

Roche Foundation Medicine Patient Consent Form

[To be completed by the patient]

Please read carefully and discuss with your ordering physician/person obtaining consent before signing. This form must be completely filled out and signed by you, your parent/legal guardian or legally authorised representative.

Purpose

Foundation Medicine, Inc (“FMI”) profiles are designed to look at the genetic profile of your tumour and to look for specific genomic alterations (mutations or variants) that may be affecting its growth. This information is primarily intended to help your physician determine what targeted therapies may be available to treat your cancer or clinical trials in which you may be able to participate. This is managed by Roche Singapore Pte Ltd.’s (“RSPL”) authorised third party service provider, as may be engaged by RSPL from time to time on behalf of RSPL and is termed the Roche FMI Program.

Process

A sample of your tumour, usually one or more removed in connection with a biopsy or completed surgery or a blood sample, will be sent to FMI’s laboratory in Massachusetts, United States where it can be examined for genomic alterations. FMI will then send your physician a detailed report with information about your tumour’s genomic makeup and potential treatment options and clinical trials. You and your physician can then evaluate the results along with other information (e.g. your medical history, other tests) to determine what next steps are right for you.

Potential benefits and risks

It is possible that the results will show one or more genomic alterations that are “actionable” meaning that there may be FDA-approved therapies available that target your specific type of cancer or clinical trials that are studying investigational therapies for your type of cancer.

Knowledge about the impact of genetic changes is constantly changing. As a result, 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. It is possible that the profiles will not reveal the cause of your disease or help identify possible treatments.

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.

I certify that my physician or the person ordering these profiles have explained the purpose, benefits and risks of the FMI profiles and I provide my consent in respect of the following:

- (i) I understand and acknowledge the nature and purpose of the profiling to be performed under the Roche FMI Program and I hereby give my consent for FMI to: (a) perform the profiling specified herein, (b) retain the results for internal quality assurance/operations purposes, and (c) de-identify the profile results and use or disclose such de-identified results for future genomic

research (collectively “the Purpose”). FMI, RSPL and RSPL’s authorized third party service provider will not be responsible or liable for any other use of the FMI Profiles by my physician.

- (ii) I understand, acknowledge and agree to disclose my personal data, including medical records and/or results of the FMI profiles, to FMI, RSPL, RSPL’s authorized third party service provider, entities authorised by law or myself, government or third party payers, including my current and future insurance carriers, for the purposes of reimbursement under any insurance or government health care plans, invoicing in relation to the Roche FMI Program or any other applicable purposes which may arise from carrying out and arranging the provision of the Roche FMI Program. RSPL’s authorized third party service provider and their affiliated organizations will collect and use my personal data for the purposes of managing and administrating the Roche FMI Program, which include for the: (a) reporting on my participation in the Roche FMI Program and providing me with any further information about the Roche FMI Program, (b) sourcing and sending of tissue or blood samples to FMI, and (c) invoicing in relation to the Roche FMI Program. I understand, acknowledge and agree that my personal data may be disclosed to third party service providers, agents and other organisations we have engaged to manage and administer the Roche FMI Program.
- (iii) My tissue samples will be removed from Singapore and processed in FMI’s laboratory in Massachusetts, United States, and FMI shall return any unused sample tissue to my treating physician or the pathology laboratory once testing is completed. My sample tissue will not be used for any purpose other than the Roche FMI Program.
- (iv) I understand, acknowledge and agree that FMI will collect genomic data from the processing of my sample tissues (“FMI Results”), and that FMI will use the FMI Results for the Purposes. No other person or entity may have access to or retain my FMI Results without my written authorisation. I may request for FMI to remove or destroy my FMI Results or any other identifiable genetic information or personal data held by FMI to the extent permitted by law. I may request for FMI to provide information on what personal data and identifiable genetic information of mine it has and how FMI has used and shared my FMI Results, personal data and identifiable genetic information within a year before the date of my request. FMI may charge a reasonable fee to cover the administrative costs of responding to my request for information. I may withdraw my consent to FMI’s processing of my FMI Results, personal data and identifiable genetic information at any time. I understand that such withdrawal of consent may affect the continuation of FMI’s provision of services to me. I understand that any of the requests made to FMI pursuant to this clause can be made at any time for any reason by notifying FMI in writing at singapore.fmi@roche.com.
- (v) I agree that my personal data may (a) be stored on RSPL’s, RSPL’s authorized third party service provider and/or FMI’s secured servers in and/or outside of Singapore or on cloud; and (b) may be transferred by employees of RSPL’s authorized third party service provider, RSPL or FMI in and/or outside of Singapore for the aforesaid Services and I acknowledge that the Personal Data transferred and stored outside Singapore will be protected at a standard that is comparable to that under the Singapore Personal Data Protection Act 2012 (No. 26 of 2012) (“**PDPA**”).

- (vi) I understand that RSPL and RSPL's authorized third party service provider may share my personal data with any third party service providers for the purpose of introducing and/or providing to me support under any of Roche's patient support programs.
- (vii) I understand that RSPL and/or RSPL's authorized third party service provider are entitled to amend any of the terms and conditions of the Roche FMI Program and/or to terminate the Roche FMI Program at any time, for any reason, without notice.
- (viii) I also understand that (i) I am allowed to withdraw from participating the Roche FMI Program; (ii) I am allowed to request for access or amendment to my personal data and/or withdraw my consent for the use and/or disclosure of my personal data for any or all of the purposes listed above, at any time for any reason by notifying RSPL's authorized third party service provider in writing at singapore.fmi@roche.com. I understand that such withdrawal of consent may affect the continuation of FMI's provision of services to me.
- (ix) I may be contacted using the contact details provided in this form by RSPL's authorized third party service provider, FMI or RSPL for further consent in relation to the use of my FMI profile, FMI Results, personal data or genetic information.

Additional use of the results for future genetic research:

To the extent my consent is required by law (including the United States Health Information Portability and Accountability Act of 1996 ("HIPAA") and the PDPA), I authorize FMI to de-identify my genetic information and results in accordance with the de-identification standards under the HIPAA and retain, use or disclose such de-identified genetic information/results for future genetic research.

- (i) I understand that my consent to de-identify my genetic information/results is not a condition of receiving the FMI profiles.
- (ii) I understand that once my genetic information and results have been de-identified, I will no longer be able to withdraw my consent to FMI's future use or disclosure of such de-identified data.
- (iii) I have been asked if I have questions about or want a more detailed explanation of the risks and benefits of the FMI profiles. I am satisfied with the explanation provided to me and do not need more information. If I have any questions, complaints or require additional information on FMI's collection, use, disclosure or retention of my Personal Data or the purposes for which my sample tissue will be used, I can contact Roche Foundation Medicine at singapore.fmi@roche.com

If you want to opt out of sharing your data or your child's/ward's data for research as described above under "Additional use of the results", please check the following box

	I would like to opt out of sharing my data, my child's/ward's* data for research as described above under "Additional use of the results" *Delete where appropriate
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To be completed if **you are the patient**

Patient Name (Print)

Patient Signature

Date

Contact details

Telephone number:

Email address:

Address:

To be completed if **you are the parent/legal guardian of the patient**

I am the parent/legal guardian of the patient _____
and I understand, accept and acknowledge that by signing this consent form, I agree and consent to the terms and conditions of this consent form in relation to the Services to be provided to my child/ward.

I have verified that the data provided for the patient is accurate and complete.

Name of Parent/Guardian (Print)

Signature

Date

The following has been discussed with the patient and/or the patient's parent/guardian and informed consent obtained. The following was signed in my presence.

Name of Physician or Person Obtaining Consent

Signature

(Print)

Date

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