



CDISC Advisory Council Charter

1. Purpose

The purpose of this CDISC Charter is to define the responsibilities, organizational structure and business processes associated with the CDISC Advisory Council (“CAC”).

As CDISC is a non-profit charitable organization, it must adhere to stringent rules regarding adherence to Bylaws and Policies, including neutrality and transparency, and balanced processes as a global Standards Development Organization (SDO). CDISC must also be diligent regarding the spending of funds received from membership, education, grants and other contributions and the reporting to stakeholders.

The CDISC Advisory Council was established to ensure fluid communication between CDISC Operations, CDISC Board and CDISC Platinum members.

2. Governing Policies

CDISC is organized and shall at all times be operated exclusively for purposes within the meaning of Section 501(c)(3) of the Internal Revenue Code of 1986, as amended (the “Internal Code”) and within the meaning of the Massachusetts General Laws Chapter 180, Section 4, as amended.

This Council operates in accordance with CDISC Bylaws, Policies, Charters (including this Charter) and will adhere to CDISC Operating and Internal Procedures where relevant.

3. Responsibilities

This charter in no way attempts to enumerate all responsibilities that may be associated with the CDISC Advisory Council. Instead, it represents a guidepost for establishing the primary responsibilities of the Council and its representatives.

The CDISC Advisory Council serves three main roles:

3.1. Discussion Forum

First and foremost, the CDISC Advisory Council provides a forum for sponsoring organizations to discuss, recommend and implement strategies aligned with CDISC's strategic goals (which are determined by the Board of Directors). The CDISC Advisory Council representatives are both the voice of each sponsor, and the voice of the CDISC organization back to the sponsor.

While representatives may not be directly responsible for individual actions, they are responsible for identifying the resources within their organization that can actively contribute to CDISC's goals, and supporting those resources on an ongoing basis.

3.2. Board member election

The Board of Directors is the primary governing body of CDISC, and, as such, electing a Board Member representing the sponsoring organizations is a critical function of the Advisory Council.

CDISC Advisory Council representatives are responsible for electing CDISC Board of Directors representatives in accordance with the Board governing procedures in force at the time of election (Policy 005 – Board member Election¹).

Those procedures, at the time of this Charter's authorization, allow the CDISC Advisory Council to elect one Board member at each election. For this election to be valid, it is required that 50% of the CDISC Advisory Council representatives cast a vote (either for a candidate, or as a stated abstention).

The following considerations will apply to calculate the 50% participation threshold:

- All active CAC members on the date the vote is open will be included in the base calculation, with the following possible exception: Members whose membership renewal fees are more than 60 days overdue may not be included in the base number. Exclusion will be determined on a case-by-case basis
- Voters choosing the "abstention/blank vote" option in the vote will be counted towards the 50% threshold.

In the event that fewer than 50% of the CDISC Advisory Council representatives participate in the election, it will not be valid and the corresponding seat will be filled by current Board members, as per the election policy in force at that time.

3.3. Board liaison

The CAC plays a crucial role in bringing the viewpoint of CDISC members to the Board, and conversely relaying the Board's strategy to members.

This is achieved through several means:

- CAC representation at Board meetings

The CAC Chair (or the representative) will be invited to attend face-to-face Board meetings, and any other meetings as deemed relevant by the Board.

- CAC representation in Board Committees

The CDISC Advisory Council will elect representatives (as per the election process detailed below) to serve in specific liaison roles with the CDISC Board of Director's committees, as detailed in the Charter

¹ All current Policies can be found at: <http://www.cdisc.org/about/bylaws>

for each of these Committees.

At the time of approval of this Charter, these committees are the Financial Oversight Committee and the Strategy Committee, but are subject to change. The CDISC Board of Directors, in collaboration with the CDISC Advisory Council Chair, will determine if any other committees or task forces will require or benefit from representation from the CDISC Advisory Council.

- **Board representation at CAC meetings**

The Board member most recently elected by the CAC will act as a Board representative at CAC meetings. As such, they will be invited to and should make every effort to attend all CAC teleconferences and face-to-face meetings from the time the Board membership is effective until another Board member is elected by the CAC.

4. Membership

The CDISC Advisory Council is composed of one representative from each CDISC Sponsor organization that participates at a designated level within the CDISC Membership Program². In addition, CDISC will have 2 representatives as voting members of the CAC.

CDISC Advisory Council sponsoring organizations are expected to identify a single individual to serve as their representative to the CDISC Advisory Council, and to notify the CDISC CAC liaison of any changes in this representation. CDISC Advisory Council representation resides with the sponsoring organization and not with the individual.

All CDISC Advisory Council representatives are expected to participate in all scheduled teleconferences and face-to-face meetings. If a representative is unable to attend a particular activity, they may send an alternate from their organization. The alternate assumes all voting rights for the purposes of that activity so long as the sponsor company does not exceed one vote.

If a representative (or their alternate) on the CDISC Advisory Council has attended less than two scheduled teleconference or face-to-face meetings in one year, a formal review by the the CDISC Advisory Council Leadership will be performed. Possible actions to be taken include contacting the sponsoring organization for feedback and possibly requesting a new representative.

A sponsor company may wish to send an additional participant to a CDISC Advisory Council activity. Such requests should be submitted to the CDISC CAC Liaison who will have sole responsibility for approving this request. Under no circumstance will a sponsoring organization be permitted to cast more than one vote as part of a decision-making activity.

² At the time of this document's creation, a "platinum" level member is required for representation on the CDISC Advisory Council. More information is available at: <http://www.cdisc.org/membership/benefits-and-rates#platinum>

5. Governing and decision-making process

The CDISC Advisory Council shall make decisions through simple majority voting processes, except as specifically identified elsewhere in this charter. This means that for any given issue, such as deciding between more than one course of action, the outcome of the vote will be that option which receives the most votes among present voting members. In the event of a tie, the Chair will cast the deciding vote.

Votes may be taken through whatever mechanism is deemed appropriate by the Chair – secret ballot, hand-raising, electronic means, unanimous consent, etc., and may only be conducted through official Advisory Council activities to which all known representatives have been invited by either the CDISC Advisory Council chair, the CDISC Board of Directors, or an Officer in the CDISC organization.

Each sponsoring organization receives only one vote for any decision-making activity. Proxies between representatives from different member organizations and other similar voting measures are not permitted.

6. Election and Leadership

The CDISC Advisory Council is led by a Past-chair, a Chair and a Chair-elect, each serving in the natural progression of their role over their term in office, and other elected officials.

6.1. Leadership responsibilities

- Chair

The Chair is responsible for leading all CDISC Advisory Council meeting activities, including face-to-face meetings, teleconferences and other similar events. In the event that the Chair cannot participate, the Chair-elect will lead the activity, and if she or he is unavailable, this responsibility will fall to the Past-chair. If neither the Chair-elect nor Past-chair is available, the Chair will appoint a meeting leader.

It is the responsibility of the Chair or their surrogate to represent the views, perspectives and interests of the CDISC Advisory Council in discussion at the CDISC Board of Directors meetings, which include annual face to face meetings as well as teleconferences.

The Chair shall ensure that all information and decisions associated with the CDISC Advisory Council activities are distributed to council representatives in a timely manner.

- Chair-Elect

The Chair-elect is essentially a training position for the role of Chair. The Chair-elect will be responsible for representing the CDISC Advisory Council in the event that the Chair is unavailable, as well as any

other duties assigned by the Chair.

- **Past-Chair**

The Past-Chair is primarily responsible for serving in an advisory role to the current Chair, as well as being responsible for representing the CDISC Advisory Council in the event that both the Chair and the Chair-elect are unavailable. The Past-Chair may also take on any other duties assigned by the Chair, including the continuation of any initiatives started under their term as chair.

- **CDISC Board Committee Liaison**

As described above, CAC representatives will be invited to participate in select Board Committees.

The elected CDISC Advisory Council committee members will participate in their respective committees, providing feedback both to/from the CDISC Advisory Council, and reporting back to the CDISC Advisory Council on a periodic basis. If an elected committee member is unable to participate in an individual activity, they may request one of the existing Chair representatives to participate in their absence. The committee member may not name their own alternate.

6.2. Criteria and Requirements for elected positions of the CDISC Advisory Council

Any member of the CDISC Advisory Council shall be eligible, with his or her consent, for an elected position, provided the following requirements are met:

- A person must be their company's designated representative on the CDISC Advisory Council in order to be nominated and retain their elected position.
- All nominees must have served a minimum of one year on the CDISC Advisory Council prior to nomination for the Chair.
- All nominees should have relevant experience in support of the roles to which they seek election. A biographical sketch/resume of the nominee will be required and the nomination should include their intent to serve on a specific Board Committee. (Self-nominations are acceptable.) The Board Executive Committee will vet the relevant experience of the nominees.
- Nominees must confirm that their sponsoring organization is committed to supporting their participation in all CDISC Advisory Council and Board of Directors face-to-face meetings if elected.

6.3. Terms of service for elected positions within the CDISC Advisory Council

All elected positions begin on January 1 the year following the election, except in the case where a mid-term replacement is necessary to fill a vacated position. In that case, the newly elected representative will begin serving immediately.

The representative's position will terminate on December 31 of the second year in which they began their term, unless they have been elected as a mid-term replacement. In that instance, their term's expiration date will be associated with the expiration date of the representative they are replacing.

The Chair-elect, Chair and Past-Chair roles transition on January 1. The Chair-elect most recently elected begins serving his/her term as Chair-elect. The previously elected Chair-elect begins serving

their role as Chair. The Chair begins serving their role of Past-Chair.

If no qualified (per section 6.2) candidates are identified for the Chair-elect position, the election process will be re-visited periodically (no less frequently than every 6 months) until such time as the Chair-elect position is filled.

If the Chair-elect position has not yet been filled by the end of the Chair's term, the Board will nominate an interim Chair, and elections to replace the Chair will be held no less than every 6 months until a new Chair is elected. In this situation, the newly- elected Chair will begin serving their term 10 days immediately after election, and the term expiration date will be December 31 of the following year.

Committee members may not be elected to more than 2 consecutive terms, even to a different Committee.

The Past-Chair cannot be elected to the Chair-elect position in consecutive terms.

6.4. Process for Nomination and Election for elected positions of the CDISC Advisory Council

Nomination and selection of candidates

- At least two months prior to the election, the Chair will solicit nominees for the upcoming election, by email to all current CAC members.
- Nominees may be either nominated by another CDISC Advisory Council member or self-nominated. Nominees presented by another member must choose to accept or decline the nomination
- All candidates must submit biographical sketches and letters of intent, specifying the position for which they are applying, to the current CAC Chair no later than 1 month prior to the election date
- The Board Executive Committee will vet the candidates as per the criteria detailed in section 6.2 and confirm the final slate to the CAC representatives.

Voting

- An Annual Election shall be held among the CDISC Advisory Council representatives for selection of the next Chair-elect and any other open position. The election is typically held during the CDISC??Advisory Council meeting that is scheduled in conjunction with the CDISC International Interchange. An early-voting process will additionally be conducted so that those who cannot attend the event will have the opportunity to vote. The election of the Chair-elect may take place at other times as necessary to fill a vacated position.
- Each open position, including Chair-Elect, will be filled by the candidate with the most votes cast for that position.
- There is no minimum voting turnout for the vote to be valid.

6.5. Compensation for CDISC Advisory Council elected positions

No compensation shall be paid for services rendered by any elected position. With prior approval of the Board of Directors, reasonable expenses may be reimbursed.

6.6. Voting privileges for CDISC Advisory Council elected positions

No special voting privileges are attached to the elected positions. Elected representatives retain their CDISC Advisory Council voting rights as described above.

6.7. Change in status of the representative elected to the CDISC Advisory Council Chair

In the event that the current CDISC Advisory Council Chair's membership status changes (for example, he or she is no longer employed by a sponsoring organization), he or she will relinquish the position of Chair.

Should this occur, the CDISC Advisory Council Chair-elect will assume the role of Chair for the continuation of that term. At the conclusion of that term, the Chair will continue in that role in order to fulfill the initial Chair transition plan.

6.8. Change in status of the representative elected to the CDISC Advisory Council Chair-Elect

In the event that the current CDISC Advisory Council Chair-Elect's membership status changes (for example, he or she is no longer employed by a sponsoring organization), he or she will relinquish the position of Chair-elect.

Should this occur, the CDISC Advisory Council Chair will convene a special election to elect a new Chair-Elect at the earliest practical opportunity, to fill the position for the remainder of the current term. The election process (nominations, acceptance, voting, etc.) will proceed as if this were a normally scheduled election.

6.9. Change in status of the representative elected to the CDISC Advisory Council Past-chair

In the event that the current CDISC Advisory Council Past-chair's membership status changes (for example, he or she is no longer employed by a sponsoring organization), he or she will relinquish the position of Past-chair.

Should this occur, the position will remain unfilled until the next regularly scheduled election when the Chair assumes the position of Past-chair.

6.10. Removal of the CDISC Advisory Council Chair from office

The Chair may be removed from their elected position by a three-fourths vote by the CDISC Board of Directors. In the event of the Chair's removal by this process, the CDISC Advisory Council Chair-Elect will assume the role of Chair.

6.11. Removal of the CDISC Advisory Council Chair-Elect from office

The Chair-Elect may be removed from their elected position by a three-fourths vote by the CDISC Advisory Council, in which membership participation in the vote (including documented abstentions)

is at least fifty percent. In the event of the Chair-Elect's removal by this process, the CDISC Advisory Council Chair will convene a special election as described in section 6.8.

6.12. Change in status of the representative elected to the CDISC Advisory Council Committees

In the event that any current elected CDISC Advisory Council committee member experiences a membership status change (for example, he or she is no longer employed by a sponsoring organization), he or she will relinquish the committee member position.

Should this occur, the CDISC Advisory Council Chair will convene a special election to elect a new committee member at the earliest practical opportunity, as described in section 6.8.

6.13. Removal of elected CDISC Advisory Council committee members from office

An elected committee member may be removed from their elected position by a majority vote by the CDISC Advisory Council, in which membership participation in the vote (including documented abstentions) is at least fifty percent. In the event of the committee member's removal by this process, the CDISC Advisory Council Chair will convene a special election as described in section 6.8.

7 Authorization

This document has been approved and is in effect on this date:

Name	Board of Directors
Date	14 February 2017