

2016 ANNUAL REPORT











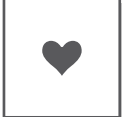
CLINICAL
TRIALS
TRANSFORMATION
INITIATIVE



Innovation Through Collaboration

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CTTI's
5 Areas of
Strategic
Focus:

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Collaboration as a Catalyst

CTTI comprises all stakeholders from the clinical trial enterprise working together as equal partners. Together, we continue to stand shoulder to shoulder and break down barriers to achieving quality, efficient clinical trials. We see an improved clinical trial system as a vehicle for bringing timely advances in care to patients and addressing pressing public health concerns.

Through strength in collaboration, we are a catalyst for transformation. We recognize that one stakeholder alone cannot provide solutions to the challenges facing clinical trials. Leveraging the ideas and experiences of all stakeholders leads to better, more efficient clinical trials. This approach is reflected in our membership and throughout our project activities.

In this report, we detail CTTI's 2016 successes confronting leading challenges. We have developed evidence-based, consensus-driven recommendations to fuel meaningful changes in medical product development, such as enhanced participant recruitment strategies and approaches for more streamlined clinical trials of new antibacterial therapies. We also drove adoption of these recommendations to make better clinical trials a reality.

While significant advancements have been made, many opportunities remain to improve clinical research, and ultimately benefit the lives of patients. Our recently updated strategic plan provides a blueprint for how we can make a difference in clinical trials. Along with sharing the progress we have made, this report outlines key areas where CTTI will be developing and driving adoption of improved practices going forward.

We look forward to continued partnerships with our members and other stakeholders to transform clinical research. Together, we can create a better system for clinical trials.

Pamela Tenaerts, MD, MBA
Executive Director, CTTI

2016 Highlights

In 2016, we made some important updates to our mission and strategic plan to ensure that CTTI continues to do timely, meaningful work that results in improved clinical trials. Driving adoption of CTTI recommendations became an official part of the mission, which emphasizes our role in translating evidence-based recommendations to real-world impact. This report will focus on the impact we have made over the past year in each of our five strategic areas of focus:

NEW CTTI MISSION:

To develop & *drive* adoption of practices that will increase the quality & efficiency of clinical trials

Results >>

Systematic Evidence Generation

Began developing recommendations to promote integration of mobile technologies in clinical trials for regulatory submissions

Facilitated 7,315 downloads of the Aggregate Analysis of ClinicalTrial.gov (AACT) datasets in 2016, which provide important insights on the state of clinical trials

Upgraded the AACT database to increase its functionality and broaden its user base; data are now refreshed nightly

Patients as Equal Partners

Partnered with the FDA to create a forum for discussing how to better engage patients in regulatory discussions across the FDA

Changed the culture of clinical research to increase meaningful engagement with patient groups in clinical trials—we continue to set the bar higher for patient engagement in clinical research

Implemented a policy to compensate patient representatives for their work on CTTI projects

Efficient & Quality Trials

Developed an innovative approach that organizations can apply to move strategic recruitment planning earlier, increasing recruitment success and alleviating downstream challenges

Released tools to help integrate recruitment planning throughout all stages of a clinical trial and to better engage all stakeholders, which can lead to increased enrollment

Facilitated >1,000 downloads of our Quality by Design recommendations, which sponsors apply to improve trial integrity and efficiency

Public Health Concerns

Developed principles for more feasible and streamlined hospital-acquired and ventilator-associated bacterial pneumonia (HABP/VABP) trials

Enrolled >5,750 patients in a risk factor study to provide evidence that following these patients may lead to possible recruitment in clinical trials, thereby supporting organizations in adopting our early enrollment strategy for more feasible HABP/VABP trials

Released evidence regarding patient and physician perspectives on the use of streamlined antibacterial drug development approaches to inform future use of these approaches

Safe & Ethical Trials

Published recommendations for data monitoring committee (DMC) organization and conduct to enhance the quality of trial oversight

Identified actions organizations can take to support the growing demand for qualified, effective DMC members

These provide a framework that focuses our efforts on high-priority areas as we work to move the needle towards a better clinical trial system.

2016 Highlights

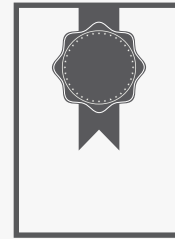
In 2016...



Our website had:

153,000 page views
(24% increase over previous year)

32,000 downloads
(59% increase over previous year)



TOP 5 DOWNLOADED RECOMMENDATIONS

1. Quality by Design
2. SAE Reporting
3. Patient Groups & Clinical Trials
4. GCP Training
5. Informed Consent



72 presentations
at conferences or
professional meetings

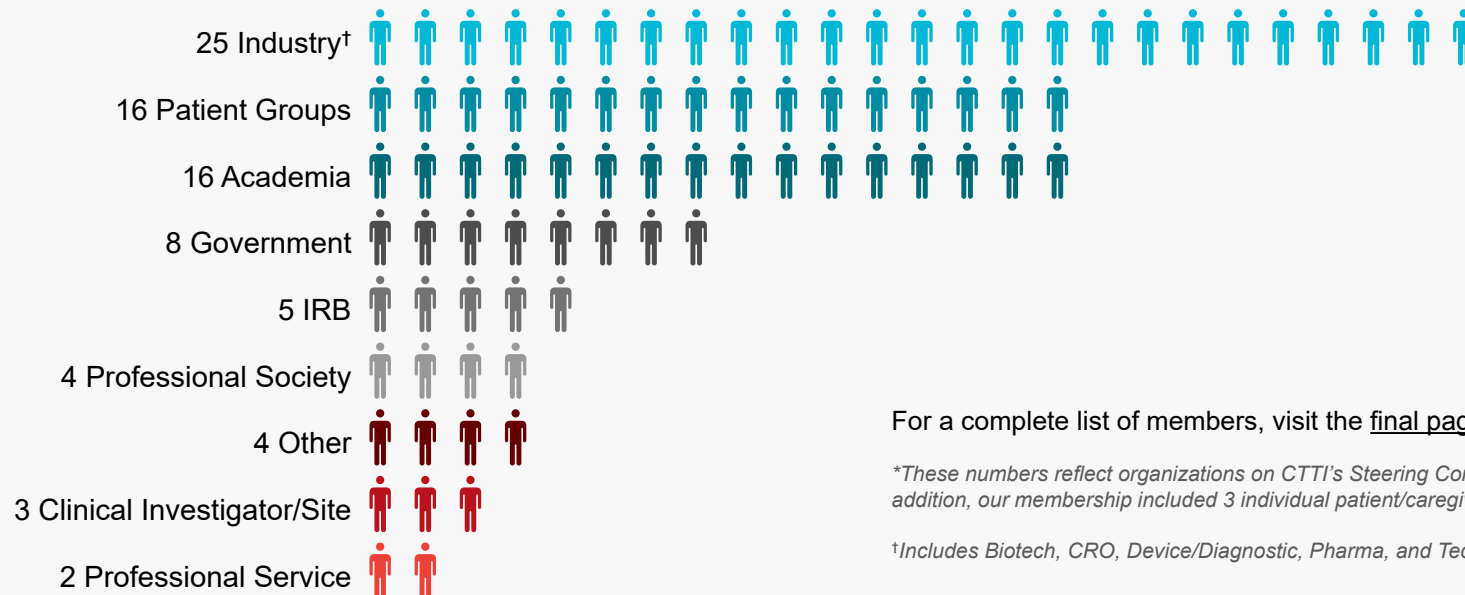


19 publications
in peer-reviewed
journals



>700
citations of CTTI
publications

2016 CTTI MEMBERSHIP*



For a complete list of members, visit the [final page](#) of this report.

*These numbers reflect organizations on CTTI's Steering Committee. In addition, our membership included 3 individual patient/caregiver representatives.

†Includes Biotech, CRO, Device/Diagnostic, Pharma, and Technology

Systematic Evidence Generation

The systematic generation of evidence to inform healthcare decisions is a top national priority, as well as one of CTTI's strategic areas of focus. CTTI's efforts are helping to transform how and what data are generated and included in clinical trials, toward the goals of increasing knowledge and creating more efficient and cost-effective research.

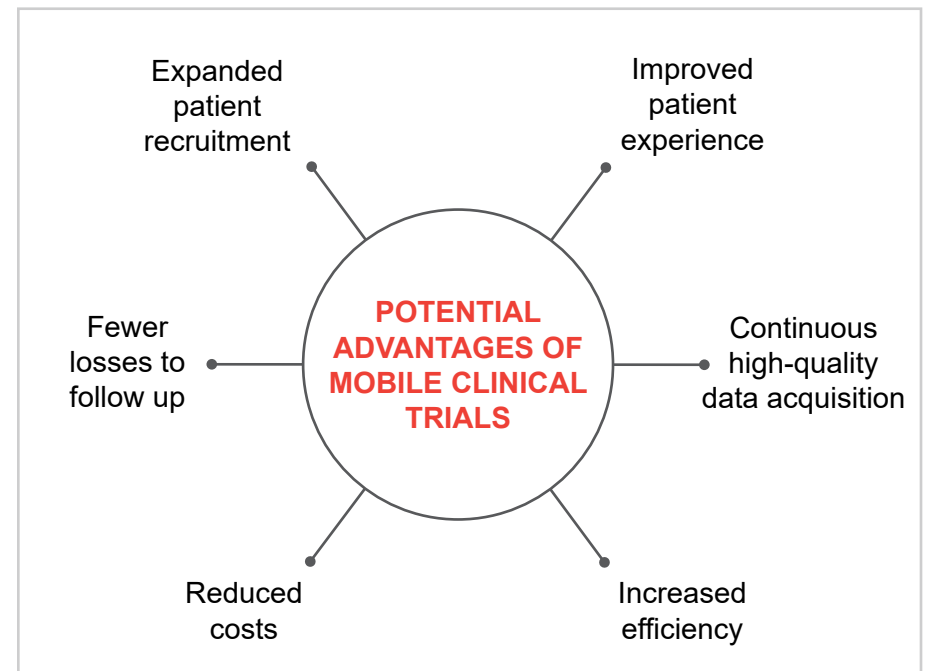
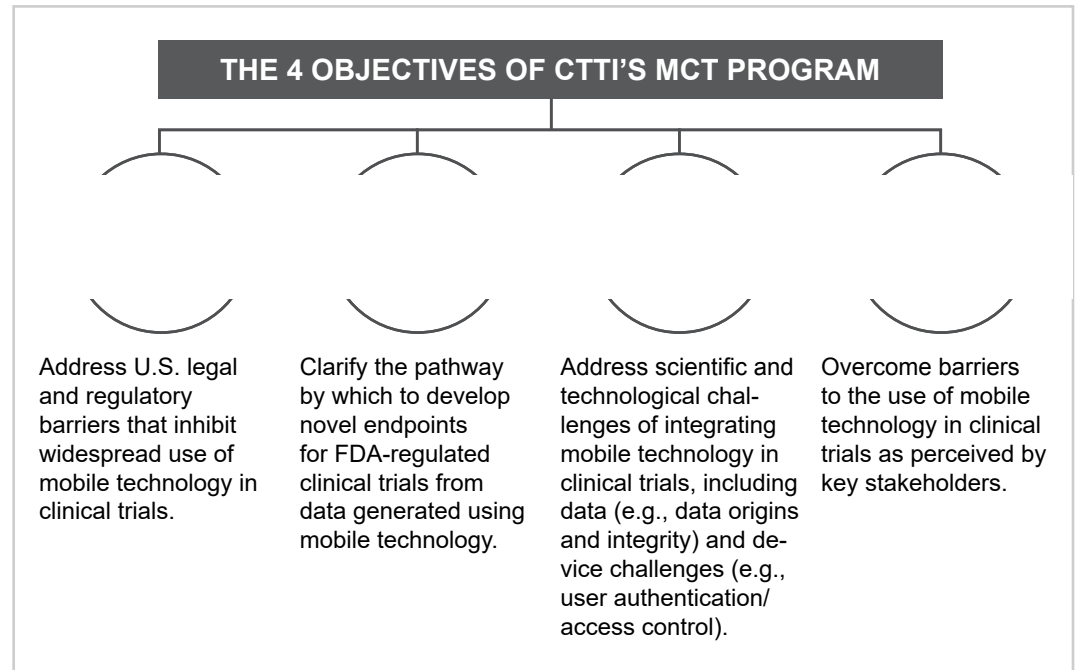
Realizing the Promise of Mobile Technologies

Through its Mobile Clinical Trials (MCT) program, CTTI is paving the way for mobile technologies to be incorporated in and transform clinical trials for regulatory submissions.

Despite enthusiasm among sponsors, patients, and other stakeholders, there is currently a lack of best practices on how to effectively integrate mobile technologies into clinical trials for regulatory submissions.

CTTI's MCT program includes four projects, each targeting a specific challenge that could threaten or delay widespread adoption of these promising technologies in clinical trials. Our multi-stakeholder teams are gathering evidence, along with expert input, to assure development of effective tools and actionable solutions that can be used by sponsors, investigators, industry, and regulators to support the use of mobile technology for enhancements to clinical trials.

For example, the Novel Endpoints Project is defining a pathway for developing novel endpoints using data generated by mobile technologies. Such technologies present opportunities to generate new endpoints that are not currently used, as well as to develop new and better ways measure existing endpoints. At an expert meeting, teams of investigators, patients, statisticians, engineers, and mathematicians, worked through four use cases to identify steps, requirements, challenges, and potential solutions for the endpoint development process. The four scenarios focused on the use of an accelerometer measuring physical activity as an outcome for Parkinson's disease, heart failure, and muscular dystrophy trials, and the use of a continuous glucose monitor measuring blood sugar level as an outcome for diabetes trials. Results from this work are being prepared for publication and will form the basis of recommendations for clarifying the pathway to develop novel endpoints.



Systematic Evidence Generation

Assessing the Clinical Trials Landscape to Direct Improvements

ClinicalTrials.gov has >220,000 registered studies; CTTI's database and tools help mine this data to uncover important insights that can prompt changes in clinical trials.

Through its Aggregate Analysis of ClinicalTrial.gov (AACT) database, CTTI provides an analyzable and publicly available dataset of ClinicalTrials.gov data that can be used to characterize the state of clinical trials and evaluate trends over time. The database has become a key resource for assessing the clinical trials enterprise.

In response to feedback, this year we upgraded this tool to improve the timeliness of data, increase functionality, and make it accessible to a broader group of people. The database now resides in the cloud and is refreshed nightly with information from ClinicalTrials.gov. Historical AACT (biannual) datasets remain available for analysis of trends over time.

Individuals can query the database directly or download it as a static dataset. The updated version of AACT is based on open-source technologies and requires no proprietary software—any program can be used for analysis. In accordance with our value of transparency, the database source code is openly available.

We hope AACT will continue to be a valuable resource. With the new NIH policy and final rule for FDAAA 801 in effect for clinical trial results reporting, there is an opportunity for more organizations to use this timely and easily accessible data to monitor their compliance.

	Original AACT	Upgraded AACT
Complete, analyzable dataset of ClinicalTrials.gov data	✓	✓
Free	✓	✓
Publicly accessible	✓	✓
Documentation for users	✓	✓
Frequency of content refresh	Every 6 months	Daily
Snapshots available for download		✓
Accessible in the cloud		✓
Based on open-source technologies		✓
Source code available		✓

EXAMPLES OF INSIGHTS POSSIBLE WITH AACT:

- ▶ View of the clinical trial enterprise as a whole
- ▶ Study design characteristics, such as phase, type of intervention, randomization, masking, age or sex restrictions
- ▶ Analysis of trials by specialty and funding source
- ▶ Enrollment goals and whether they are met
- ▶ Prevalence of DMC use
- ▶ Compliance with results reporting requirements

**THE AACT
DATABASE HAS
BECOME A KEY
RESOURCE FOR
ASSESSING THE
CLINICAL TRIALS
ENTERPRISE:**



>18,500 total downloads of AACT files
& 7,315 downloads in 2016



>20 publications since 2010



Community of regular users

Patients as Equal Partners

CTTI is setting the standard for effective engagement with patients throughout the research process.

Our recommendations, along with evidence on the effectiveness and value of engagement methods continues to move the field toward patients as equal partners.

We have developed detailed considerations and best practices for patient group involvement and relationship building in clinical trials. Our recommendations include ways to assist research sponsors with evaluation of patient group expertise, assets, stability, communications strength, and record of partnerships. Applying these strategies can help promote informed decision-making and more effective partnerships between sponsors and patient groups.

Through more recent initiatives, described on the next page, we continue to support patient engagement in medical product development. For example, work is ongoing to test and refine an economic model to help quantitatively demonstrate the value of patient group engagement in clinical trials.

By providing tools for establishing successful relationships, partnerships with patient groups around clinical trials are occurring with greater frequency. Our evidence-based recommendations for engaging patient groups around clinical trials have now been implemented by numerous organizations from different stakeholder groups, including industry, regulatory agencies, and patient advocacy groups. The “engage early, engage often” approach is resulting in meaningful connections throughout the research and development process.



USE OUR TOOLS FOR CHANGE

- ▶ Patient Groups & Clinical Trials Recommendations
- ▶ Patient Group Organizational Expertise and Assets Evaluation Tool
- ▶ Assessment of Patient Group Internal Aspects
- ▶ Assessment of Patient Group External Relationships



CTTI RECOMMENDATIONS IN ACTION: UCB PHARMACEUTICALS INC.

UCB Biosciences Inc. is applying CTTI's recommendations to develop mechanisms for implementing patient engagement strategies across the drug development life cycle. They have adapted the CTTI patient group engagement framework for their use. The result has been that UCB has developed a strategic vision to partner with patients at every step of the clinical development process to identify needs and inform study design and operations. Implementing these processes involved creating a culture shift toward patient centricity and delivering patient value. Under the new patient-centric model, there is a strategic vision considerate of all patient engagement opportunities, a focus on identifying true and actionable patient insights, a goal of delivering value to patients, and an appreciation of patients as valued partners.



CTTI RECOMMENDATIONS IN ACTION: FASTERCURES

FasterCures used CTTI's Patient Group Organizational Expertise and Assets Evaluation Tool to design a survey for patient groups to complete when applying for inclusion in FasterCures' Patients Count Network. The information gathered becomes part of this new digital directory for patient organizations, which can be accessed by research stakeholders to identify prospective partners. CTTI's tool helped to operationalize the criteria by which sponsors and researchers might gauge the capabilities of patient organizations. Several of CTTI's patient engagement-related resources are also included in FasterCures' Resource Library.

Patients as Equal Partners



FDA and CTTI Partner to Establish New Patient Engagement Collaborative

We are excited to be working with the FDA on a joint endeavor to create an ongoing, collaborative forum related to increasing patient engagement in medical product development and regulatory discussions across the FDA. Hosted by CTTI, the Patient Engagement Collaborative (PEC) will bring together members of the patient community with the FDA to exchange ideas on topics such as transparency, communication, and new models of collaboration.

The PEC is being established in response to public feedback the FDA received regarding implementation of the Food and Drug Administration Safety and Innovation Act, section 1137, Patient Participation in Medical Product Discussions. Comments suggested, among other topics, that an external group be established to provide input on patient engagement strategies across FDA's Centers.

When it formally launches in 2017, the PEC is anticipated to include 16 diverse representatives of the patient community, together with representatives from FDA and CTTI.

CTTI's New Policy on Compensating Patient Representatives

CTTI values the important contributions from the patient community, as it does all stakeholders involved in clinical trials. However, we recognize that patients may have different barriers to participation. Effective in 2016, we provide monetary compensation to patient representatives for time spent on CTTI activities. This policy is in alignment with the Patient-Centered Outcome Research Institute's Framework for Financial Compensation for Patient Partners in Research. Compensation is provided in the form of bi-annual stipends and is in addition to travel support for CTTI meetings.

Trials Designed with a Focus on Efficiency & Quality

Quality and efficiency have been at the core of CTTI's mission since its inception. Our results and recommendations help organizations that design, conduct, regulate, sponsor, and participate in clinical trials to produce high-quality evidence while reducing waste and delays.

Rethinking Clinical Trial Recruitment

CTTI's recommendations address recruitment challenges through strategic recruitment planning, and by advocating for this planning to begin earlier—during clinical trial design rather than execution.

Trials that fail to recruit can delay the availability of new medical products to patients. Sponsors, sites, and trial managers will commonly ask while a trial is underway, “We are not meeting our recruitment goals. What can we do to fix this?” Our recommendations propose a fundamental shift in clinical trial recruitment to an approach that integrates strategic recruitment planning throughout all stages of a clinical trial. Thinking about protocol elements that may affect recruitment during the design and development phases—before study activation—will help alleviate recruitment challenges later. We call this “creating recruitable protocols.”

Another critical element is that

recruitment planning needs to be more inclusive of all relevant stakeholders. Gathering insights from patients, study coordinators, and clinical investigators during study planning can provide perspectives on things these individuals value, as well as factors that may inhibit effective recruitment, such as an overly burdensome study visit schedule.

This work reinforces and builds upon CTTI's recommendations for clinical trial quality by design and effective engagement with patient groups. We have provided the framework and tools for implementing an improved approach to clinical trial recruitment planning. To date, the recruitment recommendations are being used by Eli Lilly and Company, the National Cancer Institute's Experimental Therapeutics Clinical Trials Network, and Duke University's Clinical & Translational Science Institute (CTSI) Recruitment Innovation Center.



The Recruitment Project recommendations are the result of an in-depth study evaluating why too often clinical trial recruitment efforts fail. These recommendations have the potential to catalyze greater efficiencies in diverse patient recruitment—women, minorities, and older adults—by focusing on the earliest stages in protocol development.”

-Jonca Bull, MD, Assistant Commissioner for Minority Health, US FDA

TRIAL DESIGN & PROTOCOL DEVELOPMENT

- ▶ Identify & engage all stakeholders
- ▶ Ensure the relevance of the scientific question
- ▶ Limit complexity to reduce burden
- ▶ Have realistic eligibility criteria
- ▶ Optimize data collection

TRIAL FEASIBILITY & SITE SELECTION

- ▶ Conduct evidence-based feasibility analysis
- ▶ Have realistic metrics & milestones
- ▶ Develop an adequate budget & resources
- ▶ Ensure appropriate site selection
- ▶ Engage suitable performance monitoring



RECRUITMENT COMMUNICATION PLANNING

- ▶ Identify and engage all stakeholders
- ▶ Identify where participants seek treatment & relevant information
- ▶ Develop & test tailored messages
- ▶ Develop creative material & select appropriate delivery channels
- ▶ Have a realistic budget
- ▶ Monitor & evaluate process & performance
- ▶ Embed recruitment intervention studies & share results



USE OUR TOOLS FOR CHANGE

- ▶ Recruitment Recommendations
- ▶ Decision Tree for Optimizing Protocol Design
- ▶ Stakeholder Identification and Analysis Tool
- ▶ Monitoring Recruitment Process & Performance
- ▶ Special Note on Patient-Reported Outcomes

Addressing Emerging Public Health Concerns

CTTI undertakes projects in therapeutic areas where better clinical trials are needed to address specific public health concerns. A current area of focus is antibacterial drug development.

CTTI is advancing the field of antibacterial drug development with strategies to make trials more feasible and efficient.

The staggering rates of antibacterial-resistant infections and associated complications speak to the desperate need for new treatment options that are safe and effective. The FDA has several initiatives aimed at combating antibiotic-resistant bacteria. One of these is CTTI's Antibacterial Drug Development (ABDD) program, which is targeting high-priority areas to accelerate the development of new antibacterial therapies as a way of addressing the public health crisis of antibacterial resistance.

Streamlined Development to Address Unmet Needs in Antibacterial Drug Development

This year, CTTI released new findings that can help inform the use of streamlined development pathways for antibacterial drugs, as well as labeling and risk communication for drugs developed using these approaches. CTTI's findings indicate that patients and providers recognize the usefulness of streamlined development approaches in situations with limited or no treatment options, though they expressed preferences for careful oversight, transparency in risk communication, and monitoring and reporting of safety and efficacy post-approval.

¹Review on Antimicrobial Resistance. Antimicrobial Resistance: Tackling a Crisis for the Health and Wealth of Nations. 2014. Available at <https://amr-review.org/>.

GLOBALLY, IF ANTIBACTERIAL RESISTANCE IS NOT ADDRESSED¹ BY 2050, DRUG-RESISTANT INFECTIONS COULD RESULT IN:



10,000,000 deaths annually



100,000,000,000,000 worldwide cost



Chemotherapy would not be possible



Routine surgeries such as caesarean sections or joint replacements could be life-threatening



As someone whose susceptibility to multiple infections and pneumonias has plagued me for six decades, these recommendations signal a transformational breakthrough."

-Stephen Mikita, patient advocate

Making HABP/VABP Trials More Feasible and Efficient

CTTI released two sets of recommendations to advance clinical trials for an important and particularly challenging area: hospital-acquired and ventilator-associated bacterial pneumonia (HABP/VABP). HABP/VABP occurs in seriously ill patients and is associated with high rates of antibiotic resistance and mortality. CTTI's innovative approaches to designing clinical trials for HABP/VABP include early enrollment strategies and the streamlined collection of safety data. Principles from this work informed FDA's 2014 HABP/VABP draft guidance¹ and may be useful for other types of ABDD trials.

The CTTI HABP/VABP recommendations appeared as part of a *Clinical Infectious Diseases* supplement featuring a variety of approaches for strengthening the pipeline of new antibacterial drugs. CTTI engaged global experts in the development of the supplement, which highlights the important role of public-private partnerships and is illustrative of the types of collaborations needed to advance ABDD.

¹U.S. Food and Drug Administration. Draft Guidance for Industry on Hospital-Acquired Bacterial Pneumonia and Ventilator-Associated Bacterial Pneumonia: Developing Drugs for Treatment. May 7, 2014.



USE OUR TOOLS FOR CHANGE

- ▶ Recommendations for Streamlining Protocol Elements for Hospital-Acquired Bacterial Pneumonia (HABP)/Ventilator-Associated Bacterial Pneumonia (VABP) Trials
- ▶ Recommendations for Optimizing Operational Efficiency for Data Collection in Hospital Acquired Bacterial Pneumonia (HABP)/Ventilator Acquired Bacterial Pneumonia (VABP) Trials

Driving Adoption of Improved Practices for HABP/VABP Trials

CTTI is conducting its first multi-center observational study, the results of which will provide an improved understanding of risk factors associated with HABP/VABP development and causes of clinical trial ineligibility. Optimizing the screening process and reducing screening failures could improve the feasibility of HABP/VABP trials, which are costly and challenging to conduct. Findings from this research will inform adoption of CTTI's recommended early enrollment strategy for HABP/VABP trials. Enrollment started in February 2016, and over 5,750 adults have been enrolled across 28 U.S. sites. CTTI is also collaborating with the NIH Pediatric Trials Network to conduct the risk factors study in pediatric patients. Enrollment began in August 2016, and over 180 patients have been enrolled.

Additional CTTI recommendations are forthcoming regarding how to address the unique challenges of ABDD in pediatric populations.



This type of work to develop and refine the approaches for testing antibacterial drugs for treating HABP/VABP would not be performed by any one individual drug company, but it is the type of science that can benefit the overall field of antibacterial drug development... We look forward to continued progress of the CTTI effort and the results from additional studies that will evaluate proposed solutions to these challenges."

-Edward M. Cox, MD, MPH, Director of the Office of Antimicrobial Products, Center for Drug Evaluation and Research, US FDA

Safe & Ethical Clinical Trials that Are Streamlined

CTTI recognizes that the safety of participants remains paramount in clinical research. Projects in this area of focus are aimed at ensuring that appropriate, value-added safeguards are in place to assess safety and that ethical standards for informing trial participants are met.

Best Practices for Data Monitoring Committees

CTTI has developed actionable recommendations for how to organize and conduct a data monitoring committee (DMC) in order to enhance the quality of trial oversight.

The use of DMCs has evolved over the past 50 years, and for a growing number of trials, DMCs play a unique and critical role in monitoring emerging data to assess the benefit-risk ratio for participants and make independent decisions regarding the need to modify or terminate a trial early.

Despite their important role in assuring the safety of trial participants, few DMC members receive any formal training on DMC operations, and published standards on DMC organization and conduct were lacking. Through research and multi-stakeholder input on DMC practices, CTTI developed recommendations that sponsors and DMCs can apply to enhance the quality of trial oversight. These include best practices for DMC composition, communications, and data reviews. Our recommendations also outline steps that organizations can follow to develop and identify qualified DMC members in order to keep up with the growing demand. Results from this project were published in *JAMA* and *Clinical Trials*.



USE OUR TOOLS FOR CHANGE

- ▶ DMC Recommendations, which include:
 - Specific DMC Responsibilities
 - Best Practices for DMC Meetings & Related Communication
 - Sample DMC Charter Table of Contents & Points of Consideration



CTTI RECOMMENDATIONS IN ACTION: CYSTIC FIBROSIS FOUNDATION LOOKS TO IMPROVE ITS DMC

The Cystic Fibrosis Foundation has applied CTTI's recommendations to improve its DMC operations in several ways. After reviewing the recommendations, the foundation initiated a survey to get sponsor feedback on whether there were opportunities to improve its DMC operations. It also plans to review and possibly revise the data report template provided to sponsors. In negotiating with more than 60 trial sponsors, the recommendations serve as a helpful reference document and source of support on DMC issues. The CTTI recommendations also encouraged the foundation to consider how much data the DMC should see and in what format. Finally, though the foundation had a comprehensive training program for DMC members, it has now adopted CTTI's recommendation to train the next generation of DMC members by proactively involving fellows and junior faculty in new DMCs.

EVIDENCE

Survey & focus groups of DMC members, patient advocates, IRB & FDA representatives, sponsors (industry, government, & nonprofit), & statistical data analysis center representatives.

Multi-stakeholder input

Best practices for DMC composition, member training & qualifications, roles & responsibilities, charter development, communication practices.

1. Enhanced quality of trial oversight
2. Support development of next generation of DMC members

IMPACT

Safe & Ethical Clinical Trials that Are Streamlined

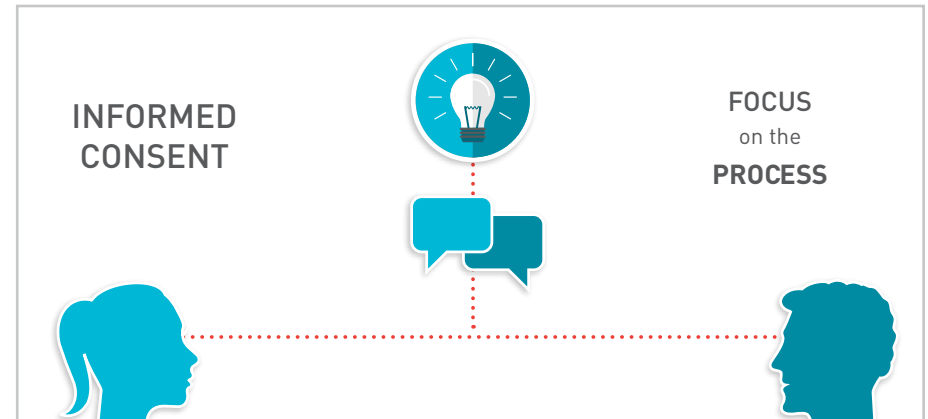
Creating a More Effective Informed Consent Process

We continue to support implementation of CTTI's recommendations for improving informed consent. The recommended strategies and tools reorient the informed consent process to an interactive conversation that better facilitates patient understanding and decision-making. Suggestions also help organizations create a more patient-friendly informed consent document, including the use of a tiered consent approach that presents critical information first. However, the document should be viewed as supportive and not the focus of the consent process. We are collecting and sharing information on implementation of these recommendations so that others will have real-world examples to follow as they apply the recommendations within their own organizations.



CTTI RECOMMENDATIONS IN ACTION: ELI LILLY

Eli Lilly and Company is implementing CTTI's informed consent recommendations through their new e-consent model, which also follows health literacy best practices and includes multimedia formats such as video to address a variety of learning types and improve overall comprehension. Their proposed model to transform consent includes an interactive electronic consent that can customize the informed consent experience to the user's preference. It incorporates CTTI's recommendation for a tiered consent model that delivers the most important information to the patient, such as risk-benefit considerations, and includes a detailed reference section for additional information. The ultimate goal is improved patient satisfaction and decision-making, as promoted in CTTI's recommendations.



We are confident these recommendations will result in a more efficient and higher quality informed consent process conducted by clinical research professionals. A clear understanding of the risks and expectations clinical trial participants face will enhance their experience and drive better quality research.”

-Jim Kremidas, ACRP Executive Director



USE OUR TOOLS FOR CHANGE

- ▶ Informed Consent Recommendations
- ▶ Informed Consent Discussion Tool
- ▶ Informed Consent Training Resources
- ▶ Sample Tiered Informed Consent Model

A Look Ahead

The progress we are accomplishing together is inspiring. We have made important strides this year in making trials more efficient and quality driven. Looking to the future, CTTI will be sharing new strategies to curb the epidemic of investigators leaving clinical research, best practices for conducting clinical trials for regulatory purposes within registries, and ways to overcome challenges of conducting antibacterial drug trials for children, to name a few. Also, within the next year, the MCT program will be producing actionable recommendations to support the use of mobile technology in regulatory submission trials.

Driving Adoption

In addition to these forthcoming recommendations, CTTI's mission was recently refined to reflect our commitment to actively drive adoption of the improved practices we recommend. Our work does not end when we issue our recommendations. We hope you will be involved with us as an innovator and apply our evidence-based tools and recommendations to improve your clinical trials.

LIST OF ALL CTTI RECOMMENDATIONS & TOOLS:

Streamlining Protocol Elements for HABP/VABP Trials *August 2016*

Optimizing Operational Efficiency for Data Collection in HABP/VABP Trials *August 2016*

Data Monitoring Committees (DMCs) *May 2016*

Efficient and Effective Clinical Trial Recruitment Planning *May 2016*

- ▶ Decision Tree for Optimizing Protocol Design
- ▶ Stakeholder Identification and Analysis Tool
- ▶ Monitoring Recruitment Process & Performance
- ▶ Special Note on Patient-Reported Outcomes

Desired Attributes of Electronic Portals for Expedited Safety Reporting *December 2015*

Informed Consent *November 2015*

- ▶ Informed Consent Discussion Tool
- ▶ Informed Consent Training Resources
- ▶ Sample Tiered Informed Consent Model

Effective Engagement with Patient Groups around Clinical Trials *October 2015*

- ▶ Patient Group Organizational Expertise and Assets Evaluation Tool
- ▶ Assessment of Patient Group Internal Aspects
- ▶ Assessment of Patient Group External Relationships

Quality by Design *June 2015*

- ▶ Principles Document
- ▶ QbD Toolkit

Advancing the Use of Central IRBs for Multi-center Clinical Trials *April 2015*

- ▶ Evaluation Checklist
- ▶ Template IRB Authorization Agreement
- ▶ Considerations Document

Good Clinical Practice (GCP) Training For Investigators *January 2015*

IND Safety Assessment and Communication *November 2013*

Use of Central IRBs for Multi-center Clinical Trials *January 2013*

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 *May 2011*

CTTI Portfolio of Projects & Collaborations



Strategic Focus:	SYSTEMATIC EVIDENCE GENERATION	PATIENTS AS EQUAL PARTNERS	EFFICIENT & QUALITY TRIALS	PUBLIC HEALTH CONCERN	SAFE & ETHICAL TRIALS
Completed Projects:	Large Simple Trials		GCP Training Monitoring Quality by Design Recruitment Site Metrics	ABDD Streamlining HABP/ VABP Trials ABDD Unmet Need Long-Term Opioid Data	Central IRB Central IRB Advancement DMCs Informed Consent IND Safety IND Safety Advancement SAE Reporting
Active Projects:	MCT Legal & Regulatory MCT Mobile Devices MCT Novel Endpoints MCT Stakeholder Perceptions Registry Trials State of Clinical Trials	Patient Groups & Clinical Trials	GCP Follow On Investigator Turnover	ABDD HABP/VABP Studies ABDD Peds Trials	Pregnancy Testing
Completed Collaborations:	Clinical Trials for Comparative Effectiveness Electronic Healthcare Data	Patient Engagement Survey	Clinical Trials Poll FDA Training Course	Cardiovascular Endpoints	
Active Collaborations:	Sentinel IMPACT-AFib	Patient Engagement Collaborative		ABDD PTN	

LOOK FORWARD TO MORE WORK FROM OUR ACTIVE PROJECTS AND COLLABORATIONS IN 2017.

Thank You

We would like to thank all of our members for their active involvement over the past year. Through your contributions, we have made great strides in improving the clinical trials enterprise. CTTI members often serve as early adopters of improved practices and as trailblazers for the rest of the clinical trial enterprise.

THANK YOU

2016 CTTI MEMBERS:

ACI Clinical
ActiGraph
AdvaMed
Agency for Healthcare Research and Quality
Alexion Pharmaceuticals Inc
Alliance for Lupus Research
Alnylam Pharmaceuticals
American Society of Clinical Oncology
Amgen Inc
Arthritis Foundation
Association of Clinical Research Professionals
Biomedical Advanced Research and Development Authority
Biomedical Research Alliance of New York
Biotechnology Innovation Organization
CR Bard Inc
Celgene Corporation
Cempra Pharmaceuticals Inc
Centers for Disease Control and Prevention
Centers for Medicare & Medicaid Services
Chesapeake IRB
CITI Program
Cleveland Clinic Coordinating Center for Clinical Research
Clinical Data Interchange Standards Consortium
Consortium of Independent Review Boards
Crohn's & Colitis Foundation of America
Dana-Farber Cancer Institute
Department of Veterans Affairs
Drug Information Association

Duke University
Eli Lilly
EMD Serono Inc
FasterCures, a Center of the Milken Institute
Feinstein Institute for Medical Research
Food and Drug Administration
Foundation for Prader-Willi Research
Friends of Cancer Research
Genentech – a member of the Roche Group
GlaxoSmithKline
Greenleaf Health LLC
JDRF International
Johnson & Johnson
Julius Clinical
King & Spalding LLP
Medidata Solutions
MedStar Health Research Institute
Medtronic Inc
Melanoma Research Alliance
Merck & Company
MPN Research Foundation
National Institutes of Health
National Organization for Rare Disorders
NC TraCS-University of North Carolina at Chapel Hill
New York University Langone Medical Center
Office for Human Research Protections
Palo Alto Investors LLC
Parent Project Muscular Dystrophy

Parkinson's Disease Foundation
Pfizer
PhRMA
PMG Research
Population Health Research Institute–McMaster University
Pulmonary Fibrosis Foundation
Purdue Pharma LP
Quorum Review IRB
Rexahn Pharmaceuticals
Society for Clinical Research Sites
Society for Clinical Trials
St Jude Medical
Susan G Komen
Target Health Inc
The George Institute
The Life Raft Group
The Medicines Company
The Michael J Fox Foundation for Parkinson's Research
University of Kansas Medical Center
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University of Oxford Clinical Trials Service Unit
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WIRB-Copernicus Group
Women's Heart Alliance
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