



Board of Directors Committee Charter Technical Advisory Committee

Revision History

Date	Revision	Description	Author
February 2006	V0.5	Original	A. Fleming D. Fridsma E. Helton W. Kubick
February 2006	V1.0	Final	See above.

1 Purpose

This CDISC Charter describes the purpose, membership and scope of work for the Technical Advisory Committee (TAC).

The core work of CDISC is the development of specifications and implementation guides for the standards-based exchange of information, including support and enhancement of the products developed and relevant implementation services. The TAC was established to provide oversight and guidance by the Board of Directors for CDISC's core work and processes.

2 Authority and Scope

This document is approved by the CDISC Board of Directors and applies to all CDISC Board Members, project or team leaders, staff, contractors or consultants.

3 Membership

The TAC shall be comprised of at least three directors as determined and appointed by the Board of Directors, each of whom shall be free from any relationship that, in the opinion of the Board, would interfere with the exercise of independent judgment as a member of the Committee. The chair, a CDISC Board Member, is appointed by the BOD Executive Committee.

Additional members will be the lead for each of the CDISC Focus Area/CDISC Operations sections (see below), one IAB member and additional subject matter experts or consultants as needed or required. Each TAC member will have full voting rights and privileges regarding TAC decisions.

A quorum is defined as a simple majority of total membership.

4 Policy

CDISC will seek to meet the needs of its constituents for exchange of clinical data to support regulated clinical research and interoperability with healthcare information.

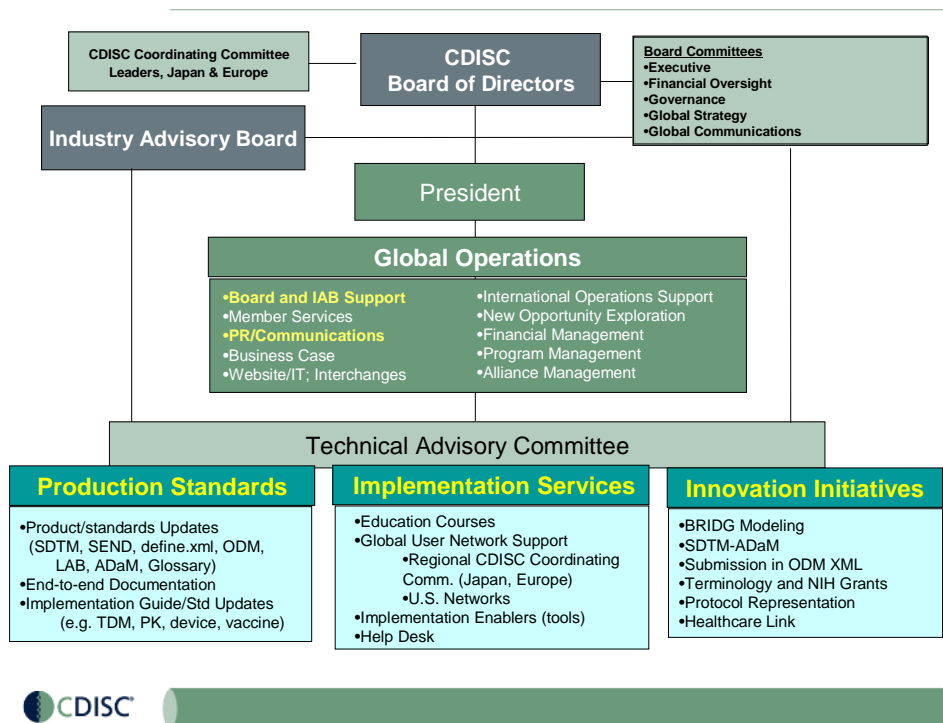
CDISC will respect all applicable regulatory requirements.

CDISC will seek to align its specifications with other relevant standard development organizations, including HL7 and ICH.

5 TAC Structure

The TAC will review the following listed activity areas and other matters relevant to the development, maintenance, support and implementation of CDISC standards and related products. It may, with approval of the Board, engage additional assistance to undertake reviews of technical development and management performance as it deems necessary. The primary technical work of CDISC will be managed through the CDISC Focus Area (CFA) organization units, with technical and project teams under the oversight or supervision of the Technical Advisory Committee. The three primary CFA sections are represented by the following structure, each of who will have a designated manager who participates as a TAC member. The TAC will report to the Board of Directors and to other CDISC committees as requested.

Production Standards (CFA-PS)
 Implementation Services (CFA-IS)
 Innovation Initiatives (CFA-II)



6 TAC Management Responsibilities

Generally, the TAC will be responsible for ensuring effective planning, management and harmonization of activities relevant to CDISC standards. The TAC will also provide the forum for the exchange of information that will facilitate and ensure synchronization of activities among the individual CFA sections. In addition, the TAC will address specific CDISC management issues related to project/team deliverables and goals of each CFA section compatible with the directions of the Board and the current CDISC strategy and roadmap.

Specific responsibilities include:

- Reviewing proposed plans and budgets for technical and project teams and recommending action to the board
- Setting annual priorities for the work of the technical and project teams
- Recommending an annual technical plan to the board that will serve as the guidelines for the Technical Advisory Committee major areas of core activity and will contribute to the overall strategic plan
- Reviewing team and project quarterly and annual progress and budget reports as compared to the plan.
- Reviewing proposed new technical projects for funding consideration, in conjunction with the Finance Committee, and making recommendations to the Board
- Reviewing projects for closure as appropriate and making recommendations to the Board
- Coordinating CDISC plans with the Strategy Committee
- Overseeing education and implementation activities
- Recommending resolutions to the board along with sufficient background information and analysis to further the technical work of the organization.
- Making recommendations to the Board regarding any agreements with outside technical consultants, the need for such and payment thereof.
- Identifying opportunities and working with other standards or information organizations to facilitate the interoperability of CDISC products in the industry
- Adjudicating issues related to maintenance or harmonization that are raised by governance committees or leaders.