



EDCTP General Contract Terms (August 2008)

WHEREAS, these General Terms shall, where applicable, as an **Annex A** be part of agreements providing grants to third parties;

NOW THEREFORE, the General Terms are:

Article 1: Definitions

1.1 The definitions given in ICH/GCP (CPMP/ICH/135/95. status: September 1997, version July 2002) are applicable.

1.2 The following expressions shall have the meanings specified.

Background Intellectual Property:	IP-rights relating to the subject matter of the Project and already existing at the Effective Date;
Collaborators:	all investigators of the research team other than the Project Coordinator (normally institutions) and, if any, their employees, and including any subcontractors who are hired by the Collaborators to carry out specific parts of the grant;
Confidential Information:	information regarding the Project that is designated 'confidential', or the nature of such information itself and/or the circumstances of such information's disclosure reasonably indicate that such information is considered confidential;
Contractor:	the party/parties – normally the Project Coordinator and his/her employer - with whom the EDCTP enters into a (grant) Agreement before contributing to the investigations and - if any - other proposed activities, and including any subcontractors who are hired by the Contractor or the PC to carry out specific parts of the grant;
EMA:	the European Medicines Agency, a decentralized body of the European Union with its headquarters in London, United Kingdom;
Financiers:	third parties providing/having provided a substantial financial contribution to the Action under this Agreement through EDCTP, being the sole counter-party of Contractor;
Force Major:	any unforeseeable occurrence beyond the reasonable control of Parties (inclusive strikes and lockouts) which prevents defaulting Party from fulfilling its obligations under the Agreement, not attributable to error or negligence of the defaulting Party, and/or not being



defects in equipment or material needed for the performance of the project or delays in making them available, and/or not being financial difficulties other than cessation of funding to EDCTP;

Foreground Intellectual Property:	IP-rights generated in or arising out of the Project;
IP-rights:	copyright and related rights as well as Industrial Property Rights, in particular patents;
Patent:	any and all patents and patent applications, including all related patents anywhere in the world or claiming priority there from;
Project:	the conduct and/or performance of research activities as described in the Project Document's Work Plan;
Results:	the results, conclusions and findings of the funded activities;
Subcontractors:	all consultants and subcontractors working for the Project directly or indirectly supervised by the PC other than Collaborators;
Trial Data:	all Information needed for the filing of the Investigational Product for a marketing authorization with the EMEA or similar regulatory agencies;
Knowledge management:	The procedure to protect, publish and/or translate any new findings from the study in order to make them available to the benefit of the general public.

Article 2: Currency

- 2.1 All monetary amounts are in Euro. For reporting purposes foreign currency expenditure needs to be translated into Euro at the monthly rate which the expenditure is incurred as quoted by the European Commission (last known internet address being: <http://ec.europa.eu/budget/inforeuro/index.cfm?Language=en>).
- 2.2 Where there is a significant movement in the exchange rate (i.e. greater than 15%) between local currency and the Euro from the effective date of the contract, which would lead to any grantee or contractor not being able to carry out the action as originally intended without suffering losses, then, following a written application from the Project Coordinator to the Executive Director, EDCTP may, renegotiate all or part of the grant at its sole discretion. The renegotiation could cover either altering the size of the budget or the scope of the work to be carried out, or a combination of both. A new, revised budget will be required from the Project Coordinator which must be agreed as justified and reasonable by both the ED and FM in order for the amendment to be put before the General Assembly for formal approval.

Article 3: Applicable Standards

- 3.1 Contractor shall ensure a high level of scientific excellence and shall undertake the Project in conformity with fundamental and international accepted standards and ethical principles as well as in conformity with the current legislation and regulations in the countries where the research will be carried out and where the Project Coordinator is located.
- 3.2 As a specification of article 3.1 applies that documentation of research shall be consistent with the need to establish corroborated dates of invention and reduction to practice with respect to inventions where this is relevant.
- 3.3 Institutional policies regarding what care will be provided to personnel who are injured (for example but not exclusively by the so called needle stick injuries) as a result of their work to the Project shall be developed, approved and implemented with notice to employees similarly to the care and/or referrals available through participation in the Study.
- 3.4 Any reference to generally accepted accounting principles refers to International accounting standards.
- 3.5 Contractor warrants that it shall exercise reasonable care and take the precautions necessary to ensure that it shall not employ, contract with or retain any individual directly or indirectly to perform services under the Agreement if such a individual is debarred or disqualified by an internationally recognised drug authority or ethics committee, or is known as a person supporting or promoting violence, terrorist activity or related training, or money laundering. In the event that Contractor or its employees become aware of, or receive notification of, the debarment or disqualification of any individual and/or institution taking part in the performance of the Agreement, Contractor agrees hereby to notify EDCTP immediately and address the issue as mutually agreed by the Parties, such address including, but not limited to immediate removal of any such debarred or disqualified individual and/or institution from performance of the Project. The forgoing applies also when Contractor becomes aware of any fraud including attempts thereto, related to the Project.**
- 3.6 There are potential negative environmental impacts associated with the development and production of drugs. These include handling and disposal of hazardous medical wastes and chemicals which have potential impact on the environment (pollution) and can also have impact on human health. Therefore Contractor agrees:**
- a. to conform to international guidelines minimizing environmental impact, and**
 - b. to supply all relevant information requested by EDCTP on this area.**

Article 4: Conflicts Of Interest

- 4.1 The Contractor shall take every necessary precaution to avoid any possible conflict of interest. In a situation constituting or likely to lead to a conflict of interest the Contractor shall take immediately all necessary measures to remedy the situation. A conflict of interest may arise in particular from economic interest, political or national affinities, family or emotional ties, or any other common interest that are liable to influence the impartial and objective performance of the Agreement.
- 4.2 Contractor declares that it has not granted and shall not grant, has not sought and shall not seek, has not attempted and shall not attempt to obtain, and has not accepted and



shall not accept, any advantage, financial or in kind, to or from any party whatsoever, constituting an illegal practice or involving corruption or supporting or promoting violence, terrorist activity or related training, either directly or indirectly, as an incentive or reward relating to the performance of the Agreement;

- 4.3 Contractor shall pass on the obligations laid down in the first three paragraphs of this Article in writing to his/her staff, and directors (if any) as well as to third parties involved in performance of the Agreement. A copy of the instructions given and the undertakings made in this respect shall be sent to EDCTP if requested.
- 4.4 In case EDCTP encounters a conflict of interest in the context of the Project, EDCTP reserves the right to impose additional measures after consultation with Contractor. In case the conflict of interest is sufficiently serious and its consequences cannot be corrected, the EDCTP may stop to financially contribute to the Project.

Article 5: Dissemination of knowledge and promotial activities

- 5.1 Contractor shall take care that the investigator(s) shall disseminate as soon as practical the Results in scientific journals and/or the internet, irrespective of the success of the Project, and make oral and visual presentations at conferences where appropriate.
- 5.2 Any communication or publication by the Contractor about the Agreement, the performance thereof and the Results, including at a conferences or seminars, shall state in readable format:

“The author of this publication received funding from the EDCTP through a project entitled “(PROJECT TITLE)”. However EDCTP can not accept any responsibility for information or views expressed herein.”

Contractor shall not make any statement or otherwise imply to the media, the general public or any other donor or investor that Contractors organisation, its operations, or its participation to this Project is supported by any organisation other than the EDCTP, unless Contractors organisation has directly received funds from the other organisation.

- 5.3 EDCTP retains the right to react without further notification to any dissemination having a direct or indirect relation with this Agreement or EDCTP and to disclose other views, and Trial Data or other Information regarding the Clinical Trial (where at stake) at its sole discretion.
- 5.4 The Contractor authorizes EDCTP and its Financiers to publish in any form and medium, including via the Internet, (i) the Contractors name and address, (ii) a summary of the Project including the subject and purpose of the Project, (iii) the amount granted, (iv) the proportion of the Studies total cost covered by the funding, and (v) the holder of the IP-rights of Information and Investigational Product (wherever applicable) used or generated in the Project.
However, upon a reasoned and duly substantiated request by the Contractor, EDCTP may agree to forgo such publicity if disclosure of the information indicated above would risk compromising the Contractors security or prejudicing his commercial interests.
- 5.5 In the event the Contractor and/or investigator(s) do not disseminate (part of) the Results within 2 years time, then EDCTP retains the right to publish such Information via its website, or otherwise in the public interest.

Article 6: Ownership/use of the results and ip-rights

- 6.1 In case the (specific granting) Agreement with Contractor does not contain any stipulations regarding intellectual property rights regulating the ownership of the results or Foreground Intellectual Property generated during the contingency of the Project, the terms as contained herein, shall apply to such Agreement.
- 6.2 All background intellectual property owned by the Contractor shall remain so vested.
- 6.3 Any background intellectual property owned by EDCTP shall remain so vested.
- 6.4 Any Foreground Intellectual Property Rights or results developed during the contingency of the Project shall be owned by the Contractor, however subject to the Contractor granting EDCTP the rights to make use of the results and/or such Foreground Intellectual Property of the Project as it deems fit, but at it's own risk, and subject to the Contractor not being in breach of it's obligations of confidentiality or - at the date of forwarding the application of the project - existing industrial and intellectual property rights, and provided that such use does not jeopardise the Project.
- 6.5 In spite of the previous paragraphs EDCTP shall, without any (further) action required or needed by the Contractor, in any case have and hold a transferable, non-exclusive and irrevocable (/sub)license at most favorable conditions to make use of the IP-rights anywhere and everywhere in the world to ensure that the Investigational Product or its successors shall in product form obtain and maintain the status of tiered priced product as pursuant in the Council regulation (EC) No 953/2003 of May 2003, regarding tiered priced products.
- 6.6 All know-how and other results of studies that were funded by EDCTP and for which it was decided not to apply for a patent or which results have appeared not to be patentable, shall become public knowledge and be easily accessible for the public.
- 6.7 EDCTP has the right to share according to a fair standard in any profits made with the Foreground Intellectual Property by Contractor and/or Collaborator(s) or their eventual successors in the Foreground Intellectual Property.

Article 7: Checks and audits

- 7.1 EDCTP and its Financiers may visit the Trial Site(s) and/or any other location where the Project is actually conducted and/or performed, at reasonable times and with reasonable frequency, to conduct financial and technical audits in order to verify the progress and conduct of the Project.
- 7.2 Contractor undertakes to allow EDCTP and its Financiers appropriate access to sites and premises of Contractor and to all the Information, including Information in electronic format, needed in order to conduct said audits. Duly authorised officers of Contractor who are dedicated to the Project shall assist EDCTP (officer) on its first request in scheduling such visits, and providing direct access to source data.
- 7.3 For Trials, the Contractor shall keep at the disposal of EDCTP and its Financiers all original documents, especially accounting, tax records and Results, or in exceptional and duly justified cases certified copies of original documents, relating to the Agreement for a period of six years after the date of termination of the Agreement.



- 7.4 EDCTP and its Financiers shall enjoy the rights under this Article throughout the term of the Agreement and for a period of six years thereafter. At first written request of EDCTP to the Contractor, any third party designated by EDCTP as having a financial interest in this Agreement shall enjoy the same rights as EDCTP but only for the purpose of the audits as referred to in paragraph 7.1. Employees, agents, and authorized representatives from the organizations referred to in this paragraph shall enjoy the same rights as granted to their respective organizations.

Article 8: Confidentiality

- 8.1 The Parties and its (/ex-)employees agree to keep the Confidential Information confidential for the duration of 6 (six) years after it received this confidential information for the first time and to take all reasonable precautions to prevent the disclosure of the Confidential Information to any third-party.
- 8.2 Notwithstanding the preceding, information shall not be considered Confidential Information if it:
- (i) is rightfully in the public domain other than by a breach of a duty to the disclosing party; or
 - (ii) is proven by written records to be rightfully received from a third party without any obligations of confidentiality; or
 - (iii) is proven to be rightfully known to Recipient Party or its employees without any limitation on use or disclosure prior to its receipt from the disclosing party; or
 - (iv) is in the Agreement explicitly except from being Confidential Information or is disclosed after written permission of the Disclosing Party; or
 - (v) has to be disclosed pursuant any judicial or governmental requirement or order, and only for that particular disclosure. In such a case the one Party shall inform the other Party prior to disclosure thereof, and the Party required to disclose shall limit the disclosure to the amount necessary, and shall place a confidentiality notice on all such Information.

Article 9: Legal authority

- 9.1 Each of EDCTP and Contractor represents and warrants that it has the legal authority and is qualified to enter into the Agreement and that the terms of the Agreement are not inconsistent with its other contractual arrangements. Each of EDCTP and Contractor represents and warrants that it is not constrained by any existing agreement in performing its obligations under the Agreement.
- 9.2 For Trials, the Contractor represents and warrants nor currently being involved in any litigation, nor being aware of any pending litigation proceedings relating to its role in the conduct of a clinical trial, nor having received any warnings from the EMEA or other regulatory authority that deals with registration of pharmaceutical products.

Article 10: Liability and indemnifications

- 10.1 The Contractor shall have sole responsibility for complying with any legal obligations incumbent on him/her/it under the Agreement and cannot recoup consequences/losses resulting from these obligations on EDCTP, its members or the Financiers and their members or financiers.

- 10.2 The EDCTP takes in good faith any signed statement by the legal representative(s) of Contractor, its Subcontractor(s), its financial manager(s), and/or the Project Coordinator of the Project that the figures in the financial reports, including the co funding figures, forwarded to EDCTP, are accurate and complete. If a financial or technical audit as meant in article 7 reveals that those figures are actually incorrect, the Hosting Institution(s) in deficit and the Contractor agree that they shall be held jointly and severally liable for the deficit(s) assessed by the audit.
- 10.3 Contractor shall indemnify, defend and hold harmless EDCTP and the Financiers, including the directors, officers, employees, representatives and agents of EDCTP and the Financiers, from and against any and all claims, suits, losses, damages, costs, fees and expenses (including reasonable attorneys' fees), and other liabilities asserted by any third party, resulting from or arising out of any breach, violation or non-performance of this Agreement by Contractor, safe to the extent that such claims, suits, losses, damages, costs, fees and expenses (including reasonable attorneys' fees), and other liabilities asserted by any third party are due to the breach, violation or non-performance of this Agreement by EDCTP.
- 10.4 The Contractor shall not, in any circumstances or on any grounds, hold EDCTP, its members or the Financiers and their members or financiers liable in the event of any claim of any third party relating to any damage caused during the execution of the Agreement and not falling under paragraph 10.2, safe to the extent that such claim is due to the breach, violation or non-performance of this Agreement by EDCTP.
- 10.5 The indemnity of the paragraphs 10.2 and 10.3 shall not apply to the EDCTP, being the sole counterparty of Contractor (a) if EDCTP fails to give Contractor prompt written notification of any claim it receives and such failure materially infringes Contractors rights, and (b) unless Contractor is given the opportunity to approve any settlement. Furthermore, Contractor shall not be liable for attorneys' fees or expenses of litigation of EDCTP unless EDCTP gives Contractor the opportunity to assume control of the defense or settlement. In addition, if Contractor assumes such control, it shall only be responsible for the legal fees and litigation expenses of the attorneys it designates to assume control of the litigation unless the competent judge decides differently. In no event shall Contractor assume control of the defense of EDCTP without the consent of EDCTP (which consent shall be given or not at its sole discretion).
- 10.6 The Contractor shall obtain adequate Clinical Trials insurance coverage and up until the Clinical Trial has been completed, be able at any time to produce a proof of the insurance coverage.
- 10.7 EDCTP and the Financiers assume no responsibility or liability in respect of any losses or injuries sustained by any party who's travel is funded by an EDCTP-grant. The Contractor is expected to obtain adequate insurance coverage for these purposes.

Article 11: Force major

- 11.1 Subject to Force Major, the Contractor shall use reasonable endeavours to fulfil the results intended for the project. The Contractor shall use reasonable endeavours to fulfil obligations of a defaulting Subcontractor. The Contractor shall not be liable to take actions beyond its reasonable control or to reimburse money due to a defaulting Subcontractor unless he/she/it has contributed to the default. Measures to be taken in the event of Force Major shall be agreed between EDCTP and Contractor.



- 11.2 Contractor shall notify the EDCTP in writing of the reason of the delay or failure within five (5) working days of the due date.

Article 12: Termination of the agreement

- 12.1 Either Party may terminate the Agreement immediately by written notification to the other Party upon the occurrence of any of the following events:
- (i) If the defaulting Party commits a material breach of its obligations under the Agreement, and – if the breach is capable of remedy – fails to remedy the breach within thirty (30) days of being specifically required in writing to do so by the other Party; or
 - (ii) If any execution, sequestration or other similar process is levied or enforced upon or against the property of the defaulting Party which is not discharged within thirty (30) days, or a liquidator is appointed over the whole or any substantial part of the defaulting Party's undertaking, property or assets, or an order is made or a resolution is passed for the winding-up or analogous proceedings in any jurisdiction of the defaulting Party; or
 - (iii) That it becomes known to Parties that the Investigational Product is not safe to use or that the Project shall not achieve its objectives; or
 - (iv) EDCTP shall cease to receive funding, in which case the already paid upfront payments shall be the final payments for the Project.
- 12.2 In the event of termination by EDCTP the disbursement of EDCTP contribution shall be suspended and EDCTP shall decide, in view of the concrete facts and circumstances, which percentage of the amounts already transferred to Contractors pursuant to Article 3 of this Agreement Contractor(s) shall have to pay back to EDCTP and within which term(s).
- 12.3 Should the Contractor fail to execute this Agreement as intended, EDCTP may decide to exclude Contractor from future grant calls.

Contractor agrees that EDCTP may deploy the means of reimbursement and financial penalties in cases of overstated expenses, for example following regular audits, without necessarily involving the termination/exclusion of the Contractor.

Article 13: Required information

- 13.1 Any delay in receiving the signed clinical protocol and/or ethical clearance exceeding 3 months from the signing date of the Contract (the Effective Date), may prima facie result in EDCTP suspending or canceling the grant. If such delay is likely to occur, the Contractor must write to the Executive Director (ED) of EDCTP setting out the reasons for the delay and a time scale for the situation to be resolved.
- 13.2 Where the Project Coordinator signs (an) agreement(s) with the Subcontractor(s) which differ(s) in financial amount from the budget accepted by EDCTP in the signed contract, then a written explanation needs to be provided to the EDCTP Project Officer by the Project Coordinator. In case that explanation is not accepted, this may lead to a change in the approved Budget.



Article 14: Miscellaneous

No waiver and sever ability

14.1 Either Party's failure to require the other party to comply with any provision of the Agreement shall not be deemed a waiver of such provision or any other provision of the Agreement. In case any one or more of the provisions contained in the Agreement shall be held invalid in any respect, such invalidity shall not affect the other provisions of the Agreement, and the applicable provision shall be deemed to be construed in the spirit of the Agreement.

Ban on making profits

14.2 Contractor declares not to make any profit, now or in the future, from the receipt of the Grant.

Notifications

14.3 Notifications shall be deemed received:

- (i) immediately, in case delivered personally, or
- (ii) five (5) business days after sent if sent by recognized courier, as evidenced by such courier's written records, or
- (iii) on the date transmitted if sent via facsimile with confirmation of receipt, or
- (iv) within 7 (seven) days of posting if sent to the Parties at the addresses stated in the Agreement, or such other addresses as the Parties may designate in writing, or
- (v) send via internet where acknowledged as received by EDCTP.

Assignment

14.4 The Agreement and/or any rights or obligations hereunder shall not be assignable or transferred by Contractor without the prior written consent of EDCTP; any such attempted assignment shall deemed to be void.

Independent contractor

14.5 For the purpose of the Agreement each Party shall (deemed to) be an independent contractor and not an agent or employee of the other Party. Neither Party shall have authority to make any statements, representations or commitments of any kind, or to take any action, which shall be binding on the other Party. EDCTP shall not be responsible for the employment of any individual employed or otherwise engaged by Contractor. Neither Party shall be responsible for acts or omissions of individuals engaged by the other Party or for the health, safety and security of such individuals and their property. The foregoing takes exception in case Parties in writing explicitly agree differently.

Breach of General Terms/ Agreement

14.6 Any action or omission not in accordance with these terms and conditions set forth above is deemed to be null and void between Parties, unless the Agreement specifically provides for such act or omission. EDCTP is entitled to recover from Contractor any financial damage incurred by EDCTP pursuant of such non-compliant act or omission.

Modification of Agreement

14.7 Any modification to a signed Agreement concluded with EDCTP shall be made by an amendment signed by both of the Parties.