Réunion du Groupe des Utilisateurs Francophones des standards CDISC

CLINICAL DATA INTERCHANGE STANDARDS CONSORTIUM

CDISC®

Setting the Global Standard for Clinical Data

Pierre-Yves Lastic

Chairman, CDISC E3C & French User Network

Senior Director, Data Privacy & Healthcare Interoperability Standards, Sanofi-Aventis R&D

Chilly-Mazarin, 10 février 2011

Programme de la journée

10h-13h

- Introduction, le point sur les activités de CDISC (Pierre-Yves LASTIC, sanofi-aventis)
- Standards CDISC développés dans l'Alzheimer pour le projet CAMD (Marie-Rose VAN KEER, sanofi-aventis)
- Comment s'assurer de la compliance des données au format SDTM en un simple click? (Xavier GOBERT et Nick DE DONDER, BDLS)

13h-14h30

- Déjeuner au restaurant d'entreprise sanofi-aventis (gratuit pour les participants externes uniquement)

14h30-17h

- CDASH en pratique (Wafaa JABERT, Pierre Fabre)
- Clinical Data Integration, création de DataWarehouse clinique au format CDISC (Francis DESTIN, SAS)
- Conversions de données vers SDTM (Thierry LAMBERT, AdClin)
- Conclusion de la journée, calendrier des activités 2011 du groupe (Pierre-Yves LASTIC, sanofi-aventis)

Où sommes-nous?

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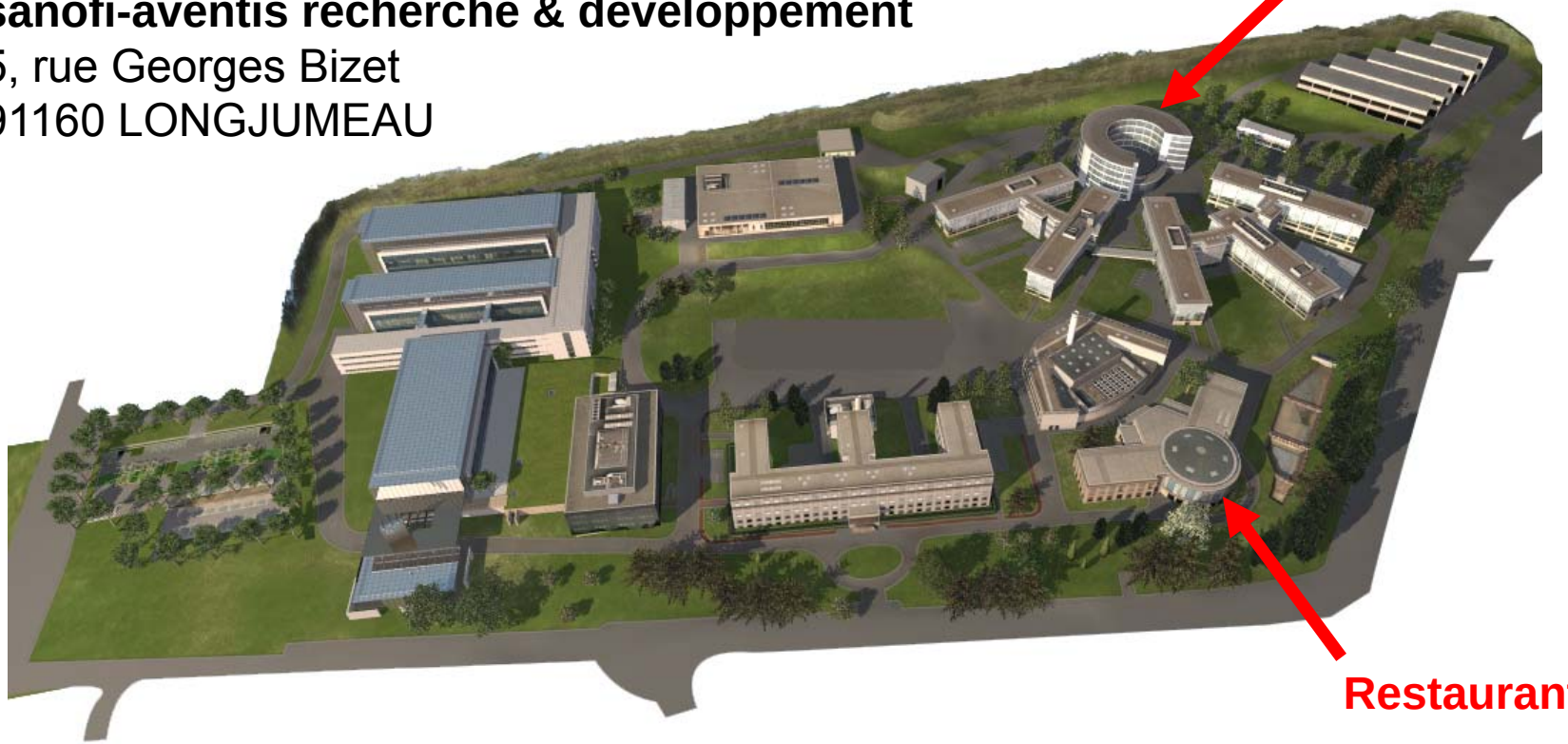
1, avenue Pierre Brossolette
91385 CHILLY-MAZARIN Cedex
Phone :+33 (0)1 69 79 77 77
sanofi-aventis recherche & développement
5, rue Georges Bizet
91160 LONGJUMEAU

sanofi aventis
L'essentiel c'est la santé.



Le point sur les activités de CDISC

- **CDISC Interchange Europe**
  and other EU activities
  - **Just Published in the Members Only Area**
    North American Interchange Round Table Discussion Groups' Report.
  - **Identification of Medicinal Products - ISO Draft International Standard available for CDISC**
    Closes: Wednesday 23 February 2011
- **Joint CDISC & C-Path Press Release**
  Critical Path Institute and Clinical Data Interchange Standards Consortium announce innovative partnership to address major diseases.
  - **Alzheimer's disease / Mild Cognitive Impairment Data Standard**
    Public Review Period Now Open - Closes Friday 18 February 2011
- **FDA CDER Data Standards Plan & PDUFA IV Update**
  Dr. Rebecca Kush highlights the important points in the latest FDA documentation.
- **BRIDG Release 3.0.3 Now Available**
  BRIDG Release 3.0.3, which contains new semantics from CDASH V1.1, SDTM V3.1.2 and ICSR is now available.
- **CDASH Standard Version 1.1 Released**
- **Terminology Public Review Period Open**
  Closes Friday 4 February 2011
- **SEND IG V3 Now Open for Public Review!**
  Comments due 4 February 2011
- **In Members Only Area: ADaM Validation Checks!**
  ADaM Validation Checks Documentation available now!


Bruxelles Palace et Boulevard du Jardin Botanique.
LE PALACE
CROWNE PLAZA

BRUSSELS CROWNE PLAZA

- 4 star-hotel
- Traditional hotel in modern art-deco style
- situated the middle of the city
- 5 minutes to the train station
- 15 minutes from train station to the airport
- 300 rooms
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- trendy restaurant and Art deco style-bar
- free high speed WIFI internet throughout the hotel
- permanent fresh coffee, tea, juices in meeting facilities from 8 o‘clock

- **CDISC Rate: 149 Euro including VAT, breakfast and free WLAN**

- More information: www.crowneplazabrussels.be

European Interchange Innovations

- **Break-Out Sessions**
  - More Interactivity for Participants
  - Better Feedback for CDISC
  - Summary of break-out sessions discussions are available in the member only area of the CDISC Website and are also available for the conference participants !
- **Posters**
  - More space to share experience

Round Table Discussion Reports

Round Table Discussions (RTD)
EU Interchange Apr 2010

Full Report

Prepared by the
Jason Housley / Niels Both – E3C

Session Chairs and Notes Takers:

Chris Tolk, Chris Decker, Frank Newby, Becky Kush, Julie Evans, Phillip Verplancke, Jozef Aerts, Rhonda Facile, Elke Sennewald, Monica Kawohl, Jason Housley, Niels Both,

Round Table Discussions (RTD)
US Interchange November 2010

Full Report

Prepared by the
Chris Decker – CDISC Interchange Committee

Session Chairs and Notes Takers:

Terminology: Chris Tolk, Bron Kisler
Protocol: Dave Gemzik
XML Technologies: Sam Hume
CDASH: Rhonda Facile, Kit Howard, Melissa Binz, Melissa Cook,
ADaM: Jan Wruck, Niels Both, John Troxell, Dana Soloff
SDTM: Barrie Nelson, Gail Stoner, Robert Stemplinger, Pat Wozniak

European CDISC Coordinating Committee (E3C): Current Members

- **Chair**
  - Pierre-Yves Lastic, sanofi-aventis, France
- **Vice-Chair**
  - Herbert Noack, Boehringer Ingelheim, Germany
- **Full Members**
  - Ann-Sofie Bergström, SAS, Sweden
  - Niels Both, S-Cubed, Denmark
  - Jörg Dillert, PhaseForward, Germany
  - Jason Housley, Shire, UK
  - Dave Iberson-Hurst, Assero, UK
  - Peter van Reusel, BDLS, Belgium
  - Wolfgang Summa, Omnicom, Germany
  - Philippe Verplancke, Xclinical, Germany
- **Ex-officio Members**
  - Tim Jäger, Roche, Germany (past chair)
  - Isabelle de Zegher, PAREXEL, Belgium (past Board member)
- **CDISC funded Support**
  - Barry Burnstead, UK, E3C Secretary & EMA liaison
  - Amanda de Montjoie, UK, Conferences, Website & Communication support
  - Dominik Ruisinger, Germany, EuroInterchange Organization & Meetings logistics

Key initiatives in Europe

Think globally – act locally

- **Awareness and Training**
  - Annual European CDISC Interchange
  - CDISC Roadshows
  - Support European User Groups

- **Key stakeholder dialogue**
  - Collaboration with ***European Medicines Agency (EMA)***
  - Collaboration with ***European Federation of Pharmaceuticals Industries and Associations (EFPIA)*** and ***European Commission*** on Electronic Health Record use for clinical research and pharmacovigilance within the ***Innovative Medicine Initiative (IMI)*** and the EFPIA eHealth Task Force
  - Engage with national ***ISO*** committees
  - Liaise with ***HL7 Europe*** and ***European HL7 Affiliates***

- **Colead global CDISC projects**
  - CDISC SHARE

European Medicines Agency (EMA)

- CDISC participates in the Joint Operations Group of the EMA Telematics Implementation Group
- Since October 1st, 2010, the E3C Chair is member of the EudraVigilance Expert Working Group
- Contributes together with HL7 in creating and maintaining standards for
  - Clinical Trials Protocols (EudraCT Database) => **BRIDG, Protocol, CTR&R**
  - Adverse Events Reporting (EudraVigilance) => **ICSR**
  - Drug Terminology (EudraPharm) => **IDMP**
- CDISC published the eSDI document that is the basis for the new EU Guidance on Electronic Source Documents used in Clinical Trials

Identification of Medicinal Products
ISO Draft International Standard

- The five IDMP standards were developed in response to a worldwide demand for internationally harmonized specifications for medicinal products. Together they provide the basis for the unique identification of medicinal products. The group of standards comprises (click to download the pdfs):

  - ISO/DIS 11615 Health Informatics - Identification of Medicinal Products - Data elements and structures for the unique identification and exchange of regulated medicinal product information
  - ISO/DIS 11616 Health Informatics - Identification of Medicinal Products - Data elements and structures for the unique identification and exchange of regulated pharmaceutical product information
  - ISO/DIS 11238 Health Informatics - Identification of Medicinal Products - Data elements and structures for the unique identification and exchange of regulated information on substances
  - ISO/DIS 11239 Health Informatics - Identification of Medicinal Products - Data elements and structures for the unique identification and exchange of regulated information on pharmaceutical dose forms, units of presentation, routes of administration and packaging
  - ISO/DIS 11240 Health Informatics - Identification of Medicinal Products - Data elements and structures for the unique identification and exchange of units of measurement

IDMP

DRAFT INTERNATIONAL STANDARD ISO/DIS 11615

ISO/TC **215**

Secretariat: **ANSI**

Voting begins on:
2010-09-23

Voting terminates on:
2011-02-23

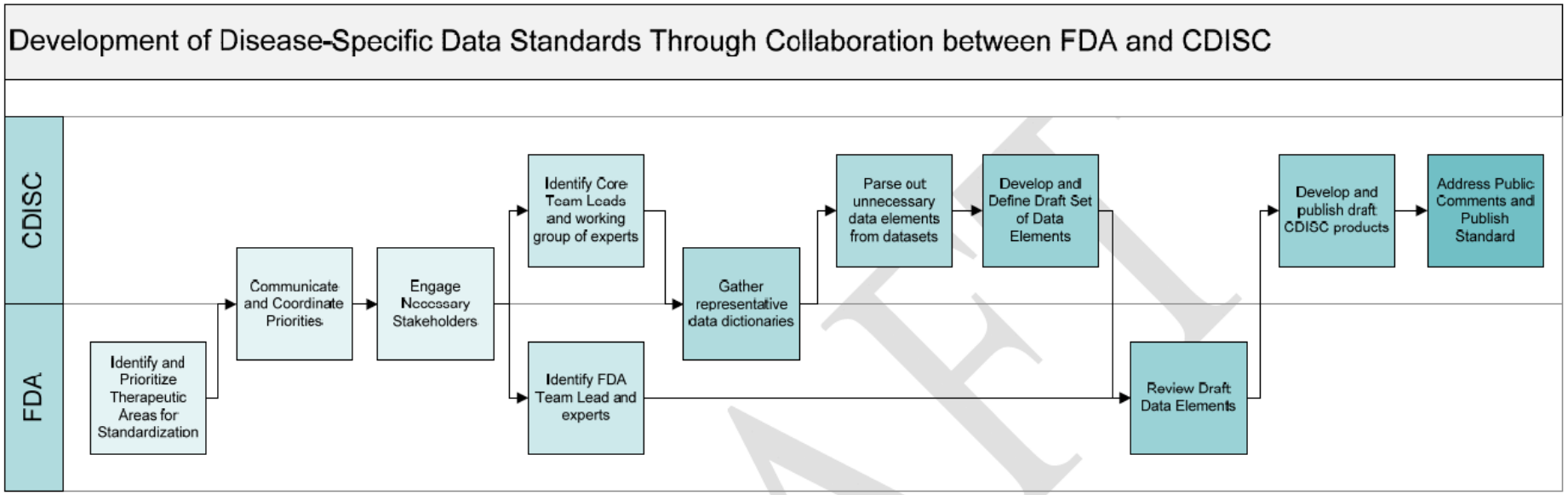
INTERNATIONAL ORGANIZATION FOR STANDARDIZATION • МЕЖДУНАРОДНАЯ ОРГАНИЗАЦИЯ ПО СТАНДАРТИЗАЦИИ • ORGANISATION INTERNATIONALE DE NORMALISATION

Health informatics — Identification of medicinal products — Data elements and structures for unique identification and exchange of regulated medicinal product information

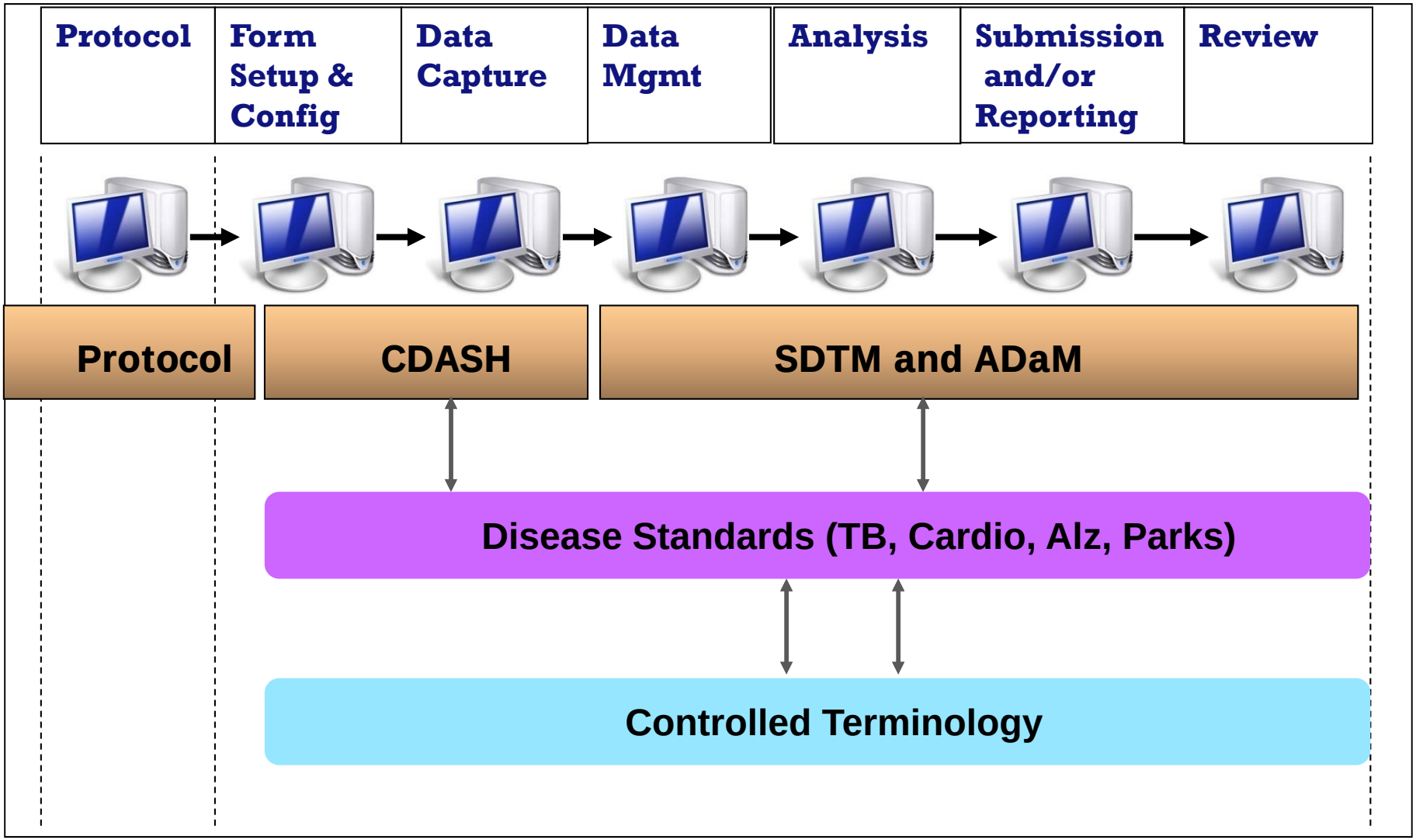
C-Path and CDISC

- C-Path and CDISC are both non-profit organizations committed to forming precompetitive collaborations to address process gaps responsible for delays and inefficiencies in medical product development.
- After working together to build the landmark Alzheimer's disease clinical database launched publicly by C-Path's Coalition Against Major Diseases (CAMD) in June 2010, C-Path/CDISC will now take on other brain diseases (**Huntington's disease, ALS, multiple sclerosis**), as well as **lung cancer**, **diabetes mellitus**, and other diseases identified by the U.S. Food and Drug Administration (FDA) as high priority public health challenges.

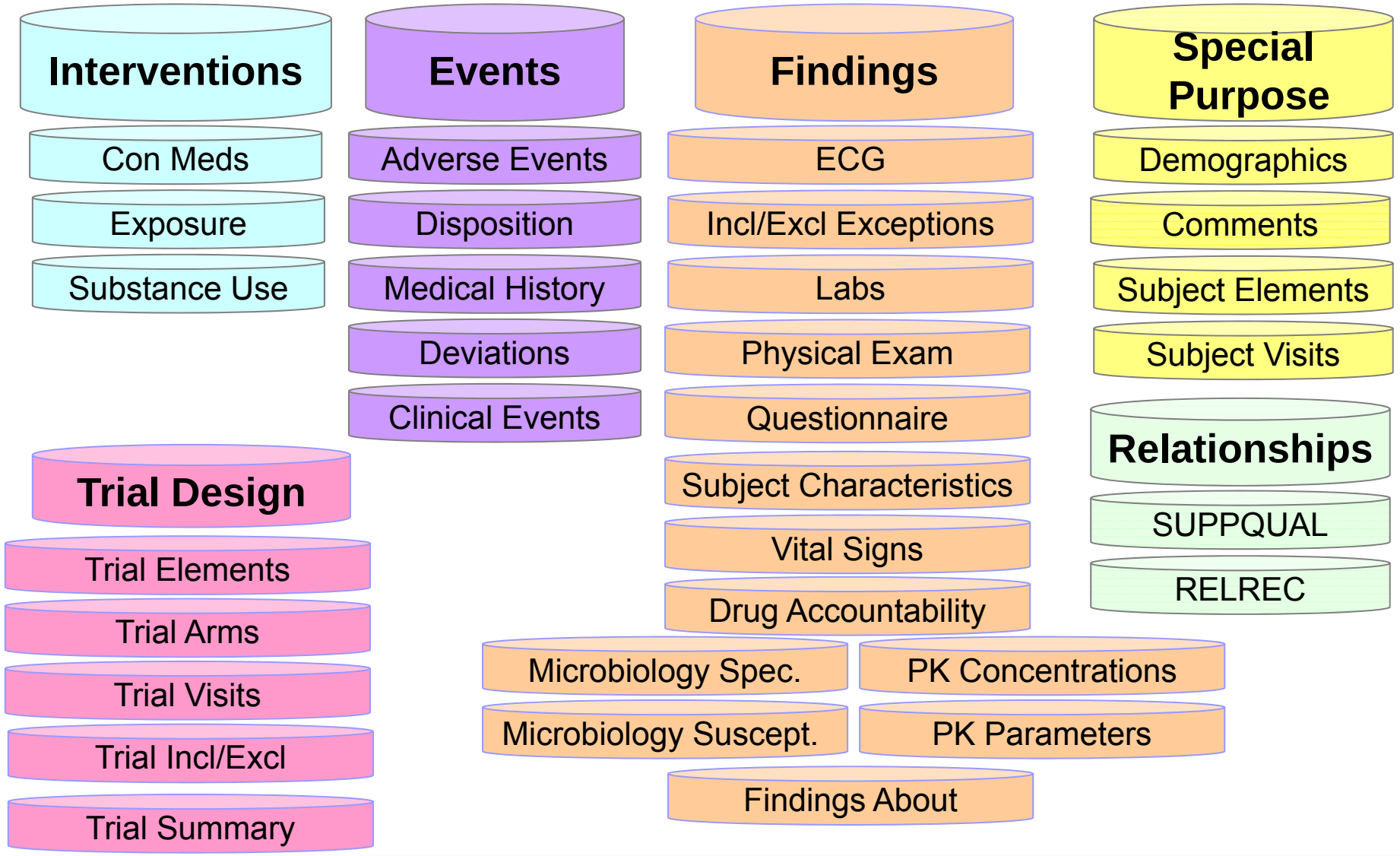
FDA Data Standards Plan



Disease Specific Standards

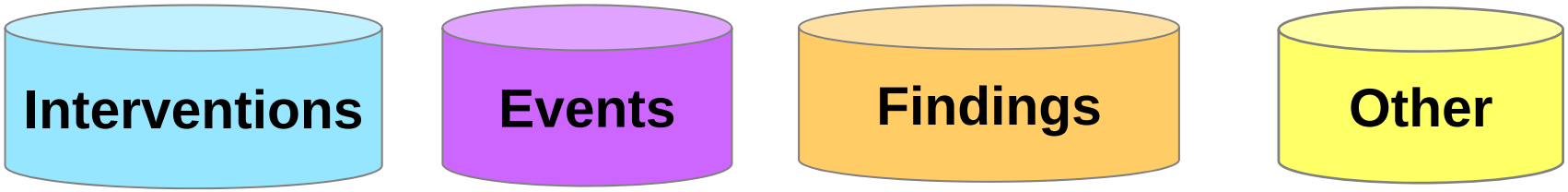


SDTM – Study Data Tabulation Model



SDTM General Observation Classes

What kinds of observations are these?

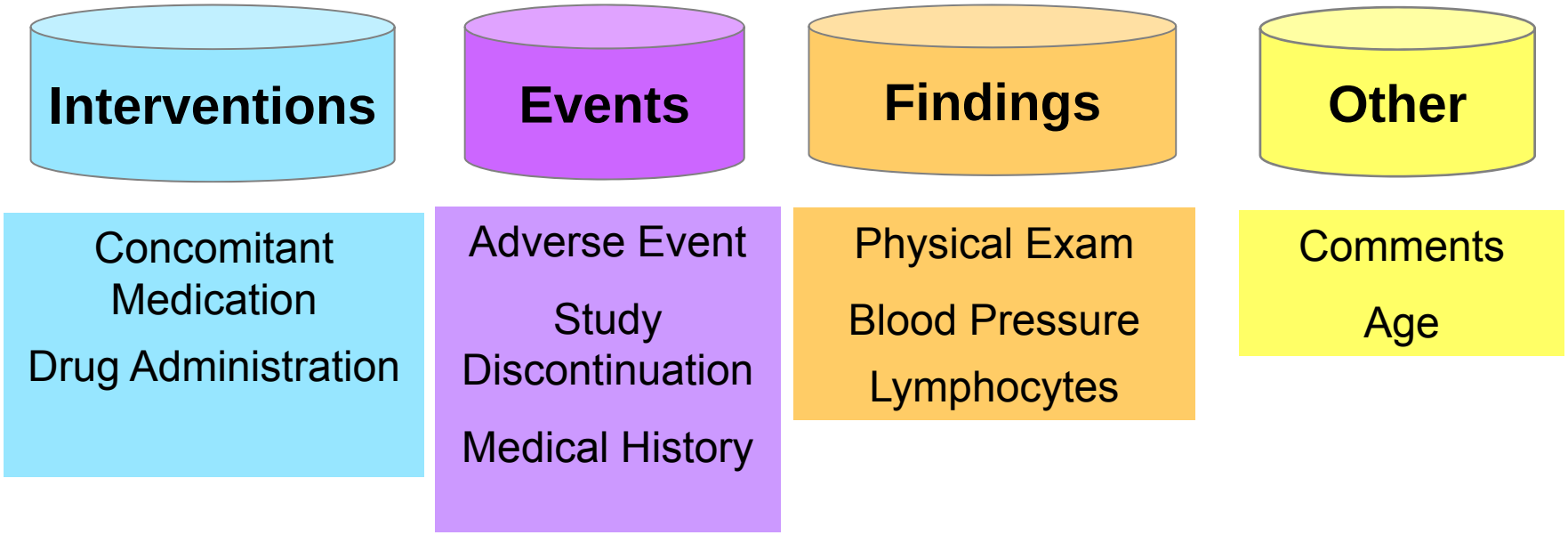


Blood Pressure
Drug Administration
Physical Exam
Medical History
Age

Lymphocytes
Adverse Event
Study Discontinuation
Concomitant Medication
Comments

SDTM General Observation Classes

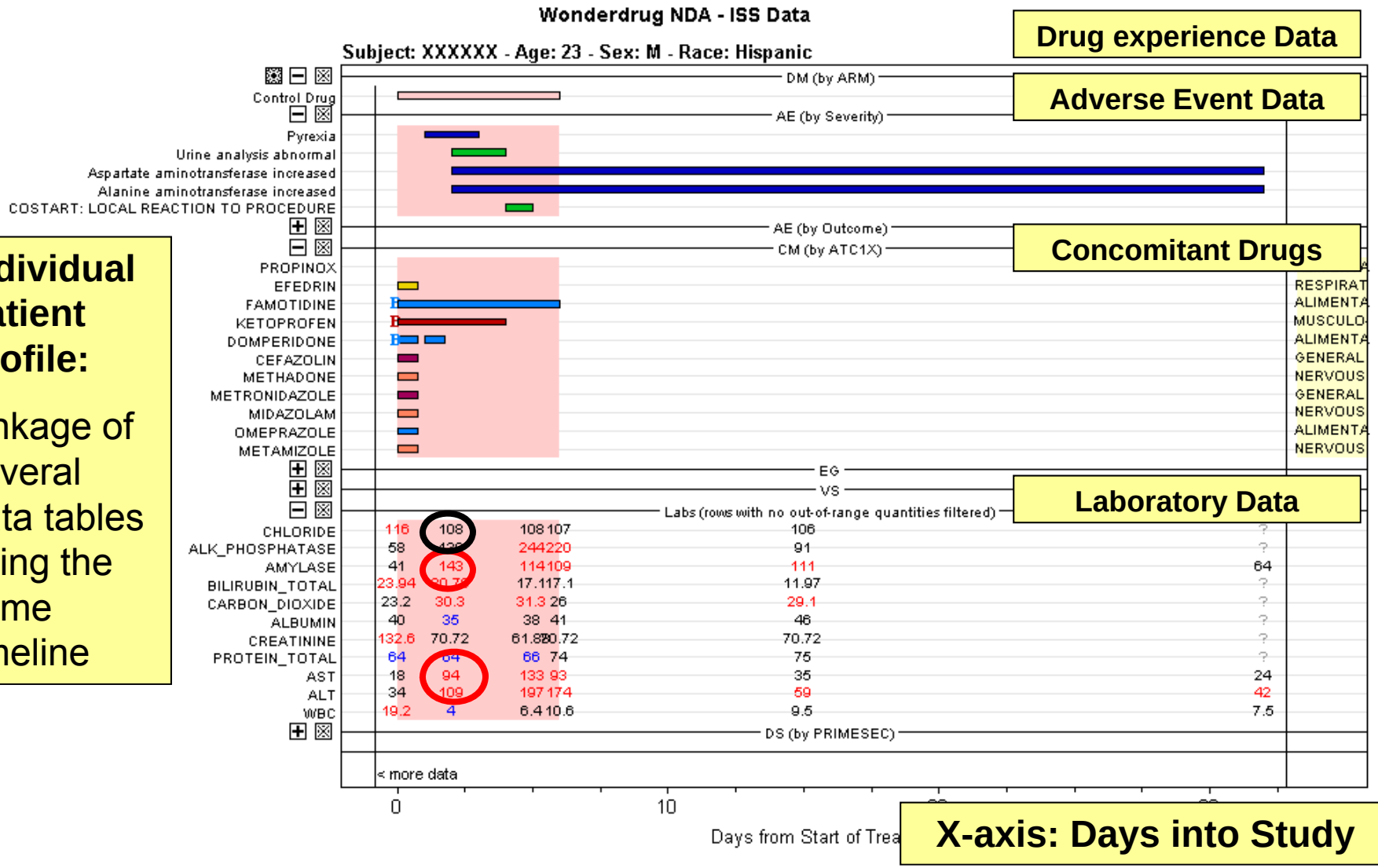
What kinds of observations are these?

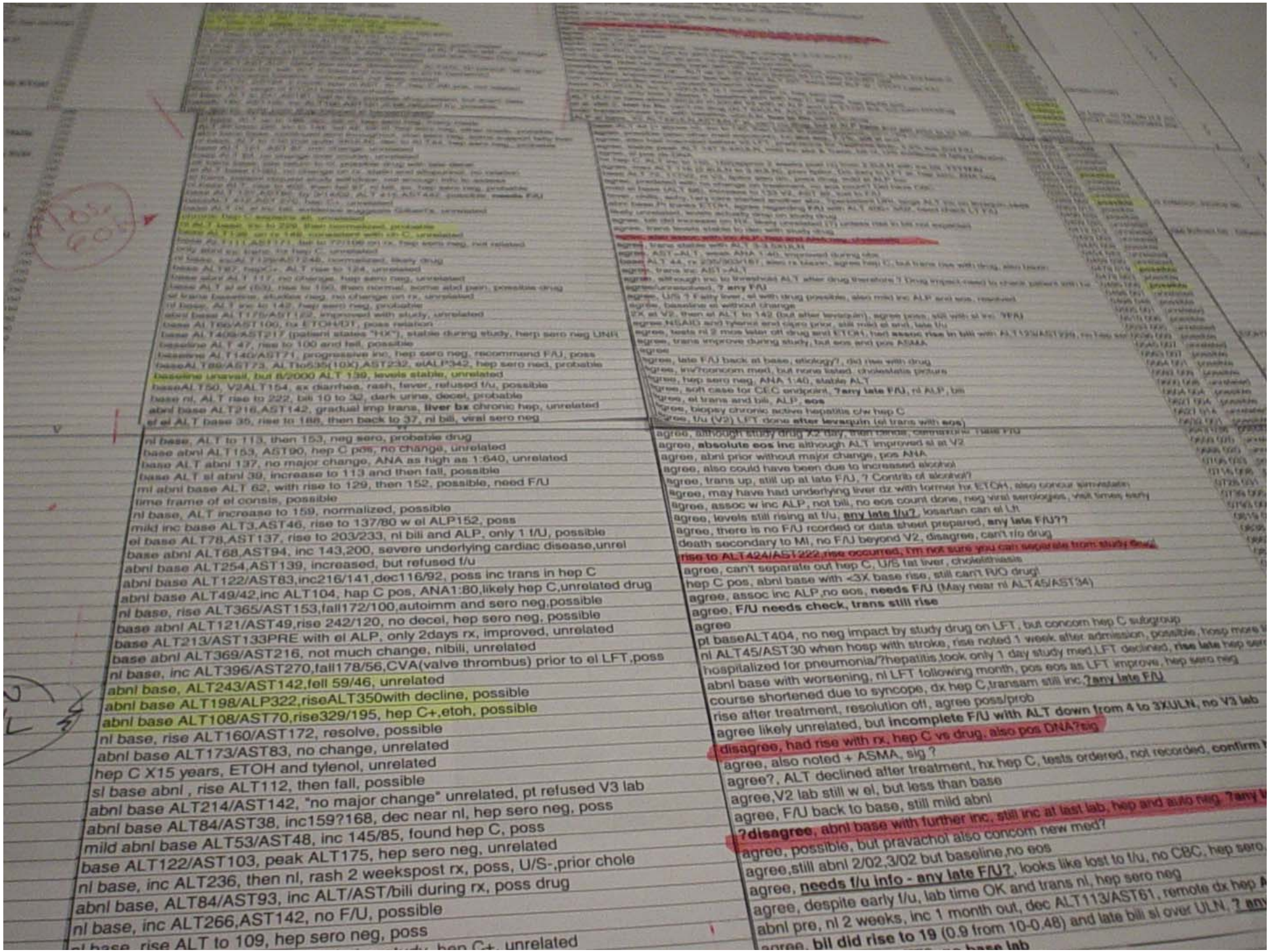


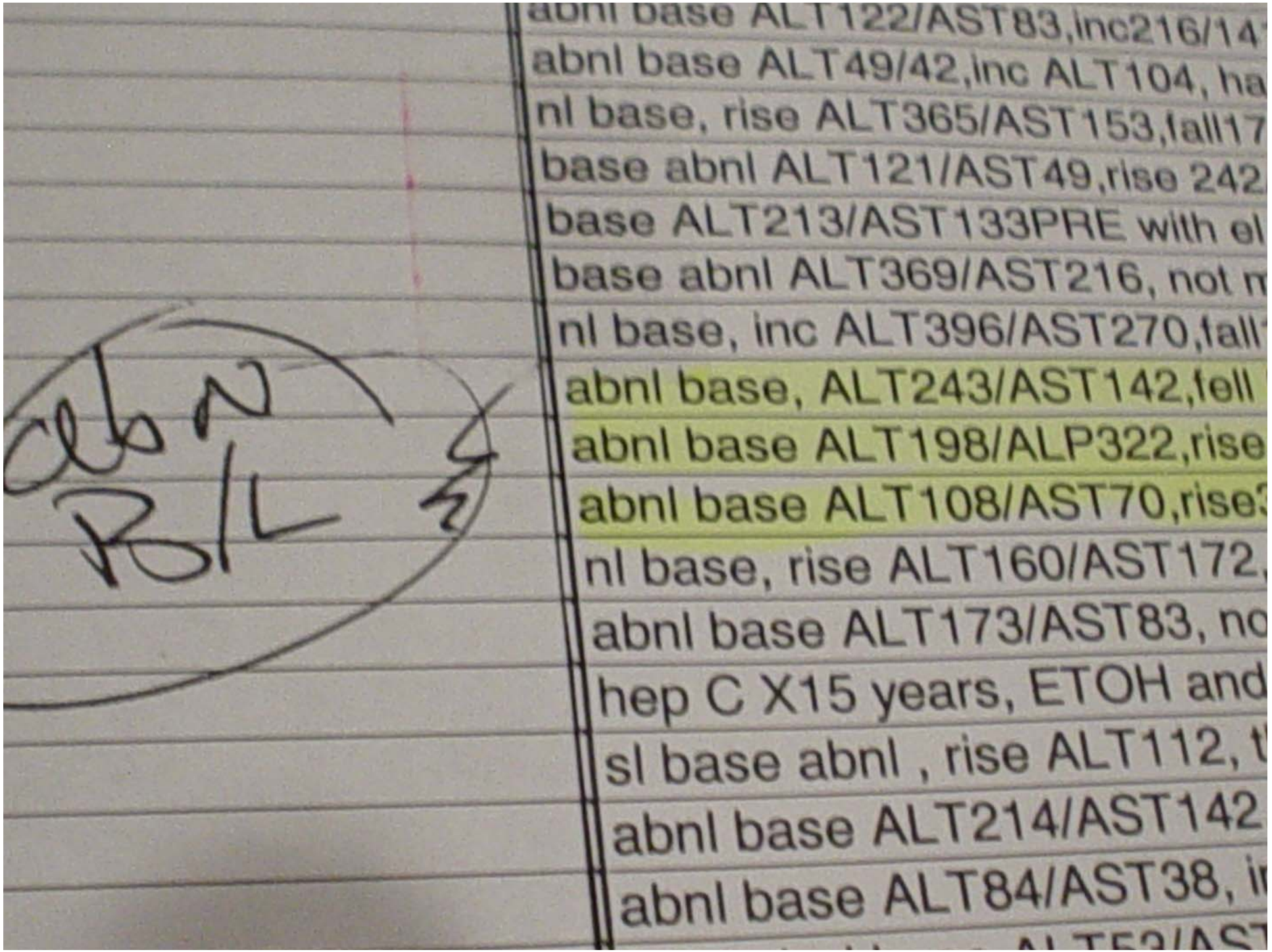
IN ONE STEP with SDTM: Assessing Potential Liver Injury by Analyzing Increases in Serum Alanine Aminotransferase (ALT) and Total Serum Bilirubin (TBILI)

Individual Patient Profile:

Linkage of several data tables using the same timeline



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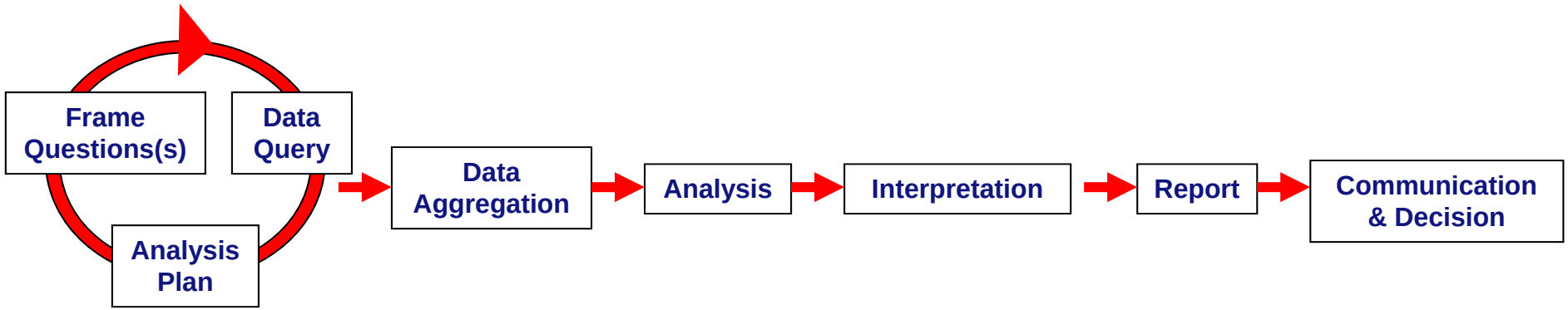
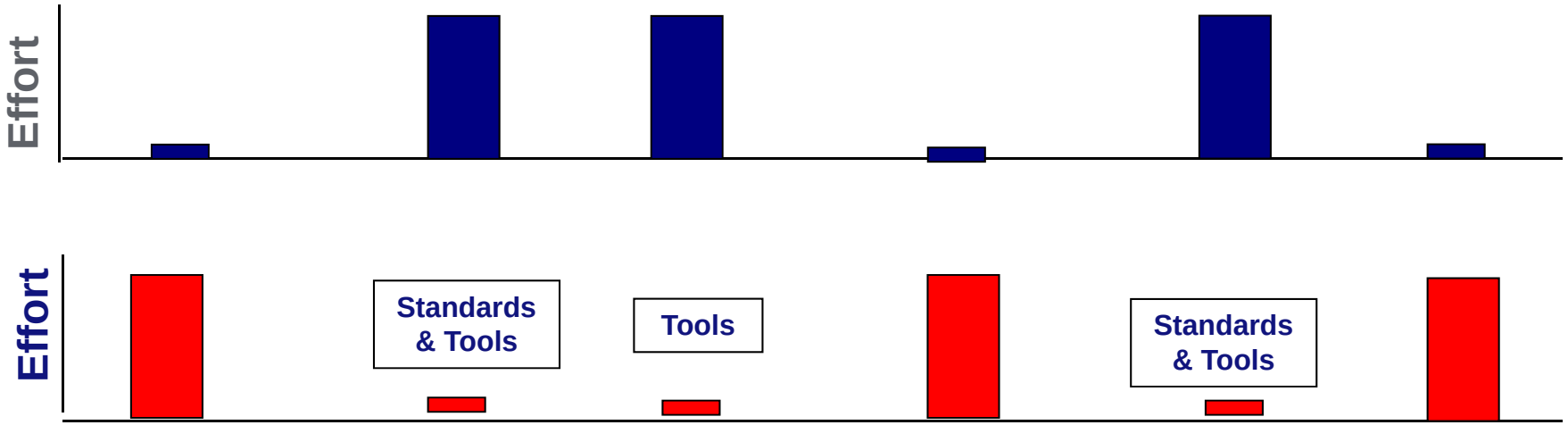
US FDA Goal: Reduce Time to Access / Analyze Data to Increase Time for Review



Present Time Emphasis- 'Doing'



Source: Theresa Mullen, PhD, FDA CDER Associate Director

CDISC Controlled Terminology

- Primary Objective: to define and support the terminology needs of CDISC standards across the clinical trial continuum (CDASH → SDTM)
- Focus on "standard" terminology codelist development and publication, beginning with SDTM v3.1.1 & CDASH v1.0 (for "safety data")
- Key partnership with US National Cancer Institute Enterprise Vocabulary Services (NCI EVS) with terms coded in *NCI Thesaurus*
- Key harmonization activities with FDA, EMA, NCI, ISO, NCI, HL7 RCRIM etc.

Guiding Principles

- Adopt...Adapt...Develop Philosophy
- Evaluate and/or utilize existing terminology 1st
- Extend existing vocabularies where incomplete, working with vocabulary developer / owner
- Harmonize across CDISC standards and with other pre-existing vocabulary initiatives
- Address international needs for global projects and organizations
- Ensure an open, free and viable environment and infrastructure for production terminology that supports terminology evolution

CDISC-NCI EVS Partnership

- Dedicated terminology experts and resources to CDISC global terminology activities
- Controlled terminology development, harmonization, publication and maintenance
- Established terminology infrastructure and standard operating procedures
- CDISC terms are coded and tagged in *NCI Thesaurus*

NCI EVS Terminology Services

- Subject Matter Expertise
- Definition writing and analysis
- Terminology tagging, sub-setting and value set management
- Terminology coding that ensures cross-harmonization with key partner organizations
- Terminology requests and maintenance
- Links to other controlled terminologies as needed (e.g. FDA, MedDRA, ISO, UCUM etc.)
- Extending into new disease areas

Controlled Terminology example

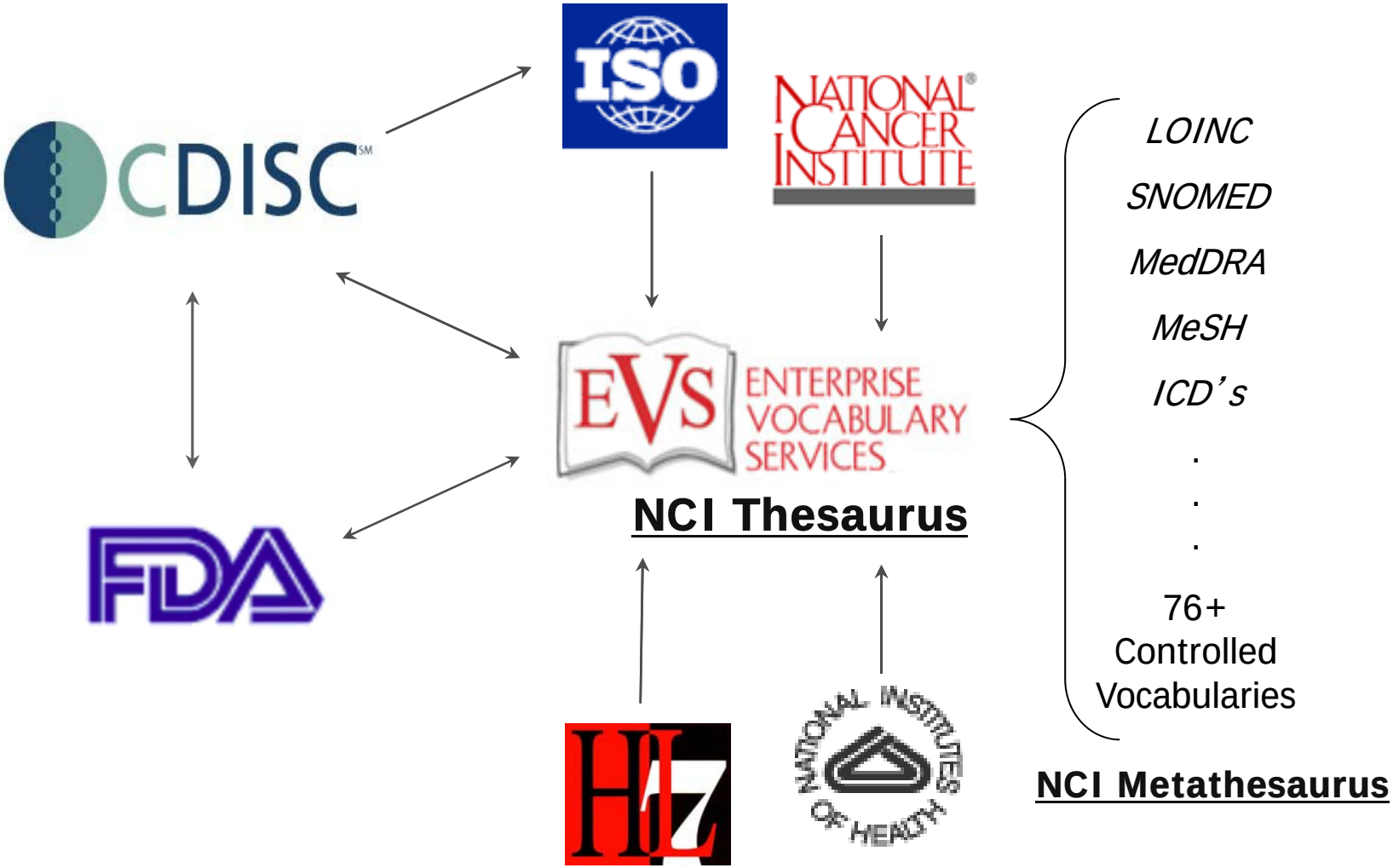
Position Codelist Example

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 Alignment



Terminology Subsets in NCIt

to access and download CDISC terminology go to
http://www.cancer.gov/cancertopics/terminologyresources/CDISC

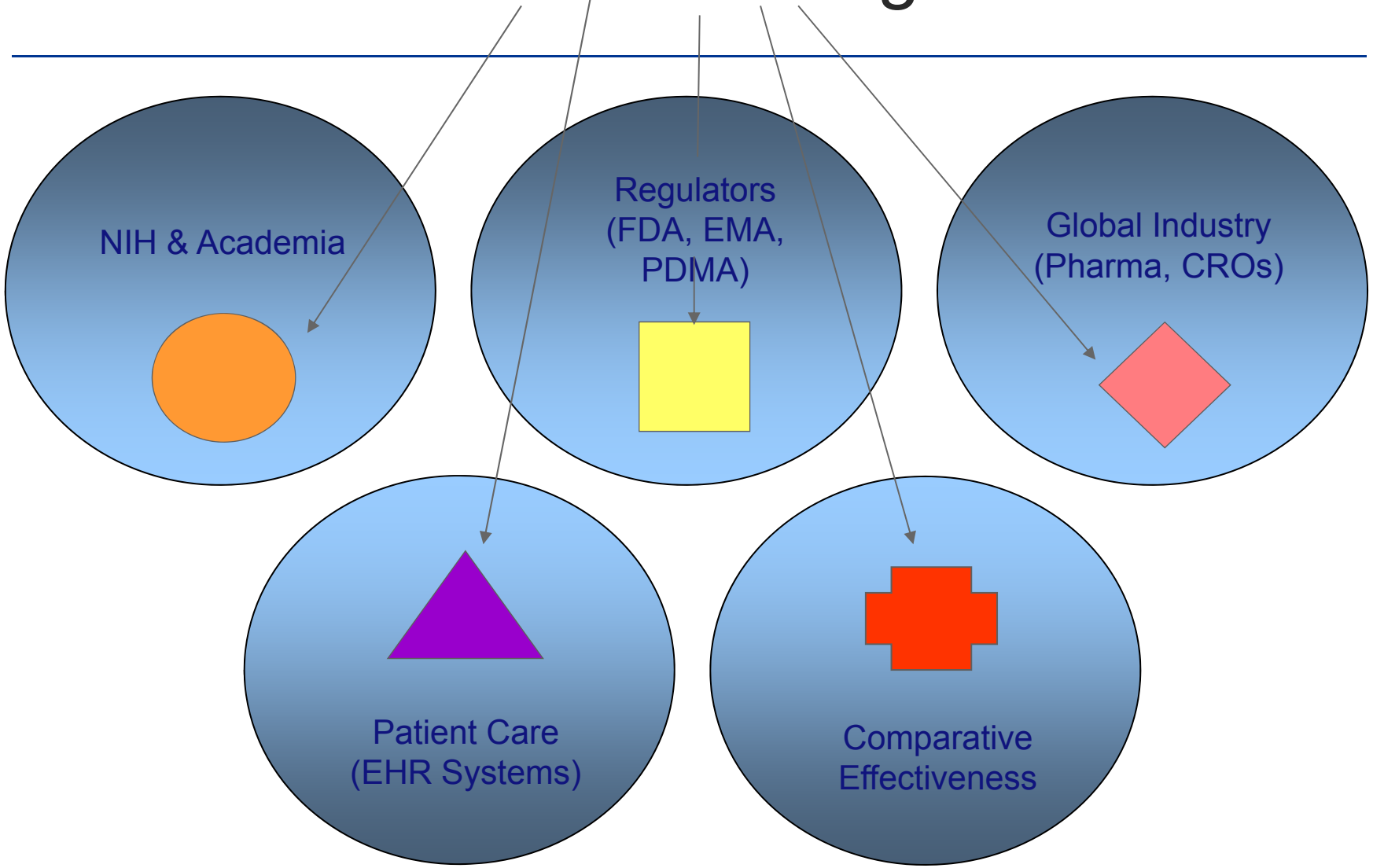
	Production Total	Novel Terms	Codelists
SDTM	4736	3745	63
SEND	3952	1800	62/*40
CDASH	135	-	16
ADaM	29	29	4

*Indicates SEND-only codelists

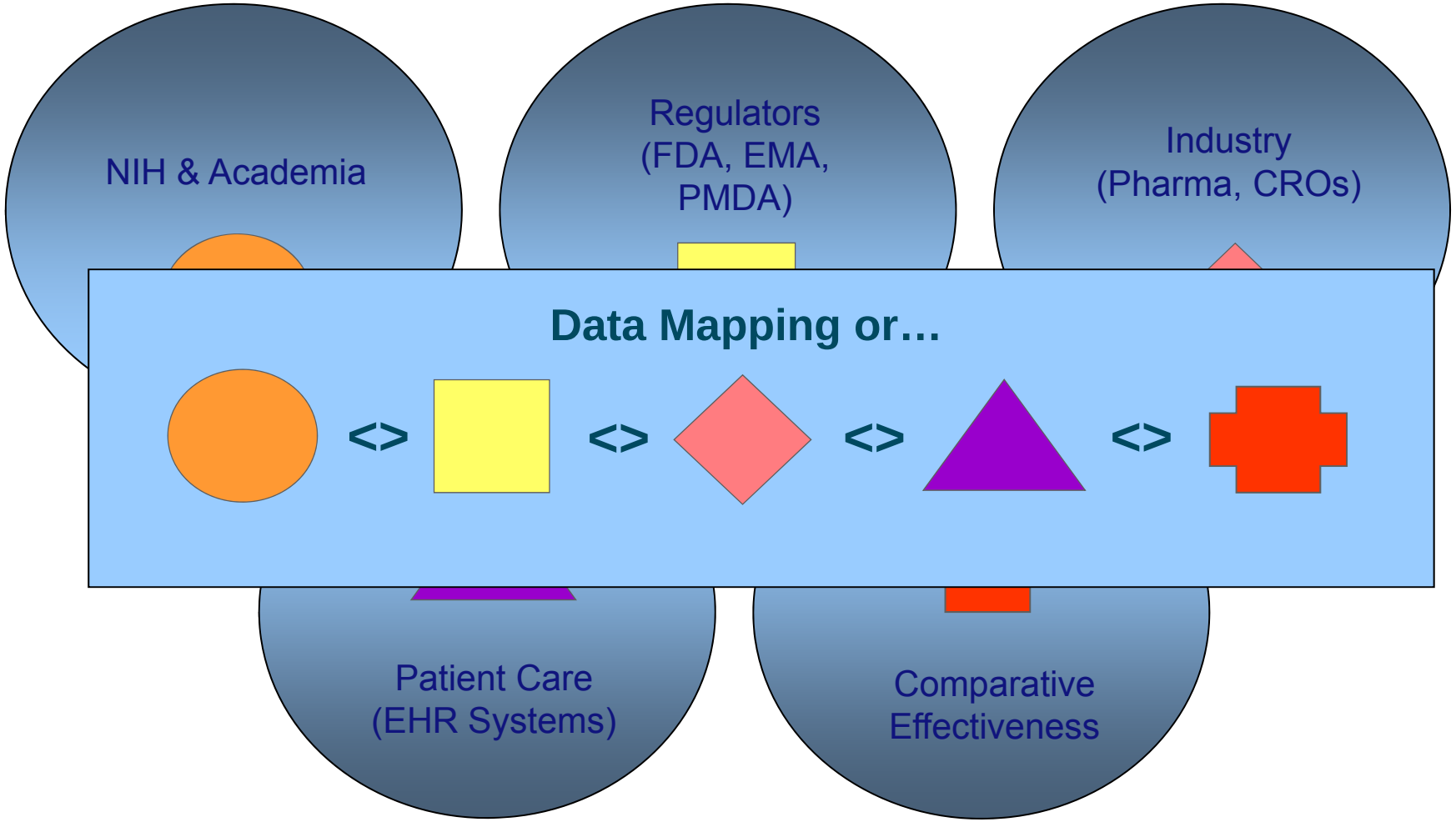
	Term Numbers
CDISC	5627
NCPDP	511
FDA UNII Codes	11578
FDA CDRH	1978
FDA SPL	753
FDA ICSR	202
NICHD	598
CTCAE	6361

Note: Terms for TB, Cardiology, Polycystic Kidney Disease also coded

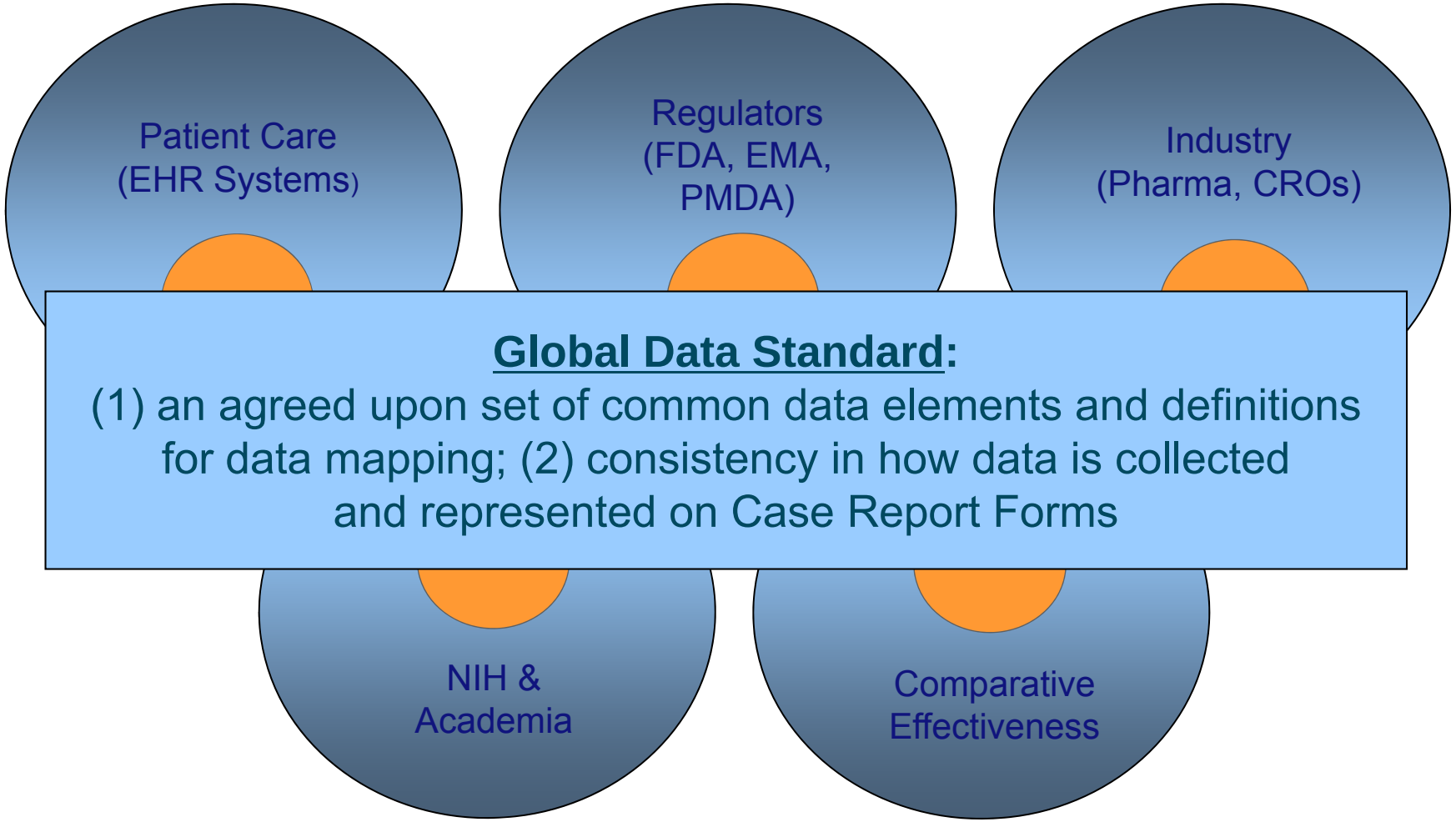
Clinical Data Element: Angina



Clinical Data Element: Angina



Standard Data Element: Angina



CDISC Disease Projects

- Pulmonary Tuberculosis (TB); joint CDISC-HL7 standard released fall 2008; 139 TB data elements and definitions
- Acute Coronary Syndrome (ACS); joint CDISC-HL7 standard released fall 2008
- Cardiovascular Disease; CV Endpoint definitions available for public review; clinical data elements being developed to standardize data collection in Cardiovascular trials
- Alzheimer's Disease with Coalition Against Major Diseases (CAMD) and Nat'l Institute of Neurological Disorders & Stroke (NINDS); Implementation Guide available for public review
- Parkinson's Disease with NINDS; clinical data elements and definitions developed
- Other Projects: Polycystic Kidney Disease, Oncology, Diabetes, Pain & Analgesics, Hepatitis C, Pediatrics

ACS Standard Data Element

Data Element Name: History of peripheral vascular disease
Clinical Definition: Indicate if the patient has a history of peripheral vascular disease. This can include: 1. Claudication either with exertion or at rest. 2. Amputation for arterial vascular insufficiency. 3. Aorto-iliac occlusive disease reconstruction, peripheral vascular bypass surgery, angioplasty or stent; or percutaneous intervention to the extremities. 4. Documented abdominal aortic aneurysm (AAA) repair or stent. 5. Positive non-invasive/invasive test. This does not include procedures such as vein stripping, carotid disease, or procedures originating above the diaphragm.
Valid Values: Yes, No

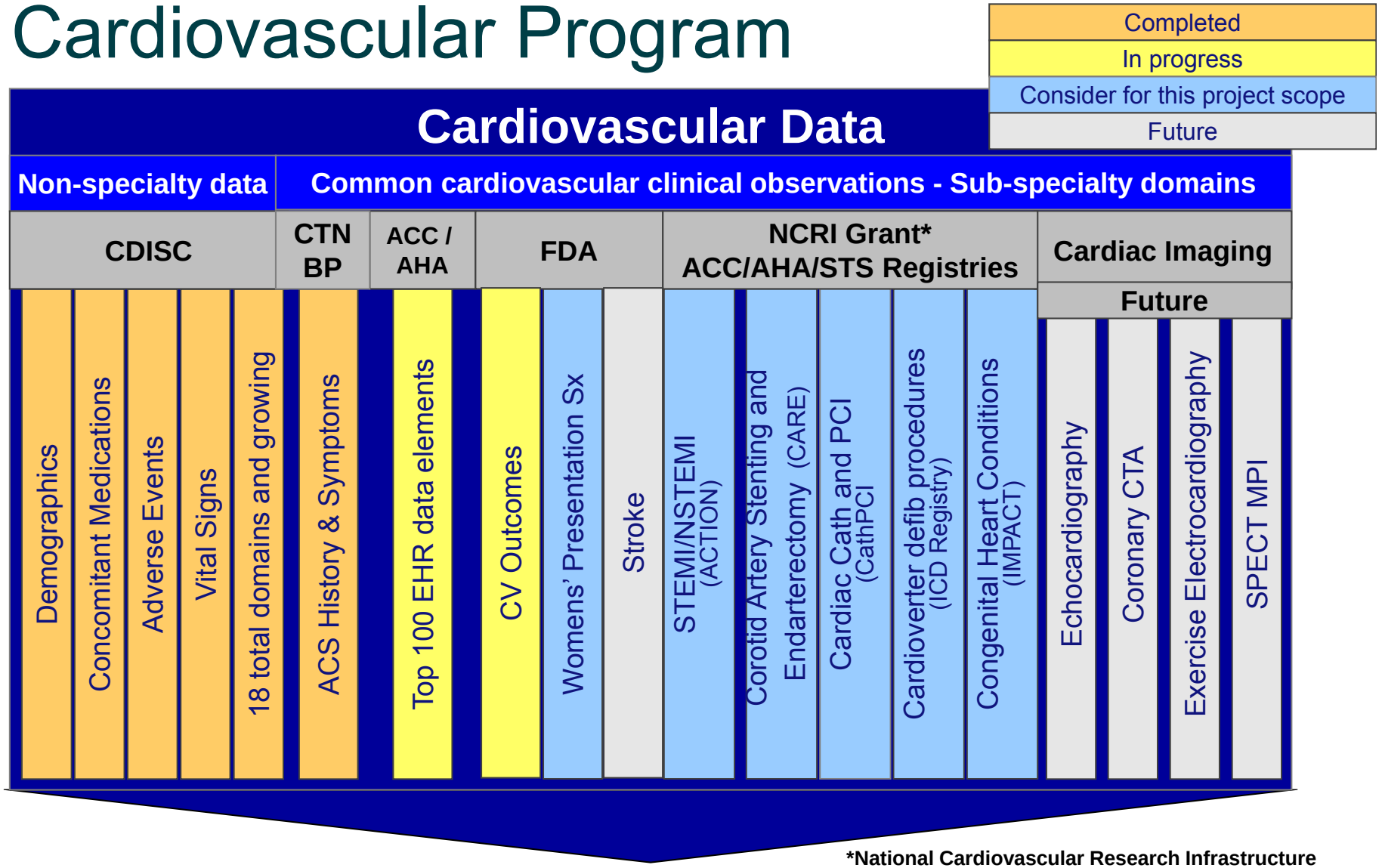
ACS Data Collection Module

Acute Coronary Syndrome
Common Data Elements

History and Risk Factors

History and Risk Factors	
Angina pectoris: *Previous or current symptoms described as chest pain or pressure, jaw pain, arm pain, or other equivalent discomfort suggestive of cardiac ischemia.*	☐ No ☐ Yes
Unstable angina pectoris: *Angina pectoris (or equivalent type of ischemic discomfort) with any 1 of the 3 following features:* *a) Angina occurring at rest and prolonged, usually greater than 20 minutes;* *b) New onset angina of at least Canadian Cardiovascular Society Grading Scale (or CCS classification system) classification severity III or greater;* *c) Recent acceleration in angina accentuated by an increase in severity of at least 1 CCS class to at least CCS class III. The biomarkers of necrosis are below the threshold of myocardial infarction.*	☐ No ☐ Yes
Stable angina pectoris: *Angina without a recent change in frequency or pattern.* *Angina is relieved by rest and/or sublingual/oral/transdermal medications.*	☐ No ☐ Yes

Cardiovascular Program



CV Clinical
- Data Elements
- Event definitions
- Clinical terminology and data definitions

CDISC
- SDTM standard for FDA submission
- Controlled Terminology alignment
- CRF templates
- Stds adoption by researchers

HL7
- Mappings to HL7 standards
- Adoption support for EHR's
- CCHIT EHR Certification (future)

Why Cardiology Data Standards

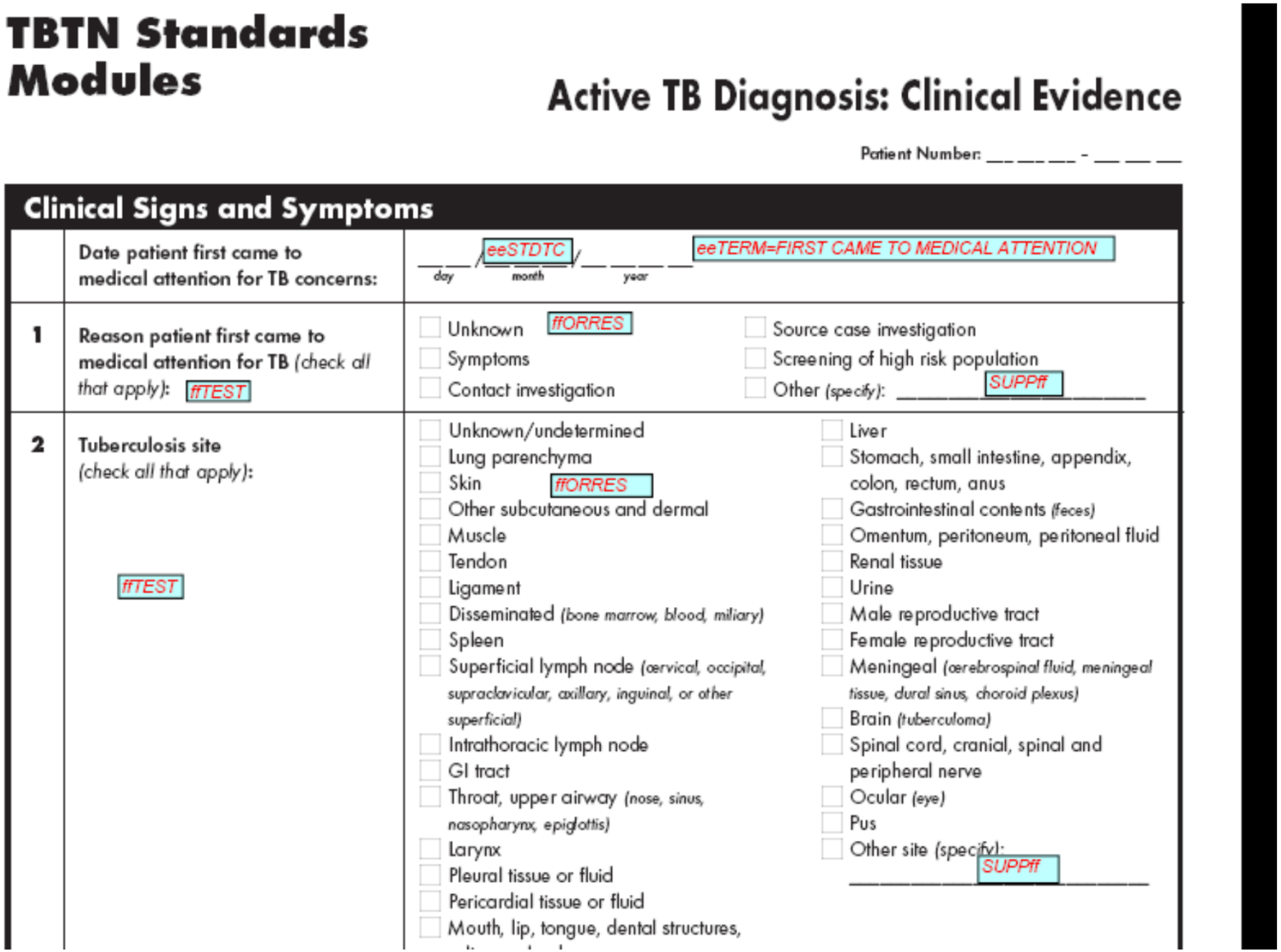
- To improve the quality and efficiency of cardiovascular trials
- To provide end point definitions so that events are clearly characterized by objective criteria and reported uniformly
- To standardize data collection to capture key data elements
- To simplify analysis of events in drug development programs or among different clinical trials and to more easily identify trends and other safety signals

Source: Dr. Karen Hicks, FDA Medical Officer

TB Standard Data Element

Data Element Name: Reason subject first came to medical attention
Clinical Definition: The reason the subject was first medically evaluated for possible TB disease or Latent TB infection Note: clinical data elements are the “currency of exchange”
Valid Values: Symptoms, Contact Investigation, Source Case Investigation, Screening of High Risk Population, Unknown, Other (specify)

TB Data Form with SDTM Annotation



TBTN Standards Modules

Active TB Diagnosis: Clinical Evidence

Patient Number: __ __ __ - __ __ __

Clinical Signs and Symptoms

	Date patient first came to medical attention for TB concerns:	__ __ / eeSTDTC / __ __ __ __ (day / month / year) eeTERM=FIRST CAME TO MEDICAL ATTENTION
1	**Reason patient first came to medical attention for TB** *(check all that apply)*: ffTEST	☐ Unknown ffORRES ☐ Symptoms ☐ Contact investigation ☐ Source case investigation ☐ Screening of high risk population ☐ Other *(specify)*: _____ SUPPff
2	**Tuberculosis site** *(check all that apply)*: ffTEST	☐ Unknown/undetermined ☐ Lung parenchyma ☐ Skin ffORRES ☐ Other subcutaneous and dermal ☐ Muscle ☐ Tendon ☐ Ligament ☐ Disseminated *(bone marrow, blood, miliary)* ☐ Spleen ☐ Superficial lymph node *(cervical, occipital, supraclavicular, axillary, inguinal, or other superficial)* ☐ Intrathoracic lymph node ☐ GI tract ☐ Throat, upper airway *(nose, sinus, nasopharynx, epiglottis)* ☐ Larynx ☐ Pleural tissue or fluid ☐ Pericardial tissue or fluid ☐ Mouth, lip, tongue, dental structures, ☐ Liver ☐ Stomach, small intestine, appendix, colon, rectum, anus ☐ Gastrointestinal contents *(feces)* ☐ Omentum, peritoneum, peritoneal fluid ☐ Renal tissue ☐ Urine ☐ Male reproductive tract ☐ Female reproductive tract ☐ Meningeal *(cerebrospinal fluid, meningeal tissue, dural sinus, choroid plexus)* ☐ Brain *(tuberculoma)* ☐ Spinal cord, cranial, spinal and peripheral nerve ☐ Ocular *(eye)* ☐ Pus ☐ Other site *(specify)*: _____ SUPPff

Sample TB Codelist: CXR Image Parenchymal Result

Standard Terminology Codelist

CDISC Controlled Terminology

- Cavity
- Fibrosis
- Infiltrates
- Mass calcified
- Nodule not calcified
- Volume loss
- Volume collapse
- Miliary Tuberculosis
- Unable to determine

Codelist = Value Set = Permissible Values

Parkinson's Data Element (NINDS)

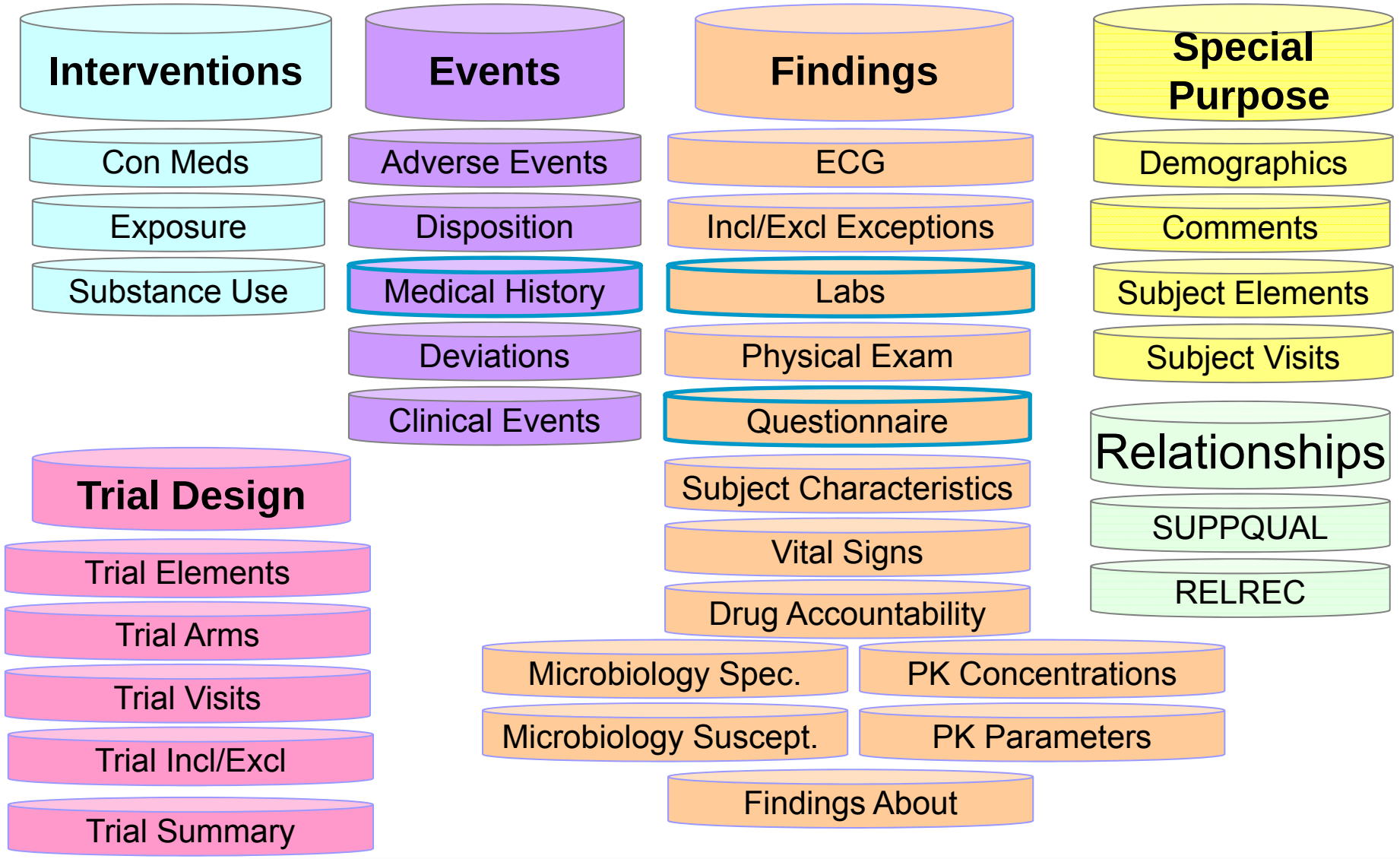
Standard Data Element (Neuropathology)**:** Density of "Lewy Related Pathology" by regions: Temporal Cortex

Clinical Definition: Indicates the density of "Lewy related pathology" in temporal cortex, if present

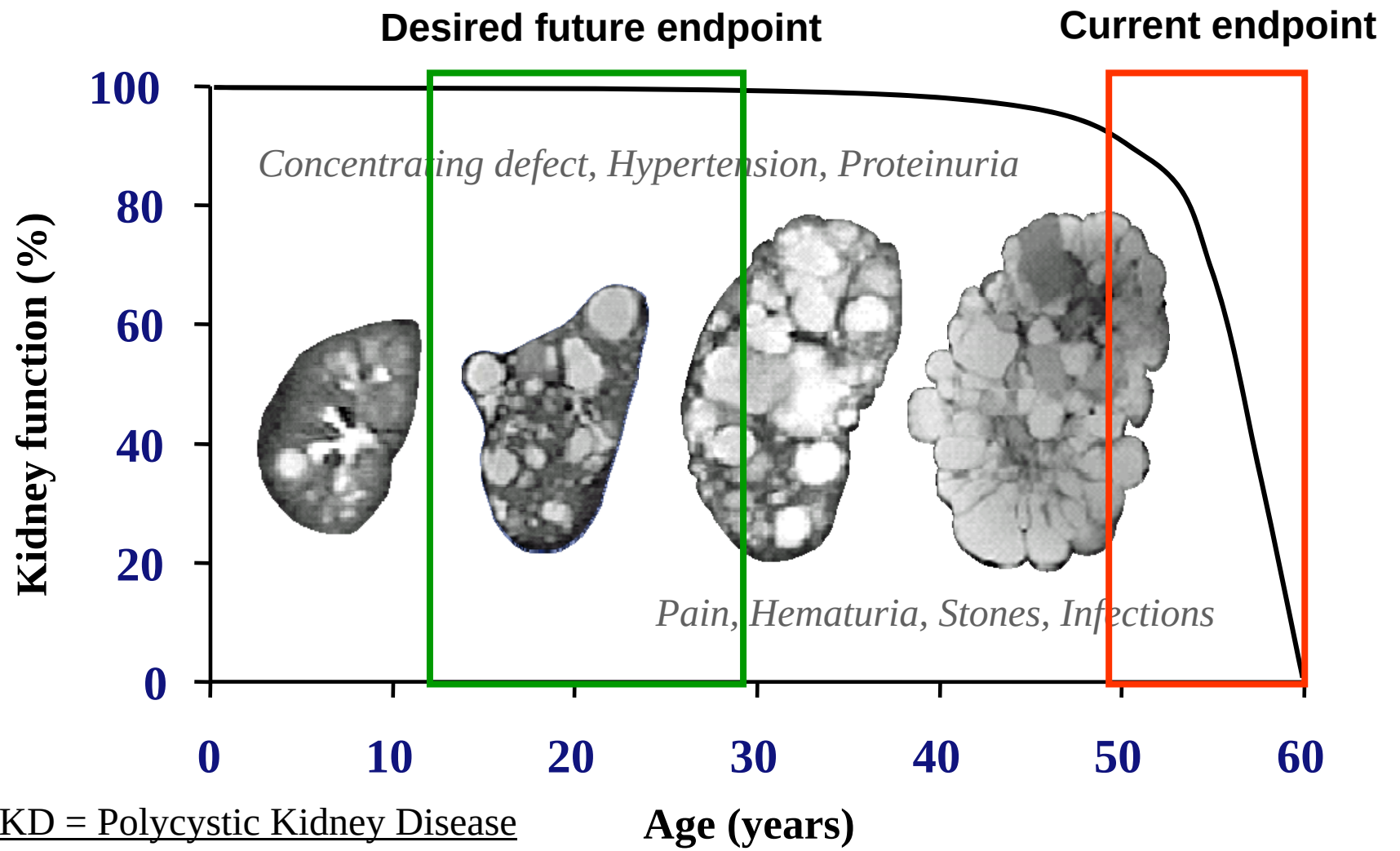
Valid Values: 0 = Absent
1 = Mild
2 = Moderate
3 = Severe
4 = Very severe
5 = Not assessed
9 = Missing/unknown

Another Example (Cognitive Instrument)**:** Alzheimer's Disease Assessment Scale – Cognitive (ADAS-COG)

Aligning Alzheimer's Data with SDTM



PKD Use Case: Changing the Paradigm



PKD = Polycystic Kidney Disease

Source: Dr. Ron Perrone PKD Foundation & Tufts Univ.

PKD Opportunity for Intervention

- The ideal therapeutic agent would block formation and/or growth of cysts at an early stage of life, thereby preventing the *inexorable* expansion, irreversible scarring, and structural distortion of kidneys, which are associated with all of the kidney complications of PKD
- Adoption of total kidney volume (TKV) as a target endpoint for regulatory approval will greatly accelerate the pace of clinical research and introduction of new therapies, thereby benefiting all PKD patients

Source: Dr. Ron Perrone PKD Foundation & Tufts Univ.

PKD Project Key Aims

- Develop standard clinical data elements and definitions that are specific to PKD to enable the remapping of retrospective data and collecting prospective data in a standards format
- Develop the PKD standard with clinical (and standards) experts and obtain broad consensus through CDISC public comment; ensure input from both FDA and EMA
- Create a new database of aggregated data from existing multiple, longitudinal, and well-characterized research registries maintained over decades by leading academic institutions in PKD clinical investigation
- The disease models will be used as evidence in a formal application to the FDA and the EMA for *qualification of Total Kidney Volume as a biomarker "fit for use"* in evaluating the efficacy of new therapies and treatments for PKD

Source: Dr. Ron Perrone PKD Foundation & Tufts Univ.

Innovative Medicine Initiative (IMI)

EHR4CR

Electronic Health Records for Clinical Research

HOME CONSORTIUM WORKPLAN

Website under construction

HOME

The EHR4CR (Electronic Health Records for Clinical Research) project aims to design and demonstrate a scalable and cost-effective approach to interoperability between Electronic Health Record systems (EHRs) and Clinical Research through multiple but unified initiatives across different therapeutic areas, with varying local and national stakeholders and across several countries under various legal frameworks. This unified approach will be made possible by both an EHR4CR business model and an EHR4CR platform.

Working closely with the EFPIA partners, the consortium will confirm priority clinical trials scenarios, such as patient recruitment, to be addressed and the requirements for these scenarios. The present gap between EHR systems and clinical research systems to deliver these scenarios will be analysed, which will direct the business model and the platform design.

The EHR4CR platform will:

- enable trial eligibility and recruitment criteria to be expressed in ways that permit searching for relevant patients across distributed EHR systems, and initiate participation requests confidentially via the patients' authorized clinicians;
- support the feasibility, exploration, design and execution of clinical studies and long-term surveillance of populations;
- provide harmonised access to multiple heterogeneous and distributed clinical (EHR) systems and

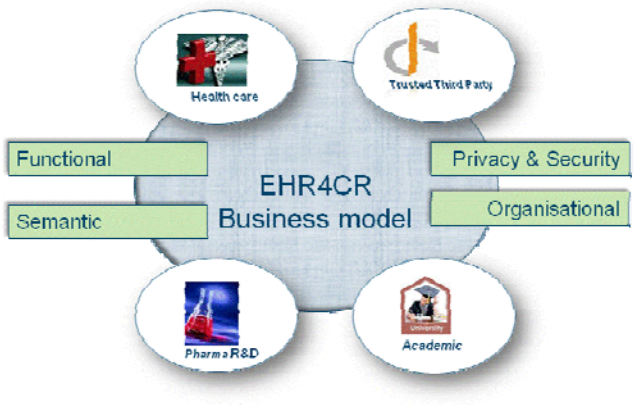
SUPPORTED BY

The EHR4CR project is funded by the IMI Programme.

imi

The Innovative Medicines Initiative (IMI) is a unique public-private partnership designed by the European Commission and European Federation of Pharmaceutical Industries and Associations (EFPIA). It is a pan-European collaboration that brings together large biopharmaceutical companies, small- and medium-sized enterprises (SMEs), patient organisations, academia, hospitals and public authorities. The initaive aims to accelerate the discovery and

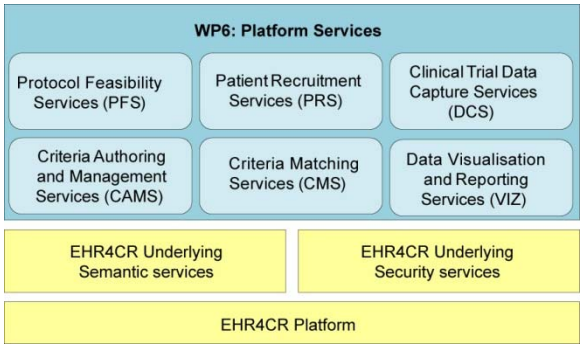
EHR4CR Business model



EHR4CR business model will:

- Specify in detail the product and service offering;
- Include an impact analysis on multiple stakeholders;
- Deliver a self-sustaining economic model including sensitivity analysis;
- Define appropriate governance arrangements for the platform services and for pan-European EHR4CR networks;
- Define operating procedures and trusted third party service requirements;
- Identify the value proposition and incentives for each of the key players and stakeholders impacted by EHR4CR;
- Define accreditation and certification plans for EHR systems capable of interfacing with the platform;
- Provide a framework to define public and private sector roles in reusing EHRs for clinical research;
- Define a roadmap for pan-European adoption and for funding future developments.

EHR4CR Technical Platform



EHR4CR platform will:

- **Support the feasibility, exploration, design and execution of clinical studies and long-term surveillance of patient populations;**
- **Enable trial eligibility and recruitment criteria to be expressed in ways that permit searching for relevant patients across distributed EHR systems, and initiate confidentially participation requests via the patients' authorised clinicians;**
- **Provide harmonised access to multiple heterogeneous and distributed clinical (EHR) systems and integration with existing clinical trials infrastructure products (e.g. EDC systems);**
- **Facilitate improvements of data quality to enable routine clinical data to contribute to clinical trials, and importantly vice versa, thereby reducing redundant data capture.**

The partners

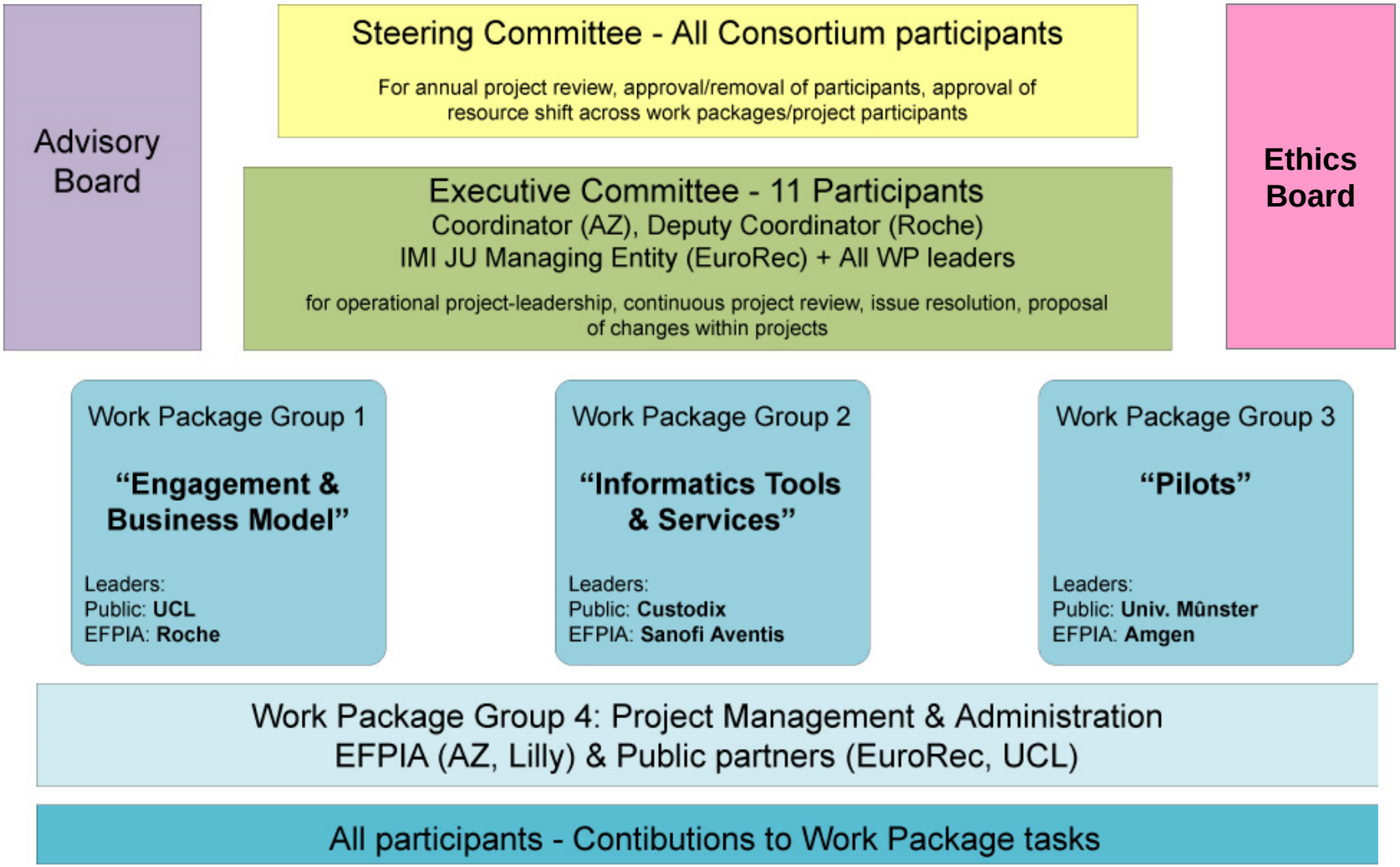
- **10* Pharmaceutical Companies (members of EFPIA)**
- **22 Public Partners (Academia, Hospitals and SMEs)**
- **5 Subcontractors (Advisory Board).**

** May increase up to 11 pharmaceutical companies*

The partners

AMGEN
Bayer
MANCHESTER 1824
Lilly
Roche
HUG Hôpitaux Universitaires de Genève
EUROREC
EPPOSI European Platform for Patients' Organisations, Science and Industry
TMF
AstraZeneca INTERNATIONAL
University of Glasgow
NOVARTIS
University of Dundee
gsk GlaxoSmithKline
UCL
CUSTODIX
Friedrich-Alexander-Universität Erlangen-Nürnberg
UNIVERSITÉ DE RENNES 1
ASSISTANCE PUBLIQUE HÔPITAUX DE PARIS
HEINRICH HEINE UNIVERSITÄT DÜSSELDORF
sanofi aventis L'essentiel c'est la santé.
Instituts thématiques Inserm Institut national de la santé et de la recherche médicale
Assero
MERCK
JANSSEN PHARMACEUTICA
KING'S College LONDON
A NETWORK POWERED BY PEERS eClinical forum
MEDICAL UNIVERSITY OF WARSAW
clinical
WESTFÄLISCHE WILHELMS-UNIVERSITÄT MÜNSTER
EMBL
CDISC

Governance structure



EHR4CR Timeline

Stage 1 (Consortia evaluation & selection) - completed in March

- Forming one EHR4CR consortia of 32 private and public partners to develop a full project proposal for 2009 IMI call topic 9
  - The project is coordinated by AZ
  - EuroRec acts as managing entity for public partners
  - Roche acts as deputy coordinator and E Lilly to cover Project Management

Stage 2 (Full project proposal) – completed July

- June 28th: Full Project Proposal submitted
- July 16th: IMI Consensus Expert Panel Meeting
- July 20th: IMI Governing board decision on the list of full project proposals

Stage 3 Current status

- September 19th: Novartis joins the EHR4CR project
- Preparations is now underway to finalise the final grant and project agreement during Q3.

- **Kick-Off Meeting March 3-4, 2011.**

Suite du programme…

- Standards Alzheimer
- Validation SDTM
- CDASH en pratique
- DataWarehouse Clinique
- Conversion vers SDTM

Conclusions

- Activités du groupe en 2011
- Prochaines Réunions
  - Mardi 12 avril 17-19h (EuroInterchange Bruxelles)
  - Juin à Genève
  - Automne à l'APHP

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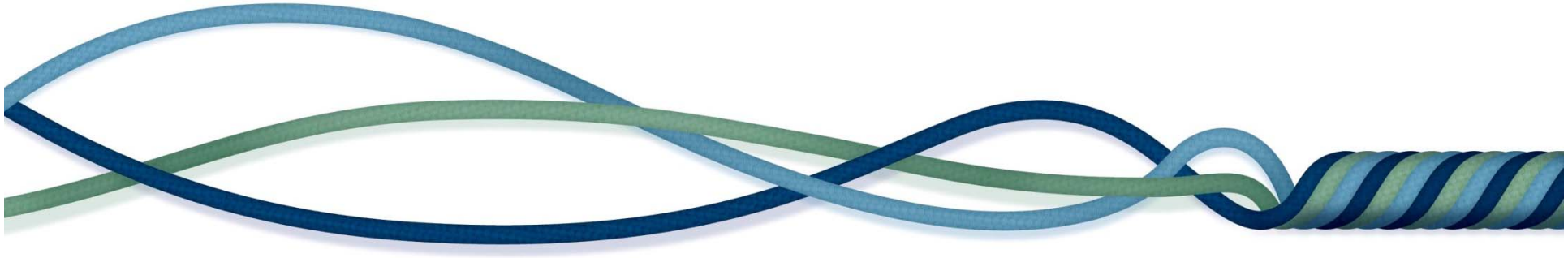

Strength *through collaboration.*