

Agreement

between

AO Foundation
AOCMF
Grabenstrasse 15
7000 Chur (Switzerland)

(hereinafter referred to as AOCMF)

and

xx
{Legal entity of contractor}

(hereinafter referred to as Contractor)

regarding project

AOCMF-
xx

Either AO Foundation or Contractor may be referred to hereinafter as a “Party” or collectively as “Parties”.

WITNESSETH:

Whereas AOCMF as a Clinical Division of the AO Foundation, a foundation established under the laws of Switzerland, focused on improving the quality of medical service through education, research, documentation, and communication;

Whereas Contractor is **Name** incorporated in **Country** with registered office in **City** and has presented Project No. **AOCMF-** as a Full Proposal with the title '**Insert title**' to AO Foundation on **Date**;

Whereas Project No. AOCMF- has been accepted by AOCMF after a peer-review process by the AO Research Review Commission, and a final decision by letter dated **Date**.

Whereas AOCMF is willing to financially support this Project and Contractor is willing to assume the role of a Sponsor in the sense of the ICH-GCP Guideline.

Therefore and in consideration of the mutual covenants contained herein, the Parties hereto agree as follows:

Article 1 — Definitions

For the purposes of this Agreement, the following terms shall have the meaning as set forth below:

Contractor	means the legal entity which has concluded this Agreement with AOCMF as a Specialty of the AO Foundation and which is the sole party contracting with AOCMF responsible for the carrying out of the Project
Director	means the person named by Contractor who shall represent Contractor and be responsible for coordinating all work to be performed under the Project
Principal Investigator	means the person named by Contractor who shall be responsible for the performance of the clinical trial as described in the Full Proposal
Full Proposal	means the description of the Project, which has been submitted by Contractor, and is attached to this Agreement as Annex I
Confidential Information	means all information, data, documents and other related information, received by either Party from the other Party under this Agreement
Intellectual Property	means any patents, patent applications, copyrights, trademarks, service marks, trade names, trade secrets, know-how, or other intellectual property rights recognized in any country or jurisdiction in the world, including, without limitation, any and all art, method, process, procedure, invention, idea, design, concept, technique, discovery, improvement or moral right, regardless of patentability; it is not required, but possible, that Intellectual Property is linked directly to the Project or a result of the Project
Intellectual Property Protection	means the registration, application, filing, prosecution or maintenance of a patent, copyright, trademark or other protective measure for Intellectual Property
Knowledge	means the results, including accompanying documentation, generated or arising in the performance of the Project, and all intellectual property rights relating to such results and documentation, including but not limited to copyrights, patents,

	designs and models, plant varieties, additional certificates, or other similar forms of protection and any related rights to patentable and non-patentable inventions; Knowledge is linked directly to the Project and comes out of the Project
Project	means Project No. AOCMF- with the title ' Insert title ', and all work relating thereto, as described in detail in the Full Proposal and as accepted by AO Foundation after a peer-review process by the AO Research Review Commission, and a final decision by letter dated Date .
Project Duration	means the period of performance of the Project, starting the day after the last signature of the Parties and continuing for 24 months from that date
Project Completion	means the receipt and written approval of Contractor's final report pursuant to Article 4.2.2 by AOCMF
Sponsor	means an individual, company, institution, or organization which takes responsibility for the initiation, management, and/or financing of a clinical trial
Subcontractor	means a third party as referred to in Article 4.3.1 of this Agreement entering into an agreement with Contractor

Article 2 — Subject of Agreement

- 2.1 This Agreement governs the carrying out of the Project by Contractor and the financial support granted therefor by AOCMF. The Project includes patients or healthy volunteers (collectively referred to hereinafter as "Trial Subjects").
- 2.2 AOCMF hereby names Anita Anthon, AOCMF Research & Development Manager, to be responsible for all administrative, scientific and technical questions addressed by Contractor. AOCMF shall not take over any responsibility for carrying out the Project.
- 2.3 Contractor hereby names **[Name to be inserted by Contractor]** as Director of the Project and **[Name to be inserted by Contractor]** as Principal Investigator of the clinical trial as described in the Full Proposal.

Article 3 – Obligations of AOCMF

- 3.1. AOCMF shall finance the Project for **24 (twenty four)** months with a maximum amount of CHF **00,000 (zero thousand and zero hundred)** Swiss Francs); incl. all costs, expenses and taxes, as far as applicable. An extension of the Project and/or further financial support is possible in exceptional cases, but only subject to a prior written agreement between the Parties.
- 3.2 The amount referred to in Article 3.1 shall be transferred to an account of Contractor and not to the account of an individual. AOCMF shall pay the amount[s] in accordance with the following schedule:
 - CHF **00,000 (zero thousand)** Swiss Francs are due after signature of this Agreement by both Parties and the written confirmation of Contractor that the Project has started;
 - CHF **00,000 (zero thousand thousand and zero hundred)** Swiss Francs) are due after AOCMF's approval of the 'First Year Report' pursuant to Article 4.2.1 **CHF 00,000 (zero thousand and zero hundred)** guarantee retention.

- CHF 00,000 (zero thousand and zero hundred) is the guarantee retention. The guarantee retention period shall be thirty (30) days from the date of the approval or rejection of the final report. In the absence of any claims by AOCMF against Contractor with respect to this Agreement, the guarantee retention shall be paid to Contractor within sixty (60) days after expiration of the guarantee retention period.
- 3.3 AOCMF shall make all payments due pursuant to Article 3.2 within thirty (30) days. Contractor shall provide the corresponding bank account information for transfers. Contractor shall be exclusively responsible for any and all taxes which may be incurred as a result of this Agreement and/or the Project.

Article 4 – Obligations of Contractor

4.1 Carrying out of the Project

4.1.1 Contractor shall:

- (a) carry out the Project with suitable qualified, trained and competent investigators and employees only, and in accordance with all applicable laws and regulations, and all provisions as set forth in this Agreement;
- (b) carry out the Project within the time frame as set forth in the Full Proposal;
- (c) provide all necessary facilities therefore;
- (d) nominate in due time a sufficiently qualified new Director and/or new Principal Investigator in the event that the Director and/or Principal Investigator nominated according to Article 2.3 of this Agreement leaves/leave Contractor by leaving the Project with the Contractor.

4.1.2 Contractor shall ensure that all payments made to Contractor pursuant to Article 3 above shall be used exclusively for carrying out the Project. Upon request by AOCMF, Contractor shall provide details on the use of AOCMF's financial support and the Project account.

4.1.3 AOCMF is entitled to request free of charge an update and/or amendment of the Project after receipt of a yearly or final report if AOCMF is of the opinion that such update and/or amendment is appropriate and/or justified for scientific or business reasons.

4.1.4 AOCMF and Contractor shall discuss any substantial material update and/or amendment of the Project with. Such update and/or amendment shall be possible only by prior written agreement between AOCMF and Contractor.

4.1.5 Contractor shall use its best efforts and professional expertise to carry out the Project in accordance with the Full Proposal and in compliance with the current ICH-Good Clinical Practices Guideline ("ICH-GCP") and all applicable legal and regulatory requirements referring to clinical trials. Contractor shall in particular, but not limited

4.1.5.1 assume all obligations of a Sponsor pursuant to the ICH-GCP, designate the necessary number of competent investigators and make sure that all obligations of an investigator pursuant to the ICH-GCP are assumed by these persons;

4.1.5.2 be responsible for submission and obtaining approval of the Protocol, Informed Consent and Study advertisements, if any, from the appropriate IRB/IEC at each site prior to commencement of the Project;

- 4.1.5.2 be responsible for the notification to the competent national health authority;
 - 4.1.5.3 be responsible for the notification of adverse events to the competent IRB/IEC and national health authorities;
 - 4.1.5.4 be liable for harm caused to a Trial Subject within the framework of the Project and take out an insurance policy for full and complete compensation for injuries suffered by a Trial Subject in the course of the Project;
 - 4.1.5.5 agree that AOCMF shall in no event be liable for injuries suffered by a Trial Subject in the course of the Project.
- 4.1.6 Contractor shall become member of the «AOCMF network» when accepting AOCMF's financial support. The AOCMF network is a loose affiliation of institutions and individual persons who received a financial support from AOCMF for a research project. Contractor agrees to participate in the meetings that are organized by AOCMF for the members of the AOCMF network. All travel-related expenses must be covered by this grant award.
- 4.2 Reporting
- 4.2.1 Contractor shall provide AOCMF with a report and a cost statement within thirty (30) days after the end of each year of the Project (i.e. every 12 months after the beginning of the Project). The periodic reports shall contain detailed information about the progress of work, resources employed, detailed financial statement, departures from the work schedule, and results, as required by the Full Proposal.
 - 4.2.2 Contractor shall provide AOCMF with a complete and detailed final report on the Project and a detailed final cost statement within thirty (30) days after completion of the Project for AOCMF's review and approval. Upon written request by AOCMF, Contractor shall make any scientifically reasonable modification within thirty (30) days after receipt of such request.
 - 4.2.3 The reports and the cost statements shall be submitted electronically to AOCMF by the Director and/or Principal Investigator.
 - 4.2.4 Contractor shall respect the Trial Subjects' rights for data privacy when drafting the reports.
 - 4.2.5 All reports shall be in English.
- 4.3 Communication of data for evaluation purposes
- 4.3.1 Without prejudice to Article 6, Contractor shall provide, at the request of AOCMF or its authorized representatives, any data necessary for the ongoing review of the Project. Such request may be made throughout the term of this Agreement and up to three (3) years after the Project Completion. Contractor shall not provide any data of Trial Subjects that are not made anonymous irreversibly. The data collected shall be used for statistical purposes.
 - 4.3.2 Contractor shall retain and not destroy all media containing information on the Project, including, without limitation, books, paper- and electronic files, logs, films, videos, photographs, plans, etc. for a period of ten (10) years. This period starts with the Project Completion or the early termination of the Project.
 - 4.3.3 Without prejudice to Article 6 and the provisions regarding protection and use of Knowledge, as set forth in Article 7, Contractor shall inform AOCMF without

delay of Knowledge which may contribute to the preparation of another research project or to commercial exploitations.

Article 5 – Subcontractors

- 5.1. Contractor is entitled upon prior written consent of the Sponsor to delegate all or part of its obligations under this Agreement to any third party (each, a 'Subcontractor'), but only after the Subcontractor has agreed in writing to be subject to and to comply with all obligations, terms and conditions stipulated in Articles 5 to 9 of this Agreement. Nevertheless, the Contractor will remain fully liable with regard to the project.

Article 6 – Confidentiality

- 6.1. All information, data, documents and other related information, received by either Party from the other Party under this Agreement ("Confidential Information") is and shall be considered throughout, and for three (3) years after, the term or termination of this Agreement, as confidential, except for information which:
 - 6.1.1 at the time of disclosure thereof is or becomes part of the public domain through no breach or fault of one of the Parties or its employees, agents, or Subcontractors;
 - 6.1.2 at the time of disclosure thereof by one of the Parties is the other Party's lawful possession as evidenced by the concerned Party's competent written records;
 - 6.1.3 the Party receives from a third party which has the right to disclose same and which did not obtain such information in violation of the other Party's rights;
 - 6.1.4 is required by law or by the competent authorities within fulfilment of their responsibilities;
 - 6.1.5 has been discovered or developed by the concerned Party independently of the present Agreement;
 - 6.1.6 will be used for a potential future collaboration or will be subject to a license for AOCMF pursuant to Article 7.3.1;
 - 6.1.7 will be used for the purpose of scientific communications and publications or the disclosure of AOCMF's financial support of the Project, but only to the extent needed for such purpose and not exempted by Article 8.2
- 6.2. Each Party shall hold Confidential Information in strict confidence and shall disclose Confidential Information to its employees, agents, or Subcontractors only on a need-to-know basis. Each Party shall ensure and shall be responsible that such employees, agents, or Subcontractors shall be bound and obligated by provisions of confidentiality identical to the Party's own hereunder.
- 6.3. Contractor agrees and acknowledges that nothing in this Article shall operate so as to adversely affect AOCMF's rights to use all Knowledge as provided for under Article 6 of this Agreement and AOCMF remains free to use and disclose same at its sole discretion.
- 6.4. The terms of this Agreement are Confidential Information, except for the fact of AOCMF's financial support.

Article 7 – Intellectual Property Rights

7.1. Ownership

- 7.1.1 Any Intellectual Property developed by Contractor independently of this Agreement, and/or reduced to practice by Contractor prior to the date of this Agreement, shall be owned exclusively by Contractor.
- 7.1.2 Any Intellectual Property owned by AOCMF and/or reduced to practice by AOCMF prior to the date of this Agreement shall be owned exclusively by AOCMF.
- 7.1.3 Any Knowledge discovered, developed and/or reduced to practice by Contractor under this Agreement, shall be owned by Contractor. Any potential transfer to AOCMF shall be subject to a separate agreement between the Parties. AOCMF shall be entitled to request such transfer free of charge.

7.2. IP Filings

- 7.2.1 Contractor may, at its discretion, file an application for, and take steps to obtain and maintain Intellectual Property Protection in any country related to any Knowledge discovered or developed by Contractor in connection with the Project.
- 7.2.2 If Contractor chooses not to apply for and/or to maintain such Intellectual Property Protection, AOCMF may request, and Contractor thereupon shall pursue, such Intellectual Property Protection in any country at AOCMF's expense.

7.3. Licensing

- 7.3.1 AOCMF License. AOCMF shall be entitled to a permanent, non-exclusive, non-transferable, royalty-free license to use and make derivative works of all Knowledge, including, but not limited to the results, as soon as such Knowledge and results are known. AOCMF shall be entitled to use such license for AOCMF's internal operations, further research use, internal and external teaching purposes, commercial exploitations, communications and publications, but the last ones only under the reservation of Article 8 of this Agreement. Contractor shall grant, within due time, AOCMF all rights that are necessary for such use.
- 7.3.2 Commercial Exploitation. In case Contractor intends to commercially exploit the Knowledge or products embodying part or all of the Knowledge, prior to such exploitation, the Parties shall negotiate a profit-sharing agreement, including also AOCMF's royalties.

7.4. Use of Name and Disclosure of AOCMF's financial support

- 7.4.1 The Parties shall neither publish, disseminate nor otherwise use a reference to this Agreement, the Project or its relationship to the other party nor use the other party's name or a name similar to that, except with the prior written consent of AOCMF and as set forth in Article 7.4.2. Any reference to AOCMF in a scientific publication shall be governed by the terms of Article 7.
- 7.4.2 Each Party is entitled to disclose AOCMF's financial support, but without giving any details of this Agreement and/or the Project, or only with the prior written consent of the other Party.
- 7.4.3 Neither Party may use the name, mark or symbol of the other Party or its employees in any commercial manner, including advertising or promotional sales literature, without the prior written consent of the other Party.

Article 8 – Publications

- 8.1. Contractor shall ensure that publications or other disclosures do not include personal data of Trial Subjects.
- 8.2. Contractor shall indicate AOCMF's financial support in an appropriate manner ('Project no **AOCMF-** was supported by AOCMF, Switzerland) in any oral presentation, publication, paper and/or further communication.
- 8.3. AOCMF shall be entitled to submit an own publication if Contractor has failed to submit its publication within six (6) months after Project Completion. Contractor shall provide AOCMF the necessary Knowledge and results upon its request within due time.

Article 9 — Term and termination

- 9.1. This Agreement shall enter into force following its signature by all of the Parties and shall end automatically upon Project Completion.
- 9.2. Either Party may terminate this Agreement by written notice, if the other Party breaches this Agreement in any material manner and has failed to remedy such default within thirty (30) days after written notice thereof by the terminating Party.
- 9.3. AOCMF may terminate this Agreement by written notice in the cases set forth hereinafter provided that Contractor has failed to remedy such situations within thirty (30) days after written notice thereof by AOCMF:
 - 9.3.1 if the potential to use the results of the Project diminishes in AOCMF's judgment to a considerable extent;
 - 9.3.2 if Contractor has not performed his contractual obligations fully and/or in a timely manner;
 - 9.3.3 if Director and/or Principal Investigator leave/s Contractor by taking the Project with them/him;
 - 9.3.4 if Director and/or Principal Investigator leave/s Contractor by leaving the Project with the Contractor and Contractor fails to nominate a new Director and/or Principal Investigator with appropriate qualification within due time or if the new Director and/or Principal Investigator is/are not acceptable for AOCMF from any reason;
 - 9.3.5 if in AOCMF's judgment a change of control over Contractor or a change of the individual investigator(s) assigned to the Project is likely to adversely affect the Project or the interests of AOCMF. Contractor shall give prior written notice of any change of control to AOCMF; in the absence of such notice AOCMF is entitled to terminate this Agreement irrespective of the effects of the change of control on the Projects or the interests of AOCMF. For the purposes of this Agreement the term "change of control" means:
 - 9.3.5.1 The sale or other transfer to a person or legal entity (including affiliates) of a controlling interest in the ownership of the business that includes a majority of all tangible and intangible assets of Contractor. "Controlling interest" shall mean an effective majority, directly or indirectly, of either the voting rights or value of the shares (or other evidence of ownership) and shall include direct and indirect ownership.

9.3.5.2 The sale or other transfer to a person or legal entity (including affiliates) of all or substantially all of the tangible and intangible assets.

9.4. In the event of a termination of this Agreement pursuant Article 9.3 or 9.4, the obligations of AOCMF under Article 3 shall cease with immediate effect, and any sums paid by AOCMF but not used by Contractor up to such date shall be returned to AOCMF. AOCMF shall be entitled to request appropriate compensation in the event that no results nor Knowledge has resulted from the so far performed Project. In addition, Contractor shall immediately deliver to AOCMF all reports pursuant to Article 4.2 – finalized and/or in draft form only – and other documentation, if any, related to the Project.

9.5. The provisions of Article 6 to 9 shall survive the termination of this Agreement for a period of three years.

Article 10 — Liability and Indemnity

10.1. Contractor shall indemnify, defend and hold AOCMF harmless against any and all liabilities, claims (including without limitation threatened claims), damages, losses, costs and expenses, including attorneys' fees and expenses, experts' fees and expenses and arbitrators' and the arbitration organization's fees and expenses (collectively, "Claims"), incurred by AOCMF, resulting

- from claims raised by Trial Subjects because of injuries suffered by them in the course of the Project, or
- from negligence, bad faith, willful misconduct or failure to perform obligations as set forth in this Agreement, on the part of Contractor.

10.2. Contractor shall not be liable to indemnify AOCMF to the extent that Claims arise out of bad faith or willful misconduct by AOCMF's execution of its obligations under this Agreement.

10.3. AOCMF shall in no event be liable to indemnify and hold Contractor harmless against any claims asserted against Contractor resulting from the carrying out of the Project by Contractor.

Article 11 — General Terms

- 11.1. Notwithstanding Article 5, contractor shall not be entitled to assign or otherwise transfer its rights and obligations under this Agreement in whole or in part to any third party without the prior written consent of AOCMF.
- 11.2. This Agreement together with its Annexes sets forth the entire agreement between the Parties and supersedes all previous agreements regarding the subject matter hereof. This Agreement may be amended only in writing.
- 11.3. If any provision of this Agreement should be found to be invalid or unenforceable, the invalidity or unenforceability of such provision shall not affect the other provisions of this Agreement, and all provisions not affected shall remain in full force and effect. The Parties agree to attempt to replace the invalid or unenforceable provision taking into account the sense and the objectives of this Agreement.
- 11.4. The Parties are acting as independent parties hereunder and not as employees nor agents or Subcontractors of the other Party.
- 11.5. Neither Party shall be liable for delay or failure to perform hereunder due to Force Majeure, provided such Party promptly gives the other Party written notice claiming Force Majeure and uses its best efforts to eliminate the effect of such Force Majeure. Force Majeure means any unforeseeable and insurmountable event beyond the reasonable control of the Party affected thereby. If the period of delay or failure extends for more than three (3) months, either Party shall have the right to terminate this Agreement upon written notice at any time after expiration of said three (3) month period.
- 11.6. This Agreement shall be governed by, and construed in accordance with, the substantive laws of Switzerland. The place of venue shall be Zurich (Switzerland).
- 11.7. Any controversies arising out of or relating to this Agreement that cannot be resolved in good faith discussions between the Parties shall be subject to arbitration in accordance with the Swiss Rules of International Arbitration of the Swiss Chambers of Commerce in force on the date when the Notice of Arbitration is submitted in accordance with these Rules. The number of arbitrators shall be one. The seat of the arbitration shall be in Zurich, Switzerland, and the arbitral proceedings shall be in English. All notices by one Party to the other in connection with any arbitration shall be in writing.
- 11.8. All notices (“Notices”) to the Parties pursuant to this Agreement, other than regular business correspondence, shall be sent in writing by registered letter (return receipt requested) or international courier to the addresses of the Parties as indicated below or to another address indicated in writing by the Party in question. The 'Date of Notice' shall be the date of delivery indicated on the registered mail receipt.

To AOCMF

Anita Anthon
AOCMF
Stettbachstrasse 6
CH-8600 Dübendorf

In case of legal and intellectual property aspects with copy to:

AO Foundation
Heiner Lehmann, Legal Counsel
Clavadelerstrasse 8
CH-7270 Davos Platz

To Contractor

[Director NAME AND ADDRESS]

In Witness Whereof, the Parties hereto have caused this Agreement to be executed in duplicate by their duly authorized representatives.

AOCMF

Place and Date

Dr Rolf Jeker, Vice-Chairperson of the AOVA
and CEO of the AO Foundation

Place and Date

Lukas Kreienbühl, COO of the AO Foundation

Contractor

Place and Date

• Authorized representative
[insert Name and Function]

• Authorized representative
[insert Name and Function]

• *[insert Name]*
Director of the Project

• *[insert Name]*
Principal Investigator



Annex I: Description of the Project (Full Proposal)