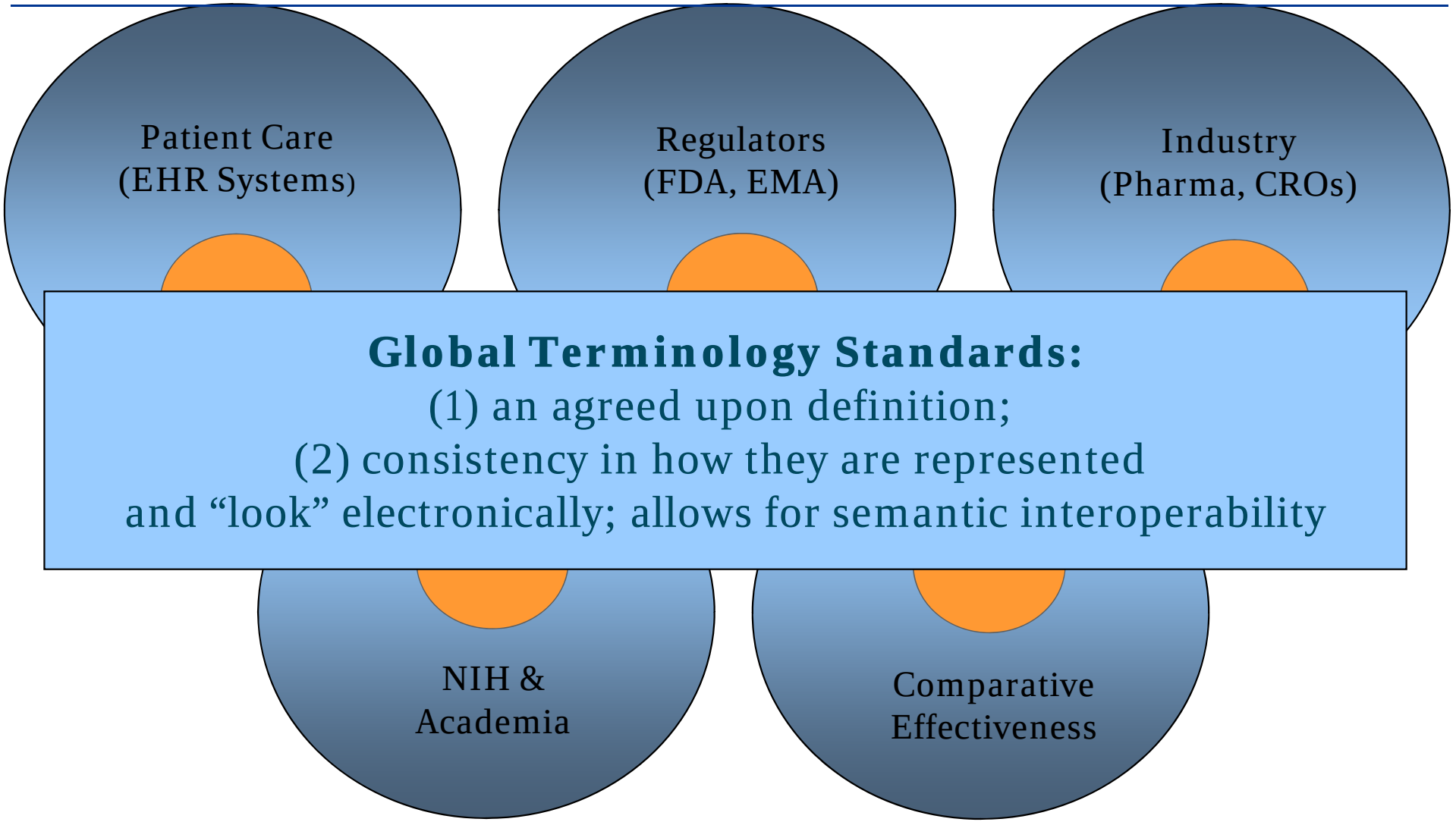
Data Element: Sex



Data Element: Sex



Standard Data Element: Sex



POSITION Codelist Example
SDTM and CDASH: VSPOS, EGPOS

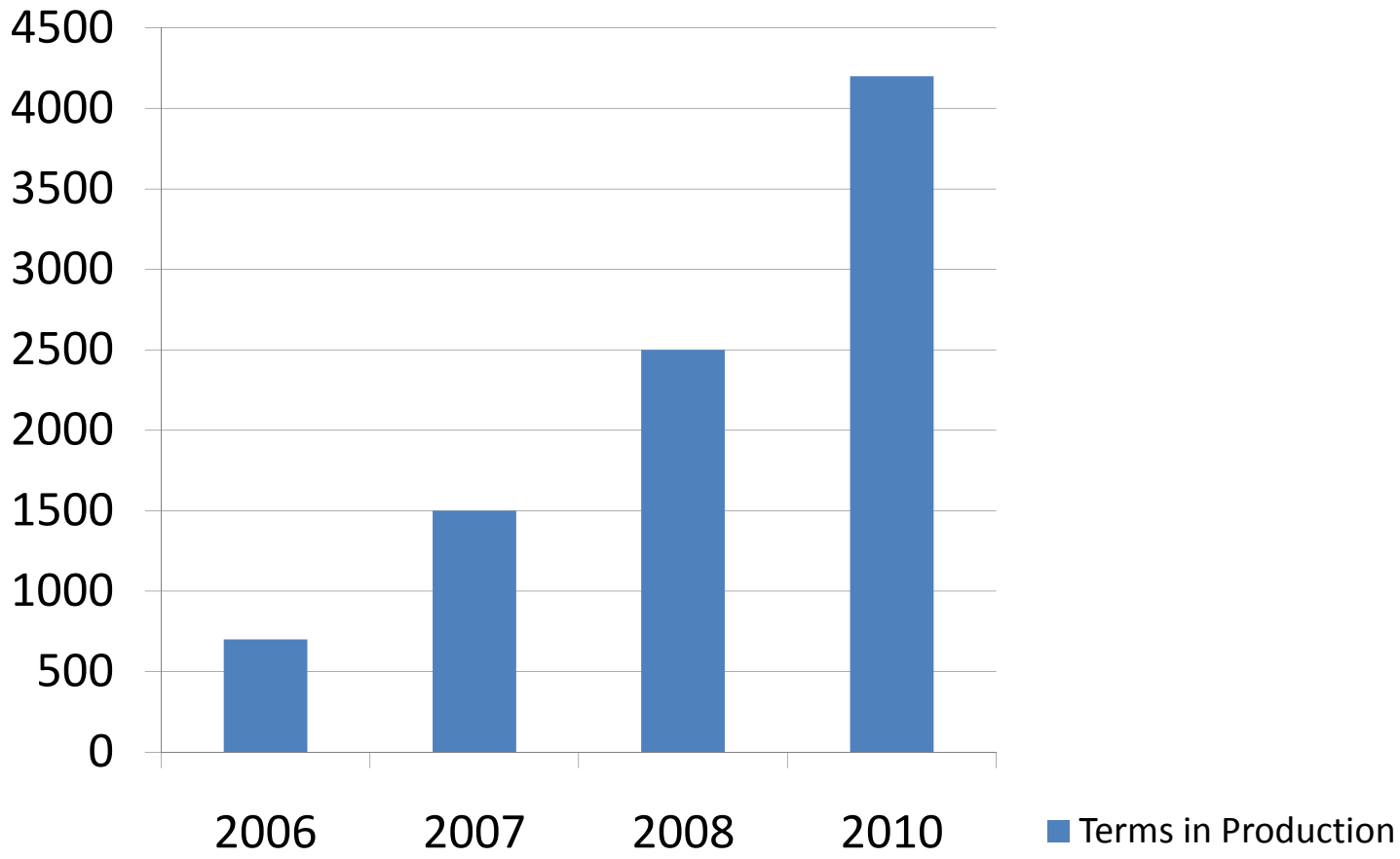
Standard Terminology Codelist

CDISC Controlled Terminology

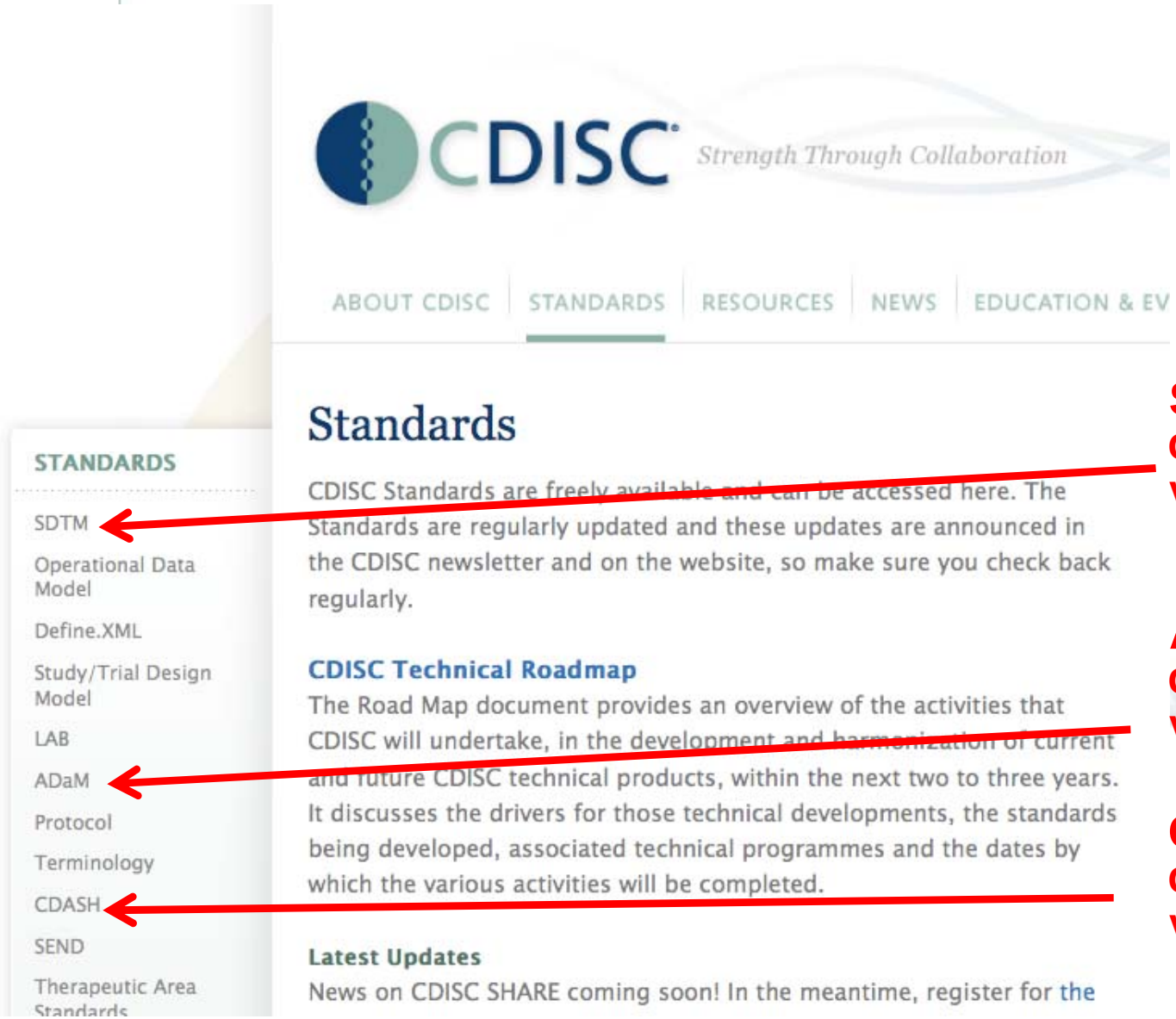
- Sitting
- Prone
- Standing
- Supine
- Fowlers
- Semi-Fowlers
- Trendelenburg
- Reverse Trendelenburg
- Right Lateral Decubitus
- Left Lateral Decubitus

Codelist = Value Set = Permissible Values

Terminology Group Internal CDISC Standards Development



For More Information on CDISC Standards



www.CDISC.org

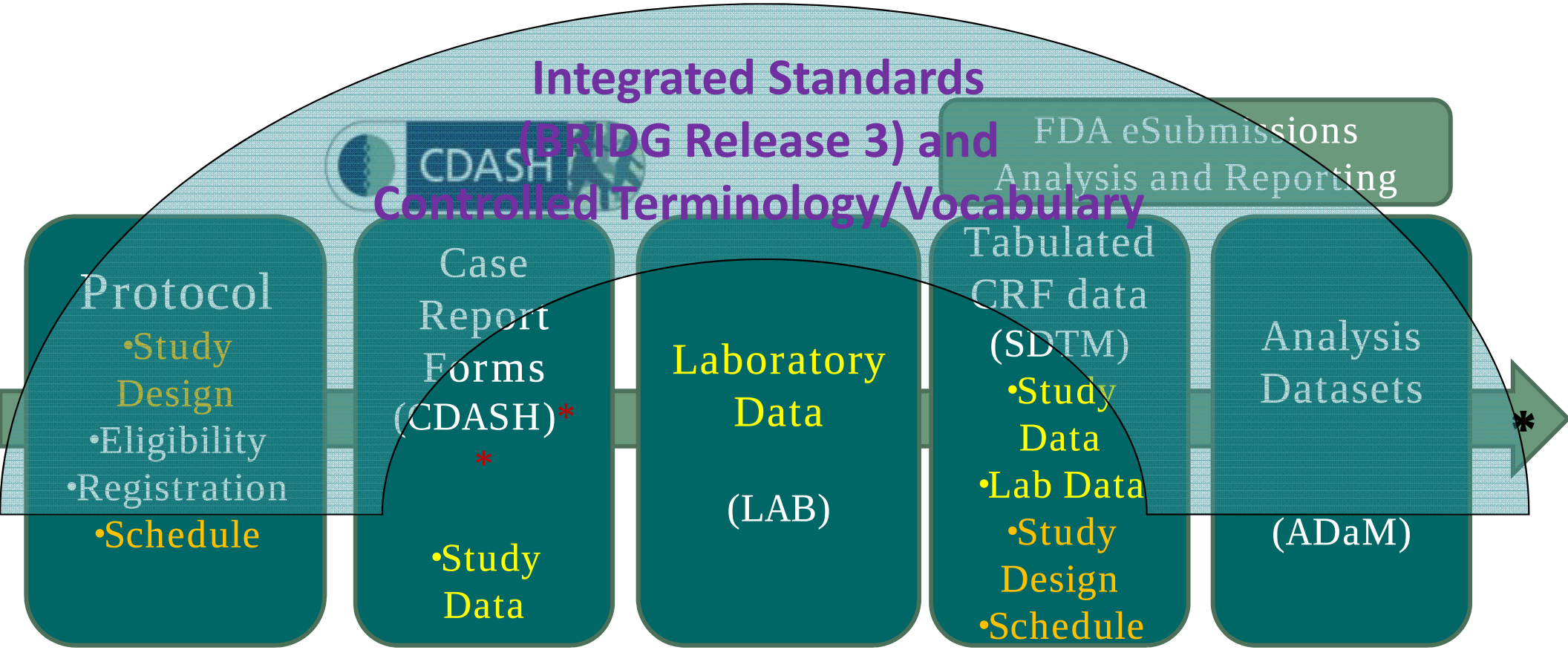
SDTM and SDTMIG
Current production version

ADaM
Current production version

CDASH
Current production version

End-To-End Use of CDISC Standards

Global Biomedical Research Standards (Protocol →Reporting)



** Harmonized w/ NCI caBIG CRFs

* CDISC and/or HL7

BRIDG = Biomedical Research Integrated Domain Group Model

*Biomedical Research Integrated Domain Group (BRIDG) Model

A clinical research domain analysis model initiated by CDISC,

BRIDGing

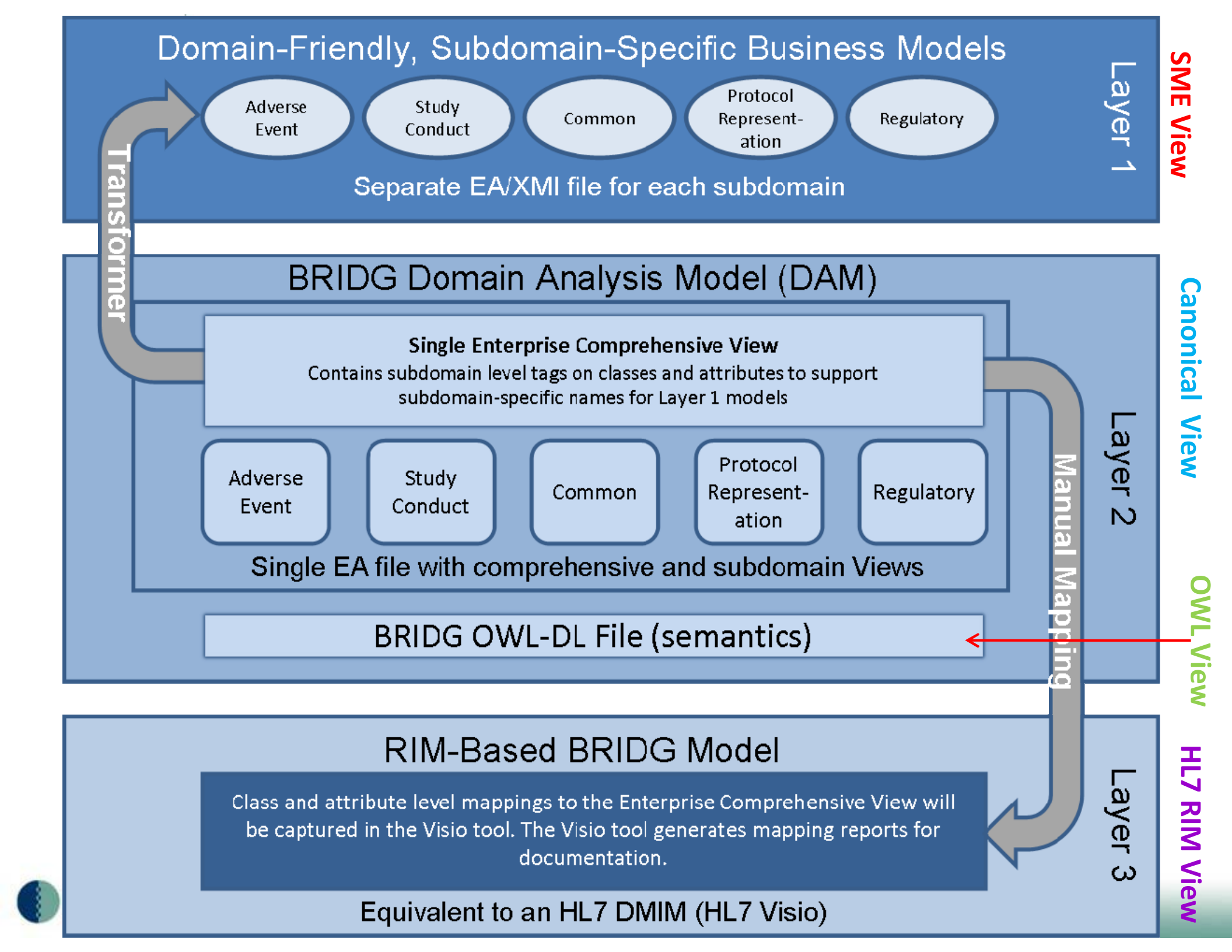
- Organizations (CDISC, HL7, FDA, NCI…)
- Standards
- Research and Healthcare

- www.bridgmodel.org (or via CDISC website)

BRIDG Scope

Protocol-driven research and its associated regulatory artifacts:

i.e. the data, organization, resources, rules, and processes involved in the formal assessment of the utility, impact, or other pharmacological, physiological, or psychological effects of a drug, procedure, process, subject characteristic, or device on a human, animal, or other subject or substance plus all associated regulatory artifacts required for or derived from this effort, including data specifically associated with post-marketing adverse event reporting.

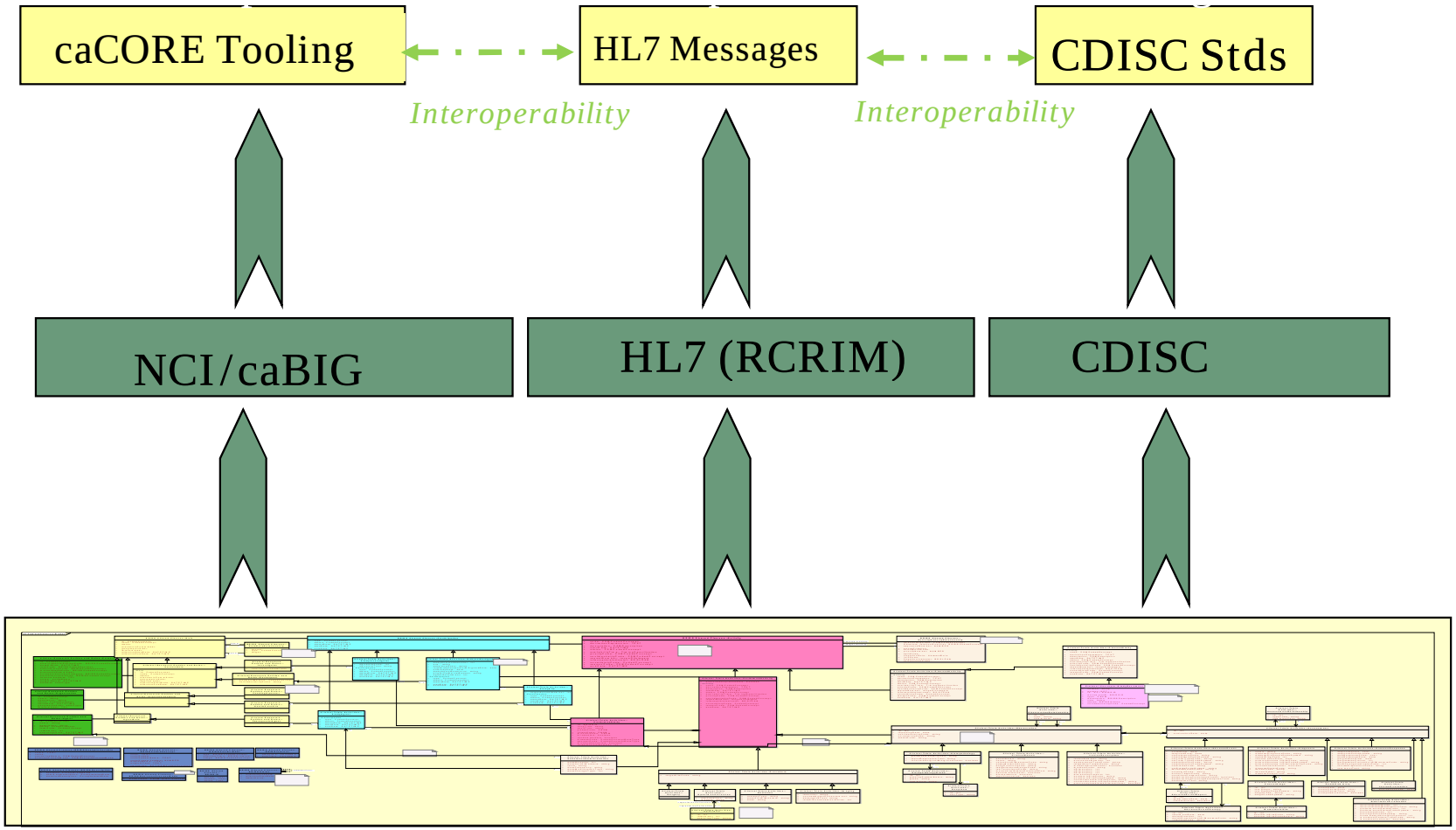

Domain-Friendly, Subdomain-Specific Business Models
Adverse Event
Study Conduct
Common
Protocol Represent-ation
Regulatory
Separate EA/XMI file for each subdomain
Layer 1
SME View
Transformer
BRIDG Domain Analysis Model (DAM)
Single Enterprise Comprehensive View
Contains subdomain level tags on classes and attributes to support subdomain-specific names for Layer 1 models
Adverse Event
Study Conduct
Common
Protocol Represent-ation
Regulatory
Single EA file with comprehensive and subdomain Views
BRIDG OWL-DL File (semantics)
Layer 2
Canonical View
Manual Mapping
OWL View
RIM-Based BRIDG Model
Class and attribute level mappings to the Enterprise Comprehensive View will be captured in the Visio tool. The Visio tool generates mapping reports for documentation.
Equivalent to an HL7 DMIM (HL7 Visio)
Layer 3
HL7 RIM View

Achieving Interoperability

IMPLEMENTATION SOLUTIONS

STAKEHOLDERS

FOUNDATION MODEL



BRIDG – Domain Analysis Model for Clinical Research

Rigorously defined Controlled Terminology

BRIDG as a Global Standard

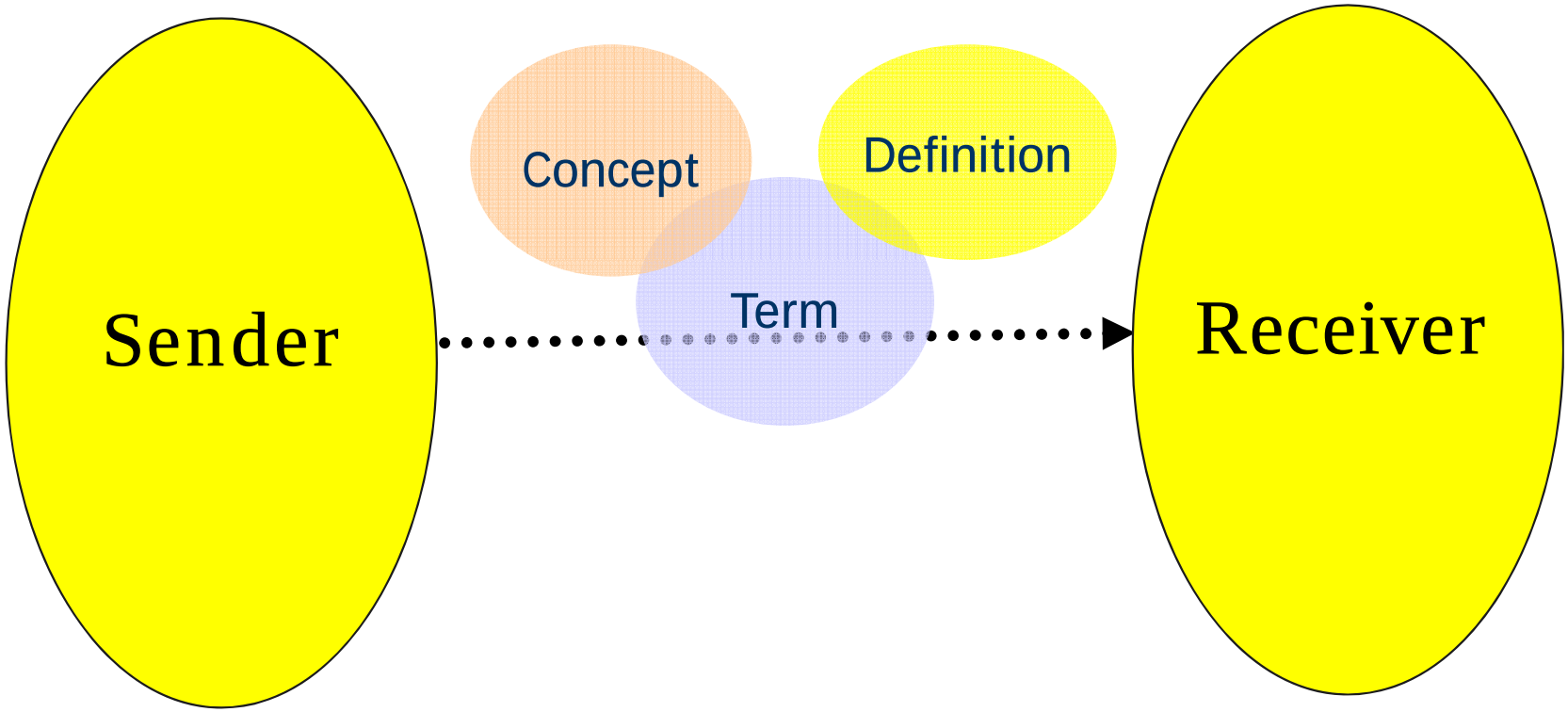
- BRIDG is going through the JIC (Joint Initiative Council) process to become a global standard
- BRIDG is now a CDISC standard and an HL7 Standard.
- BRIDG has passed two ballot cycles in ISO; the goal is for BRIDG to be an ISO standard (and CEN standard) in 2011.

Why is…

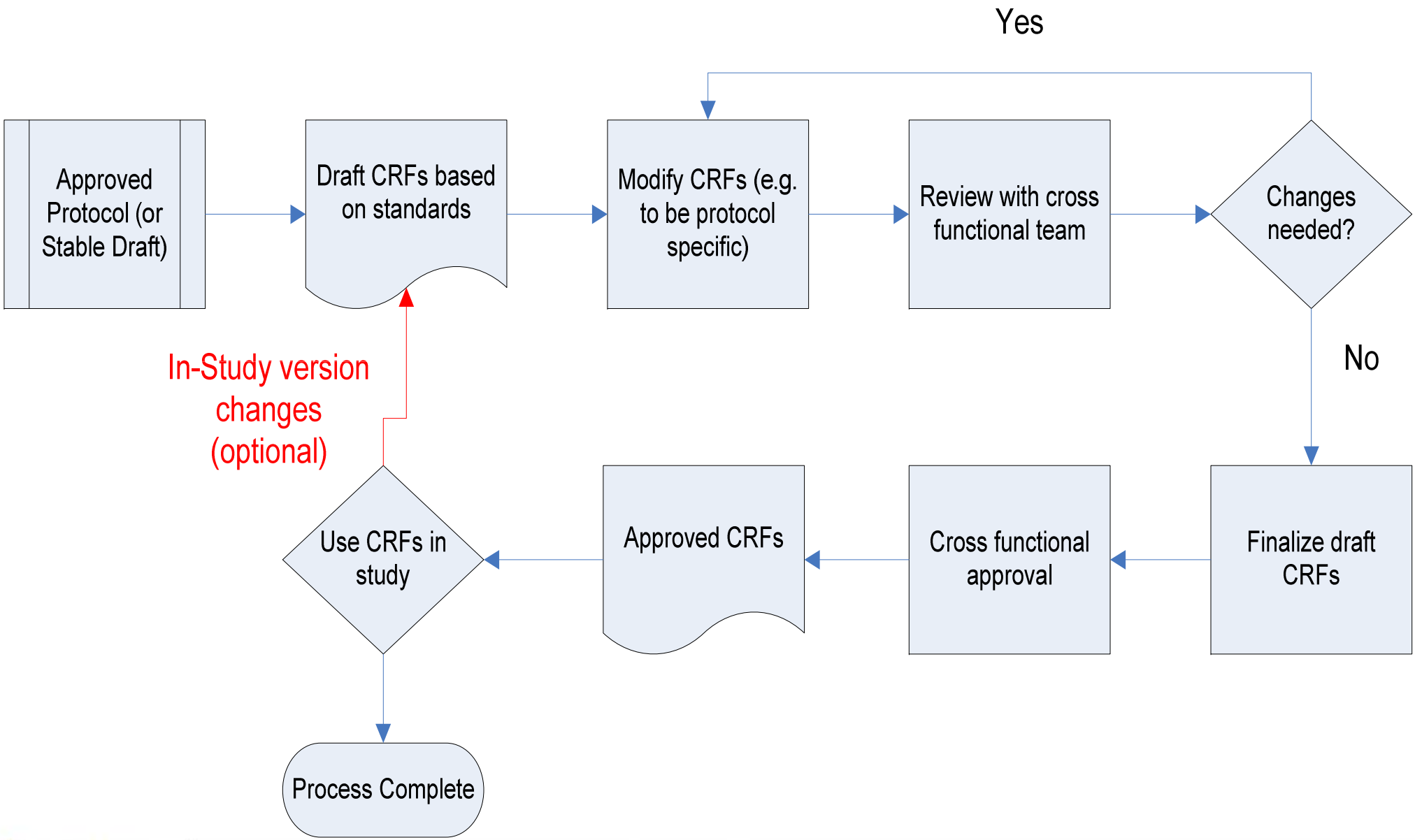
Standard Controlled Terminology

…Important?

Semantic Interoperability In eClinical Systems



Suggested CRF Development Workflow



ACRO Adverse Event Form

SPONSOR NAME

Protocol No.	Investigator No.	Subject No.	Subject Initials
ABC123	☐☐☐	☐☐☐	☐☐☐

ADVERSE EVENTS Has the subject experienced any adverse events? 1 ☐ Yes 0 ☐ No If Yes, describe below.

Event No.	Adverse Event	Start Date / Stop Date		Was Event Serious?	Severity	Is there a reasonable possibility that the AE may have been caused by the study drug(s)?*	Action Taken with Study Drug	Subject Outcome
	(Please list one event per line)	Either provide a stop date or mark box (√) if event is continuing ↓		Mark only 1 response 0 = No 1 = Yes	Mark only 1 response 1 = Mild 2 = Moderate 3 = Severe	Mark only 1 response 0 = No 1 = Yes	Mark only 1 response 0 = None 1 = Study drug regimen changed 2 = Temporarily stopped study drug 3 = Study drug discontinued	Mark only 1 response 0 = Subject remains in study 1 = Withdrawn from study 2 = Lost to follow-up 3 = Death
		☐☐-☐☐☐-☐☐☐☐ day month year ☐☐-☐☐☐-☐☐☐☐ day month year	1 ☐	0 ☐ 1 ☐	1 ☐ 2 ☐ 3 ☐	0 ☐ 1 ☐	0 ☐ 1 ☐ 2 ☐ 3 ☐	0 ☐ 1 ☐ 2 ☐ 3 ☐
		☐☐-☐☐☐-☐☐☐☐ day month year ☐☐-☐☐☐-☐☐☐☐ day month year	1 ☐	0 ☐ 1 ☐	1 ☐ 2 ☐ 3 ☐	0 ☐ 1 ☐	0 ☐ 1 ☐ 2 ☐ 3 ☐	0 ☐ 1 ☐ 2 ☐ 3 ☐
		☐☐-☐☐☐-☐☐☐☐ day month year ☐☐-☐☐☐-☐☐☐☐ day month year	1 ☐	0 ☐ 1 ☐	1 ☐ 2 ☐ 3 ☐	0 ☐ 1 ☐	0 ☐ 1 ☐ 2 ☐ 3 ☐	0 ☐ 1 ☐ 2 ☐ 3 ☐

*A "reasonable possibility" means you cannot rule out a relationship between the event and the study drug.

Annotated Version

SPONSOR NAME

Protocol No.	Investigator No.	Subject No.	Subject Initials
ABC123			

ADVERSE EVENTS Has the subject experienced any adverse events? 1 ☐ Yes 0 ☐ No If Yes, describe below.

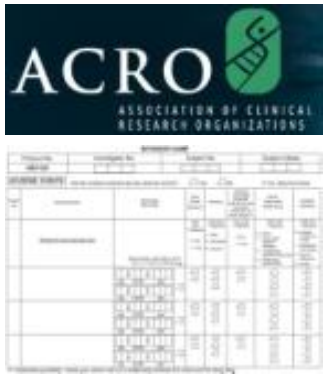
YES/NO QUESTION NOT INCLUDED IN CDISC SDTM

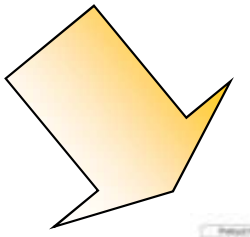
Event No.	Adverse Event	Start Date / Stop Date		Was Event Serious?	Severity	Is there a reasonable possibility that the AE may have been caused by the study drug(s)?*	Action Taken with Study Drug	Subject Outcome
	(Please list one event per line)	Either provide a stop date or mark box (√) if event is continuing ↓		Mark only 1 response 0 = No 1 = Yes	Mark only 1 response 1 = Mild 2 = Moderate 3 = Severe	Mark only 1 response 0= No 1= Yes	Mark only 1 response 0 = None 1 = Study drug regimen changed 2 = Temporarily stopped study drug 3 = Study drug discontinued	Mark only 1 response 0= Subject remains in study 1 = Withdrawn from study 2 = Lost to follow-up 3 = Death
AESPID char	*AETERM contains the initial verbatim value. AEMODIFY contains the modified text, if AETERM was changed* *AETERM char* *AEMODIFY char*	*AESTDTC char* day month year *AEENDTC char* day month year	*AEENRF char*	0 ☐ 1 ☐	1 ☐ 2 ☐ 3 ☐	0 ☐ 1 ☐ *AEREL char*	0 ☐ 1 ☐ 2 ☐ *AEACN char*	0 ☐ 1 ☐ *AEOUT char*
	AEDECOD char *AEBODSYS char* *(coding variables)*	day month year day month year	*AESER char*	0 ☐ 1 ☐	*AESEV char* 2 ☐ 3 ☐	0 ☐ 1 ☐	0 ☐ 1 ☐ 2 ☐ 3 ☐	0 ☐ 1 ☐ 2 ☐ 3 ☐
	AEENRF variable should contain the word 'AFTER' if the event is ongoing after the reference time period	day month year day month year		0 ☐ 1 ☐	1 ☐ 2 ☐ 3 ☐	0 ☐ 1 ☐	0 ☐ 1 ☐ 2 ☐ 3 ☐	0 ☐ 1 ☐ 2 ☐ 3 ☐

*A "reasonable possibility" means you cannot rule out a relationship between the event and the study drug.

Practical Experience

1. ACRO Standard Form





3. ACRO Form + CDISC SDTM Standard = Annotated Form

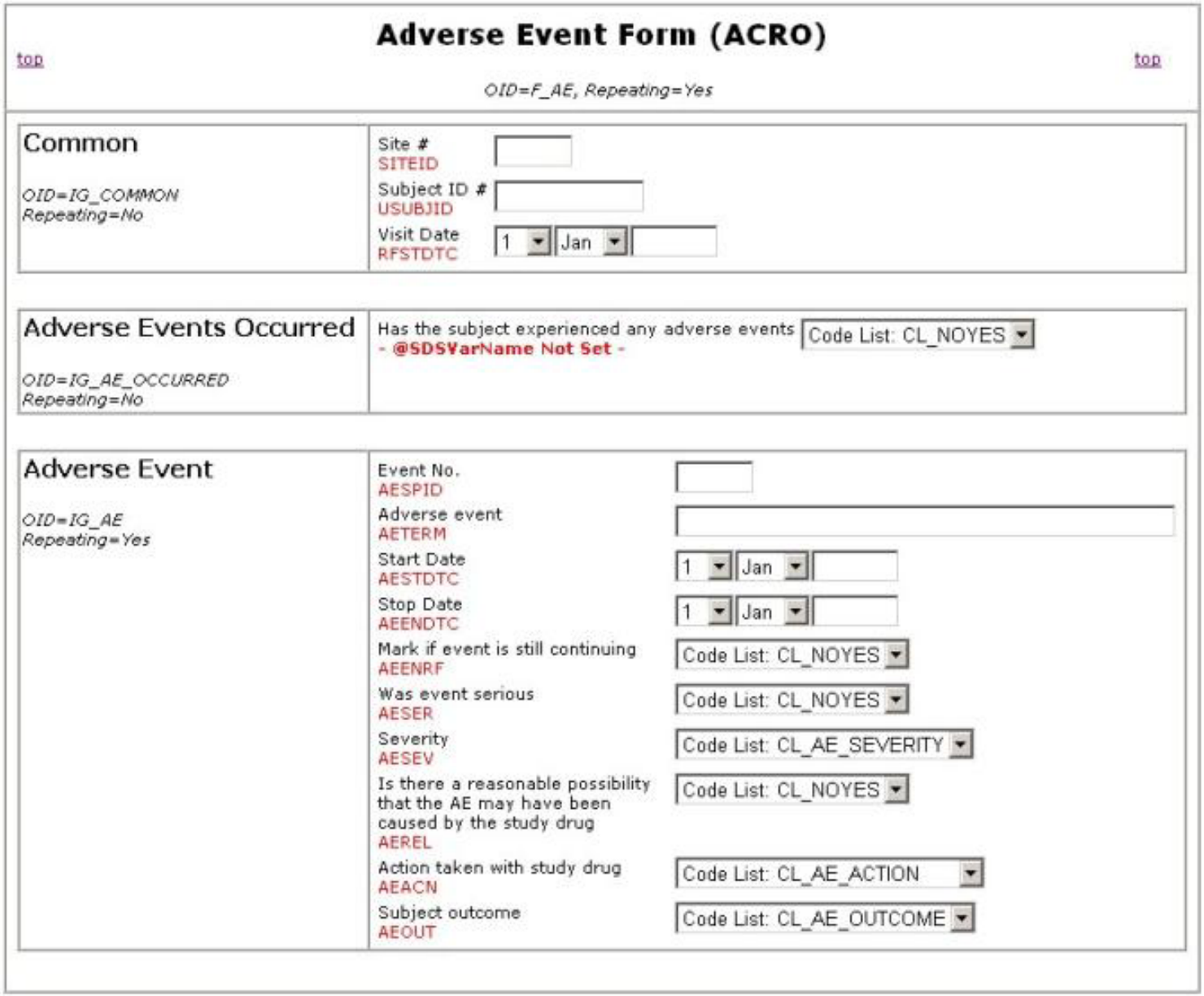
4. Annotated Form + ODM Standard = Standard electronic metadata (XML)

```
<ODM>
  <Study>
    <Meta…
    </Meta…
  </Study>
</ODM>
```

5. Standard electronic metadata configures collection system

2. CDISC SDTM Standard

Electronic Configuration



Adverse Event Form (ACRO)

top top

OID=F_AE, Repeating=Yes

Common

OID=IG_COMMON
Repeating=No

Site #
SITEID

Subject ID #
USUBJID

Visit Date
RFSTDTC
1 Jan

Adverse Events Occurred

OID=IG_AE_OCCURRED
Repeating=No

Has the subject experienced any adverse events
- @SDSVarName Not Set -
Code List: CL_NOYES

Adverse Event

OID=IG_AE
Repeating=Yes

Event No.
AESPID

Adverse event
AETERM

Start Date
AESTDTC
1 Jan

Stop Date
AEENDTC
1 Jan

Mark if event is still continuing
AEENRF
Code List: CL_NOYES

Was event serious
AESER
Code List: CL_NOYES

Severity
AESEV
Code List: CL_AE_SEVERITY

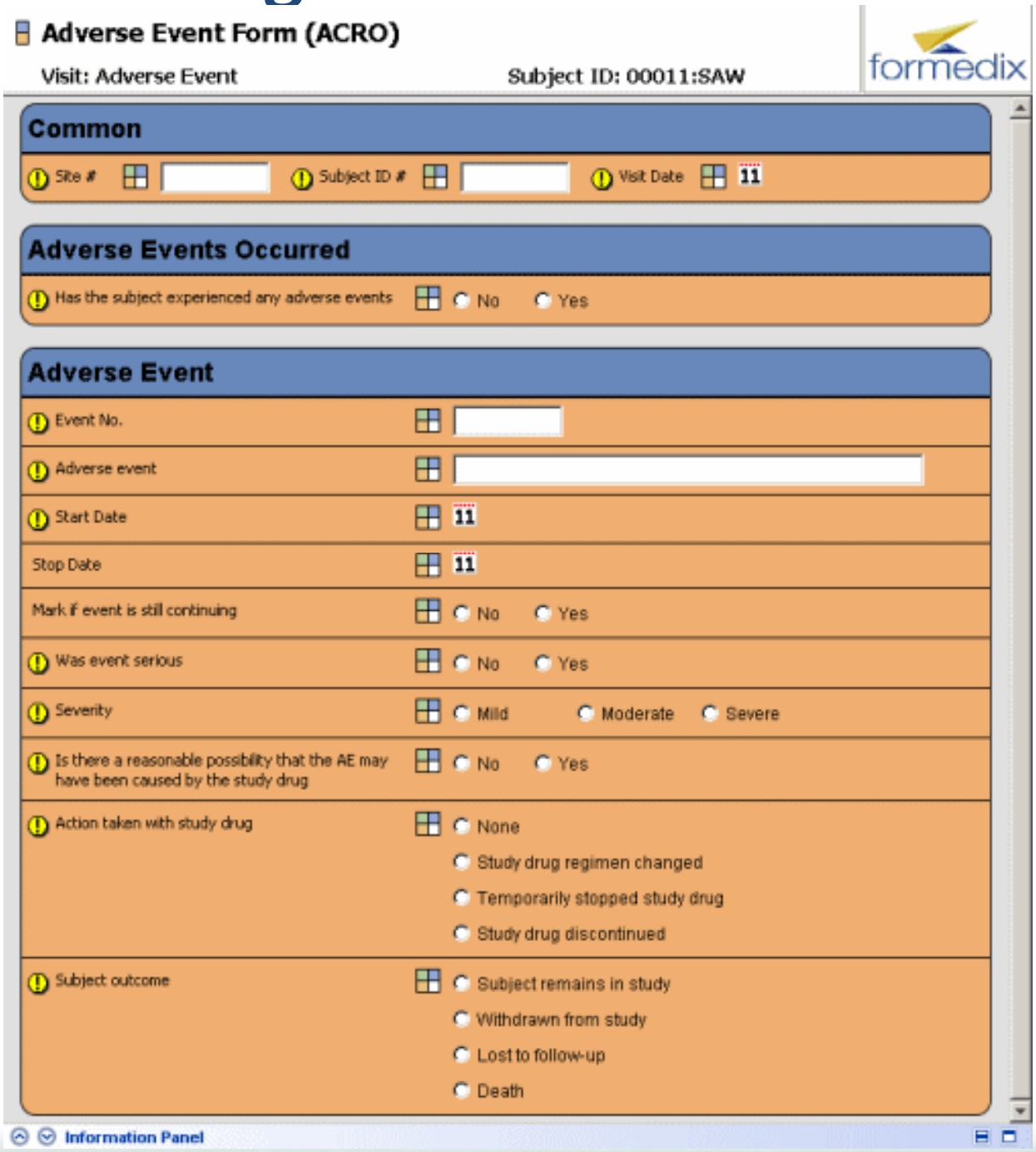
Is there a reasonable possibility that the AE may have been caused by the study drug
AEREL
Code List: CL_NOYES

Action taken with study drug
AEACN
Code List: CL_AE_ACTION

Subject outcome
AEOUT
Code List: CL_AE_OUTCOME

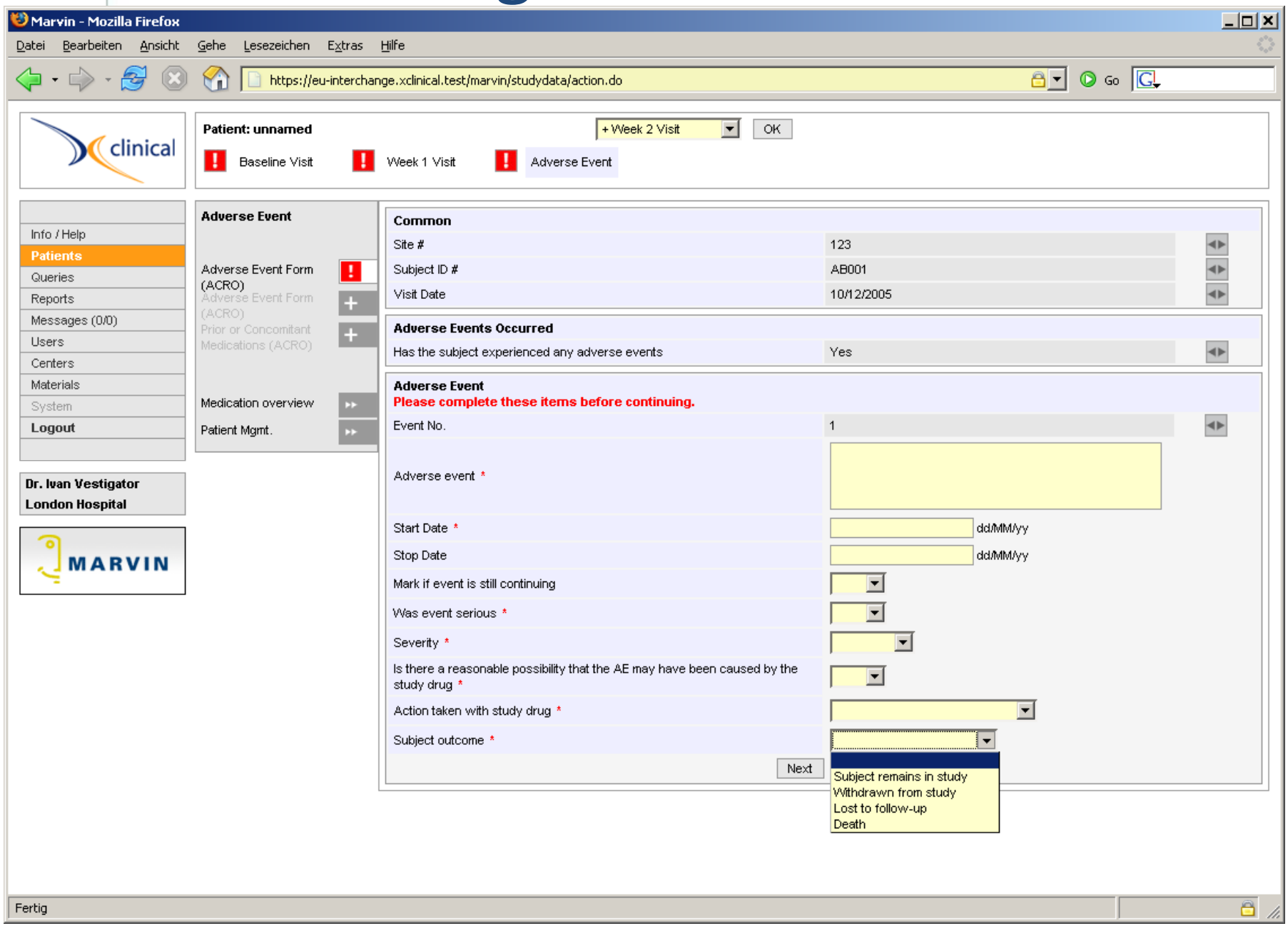
Courtesy of Assero

Electronic Configuration



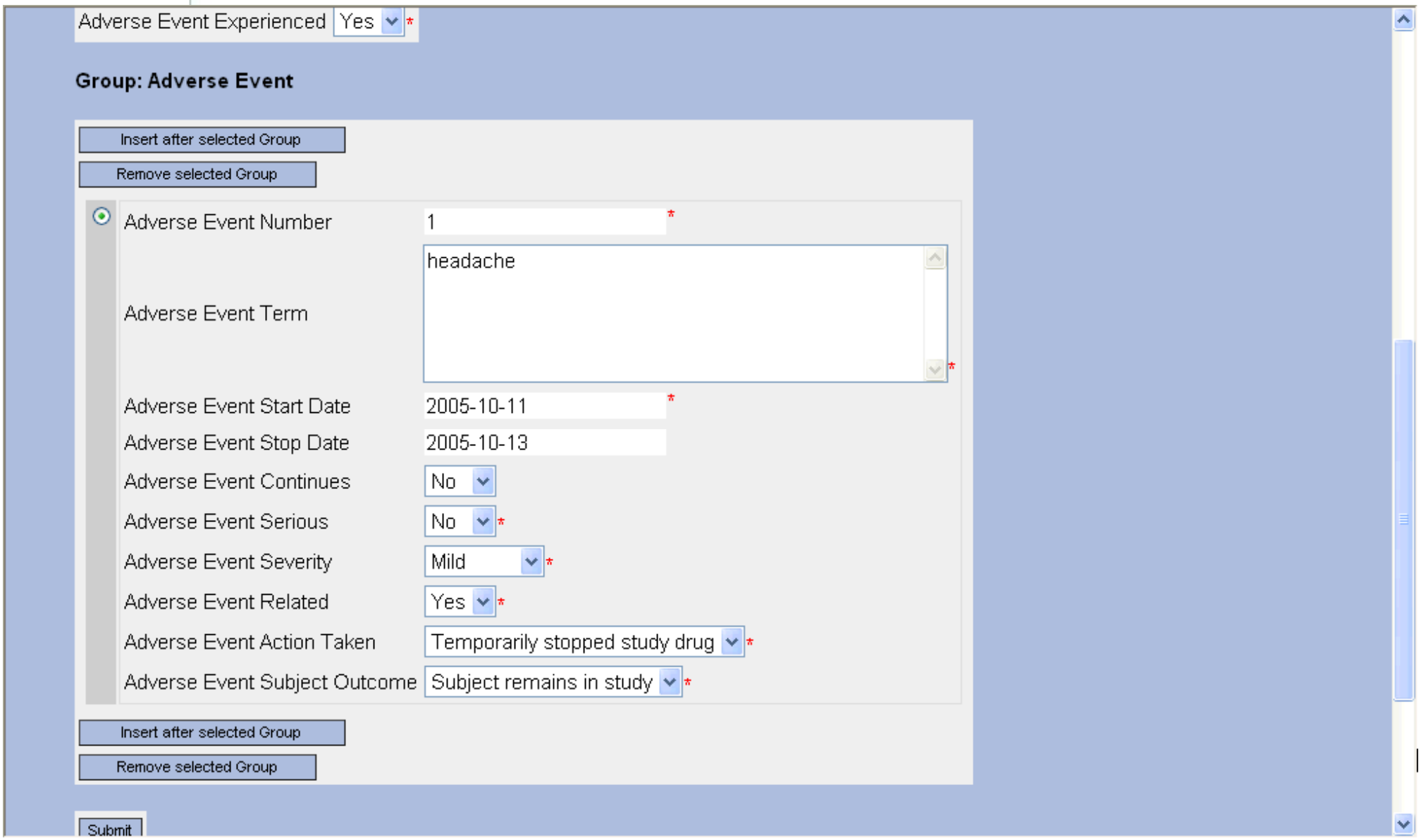
Courtesy of Formedix

Electronic Configuration



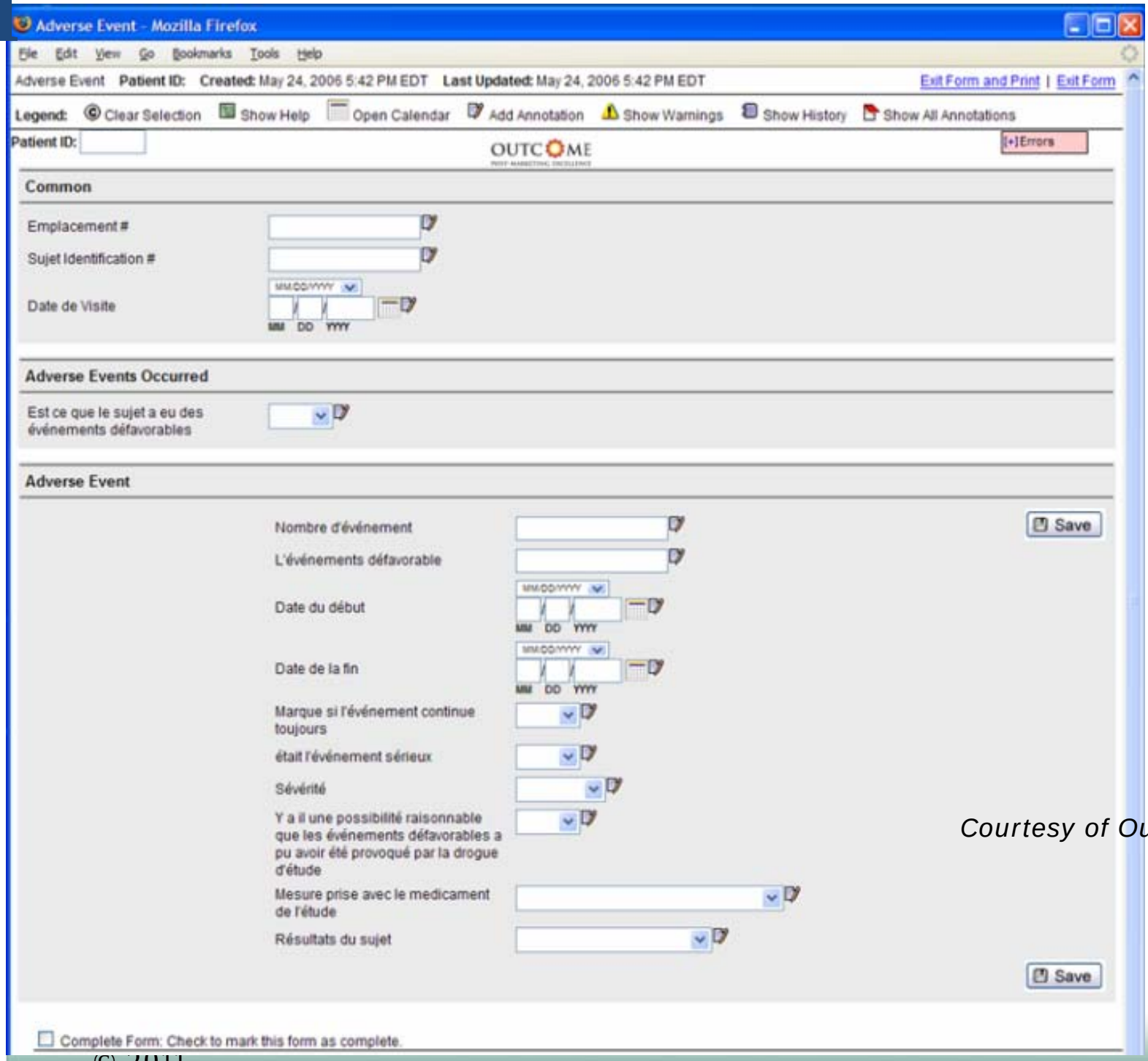
Courtesy of XClinical

Electronic Configuration



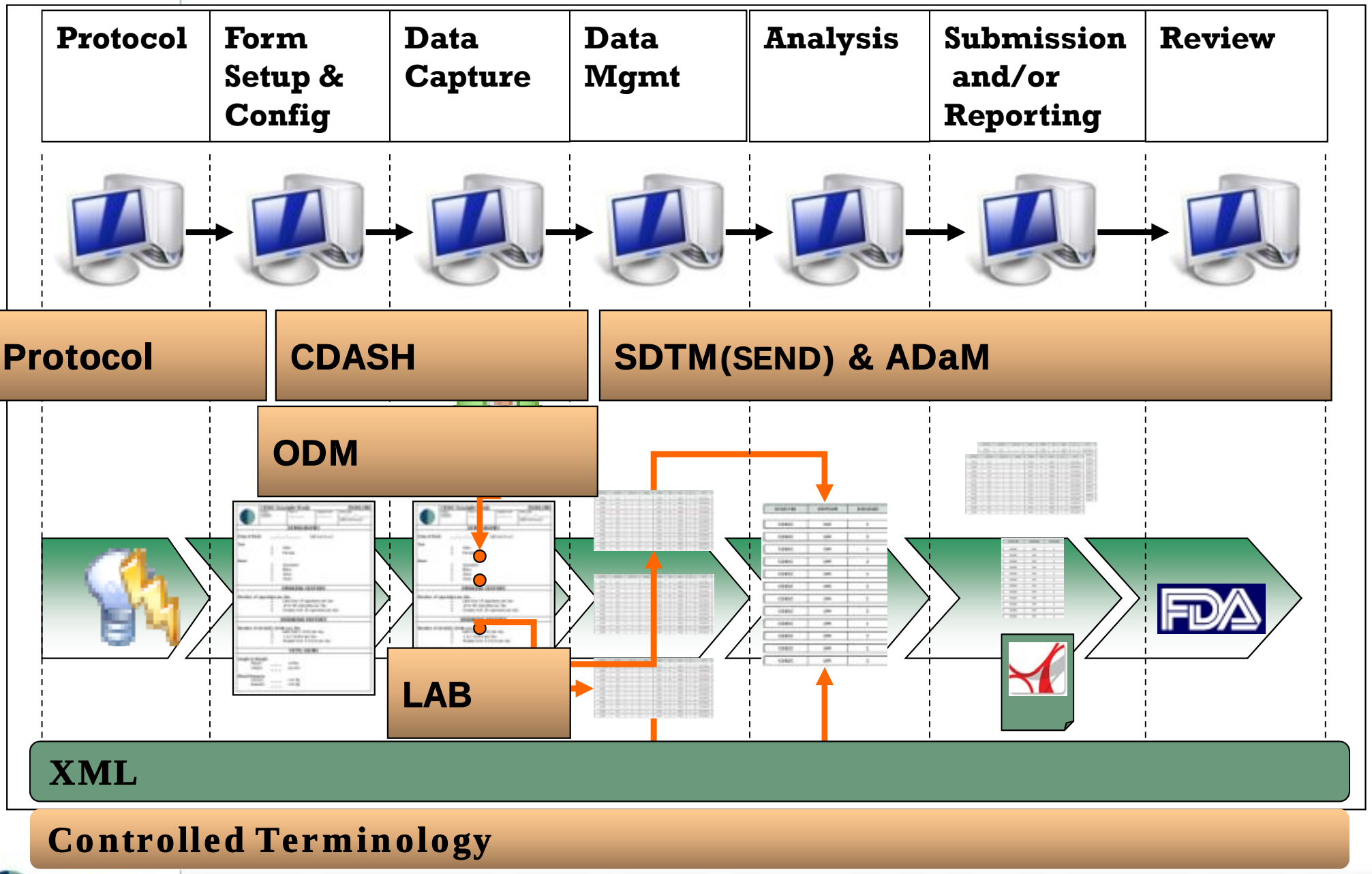
Courtesy of XML4Pharma

Electronic Configuration through ODM

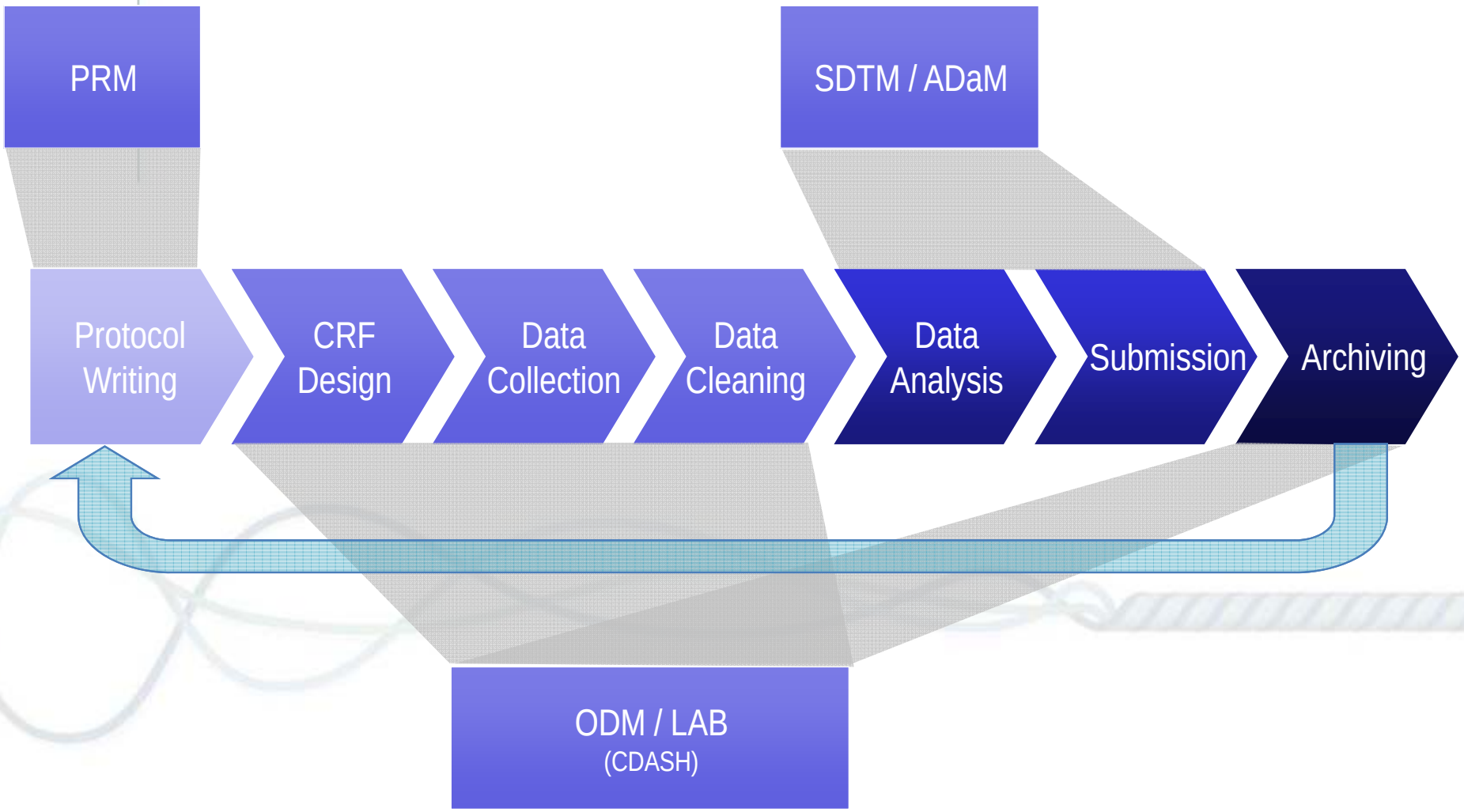


Courtesy of Outcome

Clinical Information Flow the CDISC Way



End to End Process with CDISC



Graphic courtesy of Dr. Philippe Verplancke, Founder and CEO, XClinical

SHARE

Accelerating Standards Development

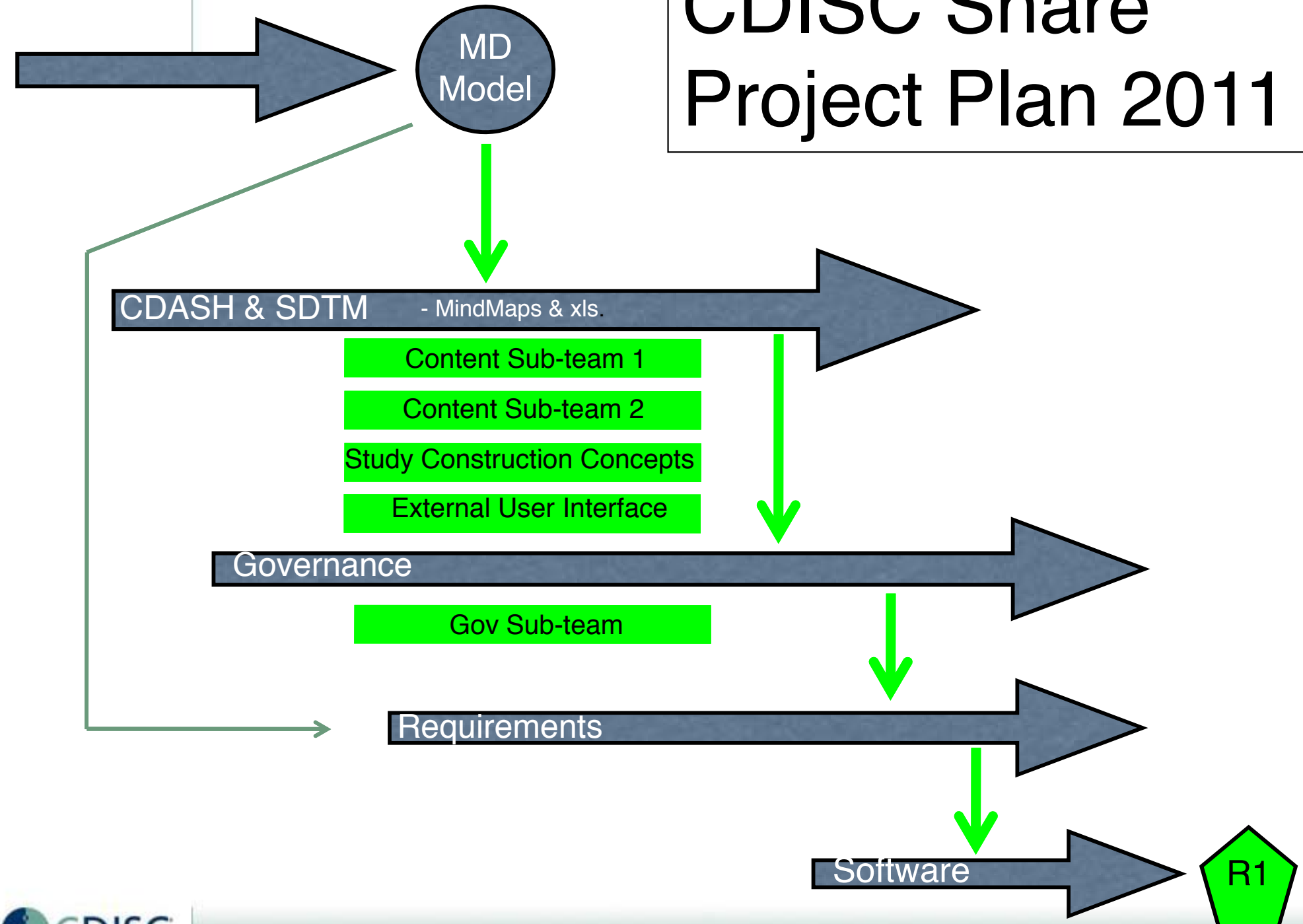
CDISC SHARE

SHARED HEALTH AND CLINICAL RESEARCH ELECTRONIC LIBRARY

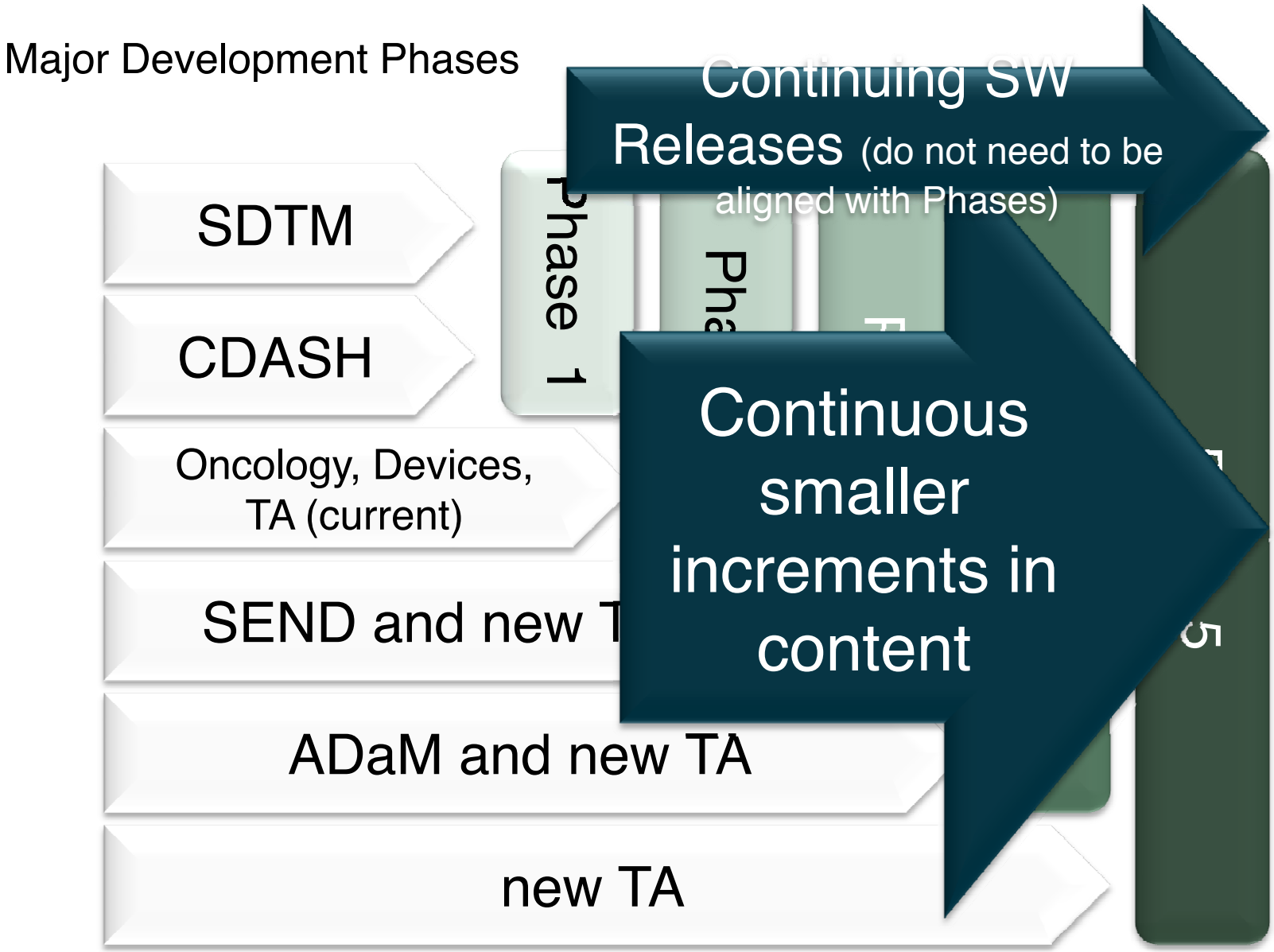
A global, accessible electronic library, which through advanced technology, enables precise and standardised data element definitions (including value sets) that can be used in applications and studies to improve biomedical research and its link with healthcare

Key purposes: Develop efficacy standards faster and make the CDISC standards more accessible.

CDISC Share Project Plan 2011

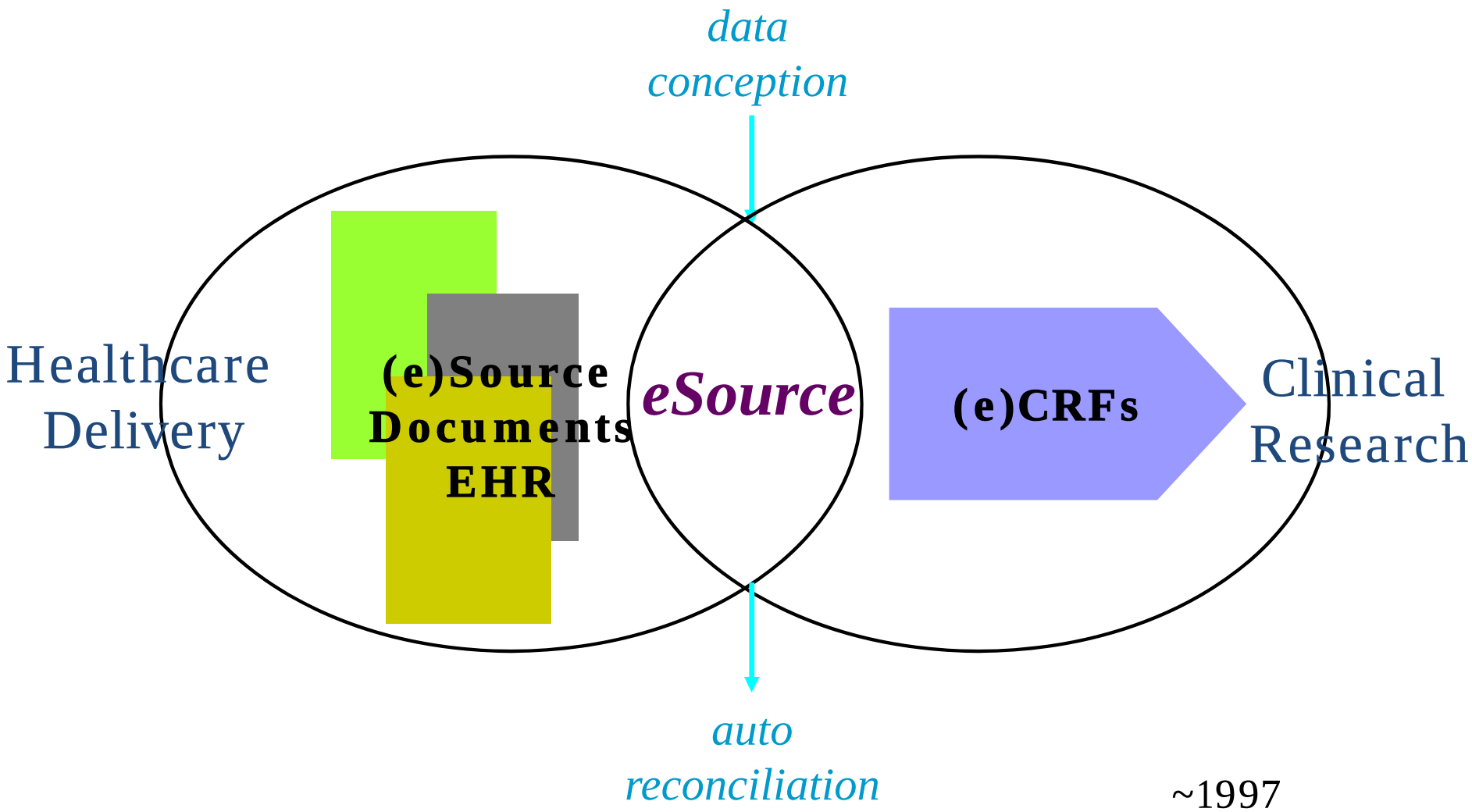


Longer Term CDISC Share Development Plan



Linking Research and Healthcare

Optimizing the Process



~1997

eSource Data Interchange (eSDI) Initiative

- **Purpose:** FDA initiative to facilitate the use of electronic technology in the context of existing regulations for the collection of eSource data in clinical research

  ***Note**: eSource pertains to collecting data electronically initially through eDiaries, ePatient Reported Outcomes, eData Collection, Electronic Health Records…*

- **Overarching Goals:**
  - to make it easier for physicians to conduct clinical research,
  - collecting data only once in an industry standard format for multiple downstream uses, and thereby
  - to improve data quality and patient safety
- **Product:** eSDI Document (with 12 requirements for eSource) (www.cdisc.org), which formed the basis for the Retrieve Form for Data Capture (RFD) Integration Profile

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

09 June 2010
EMA/INS/GCP/454280/2010
GCP Inspectors Working Group (GCP IWG)
Date for coming into effect 01 August 2010

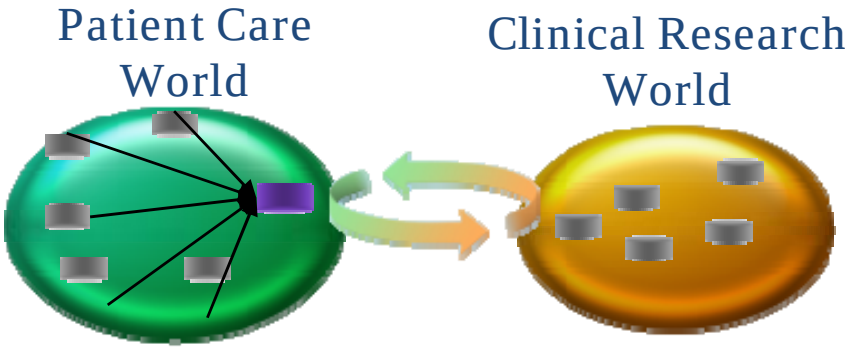
Reflection paper on expectations for electronic source data and data transcribed to electronic data collection tools in clinical trials

References

2. CDISC (Clinical Data Interchange Standards Consortium) Clinical Research **Glossary Version 8.0**, DECEMBER 2009 http://www.cdisc.org/stuff/contentmgr/files/0/be650811feb46f381f0af41ca40ade2e/misc/cdisc_2009_glossary.pdf.

3. **CDISC e-source standard requirements-CDISC** (Clinical Data Interchange Standards Consortium) Version 1.0 20 November 2006.

CDISC Initiative: Healthcare Link



An industry initiative that successfully demonstrated clinical information interoperability between physician clinical systems (EHR) and pharmaceutical clinical trials systems based on open standards.
- Duke Clinical Research Institute, CDISC, Novartis, Merck, J&J, Microsoft.

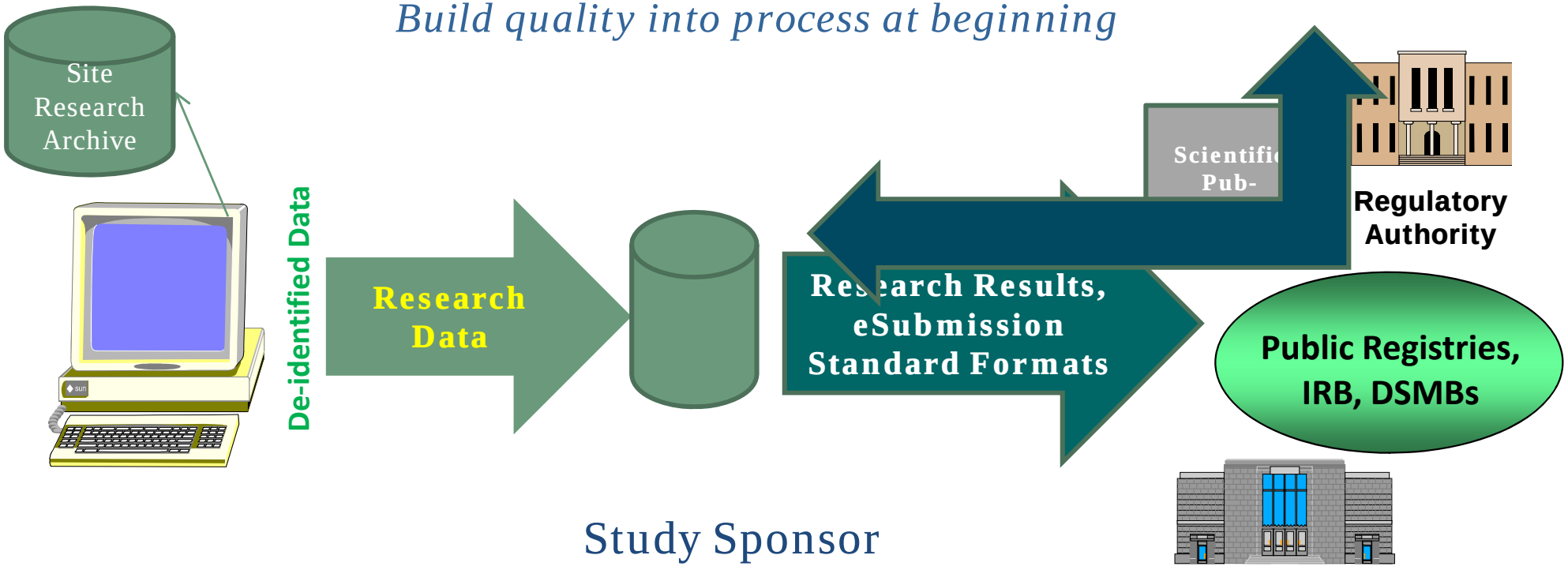
Next Step was the **Development and Demonstration of an Integration Profile called Retrieve Form for Data Capture (RFD)**

(*Project Leader: Landen Bain, lbain@cdisc.org, CDISC Liaison to Healthcare)*

Patient Value:
Quality of Healthcare, Safety

Research informs healthcare more effectively

Build quality into process at beginning



Research Site
(Healthcare Location, Investigator, Site Personnel)

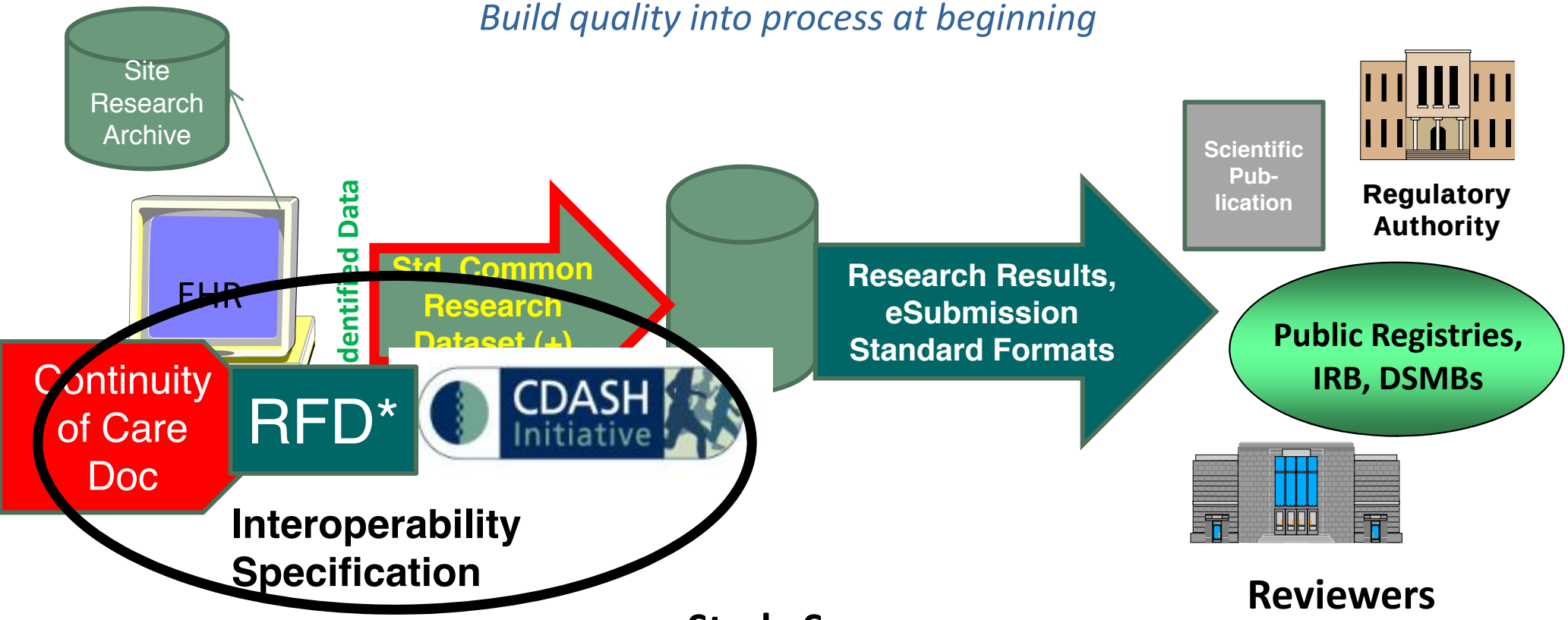
Study Sponsor
(e.g. ARO, CRO, Vendor, Principal Investigator, potentially AHRQ...)

Reviewers
(e.g. Research Partner, Sponsor, Registry, Regulator, IRB, DSMB)

CDISC Standards are NOT just for FDA eSumissions!

Patient Value:
Quality of Healthcare, Safety

Research informs healthcare more effectively
Build quality into process at beginning

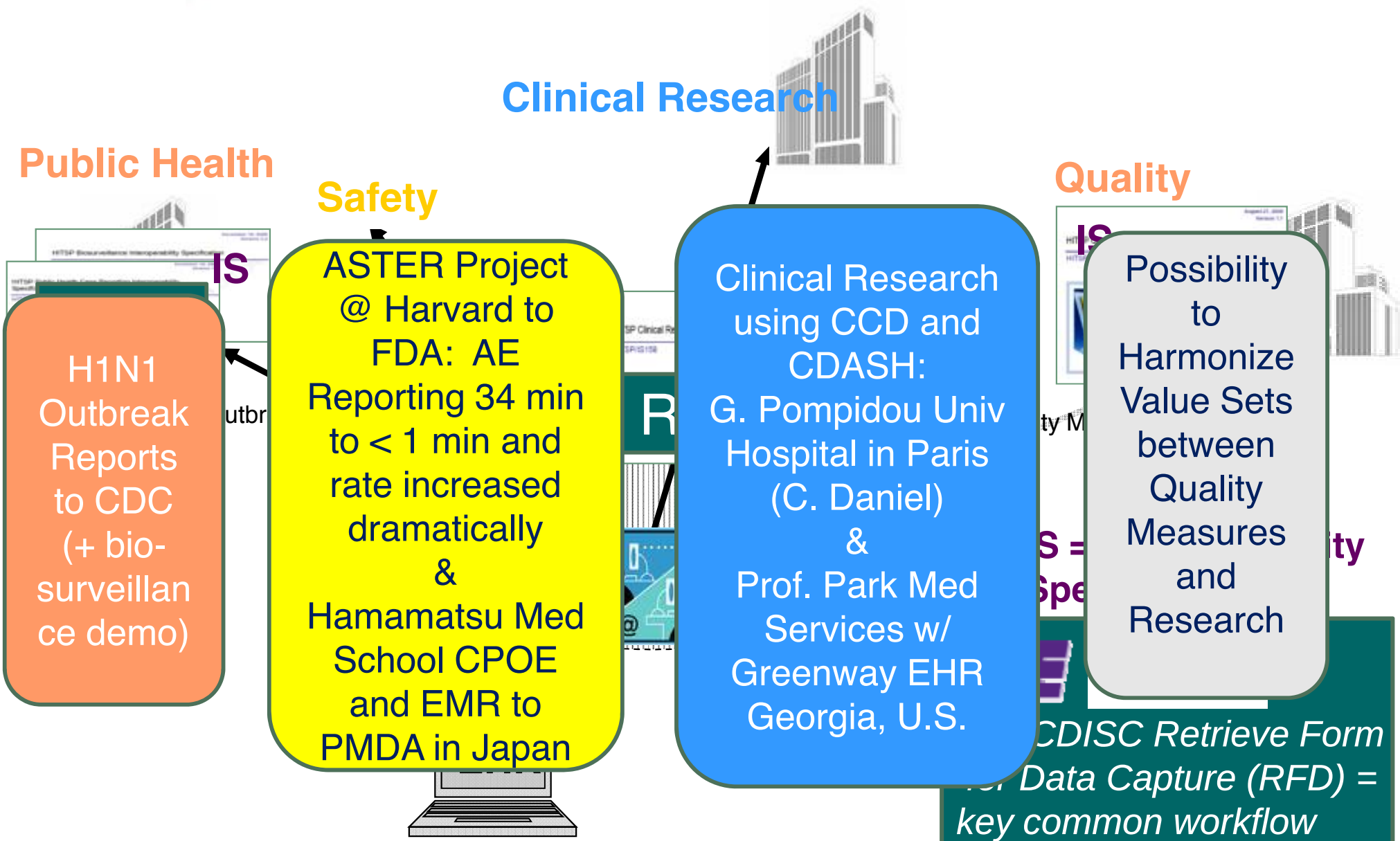


Care and/or Research Site
(Healthcare Location, Investigator, Site Personnel)

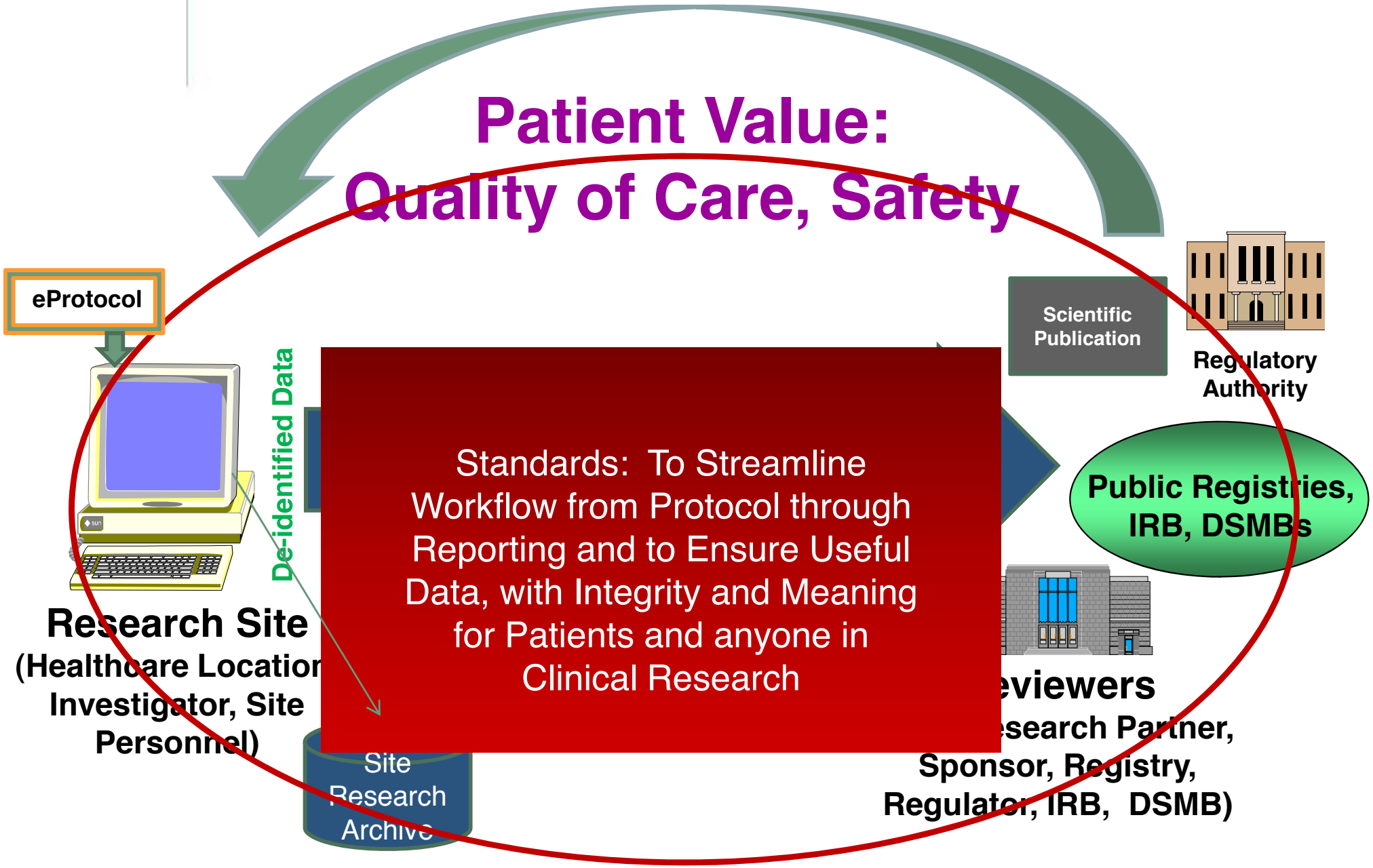
Study Sponsor
(e.g. ARO, CRO, Vendor, Principal Investigator, potentially AHRQ…)

Reviewers
(e.g. Research Partner, Sponsor, Registry, Regulator, IRB, DSMB, Quality Measures)

Integrating Workflow: EHRs and Clinical Research, Quality, Safety and Public Health



Patient Value: Quality of Care, Safety



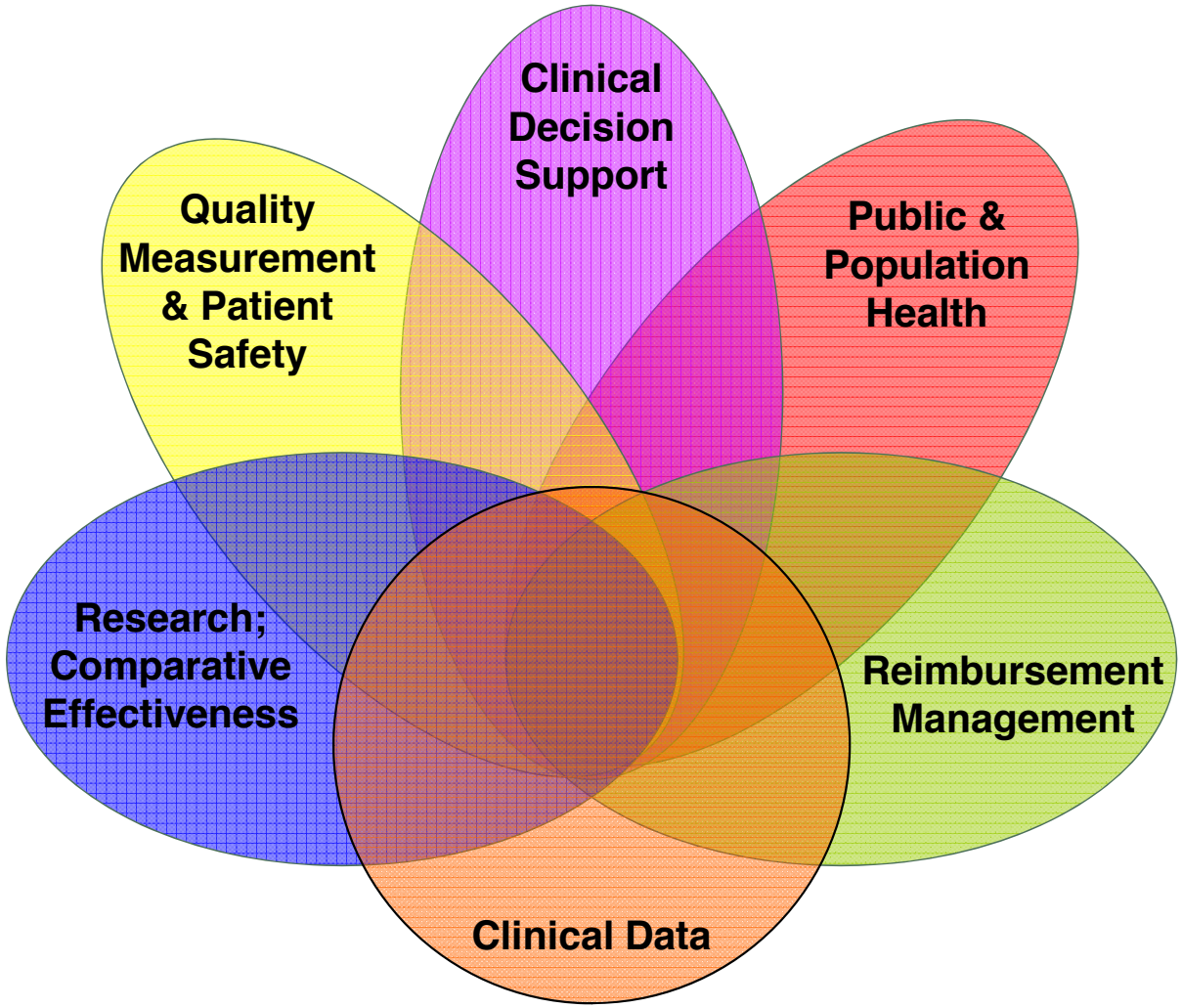
Capabilities with Available (Core) Data Standards and Integration Profiles/Interoperability Specifications (Standards-inspired Innovation)

- Dramatic **reduction in time and effort to report core data** for safety, research, public health
- Can accommodate eDiaries, patient-entered data, EDC, EHR
- Improved data quality
- Data can be more readily aggregated and analyzed or queried
- Extensible; paves the way for more complex research and clinical genomics for personalized healthcare
- Easily implemented by vendors; endorsed by EHRA

NEXT STEP (in progress):

Use Protocol (Process) Representation model (study/process design) to program business processes within EHRs to automate scheduling and data collection for research and other data re-use priorities (high throughput phenotyping).

Towards Efficiency: Collect Once, Repurpose Many Times



Donald T Mon, PhD, AHIMA

Harmonized standards/terminology for research and healthcare essential:

- To enable clinicians to perform research and safety monitoring concurrent with clinical care
- To aggregate sufficient data across partners to enable trustworthy research analyses, including comparative effectiveness
- To identify new biomarkers and link them to population characteristics and outcomes
- To reduce the ~ 17-year lag time for research information to inform healthcare decisions.

CDISC is more than Standards!

CDISC Vision

Informing patient care and safety through higher quality medical research

"Thank You Absolute Clinical Data System Co., Ltd for all the efforts that have made to promote CDISC in China, as well as this time help in translating these slides into Chinese"

"感谢北京阿贝斯努信息技术有限公司为CDISC在中国所做的工作，并感谢他们将这些幻灯片翻译成中文"