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CDISC SHARE:
Shared Health And Research Electronic Library

CLINICAL DATA INTERCHANGE STANDARDS CONSORTIUM

CDISC

Setting the Global Standard for Medical Research

CDISC French User Group
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Foreword

- These slides are a combination of
  - Slides extracted from CSHARE webinar of October 2010
  - Material developed by the TAC sub-committee (referring to CMDR as the precursor of CSHARE)

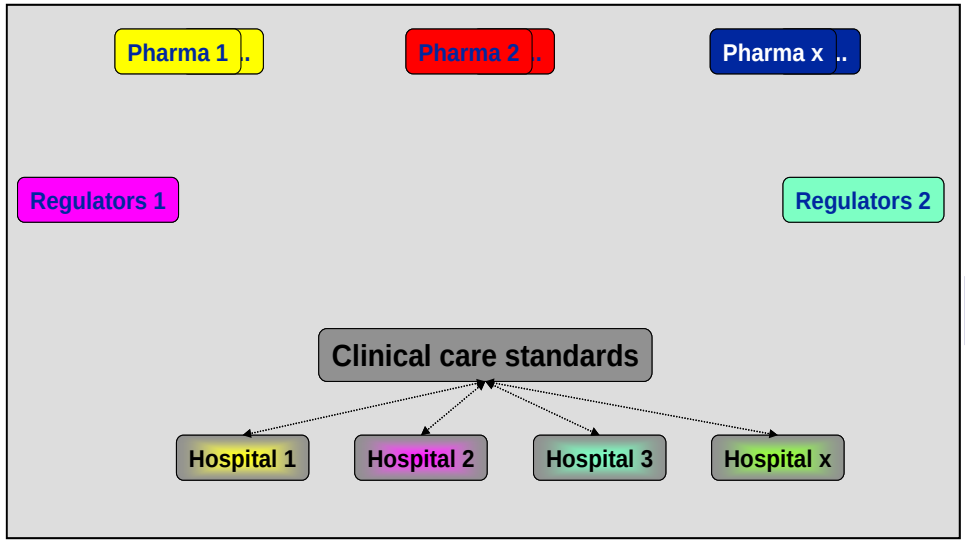
WHAT is it CDISC SHARE?

A global, accessible electronic library, which through advanced technology, enables precise and standardised data element definitions that can be ~~used~~ compared in different heterogeneous applications and studies to improve biomedical research and its link with healthcare

Note: Text in black is the official definition.
Red marks indicate personal modification

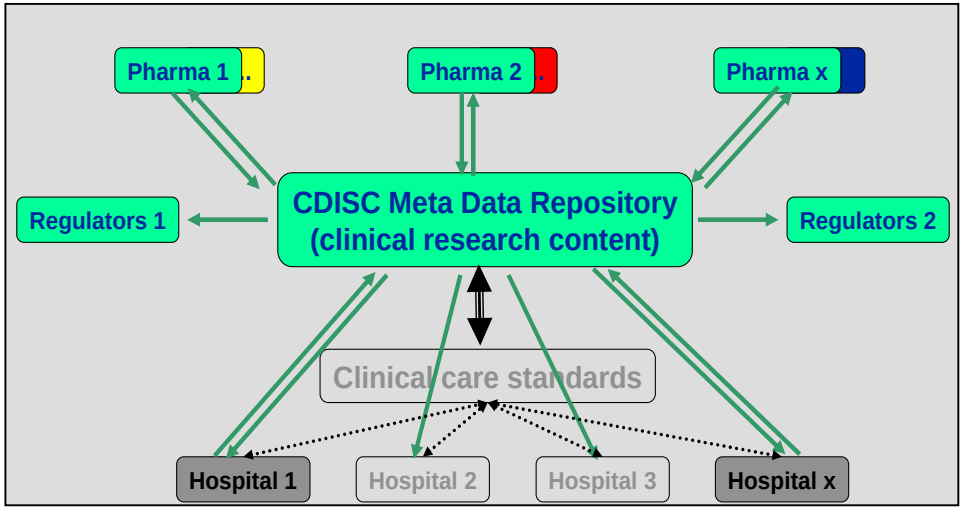
WHAT is it CDISC SHARE?

From disjointed "standards" to semantic interoperability



FROM non-interoperable, disjointed, proprietary data "standards"

TO common inter-operable data standards in clinical research, compliant with clinical care standards



WHY CDISC SHARE?

- To develop a ‘reference’ or target set of standards without duplication of existing standards
- To augment the CDISC content standards with efficacy-related domains in an electronic, accessible format

- To ensure that terminology for research standards is consistent with that needed for other purposes (e.g. quality reporting, public health, safety monitoring)
- To ensure that these standards strengthen the link between clinical care and research such that research results can inform healthcare more quickly

What is the Potential Value?

- Enables semantic interoperability and integration within clinical reserach
  - improved data consistency and quality => facilitate aggregation of data and comparisons
  - Within organizations AND across research studies (e.g. comparative effectiveness), research and/or healthcare organizations, regulators, vendors and other partners.

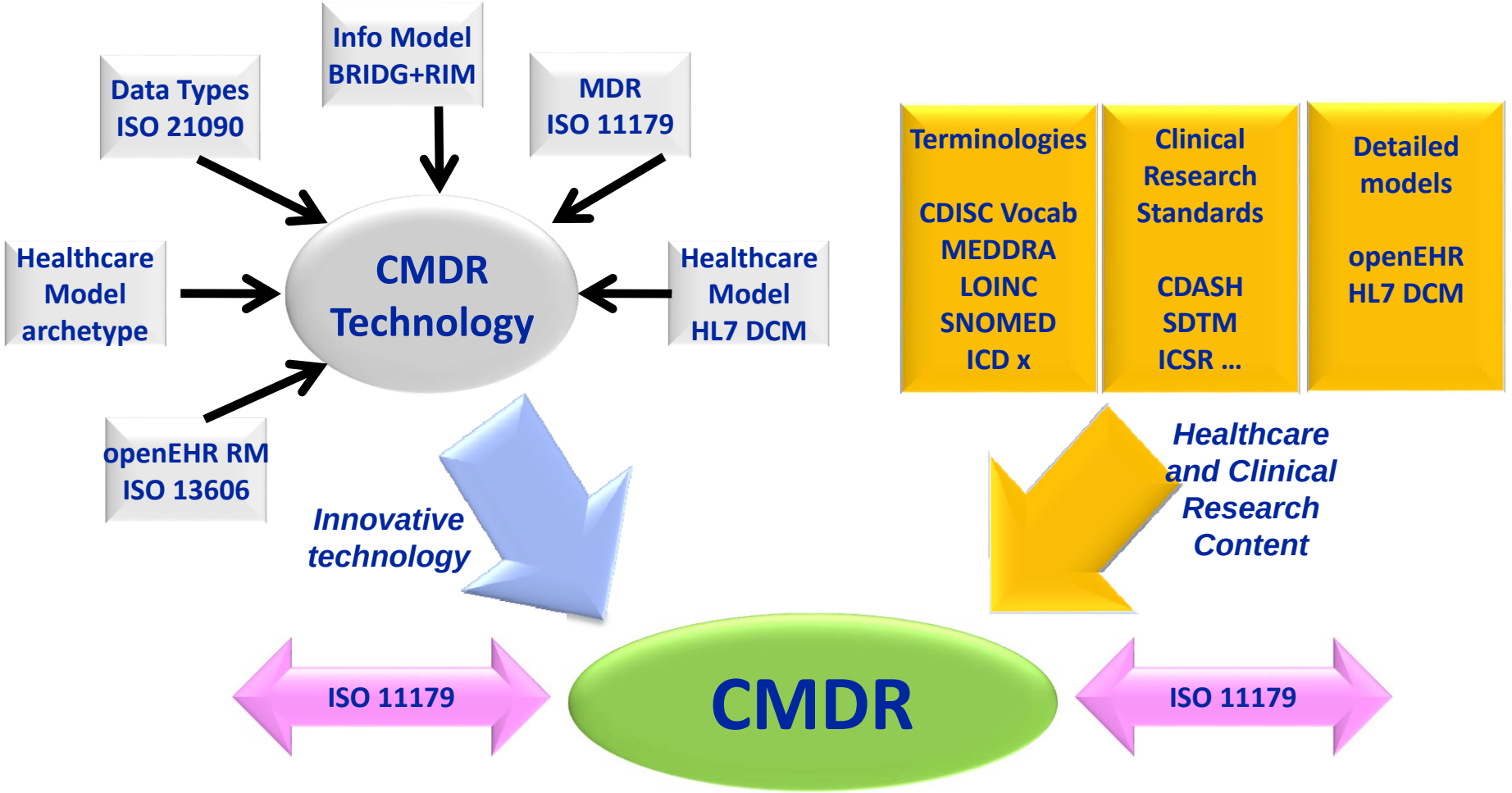
- Improve speed of data standard development through electronic and collaborative infrastructure :
  - improve the speed in developing standards and definitions
  - improve the governance surrounding the definitions
  - provide 24/7 access to the definitions

- Reduction in costs
  - To maintain individual dictionaries within each organization;
  - To share the same dictionary across different organization through downloads of reference dictionary

Description:

- SHARE is intended to be
  - a healthcare-biomedical research enriched data dictionary
    - Common information model (initially BRIDG)
    - Strong data typing (ISO 21090 – Abstract data types)
    - Common terminologies/value sets (CDISC, HL7, SNOMED, ICD, etc.)
    - Processes supporting exchange of information
  - built on the four pillars of Computable Semantic Interoperability (CSI)
  - which enables data reuse and exchanges that can be interpreted between systems
- Provides a target for mapping legacy/retrospective data and enables “the” target (reference) for new data

Description: *bringing several existing technical standards into one common "semantic" IT platform*



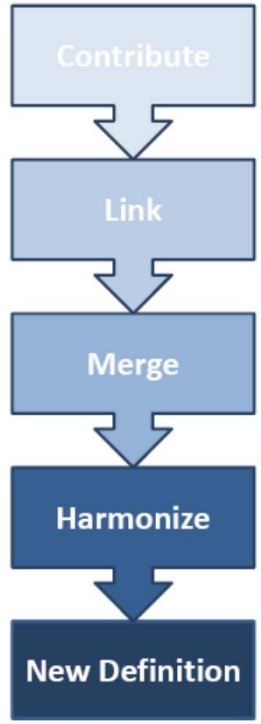
CMDR is an enriched data dictionary, built on innovative technology and filled with content combining healthcare and clinical research standards to deliver semantic interoperability between healthcare and clinical research

History

- December 2007: First proposal to the BoD
- April 2008: Description of CDE repository requirements to BoD – TAC sub-committee; approval to further explore
- April 2008 – December 2008: TAC Sub-committee
  - Several face to face meetings and TC
  - Definition of use cases to consolidate understanding on what we wanted/needed (http://asserowiki.com/index.php?title=User_requirements)
- December 2008 – April 2009: Meetings with FDA, HL7, Academia, Explored possibility to participate to FP7 and IMI calls,…

History

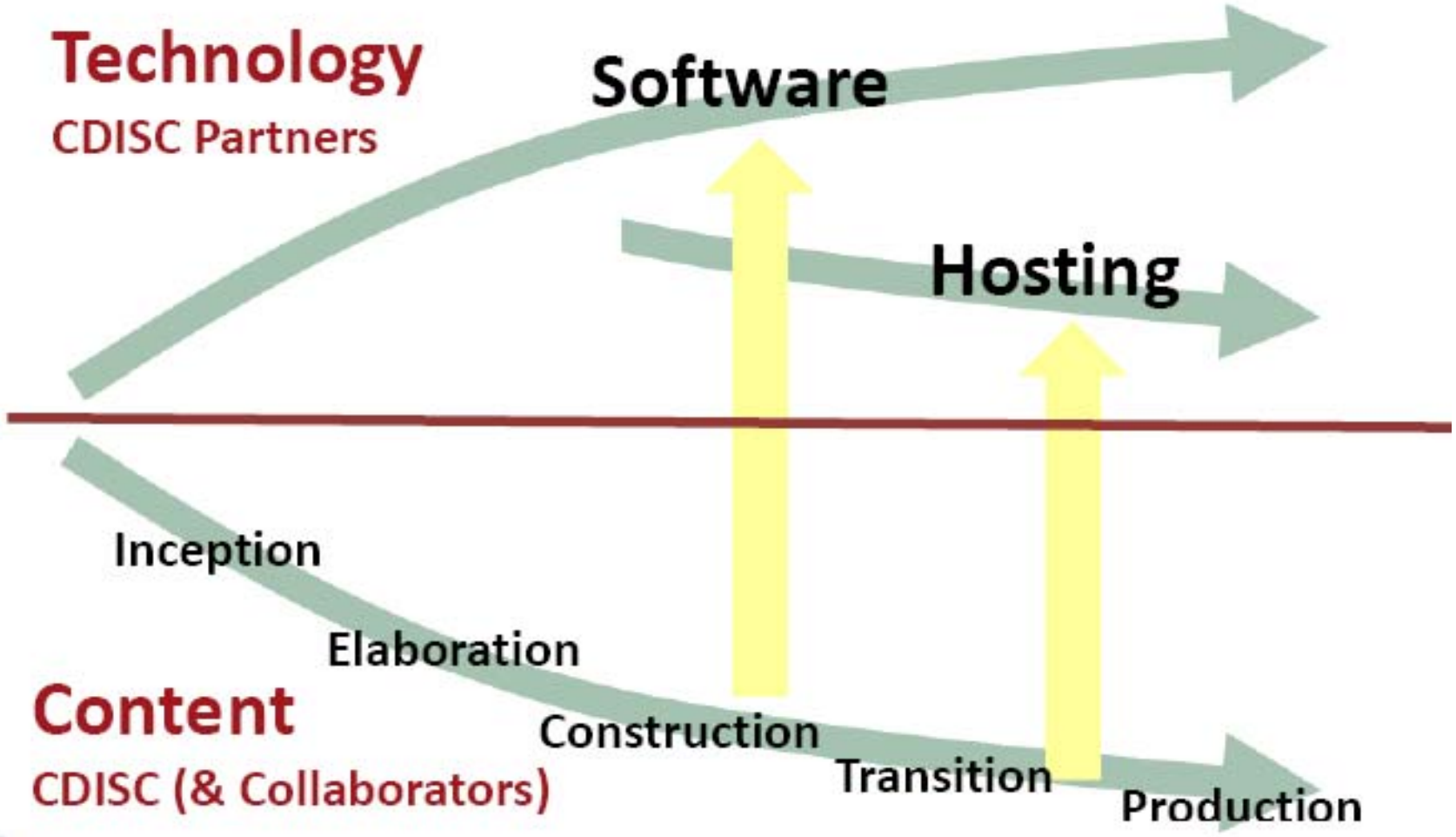
- April 2009 – October 2009: Inception Phase
  - Goals.
    - Primary: Determine whether definitions taken from multiple sources can be merged into a single version agreed to by all parties and can this be done within a timeframe that makes business sense
    - Primary: Determine whether high-quality definitions can be created and ontologies can help in ensuring such and avoid duplicate definitions being created
    - Secondary: Provide any relevant lessons to subsequent development
  - Deliverable: Evaluate feasibility; determine future path
    - Scope & Vision Document
    - Stakeholder Assessment
    - Business Requirements
    - Governance Process and Workflow
    - Business Models
    - Technology and tools (Mayo/NCI LexGrid) with comparable content (Oncology) from 5 sources (Mayo, MD Anderson, GSK, Genzyme, Lilly)



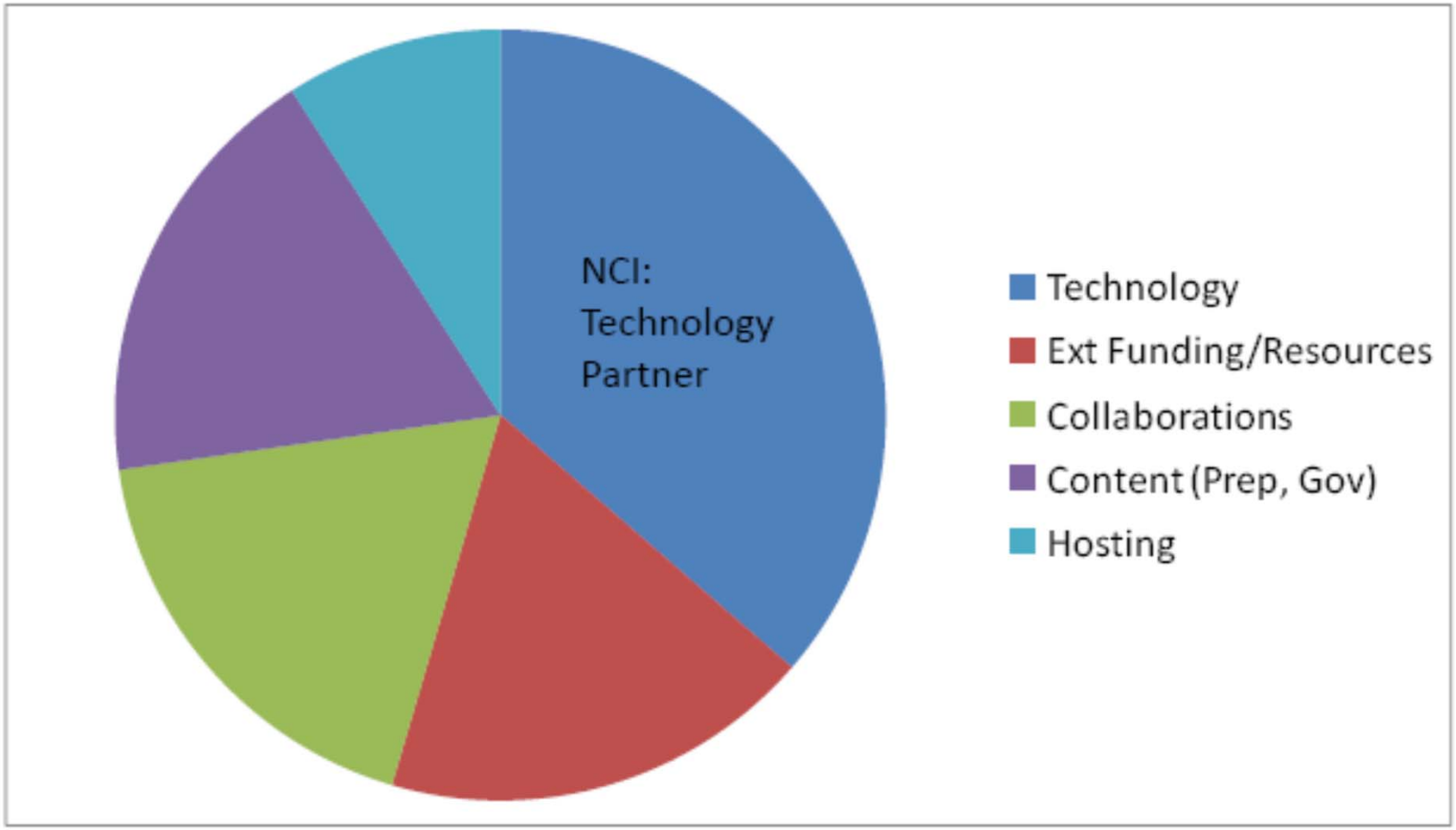
The wiki is available at:
http://informatics.mayo.edu/cshare/index.php/Main_Page

Username: cshare
Password: xTu$$9

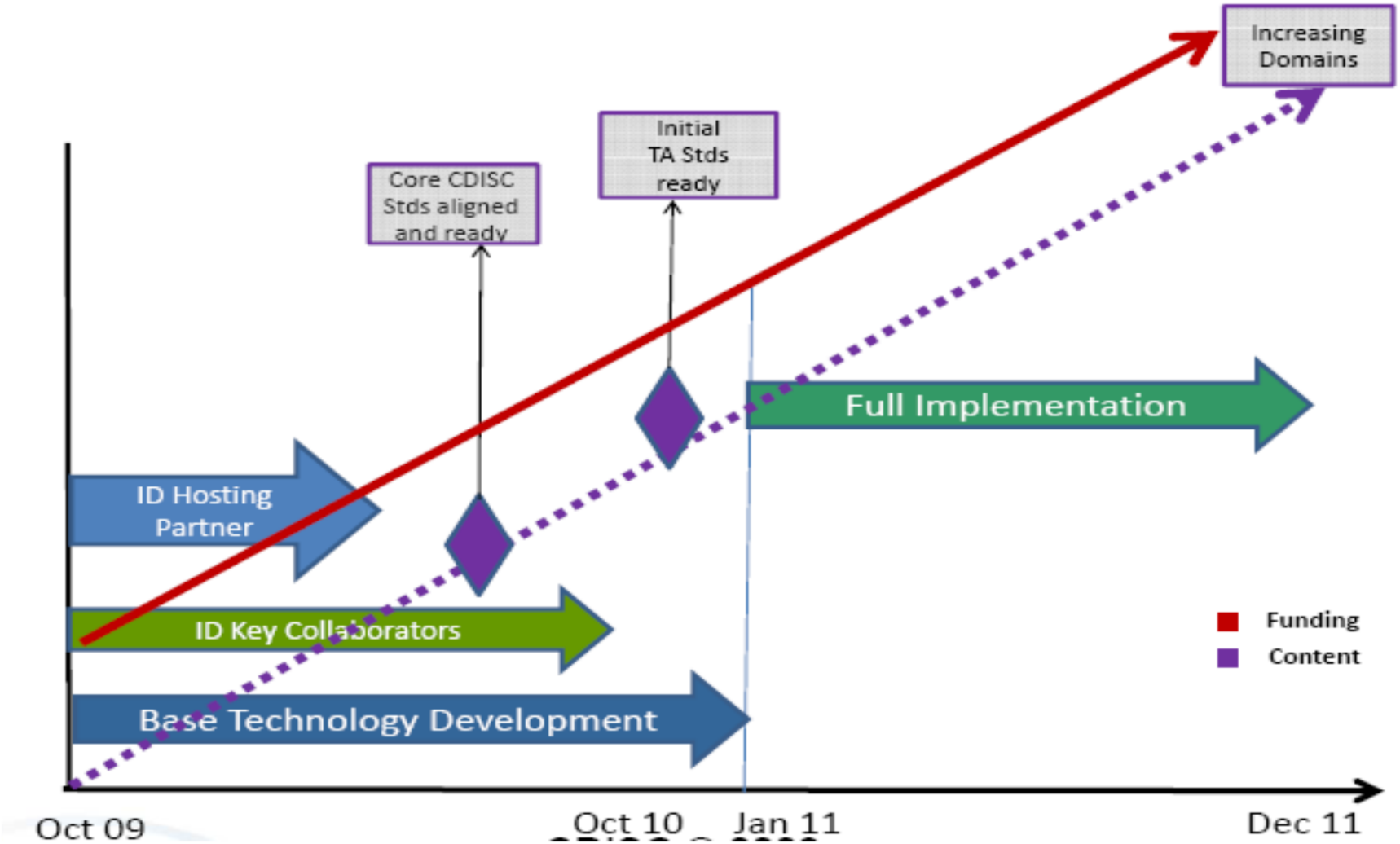
CDISC Role in SHARE: focus on content



Focus Areas: SHARE Implementation

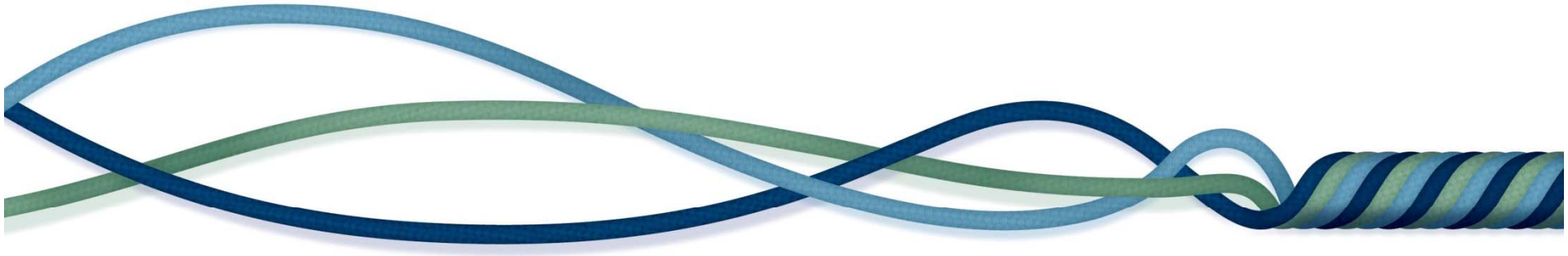


Projected Timeline



Closing remarks

- What is different about SHARE vs. other repositories?
  - Create a ‘reference standard’ vs. catalog or focused repository , to enable data aggregation and scientific comparisons that are impossible with proprietary standards
  - Leverages advanced technologies
- Why should CDISC lead the SHARE project?
  - CDISC is a global standards development organization with track record of collaboration and open, free standards.
  - CDISC will partner with other organizations on SHARE to ensure that it enables a better link between clinical care, research and other areas that benefit from high quality, accessible clinical data to benefit patient care while protecting patient privacy.



Strength through collaboration.

As a catalyst for productive collaboration, CDISC brings together individuals spanning the healthcare continuum to develop global, open, consensus-based medical research data standards.

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