



Setting the
Global Standard
for Clinical Data

CDISC – Réunion du Groupe Utilisateurs Francophones

**CLINICAL DATA INTERCHANGE
STANDARDS CONSORTIUM**

20 juin 2008 – Bagneux - France

Agenda

- Présentation des participants, compte-rendu de la dernière réunion et Informations récentes sur CDISC
 - Pierre-Yves Lastic (sanofi-aventis)
- Le Modèle BRIDG
 - Introduction par Nadji El Fadly et Christel Daniel (APHP / INSERM)
- Retour sur l’EuroInterchange de Copenhague
 - Présentation de Laurence Le Lann et Hélène Savoye (Biostatistique, sanofi-aventis)
 - Autres faits marquants retenus par les participants: tour de table
- Mapping ODM / SDTM
 - Nicolas de Saint-Jorre (Quanticsoft)
- Prochaines étapes, organisation du groupe, etc
 - tous

Compte-rendu de la réunion du GUF CDISC à Copenhague le 22/04/2008 (1/2)

- Rappel de l'évolution du groupe francophone CDISC
 - Groupe de travail au sein de DMB au départ (2001),
 - journées CDISC en septembre 2003 et en juin 2004, session au sein de l'EuroInterchange d'avril 2005
 - Relancement en temps que groupe d'utilisateurs au sein du réseau global des utilisateurs CDISC en 2007
 - Aujourd'hui : 65+ inscrits
- Objectifs du groupe :
 - promotion des standards
 - discussion avec CDISC.ORG
- Programme de la prochaine réunion (face to face – fin mai début juin – date à définir) :
 - présentation de CDISC/APHP
 - retour de la conférence CDISC
 - présentation de BRIDG (qui doit devenir un standard ISO)
 - mapping ODM - SDTM – CRTDDS

Compte-rendu de la réunion du GUF CDISC à Copenhague le 22/04/2008 (2/2)

- ‘Standard Protocol’ : sortie au 3T2008
- Il existe un portail pour le french user group : portail d’échanges et de publication des documents. Ouverture prochaine.
 - Avoir accès aux documents sans être membre d’un groupe : NON
 - Process d’inscription : bientôt sur le site. Il sera possible de contacter directement les responsables des différents standards.
- **Information** : Les commentaires concernant le modèle CDASH sont à envoyer à Nicolas de Saint Jorre avant le 7 mai 2008.

CLINICAL DATA INTERCHANGE STANDARDS CONSORTIUM

Announcements

There are currently no active announcements.

Events

There are currently no upcoming events.

CDISC Mission Statement

The mission of CDISC is to develop and support global, platform-independent data standards that enable information system interoperability to improve medical research and related areas of healthcare.

News

There are currently no active announcements.



View All Site Content

Discussions

- Team Discussion

Documents

- Summary (projects or other summaries)
- Meeting Agendas & Minutes
- Working Documents
- Approved Documents
- Presentations
- All Other Documents

Lists

- Calendar
- Tasks
- Contact List

Sites

- Asia
- Europe
- North America

Surveys

- Survey

People and Groups

-  **Recycle Bin**

Home Portal > Global User Networks

CDISC Global User Networks

Announcements 

Global User Network Portals

4/7/2008 1:47 PM

by fnewby

The CDISC Global User Network portals are in development. An announcement will be made via the CDISC newsletter as well as here when the portals are active. Thanks for you patience while we create this new shared environment!

-  Add new announcement

Calendar 

There are currently no upcoming events. To add a new event, click "Add new event" below.

-  Add new event



Links 

There are currently no favorite links to display. To add a new link, click "Add new link" below.

-  Add new link



Presentations

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 - Survey
- People and Groups**
- Recycle Bin**

New | Upload | Actions

View: **All Documents**

Type	Name	Modified	Modified By
	20080401 CDISC APHP	4/11/2008 11:39 AM	pyveslastic
	CDISC Grpe Francophone Ipsen 05 Feb 2008 final	4/11/2008 11:35 AM	pyveslastic
	CDISC GUF Meeting 05-02-2008	4/11/2008 11:35 AM	pyveslastic
	CDISC update December 2007 - January 2008 - pyl	4/11/2008 11:35 AM	pyveslastic
	Clinical Data Acquisition Standards Harmonization (CDASH)	4/11/2008 11:35 AM	pyveslastic
	SDTM and ADaM Data Flow - user experiences	4/11/2008 11:35 AM	pyveslastic
	SDTM and ADaM Data Flow_general	4/11/2008 11:35 AM	pyveslastic



Contact List

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New

Actions

View: **All contacts**

👤	Last Name	First Name	Company	Business Phone	Home Phone	E-mail Address
	Abousahl	Isabelle		+33 1 60 92 94 16		mailto:isabelle.abousahl@ipsen.com
	Ackermann	Isabelle				mailto:i.ackermann@theriamis.com
	Bellachen	Gilbert		+33 4 93 00 88 98		mailto:gilbert.bellachen@oracle.com
	Bougard	Christel				mailto:cbougard@4clinics.com
	Cabane	Vincent		+33 6 71 28 28 88		mailto:vcabane@kikamedical.com
	Campain-Teulon	Elisabeth		+33 1 60 92 94 18 +33 6 89 30 29 98		mailto:elisabeth.campain-teulon@ipsen.com
	Cauquil	Joris		+33 5 63 61 30 35		mailto:joris.cauquil@free.fr
	Charpentier	Noémie				mailto:noemie.charpentier@sanofi-aventis.com
	Culot	Patrick		+32 2 386 25 22		mailto:patrick.culot@ucb-group.com
	Daniel	Christel		+33 6 60 48 41 33		mailto:Christel.daniel@spim.jussieu.fr
	De Saint-Jorre	Nicolas		+33 6 03 34 22 28		mailto:n.de-saint-jorre@quanticssoft.fr
	Debondt	Joris				mailto:joris.debondt@sgs.com
	Declodt	Griet		+32 479203336		mailto:gdeclodt@clintec.com
	Delamarre	Dominique		+33 238618335		mailto:dominique.delamarre@parexel.com
	El Fadly	Naji		+33 6 27 20 53 57		mailto:nelfadly@yahoo.fr
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	Fourtillan	Mathieu		+33 5 56 40 77 45		mailto:mathieu.fourtillan@clinsight.fr
	Gautier	Franck				mailto:Franck.Gautier@sanofi-aventis.com
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	Le Beaudour	Christelle				mailto:Christelle.Le-Beaudour@sanofi-aventis.com
	Le Mouhaër	Jeannie		+33 1 40 21 19 04		mailto:j.lemouhaer@cardinal-sys.com
	Le-Labourier	Lucile				mailto:Lucile.Le-Labourier@sanofi-aventis.com
	Lemouroux	Erwan				mailto:Erwan.Lemouroux@sanofi-aventis.com
	Lucas	Maël		+33 1 56 00 30 00		mailto:mael.lucas@sanofi-aventis.com



Calendar

Use the Calendar list to keep informed of upcoming meetings, deadlines, and other important events.

New | Actions

View: **Calendar**

April, 2008

Expand All Collapse All | Day **7** Week **31** Month

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
30	31	1 2:00 PM Introduction à CDISC à l'APHP	2	3	4	5
6	7	8	9	10	11	12
13	14	15	16	17	18	19
20	21	22 5:00 PM Réunion du Groupe Utilisateurs Francophones	23 Conférence CDISC EuroInterchange		24	25
26	27	28	29	30	1	2
						3

◀ **2008** ▶

Jan Feb Mar
Apr May Jun
 Jul Aug Sep
 Oct Nov Dec

Today is
Friday, June 20, 2008

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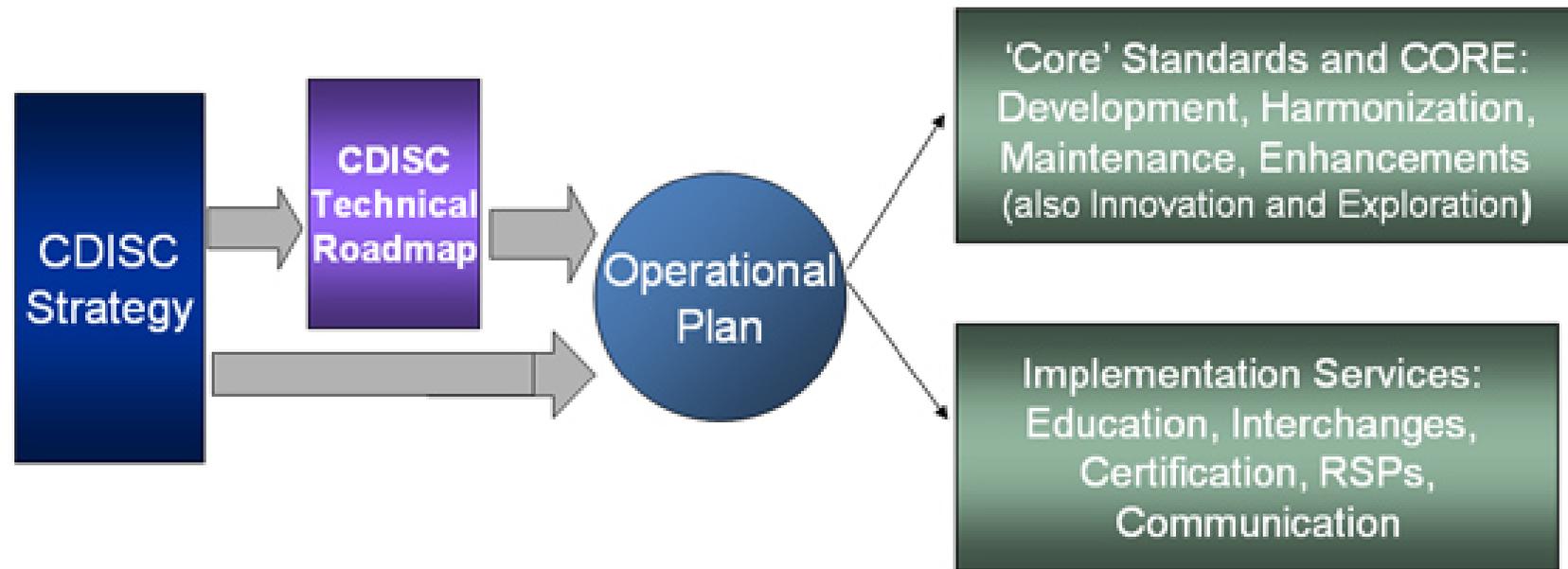
People and Groups

Recycle Bin

Last News

- **ADaM Implementation Guide v1.0 Draft for Public Comment**
Analysis Data Model v2.1 Draft for Public Comment
The ADaM Implementation Guide, Version 1.0 (ADaMIG v1.0), and the Analysis Data Model, Version 2.1 (ADaM v2.1), have been released by the CDISC Analysis Data Model (ADaM) Team for public review and comment.
- Reviewers are asked to submit comments by the close of business on Friday, September 5, 2008. Final versions are expected to be released by early 2009

CDISC Strategy to Implementation and Support



Strategy
2008 (+5y)
Document

Technical
Roadmap
Document

Operational
Goals 2008

See CDISC Website for more Information:
– Standards, Education, Events,
Procedure for Standards Development,
Registered Solution Providers (RSP),
ODM Certification, Publications.....

CDISC 2008 International Interchange

**Marriott Crystal Gateway,
Arlington, VA, USA**

Training:

26-27, 30-31 Oct 2008

Conference:

28 Oct 13:00-17:00

29 Oct 08:30-17:00

30 Oct 08:30-12:00

CALL FOR ABSTRACTS

The Interchange Program Committee is now accepting abstracts for presentations for the CDISC 2008 International Interchange to be held in Arlington, Virginia, USA, the week of 26 October.

Several sessions are planned with oral presentations lasting between 20 and 30 minutes. CDISC would like to receive abstracts in areas such as the following, or any area related to standards for medical research and healthcare, including terminology.

Implementation of CDISC standards

Adoption of CDISC models (Pharma, CRO, Biotech, Lab, and Medical Devices). Case studies and lessons learned.

SDTM & ADaM & define.xml

Practical use of SDS/SDTM and ADaM. Migration of legacy standards data to submission ready SDTM and ADaM datasets and define.xml. Lessons-learned and case studies.

SDTM & CDASH used in EDC Data acquisition

Use of and experience with CDASH forms and/or usage of SDTM domains and controlled terminology within EDC technology.

Vendor Applications and Tools

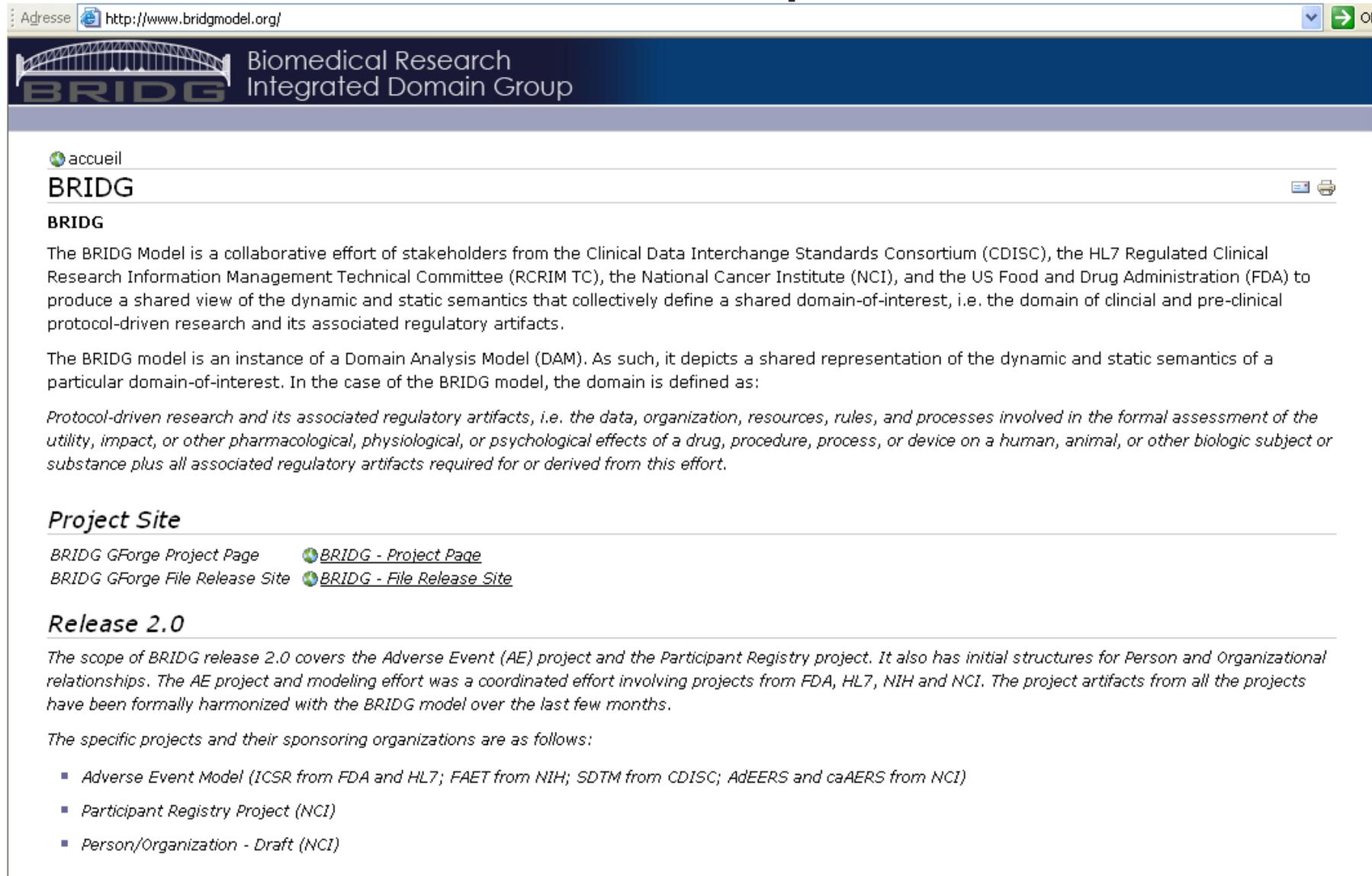
Applications and tools for data migration, data integration, compliance check with CDISC models, define.xml setup etc.

Demonstration of data integration using CDISC models (up to end-to-end integration), e.g. EDC-forms, ePRO, central lab, ECG lab, device data.

eSource and eHealth

The integration of clinical research and healthcare systems, interoperability between CDISC and HL7 standards. Case studies of any integration used for clinical trials with lessons learned. Integration at one centre/hospital and / or several centres/hospitals.

BRIDG Release 2.0 is posted



The screenshot shows a web browser window with the address bar displaying "http://www.bridgmodel.org/". The website header features the BRIDG logo and the text "Biomedical Research Integrated Domain Group". The main content area includes a navigation menu with "accueil" and "BRIDG". The "BRIDG" section contains a description of the BRIDG Model as a collaborative effort of stakeholders from CDISC, HL7, NCI, and FDA. It also includes a definition of the BRIDG model as a Domain Analysis Model (DAM) and a detailed description of protocol-driven research. Below this, there is a "Project Site" section with links to the BRIDG GForge Project Page and BRIDG GForge File Release Site. The "Release 2.0" section describes the scope of the release, covering the Adverse Event (AE) project and the Participant Registry project, and lists the specific projects and their sponsoring organizations.

Adresse  http://www.bridgmodel.org/   

 Biomedical Research
Integrated Domain Group

 accueil

BRIDG  

BRIDG

The BRIDG Model is a collaborative effort of 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 the US Food and Drug Administration (FDA) to produce a shared view of the dynamic and static semantics that collectively define a shared domain-of-interest, i.e. the domain of clinical and pre-clinical protocol-driven research and its associated regulatory artifacts.

The BRIDG model is an instance of a Domain Analysis Model (DAM). As such, it depicts a shared representation of the dynamic and static semantics of a particular domain-of-interest. In the case of the BRIDG model, the domain is 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 biologic subject or substance plus all associated regulatory artifacts required for or derived from this effort.

Project Site

BRIDG GForge Project Page  [BRIDG - Project Page](#)
BRIDG GForge File Release Site  [BRIDG - File Release Site](#)

Release 2.0

The scope of BRIDG release 2.0 covers the Adverse Event (AE) project and the Participant Registry project. It also has initial structures for Person and Organizational relationships. The AE project and modeling effort was a coordinated effort involving projects from FDA, HL7, NIH and NCI. The project artifacts from all the projects have been formally harmonized with the BRIDG model over the last few months.

The specific projects and their sponsoring organizations are as follows:

- *Adverse Event Model (ICSR from FDA and HL7; FAET from NIH; SDTM from CDISC; AdEERS and caAERS from NCI)*
- *Participant Registry Project (NCI)*
- *Person/Organization - Draft (NCI)*

CDISC vLearning Course

- Voir document pdf envoyé séparément

Plan d'actions

- Sujets
 - BRIDG: version “exemplifiée” de niveau plus abordable (Nadji, Christel, PYL)
 - Jérôme Paget: présentation de PROC CDISC
 - Jérôme & Nicolas: exemple d'upload d'ODM et mapping SDTM
 - Faire présentation CDISC de base (DMB M. Maspéro, SA MRP JLS)
 - Formations d'une demi-journée plus approfondies (SDTM, ADaM, SDTM dans BRIDG, LAB en version HL7)
 - CDASH: retour post-commentaires
 - PYL & Fabien: préparer pique de rappel à l'APHP
- Feedback pour CDISC
 - Documentation du workshop legacy data (PYL)
 - Pour le 5 septembre, commentaires nouvelle version d'ADaM (MR Peltier, L LeLann SFDS)

Prochaines Réunions

- 28/07 14-16h
 - Téléconférence
- 22/09 14-16h
 - Téléconférence
- 09/10 14-17h
 - Réunion: l'APHP, Paris
- 17/11 10-16h30
 - Réunion: sanofi-aventis, Bagneux
- 15/12 14-16h
 - Téléconférence