

**Please fax this form and purchase order to Roche Foundation Medicine Customer Care on 0800 917 8307 or email to [uk.foundation@roche.com](mailto:uk.foundation@roche.com)**

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

<b>Ordering Consultant Oncologist/Haematologist and institution:</b>		
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 _____
<b>Contact details at institution in case of queries about the completion of this form:</b>		
Name:	Phone number:	E-mail:
<b>Submitting Pathologist and sample collection address:</b>		
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 _____ <small>Roche Customer Care will confirm actual collection date</small>
<b>Test ordered (check one box):</b>		
<input type="checkbox"/> <b>FoundationOne® CDx</b> (optimised for solid tumours)	<input type="checkbox"/> <b>FoundationOne® Heme</b> (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.
<input type="checkbox"/> <b>FoundationOne® Liquid CDx</b> (liquid biopsy optimised for solid tumours)		
<b>Consent:</b>		
<input type="checkbox"/> 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 <input type="checkbox"/> Yes <input type="checkbox"/> 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		
<b>Patient information:</b>		
Patient NHS number or hospital number:		Patient date of birth:  Day ___ Month ___ Year _____
No other patient information is required by Roche		
<b>Billing Options</b>		
<input type="checkbox"/> Invoice Hospital  <small>(If the Hospital is to be invoiced, please complete the purchasing contact and email details below together with a relevant Purchase Order Number that can be referenced throughout the process).</small>  Name: _____ Email: _____		<input type="checkbox"/> Patient Self Pay  <small>Roche will contact you to arrange how your patient will make payment. (If patient has Private Health Insurance (PHI), please give details of provider and Pre-authorisation code below.)</small>  PHI Provider: _____ Auth Code: _____
<b>Purchase Order (an official purchase order from the purchasing organisation is required):</b>		
Purchase Order Number for Invoice Hospital Requests:		
<b>Authorised purchasing organisation signatory:</b>		
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 [uk.foundation@roche.com](mailto:uk.foundation@roche.com).

Further information can be found at [www.foundationmedicine.co.uk](http://www.foundationmedicine.co.uk)

All orders placed by the customer are accepted subject to Roche's General Conditions of Sale for Roche Foundation Medicine services which are printed on the back of this order form.

**These Conditions set out the basis on which we contract with you for tumour/blood sample analysis using Foundation Medicine Inc's Assay(s).**

**1. Definitions.**

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

<b>Affiliate</b>	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.
<b>Assay</b>	FoundationOne® CDx, FoundationOne® Heme and/or FoundationOne® Liquid Cdx <i>in vitro</i> diagnostic test assays, and/or any other offering(s) provided by FMI to which the parties mutually agree in writing shall be subject to this Agreement, which Roche warrants is compliant with all EU requirements of the IVD Regulation (EU) 2017/746 and registered for CE mark in the EU.
<b>Contract</b>	Any contract between us and you incorporating the Order Form and these Conditions.
<b>Data</b>	All right, title and interest in the Sample and any ancillary information provided by you.
<b>Data Privacy</b>	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 the Data Protection Act 2018, the General Data Protection Regulation 2016/679 and any other relevant laws, regulations and guidelines.
<b>Fee</b>	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.
<b>Institution</b>	The Office/Practice/Hospital/Clinic where you are seeing the Patient and the entity responsible for the Fee
<b>Order Form</b>	The form overleaf detailing the choice of Assay, together with other required information.
<b>Patient</b>	An individual under your care wishing to utilise the Services.
<b>Report</b>	FoundationOne® CDx, FoundationOne® Heme and/or FoundationOne® Liquid Cdx report issued pursuant to analysis of the Sample in the Assay.
<b>Requisition Form</b>	The form provided by us to you setting out Patient information to accompany the Sample.
<b>Sample</b>	A tissue/blood sample collected from a Patient in accordance with and in expectation of the Services.
<b>Services</b>	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.
<b>Third Party Payers</b>	Any, individual, unincorporated or incorporated legal entity, including, insurance companies and/or Patients.
<b>We/us/our</b>	Roche Products Limited, the sole licensed distributor of FMI in the United Kingdom
<b>You/your</b>	The physician responsible for the care of the Patient and, on behalf of the Institution, ordering the Services, whether themselves, or via a delegated person with authority to place the order on their behalf

**2. Sample Collection and Supplies.**

- 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.
- 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.
- 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.
- Following completion of the Services, or where the Patient withdraws their consent, any issue specimen not used by FMI (if any) will, if available in the form of a tumour block, be returned to you (the cost of shipping being borne by us). Slide return is available upon your written request. Remaining slides will be stored for 10 years and extracted DNA/RNA will be stored at FMI for a maximum of 1 year (in each case, with effect from the completion of the Services) and discarded thereafter. Blood specimens will be discarded once no longer required for the Services.
- 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.**

- 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).
- 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.
- 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.
- 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.**

- 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.
- 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.
- The Report shall comply with all applicable EU and/or US laws and regulations, including EMA and/or FDA-approved therapies and/or guidelines, currently in force at the time the Services are undertaken, and shall only relate to the Assay applied to the Sample.
- 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.
- 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.
- 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**

- 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.

- The parties, including FMI, may receive, observe or otherwise come 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.
- 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.
- 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: (a) subject to Condition 7(d)(i)(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 process 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.**

- The party listed under Billing Information on the Order Form 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). All prices quoted or specified by us exclude VAT, which will be charged at the prevailing rate.
- If the Patient is responsible for the Fee, we require payment before we provide the Service.
- If the Institution is responsible for the Fee, we will issue an invoice to you on submission of the Report. 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.
- You agree that the Fee is separate from any fees you may charge a Third Party Payers. You are solely responsible for collecting payment from Third Party Payers. Your obligations to pay Roche here under are not in anyway contingent upon you receiving payment from 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.**

- 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.
- 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).
- 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.**

- 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 agree 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 willful misconduct, except to the extent any such Claim results from the negligence, willful misconduct, or breach of these Conditions by us or FMI or any of our employees, sub-contractors and agents (collectively or individually, a "Claim").
- 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.**

- 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.
- 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 ventures, 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.
- 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.
- 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.
- 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.
- 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).
- 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.
- 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.