



# 2015 Annual Report



CLINICAL  
TRIALS  
**TRANSFORMATION**  
INITIATIVE

MISSION: To identify and promote practices that will increase the quality and efficiency of clinical trials



[www.ctti-clinicaltrials.org](http://www.ctti-clinicaltrials.org)

## LETTER FROM LEADERSHIP

We need a high quality clinical trial system that is patient-centered and efficient, enabling reliable and timely access to evidence-based therapeutic prevention and treatment options. CTTI moves the enterprise towards this vision through:

- ▶ A multi-stakeholder approach
- ▶ Evidence-based work
- ▶ Real-World Impact

This report highlights these strengths and the potential for CTTI's recommendations to re-shape clinical trials – today and in the future.

I would like to extend a special thank you to our members, project teams, and collaborators whose dedication to improve clinical trials is evident in their contributions to CTTI's work and the adoption of its recommendations.

Together, we are making a difference in people's health and lives. Onwards!

-Pamela Tenaerts, Executive Director



CTTI IS EXCEEDINGLY  
WELL-POSITIONED TO IMPROVE THE  
CLINICAL TRIAL ENTERPRISE.

Our unique approach combines three strengths:

1

MULTI-STAKEHOLDER  
ENGAGEMENT

2

EVIDENCE-BASED  
METHODOLOGY

3

REAL-WORLD  
IMPACT

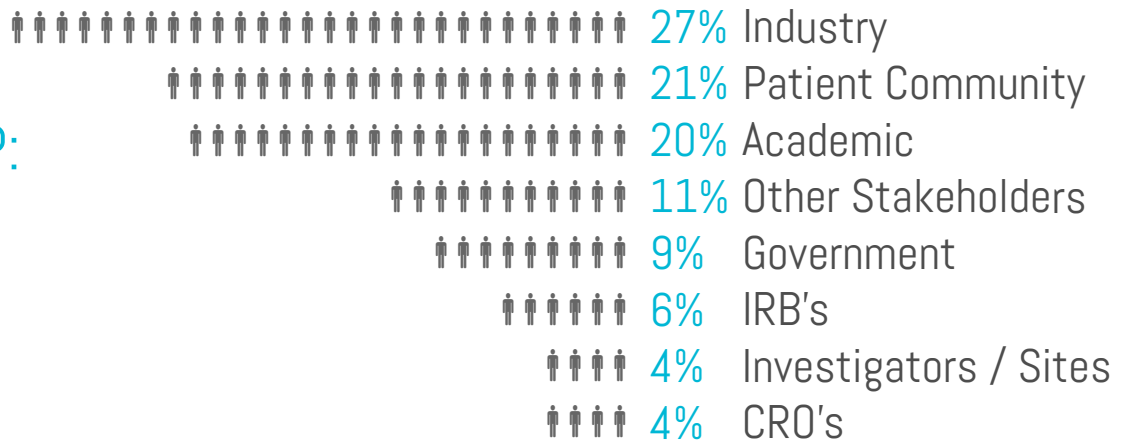
# 1 TRANSFORMATION IS A MULTI-STAKEHOLDER EFFORT

We bring together the best & brightest, often with diverse viewpoints, to engage in open, honest dialogue about impediments to efficient, quality clinical trials. CTTI members represent all key stakeholders involved in the design & execution of clinical trials. Projects likewise are conducted by a diverse team of equal partners to ensure a holistic approach to developing real-world solutions.

Every industry engages its consumers in the development of its product; it should be no different with clinical research.

CTTI sets the standard for true patient engagement. By making patients equal partners, we are closing the gap of accountability & transforming the status quo in clinical trials.

## 2015 CTTI MEMBERSHIP:



# 2 EVIDENCE GUIDES THE JOURNEY TO SOLUTIONS

CTTI uses both quantitative and qualitative research methods, selecting the method best aligned with each project's objectives in order to:

- ▶ Identify and describe "what is going on," with the overall purpose of gaining a better understanding of a particular phenomenon
- ▶ Move beyond individual views to a more complete and objective understanding of the disincentives and motivators for change

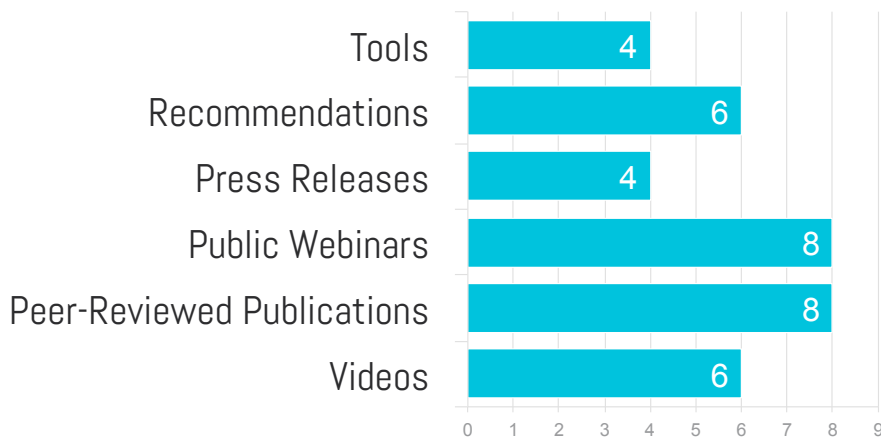
Equipped with data, we then challenge assumptions, identify roadblocks, build tools and develop recommendations to change the way people think about and conduct clinical trials.

## CTTI EVIDENCE METHODS:

- ▶ STAKEHOLDER INTERVIEWS
- ▶ FOCUS GROUP DISCUSSIONS
- ▶ SURVEYS
- ▶ SYSTEMATIC LITERATURE REVIEWS
- ▶ EXPERT MEETINGS

### 3 OUR PRODUCTS CREATE CHANGE

#### 2015 CTTI Products



CTTI has given **194** presentations at professional conferences & meetings. Of those, 46 occurred in 2015.

Tweet with us!

@CTTI\_Trials



CTTI's peer-reviewed publications have been cited **527** times to date.

In 2015, CTTI made over **127,000** Twitter impressions. Our Patient Group Project hashtag (#PGCT) made over **1,500,000** impressions.

## REAL-WORLD IMPACT IS FELT ON MANY LEVELS

#### AT THE PROJECT LEVEL

While a project is underway, participants are exposed to alternate viewpoints and given a forum to explore differing ideas. Through this exchange, new realities are normed and the seeds of innovation are sown.

#### WITHIN ORGANIZATIONS

CTTI's Central IRB tools & recommendations have been implemented at:



National Institute of  
Neurological Disorders  
& Stroke (NIH)



CTTI's Quality by Design framework is being used at:



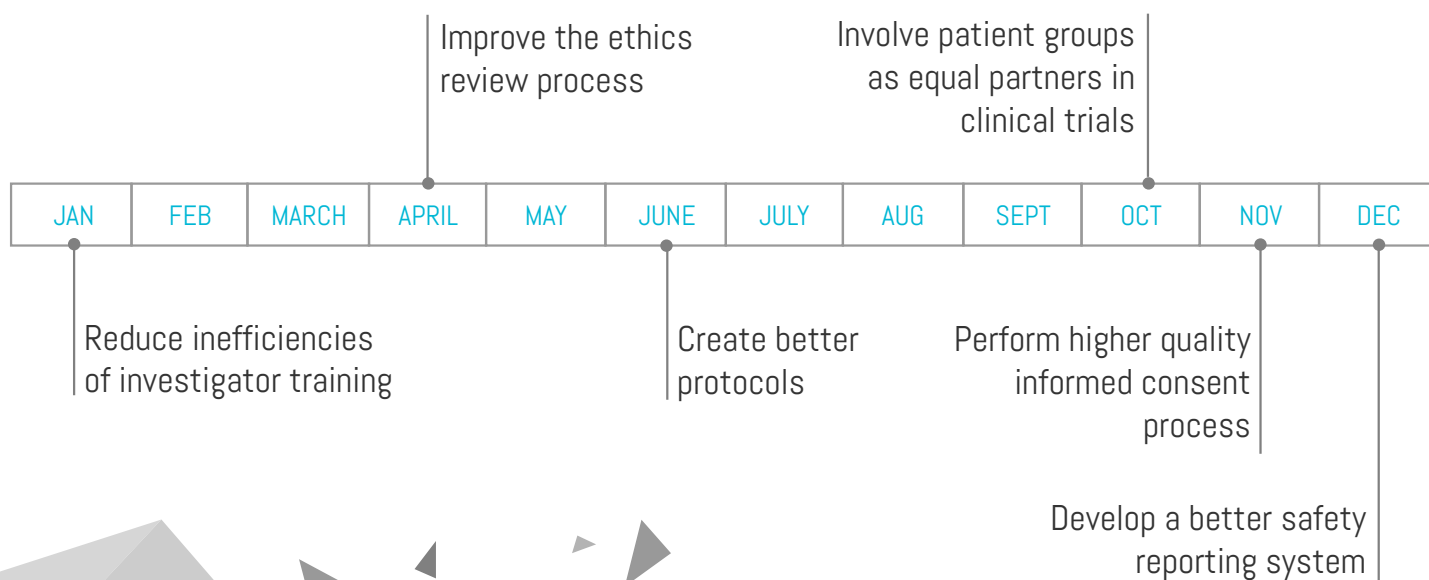
# REAL-WORLD IMPACT IS FELT ON MANY LEVELS

## AT THE POLICY LEVEL

- ▶ CTTI was referenced in the [NIH draft Policy](#) on single IRB of record in multi-center trials
- ▶ A number of ideas fostered through CTTI's Streamlining HABP/VABP Project were adopted by the FDA in its [HABP/VABP guidance document](#) & [unmet need guidance](#)
- ▶ CTTI was cited in the [FDA's newest draft guidance](#) on IND safety reporting
- ▶ CTTI's QbD work was cited in an [FDA Guidance](#) & an [EMA Reflection Paper](#)
- ▶ CTTI was cited in [21st Century Cures](#)

## LATEST RECOMMENDATIONS TO IMPROVE CLINICAL TRIALS

In 2015, CTTI released a record-breaking number of recommendations on the following topics:



# 1 CTTI RECOMMENDATIONS to REDUCE INEFFICIENCIES OF INVESTIGATOR TRAINING

“CTTI's GCP training recommendations provide another real world opportunity to improve efficiency in clinical trials.”

Christine Pierre  
President, Society for Clinical Research Sites (SCRS)

Download the:

► [Recommendations](#)

CTTI Project:

► [GCP Training](#)

# 2 CTTI RECOMMENDATIONS to IMPROVE THE ETHICS REVIEW PROCESS

“Using a single IRB for multi-site clinical research is an important step in accelerating the translation from discoveries to health benefits. The Clinical and Translational Science Awards (CTSA) program is working toward using a single IRB for multi-site studies. The CTTI Central IRB recommendations will be very helpful in advancing towards this goal.”

Petra Kaufmann, M.D., M.Sc.  
Director of the Division of Clinical Innovation at the National Center for Advancing Translational Sciences (NCATS), NIH

Download the:

► [Recommendations](#)

► [Template IRB Authorization Agreement](#)

► [Evaluation Checklist](#)

► [Considerations Document](#)

CTTI Project:

► [Central IRB](#)

# 3 CTTI RECOMMENDATIONS to CREATE BETTER PROTOCOLS

“Optimized trial designs can help us deliver important medicines to patients more quickly. In the Development Design Center, we collaborate with product teams to design and plan streamlined studies. We do this in part by posing questions to the team that challenge assumptions and stimulate creative thinking. The CTTI QbD Project Critical to Quality Factors Principles Document is a valuable reference as we plan for these group discussions.”

Julie Dietrich  
Director, Development Design Center, Amgen, Inc.

## JUST THINK

Download the:

► [Recommendations](#)

► [Principles Document](#)

Visit the:

► [Tiered Online Toolkit](#)

CTTI Project:

► [Quality by Design \(QbD\)](#)

## 4 CTTI RECOMMENDATIONS to INVOLVE PATIENT GROUPS AS EQUAL PARTNERS IN CLINICAL TRIALS

ENGAGE EARLY.  
ENGAGE OFTEN.

“The CTTI PG&CT recommendations represent a true breakthrough in establishing and maintaining productive research partnerships between clinical trials sponsors and patient groups. These important and very practical recommendations serve to provide the framework for patient groups and sponsors to initiate contact as well as provide ways in which established partnerships can enhance their quality, productivity, and measured success.”

Joel Beetsch, PhD  
VP, Global Patient Advocacy, Celgene Corporation

Download the:

- ▶ [Recommendations](#)
- ▶ [Evaluation Tools](#)

CTTI Project:

- ▶ [Patient Groups & Clinical Trials \(PG&CT\)](#)

“I LOVE the PG&CT Recommendations!!! I have highlighted, dog-eared, written in margins and made slides for my Board of Directors meeting from them!!! It is like opening a cookbook and reading a recipe. They are tangible and somehow make me feel validated and encouraged. Thank you so much!”

Donna Appell, RN  
CEO/Founder, Hermansky-Pudlak Syndrome Network Inc.

## 5 CTTI RECOMMENDATIONS to PERFORM HIGHER QUALITY INFORMED CONSENT PROCESS

FOCUS ON THE PROCESS

“As a study coordinator, I view the CTTI recommendations for a more comprehensive training program, including continuing education, as incredibly valuable and supportive of our needs. Additionally the discussion tool will assist in the training of new coordinators and help them assess the learning and communication needs of the study participant.”

Helen K. Donnelly, RN, BSN, CCRC  
Clinical Research Nurse, Pulmonary and Critical Care Medicine, Northwestern University

Download the:

- ▶ [Recommendations](#)
- ▶ [Discussion Tool](#)
- ▶ [Training Resources](#)
- ▶ [Sample Tiered Informed Consent Model](#)

CTTI Project:

- ▶ [Informed Consent](#)

# 6

## CTTI RECOMMENDATIONS to DEVELOP A BETTER SAFETY REPORTING SYSTEM



Most IND safety reports are distributed via e-portals, and this will likely only increase in coming years. The CTTI recommendations, if fully implemented, will improve the accessibility, interpretability, and accountability of e-portal safety data reporting. This has great potential to enhance the safety of participants in clinical trials."

Ray Perez, MD

Medical Director, University of Kansas Clinical Research Center,  
University of Kansas Medical Center

Download the:

► [Recommendations](#)

CTTI Project:

► [IND Safety Advancement](#)

## LOOKING AHEAD, WE WILL CONTINUE TO TACKLE TOUGH TOPICS IN 2016.

FOR EXAMPLE, HOW CAN WE...

Accelerate antibacterial drug development through recommendations to improve the design of protocols & the collection of safety data?

Increase the number of clinical trials leveraging mobile technology by addressing barriers to its use?

Improve the quality of trial oversight through the implementation of effective data monitoring committees (DMCs)?

Reduce the possibility of fetal exposure to investigational drugs by implementation of guidelines for pregnancy testing?

## MOVING THE NEEDLE, TOGETHER.



An improved clinical trial system won't just happen. We must create it.

CTTI has given you the building blocks to improve clinical trials.

We need you to adopt and act.

## THE TIME FOR CHANGE IS NOW.

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Mark B. McClellan, MD, PhD  
Chair of CTTI's Executive Committee

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John Alexander, MD, MHS, FACC  
Co-Chair of CTTI

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CDR Melissa Robb  
Co-Chair of CTTI