FOUNDATIONONE® CDx FOUNDATIONONE® HEME Roche

Please fax this form and purchase order to Roche Foundation Medicine Customer Care on 0800 917 8307 or email to welwyn.foundationmedicine_custcare@roche.com

Please fill in carefully in capital letters – omissions or errors may cause delay

Ordering Consultant Oncologist/Haematologist and institution:

Ordering Consultant Oncologist/Haematologist name:		General Medical Council registration number:
Phone number:	Fax:	E-mail:
Institution name:		Department:
Institution address: Post code: _____		Ordering Consultant Oncologist/Haematologist signature: Day __ __ Month __ __ Year __ __ __ __

Contact details at institution in case of queries about the completion of this form:

Name:	Phone number:	E-mail:

Submitting Pathologist and sample collection address:

Submitting Pathologist name:		
Phone number:	Fax:	E-mail:
Sample collection address including department:		Date when the sample will be ready for collection: Day __ __ Month __ __ Year __ __ __ __ Roche Customer Care will confirm actual collection date

Test ordered (check one box):

❑ FoundationOne® CDx (optimised for solid tumours)	❑ FoundationOne® Heme (optimised for haematologic malignancies and sarcomas)	In the event pathology and/or Requisition Form information indicates a change is required to the selected test, Foundation Medicine and/or Roche shall contact the Ordering Consultant Oncologist/Haematologist prior to undertaking the test for confirmation and acceptance. Full gene lists are available at http://www.foundationmedicine.com/f1cdx

Consent:

❑ I hereby confirm that the patient has been fully informed and provided his/her consent to the processing of his/her personal data for purposes of providing the service

❑ Yes ❑ No I hereby confirm that the patient has provided his/her consent to the processing of his/her pseudonymised (de-identified) data for research and scientific purposes

Patient information:

Patient NHS number or hospital number:	Patient date of birth: Day __ __ Month __ __ Year __ __ __ __

No other patient information is required by Roche

Purchasing organisation (for billing purposes):

Organisation Name: Address: Post code: _____	Phone number:	Fax:
	E-mail:	

If your organisation is VAT exempt a VAT exemption certificate must be provided with this order form

Invoice information including contact details for any invoice queries:	Statement information:
Invoice name and address (if different from purchasing organisation): Post code: _____	Please provide a statement address (if different from the invoice address): Post code: _____

Purchase order *(an official purchase order from the purchasing organisation is required):*

Purchase order number:

Authorised purchasing organisation signatory:

Signature:	Name:	Position:	Day __ __ Month __ __ Year __ __ __ __

Roche Products Limited
Pharmaceuticals Division, Hexagon Place, 6 Falcon Way, Shire Park, Welwyn Garden City, Hertfordshire AL7 1TW, Registered in England 100674

Contact Roche Foundation Medicine Customer Care UK Freephone **0800 731 5711** or email **welwyn.foundationmedicine_custcare@roche.com**

These Conditions set out the basis on which we contract with you for tumour sample analysis using Foundation Medicine, Inc.'s Assays.

1. Definitions.

In these terms and conditions (hereinafter "Conditions"), the following words, where the text so admits, shall have the following meaning:

Affiliate	An organisation, which: (a) directly or indirectly controls a party to these Conditions; (b) is directly or indirectly controlled by a party to these Conditions; (c) is controlled, directly or indirectly, by the ultimate parent company of a party. Control as per (a) to (c) is defined as owning more than 50% (fifty percent) of the voting stock of a company or having otherwise the power to govern the financial and the operating policies or to appoint the management of an organisation. With respect to us the term "Affiliate" shall neither include Chugai Pharmaceutical Co. Ltd., of 1-1, Nihonbashi-Muromachi 2-chome, Chuo-ku Tokyo, 103-8324, Japan ("**Chugai**") nor Foundation Medicine, Inc., of 150 Second Street, Cambridge, MA 02141, USA ("**FMI**") and their respective subsidiaries, unless we opt for such inclusion of Chugai and/or FMI and their respective subsidiaries by giving written notice to you.
Assay	FoundationOne®CDx and/or FoundationOne® Heme in vitro diagnostic test assay, compliant with all EU requirements of the IVD Directive 98/79EC and registered for CE mark in the EU.
Contract	Any contract between us and you incorporating the Order Form and these Conditions.
Data	All right, title and interest in the Sample and any ancillary information provided by you.
Data Privacy	Applicable laws relating to patient privacy and the transmission of personally identifiable, personal and sensitive personal information of the Patient, including but not limited to, in accordance with the General Data Protection Regulation (EU2016/679), as implemented by the Data Protection Act 2018 and any other relevant laws, regulations and guidelines.
Fee	The fee for the Services agreed between us and you, prior to acceptance of these Conditions, each time a Sample is provided and a Report generated pursuant to these Conditions.
Institution	The Office/Practice/Hospital/Clinic where you are seeing the Patient and the entity responsible for the Fee
Order Form	The form overleaf detailing the choice of Assay, together with other required information.
Patient	An individual under your care wishing to utilise the Services.
Report	FoundationOne®CDx/FoundationOne® Heme report issued pursuant to analysis of the Sample in the Assay.
Requisition Form	The form provided by us to you setting out Patient information to accompany the Sample.
Sample	A tissue sample collected from a Patient in accordance with and in expectation of the Services.
Services	The offering by us to you, being the provision of packing materials and shipment of the Sample in order to run the Assay and issue the Report.
Third Party Payers	Any, individual, unincorporated or incorporated legal entity, including, insurance companies and/or Patients.
We/us/our	Roche Products Limited, the sole licensed distributor of FMI in the United Kingdom
You/your	The physician (oncologist/haematologist, and as the case may be the pathologist) responsible for the care of the Patient, and on behalf of the Institution, ordering the Services.

2. **Sample Collection and Supplies.**

(a) Upon a request for the Services, you shall complete the Order Form attached to these Conditions. We may revert to you in order to clarify and/or request further information as necessary to properly provide the Services prior to acceptance. Each order for the Services by you shall be deemed to be a separate offer for you to purchase the Services subject to these Conditions. A Contract is formed between us and you for the Services once the order form has been accepted by us and communicated to you.

(b) You will be responsible for the collection and preparation of a Sample from a Patient in accordance with instructions provided by us. We shall arrange for shipping of the Sample by a third party shipper on the date specified on the Order Form (provided this is at least 48 hours' notice) to FMI's laboratories in either the USA or Germany. You confirm that the Requisition Form is accurate and correct. FMI may, acting reasonably reject any Samples not prepared in accordance with guidelines provided by us and/or not accompanied by completed requisition information. You are solely responsible for complying with all applicable laws, rules, and regulations relating to the preparation, collection and storage of Samples prior to shipping. We are responsible for shipping, including all import/export requirements applicable to the shipment of Samples to FMI.

(c) We shall provide you with sufficient packing materials which you shall neither use for any purpose other than for the collection of Samples and sending them to FMI, nor modify without our prior written consent. You agree to comply with instructions provided by us for handling and storage of the packing materials, including in preparing the Samples for shipping.

(d) Following analysis of the Sample, FMI shall, though its third party shipper, return any unused Sample to you; the cost of shipping the return shall be borne by us. Notwithstanding, you may request destruction of the unused Sample, but you must indicate your intention for destruction on the Requisition Form. FMI cannot keep any unused Sample long-term..

(e) You acknowledge and agree that failure to comply with these Conditions shall mean that FMI cannot guarantee the performance of the Assay or timely delivery of the Report, and that any warranties provided by Roche or FMI under these Conditions shall be null and void.

3. Order and Sample Acceptance.

(a) You may cancel an order for the Services up until collection by our third party shipper; thereafter, subject to agreement by us (not to unreasonably be withheld).

(b) Notwithstanding FMI's right to reject a Sample in Condition 2(b), above,it may refuse or reject any Sample that it, acting reasonably, either considers to be: (i) unsuitable in size/volume; (ii) an unacceptable health, safety, environmental, or other risk; or (iii) unviable Sample due to delivery times or shipping conditions. Notwithstanding, you shall notify us and/or FMI immediately in the event of any adverse incidents are reported that affect or likely to affect the Samples.

(c) In the event FMI determines that a more appropriate Assay is required other than indicated on the Order Form, FMI and/or we shall promptly notify you to request confirmation and acceptance of the change. In this instance, the Fee may differ, which may delay the Services in the event you are required to obtain a further purchase order for the new Assay.

(d) In the event FMI deems the Sample unsuitable for the Assay and subsequently refuses to accept the Sample, you must correct the deficiency(ies) after notification by us as soon as possible. If you fail to take any action as aforesaid, we may terminate the Contract, FMI may destroy the Sample and neither we nor FMI will have any further liability or obligation to you in relation to such Sample.

4. Report and Turnaround Times.

FMI shall use reasonable endeavours to provide you with the Report within 14 working days (accounting for any applicable worldwide public holidays) following receipt of the Sample by FMI, subject to Condition 3(c). The Report will be made available via FMI's secure portal Foundation Online ("FO");. Details regarding access to FO will be provided under separate cover. In the alternative, the Report may be emailed to you at the address provided in the Order Form; the email shall be suitably encrypted. Except as required by UK, EU or US laws or regulations, FMI will not release the Report to any third party without your prior written consent (subject to your Patient's confirmation).

5. Compliance with laws.

(a) You shall comply with all relevant local laws applicable to the Service, including, without limitation, Sample collection and storage and Data Privacy. Liability for compliance with Data Privacy rests solely with the respective party dealing with such information in or under its control. Subject to Condition 12, with regard to sensitive personal data (including genomic information), we expressly disclaim any responsibility or liability for any breach of such UK, EU or US laws, regulations, and guidelines (including applicable data protection laws) relating to the same.

(b) You shall, prior to collecting any Sample, ensure that the Patient has given his or her fully-informed and freely-given consent in a manner the same as or similar to the Patient Informed Consent Form, addressing the following: (i) the collection of the Sample; (ii) the processing of the Sample by us and/or FMI and any personal data for the provision of the Services; (iii) the transfer of the Sample (including all Data) to the US and/or Germany; and (iv) we and/or FMI may retain personal data for as long as is required by law and/or permitted under these Conditions. In addition, the Patient has confirmed their participation, or as the case may be non-participation in the use of Sample(s) for future research purposes.

(c) The Report shall comply with all applicable US laws and regulations, including FDA guidelines, currently in force at the time the Services are undertaken, and shall only relate to the Assay applied to the Sample.

(d) With regard to the Human Tissue Act 2004 (as amended), you shall inform us prior to acceptance of the Services of any and all requirements of the licence held by your Institution for the carrying on of the Services hereunder. We shall not be liable for any breaches of the licence for any relevant information that has not been communicated to you in this regard.

(e) You are solely responsible for any and all action(s) undertaken as a result of the information provided in the Report and we do not seek to recommend any particular medication(s) referred therein. It is your responsibility to evaluate and interpret the information provided in the Report, along with all other available clinical information regarding the Patient, in order to determine the best treatment decision(s) in your own independent medical judgment, and as far as possible in collaboration with other healthcare professionals involved in the care of the Patient.

(f) Neither we nor FMI make any guarantees (i) as to the effectiveness or suitability (or lack thereof) of any medications in the Report; or (ii) that any third party payer, including any governmental healthcare program, will pay for the Report or any medications listed in the same.

6. Termination.

Notwithstanding Condition 3(c), you may request in writing to us to stop or suspend the Services under a Contract, and we will make reasonable efforts to comply with such request. Notwithstanding, you may remain obligated to pay Roche for Services already performed on a pro rata basis before we received the request to stop or suspend the Services.

7. Confidentiality, Data Protection and Freedom of Information

(a) You will treat all information you receive about us or FMI, including without limitation information about our operations, facilities, methods, processes, protocols, procedures, and business, as confidential information and you will not disclose or allow the disclosure of any such information to any third party without our prior written approval. In no event may you disclose any pricing or other business related confidential information of ours without our express prior written consent.

(b) The parties, including FMI, may receive, observe or otherwise comes into possession of information or data that is subject to Data Privacy. Accordingly, the parties, including FMI, agree to fully comply with such laws, as they may be applicable to the respective party based on the nature of the Services, including without limitation, maintaining the confidentiality of any protected information. The parties, including FMI, will: (i) process data only on behalf and for the purposes of the Services, and in compliance with all applicable laws; (ii) provide adequate technical and organizational measures to prevent unauthorised processing and accidental loss of such information; (iii) not export outside of the EEA any Personally Identifiable Information ("PII") without your and your Patient's consent; notwithstanding, the transfer of information under this Condition to FMI is secured by the EU Standard Contractual Clauses (controller–controller; Set II) and/or adherence to the EU Privacy Shield or any other similar mechanism of data sharing agreed between the EU,/UK and the US; (iv) not subcontract the processing of data without express written consent; (v) immediately inform the other parties in writing, of any known or suspected data breach; and (vi) support the other parties to comply with any access to information requests by data subjects.

(c) You acknowledge and agree that in the course of conducting business with us, we and/or FMI intend to maintain and process data about you in an internal database; you acknowledge to the maintenance and processing of such data.

(d) We acknowledge that your Institution may be subject to the Freedom of Information Act 2000 ("FOIA") and the Codes of Practice issued under the FOIA as may be amended, updated or replaced from time to time: (i) if your Institution receives a request under the FOIA to disclose any information that belongs to us or our Affiliates, and for the purposes of this Condition 7(d), FMI, it will notify us and/or FMI (as applicable) as soon as is reasonably practicable, in any event, not later than five (5) working days after receiving the request and will consult with us and/or FMI in accordance with all applicable guidance; and (ii) Roche acknowledges and agree that: (aa) subject to Condition 7(d)(ii)(ab), the decision on whether any exemption applies to a request for disclosure of recorded information under the FOIA is a decision solely for your Institution; and (ab) where your Institution is managing a request as referred to in Condition 7(d), we and/or we procures that FMI shall co-operate with your Institution and shall use reasonable endeavours to respond within ten (10) working days of your Institution's request for assistance in determining whether or not an exemption to the FOIA applies.

8. Ownership of Information.

As between the parties, all Data shall remain your property, provided that we and/or FMI may use such Samples and Data as necessary in connection with performance of the Services under these Conditions and for research purposes. Except as expressly set forth in these Conditions, neither party grants to the other by implication, estoppel or otherwise, any right, title, license or interest in any intellectual property right; this shall also apply to FMI. Notwithstanding, you hereby grant to us and FMI an unrestricted, non-exclusive, perpetual, fully paid-up, royalty-free, sublicensable, worldwide license to use the Report, subject to medical confidentiality.

9. Fees; Invoices and Payment.

(a) You will pay Roche the Fee. The Fee is not dependent on the content of the Report. We reserve the right to amend the Fee at any time, but any pre-existing Fee will not change once a Contract is formed, subject to Condition 3(b). We will issue an invoice to you on submission of the Report. All prices quoted or specified by us exclude Value Added Tax, which will be charged at the prevailing rate.

(b) You must pay the Fee by the last Working Day of the month following the month stated in the date of invoice. You shall pay Roche in a timely manner by bank transfer or other mutually agreed method, without offset or deduction, in pounds sterling, even if you challenge any of the Services or claims that they breach the Warranty (defined below) or any other provision of these Conditions.

(c) You agree that the Fee is separate from any fees you may charge to any Third Party Payers. You are solely responsible for collecting payment from Third Party Payers. Your obligations to pay Roche hereunder are not in any way contingent upon you receiving payment for the Services from or on behalf of any Third Party Payers, and you are responsible for paying Roche as provided for herein without regard to when you receive payment from such Third Party Payers.

10. Warranty.

Subject to these Conditions, we will arrange for the Services to be performed in accordance with FMI's standard operating procedures and practices for conducting such Services (the "Warranty"). Your sole and exclusive remedy for any breach by us or FMI of the Warranty will be to have FMI re-perform the affected Services, contingent on you providing us and/or FMI, at our expense, any additional Sample(s) as are necessary to re-perform the affected Services.

11. Disclaimers and Limitations.

(a) Notwithstanding this Condition 11, all other warranties, whether express, implied, or statutory, including but not limited to the implied warranties of merchantability and fitness for a particular purpose are hereby disclaimed and excluded to the fullest extent of the law.

(b) You acknowledge and agree that the Services are not intended to be diagnostic, and should not be the sole basis on which you should make a clinical decision. As with any genetic test, there is no guarantee of accuracy. You specifically understand and acknowledge that false negative and false positive results are possible, and you will ensure that the Patient(s) are also advised of this (through consent forms and otherwise).

(c) In no event shall we or FMI be liable or otherwise responsible to you or any third party (including Third Party Payers) for any consequential, indirect, special, exemplary, punitive, or incidental damages, including but not limited to lost profits, loss of business, or any other commercial damage, regardless of the form of action or theory of liability. Furthermore, to the greatest extent permitted by applicable law, our and/or FMI's maximum liability arising out of or relating to these Conditions, whether arising from any claim(s) based on breach of contract, tort, products liability, strict liability, warranty, or otherwise, shall in no case exceed the actual fees paid to us for the Services.

12. Indemnity.

(a) You acknowledge that we place particular reliance upon the provisions of the Contract and in addition to any other remedy available to us, you irrevocably and unconditionally agrees to indemnify, keep indemnified and hold harmless us, our employees, sub-contractors and agents (who shall have no duty to mitigate their loss) in full and on demand from and against all costs (including the costs of enforcement), expenses, liabilities, injuries, direct, indirect and consequential loss (all three of which terms include pure economic loss, loss of profit, loss of business, depletion of goodwill and like loss), damages, claims, demands, proceedings and legal costs (on a full indemnity basis) and judgments made against or incurred or suffered by any of them and whether wholly or in part resulting directly or indirectly from the matters listed below whether or not such losses or the consequences of the matters listed below were foreseeable at the date of the Contract arising from or otherwise relating to: (i) any information, instructions, or Samples that you provide to FMI via us; (ii) your disclosure of the Report to any third party for any reason, or any use by you or any third party of any of the results provided hereunder; (iii) any failure by you to comply with any applicable law, regulation or guideline, or causing us to be in breach of any applicable law, regulation or guideline including the Data Privacy, or otherwise to comply with the requirements of Conditions 5; or (iv) your negligence or wilful misconduct, except to the extent any such Claim results from the negligence, wilful misconduct, or breach of these Conditions by us or FMI or any of our employees, sub-contractors and agents (collectively or individually, a "Claim").

(b) The indemnity provided by you in Condition 12(a) is conditional upon us, FMI or any of our employees, sub-contractors and agents (i) providing you with prompt written notice of a Claim within 20 (twenty) working days (accounting for any applicable worldwide public holidays) after being formally served; (ii) providing you the opportunity to defend and settle the Claim; (iii) providing reasonable assistance to you, at your request and expense, to defend against the Claim and (iv) taking reasonable steps to mitigate all loss, damage, costs and expenses we or any of our employees, sub-contractors and agents incurs as a result of any Claim.

13. Term and Termination.

The Contract shall govern the relationship between us throughout the provision of the Services and shall expire upon completion of the same, unless terminated earlier in accordance with the terms of these Conditions. In the event of a termination for any reason, you shall pay us for any Services rendered prior to the date of termination. Conditions 5, 7, 8, 10, 11, 12, 13 and 14 shall survive any such termination or expiration of these Conditions. Except for the foregoing sentence and notwithstanding anything to the contrary herein, the parties expressly agree that there are no early termination or cancellation fees contemplated under these Conditions. Upon termination or expiration of these Conditions, no separate termination or cancellation fees shall apply. Unless otherwise required by these Conditions or applicable law, rule, or regulation, following 7 (seven) years from the date of completion of the Services, we may destroy in a secure manner all related Data held by us.

14. General Provisions.

(a) Assignment. You may not assign these Conditions without our prior written consent. We shall have the right to assign these Conditions to any Affiliate, including any successor(s) in title of the same. These Conditions shall be binding on and inure to the benefit of each of the parties' successors and permitted assigns, if any.

(b) Relationship of the Parties. The relationship of the parties established by these Conditions is that of independent contractors, and nothing contained in this agreement shall be construed to constitute the parties as partners, joint venturers, co-owners, or participants in any joint or common undertaking, or to allow either party to act as an agent of the other or otherwise to create or assume any obligation on behalf of the other party. For the avoidance of doubt, acceptance of your order does not in any way entitle you to use any trademarks owned by us, FMI, our associates or Affiliates. Any infringement of either our or FMI's intellectual property rights, whether by substitution, passing-off, copyright or trademark infringement or any other improper use whatsoever will result in either us or FMI (as applicable) taking appropriate action to safeguard our interests.

(c) Review. We reserve the right to amend these Conditions at any time. Any changes implemented will not apply to concurrent orders, but shall apply to all new orders for the Services.

(d) Force Majeure. A party (including FMI)'s failure to perform in timely fashion shall not be a breach of these Conditions if such failure to perform results from circumstances beyond the party (including FMI)"s reasonable control, including, but not limited to, labour disputes, civil disturbances, acts or non-actions of governmental authorities or suppliers, epidemics, war, embargoes, severe weather, fire, earthquakes, Internet outage or Acts of God. This provision shall not apply, however, to your payment obligations to us.

(e) Severability; Waiver. If any of these Conditions is held to be invalid, unenforceable or unlawful for whatever reason, such decision shall not affect the validity or enforceability of the remaining conditions or the Contract which will remain valid and enforceable in all respects. Any failure or delay by either party to exercise or partially exercise any right, power or privilege under these Conditions shall not be deemed a waiver of that right, power or privilege.

(f) Entire Agreement. These Conditions constitute the entire agreement between the parties as to the subject matter hereof and supersedes all prior written and oral communications, agreements, representations, warranties, statements, negotiations, understandings, and proposals, with respect to such subject matters. No change shall be made to these Conditions except by written agreement of authorised representatives of both parties. Subject to any variation herein, these Conditions shall govern and form part of every Contract and shall prevail over and exclude any terms or conditions, whether expressed or implied, by you (including any terms and conditions which you purport to apply under any purchase order, specification or other document whatsoever and whenever).

(g) Counterparts. These Conditions may be executed in counterparts, each of which when executed and delivered shall constitute an original, but all the counterparts shall together constitute the same agreement.

(h) Governing Law & Jurisdiction. These Conditions, the Contract and any non-contractual obligations, the covering letter and any dispute or claim arising out of or in connection with them shall be governed by and construed in accordance with English law and subject to the exclusive jurisdiction of the English courts to which the parties irrevocably submit.

PATIENT INFORMATION & CONSENT FORM

Service (please select Service ordered)	
❑ FOUNDATIONONE®CDx	❑ FOUNDATIONONE®HEME

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 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 Consent 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 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.

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

Section 1
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 requested Service. Note that in order to identify the Service ordered, please see selection at the top of this Patient Consent Form. To give your consent, please tick and provide your signature at the end of this document.

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 in a de-identified form (without revealing your identity). 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

To prepare your blood and/or tissue specimen (as required for your Service), your treating physician will cooperate with the pathologist whom has access to your blood and/or tissue 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)
- Sex
- 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 not further analyse or process your genetic material. The genomic data obtained during the sequencing analysis by FMI will not contain any directly personal identifiable data.

In most cases, 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 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 Consent 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. 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 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 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 check and confirm 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 Pathologist and FMI ("Test Requisition Form Data"), information about status of the Service but in any case with the exception of the blood/tissue specimen, obtained sequencing data and DNA. 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). 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 your consent, 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, 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 10 (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 10 years after the end of the provision of Service. Curated sequencing data will be stored for a maximum of 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 consent, and provides further details about the processing of your personal data and your rights.

Section 2
Consent to the Processing of your 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 and to further understand the causes of cancer genesis and cancer progression, as well as to improve the FoundationOne® CDx, FoundationOne® Heme and 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) 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 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
dpo.fmi-cambridge@foundationmedicine.com; +1(617) 413-7313

Roche Products Limited
Hexagon Place, 6 Falcon Way, Shire Park, Welwyn Garden City, Hertfordshire AL7 1TW,
Registered in England 100674
medinfo.uk@roche.com

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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 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 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 (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.

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Patient Information and Declaration of Consent to the Processing of Personal Data For FoundationOne® CDx and FoundationOne® Heme

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 Information and 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.
Consent to the Processing of my Personal Data in accordance with Section 2	
YES ❑	I hereby consent to the processing of my personal data, including my health data, by FMI USA 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 will continue to process any data anonymised by FMI USA before the withdrawal.
NO ❑	
❑	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**

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