PART FIVE

Advancing International Pediatric Clinical Research

Promoting Global Clinical Research in Children: Informing the Future

21 March 2023, 9-11 am ET

This series is supported by an FDA Scientific Conference Grant.

MULTI-REGIONAL CLINICAL TRIALS

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

Disclaimer

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- The opinions expressed today are those of the speakers and are not intended to represent the position of Brigham and Women's Hospital, Harvard University, or any other organization, government, or entity.
- The MRCT Center is supported by voluntary contributions from foundations, corporations, international organizations, academic institutions and government entities (see www.MRCTCenter.org) and well as by grants.
- We are committed to autonomy in our research and to transparency in our relationships. The MRCT Center—and its directors—retain responsibility and final control of the content of any products, results and deliverables.
- I have no personal financial conflicts of interests to disclose.
- This webinar will be recorded and will be posted publicly on our YouTube channel.

In remembrance of Dr. Vasantha Muthuswamy

We would like to offer a brief remembrance to our valued colleague and close collaborator, Dr. Vasantha Muthuswamy, who passed away in Mumbai in February 2023.

The MRCT Center

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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

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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, their families, and community members
- Diverse leadership and membership, broad geographic diversity

Webinar Series:
Advancing International Pediatric Clinical Research

- An offshoot of the MRCT Center's *Promoting Global Clinical Research in Children* project
- Funded in part through an FDA scientific conference grant award
- 5 virtual webinars

1. Informing the future from COVID-19 lessons learned: October 2021
2. Time to Listen—Hearing from young people in clinical research: February 2022
3. Assent and Consent in the Field: Culture, Context, and Respect: June 2022
4. Facilitating Pediatrics Medicines Development: Models of Global Cooperation: Nov 2022
5. **Today - *Promoting Global Clinical Research in Children: Informing the Future***

Please see "Bio Book" for extended introductions to the speakers and panelists

Today's Agenda

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9:20 – 9:40 AM	Including Children in Decisions About Research: Towards Consistent Global Standards	**Steve Joffe** University of Pennsylvania
9:40 – 10:00 AM	Involving Young People in Research: The Pediatrics Toolbox	**Lisa Koppelman** MRCT Center **Gigi McMillan** Loyola Marymount University
10:00 – 10:15 AM	Establishing a Model to Integrate Children's Voices into the Clinical Research Process	**Thierry Lacaze** Maternal Infant Child & Youth Research Network (MICYRN)
10:15 – 10:45 AM	Innovations in the Pediatric Regulatory Space: Fireside Chat	**Dominik Karres** European Medicines Agency **Skip Nelson** Johnson & Johnson
10:45 – 10:55 AM	Closing	**Barbara Bierer** MRCT Center

Including Children in Decisions About Research: Towards Consistent Global Standards

Dr. Steven Joffe
University of Pennsylvania
Perelman School of Medicine

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European Society for Paediatric Research
Society for Pediatric Research
www.nature.com/pr

SPECIAL ARTICLE

Establishing a global regulatory floor for children's decisions about participation in clinical research

Steven Joffe[1,2]✉, Albert J. Allen[3], Jonathan M. Davis[4], Elisa Koppelman[5], Susan Z. Kornetsky[6], Grace Marie V. Ku[7], Victoria A. Miller[8], Jennifer Preston[9], Lesha D. Shah[10] and Barbara E. Bierer[5,11]

Pediat Research January 28, 2023 (online ahead of print)

Process

- Working group including 13 members, subset of larger 80+ person workgroup
- 12 monthly 90-minute Zoom meetings
- Working group identified International Council for Harmonisation (ICH) recommendations as best approximation of global standard for pediatric research
  - Analysis of ICH standards (and recommendations for improvement) in light of working group's insights

ICH
harmonisation for better health

INTERNATIONAL COUNCIL FOR HARMONISATION OF TECHNICAL REQUIREMENTS FOR PHARMACEUTICALS FOR HUMAN USE

ICH HARMONISED GUIDELINE

ADDENDUM TO ICH E11: CLINICAL INVESTIGATION OF MEDICINAL PRODUCTS IN THE PEDIATRIC POPULATION

E11 (R1)

Final version
Adopted on 18 August 2017

https://database.ich.org/sites/default/files/E11_R1_Addendum.pdf

1. Sharing information with participants & parents

- Key ICH points
  - Fully inform parents as legal decision makers in language they can understand
  - When seeking child assent, provide information appropriate to child's capabilities

1. Sharing information with participants & parents

- Recommendations—guidance should…
  - Specify what information is material
  - Distinguish research-specific elements from ordinary care
  - Ensure opportunity for questions & clarifications
  - Address the readability of documents
  - Highlight need to assess understanding (and correct misunderstandings)

2. Children’s roles in authorizing participation

- Key ICH points
  - Where appropriate, children should give assent
  - May be necessary to reconfirm assent (or obtain consent) over course of a trial

2. Children’s roles in authorizing participation

- Recommendations—guidance should…
  - Define assent
  - Clarify “when appropriate”
  - Address whether & how to engage children when assent is not required

3. Children’s signatures on “assent forms”

- Key ICH points
  - Participants of appropriate intellectual maturity should sign an assent or consent form

3. Children’s signatures indicating agreement

- Recommendations—guidance should…
  - Define “appropriate intellectual maturity”
  - Clarify the function of a signature (as opposed to other means of seeking & documenting agreement)

4. Right to withdraw or decline

- Key ICH points
  - In all cases, participants should be made aware of right to withdraw or decline
  - Refusal to assent or withdrawal of assent should be respected

4. Right to withdraw or decline

- Recommendations—guidance should…
  - Acknowledge possibility that, depending on child's capacity and other factors, meaningful dissent may not be possible
  - Recognize that, in some cases, continuing in trial may be in child's best interests despite dissent
  - Distinguish between objection to research-specific element and objection to element of ordinary care

5. Overriding request to withdraw

- Key ICH points
  - Although wish to withdraw must be respected, there may be circumstances in which parents/guardians & judge that leaving study would threaten child's welfare
  - In such circumstances, child's objection may be overriden

5. Overriding request to withdraw

- Recommendations—guidance should…
  - Reconcile contradiction between ”request to withdraw must be respected” and ability to override that request
  - Clarify role of IRB/REC in decisions to override objection

Summary

- Harmonizing practices for including children in decisions about research will facilitate global pediatric clinical trials
- ICH recommendations provide a strong global ethical framework for authorizing children's participation in research
- But they include several contradictions and areas of ambiguity that future revisions should aim to address

Thank you!

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Perelman School of Medicine
University of Pennsylvania

Involving Young People in Research: The Pediatrics Toolbox

Ms. Lisa Koppelman
MRCT Center

Dr. Gianna "Gigi" McMillan
Loyola Marymount University

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Project Objectives

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

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- Identify meaningful ways to engage patients/families/community members

18 Guiding Principles

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Children should only be enrolled in research that has scientific and social value related to the health of children or diseases that originate in childhood.

Children and their health needs are an important research priority.

Pediatric research often requires multi-site and multi-national trials. Regulations across jurisdictions should be aligned.

18 Guiding Principles

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Children are entitled to have a voice in making decisions to the extent their capacity allows throughout the research process.

INCLUDING YOUNG PEOPLE IN RESEARCH:

A "How-To" Guide

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Comic Book

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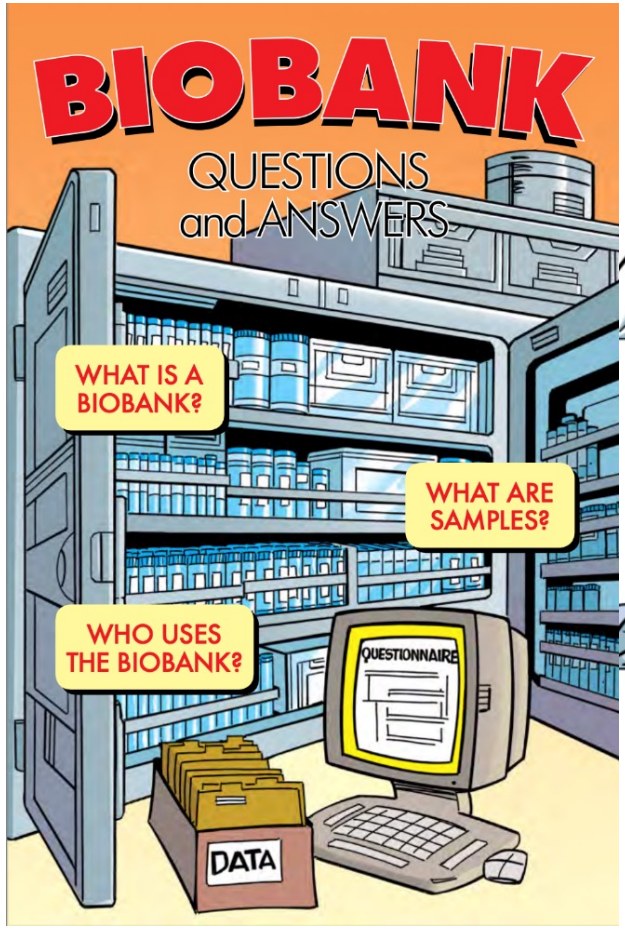

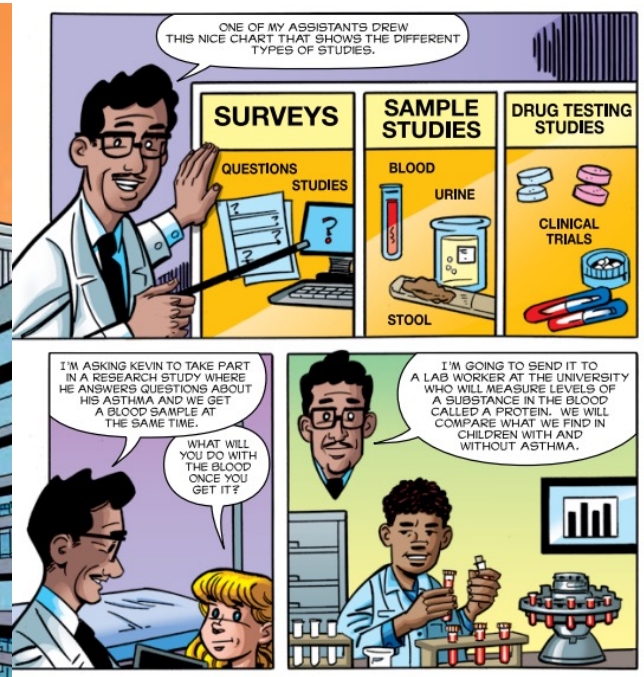

Educational Materials

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Other Materials

Pediatric Research Com

Country	Primary Applicable Laws and Guidance Adopted ICH?	What is the age of majority?	Is permission by the parent or guardian required to participate in a study? For parents, is permission by one or both required?	Is assent (or expression of will) to participate of the child required? If so, at what age?	Are a chi of w parti **over** (not requ
ICH Harmonized Guideline Addendum to ICH E11: **Clinical Investigations of Medicinal Products** in the Pediatric Population E11R(1), August 18, 2017 ("ICH E11")	N/A	Per local law	Yes; not specified	Yes; age determined by IRB/IEC or consistent with local legal requirements	Yes, for s dise rese parti jeop welf
		N/A	"…pediatric study participants are dependent on their parent(s)/legal guardian to assume responsibility for their participation in clinical studies. Fully informed consent should be obtained from the legal guardian in accordance with regional laws or regulations." (ICH E11, 2.6.3)	"All participants should be informed to the fullest extent possible about the study in language and terms they are able to understand. Where appropriate, participants should assent to enroll in a study (age of assent to be determined by IRB's/IEC's or be consistent with local legal requirements). Participants of appropriate intellectual maturity should personally sign and date either a separately designed, written assent form or the written informed consent. In all cases, participants should be made aware of their rights to decline to	"Alt wish to w must be c thera

serious or life-threatening diseases in which, in the opinion of the investigator and parent(s)/legal guardian, the welfare of a pediatric patient would be jeopardized by his or her failing to participate in the study. In this situation, continued parental (legal guardian) consent should be sufficient to allow participation in the study." (ICH E11, 2.6.3)

"Refusal to assent or

especially for long-term studies or studies that may require sample retention. During clinical studies there is a requirement for obtaining adequate informed consent for continued participation from pediatric participants once a child reaches the age of legal consent." (ICH E11, Addendum, §2)

Draft of 10-19-2021

Pediatric Research Comparison Chart: Risk Benefit Analysis

Country	Primary Applicable Laws and Guidance Adopted ICH?	How is "risk" defined?	How is "low risk" or "minimal risk" defined?	How is "benefit" defined (including for which populations is it measured)?	What risk level is acceptable for research studies that may offer the prospect of **benefit to the individual participant** ("direct benefit")	What risk level is acceptable for research studies that only may offer the prospect of **benefit to the group of children** in which the participant falls	What risk level is acceptable for research studies that only may offer the prospect of **benefit to society**, science, medicine as a whole	Are placebo controls permitted and when?	Are healthy volunteers permitted and when?
ICH Harmonized Guideline Addendum to ICH E11: **Clinical Investigations of Medicinal Products** in the Pediatric Population E11R(1), August 18, 2017 ("ICH E11")	N/A	Not defined, but risks and hazards use in connection with toxicity and adverse events. "Distress" includes procedures that may cause pain or frighten	Comparable to those risks and burdens encountered in routine clinical care	Not defined, but clinical benefit implied for participants	Greater than low risk; balance of risk and anticipated clinical benefit must be at least comparable to the available alternative treatments	Low compared to those encountered in routine clinical care	Low compared to those encountered in routine clinical care	Not specified, but possible if risk is low	Not generally, exceptions must be justified
		"Every effort should be made to anticipate and reduce known hazards. Investigators should be fully aware before the start of a clinical study of all relevant preclinical and clinical toxicity of the medicinal product. To minimize risk in pediatric clinical studies, those conducting the study should be properly trained and	"…"low, i.e., comparable to those risks and burdens encountered in their routine clinical care." (ICH E11, Addendum, Section 2)	"In addition, participants in clinical studies are expected to benefit from the clinical study except under the special circumstances discussed in ICH E6, section 4.8.14." (ICH E11, Section 2.6) "Without a prospect of direct clinical benefit from an experimental intervention or procedure, the foreseeable risks and burdens to which pediatric participants would be exposed must	"Experimental interventions or procedures that present greater than low risk to participants must offer a sufficient prospect of clinical benefit to justify or outweigh exposure of a pediatric population to such risk. Likewise, the balance of risk and anticipated clinical benefit must be at least comparable to the available alternative	"Without a prospect of direct clinical benefit from an experimental intervention or procedure, the foreseeable risks and burdens to which pediatric participants would be exposed must be low, i.e., comparable to those risks and burdens encountered in their routine clinical care." (ICH E11, Addendum, Section 2) "Non-therapeutic trials may be conducted in subjects with consent of	"Without a prospect of direct clinical benefit from an experimental intervention or procedure, the foreseeable risks and burdens to which pediatric participants would be exposed must be low, i.e., comparable to those risks and burdens encountered in their routine clinical care." (ICH E11, Addendum, Section 2)	"Without a prospect of direct clinical benefit from an experimental intervention or procedure, the foreseeable risks and burdens to which pediatric participants would be exposed must be low, i.e., comparable to those risks and burdens encountered in their routine clinical care." (ICH E11, Addendum, Section 2)	"When clinical studies are required to obtain information relevant to the use of a medicinal product, such studies should be conducted in pediatric populations having the disease or condition for which the investigational product is intended, unless an exception is justified." (ICH E11, Addendum, Section 2)

Video Series: Prioritizing Young People's Voices

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Video Series: Time to Listen

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Publications

Therapeutic Innovation & Regulatory Science (2021) 55:1109–1110
https://doi.org/10.1007/s43441-021-00339-z

DIA

COMMENTARY

Check for updates

Common Commentary on Paediatric Oncology Drug Development Published: Another Step in Optimising Global Regulatory Coordination of Paediatric Development Plans

Dominik Karres[1] · Gregory Reaman[2] · Franca Ligas[1] · Giovanni Lesa[1] · Susan McCune[3] · Suzanne Malli[3] · Ralph Bax[1] · Jean Temeck[3]

PEDIATRICS®

Monitoring the Pediatric Clinical Trials Enterprise

Robert M. Califf, MD,[a] Deborah A. Zarin, MD[b]

PEDIATRICS PERSPECTIVES

The Parent's Dilemma: Pediatric Assent in Research

Gianna McMillan, D.Bioethics

APS · European Society for Paediatric Research · spr Society for Pediatric Research

SPECIAL ARTICLE

Check for updates

Establishing a global regulatory floor for children's decisions about participation in clinical research

Steven Joffe[1,2]✉, Albert J. Allen[3], Jonathan M. Davis[4], Elisa Koppelman[5], Susan Z. Kornetsky[6], Grace Marie V. Ku[7], Victoria A. Miller[8], Jennifer Preston[9], Lesha D. Shah[10] and Barbara E. Bierer[5,11]

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A reminder of why this is so important

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Establishing a Model to Integrate Children's Voices into the Clinical Research Process

Dr. Thierry Lacaze
Maternal Infant Child & Youth Research Network (MICYRN)

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Time to Listen: Hearing from Young People in Clinical Research

Part 2 of the MRCT webinar: Advancing International Pediatric Clinical Research, 2 February 2022

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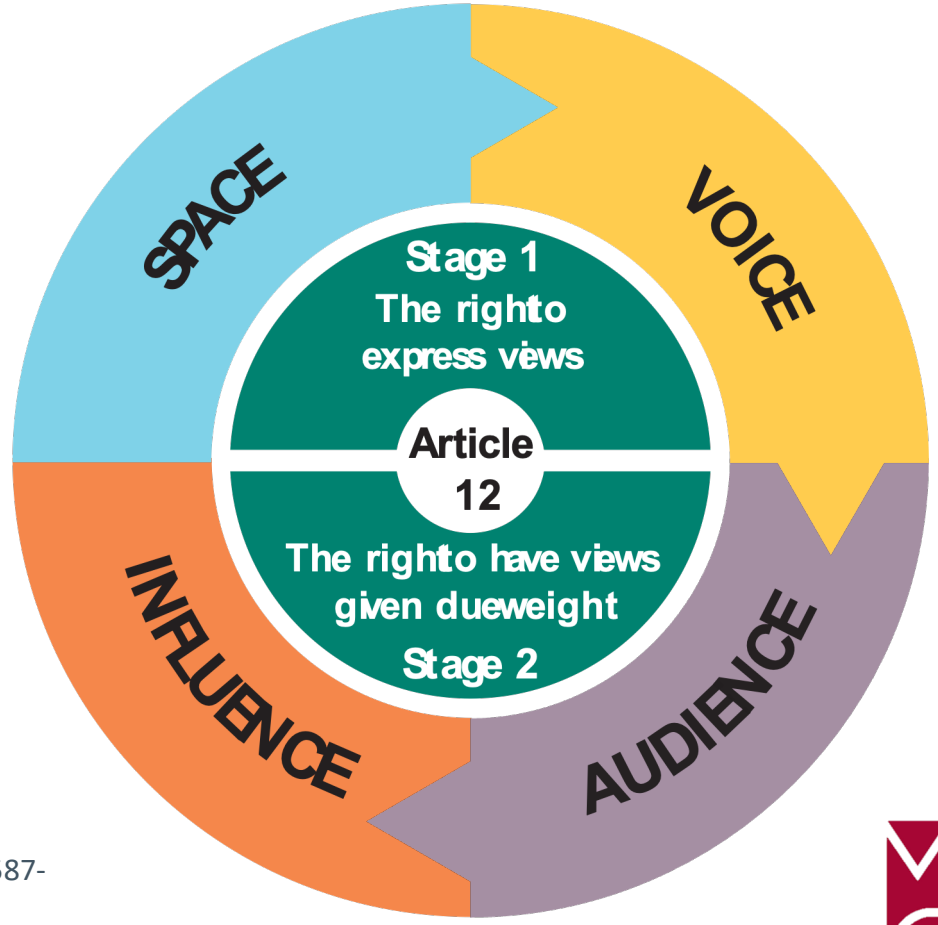
Space: Children and YP must be given safe, inclusive opportunities to form and express their views

Voice: Children and YP must be facilitated to express their views

Audience: The views must be listened to

Influence: The views must be acted upon as appropriate



Government of Ireland, 'Participation Framework: National Framework for Children and Young People's Participation in Decision-Making' (2020) Available at: https://hubnanog.ie/wp-content/uploads/2021/04/5587-Child-Participation-Framework_report_LR_FINAL_Rev.pdf

Y-POWER:
Young PeOple Work to Empower Research

- Several existing Pediatric research networks in different jurisdictions are developing capacities to integrate the voices of children and young people in the development of clinical trials
- Following the MRCT webinar #2 and building on the expertise at these existing networks, a small group of individuals who work with young people has gathered and met several times
- Can we build upon those existing networks to create a cooperative and sustainable global structure that sponsors and investigators can access?

Innovations in the Pediatric Regulatory Space

Dr. Dominik Karres
European Medicines Agency

Dr. Robert “Skip” Nelson
Johnson & Johnson

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Disclaimer

- The views and opinions expressed in the following PowerPoint slides are those of the individual presenters and should not be understood or quoted as being made on behalf of the European Medicines Agency or its scientific Committees (DK) or Johnson & Johnson (RN).

R13.4 – Enhancing Global Regulatory Collaboration

- Pediatric medicines development is a global enterprise taking place in a highly complex ecosystem.
- Existing pediatric development policies have enriched the innovative medicines development research space.
- However, for certain molecules, authorization of pediatric uses continues to lag well behind adult authorization.[1]
- Globally relevant and efficient pediatric medicines development requires global cooperation
  - In pediatric cluster calls, EMA and FDA have a high rate of convergence (~70%).[2]
- Reliance models can be used for any regulatory function.[3]
- Models discussed **each serve a useful purpose**, are **complementary** and **not mutually exclusive.**
  - ✓ Pediatric Cluster; Parallel Scientific Advice; Multi-stakeholder Forums (ACCELERATE); Reliance.

[1]Gilles Vassal, Gustave Roussy. Presentation on R13.4 Day One.;
[2]Donna Snyder, FDA. Presentation on R13.4 Day One.;
[3]Marie Valentin, WHO. Presentation on R13.4 Day One.

Enhancing global cooperation in pediatric medicines development **planning**

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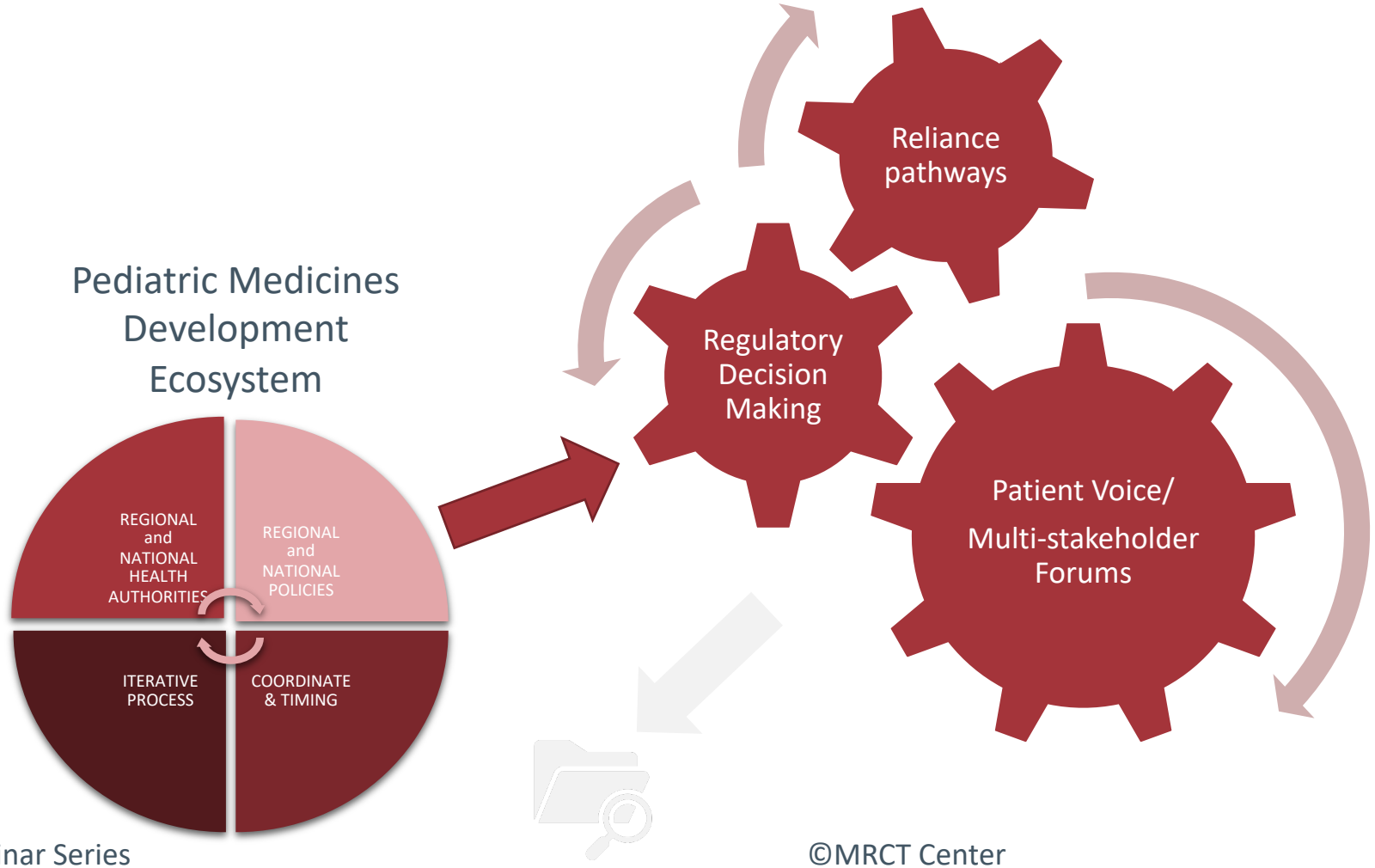

Enhancing global cooperation in pediatric medicines development **planning**

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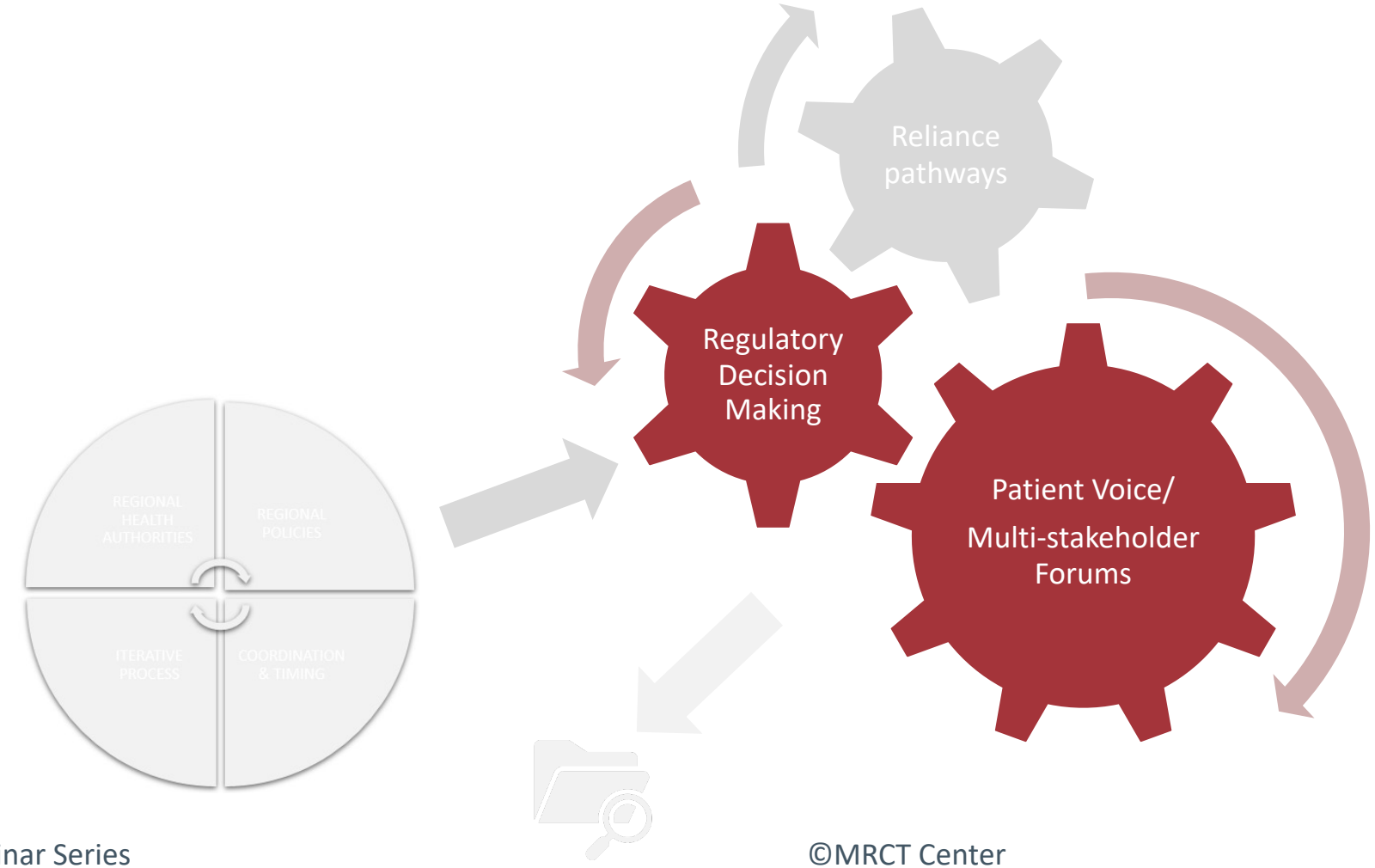

Multistakeholder Forums

- ✓ Enhance linkage to regulatory guidance (esp. when co-authored by regulators)
- ✓ Expand to other therapeutic areas and/or competitive development spheres
- ✓ If expanded into early-stage development, some structural modification needed
- ✓ Role for professional societies

Enhancing global cooperation in pediatric medicines development **planning**

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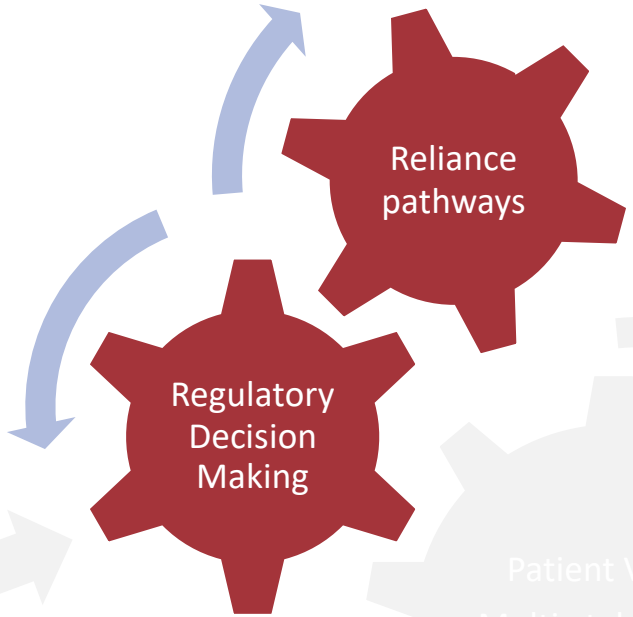
Pediatric Cluster

- ✓ Expand to all regions where pediatric policies are implemented (e.g., MHRA and SwissMedic)
- ✓ If Pediatric Cluster leads to Common Commentary, agencies should review prior Scientific Advice Meeting Minutes to reduce risk for contradictory regulatory guidance.

Parallel Scientific Advice

- ✓ A dedicated global pediatric scientific advice pathway is warranted for the 1/3 of pediatric plans where convergence on design elements cannot be achieved in Cluster.



Reliance

- ✓ Given the "*high rate of convergence*" of Cluster conversations, 2/3 of pediatric plans may be suitable to a reliance procedure (i.e., to agree a pediatric plan).
- ✓ **Model 1** (existing): Switzerland - Reliance on US a/o EU decision on an agreed pediatric plans (at submission of marketing authorization).
- ✓ **Model 2**: Submission of a PIP or PSP through usual regional procedure. Cluster held to coincide within a region's procedure or agencies invited to listen as per *pediatric memorandum of understanding (or other)*. At completion of the procedure, other agencies have the option to adopt the reviewing agency's opinion for the plan.

Meeting the Regulatory Challenges

- Growing pipelines of innovative products, how to identify and support completion of development efforts in children for products able to address existing unmet medical needs?
  - This includes avoiding premature exclusion of paediatric developments of potentially effective products, whilst acknowledging failure of a product at (early/ late) development stage being reality.
- Acknowledgment that regulatory decision making on mandated paediatric developments cannot take place in isolation
- Mindful of regulatory guidance and standards
- Whilst appreciating the need to be innovative, fostering a R&D environment that allows for evolution of scientific knowledge and takes changing evidence and unmet needs into consideration

Actions to support the development of medicines for children

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- Strengthened focus on unmet medical needs
- **Adapting regulatory processes to better support innovation**
- Increased alignment of data requirements between decision-makers


EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

6 February 2023
EMA/635567/2022
Paediatric Medicines Office

Boosting the development of medicines for children

Closing report of the European Medicines Agency and European Commission (DG Health and Food Safety) action plan on paediatrics

https://www.ema.europa.eu/en/documents/report/boosting-development-medicines-children-closing-report-european-medicines-agency-european-commission_en.pdf

Adapting regulatory processes to better support innovation

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ELSEVIER

European Journal of Cancer

Volume 177, December 2022, Pages 25-29

Original Research

European regulatory strategy for supporting childhood cancer therapy developments

Dominik Karres [a], Giovanni Lesa [a], Franca Ligas [a], Sylvie Benchetrit [b c], Sara Galluzzo [d e], Karen Van Malderen [f c], Jaroslav Sterba [g c], Maaike van Dartel [h c], Marleen Renard [i f c], Peter Sisovsky [j c], Siri Wang [k c], Koen Norga [l]

- Paediatric Investigation Plan (PIP) as a tool to fostering an environment of evolving evidence and needs

Karres D, Lesa G, Ligas F et al - EJC 2022 Dec;177:25-29. doi: 10.1016/j.ejca.2022.09.025. Epub 2022 Oct 6.

Focus on unmet medical need - the final **target population**

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- Early Phase study a starting point only, based on robust biological rational to generate PK, safety and (preliminary) activity
  - To increase knowledge and allow for evidence generation to further inform final target population and subsequent (pivotal) design considerations
  - Go/no-go decisions to be incorporated early in the development to identify lack of activity/ unexpectable toxicity

➢ An intermediate step in a PIP towards pivotal development in a target population where the need and consequential benefit of new innovative drugs is expected to be highest

Karres D, Lesa G, Ligas F et al - EJC 2022 Dec;177:25-29. doi: 10.1016/j.ejca.2022.09.025. Epub 2022 Oct 6.

Moving from early clinical trial to ‘pivotal’ development

- Inclusion of ‘placeholder’ studies/key elements in the PIP - outlined at a high level - with (inter)-dependencies included, allowing for and awaiting supportive evidence to inform subsequent regulatory decision making related to the development towards the ‘final’ target population

  - Requires **multi-stakeholder collaboration**, coordination and discussions including early academia/ (multi)-company engagement followed by early involvement of regulators

Karres D, Lesa G, Ligas F et al - EJC 2022 Dec;177:25-29. doi: 10.1016/j.ejca.2022.09.025. Epub 2022 Oct 6.

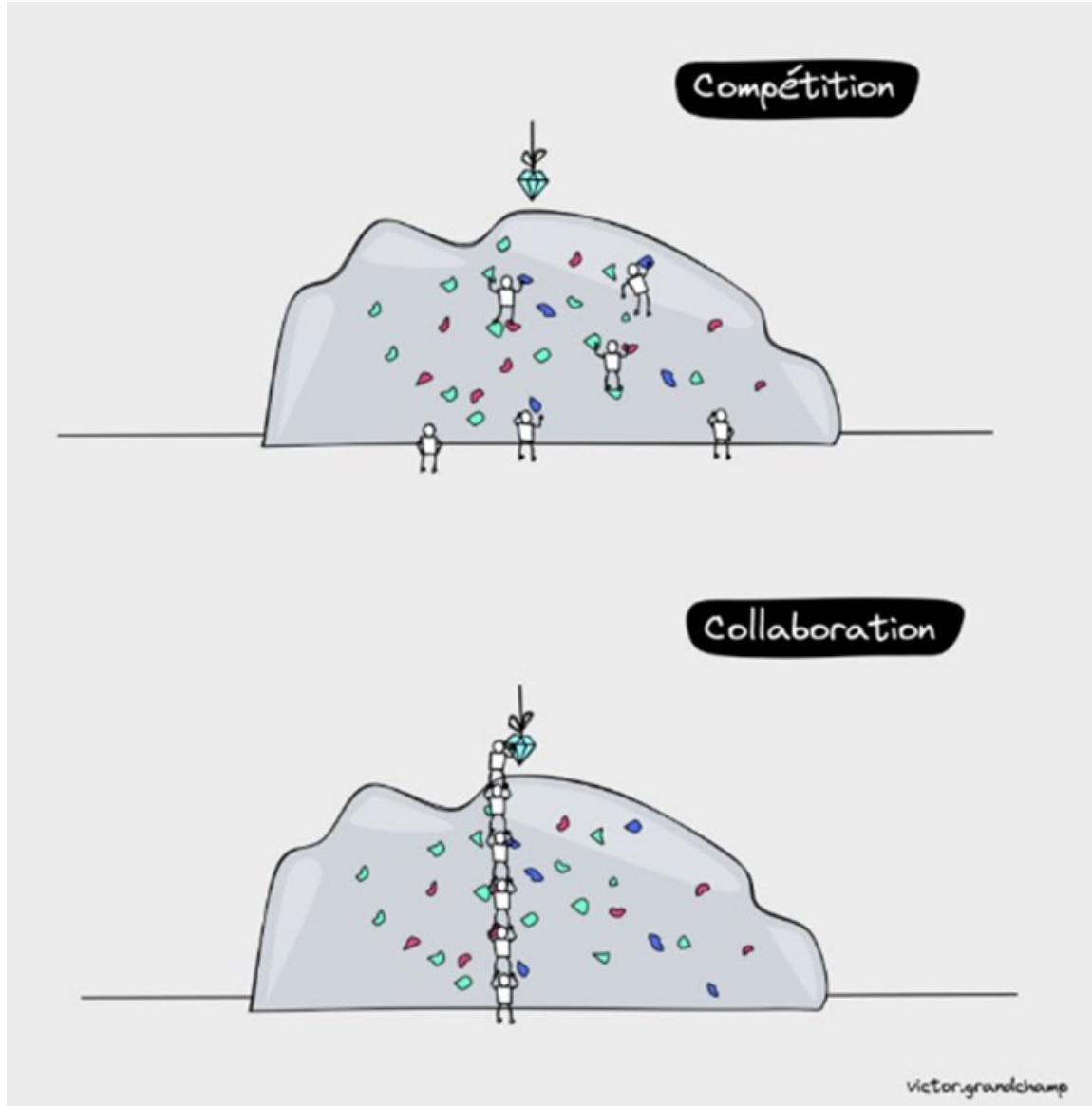
PIP – **a living document** – allowing for decision-making based on emerging evidence while advancing science*

- Bringing competing development efforts (within same condition/ same in class) together into one arena allows for **timely evidence-based** and **focused discussions on priorities** structured around **multi stakeholder meetings**.

- The agreed **content of a PIP**, which can/should be modified as evidence emerges, will need to be **fit for purpose**, allowing for evidence generation and **a focus on scientific dialogue** when interacting with the regulators.

- This will allow us to provide continuous support through the PIP development to **achieve the goal of timely authorizations** of novel agents (and subsequent access).

*Karres D, Lesa G, Ligas F et al - EJC 2022 Dec;177:25-29. doi: 10.1016/j.ejca.2022.09.025. Epub 2022 Oct 6.


Compétition
Collaboration
victor.grandchamp

References:

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- European regulatory strategy for supporting childhood cancer therapy developments: https://doi.org/10.1016/j.ejca.2022.09.025
- Actions to support the development of medicines for children including Closing report of the European Medicines Agency and European Commission (DG Health and Food Safety) action plan on paediatrics: https://www.ema.europa.eu/en/news/actions-support-development-medicines-children
- Guidance for Stepwise PIP pilot. https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/guidance-stepwise-pip-pilot_en.pdf

Fireside Chat

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Closing

- Find all these resources (and more!) on our website and on YouTube

- Direct links to all resources will be shared with the slides following the webinar

Thank You!

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Please follow the MRCT Center:

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