Leveraging Clinical Research Data Standards in Academia: What's in it for Me?

Kit Howard, Sr. Director, Standards Development and Education, CDISC

Tuesday, 28 JUL 2020
11:00 – 12:30 EDT

Today’s Agenda

1. Housekeeping
2. Presenter Introductions
3. Feature Presentations
4. Question & Answer Session
5. Upcoming Learning Opportunities + Resources

Housekeeping

Housekeeping

- You will remain on **mute** for the entirety of the call
- There will be a Q&A after all of the presentations are finished
- Audio issues? Shut down and restart the GoToWebinar app
- The slides from the presentation and a recording of this webinar will be available in the Members Only section of the CDISC website
  - To access – make sure that you create a login for the CDISC website if you haven't already
  - If you are employed by a CDISC member organization, please ensure you use your employer-issued email address with your employer's domain name, so we can verify membership for the purpose of applying discounts to purchasing event tickets, online courses, and more!

Content Disclaimer

- The purpose of this webinar is to provide examples of implementation and should not be considered official recommendations by CDISC unless otherwise stated in the presentation.
- This webinar is not an authorized CDISC course, is not developed or delivered under CDISC Operating Procedures, and should not replace a published standard. Please refer to the latest published standards for the most authoritative implementation information.

Our Presenters

- Kit Howard, Sr. Director, Standards Development and Education, CDISC

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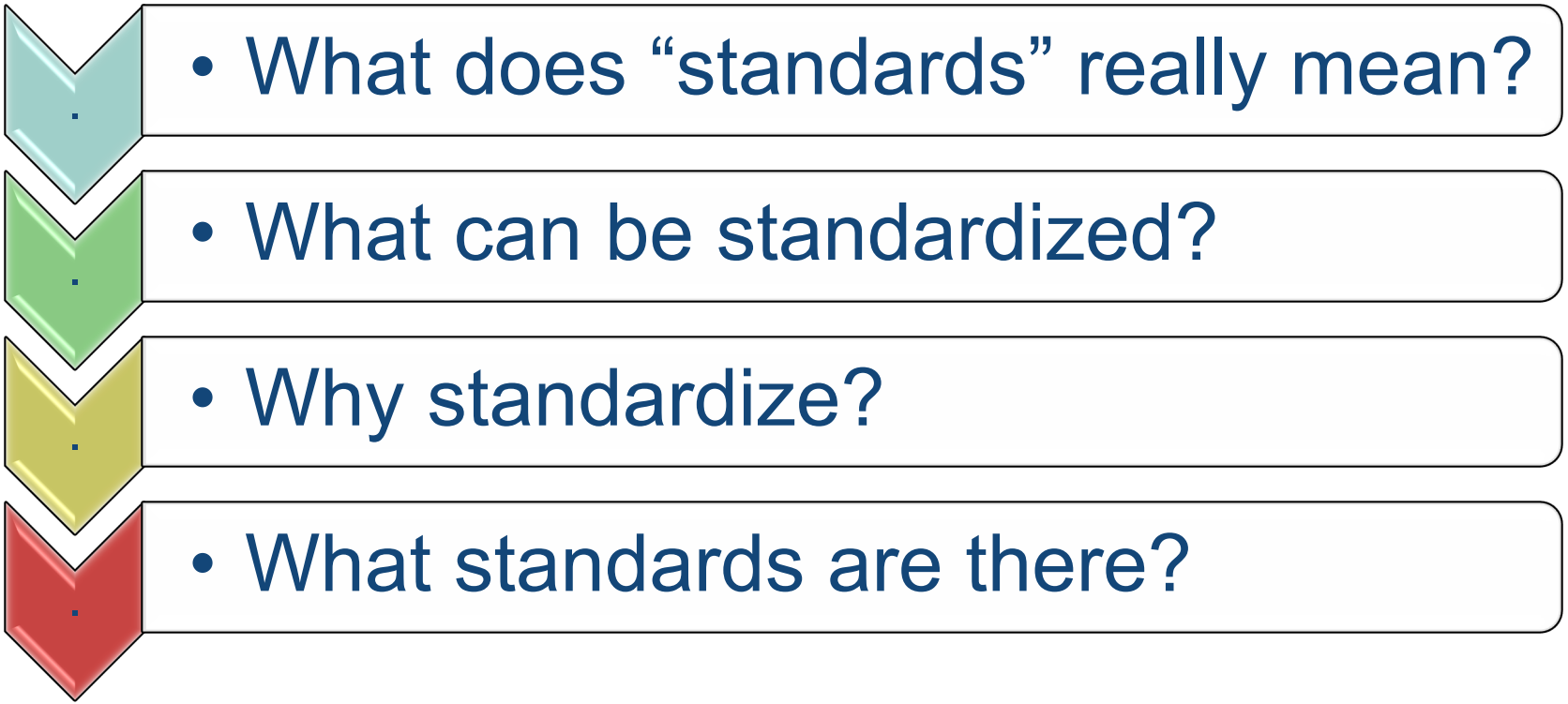
Kit Howard

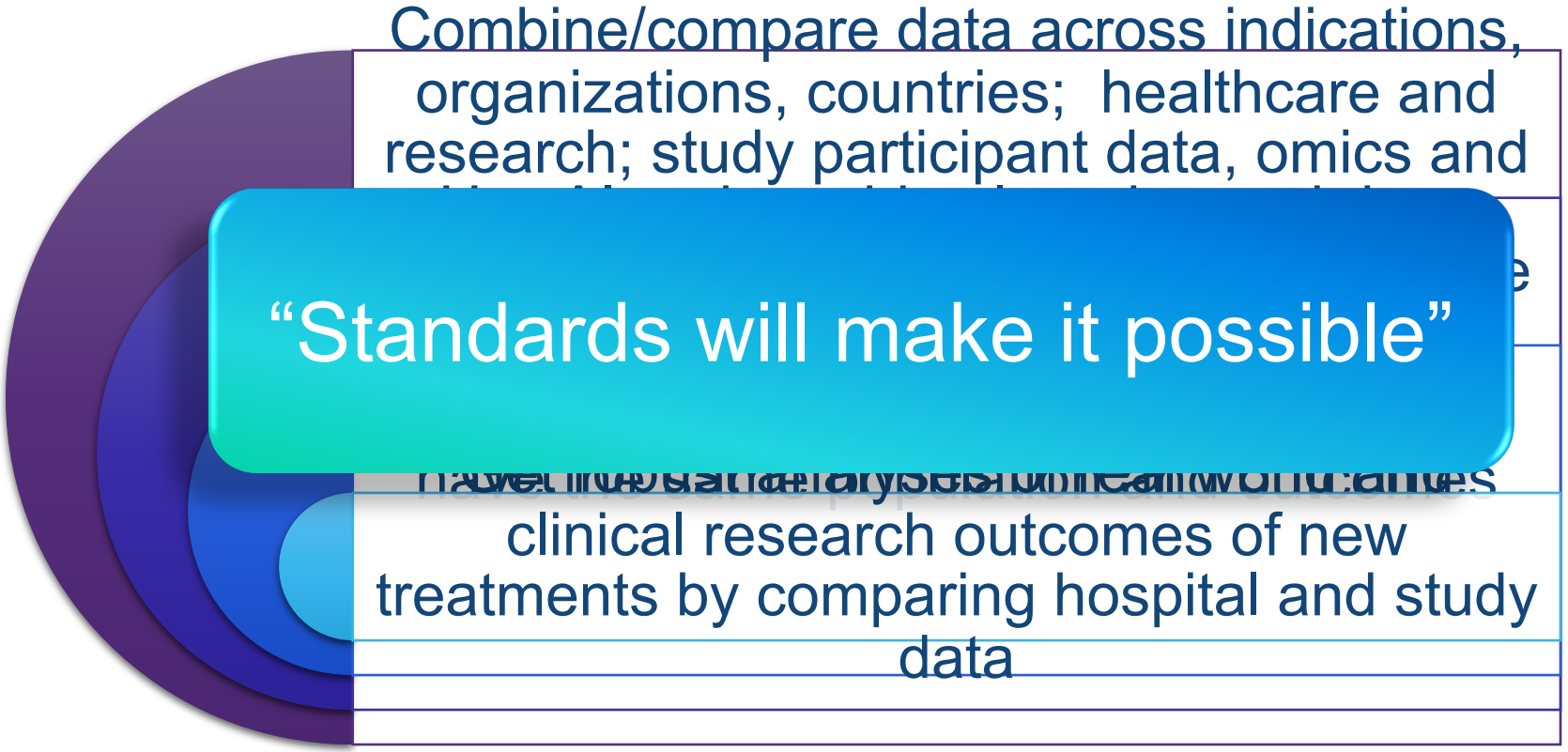
Senior Director of Standards Development and Education, CDISC

July 2020

Overview



Imagine being able to do this



What is a Standard?

Webster's Dictionary

- "something established by **authority**, custom, or general consent as a model or example"
- "the type, model, or example **commonly or generally accepted** or adhered to; criterion set for usages or practices: moral standards"
- "**a level of excellence**, attainment, etc.

Not just something done the same way every time!

An Over-Used Word…

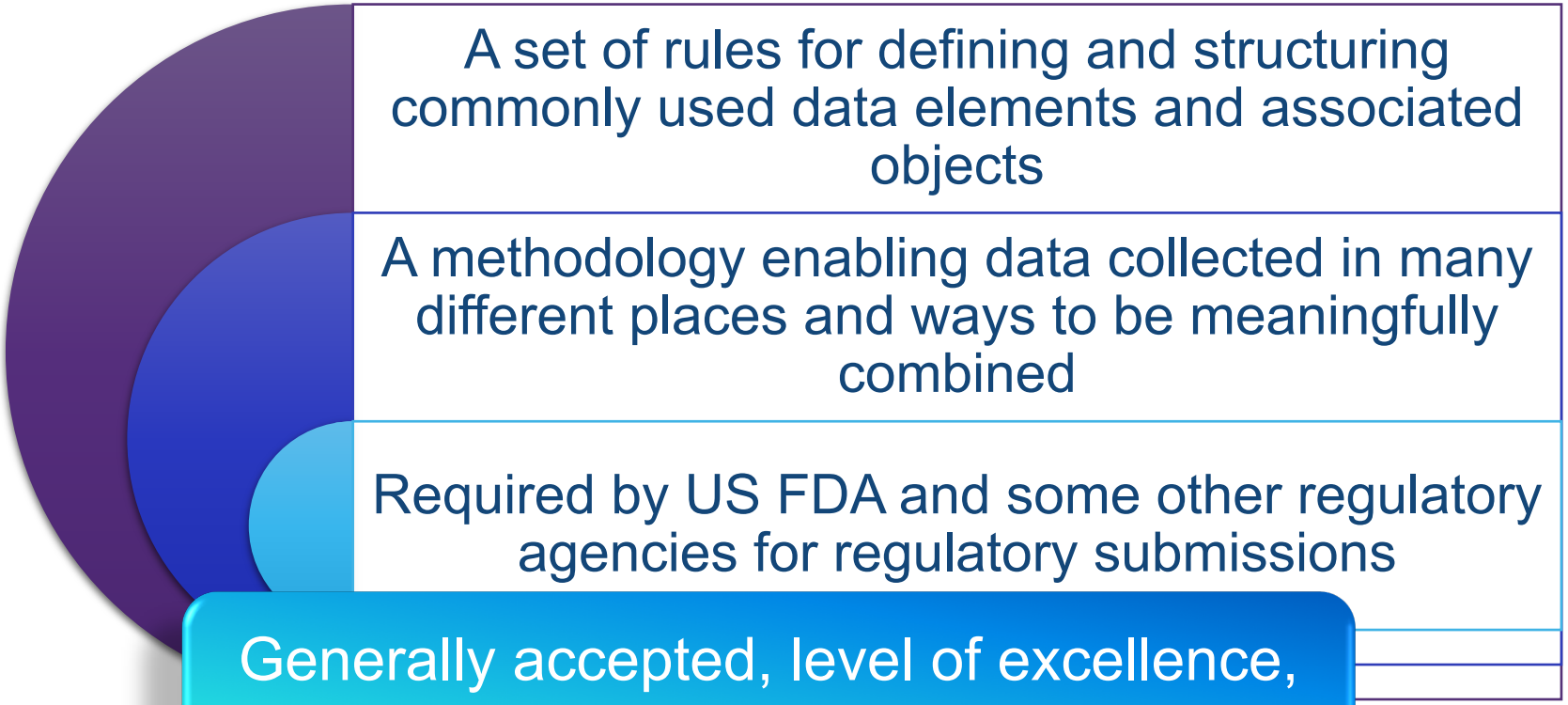
"Standards" has many meanings

- Service agreements (car repair)
- Classification methods (Dewey Decimal System)
- Manufacturing (metal purity)

Some are opposites

- Live up to the standard vs fail to do so
- Standard room vs deluxe room

What is a Clinical Research Data Standard?



Flavors of Standards in Clinical Research

Clinical
- Diagnostics
- Treatment
- Process

Data Exchange
- XML

Electronic Data
- Variable/data set name

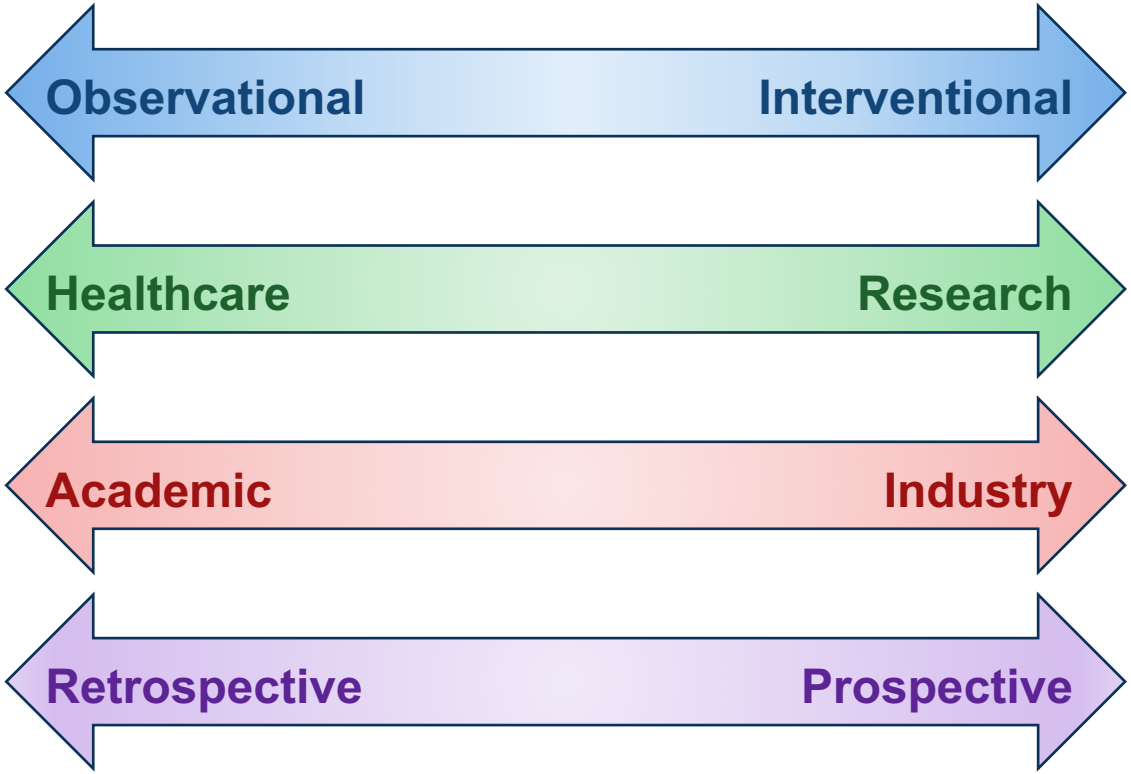
Terminology
- Common terms
- Dictionaries/code lists

Templates
- Documents
- Programs

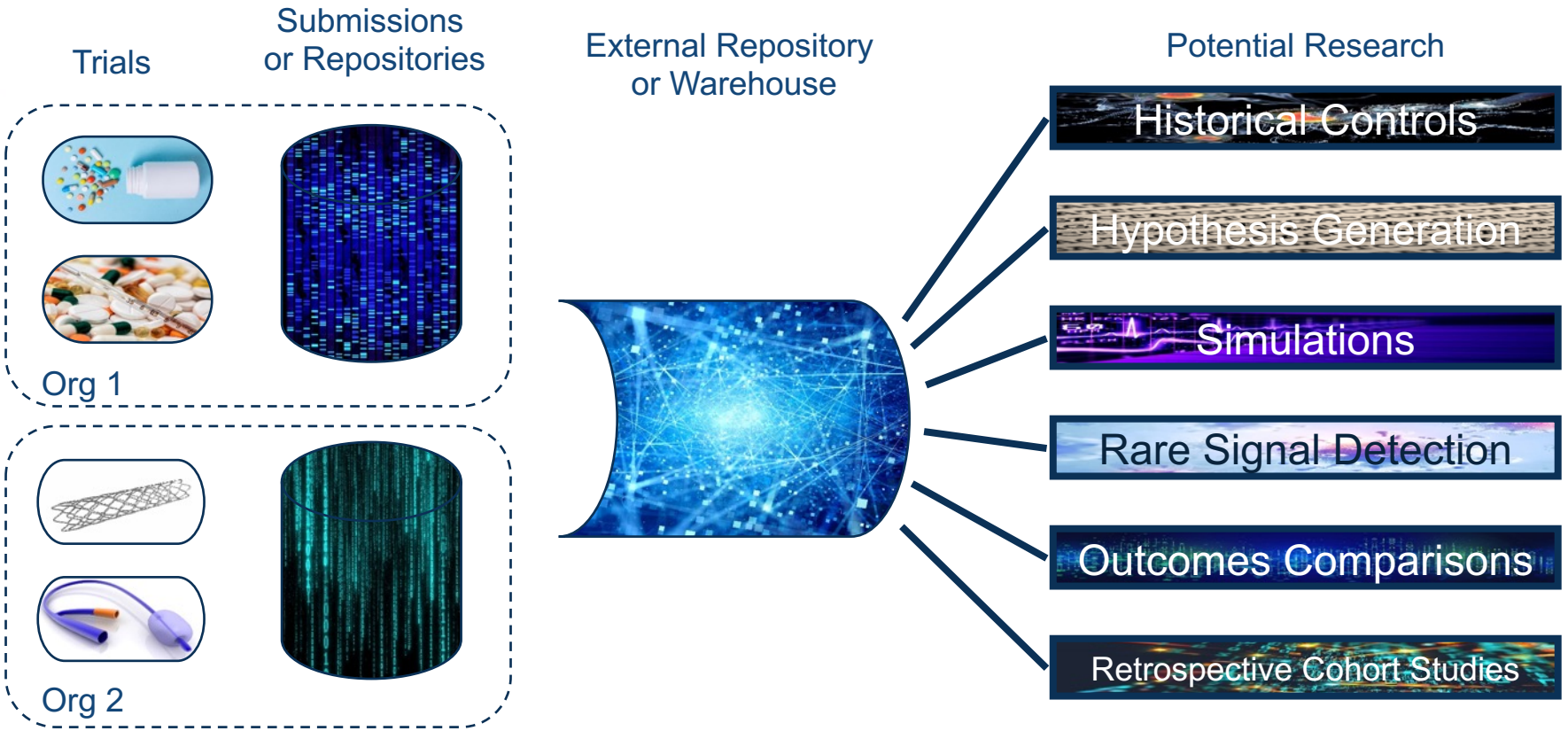
Content
- Questions
- Meaning of answers

SOPs / Processes

Data Suitable for Standardizing



Refocusing from Initial Purpose to Data Sharing



Drivers of Standardization: What's in it for Me?

Regulatory Requirements

- CDISC SDTM, ADaM, Define, SEND and Controlled Terminology are mandatory for US FDA/PMDA

Cost

- Reinventing the wheel is expensive
- Reducing treatment development costs or identifying the risk factors for hospitalization in Covid patients requires fast access to good data

Speed/Efficiency

- Reusing CRFs, programming, database structures, analysis files, code lists, etc., can dramatically shorten production time
- Frees people to work on the new science

Drivers of Standardization: What's in it for Me?

Quality

- Good standards minimize data structure and usage errors
- Harmonized use of similar fields, field names, formats, terminologies, etc., among all partners
- Helps improve understanding among partners, e.g., sponsors and vendors, collaborating universities, even divisions within an organization
- Basis for developing standardized *processes* for study activities and for

Drivers of Standardization: What's in it for Me?

Data Sharing and Pooling

- Speeds results/submissions/reviews
- Common interface allows data to flow from eHR to EDC
- Facilitates scientific breakthroughs, identification of new indications
- Ethics / safety
- For legacy data: have to map
- For prospective data: have a duty to standardize

FAIR: Guiding Principles for Scientific Data Management and Stewardship

F

- Findable (/Machine-Readable)
- Standard dataset structures with good metadata make Finding data easier

A

- Accessible
- Standard structures make creating standard data Access tools possible

I

- Interoperable
- Standards ensure that the meaning of data is clear, supporting Interoperability and enabling for common exploration and analysis tools

R

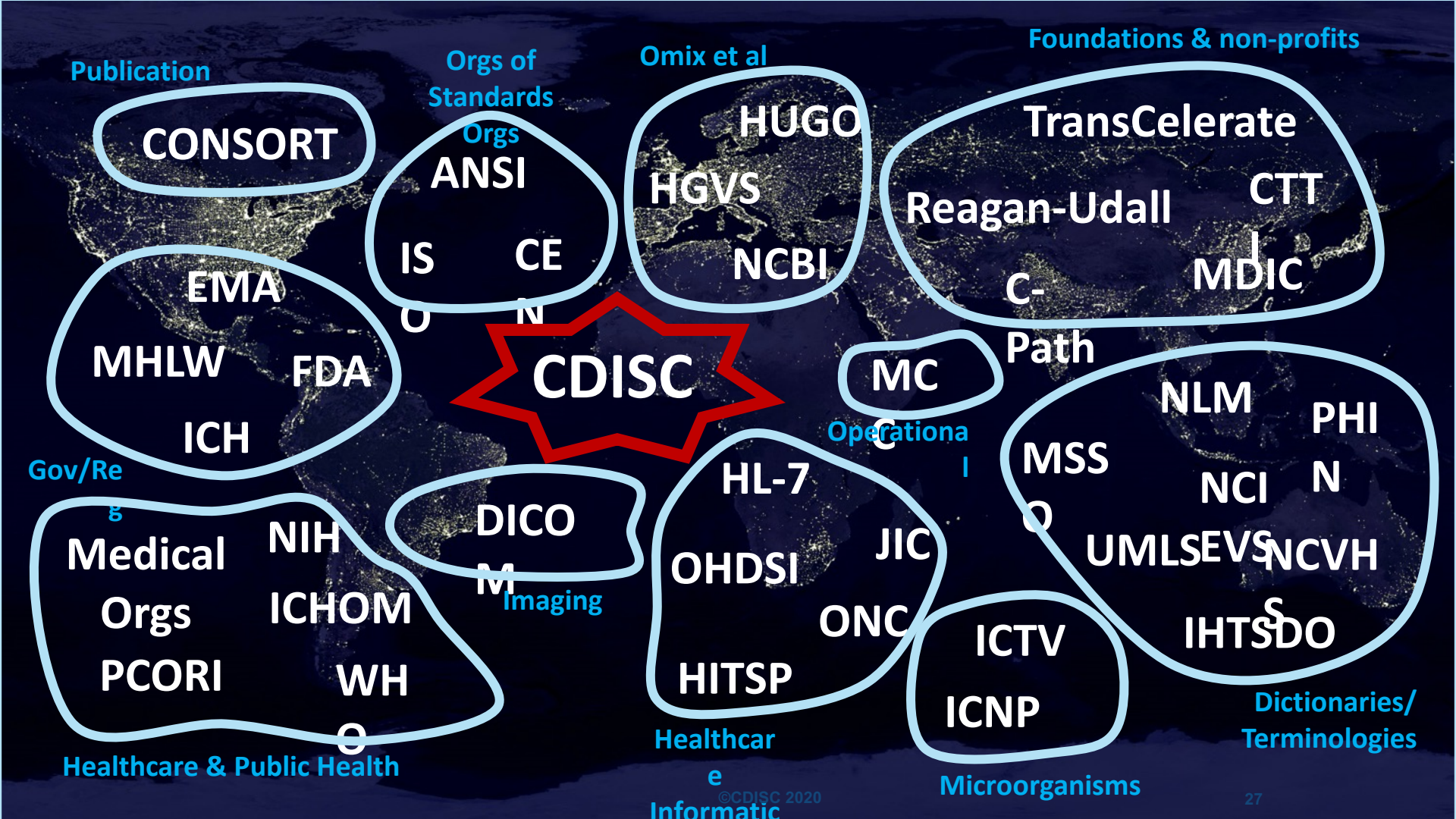
- Reusable
- Standard data can be Reused repeatedly because structure and meaning are known and documented

Impossible without standards.

Scientific Data, Nature, March 2016

What's in it for Me?

Question	Answer
I'm only doing one study. How can you standardize only one study?"	You aren't standardizing within the study. You're standardizing externally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Healthcare & Public Health
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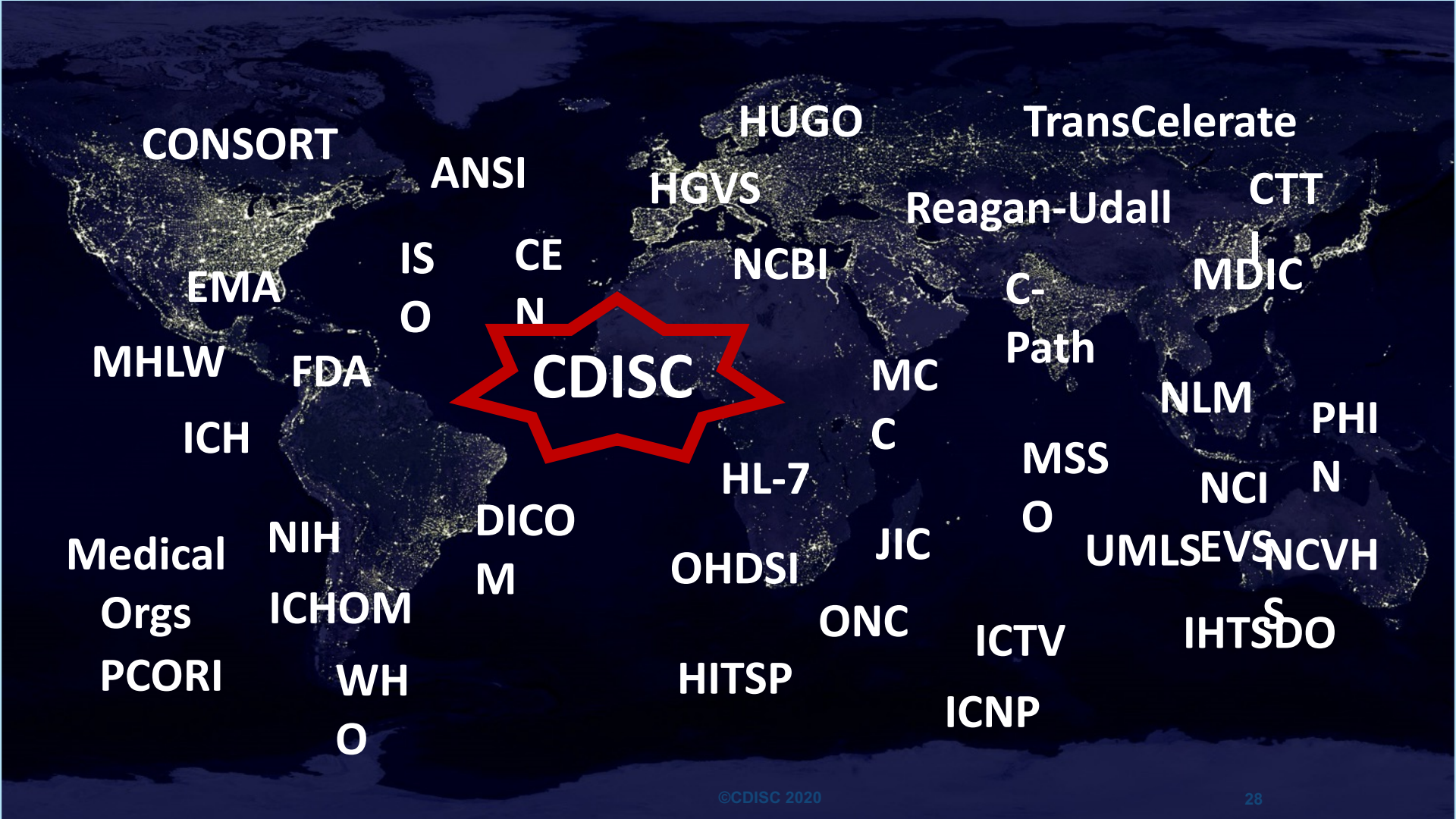
Microorganisms
Dictionaries/ Terminologies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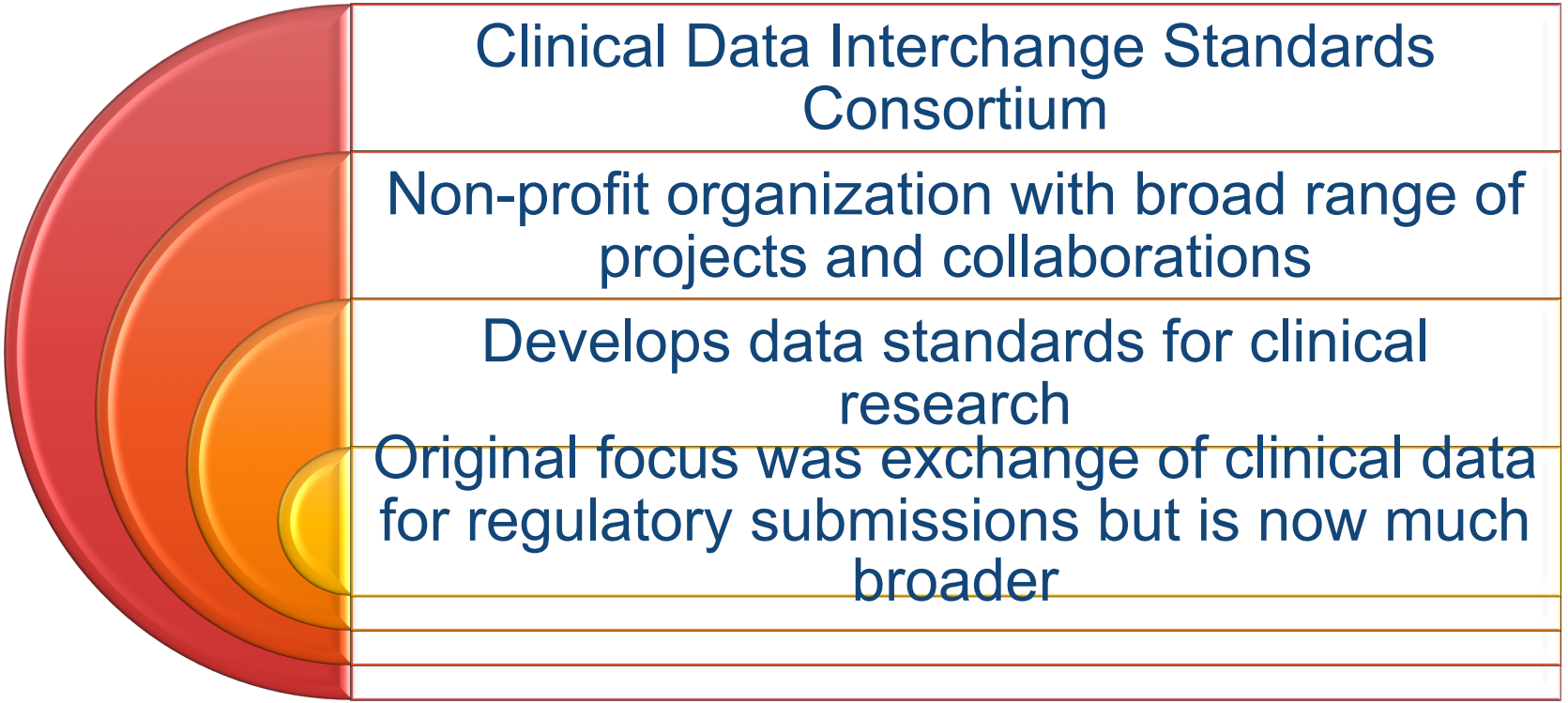
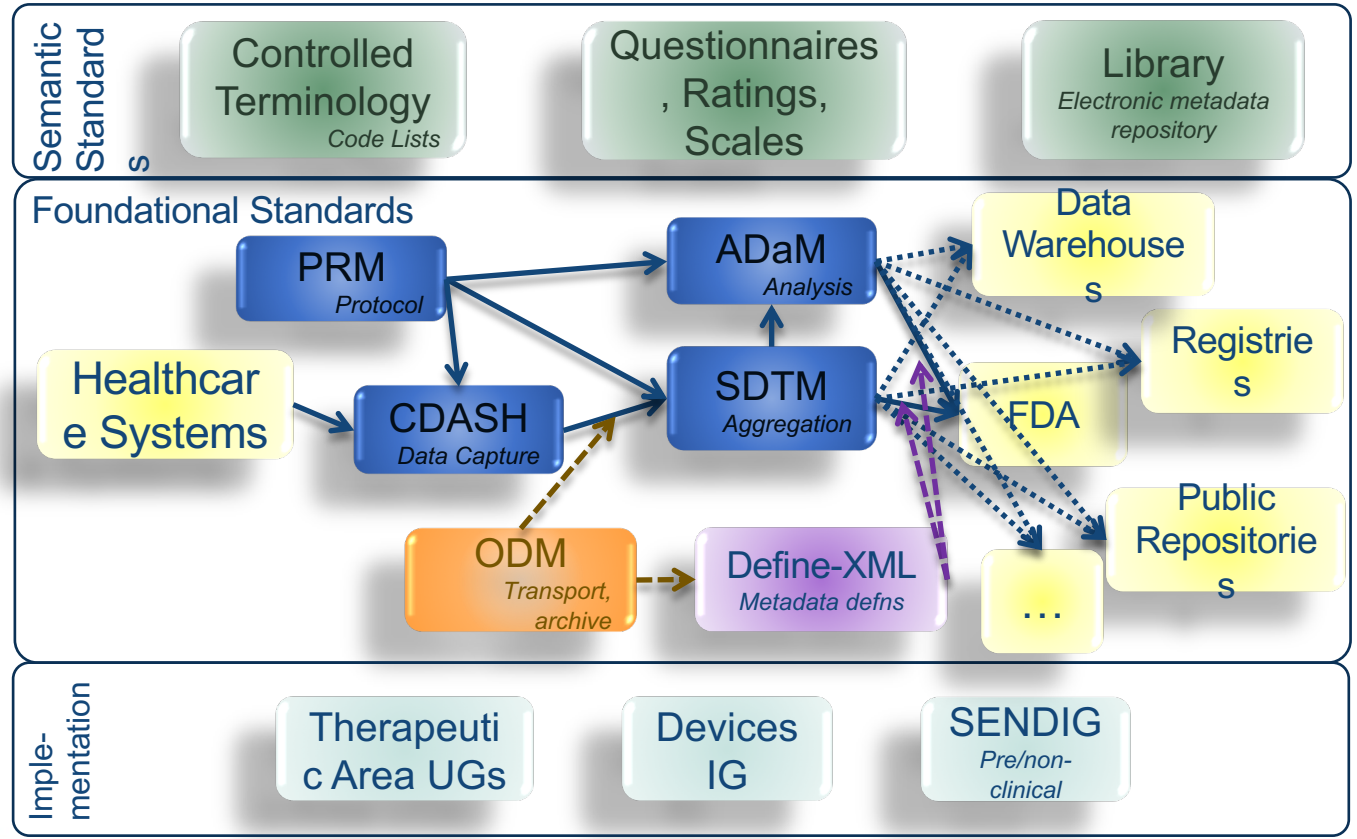
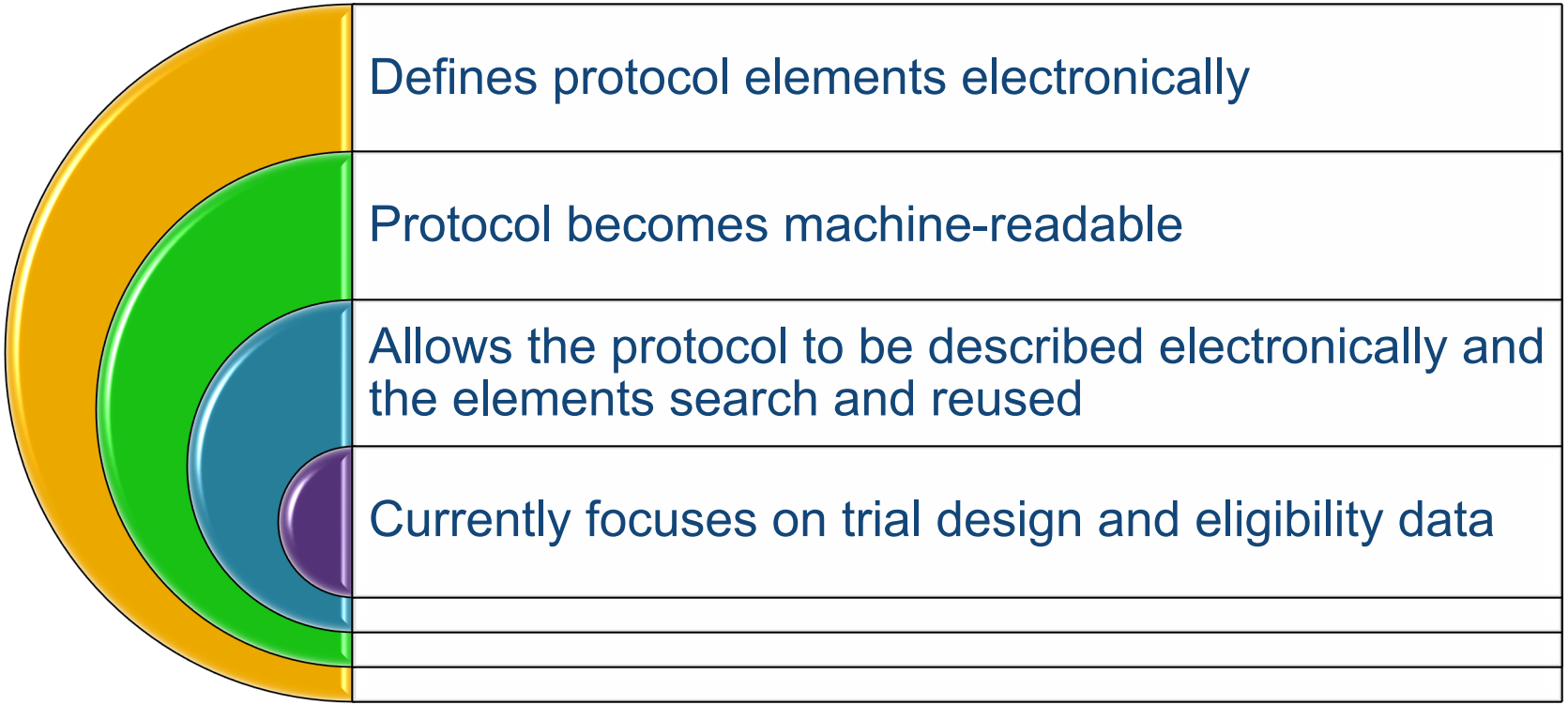


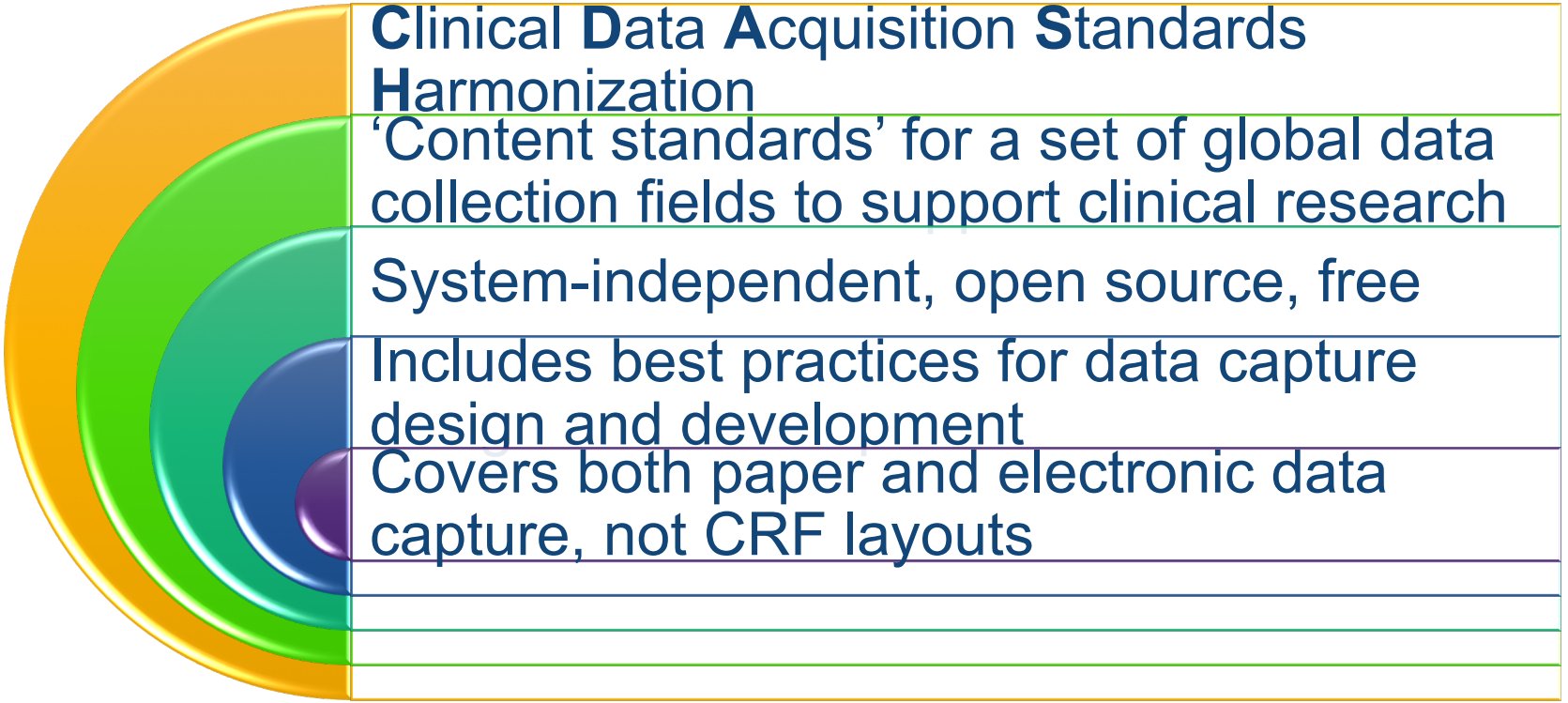
Data Flow Through CDISC Standards: How It Fits Together



Protocol Representation Model



CDASH/IG



CDASH Content

Model and Implementation Guide

Domain questions and structures

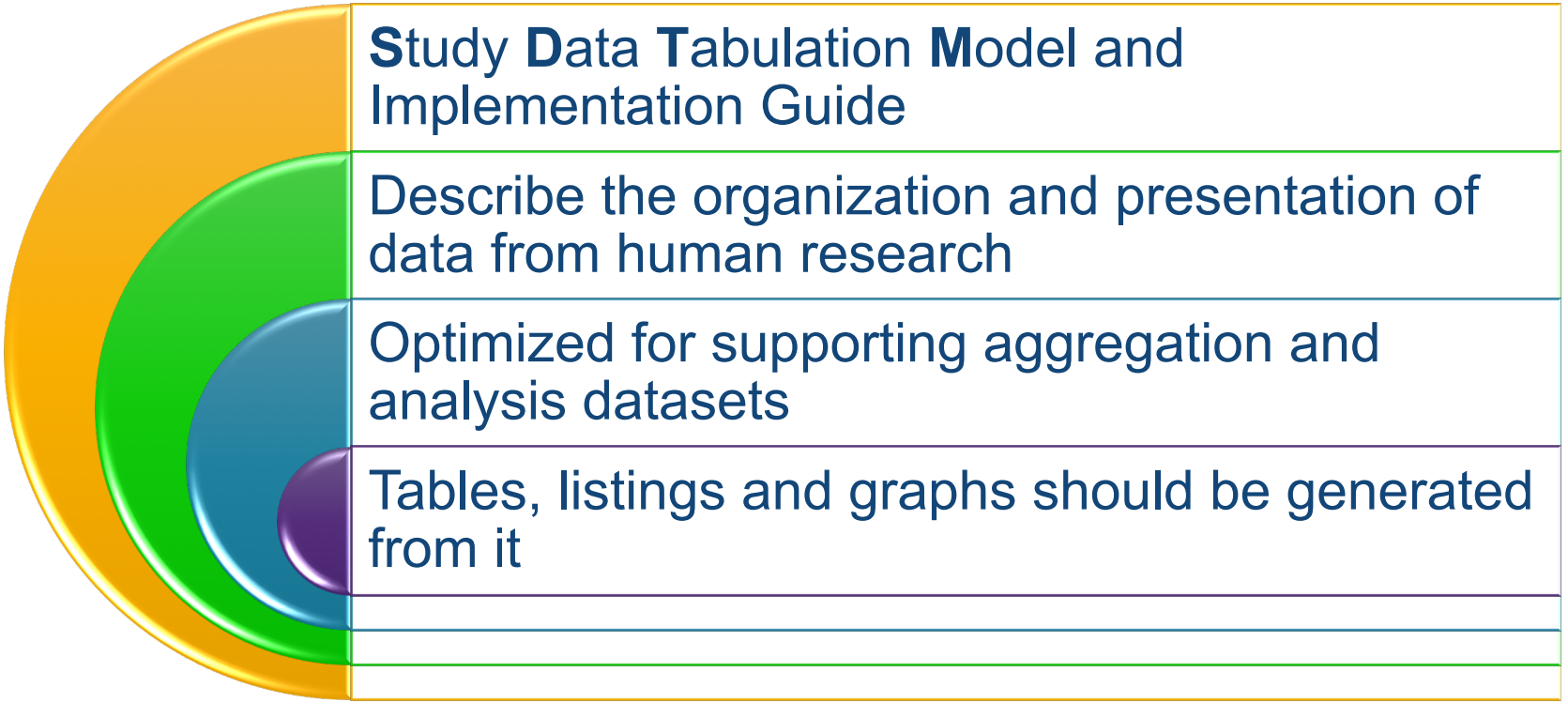
- Question text, variable name, draft CRF instructions, implementation information

Data design best practices, e.g.,

- Use of yes/no vs. ‘check all that apply’
- Date format

Recommended methods for creating data capture tools

SDTM/IG



SDTM Content

Generic Domain Descriptions
- Observation classes, variable types and characteristics

Common Domains
- Variables, characteristics, domain assumptions, implementation tips, examples

Naming Rules
- Variables, domain, variable and domain fragments

Information on classes of variables
- Identifiers, topic, timing, qualifiers

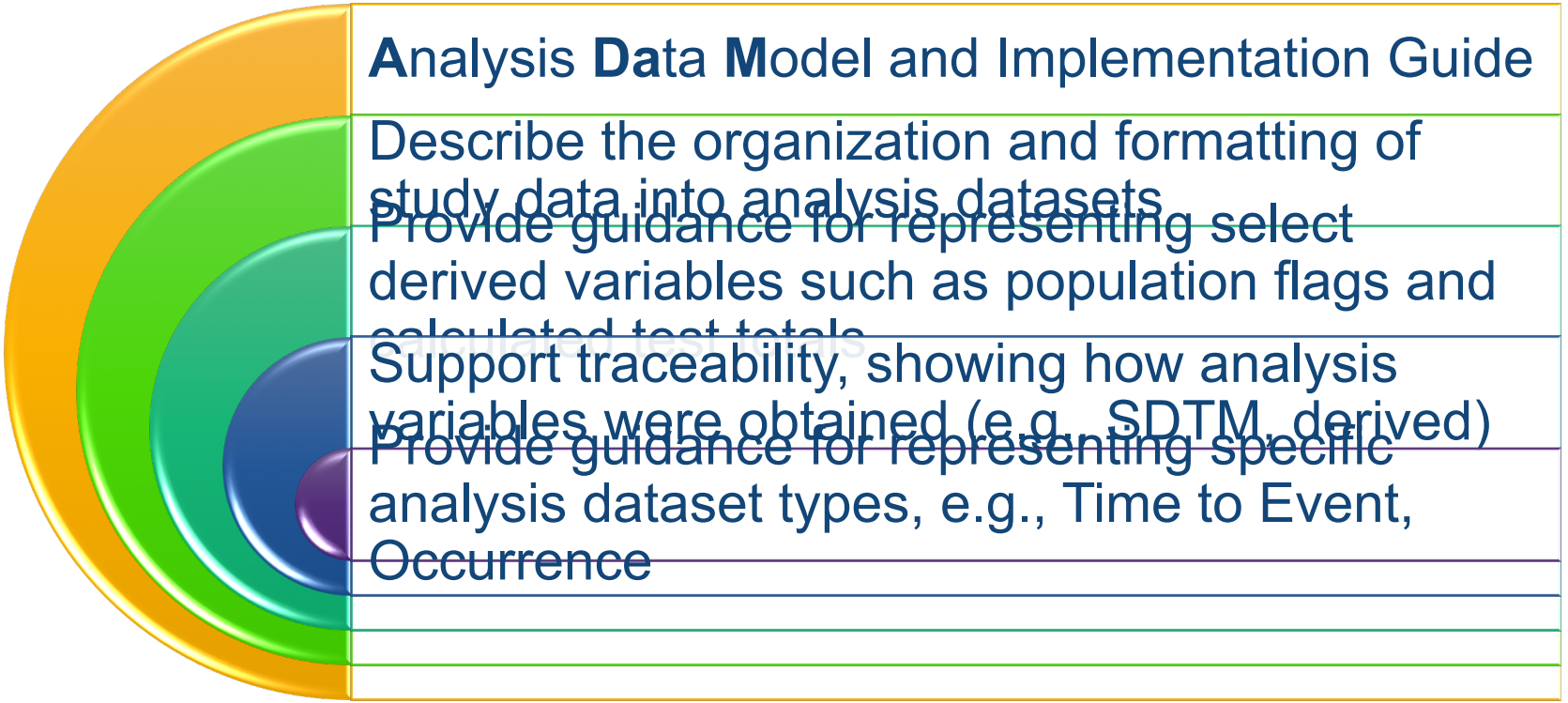
Trial design datasets

Representing relationships between variables and datasets

Example Domains (CDASH, SDTM)

Common Identifier Variables	*Common Timing Variables*	Adverse Events (AE)	Concomitant Medications (CM)	Comments (CO)
Drug Accountability (DA)	Demographics (DM)	Disposition (DS)	Protocol Deviations (DV)	ECG (EG)
Exposure (EX)	Inclusion Exclusion (IE)	Lab Test Results (LB)	Medical History (MH)	Physical Exam (PE)
	Vital Signs (VS)	Subject Characteristics (SC)	Substance Use (SU)	

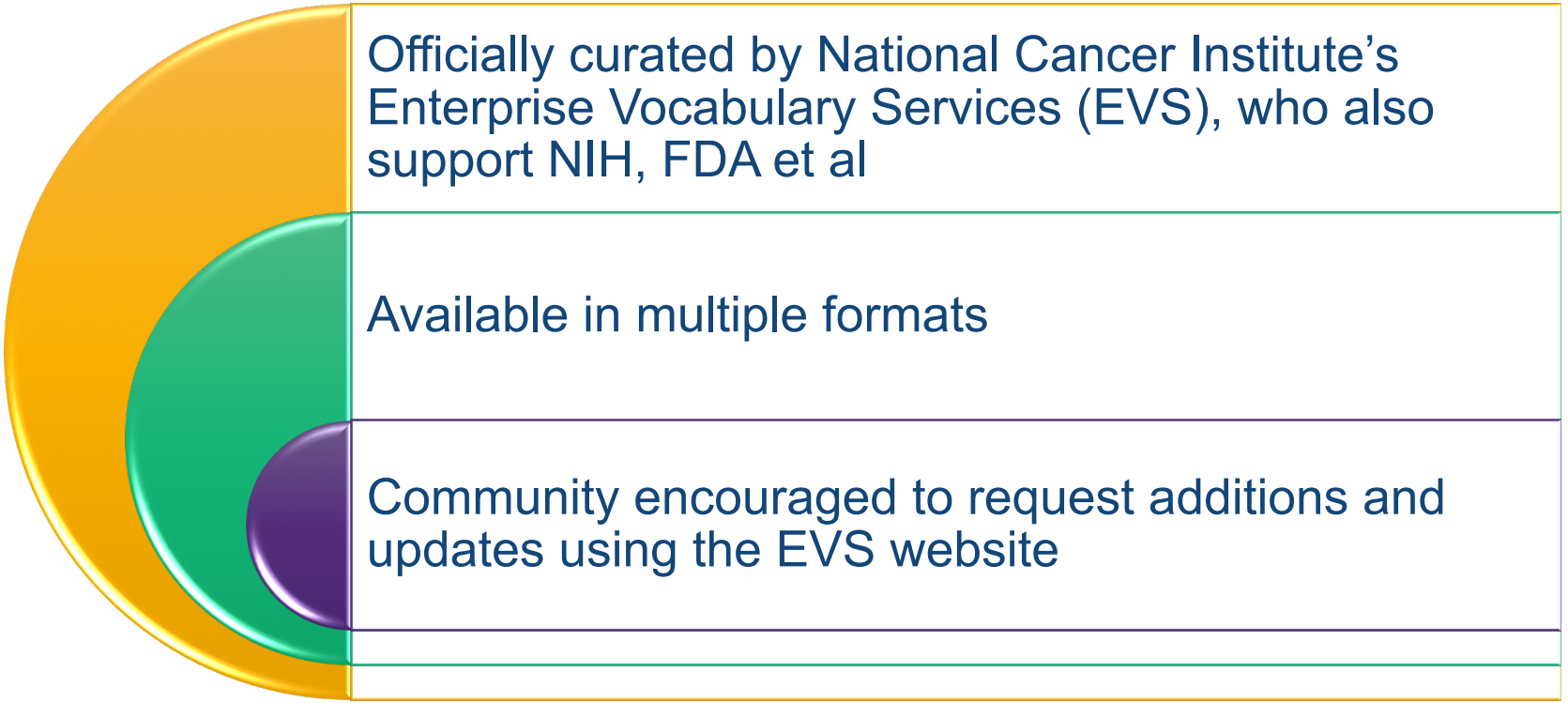
ADaM/IG



ADaM/IG Content

- Fundamental ADaM principles
- Traceability
- Data flow
- Metadata components
- Commonly used analysis datasets
  - Subject Level Analysis Dataset (ADSL)
  - Basic Data Structure (BDS)
- Additional Documents
  - Additional analysis dataset descriptions
    - Time to Event
    - Occurrence
  - Conformance Rules

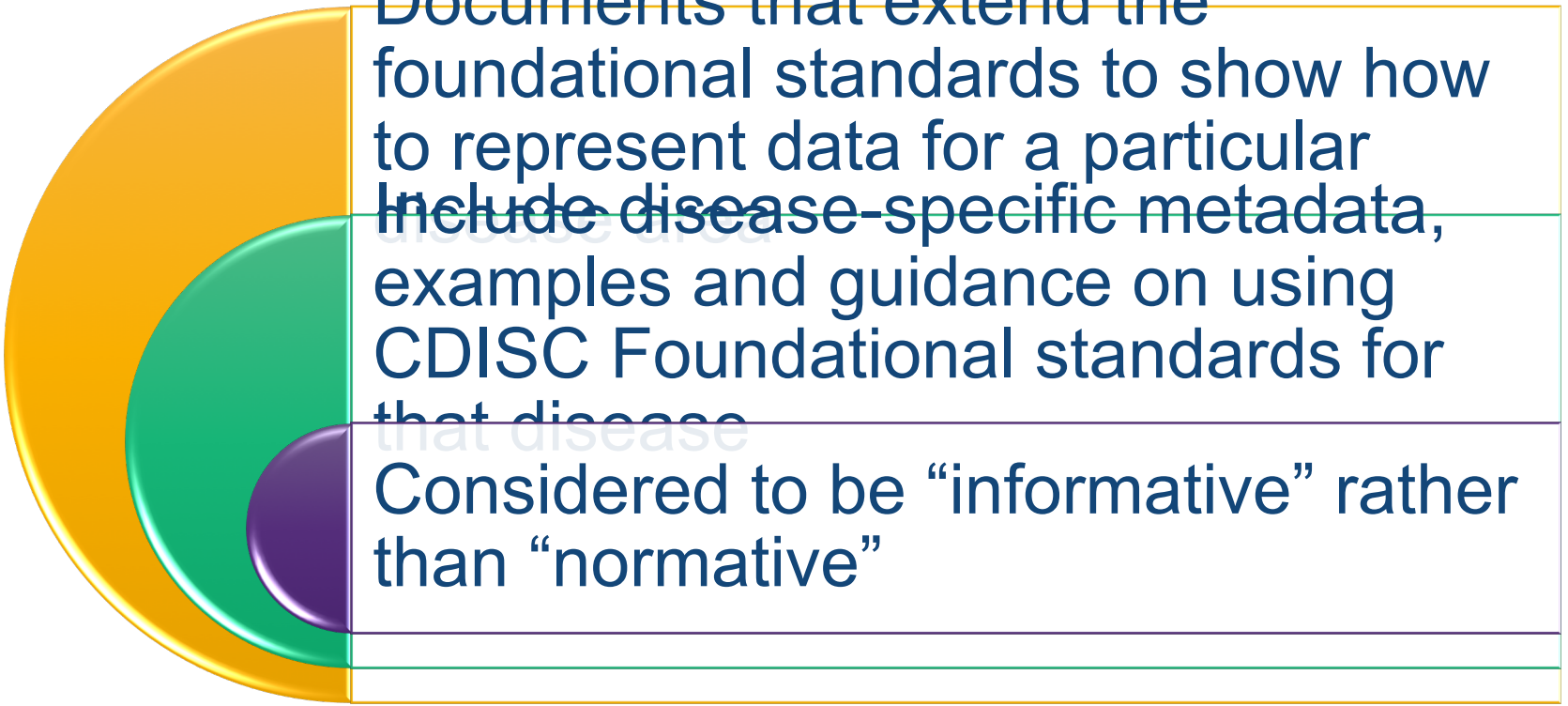
Controlled Terminology (CT)



CT Content

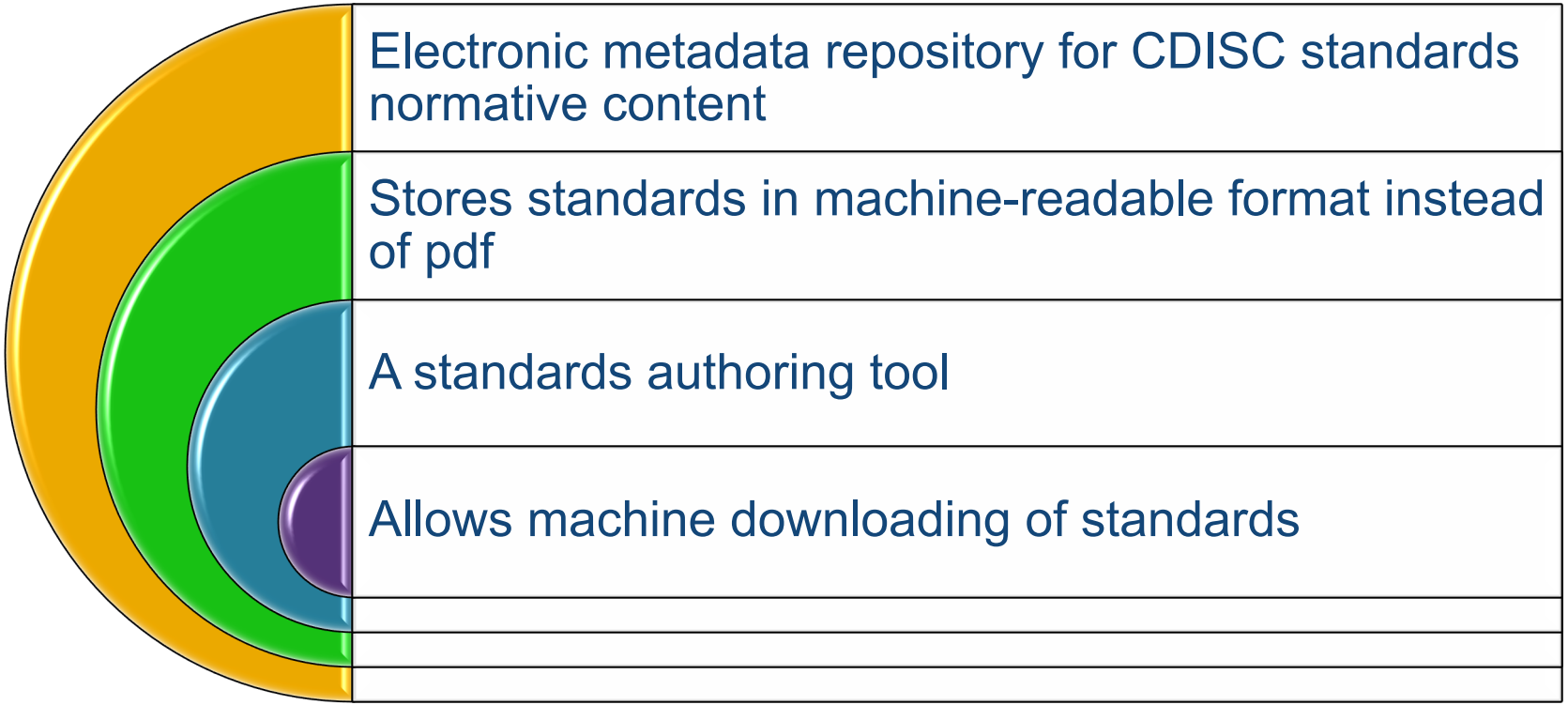
- Codelists
- Select variable names
- Definitions
- Mapping tables

Therapeutic Area User Guides

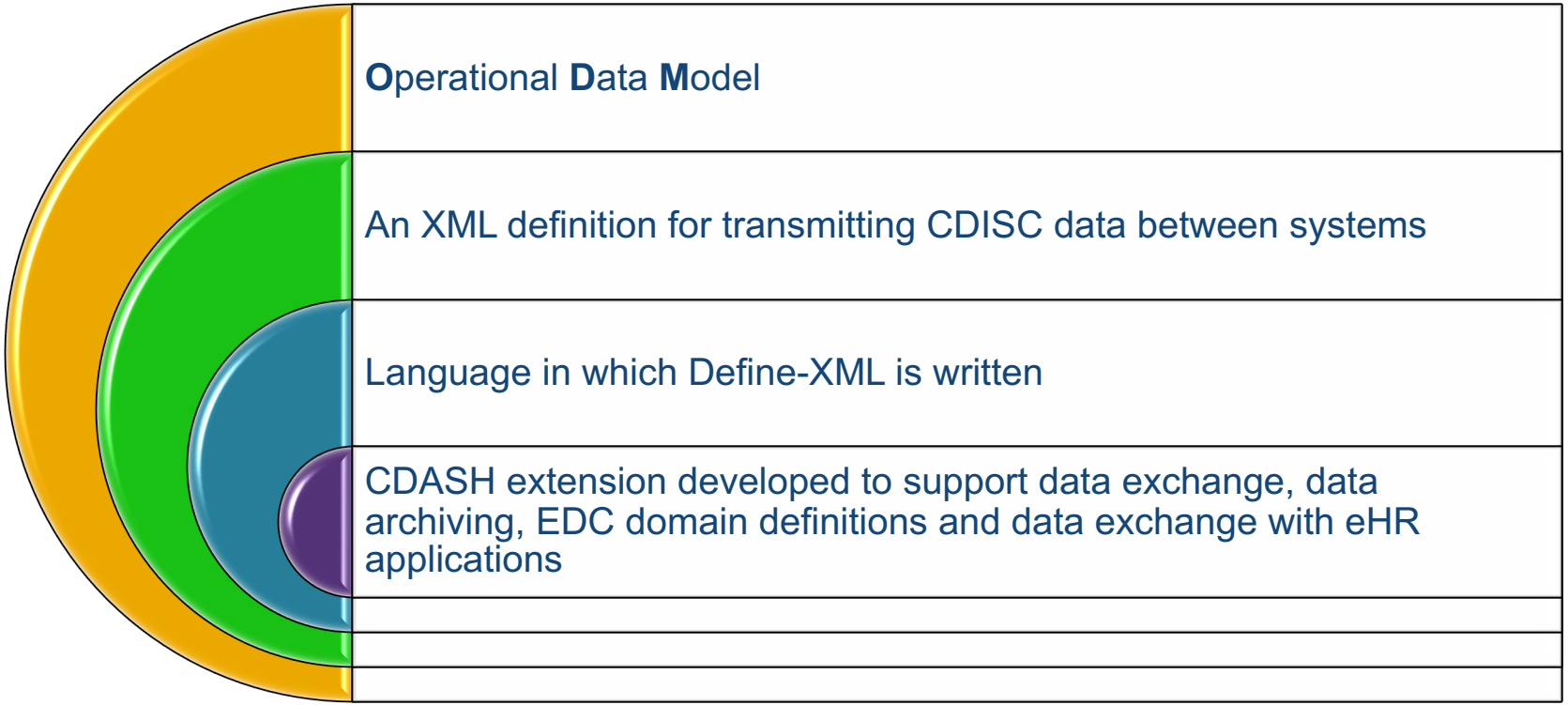


Therapeutic Area User Guides

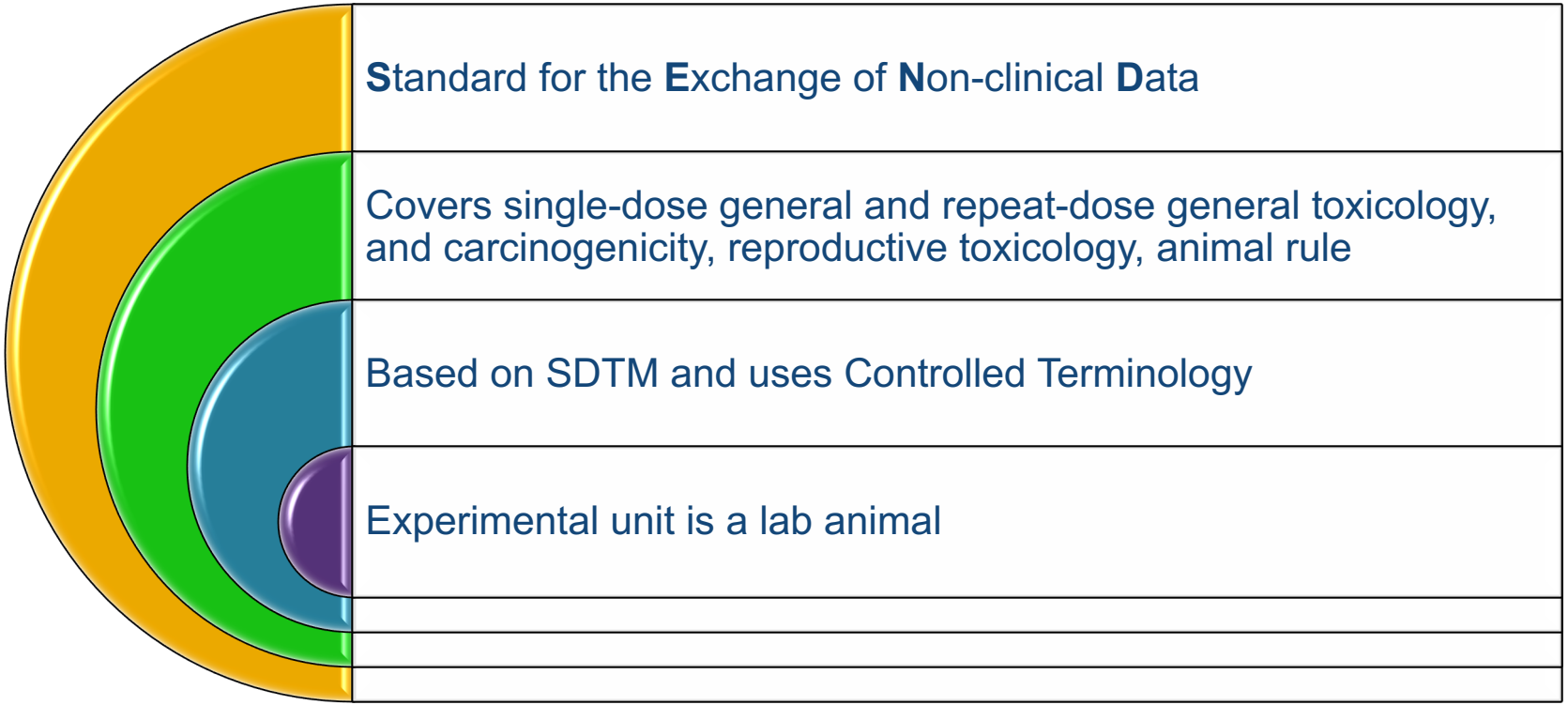
CDISC Library



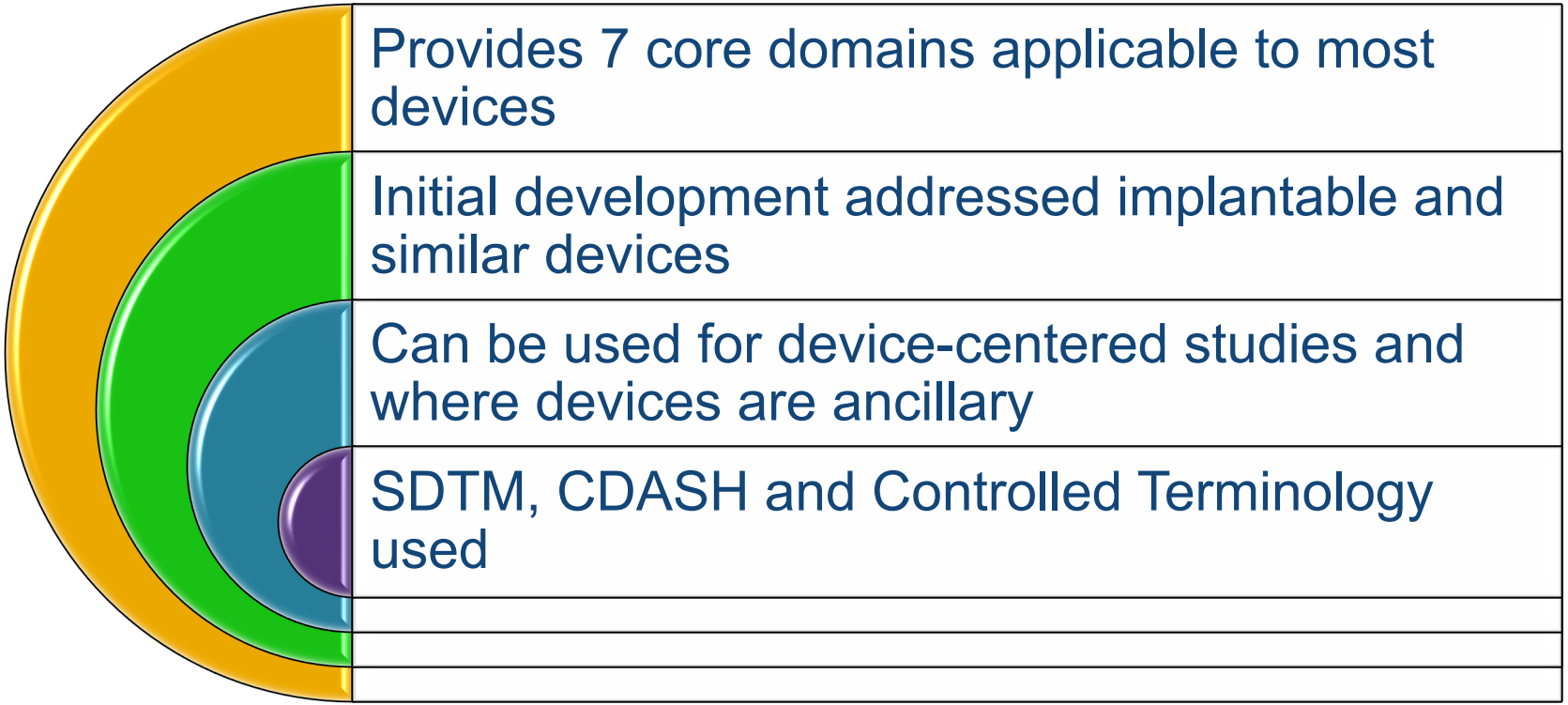
ODM

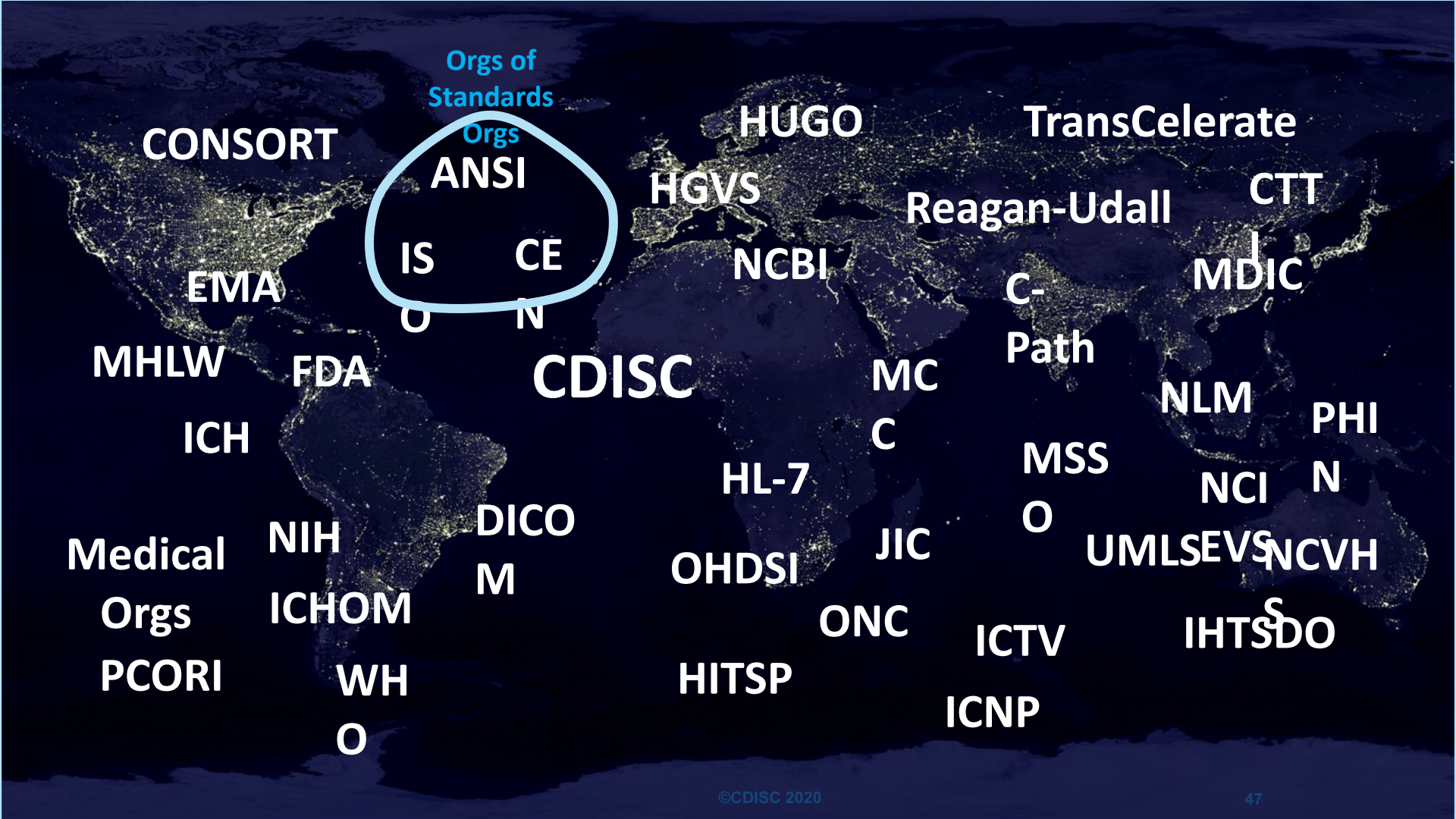


SEND IG



Medical Devices IG

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EVS
NCVHS
HL-7
DICOM
NIH
ICHOM
Medical Orgs
PCORI
WHO
OHDSI
JIC
ONC
ICTV
IHTSDO
HITSP
ICNP

General Standards Organizations

ISO

- International Standards Organization
- Combination of governmental & non-governmental organizations representing 157 countries
- Develops a very wide variety of standards
  - Graphical symbols for maps
  - Guide for radiation dosimetry for sterile insects release programs
  - ISO 8601: Data elements and interchange formats -- Information interchange -- Representation of dates and times
  - ISO 14155: Medical Devices Good Clinical Practices
  - ISO 3166: Country codes

General Standards Organizations

ISO (cont.)

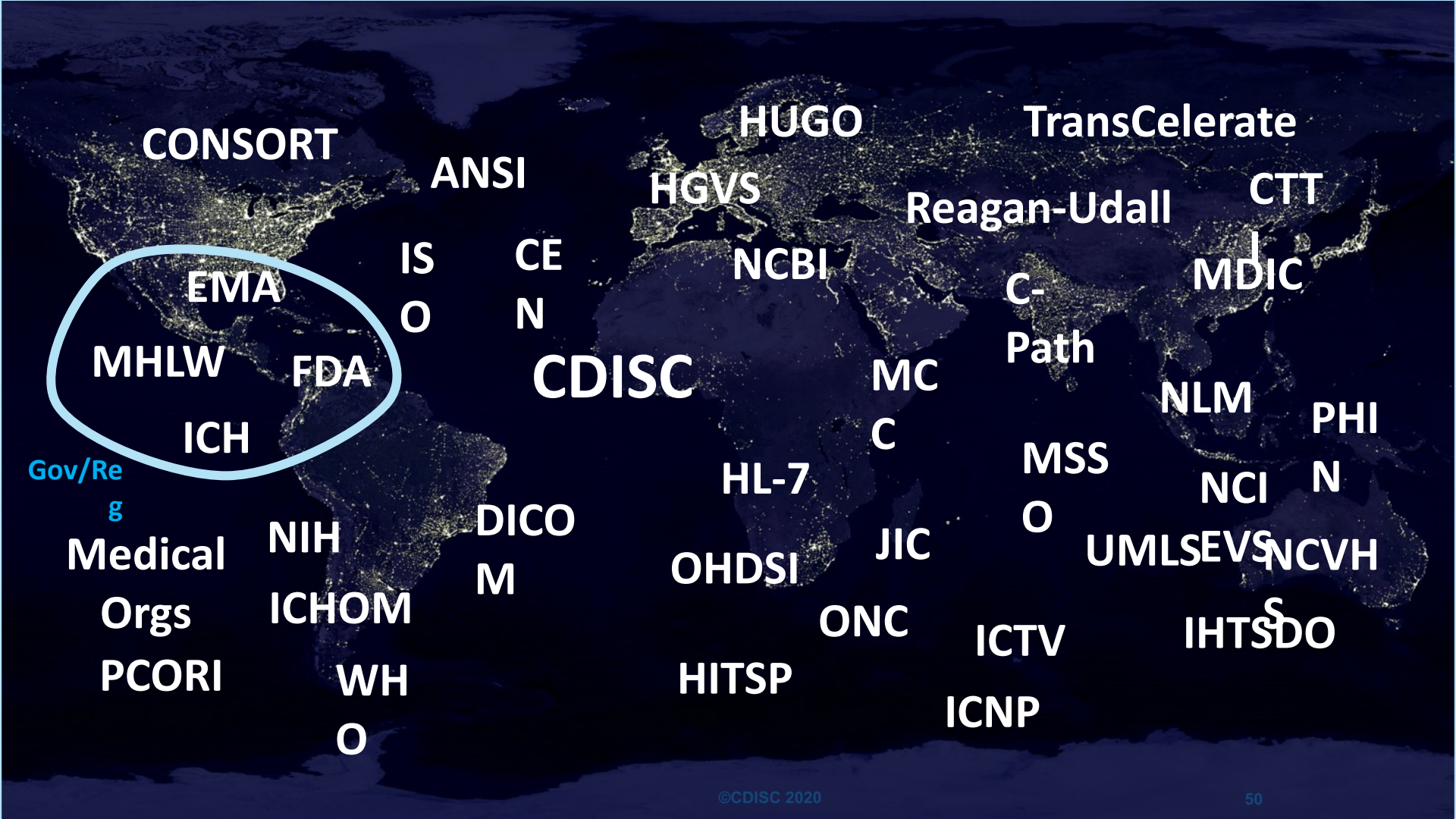
- CDISC is a Liaison A status to ISO TC 215 (healthcare standards)
  - Possible because CDISC process conforms to ISO standards
  - Means CDISC standards can be approved as ISO standards

ANSI

- American National Standards Institute, US rep to ISO
- CDISC standards developed with HL-7 can be ANSI-accredited

CEN

- European equivalent of ANSI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Regulatory Bodies

EMA

- European Medicines Agency
- The European Union's drugs/etc. regulatory body

MHRA

- Medicines and Healthcare products Regulatory Agency
- UK's drugs/etc. regulatory body

MHLW

- Ministry of Health, Labor & Welfare
- Japan's drugs/etc. regulatory body

NMPA

- National Medical Products Administration
- China's drugs/etc. regulatory body

FDA

- Food & Drug Administration – CDER, CBER, CDRH, etc.
- Part of US Dept of Health & Human Services

ICH

International Conference for Harmonisation

- Collaboration by
  - EMA, MHLW and FDA
  - Industry organizations from EU, Japan and US
  - Observers: Health Canada, Swissmedic and WHO
- Developed guidelines enabling one product submission to be acceptable to all participants

ICH

Standards include

- E2A & B: Expedited Safety Reporting
- E3: Clinical Study Report outline
- E6: Good Clinical Practices
- E15: Genomics-related Terminology Definitions
- M1: MedDRA
- M4: Common Technical Document

ICH documents contribute content & structure for CDISC standards

FDA

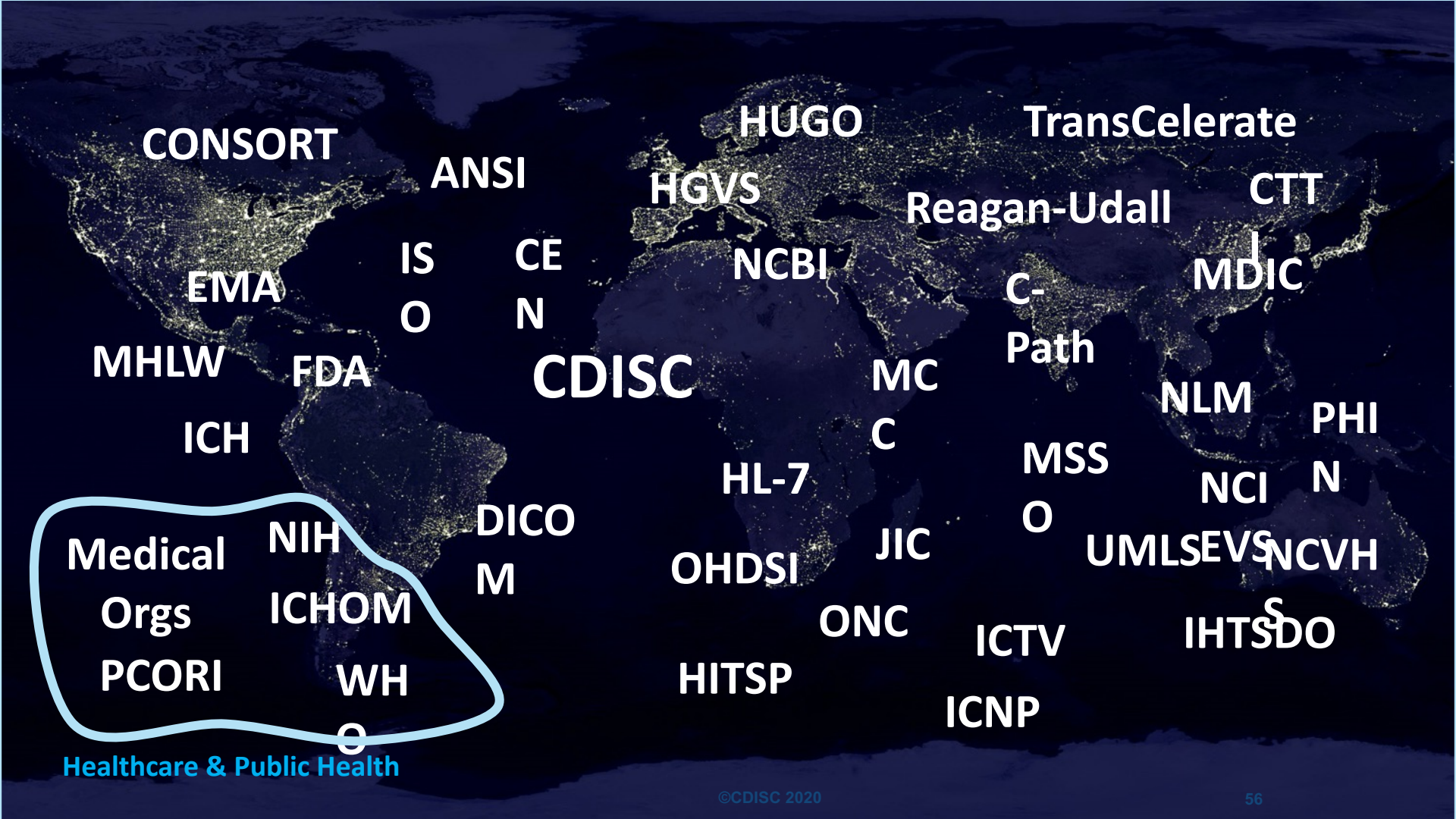
Food and Drug Administration

- Many standards activities are mandated by law
  - FDAAA
  - FDASIA, PDUFA, MDUFA, GDUFA, BsUFA
- Includes CDER (drugs), CBER (biologics) and CDRH (devices)

FDA

Each center is at a different stage

- CDER requires the use of SDTM, ADaM, SEND, Controlled Terminology and Define-XML for most submissions
- CBER also requires SDTM, ADaM and Controlled Terminology
- CDRH accepts SDTM and ADaM but does not require them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Healthcare & Public Health

WHO

World Health Organization

Directing and coordinating authority for health within the United Nations

Provides leadership on global public health matters

- Shaping the health research agenda
- Setting norms and standards
- Monitoring and assessing health trends

They own WHODrug Dictionary

Run International Clinical Trials Registry Platform

NIH

National Institutes of Health

US government body that conducts the vast majority of health research in US

27 institutes & centers

Requirement for grants with > $500K in a year must make data available

Many Institutes and Centers have data-related standards, e.g., Common Data Elements, metadata standards

Enterprise Vocabulary Services (NCI EVS)

- Publishes/manages CDISC Terminology

PCORI

Patient Centered Outcomes Research Institute

- *"Independent, non-profit, nongovernmental organization providing critical research to help patients and providers make evidence-based health care decisions that work best for them."*
- Most of its work is comparative research on different care modalities
- Developed numerous process standards for promoting the generation of quality data

PCORI Research Projects

1. Standards for Formulating Research Questions
2. Standards Associated with Patient Centeredness
3. Standards for Data Integrity and Rigorous Analyses
4. Standards for Preventing and Handling Missing Data
5. Standards for Heterogeneity of Treatment Effects (HTE)
6. Standards for Data Registries
7. Standards for Data Networks as Research-Facilitating Structures
8. Standards for Causal Inference Methods
9. Standards for Adaptive and Bayesian Trial Designs
10. Standards for Studies of Medical Tests
11. Standards for Systematic Reviews
12. Standards on Research Designs Using Clusters
13. Standards for Studies of Complex Interventions
14. Standards for Qualitative Methods
15. Standards for Mixed Methods Research
16. Standards for Individual Participant-Level Data Meta-Analysis (IPD-MA)

ICHOM

International Consortium for Health Outcomes Measurement

Develop global Standard Sets of outcome measures that matter most to patients

Drive adoption and reporting of these measures worldwide

globally to determine best approaches based on what

Standard Sets

- Standardized outcomes, measurement tools and time points and risk adjustment factors for a given condition
- Developed by a consortium of experts and patient representatives in the field

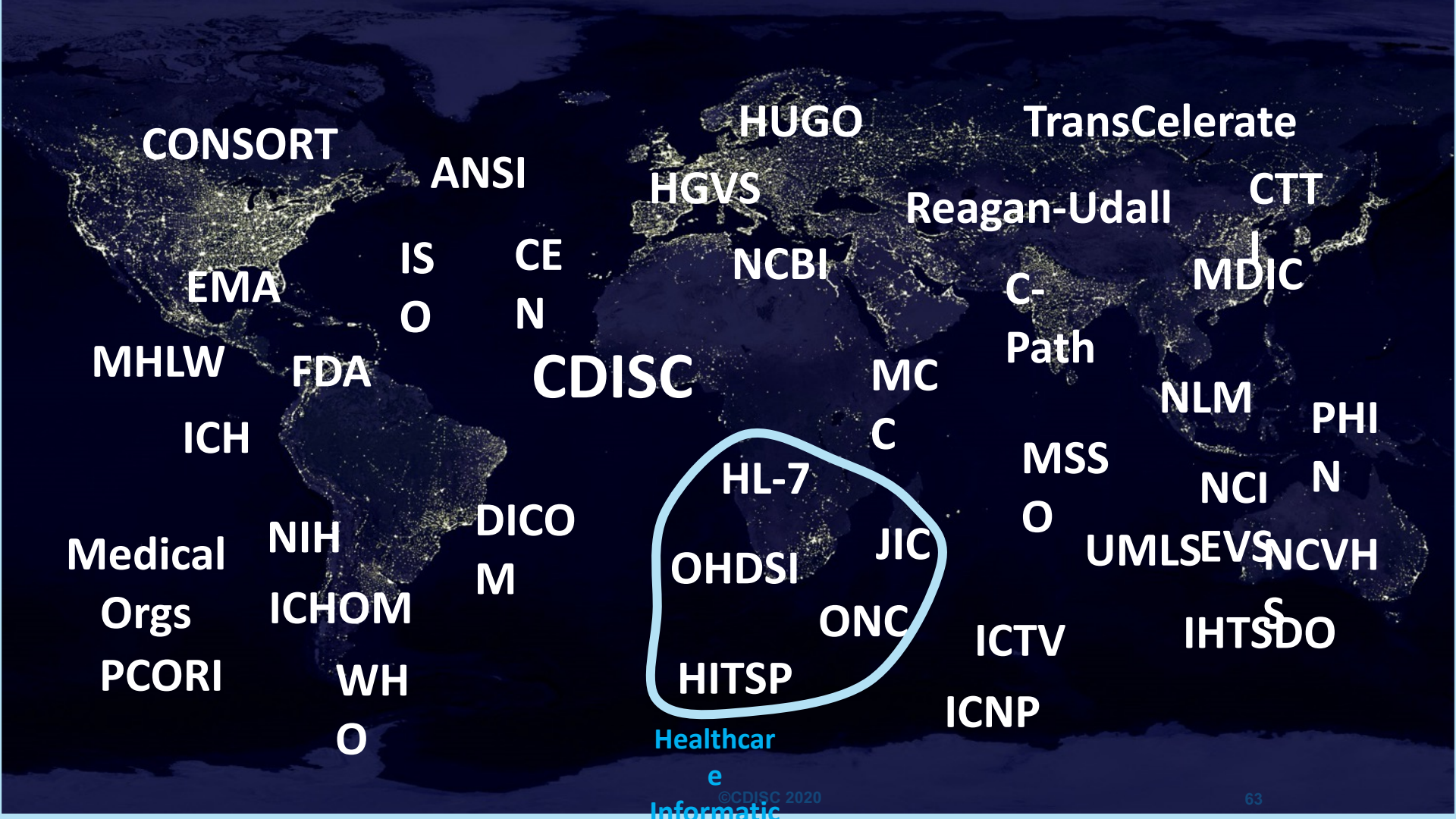
Medical Organizations

Many medical specialties and therapy areas have professional organizations, e.g.,

- American Heart Association/American College of Cardiology

Develop diagnostic, treatment, outcomes and quality guidelines and recommendations

These can provide content for therapy-specific standards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Healthcare Informatic

HL-7

Health Level 7

"A protocol for formatting, transmitting and receiving data in a healthcare environment"

- i.e., Define the envelope for transmission, not the content, e.g.,
  - Lab data: ordering, specimen collection, specimen tracking, chain of custody, and results reporting

Primary focus is exchange of health care info

CDISC is a member organization

HL-7 FHIR is being mapped to CDASH for porting research data to EDC

OHDSI

Observational Health Data Sciences and Informatics

Multi-stakeholder, interdisciplinary collaborative using large-scale data analytics to improve health data

Support observational research to generate evidence to support improvements in patient health

Developed OMOP

- Observational Medical Outcomes Partnership
- Includes a common data model for mapping data primarily from EHRs and insurance reimbursement systems
- CDISC collaborating to create mapping to clinical trials data

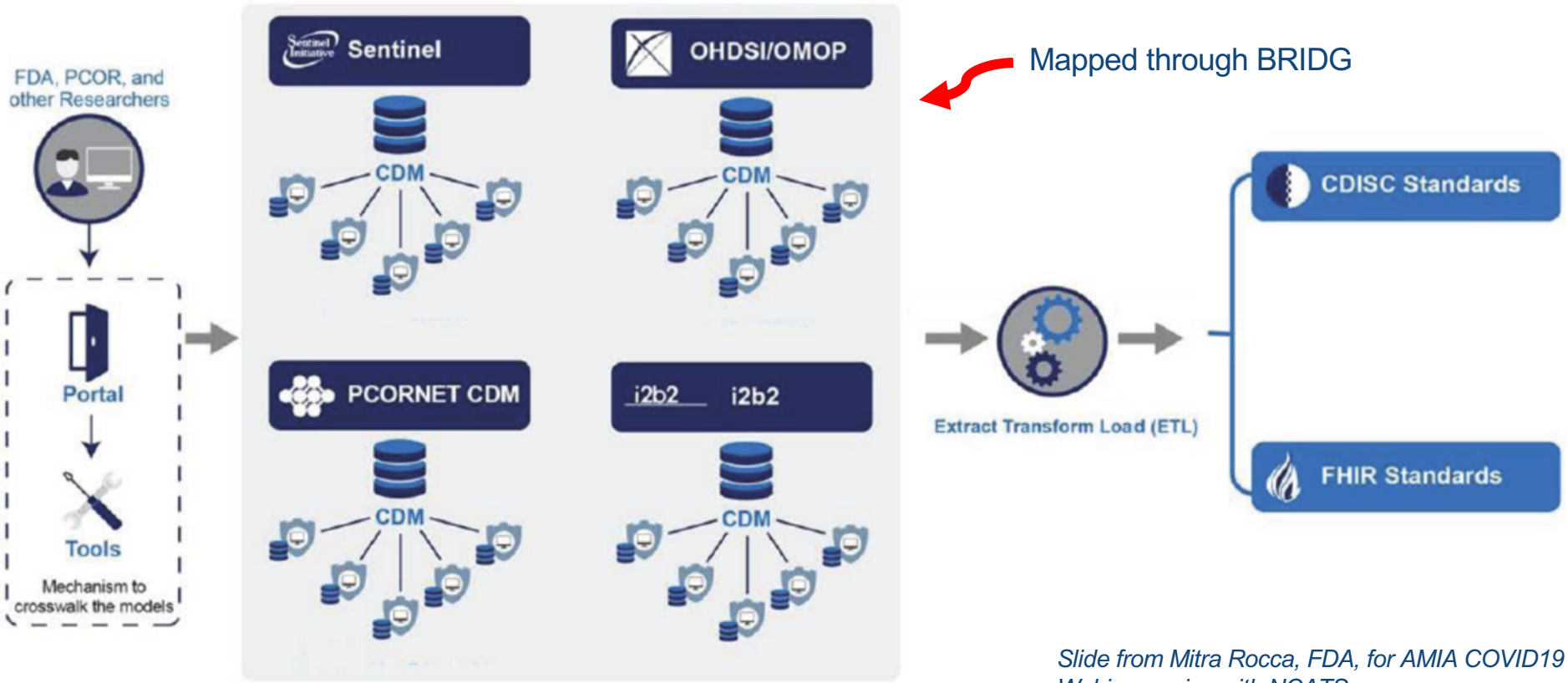
ONC

- Office of the National Coordinator for Health Information Technology
- develop and implement strategies to advance health IT and information use to achieve high-quality care, lower costs, a
- Part of US Department of Health and Human Services
- Mostly focused on patient care but some interest in linking to clinical trials data

Common Data Model Harmonization (CDMH)

- Patient-Centered Outcomes Research Trust Fund (PCORTF) with FDA and others
- Goal was to determine how to combine data from multiple sources to improve patient outcomes
- Strategy was to map first to BRIDG, then develop tools to access the result

Proposed Solution



Slide from Mitra Rocca, FDA, for AMIA COVID19 Webinar series with NCATS

Phase II Deliverables

1. Collaborate with new data partners leveraging the CDMH architecture as well as direct query from Electronic Health Records and Clinical Data Repositories.
2. Enhance the existing infrastructure to leverage Health Level Seven (HL7) Fast Healthcare Interoperability Resources (FHIR) standard as the exchange data standard.
3. Submit Real World Data (RWD) leveraging clinical trial study data, leveraging Clinical Data Interchange Standards Consortium (CDISC) Study Data Tabulation Model (SDTM) via the FDA Gateway.

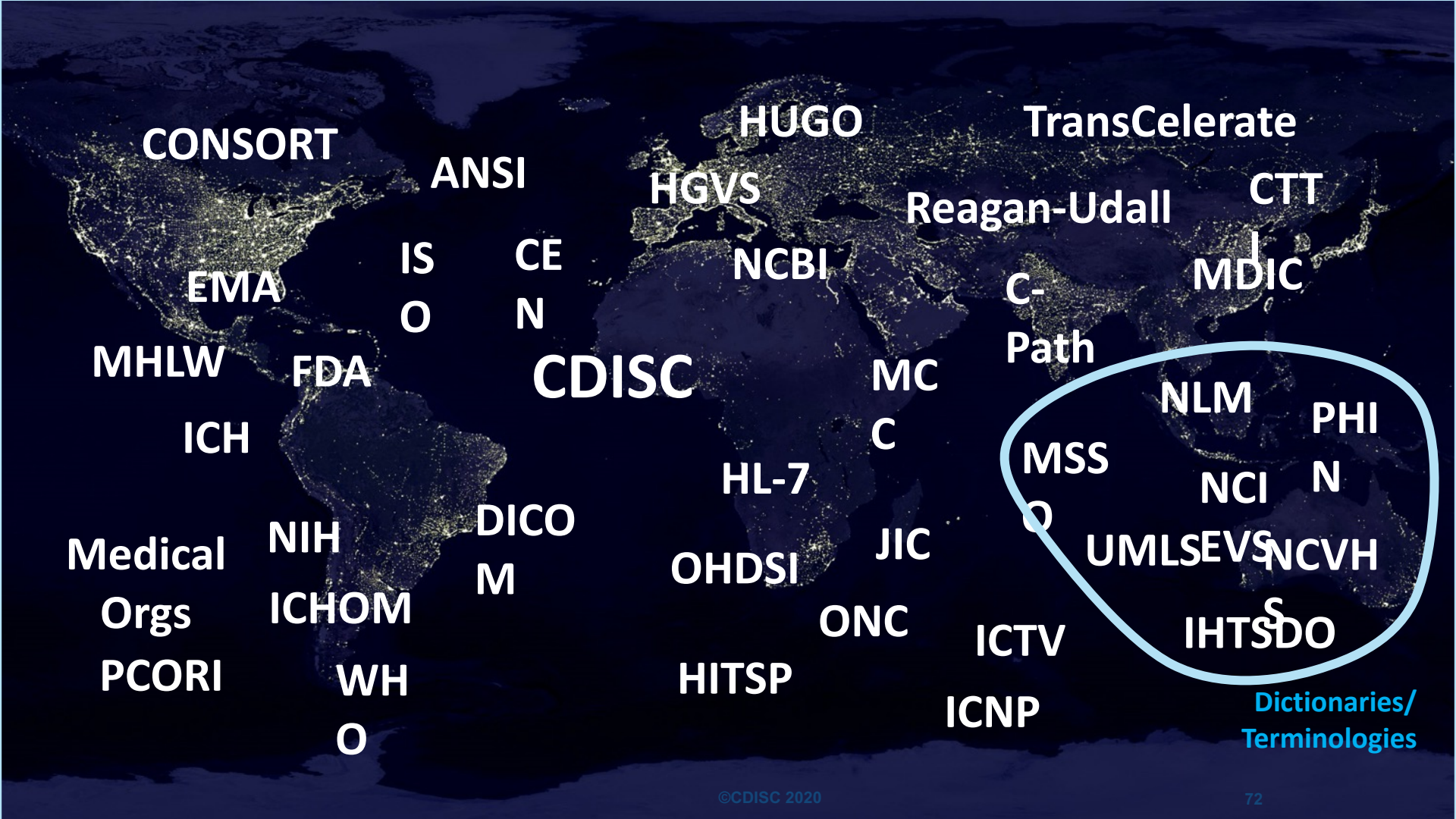
Slide from Mitra Rocca, FDA, for AMIA COVID19 Webinar series with NCATS

HIMSS

- Healthcare Information and Management Systems Society
- Promotes optimization of use and interoperability of IT and management systems in healthcare
- Primarily collaborate with others to evaluate, implement and assess interoperability standards
- CDISC participates in HIMSS Interoperability Showcase

JIC

- Joint Initiative Council – an organization of standards organizations
- Formal collaboration among ISO, HL-7, IHE, and CEN (European Committee for Standardization), CDISC, LOINC, DICOM and others
- Established in August 2007
- Goal is to harmonize healthcare informatics standards by coordinating the work of the member organizations and taking on specific initiatives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HITSP
ICNP
Dictionaries/ Terminologies

Dictionaries / Terminology

NCI EVS

- National Cancer Institute Enterprise Vocabulary Services
- Manages CDISC's controlled terminologies, mapping tables and more

IHTSDO

- International Health Terminology Standards Development Organization
- National Library of Medicine licenses SNOMED from them for general use

MSSO

- Maintenance and Support Services Organization
- Run by Northrup Grummond
- Maintains MedDRA

Regenstrief Institute

- Manages LOINC (lab codes)

Dictionaries / Terminology

Upsala Monitoring Centre

- Manages WHODrug

NLM

- National Library of Medicine
- Hosts about 277 standards-related terminologies and databases
- e.g., ClinicalTrials.gov, MeSH,

UMLS

- Unified Medical Language System
- Large collection of vocabularies with mapping between them
- Include LOINC, SNOMED, ICD-9, some HL-7

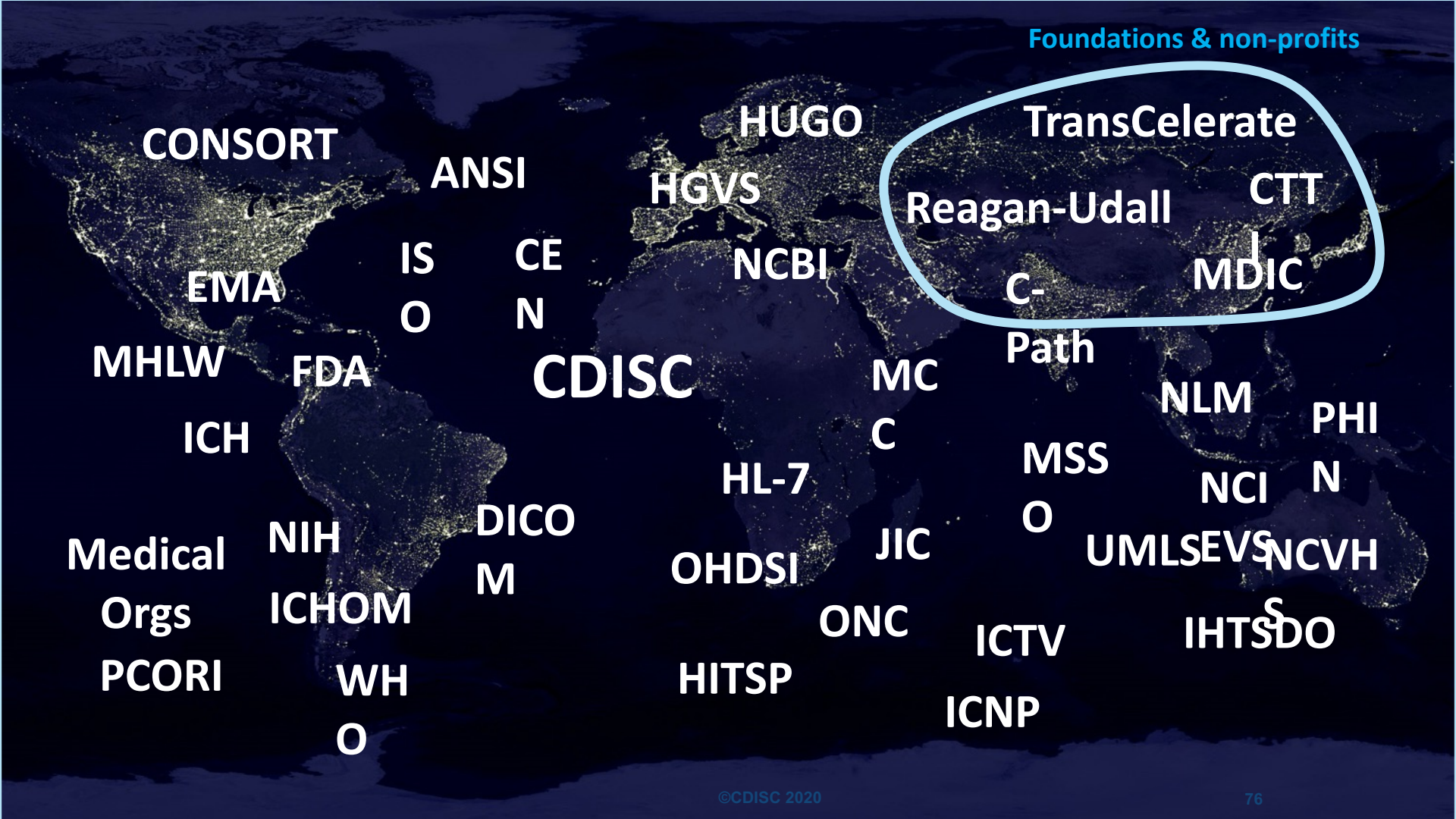
Dictionaries/Terminologies

NCVHS

- National Committee on Vital and Health Statistics
- Some overlap with public health fields
- Most don't apply but have outcomes and some clinical data

PHIN

- Part of CDC
- Primarily vocabularies
- Conditions, immunizations, other potentially useful ones


Foundations & non-profits
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Foundations & Non-profits

CTTI

- Clinical Trials Transformation Initiative
- Public-private partnership between FDA & Duke University
- Purpose is “to identify practices that through broad adoption will increase the quality and efficiency of clinical trials” *(CTTI website)*

C-Path

- Critical Path Institute
- Develop data, measurement and methods standards to speed product development
- Work in pre-competitive space

Foundations & Non-profits

TranCelerate

- Non-profit organization established by 10 large pharmas
- Collaborating and sharing knowledge to develop faster better processes to bring drugs to market
- Numerous standards-related projects have included risk-based monitoring, standard protocol template and protocol deviations

Foundations & Non-profits

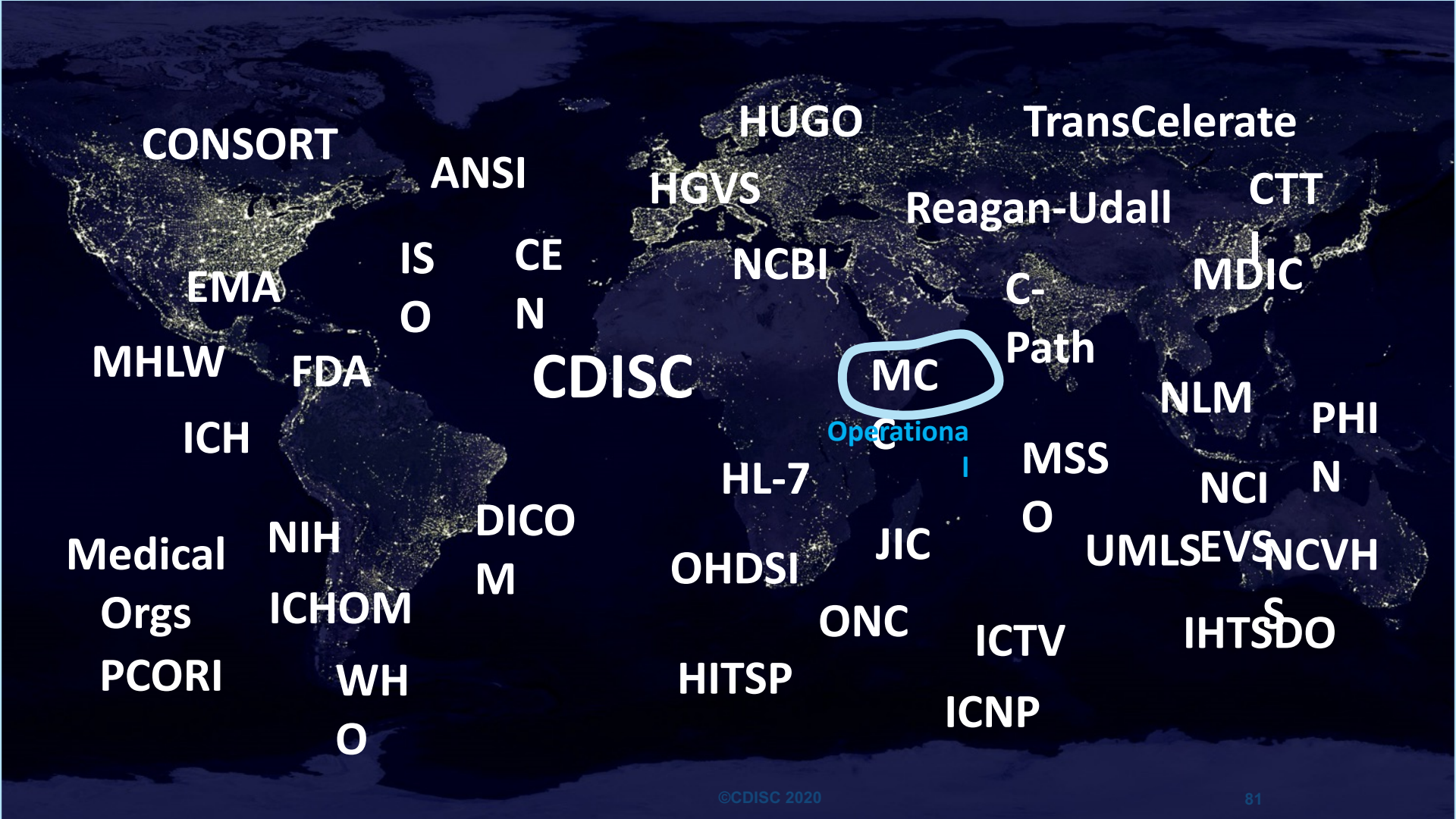
MDIC

- Medical Device Innovation Consortium
- Part of their remit is to develop quality, regulatory and methodology standards relating to medical device development
- Many use cases examining the utility of using real world data for many kinds of device-related studies

Foundations & Non-profits

Reagan-Udall Foundation

- Private & non-profit foundation for FDA
- Established by Congress
- Purpose: use public/private partnerships to develop a more efficient development and approval process while ensuring product safety
- Expect to establish standards affecting the submission and approval processes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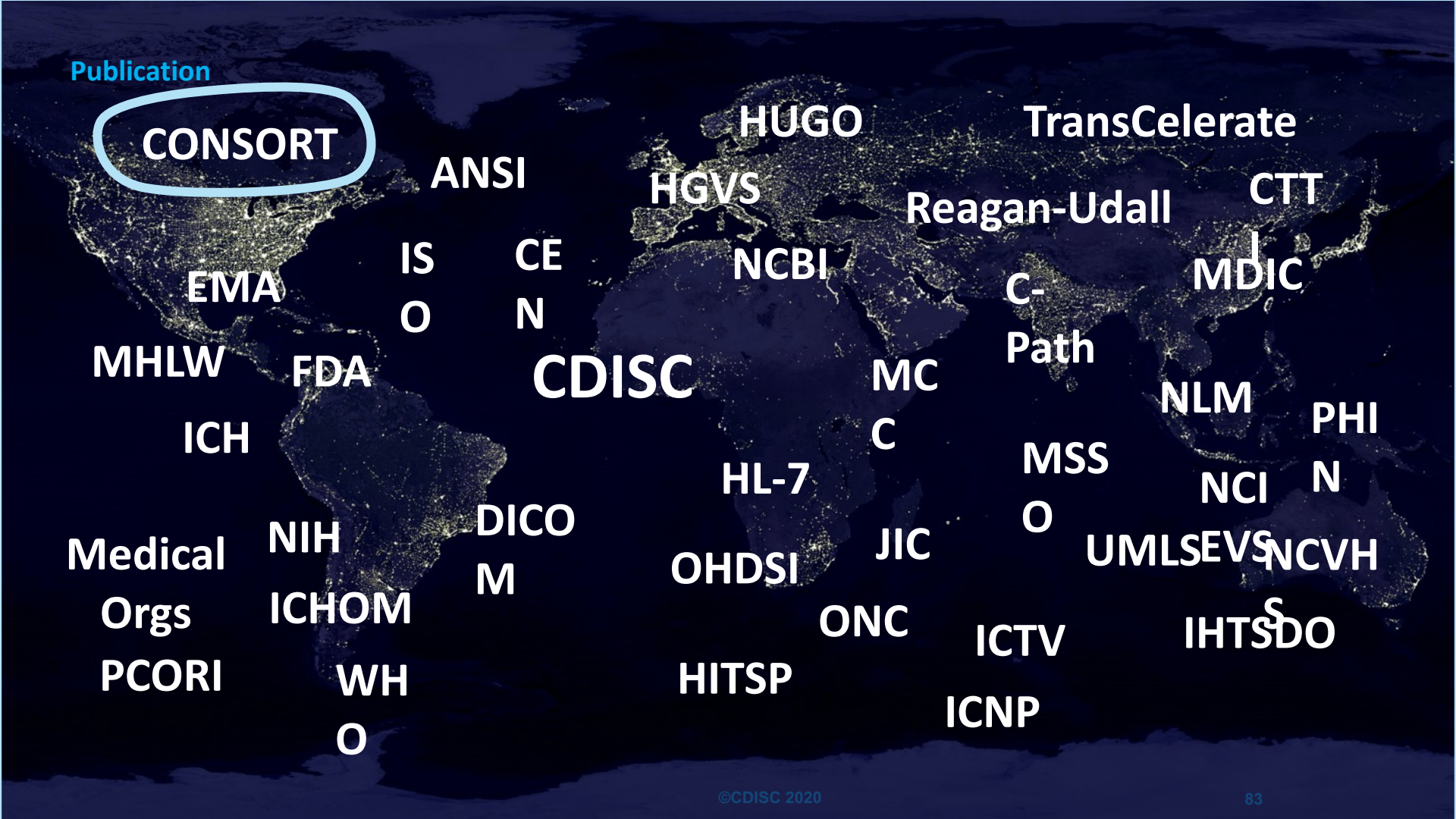
Operational Standards

MCC

- Metrics Champion Consortium
- Group of CROs, pharmas & biotechs defining standard metrics
- Initially focused on metrics for clinical trial performance
- Expanded to central lab, ECG and imaging metrics and much more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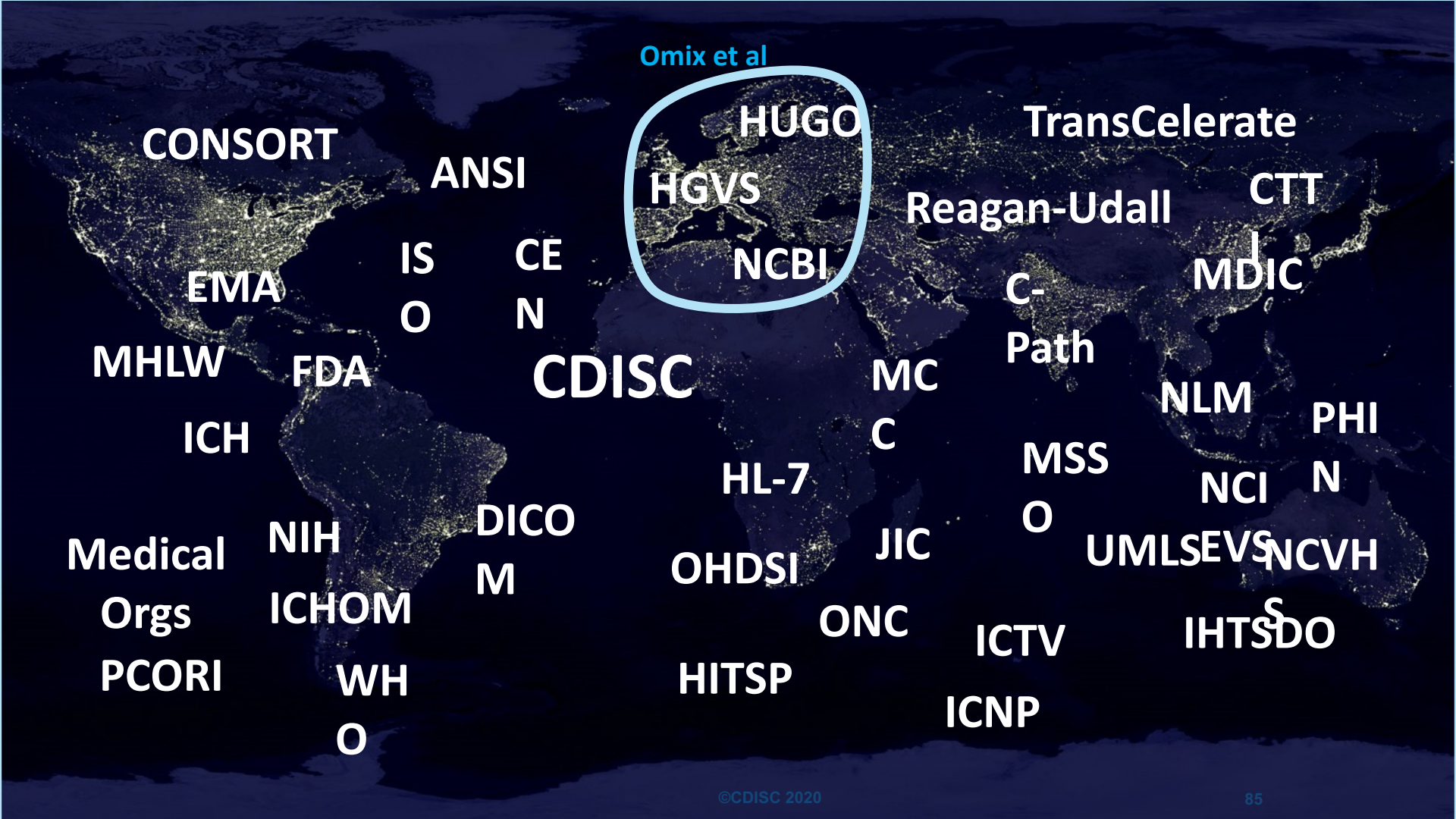
Publication Standards

- Consolidated Standards of Reporting Trials
- Transparent Reporting of Trials
- Developed methodology for evaluating the quality of clinical trials results reporting
- Intent is to ensure sufficient information is in the publication to enable proper evaluation
- Tools to support methodology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Omix and More

HUGO - Human Genome Organization

- Parent or collaborating organization for other standards groups
- Recently joined European Bioinformatics Institute

HGNC – HUGO Gene Nomenclature Committee

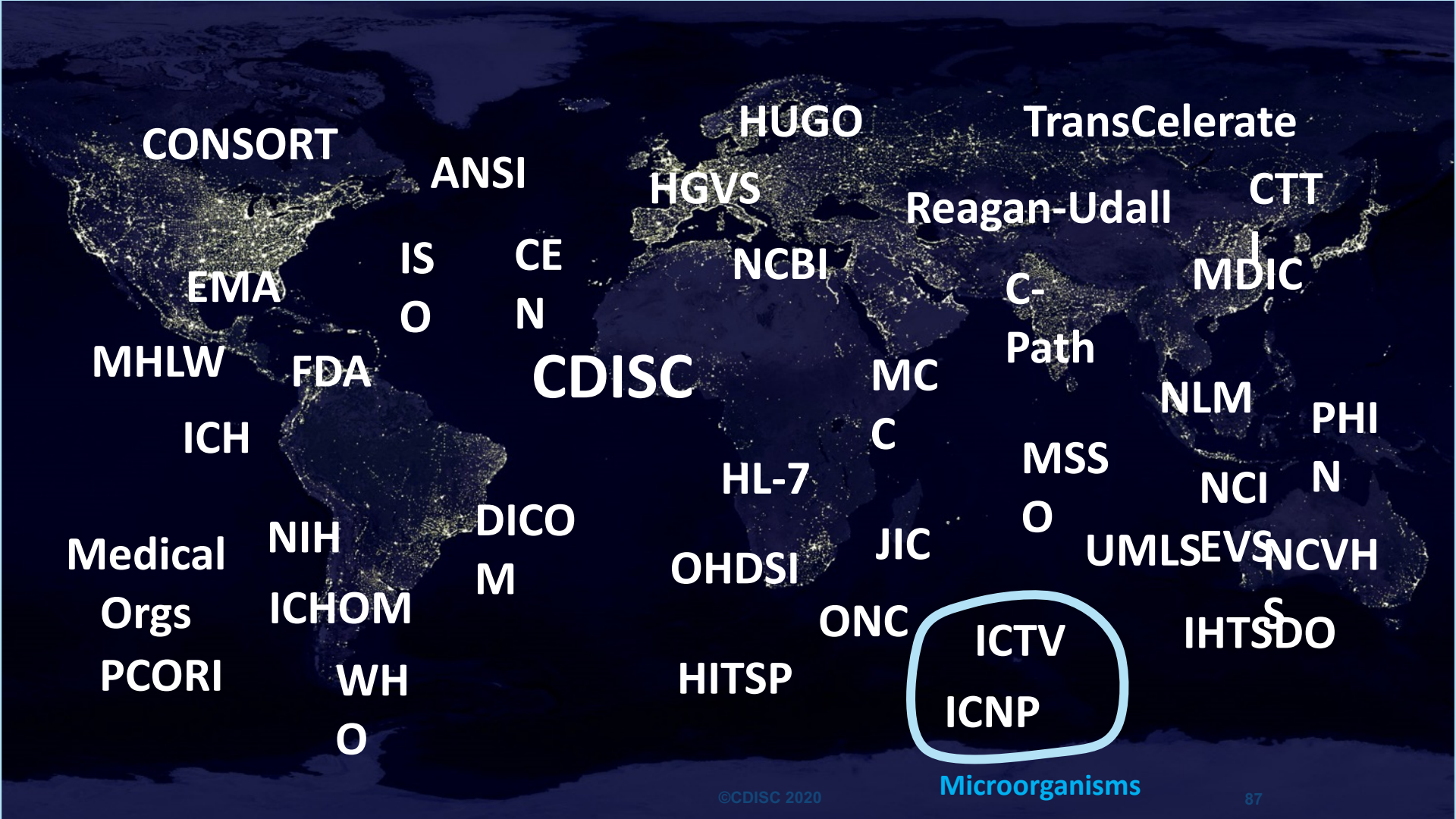
- Unique symbols and names for human loci, including protein coding genes, ncRNA genes and pseudogenes

HGVS - Human Genome Variation Society

- How to annotate and represent specific mutations

HVP - Human Variome Project

- Ensure that all information on genetic variation and its effect on human health can be collected, curated, interpreted and shared freely and openly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Microorganisms

Microorganism Standards

ICTV

- International Committee on Taxonomy of Viruses
- Maintain the official list of virus species
- Developed the rules for how to name viruses

Microbiology Society

- Publish the International Code of Nomenclature of Prokaryotes (ICNP)
- Cover bacteria & Archaea
- Developed modern rules for naming prokaryotes


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Imaging Standards

DICOM

- Digital Imaging and Communications in Medicine
- Currently the only standard of note in this arena
- Covers transmission, storage, retrieval, processing, printing and displaying medical images
- Two parts
  - Digital representation of the image (e.g., 1s and 0s that encode the voxels that comprise the image)
  - Header: information about, e.g., subject and physician, parameters of the image, some quality parameters, and metadata about all of the data

Take-home Message

There are many different kinds of standards available

It is useful to think broadly and long-term when considering standards

Search for existing standards before developing a new one…

Supplemental Materials

References

- Many thanks to CDISC staff for assistance with content and review
- Stacie Trollinger, “Data Collection vs. Data Sharing: The NINDS Common Data Elements Project”, presentation at 2007 SCDM Fall Conference
- NASA (world lights photograph)
- “Drug Development Sciences: Obstacles and Opportunities for Collaboration Among Academia, Industry and Government.” Proceedings from a conference in January 2005 organized by the American Association of Medical Colleges, FDA and The Center for Drug Development Science at University of California, San Francisco. Available at https://services.aamc.org/Publications/index.cfm?fuseaction=Product.displayForm&prd_id=135&prv_id=159
- FDASIA, http://www.gpo.gov/fdsys/pkg/PLAW-112publ144/pdf/PLAW-112publ144.pdf
- The FAIR Guiding Principles for Scientific Data Management and Stewardship. Mark D. Wilkinson et al. Scientific Data, published by the journal Nature. 15Mar2016.

Useful Links

- http://english.nmpa.gov.cn/
- http://www.fedgate.org/
- http://www.hugo-international.org/HUGO-Gene-Nomenclature
- https://aspe.hhs.gov/
- https://aspe.hhs.gov/patient-centered-outcomes-research-trust-fund
- https://pcornet.org/data-driven-common-model/
- https://reaganudall.org/
- https://www.bridgingclinical.com/resources/harmonization-for-more-effective-data-sharing/
- https://www.cencenelec.eu/Pages/default.aspx
- https://www.dicomstandard.org/
- https://www.ema.europa.eu/en
- https://www.fda.gov/industry/fda-resources-data-standards/study-data-standards-resources
- https://www.genenames.org/about/
- https://www.genome.gov/about-nhgri/Policies-Guidance/Genomic-Data-Sharing/data-standards
- https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency
- https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi
- https://www.healthit.gov/topic/about-onc
- https://www.healthit.gov/topic/scientific-initiatives/pcor/common-data-model-harmonization-cdm
- https://www.healthit.gov/topic/scientific-initiatives/pcor/research-evaluation/structured-data-capture-sdc
- https://www.hgvs.org/
- https://www.ichom.org/standard-sets/#about-standard-sets
- https://www.ncbi.nlm.nih.gov/
- https://www.ohdsi.org/
- https://www.ohdsi.org/data-standardization/
- https://www.pcori.org/
- https://www.whitehouse.gov/wp-content/uploads/2017/12/Roadmap-for-Medical-Imaging-Research-and-Development-2017.pdf
- transceleratebiopharmainc.com/
- www.ansi.org
- www.cdisc.org
- www.consort-statement.org/
- www.c-path.org/
- www.fda.gov
- www.fda.gov/oc/datacouncil
- www.himss.org/ASP/topics_hitsp.asp
- www.hl7.org
- www.ich.org
- www.ihe.net
- www.iso.org
- www.metricschampion.org/default.aspx
- www.mhlw.go.jp
- www.nih.gov
- www.trialstransformation.org
- www.who.int

CDISC Standards (1)

CDASH/IG

- **C**linical **D**ata **A**cquisition **S**tandards **H**armonization
- Model and Implementation Guide for Data Capture in Human Research
- Includes best practices for data capture design and development

SDTM/IG

- **S**tudy **D**ata **T**abulation **M**odel
- Model and Implementation Guide describing the organization and presentation of data from human research
- Optimized for supporting aggregation and analysis datasets
- Required in regulatory submissions in certain countries

ADaM/IG

- **A**nalysis **D**ata **M**odel
- Model and **I**mplementation **G**uide
- Structure of analysis datasets in human research
- Required in regulatory submissions in certain countries

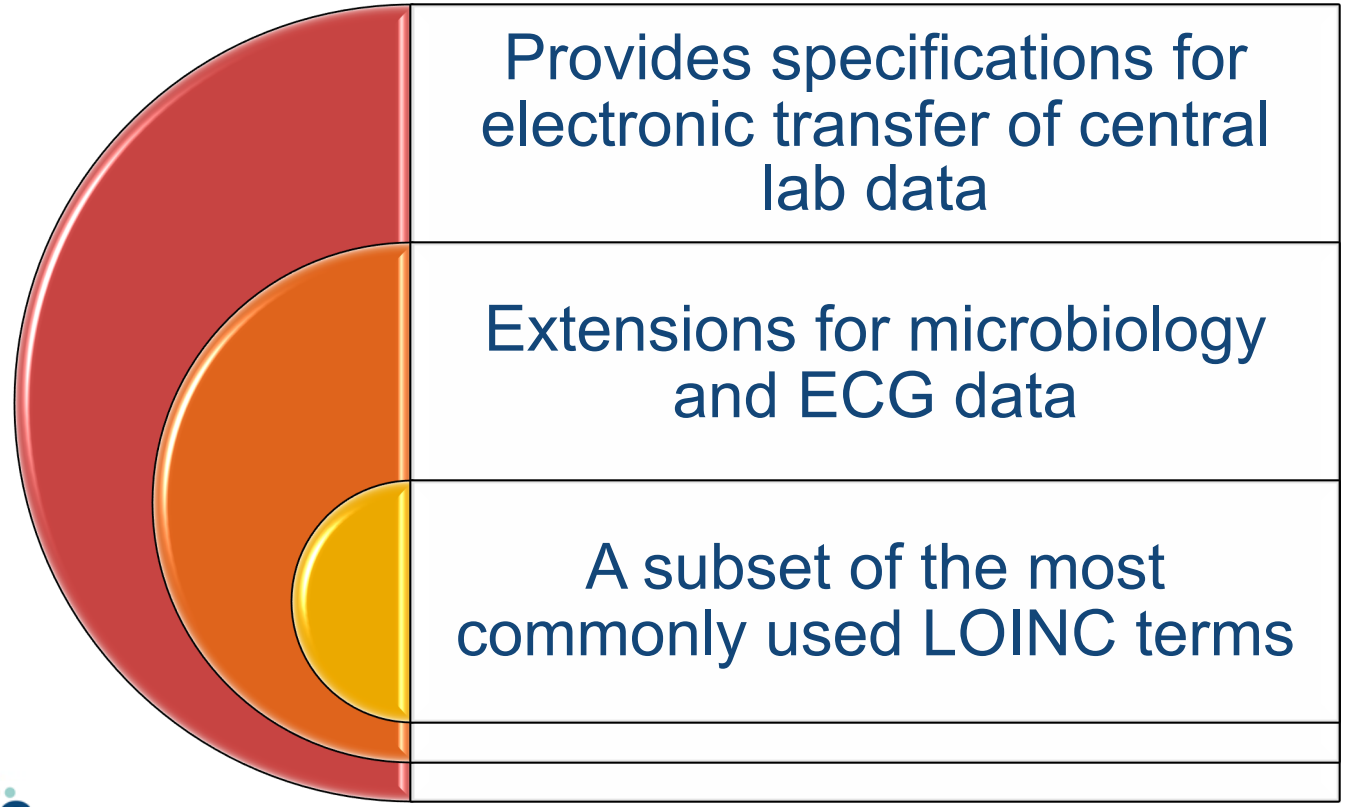
CDISC Standards (2)

ODM	• **O**perational **D**ata **M**odel • XML model for describing, transmitting & managing CRF-based data
LAB	• **Lab**oratory • Content standard for defining lab data
Controlled Terminology	• Defines code lists/controlled terms for CDISC variables • NCI's Enterprise Vocabulary Enterprises provides controlled versioned management
Devices	• Domains designed for specific device trial needs • Used in TAUGs as well as device studies

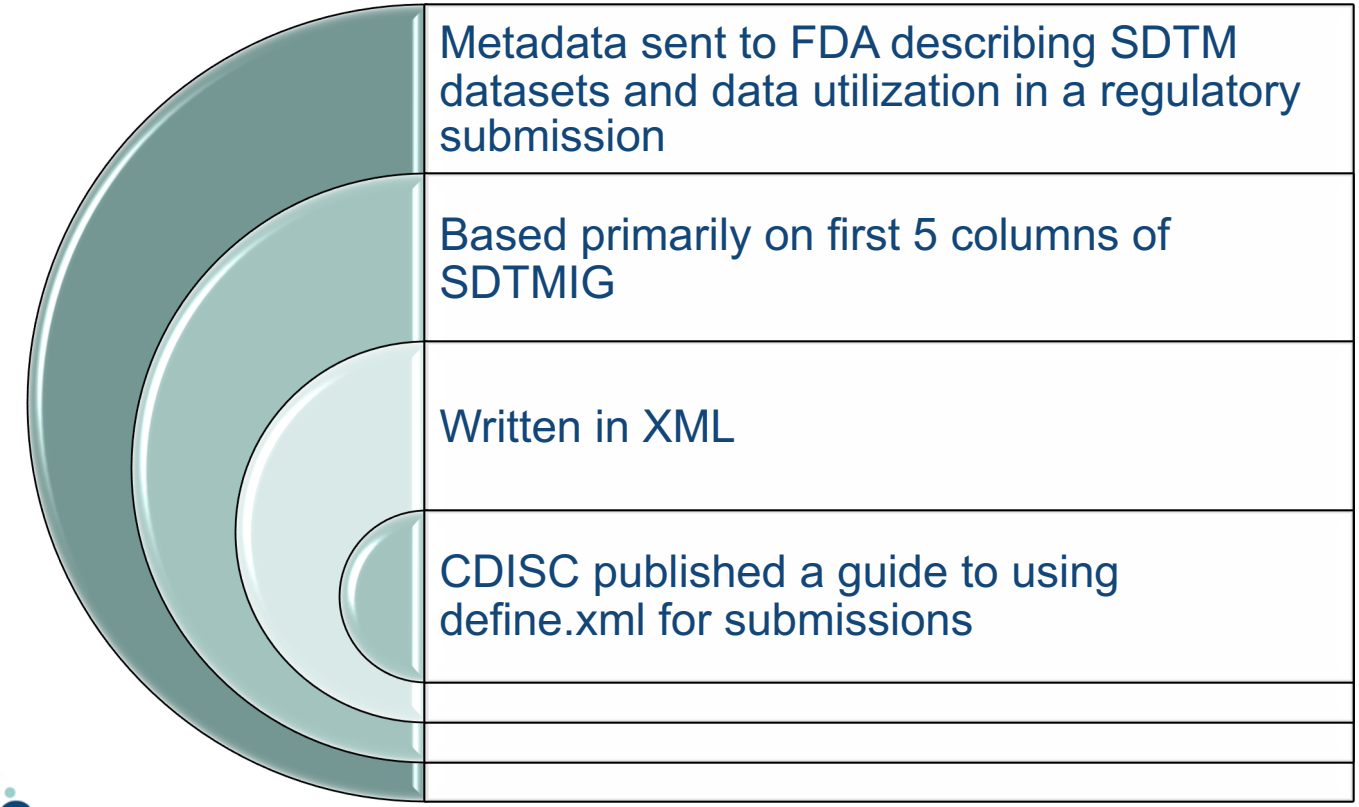
CDISC Standards (3)

Library	• Central electronic repository for CDISC standards
PRM	• Protocol Representation Model • Structured way of describing protocol elements that allows them to be searched on, e.g., eligibility criteria
SEND	• Standard for the Exchange of Non-clinical Data • Pre-clinical data exchange definitions, e.g., animal toxicology, reproductive toxicology, animal rule
Therapeutic area standards	• Alzheimer, Polycystic Kidney Disease, TB, Virology, Covid-19, TBI, numerous Cancers, et al

LAB



define.XML



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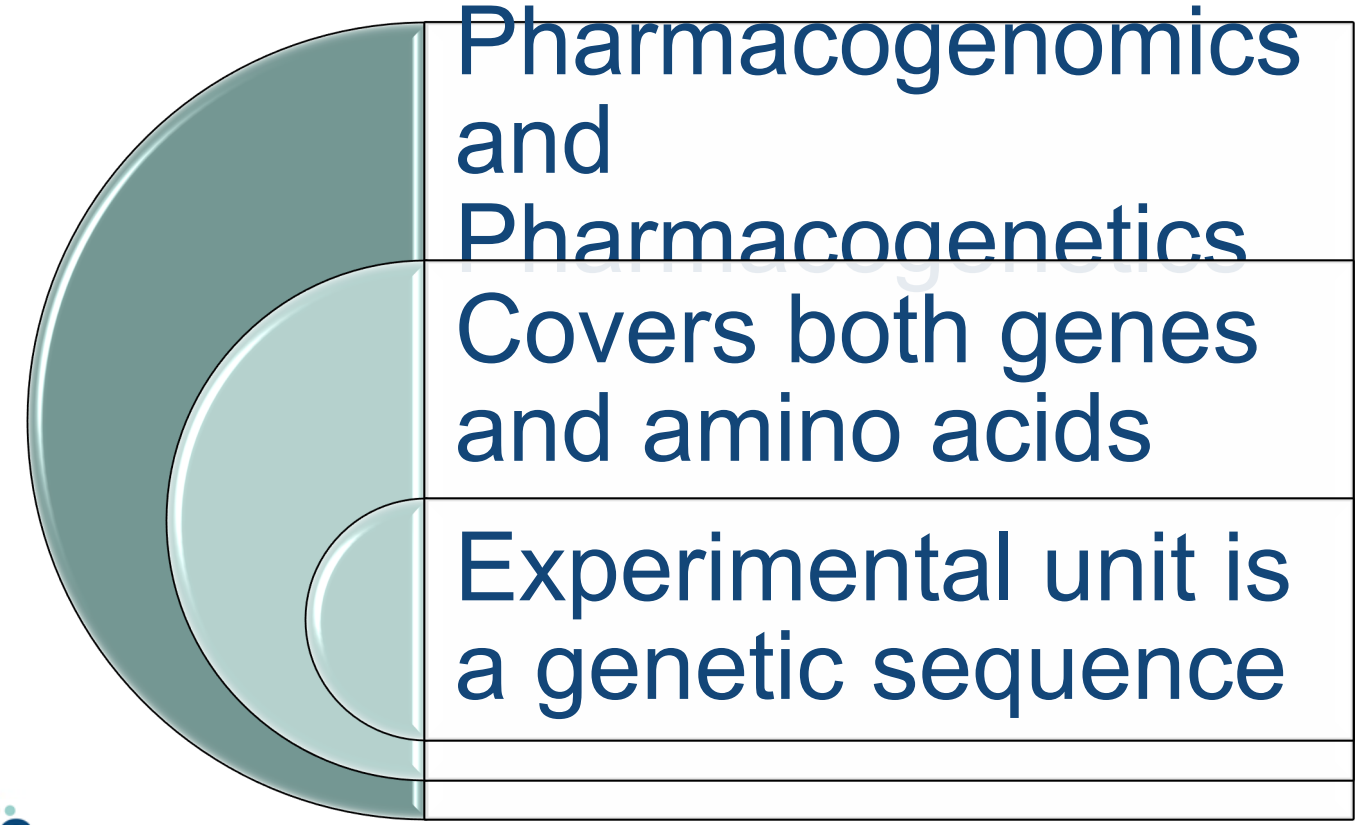

Audience Questions

Q: Will you be providing a copy of the slides?

A: Find the slides and webinar recording at:

https://www.cdisc.org/webinar/archive

Audience Questions

How do you think software tools for collecting data can/should help implement the standards?

Are there software tools CDISC enabled?

Upcoming Learning Opportunities

Events Coming Your Way Soon!

- 2020 China Virtual Interchange
  - Only Two Weeks Away!
    - 5 Aug: 8:30-17:00* (English Sessions)
    - 6-7 Aug: 8:30-12:3*0 (Mandarin Sessions)
  - CDE and FDA Presenters
  - Virtual Networking with Presenters and Sponsors

*Times listed in China Standard Time

- 2020 US Virtual Interchange
  - Registration Now Open!
  - Presenter, Sponsor and Exhibitor Opportunities Available**
  - Launching NEW Enhanced Virtual Conference Platform
    - 1:1 Virtual Netowrking
    - F2F Online and On-screen Meetings
    - 3D Exhibitor Experience

**Abstract Submissions Due 24 July

https://www.cdisc.org/events/interchanges

NEW Blended Learning from CDISC

- Self-paced online training combined with remote instructor-led Q&A
  - Developed by standards experts
  - CDISC authorized instructors
  - Currently in English, Japanese, and Mandarin
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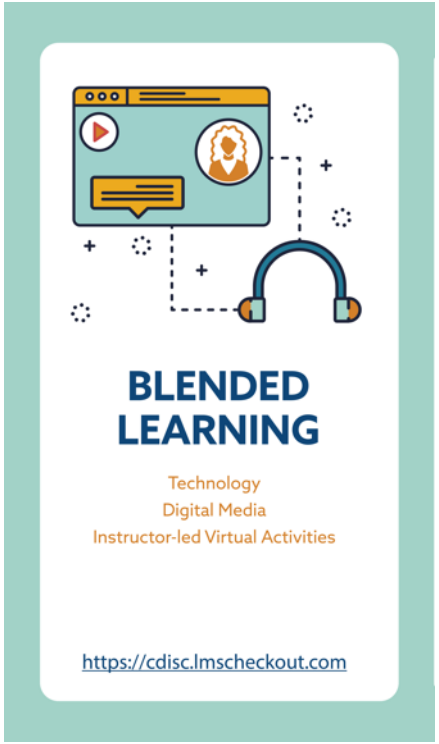
  - **Introductory Offer – Additional 25% Off!**



Now available!

NEW Blended Learning

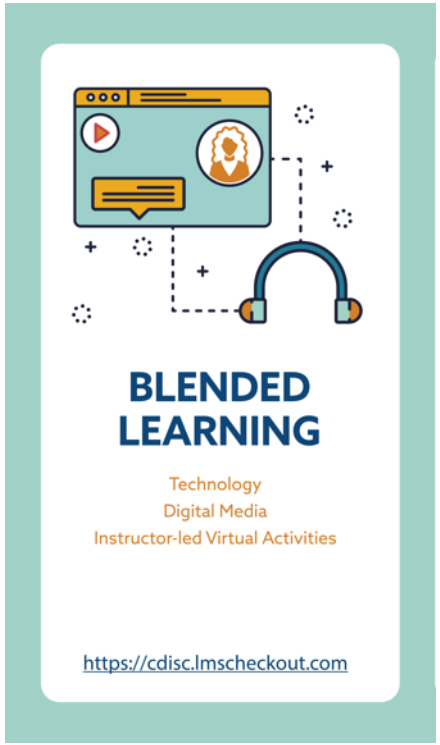
- Sessions starting soon!

SDTM Blended Learning*			
	Start Date	Live Q&A	Language
Americas	5 AUG – 9 SEP	Weekly	English
Europe	25 AUG – 29 SEP	Weekly	English
Japan	4 AUG – 8 SEP	Weekly	Japanese
China	3 – 29 SEP	Weekly	Mandarin

*Includes 19 modules & weekly Q&A sessions

CDASH Blended Learning**			
	Start Date	Live Q&A	Language
Americas	5 – 19 AUG	Weekly	English
Europe	1 – 15 SEP	Weekly	English
Japan	4 – 18 AUG	Weekly	Japanese
China	3 – 17 SEP	Weekly	Mandarin

**Includes eight modules & weekly Q&A sessions



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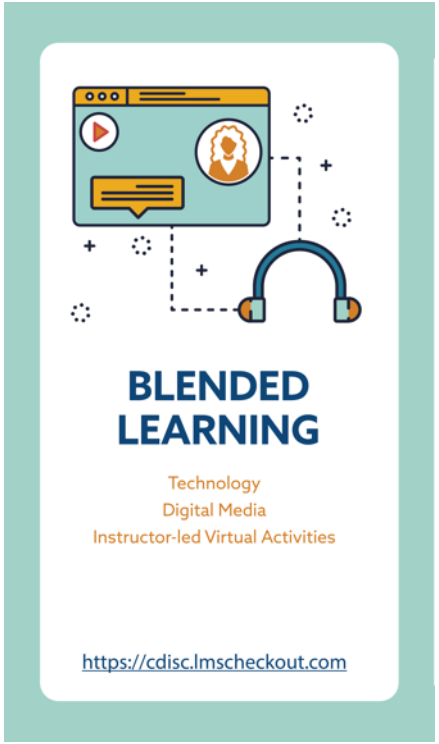


Now available!

Join CDISC for a Virtual

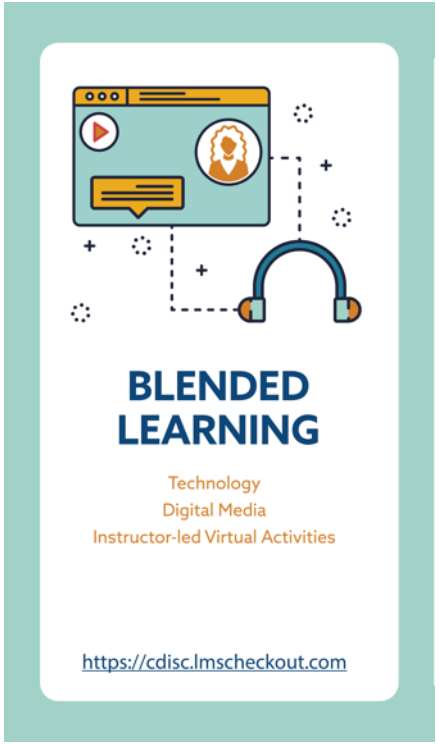
CDISC for Newcomers (Virtual)

New to **CDISC Standards**? Attend our workshop geared to getting you started with standards to amplify the full potential of data, drive operational efficiencies and expedite the regulatory review process. The workshop goes over examples of the standards, along with how to build them into the process of writing a protocol, collecting and tabulating data, and using the data in analysis. The CDISC **Data Exchange standards** are reviewed and the **CDISC Library** is discussed.

The workshop also identifies standards strategies that can make the clinical research process more efficient and offers a high-level introduction into the current regulatory requirements for submissions.

- **Agenda**:
- Topic 1: What is CDISC?
- Topic 2: Why Are Standards Needed?
- Topic 3: Overview of Regulatory Requirements
- Topic 4: Overview of CDISC Models
- Topic 5: CDISC Connects Research Globally
- Topic 6: Therapeutic Area User Guides
- Topic 7: Data Exchange Standards
- Topic 8: Implementing CDISC Standards
- Topic 9: CDISC Library
- Topic 10: How Does CDISC Work?

Date and Time:
29 JUL – Asia/Tokyo
5 AUG – Europe/Brussels



Thank You!

Questions, comments, concerns? Email bklinke@cdisc.org

Don’t forget to fill out the feedback survey!