



**EDCTP**

European & Developing Countries  
Clinical Trials Partnership

## **Frequently asked questions (FAQs)**

### **Strategic actions supporting large-scale clinical trials**

Disclaimer: The FAQs are for information only and do not constitute a legally binding document. The legal basis for information in the FAQs can be found in the Horizon 2020 Rules for Participation and the EDCTP Annual Work Plans

For more information, please go to the EDCTP website: [www.edctp.org](http://www.edctp.org)

EDCTP is supported under  
Horizon 2020, the European Union's Framework  
Programme for Research and Innovation.



## **Purpose of the FAQs**

These FAQs provide guidance for applicants to the EDCTP2 Call for Proposals '*Strategic actions supporting large-scale clinical trials*' to supplement the information provided in the *call text* and call documents. The FAQs will be regularly updated in response to questions received from applicants to the call. Please also refer to the [EDCTP2 general FAQs](#).

## **Rules for participation and funding**

**Q: Does 'in-kind' funding count as cofunding? For instance, if local staff, who are already salaried, do not claim any salary on a research application, would that count as cofunding?**

**A:** Yes, in-kind contributions can be accounted as cofunding contributions. These should be detailed clearly in the proposal and be specific to the activity. Proposals that leverage major support from other funders, in particular financial contributions, at the level of the large-scale clinical trial will be considered to have a higher impact.

**Q: For this call, is the following statement '*at least half of the costs of the large-scale clinical trial should be supported by other funders*' a strict requirement of a minimum of 50% cofunding?**

**A:** There is a strict requirement of financial support from funders other than the EDCTP Association for the call '*Strategic actions supporting large-scale clinical trials*', which ideally should cover half of the cost of the large-scale clinical trial.

**Q: The minimum 50% cofunding level requested by the call is calculated only on direct costs or on direct costs plus overheads**

**A:** The requested minimum 50% cofunding is based on the total cost of the study; and the overheads rate would be the one stipulated by the other funder(s). So, to illustrate this with an example, if you apply for an EDCTP contribution of €5 million, you are expected to match this contribution with at least of €5 million cofunding (an amount which can include direct costs and overheads, with different overhead rate depending on the cofunding source).

**Q: Does EDCTP have any guidance on the reporting requirements for the 25% fixed indirect cost?**

**A:** There is no requirement to report on the 25% indirect costs. Only direct costs must be reported.

**Q: Is the 25% overheads rate applied automatically to the participants requesting EDCTP contribution or to the total requested contribution for the project?**

**A:** The rate of 25% overheads is only applicable to the amount requested to EDCTP (not to the overall cost of the entire project).

**Q: Are we eligible for the call, even though, for the moment, we are not supported by other funders for the cost of the clinical trial?**

**A:** For this grant scheme, cofunding is taken into consideration as part of the evaluation but 50% cofunding is not an eligibility criterion. This means that reviewers will take into account the cofunding '*provision*' (in your proposal) into the evaluation. This call is a two-stage evaluation process, and at the 'letter of intent (LoI)', it is expected that the applicant shows evidence that there are other sources/funders which will financially contribute to the trial activities. Should your LoI be invited to the full proposal stage, you will need to provide full details of the cofunding.

**Q: Regarding the co-financing requirement in the 'Strategic actions supporting large-scale clinical trials' call, is other EC funding accountable for cofunding in this grant scheme or does it have to come from somewhere else? And cofunding can be in cash or in-kind?**

**A:** Cofunding can be provided by either public or private legal entities from across the world; however, EC funds will not be accountable as cofunding for this grant scheme.

Yes, cofunding can be either in cash or a combination of cash and in-kind contributions, as it is highly unlikely that a large clinical trial would be able to function on in-kind contributions alone.

**Q: Are EC funds covering the costs of some parts of a large-scale project be considered as 'cofunding'?**

**A:** Please note that funding provided through the Innovative Medicines Initiative 2 Joint Undertaking (IMI2 JU) and/or the European Commission to some parts of a large scale trial research project are not accountable as 'cofunding/co-financing' for this grant scheme. EDCTP is an initiative under the Horizon 2020 programme and 'co-financing by the Commission of a project under a programme cannot be combined with any other co-financing by another programme financed by the budget of the European Union'. Therefore, cofunding for the EDCTP-SRIA grant scheme must come from sources other than the EC's funds.

**Q: In the 'letter of intent' application form it is indicated that the declared cofunding should only cover those costs incurred within the timeframe of the EDCTP-funded activity(-ies). What type of project activities would constitute being within the timeframe as the EDCTP-funded activities?**

**A:** The value of the cofunding declared should cover only those costs to be incurred within the timeframe/life cycle of the EDCTP-funded activities and not for costs incurred prior to or after the proposed EDCTP project.

However, there are certain components of a project, such as the products to be tested, which may have been produced prior to the project. The value of the products may be considered cofunding and applicants must give details of how they estimated the product value.

**Q: Could you please better define for us in-kind cost contributions that are allowable (e.g. is salary for study-related staff that is not requested from EDCTP allowable)?**

**A:** In-kind contributions are both non-monetary or cash-equivalent resources that can be given a cash value, such as goods and/or services in support of a research project or a proposal. Examples of this can be: employee salaries for time allocated to the project; equipment (donated, loaned) and software; use of facilities (e.g. lab or meeting spaces); professional, analytical, and other donated services, etc. The contributions must be specific to the project.

**Q: In the cofunders overview section of the 'letter of intent' application form, it is requested official documentation of cofunding – what type of documentation are you looking for in this regard?**

**A:** Official declarations or letters, including the breakdown, from the donors of the cofunding. This could include an official award letter from a funding agency or other statement of funding.