PATIENT INFORMATION & CONSENT FORM

Service (please select Service ordered)

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

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

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

The Service is provided to you by Roche Products Limited (**"Roche UK"**) in conjunction with Foundation Medicine, Inc., however affiliates of these companies, as set out below may also be involved:

- Roche UK is the contracting party for performing the Service, handling local coordination and customer support service. Roche UK may receive personal data, although this may be de-identified. Furthermore, Roche Pharma AG, of Emil-Barell-Straße 1, 79639 Grenzach, Germany (**"Roche Germany"**) will become involved in the central coordination and quality of the Service provision and in this regard shall also act as joint controller of your personal data. Roche UK and Roche Germany (hereinafter referred to as **"Roche"**) may be contacted using the details set out in Section 3 below.
- To provide the Service, Roche collaborates with FMI Germany GmbH, Nonnenwald 2, 82377 Penzberg, Germany (**"FMI Germany"**) which – together with Foundation Medicine, Inc., 150 Second Street, Cambridge, MA 02141, USA (**"FMI USA"**) – conducts the molecular genetic services. In most cases, FMI Germany will be responsible for the processing of your data in the context of providing the Service as controller and instruct FMI Inc., as its processor, to assist in providing certain parts of the Service. There may be cases of an order for the Service resulting in your data also being transferred, by your treating physicians, directly to FMI in the US, which will then carry out all of the molecular genetic services as sole controller (without or with only limited involvement of FMI Germany as processor). Note that in order to identify the Service ordered, please see selection at the top of this Patient Information Form. FMI Germany and FMI, (hereinafter referred to as **"FMI"**) can be contacted at the contact details set out in Section 3 below.

This Patient Information and Declaration of Consent (**"Patient Information 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 process your personal data in accordance with the General Data Protection Regulation EU 679/2016 (**"GDPR"**) and the UK Data Protection Act 2018 (**"DPA"**)

Section 1
Processing of your Personal Data for the Purposes of Providing the Service

A. Assignment of Order ID by Roche (de-identification 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 1D).

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 in a de-identified form (without revealing your identity). Roche and FMI may also receive your NHS and/or Hospital Number for the purposes of performing the services. However, this means that, even though Roche and FMI 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. Under no circumstances will FMI receive any information to attribute the Order-ID to your person.

B. Preparation of Specimen by Pathologist/Phlebotomist
To prepare your blood and/or tissue specimen (as required for your Service), your treating physician will cooperate with the pathologist/phlebotomist who has access to your blood and/or specimen 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.

C. Laboratory Analysis and Report Creation by FMI
Your treating physician or pathologist will complete a test requisition form and transfer the below de-identified data, together with your blood and/or tissue specimen (as required for your Service), to the FMI laboratory site carrying out the laboratory analysis:

- Order-ID,
- Date of birth (day/month/year)
- 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
- Pathology report (in redacted form), including but not limited to additional local test reports and/or standard of care test reports

(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 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 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 the decision on your future therapy.

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 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.

In case your treating physician has selected certain additional pathological tests (such as PD-L1) which are offered by Roche as optional parts of the Service, FMI Germany will involve external pathologists located within Germany to carry out these tests as independent subcontractors. For these purposes, the external pathologists will receive limited Test Requisition Form Data, the results of the pathology review and your blood and/or tissue specimen (as required for the optional pathological test) solely for purposes of performing the pathological test and report creation.

Other than is necessary to provide the requested Services, FMI will not further analyse or process your genetic material. Genomic data obtained during the sequencing analysis by FMI will not contain any directly personal identifiable data.

In most cases, of the Service (and except for the optional pathological tests, such as PD-L1, which are carried out solely in Germany by external pathologists) your Test Requisition Form Data and blood and/or tissue specimen (as required for your Service) will be transferred by your treating physician or pathologist for laboratory services to FMI Germany (for the extraction of DNA/RNA and sequencing of relevant genes) and FMI Germany will further transfer, or grant access to, such de-identified

information, with the exception of the blood/tissue specimen, to FMI USA (for analysis of the obtained genomic data, matching, and report creation). In these cases, FMI Germany will be responsible for the processing of your data as controller and will instruct FMI USA to carry out the described parts of the Service, as its processor. FMI Germany will ensure, by having appropriate agreements in place, that FMI USA will process your data only on behalf of and in accordance with, the instructions of FMI Germany and only to the extent necessary to provide the described parts of the Service. In some cases, an order for the Service may result in your de-identified data also being transferred by your treating physician or pathologist directly to FMI USA which will then carry out all of the above steps as sole controller (without or with only limited involvement of FMI Germany, as its processor); note that in order to identify the Service ordered, please see selection at the top of this Patient Information Form. Only in these cases, FMI USA will also receive your blood and/or tissue specimen (as required for your Service). For more details about the roles of FMI Germany and FMI USA in the context of your specific Service, please contact your treating physician or FMI at the contact details set out in Section 3 below.

In all of the above cases, your de-identified data (Test Requisition Form Data and, as applicable, your blood/tissue specimen) 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 USA 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.

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 ensuring that the recipient is certified under the EU-US Privacy Shield (www.privacyshield.gov) or by entering into data transfer agreements on the basis of the EU Standard Contractual Clauses or standard data protection clauses adopted or approved by the European Commission (Art. 46 GDPR).

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. To obtain more information about FMI USA's Privacy Shield certification, please visit www.privacyshield.gov or contact FMI at the contact details set out under Section 3 below.

As an additional safeguard, in all of the above cases, FMI and its subcontractors only stores and processes de-identified information which is not directly attributable to your person. To the extent that FMI may accidentally receive data in fully personal identifiable form from your treating physician or pathologist (such as your name in a pathology report) FMI will redact such information upon receipt and notify Roche of such occurrence. 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.

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

Roche will 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 Pathologist and FMI, information about status of the Service but in any case with the exception of the blood/tissue specimen, obtained sequencing data and DNA/RNA. Roche Germany may, to the extent required in its capacity in handling the central coordination and quality of the Service provision and as necessary for these purposes, receive the relevant information from FMI (Test Requisition Form Data, information about status of Service, but in any case with the exception of the blood/tissue specimen, obtained sequencing data and DNA/RNA). Roche Germany may liaise with Roche UK in order to rectify any anomalies and/or corrections required for the purposes of carrying out the Services.

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. *Under no circumstances shall the report be utilised by Roche for commercial purposes; this is solely to assist in situations where there may be a technical issue(s) related to the provision of the report*. Roche and FMI 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.

E. Term of Storage; Deletion

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 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/Tissue Specimen:** After completion of the Service, or in case the Service ends because you withdraw from the Service, any tissue specimen not used by FMI (if any under the requested Service) will, if available in the form of a tumour block, be returned by FMI to the pathologist, working with your treating physician, be stored by the pathologist in accordance with applicable statutory requirements. Other residual material (e.g. extracted DNA/RNA, unstained slides); blood specimens will be discarded by FMI 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 and the report will be stored by FMI Germany for a maximum of ten (10) years after the end of the provision of the Service. In cases where the Test Requisition Form Data as well as the specimen is sent directly to FMI USA, both the data and report will be stored by FMI USA for a maximum of ten (10) years after the end of the provision of the Service.
- **Sequenced Tumour Genome:** Obtained sequencing raw data will be stored at FMI Inc. for a maximum of ten (10) years after the end of the provision of Service. Curated sequencing data will be stored for a maximum of ten (10) years after the end of the provision of the Service.

Your data will be fully deleted/destroyed after the above time periods except that FMI USA 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.

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

Section 2
Consent to De-identified Data for Research and Scientific Purposes

In case you indicate your agreement with the processing of your personal data by providing your consent at the end of this document your de-identified 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 and shall have no bearing on your ability to use the Services as defined in this document.

A. Processing of De-identified Data for Research and Scientific Purposes
With your consent, FMI USA will store the data received as part of providing the Service (i.e. Test Requisition Form Data, sequencing data) in de-identified form (under the Order-ID) together with the prepared report. FMI USA does not receive or store your name or other information which would be directly attributable to your person. FMI USA 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 Services.

Your de-identified data will be stored for a maximum of ten (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 de-identified data will be deleted without undue delay after withdrawal).

FMI USA 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) 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 Sections 1 and 2.

A. Contact Details; Data Protection Officer
The data protection and privacy officers of Roche and FMI are your points of contact for any questions, suggestions or complaints concerning the processing of your personal data.
Their contact details are as follows:

Roche UK: Roche Products Limited, Hexagon Place, 6 Falcon Way, Shire Park, Welwyn Garden City, Hertfordshire AL7 1TW, United Kingdom. dpo.dpowelwyn@roche.com; +44 1707 366000

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

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

FMI USA: Foundation Medicine Inc., 150 Second Street, Cambridge, MA 02141, USA
privacy@foundationmedicine.com; +1 (888) 988-3639

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
Under the GDPR and the DPA, Roche and/or FMI may process your personal data on the basis it is necessary for the purposes of legitimate interests pursued by Roche and/or FMI. 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 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 withdraw your consent in relation to further research at any time without affecting the lawfulness of processing based on consent before its withdrawal.

However, some of the above rights, particularly in relation to any data obtained under legitimate interests, may be restricted in order to comply with legal obligations.

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

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.

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

IMPORTANT NOTE: Please provide your acknowledgement (and if applicable, consent) on two (2) original copies of this document and return one (1) to your treating physician; the alternate copy is for your records.

Processing of my Personal Data in accordance with Section 1	
❑	I acknowledge that my personal data, including my health data, as specified in Section 1 above will be processed for the purposes of providing the requested Service (as indicated at the top of this Patient Information Form). I may withdraw from the Service at any time by contacting my treating physician or Roche. The withdrawal does not affect the lawfulness of any processing having taken place before my withdrawal.
❑	Upon withdrawal, 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.
Consent to the Processing of my Personal Data in accordance with Section 2	
Yes ❑ No ❑	I hereby consent to the processing of my personal data, including my health data, by FMI USA and/or Roche 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 USA and/or Roche may continue to process any data collected before my withdrawal.
❑	I am free to provide this consent. I understand that if I do not provide consent, or I withdraw consent at a later time, the Service will not be affected.

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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