Charter: CFAST Scientific Advisory Committee

Coalition For Accelerating Standards and Therapies (CFAST) Scientific Advisory 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) Scientific Advisory Committee (SAC).

CFAST Mission: To accelerate clinical research and medical product development by creating and maintaining data standards, tools and methods for conducting research in therapeutic areas that are important to public health.

CFAST Scientific Advisory Committee (Committee) Mission: To provide scientific advice regarding the development of therapeutic area standards to facilitate clinical research data sharing for the ultimate purpose of informing a learning health system and accelerating access to better therapies to improve public health.

Committee Goals: The CFAST Scientific Advisory Committee will provide scientific guidance for the CFAST enterprise programs, and scientific advice, as deemed appropriate, to CFAST Program Steering Committee(s) and other CFAST project-related teams as needed. [See Charter for CFAST Program Steering Committee with CDISC, C-Path, FDA and TransCelerate Biopharma: http://www.cdisc.org/therapeutic.]

More specifically, the CFAST SAC will:

- Provide scientific input and advice to the CFAST Program Steering Committee and related teams regarding the CFAST projects in therapeutic areas, e.g. recommend criteria for scoping, scoping-related divisions within therapeutic areas and how best to prioritize such divisions;
- Consider relevant, important and applicable scientific and public health criteria;
- Identify issues and risks to be mitigated and provide scientific input and advice to other CFAST Committees, programs or project teams (e.g. development of tools and methods for conducting research in therapeutic areas) in accordance with the CFAST Mission;
- Recommend partners and stakeholders (e.g. professional societies and organizations) of relevance for specific projects;
- Encourage participation and involvement by experts from the scientific research community;
- Identify potential resources for programs or projects recommended;
• Resolve issues related to scientific content brought to the CFAST SAC by CFAST Program Steering Committee(s), e.g. scoping questions.

Committee Composition: The CFAST SAC will be a multidisciplinary, balanced, jointly appointed (by CDISC and C-Path) core group of individuals with scientific and/or medical knowledge of various therapeutic areas and functions and understanding of clinical research and regulatory science and data needs. There will be a core committee (Core SAC) with one representative each from CDISC, C-Path, FDA and TransCelerate Biopharma (n=4). Additional experts in the relevant therapeutic areas will be invited to SAC teleconferences to discuss SAC issues with respect to those specific therapeutic areas. These experts will ideally be convened prior to the launch of a CFAST project and again when scientific advice in that therapeutic area is needed.
Initial Chair: Dr. Rebecca Kush (CDISC)

Operating Principles: These initial Operating Principles will be augmented as necessary during the course of the CFAST SAC experience.
• CFAST SAC Core Members agree to serve for two years, with the option of serving for a second term. [An alternate for the Core Member (from the same organization as that member) may attend a meeting on behalf of the Core Member, if that individual is not available.]
• The CFAST SAC is an advisory body providing the scientific input and serving as the scientific arbiter for CFAST projects and programs.
• A voting quorum will consists of at least the CFAST SAC Core Members (or their alternate), representing four organizations (CDISC, C-Path, FDA, TransCelerate Biopharma). Ties will be broken by the CFAST SAC leader. Voting may be done electronically in appropriate cases.

Guiding Principles: The CFAST SAC intends to follow a set of guiding principles in providing advice to CFAST and its Program Steering Committee(s).

1. Minimize bureaucracy: Use as little governance as possible but no less.
2. Minimize intervention: Push decisions down to the lowest responsible level.
3. Maximize neutrality: Use the criteria developed for making recommendations that are not biased based upon corporate pipelines but rather influenced by scientific and public health needs.
4. Leverage existing work whenever possible; assist CFAST in maintaining manageable program and project scopes that are relevant to the Mission.
5. Minimize conflict of interest or manage appropriately (e.g. recusing participants when this exists).
6. Strive to ensure that programs and projects have sufficient scientific input to be achievable.
7. Assist in removing scientific-related barriers to success.