PATIENT CONSENT FORM

Service

FOUNDATIONONE®LIQUID

Patient Information and Declaration of Consent to the Processing of Personal Data

Your treating physician has recommended performing the molecular genetic service FoundationOne®Liquid for diagnostic purposes to analyse your blood specimen (as required for your test) in order to detect gene mutations specific to your tumour.

The Service is provided to you by Roche in conjunction with Foundation Medicine as set out below:

- The Service is offered in your country by Roche Pharma AG, Emil-Barell-Str. 1, 79639 Grenzach-Wyhlen, Deutschland („**Roche“**), which is the contracting party for performing the Service. Roche handles the local coordination, provides customer support service and is responsible for the processing of any personal data received from you in the context of providing the Service as joint controller. Roche can be contacted at the contact details set out in Section 3 below.
- To provide the Service, Roche collaborates with Foundation Medicine Inc., 150 Second Street, Cambridge, MA 02141, USA (“**FMI Inc.**”) which conducts the molecular genetic services. In case of an order for the Service FoundationOne Liquid[1], your data may also be transferred, by your treating physicians, directly to FMI Inc. in the US which will then carry out all of the molecular genetic services as sole controller. FMI Inc. FMI Inc. can be contacted at the contact details set out in Section 3 below.

This Patient Information and Declaration of Consent ("**Patient Consent Form**") informs you about the processing of your personal data by your treating physicians, Roche and FMI Inc. and serves as the basis to obtain and document your consent to the processing of your personal data.

IMPORTANT NOTE: Please provide your consent on the original version of this document and return it to your treating physician. The copy is for your records.

Section 1 (Mandatory Consent) – Consent to the Processing of your Personal Data for the Purposes of Providing the Service

Your consent to the processing of your personal data pursuant to Section 1, is required to provide the FoundationOne Liquid Service, including for billing purposes. To give your consent, please provide your signature at the end of Section 1.

A. Processing of Billing and Contract Data by Roche

If you pay for the Service yourself, your treating physician will collect the following billing and contact data from you to complete the order form, and transmit such data to Roche (the Local Roche Affiliate):

- First and last name
- Date of birth (relevant for operational purposes)
- Postal address
- Phone number, email address
- Bank account details
- Information regarding the status of the examination (as relevant for the purposes of billing and coordinating the cooperation between the parties involved in the provision of the Service)

Roche will process such data to the extent necessary for the purposes of performing the contract and invoicing for the Service local coordination and for providing customer support services.

B. Assignment of Order ID by Roche (Pseudonymisation Process)

Roche will review your physician's order and assign an Order-ID to your case if the contract is accepted. Roche will transmit that Order-ID back to both your treating physician and the pathologist (as specified below under Section 1 D).

The Order-ID is a random identification number which will serve as a unique central identifier of your case, and allows your treating physicians and pathologist to exchange data with Roche and FMI Inc. in pseudonymised form (without revealing your identity). This means that, even though Roche and FMI Inc. may receive data with specific characteristics about you, including your health-related information, they are generally unable to trace those characteristics back to you, except in case your treating physician or pathologist would reveal your identity. Please note, however, that Roche will also receive your identity for billing and support purposes and will generally be in a position to attribute the Order-ID to your person (although it is ensured by technical and organisational measures that your identity is only accessible to Roche's support and billing functions). Under no circumstances will FMI Inc. receive any information to attribute the Order-ID to your person.

C. Preparation of Specimen by Physician/Nurse

Your treating physician/Nurse will take the blood sample and transfer the data which are relevant for the diagnostic Service (Section D):

Treating Physician	
Hospital	
Treating Physician/Nurse (first and last name)	
Work address	
Phone	**Fax**
Email	

D. Laboratory Analysis and Report Creation by FMI Inc.

Your treating physician will complete a test requisition form and transfer the below pseudonymised data, together with your blood specimen to FMI Inc. who will carry out the laboratory analysis:

- Order-ID,
- Date of birth (day/month/year)
- Sex
- Diagnosis, stage
- Specimen-ID (identifier of the blood specimen)
- Date of specimen collection
- International classification of the disease (ICD-10 Code)
- Contact information of your treating physician

(together the "**Test Requisition Form Data**")

Except in case you have provided optional consent to the processing of your personal data for research and scientific purposes (as set out in Section 2 below), FMI Inc. will process the above data only for the purposes of providing the requested diagnostic Service, i.e.:

- to confirm receipt of the correct specimen
- to assess a pathology review (confirm disease ontology and assess tumour content) by employed or freelance pathologists;
- extract the DNA/RNA and sequence the relevant cancer genes that are associated with tumour genesis and tumour progression; and
- analyse the obtained genomic data for gene mutations, match the data of specific mutations with targeted therapies and ongoing clinical studies and prepare the report on the identified gene mutations and the available therapy options. It cannot be guaranteed that there will be any available therapy options. The report will be sent to your treating physician and, if applicable, further recipients named by your hospital, clinic or other medical facility who will be involved in your treatment and need to have access to the report as a basis for the decision on your future therapy.

FMI Inc. will not further analyse or process your DNA. The genomic data obtained during the sequencing analysis by FMI Inc. will not contain any directly personal identifiable data.

FMI Inc. is responsible for the processing of your data as controller. Roche will ensure, by having appropriate agreements in place, that FMI Inc. will process your data only on behalf of and in accordance with, the instructions of the treating physician and only to the extent necessary to provide the described parts of the Service. For more details about the role of FMI Inc. please contact your treating physician or the contact details set out in Section 3 below.

Your pseudonymised data (Test Requisition Form Data, your blood specimen, and especially your health data) will be transmitted to the US, and thus to a country outside the EU/EEA, the laws of which may not provide for the same level of data protection as considered adequate in the European Union. FMI Inc. is, however, certified under the "EU-US Privacy Shield" which is considered under an adequacy decision of the European Commission (Art. 45 GDPR), to guarantee an adequate level of data protection, comparable to the level of protection in the EU. To obtain more information about FMI Inc.'s Privacy Shield certification, please visit www.privacyshield.gov or contact FMI Inc. at the contact details set out under Section 3 below.

As an additional safeguard, in all of the above cases, FMI Inc. only stores and processes pseudonymised information which is not directly attributable to your person. To the extent that FMI Inc. may accidentally receive data in fully personal identifiable form from your treating physician (such as your name in a report) FMI Inc. will redact such information upon receipt. FMI Inc. will, however, also be provided with your blood specimen, which contains your DNA and, therefore, your unique genetic fingerprint. FMI Inc. will not sequence and process your data to obtain your genetic fingerprint.

E. Coordination of Services, Quality of Service Provision and Customer Service by Roche

Roche will check the accuracy and completeness of the Test Requisition Form, track the status of the provision of the Service on the basis of the Order-ID for the purposes of local coordination of

Services, and handling of customer service requests and, to the extent necessary for these purposes, receive the relevant information from the treating physician (Test Requisition Form Data) and FMI Inc. (Test Requisition Form Data, information about status of the Service but in any case with the exception of the blood specimen, obtained sequencing data and DNA). In addition, to the extent necessary to handle report-specific questions from your treating physicians, Roche may also have access to the report stored at FMI Inc. Roche and FMI Inc. will ensure, by implementing appropriate technical and organisational measures that access to the report will only be made on a case-by-case basis, upon receiving a support request and to the extent required to fulfil the support request, in particular to provide the treating oncologist with information, for example, if the report was not provided to the oncologist or if your treating physicians have report-specific questions.

F. Term of Storage; Deletion

Roche will store and retain your data in accordance with the following processes:

- The data specified in Section 1 A, 1 E above will be stored by Roche for ten years and will be deleted thereafter.

Except in case you have provided your consent to the processing of your data for research and scientific purposes (as described under Section 2), FMI Inc. will store your data only for as long as necessary to provide the Service and to comply with the applicable statutory retention requirements in accordance with the following processes:

- **Blood Specimen**: After completion of the Service, or in case the Service ends because you withdraw your consent, blood specimens will be discarded by FMI Inc. once no longer required for the Service and at the latest, upon the end of the Service.
- **Test Requisition Form Data & Report**: The Test Requisition Form Data (see Section 1 E above) and the report will be stored by FMI Inc. for a maximum of 10 years after the end of the provision of the Service.
- **Sequenced Tumour Genome**: Obtained sequencing data will be stored at FMI Inc. for a maximum of 10 years after the end of the provision of Service.

Your data will be fully deleted/destroyed after the above time periods except that FMI Inc. may further process certain information in fully anonymised form (i.e., without such information being directly or indirectly attributable to your person), as set out in Section 2 below.

G. General Data Protection Information

The information in Section 3 ("General Data Protection Information") form an integral part of this consent, and provides further details about the processing of your personal data and your rights.

H. Consent to the Processing of my Personal Data in accordance with Section 1.

I hereby consent to the processing of my personal data, including my health data, as specified in Section 1 above for the purposes of providing the requested Service (as indicated at the top of this Patient Consent Form). I am aware that I am not obliged to provide this consent and that I may withdraw this consent at any time by contacting my treating physician or Roche. The withdrawal of my consent does not affect the lawfulness of any processing based on my consent before its withdrawal.

If I withdraw my consent, the requested Service will be deemed to be terminated and will be stopped at its then current stage. Roche will be released from its duty to perform the Service.

I am free to provide my consent. However, if I do not grant my consent, the Service cannot be provided.

_____	_____
Place / Date	**Patient Name (in capital letters)**

Patient's signature*

*** To be signed by the legal guardian in the case of minors**

Section 2 (Optional Consent) – Consent to the Processing of your Pseudonymised Data for Research and Scientific Purposes

In case you indicate your agreement with the processing of your personal data by providing your signature at the end of Section 2, your pseudonymised data will also be used for research and scientific purposes to improve the understanding of tumour genesis and tumour progression. Further, your data might be crucial for the development of new diagnostic and therapeutic approaches for the treatment of genetic diseases. Your consent to the processing of your personal data as described in Section 2, is voluntary.

A. Processing of Pseudonymised Data for Research and Scientific Purposes

With your consent, FMI Inc. will store the data received as part of providing the Service (i.e., Test Requisition Form Data, sequencing data) in pseudonymised form (under the Order-ID) together with the prepared report. FMI Inc. does not receive or store your name or other information which would be directly attributable to your person. FMI Inc. will process such information as controller, for research and scientific purposes, including statistical analysis, to further understand the causes of cancer genesis and cancer progression, as well as to improve the FoundationOne® Liquid service.

Your pseudonymised data will be stored for a maximum of 10 years and be fully deleted and destroyed thereafter, except in case you withdraw your consent before expiry of that period (in which case the pseudonymised data will be deleted without undue delay after withdrawal).

FMI Inc. will further anonymise and aggregate your data and disclose such information in fully anonymised form (i.e., without such information being directly or indirectly attributable to your person) to academic, industrial or other collaboration partners who will use the information to improve the understanding of cancer genesis and cancer progression and to further develop new diagnostic and therapeutic approaches for the treatment of genetic diseases, including for research, scientific and commercial purposes.

B. General Data Protection Information

The information in Section 3 ("General Data Protection Information") forms an integral part of this consent and provides further details about the processing of your personal data and your rights.

C. Consent to the Processing of my Personal Data in accordance with Section 2.

I hereby consent to the processing of my personal data, including my health data, by FMI Inc. for research and scientific purposes as specified in Section 2 above. I am aware that I am not obliged to provide this consent and that I may withdraw this consent at any time by contacting my treating physician or Roche. The withdrawal of my consent does not affect the lawfulness of any processing based on my consent before its withdrawal. In particular, I understand that even in case I withdraw my consent, FMI Inc. will continue to process any data anonymised by FMI Inc. before the withdrawal.

I am free to provide this consent. If consent is not granted, or is withdrawn at a later time, this will not affect the provision of the requested Service.

Place / Date

Patient Name (in capital letters)

Patient's signature*

*** To be signed by the legal guardian in the case of minors**

Section 3 – General Data Protection Information

The following general data protection information applies to all data processing activities described in Sections 1 and 2.

A. Contact Details; Data Protection Officer

Roche Pharma AG: Roche Pharma AG, Emil-Barell-Straße 1, 79639 Grenzach, Deutschland

FMI Inc.: Foundation Medicine Inc., 150 Second Street, Cambridge, MA 02141, USA

The data protection and privacy officers of Roche and FMI Inc. are your points of contact for any questions, suggestions or complaints concerning the processing of your personal data.

Their contact details are as follows:

Data protection officer of **Roche Pharma AG**: Roche Pharma AG, Emil-Barell-Straße 1, 79639 Grenzach, Germany, grenzach.datenschutz.gd1@roche.com, +49 (7624) 14-2829

Data protection officer of **FMI Inc**: Foundation Medicine, Inc., 150 Second Street, Cambridge, Massachusetts 02141, dpo.fmi-cambridge@foundationmedicine.com, Phone: +1(617) 413-7313

B. Security

Roche and FMI Inc. take appropriate technical and organisational measures to protect your personal data against accidental or unlawful destruction, loss, alteration, unauthorised disclosure of, or access to, personal data transmitted, stored or otherwise processed.

C. Your Rights

You have the right, in accordance with applicable data protection law,

- to request information on the data processed about you, and to obtain a copy of such data (right of access);
- to obtain the rectification of inaccurate data or, taking into account the purposes of the processing, request the completion of incomplete data (right to rectification);
- to obtain the erasure of personal data to the extent that one of the grounds provided for by statutory law applies (right to be forgotten);
- to the extent that the statutory requirements are fulfilled, to obtain the restriction of processing of your data (right to restriction of processing);
- to the extent the statutory requirements are fulfilled, to receive any personal data you provided to Roche and/or FMI Inc. in a structured, commonly used and machine-readable format and to transmit those data to another controller or, where technically feasible, have the data transmitted (right to data portability); and
- not to be subject to automated individual decision-making if the statutory requirements are not fulfilled. An automated individual decision-making is not taking place.

You further have the right to object, on grounds relating to your particular situation and in accordance with the applicable laws, to any processing of your personal data based on the grounds that the processing is necessary for the purposes of legitimate interests pursued by Roche and/or FMI Inc. (right to object).

You further have the right to withdraw your consent at any time without affecting the lawfulness of processing based on consent before its withdrawal.

To exercise your rights, please contact your treating physician, or either the companies or the data protection officers named above under Section 3.A.

You further have the right to lodge a complaint with a data protection authority, in particular the competent data protection authority for your place of habitual residence or place of the alleged infringement.