

EDCTP Association

Practical implementation of article 185 initiatives

Presentation to H2020 Legal and Financial NCPs: 1 July 2016



E D C T P

European & Developing Countries
Clinical Trials Partnership

About EDCTP

The European & Developing Countries Clinical Trials Partnership (EDCTP) is a public-public partnership between countries in Europe and sub-Saharan Africa, and the European Union.

Background

- Established in 2003 by a co-decision of the European Parliament and Council: Article 185 Initiative (Ex 169)
 - Pool research, activities to achieve greater impact against PRDs
 - Promote integrated approach to health research in Europe
- In response to MDGs and global health crises caused by PRDs
 - No economic incentive for private investments in PRDs
 - Public investments sparse and know-how fragmented
- First EDCTP programme (EDCTP1): 2003-2015
- Second EDCTP programme (EDCTP2): 2014-2024

EDCTP2 partnership

14 European Countries

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

1 Aspirant Member

Switzerland

14 African Countries

Burkina Faso, Cameroon, Rep of Congo, Gabon, Ghana, Mali, Mozambique, Niger, Senegal, South Africa, Tanzania, The Gambia, Uganda, Zambia



EDCTP Governance

General Assembly
1 Member from each
Participating State
(EC, AU and WHO as Observers)



Board
(5 Members, SAC Chair & EC as
Observer)



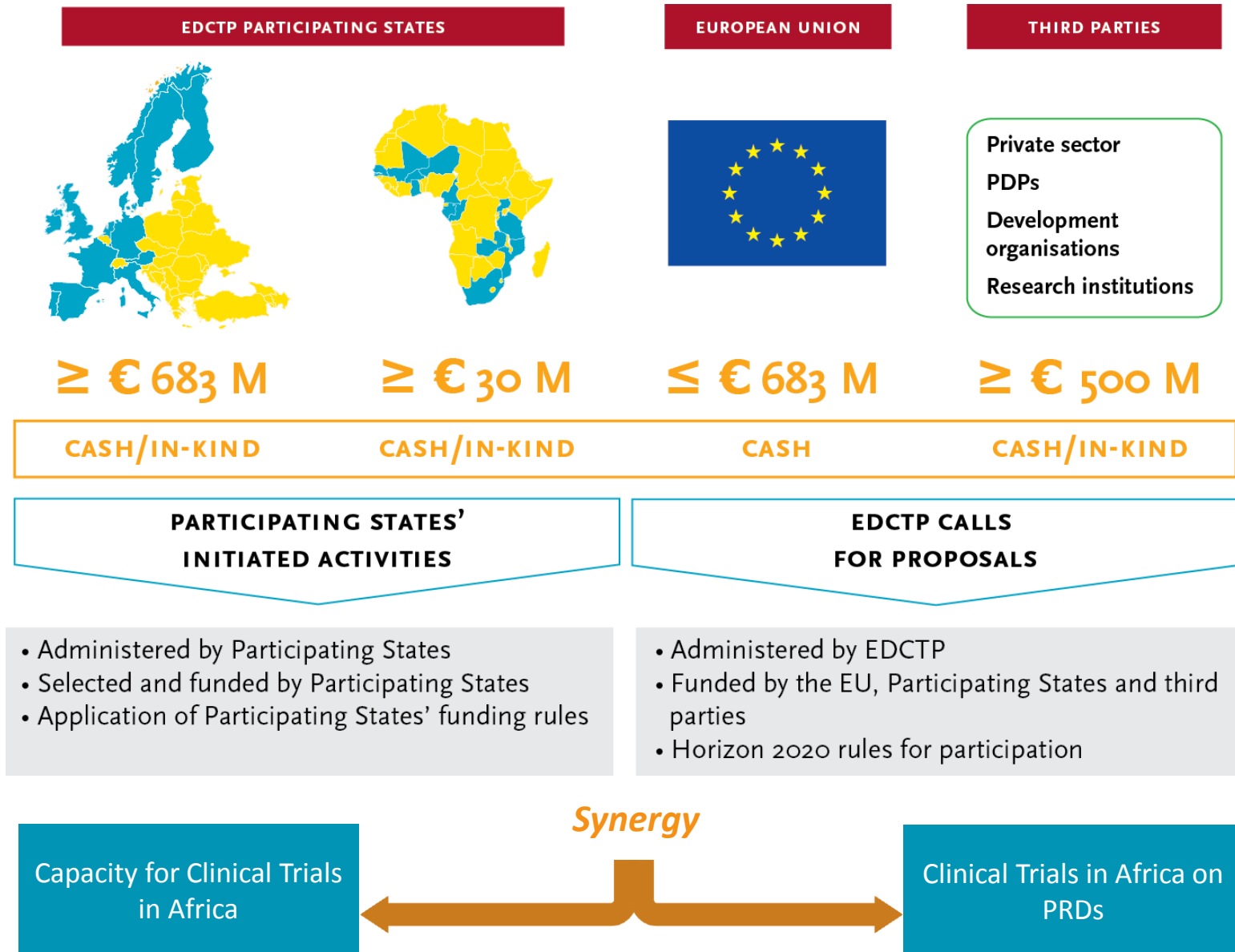
EDCTP Secretariat
The Hague, Netherlands
Cape Town, South Africa

advice
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**Scientific Advisory
Committee (SAC)**
(16 Members)

- Public-public partnership between 28 sovereign states
- Owned by the PSs
- Minimum annual contribution of € 200,000 (cash and/or in-kind)
- Operates as an independent legal entity
 - Association under Dutch private law as a non-profit organisation

The EDCTP2 programme



Countries that can receive funding

- All sub-Saharan African countries
- All EU MSs and Associated Countries

Article 185 under H2020

- Programme undertaken by several Member States in accordance
- Union participation is justified by the scope of the objectives pursued and the scale of the resources required
- There is a high level of commitment of the participating countries to integration at scientific, management and financial levels
- Proposals for such initiatives shall be identified on the basis of all of the following criteria:
 - ✓ A clear definition of the objective to be pursued and its relevance to the objectives of Horizon 2020 and broader Union policy objectives;
 - ✓ Indicative financial commitments of the participating countries, in cash or in kind, including prior commitments to align national and/or regional investments for transnational research and innovation and, where appropriate, to pool resources;
 - ✓ The added value of the action at Union level;
 - ✓ The critical mass, with regard to the size and the number of programmes involved, the similarity or complementarity of activities and the share of relevant research they cover; and
 - ✓ The appropriateness of Article 185 for achieving the objectives

Financial Guarantees

- EDCTP is categorised as a body governed by private law with a public service mission
- In accordance with Article 58(1)(c)(vi) of FR, EDCTP has to provide adequate financial guarantees.

Delegation Agreement

- Delegation Agreement was signed in December 2014 between the European Union, represented by the European Commission, and the EDCTP Association entrusting budget implementation tasks to the EDCTP Association under Decision 556/2014/EU of the European Parliament and of the Council of 15 May 2014
- By signing this Agreement, the EDCTP Association accepts the delegation of budget implementation tasks and agrees to carry out, under its own responsibility, the entrusted tasks in accordance with the Delegation Agreement and the Transfer of Funds Agreements.
- The EDCTP Association shall award grants in compliance with the Rules for Participation and the Decision 556/2014/EU of the European Parliament and of the Council of 15 May 2014.
- The EDCTP Association must use the Model Grant Agreements for Article 185 initiatives established by the Commission

Ex ante assessment

- An ex ante assessment was carried out by Moore Stephens LLP before the signature of the Delegation Agreement to obtain evidence that the requirements set out in Financial Regulation 60 (Indirect Management) are being fulfilled by the EDCTP Association . These include:
- Set up and ensure the functioning of an effective and efficient internal control system;
- Use an accounting system that provides accurate, complete and reliable information in a timely manner;
- Be subject to an independent external audit, performed in accordance with internationally accepted auditing standards by an audit service functionally independent of the entity or person concerned;
- Apply appropriate rules and procedures for providing financing from Union funds through grants, procurement and financial instruments;
- Ensure, in accordance with Article 35(2), the ex post publication of information on recipients; 91
- Ensure a reasonable protection of personal data, as laid down in Directive 95/46/EC and Regulation (EC) No 45/2001.

Objective of the ex-ante Assessment and the pillars assessed

The objective of the Ex ante Assessment was to provide reasonable assurance to the European Commission as to whether the Entity is ready to carry out the budget implementation tasks in the indirect management mode in accordance with Article 60 of the Regulation No 966/2012 of the European Parliament and of the Council on the financial rules applicable to the general budget of the Union and the provisions of the Decision on the participation of the Union in a second European and Developing Countries Clinical Trials Partnership Programme (EDCTP2) jointly undertaken by several Member States with regard to the following Pillars:

- Internal Control System
 - Accounting System
 - Independent External Audit
 - Grants/Prizes
 - Procurement
-

Cash flow forecast and Transfer Fund Agreement

- The Commission prepares a Transfer Fund Agreement (TFA) for each annual work plan, which sets out the proposed amounts and dates of the payments to be made by the Commission to the EDCTP for the implementation of the entrusted tasks.
- Each year shortly before or immediately after the approval of the annual work plan, EDCTP sends to the EC, through the EDCTP finance focal point at EC, the cash flow forecast of the European Union (EU) planned contributions for the implementation of the tasks set out in the relevant work plan. Information required for the preparation of the cash flow forecast are:
 - ✓ The call types
 - ✓ EC planned contributions (budget) for each call type
 - ✓ Estimated duration for each call type
 - ✓ Expected contract signature date

Derogations from Article 185 Model Grant Agreement

- Payments via the coordinator / Payments directly to beneficiaries
- Pre-financing guarantee
- Flexibility on the limit of the amount due as interim payment(s)

Payments via the coordinator / Payments directly to beneficiaries (Article 21 of MGA)

The decision to pay directly to a beneficiary instead of a coordinator is taken by EDCTP after consideration of many factors, including inherent risk assessment, the ability of the coordinator to effectively manage disbursements to the collaborating sites, and the risk of exchange losses, which is usually the case in countries where the opening of euro account is not permitted or extremely difficult.

Pre-financing guarantee

A pre-financing guarantee may be required by the EDCTP Association, if it considers it necessary (i.e. appropriate and proportionate), to limit the financial risks connected with the payment of pre-financing:

The pre-financial guarantee must fulfil the following conditions:

- It is provided by a bank or an approved financial institution or — if requested by the coordinator and accepted by the EDCTP Association — by a third party;
- The guarantor stands as first-call guarantor and does not require the EDCTP Association to first have recourse against the principal debtor (i.e. the beneficiary concerned), and
- It explicitly remains in force until the payment of the balance and, if payment of the balance takes the form of recovery, until three months after the debit note is notified to a beneficiary.

Flexibility on the limit of the amount due as interim payment(s)

- The total amount of pre-financing and interim payments will not exceed 90 percent of the maximum grant amount minus pre-financing and previous interim payment(s). In exceptional cases where EDCTP agrees that withholding 10% may undermine the successful completion of the project. This is usually the case for sites with no core funding. The decision to reduce the withheld amount to below 10% must be based on a financial and technical risk assessment by EDCTP.

EDCTP beneficiaries' audit findings

- Absences of fixed asset register or fixed asset registers that are not sufficiently detailed
- Non preparation of timesheets
- Poor budgetary control systems
- Limited knowledge of EDCTP financial guidelines
- Distinction between subcontracting and purchases of goods and services not clearly understood by some of the beneficiaries
- Incurring expenditure without adequate supporting documentation

Measures introduced by EDCTP

- Internal audit of beneficiaries
- Site visits
- Due diligence checks prior to grant signature
- Effective follow-up of management letter points
- User-friendly financial guidelines

Internal audit of beneficiaries

As part of the strategy to improve the quality of the financial reports submitted by grantees and to form an informed view of the general effectiveness of the grantees' internal control system, EDCTP has signed an MOU with PWC Netherlands to conduct internal audits of EDCTP-funded projects. In selecting beneficiaries for PWC to visit, more weighting is given to projects with:

- Projected expenditures greater than €325,000
 - An end date not within the next 12 months
 - Many Grant Finance Officer observations in previous financial reports
 - More than one EDCTP funded project
 - Previous unfavourable site visit reports
 - High staff turnover in the finance department
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Site visits

EDCTP operation and finance teams conduct site visits to selected EDCTP-funded projects to perform technical and financial assessments, including reviewing the internal controls over procurement. These include reviewing the following:

- Bank reconciliation statements to ensure that bank reconciliations are performed and reviewed on a regular basis
- Financial transaction documents
- Fixed asset registers
- Time sheets
- Payroll reports
- Extent of compliance with EDCTP financial guidelines
- Overall financial and internal control systems

Due diligence checks prior to grant signature

All new coordinators of EDCTP grants must complete a due diligence review questionnaire called Financial Management Assessment Questionnaire for Coordinators (FMAQC), which is used to assess the strength of all new coordinators' internal financial control environment. This questionnaire is divided into four sections: organisation of the finance department; accounting system; bank accounts; and experience of managing donor projects. The information obtained via due diligence is used to help EDCTP Grant Finance Officers (GFO) to take decisions such as which type of bank account – pooled or designated- the new site will be allowed to operate for the project.

Effective follow-up of management letter points

- The EDCTP Grant Finance Officers (GFOs) write to all the sites with a qualified report requesting them to report on the actions taken or planned in respect of the observations and recommendation raised in the external auditors' management reports. Net financial impacts resulting from unresolved observations are treated as ineligible expenditure and are accordingly deducted from actual expenditure in the final financial report
- GFOs regularly follow up on the action plans relating to all significant external audit findings detailed in the management letter and any issues that gave rise to the qualification of audit reports
- Following each site visit, letters are sent to the Project Coordinators (PC) of the sites visited informing them of the findings of the EDCTP team during their visit with recommendations and suggested action points. Similarly, in each site visit report, EDCTP action points are listed. EDCTP GFOs and Project Officers not only ensure the implementation of the EDCTP action points, but seek response from grantees to the recommendations made in the site visit report.

User-friendly financial guidelines

Financial guidelines have been prepared to supplement the GA by providing an explanation of the accounting policies, financial reporting and budgeting requirements. However, in the event a conflict arises between these guidelines and the Grant Agreement (GA), the GA takes precedence. The main objectives of preparing the financial guidelines are:

- To provide a quick reference and easy to follow guide to beneficiaries of EDCTP funding
- To act as a reference document for external auditors and other stakeholders in carrying out financial audits or other reviews of EDCTP funded projects
- To ensure consistency in the financial management of EDCTP grants.

Comparison of H2020 and EDCTP2

	SC1, H2020	EDCTP2
Programme planning and publication of calls	Work programme + participant portal	Work plan (indicative) + EDCTP website
Rules for participation	H2020	H2020 with derogation
Funding instruments (project types)	RIA, CSA, TMA	RIA, CSA, TMA
Minimum participants (RIA)	3 MS/AC	2 PS + 1 SSA
Indirect costs (overhead rate)	25%	25%
Who can participate?	Almost all	Almost all
Who can receive funding?	Most, except OECD and BRIC	Only EU/AC + SSA
Electronic proposal submission	Participant portal	EDCTPgrants
Model grant agreement	H2020	Modified H2020

EDCTP Some of the differences between EDCTP 1 (FP6) and EDCTP2 (H2020)

	FP6	H2020
Budget	JPB – 18 months cash flow projection	Annual work plans
Reporting	Interim technical report	Progress report
Transfer Fund Agreement	N/A	Prepared for each work plan
Subcontracting	Must be described in Annex 1	Must be described in Annex 1 or are specifically justified in the periodic technical report
VAT	Only African VAT was allowed	VAT unrecoverable is allowed
Budget negotiation	More intensive	Limited budget negotiation – virtually none existent
Grant Agreement	N/A	must use the Model Grant Agreements for Article 185 initiatives
Accounting system	Must be capable of generating reports at expenditure category level	The accounting system, in addition to generating reports at expenditure category level, must be capable of generating expenditure by work plan.

Pooled vs Designated bank account

EDCTP designated project account

- This is the preferred option since the bank statements will effectively show all the receipts and payments of the project. Having a project-specific bank account will not only make the preparation of the periodic financial reports easier, but it will also reduce the time that will be spent by auditors in their audit work
- The name of the account should include the name of EDCTP and the project title or acronym

Pooled bank account

- EDCTP will only pay funds into a pooled account if the following conditions are fulfilled:
- The beneficiary has a sound financial management system with a chart of accounts structure that allows the generation of financial reports by project and type of expenditure
- The beneficiary has extensive experience in managing multi-donor projects.

Process for Launching Calls for Proposals

Annual work plan with call topics

Priority setting through a bottom up approach

Thematic stakeholder meetings / SAC / commissioned studies

Internal review > review by SAC > approval by GA > review by external international peer review committee > approval by EC > adoption by GA

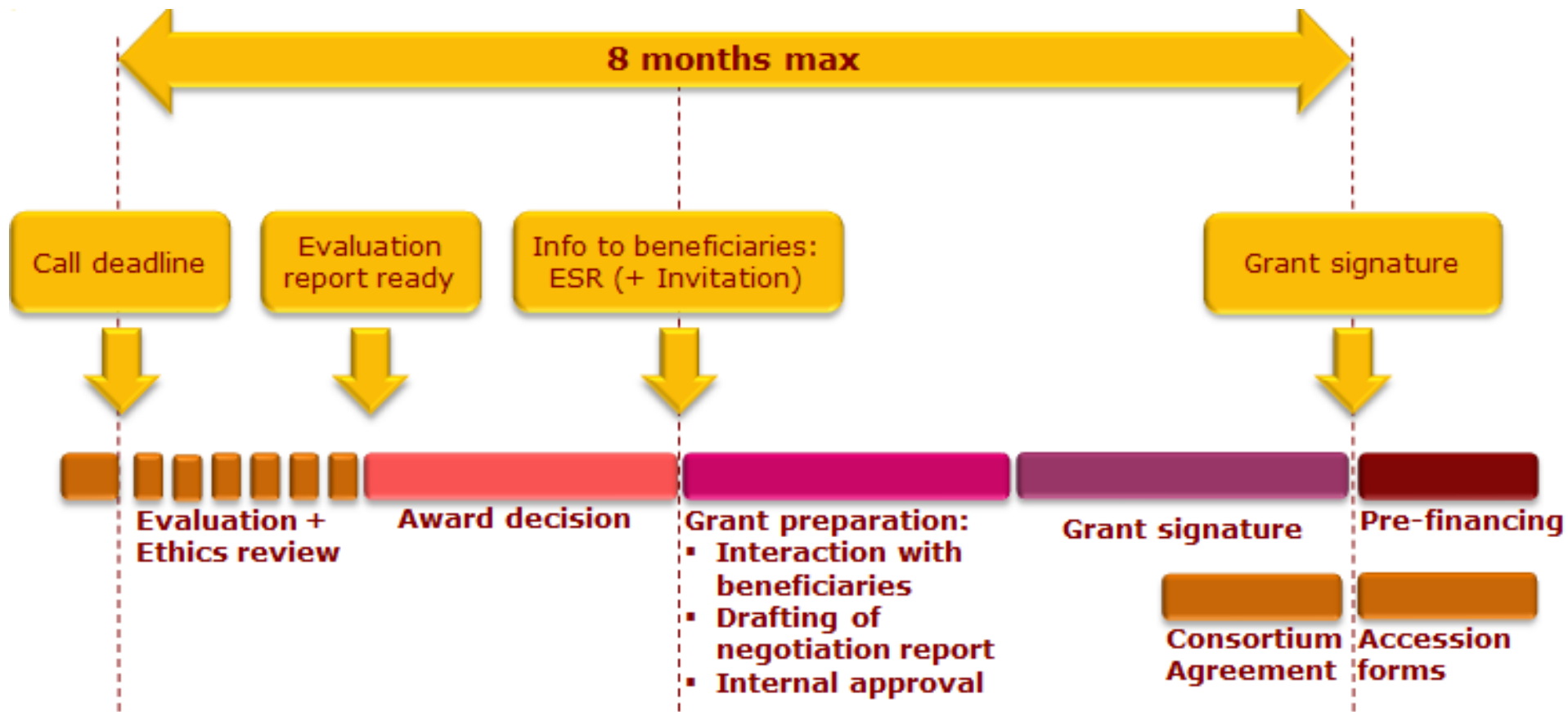
2015 WP approved – 2016 WP under review

Calls for Proposals



EDCTP Secretariat selects, funds, and manages according to Horizon2020 rules

Grant Application Process



Evaluation Criteria: For All EDCTP Actions

EXCELLENCE

- Fit with the scope and objectives of the EDCTP2 programme and the call topic description
- Importance, relevance/pertinence and clarity of the objectives
- Soundness of the concept and credibility of the proposed approach/methodology

IMPACT

- The expected impacts listed in the work plan under the relevant topic
- Likelihood to result in major advances for the field

IMPLEMENTATION

- Quality and effectiveness of the work plan; appropriateness of the management structures and procedures
- Complementarity of the participants within the consortium, and the extent to which the consortium as whole brings together the necessary expertise
- Appropriateness of the allocation of tasks and resources
- Feasibility and appropriateness of the methods and project management to achieve the objectives within the timeframe of the grant
- Compliance with national and international standards of research, GCP, ethics and safety related issues
- Operational capacity to carry out the proposed work

Evaluation Procedure

- EDCTP appoints independent experts to conduct the technical evaluation of submitted proposals and make funding recommendations to EDCTP
 - Experts are external to EDCTP and, in performing their evaluation(s), are working in a personal capacity rather than as a representative of any organisation or scientific community
- In parallel, or immediately following evaluation, proposals will be reviewed by independent ethics experts to check that they comply with ethical principles and relevant national, EU and international legislation



Thank you!
Any questions

