



**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 (clinical research activities)*' to supplement the information provided in the *call text* and call documents. The FAQs will be updated regularly 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 clearly document major financial 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 '*EDCTP contribution is to be matched by an equal or greater financial contribution from other funders*' an eligibility requirement of a minimum of 50% cofunding?**

**A:** Cofunding is not an eligibility requirement but proposals should demonstrate financial support from funders other than the EDCTP Association for the call '*Strategic actions*'. It is expected that there will be matching (or greater) cofunding provided in order to fit with the scope of the call.

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

**A:** The requested cofunding amount 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 €15 million, you are expected to match this contribution with at least of €15 million cofunding (an amount which can include direct costs and overheads, with a different overhead rate depending on the cofunding funder/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 indicated in the scope of the call. The cofunding component is part of the description of the portfolio of the clinical trial/study(ies) in its entirety and the parts financed by cofunding must be described. This means that reviewers will take into consideration the cofunding information (in your proposal) in the evaluation. Moreover, this call is a one-stage evaluation process, and it is expected that the applicant/consortium shows proof that there are other sources/funders that will contribute financially to the trial activities. Proposals without cofunding are unlikely to be competitive.

**Q: Regarding the co-financing requirement in the 'large-scale strategic actions' call, is other EC funding accountable for cofunding in this grant scheme or does it have to come from somewhere else? Can cofunding 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; however, it is highly unlikely that a large portfolio of clinical trials 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 this EDCTP grant scheme must come from sources other than the EC's funds.

**Q: In the 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 investigational products to be tested, which may have been produced prior to the start of the EDCTP project. The value of the products may be considered cofunding and applicants must give full details and justification of how the product value was estimated/calculated.

**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 and must be described clearly.

**Q: In the 'cofundors overview' section of the application form, it is requested to provide 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. The cofunding letters must include details and explanation of the large-scale programme in terms of the parts of the programme that are supported by cofunding, indicating the project activities covered, the source of the cofunding, the type of cofunding (cash or in-kind), whether the cofunding is guaranteed or provisional, and any conditions on use of the cofunding. It is expected that the cofunder has agreed to the submission of the EDCTP proposal and to the publication of information about the cofunding on the EDCTP website.