

## Clinical Trials Information Sheet

Choosing to participate in a clinical trial is an important personal decision. This information sheet may help you in making that decision for you or your child.

### **What is a clinical trial?**

A clinical trial is a medical research study that searches for a better way to treat a particular disease. Clinical trials can be designed to study how to prevent or treat cancer or how to improve a person's comfort or quality of life. In a clinical trial, participants are followed closely over time to see which treatments offer the best chance of cure with the fewest side effects. New clinical trials are planned based on results of past trials and what is known about the disease and cancer treatments.

### **Why are clinical trials needed?**

Clinical trials are necessary to show that the treatment is safe and works well in treating cancer. Clinical trials help establish if the treatment being studied will work, what, if any, are the side effects and what the correct dose should be. This helps doctors to decide if the treatment is more effective and/or safer than existing medicines or treatments. Clinical trials are usually the fastest and most efficient way to improve the care of children and adolescents with cancer. Without clinical trials, medicines cannot be approved for use in Australia and New Zealand.

### **How are clinical trials approved?**

Before clinical trials can go ahead they need to be approved by independent ethics committees. These ethics committees operate in accordance with the guidelines issued by the National Health and Medical Research Council (NHMRC) and ensure that clinical trials conform to the Declaration of Helsinki and to international Good Clinical Practice (GCP) guidelines.

### **Who runs a clinical trial?**

Each clinical trial is led by a doctor. The clinical trial team includes doctors and nurses as well as pharmacists and other health care professionals. The clinical trial team is responsible for checking the health of the participants at the beginning of the trial, monitoring them during the trial, and staying in touch with them for a period of time after the clinical trial has been completed.

### **What are the benefits from participation in a clinical trial?**

There are a number of possible advantages of participating in clinical trials. These can include:

- Receiving the most up-to-date treatment, including access to new medicines and interventions not otherwise available.
- Close monitoring of any treatment related side effects.

- Findings from clinical trials add to knowledge and progress in the treatment of cancer.

Participation in clinical trials is not, however, without its downsides, which may include:

- New drugs and procedures may have side effects or risks unknown to the doctors.
- The trial medicine may not work for you or your child.
- You or your child may be placed in the control or reference group and may receive the standard treatment, and not the trial treatment.
- You or your child may need to visit the hospital or doctors' room more frequently and/or stay there longer.

### **Randomisation**

The clinical trial offered to you or your child may compare two or more treatment arms (plans). The treatment arms come from other studies that have shown that both treatments are effective, but doctors do not know if one treatment may be better in some way. One treatment plan is thought to be the "standard" or the current best known treatment, and the other is the new treatment doctors think will work well. To learn if one treatment is better, each participant is assigned randomly to one of the treatment arms by a computer. Randomisation is a process like flipping a coin that assures each participant has a fair and equal chance of being assigned to any of the treatment arms.

### **How can I or my child participate in a clinical trial?**

After your or your child's doctor reviews the treatment plan with you, you will be asked to give your permission to start treatment. You will be asked to sign a form that describes the plan. This form lists the risks and benefits of the treatment and what other treatments may be available. When you sign the form, you are saying that you understand what the doctor has explained to you and you agree for you or your child to start the treatment.

Participation in a clinical trial is voluntary. It is important to know that if you decide that you or your child will not participate then the best known and established treatment will be given. You can withdraw yourself or your child from a trial at any time, without any effect to ongoing medical care.

### **What happens if side effects occur from taking a medicine in a clinical trial?**

By the time a medicine reaches the clinical trial stage it has already been extensively tested for likely side effects. However, especially with new medicines, there might be additional side effects. It is not possible to predict in advance if any side effects will occur but, if they do, appropriate care will be provided to you or your child.

### **What happens with the results from clinical trials?**

The results of clinical trials are made available to doctors so that they can be used to improve future treatment for other children and adolescents. The results are also

published in medical journals and other relevant publications, and are available on the internet.

In addition, study doctors will be notified of the results of the study as they are made available. Records are reviewed during the trial and if important information is discovered, it will be reviewed. All details about your or your child's treatment are kept confidential even when the results of the study are published. Results of the treatment will be analysed, but confidentiality is assured.

### **What else do I need to know about clinical trials?**

Questions you can ask include:

- What is the purpose of the study?
- What are the treatment choices for me or my child?
- Why is this treatment expected to be effective? Has it been tested before?
- What kind of tests and procedures are involved?
- How do the possible risks, side effects and benefits of the study compare with the standard treatment offered?
- What will I or my child have to do as a part of this clinical trial that is different from standard treatment?
- How long will the trial last?
- Will it be necessary to be hospitalised?
- What will happen if I or my child suffers a serious side effect as a result of the trial?
- Will I or my child have access to the treatment after the trial is over?

Further information on clinical trials can be obtained from:

Therapeutic Goods Administration

[www.health.gov.au/tga](http://www.health.gov.au/tga)

National Health & Medical Research Council

[www.health.gov.au/nhmrc](http://www.health.gov.au/nhmrc)

Medicines Australia

[www.medicinesaustralia.com.au](http://www.medicinesaustralia.com.au)

Research Australia

[www.researchaustralia.com.au](http://www.researchaustralia.com.au)

The Cancer Council of NSW

[www.cancercouncil.com.au](http://www.cancercouncil.com.au)