

What is a Clinical Trial

An information leaflet for children aged
UNDER 8



NATIONAL CHILDREN'S
RESEARCH CENTRE

What is this Booklet About?

Introduction:

We want you to know what a clinical trial is and what will happen if you are asked to take part in one.

Please listen to the person who is reading this booklet with you. Please tell them if there is something that you don't understand or if there is something that you would like to know.

What is Research?

Research is when doctors study an illness like asthma (wheeze), or tummy upsets, to understand it better.

What is a Clinical Trial?

A clinical trial is a type of research where doctors find out how well medicines or other treatments work.



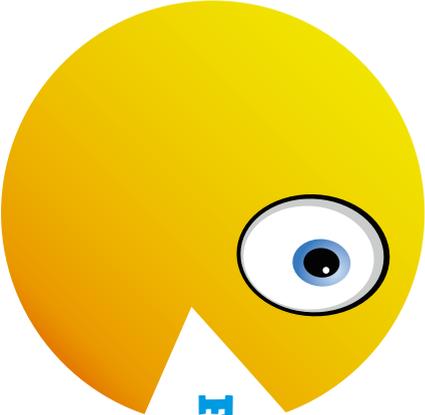
Doctors Need to Know:

- What are the best medicines to give children when they are sick
- If one medicine works better than another
- If there is a better way to give medicine, like giving a tablet instead of an injection
- If using a different amount of a medicine works better or just as well

Why are Children Asked to be Part of Clinical Trials?

The best way to know if a medicine works in children is to study children who are given the medicine.

For more answers visit
clinicaltrials.ie



What Will Happen to Me?

Your doctor will speak with you and your family about the study and give you information leaflets to read.

You can ask as many questions as you want.

Your doctor will explain what checks they need to carry out as part of the study, like listening to your heart beat, checking your breathing, your height and weight, or asking questions about how your illness makes you feel.

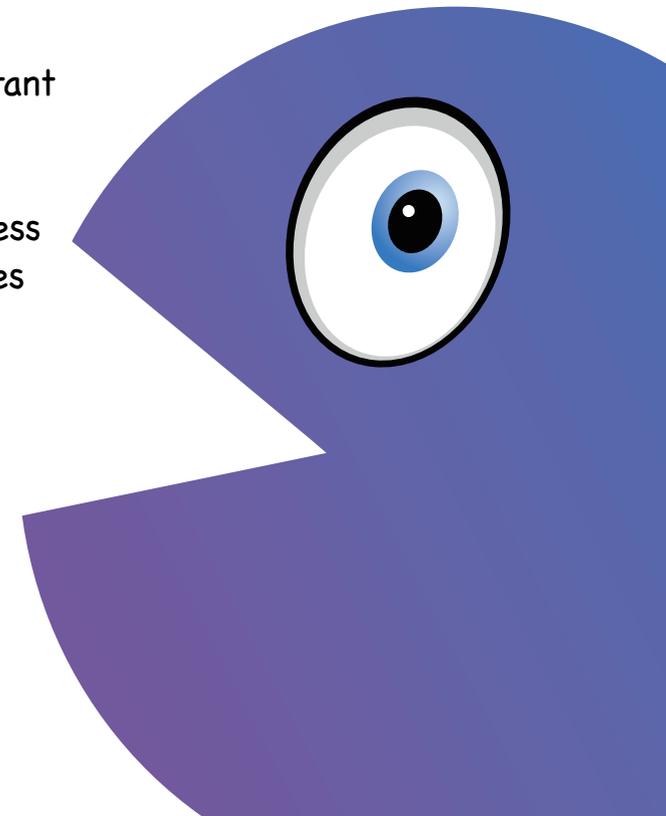
Your doctor will let you know how much time the study will take.

Your doctor will explain the good points about being in a study; like having an extra visit with the doctor to check how well you are doing.

Your doctor will explain any bad points about being in a study; like you might have a blood test, which may sting for a short while. Not all studies involve blood tests – but some do. Blood tests are important because the results tell doctors a lot of information about illness and how well medicines are working.

If you and your family decide to take part, you might be asked to sign a form that shows that you gave your own permission to be part of the study. This is called an ASSENT FORM. Signing this form does not mean that you have to continue with the study. You can stop being part of the study at any time.

For more answers visit clinicaltrials.ie



Do I Have to Take Part? **NO!**

It is your choice whether you would like to take part or not. If you don't want to, that's OK. You do not have to give a reason to your doctor and no one will be upset with you.

Will Anyone Know That I Took Part in a Study?

No one outside the hospital will know that you took part in the study.

What do I do if I Have Questions?

Taking part in a clinical trial is a big step! If you have a question that your family don't know the answer to you can always ask your doctor or nurse.

This document is part of a series of IPPOSI information leaflets, intended to advise and benefit patients. IPPOSI does not accept responsibility for this leaflet being used for any purpose, other than that described. If you are concerned about your clinical condition you should immediately contact a qualified medical professional.

Acknowledged contributions; the original IPPOSI information campaign was based on text provided by an FP7 Project, Patient Partner and EGAN. It was applied in the Irish context with the assistance of ICRIN. The text for this series of leaflets aimed at children participating in a clinical trial was developed by the National Children's Research Centre, Paediatric Clinical Research Unit, and was reviewed by the Ethics Committee of Our Lady's Children's Hospital, Crumlin; Temple Street Children's University Hospital Research Unit & Child Health Information Centre and IPPOSI.



The Irish Platform for Patient Organizations, Science and Industry ensures patients in Ireland have prompt access to new and developing innovative therapies. It is a patient-led platform which brings together patient organisations', science, industry and where possible state agencies to build consensus on policy, legislation and regulation of the development of new medicines, products, devices and diagnostics for un-met medical needs in Ireland.

www.ipposi.ie



**NATIONAL CHILDREN'S
RESEARCH CENTRE**

The National Children's Research Centre (NCRC) is a charitable organisation and the largest paediatric research facility in the Republic of Ireland, and supports investigations into the cause, diagnosis, treatment and prevention of childhood illness and injury, through a series of research grants to principal investigators (senior doctors and scientists) and through an MD/PhD/MSc academic training programme, funded by the Children's Medical Research Foundation (CMRF).

www.nationalchildrensresearchcentre.ie

For more answers
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