

CDISC 2011 Operational Goals



Strength through Collaboration

CDISC Vision

**Informing patient care and safety through
higher quality medical research**



Strength through Collaboration

CDISC Operations 2011 Goal #1

Position CDISC in new ways; enhance CDISC business model/'enterprise architecture'. (ST 5)

Bring the new vision alive through example, CDISC values, communications, new projects and other means.

- Create an Enterprise Architecture model/diagram that works for CDISC and conveys CDISC strategy.
- Develop strategic business plan for CDISC that complements other key CDISC planning.
- Assess then revise and/or develop COPs to improve/enhance CDISC processes.
- Work with legal counsel to apply to IRS to change CDISC from a 501(c)(6) to 501(c)(3) non-profit organization.
- Secure new market opportunities and revenue opportunities.
- Evaluate location and timing for registering CDISC in Europe; extend CDISC EU Collaborations (IMI, CEN).
- Ensure resource capacity to enable realization of new Vision, while ensuring ensuring funding to support additional staff.

CDISC Operations 2011 Goal #2

Continue to refine, support and educate on existing safety standards, while rapidly expanding and streamlining development of efficacy standards. (ST 1,2,5)

- Support and provide leadership for all terminology development to support CDISC standards.
- Ensure posting of terminology public review package on website within 2 weeks of the end of each quarter.
- Train, manage and support C-Path employees.
- Complete and publish Alzheimer's IG, Terminology IG, others as applicable.
- Support Alzheimer's project, Parkinson's project, CV project, Pain project and other Specialty Area development projects.
- Launch and socialize SHARE.
- Support FDA needs, e.g. Legacy Data Conversion.
- Evaluate, document and refine best practices and streamline development of disease/specialty area (SA/efficacy) standards.

CDISC Operations 2011 Goal #2

(continued)

- Revise Technical Roadmap.
- BRIDG - Continue to support JIC/ISO BRIDG activities and support BRIDG with SCC (and BRIDG Board).
- Implement ANSI Comments tool to improve process of collecting comments on SA standards.
- Harmonize semantics for statistics and Study Design and resolve gaps in ODM SDM/HL7Study Design.
- Revise Registered Solution Provider (RSP) process.
- Support dissemination of information about new standards.
- Support FDA communication efforts.
- Provide private CDISC training sessions as requested.
- Establish framework for Asian training team.
- Deliver authorized training in at least one new region.
- Develop new training course for Terminology.

CDISC Operations 2011 Goal #3

Extend the value of using ‘standards from the start’, building upon the Protocol Representation/Study Design Model, CDASH, ODM, Healthcare Link. (ST1,3)

- Continue work in support of Healthcare Link goals - Initiate a research study using EHRs at some sites, along with ODM, CDASH, RFD.
- Create opportunities through IHE for developing, testing and demonstrating research uses of EHRs.
- Support the CDISC portion of the SHARP grant; introduce RPE profile.
- Organize Interoperability Showcase at DIA.
- Support Protocol Representation Team; create spreadsheet with elements from BRIDG and template/tool.
- Publish ODM Study Design Model standard and communicate.
- Produce ODM files; CRF Examples.
- CDASH: Produce User Guide.

CDISC Operations 2011 Goal #4

Increase global reach and value to CDISC stakeholders - Qualify global opportunities.

(ST1-5)

- Continue collaboration management with key stakeholders in China.
- Continue CDISC structure for supporting and communicating with User Networks; implement User Network Policy.
- Ensure satisfaction of members, resulting in retention of existing members (at least 85% of total).
- Successfully facilitate new membership restructuring and related correspondence.
- Continue to explore CDISC value to members and increase this per survey results (NA Interchange 2010, EU Interchange 2011).
- Strengthen ties with C3C.
- Support the CDISC Advisory Board.
- Report on membership quarterly.

CDISC Operations 2011 Goal #5

Expand Communications initiatives to position CDISC in a new light per the CDISC Vision (ST 4,5)

- *Create and distribute CDISC Report (pending)*
- Modify and maintain the CDISC website, ensuring that it clearly conveys that CDISC is more than standards; support key messages for 2011.
- Use press releases to convey key messages – 15 in 2011
- Continue regular eNewsletters
- Produce CDISC publication of articles
- Conduct successful, valuable and profitable Events (e.g. Interchanges and others)
- Complete article on CDISC value and adoption.
- Reach and educate new audiences.
- Offer 'road shows' (CDISC Days) in the U.S.

CDISC Operations 2011 Goal #6

Develop means to facilitate tracking and improved monitoring of new revenue streams and ensure adequate infrastructure for CDISC. ST 1-5

- Prepare monthly project reports with hours and financials.
- Monitor the technical projects monthly in terms of financial solvency and tracking the project scope and progress.
- Provide quarterly financial reports to FOC and Ops.
- Prepare financial reports regularly for Operations.
- Prepare and send reports to Operations "Owners" quarterly.
- Prepare and submit 2010 IRS Form 990 no later than 1 May.
- Ensure success of Educational Courses.
- Reduce outstanding AR by at least 35% for 2009-2010.
- Support the CDISC website and report from analytics monthly.
- Complete requirements, make recommendations and implement new IT infrastructure to integrate databases and support CRM
- Upgrade and maintain portals and Cvent.

CDISC Operations Goal #7

Continue to enhance CDISC Collaborations, Global Reach and Partnering (ST 3,4,5)

- Lead the Joint Initiative Council and participate on BRIDG Board, position CDISC within the Global Standards Marketplace.
- Continue shepherding CDISC-related standards through ISO.
- Continue to expand and optimize strategic relationships (update key collaborations strategy).
- Identify new growth opportunities for CDISC; extend CDISC strategic alliance into new markets – clinical and patient organizations.
- Develop qualification criteria and process for new opportunities.
- Create collaborative method to develop requirements for a Protocol Representation ‘tool.’

Cross-Operations Responsibilities (for everyone in CDISC Operations)

- Live the CDISC Values
- Ensure breakeven budget at end of 2011
- Work efficiently, effectively; "watch time spent on telecons and e-mail (work smart)
- Communicate "professionally" in a friendly manner (e-mail)
- Write eNews Articles, Blogs, Tweets for CDISC website
- Support CDISC and non-CDISC events as appropriate
- Assist in bringing in new members and retaining existing members