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# Summary Information

***The content of this “Summary Information”section must be re-entered in the online start of the application***

### Title

[Add text here] (maximum 50 words or 350 characters)

### Acronym

[Add text here] (maximum 20 characters)

### Abstract

*Please provide an abstract of the proposal. The abstract should be a short summary to explain clearly:*

* *The objectives of the proposal*
* *How they will be achieved*
* *Their relevance to the call topic.*

*Do not include any confidential information. Use plain typed text, avoiding formulae and other special characters. If your proposal is funded, the abstract may be published on the EDCTP website.*

[Add text here] (maximum 400 words)

### Keywords

[Add text here]

Please select a maximum of five keywords relevant to the scope of your proposal

### Proposed start date:

[Add text here]

*Please add a start date for the project after referring to the Call text.*

### Proposed duration

*Please select a proposed duration of the project in months. Refer to the Call text for guidance on project duration.*

### Requested EDCTP contribution (in Euros)

*Please provide the total amount requested from EDCTP (direct + indirect costs) in Euros*

# Excellence

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| **Research Proposal**  *Provide a summary of the purpose, aims, objectives and methods of the proposed work, including details of proposed capacity development and networking activities. Please refer to the call text and the evaluation criteria, making sure that your proposal fits with the call and that you include all the requested information.*  *The description should include details of:*   * *Importance and relevance of the proposed activities to EDCTP2 and to the call topic* * *The concepts underpinning the project, including the ideas, models or assumptions* * *Aims and specific objectives of the proposal and how they fit with the scope and objectives of EDCTP2 and the call topic description. The objectives should be clear, realistic and measurable within the duration of the project. Objectives should be consistent with the expected exploitation and impact of the project* * *The approach and methods to be used, with details of the action to be supported, coordination and support activities, capacity development and networking activities* * *Expected key deliverables.*   *For all clinical studies for product development (including repurposed drugs, new indication, label extension, fixed-dose combinations), the following information must be included:*   * *Comprehensive details of the Target Product Profile (TPP)* * *Details of the products to be tested (composition, stability, prior safety data etc)* * *Details of the regulatory strategy and of any consultation with/advice received from regulators (e.g. European Medicines Agency) and/or from WHO.*   *For implementation studies/testing under real life settings/phase 4 studies evaluating registered products, details must be given of the product characteristics described in the relevant regulatory document (e.g. marketing authorization, product package insert, etc.) and how it is intended to use the product in this proposal, with justification for this use, including an in-depth analysis of the product risk/benefit for the particular disease, likely concomitant diseases, situation. A risk minimization plan considering the known side effects and product contraindication must be described as well as how data on how the side effects will be collected and what actions will be taken as part of the pharmacovigilance plan.*  *For Strategic RIAs testing a portfolio of products, see Call Specific Questions below.*  *References should be cited in text; a list of references (using Vancouver style) should be provided in the Reference section of the application form.* |
| [Add text here] (maximum 5000 words) |

**Insert a Figure or Table in support of application (optional)**

*Please insert* ***1 page Max****. with figures or table in support of the application (optional).*

**Do you intend to conduct a clinical study within this project?**

*1.* ***Clinical trials and clinical intervention studies****: studies which meet the broad definition used by the World Health Organization (WHO) for a clinical trial (*[*http://www.who.int/topics/clinical\_trials/en/*](http://www.who.int/topics/clinical_trials/en/)*), which includes all studies evaluating the impact of interventions on human participants: “any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes.”*

*Interventions may include drugs, vaccines, cells and other biological products, surgical procedures, radiological procedures, devices including diagnostic devices, behavioural treatments, process-of-care changes, preventive care, or other treatments. Clinical trials at all stages, from Phase 1 to Phase 4, and global health trials are included in this policy.*

*2.* ***Public health intervention studies****: studies in which there is a public health intervention to promote or protect health, or prevent ill-health, in communities or populations rather than individuals.*

*3.* ***Observational studies****: studies in which the researcher assesses outcomes in groups of human participants according to a research protocol, in order to investigate the effects of lifestyle or behaviours, or interventions that are part of routine care and not influenced by the researcher.*

**[Yes or no]**

*If yes, download the template for essential information for proposals including clinical studies (available in EDCTPgrants and on www.edctp.org in the ‘Documents & info section’ of the call); once completed,* ***upload*** *in the online part of application ‘Completed’ clinical studies essential information document as a pdf.*

# Impact

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| **Anticipated impact of proposed work**  *Describe how your proposal will contribute to the expected impacts listed in the call text and the EDCTP2 work plan.*  *Please be specific, and provide only information that applies to the proposal and its objectives. Wherever possible, use quantified indicators and targets.*  *Give full details of the actions that will be taken to achieve impact in terms of the following, where applicable*   * *Changes to policy and clinical practice (national and international)* * *Product development, including advancement along the clinical development pipeline, product registration (new products and changes of indication), prequalification* * *Partnerships (beyond the immediate proposal) including sustainability of capacity and infrastructure, after-study benefits for the participating population (site, community), integration of the study activities within health system strengthening, etc.*   *Describe any barriers/obstacles, and any framework conditions (such as regulation and standards), that may determine whether and to what extent the expected impacts listed in the call text will be achieved. (This should not include any risk factors concerning implementation, which are covered elsewhere in the application.)* |
| [Add text here] (maximum 2500 words) |

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| **Dissemination and exploitation of results**  *Provide a draft plan for the exploitation and dissemination of the project’s results. For innovation actions describe a credible path to deliver the innovations to the market. The plan, which should be proportionate to the scale of the project, should contain measures to be implemented both during and after the project.*  *Your plan for the dissemination and exploitation of the project's results is key to maximising their impact. This plan should describe, in a concrete and comprehensive manner, the area in which you expect to make an impact and who are the potential users of your results. Your plan should also describe how you intend to use the appropriate channels of dissemination and interaction with potential users. Consider the full range of potential users and uses, including research, commercial, investment, social, environmental, policy-making, setting standards, skills and educational training where relevant.*  *Please ensure that you include activities for the project partners, including junior researchers, to disseminate information about and the results of the project at local, national and international conferences including the biennial EDCTP Forum in 2020 and beyond.*  *Your plan should give due consideration to the possible follow-up of your project, once it is finished. Its exploitation could require additional investments, wider testing or scaling up. Its exploitation could also require other pre-conditions like regulation to be adapted, or value chains to adopt the results, or the public at large being receptive to your results.* ***The plan for the dissemination and exploitation of the project’s results must be included as a distinct deliverable wihin the first 6 months of the project.*** |
| [Add text here] (maximum 1500 words) |

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| **Communication activities**  ***Describe the proposed communication measures for promoting the project and its findings during the period of the grant. Measures should be proportionate to the scale of the project, with clear objectives. They should be tailored to the needs of various audiences, including groups beyond the project's own community and should include consideration of Good Participatory Practices. Where relevant, include measures for public/societal engagement on issues related to the project.*** |
| [Add text here] (maximum 1500 words) |

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| **Data management and sharing**  *Please give details of your plans to store, manage and share the data and knowledge that will be generated by this project.*  *When giving details of your plans, take into consideration:*   * *The types of data that will be generated/collected and how it will be curated and preserved* * *What standards will be used* * *The value of the data to other researchers and to potential users in a range of sectors (e.g. health, commercial, social, environment, governmental, policy) and potential relevance to policy making, setting standards, skills and educational training* * *How the data will be exploited and/or shared/made accessible for verification and re-use* * *Details of the data ownership, any limits to the data sharing, for example to protect study participants or intellectual property, must be provided* * *How will the costs for data curation and preservation be covered?*   *Please refer to the H2020 online manual for more details on* [*Open access and data management*](http://ec.europa.eu/research/participants/docs/h2020-funding-guide/cross-cutting-issues/open-access-dissemination_en.htm) *and to* [*ICMJE guidelines for data sharing for clinical trials*](http://www.icmje.org/news-and-editorials/data_sharing_june_2017.pdf) *and see Article 29.3 of the model grant agreement on data sharing.* ***A data management plan must be included as a distinct deliverable wihin the first 2 months of the project.*** |
| [Add text here] (maximum 1500 words) |

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| **Extended Open Research Data Pilot in Horizon 2020**  *If selected, applicants will by default participate in the* [*Pilot on Open Research Data in Horizon 2020*](https://www.openaire.eu/opendatapilot) *, which aims to improve and maximise access to and re-use of research data generated by actions. However, participation in the Pilot is flexible in the sense that it does not mean that all research data needs to be open. After the action has started, participants will formulate a Data Management Plan (DMP), which should address the relevant aspects of making data FAIR – findable, accessible, interoperable and re-usable, including what data the project will generate, whether and how it will be made accessible for verification and re-use, and how it will be curated and preserved. Through this DMP projects can define certain datasets to remain closed according to the principle "as open as possible, as closed as necessary". A DMP does not have to be submitted at the proposal stage. Furthermore, applicants also have the possibility to opt out of this Pilot completely at any stage (before or after the grant signature). In this case, applicants must indicate a reason for this choice (see options below). Please note that participation in this Pilot does not constitute part of the evaluation process. Proposals will not be penalised for opting out.*  *Please select ‘’opt in’’ or ‘’opt out’’.*  Please indicate if the consortium wishes to opt out of the Pilot on Open Research Data in Horizon 2020. |
| **[Choose opt in or opt out]** |
| *If opt out, explain why the consortium wishes to opt out, making reference to the points below*   * *the project does not generate any data* * *to allow the protection of results (e.g. patenting)* * *incompatibility with the need for confidentiality linked to security* * *incompatibility with privacy/data protection* * *achievement of the project's main aim would be jeopardised* * *other legitimate reasons (please specify)* |
| [Add text here] (maximum 1000 words) |

# References

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| **References**  *Please provide a list of references cited up to a maximum of 50 references.*  *References should be listed in Vancouver style:*  *Journal articles: Author Surname Initials. Title of article. Title of journal, abbreviated. Date of Publication: Volume Number (Issue Number): Page Numbers and the DOI reference provided, where available.*  *Example: Oscar W, Arrami N. Choosing wind energy. Renew Sust Energ Rev. 2008:456 (22): 398-400. doi:11.1106/j.rser.2008.05.003*  *Books: Author Surname Initials. Title: subtitle. Edition (if not the first). Place of publication: Publisher; Year*  *Example: Cook GC and Zumla AI. Manson’s Tropical Diseases. 22nd Edition. Oxford: Elsevier Ltd; 2009* |
| [Add text here] (maximum 5000 words) |

# Implementation

**Overview of Implementation Section**

* Participants
  + Participants (organisations)
  + Coordinator and CV
  + Co-applicant and CVs (individuals)

Please note that on the final PDF of your application form, participant data of individuals is displayed after the ‘Declarations’ page while the Organisations table is displayed after the 'Table of Contents' page

* Work Plan (maximum 1500 words)
* Work Packages
  + Work package(s) (maximum 1000 words per work package)
  + List of deliverables from work packages
  + List of milestones from work packages
  + Gantt chart or similar document upload (mandatory, limit 1 page)
* Consortium and Risk Management
  + Management structure and procedures (maximum 1000 words)
  + Third parties involved in the project (including use of third party resources) (maximum 500 words, per question)
  + Consortium as a whole (maximum 1000 words)
  + Critical risks for implementation (maximum 100 words per risk)

# Participants

#### Participating organisations

Please note that on the final PDF of your application form, the Organisations table is displayed after the 'Table of Contents' page

**Important guidance:**

*List each organisation (legal entity) participating in the proposal,* ***including*** *the coordinating organisation. Include only those organisations (legal entities) which have given their explicit consent concerning their participation, confirmed their financial and operational capacity to carry out the proposed work and their commitment to be jointly and severally liable for the technical implementation of the action (see Article 41.1 of the general EDCTP2*[*multi-beneficiary*](http://ec.europa.eu/research/participants/data/ref/h2020/other/mga/art185/h2020-mga-edctp-multi_en.pdf)*grant agreement) such that they will sign the Accession forms to the grant agreement.*

***Each participating organisation must be represented by an individual (co-applicant) in the application.***

*If your proposal is selected for funding, alterations to the consortium are allowed* ***only under exceptional circumstances****. If there are substantial changes to the organisations during grant preparation (i.e. organisations indicated in the proposal drop out prior to the grant agreement), then your proposal may be rejected on the basis that you provided false information in the proposal and that the project no longer reflects the proposal you submitted and that was evaluated by EDCTP. Only organisations that have given explicit consent concerning their participation should be included in the proposal.*

*For H2020 type of organisation, please refer to the* [H2020 grants manual: Legal entity validation and financial viability check](http://ec.europa.eu/research/participants/docs/h2020-funding-guide/grants/applying-for-funding/register-an-organisation_en.htm) *for more information.*

***If you cannot find an organisation in our database, please request the person affiliated to this organisation to update their existing account, or in case they do not have an account to create one with this organisation.***

### Participants [Organisations, including coordinating organisation]

*List each organisation participating in the proposal,* ***including*** *the coordinating organisation.*

*Press 'Add Participating Organisation' to get started. For ease in filling out the application, please ensure that all participants are registered in EDCTPgrants before starting this section of the online application.*

| **Organisation** | **Country** | **Role** | **H2020 type of organisation** | **Public or private** | **Profit or non-Profit** |
| --- | --- | --- | --- | --- | --- |
| [Add text here] | [Add text here] | Coordinator | [Add text here] | [Add text here] | [Add text here] |
| [Add text here] | [Add text here] | Participant | [Add text here] | [Add text here] | [Add text here] |

### Coordinator

*The Coordinator is the lead applicant who is based at the coordinating organisation and is responsible for submission of the proposal on behalf of all participants and for all correspondence with EDCTP. The Coordinator is responsible for administration and management of the project, if selected for funding.*

*The Coordinator(Lead Applicant) must be registered in EDCTPgrants in order to access the application form.*

|  |  |
| --- | --- |
| **Title** | [Add text here] |
| **Forename(s)** | [Add text here] |
| **Surname** | [Add text here] |
| **Nationality** | [Add text here] |
| **Gender** | [Add text here] |
| **Organisation** | [Add text here] |
| **County** | [Add text here] |
| **Date of Birth** | [Add text here] |

| **Career summary – qualifications**  *The 'Career Summary - Qualifications section is automatically populated directly from your EDCTPgrants profile* | | | | | | |
| --- | --- | --- | --- | --- | --- | --- |
| **From** | **To** | **Degree** | **Institution** | **Country** | **Subject** |  |
| [Add text here] | [Add text here] | [Add text here] | [Add text here] | [Add text here] | [Add text here] |  |

| **Career summary - employment**  *The 'Career Summary - Employment' section is automatically populated directly from your EDCTPgrants profile* | | | |
| --- | --- | --- | --- |
| **Start Date** | **End Date** | **Job Title** | **Employer** |
| [Add text here] | [Add text here] | [Add text here] | [Add text here] |

| **Career summary - grants held**  *The 'Career Summary – grants held' section is automatically populated directly from your EDCTPgrants profile* | | |
| --- | --- | --- |
| **Date** | **Title** | **Awarding Body** |
| [Add text here] | [Add text here] | [Add text here] |

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| **Five relevant previous projects or activities connected to the subject of the proposal**  *Please list of up to five relevant previous projects or activities connected to the subject of the proposal.*  *Please list the activity with a summary of the major outputs.*  *For example:*   * + 1. *Activity name - narrative summary of major output* |
| [Add text here] (maximum 1000 words) |

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| **Five of the Coordinator's publications, and/or products, services (including widely-used datasets or software), or other achievements that are most significant or relevant to this proposal**  *Please list up to five (5) of your publications, and/or products, services (including widely-used datasets or software), or other achievements that are most significant or relevant to this call for proposals*    *References should be listed in Vancouver style:*  *Journal articles: Author Surname Initials. Title of article. Title of journal, abbreviated. Date of Publication: Volume Number (Issue Number): Page Numbers and the DOI reference provided, where available.*  *Example: Oscar W, Arrami N. Choosing wind energy. Renew Sust Energ Rev. 2008:456 (22): 398-400. doi:11.1106/j.rser.2008.05.003*  *Books: Author Surname Initials. Title: subtitle. Edition (if not the first). Place of publication: Publisher; Year*  *Example: Cook GC and Zumla AI. Manson’s Tropical Diseases. 22nd Edition. Oxford: Elsevier Ltd; 2009* |
| [Add text here] (maximum 500 words) |

**Co-applicants [Individuals]**

**Important guidance:**

List each individual who is a co-applicant in the proposal, **excluding** the coordinator. Please make sure the individuals' affiliated organisations match the names listed in the participants [organisations] list.

**Please note the following important points:**

* Each individual (co-applicant) added must be the representative of an organisation in the proposal and be participating in the proposal with the agreement of their organisation.
* **Only individuals with a clear, defined, substantial and essential role in the proposal should be added. You are advised to add only one co-applicant per organisation (multiple people per organisation are not necessary).**
* **Each individual should have specific tasks assigned to him/her, which should be reflected in the deliverables and milestones**

### Participants [Individuals]

**Please add ONLY ONE individual per participating organisation**

|  |  |
| --- | --- |
| **Organisation** | [Add text here] |
| **Full Name** | [Add text here] |
| **Gender** | [Add text here] |

| **Career summary - Qualifications**  *The 'Career Summary - Qualifications section is automatically populated directly from your EDCTPgrants profile* | | | | | |
| --- | --- | --- | --- | --- | --- |
| From | Degree | Class | Country | Subject | University/Institute |
| [Add text here] | [Add text here] | [Add text here] | [Add text here] | [Add text here] | [Add text here] |
| [Add text here] | [Add text here] | [Add text here] | [Add text here] | [Add text here] | [Add text here] |

| **Career summary – Employment**  *The 'Career Summary - Employment' section is automatically populated directly from your EDCTPgrants profile* | | | |
| --- | --- | --- | --- |
| **Start Date** | **End Date** | **Job Title** | **Employer** |
| [Add text here] | [Add text here] | [Add text here] | [Add text here] |

| **Career summary - Grants held**  *The 'Career Summary – grants held' section is automatically populated directly from your EDCTPgrants profile* | | |
| --- | --- | --- |
| **Date** | **Prize** | **Awarding Body** |
| [Add text here] | [Add text here] | [Add text here] |

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| **Five previous or current projects connected to the subject of the proposal.**  *Please list of up to five relevant previous projects or activities connected to the subject of the proposal.*  *Please list the activity with a summary of the major outputs.*  *For example:*   * + 1. *Activity name - narrative summary of major output* |
| [Add text here] (maximum 1000 words) |

|  |
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| **Five publications, and/or products, services, or other achievements that are most significant or relevant to this proposal**  *Please list up to five (5) of your publications, and/or products, services (including widely-used datasets or software), or other achievements that are most significant or relevant to this call for proposals*    *References should be listed in Vancouver style:*  *Journal articles: Author Surname Initials. Title of article. Title of journal, abbreviated. Date of Publication: Volume Number (Issue Number): Page Numbers and the DOI reference provided, where available.*  *Example: Oscar W, Arrami N. Choosing wind energy. Renew Sust Energ Rev. 2008:456 (22): 398-400. doi:11.1106/j.rser.2008.05.003*  *Books: Author Surname Initials. Title: subtitle. Edition (if not the first). Place of publication: Publisher; Year*  *Example: Cook GC and Zumla AI. Manson’s Tropical Diseases. 22nd Edition. Oxford: Elsevier Ltd; 2009* |
| [Add text here] (maximum 500 words) |

**The Coordinator confirms**

that they have listed at least one co-applicant for every organisation listed in the organisations table and that names of organisations are identical in both tables

Yes or No

# Workplan

|  |
| --- |
| **Overview of workplan**  *Please give a summary description of the overall structure of the proposed workplan, including information about the constituent work packages, and how they inter-relate. Please note that subsequent sections of the form request full details of each work package and its deliverables and milestones.*    ***Definitions:***  ***Work package****- major sub-division of the proposed project*  ***Deliverable****- distinct output of the project, meaningful in terms of the project’s overall objectives, and constituted by a report, a document, a technical diagram, software or other output*  ***Milestones****- concrete and communicable events or activities occurring during the course of the project that demonstrate and chart forward progress to participants and external reviewers in a transparent manner. The Key Milestones in each work package that must be completed before the next stage of the project can move forward (known as Critical Path milestones) should be clearly indicated in the project plans. Milestones may correspond to the completion of a key deliverable. They are required at intermediary points so that, if problems have arisen, corrective measures can be taken in timely manner. A milestone may be a critical decision point in the project where, for example, the consortium must make a key decision concerning the next steps (e.g. a Go-No Go decision). The interdependence of critical path milestones between work packages should be indicated.*    ***Notes on how to complete the work plan and work packages sections of the form:***  *Overview of workplan:*   * *Brief description of the overall structure of the proposed workplan* * *A numbered list of the individual work packages, a brief summary of each workpackage and details of the relationship between them* * *Indicate the timing of the different work packages and their components (A Gantt chart or similar document should be uploaded).*   ***Work packages:***  *For each individual workpackage, you should provide the following:*   * *Detailed description of the activities under each work package* * *List of the deliverables per work package given chronologically* * *List of milestones per work package given chronologically, indicating clearly which are critical path milestones (without which the project cannot proceed)* * *Details of the lead participant(s) per workpackage, and their role and responsibilities in the work package* * *Details of all participants involved in the work package and their roles and responsibilities.*   *Please ensure that you provide sufficient details and the information is presented according to the logical structure of the project and the stages in which it is to be carried out. Include details of the resources to be allocated to each work package. Please ensure that timelines, resources and budgets are realistic and not overly optimistic.*  *The number of work packages should be proportionate to the scale and complexity of the project.*  *You should give enough detail in each work package to justify the proposed resources to be allocated.*  *Please consider the inclusion of a distinct work package on ‘Management’ and to give due visibility in the workplan to ‘dissemination and exploitation’ and ‘communication activities’, either with distinct tasks or distinct work packages.* |
| [Add text here] (maximum 1500 words) |

### Work packages

|  |  |
| --- | --- |
| **Work package identifier** | [Add text here (i.e. 1.0)] |

|  |  |
| --- | --- |
| **Work package title** | [Add text here] |

|  |  |
| --- | --- |
| **Organisation that leads the work package** | [Add text here] |

|  |  |
| --- | --- |
| **Start month of work package** | [Add text here] |

|  |  |
| --- | --- |
| **End month of work package** | [Add text here] |

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| **Objectives**  *Please provide a short list of the main objectives.*  *Please note that this box is not rendered in the table in the online form but is available in the PDF of the application form.* |
| [Add text here] (maximum 150 words) |

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| **Description of work to be conducted in the work package**  *Description of work (where appropriate, broken down into tasks), lead partner and role of participants.*  ***Provide an estimated total cost per work package.***  *Please note that this box is not rendered in the table in the online form but is available in the PDF of the application form.* |
| [Add text here] (maximum 1000 words) |

***Repeat this section for the number of Work Packages in the application.***

### List of Deliverables from Work packages, chronologically by work package

***Mandatory deliverables for clinical studies***

*For each clinical study, the following mandatory deliverables (with the indicated title and scope as defined) have to be included in the proposal:*

*1. '****First study subject approvals package****' (prior to enrolment of first study subject):*

*a. Final version of study protocol as approved by first regulator / ethics committee(s) (no need to change deliverable if later amendments)*

*b. Registration number of clinical study in a WHO- or ICMJE- approved registry that also allows later posting of study results.*

*c. Approvals required for invitation / enrolment of first subject in at least one clinical centre (if applicable): ethics committees, national competent authorities and copies of opinion or confirmation by the competent Institutional Data Protection Officer and/or authorization or notification by the National Data Protection Authority. If the position of a Data Protection Officer is established, its opinion/confirmation that all data collection and processing will be carried out according to EU and national legislation*

***2. 'Midterm recruitment report'***

*Deliverable to be scheduled for the time point when 50% of the study population is expected to have been recruited. The report shall include an overview of recruited subjects by study site, potential recruiting problems and, if applicable, a detailed description of implemented and planned measures to compensate delays in the study subject recruitment.*

***3. 'Report on status of posting results'*** *Report on the status of posting results in the study registry/ies (including timelines when final posting of results is scheduled after end of funding period). To be scheduled for the time of expected results posting or for the last months of the project, whichever comes earlier.*

| **Deliverable Number** | **Deliverable Name** | **Lead Participant Organisation** | **Type of deliverable\*** | **Dissemination Level\*\*** | **Month of project when deliverable will be achieved** |
| --- | --- | --- | --- | --- | --- |
| [Add deliverable number] | [Add text here] | [Add text here] | [Add text here] | [Add text here] | [Add text here] |
| [Add deliverable number] | [Add text here] | [Add text here] | [Add text here] | [Add text here] | [Add text here] |
| [Add deliverable number] | [Add text here] | [Add text here] | [Add text here] | [Add text here] | [Add text here] |

\***Type of deliverable**

* **R** (*Document, report (do not include the periodic or final reports to EDCTP as deliverables)*)
* **DEM** *(Demonstrator, pilot, prototype, plan designs)*
* **DEC** (*Websites, patents filing, market studies, press and media actions, videos, etc*)
* **Other** (*Software, technical diagram, etc*)

**\*\* Dissemination Level**

* **PU** (*Public, fully open, e.g. website*)
* **CO** (*Confidential, restricted under conditions set out in Model Grant agreement*)
* **Cl** (*Classified, information as referred to in Commission Decision 2001/844/EC*)

### List of Milestones from Work packages, chronologically by work package

| **Milestone name** | **Means of verification** | **Month of project when milestone will be attained** |
| --- | --- | --- |
| [Add text here] | [Add text here] | [Add text here] |
| [Add text here] | [Add text here] | [Add text here] |

**Gantt chart or similar document upload (mandatory)**

*A Gantt chart or similar document illustrating the project timeline should be* ***uploaded*** *in support of your application. Supported file format is pdf only.*

### Consortium and risk management

|  |
| --- |
| **Management structure and procedures**  *Describe the organisational structure and the decision-making process*    *Please give an overview of day-to-day management of the work that will be conducted, including an organogram that sets out the framework for decision-making. Explain why the organisational structure and decision-making mechanisms are appropriate to the complexity and scale of the project.* |
| [Add text here] (maximum 1000 words) |

|  |
| --- |
| **Third parties involved in the project (including use of third party resources)**  Do the participants plan to subcontract certain tasks? (Please note that core tasks of the project should not be sub-contracted). |
| [Yes or no] |
| If yes, please describe and justify the tasks to be subcontracted. |
| [Add text here] (maximum 500 words) |
| Do the participants envisage that part of its work is performed by linked third parties? |
| [Yes or no] |
| If yes, please describe the third party, the link of the participant to the third party, and describe and justify the foreseen tasks to be performed by the third party. |
| [Add text here] (maximum 500 words) |
| Do the participants envisage the use of contributions in kind provided by third parties? (Articles 11 and 12 of the General Model Grant Agreement) |
| [Yes or no] |
| If yes, please describe the third party and their contributions |
| [Add text here] (maximum 500 words) |

|  |
| --- |
| **Organogram** |
| *You may* ***upload an organogram*** *showing the management and decision-making framework of the project.* |

|  |
| --- |
| **Consortium as a whole**  *Describe the consortium and how it matches with the project objectives.*    *Consider how the participants complement one another (and cover the value chain, where appropriate). Describe how each participant contributes to the project and how they will be able to work together effectively.*    *Where applicable, describe the involvement of other stakeholders (e.g. governmental, industrial, commercial) in the project and explain how their involvement will contribute to the successful implementation and to the impact of the project.* |
| [Add text here] (maximum 1000 words) |

**Critical risks for implementation**

*Describe any critical risks to the implementation of the project, indicating the work package(s) involved and outline the proposed risk-mitigation measures.*

| **Description of risk** | **Work package involved** | **Proposed risk-mitigation measures** |
| --- | --- | --- |
| [Add text here] | [Add work package number] | [Add text here] |
| [Add text here] | [Add work package number] | [Add text here] |

# Budget

**Budget Instructions**

*This section requests details of the estimated budget for the proposal. The budget form is organized according to the following categories: A. Direct personnel costs, B. Direct costs of subcontracting, C. Direct costs of financial support (not in use), and D. Other direct costs.*

*When filling in amounts for the budget categories, you must enter the organisation (participant) to which the budget request relates. Amounts should be rounded off to the nearest euro. The budget is not split into years, rather the amount to be entered is for the entire duration of the proposed project. EDCTP only requires a single overall category total per organisation. Each organisation should, then, appear only once within each budget category.*

*More information about the budget form preparation for H2020 can be found at the following links:*

* [*Planning your project*](http://ec.europa.eu/research/participants/docs/h2020-funding-guide/grants/applying-for-funding/submit-proposals/get-prepared_en.htm)
* [*H2020 Rules for Participation*](http://ec.europa.eu/research/participants/data/ref/h2020/legal_basis/rules_participation/h2020-rules-participation_en.pdf)
* [*Annotated H2020 grant agreement with explanations of the budgetary items*](http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/amga/h2020-amga_en.pdf)
* [*EDCTP 2 Model Grant Agreement*](http://ec.europa.eu/research/participants/data/ref/h2020/other/mga/art185/h2020-mga-edctp-multi_en.pdf)

*Please note that the online budget form will automatically apply a flat rate of 25% to the budget request (except for the Direct subcontracting costs) as provision for indirect costs. This amount is shown as ‘EDCTP E Indirect costs’ once the “Save” button is clicked.*

***IMPORTANT: Check the budget total with the indirect costs added before submission. You must make sure that once the 25% provision for indirect costs is added to your budget proposal the total does not exceed the maximum EDCTP contribution applicable for your proposal. If the total budget goes above the maximum amount, it will be considered ineligible.***

*If you are invited to grant preparation, you will be requested to send your detailed per year budget spreadsheet for further review. The spreadsheet must include job title, person months contribution and the work package for each personnel budgeted under personnel costs category. Other direct costs must include the separate budget lines for travel, other goods & services and equipment (depreciated costs as per the organisation’s internal policy).*

**A. Direct personnel costs - ACTUAL**

Please enter the single total amount per organisation for this category

* A.1 Employees (or equivalent)
* A.2 Natural persons under direct contract
* A.3 Seconded persons
* [A.6 Personnel for providing access to research infrastructure- not applicable]

*A.1 This budget category covers the costs of personnel working for the beneficiary under an employment contract (or equivalent appointing act) and assigned to the action. The personnel costs must be limited to salaries (including during parental leave), social security contributions, taxes and other costs included in the remuneration, if they arise from national law or the employment contract (or equivalent appointing act).*

*A.2 This budget category covers the costs of personnel working under a direct contract (that is not an employment contract) with the beneficiary. This budget category covers typically the costs for field workers, in-house consultants and similar persons that will work on the action (i.e. self-employed natural persons working part-time or full-time for the action under a contract which is not governed by labour law).*

*A.3 This budget category covers the costs of personnel that work on the action and that are seconded by a third party as an ‘in-kind’ contribution against payment. ‘Seconded’ means the temporary transfer of personnel from a third party to the beneficiary. The seconded person is still paid and employed by the third party, but works for the beneficiary. S/he is at the disposal of the beneficiary.*

***Within each category a particular organisation should only appear once, there is no need to itemise the details beyond the organisation level***

| **Organisation** | **Estimated budget for each participant (€)** |
| --- | --- |
| [Insert organisation here] | €[Add amount here] |
| [Insert organisation here] | €[Add amount here] |
|  | **€**[Total here] |

**A. Direct personnel costs - UNIT**

Please enter the single total amount per organisation for this category

**Unit Costs - Personnel costs on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices**

* A.1 Employees (or equivalent)
* A.2 Natural persons under direct contract
* A.3 Seconded persons
* A.4 **Costs of owners** of beneficiaries that are small and medium-sized enterprises (‘**SME owners**’),
* A.5 **Costs of** ‘**beneficiaries that are natural persons** not receiving a salary
* [A.6 Personnel for providing access to research infrastructure- not applicable]

*A.1 This budget category covers the costs of personnel working for the beneficiary under an employment contract (or equivalent appointing act) and assigned to the action. The personnel costs must be limited to salaries (including during parental leave), social security contributions, taxes and other costs included in the remuneration, if they arise from national law or the employment contract (or equivalent appointing act).*

*A.2 This budget category covers the costs of personnel working under a direct contract (that is not an employment contract) with the beneficiary. This budget category covers typically the costs for field workers, in-house consultants and similar persons that will work on the action (i.e. self-employed natural persons working part-time or full-time for the action under a contract which is not governed by labour law).*

*A.3 This budget category covers the costs of personnel that work on the action and that are seconded by a third party as an ‘in-kind’ contribution against payment. ‘Seconded’ means the temporary transfer of personnel from a third party to the beneficiary. The seconded person is still paid and employed by the third party, but works for the beneficiary. S/he is at the disposal of the beneficiary.*

*A.4 Costs of owners of beneficiaries that are small and medium-sized enterprises (‘SME owners’), who are working on the action and who do not receive a salary are eligible personnel cost, if they correspond to the amount per unit set out in Annex 2a multiplied by the number of actual hours worked on the action*.

*A.5 Costs of ‘beneficiaries that are natural persons**not receiving a salary are eligible personnel costs, if they correspond to the amount per unit set out in Annex 2a multiplied by the number of actual hours worked on the action.*

***Within each category a particular organisation should only appear once, there is no need to itemise the details beyond the organisation level***

| **Organisation** | **Estimated budget for each participant (€)** |
| --- | --- |
| [Insert organisation here] | €[Add amount here] |
|  | **€**[Total here] |

**B. Direct costs of subcontracting**

Please enter the single total amount per organisation for this category

*If necessary to implement the action, the beneficiaries may award subcontracts covering the implementation of certain action tasks. Subcontracting may cover only a limited part of the action. The beneficiaries must award the subcontracts ensuring the best value for money or, if appropriate, the lowest price. In doing so, they must avoid any conflict of interests. Please note that the subcontracting costs do not receive the additional 25% indirect costs.*

**B. Subcontracting**

|  |  |
| --- | --- |
| **Organisation** | **Estimated budget for each participant (€)** |
| [Insert organisation here] | €[Add amount here] |
|  |  |

**C. Direct costs of financial support-**

**Not applicable for this call**

**D. Other direct costs**

Please enter the single total amount per organisation for this category

* *D.1 Travel*
* *D.2 Equipment*
* *D.3 Other goods and services*
* *[D.4 Costs of large research infrastructure- not applicable]*

*D.1 Travel*

*This budget category covers the travel costs and related subsistence allowances spent for the action. Travel and subsistence costs may relate to the personnel of the beneficiaries as well as to external experts that participate in the action on an ad hoc basis (e.g. attending specific meetings), if the experts’ participation is detailed in the project. Please ensure to include travel costs and related subsistence allowances for project partners, including junior scientists, to present the project and its results at local, national and international conferences and meetings, including the biennial EDCTP Forum.*

*D.2 Equipment*

*Funding for equipment, infrastructure or assets should be entered in this section.  The* ***depreciation costs of equipment, infrastructure or other assets*** *(new or second-hand) as recorded in the beneficiary’s accounts are eligible, if these are essential for the action and are written off in accordance with international accounting standards and the beneficiary’s usual accounting practices.*

*The* ***costs of renting or leasing*** *equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

*D.3 Other goods and services*

*This budget category covers the costs for goods and services that are purchased  for the action (or contributed in-kind against payment), including:*

* *study costs ( consumables, supplies, reagents, raw materials, scientific publications, small equipment) needed to implement the action*
* *training costs*
* *networking costs (meetings and workshops)*
* *dissemination costs (including open access during the action) and conference fees for presenting project-related research*
* *costs related to intellectual property rights (IPR) (including costs to protect the results or royalties paid for access rights needed to implement the action)*
* *costs for certificates on financial statements (CFS) and certificates on methodology (unless unnecessary, for instance because the total direct costs per organisation are less than EUR 325 000)*
* *translation costs (if translation is necessary for the action’s implementation and is justified)*
* *other essential costs to carry out the action*

[*D.4 Costs of large research infrastructure- not applicable]*

***Within each category a particular organisation should only appear once, there is no need to itemise the details beyond the organisation level.***

| **Organisation** | **Estimated budget for each participant (€)** |
| --- | --- |
| [Insert organisation here] | €[Add amount here] |
| [Insert organisation here] | €[Add amount here] |
|  | **€**[Total here] |

|  |  |  |
| --- | --- | --- |
| **Summary Totals - By Organisation**  Does not include the 25% Indirect Costs | | |
|  |  | **Total€** |
| [Insert organisation here] |  | €[Add amount here] |
| [Insert organisation here] |  | €[Add amount here] |
| [Insert organisation here] |  | €[Add amount here] |
| **Total** |  | €[Total here] |

|  |  |
| --- | --- |
| **Summary Totals - By Category**  Includes Category E - Indirect Costs which is calculated automatically | |
|  | **Total (€)** |
| A Personnel Actual | €[Add amount here] |
| A Personnel Unit | €[Add amount here] |
| B Sub contracting | €[Add amount here] |
| C Financial support | €[Add amount here] |
| D Other direct costs | €[Add amount here] |
| E Indirect costs | €[Add amount here] |
| **Total** | €[Total here] |

**IMPORTANT:** Check the budget total with the indirect costs added. You must make sure that once the 25% indirect costs are added to your proposal it does not take the budget above the maximum amount per proposal. **If your budget total goes above the maximum amount it will be ineligible.**

# Budget Justification

|  |
| --- |
| **Budget justification**  *Please provide a detailed description and justification for the requested budget for the proposal. You should present the justification by organisation (participant) in the proposal, making reference to the project activities conducted by each participant in your justification. The evaluation will examine the requested resources, whether they are appropriate for the proposal and whether the budget represents value for money (do the anticipated outputs merit the project cost).*  *For each organisation, give an explanation of the budget items requested per budget category.*  *For example, give details of the personnel to be supported on the grant, their role in the project including which work packages they will work on, duration of appointment and percentage time on the project. For direct costs, give details of the requested costs, relating this to the work to be conducted by the participant and to the workpackages of the project.*  ***Provide an estimated total cost per work package.*** |
| [Add text here] (maximum 2000 words) |

# Supporting Information and Related Applications

|  |  |
| --- | --- |
| Is this or a related application currently being submitted elsewhere? | [Yes or no] |

|  |  |
| --- | --- |
| To which organisation? | [Add text here, if applicable] |

|  |  |
| --- | --- |
| When is a decision expected? | [Add text here, if applicable] |

|  |  |
| --- | --- |
| Has this or a similar/related application, or parts of this application, been submitted to EDCTP in the past two years? | [Yes or no] |

|  |
| --- |
| To which EDCTP call was the original application submitted? |
| [Add text here, if applicable] |

|  |  |
| --- | --- |
| What was the EDCTP reference number? | [Add text here, if applicable] |

|  |  |
| --- | --- |
| What was the application outcome? | [Add text here, if applicable] |

|  |
| --- |
| Justification  *Please explain the relationship between the current application and the other applications.* |
| [Add text here, if applicable] (maximum 250 words) |

|  |  |
| --- | --- |
| For applicants submitting a second-stage proposal to a call. Are there substantial differences compared to the letter of intent proposal? | [Yes or no] |

# Ethics Issues Table

|  |  |
| --- | --- |
| **1. Human embryos, foetuses** |  |
| Does your research involve Human Embryonic Stem Cells (hESCs)? | [Yes or no] |
| Will they be directly derived from embryos within this project? | [Yes or no] |
| Are they previously established cells lines? | [Yes or no] |
| Does your research involve the use of human embryos? | [Yes or no] |
| Can you confirm that your research will not destroy those embryos? | [Yes or no] |
| Does your research involve the use of human foetal tissues / cells? | [Yes or no] |
|  |  |
| **2. Humans** |  |
| Does your research involve human participants? | [Yes or no] |
| Are they volunteers for social or human sciences research? | [Yes or no] |
| Are they persons unable to give informed consent? | [Yes or no] |
| Are they vulnerable individuals or groups? | [Yes or no] |
| Are they children/ minors? | [Yes or no] |
| Are they patients? | [Yes or no] |
| Are they healthy volunteers for medical studies? | [Yes or no] |
| Does your research involve physical interventions on the study participants? | [Yes or no] |
| Does it involve invasive techniques? | [Yes or no] |
| Does it involve collection of biological samples? | [Yes or no] |
|  |  |
| **3.Human cells/tissues** |  |
| Does your research involve human cells or tissues? (other than from Human Embryos/Foetuses, i.e. section 1?) | [Yes or no] |
| Are they available commercially? | [Yes or no] |
| Are they obtained within this project? | [Yes or no] |
| Are they obtained from another project, laboratory or institution? | [Yes or no] |
| Are they obtained from a biobank? | [Yes or no] |
| **4. Personal data** |  |
| Does your research involve personal data collection and/or processing? | [Yes or no] |
| Does it involve the collection and/or processing of sensitive personal data (e.g.: health, sexual lifestyle, ethnicity, political opinion, religious or philosophical conviction)? | [Yes or no] |
| Does it involve processing of genetic information? | [Yes or no] |
| Does it involve tracking or observation of participants? | [Yes or no] |
| Does your research involve further processing of previously collected personal data (secondary use)? | [Yes or no] |
|  |  |
| **5. Non-European Union (EU) countries** |  |
| In which non-EU countries will the research take place? | [List non-EU countries involved in research] |
| Do the research related activities undertaken in these countries raise potential ethics issues? | [Yes or no] |
| Do you plan to use local resources (e.g. animal and/or human tissue samples, genetic material, live animals, human remains, materials of historical value, endangered fauna or flora samples, etc.)? | [Yes or no] |
| Do you plan to import any material – including personal data – from non-EU countries into the EU? | [Yes or no] |
| Do you plan to export any material – including personal data – from the EU into non-EU countries? | [Yes or no] |
| If your research involves low and/or middle income countries, are benefits sharing actions planned? | [Yes or no] |
| Could the situation in the country put the individuals taking part in the research at risk? | [Yes or no] |
|  |  |
| **6. Environment & Health and Safety** |  |
| Does your research involve the use of elements that may cause harm to the environment, to animals or plants? | [Yes or no] |
| Does your research deal with endangered fauna and/or flora and/or protected areas? | [Yes or no] |
| Does your research involve the use of elements that may cause harm to humans, including research staff? | [Yes or no] |
|  |  |
| **7. Dual use** |  |
| Does your research involve dual-use items in the sense of Regulations 428/2009, or other items for which an authorisation is required? | [Yes or no] |
|  |  |
| **8. Exclusive focus on civil applications** |  |
| Could your research raise concerns regarding the exclusive focus on civil applications? | [Yes or no] |
|  |  |
| **9. Misuse** |  |
| Does your research have the potential for misuse of research results? | [Yes or no] |
|  |  |
| **10. Security** |  |
| Will your project involve activities or results raising security issues? | [Yes or no] |
| Will your project involve 'EU-classified information' as background or results | [Yes or no] |
|  |  |
| **11. Other ethics issues** |  |
| Are there any other ethics issues that should be taken into consideration? Please specify in the ethics self-assessment attachment | [Yes or no] |

**If you answer yes to any question**, you must **upload** a pdf attachment of unlimited page length as an **ethics self-assessment** which:

Describes how the proposal meets the national legal and ethical requirements of the country or countries where the tasks raising ethical issues are to be carried out

Explains in detail how you intend to address the issues in the ethical issues table, in particular as regards:

* research objectives (e.g. study of vulnerable populations, dual use, etc.)
* research methodology (e.g. clinical trials, involvement of children and related consent procedures, protection of any data collected, etc.)
* the potential impact of the research (e.g. dual use issues, environmental damage, stigmatisation of particular social groups, political or financial retaliation, benefit-sharing, misuse , etc.).

Provide the documents that you need under national law (if you already have them), e.g.: an ethics committee opinion; the document notifying activities raising ethical issues or authorising such activities. If these documents are not in English, you must also submit an English summary of them (containing, if available, the conclusions of the committee or authority concerned). If you plan to request these documents specifically for the project you are proposing, your request must contain an explicit reference to the project title.

For more guidance, see the document "[How to complete your ethics self-assessment"](http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/ethics/h2020_hi_ethics-self-assess_en.pdf). When providing the self-assessment, please reference the page number, section(s) and work packages of your proposal where the activities that raise ethics issues are described.

# Declarations

The Coordinator declares:

|  |
| --- |
| 1.To have the explicit consent of all applicants on their participation and on the content of this proposal |
| [Yes or no] |

|  |  |
| --- | --- |
| 2.That the information contained in this proposal is correct and complete | [Yes or no] |

|  |
| --- |
| 3.That this proposal complies with ethical principles (including the highest standards of research integrity - as set out, for instance, in the European Code of Conduct for Research Integrity - and including, in particular, avoiding fabrication, falsification, plagiarism or other research misconduct) |
| [Yes or no] |

|  |
| --- |
| 4a. The coordinator is exempt from the financial capacity self-check because:   * His/her employing organisation is a public body including international organisations, higher or secondary education establishment or a legal entity, whose viability is guaranteed by a Member State or associated country, as defined in the H2020 Grants Manual ([Chapter on Financial capacity check](https://ec.europa.eu/research/participants/portal4/desktop/en/organisations/lfv.html));           or   * He/she is a sole participant |
| [Yes or no] |

|  |  |
| --- | --- |
| The Coordinator confirms:   |  | | --- | | 4b. To have carried out the self-check of the financial capacity of the organisation on <https://ec.europa.eu/research/participants/portal4/desktop/en/organisations/lfv.html>. Where the result was "weak" or "insufficient", the coordinator confirms being aware of the measures that may be imposed in accordance with H2020 Grants Manual ([Chapter on Financial capacity check](https://ec.europa.eu/research/participants/portal4/desktop/en/organisations/lfv.html)). | |
| [Yes or no, if applicable] |

The Coordinator hereby declares that the participants have confirmed:

|  |
| --- |
| 5a. That they are fully eligible in accordance with the criteria set out in the specific call for proposals, and |
| [Yes or no] |

|  |  |
| --- | --- |
| 5b. That they have the financial and operational capacity to carry out the proposed action | [Yes or no] |

**Responsibility for the correctness of the information:** *The Coordinator is solely responsible for the correctness of the information relating to his/her own organisation. Each participant remains responsible for the correctness of the information related to him/her and declared above. If this proposal is selected for funding, all beneficiaries will be required to provide a formal declaration in this respect.*

**Privacy statement on grants management**

The EDCTP-Association (EDCTP) is committed to protecting and respecting the privacy of applicants and its beneficiaries.

The data you provide in “EDCTPgrants” are collected to allow EDCTP (the controller) to evaluate your proposal and/or organisation, to award funding if your proposal is successful, to manage grant agreements, and to fulfil its obligations towards its funders. The data may also be used for research purposes and/or for analysis at a programmatic level (which will, in principle, not involve the processing of personal data).

A limited subset of this information may be used by EDCTP for communication purposes, in accordance with the rules of each call for proposals or contest for prizes. EDCTP may also use the contact details of successful applicants to compile invitation lists for EDCTP conferences and other EDCTP organised events.

The contact details of administrative staff of beneficiaries may be shared with other interested parties (for example, funding agencies not involved in the action, researchers or journalists), but only after having received the unambiguous consent from the relevant data subjects.

Full details of the EDCTP policy: [Privacy Statement on Grants Management is available](https://www.edctp.org/web/app/uploads/2018/05/Privacy-Statement-Grants-Management.pdf) on the EDCTP website.

Submission of proposals via EDCTPgrants constitutes acceptance of the Privacy Statement.