Grant Agreement Preparation in EDCTP2 projects
Content

1. Overview:
   a) The EDCTP
   b) The project lifecycle
   c) Grant Agreement Preparation

2. The Agreements:
   a) The Grant Agreement
   b) The Consortium Agreement

3. “Who is who & what to do” in the GAP process:
   a) EDCTP, Coordinator, Partners
   b) The process step-by-step
   c) Helpful advice
EDCTP2 Background and Mission

Background

• Established in 2003 by a co-decision of the European Parliament and Council under Article 185 Initiative (Ex 169)
  • Pool research, activities to achieve greater impact against poverty-related diseases (PRDs)
  • Promote integrated approach to health research in Europe
• Contribute to the achievement of MDGs and global health crises caused by Poverty-Related Diseases (PRDs)
  • No economic incentive for private investment in PRDs
  • Public investment is sparse and fragmented

Mission

• To reduce poverty in sub-Saharan Africa through improved health by funding collaborative research to accelerate the development of new or improved medical interventions against poverty-related and neglected infectious diseases (PRNIDs).

EDCTP1: completed in December 2015
EDCTP2: will run from 2014-2024

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EDCTP2 Objectives

1. Support collaborative research in sub-Saharan Africa to accelerate the clinical development of medical interventions for poverty-related and neglected infectious diseases.

2. Support international alignment of national research agendas for poverty-related and neglected infectious diseases.

3. Seek the advice, support and collaboration of many stakeholders.

4. Offer a single European-African platform for research cooperation and funding.

5. Promote African co-ownership of the EDCTP programme and the development of scientific leadership.

6. Support capacity for conducting research in sub-Saharan Africa compliant with regulatory standards.
EDCTP Association

EDCTP2 Participating States (PSs)

14 European Countries
Austria, Denmark, Finland, France, Germany, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden and United Kingdom

14 African Countries

1 Aspirant Member
Switzerland

Countries that can receive funding
- All sub-Saharan African countries
- All EU MSs and Associated Countries to H2020
What EDCTP2 funds

Registration of a new Medicinal Product (MP)

New indications or formulation of a marketed MP

Therapeutic use

Discovery & Pre-clinical research

Phase I

Phase II

Phase III

Phase IV

Implementation research

Clinical studies

Safety and or efficacy of investigational medicinal product

product formulation, dosing recommendations

Biomarkers, Pharmacogenomics

Clinical trial on specific populations

Low interventional trial

Pragmatic trial

Comparing medical intervention strategies

Effectiveness

Product focused implementation research

Registration of a new Medicinal Product (MP)

Low interventional trial

Clinical trial on specific populations

Pragmatic trial

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Effectiveness

Product focused implementation research

Discovery & Pre-clinical research

Phase I

Phase II

Phase III

Phase IV

Implementation research
What EDCTP2 funds

- **Diseases:** HIV/AIDS, TB, Malaria, NIDs, emerging infectious diseases of particular relevance for Africa (incl. Ebola), diarrhoeal diseases, lower respiratory tract infections
- **Results:** New tools and interventions (diagnostics, drugs, vaccines and microbicides)
- **Capacity Development:** Fellowships, Networks, Ethics, Regulatory
Project Types

Research and Innovation Actions (RIA) incl. Strategic actions supporting large-scale clinical trials
- Primarily clinical research and clinical trials
- Phase I to IV trials
- Additional activities such as sub-studies, networking, capacity development, etc.

Coordination & Support Actions (CSA)
- Accompanying measures such as
  a. Strengthening research capacities in sub-Saharan Africa
  b. Promoting networking and collaboration
  c. Fostering cooperation between public and private funders

Activities may comprise: dissemination, awareness-raising, communication, networking, support services, policy dialogues, mutual learning exercises, strategic planning, etc.
Project Types

Training and Mobility Actions (TMA)

- Fostering career development of sub-Saharan African fellows
- Training and mentorship of researchers
- Promoting mobility of individual researchers and research staff
Calls for proposals in EDCTP2

- Annual Work Plan: Outline of calls and timetable
- Priority setting through thematic stakeholder meetings; SAC; other
- Approval by EC and EDCTP General Assembly

- Calls for proposals (published on www.EDCTP.org)
- Submission (electronic submission)
- Evaluation by independent experts and selection for funding

Managed by EDCTP Secretariat, mainly according to H2020 rules
EDCTP Project Lifecycle

- Call deadline
- Award decision
- Grant signature
- Contractual end date

- Evaluation + Ethics review
- Grant Preparation and Negotiation
- Grant implementation
- Final report and exploitation plan

- Periodic report
Grant Agreements in EDCTP2

<table>
<thead>
<tr>
<th>Type of activities</th>
<th>1 participant</th>
<th>&gt;1 participant</th>
</tr>
</thead>
<tbody>
<tr>
<td>RIA</td>
<td>N/A (minimum 3 participants)</td>
<td>Multi-partner Grant Agreement</td>
</tr>
<tr>
<td>TMA</td>
<td>Mono-partner Grant Agreement (TMA)</td>
<td>N/A</td>
</tr>
<tr>
<td>CSA</td>
<td>Mono-partner Grant Agreement</td>
<td>Multi-partner Grant Agreement</td>
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</tbody>
</table>

EDCTP2 uses the same model grant agreements as H2020
All grant agreements are variations of the same Model Grant Agreement
The Grant Agreement (GA) defines the relation between the EDCTP and the Coordinator / the Consortium.
Grant Agreement: Overall Structure

1. CORE GRANT AGREEMENT
2. ANNEX 1: Technical Description of Activities (DoA)
3. ANNEX 2: Budget Table
4. ANNEX 3: Accession Form
5. ANNEX 4: Model for the financial statements
6. ANNEX 5: Model for the certificate on the financial statements
7. ANNEX 6: Model for the certificate on the methodology
EDCTP Grant Agreement

- Grant Agreement is concluded between EDCTP and institutions (not individuals)
- Grant Agreement is signed by the authorized legal representatives
- All partners in the consortium must accede to/sign the Grant Agreement
- Grant "belongs" to the institution with rights and obligations
Core Grant Agreement

- The **Core Grant Agreement** contains all essential project details (title, consortium members, amount of pre-financing, maximum funding, etc.) as well as all rights and obligations of the EDCTP and the beneficiaries (including all financial rules and regulations).
Description of the Action and Budget

- The Description of the Action (DoA) is **Annex I** to the Grant Agreement. It contains the implementation details: work packages, deliverables, milestones – and a detailed narrative description of the work.
Description of the Action and Budget

- The budget Table is **Annex II** to the Grant Agreement
Project Structure

**Coordinator**

- Monitors project implementation
- Acts as focal point for EDCTP communication
- Collects and submits reporting to EDCTP
- Receives and distributes EDCTP funding

**Partners**

- Notify of any changes in name, address, legal representative, ownership etc.
- Events that affect/delay project
- Timely submit financial and technical reports, ethics and clinical trials approvals and other relevant documentation

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Project Consortium

- The Coordinator is the main (only) point of contact between the EDCTP and the consortium
- Principles of equal partnership and consensus decisions
The Consortium Agreement (CA)

regulates the relation between consortium partners (= beneficiaries)
Consortium Agreement

- **Consortium Agreement** is mandatory in EDCTP projects for multi-beneficiary actions!
- Consortium Agreement is building on GA as a legal basis
- Should be negotiated and concluded **before signing the GA**

- Aspects to be addressed:
  - Management and decision making; Ownership of results; Settlement of disputes; Reporting obligations and timelines; Sharing of costs; Distribution of EDCTP funds between partners, etc.
DESCA – an established CA model

- Development of a Simplified Consortium Agreement
- European Initiative by key FP actors, co-developed by the FP community
- www.desca-2020.eu
Grant Agreement & Consortium Agreement

Why do we need another agreement if we already have the GA?

- The GA is largely a standard agreement and sets the main frame;
- The CA regulates all project specific aspects in detail, incl. IP management;
- The CA is in no way allowed to contradict the Grant Agreement; the latter always takes precedence!
- The CA makes project management (decision making) quicker and easier;
- In case of conflict, the CA provides clear guidance.
Time to Grant

Two primary time limits for EDCTP grants:

- maximum of 8 months between call deadline and grant signature
- maximum of 5 months to inform applicants of the outcome of the scientific evaluation (i.e. evaluation by the experts)

The period for preparing and signing grants may exceed 3 months as long as the overall time-to-grant remains a maximum of 8 months (i.e., time saved during the evaluation may be used for grant preparation).
Grant Agreement Preparation

Call deadline → Evaluation report ready → Info to beneficiaries: ESR (+ Invitation) → Grant signature

8 months max

Grant preparation:
- Interaction with beneficiaries
- Declarations of Honour
- Internal approval

Accession forms
Consortium Agreement
Pre-financing

Evaluation + Ethics review → Award decision

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First step: Declaration of Honour

- to be signed by all project partners
Second step: Legal Entity Form

- to be stamped and signed by all partners
- must be submitted to EDCTP
Coordinator: Financial Management Assessment Questionnaire

- to be submitted to EDCTP

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**Financial Management Assessment Questionnaire for Coordinators (FMAQC)**

1. **Introduction**
   - The questionnaire is divided into five areas:
     1. Organisation of the finance department
     2. Accounting system
     3. Time recording system (Timesheets)
     4. Fixed asset register
     5. Experience of managing donor funded projects
   - The purpose of this questionnaire is to assist EDCTP Grant Finance Officers and Grant Finance Assistants to form an informed opinion of new coordinating sites' internal financial control systems with the objectives of:
     - Deciding whether the control environment is strong enough for EDCTP funds to be paid into an existing bank account of the coordinating site (pushed bank account), an account into which funds from EDCTP and those from other donors may be paid into, or to request the coordinating site to open a new bank account (EDCTP designated project bank account), an account into which only funds for the particular EDCTP project under consideration may be paid into.
     - Getting an overview of the financial management systems and procedures, and to identify areas where improvements are required.

2. **Organisation**
   - 2.1. Is there a designated person within the finance department that will be responsible for preparing the financial reports for the project?
   - 2.2. Is the staff of the finance department adequately trained to handle the tasks that will be responsible for the financial management of this project?

3. **Accounting system**
   - 3.1. Do you have an accounting procedures manual? If yes, when was it last updated? Please send a copy of this manual.
   - 3.2. Is your accounting system computerised? If yes, please provide the name of the software and the date it was implemented. If yes, what financial records do you maintain to record financial transactions?
   - 3.3. If your accounting system is computerised, how regularly is it backed-up? Who is responsible for taking backups and the frequency?
   - 3.4. Is each project assigned a unique code?
   - 3.5. What controls/audits are in place to prevent corruption of costs by project?
   - 3.6. How do you ensure the budget of a project is not exceeded?

4. **Time recording system (Timesheets)**
   - 4.1. Do you have a reliable time recording system? If yes, is it paper or computer based? If it is a paper based, please send samples of your timesheets. If a computerised, please send a sample of a timesheet generated from the system. For at least one employee, preferably one who works on different projects.
   - 4.2. Has your site ever managed a grant that requires timesheets to be prepared regularly? If so, are you confident that the independent auditor can make any observations regarding the reliability of your time recording system?

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**5 Fixed asset register**

- Do you maintain a fixed asset register? If yes, is it sufficiently detailed to allow easy identification of fixed assets, particularly by funding source?

**6 Bank accounts**

- 6.1. How many bank accounts are currently maintained in your institution? Please provide a list of the bank accounts, showing the name of the bank, where each account is located, name of the account, type of account, interest or non-interest bearing, and the current balance. Include any sub-accounts.
- 6.2. What is the bank account signature? Where are your signature lines required for each bank transaction? Please provide a list of bank account signatures and their designation within the institution.
- 6.3. Do you regularly prepare monthly bank reconciliation statements? If yes, please provide the name and position of the preparer and reviewer.
- 6.4. How long does it take your institution to open a foreign currency bank account in the country?

**7 Experience of managing donor funded projects**

- 7.1. Do you currently manage any donor funded projects? If yes, please provide a list of these projects including the name of the funding agencies.
- 7.2. Has any of the projects managed by your site been recently audited? If yes, please provide a copy of the audit report and management letter.
- 7.3. Has your site ever been reviewed? If yes, please provide a copy of the review report and the management letter.
Coordinator: Ethics self assessment template

- narrative part + ethics tables
- guidance notes are provided
Grant Preparation TO DOs

- **Transfer** information from the proposal into the grant agreement
- **Ensure** consistency between proposal and grant agreement
- **Collect** additional information not present in the proposal (e.g. legal representatives, budget details, third parties)
- **Implement** any requirements from the expert evaluators, ethics review or security scrutiny
- **Ensure** proper implementation of legal provisions, including financial viability check if needed
Changes to be implemented

Successful proposals are expected to be **mature and ready** to be implemented.

No substantial changes are allowed between the proposal and the project. **NO NEGO approach!**

**Optional** changes:
- Obvious errors or inconsistencies may be removed
- Coordinator may correct minor shortcomings identified by the experts during evaluation

**Necessary** changes:
- Ethics review or security scrutiny
- Removal or replacement of a participant (if agreed with EDCTP)
- **Major** shortcomings identified by the expert evaluators or the EDCTP secretariat during evaluation or grant preparation
Examples of changes

- Adjustment of number of deliverables (depending on project, but normally <20)
- Periodic reports removed from list of deliverables
- Correct description of subcontracts in the right section (4.2)
- Addition of mandatory website deliverable (with basic structure available soon, final version max. 6 months after project start)
- Clarification on adequate management structure and decision making process to secure implementation
- Check of realistic timelines
Examples of changes

- Sufficient contingency plans in place?
- Adequate plans for open access and data sharing
- Adequate plans for exploitation and uptake of results
- Synergies with other (EDCTP)-projects: Joint meetings, SAB members etc.

Changes to be made by the Coordinator in the electronic system (EDCTPgrants)

→ **BUT** at the moment process is still based on exchange of Excel/Word files with EDCTP! You will be guided by your EDCTP Project Officer in charge.
Ethics Review and Security Scrutiny

The **results of the ethics review** and/or a **security scrutiny must be implemented** in the grant agreement

- Coordinator needs to update the ethics section in Anney I(DoA) to ensure that any 'ethics requirements' are met
- There may be 'ethics requirements' that need to be met before the grant can be signed
- The same applies for security scrutiny
Budget Table

- Currently: Excel file with budget summary and individual site budgets
- Individual budget items might need to be adjusted during Grant Preparation (e.g. remove tuition fees, add audit costs, etc.)
- Plan: Budget to be managed electronically in the future via EDCTPgrants system
Formal data and further information

- Authorized legal representative: proof needed
  - at the moment either through
    - screenshot of corresponding role (LSign) in H2020 Research Participant Portal or
    - legal documents (e.g. university constitution)

- Additional information needed:
  Address of legal entity
  Type of organization
  Registration number in country of origin
  VAT number

CV information of scientists involved must be up-to-date and complete (EDCTPgrants system)
Timing for Grant Agreement Data

**Invitation to grant preparation**

- 3 weeks
  - consortium
  - Submit data

**Grant signature**

- ~1-3 weeks
  - PO
  - remaining issues (if any)

- 3 weeks
  - consortium
  - submit GA data (final)

38

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Grant Agreement signature process

- The GA is sent (by e-mail) to the Coordinator for signature by the legal representative.
- The GA is returned to EDCTP for counter-signing: the GA enters into force. **Project starts on first day of following month.**
- All Partners must sign the Accession Form within 30 days. The Coordinator must collect the Accession Forms and submit them to EDCTP.
- If one (or more) partners do not sign the Accession Form Coordinator must propose an alternative and submit an amendment request within 30 days.
Some helpful advice

- Coordinators: Get in touch with EDCTP Project Officer in charge right away! Frequent and open communication is a benefit.
- Keep deadlines set by EDCTP! If there are delays, inform your Project Officer!
- If something is unclear – ask.
Some helpful advice

- Start early with preparation of Consortium Agreement; use an established Model Agreement
- Coordinators: Collect bank details from project partners as you must forward the EDCTP payment to them
- Coordinators: Prepare a ‘payment table’ indicating how much pre-financing each partner will receive
- Payments can only be forwarded to partners once they have signed the Accession Forms
Some helpful advice

- Don’t be scared: the rules laid out in the GA & CA are relevant and helpful for your project; they provide a safe framework for project implementation.
- Familiarize yourself with the Programme rules (GA and Financial Guidelines) NOW.
- GA and CA are complementary agreements: Consistency should be ensured; redundancy should be avoided.
- Do not hesitate to seek support!
Further information

European IPR helpdesk:
https://www.iprhelpdesk.eu/

Fit for Health 2.0:
http://www.fitforhealth.eu/
(including answers to questions asked today, and future webinar on EDCTP2 project implementation and management)

Proposal submission tool:
https://www.edctpgrants.org/

Current calls:
http://www.edctp.org/funding-opportunities/calls/
Thank you!

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