

Coalition for Epidemic Preparedness Innovations

Guidance document for online applications: CfP-2: Call for proposals for platform technologies to enable rapid vaccine development for epidemic prone infections

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Guidelines for online applications

CEPI is pleased to announce its second funding opportunity for the development of vaccines against epidemic infectious diseases. This document provides guidelines for the online application of proposals and the requested documents. The scope, requirements and templates for proposal submission can be found on the CEPI website.

CEPI uses the online application system of the Research Council of Norway (RCN) for the submission of proposals. The Guidelines provided in the online application form can deviate from CEPI's requirements, therefore we ask applicants to use the guidelines below when filling out the form.

Online application system of the RCN

Project owner

This is where you enter information about the Project Owner (institution/company) and the designated project administrator.

Definitions

(This is a general definition of Project Owner. Please consult the [general information about the application type](#) for more information about requirements relating to Project Owners)

Project Owner: The institution, company or activity that is responsible vis-à-vis CEPI for ensuring that the project is carried out in accordance with the contract (legally responsible party). In the application form, the administrative unit/institute where the project will be performed is to be specified in the field "institution/company". The legally responsible party will be retrieved automatically from the Research Council's list of registered organisations, if the responsible party is not listed in the Research Council's list of registered organisations, you can enter it manually. The Project Owner cannot be an individual.

Project administrator: The individual who is authorised to represent and assume obligations on behalf of the Project Owner in respect to your application.

To enter information about the Project Owner from the list of registered organisations into the application form, search for the relevant information in the following manner:

- Click on "Find Project Owner" (Find organisation).
- Search for the relevant institution/company.
- Select the correct organisation from the list that appears below the search field. You must select the specific administrative unit (department, institute, etc.) within the organisation where the project will be performed, and enter this as the Project Owner in the application form.

If the organisation you need is not included in the list you may enter the information manually in the application form. Click on "Back" to return to the empty fields on the application form to fill these in manually.

If the information obtained from the list of organisations is erroneous or incomplete, you must click on “Clear” in order to fill in the fields manually.

Disregard that it says “Norwegian name” behind; please use the official, English name.

- **For the application types Personal Doctoral Research Fellowship and Personal Post-Doctoral Research Fellowship:** This does not apply for CEPI CfP.

Confirmation

Before sending the grant application, the submitter must obtain confirmation that the project administrator is willing to assume responsibility for the project on behalf of the Project Owner (institution).

The Research Council will confirm receipt of the grant application by means of an email sent both to the email address listed in the field “E-mail” and to the person who has submitted the application.

Project manager

This is where you enter information about the project manager.

Definition

Project manager: the individual who is responsible for the performance of the project on behalf of the Project Owner.

For applications for Researcher Projects, Research Institution-based Strategic Projects and Research Infrastructure: The project manager must be formally qualified for employment at associate professor level, which usually entails a completed doctorate.

Once the official registration process has been completed by the Research Council, the project administrator and the project manager will be notified by email, of the assigned project number and name of the case officer.

Preferred language: Please choose the language you would like the Research Council to use in its correspondence about the project.

Project title

Please give your application a short title that describes the planned research activity.

The project title will be included in the list of all grant applications under processing that is made publicly available. The title should therefore not disclose any sensitive information.

- **For Project Establishment Support applications:** This does not apply for the CEPI preliminary CfP.
- **Are you working with revision of a grant application?** This does not apply for the CEPI preliminary CfP.

Primary and secondary objectives of the project

Please provide a specific and verifiable primary objective that describes the results you expect to achieve during the course of the project period. Specify verifiable secondary objectives as separate points.

- **For Project Establishment Support applications:** This does not apply for the CEPI preliminary CfP.

Project summary

Please provide a brief summary of the project description, emphasising the objectives of the project, the most critical R&D challenges.

- **For Project Establishment Support applications:** This does not apply for the CEPI preliminary CfP.

Please note that the project summary will be made publicly available if the application is approved for funding. The text provided should therefore be suitable for public access, and should be comprehensible to professionals and non-professionals alike. The project summary will also be forwarded to the referees who are asked to assess the application. The project summary should therefore not disclose sensitive information. For more information about public access, see the established [requirements](#).

The application form will be **closed automatically after two hours, without being stored**, unless you have actively saved the document yourself or moved on to another section. Applicants are therefore advised to compose their project summary locally and thereafter copy it into the application form.

- **Are you working with revision of a grant application?** This does not apply for the CEPI preliminary CfP.

Supplementary information from applicant

This is where you enter the discipline/specialist field to which the application belongs and further information about related applications that have been submitted. The application will be processed in relation to the programme/activity to which it has been submitted. If the project is relevant to other programmes/activities with active funding announcements you may specify these here.

Progress plan: Project period

Here you are to fill in the planned project period as well as the main activities of the project and milestones to be achieved during the whole of this period. The project periods are mutually exclusive in the online application form and do not allow for reporting parallel processes with overlapping time periods.

Definition

The project period is normally the period of time for which CEPI will be contributing funding.

Please make sure that the start-up date and duration of the project period conform to the requirements set out in the call for proposals application guidelines (**a maximum of 3 years for CfP-2**).

Please use key words to indicate the main activities, milestones, and deliverables with anticipated use of resources for the project. Select the year and quarter in which the individual activities are expected to be initiated and completed. All main activities, milestones and deliverables must be scheduled within the project period.

It is possible to sort the main activities and milestones in chronological order by clicking on “Sort chronologically”. You may also sort the data by clicking and dragging the arrows to the left of the entry.

Dissemination of project results

A short dissemination plan is to be drawn up for each project. Please provide information regarding plans for scientific and popular dissemination activities and contact with users, including relevant target groups and type of dissemination.

Budget

For a detailed description of the budget reporting requirements please refer to the section “Budget” on page 7 of this document

Fellowship

This does not apply for the CEPI preliminary CfP.

Partners

Partners are **all institutions/companies (partners)** that will be under obligation to contribute to the project by performing R&D activities and/or providing funding, and/or that will be granted rights to the project, should be entered in the application form. One contact person must be provided for each institution/company listed. If the project is granted funding, each of these partners must sign a bilateral or joint collaboration agreement with the Project Owner that sets out their obligations.

If you wish to enter partners in the online application form:

- Click on “New partner” or “Change partner”.
- Search for the relevant partner organisation.
- Select the correct institution/company/organisation from the list.

If the organisation is not included in the list of organisations, you may enter the information manually in the application form. Click on “Back” to return to the empty fields on the application form to fill these in manually.

If the information obtained from the list of organisations is incorrect or incomplete, you must click on “Clear” in order to fill in the fields manually. To remove a partner, click on the “X” at the right of the partner field.

If you do not have the enterprise identity number, leave this field blank.

Use the dropdown menu under “Partner’s role” to indicate whether each partner will provide financing, research activity or both. “*Research activity*” indicates that the partner will be carrying out R&D activities under the project. “*Financing*” means that the partner will be providing cash financing and/or in-kind resources. A financing partner that is not also involved as a research activity partner may only contribute cash financing.

NOTE: *If you have started to enter a new partner and the fields marked with a * are not filled in, you will not be able to submit the application form. Click on the “X” at the right to delete the empty fields.*

Attachments - CEPI requested documents

Only items that are stipulated in the call for proposals should be attached to the grant application. Types of attachments that have not been requested will not be included in the application review process. **Please upload all requested documents in pdf format.**

- A completed project description form (**max 10 pages**)
- A milestone plan (for each target pathogen), showing the key activities and events on a relevant timescale (**which should also be sent to cfp@cepi.net in excel format**)
- A completed budget plan (**which should also be sent to cfp@cepi.net in excel format**)
- Short bio sketches of project leader/principal investigator (**max 1 page per sketch**), including up to five co-investigators/key staff. In the case of consortia of collaborating organisations, co-applicants must provide electronic copies of signed letters of intent, confirming their agreement to participate in the proposed projects and agreeing with the content of the proposals.

As the RCN needs to be able to copy the contents of the attachment file, attachments in pdf-format must not be password-protected in a manner that would prevent this. If you normally use “Security Settings”, please make sure to tick the box marked “Enable copying of text, images and other content”.

Uploading attachments

All attachments to applications must be submitted in **pdf-format**. Please note that the file must have a valid filename, as certain characters/letters may not be used in filenames. An error message will be generated if you attempt to submit files bearing names that contain illegal characters and letters. Attachments larger than 40Mb are not accepted.

How to upload a file:

- Click on “Browse” to locate and select the file you wish to upload.
- Click the “Upload” button to upload the file selected.
- Wait until the file upload is complete. This may take several minutes, depending on the speed of your Internet connection and the size of the document.
- The filename will appear in the field “Uploaded file” when the uploading process is complete.

How to delete a file:

- Click on the X to the right of the field “Uploaded file”.

How to update or replace a file:

- You must delete the previously uploaded file before you can upload a new version.

How to upload more than one file

- There are some attachment types for which more than one file may be uploaded.
- Click on the button “Add new line” to upload more than one file.
- Max 20 files for each attachment type.

Decreasing file size

In order to minimise file size, please refrain from using overly high resolution in the graphics contained in the attachments.

Attachments containing a virus

If an attachment contains a virus, it will be automatically deleted from our server and you will receive an error message when you try to submit it. Applicants must ensure that all attachments are free from viruses. You can monitor whether any attachments have been automatically deleted from our server by using the function “Check page”/“Check entire”.

Project Description

Use the CEPI “Project description template - Cfp2 step 1”. Please note that it is not possible to upload a file that exceeds 10 pages.

In the “Project description template - Cfp2 step 1” template all instructions on how to complete the form are presented in *italics*. Before submission, please delete the disclaimer text, as well as all guideline text in *italics* in sections throughout this document; please keep the headings in bold under each section and indicate if not applicable.

The text format requirements for the Project description **Step 1** document are:

- Calibri light theme font size 10, single spacing
- Maximum page length: **10 pages in total**. *Documents longer than 10 pages will be rejected*

Budget

CEPI – Budget template

CEPI provides applicant with a budget template (www.cepi.net/cfp2). Please see [CEPIs cost guidance document](#) for specifications of items that is eligible for CEPI funding. Please upload the budget plan as **pdf** to the online application, and **send the budget plan in excel format to cfp@cepi.net**.

In the budget template, applicants are requested to fill out the light blue cells, whereas green cells are automated calculations based on values entered into the light blue cells. In the paragraphs below, we have specified the requested cost details.

Completing the CEPI budget template:

In the budget template, we ask applicant to provide information on the following costs aspects:

- **FTE and personnel costs:** Total FTE and costs of these for the specified activities in US\$
- **Equipment:** Total costs of equipment for the specified activities in US\$
- **All other direct costs;** all other direct costs, including travel and consultants in US\$
- **Indirect cost:** the indirect costs as a percentage of the total direct costs (personnel costs, equipment and other direct costs) excluding sub-awardee costs (specify %). *Please note that CEPI is currently reviewing its indirect costs position and this will be available prior to Step 2*
- **Sub-awardee names:** Please specify all sub-awardees that will receiving funding for the specified activity.
- **Comments:** Please provide any (high level) comments if you feel the costs specified need an explanation

Activity sections

The template has a section for costs related to preclinical and clinical development. Under each section, costs for specific activities are identified as follows:

Preclinical development

- **Preclinical development:** Please include all preclinical costs up to enabling Phase 1 clinical trials, including immunology, challenge studies, stability and toxicology studies
 - Change the labels “pathogen 1” etc into the name of the targeted pathogen
 - Please specify the costs for each of the targeted pathogens
 - Total cost are calculated by summing costs for pathogen 1, 2 and 3
- **CMC:** costs of CMC development including the costs of production of Phase I clinical trial material (CTM)
- **Total program management:** include the total costs of programme management for the preclinical development
- **Other costs:** include all other costs of preclinical development that have not been covered by any of the activities above. Please specify with keywords what activities fall under these costs

Clinical development

- **Clinical development:** Please include all costs related to clinical development, excluding costs of clinical samples laboratory testing
 - Change the labels “pathogen 1” etc into the name of the targeted pathogen
 - Please specify the costs for each of the targeted pathogens
 - Total cost are calculated by summing costs for pathogen 1, 2 and 3
- **Clinical samples laboratory testing:** Costs for clinical sample laboratory testing for each pathogen taking into clinical development
 - Change the labels “pathogen 1” etc into the name of the targeted pathogen
 - Please specify the costs for each of the targeted pathogens
 - Total cost are calculated by summing costs for pathogen 1, 2 and 3
- **CMC:** CMC costs to enable Phase II and III clinical trials
- **Total program management:** Total costs of program management for clinical development
- **Other costs:** Include all other costs of clinical development that have not been covered by any of the activities above. Please specify with keywords what activities fall under these costs

Please note that we will only accept budgets that are complete and that are based on realistic assumptions. In Step 2 of this call, we will require applicants to provide a more detailed cost plan (for more information see the template used in CfP on MERS, Lassa and Nipah; <http://cepi.net/CfP#Step-2-Proposal-Templates>)

RCN – Online application system

All amounts should be given in USD, where 1000 USD = 1 (in the online application form).

For example, US\$550,000 = 550 in the online application budget. Disregard that the online application form specifies NOK.

In the online application form, you will have to provide the budget in three different sections (specified below). **The total amount for each budget year must be identical for all three tables.** Please use the “check page” function to make sure this is the case.

Budget

Please fill in online application form by using the total costs (summed costs from preclinical and clinical development) from the excel template as indicated in the table 1 below. The total budget in the online application form and excel sheet should be identical.

Please note that we do not require the costs per year in step 1 of Cfp2.

Table 1 Corresponding cost sections for online applications

CEPI Budget template – excel sheet	RCN Online application form
“Personnel costs” PLUS “Total indirect costs”	“Payroll and indirect expenses”
“Equipment”	“Equipment”
“Other direct cost”	“Other operating expenses”
“Sub-awardee costs”	“Procurement of R&D services”

Cost codes

This section is used to indicate the sector in which costs are incurred. The project costs (as shown in the Cost plan) are to be distributed among the sectors according to where the various project participants belong. The total amount for each budget year must be identical to the total in the Cost plan. *Please use the “check page” function to make sure this is the case.*

Funding plan

The Funding plan shows how the financing of the project will be distributed between funding from CEPI, funding from other sources, and any internal funding from the applicant. The financing may encompass support both from cash contributions and from in-kind resources made available to the project (personnel, research infrastructure, materials, etc.).

The Cost plan, Cost codes and Funding plan represent different methods of categorising the use of funds within the project budget.

- **Own financing:** Resources to be provided by the applicant institution for the implementation of the project should be entered here. This may encompass cash financing and/or in-kind resources such as personnel, research infrastructure, materials, etc.
- **International funding:** Anticipated project funding from international sources (such as from the EU’s research programmes) should be entered here. Please include funds that have been applied for as well as funds that have been granted. Cash financing from partners outside Norway should also be entered here.
- **Other public funding:** Funding from the public sector and contributions from other public sources should be entered here.
- **Other private funding:** Private funding from cooperating companies, industrial organisations, private funds, etc., should be entered here. This may comprise cash financing, personnel, research infrastructure, goods, etc.
- **From Research Council:** CEPI funding.
- **Specification:** The current status (applied for, granted, etc.) and any other important information relating to the funding specified in the Funding plan should be described in more detail here.

Milestones

CEPI provides applicants with a milestone template (www.cepi.net/cfp2). Please complete and upload the milestone plan as **pdf** to the online application, and also **send the milestone plan in excel format to cfp@cepi.net**.

Completing the CEPI Milestone template:

As the excel template includes three tables for each of the targeted pathogens; please identify which pathogen the milestone table addresses at the top of the table.

Please specify the **projected start and completion date** for each pathogen in the table for the following three sections with specified activities:

Product Development Plan

- **Draft integrated PDP**

Preclinical Candidate Development

- **Animal studies:** Preclinical activities leading to proof of concept
- **CMC:** Activities up to defined process for Phase I clinical trial material (CTM)
- **Stability:** Preclinical activities up to enabling Phase 1 clinical trials

Clinical development (First in Human to End of Phase1)

- **Regulatory:** Scientific advice from regulatory authorities
- **CMC:** Production of phase I Clinical Trial Material (CTM)
- **Animal study:** IND-enabling Preclinical Studies, including toxicology
- **Regulatory:** Approval for FIH
- **Clinical:** First Subject First Visit, Last Subject Last Visit, Report drafted; Proof of Principal in human