Clinical Feasibility Consortium Charter

Ratification Date: January 15, 2021

The Clinical Feasibility Consortium ("Consortium") aims to advance medical science through the identification, prioritization and resolution of the clinical trial issues that most affect the biopharmaceutical industry. Our mission is to enhance and optimize the execution of trials through strategic and forward-thinking collaboration amongst feasibility leaders, faster than any organization operating alone could achieve.

The CONSORTIUM will provide a venue to:

- Investigate the meaning and role of clinical trial feasibility organizations in the era of data science, advanced analytics and technology;
- Help clinical operations executives prepare their organizations and professions to take ownership and prove leadership in the new data-driven world; and
- Act as a think tank, focusing on clinical feasibility challenges in R&D, including role accountabilities and organizational structures, talent engagement and retention and data and analytical requirements.

THE CONSORTIUM WILL CONVENE UNDER DEFINED OPERATING PRINCIPLES TO BETTER PURSUE ITS MISSION AND PURPOSE.

- The Consortium will operate independently from existing industry pharmaceutical or biotech associations. However, we see partnerships with these and other groups as important.
- The Consortium will operate noncompetitively, meaning that information exchange and collaboration will be consistent with academic norms and typical industry discourse published or observed in public settings that generally advances the discipline, rather than specific companies.
- The Consortium will operate under Chatham House rules of confidentiality.
- ZS Associates, Inc. ("ZS") will aim to enforce all rules listed in the charter and will act as a third party to resolve any issues that arise among the members.
- ZS will also act as an intermediary for the Consortium and its members and will synthesize all proprietary/confidential information as a third party.
- **Meetings:** In-person (when possible) Consortium meetings will be held twice a year. Additionally, there will be two (or more if needed) virtual meetings. Meetings are led by the officers of the Consortium with input from its members. Members are expected to attend the Consortium meetings but may delegate a representative if necessary.

Membership: Membership of the Consortium will consist of those from biopharmaceutical companies with industry-leading clinical feasibility processes. Inaugural members under this charter include all those actively participating as of the charter ratification date. In order to maximize the standing of the consortium, members (one per company) should have a significant level of responsibility regarding clinical trial feasibility and/or trial operations at their respective companies.

New members may be invited at ZS's discretion based on their involvement and/or experience with: (1) data-driven feasibility/operations processes, (2) innovations in trial execution, (3) clinical feasibility challenges in R&D and others. New members may also be invited by existing Consortium members as well. All invitations to join will require at least 50% approval of existing Consortium members.

Members may be excluded, or membership may be rescinded, with 75% of support from existing Consortium members.

Member expectations: Members are expected to be active and willing participants, acting in good-faith to advance the Consortium's mission and purpose. This includes, but is not limited to: responding to emails, participating in surveys, attending Consortium meetings, traveling when necessary and funding/paying for any costs incurred that may arise from participation in this forum. Delegates are generally discouraged and will be allowed only on an exception-basis from ZS.

If a member no longer wishes to participate or leaves their position at the company, the member must notify the Consortium and provide a replacement in a timely manner. ZS reserves the right to replace a nonresponsive or inactive member with someone from the same company. Replacement members are not subject to the 50% new member Consortium vote stated above.

Lastly, all views and opinions expressed by the members of this Consortium are understood to be on behalf of that specific individual and not on behalf of their respective companies.

Company staff support: For any specific activity conducted at the Consortium meetings, each participant may identify supporting staff colleagues relevant to that topic to execute additional activities as specified by the Consortium (research and information gathering, proposal generation, etc.). These activities should be communicated back to the Consortium. These support staff are not considered to be members of the Consortium. However, they may be brought in to present their findings and recommendations to the Consortium.

Key stakeholders may also be invited to attend Consortium meetings. Specific attendees may vary from year to year depending on the topics to be discussed; for example, leaders from the U.S./FDA, EU/EMA, cFDA, PMDA, CROs, as well as key thought leaders, may be invited.

ZS: ZS will fund and be responsible for the administration and organization of this Consortium. In addition to the duties and expectations listed explicitly in this document, ZS will serve as a historian and custodian to all materials and outputs generated from this Consortium. ZS, at its discretion, may provide subject matter experts, project managers and other personnel to assist with the Consortium when necessary.

ZS will also be entitled to membership within this Consortium. **One** qualified individual from ZS will be identified and act as a full member in the Consortium.

Fees: There are no fees to join, participate or lead the Consortium. All members are responsible for their own individual expenditures, including but not limited to: travel (transportation, lodging), meals, telecommunications, equipment, billable time and/or any other ancillary business expenses.

While there is no formalized organizational structure, the Consortium will have two officers—the chair and the vice chair. Other Consortium executive roles may be considered in due course. All roles will be for one-year terms unless otherwise specified.

Officers:

Chair: The chair will oversee the Consortium meeting agenda, help set future goals and direction of the Consortium and decide on future outputs from the Consortium. This includes a potential first-authorship on any published materials. Members serving as chair may not serve more than two consecutive terms.

Vice chair: The vice chair will help support the chair in the aforementioned duties and will also play the role of acting chair when the chair is unavailable. If the chair leaves the Consortium or steps down from the role, the vice chair will become chair for a new full term.

Any member may nominate themself or another member for these roles. In situations where there is more than one nomination, a simple anonymous vote will be used (majority wins). In cases of a tie, ZS reserves the right to break the tie.

Unless specified above, any vacancy will result in a new election for that role for a new full term.

Issues arise that may require discussion with biopharmaceutical industry bodies, such as PhRMA, EFPIA, EFSPI, BIO, IFPMA, TransCelerate, etc. These issues can be the subject of discussion at Consortium meetings and, where appropriate, position papers can be developed by Consortium members on specific topics. Partnerships between the Consortium and these associations can be utilized to assist with the implementation of Consortium initiatives. Informal liaisons between the Consortium and others may also be established as necessary.

Amendments can be proposed by either ZS or a member of the Consortium. An amendment to this charter may be ratified with the consent of 75% of its members. Ratification of this document also requires consent from 75% of its inaugural members. All votes by the members of this Consortium are understood to be on behalf of that specific individual and not on behalf of their respective companies.

Contact us: clinicalfeasibilityconsortium@zs.com

About ZS

ZS is a professional services firm that works side by side with companies to help develop and deliver products that drive customer value and company results. We leverage our deep industry expertise, leading-edge analytics, technology and strategy to create solutions that work in the real world. With more than 35 years of experience and 10,000-plus ZSers in more than 25 offices worldwide, we are passionately committed to helping companies and their customers thrive.