



SUPPORTING PARENTS MAKING CLINICAL  
TRIAL DECISIONS FOR THEIR CHILD

[www.DeltaDecision.com](http://www.DeltaDecision.com)

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The information sheet for the specific clinical trial your child was invited to can be found in the sleeve at the back of the booklet.

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



# CLINICAL TRIAL INFORMATION

This section provides a general overview about clinical trials.

## WHAT IS A CLINICAL TRIAL?

*Clinical trials are really important to improve treatments and learn more about cancer. It is because of clinical trials that survival rates of childhood cancer have increased so much. Having clinical trials helps other children with cancer in the future.*

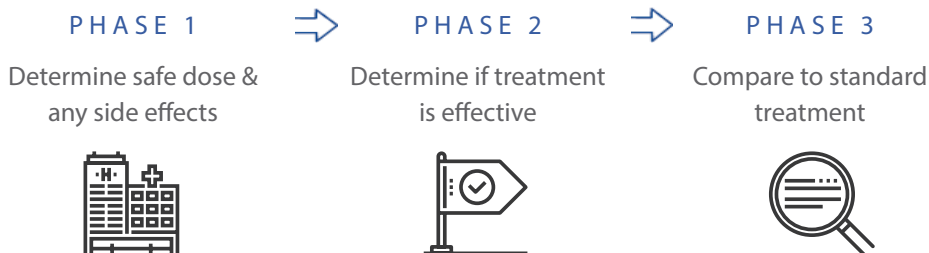
A clinical trial is a medical research study. Clinical trials differ in aims, but usually they are testing:

1. A new treatment, or
2. A new combination of drugs, or
3. A new procedure for drug administration, or
4. An increase (escalation) or a decrease (de-escalation) in dose

Clinical trials are done to:

- test and compare new treatments or procedures, and
- to refine and improve treatments and patient outcomes

There are three main types of clinical trials (known as phases). Each phase of a clinical trial aims to find out something different about the new treatment. Clinical trial usually usually run in order, from Phase 1 to Phase 2 to Phase 3.



## SUMMARY OF A CLINICAL TRIAL PHASES

### PHASE 1 Clinical Trials

- Phase 1 trials aim to test a new treatment or combination of treatments for the first time.
- They determine the correct and safe dose of the new treatment
- Effectiveness of the drug or drug combination in curing cancer is not the main outcome of these clinical trials.



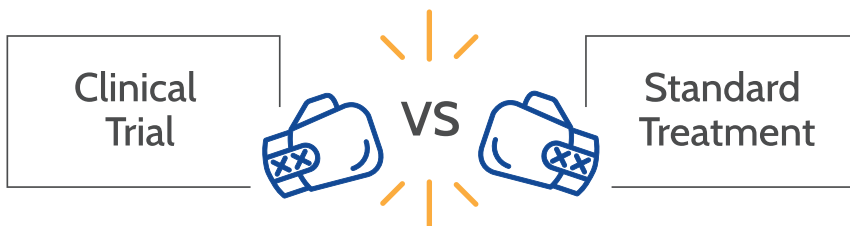
### PHASE 2 Clinical Trials

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



### PHASE 3 Clinical Trials

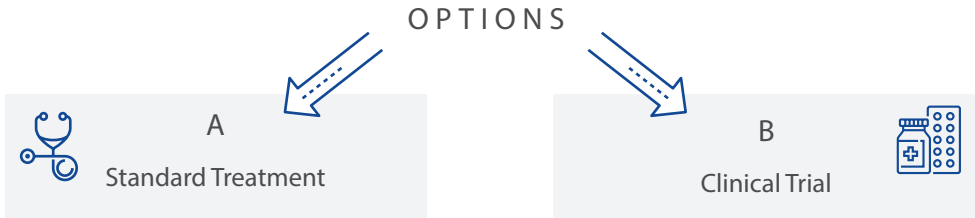
- Treatments being tested in a Phase 3 trial have been proven to be safe and effective.
- These trials compare the new version of treatment with the standard treatment.
- To compare treatments, patients will sometimes be randomised to a control group (standard treatment) or the clinical trial treatment.



See [www.DeltaDecision.com](http://www.DeltaDecision.com) for a more detailed overview of the types of Phases.

## CLINICAL TRIALS VERSUS STANDARD TREATMENT

Enrolling in a clinical trial is voluntary – you do not have to enrol in a trial if you do not want to. You always have an alternative option. Your alternative option is standard treatment. Standard treatment is the best known available treatment based on published reports from previous clinical trials.



If you are offered a Phase 1 or Phase 2 clinical trial, standard treatment may not be available for your child's diagnosis. For Phase 3 clinical trials, treatment on the trial may also be standard treatment or be very similar.

Read your clinical trial information sheet for more information about what your standard treatment is, or ask your treating team.

“ He was enrolled on a clinical trial, but the treatment was the same as standard treatment because we declined the experimental randomisation. It's more data from it that has been used to contribute to the study. – Mother of a 1 year old boy diagnosed with Acute Lymphoblastic Leukaemia ”

“ My main concern was just as long as he gets the best treatment. We were just overwhelmed that our son had cancer and all we wanted was the best available treatment for him. – Mother of a 16 year old adolescent diagnosed with Acute Lymphoblastic Leukaemia ”

## Clinical trials vs. standard treatment

	CLINICAL TRIALS	STANDARD TREATMENT
Aim	Aims to determine the dose of new treatment or if it is safe (Phase 1), if it is effective (Phase 2) or to compare against standard treatment (Phase 3).	Treats the needs of the individual patient based on the best available evidence and results from previous clinical trials.
Purpose	Generally designed and intended to benefit future patients (Phase 1, 2 and 3), or to benefit the current patient (Phase 3).	Intended to benefit the current patient.
Funding	Patients do not need to pay for any associated treatments on a clinical trial. You may have additional costs such as transport or accommodation if you need to come in to hospital more frequently.	Patients with Medicare and receiving treatment through the public system do not need to pay for any associated treatments on standard treatment.
Assessment	Involves ongoing collection of patient data.	Based on as-needed patient assessment.
Treatment	Tests new drugs and/or procedures of unproven benefit to the patient. Treatment has been tested in the lab and often with adults. Phase 2 clinical trials have been proven to be safe in a Phase 1 clinical trial. Phase 3 clinical trials have been proven to be safe and effective.	Uses products and procedures accepted by the medical community as “best known treatment”.

## WHY HAS MY CHILD BEEN ASKED TO ENROL IN A CLINICAL TRIAL?

### Why are children offered a PHASE 1 or 2 clinical trial?

1. because your child is eligible for a trial that is working out the best way to treat them.
2. because there is no other standard treatments available to treat them.
3. because your child has relapsed.

### Why are children offered a PHASE 3 clinical trial?

1. because the Phase 3 clinical trial is considered the best standard of care.
2. because your child is eligible for a clinical trial that seems promising for their diagnosis.
3. there may not be any other treatments available to treat their specific cancer.

A clinical trial is a medical research study that tests a new treatment in people.

Remember that enrolling in a clinical trial is completely voluntary – it is completely up to you and your family whether or not you decide to enrol your child in the trial. There are no consequences if you decide not to enrol.

## CONSENT, NON-PARTICIPATION AND WITHDRAWAL

### Do I have to enrol?

Enrolling in a clinical trial is completely voluntary – it is up to you and your child. You are not obliged to participate. In the case that you do not want to enrol, your treating team will respect your choice, and will provide your child with the standard treatment.

### What is the consent process?

If you do decide to enrol your child in a clinical trial, you will be asked to provide your informed consent. Your child may also be asked to sign a similar form, called an assent form.

### What if I want to withdraw from the clinical trial after I consent?

The consent form is not a contract – this means you can withdraw from the trial at any time without giving a reason. Your decision to withdraw will not impact the relationship between you, your doctor or the hospital. If you decide to withdraw, your child will be offered standard treatment.

If you decide to withdraw once treatment on a clinical trial has started, you need to talk about this with your doctor. If you decide to withdraw, your treating team will most likely stay the same.

#### ► SUMMARY

- Enrolling in a clinical trial is voluntary.
- You will be required to provide your informed consent.
- Your child may also be required to provide assent.
- You can withdraw your consent at any time without reason.

“ I felt like we were benefitting from that having occurred in the past, and I wanted to contribute to it in the future. I didn't really need to get into the specifics because I knew that there was always the opt-out if, at a point down the track, I became uncomfortable with it”.

– Mother of a 1 year old boy diagnosed with Acute Lymphoblastic Leukaemia



## HOW DO CLINICAL TRIALS WORK?

### What happens if I enrol my child?

Once enrolled on the trial, your child may need to meet with a team of doctors. Your child may also have extra tests and visits to the hospital. Your child's progress will be monitored very closely to ensure their safety and to collect data. There may also be requirements around treatment adherence that your child will have to meet.

Like any other treatment, your child will be treated on a very specific treatment plan (or protocol). Read your clinical trial information sheet to find out more details about the procedures and treatment protocol.

### Who is responsible for clinical trials?

Clinical trials are run by medical researchers. These researchers may include your doctor, a doctor or healthcare professional from a clinical trials research team at your hospital, or a pharmaceutical (drug) company.

### Where do clinical trials take place?

Your child will most likely receive their treatment in the same hospital, regardless of whether they are on a trial or not. However, there may be cases where a trial is not available from your child's usual centre, so travel may be required. Talk to your treating team if this is a concern.

### Potential impact of being part of the clinical trial

If you decide to enrol your child in a clinical trial, there are several things that may impact yours and your child's quality of life.

Potential positive impact on quality of life:

- Your child may receive new treatments that might not otherwise be available
- You may be glad to help other children
- You may like to know that you have "tried everything"

Potential negative impact on quality of life:

- Your child may have more appointments and tests, or need to spend more time in hospital
- Your child or you may need to fill in extra paperwork
- Your child may have extra side-effects (some of which may be unexpected)
- Your child may not be able to eat certain foods (e.g. grapefruit), or take herbal medicines or prescription medicines. Some anti-nausea medicines are still allowed.
- If of childbearing age, your child may need to use contraception/refrain from sex.

## Financial

Cancer treatment can sometimes cause a financial strain on some families as parents may not be working, or they may have to travel long distances. Enrolling on the trial may also involve more transport costs and accommodation costs due to more time at hospital.

If your child has Medicare and your child receives treatment through the Australian public hospital system, regardless of whether your child is on a clinical trial or has standard treatment, all procedures and treatments listed in the protocol will be free of charge.

Clinical trial patients are not paid for their participation. Should any adverse events happen to your child, your child may receive compensation.

### ► SUMMARY

- Your child may require extra tests and visits to the hospital on a clinical trial.
- Enrolling your child in a clinical trial may have a positive and/or negative impact.
- Standard treatment and clinical trial treatments are free of charge.

“ I don't know much about how the studies are really run, and at the end of the day it was always as long as he's getting the best level of care. ”

– Mother of a 16 year old diagnosed with Acute Lymphoblastic Leukaemia

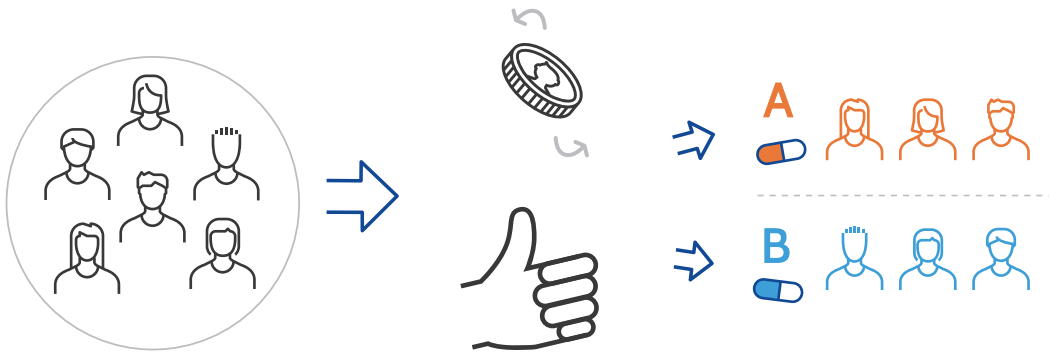
“ I didn't feel as though I had to understand it though because I didn't have an option. It was a streamlined process. If you break your arm, you get it fixed. It was like that. ”

– Mother of a 4 year old diagnosed with a Central Nervous System tumour

## RANDOMISATION

Many Phase 3 clinical trials or Phase 2 clinical trials randomise patients. Randomisation is done to compare two treatments to see if one is better. The doctors will always obtain your consent for randomisation before any treatment is given.

Randomisation means that patients are randomly assigned to different treatments. Randomisation is like flipping a coin with heads meaning your child receives Treatment A, and tails meaning your child receives Treatment B. One treatment will always be the standard treatment (which is what is offered to treat your child even if you do not enrol them on a clinical trial), and the other will be the new treatment.



Randomisation is usually done by a computer, which means that patients and doctors are unable to choose a group that they are allocated to. This is done so that results are not biased in any way. If you would like to know which treatment you have been randomised to, ask your doctor and if they are able, they will tell you.

“

When we were offered a randomisation I certainly found that to be very challenging and somewhat of a stressful decision.

”

– Mother of a 1 year old boy diagnosed with Acute Lymphoblastic Leukaemia

## REASONS TO ENROL/NOT ENROL IN A CLINICAL TRIAL

There are many reasons that families decide to enrol or not enrol in a clinical trial. Here are some reasons that other families chose to enrol or not enrol in a clinical trial.

### SOME REASONS TO ENROL

To try to reduce my child's pain and symptoms
To take a chance that my child may receive better treatment than standard treatment
To access the newest treatments and technologies
To maintain hope
To contribute to medical research and help future children
To feel as though they have closer monitoring and care from the treating team
Because no other treatment available as 'standard treatment' has worked
To try and stop the cancer getting worse
To access more health information and knowledge from a larger team
To possibly be one of the first to benefit from a new treatment

### SOME REASONS TO NOT ENROL

Worried that the clinical trial treatment may not work
Fear that the clinical trial treatment may be less effective than standard treatment
Fear that the clinical trial treatment may have unexpected side-effects
Feeling that extra tests and appointments at the hospital are inconvenient
Feeling that their child is not safe, or is a guinea pig on a clinical trial
Believing their child will experience greater discomfort or pain on the clinical trial
Worry that their child could be randomised to an ineffective treatment, or a more toxic treatment
To access more treatment that has a more known evidence base
To have an idea of outcomes following treatment
Peace of mind that standard treatment has already been proven to work

“ Fundamentally, it comes to a parent’s judgement. You can look to the literature and you can try and inform yourself to make the best judgement possible for your child but, in the end, I think, in the absence of any real evidence, it comes down to an intuitive decision about what’s best for them. ”

- Mother of a 1 year old boy diagnosed with Acute Lymphoblastic Leukaemia

“ Without participation of past patients, I don’t think we would be in nearly as fortunate a position as we were. I felt, I guess, a moral obligation to contribute to any future improvements. ”

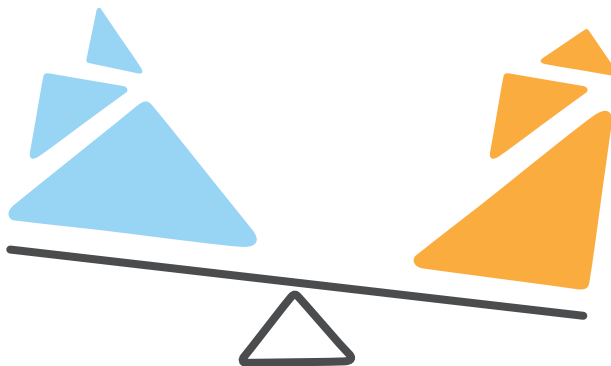
- Mother of a 1 year old boy diagnosed with Acute Lymphoblastic Leukaemia

“ 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

“ 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. ”

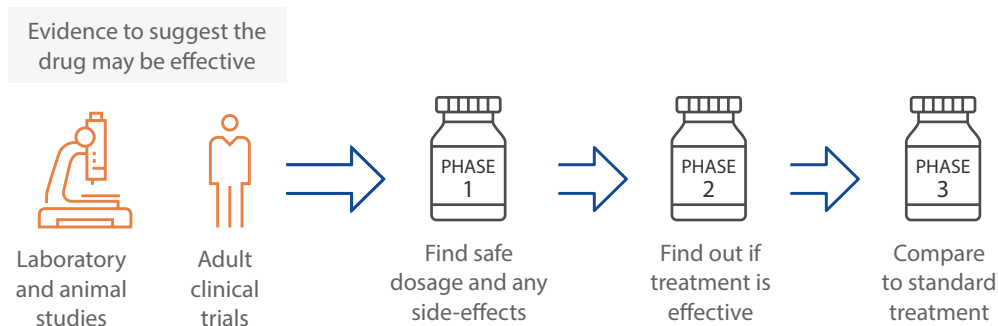
- 13 year old male diagnosed with Osteosarcoma



## SAFETY AND CONFIDENTIALITY

### How can you be sure that my child is safe?

Prior to being offered in children, clinical trial treatments have gone through rigorous testing already. This is the general process:



Each stage leads on to the next. This means that there is some evidence supporting the clinical trial before it moves on to the next stage.

Trials are well-designed with extensive protocols. To ensure patient safety, all clinical trial protocols have been reviewed and approved by multiple ethics and regulatory committees. If there are any concerns about the conduct of the trial, patient safety, or any concerns that patients are doing less well than expected, the trial will be stopped immediately.

If the treating team is worried about your child's health, or that your child's cancer is progressing, they will remove your child from the study and be cared for in the best way possible.

### Where does my child's information go?

Information from your child will be collected and reviewed by the treating team. It will also be sent to the team responsible for coordinating the trial. Your child's information will always be de-identified (meaning that their name will not be linked to their data).

Clinical trial data is usually kept for 15-25 years from the end of the study (paper and electronically). You will not have access to all your child's specific information from the research tests; however you may be able to access a summary of the overall study at the end of the trial. You and your treating team will also be informed of any test results that impact treatment decisions.

#### ► SUMMARY

- If your child enrolls in a clinical trial, their information will be reviewed by the treating team and the team coordinating the clinical trial.
- Your child's information will always be kept secure and will never be identified to the public.
- Clinical trials are well-designed, and are reviewed by multiple scientific ethics committees to ensure the safety of patients.
- If there is any doubt that your child is not safe on the clinical trial, the treating team will immediately withdraw your child from the study.



## COMMUNICATION

### Communicating with your doctor

Some parents may find talking with doctors about clinical trials difficult. Doctors often use a lot of medical jargon and there can be a large amount of information to understand. If you have any questions or concerns, or would like information repeated, you can always raise this with your treating team. You may feel uncertain of what questions to ask however. See the next page for list of some questions for your medical team that may be useful.





### General questions:

- ☐ What are my child's treatment options?
- ☐ Why was my child invited to this specific clinical trial?
- ☐ What is the purpose of this clinical trial?
- ☐ Is my child eligible for any other clinical trials?

### Questions about standard treatment versus this clinical trial

Are there differences in:

- |  |   |
|--|---|
| <input type="checkbox"/> The risks and benefits, side effects, etc.? | <input type="checkbox"/> The length of treatment or follow-up?                |
| <input type="checkbox"/> Tests and procedures?                       | <input type="checkbox"/> The location of treatment?                           |
| <input type="checkbox"/> The number of appointments?                 | <input type="checkbox"/> Impact on my child's day-to-day life and activities? |
| <input type="checkbox"/> The likelihood of cure?                     |   |

### Questions about treatment benefits and risks

- ☐ What is already known about the treatment being used in this clinical trial?
- ☐ Can I talk to other families who have enrolled in the clinical trial?
- ☐ What happens if my child gets more sick on the clinical trial?

### Questions about the logistics of the clinical trial

- ☐ Is the study randomised, and what does this mean for my child?
- ☐ Is there any financial support for being on the trial?
- ☐ Can we still use alternative therapies if we decide to go on the trial (e.g. vitamins, herbal remedies, naturopathy)?

### Questions about withdrawal, non-participation, consent

- ☐ What will happen to my child if we don't enrol on the clinical trial?
- ☐ Will you still treat my child if we decide not to participate in the clinical trial?
- ☐ What happens if I want to withdraw my child from the clinical trial after treatment has already started?
- ☐ Is this new treatment only available through the trial?
- ☐ If my child participates in the clinical trial, will they not be eligible for any new treatment opportunities (such as another trial or standard treatment later)?
- ☐ How much time do I have to think about whether to enrol my child on the trial?

### Communicating with your partner and/or loved ones

You might find it useful to talk to your friends and family when making the decision about whether your child should participate in a clinical trial.

Family and friends may be able to:

- provide you with some questions you had not thought of,
- support you in making a decision,
- talk to you about how you are feeling, and/or
- distract you or help you relax

EXAMPLE SITUATION	RECOMMENDATION
You may find it hard to decide who to tell, and how much detail to give.	<ul style="list-style-type: none"> <li>• Writing a list of who to talk to, and the basics of what is happening may help.</li> <li>• Think ahead of what to say for common questions such as “what can we do to help?” and “will he/she be okay?”</li> </ul>
Sometimes family and friends may trigger sensitive issues for you, they may say unhelpful things, ask questions you don’t want to answer, or become angry.	<ul style="list-style-type: none"> <li>• Talk to different friends or family members who can handle the situation better,</li> <li>• Be prepared to change topics (e.g. “Let’s talk about something else”).</li> <li>• Prepare answers to tricky questions ahead of time</li> <li>• Tell people how they can help you</li> </ul>

“ Throughout this whole process my husband trusts my judgement on most of these matters. He was a good sounding board for talking about the pros and cons...  
 – Mother of a 1 year old boy diagnosed with Acute Lymphoblastic Leukaemia

“ Other people are at different stages and you can get a bit of an insight at what’s ahead and then pay it forward to other people that have just started. It’s a community of people that are travelling similar paths.  
 – Mother of a 16 year old adolescent diagnosed with Acute Lymphoblastic Leukaemia

## COMMUNICATING WITH YOUR CHILD WITH CANCER

Talking to your child about the clinical trial can be tricky. It is up to you as to whether you think your child is mature enough to understand what is happening. It is really important, where possible, to try and involve your child in the consultations, discussions and decision-making process. This may not necessarily mean your child makes the final decision, but may be encouraging them to be involved in how the final decision comes about, or in any within treatment decisions (see “Within treatment decisions” on Page 26 for more on this). Doing so can help children feel more in control and valued. It may also be useful to ask your child about how much information and involvement in decision-making they want.

For all children, regardless of age, it is also really important that: information is provided to children in an age-appropriate way (e.g. drawings or online videos) and in simple language.

- your child is reassured that they are loved and not alone.
- your child has been given permission to feel sick – some children feel the need to stay brave and not show any weakness for their parents.
- you talk openly and honestly with your child.
- encourage your child to voice their opinions and thoughts.
- seek psychological support or peer-support for your child if necessary.

## COMMUNICATING WITH YOUR OTHER CHILDREN

If you have other children, discussing the clinical trial with them may also be difficult. Depending on your family dynamics, it may not be possible to talk to your other children about what is happening. It is important however to try and keep your children informed where possible so they:

- do not feel isolated.
- have someone to talk to if they are upset or worried.
- do not become anxious about the unknown.

Children tend to react based on how their parents or other close adults respond to the situation. When discussing your child's cancer and treatment with their siblings, try to remain calm as children can often feel your emotions.

If you are unsure as to how much you should tell your child, here is a general guideline.:

SUGGESTION	CHILD AGE			
	1-3	3-7	7-12	12+
Reassure your child you will not abandon them at hospital				
Inform your child of how long they will be in hospital for				
Explain to your child they did not do anything to cause their cancer				
Have multiple brief conversations, rather than one long discussion				
Inform your child of any tests, and why they are needed				
Be honest about likely pain from tests/procedures				
Involve your child in within-treatment decisions where possible				
Involve them in discussions about their cancer				
Discuss what the child understands, and clarify any false beliefs				
Prompt question-asking				
Encourage involvement in discussions about their cancer and decision-making				
Elicit decision-making and information preferences				

### ► SUMMARY

- Communicating about clinical trials can be difficult. Try to go to your consultation with a list of prepared questions.
- Talking to your partner and/or loved ones may be useful. It is up to you how much to share or discuss.
- Being aware of your child's understanding and maturity is important to consider when discussing treatment options.

## EMOTIONS

Making the decision about whether to enrol your child in a clinical trial can be difficult for some families, and easy for others. This section provides some suggestions to help you reduce your distress, if you are experiencing any.

Different strategies to reduce distress work for different people. Some of these strategies may also not be possible at the current time. If you have any strategies that you know help you de-stress, then take some time for these activities. You may also wish to seek more support through any of the Support Services on Page 30. You can also contact the hospital psychologist or social worker if you need some support from them.

// A lot of the decisions we had no say over. //  
I think that's why I found this particular decision so stressful because ultimately it was putting the power in my hands without any certainty about whether there was a benefit to doing that or not.  
- Mother of a 1 year old boy diagnosed with Acute Lymphoblastic Leukaemia

// There were times that I would go for walks //  
and cry my heart out. I saw people here, then I see friends... we just go for walks and talk.  
I do yoga a lot and that has really helped.  
- Mother of a 16 year old diagnosed with Hodgkins Disease

// We were given a lot of that information... there was just so much and I couldn't even think of sitting and reading it... //  
let's just say the emotion overwhelmed me so much that my thinking brain probably wasn't kicking in.  
- Mother of a 16 year old diagnosed with Acute Lymphoblastic Leukaemia

Here are some suggestions of strategies that may help you reduce your distress, if you are experiencing any. You can also write down some strategies that you know make you feel better when you are feeling distressed.

**Suggestions of activating strategies:**

- Walking, running, going to the gym
- Cleaning
- Gardening
- Cooking
- Calling a friend
- Shopping
- Reading a book
- Watching a movie
- Writing a letter



**Suggestions of soothing strategies:**

- Having a good meal
- Getting a massage
- Taking a long shower
- Breathing slow
- Imagining a relaxing scene
- Listening to some favourite music
- Hugging a loved one
- Visiting a favourite place
- Lighting some candles



**MY STRATEGIES**

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# DECISION MAKING

This section aims to help you make the decision of whether to enrol or not enrol your child in a clinical trial.

## CHECKLIST

Before you make your decision, it is important that you have a good understanding of what clinical trials are and what it means for your child. Here is a checklist to check your understanding before you make your decision.

**Do you feel as though you have a good understanding of:**

1. The purpose and aim of the clinical trial that your child was invited to?

☐ YES ☐ NO If no, we suggest you read 'What is a clinical trial?' (page 1).

2. What will happen to your child if they take part in the clinical trial?

☐ YES ☐ NO If no, we suggest you read 'How do clinical trials work?' (page 7).

3. The difference between standard treatment and clinical trial treatment?

☐ YES ☐ NO If no, we suggest you read 'Clinical trials vs. standard treatment' (page 3).

4. Reasons for and against enrolling in a clinical trial?

☐ YES ☐ NO If no, we suggest you read 'Reasons to enrol/not enrol in a clinical trial' (page 10).

5. How to withdraw from the clinical trial?

☐ YES ☐ NO If no, we suggest you read 'Consent, withdrawal and non-participation' (page 6).

6. How your child's safety and confidentiality will be ensured?

☐ YES ☐ NO If no, we suggest you read 'Safety and confidentiality' (page 12).

7. How to talk with your child and the doctors about the clinical trial?

☐ YES ☐ NO If no, we suggest you read 'Communication' (page 14).

## MAKING A DECISION

### Importance of the decision making process

The decision to enrol in a clinical trial is completely up to you. There are two options for your child's treatment:



Regardless of which option you choose, your child's treating team will ensure that your child is well cared for. It is important to remember that there is no simple answer as to whether you should enrol. This decision is a very personal one, and strongly depends on your personal and family values, preferences and priorities.

There are 3 main steps to take when making your decision:

1. Read and understand the information about clinical trials,
2. Talk to your treating team and ask any questions you have, and
3. Consider your family values when making the decision.

### Involving your child in the decision

Depending on the maturity of your child, you may want to involve your child in this decision. There is no best age for when to include your child, it is a case-by-case scenario. It is best to always ask your child their preference for how much involvement they want in this decision. See the "Communicating with your child" section on Page 19 for some suggestions on how to talk with your child about the decision.



## WITHIN TREATMENT DECISIONS

### Within treatment decisions

The decision to enrol in a clinical trial may not be the only decision you have to make. You may not feel as though you are able to make certain decisions, but there may be some opportunities that allow you to have more control.

Within treatment decisions are a way to be more involved in aspects of the treatment. They include decisions about the delivery of care (e.g. methods and timing of drug delivery, location of procedures). Some common examples of within treatment decisions include whether to use pain medications, or whether to go ahead with the randomised treatment (if you do decide to enrol in the clinical trial). Once again, it is up to you and your child as to whether you go ahead with any of these things.

Your child may not want to decide whether they enrol or not, and they are happy for you decide on their behalf. Your child may however want to have a say in smaller decisions such as the pain medications (if any), what they decide to pack for the hospital, or if they want to visit any play rooms at the hospital. Having input into these smaller decisions can help your child feel as though they are, at least a little bit, in control of part of their treatment.

“ There was a lot of day-to-day decisions for us regarding asking for different pain medication and managing the side effects.  
– Mother of a 1 year old boy diagnosed with ALL ”

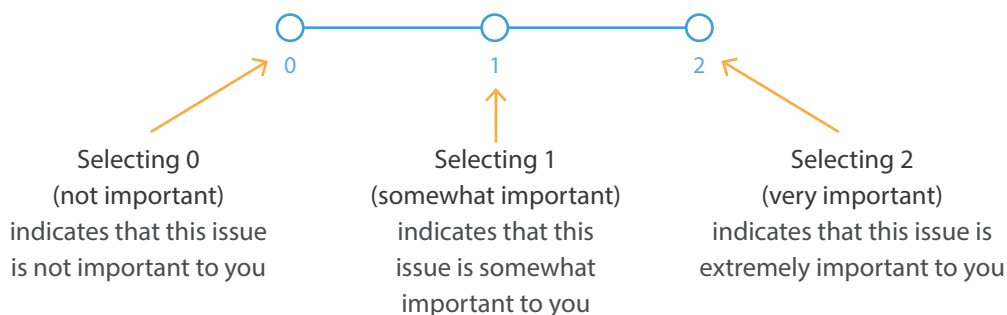
“ Having him making decisions... that was helpful because it's his body, he's going through it. So him being able to articulate how he was feeling with pain relief and all that sort of stuff was helpful.  
- Mother of a 16 year old diagnosed with Acute Lymphoblastic Leukaemia ”

## MAKING SURE YOUR DECISION REFLECTS YOUR VALUES

This is an exercise to help you make your decision. This exercise is individual, and there are no right or wrong answers. This exercise is purely to help you weigh up what is most important to you when making the decision about whether to enrol in a clinical trial.

### Instructions

When thinking about enrolling in clinical trial, rate each of the statements on a scale of 0-2 based on how important each is to you:



Your responses will provide some indication as to which option you are more inclined to choose. You can then use this exercise to talk with your treating team, family and child.

## YOUR DECISION EXERCISE

### REASONS TO ENROL YOUR CHILD IN THE TRIAL

I want to help my child live, no matter what it takes	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	0	1	2
I believe my child will be more closely monitored, and have more care on the trial	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	0	1	2
My child may get access to a new and better treatment	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	0	1	2
Enrolling my child may help future children with cancer	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	0	1	2
I believe the trial will reduce my child's symptoms	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	0	1	2
I have complete confidence in the medical care that is offered and provided to my child	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	0	1	2
I am open-minded to all medical options	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	0	1	2
Others recommend enrolling on the trial (e.g. doctors, family members, my child)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	0	1	2
My child's quality of life might be better on the trial	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	0	1	2
I feel my values are in line with enrolling on the trial	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	0	1	2
I want to maintain hope for as long as possible	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	0	1	2
Other:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	0	1	2
Other:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	0	1	2

Add up your total number on this page: \_\_\_\_\_ = this is your **SCORE A**

## YOUR DECISION EXERCISE

REASONS NOT TO ENROL YOUR CHILD IN THE TRIAL

I don't want my child to go through any more additional tests than required



I want to make sure my child is as safe as possible



I believe my child will receive better care if they receive standard treatment



I believe the clinical trial will be less effective than standard treatment



I want to spend more time at home with my family



I don't want to risk unknown side-effects



I do not have confidence in the medical care that is offered and will be provided to my child on the trial



I am fearful of what will happen on the trial



Others recommend not enrolling on the trial (e.g. doctors, family members, my child)



My child's quality of life might be worse on the trial



I feel my values are not in line with enrolling on the trial



Other:



Other:



Add up your total number on this page: \_\_\_\_\_ = this is your **SCORE B**

What is your **Score A**? \_\_\_\_\_ What is your **Score B**? \_\_\_\_\_

If your Score A  
is higher than  
Score B



you are leaning  
towards enrolling  
your child in a  
clinical trial

If your Score A and  
Score B are the same,  
or very similar



you do not appear  
to be leaning  
either way

If your Score B  
is higher than  
Score A



you are leaning  
towards not  
enrolling your child  
in a clinical trial

Give yourself time to reflect the outcome of this exercise, and review the information in this booklet. Try to think about what matters to you most. Feel free to review the exercise again.

### Are you satisfied with your decision?

It is really important to also make sure that you are satisfied with your decision and feel you made the right decision. Some things to consider when you feel as though you have made your decision are:

- Does this feel like the right decision?
- Whatever happens to my child, will I feel as though I have made the right choice?
- Is making this decision in line with my values and priorities?
- In 5 years or 10 years' time, will I be satisfied with my decision?
- Have I been involved/not involved in the final decision as much as I would like?

Once you feel confident with your decision, talk to your doctor about your decision.

Remember, taking part in a clinical trial is voluntary, and you can withdraw your child at any point in time (see the "Consent, non-participation and withdrawal" section for more information).

## POST-DECISION

Sometimes when you make a complex decision you may experience decisional regret after you have made the decision. If at any point you feel you may have made the wrong decision, talk to your doctor about how you are feeling. If you regret enrolling, you can always withdraw your consent. If you regret not enrolling, your doctor will be able to discuss the options available.

If you are feeling extreme anxiety or distress, you may also wish to seek more support through any of the services listed in the “Support services” section (page 2).

//

I feel 90 per cent comfortable with my decision.

//

I think, ultimately, you're faced with situations where you have to make very tough decisions. Once you've come to a decision you need to accept it.

- Mother of a 1 year old boy diagnosed with Acute Lymphoblastic Leukaemia

// It was clear that we should proceed that way to help //

him and I felt comfortable that it happened. It was hard afterwards and I was more anxious too and he became very anxious afterwards. We took a little while to get through that.

- Mother of a 13 year old diagnosed with Osteosarcoma



# ABOUT DELTA

Information about what Delta is

Delta has been developed to help you decide whether you want to enrol your child in a clinical trial. This decision may be difficult or easy for others. We hope that this booklet will provide you with a better understanding of what clinical trials are, and help you to make a decision that is best 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

This booklet has been named Delta as 'delta' is a triangle in the Greek alphabet. The triangle represents the decision making process between patients, parents and health care professionals. The triangle also represents the combination of information, communication support and decision-making support that is in this tool.

Delta has been developed over the past 12 months. It has been developed in line with several guidelines, and with the support of an extensive team of oncologists, psychologist, nurses, researchers and families.

All quotes used in this booklet have been used with the parents'/adolescents' consent.

### Contact us

Should you have any concerns about this website or would like to provide feedback, please contact the study team on [DeltaStudy@unsw.edu.au](mailto:DeltaStudy@unsw.edu.au), or send feedback via our online feedback form ([www.deltadecision.com](http://www.deltadecision.com)).

## SUPPORT SERVICES

If you need support or information about getting support, please contact any of the organisations listed below:

- **Beyond Blue:** [www.beyondblue.org.au](http://www.beyondblue.org.au)
- **Canteen:** <https://www.canteen.org.au/>
- **Cancer Council:** <http://www.cancer.org.au/> or call 13 11 20
- **Kids Helpline:** <https://kidshelpline.com.au/> or call 1800 55 1800
- **Lifeline:** [www.lifeline.org.au](http://www.lifeline.org.au) or call 13 11 14
- **Reach Out:** [www.reachout.com.au](http://www.reachout.com.au)
- **Tune In Not Out:** [www.tuneinnotout.com](http://www.tuneinnotout.com)
- **Youth Cancer Services Australia:** [www.youthcancer.com.au](http://www.youthcancer.com.au)

If you are in an emergency, please call 000.

Should you wish to seek support from the a psychologist or social worker, please talk to your treating team or GP about this.





# GLOSSARY

## GLOSSARY

TERM	DEFINITION/EXPLANATION
Adverse events	Adverse events are any medical occurrence associated with the use of the treatment.
Anti-nausea medication	Anti-nausea medications, or anti-emetics are drugs used to stop vomiting.
Anti- cancer activity	The anti-tumour activity is looking at potential tumour shrinkage or reduction in lymphoblast cell (cancer cells) count.
Assent	The assent process involves your child receiving age-appropriate information about the purpose of the trial and what procedures they will undergo. Although formal consent for a child's participation comes from the parent(s), your child may be required to agree to participate as well.
Clinical trial	A clinical trial is a medical research study that tests a new treatment.
Contraception	Methods or techniques to prevent pregnancy (e.g. the pill, condoms)
Control group	A control group in a Phase III clinical trial receives the usual or standard treatment for their type of cancer.
Decisional regret	Decisional regret is when you experience distress or remorse following a health care decision.
De-identified data	De-identified data means that the person's identity has been removed from their information. This may involve using a unique study participant code.

TERM	DEFINITION/EXPLANATION
Ethics committee	Ethics committees play a large role in overseeing research involving humans. They ensure the research is ethically acceptable and in accordance with relevant standards and guidelines.
Experimental therapy	Experimental therapies are treatments that are intended to treat the disease, but have not yet been proven to work.
Guidelines	These guidelines include: International Patient Decision Aids Standards (IPDAS) ( <a href="http://www.ipdas.ohri.ca/">http://www.ipdas.ohri.ca/</a> ), Research –based Web Design and Usability Guidelines ( <a href="https://www.usability.gov/sites/default/files/documents/guidelines_book.pdf">https://www.usability.gov/sites/default/files/documents/guidelines_book.pdf</a> ), and the National Health and Medical Research Councils Statement on Consumer and Community Participation in Health and Medical Research ( <a href="https://www.nhmrc.gov.au/research/consumer-and-community-involvement">https://www.nhmrc.gov.au/research/consumer-and-community-involvement</a> ).
Informed consent	Informed consent involves you signing a consent form which indicates you have read and understand the information provided and agree for your child to be treated on the clinical trial. Your written consent is required before any treatment on the clinical trial can start.
Medicare	Medicare is Australia's health scheme that provides Australians with a wide range of health services at little or no cost.
Palliative care	Palliative care is given to improve the quality of life of a patient. Palliative care aims to prevent or treatment symptoms and side effects of treatment.
Phase 1 trials	Phase 1 trials test a new treatment or a combination of treatments for the first time in children. They to determine the correct and safe dose of the new treatment.
Phase 2 trials	Phase 2 trials occur once a new treatment or a combination of treatments is proven to be reasonably safe. Phase II trials further evaluate safety, as well as efficacy of the new treatment.

TERM	DEFINITION/EXPLANATION
Phase 3 trials	A Phase 3 trial compares the new version of treatment with the standard treatment.
Placebos	Sham or inactive treatments.
Protocols	Protocols are documents that describe, in the detail, the plan for conducting the study, as well as the study purpose and function.
Randomisation	Randomisation means that patients are randomly assigned to different treatments
Reasonably safe	Reasonably safe indicates whilst the treatment may cause some minor side-effects, there are no major safety concerns of use.
Relapse	Also known as a cancer recurrence, a relapse is when cancer returns following treatment
Standard treatment	Standard treatment is the best known and proven treatment.
Stopping rules	Stopping rules tell the doctors when to end the trial, and what action is taken next. A stopping rule can be either because there was no response, or because the response was better than expected or less than expected.
Treatment adherence	Medicare is Australia's health scheme that provides Australians with a wide range of health services at little or no cost.
Values	Values are something that are considered worthwhile or important to you.
Within treatment decisions	These are smaller non-life threatening decisions about care delivery (e.g. administration of pain medication, appointment scheduling)



## NOTES

[illegible]

[illegible]

[illegible]

[illegible]

