



CHANGE

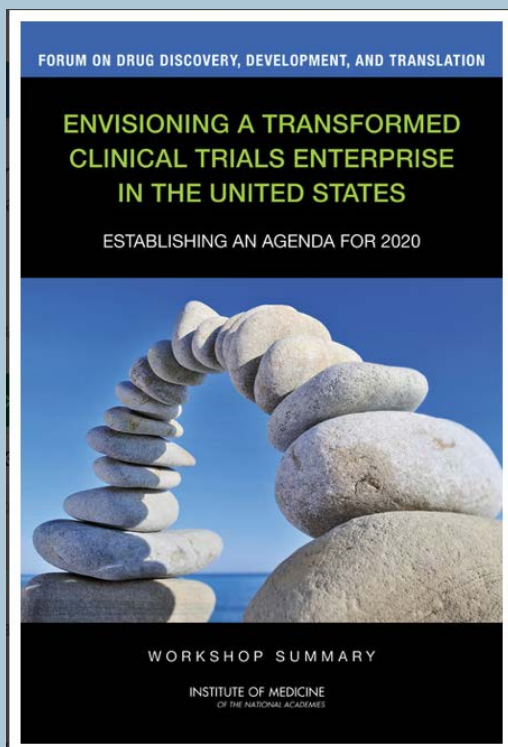
FRONTLINE EXPERIENCE

A ROAD TRAVELLED BY CTTI

Pamela Tenaerts, MD, MBA
Former Executive Director, CTTI

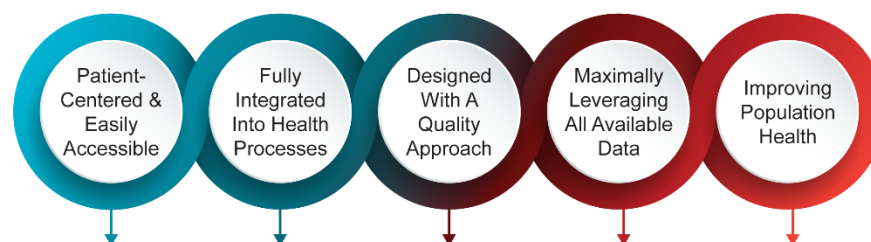
VISION





TRANSFORMING TRIALS 2030

By 2030, clinical trials need to be:



A critical part of the Evidence Generating System



*The National
Academies of* | SCIENCES
ENGINEERING
MEDICINE



Forum on
**DRUG DISCOVERY, DEVELOPMENT,
and TRANSLATION**

*Envisioning a Transformed Clinical Trials Enterprise for 2030 –
A Virtual Workshop*

TRUST

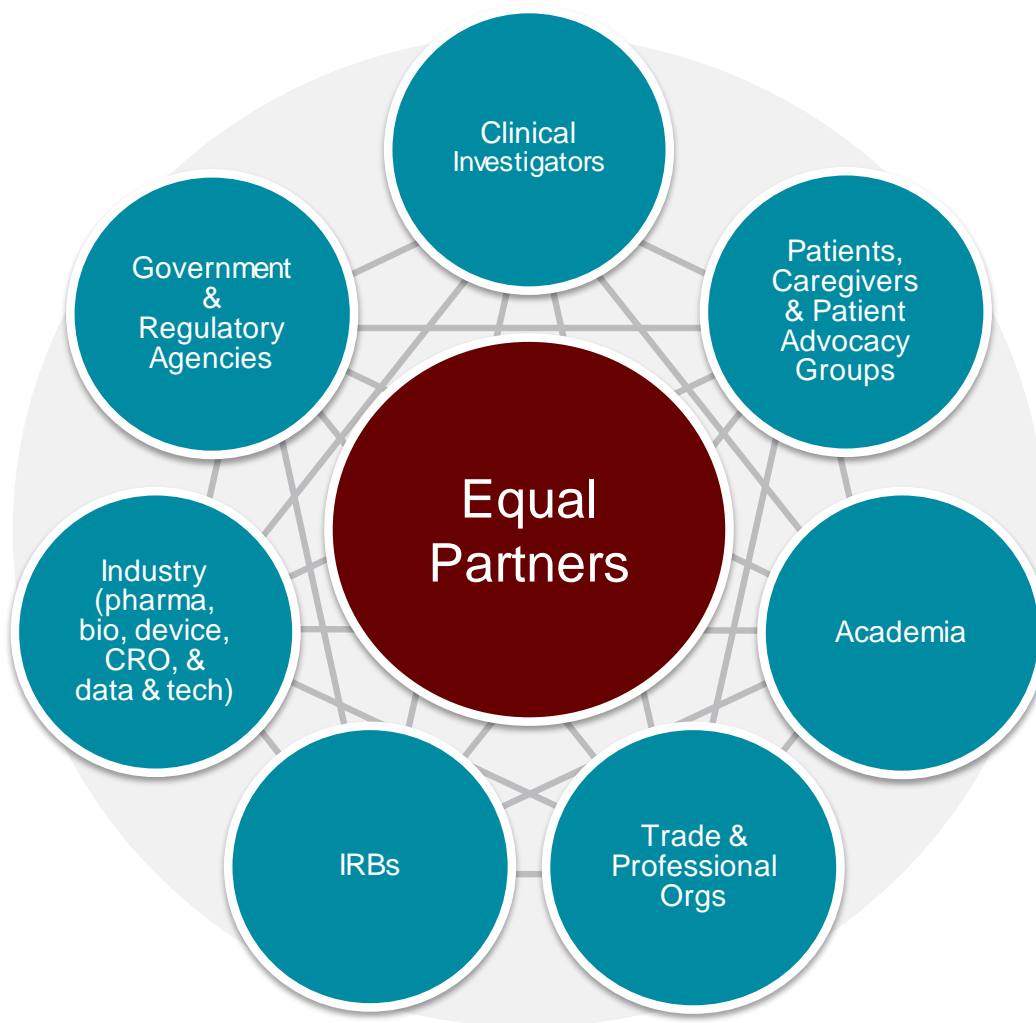
Participatory
Evidence-based



CLINICAL
TRIALS
TRANSFORMATION
INITIATIVE



Equal voice





Evidence-Based

➤ We use quantitative & qualitative research methods, selecting those best aligned with each project's objectives, to:

- Identify/describe “what is going on” to gain 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.

RESEARCH METHODS

STAKEHOLDER
INTERVIEWS

FOCUS GROUP
DISCUSSIONS

SURVEYS

SYSTEMATIC LITERATURE
REVIEWS

EXPERT MEETINGS

HOW

Process

Tools

Examples

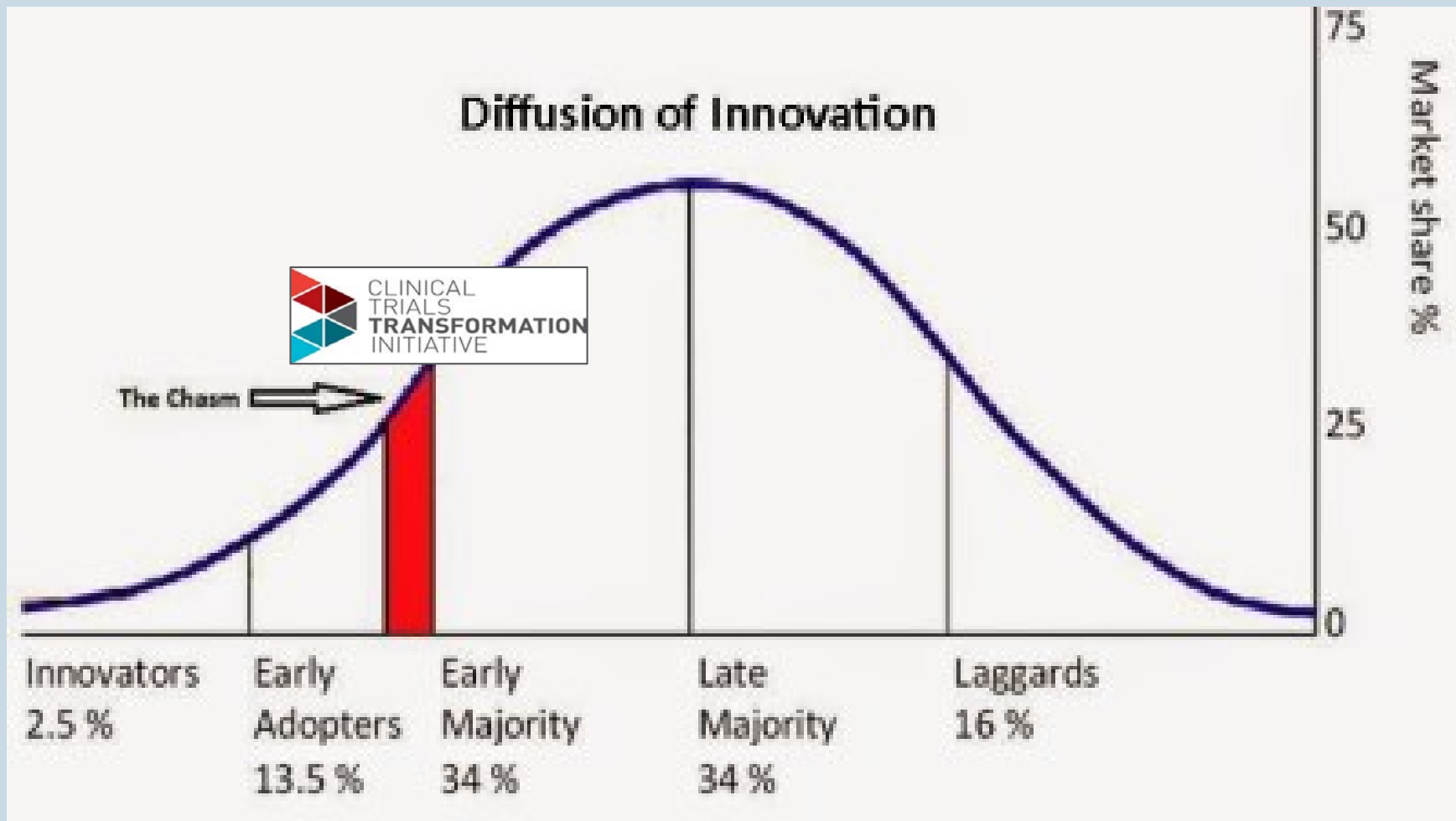
Process

- Past Membership Survey indicated that projects without recommendations have already created a change and had impact
 - *“A-ha!” Moments*
 - *Group therapy*
- Result
 - *Ensure diverse participation on projects*
 - *Allow wider participation*

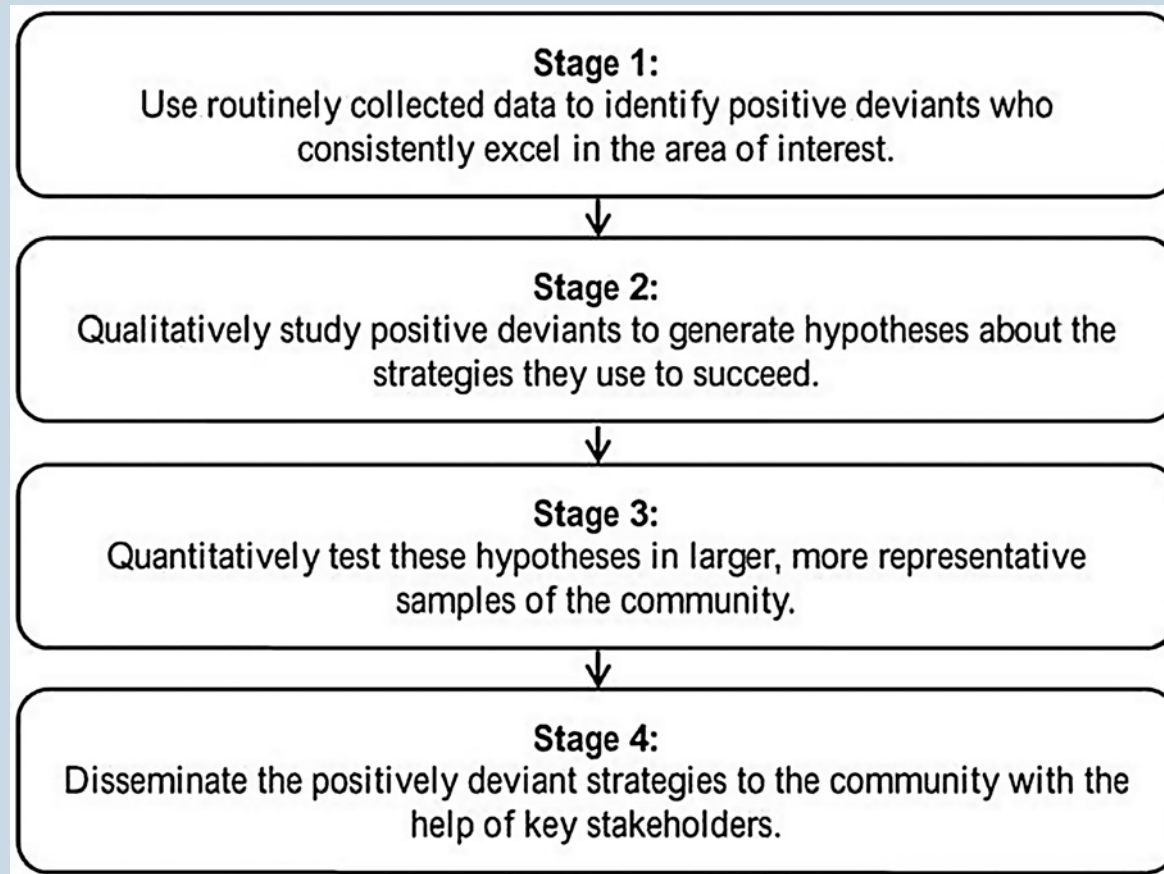
CTTI General Principles

- ▶ Open discussion is fostered by respect and collaboration with diverse members of the team
- ▶ Recognize that there will be setbacks and disagreement along the way
 - To maximize the benefit of collaborating, you need to diverge before you converge
 - Team members with minority perspectives should be given the opportunity to speak up if the team's thinking becomes lopsided

Harnessing Positive Deviants



The Positive Deviance Process for Healthcare

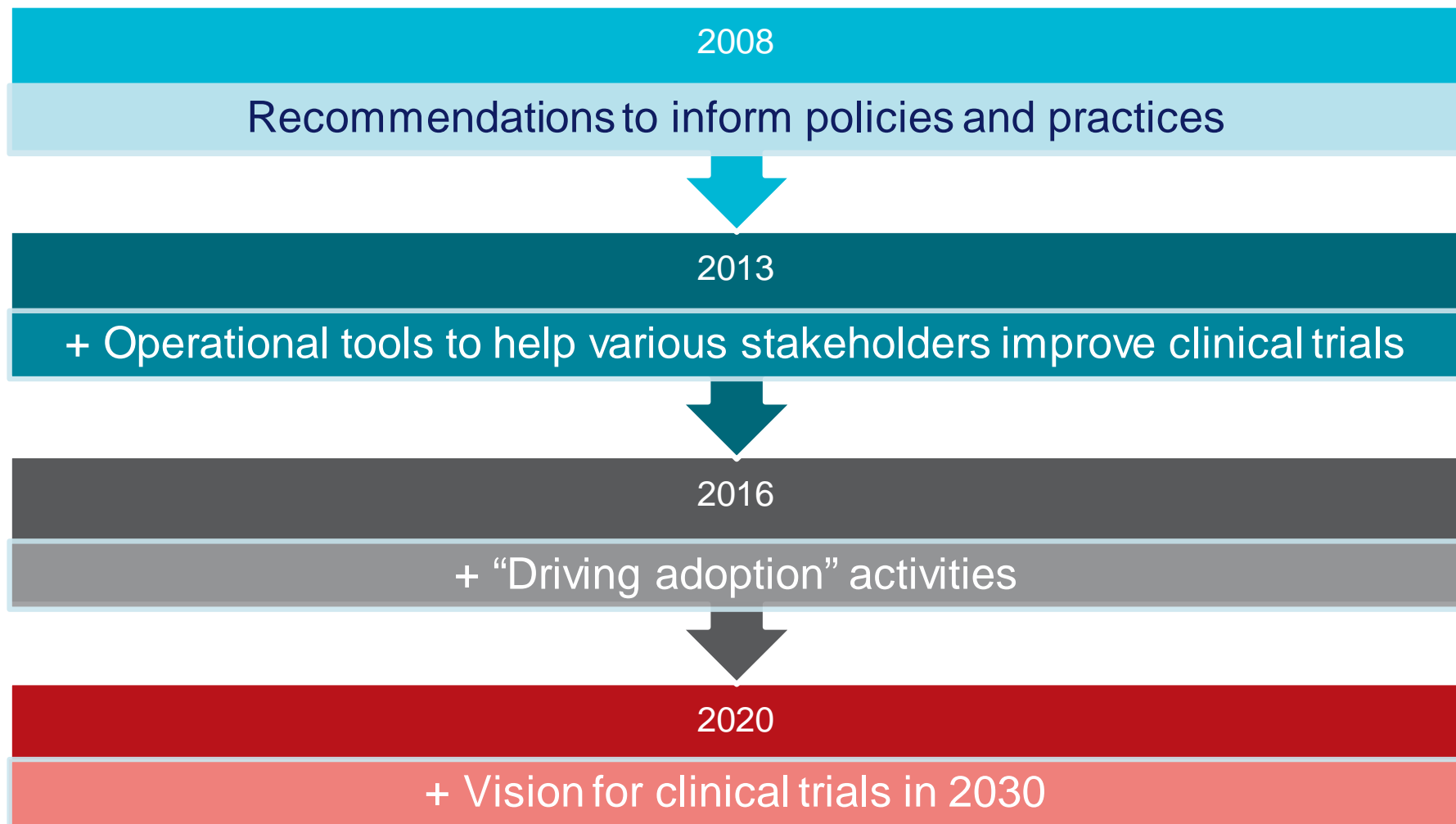


Ruth Baxter et al. BMJ Qual Saf 2016;25:190-201

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BMJ Quality
& Safety

Evolution of CTTI Approach



Below are CTTI-developed tools that can improve the quality and efficiency of your clinical trials today. CTTI's tools are created to facilitate the adoption of our [official recommendations](#). These recommendations are based on evidence generated by engaging all stakeholders involved in the clinical trial process.

QUALITY BY DESIGN (QBD) ADOPTION RESOURCES

A suite of new resources has been developed to facilitate the adoption of Quality by Design (QbD) in clinical trials:

- [QbD Metrics Framework](#)
- [QbD Maturity Model](#)
- [QbD Implementation Guide](#)
- [QbD Documentation Tool](#)
- [QbD Maturity Model Walkthrough and Scoring Examples](#)

SINGLE IRB ADOPTION RESOURCES

A suite of new resources has been developed to facilitate the implementation of single IRB (sIRB) in multicenter trials:

- [Single IRB: Determination of Institutional Engagement Overview](#)
- [Resource of Resources Document](#)
- [Single IRB: Institutional Engagement Scenarios](#)
- [Single IRB: Institutional Engagement Definitions](#)
- [sIRB Flowchart: Determining Engagement of Institutions in Research](#)

TOOLS

Building Better Trials Together: A Case Study Exchange

➤ Released last week

- 30+ case studies on how organizations have used CTTI's recommendations and resources to create more efficient, streamlined trials
- Online forum for people to share and learn from each other's experiences
- Provides examples for those interested in using CTTI's recommendations and resources
- Demonstrates the impact of CTTI's work

▪ Link [here](#)

BUILDING BETTER CLINICAL TRIALS

A Case Study Exchange

Creating better clinical trials is a community effort—and by sharing best practices, examples, and lessons learned with each other, we can learn and grow at a faster pace.

 Search

TOPICS

Check all that apply

- ☐ Antibacterial Drug Development
- ☐ Decentralized Clinical Trials
- ☐ Digital Health Technologies
- ☐ Informed Consent
- ☐ Investigators & Sites
- ☐ Large Simple Trials
- ☐ Novel Endpoints
- ☐ Patient Engagement
- ☐ Quality
- ☐ Recruitment
- ☐ Safety Reporting
- ☐ Single IRB

[Select All](#) [Clear All](#)

ORGANIZATION TYPE

Check all that apply

- ☐ Academia
- ☐ Clinical Investigator/Site
- ☐ Government
- ☐ Healthcare Delivery/Payer
- ☐ Industry
- ☐ Other
- ☐ Patient
- ☐ Professional Service
- ☐ Professional Society

[Select All](#) [Clear All](#)

Explore this database to see how others across the enterprise have implemented recommendations and resources from the [Clinical Trials Transformation Initiative](#) (CTTI) to run better, more efficient trials. Then, use these ideas to enhance your own clinical trials and share your results [here](#).

[Share](#)

The University of Kansas Medical Center Uses CTTI's Quality by Design Recommendations to Drive Efficiency Across its Organization

The University of Kansas Medical Center Applies CTTI's Quality by Design Recommendations

[Quality](#)
[Academia](#)

The Power of the Patient Voice: Cystic Fibrosis Foundation Uses CTTI's Patient Group Engagement Recommendations to Integrate Patients into Data Safety Monitoring Boards

Cystic Fibrosis Foundation Applies CTTI's Patient Group Engagement Recommendations

[Patient Engagement](#)
[Patient](#)

Orikami Uses CTTI's Novel Endpoints Recommendations to Build and Validate a Digital Biomarker to Monitor Fatigue in Multiple Sclerosis Patients

Orikami BV Applies CTTI's Novel Endpoints Recommendations

[Novel Endpoints](#)
[Industry](#)

Where to Begin with Digital Health Technologies? A Digital Health Scientist with Genentech Explains How CTTI's Recommendations Work

Genentech Applies CTTI's Digital Health Technologies Recommendations

[Digital Health Technologies](#)
[Industry](#)

Curebase Uses CTTI's Decentralized Clinical Trials Recommendations to Build a Completely Virtual Site Leveraging its Proprietary Software Technology

Curebase Applies CTTI's Decentralized Clinical Trials Recommendations

[Decentralized Clinical Trials](#)
[Industry](#)

The Feinstein Institutes' Innovative Central Support Office Inspired by CTTI's Investigator Qualification Recommendations

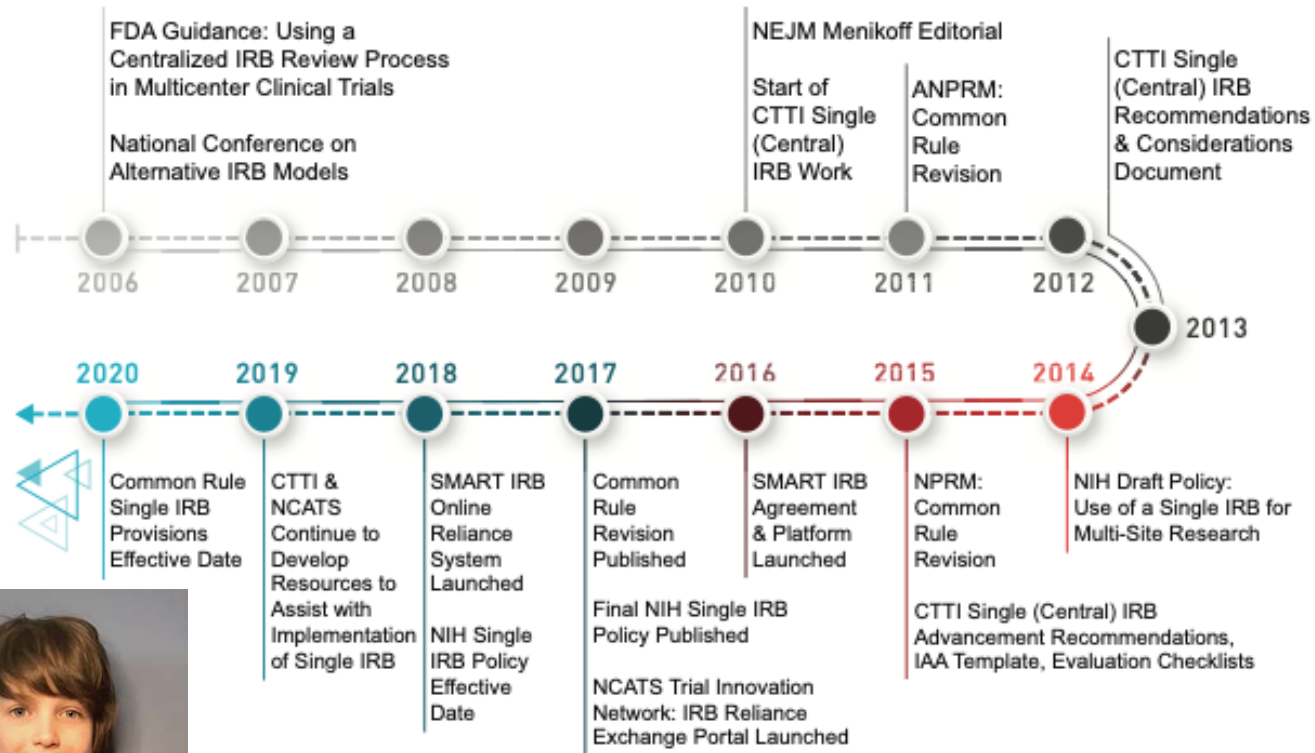
The Feinstein Institutes for Medical Research at Northwell Health Applies CTTI's Investigator Qualification Recommendations

[Investigators & Sites](#)
[Healthcare Delivery/Payer](#)

TIME



Overview sIRB Timeline



THANK YOU

@pamelatenaerts

<https://www.ctti-clinicaltrials.org>

