Pediatric engagement in research: Young people have a voice

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Panel:
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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
- Global Regulatory Engagement
- Ethics, Conduct, and Oversight
- Transparency
- Capacity Building
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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