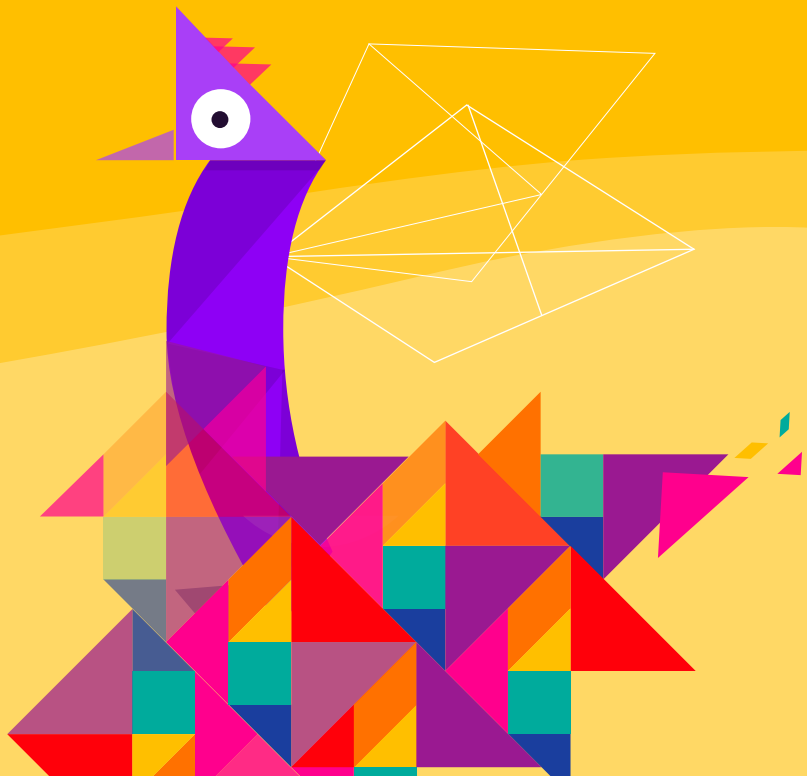
Welcome to the Clinical Research Unit

SJD Unitat de Recerca Clínica



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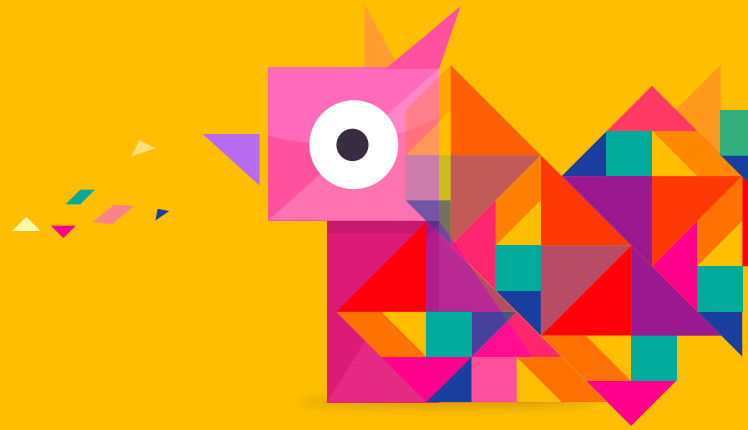
PARTICIPATING IN A CLINICAL TRIAL IS AN IMPORTANT DECISION THAT INVOLVES THE WHOLE FAMILY. WE HOPE YOU WILL FIND THE INFORMATION IN THIS BROCHURE USEFUL THROUGHOUT THIS NEW EXPERIENCE.

Welcome

to the Clinical Research Unit of the
Fundació Sant Joan de Déu.



The **URC** (Unitat de Recerca Clínica in Catalan) is the Clinical Research Unit, the department of the Fundació Sant Joan de Déu responsible for carrying out all the clinical trials at Hospital Sant Joan de Déu.

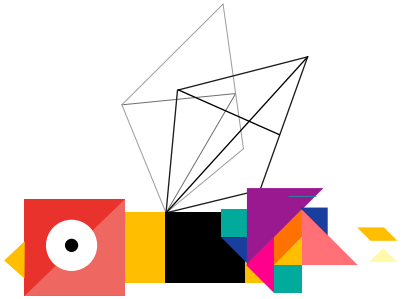
We'll be with you throughout your participation in the trial and our aim is to make you feel welcome and cared for. We know that participating in a research study because of a health problem, and in many cases being far from home, is difficult for everyone involved (the child or adolescent and their family), so we will ensure that your time at the unit is as pleasant as possible.

We encourage you to read this document which provides information on some basic aspects that will be useful during your participation in the clinical trial.

The URC team

THE TEAM

WHO WILL YOU BE IN CONTACT WITH DURING THE CLINICAL TRIAL?



Our team is made up of different professionals, but you will mostly be in contact with medical, nursing and pharmacy staff.

Clinical Trial Nurse Coordinators

We'll be your main point of reference and contact and will accompany you throughout the trial, so you can ask us anything you want about it. We also carry out nursing procedures, administer treatment and coordinate family visits.

Medical team

We're responsible for offering clinical trial participation to patients and their families. Our team is familiar with the scientific aspects of the trial and can answer any questions you might have. We carry out the control visits and monitor the trial patient's treatment and health at all times.

Pharmacist

We deal with all medication issues.

What is a paediatric clinical trial

A paediatric clinical trial involves the study of **the effect of a medicine** or treatment in children.

Why are clinical trials in children necessary?

Children are not ‘little adults’.
Depending on the child’s stage of development, it is necessary to:

Adjust dosages

Offer paediatric formulations
(syrups, tablets, etc.)

Who can participate in a clinical trial?

Clinical trial participants are carefully selected and have to meet a number of requirements (known as **inclusion and exclusion criteria**) that are checked by the trial's medical team.

Criteria include being a certain age, having had previous treatment, having specific blood test results, having a certain disease, and even being healthy.

All the inclusion criteria must be met to be able to participate in a clinical trial.

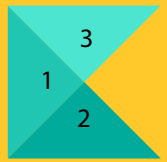
The potential participant cannot take part in a clinical trial if they have any of the **exclusion criteria.**

E.g. For a clinical trial with 4 inclusion criteria:

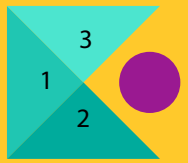
Inclusion criteria

Exclusion criteria

The patient CAN participate



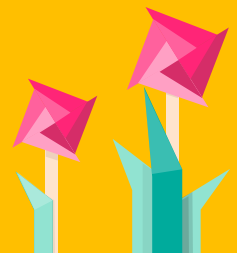
The patient CANNOT participate



The patient CANNOT participate

THE IMPORTANCE OF CLINICAL TRIALS

CLINICAL TRIAL CAN HELP US TO:




Understand how children's bodies change (and how they function) as they grow
Find the right dose of a medicine that is effective and has the least number of side effects
Develop medicines that children can take easily (syrups, chewing gum, etc.)
Find treatments to cure or slow the progression of diseases that only affect children
Find treatments for diseases that also affect adults but which behave differently in children
Check that treatments that are safe in adults are also safe in children
Find treatments that help to improve the quality of life of children

CONSENT AND ASSENT

An informed consent form is a document that contains all the necessary information about the clinical trial. The parents/legal guardians of a minor must sign it to acknowledge that they have received the information and that they agree to the child's participation in the trial. You will review this document with the medical team and discuss any questions you may have.

If the trial participant is aged **between 12 and 17 years old**, he or she must also agree to their participation by signing another document, called an **informed assent form**.

Although assent is not legally required with regard to children **under 12 years of age**, the trial will be explained to them with the help of the team and the parents.

PARTICIPANTS UNDER 12 YEARS

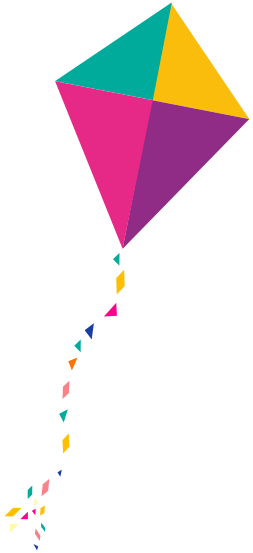
Participant (child)	Is informed
Parent/ Legal guardian	Signs Informed Consent Form

PARTICIPANTS OVER 12 YEARS

Participant (child)	Signs Informed Assent Form
Parent/ Legal guardian	Signs Informed Consent Form

Even if you have signed the forms for participation in the clinical trial, you are free to change your mind and opt out of the trial at any time.

CLINICAL TRIAL DESIGN AND PROTOCOL



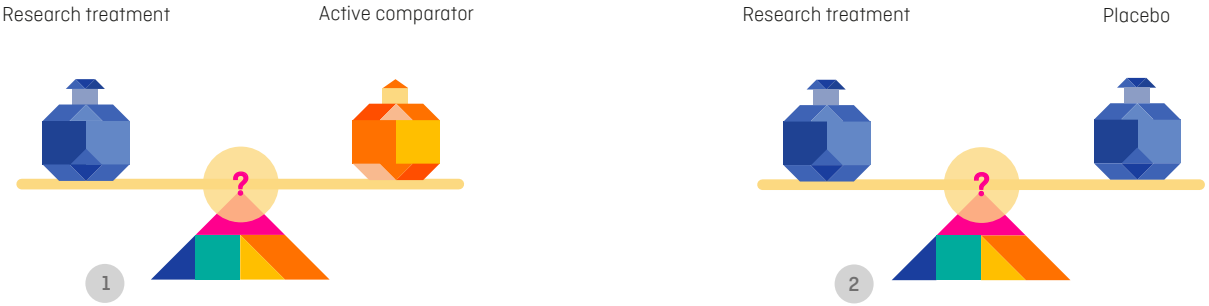
WHATEVER THE DESIGN, **WE WILL ENSURE THE SAFETY** OF THE CHILD OR ADOLESCENT THROUGH CLOSE AND CONTINUOUS MONITORING BY OUR TEAM.

The design of a clinical trial (how the study will be done) is decided according to the research questions to be answered.

THE DETAILED PLAN THAT DESCRIBES THE ENTIRE CLINICAL TRIAL IS CALLED A **PROTOCOL**.

Usually, **the drug or treatment being investigated** can be compared either with an approved treatment (known as an **active comparator**), or with a **placebo** (which looks the same as the drug being investigated but does not contain any active substances).

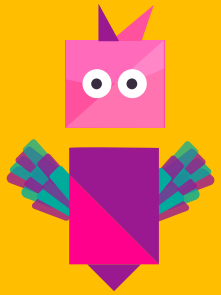
Examples of treatment comparison:



Randomisation

is the **random assignment** of participants to **one treatment group or another**. It is used for comparing results and to see whether any differences between the two groups are due to the treatment received in each one.

Will the participant, family and study team know which treatment group the participant has been assigned to?
This depends on the type of trial.

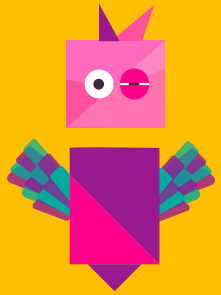


OPEN-LABEL TRIAL

Who will know?

Patient and family ✓

Study team ✓

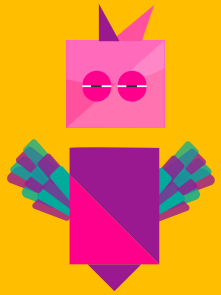


SINGLE-BLIND TRIAL

Who will know?

Patient and family ✗

Study team ✓



DOUBLE-BLIND TRIAL

Who will know?

Patient and family ✗

Study team ✗

They will know at the end of the trial.

Rights

- Withdraw your consent and opt out of the trial at any time. The child or adolescent will still be guaranteed medical care.
- Have your data kept confidential and protected from access by third parties (you have the right of access, rectification, deletion and withdraw of consent with regard to your data).
- Be informed about the treatment options available for the condition of the patient.
- Receive appropriate and specialised medical care while the patient is participating in the trial.
- Not have to pay for the drug under investigation.
- Ask questions at any time during the clinical trial and about any aspect that affects your quality of life (economic impact, hours at the hospital, inconvenient trips, number of procedures, etc.).
- Be informed about the progress of the clinical trial.

Responsibilities

- Attending visits and notifying if unable to attend a visit.
- Taking the medication as prescribed.
- Following the established plan.
- Informing of any change to the base medication (the patient's usual medication).
- Informing of any change in the patient's state of health.
- Providing a complete medical history.

Questions

Write here any questions you have (at the start or at any time during the clinical trial).

THANK YOU

FOR TAKING PART IN A CLINICAL TRIAL

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