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# Pediatric engagement in research: Young people have a voice

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MULTI-REGIONAL CLINICAL TRIALS

THE MRCT CENTER of BRIGHAM AND WOMEN'S HOSPITAL and HARVARD

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# The Multi-Regional Clinical Trials Center (MRCT Center)

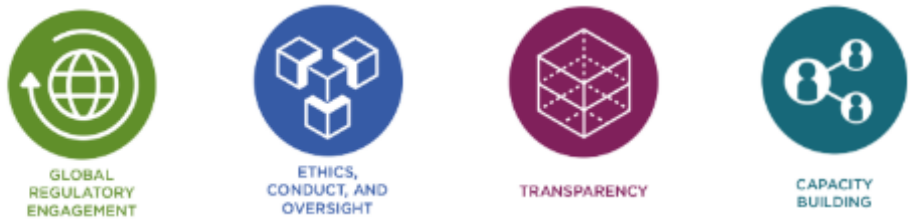
## Our Vision

Improve the integrity, safety, and rigor of global clinical trials.

## Our Mission

Engage diverse stakeholders to define emerging issues in global clinical trials and to create and implement ethical, actionable, and practical solutions.


Addressing emerging issues of MRCTs



# Promoting Global Clinical Research in Children

## Where we started & why this is important:

- Children **deserve access** to safe and effective medicines
- Children **historically excluded** from or underrepresented in research
- **Pediatric population widely dispersed** so clinical trials must be conducted in multiple jurisdictions
- Pediatric **market is small** but important
- **Persistent ethical issues:** while governing ethical principles may be generally agreed on, differences in interpretation and application of principles exist
- Differing or nonexistent pediatric **regulations**
- Challenges in **trial initiation and conduct**
- The **pediatric patient and family voice** is not routinely solicited and included in product development/clinical research life-cycle**.**

# Meaningful Patient Engagement: moving beyond checking the box

- How best to gather and reflect the input of the child and parent/guardian
- How to strengthen and integrate the position of the child and parent/guardian
- How to solicit and hear young people's voices
- What is representative and sufficient input

# How to enhance and strengthen clinical trial enterprise and public trust

- **Collect diverse and representative input** from pediatric patients and their families (guardians)
- **Share, present and summarize data** for various oversight bodies (IRBs, ethics committees, and regulatory agencies).
- **Be transparent** with information sharing
- **Understand and convey** how the pediatric patient and parent/guardian voices were collected and implemented in development plans throughout the product life cycle.

# Panel Objectives

- **Discuss** the ways IRBs, ethics committees and regulators currently view and utilize patient/family input.
- **Describe approaches** for enhanced incorporation of the patient/family perspective into the life-cycle of product development

# Panel Discussion

- The pediatric patient perspective
- The power of narrative
- Theoretical underpinnings and how we do the work
- Industry and regulatory perspectives

# Introduction to the panel

***Gianna "Gigi" McMillan***
Faculty and Program Administrator, Bioethics Institute at Loyola Marymount University

***Jennifer Preston***
Sr. Patient and Public Involvement Manager, University of Liverpool; eYPAGnet

**Albert J. "AJ" Allen**
Senior Medical Fellow, Pediatric Capabilities
Lilly Research Labs
Eli Lilly and Company

**Nathalie Bere**
Patient Engagement
European Medicines Agency (EMA)

# Panel presentations and questions

# Thank you!

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