

## Master Subscription Agreement

THIS MASTER SUBSCRIPTION AGREEMENT (this "Agreement") is made and entered into effective as of the date of final signature below (the "Effective Date") between OpenClinica, LLC, a Delaware limited liability company with offices at 1075 Main Street, Suite 163 Highland Ave. # 1173 Needham, MA 02494 ("OpenClinica") and Università degli Studi di Palermo – Dipartimento di Medicina di Precisione in Area Medica, Chirurgica e Critica – with offices at Palermo, Via Liborio Giuffrè 5 ("Subscriber").

Subscriber and OpenClinica (collectively, the "Parties" and each, a "Party") agree as follows:

1. Definitions. The definitions for some of the defined terms used in this Agreement are set forth below. The definitions for other defined terms are set forth elsewhere in this Agreement.

**"Affiliate"** means, with respect to any entity, any other entity who, directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with, such entity. The term "control" means the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of an entity, whether through the ownership of voting securities, by contract, or otherwise.

**"Applicable Law"** means any applicable federal, state, county, and local law, ordinance, regulation, rule, code, and order, including, but not limited to, the Food, Drug and Cosmetic Act (as amended) and its associated regulations and guidances, HIPAA, 21 CFR Part 11, and all applicable UK and EU data privacy regulations, including the General Data Protection Regulation (GDPR).

**"Authorized User"** means an employee, research site personnel, study participant, customer, or individual contractor of Subscriber or of any of its Affiliates who has been authorized by Subscriber to use the Subscription Services as a component of Subscriber's clinical research activities.

**"Disclosing Party"** is a Party disclosing Confidential Information to the other Party.

**"Documentation"** means the user guides, manuals, software validation and quality system documentation for the Subscription Services, and any other written information that OpenClinica provides to Subscriber to support the Subscription Services.

**"Order Form"** means a written order for Services signed by the Parties which references this Agreement. Each Order Form entered into by the Parties, once executed, shall be automatically incorporated herein by this reference and shall constitute a part of this Agreement and will each be subject to the terms and conditions hereof, although, in each case, the terms in an individual Order Form shall govern only Services described in that Order Form.

**"Receiving Party"** is a Party receiving Confidential Information from the other Party.

**"Subscriber Studies"** means the clinical research studies carried out by Subscriber.

**"Subscription Services"** has the meaning set forth on the Order Form.

**"Term"** means the Initial Term and any Renewal Terms.

**"Update"** means any and all new releases, new versions, patches and other updates for the Subscription Services that OpenClinica makes generally available without additional charge to its other subscribers of the Subscription Services.

**"Website"** means the OpenClinica site located at openclinica.com, openclinica.io and other web services (including APIs) through which OpenClinica provides the Subscription Services under this Agreement.

2. Services. OpenClinica will provide Subscriber with the following services (collectively, the **"Services"**):

2.1. Subscription Services. OpenClinica hereby grants to Subscriber the right to access and use the Subscription Services during the Term. OpenClinica will provide Subscriber and its Authorized Users with Subscription Services for Subscriber Studies and any Updates thereto through the Website in accordance with the terms and conditions of this Agreement. OpenClinica will be responsible for hosting the Subscription Services, and Subscriber and its Authorized Users will be responsible for obtaining internet connections and other third party services necessary for it to access the Website.

2.2. Restrictions on Use. Subscriber will not (and will not permit its Affiliates, Authorized Users, or any third party to): (i) remove or modify any proprietary marking or restrictive legends placed on the Subscription Services; (ii) interfere, disrupt or attempt to disable the Subscription Services or gain unauthorized access to other accounts on the Subscription Services, or (iii) use the Subscription Services in violation of any Applicable Law to Subscriber and its Authorized Users.

2.3. Access to Documentation. OpenClinica will provide Subscriber via the Website or other means with access to the Documentation, as may be updated from time to time in order to reflect any Updates. Subscriber may print copies of, use, and permit its Affiliates and Authorized Users to use the Documentation solely in connection with the use of the Subscription Services. Subscriber will not remove any copyright, trademark or other notices from any copies of the Documentation.

- 2.4. Professional Services. OpenClinica will provide Subscriber with consulting, training, and other professional services (if ordered) by Subscriber under this Agreement.
3. Fees and Payment Terms.
- 3.1. Fees and payment. Subscriber will pay OpenClinica fees as stated on the Order Form (the “Fees”) in accordance with the payment schedule set forth on the Order Form. Except as provided herein, payments of Fees are non-refundable, and must be received by OpenClinica within the time specified on the Order Form.
- 3.2. Overdue payments. Overdue payments will be assessed interest at the lesser of one and one-half percent (1.5%) per month or the maximum allowable interest under Applicable Law, from due date until paid.
- 3.3. Taxes. When set forth on a valid invoice, Subscriber will pay any sales, use or other tax related to the Services provided hereunder, exclusive of taxes imposed on, or with respect to, OpenClinica’s income, revenues, gross receipts, personnel, property, payroll taxes relating to OpenClinica’s employees, or other assets, or similar taxes not directly based on Subscriber’s use or consumption of the Services.
- 3.4. Suspension of Services due to Non-Payment. If payment is overdue by 60 days or more, OpenClinica, at its sole discretion, may suspend Services to Subscriber. Subscriber may need to pay a reactivation fee in order to restore the Services. Subscriber is responsible for costs of collection, including attorney's fees.
- 3.5. Usage Overage. Any studies Subscriber adds beyond the quantity allowed in the Order Form will be invoiced at the same per-study rate in that Order Form for the remainder of the current Term.
4. Term and Termination.
- 4.1. Initial Term. The initial term of this Agreement begins on the Effective Date and will continue for the period set forth on the Order Form, unless and until terminated in accordance with this section 4 titled “Termination” (the “**Initial Term**”).
- 4.2. Renewal Terms. Upon expiration of the Initial Term or any Renewal Term, this Agreement will automatically renew for successive one year periods (each, a “**Renewal Term**”) unless either Party provides the other with written notice of non-renewal at least one month prior to the expiration of the then-current term. The pricing during any Renewal Term may be modified by OpenClinica if OpenClinica provides Subscriber written notice of a pricing change at least forty-five (45) days before the end of that prior Term. If no notice of a pricing change is provided by

OpenClinica, the prior term's pricing will be in effect upon renewal, automatic or otherwise, and thereafter.

- 4.3. Termination for cause. In the event of a material breach of this Agreement by a Party, the other Party may terminate this Agreement by giving thirty (30) days prior written notice to the breaching Party; provided, however, this Agreement will not terminate if the breaching Party has cured the breach before the expiration of such thirty (30) day period.
- 4.4. Effect of Termination. In the event of an early termination of this Agreement, Subscriber shall be invoiced for all outstanding amounts and pay OpenClinica for all amounts payable hereunder as of the effective date of termination. Upon expiration or termination of this Agreement, all rights and licenses granted hereunder to Subscriber (as well as all rights granted to any Affiliates or Authorized Users of Subscriber) will immediately cease, including but not limited to all use of the Subscription Services and the Documentation.
- 4.5. Survival. The provisions within the following sections will survive any termination or expiration of this Agreement: "Definitions", "Effect of Termination", "Subscriber Data", "Confidentiality", "Disclaimer" "Limitation of Liability", "Indemnification", "Miscellaneous Provisions" and this "Survival".

5. Title.

- 5.1. Title. OpenClinica retains title to and ownership of the Subscription Services and the Documentation, including all copyrights and other intellectual property rights relating thereto. Subscriber will have no rights with respect to the Subscription Services or the Documentation other than those expressly granted under this Agreement.
- 5.2. Subscriber Data. Subscriber owns or has the right to use all data transmitted or stored by Subscriber or by an Authorized User through the Subscription Services or provided or created in the course of any other Services (collectively, the "**Subscriber Data**"). In order to provide the highest quality of support service, at times OpenClinica may need to access Subscriber Data for rapid-response troubleshooting and issue resolution. Subscriber hereby grants OpenClinica a non-exclusive, non-transferable, limited license solely to use the Subscriber Data to provide the Subscription Services in accordance with this Agreement.
- 5.3. Usage Data. OpenClinica collects data pertaining to Subscriber's use of Subscription Services in order to gauge the quality and reach of OpenClinica's products and services, and to support improvements thereto. This includes metadata, such as information pertaining to the number and status of studies,

sites, CRFs, event definitions, rules, study subjects, and data extracts. It may also include data related to system usage patterns and user load.

6. Confidentiality.

- 6.1. Definition of Confidential Information. For the purposes of this Agreement, “**Confidential Information**” means any non-public information or material regarding either Party’s legal or business affairs, financing, technology, methodologies, personally identifiable information, hosting/network infrastructure, customers, properties or data, and anything reasonably understood to be confidential. Notwithstanding any of the foregoing, Confidential Information does not include information which: (i) is or becomes public knowledge without any action by, or involvement of, the Receiving Party; (ii) is documented as being known to the Receiving Party prior to its disclosure by the Disclosing Party; (iii) is independently developed by the Receiving Party without reference or access to the Confidential Information of the Disclosing Party and is so documented; or (iv) is obtained by the Receiving Party without restrictions on use or disclosure from a third party who is not under any confidentiality obligations with regard to the information.
- 6.2. Use and Disclosure of Confidential Information. With respect to any Confidential Information disclosed by the Disclosing Party, the Receiving Party: (i) shall use such Confidential Information only in connection with the Receiving Party’s performance pursuant to this Agreement; (ii) subject to the “Employee Compliance” section below, shall restrict disclosure to only those of the Receiving Party’s employees and agents who have a need to know such Confidential Information in connection with the Receiving Party’s performance pursuant to this Agreement, and (iii) shall not disclose such Confidential Information to any third party unless authorized in writing by the Disclosing Party to do so.
- 6.3. Protection of Confidential Information. The Receiving Party shall protect the confidentiality of any Confidential Information disclosed by the Disclosing Party using at least the same degree of care that it uses to protect its own Confidential Information (but no less than a reasonable degree of care).
- 6.4. Employee Compliance. Prior to providing an employee or agent access to any Confidential Information of the Disclosing Party, the Receiving Party shall inform such employee or agent of the confidential nature of such Confidential Information and require such employee or agent to comply with confidentiality obligations substantially similar to those set forth in this Agreement.
- 6.5. Required Disclosures. If the Receiving Party is required to disclose any of the Disclosing Party’s Confidential Information pursuant to Applicable Laws, any judicial or governmental order, or other bona fide legal process, the Receiving

Party will not disclose the Confidential Information without first giving the Disclosing Party written notice of the request and sufficient opportunity to contest the law, order, or process, to the extent such notice and opportunity to contest may be lawfully given, and will only disclose as much information as necessary to comply with the law, order, or process.

- 6.6. Injunctive Relief. In the event of a breach of the confidentiality obligations set forth in this Agreement, the Parties acknowledge that such breach may cause irreparable harm for which remedies at law would be inadequate, and therefore, the Parties agree that such breach will entitle the non-breaching Party to seek injunctive relief.

7. Data Security and Privacy.

- 7.1. Regulatory Compliance. OpenClinica offers products and services which are designed to be compliant with regulatory requirements such as ICH GCP, 21 CFR Part 11, HIPAA, and GDPR (or similar ones as mutually agreed upon by the Parties). Where applicable, OpenClinica will continue to maintain its compliance for the Term of this Agreement.
- 7.2. Subcontractors. OpenClinica, at its option, may engage subcontractors to fulfill certain aspects of the Services. OpenClinica will maintain a commercially reasonable process for qualifying these subcontractors to ensure they comply with Applicable Law.
- 7.3. Data Center Security. OpenClinica's data centers are compliant with industry standard security, privacy, and availability programs and OpenClinica will ensure they continue to maintain compliance with such programs for the Term of this Agreement.
- 7.4. Protection of Personal Information. OpenClinica will use technical, administrative and procedural measures as required by Applicable Law and this Agreement to protect personal information against accidental or unauthorized access or use.
- 7.5. Privacy Policy. OpenClinica collects and handles information according to the privacy policy at <https://www.openclinica.com/openclinica-privacy-policy/>.

8. Representations and Warranties; Disclaimer.

- 8.1. Mutual Representations and Warranties. Each Party represents and warrants that: (i) it has the full right, power and authority to enter into this Agreement and to discharge its obligations hereunder; and (ii) it will comply with all Applicable Laws in the performance of its obligations under this Agreement.

8.2. Representations and Warranties of OpenClinica. OpenClinica represents and warrants that: (i) the Subscription Services will not infringe any intellectual property right or proprietary right of any third party; (ii) OpenClinica shall use commercially reasonable efforts to ensure that the Subscription Services will not contain any malicious code (such as computer virus, Trojan horse, worm, time bomb, or other similar code designed to disable, damage, or disrupt the operation of, permit unauthorized access to, erase, destroy, or modify any software, hardware, network, or other technology); (iii) the Subscription Services will operate substantially in compliance with the Documentation; (iv) all Services shall be performed in a professional and workmanlike manner; and (v) it has full capacity and all necessary licenses, permits, and consents to enter into and perform under this Agreement. The foregoing representations and warranties do not apply to any third party software applications or web-based services used in connection with the Services.

8.3. Disclaimer. OpenClinica cannot guarantee that every error in the Subscription Services or problem raised by Subscriber will be resolved. EXCEPT AS EXPRESSLY SET FORTH IN SECTION TITLED "DATA SECURITY AND PRIVACY", THE SUBSCRIPTION SERVICES, ANY UPDATES, THE DOCUMENTATION, AND ANY OTHER MATERIALS AND SERVICES PROVIDED HEREUNDER ARE PROVIDED "AS IS" AND "AS AVAILABLE," AND NEITHER PARTY MAKES ANY WARRANTY IN CONNECTION WITH THE SERVICES OR THIS AGREEMENT AND HEREBY DISCLAIMS ANY AND ALL IMPLIED OR STATUTORY WARRANTIES, INCLUDING ALL IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, ERROR-FREE OR UNINTERRUPTED OPERATION AND ANY WARRANTIES ARISING FROM A COURSE OF DEALING OR USAGE OF TRADE. To the extent that a Party may not as a matter of Applicable Law disclaim any implied warranty, the scope and duration of such warranty will be the minimum permitted under such law.

9. Limitation of Liability.

9.1. Exclusion and Damages. NEITHER PARTY WILL BE LIABLE FOR ANY SPECIAL, INDIRECT, INCIDENTAL, EXEMPLARY, PUNITIVE OR CONSEQUENTIAL DAMAGES, INCLUDING LOST PROFITS OR LOST REVENUE, WHETHER IN CONTRACT, TORT, NEGLIGENCE OR OTHERWISE, EVEN IF SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY THEREOF. THE TOTAL AGGREGATE LIABILITY OF EITHER PARTY, OR ITS SUPPLIERS OR LICENSORS TO THE OTHER PARTY AND ITS OFFICERS, DIRECTORS, CUSTOMERS AND EMPLOYEES FOR ANY CLAIMS OR CAUSES OF ACTION ARISING UNDER THIS AGREEMENT WILL NOT EXCEED THE AGGREGATE AMOUNT OF THE FEES PAID AND PAYABLE TO OPENCLINICA BY SUBSCRIBER DURING THE TWELVE (12) MONTH PERIOD PRECEDING THE DATE ON WHICH THE CLAIM ARISES. THIS LIMITATION OF LIABILITY

APPLIES TO ALL CAUSES OF ACTION IN THE AGGREGATE, INCLUDING BREACH OF CONTRACT OR BREACH OF WARRANTY, OR NEGLIGENCE, STRICT LIABILITY, MISREPRESENTATIONS AND ALL OTHER TORTS AND ALL STATUTORY CAUSES OF ACTION.

- 9.2. Exceptions. NOTWITHSTANDING THE FOREGOING LIMITATIONS, THE EXCLUSIONS AND LIMITATIONS OF LIABILITY SET FORTH IN THE SECTION TITLED "LIMITATION OF LIABILITY" SHALL NOT APPLY TO DAMAGES ARISING FROM: (I) EITHER PARTY'S BREACH OF ITS CONFIDENTIALITY OBLIGATIONS HEREUNDER; (ii) EITHER PARTY'S INDEMNITY OBLIGATIONS UNDER THIS AGREEMENT, OR (III) EITHER PARTY'S GROSS NEGLIGENCE OR WILLFUL MISCONDUCT.

10. Indemnification.

- 10.1. Indemnification by OpenClinica. OpenClinica will defend, indemnify and hold harmless Subscriber and its Authorized Users, Affiliates, and each of their officers, directors, managers, shareholders, members, and employees from any and all claims, liabilities, costs and expenses (including reasonable attorney's fees and expert and consulting fees) in connection with any third party claim (i) that the use of the Subscription Services in accordance with this Agreement infringes or misappropriates intellectual property or proprietary rights of any third party; or (ii) arising out of OpenClinica's violation of Applicable Law; provided, however, that the foregoing obligations shall be subject to Subscriber (a) promptly notifying OpenClinica of the claim, (b) providing OpenClinica with reasonable cooperation in the defense of the claim when Subscriber becomes aware and (c) providing OpenClinica with sole control over the defense and negotiations for a settlement or compromise; provided OpenClinica obtains Subscriber's prior written consent to any settlement, such consent not to be unreasonably withheld and that Subscriber may participate in the defense at its own cost.

Notwithstanding the foregoing, OpenClinica shall have no obligation with respect to a third party claim to the extent the third party claim arises from: (x) use of the Subscription Services in combination with modules, apparatus, hardware, software, or services not developed or authorized by OpenClinica or contemplated for use with the Subscription Services; (y) use of the Subscription Services in a manner that is not in accordance with this Agreement or the Documentation; or (z) the alteration or modification of the Subscription Services by a party other than OpenClinica, unless such alterations and modifications were authorized by OpenClinica and contemplated for use with the Subscription Services.

The foregoing indemnification obligations do not apply to the extent failures or losses were caused solely by third party software applications or web-based services used in connection with the Services. This Section states Subscriber's

sole and exclusive remedy and OpenClinica's sole and exclusive liability regarding infringement of any third-party intellectual property or proprietary rights by the Subscription Services.

- 10.2. Indemnification by Subscriber. Subscriber will defend, indemnify and hold harmless OpenClinica and its Affiliates, and each of their officers, directors, managers, shareholders, members and employees from any and all claims, liabilities, costs and expenses (including reasonable attorney's fees and expert and consulting fees) in connection with any third party claim: (i) that any data, information or materials provided by Subscriber hereunder, including, without limitation, the Subscriber Data, when used in connection with the Subscription Services infringes or misappropriates any intellectual property or proprietary rights of a third party; (ii) arising out of Subscriber's violation of Applicable Law, or (iii) any unacceptable use of the Services, including, without limitation, any statement, data or communication made, transmitted, or republished by an Authorized User.

11. Miscellaneous Provisions.

- 11.1. Insurance. OpenClinica will maintain at all times during the Term of this Agreement commercial general liability insurance of not less than \$1,000,000 per occurrence and in aggregate, professional liability of not less than \$2,000,000 per occurrence and in aggregate, cyber security liability insurance of not less than \$5,000,000 per occurrence and in aggregate, and worker's compensation insurance at or greater than the minimum levels required by Applicable Law.
- 11.2. Notices. Unless otherwise specified herein, all notices and other communications between the Parties required or permitted by this Agreement or by Applicable Law, will be deemed properly given, if given by (i) personal service, (ii) electronic mail, (iii) registered or certified mail, postage prepaid, return receipt requested, or (iv) nationally recognized private courier service, to the respective addresses of the Parties set forth below or such other addresses as the respective Parties may designate by like notice from time to time. Notices so given will be effective upon (a) receipt by the Party to which notice is given; or (b) on the fifth (5th) business day following mailing, whichever occurs first:

|                                                                                                  |                                                                                                                                     |
|--------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------|
| If to OpenClinica:                                                                               | If to Subscriber:                                                                                                                   |
| OpenClinica, LLC<br>163 Highland Ave. #1173<br>Needham, MA 02494                                 | Università degli Studi di Palermo<br>Dipartimento Me.Pre.C.C.<br>Palermo, Via Liborio Giuffrè 5                                     |
| Attn: General Counsel<br>Email: <a href="mailto:legal@openclinica.com">legal@openclinica.com</a> | Attn: Dipartimento Me.Pre.C.C.<br>Email: <a href="mailto:dipartimento.meprecc@cert.unipa.it">dipartimento.meprecc@cert.unipa.it</a> |

- 11.3. Relationship of the Parties. Each Party is an independent contractor of the other Party. Nothing herein will constitute a partnership between or joint venture by the Parties, or constitute either Party the agent of the other.
- 11.4. Assignment. Neither Party may assign this Agreement without the prior, written consent of the other Party; provided, however, that either Party may, upon prior, written notice to the other Party and without the consent of the other Party, assign this Agreement in connection with a merger, corporate reorganization or sale of all of its assets. Any assignment in violation of this Section will be null and void. Subject to the foregoing, this Agreement will be binding upon and inure to the benefit of the Parties hereto and their permitted successors and assigns.
- 11.5. Force Majeure. Except with respect to failure to pay any amount due under this Agreement, nonperformance of either Party will be excused to the extent that performance is rendered impossible by strike, fire, flood, hurricanes, other natural disasters, governmental acts, orders or restrictions, failure of suppliers, or any other reason where failure to perform is beyond the control and not caused by the negligence of the non-performing Party ("Force Majeure Event").
- 11.6. Choice of Law and Exclusive Forum. This Agreement, and any disputes directly or indirectly arising from or relating to this Agreement, will be governed by and construed in accordance with the laws of the Commonwealth of Massachusetts, without regard to principles of conflicts of law. Each Party hereby consents to jurisdiction of courts in Middlesex County, Massachusetts, and waives any objections to such jurisdiction. In any action or proceeding arising out of this Agreement, the Party prevailing in such action shall be entitled to recover its reasonable attorneys' fees and costs. This Agreement will not be governed by the United Nations Convention on Contracts for the International Sale of Goods, or the United Nations Convention on the Limitation Period in the International Sale of Goods, or the Uniform Computer Information Transactions Act, the application of which are expressly excluded.
- 11.7. Modification. No modification of or amendment to this Agreement will be effective unless in writing signed by authorized representatives of both Parties.
- 11.8. No Waiver. The rights and remedies of the Parties to this Agreement are cumulative, not alternative, and not exclusive of any other rights or remedies that may be available to the Parties, whether provided by law, equity, statute, in any other agreement between the Parties or otherwise. No waiver of any rights is to be charged against any Party unless such waiver is in writing signed by an authorized representative of the Party so charged. Neither the failure nor any delay by any Party in exercising any right, power, or privilege under this Agreement will operate as a waiver of such right, power, or privilege, and no single or partial exercise of

any such right, power, or privilege will preclude any other or further exercise of such right, power, or privilege or the exercise of any other right, power, or privilege.

- 11.9. Severability. If any provision of this Agreement is held invalid or unenforceable by any court of competent jurisdiction, the other provisions of this Agreement will remain in full force and effect, and, if legally permitted, such offending provision will be replaced with an enforceable provision that as nearly as possible effects the Parties' intent.
- 11.10. Entire Agreement. This Agreement (including all Order Forms) contains the entire understanding of the Parties with respect to the subject matter hereof. There are no other oral or written understandings, terms or conditions and neither Party has relied upon any representation, express or implied, not contained in this Agreement.
- 11.11. Execution in Counterparts. This Agreement may be executed in counterparts (which may be exchanged by email), each of which will be deemed an original, but all of which together will constitute the same Agreement.

The Parties have caused this Agreement to be executed by their duly authorized representatives:

For Subscriber:

For OpenClinica:

Firmato digitalmente da:  
Antonino Giarratano  
Data: 10/03/2025 16:34:22  
Signature:

Name:

Prof. Antonino Giarratano

Title:

P.I. Sis-Net Project

Date:

See Electronic Signature

Signature:

Name:

Title:

Date: