

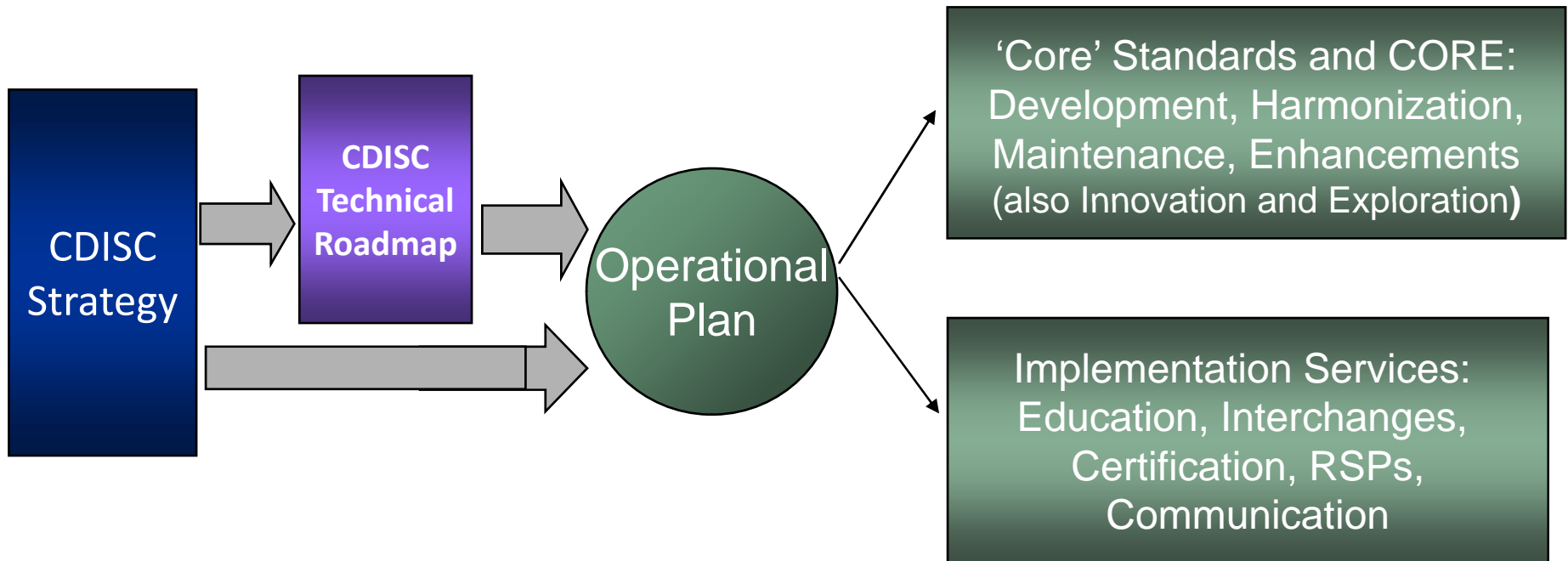


*Setting the
Global Standard
for Medical Research*

CDISC Goals 2009

CLINICAL DATA INTERCHANGE
STANDARDS CONSORTIUM

CDISC Strategy to Implementation/Support



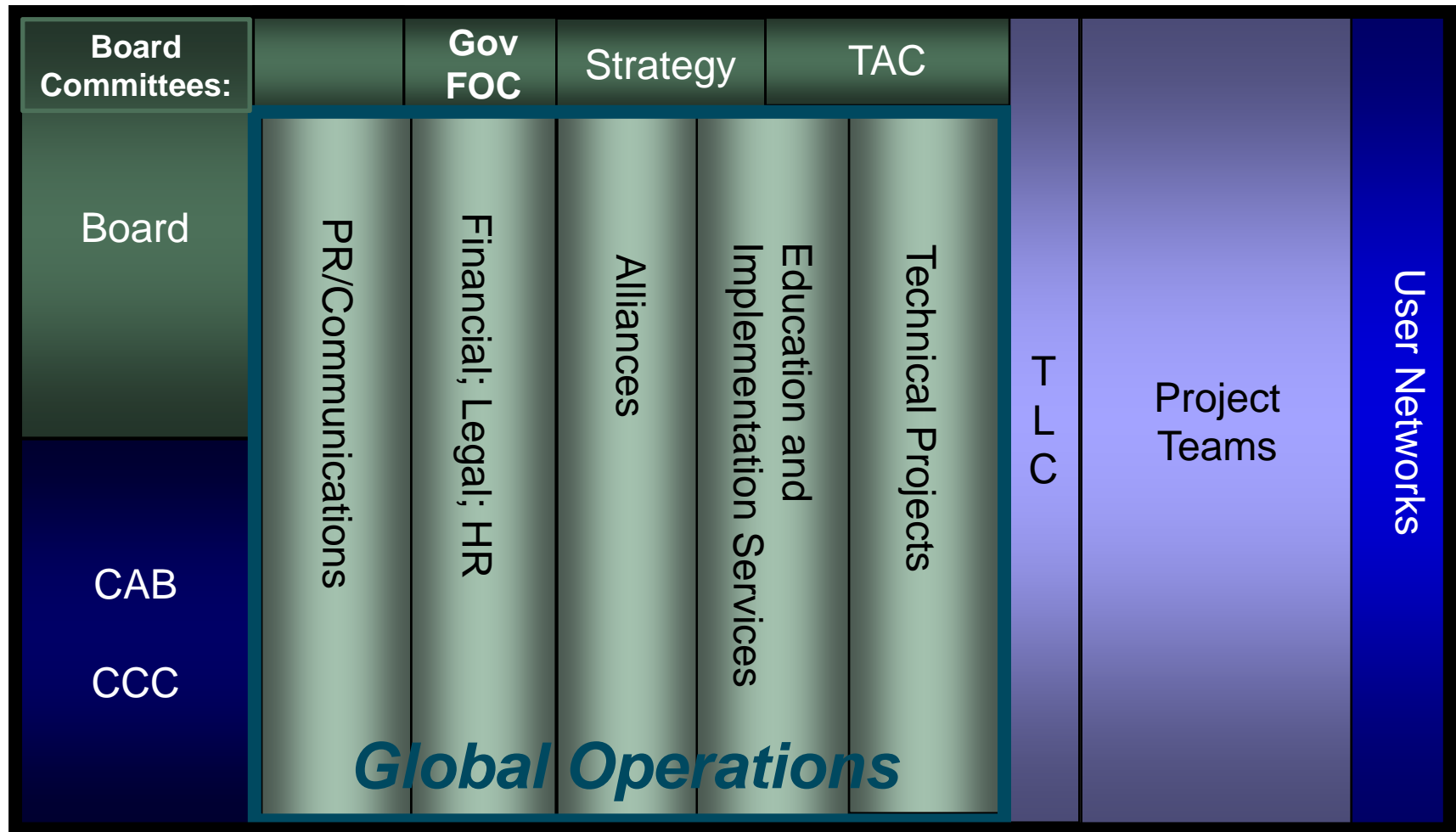
Strategy
2009 (+5y)
Document

Technical
Roadmap
Document

Operational
Goals 2009

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

CDISC Organizational Structure to Support Operational Plan



CDISC Strategy

Specific to the CDISC Strategy for 2008 (+ 5 and beyond), we recognize that CDISC brings unique value to the health care industry in the following ways.

Strategic Themes

- Approach to leveraging our global, nonprofit, vendor neutral, independent status
- Ensuring the existence, harmonization, acceptance and support of standards for medical research
- Preparing the integration with Electronic Health Record (EHR) / Health Information Technology (HIT)

CDISC Strategic Themes (Con't)

- Alliances to Standards Development Organizations (SDOs) and to other key stakeholder organizations.
- Standards and terminology education, and communication of best practices
- Safety data collection and reporting, including a focus on data aggregation enhanced by use of CDISC standards
- Relationship to the US Food and Drug Administration (FDA), European Medicines Agency (EMA), and Japan's Ministry of Health Labor & Welfare (MHLW) and other regulatory and health agencies

Key Drivers for 2009 Operations Goals

- Appropriately 'roll out', drive adoption of and support new and existing standards (technical, communications and education support)
 - CDASH
 - Protocol Representation
 - IHE RFD
 - ADaM
 - BRIDG/CMDR
- Bind healthcare link with core CDISC standards development and support; integrate healthcare link roadmap with CDISC technical roadmap
- Participate in other global standards organizations and contribute to relevant joint projects (e.g. HL7, ISO, JIC, SDO Summit)
- Focus on serving member and stakeholder needs (education, communication, etc.) and communicating the value of standards

CDISC Operational Goals – 2009 (1)

- **Focus *Global Technical Strategy* on the maturation of BRIDG and roll-out of new production standards. (DIH)**
 - In accordance with the technical roadmap:
 - Ensure existing CDISC content (including terminology) are available and useful through BRIDG and supporting metadata repository
 - Globally support implementation, communication and education for new production standards: Protocol Representation, CDASH, IHE RFD Integration Profile and ADaM
 - Create means of developing therapeutic area domains in CMDR
 - Continue to consolidate CDISC standards per the Technical Roadmap
 - Continue execution of pilot projects with regulatory authorities
 - Continue efforts with RCRIM/FDA in the development of HL7 regulatory submission mechanisms and communicating accurately and broadly in this regard

CDISC Operational Goals – 2009 (2)

- **Fully integrate Healthcare Link initiatives into CDISC Technical Strategy/Roadmap. (DIH)**
 - Continue to focus on BRIDG for semantic interoperability between healthcare and medical research
 - Finalize and Integrate Healthcare Link Roadmap (in sync with CDISC Technical Roadmap and Strategy)
 - Roll out IHE RFD as a production standard
 - Continue working with HIT collaborations to further the healthcare link cause (e.g. HIMSS, EHR/CR, CCHIT)
 - Represent global Clinical Research standards in JIC and promote and support a Clinical Research pathway in HITSP and other such initiatives, e.g. IMI, MHLW, IHE, SDO Summit, HIMSS.

CDISC Operational Goals – 2009 (3)

- **Implement and refine Collaboration Management process and Global Expansion plan. (RDK)**

- Review and focus Collaboration Management plan quarterly and revise appropriately
- Ensure that Collaborations result in desired outcomes/benefits
 - Provide input to courses or other such contributions
- Continue to support CDISC in China (C3C) along with other Coordinating Committees.
- Explore viability of I3C (India)

CDISC Operational Goals – 2009 (4)

- **Refine and implement a proactive CDISC *Communication Plan*, focusing on key messages. (RDK)**
 - Ensure communication support for roll-out of new production standards (CDASH, Protocol Representation, IHE RFD, BRIDG/CMDR and ADaM) and develop key technical messaging (content vs. transport)
 - Improve communication content with coherent and consistent key messages (via website, portal, newsletter, etc.)
 - Reach new audiences (e.g. CPMs, CRAs, CRCs, IRBs, HIT organizations)
 - Measure effectiveness of CDISC Communications

CDISC Operational Goals – 2009 (5)

- **Increase value of CDISC to members and key stakeholders; solidify member base (FN)**
 - Retain at a minimum 90% of existing members (anticipated membership renewal income for 2009 at least 12% higher than 2008 actual amount)
 - Increase the number of new membership organizations by at least 10% above the 2008 year end number
 - Increase new membership income by 20% above the 2008 year end amount
 - Interface with User Networks for memberships and retention
 - Evaluate IAB member survey results and work with Governance Committee and IAB to recommend future structure and support from CDISC

CDISC Operational Goals – 2009 (6)

- **Continue to focus, improve and deliver key *Events and Education* that support CDISC strategy (FN, SW)**
 - Develop and/or refine curriculum and deliver
 - New courses: BRIDG, Protocol Representation, CDASH, IHE RFD,
 - FDA Training per RFP
 - Focused and complementary seminars, webinars and roadshows to support roll-out of new production standards and other identified focus areas
 - Optimize events coordination efforts
 - Ideas, qualification, planning, execution, resourcing, marketing and follow up
 - Continue to support Registered Solution Provider area of CDISC website
 - Support CDISC Coordinating Committees (CCC)

CDISC Operational Goals – 2009 (7)

- **Ensure adequate *Infrastructure* to support entire organization. (FN, SW)**
 - Improve CDISC IT infrastructure
 - Ensure continued funding for the organization; find new funding sources
 - Uphold fiscal and legal responsibility
 - Ensure adequate operational resources across the organization
 - Define and implement process improvements to ensure efficiencies



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.