



FOR YOUNG PEOPLE WITH CANCER
Helping you to understand clinical trials

www.DeltaDecision.com

CONTENTS

1 CLINICAL TRIAL INFORMATION

- 1 What is a clinical trial?
- 2 Summary of clinical trial phases
- 3 What is standard treatment?
- 3 Why was I asked to participate in a clinical trial?
- 4 Do I have to enrol?
- 5 How do clinical trials work?
- 7 What is randomisation?
- 8 Why do people decide to enrol or not enrol in a trial?
- 9 How do I talk about clinical trials?
- 12 How I am feeling

14 MY PREFERENCES EXERCISE

18 GLOSSARY

19 ABOUT

If there is a young person information sheet for the clinical trial you were invited to, you will find it in the sleeve at the back of this booklet.

Visit the Delta website at [DeltaDecision.com](https://www.DeltaDecision.com) for more information



CLINICAL TRIAL INFORMATION

This section will help you understand what clinical trials are and how they work.

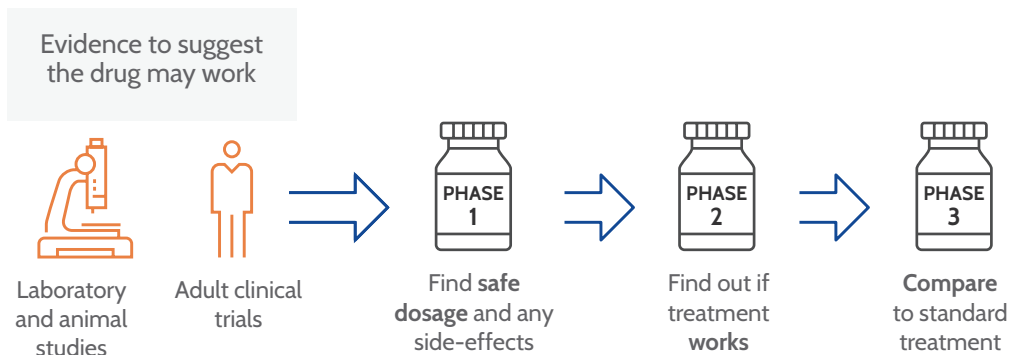
WHAT IS A CLINICAL TRIAL?

Clinical trials help improve cancer treatments. Clinical trials help other young people with cancer in the future.

A clinical trial is a medical research study. There are many different clinical trials. They are usually done to find out more about:

1. a new treatment, or
2. a new mix of different treatments, or
3. a new procedure or test

There are three types of clinical trials (called phases). Each phase aims to find out something about the new treatment. Clinical trials usually run in order. That means they start at Phase 1, then go to Phase 2, then to go to Phase 3.



SUMMARY OF CLINICAL TRIAL PHASES

Phase 1 Clinical Trials

- Phase 1 trials test a new treatment for the first time.
- These trials aim to find out if the new treatment is safe. They also aim to work out the correct dose to give to children.



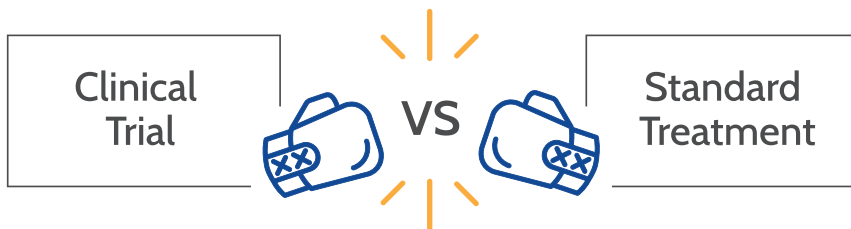
Phase 2 Clinical Trials

- If a new treatment is found to be safe in a Phase 1 trial, it can then be tested in a Phase 2 trial to see if it works.
- Phase 2 trials aim to determine if the new treatment works for particular types of cancer,



Phase 3 Clinical Trials

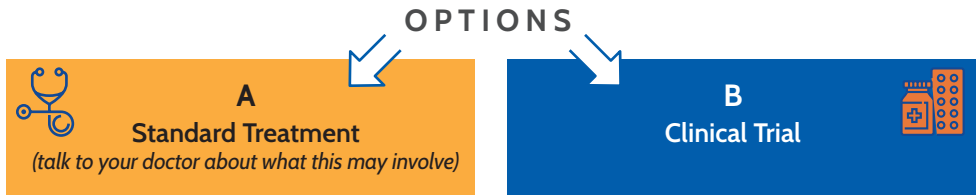
- Treatments being tested in a Phase 3 trial have been proven to be safe and to cure cancer.
- Phase 3 trials compares the new treatment with the standard treatment.
- To compare treatments, patients will sometimes be randomised to either have standard treatment or the clinical trial treatment. See Page 7 for more information about randomisation



See DeltaDecision.com.au for a more detailed overview of the types of Phases.

WHAT IS STANDARD TREATMENT?

Enrolling in a clinical trial is up to you and your parents. You don't have to enrol if you and your family decide not to. You always have another option. Your other option is standard treatment. Standard treatment is the best known available treatment. Standard treatment has already gone through the clinical trial process.



If you are offered a Phase 1 or Phase 2 clinical trial, standard treatment may not be available. For Phase 3 clinical trials, the clinical trial treatment and the standard treatment may be very similar. Talk to your doctor if you want to know more about your options.

WHY WAS I ASKED TO BE PART OF A CLINICAL TRIAL?

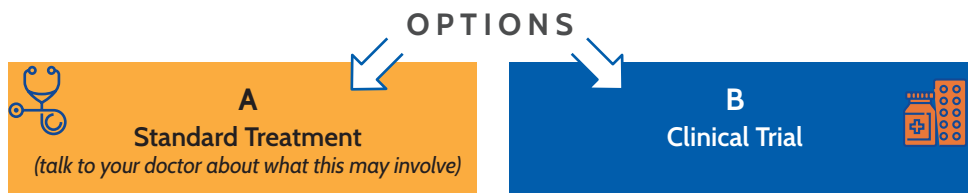
You may have been asked to enrol in a clinical trial because:

- you are eligible for a trial that the doctors think will work for you, or
- there may not be any standard treatments available for your diagnosis, or
- because you have tried standard treatment and it has not worked.

Enrolling in a clinical trial is up to you and your family. You don't have to enrol if you don't want to. It won't change your relationship with your doctors and nurses.

DO I HAVE TO ENROL?

No, you always have two choices.



Enrolling in a clinical trial is up to you and your parents. You do not have to enrol if you don't want to. If you don't enrol you will receive standard treatment. Standard treatment is the best known treatment available for you.

What happens if I want to enrol?

If you decide to enrol in a clinical trial, your parents will need to sign a consent form.

This means that they agree for you to be on the clinical trial. You may also be asked to sign a similar form, called an assent form. This is usually required for young people between 12-18 years old.

What happens if I change my mind, and don't want to enrol?

If you decide you do not want to be part of the clinical trial, you will need your parents to withdraw their consent. You can withdraw at any time. If you decide to withdraw, you will get standard treatment. Changing your mind will not affect how your doctors and nurses feel about you.

HOW DO CLINICAL TRIALS WORK?

What happens if I enrol?

If you enrol, you may have extra tests and visits to the hospital. Talk to your doctor about the tests you might have. You will be checked up on very closely to make sure that you are safe. This is also to collect information about how you are going.

You will most likely have your treatment in the same hospital, whether you're on a clinical trial or not.

Who runs the clinical trials?

Clinical trials are run by medical researchers. These researchers may include your doctor, another doctor from a research team at your hospital or someone from a drug company.

Will I be safe?

Lots of testing has been done before treatment reaches a clinical trial for young people. They have been tested in science labs and often in adults first. These previous tests suggest the treatment will help cure cancer.

Clinical trials are checked by groups of people called “ethics committees”. Ethics committees include lots of people who are experts, doctors, and community members. Ethics committees make sure that the research is done correctly and that you will be safe.

Your doctors will withdraw you from your trial if they are worried about your safety.

Only your doctors and the team running the clinical trial can look at your medical information. Your information will always be kept secure and will never be identified to the public. Information given to a drug company is always ‘de-identified’. This means it does not have your name on it.

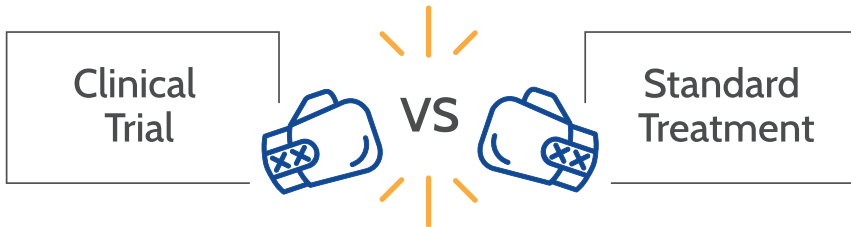
Impact on you

If you enrol in a clinical trial, this may impact you in a good and/or a bad way.

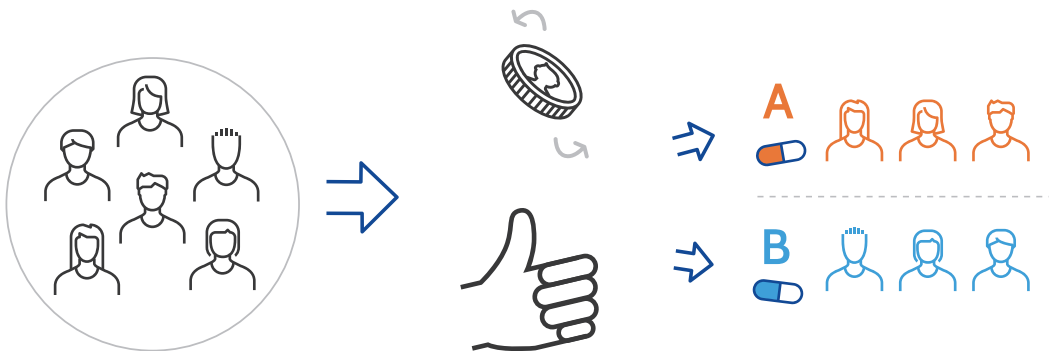
- Possible positive impacts:
 - › You may be able to receive new treatments
 - › You may feel that you are helping other young people
 - › You may feel happy you have “tried everything”
- Possible negative impacts:
 - › You may have more appointments and tests.
 - › You may need to spend more time in hospital. This may mean that you have more time out of school.
 - › You may have more side-effects
 - › You may not be allowed to eat certain foods (e.g. grapefruits), or take certain medicines.
 - › If you are male and want to have sex, you may need to use condoms during the trial. This may be the same if you have standard treatment.
 - › If you are female and want to have sex, you may need to use condoms or be on ‘the pill’ during the trial. This may be the same if you have standard treatment.

WHAT IS RANDOMISATION?

Randomisation often happens in Phase 3 trials. It can sometimes be done in Phase 2 trials as well. Randomisation is done to compare a new treatment to standard treatment. It is important because the researchers and doctors are not sure which treatment is better.



Randomisation means that patients are randomly put in different treatments. Randomisation is like flipping a coin. If the coin lands on heads you receive the clinical trial treatment. If the coin lands on tails you receive standard treatment.



You can always withdraw if you are randomised to the clinical trial treatment. This will mean you will receive standard treatment. Ask your doctor if you want to know more about randomisation.

WHY DO OTHER PEOPLE DECIDE TO ENROL OR NOT ENROL IN A TRIAL?

There are lots of reasons why young people want to enrol, or not enrol in a clinical trial. These reasons may not all be true, but here are some reasons that other people have talked about.

SOME REASONS WHY PEOPLE DECIDE TO ENROL IN CLINICAL TRIAL

To try to reduce pain
To take a chance that they may get better treatment
To access the newest treatments
To keep hope
To help medical research and future young people
To get more care from the hospital
Because no other treatment has worked
To try to stop the cancer getting worse
To meet other young people in a similar situation
To possibly be one of the first to benefit from a new treatment
Because their parents/doctors want them to

SOME REASONS WHY PEOPLE DECIDE TO NOT TO ENROL IN CLINICAL TRIAL

Worry that the clinical trial won't work
Fear that the clinical trial may have unexpected side-effects
Fear that the clinical trial may cause more pain
Not wanting any extra tests and appointments
Worry that the clinical trial won't work
Feeling like that they are a guinea pig
They trust the standard treatment
Fear that the clinical trial may make the cancer worse
Because their parents/doctors don't want them to

It is important that you talk to your doctor and parents about your reasons for wanting to enrol or not enrol in a clinical trial.

HOW DO I TALK ABOUT CLINICAL TRIALS?

Talking with your doctor

Sometimes it can be hard to talk to your doctors about clinical trials. Doctors often use a lot of hard medical words and there can be lots of information. If you have any questions, you can always raise this with your doctors and nurses.

Here are some questions that may help.

“
[The doctor] was explaining the side effects and stuff. That was good because he told me; he was talking to me which was good.
16 year old male diagnosed with Acute Lymphoblastic Leukaemia
”

QUESTION LIST

General questions

- ☐ What are my treatment options?
- ☐ Why is this clinical trial being done?
- ☐ What happens if I get more sick on the clinical trial?
- ☐ Is the study randomised?

Questions about standard treatment versus this clinical trial

Are there differences in:

- ☐ The negatives and positives?
- ☐ Side-effects?
- ☐ Tests and procedures?
- ☐ The number of appointments?
- ☐ The length of treatment?
- ☐ Impact on my ability to go to school or see my friends?
- ☐ Chance of cure?

Questions about enrolling

- ☐ What will happen if I don't enrol?
- ☐ What happens if I change my mind?
- ☐ How much time do I have to think before deciding?
- ☐ Can I talk to other young people who have enrolled in the clinical trial?

Talking with your parents

Your parents need to consent to which treatment you receive. Because of this, it is really important to talk to them about whether you want to enrol in the clinical trial or not.

Talking to your parents may:

- help you better understand the information,
- provide you with some questions you had not thought of,
- support you emotionally,
- help you talk about how you are feeling, and/or

“ My parents did give me a bit of information. They told me about some stuff. I didn't go poking around a whole lot on the web because I didn't want to freak myself out.

13 year old male diagnosed with Osteosarcoma

IDEAS TO HELP YOU TALK WITH YOUR PARENTS

Think about what you want to say before you start talking

Organise a time to sit down with you parents and talk about how you feel.

Try to have some short chats across a few days, rather than just one long chat.

Try to talk to your parents while doing something else – maybe in the car.

Be honest with about how you are feeling and thinking. Sometimes parents won't know how you are feeling.

Remember that it is okay to be scared, confused, worried or sick; and it is also okay if you feel happy, confident or not worried about the clinical trial

Create a list and ask any questions you have

Let your parents know how they can support you

Take time out to talk to your parents about normal life stuff as well

Be aware that your parents may be upset, but that this is not your fault

Talk to your parents about how much information, and how involved you would like to be

What happens if I don't agree with my parents?

Sometimes you might not agree with your parents. You might disagree about your treatment, what foods to eat, or whether you are well enough to see your friends. If you do disagree with your parents, it is important that you talk to them. You may not always get what you want, but it is important to tell your parents how you are feeling, and what you would prefer. You may also want to talk to your psychosocial team about this. This may be the psychologist at the hospital, the clinical nurse consultant or the social worker.

Talking with your friends

Talking about cancer and clinical trials can be difficult. It is up to you who you decide to talk to. Talking to a friend may help you. It may also not be useful for you. If you to decide to talk to your friends about your cancer and treatment, here are some things that may help.

IDEAS ABOUT TALKING TO YOUR FRIENDS

Think about what you want to say before you talk to them

Remember it is up to you who you tell, and how much you share

Talk to friends that you trust

Let your friend know what they can do to help you (e.g. do you want them to just distract you, or do you want their opinion?)

Facebook, emails or a personal blog may be one way to share what your thoughts and experiences. But remember, lots of people might see what you write so maybe get a parent to read what you have written before you post it.

Read stories about other young people with cancer

Know that sometimes your friends may not know what to say. They may also not understand

Making new friends who are going through a similar experience to you may help
Your social worker can link you in with other young people with cancer.

HOW I AM FEELING

Deciding if you want to enrol in a clinical trial can be difficult. It is okay if you are feeling upset or worried. It is also okay if you are not upset or worried.

If you are feeling upset, you can always talk to your doctor, clinical nurse consultant, or your parents. Your treating team may have also introduced you to someone who can support you through the emotional side of having cancer. This might be a social worker or a psychologist. Ask your doctor about this if you have not met them yet, and you would like to.

If you are feeling very worried, anxious, nervous, or sad a lot of the time, it might be helpful for you to chat with the psychologist on your team. They can talk to you about ways to deal with these feelings. They can also show you some ways to cope with your cancer treatment better.

You can also call any of the services from the Support Services section on page 20.

If you are feeling okay, but sometimes get a bit worried or sad, here are some things you can do to make you feel better.

EXAMPLES

- Browse videos online
- Draw or paint
- Do some puzzles
- Play a game
- Visit the Starlight Room or ask for a Starlight Captain to visit you
- Call a friend
- Read a book
- Watch a movie
- Go outside and watch the clouds
- Have a massage
- Take a long shower or bath
- Imagine your favourite place
- Listen to some favourite music
- Hug a loved one
- Visit a favourite place
- Go for a walk or do some stretches
- Take some deep breaths
- Organise some time to talk with a social worker, a psychologist or a

For example, I like to cuddle my dog

[illegible]



MY PREFERENCES

Parents often want to make the treatment decisions for their child. If you are under 18 years old, your parents will give consent for your treatment. If you are old enough, you may also be asked to sign an assent form.

No matter how old you are, you have a right to voice your opinion and preferences.

On the next page is an exercise to help you decide how much you want to be involved in deciding whether to enrol in the clinical trial. Once you have completed this activity, it is a good idea to show your parents and doctor. It helps to explain how you are feeling. You may also want to talk to your psychosocial team about this. This may be the psychologist at the hospital, the clinical nurse consultant or the social worker.

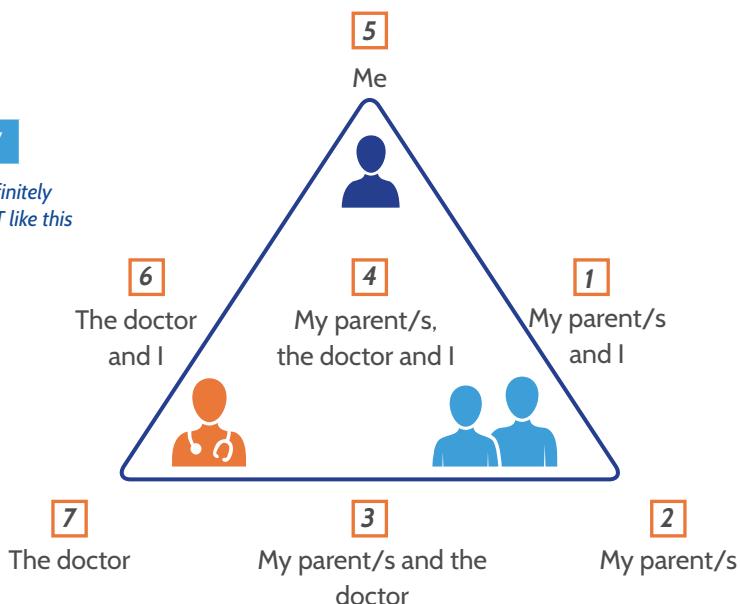
Example.

SCALE:



Yes, I would
most like this

No, I definitely
would NOT like this



Who would you like to make the final decisions about your treatment?

Please rate, from 1 to 7, your preferences.
1=favourite, 7=least favourite (write each number once only)

SCALE:

1	2	3	4	5	6	7
Yes, I would most like this		I like this a bit		I don't really like this		No, I definitely would NOT like this

Me

The doctor and I

My parent/s, the doctor and I

My parent/s and I

The doctor

My parent/s and the doctor

My parent/s

Your reasons to enrol or not enrol

If you want to be involved in the decision, here is a worksheet to help you think about whether your reasons why you want to enrol or not enrol in the trial.

MY LIST OF REASONS I WANT TO ENROL

For example, I think the clinical trial might help me

MY LIST OF REASONS I DON'T WANT TO ENROL

For example, I am worried about side effects

Right now, do you feel that you want to enrol or not enrol in the clinical trial?

Circle your answer...



Remember.... once you have completed this activity, it may be useful to show your parents and doctor. It may help to explain how you are feeling. You may also want to talk to your psychosocial team about this. This may be the psychologist at the hospital, the clinical nurse consultant or the social worker.

“ Well, even though it makes you feel sick it's still really, really important to do it because it's curing your cancer and without it tumours do spread... They don't stop just because we want them to. ”

13 year old male diagnosed with Osteosarcoma

“ Well I didn't really mind doing the clinical trial - a lot of it was under anaesthetic so I wouldn't really have noticed anything. ”

16 year old male diagnosed with Acute Lymphoblastic Leukaemia



GLOSSARY

GLOSSARY

TERM	DEFINITION/EXPLANATION
Assent	The assent form is a document you might be asked to sign if you decide to participate in the clinical trial. You can still withdraw from the study if you sign this document.
Clinical nurse consultant (CNC)	A CNC provides expert care and support for you throughout your cancer journey. They are available 24/7.
Clinical trial	A clinical trial is a medical research study that tests a new treatment.
Consent	Consent is the permission that your parents will give if you decide to enrol on the clinical trial.
De-identified data	De-identified data means that your name will be removed from any of your medical information.
Phase 1 trial	These trials aim to determine the correct and safe dose of the new treatment.
Phase 2 trial	These trials aim to determine whether the new treatment works to cure cancer.
Phase 3 trial	These trials compare the new treatment with standard treatment to find out which one works better.
Psychologist	A psychologist is someone who can help you if you are often feeling upset or worried.
Social worker	A social worker can also help you if you are upset or worried. They can also help support your family with a range of practical issues.
Standard treatment	Standard treatment is the best known and proven treatment.



ABOUT DELTA

“The decision is yours”

You have a right to have a say whether you want to enrol in a clinical trial.

We have made this tool to help you understand what clinical trials are. We are testing how helpful this tool is in this study.

Some young people are faced with the decision as to whether they should enrol in a clinical trial. This decision may be difficult or easy for some. We hope that this booklet will help you understand what clinical trials are, and what it may mean for you and your family. The decision to enrol is completely up to you - Delta is just here to support you in that process.

WHAT IS DELTA?

Delta has been developed to help parents and young people decide whether they should enrol in a clinical trial. Delta is available as this booklet or as the website (DeltaDecision.com). The website has slightly more information and contains interactive exercises.

Delta provides information about clinical trials, tips to help you talk about clinical trials, and exercises to help you understand how involved you would like to be in the decision.

For further information about the development of Delta, please visit the website (DeltaDecision.com).

SUPPORT SERVICES

If you need support, please visit the website or call any of the organisations listed below.

Beyond Blue: www.beyondblue.org.au

Canteen: <https://www.canteen.org.au/>

Cancer Council: <http://www.cancer.org.au/> or call 13 11 20

Headspace: <http://headspace.org.au/> or call 1800 650 890

Lifeline: www.lifeline.org.au or call 13 11 14 Reach Out: reachout.com.au

Tune In Not Out: www.tuneinnotout.com

Youth Cancer Services Australia: www.youthcancer.com.au

If you are in an emergency, **please call 000**

If you would like some support from a psychologist or social worker, please talk to your **parents**, doctor or GP.

CONTACT US

If you have any questions about this booklet or would like to provide feedback, please contact the study team on **DeltaStudy@unsw.edu.au** or at www.deltadecision.com

DELTA | 21

