

Patient Information and Consent Form

To be completed by the patient and retained by the requesting doctor



PATIENT INFORMATION:

Please read carefully and discuss this information and any questions you have with your doctor or healthcare professional (HCP) ordering this genomic profile.

Who is Foundation Medicine?

Foundation Medicine, Inc. ('Foundation Medicine') provides genetic profiling services from its laboratory in the United States of America. It analyses acquired alterations or variants in genes known to drive tumour growth of most cancers. Foundation Medicine products and services are distributed in New Zealand by Roche Products New Zealand Ltd. ('Roche').

What is the purpose of genomic profiling?

Foundation Medicine profiles are designed to look at the genetic profile of your tumour and to look for specific genomic alterations (mutations or variations in the tumour makeup) that may be affecting its growth. This information may help your doctor determine what targeted therapies may be available to treat your cancer (treatment that targets the mutations in the tumour) or clinical trials in which you may be able to participate. Additional information about the profiles are available at www.foundationmedicine.co.nz

What is the process in obtaining a Foundation Medicine profile?

A blood sample or a sample of your tumour (usually one removed in connection with a biopsy or surgery you have had) will be sent to Foundation Medicine's laboratory, 150 Second Street Cambridge, MA 02141, USA, where it can be examined for genomic alterations. The sourcing and preparation of your sample may be managed by IGENZ Ltd ('IGENZ'), a medical testing laboratory located in Auckland. Foundation Medicine will then send IGENZ and your doctor a detailed report with information about your tumour's genomic makeup and potential treatment options and clinical trials. You and your doctor can then evaluate the results along with other information (e.g. your medical history, other tests, availability of medicines in NZ) to determine what next steps are right for you.

Potential benefits and risks

Cancers are caused by alterations in the DNA within a few hundred specific genes. Alterations in one or more of these genes can lead to abnormal cell growth and the formation of cancer tumours. With many possible alterations in each gene, the number and combination of these alterations make each person's cancer unique.

DNA alterations can be inherited from our parents or acquired during a person's lifetime. These acquired alterations are thought to cause the majority of cancers. Foundation Medicine profiling provides information about acquired genetic alterations in your tissue sample.

Foundation Medicine profiling does not provide information about inherited genetic alterations which can be passed down from generation to generation in families.

It is possible that the results will show one or more genomic alterations that are "actionable" meaning that there may be therapies available that target your specific type of cancer or clinical trials that are studying investigational therapies for your type of cancer. It is also possible that the profiles will not reveal the cause of your disease or help identify possible treatments.

Knowledge about the impact of genetic changes is constantly changing. We may not yet understand the significance of certain mutations or variations we observe or whether anything can be done to address those mutations or variations. As a result, physicians may have different opinions about what the results mean and what treatment should be provided in light of the results. These profiles do not examine every possible mutation or variant that may exist and our technology also may not identify all mutations related to your cancer. There is also a small possibility of errors.

You may learn medical information about yourself that you did not expect, including learning of additional diagnoses or a change in your condition, which may or may not be treatable and may make you upset or cause distress. You may wish to discuss with your doctor whether you would like this information to be communicated to you.

It is important for you to know that because genetic information is involved, it is possible that the results of these profiles could impact your ability to obtain life, disability or long-term care insurance.

PATIENT DECLARATION OF CONSENT:

This form must be completely filled out and signed by you, your parent/legal guardian or legally authorised representative.

I (*insert name*) _____ certify that my doctor or healthcare professional has explained the purpose, benefits and risks of Foundation Medicine profile and also has provided the following information to me:

General information on Foundation Medicine profiles:

1. The results of the Foundation Medicine profile will be provided to IGENZ and my doctor (or the healthcare professional ordering the Foundation Medicine profile) and become part of my medical record. They will also be retained by Foundation Medicine in accordance with applicable law and accessed by Roche at the direction of Foundation Medicine or my doctor for purposes directly related to the delivery and interpretation of the Foundation Medicine profile. They may be made available to individuals/organisations with authorised access to my medical records including, but not limited to the doctors and nursing staff directly involved in my care, employees of Foundation Medicine, my current and future insurance carriers, others authorised by law or a court order, and others specifically authorised by me or my authorised representative to gain access to my medical records. No other person or entity may have access to or retain my Foundation Medicine results without my written authorisation.

2. Foundation Medicine shall return any unused sample tissue to my treating doctor or the pathology laboratory once testing is completed.
3. Results will be retained by Foundation Medicine for the minimum retention period of 10 years and thereafter as required for internal quality assurance/operations purposes.
4. Roche Products New Zealand Ltd., its affiliates or distributors, may receive Personal Data as part of its role in the sourcing and sending of tissue or blood samples to Foundation Medicine. Roche may also receive Personal Data information from PayPal related to credit card payments.
5. I understand that:
 - a) the Foundation Medicine privacy policy describes how I may access or request an amendment to my personal information and how I may complain about any use or disclosure of my personal information in breach of any applicable privacy laws;
 - b) the Foundation Medicine privacy policy is available to download at <https://www.foundationmedicine.com/pages/legal/> and I can also request a copy using the contact details below; and
 - c) I should contact Foundation Medicine if I have any privacy related queries at + 1-617-418-2200 or by writing to the Privacy Officer, Foundation Medicine, Inc at 150 Second Street, Cambridge MA 02141 USA

Additional use of the results:

6. To the extent my consent is required by law (including the *United States Health Information Portability and Accountability Act of 1996* (HIPAA) and the *New Zealand Privacy Act 1993* ('Act'), **I authorise** Foundation Medicine to de-identify my genetic information and results and use or disclose such de-identified genetic information/results for a range of future purposes, including research and commercial purposes.
7. **I agree** that Foundation Medicine may retain this de-identified information for as long as it believes it is useful. I understand that this information will be de-identified in a manner that meets de-identification standards under the HIPAA.
8. **I understand** that I am not required to consent to de-identification of my genetic information/results as a condition of receiving the Foundation Medicine profile.
9. **I understand** that once my genetic information and results have been de-identified such that Foundation Medicine will not be able to determine which genetic information and results relate to me, I will no longer be able to withdraw my consent to Foundation Medicine's future use or disclosure of such de-identified data.
10. **I have been asked** if I have questions about or want a more detailed explanation of the scope and limitations, risks and benefits of the Foundation Medicine profiles. I have had enough time to consider the information I have been given and discuss it with my whanau/family if desired. I am satisfied with the explanation provided to me and do not need more information.

I consent to Foundation Medicine conducting the requested profile (points 1–5, 10), as well as de-identifying my results and using them for research as described above (points 6–9).

OR

I consent to Foundation Medicine conducting the requested profile (points 1–5, 10) only.

Patient Name (Signature)	Patient Name (Print)	Date
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Personal Representative (if applicable)	(Relationship to Patient)	Date
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**The above has been discussed with the patient or the legal guardian and informed consent obtained.
The above was signed in my presence.**

Name of Doctor or HCP	Signature	Date
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**FOUNDATION
MEDICINE®**

