Advancing International Pediatric Clinical Research

TIME TO LISTEN: HEARING FROM YOUNG PEOPLE IN CLINICAL RESEARCH

February 2, 2022
8:00PM – 10:00PM EDT

This series is supported by an FDA Scientific Conference Grant.
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.
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
- **Persistent ethical issues**: while governing ethical principles may be generally agreed upon, 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 nor included in research life-cycle.
- **Children are not routinely offered a seat at the table.**
Project objectives

Broadly, sought to identify and propose solutions to regulatory, ethical, and operational challenges

- Current global landscape of pediatric research governance, focusing on legislative, regulatory, and guidance gaps and inconsistencies
- Identify current initiatives to improve pediatric research globally
- Identify challenges related to decision making by and on behalf of children
- Address benefit and risk considerations that create barriers and inefficiencies in transnational research with children.
- Identify meaningful ways to engage patients/families/community members

- Diverse leadership (Academia, EMA, Industry, participant advocates)
- 80+ members from all stakeholder groups with geographic diversity
Webinar Series: Advancing International Pediatric Clinical Research

- Funded through an FDA scientific conference grant award
- 5 virtual webinars; each session planned to be hosted twice, with similar content and different speakers and panelists, to allow for wide attendance and participation.
- An offshoot of the MRCT Center’s Promoting Global Clinical Research in Children project
Advancing international pediatric clinical research—looking ahead

1. *Informing the future from COVID-19 lessons learned:*  
   6 October 2021 & 7 October 2021

2. 2 February 2022: *Time to Listen—Hearing from young people in clinical research*

3. June 2022: Decision making at ethics committee level including strengthening of ICH E11, concept of an ethical floor

4. Fall 2022: Regulatory convergence to facilitate international cooperation

5. Early 2023: TBD

Today:

Please see ”Bio Book” for extended introductions to the speakers and panelists
Prioritizing Young People’s Voices in Clinical Research

MULTI-REGIONAL CLINICAL TRIALS

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

iCAN
International Children’s Advisory Network
Advancing International Pediatric Clinical Research

TIME TO LISTEN: HEARING FROM YOUNG PEOPLE IN CLINICAL RESEARCH

PART TWO

KEYNOTE SPEAKER
Dr. Sandhya Kanaka Yatirajula
The George Institute for Global Health, India

YOUTH GUEST SPEAKER
Rohit

This series is supported by an FDA Scientific Conference Grant.
Adolescent ‘Experts’ take the lead – Experiences and Lessons from ARTEMIS

Dr. Y.K. Sandhya
George Institute for Global Health
Research and engaging with adolescents and children

• Prior to 1988, much of the research on children and young people was adult centric (Coyne I. 1988)

• Data about children and young people was collected by consulting their parents/guardians/adults close to them

• The child was treated as a passive participant

• Such type of research failed to take into consideration the child’s ability to contribute
Recognising children as ‘social actors’

- The passing of the UN Convention on the Rights of the Child in 1988 marked a significant change in the way children were perceived.

- Researchers began to realise that it was necessary to talk to the children themselves about their experiences and feelings.

- The World Medical Association in 1989 recognised that it was necessary for researchers working with children/young people, to not only seek consent from their parents but also to seek consent from the children/young people themselves.

- Children began to be recognised as ‘social actors’ who possessed ‘genuine competencies’ that were as valid as that of adults.
Engaging with adolescents in ARTEMIS

- **ARTEMIS (Adolescent Resilience and Treatment Needs for Mental Health in Indian Slums) – A cluster randomised controlled trial running in two cities in India**

- Covering approximately 70,000 adolescents

- **Aim** - To test whether a community-based anti-stigma campaign leads to significant improvements in community behaviours toward adolescents with stress, depression and increased risk of self-harm/suicide
• ARTEMIS has very consciously incorporated the ethical aspect of working with adolescents.

• The setting up of the AEAG is a step in the direction of ethical research that views adolescents as active participants who are the most competent to design and deliver an intervention that affects them.

• Within ARTEMIS, the anti-stigma campaign is guided by the AEAG and informs the components of the anti-stigma campaign.

• The AEAG has been suggesting contextually relevant modalities of delivering the anti-stigma campaign.
Methods

• Formation of Adolescent Expert Advisory Groups (AEAGs) to craft the anti-stigma campaign
• Three AEAGs have been constituted in both cities
• Initial contact meetings organised with adolescents
• AEAG members selected based on their interest and the quality of their participation in these pre-AEAG meetings
• Written consent obtained
• Fortnightly AEAG meetings being held
• First AEAG meeting reiterated that AEAG members were the ‘experts’
Results

• AEAG meetings yielded rich discussions and suggestions from adolescents

The AEAG suggested a mix of:

✓ awareness raising to tackle lack of information on mental health, and
✓ sensitization events to force an examination of biases and its impacts on the mental wellbeing of adolescents

• Findings from the formative research showed that all anti-stigma materials were well received and effectively communicated messages
Rohit – our AEAG member
Lessons learnt

• The process of co-creation is an empowering one for the adolescents who are part of it.

• The process of co-creation ensures that the intervention is culturally and locally relevant thereby making it more inclusive and therefore potentially more scalable.

• Co-creation also made it possible to source adolescents with lived experience of mental disorders easily, contrary to the experiences of earlier projects.

• Ethical dilemmas faced were resolved by engaging in discussions with the adolescents themselves and arriving at an acceptable solution that did not compromise on ethical principles.
Conclusion

• The AEAGs have strengthened adolescent-practitioner-researcher collaboration and partnership that has provided useful insights and enriched the programme.

• The process of co-creation has ensured that ARTEMIS is culturally and locally relevant thereby making it more inclusive and therefore potentially more scalable.

• While conducting research with children it is essential to engage with them, especially if they are vulnerable and marginalised, and find solutions to ethical dilemmas that are acceptable to them.

• It is importance to maintain a balance between protect the interest of children and young people and recognise ‘their right to exert their competence’.
Thank you!
Time to listen: Hearing from young people in clinical research

View Video
Advancing International Pediatric Clinical Research

PART TWO

TIME TO LISTEN: RESPONDING TO YOUNG PEOPLE TALKING ABOUT CLINICAL RESEARCH

PANEL DISCUSSION

Moderator:
Dr. Thierry Lacaze
University of Calgary
Canada

Guest Speaker
Ms. Sheila Varadan
Independent Child Rights
Legal Researcher
Thailand

Guest Speaker
Dr. Min Soo Park
Severance Children’s Hospital
Korea

MULTI-REGIONAL CLINICAL TRIALS
THE MRCT CENTER of BRIGHAM AND WOMEN’S HOSPITAL and HARVARD

This series is supported by an FDA Scientific Conference Grant.
Clinical Research with Children and Young People: Different and Conflicting Perspectives

Investigators

Research journey
- design
- funding
- implementation
- execution
- dissemination

Institutions

Regulators

Health care providers

Sponsors, funders

Participating

Children/YP and parents

R13 Webinar Series

©MRCT Center
• How can we ethically undertake the research needed to ensure children and young people healthcare services are safe and effective, given that research often involves burdens and risks?

• Moreover, what role should children, young people and parents themselves play in influencing how research studies are carried out, and how can their voices help influence the wider research agenda?

Advancing International Pediatric Clinical Research

TIME TO LISTEN: HEARING FROM YOUNG PEOPLE IN CLINICAL RESEARCH

PART TWO

Guest Speaker
Ms. Sheila Varadan
Independent Child Rights Legal Researcher
Thailand
Talk directly to the child

Every child is an individual and an independent rights-holder

‘I really don’t like it when they talk to the adult but they don’t talk to me because it is as if they think my opinion doesn’t matter’
(Megan, USA, 11 years)

‘When I am the one who is ill, why is the doctor not discussing it with me?’
(Sandhya, India, 18 years)

‘If I was younger, maybe I should not listen to all of it’
(Jan, Spain, 16 years)
Talk directly to the child
Every child is an individual and an independent rights-holder

UN Convention on the Rights of the Child
A legally-binding instrument under international law
Most ratified treaty in history – adopted in 1989 – 196 States parties

All children, even very young children, are individuals and rights-holder under international law

Children should be treated as **active participants** and **collaborators** in research –

- Right to be **HEARD** (Art 12(1))
- Right to **FREEDOM OF EXPRESSION** (Art 13)
- Right to **ACCESS INFORMATION** (Art 17)
- Right to receive guidance and support that enables their **Evolving Capacities** in decision-making (Arts 5 and 18)
Accessing the ‘child voice’

Children have a right to be part of the decision-making process

• ‘We kids need to recognize the difference between people who say they are listening…and people who say they are listening and actually are’ (Megan, USA, 11 years)

• ‘I have been part of programs that do a good job listening to the voices of children…They take our opinions and incorporate them into their programs’ (Sandhya, India, 18 years)

• ‘I am in Kids Barcelona so…I am really being heard because I am in an advisory group. Doctors and specialists come to us when they have questions they want us to answer’ (Jan, Spain, 16 years)

Really listen to kids
Accessing information, expressing views and having those views taken seriously

'I like it when they use visual information, like videos which help me understand the medical procedures…'
(Jan, Spain, 16 years)

'I understand the most when I am actually talking to someone. I can say something back and they can fill me in on more if they need to'
(Megan, USA, 11 years)

'Body language, the way of talking and the environment should build confidence in the child'
(Sandhya, India, 18 years)


©MRCT Center
Supporting parents and carers

Parents and carers are part of the information-delivery process

• ‘It is essential for parents to understand as well as the children, because the parents are the one who know their son or daughter’ (Jan, Spain, 16 years)

Parental rights
• Information and support that is directed towards the child’s participation and involvement in decision-making

Children’s rights
• Guidance that supports the child’s participation and aligns with her evolving capacities in decision-making in the research setting
Children are not the people of tomorrow, but people today. They are entitled to be taken seriously. They have a right to be treated by adults with tenderness and respect, as equals. They should be allowed to grow into whoever they were meant to be. The unknown person in side each of them is the hope for the future.

-- Janusz Korczak (1878 – 1942)
Advancing International Pediatric Clinical Research

TIME TO LISTEN: HEARING FROM YOUNG PEOPLE IN CLINICAL RESEARCH

Guest Speaker
Dr. Min Soo Park
Severance Children’s Hospital
Korea

This series is supported by an FDA Scientific Conference Grant.
Advancing International Pediatric Clinical Research

TIME TO LISTEN: HEARING FROM YOUNG PEOPLE IN CLINICAL RESEARCH

And in closing...

February 2, 2022

This series is supported by an FDA Scientific Conference Grant.

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

- Age-appropriate materials for young people considering participation in clinical trials
- The MRCT Center is developing a suite of educational materials for youth aged 12-17 (age 7-11 pending) to address that gap in accessible general information about clinical research.

All materials were developed by youth and reviewed by young people’s advisory groups and international stakeholders.
• What is clinical research?
• What is assent?
• What happens at the end of the study?
• Assent to consent.

In development:
• Sharing your information (data) in research
• What is a Focus Group and Why Should I Join One?
• Sensitive Information in Research
In collaboration with Boston Children’s Hospital and Harvard Catalyst (CTSA)

https://catalyst.harvard.edu/services/rsa/
Meaningful Engagement: let’s move beyond checking the box

• Youth participation *assent* and parental/guardian *consent* form for non-research activities

• Process considerations for pediatric patient engagement in non-research activities
  • Preparation and understanding
  • Right to review materials before and after
  • Privacy and security considerations
  • Transitions before and after engagement

• Questions offered to help stimulate consideration and adaptation to the specific context, including:
  • Initiating the conversation with young people, their parents/guardians, and caregivers
  • Youth engagement throughout the product lifecycle
  • Considerations to aid decisions around youth engagement
INCLUDING YOUNG PEOPLE IN RESEARCH: A TOOLKIT
Resources to facilitate & support inclusion of youth in (non)-research activities

Instructions for use

Parent/Guardian/LAR Consent

Young Person’s Assent
Use, translations, and the future of materials

- Please use and disseminate

- If you translate materials, we ask:
  1. Work with us
  2. Ensure that translated material remain age-appropriate
  3. Allow us to repost so that others need not expend resources replicating effort

- Please let us know if you have future suggestions for additional materials
• Webinar recording and slides will be posted in approximate one week
• Youth videos will be also be available on YouTube
• We look forward to hearing from you
• Sign up for future webinar(s)
Special Acknowledgements

Thank you to our speakers, participants, and particularly the young people who shared their stories and taught us so much.

**Dr. Gianna “Gigi” McMillan**, producer of “*Time to Listen-Hearing from Young People in Clinical Research*” video

**International Children’s Advisory Network (iCAN)**, producer of “*Prioritizing Young People’s Voices in Clinical Research*” video

All the youth who shared their time, expertise and stories with us from iCAN and Kids Barcelona
Please follow the MRCT Center

Thank you!