

MASTER DATA SHARING AND USE AGREEMENT

This MASTER DATA SHARING AND USE AGREEMENT (this “Agreement”) between:

..... (“**Institution**”), located at
[Instructions: please select legal entity and complete location of legal entity]
and

F. Hoffmann-La Roche Ltd., located at Grenzacherstrasse 124, 4070 Basel, Switzerland (“**Roche**”).

(hereinafter referred to collectively as “the Parties” and individually as “a Party”).

BACKGROUND

Roche and its Affiliates (as defined below) are conducting an observational, non-interventional, prospective, multi-national, and multi-centre solid tumor cancer registry (“WAYFIND-R Registry”). The WAYFIND-R Registry will collect clinical data on patients diagnosed with solid tumors who have undergone next-generation sequencing-based molecular profiling in routine clinical care.

Institution is a nonprofit organization, a healthcare organization, an academic research and educational institution or a patient group organization and desires access to the data collected by Roche (and its Affiliates) in order to conduct certain analyses for non-commercial scientific research purposes as further described below. Roche (and its Affiliates) is willing to grant access to these data.

Roche and Institution intend to establish the terms and conditions under which Roche will grant access to the Institution for each Research Project issued under this Agreement.

In consideration of mutual promises, Roche and Institution (each, a “Party” and collectively, the “Parties”) agree as follows:

1. DEFINITIONS

- 1.1. “**Affiliate**” shall mean (i) an organization, which directly or indirectly controls a Party to this Agreement; (ii) an organization, which is directly or indirectly controlled by a Party to this Agreement; (iii) an organization, which is controlled, directly or indirectly, by the ultimate parent company of a Party. Control as per (i) to (iii) is defined as owning more than 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 organization. With respect to Roche the term “Affiliate” shall not include Chugai Pharmaceutical Co. Ltd., 1-1, Nihonbashi-Muromachi 2-chome, Chuo-ku Tokyo, 103-8324, Japan (“Chugai”) unless Roche opts for the inclusion of Chugai by giving written notice to Institution.

- 1.2. “**Analysis/Analyses**” refers to any and all analysis of the anonymized individual-level or aggregated data from the Research Project, or any other source, as specifically described in the Research Project.
- 1.3. “**Analytical Tools**” includes, but is not limited to, any methodology, statistical methods, formulae or other methods or tools used in conducting the Analyses.
- 1.4. “**Committee**” means a group of independent, external experts who collectively have the scientific and medical experience to evaluate the research proposal.
- 1.5. “**Data**” means all information including, without limitation, anonymized individual-level or aggregated data, research specifications or clinical trial/study protocols, reports, specifications, computer programs or models and related documentation, of Roche or any of its Affiliates that is provided to or otherwise made available to the Institution or a Researcher in connection with this Agreement.
- 1.6. “**Lead Applicant**” means the Researcher identified as the “Lead Applicant” in the Research Project and authorised by the Institution to represent the Institution for the execution of any Research Project issued via the WAYFIND-R IT Platform.
- 1.7. “**New Intellectual Property**” means all results, discoveries, developments, inventions (whether patentable or not), improvements, methods of use or delivery, processes, know-how, or trade secrets which are made by a Researcher as a result of the conduct of Analyses or as a result of the use of any information provided to Institution or a Researcher by Roche under this Agreement.
- 1.8. “**Patent**” means all rights under any patent or patent application, in any country of the world, including any patents issuing on such patent application, and further including any substitution, extension or supplementary protection certificate, reissue, reexamination, renewal, divisional, continuation or continuation-in-part of any of the foregoing.
- 1.9. “**Project Space**” For each Research Project, Roche will establish a new and independent Project Space. Any given Project Space will contain only the data associated with a single Research Project and access will be limited to the Lead Research and Researcher/s.
- 1.10. “**Research Project**” has the meaning set forth in Section 2.1 and as further defined in a description of the Research Project as laid down in the template heretere attached as **Exhibit A** of this Agreement. The Research Project is issued via the WAYFIND-R IT Platform and confirmed in a legally binding manner by the Lead Applicant.
- 1.11. “**Researcher**” means each and any of the researchers listed in a Research Project including the Lead Applicant who is provided access to the Data in connection with this Agreement for the Research Project.

- 1.12. “**Roche Product**” means any pharmaceutical, diagnostic or digital product, or investigational drug or medical device in pre-clinical or clinical development or which is the object of an IND or CTA, either marketed or developed by Roche, its Affiliates or licensees thereof.
- 1.13. “**Roche Uses**” means any and all uses of or related to any Roche Product, which would otherwise be an infringement of any Patent owned or controlled by Institution and covering a New Intellectual Property. For the avoidance of doubt, a related use includes, but is not limited to, a diagnostic test applicable to a disease treated by the compound or the class to which it belongs.
- 1.14. “**Term**” has the meaning set forth in Section 10.1.
- 1.15. “**WAYFIND-R IT Platform**” means a global oncology real-world data sharing and collaboration platform that embeds technologies to allow highly secure data sharing (i.e., data privacy by design) to perform analyses using an integrated interface.

2. DATA SHARING

- 2.1. Roche hereby grants to Institution, for the Term and for each Research Project as defined in a description issued under this Agreement, a non-exclusive, non-transferable license for use by Institution and the Researchers of the Data for the defined duration of the Research Project approved by the Committee (the “Research Project”) and for no other purpose. The Parties agree that the execution of any Research Project issued via the WAYFIND-R IT Platform shall have the same legal force and effect as the exchange of original signatures on a printed version.
- 2.2. Institution shall provide Roche with names of the Lead Applicant and Researchers. Institution acknowledges that the Lead Applicant can execute Research Projects via the WAYFIND-R IT Platform in a legally binding manner and Institution shall ensure that the Lead Applicant is authorised to represent the Institution.
- 2.3. Access to the new Project Space will be limited to Researchers. Institution shall establish appropriate administrative, technical, and physical safeguards, recognized as a market and industry standard to prevent unauthorised use of or access to Data other than as provided for in this Agreement. Roche makes no representations or warranties regarding the suitability of the Data provided to Institution for the Analysis.
- 2.4. Institution shall notify Roche prior of any replacement of the Lead Applicant or Researchers. Such replacement of the Lead Applicant or Researcher acknowledges and agrees to the terms of this Agreement via the WAYFIND-R IT Platform and confirms them in a legally binding manner. A Researcher’s access to and usage of the Data will be subject to compliance with the terms of this Agreement. Any Researcher may be denied access to the Data and Institution shall be liable for any direct or indirect damages or liability arising from any non-compliance by a

Researcher with the terms of this Agreement. Roche disclaims all liability to Institution or to any Researcher in connection with access or use of the Data.

- 2.5. Institution will provide to Roche prompt written notice, within forty eight hours (48), of all suspected security incidents that involve, or which Institution reasonably believes to involve the attempted breach, successful breach, unauthorised use, unauthorised access, or inappropriate disclosure of the Data; provided further, such notice shall summarise in reasonable detail the impact on Data, and the corrective action taken or to be taken by Institution. Institution shall not disclose any information related to the suspected security incident(s) to any third party without Roche's prior written approval, which approval shall not be unreasonably withheld.
- 2.6. Data provided by Roche in connection with this Agreement is Roche's Data. This grant of a license shall not transfer any title or ownership rights in Roche's Data, including any intellectual property embodied therein, which title and ownership rights shall at all times remain with Roche. The Institution agrees that it will use the Data only for the approved Analysis and the Research Project.
- 2.7. Institution and Researchers shall obtain any regulatory or ethical approvals required by law or institutional policy before beginning the analysis, including but not limited to institutional review board and research ethics committee approval.
- 2.8. Institution and Researchers shall comply with all applicable laws, regulations, codes, and guidelines, regarding handling, analysing and reporting analyses of Data.
- 2.9. Institution shall inform Roche immediately, no later than within twenty-four (24) hours, (and may also inform any regulatory authority) of any information concluded from the research conducted pursuant to the Research Project that in the Lead Applicant's judgment could impact the risk-benefit assessment of a Roche Product, including but not limited to, any safety concerns, identified as part of the Analysis. Sponsor(s) pharmacovigilance contact details are provided in Exhibit B. Roche may take action regarding such information, including informing regulatory authorities or healthcare providers, or otherwise making such information public, even in advance of publication of the Analysis by Institution. Institution shall provide access and reasonable assistance to Roche to utilize and implement any Analytical Tools for the sole purpose of reproducing the Analysis.

3. CONFIDENTIALITY

- 3.1. The Data and all tangible expressions, in any media, of Data are the sole property of Roche. Institution agrees that neither Institution nor any Researcher shall use the Data for any purposes other than the purpose(s) described in this Agreement. Institution further agrees that neither Institution nor any Researcher shall disclose the Data to any third party without the prior written consent of Roche. Institution shall safeguard the Data with the same standard of care that Roche generally applies and all generally applicable market and industry standards for safeguarding confidential information.

- 3.2. The obligations of confidentiality and limited use under this Section shall not extend to any information:
- 3.2.1. which is or becomes publicly available, except through breach of this Agreement;
 - 3.2.2. which Institution can demonstrate that it possessed free of any obligation of confidence prior to, or developed independently from, disclosure under this Agreement;
 - 3.2.3. which Institution receives from a third party which is not legally prohibited from disclosing such information; or
 - 3.2.4. which Institution is required by law to disclose, provided that Roche is notified of any such requirement with sufficient time to seek a protective order or other modifications to the requirement.
- 3.3. The obligations of this Section shall survive this Agreement for a period of fifteen (15) years after the Effective Date.

4. INTELLECTUAL PROPERTY

- 4.1. All New Intellectual Property shall be the sole property of Institution; however, Institution will notify Roche, within thirty (30) days of filing and in writing, of any Patent covering a New Intellectual Property. Institution hereby grants to Roche a perpetual, non-exclusive, fully-paid up, royalty-free, irrevocable, worldwide, unrestricted license under any Patent relating to a Roche Product or a class thereof for Roche Uses, with the right to sublicense through multiple tiers. Institution further grants an exclusive option, to be exercised within one hundred eighty (180) days from notice of the Patent filing to negotiate in good faith an exclusive, fee-bearing, worldwide license with the right to sublicense through multiple tiers to any such Patent which Institution may have or obtain..
- 4.2. If Roche exercises its option to negotiate an exclusive license, Roche and Institution will exclusively negotiate in good faith, for up to one hundred eighty (180) days or such mutually agreeable longer period, regarding commercially reasonable terms for an exclusive, worldwide, fee-bearing license, including the right to sublicense, for Roche and its Affiliates to make, have made, use, sell or otherwise dispose of the subject matter of the New Intellectual Property or products incorporating the subject matter of the New Intellectual Property subject to any non-exclusive licenses granted in section 4.1. In the event that Roche does not exercise its option to negotiate an exclusive license, or in the event Institution and Roche fail to agree to commercially reasonable exclusive license terms following good faith negotiation, Institution may negotiate further non-exclusive license terms with third parties. Any such terms shall be consistent with the non-exclusive license granted to Roche in section 4.1 above. Should any terms be agreed with a third party in accordance with this section, then for five (5) years after the Effective Date, Institution will notify Roche, within thirty (30) days of the Effective Date of any such agreement, of the identity of the third party.

- 4.3. Institution will obtain all rights, titles and interest in New Intellectual Property through written agreements with all Researchers who contributed to the New Intellectual Property, prior to executing the license of articles 4.1 and 4.2.
- 4.4. To the extent Roche requires assistance from Institution to utilize or enforce any licensed Patent, Institution agrees to provide reasonable assistance, at Roche's cost, in relation to the actual Patent utilization or enforcement.
- 4.5. The obligations of this Section shall survive termination of this Agreement in accordance with Clause 10 of this Agreement.

5. PUBLICATION

- 5.1. Institution shall submit to Roche a copy of the summary results of every Analysis as well as a copy of any proposed Publication at least twenty-one (21) days before the date of the proposed submission for publication. Roche may provide comments as a courtesy to the Institution. In the event that information considered to be confidential is included in the text, Roche may, by giving written notice to the Institution, prevent the publication of any of Roche's Confidential Information. Furthermore, at the request of Roche, the Institution will file priority patent applications to protect any invention relating to a Roche Product identified by Roche before the proposed publication is submitted.
- 5.2. A publication must give appropriate credit to Roche and the WAYFIND-R Registry by this statement "We thank the patients and their families who take part in WAYFIND-R, as well as the staff, research coordinators, and investigators at each participating institution."
- 5.3. Institution is expected to make the Analysis results publicly available, and Institution shall use reasonable efforts to obtain public disclosure of the Analysis Results in a peer-reviewed journal.
- 5.4. Additionally, the Institution shall provide Roche a reference citation upon publication which will be made public by Roche after the research is published. Institution agrees, following publication, to provide other institutions with additional details of the Analysis on request and to provide access and reasonable assistance to those other institutions to utilize and implement any Analytical Tools for the sole purpose of reproducing the Analysis.
- 5.5. However, notwithstanding any other provision of this Agreement, Institution or Researcher shall not send or provide copies of any Data made available to Researcher under Section 2.1 above, to any third party.
- 5.6. Roche will share the users name, the name of Institution and the project title of the Research Project on the IT Platform.
- 5.7. The obligations of this Section shall survive termination of this Agreement.

6. INDEPENDENT CONTRACTOR

The relationship of the Parties is that of independent contractors. Neither Party is the partner, joint venturer, or agent of the other and neither Party has authority to make any statement, representation, commitment, or action of any kind which purports to bind the other without the other's prior written authorization.

7. ASSIGNMENT

Roche may assign its rights and duties under this Agreement without Institution's consent. Any assignment by Institution is valid only upon the prior written consent of Roche. To the extent permitted above, this Agreement shall be binding upon and inure to the benefit of the Parties and their permitted successors and assigns.

8. REPRESENTATIONS AND WARRANTIES

- 8.1. Institution represents and warrants that it does not have, and will not enter into, any legal or contractual obligations that would prevent it from complying with its obligations under this Agreement, including without limitation, the obligations of Section 4.
- 8.2. Institution shall be responsible for the compliance of the Lead Applicant and any other Researcher to the terms of this Agreement.
- 8.3. Lead Applicant will obtain any regulatory or ethics approvals necessary to conduct the Analysis.
- 8.4. Institution represents and warrants that it has the authority to bind to the terms of this Agreement any individual proposed by Institution to have access to the Data made available to Institution in connection with this Agreement, and that the term "Researcher" shall apply to all such individuals.

9. DATA PROTECTION

Institution acknowledges the importance of data privacy of individuals to whom accessed data may relate, and commits to comply with all applicable federal, state and local laws and regulations relating to data protection and the privacy of subject health information. For the purpose of the Research Project, the Institution will process anonymized individual-level or aggregated data, the Institution shall not attempt to identify subjects, and not to combine accessed data with other sources of data that would lead to the identification of any individual.

10. TERM and TERMINATION

- 10.1. The term of this Agreement shall be effective as of the latest date in the signature blocks below ("Effective Date") and end on the date three (3) years thereafter. It is automatically extended for a further year if the Parties do not terminate it with a notice of three months and unless otherwise terminated or amended in accordance with the provisions of this Agreement or extended by mutual written agreement of

the Parties. The term of the Research Project is specified in each Project Description and ends after the specified term. Promptly after completion of the Analysis of a Research Project, Institution shall provide Roche written notice of such completion. Certain provisions of this Agreement survive termination of this Agreement as expressly set forth herein. In the event this Agreement is terminated, its terms shall continue to apply to all Research Projects under which the activities have not been completed at the effective date of such termination.

- 10.2. Institution's or a Researcher's use of any of Data in violation of any law or of any terms or limitations imposed by this Agreement shall be a violation of this Agreement and Roche may immediately terminate the rights granted under this Agreement or under a Research Project unless earlier terminated as set forth below.
- 10.3. Roche may, in addition to any other rights and remedies available to Roche, terminate this Agreement or any Research Project by giving Institution written notice of such termination in the event Institution or any Researcher materially breaches any of the terms and conditions of this Agreement and fails to cure such breach or default as promptly as practicable and, in any event, not more than thirty (30) days after respective Roche gives Institution written notice specifying the details thereof. Notwithstanding the foregoing, in the event that any breach is not reasonably capable of cure within the thirty (30) day period, it shall be sufficient if Institution promptly commences appropriate action to cure and diligently pursues such action until complete.

11. NOTICES

Except as otherwise expressly provided in this Agreement, any notice required under this Agreement shall be in writing and in English and shall specifically refer to this Agreement. Notices shall be sent via one of the following means and will be effective (i) on the date of delivery, if delivered in person; (ii) on the date of receipt, if sent by a PDF image sent by email or other electronic transmission (with delivery confirmed); or (iii) on the date of receipt, if sent by private express courier or by first class certified mail, return receipt requested (or its equivalent).

12. GOVERNING LAW; VENUE

This Agreement shall be governed by and interpreted in accordance with the laws of Switzerland. Any dispute arising under or in connection with this Agreement shall be subject to the exclusive jurisdiction of the courts of Basel-City.

13. ENTIRE AGREEMENT

This Agreement represents the entire and integrated agreement between the Parties and supersedes all prior negotiations, representations or agreements, either written or oral, regarding its subject matter.

14. ELECTRONIC SIGNATURES

The Parties agree that execution of this Agreement by e-Signatures (as defined below) shall have the same legal force and effect as the exchange of original signatures.

Pursuant to this Agreement, e-Signatures shall mean a signature that consists of one or more letters, characters, numbers or other symbols in digital form incorporated in, attached to or associated with the electronic document, that (a) is unique to the person making the signature; (b) the technology or process used to make the signature is under the sole control of the person making the signature; (c) the technology or process can be used to identify the person using the technology or process; and (d) the electronic signature can be linked with an electronic document in such a way that it can be used to determine whether the electronic document has been changed since the electronic signature was incorporated in, attached to or associated with the electronic document.

Agreed and signed by the Parties through their duly authorised representatives:

[The institution must ensure that the signatory is authorised to sign official documents, contracts, agreements or other legal instruments on behalf of the institution. If these authorisations include signing alone (and not just with someone else), a signature can be made alone.]

Roche: F. Hoffmann-La Roche Ltd

By

By

Signature

Signature

Name

Name

Title

Title

Date

Date

Institution

By

By

Signature

Signature

Name

Name

Title

Title

Date

Date

Attachments:

Exhibit A – Template Description of the Research Project.

The Parties agree that the execution of any Research Project issued via the WAYFIND-R IT Platform shall have the same legal force and effect as the exchange of original signatures on a printed version.

The following is an example of which points and questions are requested within the WAYFIND-R IT Platform.

Project Title

Project Summary

Please summarise the scope of your project in lay language.

Query Builder

Build a query by adding parameters or load previously saved one using saved queries. You can still add/edit parameters in the saved query.

Research Proposal

In each section, please describe the overall research project design and rationale for design choice, including key elements of the design, such as the population, intervention/exposure, comparators and outcomes, when applicable, as well as a summary of the planned analysis and key considerations/limitations.

Research Question

Please describe your research question or hypothesis.

Project Design

Please describe the project design (e.g., cohort/subgroup analyses), the rationale for design choice, and how it answers the research question.

Population

Please describe the rationale for any inclusion and exclusion criteria and impact on the number of subjects/patients available for analysis.

Intervention/Exposure

Please provide the rationale and the definition of intervention/exposure of interest, according to the research project design.

Comparator

Please describe the comparison group especially for studies assessing treatment effects; describe methods to identify comparator group, characteristics of comparison group compared to main studied cohort.

Outcomes

Please provide a definition and the rationale for the outcomes (primary/secondary/exploratory) and endpoints of interest.

Analysis

Please provide a summary of the rationale for the choice of statistical techniques and statistical procedures to be applied to the data to obtain point estimates and confidence intervals of measures of occurrence or association and sensitivity analyses.

Considerations/Limitations

The strength of the project design to answer the research question may be explained in this section. Provide rationale for data use time period of research project, any follow-up and how other variables are to be used (e.g., to address potential for bias).

Publication Plan

Please provide plans for disseminating and communicating your results.

Is this study sponsored by a non-independent organisation, such as a pharmaceutical industry or diagnostics company? If yes, please provide more details on the management of potential conflicts of interest:

Project Privacy

Please note that your name, the name of your institution and the project title will be published on the platform. Only registered platform users are able to see this information.

Please select this button if you do not wish your research project title to be displayed to other WAYFIND-R Platform users.

Invite collaborators

Maximum 15 Collaborators can be added.

Team Member Name:

E-mail:

Institution Name:

Project Role:

Acknowledgement of Data Use Conditions:

- I hereby confirm that the information I have provided about the Research Project is correct and true.
- I have understood and confirm that this Research Project, is entered into under the terms and conditions of the Master Data Sharing and Use Agreement with [Institution], and any amendments thereto and that all terms and conditions of the Master Data Sharing and Use Agreement shall remain in full force and effect.
- By submitting this Research Project, I accept and confirm that I have declared any potential conflicts of interest and defined potential management of those.
- By submitting this information, I confirm that I have obtained consent and informed the individual persons whose personal data I am sharing.

Tickbox: I have read, understood the data use conditions and confirm that I am entering into a legally binding contract.

Exhibit B

Sponsor(s) pharmacovigilance contact details:

Drug Safety Contact Line: contact_line.drug_safety@roche.com