



Job Description
Executive Director
Clinical Trials Transformation Initiative (CTTI)

Occupational Summary

The Executive Director (ED), as an employee of Duke University, will provide senior level oversight, management and coordination of CTTI operations and activities. The Executive Director will assist the Executive Committee in developing and refining strategies to accomplish CTTI's mission, and will identify and implement the infrastructure necessary to support the successful execution of these strategies. The Executive Director will orchestrate efforts to effectively leverage the participation of member organizations and a variety of external stakeholders, foster collaborations, and promote the reach and awareness of CTTI. The Executive Director will lead internal Duke staff working for the initiative, and oversee project management functions to expedite the conduct and completion of CTTI projects. The Executive Director will manage and report on CTTI's finances, and oversee efforts to identify and secure funding opportunities.

Work Performed

Lead efforts to identify and approach prospective members and to receive and respond to inquiries from interested parties regarding their participation in CTTI. When appropriate, discuss directly with prospective members options for their participation and opportunities to achieve optimal value of their contributions.

Identify key non-member stakeholders and constituents who will be critical to the success of the partnership. Establish close communications and interactions with representatives of these organizations, solicit their guidance and direction on a regular basis, and ensure that their needs are met in obtaining updates and reports regarding the activities of the partnership.

Keep abreast of activities associated with the FDA's Critical Path Initiative, the Institute of Medicine's Forum on Drug Discovery, Development, and Translation, the Clinical Research Forum, Faster Cures, and other organizations aligned with CTTI's mission; coordinate CTTI-related activities with these efforts. Maintain communication with the leaders of these and other such partnerships in order to identify potential synergies and foster opportunities for collaboration.

Determine staffing requirements and resources needed to ensure the successful execution of Duke's role in the partnership. Oversee hiring and supervision of Duke personnel assigned to

support the partnership. Directly manage CTTI's professional staff, e.g., project managers and Director of Strategy¹. Perform personnel evaluations and assign work activities for direct reports.

Oversee financial management and reporting of all funds raised and expended in association with the activities of the partnership. Ensure appropriate stewardship of funds and compliance with the accounting procedures of Duke University. Provide regular financial reports to the Executive Committee and the Chief Operating Officer of the Duke Translational Medicine Institute. Conduct an annual review of membership fees based on requirements for CTTI's operations and projects and make recommendations to the Executive Committee. Communicate information regarding membership fees to participating and prospective organizations and oversee the collection of fees.

Oversee efforts to obtain funds beyond membership fees to support the partnership and projects, including the identification of grant opportunities and development of proposals and budgets.

Oversee efforts to support and facilitate the work of the Executive and Steering Committees. Make recommendations regarding strategies to foster the transparent and efficient conduct of committee activities and the effective engagement of committee members

Oversee efforts, led by project managers, to form project teams, develop project plans and deliverables for approved projects. Facilitate efforts to identify and engage individuals and organizations, within and outside of CTTI membership, who can provide expert technical input and guidance for each project. Ensure that progress reports on projects are prepared on a regular basis and communicated to the Executive and Steering Committees.

Contribute to the development of project strategies, implementation, products, final recommendations and dissemination plans.

Oversee the development and implementation of a communication plan to ensure that the activities of the partnership are well publicized to the clinical research community and the public as a whole. Identify appropriate communication vehicles; oversee the drafting, editing and approval of all non-project specific written communications, including an annual report to members of CTTI's accomplishments.

Work closely with necessary press offices to ensure that all press releases and other official public communications have received appropriate approval prior to dissemination.

¹ Project managers have responsibility to help develop project ideas into concrete operational plans with budgets, and to manage, monitor, and report on project implementation and progress. In this capacity they work with representatives of CTTI member organizations, internal staff at Duke, and external collaborators and contractors. The Director of Strategy supports efforts to develop and refine CTTI's strategy to accomplish its mission, to identify and track activities of organizations with related goals, and to improve the reach and awareness of CTTI. The Director of Strategy coordinates the ongoing activities of the EC and SC and supporting committees, including assurance of appropriate agendas and documentation of actions.

Prepare and deliver public presentations regarding CTTI efforts at professional and trade meetings, (e.g., Society of Clinical Trials, Drug Information Association) and other appropriate venues.

Oversee the preparation, approval, maintenance and dissemination of key documents pertaining to the operation of the partnership including, but not limited to, guiding principles, policies and procedures, roles and responsibilities of the Executive and Steering Committees, etc. Interact closely with members to ensure a consistent understanding of roles, responsibilities, and expectations.

Plan and oversee the formal evaluation of CTTI's performance toward its goals and report on that evaluation to the Executive Committee and the FDA.

Required Qualifications

Education/Training:

Bachelor's degree in a life science, clinical, clinical research, technical or related field. Strongly prefer candidates with an advanced degree such as an MD, PhD, PharmD, MPH, MBA, etc.

Experience:

Minimum of ten years in progressively responsible senior management roles in the health care, medical products, or clinical research industries (public or private); regulatory agencies; health care-related foundations; patient advocacy organizations; professional societies; or academic institutions. Strongly prefer candidates with experience in multiple sectors.

Strongly prefer candidates with prior experience related to public-private partnerships.

Extensive knowledge of the field of drug and device development and clinical research operations.

Proven leadership and management skills with the ability to execute with a sense of urgency and inspire both staff and volunteers. Strong skills in planning, prioritization, delegation and organizational development.

Collegial, collaborative, and diplomatic interpersonal style and ability to implement inclusive approaches to foster consensus and engagement across diverse stakeholders and constituents.

Exceptional oral and written communication skills, and experience preparing and delivering presentations for professional and industry forums.