Clinical Trials Transformation Initiative (CTTI)

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Research Areas

Tool Development
Clinical Trial

Data-Sharing Enabler

At a Glance

- Status: **Active Consortium**
- Year Launched: **2007**
- Initiating Organization: **Duke University**
- Initiator Type: **Academia**
- Location: **North America**

Abstract

The U.S. Food and Drug Administration (FDA) and Duke University co-founded the Clinical Trials Transformation Initiative (CTTI) to identify and promote practices that will increase the quality and efficiency of clinical trials. Their evidence-based work is being used to inform both policy and decision-making in the interest of public health, as well as to streamline the operation of clinical trials. CTTI engages all stakeholders as equal partners to analyze existing research impediments and recommend consensus-driven, actionable solutions that will lead to a more sustainable and effective clinical trial system.

Mission

CTTI's mission is to identify and promote practices that will increase the quality and efficiency of clinical trials. Its vision is a high-quality clinical trial system that is patient-centered and efficient, enabling reliable and timely access to evidence-based prevention and treatment options.

Core Values:

- Act in the interest of the public's health to improve the clinical trial enterprise

- Hold paramount the need to protect human subjects and their privacy
- Encourage the input and participation of all stakeholders (e.g., academia, industry, investigators, patients, and regulators) to move the system forward
- Work to identify and manage conflict of interest and bias to avoid undue influence of any individual, organization, or sector
- Hold that, to the extent possible, recommendations for change should be scientifically derived
- Activities and innovations deriving from CTTI will be rapidly communicated to interested parties and the public
- The integrity and transparency of CTTI, as a collaborative organization, is of utmost importance

CTTI projects are organized into five categories: AB (Antibacterial) Drug Development, Investigational Plan, Study Start-Up, Study Conduct, and Analysis and Dissemination.

AB Drug Development was created in response to growing rates of bacterial resistance and slowing development of new antibacterials, creating an urgent need for treatment options for patients infected by resistant bacteria.

The Investigational Plan describes the essential background documentation related to the test article, protocol creation, and all operational aspects of a study. It also includes how ethical and regulatory considerations will be managed during the course of the study. The CTTI projects that fall under this category focus on innovating this preparatory phase of the clinical trial process.

Study Start-Up includes all of the activities associated with identifying, qualifying, and activating investigational sites. The CTTI projects that fall under this category are concerned with site-level regulatory approvals and site preparation for successful enrollment.

Study Conduct describes the active data collection phase of an investigation in which patients, sites, and sponsors interact to test the safety and/or efficacy of the investigational article. The CTTI projects that fall under this category are concerned with (a) protocol adherence issues, (b) patient follow-up and safety, and (c) monitoring and transfer of safety data between sites and sponsor.

Analysis and Dissemination addresses the phase of an investigation in which data are cleaned and analyzed, then presented and published in the public domain. The CTTI projects that fall under this category analyze data output from clinical trial research, identify areas of improvement, and focus on the dissemination of clinical trial results to the scientific community and public.

Consortium History

Published Recommendations:

- May 2011: Effective and Efficient Monitoring as a Component of Quality Assurance in the Conduct of Clinical Trials
- May 2011: Improving Reporting of Unexpected Serious Adverse Events (SAEs) to Investigational New Drug (IND) Investigators
- January 2013: Use of Central IRBs for Multicenter Clinical Trials
- November 2013: IND Safety Assessment and Communication
- January 2015: Good Clinical Practice (GCP) Training for Investigators
- April 2015: Advancing the Use of Central IRBs for Multicenter Clinical Trials
- June 2015: Quality by Design
- October 2015: Best Practices for Industry and Patient Organization Collaboration in Clinical Trials

Structure & Governance

An Executive Committee sets the overall direction and strategy for the initiative and oversees the use of annual membership fees. A Steering Committee, consisting of representatives from CTTI members across multiple sectors, provides input into decisions about CTTI priorities, projects, and recommendations. CTTI members also play an important role in facilitating improvements in the design and conduct of clinical trials within their organizations and the overall enterprise. A central staff supports the development and execution of projects and dissemination of project results. In addition, staff members organize and support activities of the Executive and Steering Committees.

Financing

CTTI receives financial and in-kind support from many groups committed to improving clinical trials.

Duke University, as the host of CTTI, received a cooperative agreement (U19 FD003800) from FDA, followed by a grant (R18 FD005292), which provides some support for all current projects. Member

organizations pay an annual fee, which supports CTTI infrastructure expenses and projects.

In addition, individuals from many member organizations, and some nonmember organizations, contribute time and other resources to make CTTI projects successful.

CTTI encourages the use of all materials listed on its website in the pursuit of improving the clinical trials enterprise. Its recommendations, tools, meeting summaries, and more are available to the public for free.

Patent Engagement

Patient engagement is an integral component of CTTI's approach to identifying and promoting practices that will increase the quality and efficiency of clinical trials. It promotes patient engagement across the clinical trial continuum and maintains education materials for patients, patient advocates, and the general public on understanding clinical trials.

CTTI membership also includes four patient/caregiver representatives.

Impact/Accomplishment

CTTI has published recommendations and articles on clinical trials that are highly regarded and used by many stakeholders in the clinical trial process. From 2011 to 2015, CTTI published 26 papers on its projects and progress. It has contributed greatly to innovative trial design including working to establish centralized institutional review boards (IRBs) for multicenter trials. FDA participation in CTTI has allowed the agency to learn from partners and stakeholders and to begin to implement new recommendations for clinical trials so that efficient trials with flexible designs aided by innovative technologies are no longer the exception to the rule.

CTTI hosts expert meetings where a diverse cross-section of stakeholders from the clinical trial enterprise can tackle existing challenges and collaborate to find innovative solutions. Upon completing an expert meeting, CTTI aims to share the discussions with a wider audience and promotes adoption of novel approaches to existing issues in the clinical trials enterprise.

CTTI's tools are created to facilitate the adoption of official recommendations and are available on its website. These recommendations are based on evidence generated by engaging all stakeholders involved in the clinical trial process.

Links/Social Media Feed

Homepage	http://www.ctti-clinicaltrials.org/
LinkedIn	https://www.linkedin.com/company/clinical-trials-transform initiative-ctti-?trk=biz-companies-cym
Twitter	https://twitter.com/CTTI_trials
Facebook	https://www.facebook.com/CTTI.ClinicalTrials

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Sponsors & Partners

ACI Clinical	Amgen	AstraZeneca	Bard	Bristol-Myers Squibb (BMS)	Celegene	Cempra
EMD Serono	Genetech	GlaxoSmithKline (GSK)	Johnson and Johnson	Lilly	Medtronic	Merck
Pfizer	Purdue	St. Jude Medical	Target Health, Inc.	The Medicines Company	Office for Human Research Protections (OHRP)	Department of Veterans Affairs
Agency for Healthcare	Centers for Disease	Centers for Medicare &	U.S. Food and Drug	National Institutes of	Clinical Data Interchange	Chesapeake IRB

Research and Quality (AHRQ)	Control and Prevention (CDC)	Medicaid Services (CMS)	Administration (FDA)	Health (NIH)	Standards Consortium (CDISC)	
American College of Radiation Oncology (ACRO)	Association of Clinical Research Professionals (ACRP)	AdvaMed	Bio	Biomedical Research Alliance of New York (BRANY)	MedStar Health Research Institute	Palo Alto Investors
Consortium of Independent Review Boards (CIRB)	CITI Program	DIA	Greenleaf Health LLC	King & Spalding	Melanoma Research Alliance	The Michael J Fox Foundation for Parkinson's Research
PMG Research	Quorum Review IRB	Society for Clinical Trials	Society for Clinical Research Sites (SCRS)	WCG	Susan G. Komen	NYU Langone Medical Center
Alliance for Lupus Research	Foundation for Prader-Wili Research	Friends of Cancer Research	Juvenile Diabetes Research Foundation (JDRF)	The Life Raft Group	University of Kansas (KU) Medical Center	UW Health
MPN Research Foundation	NORD	Parent Project Muscular Dystrophy	Parkinson's Disease Foundation	Pulmonary Fibrosis Foundation	The University of Sydney	
C5 Research	Dana-Farber Cancer Institute	Duke Medicine	The Feinstein Institute for Medical Research	The George Institute for Global Health		
Population Health Research Institute (PHRI)	University of Missouri Health System, School of	University of North Carolina (UNC) Healthcare	University of Oxford	University of Rochester Medical Center		

Medicine

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