CTR – (Clinical Trial Registration) & CTR2 & (PRIM)

CDISC CTR

Clinical Trial Registration

CDISC PRIM

Protocol Representation Implementation Model

CDISC CTR_2

Clinical Trial Registration & Results 2

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Goal of the project

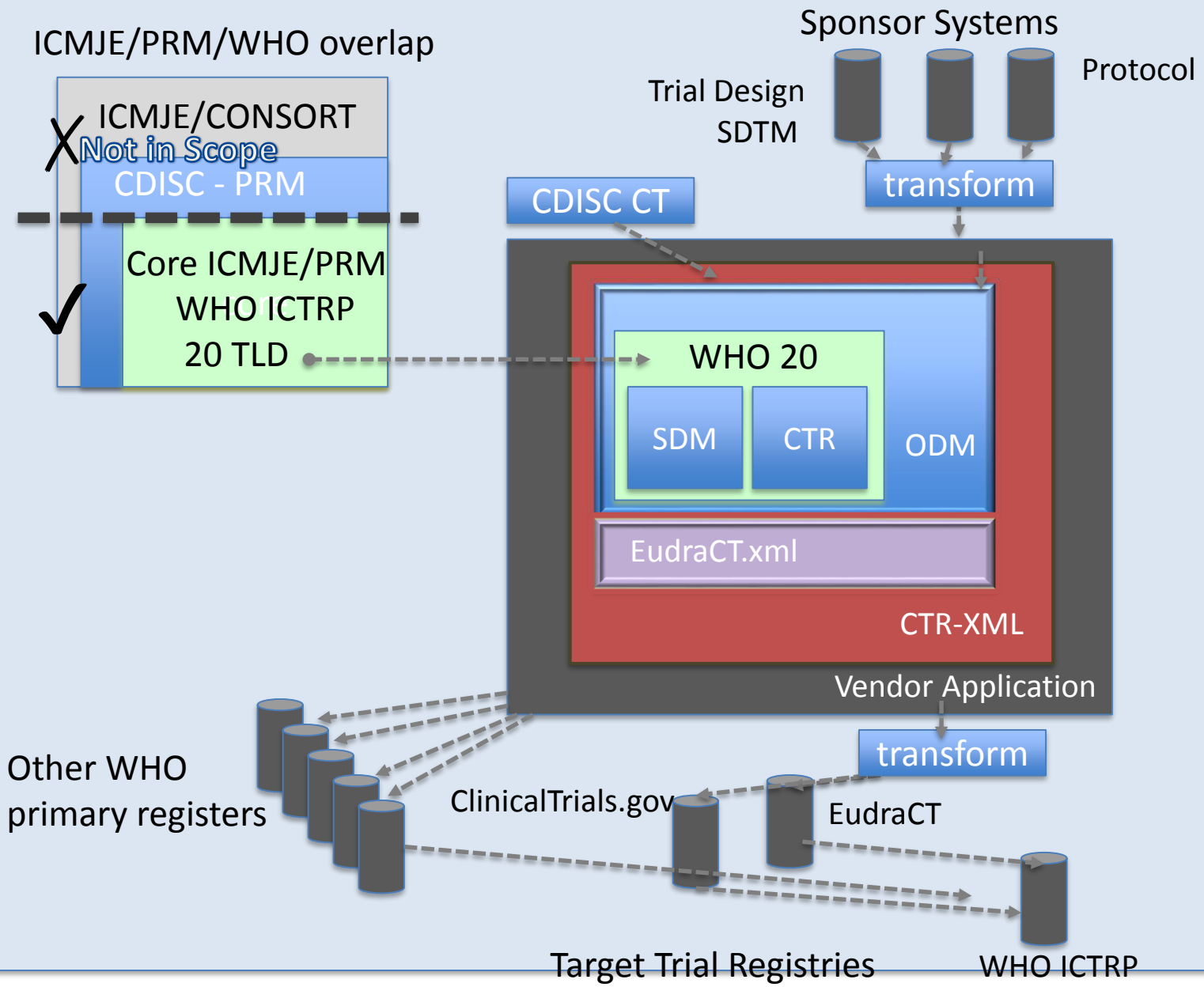
- Develop a draft standard, specification and XML-Schema to cover Clinical Trial Registrations of Study Designs to:
  - ClinicalTrials.gov
  - Eudra-CT
  - Other WHO primary registries
  - obeys the 20 base requirements of the WHO
  - Trial results is out of scope for this stage

What can it be used for?

- Software vendors can develop software that provides a “develop once, submit multiple” solution, i.e.
- One software tool for generating CTR submissions to as well ClinicalTrials.gov as to Eudra-CT as to …
- Starting from scratch or from an existing Study Design in ODM
- Improve beginning to end integrity of data with extended protocol elements and SDM elements

CDISC CTR1 - WHO 20 TLD

http://www.cdisc.org/ctr-xml



Thanks to….

Special thanks to the CTR Team: Neil John Newman (Lilly/EFPIA), Sarah Larson (Biogen Idec), Vojtech Huser(NIH), Ghassan Karam (WHO), Nick Sykes (Pfizer/EFPIA) Keith Rodgers (Trial Scope) Thomas Wicks (TrialScope), Saraub Aggarwal (Trial Scope), Paul Ngai (Xogene), Nick Halsey (EMA), Noemi Manent (EMA), Rafella Chersoni (EMA), Erin Muhlbradt (NCI), Nick Ide ((NIH/NLM), David Gemzik (Clinical Ink). Also, many thanks to the CDISC technical authoring team: Diane Wold, Sam Hume, Darcy Wold and Sally Cassells.

Next Stage - 2 new standards

CDISC PRIM

Protocol Representation Implementation Model

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Clinical Trial Registration & Results 2

Looking for Sponsors and team members now.
Required contributions of $250K

Stakeholders: EMA,FDA, PMDA, NIH, WHO,Trialscope, EFPIA, P*h*RMA etc, Southampton University, Nuffield - Oxford Uni

Project Goals

Project ‘Optimus’ as a second stage of CDISC CTR will focus on defining fully structured protocol and results summary elements. The CTR_2 standard will therefore utilize and necessitate the development of a new Protocol standard – PRIM. The goal of these two new standards being:

- To advance the beginning to end support of clinical trials
- Ensure CDISC Standards are compliant and utilize IDMP terminologies
- Create reliable and structured trial repositories

PRIM Deliverables

- A definitive Protocol schema that can be implemented in software.
- A protocol model implemented in SHARE and integrated into a beginning-to-end CDISC metadata model.
- RDF and XML export formats.
- Extensions to SDM,CTR, SDTM, and ADaM where appropriate.
- A short user guide to explain how to use the SHARE content and tools, including examples
- Controlled vocabulary sets with relationships expressed to the foundational standards

PRIM Drivers

- To enable traceability of all protocol and Statistical Analysis Plan elements throughout the study achieving true beginning to end support of clinical trial elements
- Improve protocol quality and minimize amendments though re-use and consistency checks
- Improves reporting by explicitly aligning study objectives and endpoints with the data being captured and analyzed.
- Give greater flexibility, structure and reliability to biomarker design and analysis
- More effective EDC Study Setup
- Easier preparation of submission deliverables

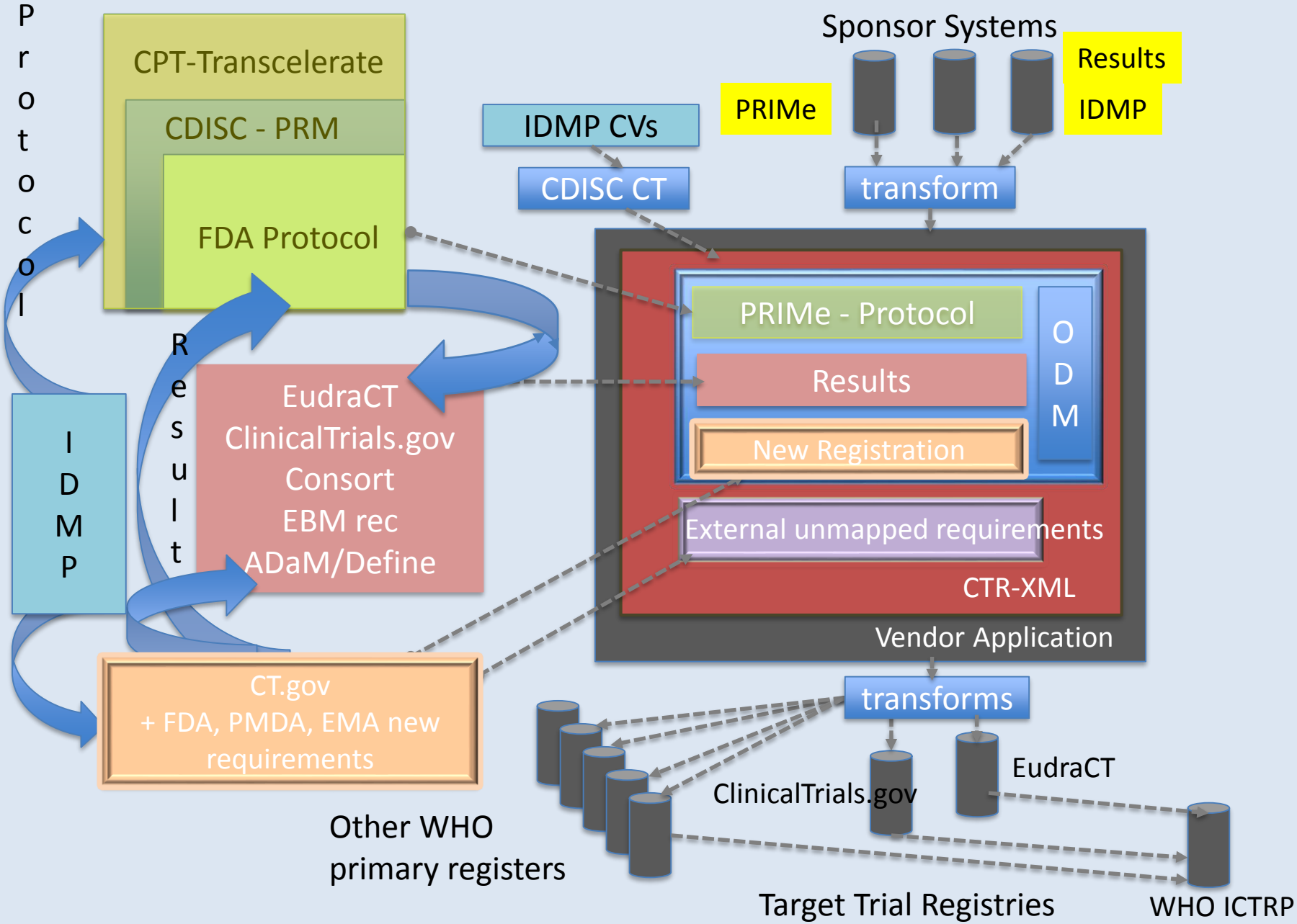
CTR_2 Deliverables

- A set of registration standard elements represented in an extended version of ODM and where appropriate mapped to the standards metadata model in SHARE.
- **Summary result data elements** as defined by the stakeholders and extensible as desired (ADaM and Define-XML data set configurations to present summary results)
- A short user guide to explain how to use the SHARE content and tools, including examples.
- Controlled vocabulary sets with relationships expressed to the foundational standards

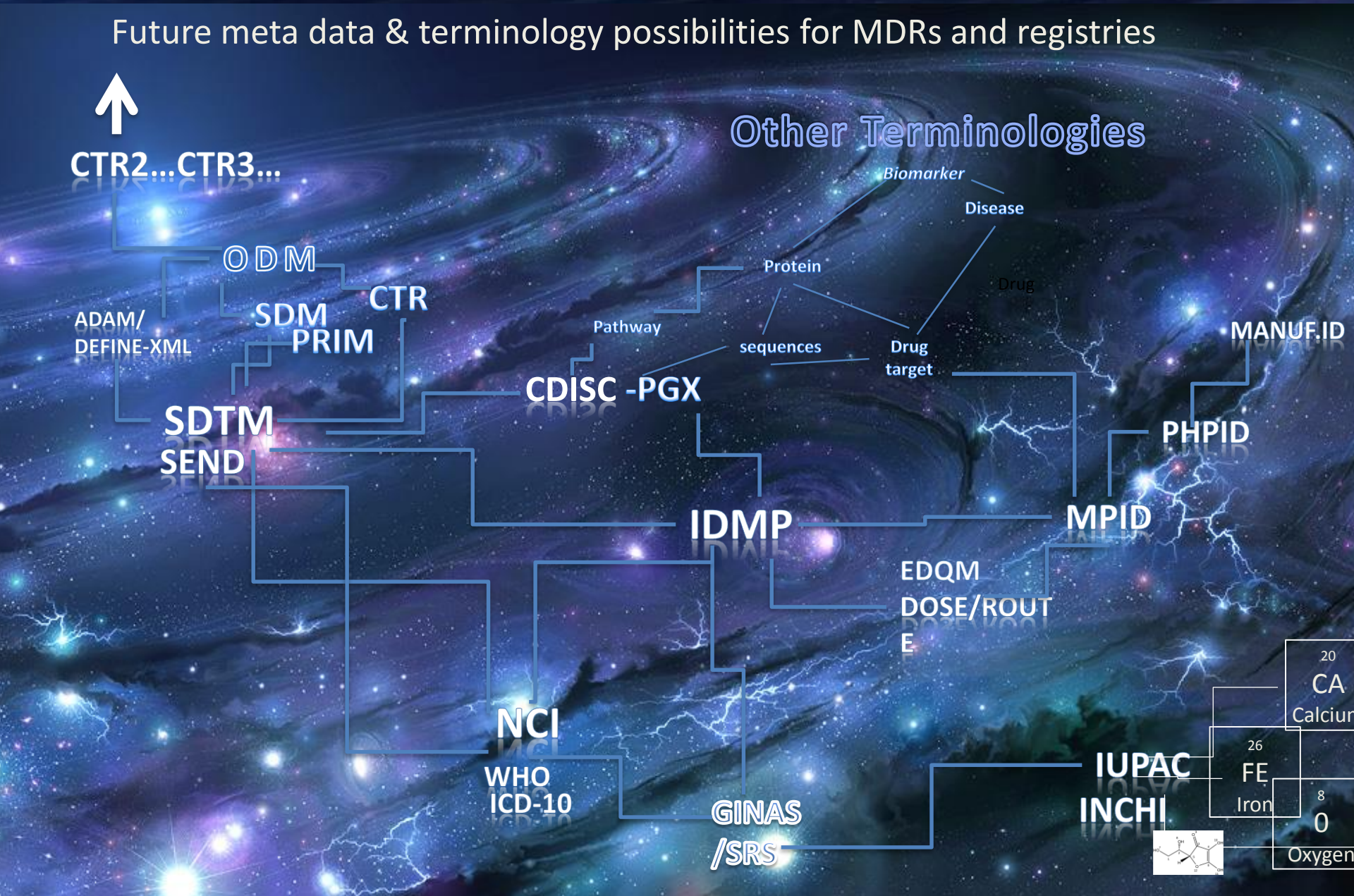
CTR2 drivers

- Create structured and traceable results summary data sets for registries and publications
- to allow the same information to be accurately replicated around the worlds registries.
- to increase the accuracy and reliability of the information in trial registries with structured and study metadata linked data
- Negate human error in data entry and build in validation rules
- Harmonisation with regulatory IDMP requirements
- Further enrich the registries with more extensive summary information to support more granular searching

CDISC CTR2 - Phase 1 - CDISC PRIMe, IDMP, Results Summary



Future meta data & terminology possibilities for MDRs and registries



CTR3

- Continue Harmonization
- Enrich Results datasets Evidence Based Medicine
- Extend granularity of info to include links to external Terminologies, site identifiers, ORCHIDS etc.
- Look at CDASH extensions

Questions?

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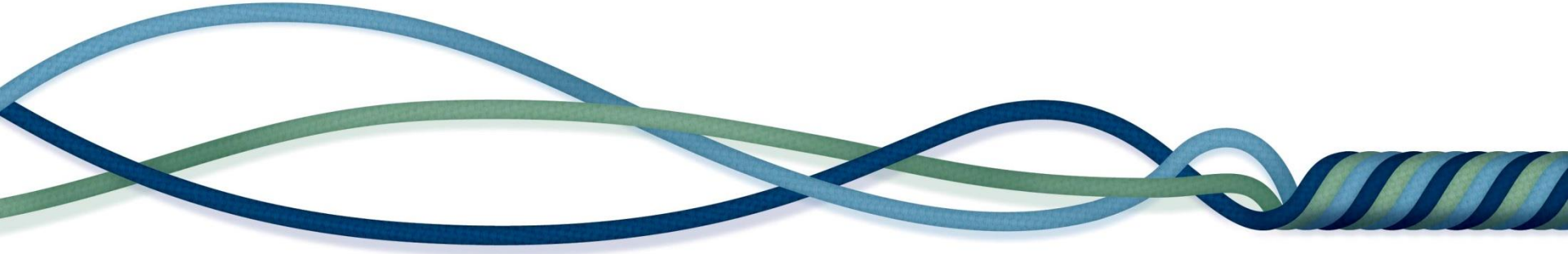

Strength *through collaboration.*