

Frequently asked questions

1. What is precision oncology and why does it matter?

Precision oncology is a ground-breaking and rapidly evolving approach to cancer treatment. It helps doctors choose the most effective treatment by studying the unique features of a person's tumour. Cancer starts when certain changes happen in the DNA of a cell. DNA is like the instruction manual for a cell. Some DNA changes cause cancer to grow uncontrollably. Precision oncology identifies these changes and finds precise treatments that target the changes aiming to slow or stop the cancer from growing. In this way, treatment is precisely matched to the features of the person's cancer. This personalised approach can mean better treatment results and fewer side effects, making the treatment journey smoother for patients.

2. What is comprehensive genomic profiling and how can it help me?

Cancer can be as unique as an individual fingerprint. Comprehensive genomic profiling (sometimes called molecular profiling) makes it possible to identify your cancer's "fingerprint" – that is, the specific genetic features that make up your tumour and what is driving it to grow. Comprehensive genomic profiling takes a very close look at your cancer, looking in over 500 genes for changes to genes that are causing your cancer to grow. These changes in genes (called biomarkers) are part of your cancer fingerprint. Identifying biomarkers means we can potentially match you to a targeted treatment or a clinical trial of a new targeted therapy tailored to the specific features of your cancer. In this way, comprehensive genomic profiling gives a detailed picture of your cancer, opening the door to more personalised and effective treatment options.

Talk to your cancer doctor (oncologist) to see if you're eligible for free comprehensive genomic profiling through Omico. Our Cancer Screening Program (CaSP) provides access to comprehensive genomic profiling for Australians who have advanced or incurable cancer, or an earlier diagnosis of a cancer that has a poor prognosis (i.e., the cancer has a low chance of being cured or controlled by treatment), and identifies potential matches to targeted treatments or clinical trials with new targeted therapies.

You can find out more about CaSP here

3. What role do clinical trials play in providing important treatment options?

The newest precision oncology treatments are almost always tested in clinical trials before they become widely available. Clinical trials can be a positive step to accessing potentially ground-breaking treatments tailored precisely to your cancer's fingerprint. Everyone enrolled on a clinical trial gets the treatment being tested or the current standard of care treatment that they would normally get outside the clinical trial. There is no placebo or non-treatment option used in cancer clinical trials. Being on a clinical trial also means that your health and wellbeing is closely monitored by a medical team throughout the trial. Your safety and wellbeing are a priority to the researchers who run clinical trials.

Prospect (Precision Oncology Screening Platform Enabling Clinical Trials) is a world-leading initiative that aims to match the right patient to the right clinical trial. By choosing to participate in a clinical trial, you can help researchers to better understand the nature of your cancer and develop treatments that people with cancer like yours will respond to.

You can find out more about PrOSPeCT here

4. What are Omico, PrOSPeCT and CaSP, and how are they connected?

Omico is a national not-for-profit organisation aiming to change the way we fight cancer through increasing access to precision oncology and improving health outcomes for Australians with cancer. (See Question 1 'What is precision oncology and why does it matter?' for details on precision oncology.)

Omico is conducting a world-leading initiative called PrOSPeCT (short for Precision Oncology Screening Platform Enabling Clinical Trials). PrOSPeCT is for Australians who have advanced or incurable cancer, or an earlier diagnosis of a cancer that has a poor prognosis (i.e., the cancer has a low chance of being cured or controlled by treatment). PrOSPeCT aims to match the right patient to the right treatment or clinical trial to provide more personalised and effective treatment options.

You can find out more about PrOSPeCT here

CaSP (Cancer Screening Program) is a part of PrOSPeCT. CaSP provides access to free comprehensive genomic profiling of a patient's cancer and then identifies any potential treatments that precisely target what is driving the cancer to grow. (See Question 2 for more information on comprehensive genomic profiling.)

You can find out more about CaSP here

5. Is my type of cancer eligible for Omico's Cancer Screening Program (CaSP)?

To participate in our Cancer Screening Program (CaSP), you must be aged 16 years and older, and have advanced or incurable cancer, or an earlier diagnosis of a cancer that has a poor prognosis, i.e., the cancer has a low chance of being cured or controlled by treatment. Precision oncology is based on genetic changes within your tumour tissue. So, when you have completed comprehensive genomic profiling with CaSP and we know the specific features of your tumour, we can determine if there are potential targeted treatments or clinical trials that you can be matched to.

We encourage you to talk to your cancer doctor (oncologist) to understand if accessing CaSP is appropriate for you.

6. If my cancer is not curable, why would I bother with comprehensive genomic profiling and treatment matching?

Even if a cure for your cancer isn't currently possible, comprehensive genomic profiling and treatment matching can offer valuable opportunities to optimise your treatment plan, reduce treatment side effects, manage symptoms, potentially extend your life, and maintain your quality of life. It's about finding the best possible approach to support you through your treatment journey.

You might also find question 14 'How likely is it that my cancer will be matched to a new, precision treatment?' useful.

7. How can I access comprehensive genomic profiling for my cancer in Australia?

- 1. If your cancer is advanced or incurable, or you have an earlier diagnosis of a cancer that has a poor prognosis (i.e., the cancer has a low chance of being cured or controlled by treatment), ask your cancer doctor (oncologist) to refer you to CaSP (Omico's Cancer Screening Program).
- 2. Once your oncologist has submitted your referral online, you will be contacted by the CaSP team to take you through the consent process. They will help to organise blood tests and ask you to fill out a questionnaire.
- 3. The CaSP team will request a piece of your cancer tissue which has been collected during a previous procedure and will arrange to send this to an accredited pathology laboratory for comprehensive genomic profiling (CGP).
- 4. Omico's team of experts, known as the Molecular Oncology Board (MOB), will review the CGP results and other information about you to see if the features of your cancer (the biomarkers) match with a clinical trial or other treatment designed to target your specific cancer fingerprint.
- 5. Your MOB report will be sent to your cancer doctor. They will then contact you to discuss your results and any next steps.

8. Will I need to have a new biopsy taken?

We use existing cancer samples where possible, but sometimes there may not be enough existing sample for us to process. In this case we will let your doctor know and they will discuss further options with you.

9. How long does the comprehensive genomic profiling process take?

It typically takes 8–10 weeks from the day you have given written consent to take part, to your referring doctor receiving the results and recommendations in a report from the Omico Molecular Oncology Board (MOB).

If your referring doctor flags that your case is urgent, your results will usually be provided in 5-6 weeks.

10. Will there be any costs involved?

Omico will cover the cost of the comprehensive genomic profiling of your cancer tissue.

11. Why is Omico offering free comprehensive genomic profiling and what would I pay otherwise?

Omico is a national not-for-profit organisation, aiming to change the way we fight cancer through improving access to precision oncology. We are able to offer comprehensive genomic profiling free to eligible Australian cancer patients through our partnerships and funding. If you accessed comprehensive genomic profiling in other ways (not via the Omico CaSP program), costs can be several thousands of dollars. E.g. \$5,000 to \$6,000

12. How is Omico's comprehensive genomic profiling funded?

Prospect (Precision Oncology Screening Platform Enabling Clinical Trials) is the largest cancer genomics initiative in Australia and is funded by governments (Commonwealth and state) and by private companies who specialise in cancer research, diagnosis and treatment to improve patient outcomes. For Prospect, Omico is grateful to have secured funding from the Australian Government's Department of Industry, Science and Resources (\$61.2M grant funding from the Australian Government as part of the Modern Manufacturing Strategy), New South Wales Government, Roche Australia, National Computational Infrastructure (NCI) Australia, Children's Cancer Institute and many other partners.

13. What does Omico do with my data that is collected?

Your individual data is kept private and confidential. Results are not disclosed to any party other than to your referring cancer doctor (oncologist), unless under exceptional circumstances required by law.

The data from all patients, including yours, is deidentified and combined together to build a dataset. This collective data is used for doing additional research, now and in the future to help us better understand the or in the future.

14. How likely is it that my cancer will be matched to a new, precision treatment?

When considering treatment options for advanced or incurable cancer, it is helpful to have as much information as possible about your cancer to guide treatment decisions effectively and increase the chances of finding a precision treatment that matches your cancer.

To date, approximately 75% of patients who have undergone comprehensive genomic profiling in our cancer screening program (CaSP) have received a recommendation to be potentially matched to a therapy. Not everyone referred to CaSP for comprehensive genomic profiling will get a "fingerprint" result that has a matching precision treatment. Sometimes, even if a precision treatment is identified there may be no clinical trial in Australia or the potential treatment may not be available. You and your doctor can discuss which treatment options might be best for you.

If a clinical trial with a matching precision treatment starts in Australia after your doctor gets your results and report, Omico will contact your referring doctor with the information, allowing them to discuss the option with you.

Your participation in CaSP not only provides you and your cancer doctor (oncologist) with more information about your cancer, which may help to match you to a precision treatment, it also advances the understanding of cancer and treatment, potentially benefiting others facing similar challenges in the future.

15. What happens if my comprehensive genomic profiling finds I may have an inherited gene change that increases the chance of getting cancer – am I going to pass this onto my children?

If your comprehensive genomic profiling identifies a potential inherited gene change associated with a specific cancer risk, you may wonder about the chances of passing this gene change to your children. It's crucial to differentiate between genetic changes occurring within a tumour only and inherited genetic changes, known as germline changes.

Tumours form when changes in genes cause cells to grow uncontrollably. The purpose of comprehensive genomic profiling is to pinpoint genetic changes within the tumour that are driving it to grow. These changes can be potentially matched to a precision treatment that may stop or slow the tumour growth.

In contrast, inherited genetic changes, or germline changes, are present in all cells of the body including a tumour. They are inherited from our biological parents and can be passed down to future generations. While the likelihood of cancer being caused by a germline change is relatively small (5–10%), we will notify you if your testing suggests this. There are targeted treatment options for some inherited genetic changes also.

At this point, consulting a genetic counsellor can help you understand the implications and explore necessary next steps for you and your family.

16. Will comprehensive genomic profiling affect my current life insurance policy or access to insurance in the future? What about my children's policies?

Omico can't confirm the specific implications of testing on the insurance needs of you and your family. The purpose of comprehensive genomic profiling is to pinpoint genetic changes within a tumour that are driving it to grow. These changes can be potentially matched to a precision treatment that may stop or slow the tumour growth. In contrast, inherited genetic changes, or germline changes, are present in all cells of the body and can be passed down to future generations. While the likelihood of your cancer being caused by a germline change is relatively small (5-10%), we will notify you if your testing suggests this.

Your healthcare provider will not provide your results to an insurance provider without your permission. You may be obliged to disclose your results on any future application for insurance, should it be requested.

For more information on life insurance and genetic testing in Australia

17. Can I withdraw from the cancer screening program (CaSP)?

Patients are welcome to withdraw consent from CaSP at any time. We recommend that you talk to your doctor first to discuss why you would like to withdraw. Any data already collected will have been anonymised and included in the dataset, and any further data collection can be discontinued after you have advised that you would like to withdraw.

If you would like to withdraw from CaSP, simply email the Omico CaSP team to let them know on casp@omico.org.au