



What is Paediatric Research

Children's rights in health and research

November 2nd 2024



Silvia Torretta, PhD



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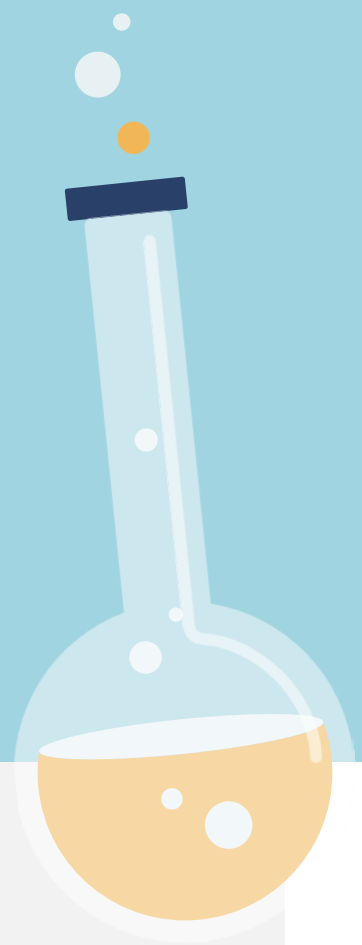


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New Medicines Development and Testing Process



1

**Discovery and
Development**



2

**Clinical
Research**



3

**Government
Safety Review,
Monitoring**



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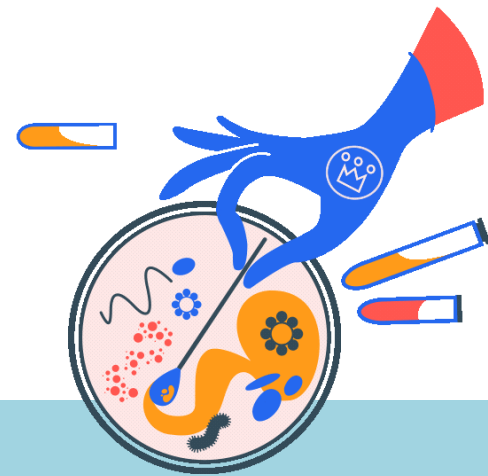
Types of Research Studies

Clinical and Non-clinical



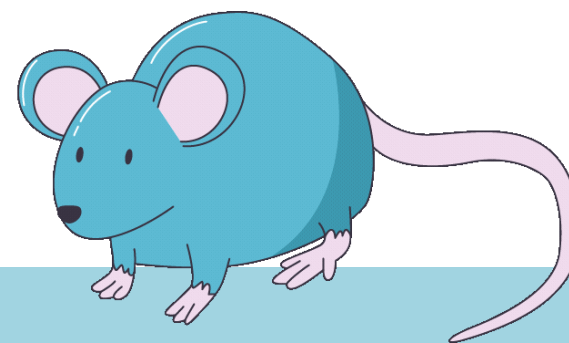
In vitro

Experiments done in controlled environments **outside the body**, in cells or tissues, to see how they react to a treatment.



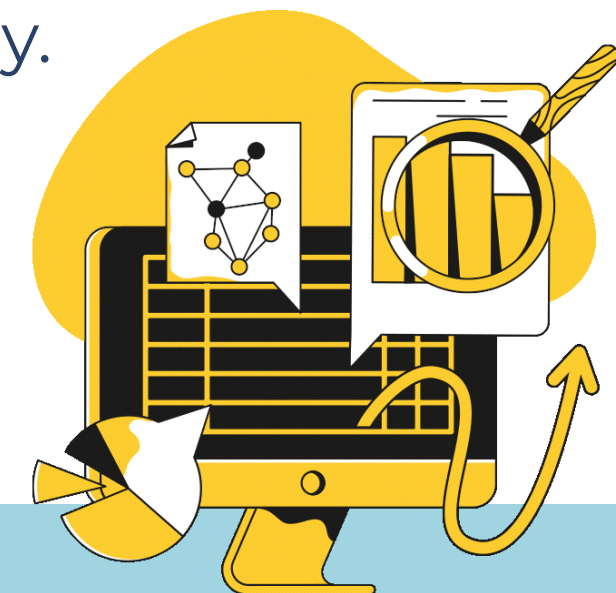
In vivo

Research done on **living organisms**, like humans or animals, to understand how a treatment works in a real body.

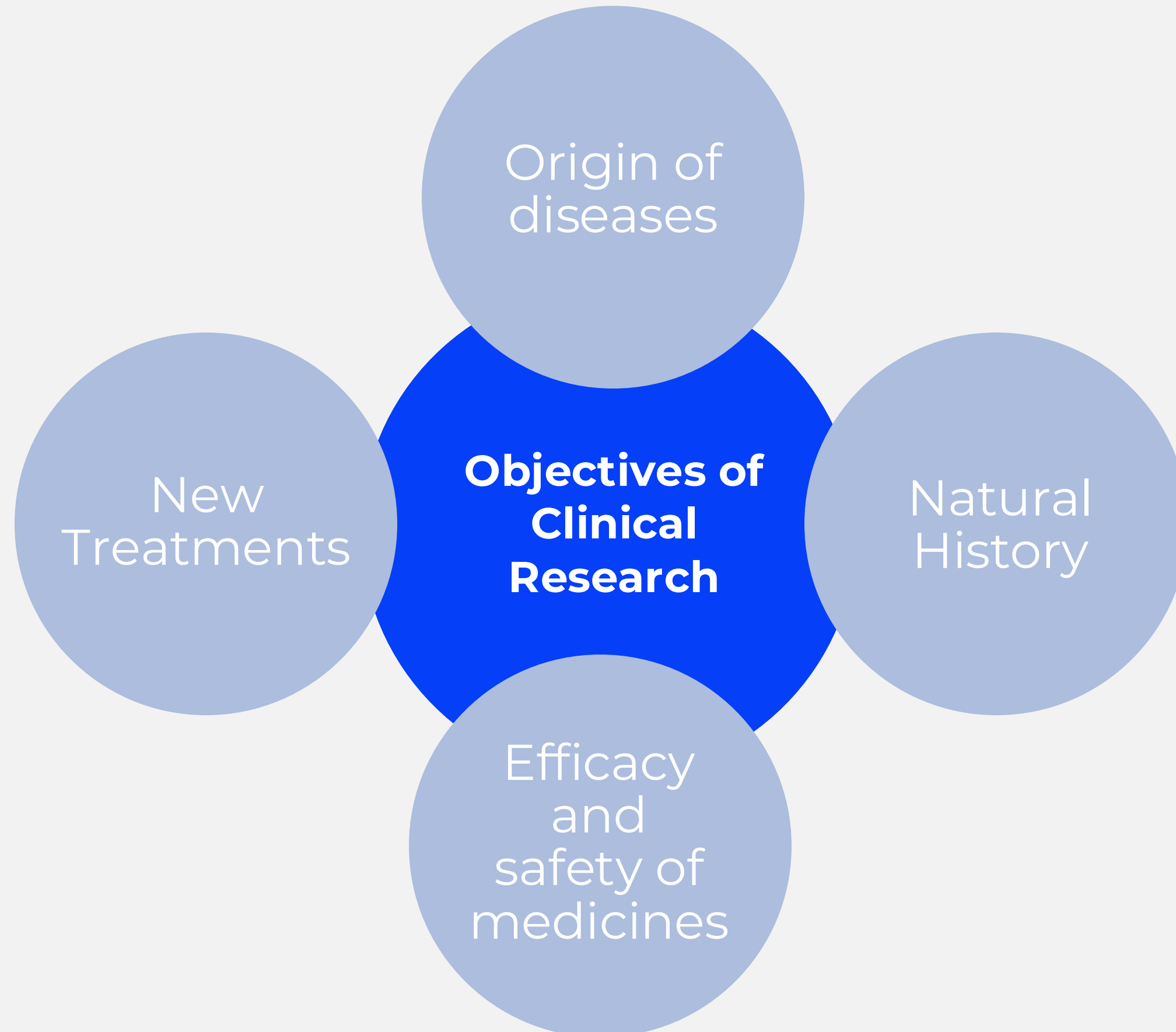


In silico

Simulations using computers and health data to predict how treatments might work in the human body.



Why is Clinical Research Important?



Clinical Trials

Before an investigational drug can be made available to the public, it must pass 3 phases.



First study in humans.
Tests the drug's **safety**
and **dosage** range of
efficacy on a **small**
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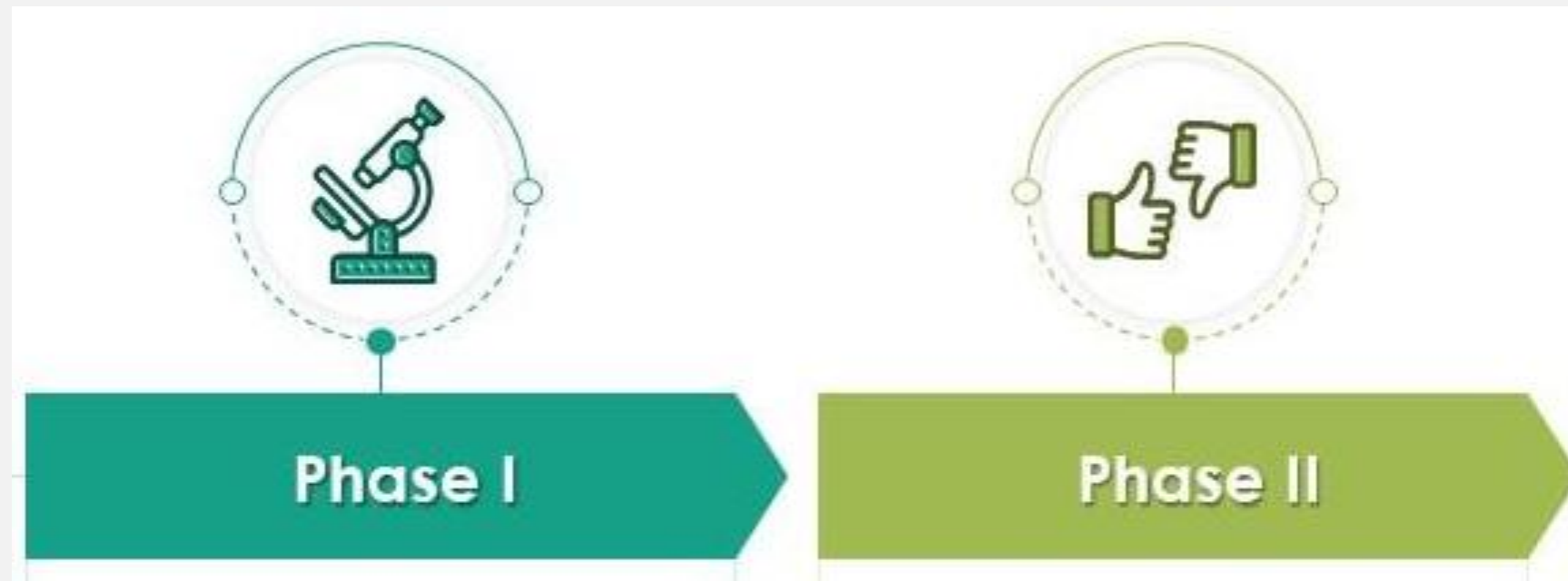
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Clinical Trials

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First study in humans. Tests the drug's **dosage** range of efficacy and **side effects** on a **small group**.

Focuses on the drug's **efficacy** and further evaluates its **safety** in a **larger group** of patients with the targeted disease.



Clinical Trials

Before an investigational drug can be made available to the public, it must pass 3 phases.



First study in humans. Tests the drug's **safety, dosage** range, and **side effects**

Focuses on the drug's **efficacy** and further evaluates its safety in a larger group of patients with the targeted disease.

Involves **large-scale** testing to confirm efficacy, monitor side effects, **compare** the drug to commonly used treatments.



Clinical Trials

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First study in humans. Tests the drug's **safety, dosage** range, and **side effects**

Focuses on the drug's **efficacy** and further evaluates its safety in a larger group of patients with the targeted disease.

Involves **large-scale** testing) to confirm efficacy, monitor side effects, **compare** the drug to commonly used treatments, and collect information for safe usage.

Research continues once the **drug is on the market**. Designated bodies **collect and analyse data** from patients to **monitor** side effects and confirm efficacy.



Why do we need Paediatric Research?

QUESTION
TIME



Thinking about the use and effect of drugs, what are the main differences between an adult and a child/adolescent?



SCAN HERE!



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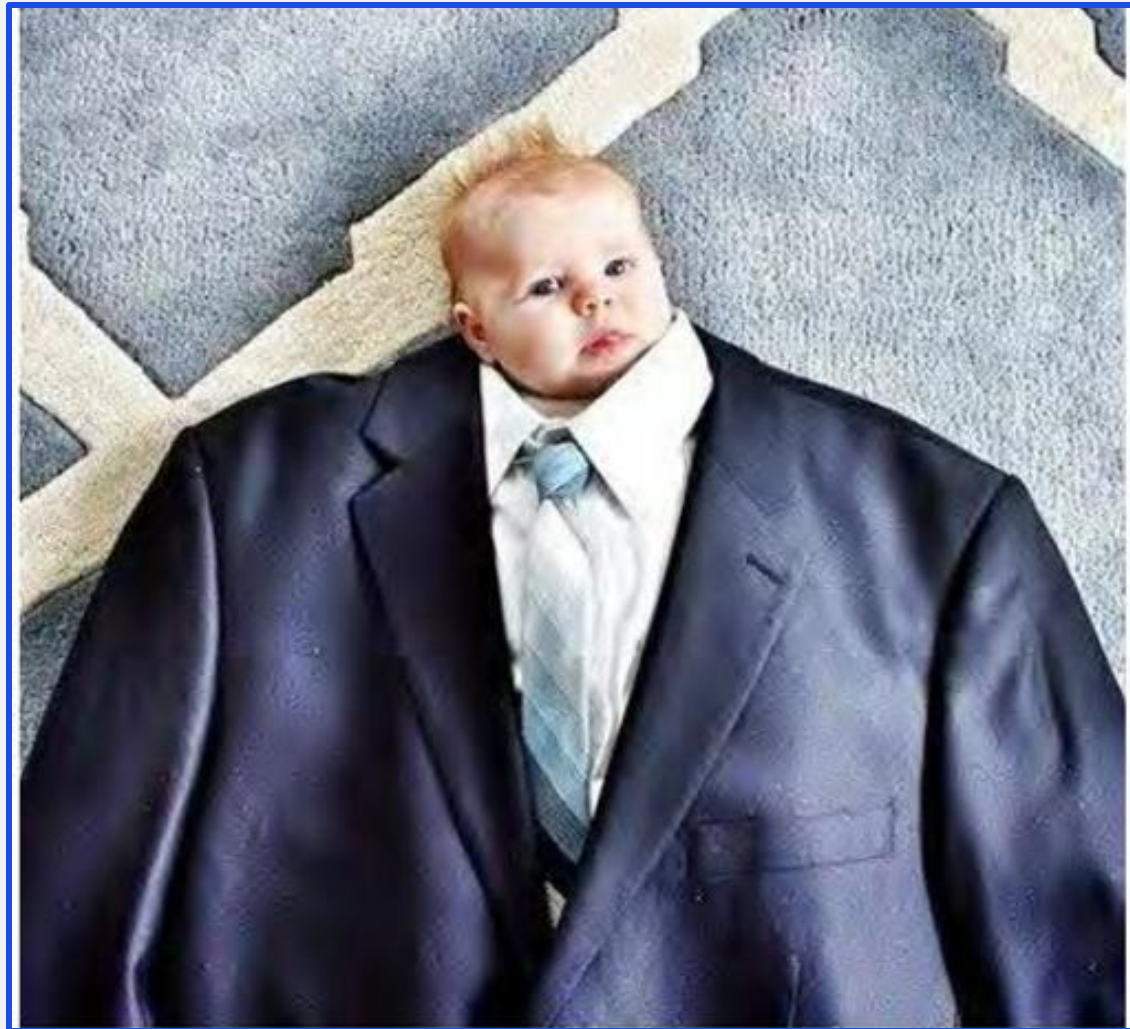


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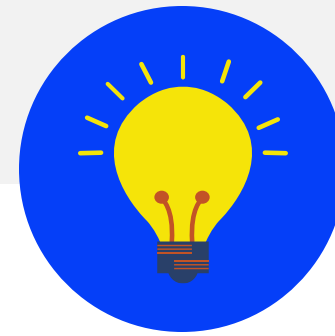


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Why do we need Paediatric Research?



Children are not small adults!



When we talk about **paediatric medicines**, we are referring to medicines that have to be used in **groups with very different characteristics!**

They must have a paediatric **indication**

They must have a paediatric **dosage**

Why do we need Paediatric Medicines?

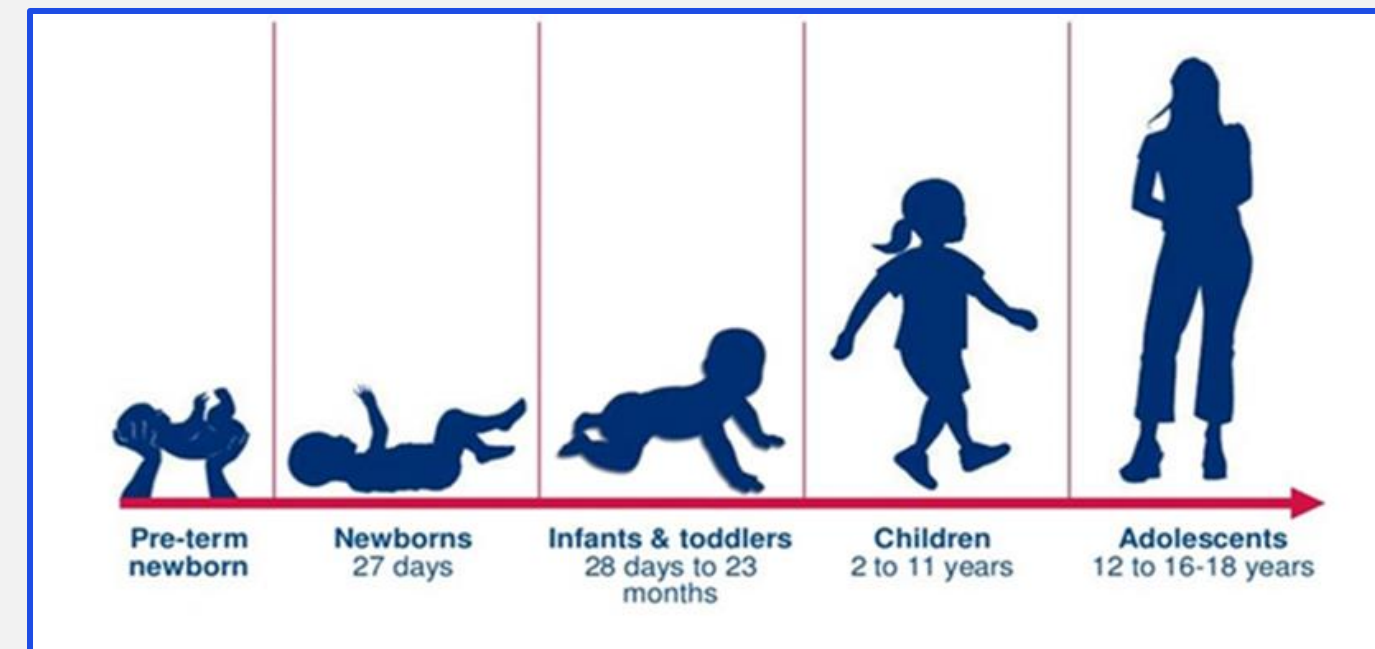
✓ **Pharmaceutical Form** The way infants, children, adolescent and adults take medications is different.

✓ **Growth** Children grow up and change very quickly, so the different stages of growth must be considered.

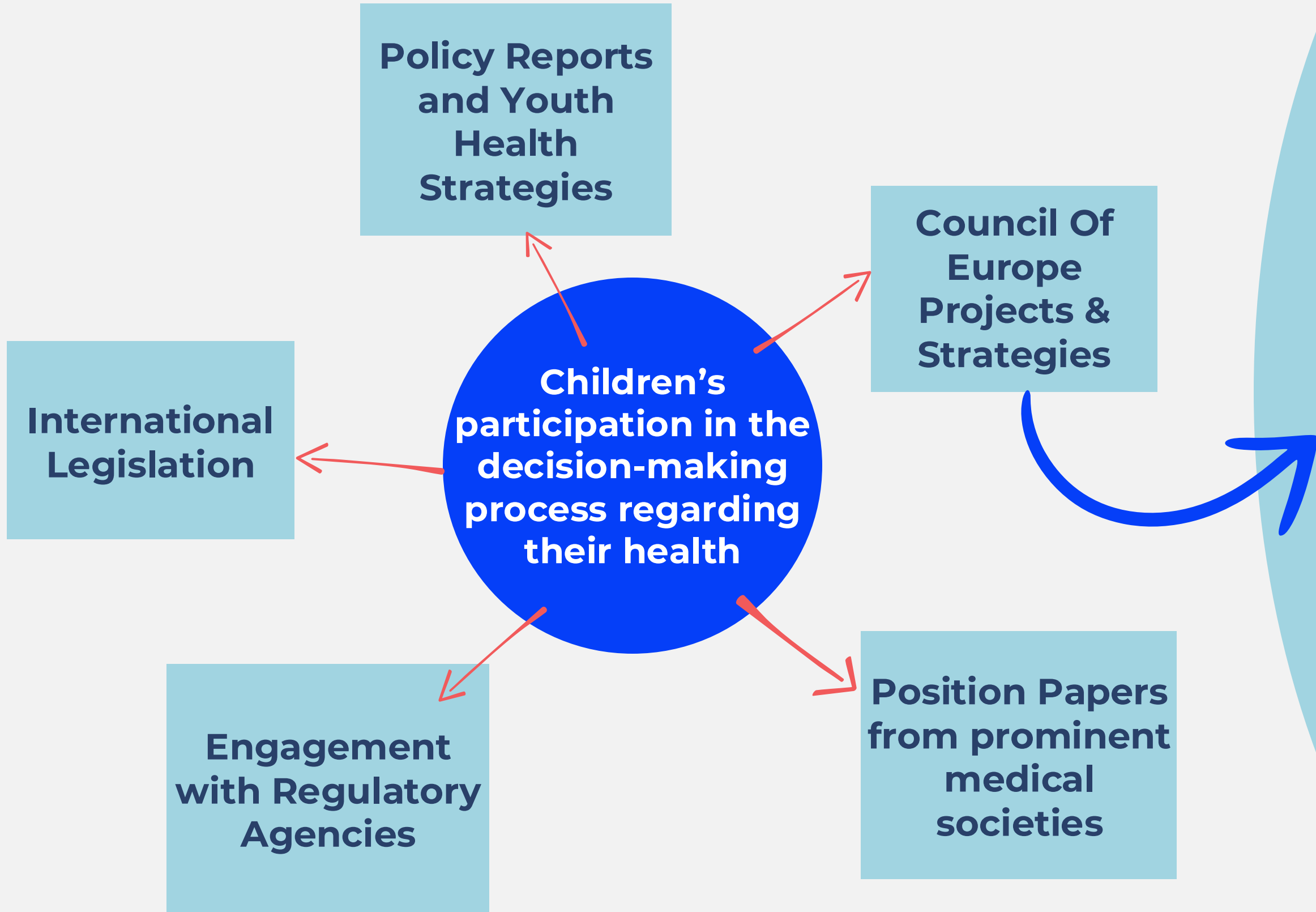
✓ **Response** The response of babies, children and adolescents to medicines is different.

✓ **Reaction** Some adverse reactions to medicines are different in children and young people.

✓ **Occurrence** Some diseases only occur in infants, children and young people.



Your rights in health and research



Strategic objectives for protecting and promoting the rights of the child (2022-2027)



Equal opportunities and social inclusion



Freedom from violence



Access to and safe use of technologies



Giving a voice to every child



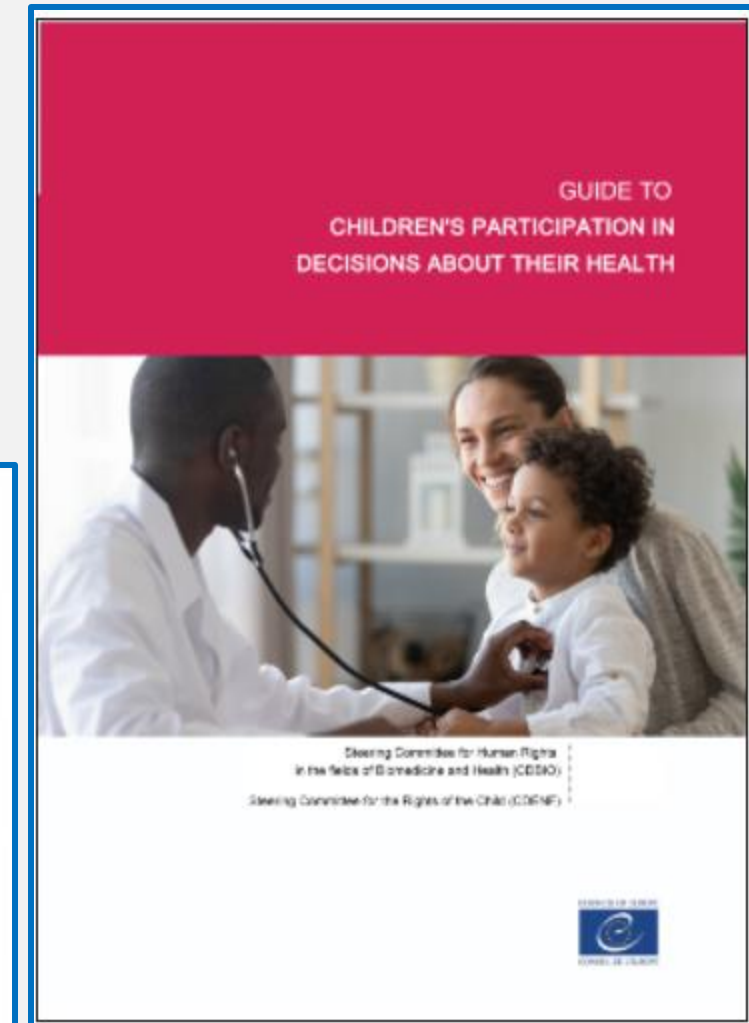
Child-friendly justice



Children's rights in crisis and emergency situations

Key concepts for children's participation in the decisions-making process regarding their health

- * Right to Participate
- * Clear and Accessible Information
- * Evolving Capacities
- * Autonomy and Future Options
- * Integration of Voices
- * Service Planning



Children's participation in the decisions-making process regarding their health



This video was developed by TEDDY Network and TEDDY Kids, in coordination with the Council of Europe. A group of children aged 12-18 years, including young patients and healthy children, took part in its design; they come from Italy, France, Greece and Albania.

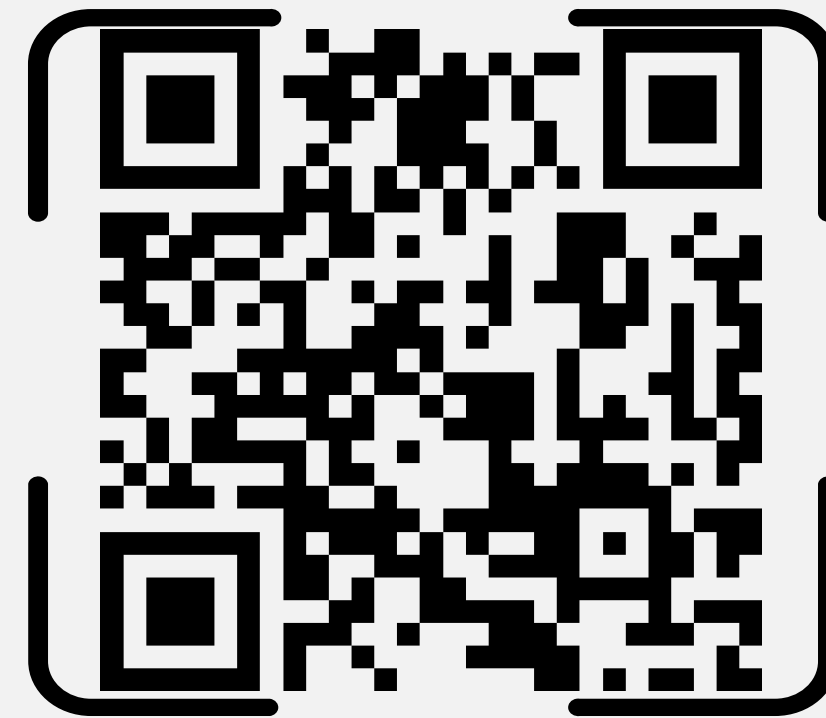


Your rights in health and research



When it comes to your rights in health and being part of decisions about it, what values are most important to you?

HAVE YOUR SAY



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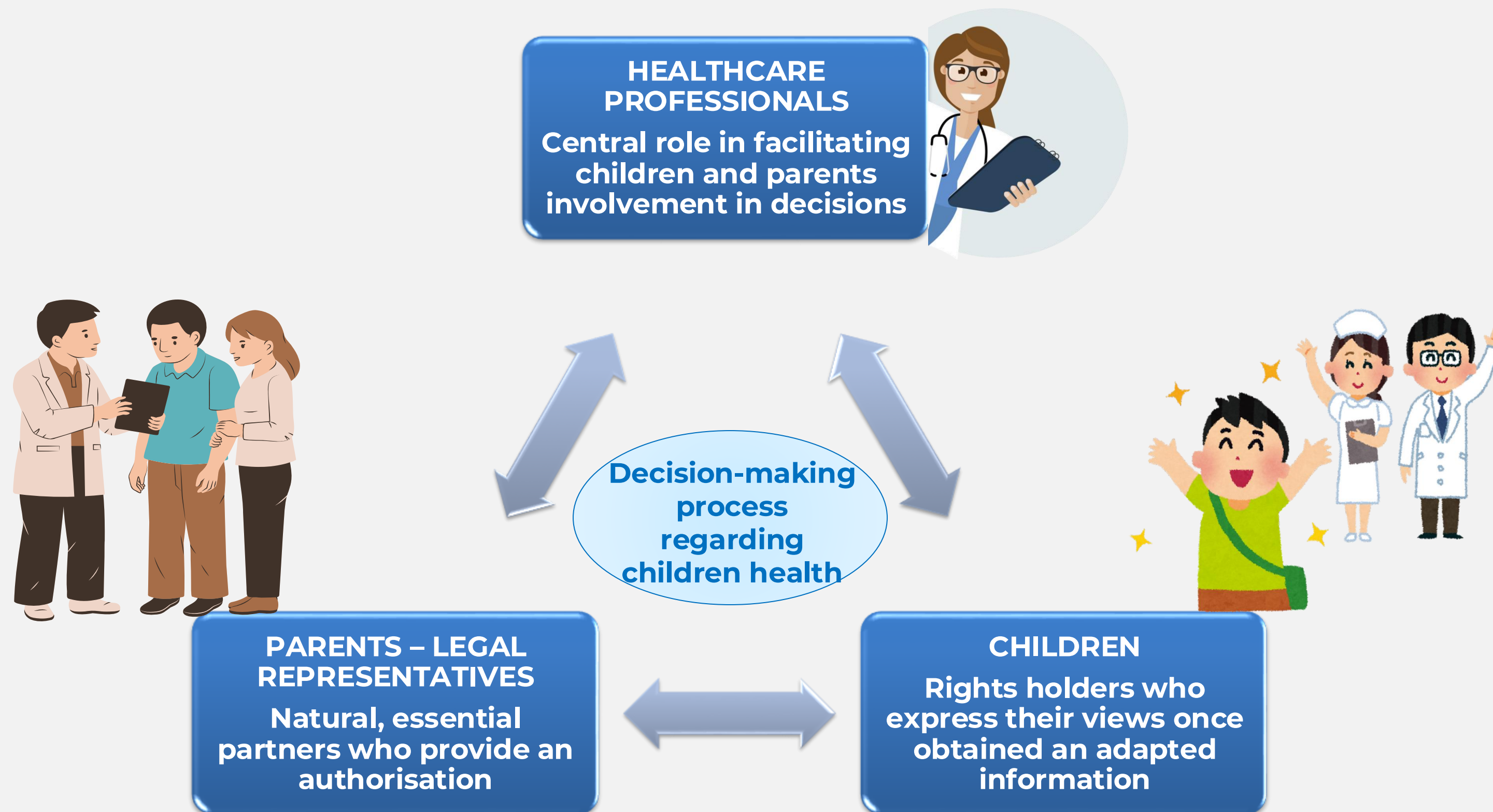


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Role of parents(legal representatives), Children and Healthcare Professionals



What is Consent and Assent?



Consent

The **free** and **voluntary** expression of a subject to participate in a particular clinical trial, after having been informed of all aspects of the trial relevant to making the decision or, in the case of minors and incapacitated subjects, the authorisation or agreement of their parents or legal representatives.

Assent

... in addition to the informed consent provided by parents/legal representatives, **minors** who are capable of forming their **own opinion** and assessing the information provided to them may also **give their consent** to participate in a clinical trial!



INFORMED ASSENT

What happens when differences of opinion occur?



1

Respect differences

Every effort should be made to understand and respect differences of opinion between the child and his/her parents or legal representatives.

2

Reconcile differences

The doctor in charge of the trial should try to reconcile these differences to do justice to the (growing) ability of the child to make decisions similar to adults.

3

Respect of dissent

If, after reasonable efforts to reach consensus, they remain in disagreement over participation, the dissent of any of the parties is decisive.





And now...
...Let's play!

Silvia Torretta, PhD

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FONDAZIONE
PER LA RICERCA FARMACOLOGICA
GIANNI BENZI
ONLUS



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