PATIENT INFORMATION & CONSENT FORM

Service (please select Service ordered)

❑ FOUNDATIONONE®CDx ❑ FOUNDATIONONE®HEME ❑ FOUNDATIONONE®LIQUID CDx

IMPORTANT NOTE: Please provide your consent on two (2) original copies of this document and return one (1) to your treating physician; the other copy is for your records. **Please do not return a copy of this document to Roche.**

Patient Information and Consent to the Processing of Personal Data

Your treating physician has recommended performing a molecular genetic test for diagnostic purposes to analyse your blood (which may include bone marrow) and/or tissue specimen (as required for your test) in order to detect genomic biomarkers, such as gene mutations, specific to your tumour. The appropriate diagnostic test was selected by your physician (FoundationOne CDx, FoundationOne Heme or FoundationOne Liquid CDx) and is indicated at the top of this document (**"Service"**).

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 Products Ltd (**"Local Roche Affiliate"**) which is the contracting party for the performance of the Service. The Local Roche Affiliate is responsible for the processing of any personal data received from you in the context of providing the Service as joint controller together with Roche Pharma AG, Emil-Barell-Straße 1, 79639 Grenzach, Germany (**"Roche Pharma AG"**). Roche Pharma AG handles the central coordination and quality of the Service provision in Europe and is also responsible for providing customer support services. The Local Roche Affiliate and Roche Pharma AG are hereinafter, collectively, referred to as "**Roche**". Roche can be contacted at the contact details set out in **Section 3** below.
- To provide the Service, Roche collaborates with Foundation Medicine GmbH, Nonnenwald 2, 82377 Penzberg, Germany (**"FMI GmbH"**) which – as joint controller together with Foundation Medicine Inc., 150 Second Street, Cambridge, MA 02141, USA (**"FMI Inc."**) – conducts the molecular genetic services. FMI GmbH and FMI Inc. will jointly process your personal data on systems and applications operated by FMI Inc. In most cases, FMI GmbH will carry out the data processing activities as needed to provide the laboratory services for the applicable test and FMI Inc. will provide certain parts of the data analytics for the Service, as further explained in **Section 1** below. In limited cases, as further set forth in **Section 1.C.iv** below, FMI Inc will be primarily responsible for the Service, in which case your data will be transferred to FMI Inc. in the US. FMI GmbH and FMI Inc. are hereinafter, collectively, referred to as "**FMI**". FMI can be contacted at the contact details set out in **Section 3** below.

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

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

Your consent to the processing of your personal data pursuant to this Section 1 is required to provide the requested Service. To give your consent, please provide your signature at the end of this **Section 1**.

A. 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 make that Order-ID available to your treating physician, your pathologist (as specified below under **Section 1.B**) and FMI as required to provide the Service to you.

The Order-ID is a central identifier of your case that does not reveal your identity but allows your treating physicians and pathologist to exchange data on your case with Roche and FMI in pseudonymised form.

This means that even though Roche and FMI may receive data with specific characteristics about you, including your health-related information, they will not be able to trace those characteristics back to you unless your treating physician or pathologist reveals your identity.

Under no circumstances will FMI receive any information to attribute the Order-ID to your person.

B. Preparation of Specimen by Pathologist (if applicable)

To prepare your tissue specimen (as required for your Service), your treating physician will cooperate with the following pathologist and exchange with that pathologist the data which are relevant for the diagnostic Service (e.g. diagnosis and date of birth), including, if necessary, the complete patient file. This Section B does not apply where only blood sample is required for your Service. See **Section C.ii** below

Pathologist	
Hospital	
Pathologist (first and last name)	
Business address	
Phone	Fax
Email	

C. Laboratory Analysis and Report Creation by FMI

i) Test Requisition Form Data

Following assignment of the Order-ID by Roche, your treating physician or pathologist will complete a test requisition form with the below pseudonymous data (together the "**Test Requisition Form Data**") and provide it to Roche and FMI:

- Order-ID
- Date of birth
- Gender
- Diagnosis, stage
- Specimen site
- Specimen-ID (identifier of the blood/tissue specimen)
- Date of specimen collection
- International classification of the disease (ICD-10 Code)
- Status of transplant
- Contact information of your treating physician and pathologist

In addition to the information above, your treating physician or pathologist may also provide:

- your pathology report (in redacted form) where more detailed diagnosis and sample information could be helpful for the provision of the Service; or
- through the test requisition form, a unique identification number (such as a patient reference number). This number will be printed on the Report as this should help your treating physician or pathologist to directly identify you and to assign the report to you more efficiently. Furthermore, where your treating physician orders another FMI Service for you in the future, FMI may use this number to link your new Service to your previous Services and create reports that capture your genomic results over time to monitor evolution of your disease.

ii) Sharing and processing of your Test Specimen and Test Requisition Form Data

The FMI laboratory site carrying out the laboratory services for the applicable test (i.e. either FMI GmbH or FMI Inc.) will receive (i) your blood or tissue specimen from your treating physician or pathologist (as required by your Service, as described in **Section 1.B above**) and (ii) your Test Requisition Form Data from either Roche or directly from your treating physician or pathologist. The Test Requisition Form Data will be stored and jointly processed by FMI Inc. and FMI GmbH on systems and applications operated by FMI Inc. in the US. Where you have provided your optional consent to the processing of your personal data for research and scientific purposes (as set out in **Section 2 below**), FMI will only process the Test Requisition Form Data for the purpose 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 and scan the tissue slide;
- to extract the DNA/RNA from your test specimen and sequence the relevant cancer genes that are associated with tumour genesis and tumour progression; and
- to analyse the obtained genomic data for genomic biomarkers, such as gene mutations, match the data of specific genomic biomarkers with targeted therapies and ongoing clinical studies and prepare the final report ("**Report**") on the identified genomic biomarkers and the available therapy options. It cannot be guaranteed that there will be any available therapy options.

Where your treating physician has selected certain additional pathological tests (such as PD-L1) which are offered by Roche as optional parts of the Service, Roche and FMI will involve either (i) external pathologists located within Germany (as Roche's subcontractors) or (ii) an FMI laboratory site located in the US that offers such additional pathological testing, to provide the Service. Where external pathologists (not FMI) are engaged for these purposes, the external pathologists will receive limited Test Requisition Form Data, the results of the pathology review and your tissue specimen (as required for the optional pathological test) solely for the purpose of performing the pathological test and report creation.

Other than as necessary to provide the requested Service (and except where you have provided your optional consent as set out in **Section 2** below), FMI will not further analyse or process your DNA/RNA. The genomic data obtained during the sequencing analysis by FMI will not contain any directly personal identifiable data. For the avoidance of doubt, Roche will not have access to your DNA/RNA.

iii) Sharing of your Report

FMI will involve external pathologists located within Germany who will be granted with access to your Report to verify and release the final Report, as required for internal quality assurance and compliance with regulatory requirements.

The Report will then be transferred to your treating physician and pathologist 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 a decision on your future therapy.

Your Report and information may also be made available to other appropriate teams at FMI Inc. or external service providers acting as processors on behalf and in accordance with the instructions of FMI for uses that support your treatment. These include

- using and sharing your information in the context of a multi-disciplinary Molecular Tumour Board where your healthcare provider desires to discuss your report and treatment options with other physicians and oncology experts; and
- using your information to identify standard of care treatments and/or clinical trials you may be eligible for and, where appropriate, informing your treating physician (and/or other healthcare providers within the same institution) of those treatment and/or clinical trials options.

FMI may access and use your pseudonymised data for these trial and treatment matching services for a period of up to 3 years after the release of your Report to your treating physician; in no event will any (bio)pharmaceutical partner, clinical research organisations or any other third party that is not acting as a processor on behalf of and in accordance with the instructions of FMI to perform the treatment services described in this **Section 1,** receive from FMI any of your data without your prior explicit consent.

iv) FMI Site for Service

In most cases of the Service (and except for the optional pathological tests, such as PD-L1, as described in **Section 1.c.ii**):

- (1) FMI GmbH will carry out the laboratory service for the applicable Service and be responsible for the processing of: (a) your Test Requisition Form Data and (b) your blood and/or tissue specimen (as required for your Service) in order to extract your DNA/RNA and sequence the relevant genes; and
- (2) FMI will have access to and process your pseudonymised Test Requisition Form Data and sequenced data, as necessary for conducting an analysis of the obtained sequenced data, matching potential therapies and clinical trials to the identified mutations, and creating your Report. FMI Inc. will not generally have access to your blood/tissue specimen or the extracted DNA/RNA.

In the case of **a)** an order for the Service FoundationOne Liquid CDx, prior to the time when FMI GmbH is able to perform the laboratory services portion of the FoundationOne Liquid CDx test or **b)** exceptional cases where FMI GmbH is unable to carry out the steps in (1) above: your pseudonymised Test Requisition Form Data and blood or tissue specimen (as applicable) will be transferred by Roche and/or your treating physician or pathologist directly to FMI Inc. in the US, and FMI Inc. will then carry out all of the above steps (without or with only limited involvement of FMI GmbH). For more details about the roles of FMI GmbH and FMI Inc. in the context of your specific Service, please contact your treating physician or FMI at the contact details set out in **Section 3** below.

v) Data Transfer Protections

As necessary to provide the Service, and where you have provided your optional consent to the processing of your data for research and scientific purposes (as set out in **Section 2** below), your pseudonymised data (e.g. Test Requisition Form Data and, as applicable, your blood specimen and, in exceptional cases, tissue specimen) will be transmitted to FMI Inc. in the US, and thus to a country outside the UK, the laws of which may not provide for the same level of data protection as considered adequate in the UK.

This triggers certain risks for the protection of your personal data, including that it may be more difficult to enforce your data protection rights as a data subject and that your pseudonymised personal data may be subject to access requests under applicable US law by public authorities which may have more extensive powers than the authorities in the UK. However, to ensure that your data are adequately protected as required by UK data protection laws, Roche and FMI have:

- entered into contractual safeguards on the basis of the EU Standard Contractual Clauses (according to Art. 46 EU GDPR) between FMI GmbH and FMI Inc. as well as between Roche Pharma AG and FMI Inc.; and
- implemented further supplementary measures, including a privacy by design concept that ensures that only pseudonymised data not directly attributable to your person will be transferred to and processed and stored by FMI Inc. or its further subcontractors (as explained below) in the US. To the extent FMI may accidentally receive data in identifiable form (such as your name in a pathology report), FMI will redact such information upon receipt.

To the extent your pseudonymised data is transferred to FMI Inc. directly by your treating physician or pathologist such as in case of an order of the Service FoundationOne Liquid CDx, FMI Inc. will protect the data received equally under the EU Standard Contractual Clauses entered into with FMI GmbH and Roche.

As necessary to provide the Service, FMI may further engage technical service providers as processors for the hosting and operation of its databases, portals and applications. These service providers may be located in the EU/EEA or the US. In case of service providers in the US,

FMI will ensure that appropriate safeguards are in place to provide for an adequate level of data protection, such as by entering into data transfer agreements with the applicable service provider on the basis of the EU Standard Contractual Clauses or standard data protection clauses adopted or approved by the European Commission (Art. 46 GDPR).

FMI will, however, also be provided with your blood and/or tissue specimen (as required for your Service), which contains your DNA/RNA and, therefore, your unique genetic fingerprint. FMI will not sequence and process your data to obtain your genetic fingerprint. Any report provided to Roche will also be free of such information.

You can find out more information about the safeguards implemented by FMI, including how to obtain a copy of them, by contacting FMI at the contact details set out under Section 3 below.

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

Roche will process your personal data for, the purposes of: central coordination of the Services in Europe, ensuring the quality of the Service provision, and handling of customer service requests. To the extent necessary for these purposes, Roche receives the relevant information from your treating physician or, as applicable, the pathologist (Test Requisition Form Data) and FMI (Test Requisition Form Data, information about status of Service). Roche will never receive your blood/tissue specimen, extracted DNA/RNA or obtained sequenced data. In connection with the purposes described above, Roche will:

- manage access to the Test Requisition Form Data and make it available to FMI and, in the event of missing or inaccurate Test Requisition Form Data, work with the pathologist identified in Section 1.C (as applicable) and your treating physician to correct the data set;
- track the status of the provision of the Service on the basis of the Order-ID; and
- to the extent necessary to handle report-specific questions from your treating physicians, have access to the Report stored at FMI.

Roche and FMI will ensure, by implementing appropriate technical and organisational measures, that Roche's access to the Report will only be made on a case-by-case basis, upon receiving a support request and then only to the extent required to fulfil the support request, in particular to provide the treating physician with information, for example, if the Report was not provided to the physician or if your treating physicians have Report-specific questions.

E. Term of Storage; Deletion

The data and documents received, collected or generated in relation to the Service (including the Report and the information specified in Sections **1B**, and **1C** above will be stored by Roche in the systems used for Services in regular production operation (as opposed to archive systems) for 90 days starting from the date of the release of the Report to your treating physician ("**Completion of the Service**"), then archived for 10 years and will be deleted thereafter.

Except where you have provided your consent to the processing of your data for research and scientific purposes (as described under **Section 2**), FMI will store your data and any portion of your blood/tissue specimen remaining after or generated as part of performing the Service only for as long as necessary to provide the Service and for the purposes of providing a physical audit trail, in case the integrity or identification of the specimen needs to be established, in accordance with the following timelines:

- Blood /Tissue Specimen: After Completion of the Service, or in case the Service ends because you withdraw your consent:

i. any remaining tissue specimen in the form of a tissue block that was not used up by FMI in the performance of the Service will be returned by FMI to the pathologist specified above under Section **1B**;

ii. any slides of tissue specimen received or created during performance of the Service will be returned upon request and otherwise stored for 10 years by FMI GmbH and otherwise by FMI for 20 years and discarded thereafter;

iii. any extracted DNA/RNA will be stored at FMI Germany for a maximum of 1 year and otherwise by FMI for a maximum of 10 years; and

iv. blood specimens will be discarded by FMI once no longer required for the Service.

- **Test Requisition Form Data & Report:** The Test Requisition Form Data (see Section **1C** above) and the Report will be stored by FMI GmbH for a maximum of 10 years after the Completion of the Service. In cases where the Test Requisition Form Data as well as the specimen is sent directly to FMI Inc., both the data and Report will be stored by FMI Inc. for a maximum of 10 years after the Completion of the Service, except where stored in combination with a specimen that requires a longer retention time than 10 years, in which case your data will be stored for the longer period described above.
- **Scanned Tissue Slides and Sequenced Tumour Genome:** The scanned tissue slides and the obtained sequencing raw data will be stored at FMI Inc. for a maximum of 10 years after the Completion of the Service. Curated sequencing data will be stored for a maximum of 10 years after the Completion of the Service.

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

F. General Data Protection Information

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

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

If you give your consent by providing your signature at the end of this form, your pseudonymised data and any material, other than any tumour block, remaining after the performance of the Service and/or generated as part of providing the Service (referred to as "residual material" in this **Section 2**) will also be used by FMI, including in a commercial context, for research and scientific purposes to improve the understanding of tumour genesis and tumour progression and to facilitate the improvement, validation and development of new diagnostic and therapeutic approaches for the treatment of genetic diseases. Your consent to the processing of your personal data and use of your residual material as described in this **Section 2** is voluntary, and you can freely decide whether and to what extent you wish to grant your consent.

A. Processing of Pseudonymised Data and Residual Material for Research and Scientific Purposes

If you give your your consent to the processing of your pseudonymised data and residual material on the final page of this Patient Consent Form, you agree that FMI GmbH and FMI Inc. will, as joint controller:

- store (i) any data received and/or generated as part of providing the Service (i.e., Test Requisition Form Data, scanned tissue slides, sequencing data, supplementary molecular information if applicable) together with the prepared report and (ii) any residual material for research and scientific purposes for a maximum period of 10 years after Completion of the Service. FMI will store your data and residual material only in pseudonymised form (under the Order-ID) and will not receive or store your name or other information which would be directly attributable to your person. For the avoidance of doubt, any residual material available as tumour block and not fully used up will be returned to the pathologist specified above under Section **1B**;
- process such data and residual material in pseudonymised or anonymised form, including in a commercial context, for research and scientific purposes, including statistical analysis, to further understand the causes for tumour genesis and tumour progression as well as to improve, validate and/or develop new diagnostic and therapeutic approaches for the treatment of genetic diseases, including to improve the Services FoundationOne CDx, FoundationOne Liquid CDx and FoundationOne Heme; and
- disclose such data and provide the residual material for the above purposes in pseudonymised or anonymised form, including in a commercial context, to external academic, industrial or other collaboration partners. Your residual material will only be disclosed in a de-identified form without any additional information which could either directly or indirectly be attributed to your person.

Your personal data and residual material will not be used for any other purposes, except in fully anonymised form (i.e. where the information has been rendered anonymous so that it can no longer in any way (neither directly nor indirectly) be attributed to your person).

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.

Section 3 – General Data Protection Information

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

A. Contact Details; Data Protection Officer

Local Roche Affiliate: Roche Products Limited, Hexagon Place, 6 Falcon Way, Shire Park, Welwyn Garden City, Hertfordshire, AL7 1TW, UK.

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

FMI GmbH: Foundation Medicine GmbH, Nonnenwald 2, 82377 Penzberg, Germany

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

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

Their contact details are as follows:

Roche Products Limited, Hexagon Place, 6 Falcon Way, Shire Park, Welwyn Garden City, Hertfordshire AL7 1TW, UK
dpo.dpowelwyn@roche.com, Phone: +44 (1707) 366 000

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 GmbH: Foundation Medicine GmbH, Nonnenwald 2, 82377 Penzberg, Germany;
dpo.fmi-germany@foundationmedicine.com, Phone: +49 (8856)905-3715

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 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 about 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 one of the grounds provided for by statutory law applies (right to be forgotten);
- to the extent 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 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 an 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 applicable law, to any processing of your personal data based on the ground that the processing is necessary for purposes of legitimate interests pursued by Roche and/or FMI (right to object);
- withdraw your consent at any time without affecting the lawfulness of processing based on consent before its withdrawal; and
- lodge a complaint with a data protection authority, in particular the data protection authority competent for your place of habitual residence or place of the alleged infringement.

To exercise your rights, please contact your treating physician. You may also contact any of the data protection officers named above under Section 3. A. Please note, however, that FMI generally only receives pseudonymised data. Therefore, FMI cannot ensure it will be able to verify your authorisation or identify your person or the data concerning you can in the context of your requests without receiving additional information from you and your treating physician or pathologist. Therefore, in order to effectively exercise your rights (and to avoid having to identifying yourself to FMI), please contact your treating physician or pathologist directly, even if you wish to exercise your rights against FMI GmbH and/or FMI Inc.

Roche Products Limited
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Patient Information and Consent to the Processing of Personal Data For FoundationOne® CDx, FoundationOne® Heme or FoundationOne® Liquid CDx

IMPORTANT NOTE: Please provide your consent on two (2) original copies of this document and return one (1) to your treating physician; the other copy is for your records. **Please do not return a copy of this document to Roche.**

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 purpose of providing the requested Service (as indicated at the top of this Patient Consent Form), including the transfer of my personal data to FMI Inc. in the US. 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. I may also contact any of the data protection officers named under Section 3 A. 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.
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, and residual material by FMI, including in a commercial context, 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. I may also contact any of the data protection officers named under Section 3 A. The withdrawal of my consent does not affect the lawfulness of any processing based on such consent before its withdrawal. I understand that even if I withdraw my consent, FMI will continue to process any data and/or residual material already fully anonymised by FMI before the withdrawal. I am free to provide my consent to the above. If I do not provide consent, or I withdraw my consent at a later time, such withdrawal 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**

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