Coalition For Accelerating Standards and Therapies

Therapeutic Area Standards Program Steering Committee Charter

**Purpose:**

The purpose of this document is to define the bylaws and operating principles for the operation of the Coalition for Accelerating Standards and Therapies (CFAST) Therapeutic Area standards Program Steering Committee (TAPSC).

**Program Mission:**

To accelerate the development of therapeutic area data standards to help the FDA meet commitments set under PDUFA V.

**Program Goals:**

The CFAST Therapeutic Area Standards Program has been approved by the founding members of CFAST (CDISC and Critical Path Institute) to oversee a program to define therapeutic area data standards. The Program intends to develop an initial version of data standards for therapeutic areas identified by FDA according to priorities set by the Program Steering Committee. It is also anticipated that each data standard will require ongoing maintenance and enhancement over time.

**Operating Principles:**

1. CFAST achieve its mission to accelerate clinical research and medical product development through targeted programs. A program is an ongoing initiative that consists of a series of projects to achieve a mission or set of specified goals.
2. The CFAST Therapeutic Area Standards Program will achieve its objectives through projects, which are sets of activities performed by teams to complete a set of deliverables for an individual therapeutic area within a specified period.
3. Initial program committee membership will consist of one appointed representative from CDISC, C-Path FDA and TransCelerate Biopharma, Inc., which are sponsoring organizations for the program. Each organization may also select one alternate who may vote in the absence of a sitting member. The appointed members can choose to increase the number of appointed members of each sponsoring organization as long as an equal balance of representation is maintained, or elect additional at large members with the approval of a two-thirds majority of the TAPSC.
TA Program Steering Committee

4. Steering Committee membership must be reaffirmed by sponsoring organizations every two years.

5. Members may invite external advisors to attend meetings where appropriate to assist in decision-making.

6. A voting quorum consists of a simple majority of sitting members. Voting procedures may be by electronic media.

7. The Chair is elected by majority vote of sitting members for a term of two years; the Chair may not serve more than two consecutive terms. An interim chair may be selected by unanimous vote prior to an election.

8. The TAPSC meeting schedule may be revised by majority vote. The Chair may cancel meetings due to unavailability of members or for lack of topics by notifying all members in advance.

9. The TAPSC is responsible for approving each project to proceed to the scoping stage. A project must be defined in a project charter before it can be approved for initiation and scoping.

10. The TAPSC is responsible for approving each project to proceed into the development stage after verifying that the scope is well defined and sufficient resources are available.

11. The TAPSC will support the acquisition of any resources necessary to perform the project, and provide oversight to ensure the project uses resources wisely, and remains on schedule within budget.

12. All data standards developed under this program will be processed by CDISC as CDISC standards according to the documented CDISC Standards Development Process, with sufficient controls to ensure acceptable quality of deliverables.

13. Changes to TAPSC Charter can be made by 2/3 affirmative vote of the voting membership present at any meeting. Proposed changes must be published to the TAPSC 30 days before the scheduled meeting.

14. A program can be discontinued with the approval of the CFAST Board when (1) the TAPSC votes to recommend its discontinuation, or (2) when the program is no longer active and the PSC is no longer meeting at minimum specified intervals.

Guiding Principles:

The TAPSC intends to follow a set of guiding principles in developing therapeutic area standards, which will include the following:

1. Minimize bureaucracy: “Use as little governance as possible but no less”
2. Minimize intervention: Push decisions down to the lowest responsible levels
3. Leverage existing work where possible and clearly define boundaries and links to other existing standards; develop only when needed
4. Define a manageable scope to fit a pre-determined timeframe.
5. Strive to adjust scope and ensure sufficient resources before extending time schedule for each project
6. Ensure that regulatory review and analysis use cases are addressed.
7. Consistently define all concepts. Reuse, don't recreate.
8. Ensure that all projects are defined as to deliver value to both FDA reviewers and industry.

**Guidelines for Prioritizing Projects:**

The TAPSC will define a set of guidelines used to prioritize projects, which will include the following:

1. Well defined, manageable scope, capable of being accomplished within a predetermined timeframe
2. Availability of sufficient prior work to minimize the need to conduct extensive preparatory analysis (must be able to start quickly)
3. Limited complexity -- any large-scale area like Oncology must be able to be broken down into a manageable chunk.
4. Relative significance of this therapeutic area – potential impact on public health
5. Relevance to FDA’s goals to improve the overall review process
6. Relevance to product pipelines of participating organizations (including TransCelerate)
7. Consistent with priorities set by FDA (Tier 1) and TBI member survey.
8. Availability of subject matter experts within the TBI member companies, FDA or other expert groups.