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caBIG™ cancer Biomedical Informatics Grid™

Delivering caBIG™ Compatible Solutions

caBIG™ Industry Partners Meeting

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National Cancer Institute

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Natcher Conference Center
National Institutes of Health

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Approaches Taken by NCI and caBIG™ in Delivering caBIG™ Compatible Solutions

1) Modify/enhance existing vendor solution

2) Custom develop solution leveraging caCORE/caBIG™ tools where appropriate

3) Open standards middleware layer for integration

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Case Study: C3D – Oracle Clinical

Vendor solution made caBIG™ compatible

- NCI made C3D “bronze level” compatible early on
  - Integrated C3D with caDSR metadata via open source scripts and procedures
  - Provided external interfaces necessary for clinical trials management
  - Developed open source solution for CDUS and Theradex/CTMS transmissions
- NCI is working with Oracle to make application “silver-level” compliant
  - Oracle has committed to accept/process a standards-based (HL7 eDCI) CRF message
  - We are talking about provision of complete metadata APIs

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Case Study: C3D Made caBIG™ Compatible

C3D Extensions for “Bronze” Level Compatibility

- CDE Loader
- Lab Loader
- CTMS Submission Extraction
- CDUS Submission Extraction
- Validation and Derivation Procedures
- CDE Compliance Tools
- Library of Template eCRFs
- Cross Study Reports
- New OC API for central patient registry

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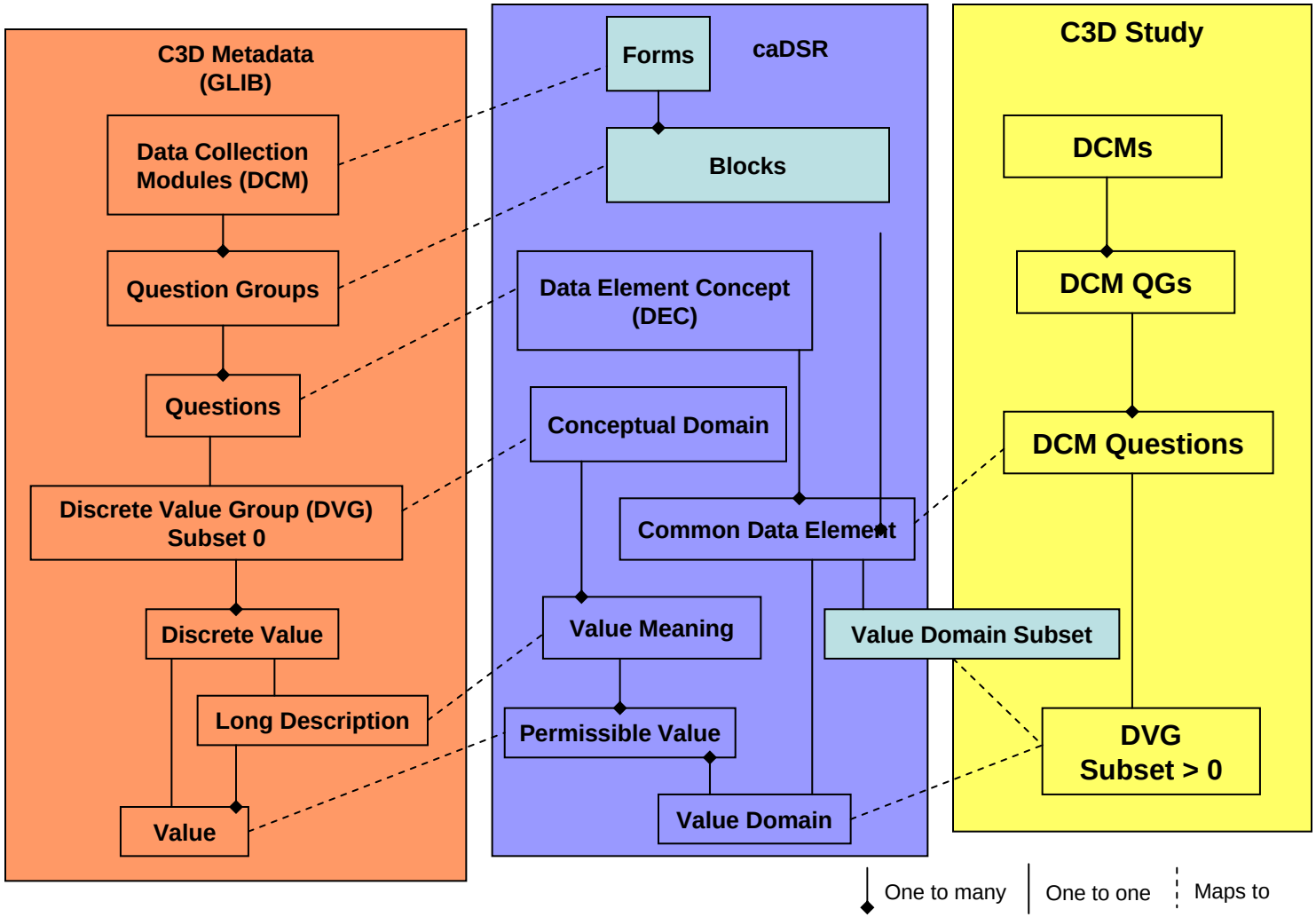
Case Study: C3D Made caBIG™ Compatible

C3D Mapping to caDSR



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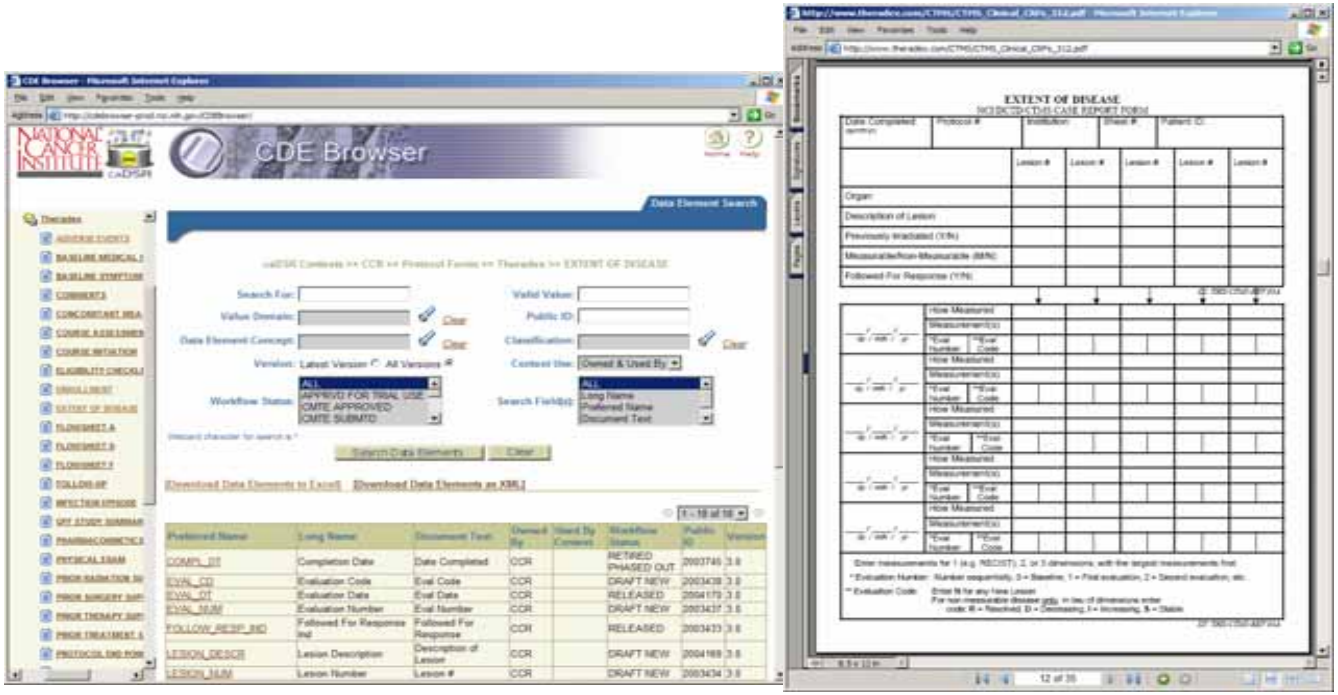
Case Study: C3D Made caBIG™ Compatible

Library of Template CRFs Built with CDEs

- Forms and CDEs defined in caDSR
- Template CRF layouts defined as PDFs



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Case Study: C3D Made caBIG™ Compatible

Moving towards "Silver" Compatibility, Later "Gold"

- The "Silver" and Later "Gold" Vision for C3D includes:
  - C3D would receive HL7 v3 eDCI messages in define mood to load its metadata.
  - The HL7 v3 messages would, of course, be made up of common data elements and use standard terminology.
  - C3D would render screens for the collection of the data in a way that enables it to generate the same message in an event mood.
  - For electronic data collection C3D would accept HL7v3 event messages from any source to which it has registered interest and consent to receive consented patient clinical data.
  - C3D would also be able to natively generate HL7v3 messages for all its data and metadata.
  - C3D's repository would be based on HL7 v3 RIM
  - Expose C3D data through CTOM APIs

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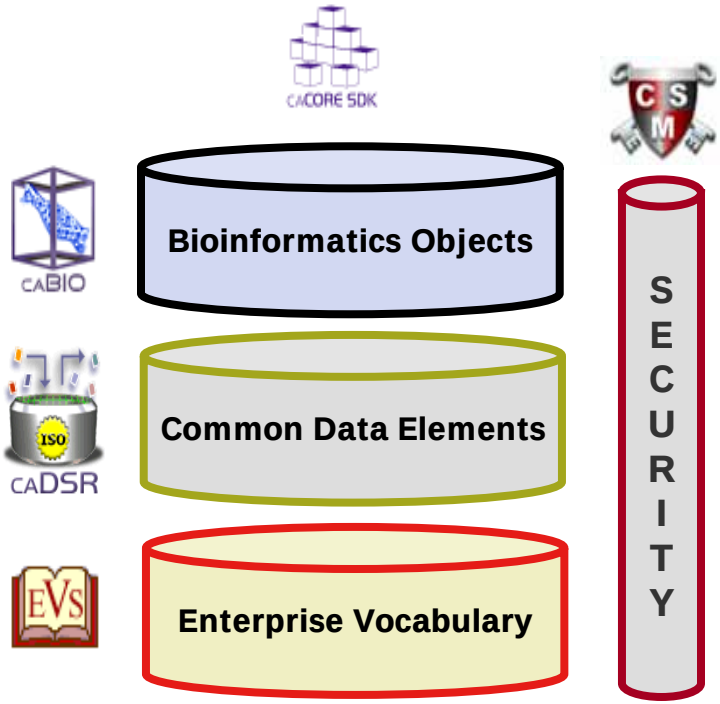
Custom caBIG™ Development

Leveraging Core NCI/caBIG™ Infrastructure

- Many NCI applications built on top of caCORE Infrastructure today including:
  - caArray
  - I3
  - Firebird
  - C3PR
  - CIAF
  - HL7 SDK
  - among others



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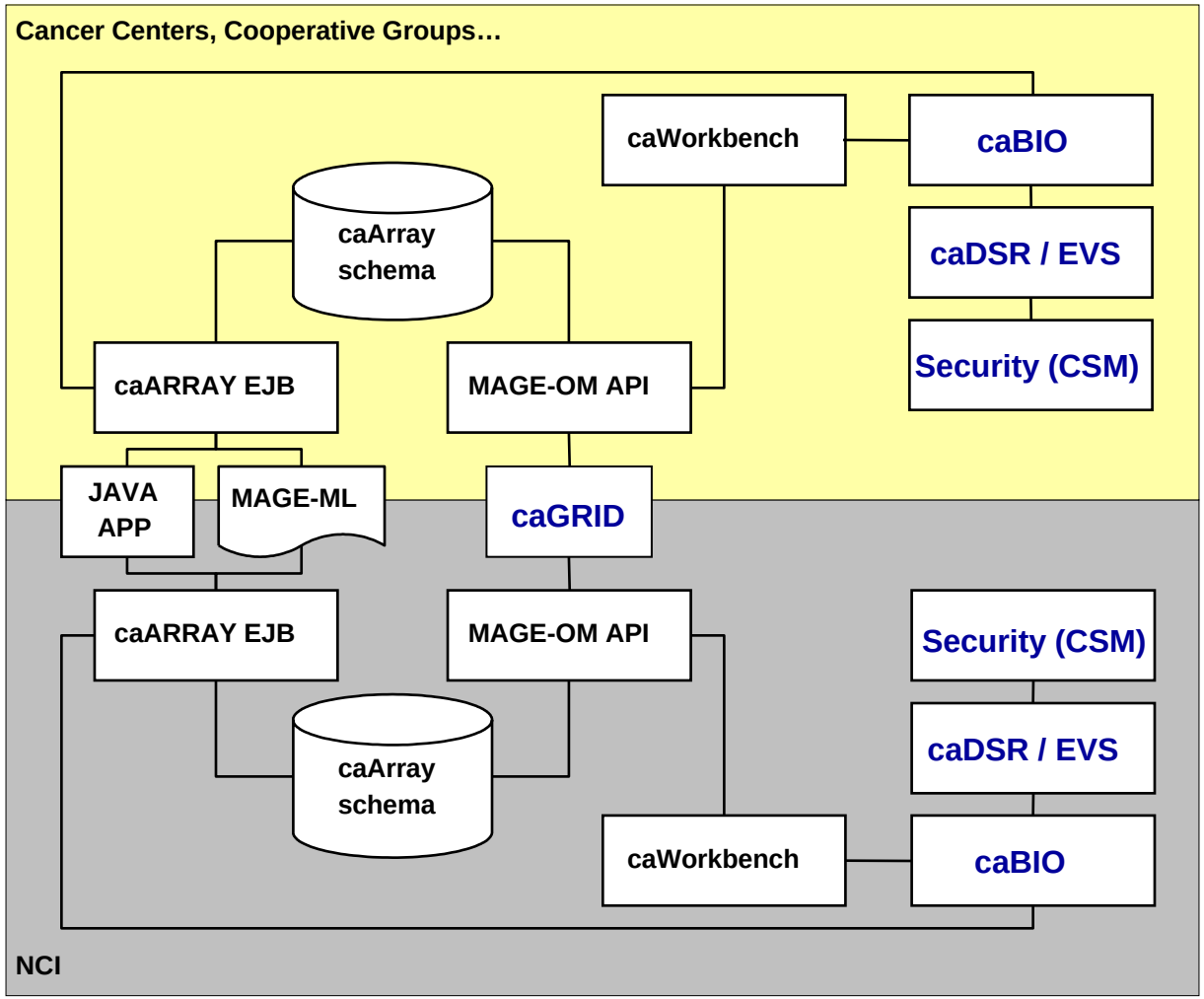
Case Study: Custom caBIG™ Development

"Gold Level" caArray Configuration



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Case Study: Custom caBIG™ Development

caArray Compliance with caBIG™ Principles

- Open source
  - caArray source code and all other artifacts are available under an open source license
  - caArray utilizes only open source technologies such as MAGE-stk, JBoss, Xerces, Struts, Ant, OJB, etc
- Open development
  - All caArray development plans, artifacts are shared with the community
- Open Access
  - caArray allows submission and retrieval of all public data. The protection group/element concept in caArray allows researchers to preclude sharing of sensitive data
- Federated
  - caArray is one of several caGrid reference implementations

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Case Study: Custom caBIG™ Development

caArray Compliance with caBIG™ Architecture

- caArray allows programmatic interface to its data via the EJB Managers, MAGE-OM API, and the MAGE-ML document.
- caArray is built upon MAGE-OM object model, MIAME and MGED-Ontology standards
- caArray APIs and messages support the delivery of data and also of accompanying metadata, in order to ensure that aggregated data sets are comparable
- caArray supports and extends MAGE-OM which allows for the deep annotation of microarray experiments according to MIAME
- caArray is built to utilize and complement the caCORE infrastructure

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caArray Compliance with caBIG™ Data Standards

- caArray metadata resides in caDSR, a ISO/IEC 11179 derived repository
- caArray is built to support MAGE OM (an OMG specification), as described in Uniform Modeling Language (UML)
- caArray utilizes the MGED Ontology, a set of open and standard controlled vocabularies and ontologies built to support annotation of microarray data.
- caArray is built upon MAGE-OM object model, MIAME 1.1, and MGED-Ontology standards

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Case Study: Open Standards Integration Layer

The BRIDG Model for Clinical Research

- The BRIDG (Biomedical Research Integrated Data Group) model is an open standards model based on a collaboration between HL7, CDISC, NCI/caBIG, FDA and industry
- Several early BRIDG implementations represent an open standards approach to achieving interoperability:
  - Focus is on defining the APIs that a clinical trials application must implement to interoperate with other clinical trials applications
  - Approach does not dictate application functionality or design

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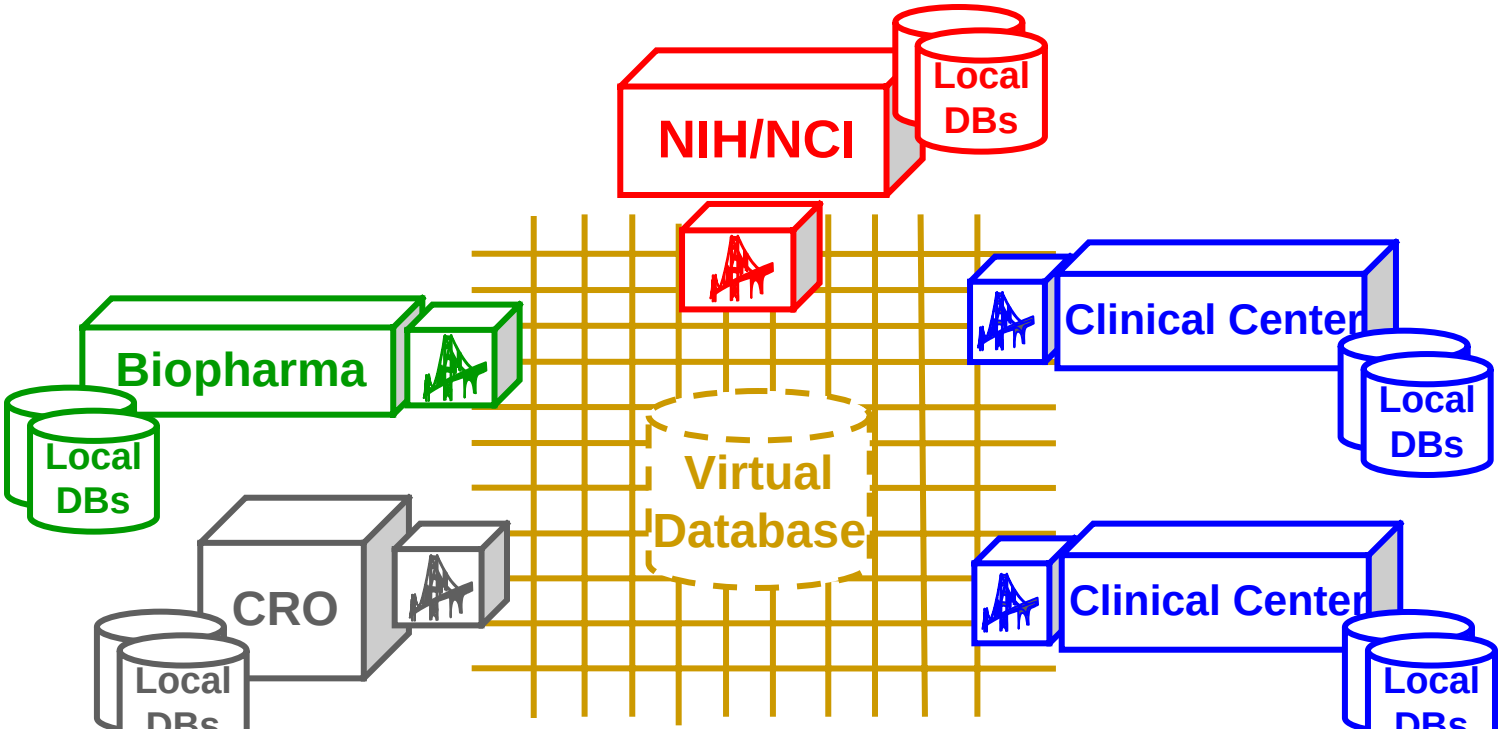
Case Study: Open Standards Integration Layer

CTOM (Clinical Trials Object Model): A reference implementation of BRIDG to support collaborative research



caGRID – Grid Services:

- Data Services (caBIO/CTOM/BRIDG)
- Security Services (CSM)
- Semantic Services (caDSR)
- Vocabulary Services (EVS)
- etc.

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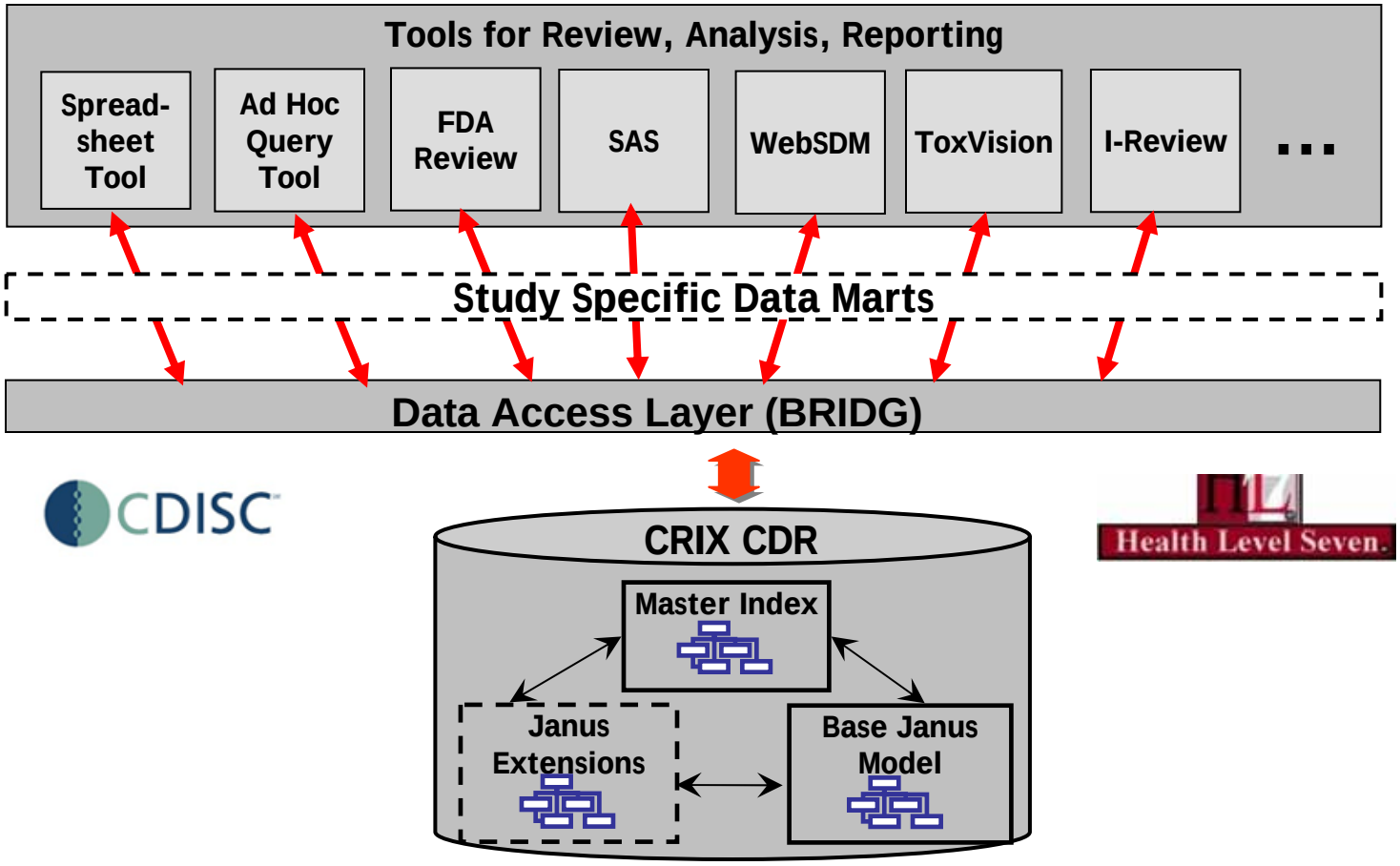
Case Study: Open Standards Integration Layer

CRIX (Clinical Research Information Exchange) data access layer based on BRIDG



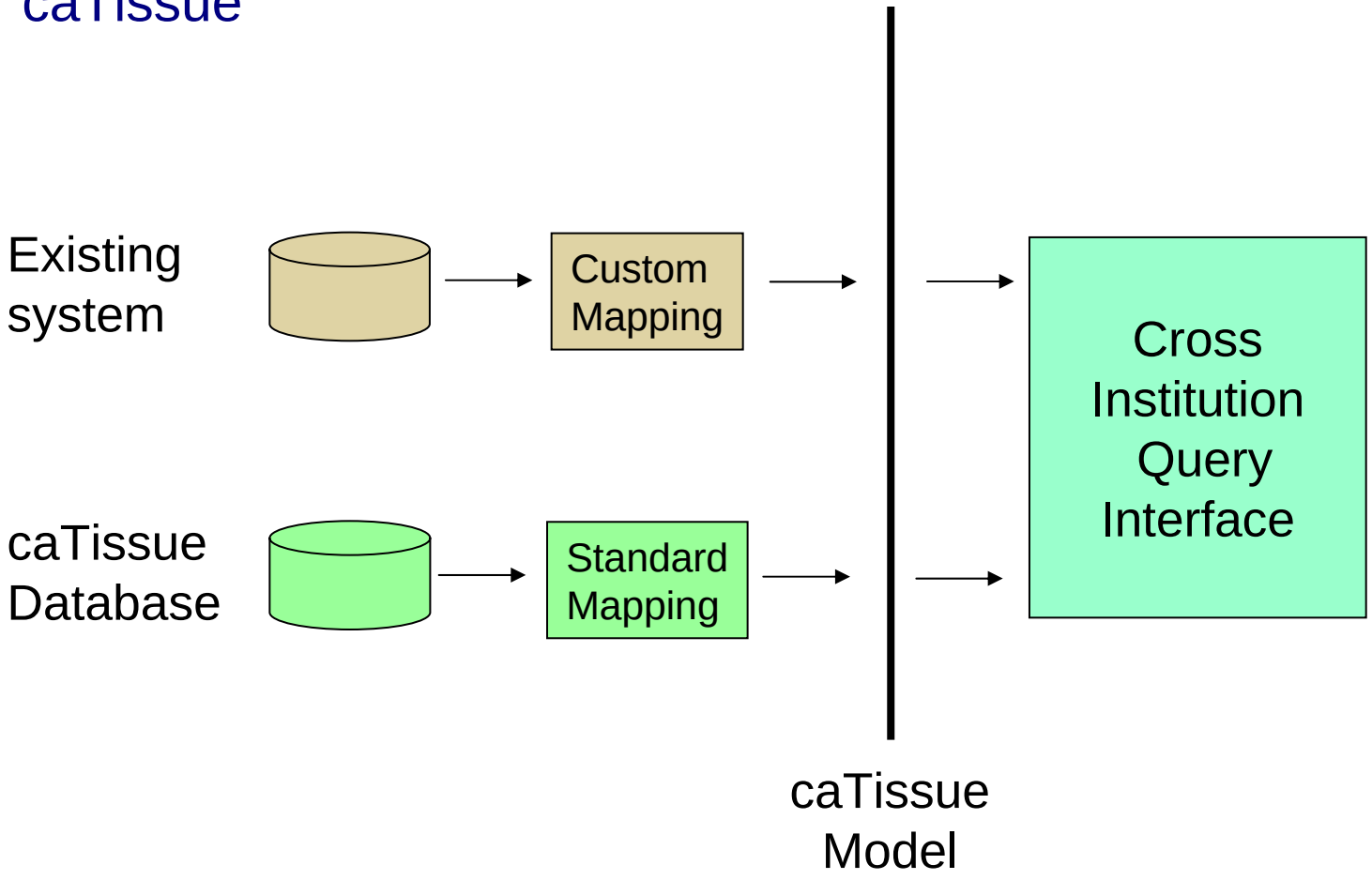
Case Study: Open Standards Integration Layer

caTISSUE Object Model

- Model to expose existing biospecimen informatics systems
- Plays well with others - via caBIG compatibility
- Modular design so that additional functionality (biological annotations, billing and financial modules, etc.) can be added without architectural redesign

caTISSUE Object Model

Allows sites to use existing/vendor solutions or adopt caTissue



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Summary

- There is no single approach to caBIG compatibility
- Existing vendor solutions have been made caBIG™ compatible relatively easily
- Open standards models for interoperability are progressing
- CDEs are being harmonized across the caBIG community
- Tools to support development of caBIG™ compatible solutions are improving and these types of implementations are getting easier