PhUSE Single Day Event

Future Trends in the Standards Landscape
Industry Case Stories

Basel, 9th March 2010

Niels Both
Standardisation and Integration Specialist

- Where are the standards today?

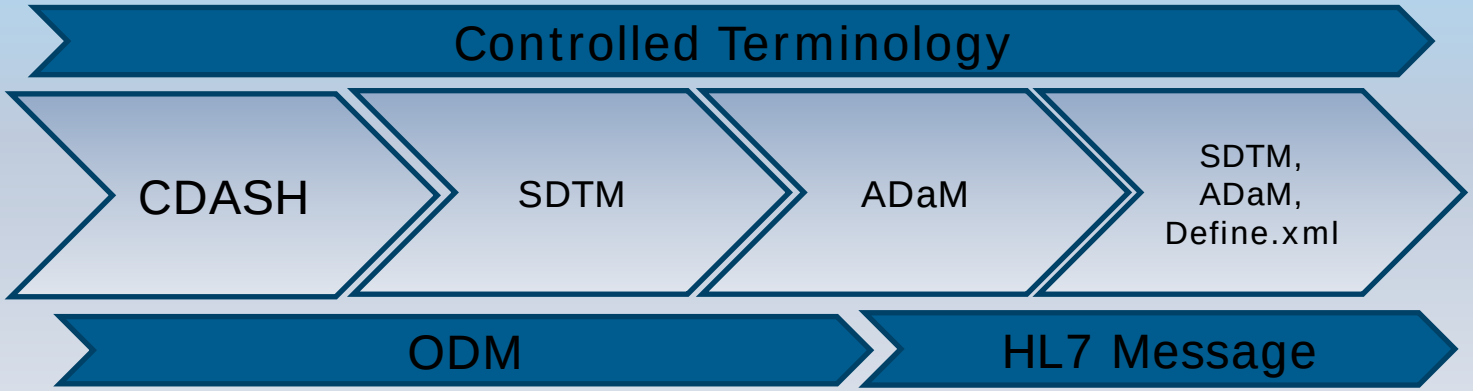
- Which trends are driving the models forward?

- What initiatives are taken to solve the issues of today?

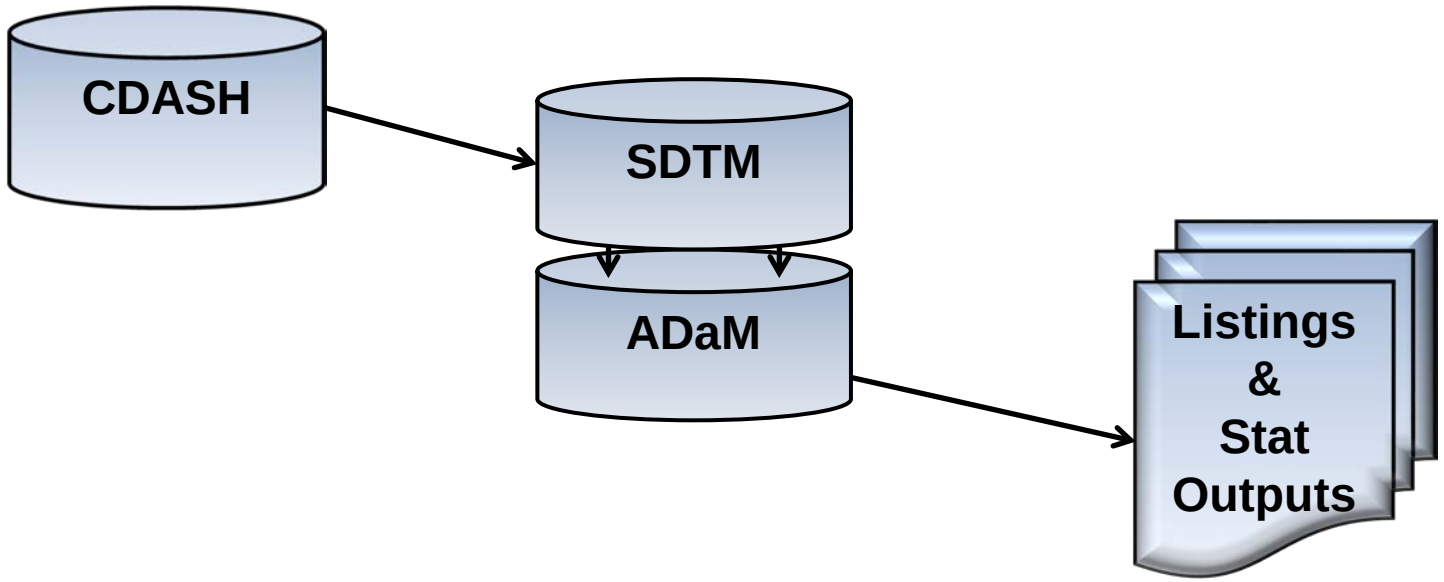
- What is the use of global standards expected to offer in the medium term?

- What is the vision for the long term?

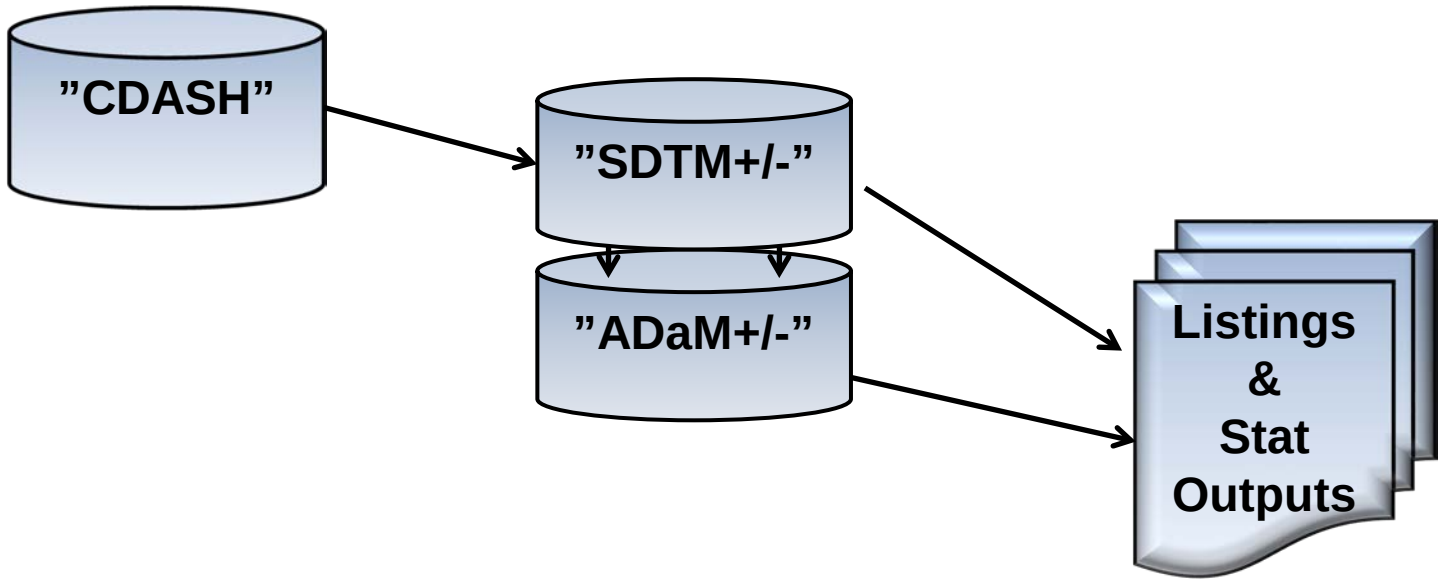
BRIDG &
Electronic Protocol Representation



Ideal View



More Realistic View



Risks in Near Future

Risks in Near Future

CDISC Trial Design Domains are currently not matured enough to use in metadata driven environment.

May change as electronic protocol standard matures.

Risks

BRIDG &
Electronic Protocol Representation

Controlled Terminology

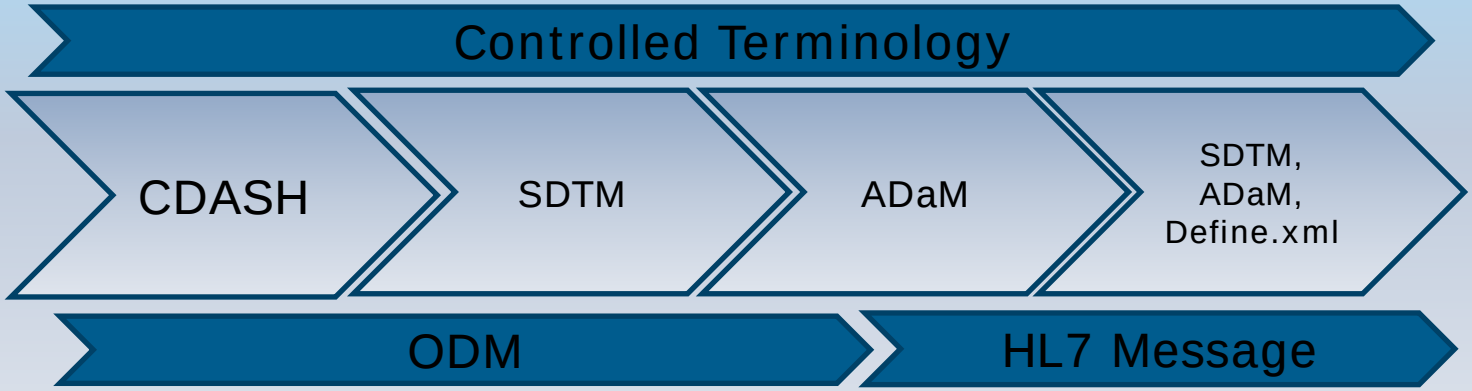
CDASH → SDTM → ADaM → SDTM, ADaM, Define.xml

ODM → HL7 Message

2013

Risks

BRIDG &
Electronic Protocol Representation



FDA has officially stated that the introduction of HL7 standards as a transport vehicle will not happen in the near future

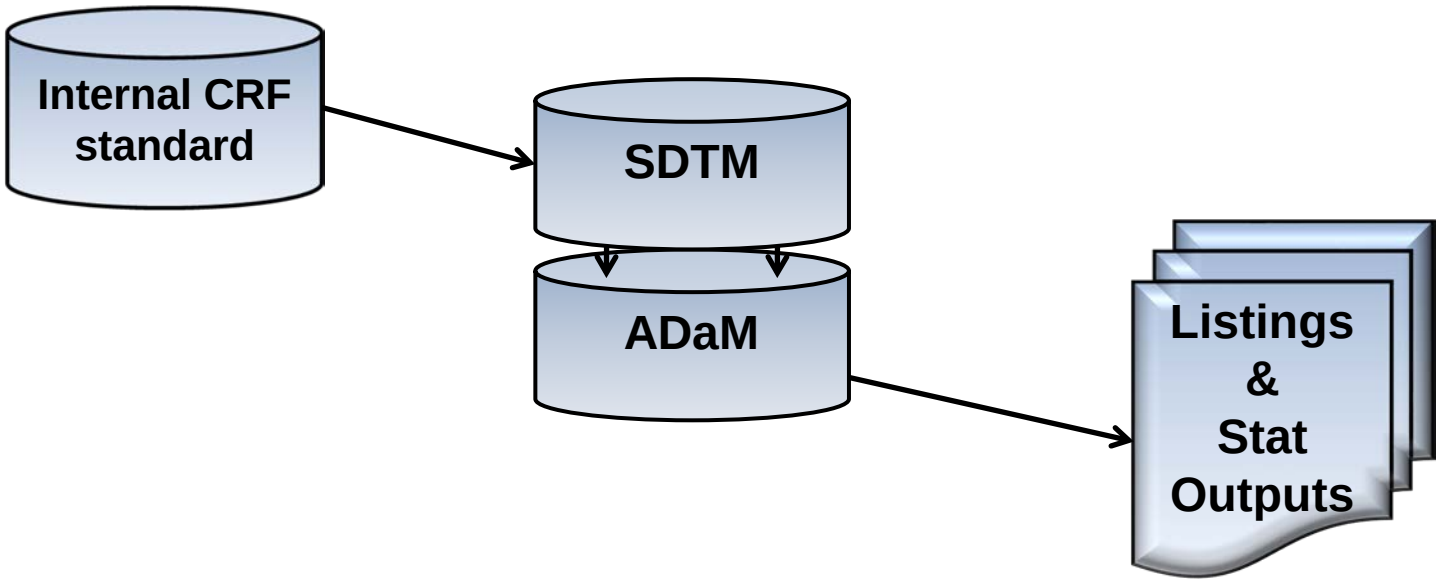
Current Trends

Regulatory requires increased transparency in the processes and data flows.

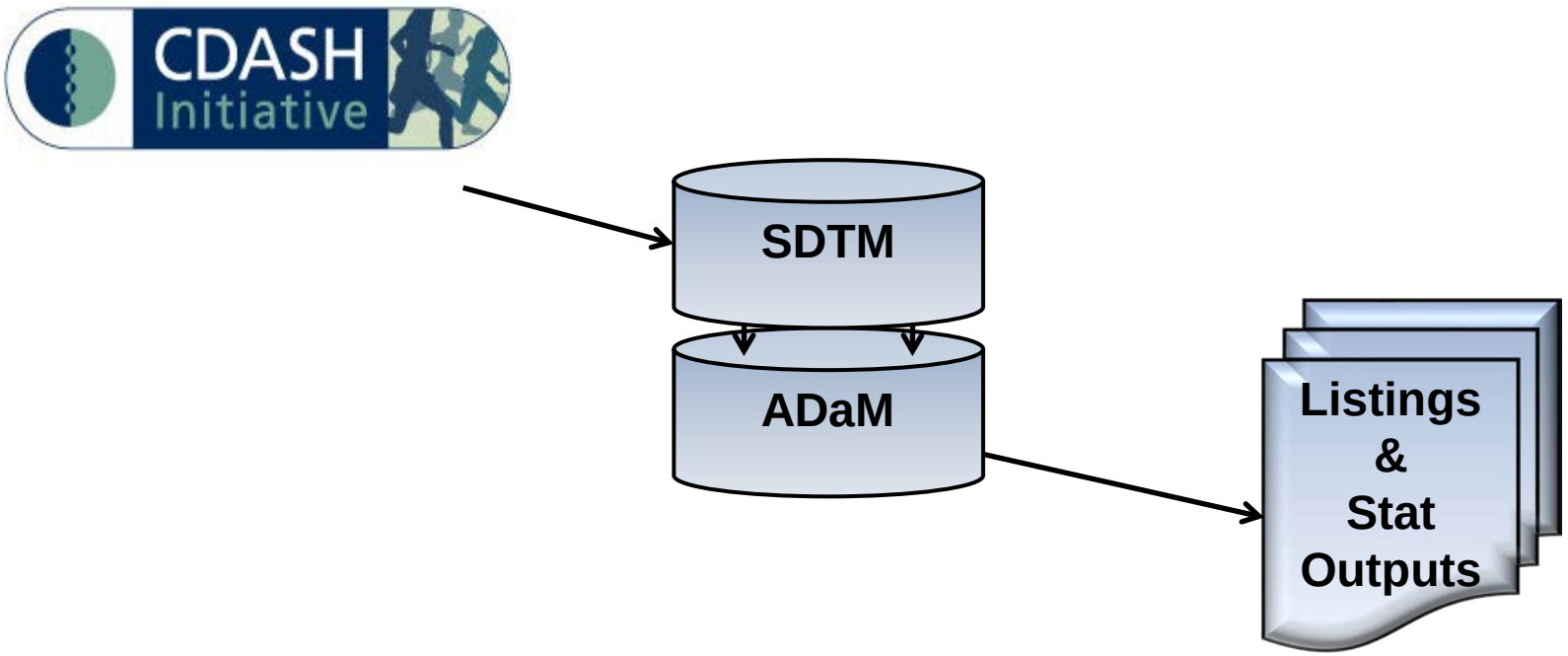
Pharma industry need to save resources and avoid costly remapping.

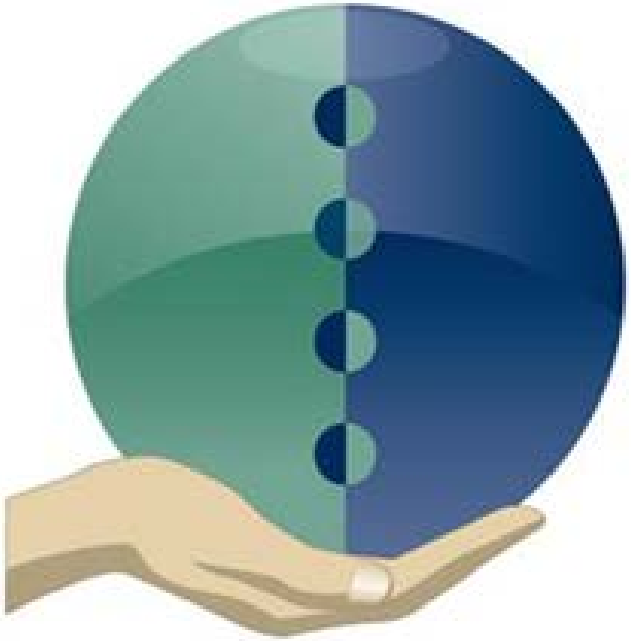
The standards – ie SDTM – need to be static, yet expand into new areas.

Current Trends



Current Trends





CDISC

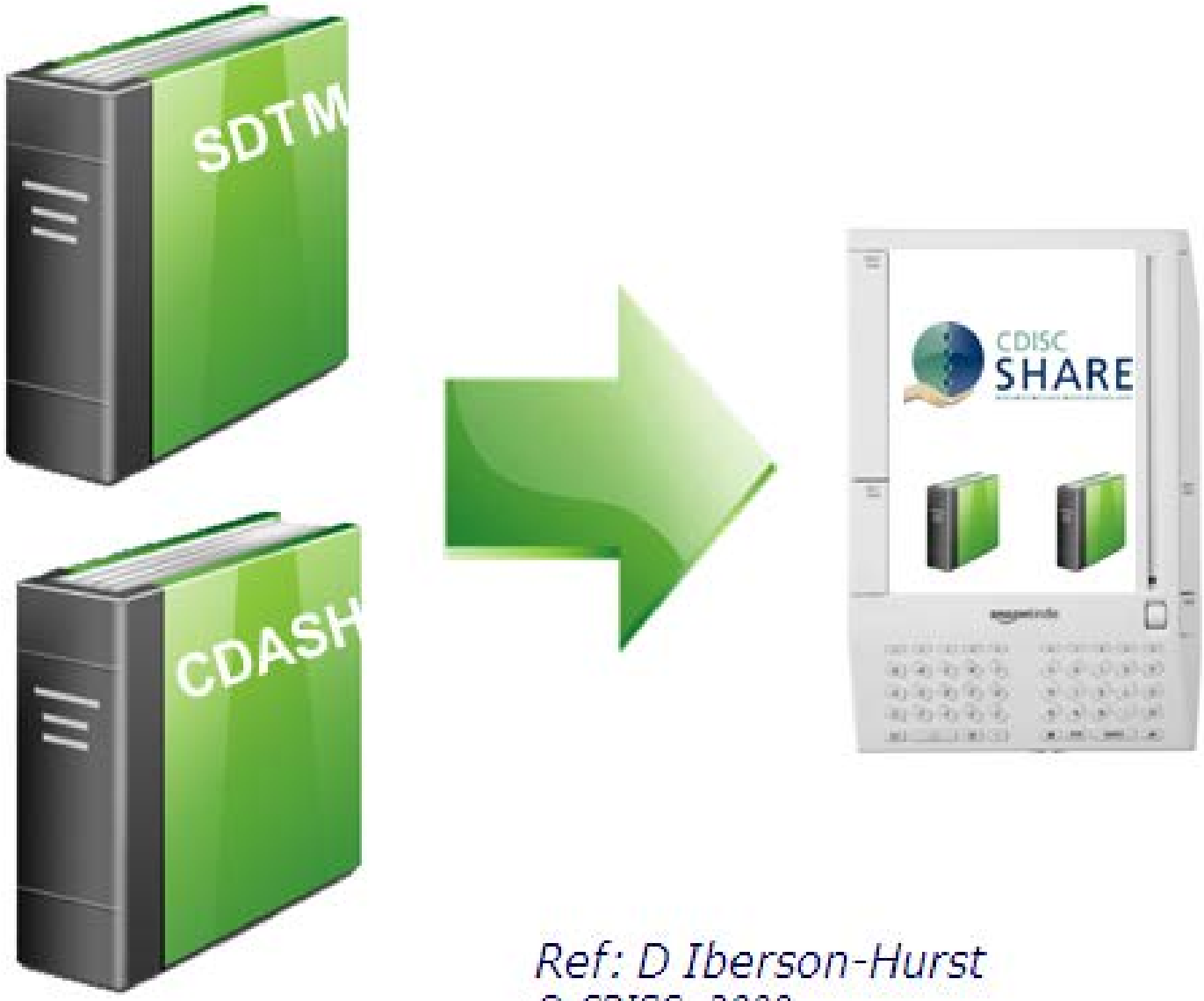
SHARE

SHARED HEALTH AND CLINICAL RESEARCH ELECTRONIC LIBRARY

Data Elements & Semantics

US Interchange, Baltimore
11th November 2009
D Iberson-Hurst

Share



Ref: D Iberson-Hurst

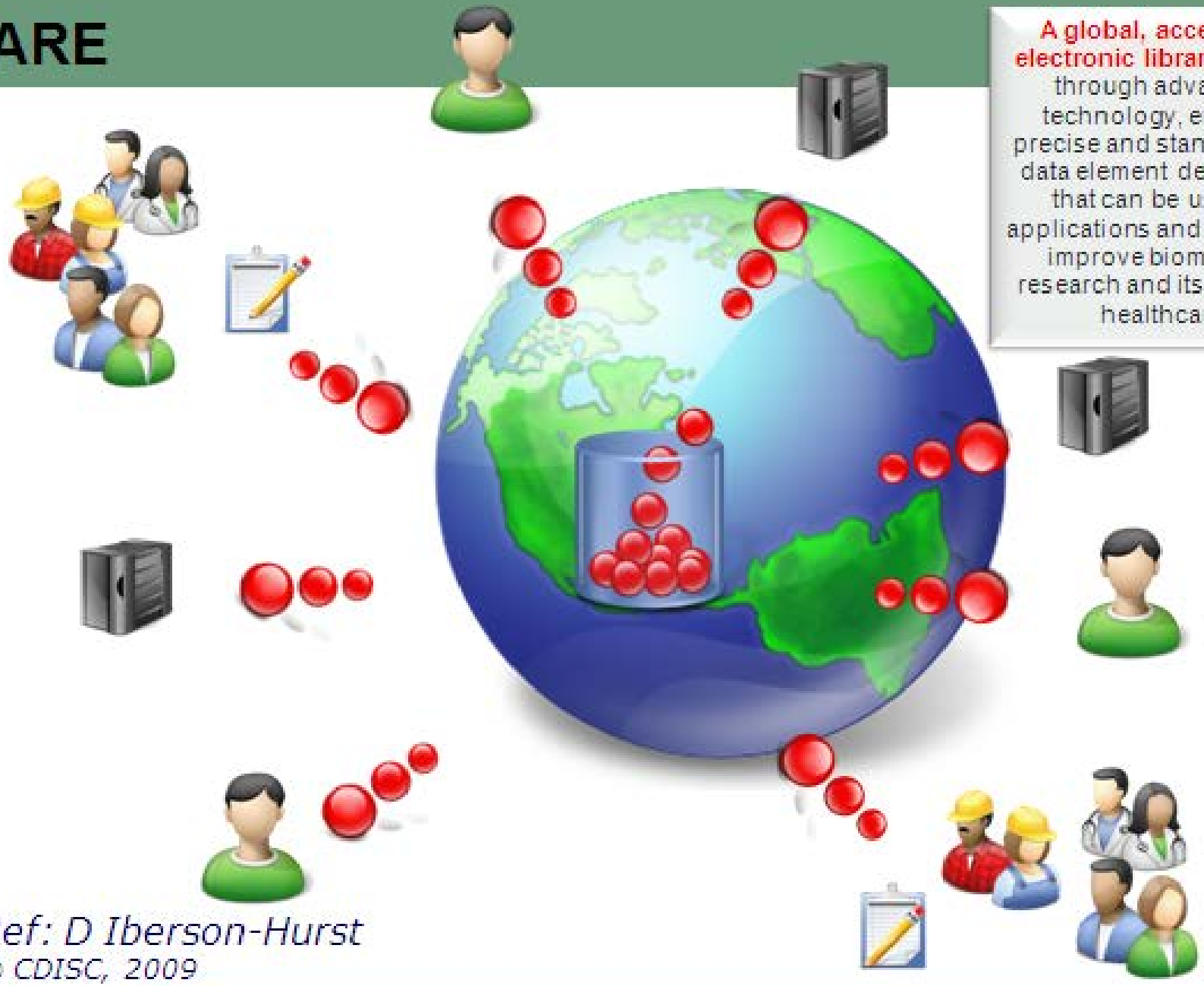
Share

Ref: D Iberson-Hurst

Share

Ref: D Iberson-Hurst

SHARE



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

Ref: D Iberson-Hurst


HOME BLOG SITE MAP FAQ CONTACT
CDISC
Strength Through Collaboration
ABOUT CDISC STANDARDS RESOURCES NEWS EDUCATION & EVENTS MEMBERSHIP MEMBERS ONLY
Setting the Global Data Standards for Medical Research
Strength through Collaboration
What's New
Follow us on Twitter
Become a CDISC Member
Become A Member
Member Log-in
forgot your password?
SHARE

CDISC

mplete our survey which
16 March 2010 at
GMT. Thank you!

ur Only

Domains Review Packages –
Review for Member Only.
your password? Click Here.

ur Only

Summary of the recent
C meeting! NEW FDA
ET OF THE Blog Post

Release 2.0.1 – Now

se of BRIDG is being taken
the ISO Joint Initiative
JIC) process which will
L7 and ISO ballots as well
r CDISC review and

cycle.

European Interchanges –
REGISTRATION NOW OPEN

You can register online and offline.
See the Interchanges page for details!

European Interchanges –
PRELIMINARY PROGRAMME

Preliminary Programme now posted!

PROTOCOL REPRESENTATION
MODEL V 1.0 – NOW
RELEASED

CDISC is pleased to announce that
the PRM V1.0 is now available for
download. >> Blog Post Here <<

CDISC SHARE – Pilot Report
Now Released

Read it now on the SHARE Page

SHARE

FDA accepts SDTM V3.1.2

Latest version of FDA Study Data

Follow us on
Twitter

Become a CDISC Member

Become A Member

Member Log-in

user name

Log In

forgot your password?

CDISC

mplete our survey which
16 March 2010 at
GMT. Thank you!

ur Only

Domains Review Packages –
Review for Members Only.
your password? Click Here.

ur Only

Summary of the recent
C meeting! NEW FDA
ET ON THE Blog Post

Release 2.0.1 – Now

ase of BRIDG is being taken
the ISO Joint Initiative
JIC) process which will
L7 and ISO ballots as well
r CDISC review and
t cycle.

European Interchange –
REGISTRATION NOW OPEN

You can register online and offline.
See the Interchange page for details!

European Interchange –
PRELIMINARY PROGRAMME

Preliminary Programme now posted!

PROTOCOL REPRESENTATION
MODEL V 1.0 – NOW
RELEASED

CDISC is pleased to announce that
the PRM V1.0 is now available for
download. >> Blog Post Here <<

CDISC SHARE – Pilot Report
Now Released

Read it now on the SHARE Page

SHARE

FDA accepts SDTM V3.1.2
latest version of FDA Study Data

Follow us on
Twitter

Become a CDISC Membe

Become A Member

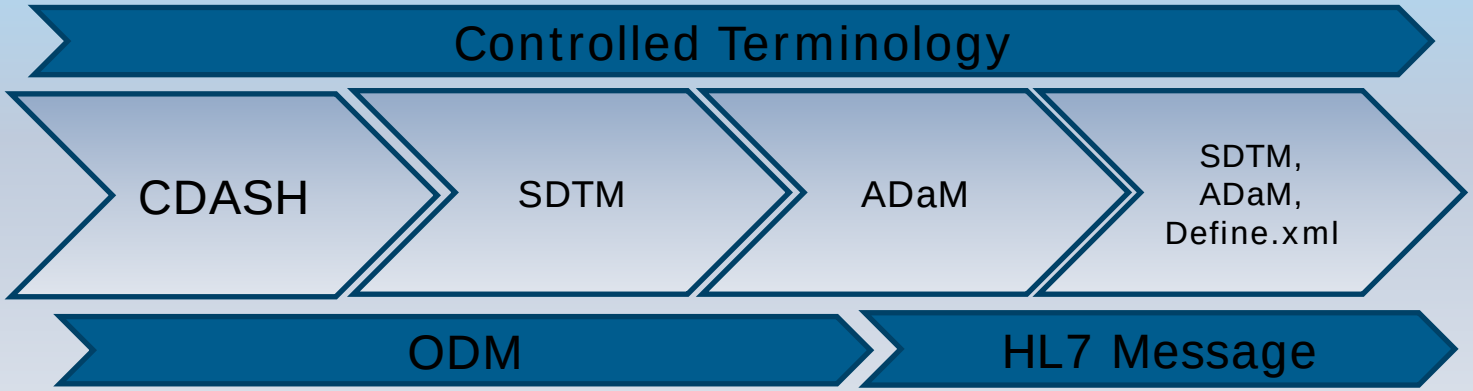
Member Log-in

user name

Log In

forgot your password?

BRIDG &
Electronic Protocol Representation



Electronic Protocol Representation:

Example

3.1. Summary of Study Design

This is a prospective, randomized, double-blind, double-dummy, placebo controlled, forced-titration, multicenter, parallel group trial. Stage I or II hypertensive patients, age 18 years of age or older, who meet all other inclusion and exclusion criteria and successfully complete the placebo run-in period will be randomized at the site level.

Electronic Protocol Representation:

Example

3.1. Summary of Study Design

This is a prospective, randomized, double-blind, double-dummy, placebo controlled, forced-titration, multicenter, parallel group trial. Stage I or II hypertensive patients, age 18 years of age or older, who meet all other inclusion and exclusion criteria and successfully complete the placebo run-in period will be randomized at the site level.

Degree of blind

Electronic Protocol Representation:

Example

3.1. Summary of Study Design

This is a prospective, randomized, double-blind, double-dummy, placebo controlled, forced-titration, multicenter, parallel group trial. Stage I or II hypertensive patients, age 18 years of age or older, who meet all other inclusion and exclusion criteria and successfully complete the placebo run-in period will be randomized at the site level.

Diagnosis

Electronic Protocol Representation:

Example

3.1. Summary of Study Design

This is a prospective, randomized, double-blind, double-dummy, placebo controlled, forced-titration, multicenter, parallel group trial. Stage I or II hypertensive patients, age 18 years of age or older, who meet all other inclusion and exclusion criteria and successfully complete the placebo run-in period will be randomized at the site level.

Age Criteria

Advanced Search - ClinicalTrials.gov - Mozilla Firefox

File Edit View History Bookmarks Tools Help

http://clinicaltrials.gov/ct2/search/advanced

CT Advanced Search - ClinicalTrials.gov

ClinicalTrials.gov

A service of the U.S. National Institutes of Health

Home

Basic Search | Advanced Search | Studies by Topic | Studies on Map

Fill in any or all of the fields below.

Click on a label to the left for further explanation or read the Help.

Search Terms: depression Search Help

Recruitment: All Studies

Study Results: Studies With Results

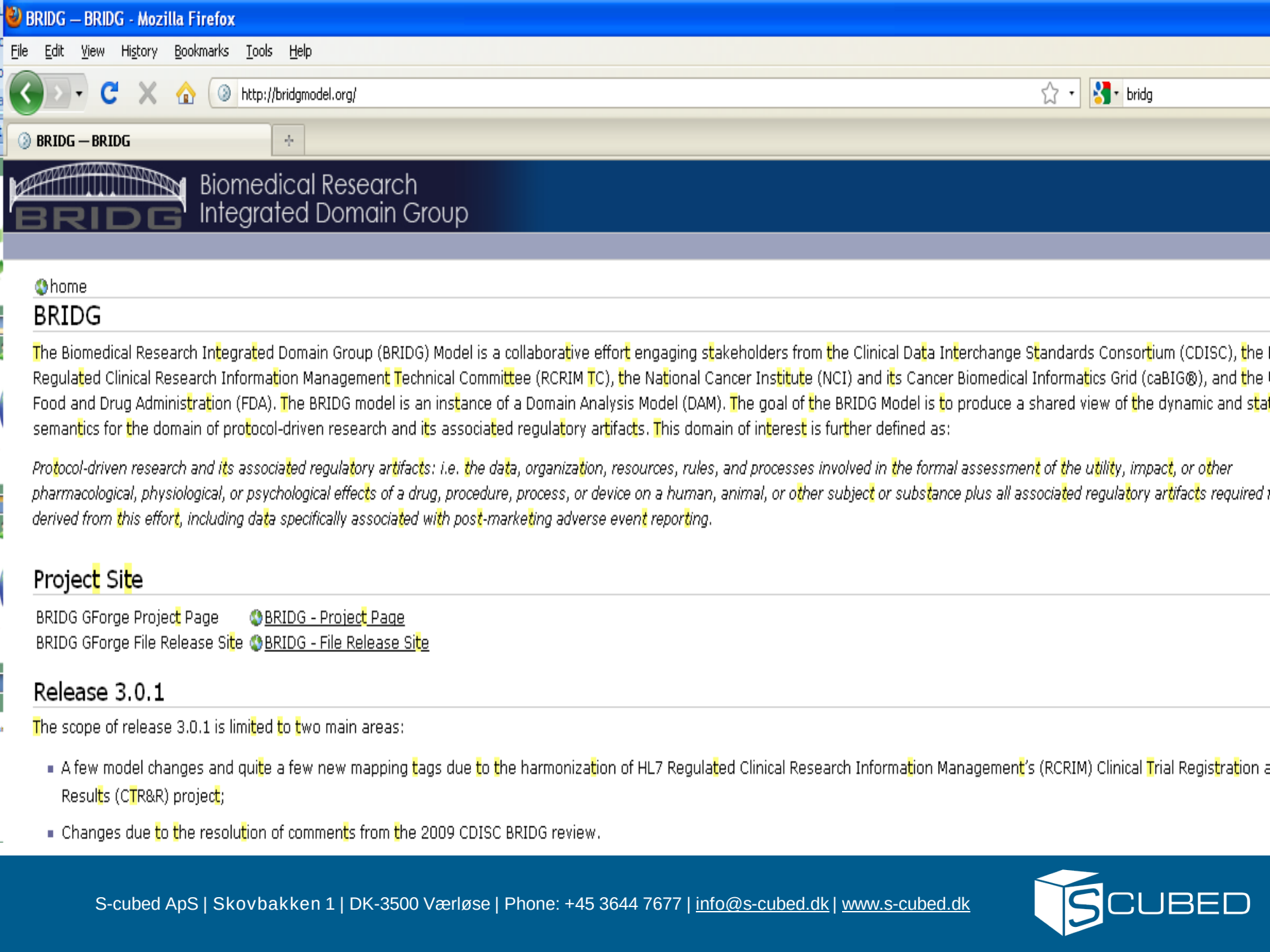
Study Type: Interventional Studies

List Results | Refine Search | Results by Topic | Results on Map | Search Details

Found 71 studies with search of: depression | Studies With Results | Interventional Studies

Hide studies that are not seeking new volunteers.

Rank	Status	Study
1	Completed Has Results	Study Of Bupropion SR (323U66) In Patients With Major Depressive Disorder In Japan Condition: Major Depressive Disorder (MDD) Intervention: Drug: 323U66 SR
2	Completed Has Results	Study In Patients With Depression Not Responding to Selective Serotonin Re-uptake Inhibitors Condition: Major Depressive Disorder (MDD) Interventions: Drug: Placebo; Drug: 323U66 (Bupropion Hydrochloride Sustained Release)
3	Completed Has Results	Magnetic Resonance Imaging Study of Geriatric Depression Condition: Major Depressive Disorder Intervention: Drug: Sertraline
4	Completed Has Results	Treatment for Post-Stroke Depression Conditions: Stroke; Depression Intervention: Other: case management
5	Completed Has Results	The Effects Of Ropinirole On Mood Or Mild Depression In Patients With Moderate To Severe Restless Legs Syndrome Condition: Moderate to Severe Idiopathic Restless Legs Syndrome (RLS)


BRIDG – BRIDG - Mozilla Firefox
File Edit View History Bookmarks Tools Help
http://bridgmodel.org/
bridg
BRIDG – BRIDG
BRIDG
Biomedical Research
Integrated Domain Group
home
BRIDG
The Biomedical Research Integrated Domain Group (BRIDG) Model is a collaborative effort engaging stakeholders from the Clinical Data Interchange Standards Consortium (CDISC), the
Regulated Clinical Research Information Management Technical Committee (RCRIM TC), the National Cancer Institute (NCI) and its Cancer Biomedical Informatics Grid (caBIG®), and the
Food and Drug Administration (FDA). The BRIDG model is an instance of a Domain Analysis Model (DAM). The goal of the BRIDG Model is to produce a shared view of the dynamic and stat
semantics for the domain of protocol-driven research and its associated regulatory artifacts. This domain of interest is further defined as:
Protocol-driven research and its associated regulatory artifacts: i.e. the data, organization, resources, rules, and processes involved in the formal assessment of the utility, impact, or other
pharmacological, physiological, or psychological effects of a drug, procedure, process, or device on a human, animal, or other subject or substance plus all associated regulatory artifacts required
derived from this effort, including data specifically associated with post-marketing adverse event reporting.
Project Site
BRIDG GForge Project Page
BRIDG - Project Page
BRIDG GForge File Release Site
BRIDG - File Release Site
Release 3.0.1
The scope of release 3.0.1 is limited to two main areas:
A few model changes and quite a few new mapping tags due to the harmonization of HL7 Regulated Clinical Research Information Management's (RCRIM) Clinical Trial Registration
Results (CTR&R) project;
Changes due to the resolution of comments from the 2009 CDISC BRIDG review.

Long Term Vision

Connect CRF Systems and Electronic Health Care Systems:

The Biomedical Research Integrated Domain Group (BRIDG) Model is a collaborative effort engaging stakeholders from the Clinical Data Interchange Standards Consortium (CDISC), the HL7 Regulated Clinical Research Information Management Technical Committee (RCRIM TC), the National Cancer Institute (NCI) and its Cancer Biomedical Informatics Grid (caBIG®), and the US Food and Drug Administration (FDA).

Long Term Vision

Connect CRF Systems and Electronic Health Care Systems:

Imagine collection of Medical History:

Initially a doctor enters it into a Health Care system.

Years later an investigator manually transfers it to the CRF system during a clinical trial.

This is then carefully checked by a CRA and cleaned by Data Managers

Long Term Vision