

Coalition for Epidemic Preparedness Innovations (CEPI)

Call for proposals (CfP3i)

Topic: Human vaccine development against Rift Valley Fever and Chikungunya diseases

Reference number: CEPI-CfP-003i

CEPI is pleased to announce its third call for proposals (CfP3i) for the development of human vaccines against Rift Valley Fever (RVF) and Chikungunya (CHIK) disease, with anticipated support from the European Commission. This document describes the scope, requirements, and processes for proposal submission, review, and selection for funding. Further details can be found at www.cepi.net.

CEPI envisions a world in which epidemics are no longer a threat to humanity. CEPI is working to achieve this vision through: accelerating development of vaccines against emerging infectious diseases; and securing stockpiles of investigational products to enable equitable access to these vaccines for populations who need them during outbreaks.

CEPI invites applicants (i.e. relevant vaccine development organizations and/or consortia) to submit proposals for funding. Applicants should submit detailed plans for product development, manufacturing, and related activities as described in this document, including a clear development plan that describes milestones, timelines and criteria for success, and an assessment of risks and proposed mitigation measures to ensure their resolution.

CfP3i is the first of two potential calls for proposals in which CEPI is seeking to fund human vaccine development against Rift Valley Fever (RVF) and Chikungunya (CHIK) diseases. CfP3ii, which will also pertain to RVF and CHIK diseases, is expected to open in late 2020. Due to the structuring of anticipated funding from the European Commission to CEPI, applicants are presented with this first funding opportunity in 2019 (CfP3i), with a likely second, open call in 2020 (CfP3ii), which could make additional funding available to successful candidates. Successful CfP3i applicants could be granted further funding through the CfP3ii call dependent on the progress of their vaccine development projects between initial funding and the launch of the CfP3ii. Applications for funding in CfP3i (first call) is not a precondition for applying for funding in CfP3ii (second call).

The budget of CfP3i is USD 48 million, with the potential to increase to USD 148 million in aggregate after a second call (CfP3ii). CfP3i is expected to fund 1 to 8 grants. Applicants who are able to provide co-funding, complimentary funding, or in-kind support will be considered favourably.

CfP3i projects must be completed within 3 years from January 2019 and should have made significant progress in the 12 to 15 months after the signing of a CEPI funding agreement.

If you are planning to submit, please let us know by the **1st of February 2019. By the 26th of February (15:00 CET) you must send a request to receive instructions on how to submit your application.** The submission deadline for this call for proposals is Tuesday, **the 5th of March 2019, 15:00 CET.**

Contents

1. Introduction.....	3
1.1. The Coalition for Epidemic Preparedness Innovations (CEPI).....	3
1.2. About this call for proposals.....	3
1.3. European Commission and the Horizon 2020 programme.....	4
1.4. Funding opportunity.....	4
2. Objectives of CfP3i.....	5
3. Scope and call for proposals structure.....	5
3.1. RVFV pre-clinical and Phase I/II clinical vaccine development.....	5
3.2. CHIKV late stage clinical vaccine development.....	7
4. Applicant eligibility criteria.....	9
5. Applicant guidelines.....	9
5.1. Proposal and templates.....	9
5.2. Submission overview.....	10
6. Review criteria.....	10
7. Review and due diligence process timeline.....	12
8. Award conditions from funders.....	12
9. Animal Welfare and Well-being.....	13
10. Technical and administrative questions.....	14

1. Introduction

1.1. The Coalition for Epidemic Preparedness Innovations (CEPI)

Epidemics of emerging infectious diseases (EIDs), particularly those prioritised by the WHO in its “[R&D Blueprint for Action to Prevent Epidemics](#)”, are a significant threat to global health security. In a world with increased urbanisation, mobility, and ecological change, their potential for disruptive impact is increasing.

At CEPI we envision a world in which epidemics are no longer a threat to humanity. Our contribution to this goal is to accelerate the development of vaccines against EIDs and enable equitable access to these vaccines for populations who need them during outbreaks.

CEPI is an international non-profit association established to develop vaccines to prevent and respond to future epidemics and to secure access to such products for the populations who need them. CEPI will advance safe, effective and affordable vaccines that can help to contain outbreaks at the earliest possible stage.

CEPI was launched in January 2017 by the governments of Norway, India, the Bill & Melinda Gates Foundation, the Wellcome Trust, the World Economic Forum. CEPI has since then received commitments for additional support from the European Commission and the governments of Germany, Japan, Canada, Australia, Belgium, and Ethiopia.

To accomplish our mission, CEPI will:

- Directly fund and coordinate vaccine development up to and including Phase IIb, advocate for regulatory innovation and harmonisation, and fund associated costs for meeting regulatory requirements;
- Support the development of vaccine technologies and manufacturing capabilities that can be deployed rapidly against outbreaks of known and recently emerging pathogens;
- Take a role alongside other organisations—including other funders—in support of sustainable manufacturing and in the maintenance and release of investigational vaccine stockpiles (free of charge where funded by CEPI) when an outbreak occurs;
- Together with awardees of CEPI funding and relevant stakeholders, facilitate and coordinate resource mobilisation for Phase III trials to be conducted during outbreaks for the purpose of licensure;
- Take all possible actions at each stage of product development and manufacturing to maximise the achievement of equitable access to our vaccines.

1.2. About this call for proposals

This new call for proposals builds on CEPI’s prior investments in Lassa fever, MERS-CoV, and Nipah vaccine candidates and versatile vaccine platforms, and was informed by a thorough review of the R&D pipeline of EID vaccines in 2018. In September 2018 the CEPI Scientific Advisory Committee (SAC) advised that CEPI should invest in human vaccine development against Rift Valley Fever virus (RVFV) and Chikungunya virus (CHIKV). This advice was based on the feasibility of vaccine development, and the potential public health impact of vaccines against these diseases, in the anticipation of substantial new funding from the European Commission. While vaccines against both viruses appear to be technically feasible, the commercial prospects for vaccines against RVFV are non-existent and are uncertain, at best, for CHIKV.

RVF disease was included among the [WHO R&D Blueprint list of priority pathogens in 2018](#), while CHIK disease was among the diseases deemed to present major public health risks for which “further research and development is needed” and would require “efforts in the interim to understand and mitigate the public health risks”.

The current RVFV vaccine pipeline includes 17 candidates. However, only two are in Phase II while other candidates are at a preclinical stage.¹ Therefore, the focus of CfP3i is to further advance those vaccine candidates already in clinical development, and/or to advance the most promising candidates with preclinical proof of concept into clinical development. CEPI aims to shorten the time to develop a vaccine that can be tested in a pivotal trial in the event of a future epidemic. To achieve this outcome for the RVFV vaccines, vaccine developers should include in their product development plans adaptive trial designs to accelerate vaccine development (e.g., initiate Phase II in parallel to Phase I once safety data justify this). Their plans should also aim to have vaccine candidates enter Phase II by the end of a 3-year period.

By contrast, the CHIKV vaccine pipeline contains 27 candidates of which five of them are in Phase I and two of them are in Phase II.¹ The development of these candidates has been supported mainly by public sector investment with some degree of private sector financing. In line with CEPI’s mission, commitment to equitable access, and recognition that most of the CHIKV disease burden is in low-income and middle-income countries (LMICs), CEPI will focus its funding on activities that will enable Phase III trials and other activities in support of WHO prequalification and future licensure. Our investments will facilitate access to CHIKV vaccines for vulnerable populations in affected LMICs. CEPI will not provide sole funding to a pivotal efficacy trial but is open to investment in this kind of activity if there is a significant co-funding and investment by the vaccine developer, to maximise the impact of CEPI’s investment.

1.3. European Commission and the Horizon 2020 programme

This potential new funding opportunity results from the Horizon 2020 programme², where CEPI and the European Commission will work in partnership to support the advancement and diversification of the current vaccine-development pipeline against priority EIDs. Due to the structuring of potential funding from the European Commission to CEPI, applicants are presented with the first funding opportunity in 2019 (CfP3i), with an anticipated second open call in 2020 (CfP3ii) that could provide additional funding to successful candidates. Successful CfP3i applicants could be granted further funding through the CfP3ii call dependent on the progress of their vaccine development projects between initial funding and the launch of the CfP3ii. Application for funding in CfP3i is not a precondition for applying for funding in CfP3ii.

1.4. Funding opportunity

Allocated funding: total funds allocated for CfP3i is USD 48 million with anticipated USD 100 million follow-up funding (CfP3ii). In CfP3i CEPI will allocate in total USD 48 million across 1 to 8 projects.

¹Gouglas D, Thanh Le T, Henderson K, et al. Estimating the cost of vaccine development against epidemic infectious diseases: a cost minimisation study. *Lancet Glob Health* 2018; published online Oct 17. [http://dx.doi.org/10.1016/S2214-109X\(18\)30346-2](http://dx.doi.org/10.1016/S2214-109X(18)30346-2).

² http://ec.europa.eu/research/participants/data/ref/h2020/wp/2018-2020/main/h2020-wp1820-health_en.pdf

Applicants that are able to provide co-funding, complimentary funding, or in-kind support will be considered favourably.

Project duration: 1 to 3 years. There is an expectation that applicants will undertake the most cost-intensive part of their projects within the first 12 to 15 months of the project. Successful CfP3i applicants could be granted further funding through the CfP3ii call dependent on the progress of their vaccine development projects between initial funding and the launch of the CfP3ii. Applications for funding in CfP3i is not a precondition for applying for funding in CfP3ii.

Funding Certain Pre-Award Costs: CEPI may provide funding for pre-award costs that are incurred in the period from proposal submission to signature of a partnering agreement to advance the implementation of the project which is the subject of the proposal. Any such pre-award costs are, however, undertaken **at the risk of the applicant**. Funding by CEPI of pre-award costs would only be provided to applicants that: (i) are ultimately successful in their CfP3i application to CEPI, (ii) provide documentation to demonstrate to CEPI's satisfaction that such costs did relate to advancing the activities proposed in the CfP3i application, and (iii) comply with CEPI budgetary rules and procedures (see section 8). For the purpose of clarity, the pre-award costs eligible for CEPI funding do not include costs related to the preparation of the application itself (such as costs of technical, legal, and financial consultants to develop or revise the CfP3i application and the product development plan).

2. Objectives of CfP3i

Through CfP3i CEPI aims to achieve the following objectives:

- a) For RVFV vaccines, to support accelerated clinical testing or activities enabling clinical Phase I/II testing of the most advanced RVFV candidates, including identification of correlates of protection and their validation that can facilitate future regulatory approval.
- b) For CHIKV vaccines, to support the rapid progression of the most advanced clinical CHIKV vaccine candidates through mid-stage and late-stage clinical development, and to support activities enabling future Phase III, including identification of correlates of protection and their validation that can facilitate future regulatory approval.

3. Scope and call for proposals structure

3.1. RVFV pre-clinical and Phase I/II clinical vaccine development

Disease scope: human vaccines to protect against RVF disease

Indicative work package (WP): funding will be targeted towards WPs that will result in and include clinical testing of vaccine candidates suitable for reactive and/or preventive use in target populations in countries affected by RVF disease, as described in Table 1 below.

Project eligibility criteria:

- *Key criterion:* data demonstrating protective efficacy studies in relevant animal challenge models must exist. This data must be shared with CEPI on submission of this call and will be evaluated for quality.
- *Specific additional criteria:* see Table 1.

Table 1: RVFV vaccine development WPs and additional eligibility criteria

Work packages	Specific additional eligibility criteria
(1) Clinical trials assessing vaccine safety and immunogenicity in accelerated mode ³ , as well as regulatory planning for execution of Phase II/III studies, including in affected countries and in populations at high risk of infection.	<p>Applicants must propose a clinical development plan including testing in countries with documented burden of RVF disease.</p> <p>Applicants will need to demonstrate a coherent and comprehensive development plan as described in section 5 (project description).</p>
<p>(2) Chemistry, Manufacturing, and Control (CMC), formulation and presentation of the vaccine:</p> <ul style="list-style-type: none"> • Development of GMP process and scale up • Manufacturing of clinical trial material • Development of suitable batch release and potency assays (may include animal model development) • Optimisation of vaccine formulation (focus on thermostability, excipients, and volume). 	Applicants must provide the evidence of partnership with experienced CMC human vaccine manufacturing providers or in-house capacity (having produced GMP material used in clinical study in conjunction with national and international regulatory guidelines).
<p>(3) Activities related to WHO prequalification to drive access in LMICs:</p> <ul style="list-style-type: none"> • Thermostability studies including extended controlled temperature conditions (ECTC) and determination of appropriate vaccine vial monitoring (VVM) category • Programmatic suitability, including packaging and presentation, cold-chain footprint, multidose vial presentation, device and ease of use • Clinical studies: <ul style="list-style-type: none"> - to demonstrate safety and immunogenicity in diverse populations including in affected countries and in populations at high risk of infection - to increase the size of the safety database towards the minimum requirement of 3 000 subjects. 	
(4) Further immunogenicity studies in animal models to generate sufficient evidence to transition into clinical development.	Studies are critical to inform regulatory approval to initiate Phase I/II trials.
(5) Further protective efficacy studies in animal challenge models to generate sufficient evidence to transition into clinical development.	Studies are critical to inform regulatory approval to initiate Phase I/II trials, in particular the choice of the challenge dose.

³ RVFV vaccine developers should include adaptive trial designs in their product development plans to accelerate vaccine development (e.g. initiate Phase II in parallel to Phase I once safety data justify this). Their plans should also aim to have vaccine candidates enter Phase II by the end of a 3-year period.

(6) Transition from animal-vaccine concept to human-product development including the implementation of First-in-Human, Phase I/II studies aspiring to adaptive study designs enabling accelerated vaccine development.	Partnership with experienced human-vaccine product-development groups.
(7) Reproductive toxicology studies.	Study design and conduct in compliance with national and international guidelines.
(8) Studies to inform the determination of a correlate of protection, linked to clinical testing of vaccine candidates: Regulatory science relevant research to contribute to identification, testing, evaluation and prioritization of surrogate-endpoints of protection in RVF disease, including immunobridging between human survivor studies, clinical trials and relevant animal challenge studies.	<ul style="list-style-type: none"> • Demonstration at the application stage of pre-existing data on human survivor studies, clinical trials and/or animal challenge studies, in relation to correlate of protection • Data is expected to be shared in relation to correlates of protection with any other developers irrespective of CEPI funding.
(9) Enabling science: biological standardisation studies to facilitate vaccine licensure (i.e., assays, standards, animal models), including development and validation of assays used to measure potency or correlates of protection.	Expectation to share the resulting assays, standards, and animal models with any other developers irrespective of CEPI funding.

3.2. CHIKV late stage clinical vaccine development

Disease scope: human vaccines to protect against CHIK disease

Indicative WP: funding will be targeted towards development activities that will facilitate access to vaccine for populations in low-resource settings, as described in Table 2 below. Activities that will be considered within the scope of funding should support the applicant’s plan leading to WHO prequalification, licensure in affected countries, or both.

Project eligibility criteria:

- *Key criterion:* all available Phase I data must be available and shared with CEPI on submission date of this call and will be evaluated for quality.⁴
- *Specific additional criteria:* see Table 2.

Table 2: CHIKV vaccine development WPs and additional eligibility criteria

Work packages	Specific additional eligibility criteria
(1) Clinical trials assessing vaccine safety and immunogenicity, as well as regulatory planning for execution of Phase II/III including affected countries and populations at high risk of infection.	<p>Applicants must propose Phase II and later clinical testing in countries with documented burden of CHIK disease.</p> <p>Applicants will need to demonstrate a coherent and comprehensive development plan through licensure as described in section 5, including a</p>

⁴ CEPI’s preference is to receive the pre-clinical documentation and final Phase I clinical study reports; if such reports are not available, please contact CEPI to discuss the format in which the data will be provided.

	regulatory approach in case Phase III efficacy trials are deemed as not being feasible.
<p>(2) Chemistry, Manufacturing, and Control (CMC), formulation and presentation of the vaccine:</p> <ul style="list-style-type: none"> • Development of GMP process and scale up • Manufacturing of clinical trial material • Development of suitable batch release and potency assays (may include animal model development) • Optimisation of vaccine formulation (focus on thermostability, excipients, and volume). 	<p>Applicants must provide:</p> <ul style="list-style-type: none"> • evidence of intent to pursue WHO prequalification and/or local licensing in affected countries, including specific development plan elements for this purpose, or evidence of interactions with regulatory authorities on CMC and plans for licensing in line with national and international guidelines • evidence of partnership with experienced CMC human vaccine manufacturing providers or in-house capacity (having produced GMP material used in clinical study in conjunction with national and international regulatory guidelines).
<p>(3) Activities related to achieving WHO prequalification to drive access in LMICs:</p> <ul style="list-style-type: none"> • Thermostability studies including extended controlled temperature conditions (ECTC) and determination of appropriate vaccine vial monitoring (VVM) category • Programmatic suitability, including packaging and presentation, cold chain footprint, multidose vial presentation, device and ease of use • Clinical studies: <ul style="list-style-type: none"> - to demonstrate safety and immunogenicity in diverse populations including affected countries and populations at high risk of infection - to increase the size of the safety database towards the minimum requirement of 3 000 subjects. 	
<p>(4) Studies to inform the determination of a correlate of protection: Regulatory science relevant research to contribute to identification, testing, evaluation and prioritization of surrogate-endpoints of protection in CHIK disease, including immunobridging between human survivor studies, clinical trials, animal challenge studies, and adoptive/passive transfer studies.</p>	<ul style="list-style-type: none"> • Demonstration at the application stage of pre-existing data on human survivors, clinical trials and/or animal challenge studies, in relation to correlate of protection • Data is expected to be shared in relation to correlates of protection with any other developers irrespective of CEPI funding.
<p>(5) Enabling science: biological standardisation studies to facilitate vaccine licensure (i.e., standards, assays and animal models), including development and validation of assays to measure potency or correlates of protection.</p>	<p>Expectation to share the resulting assays, standards and animal models with any other developers irrespective of CEPI funding.</p>
<p>(6) Reproductive toxicology studies.</p>	<p>Study design and conduct in compliance with national and international guidelines.</p>

4. Applicant eligibility criteria

The funding opportunity through this CfP3i is open worldwide to all types of non-profit research organisations, for-profit companies, international organisations and foundations, joint R&D ventures, government research organisations, and academic institutions. Applicants must be legal entities, or consortia comprised of legal entities. At least one of the partners in the applicant organisations or consortia of partnering organisations should have experience in **human vaccine development** and have a track record of bringing vaccine candidates through to human clinical trials in the past 10 years. Applicants unable to demonstrate this experience will not be eligible for funding.

Proposals will be eligible for funding only if they are:

- **Coherent** with the CfP3i objectives described in section 2
- **Relevant** to the CfP3i's disease scope, as described in section 3
- **Consistent** with the CfP3i timeline and award conditions as described in sections 1.4 and 8
- **Complete** in terms of required content in the proposal templates described in section 5.1.

5. Applicant guidelines

Proposals must include essential evidence as described in the "Proposal and templates" section below, meet the presented timeline requirements for completion, contain sufficient detail for review of the proposed product development process, and any claims made within the proposal must be supported by evidence. Adherence to CEPIs policies is a condition for receiving funding (see section 8).

5.1. Proposal and templates

Entities that want to respond to this call for proposals must submit their proposal to CEPI via the dedicated secure platform by the **March 5, 2019 (15.00 CET)**. All documents must be uploaded in the file formats specified below:

- **Project description, including the integrated product development plan** (40 pages max) (pdf file)
- **Overall budget** (Excel file) and **overall budget narrative** (pdf file)
- **Individual sub-awardee budget** (Excel file) and **sub-awardee budget narrative** (pdf file)
- A maximum of 10 **CVs or bio sketches** (*max. 2 pages per CV/bio sketch for applicants, partners and key experts*) (pdf file)
- Signed **letters of support** for **all partners** confirming their agreement to participate in the proposed projects and agreeing with the content of the proposals (pdf file)

No additional documents should be submitted.

Templates and guidelines for the required attachments are accessible via www.cepi.net.

Submissions that exceed the specified page limits or fail to meet the above criteria will not be considered for further review.

Personal data included in proposals will be handled according to CEPI's Privacy Notice on www.cepi.net.

5.2. Submission overview

If you are planning on submitting, please let us know by the **1st of February 2019** in order for CEPI to best plan for the subsequent review process.

To ensure a secure submission process, you must request instructions on how to submit your application by emailing cfp@cepi.net **by the 26th of February 15:00 CET**. We encourage you to submit your proposal well in advance of the deadline.

For the submissions to be accepted and registered, applications must fulfil the following norms:

- Submission must be completed by **Tuesday the 5th of March 2019 15:00 CET**
- Requirements in section 5.1 must be completed
- All communication of information and documents related to this call must be conducted in English
- All budget proposals should be submitted in US Dollars

In case of questions in relation to the submission system, access to proposal form templates, or any other issue related to this call for proposals, please contact cfp@cepi.net. The CEPI secretariat will address your questions within the shortest possible timeframe. Any questions submitted, along with answers, may be made public if having relevance to inform preparation of the application. Instructions for applicants as well as a summary of frequently asked questions and answers (FAQs) will be uploaded to the CEPI website.

It is the responsibility of the applicant to ensure that all requested documents are submitted within the deadline, and to contact CEPI in advance of the submission deadline in case there are any issues regarding the completeness of the submission. All applications will be stored in a restricted access repository.

No costs incurred by the applicants for the development and submission of proposals will be covered.

6. Review criteria

Proposals will be assessed against the criteria listed in Table 3 below. Performance of proposals will be evaluated through the evidence provided on all aspects listed under each criterion. Therefore, the quality of the information provided by applicants is crucial to CEPI's funding decision. The basis for selecting proposals for funding will be technical performance, the total costs and timeframes for completing the projects, and the realism and reasonableness of the proposed project plans. Information requirements to address the criteria are provided in the documents listed in section 5.1.

Table 3: Review criteria

Criterion	Aspects to consider where appropriate
1. Applicant competencies, experience and track-record	<ul style="list-style-type: none"> ▫ Technical competency/expertise of project staff ▫ Experience in preclinical testing of vaccines⁵ ▫ Experience in conduct of clinical vaccine trials ▫ Experience in regulatory interactions with competent authorities and licensing of vaccines ▫ Manufacturing capabilities and skills
2. Technical feasibility	<ul style="list-style-type: none"> ▫ Soundness of the theoretical concept ▫ Scientific appropriateness of the preclinical development approach and quality of the available data ▫ Scientific appropriateness of the clinical development and regulatory approach and quality of the available data
3. Manufacturing scalability and speed	<ul style="list-style-type: none"> ▫ Scientific rationale of proposed manufacturing processes/technologies supporting the candidate vaccine ▫ Current status/availability of manufacturing ▫ Robustness of the CMC approach and quality of the available data to demonstrate this
4. Use potential for target pathogens	<ul style="list-style-type: none"> ▫ Suitability of the candidate vaccine for reactive use during outbreaks ▫ Suitability of the candidate vaccine for preventive use in countries disproportionately affected/LMICs
5. Use potential for other pathogens	<ul style="list-style-type: none"> ▫ Suitability of the technology platform for other pathogens on the WHO priority list of emerging infectious diseases ▫ Suitability of the technology platform for other pathogens beyond the WHO priority list of emerging infectious diseases
6. Cost	<ul style="list-style-type: none"> ▫ Each cost response will be reviewed for cost realism, reasonableness, and overall best value ▫ Proposals will be reviewed to determine if the costs proposed are based on realistic assumptions, reflect a sufficient understanding of the technical goals and the objectives of the call and are consistent with the proposed technical approach ▫ Applicants who are able to provide co-funding, complimentary funding, or in-kind support will be considered favourably.

⁵ For Chikungunya, the indicative scope for funding is clinical vaccine development and hence not all listed aspects may apply.

7. Review and due diligence process timeline

The Secretariat will assess whether received applications fulfil the published eligibility criteria of the call, and then will send the eligible proposals to internal and independent external experts for review. All reviewers who participate in the review process will be evaluated for any potential conflicts of interest and will be required to sign non-disclosure agreements. CEPI's Scientific Advisory Committee will advise on the selection of proposals to be considered for funding.

Applicants may be invited for interviews when required to ensure that any outstanding questions are resolved prior to concluding the full review. CEPI will cover reasonable travel costs for this purpose⁶. Proposals and budgets will be subject to a cost challenge undertaken in the context of the applicant's projects and CEPI's policies and cost guidance.

Contract arrangements will be initiated along with technical and financial due diligence and pursued to recommendations for funding to the Board by Q2-Q3 2019. For the candidates not proceeding to due diligence the Secretariat will seek to communicate this as early as possible.

The CEPI Secretariat will publicly announce each award when the partnering agreement has been signed. Applicants whose proposals do not advance to contract will be notified confidentially of the outcome of the process in a timely fashion.

8. Award conditions from funders

Funding must reflect the proposed activities and agreed conditions of the award decision made by CEPI. CEPI reserves the right to terminate agreements according to mutually agreed "go/no-go" decision criteria.

CEPI is committed to achieving equitable access to all CEPI-supported programmes including vaccines, platforms, data, results, and materials. Specifically, equitable access to epidemic vaccines in the context of an outbreak means that appropriate vaccines are first available to populations when and where they are needed to end an outbreak or curtail an epidemic, regardless of ability to pay. To ensure that CEPI delivers on its commitment to equitable access, CEPI must include access considerations as a component of any agreement with an awardee. If you have specific questions regarding the equitable access policy, please contact CEPI at cfp@cepi.net.

CEPI maintains the following [research-related policies](#) to provide further guidance to its research partners on:

- Animal research
- Clinical trials (including transparency requirements)
- Equitable access policy
- Scientific integrity

⁶ CEPI will cover travel costs for three consortium members for those invited to a bid defense meeting if applicants are selected for funding.

Other policies/guidance designed to support CEPI partners on general administrative issues and ensure investor requirements and industry best practices include:

- Anti-corruption
- International sanctions
- Managing conflict of interest
- Procurement
- Travel
- Transparency and confidentiality
- Cost guidance
- European Commission and its regulatory bodies rights of review and audit plus acknowledgement of EC funding

9. Animal Welfare and Well-being

The National Centre for the Replacement, Refinement & Reduction of Animals in Research (NC3Rs) is collaborating with CEPI to embed the 3Rs into CEPI funded projects. The collaboration focuses on reviewing proposals to ensure that animal welfare standards are genuinely high and exceed the legal minima, local issues relating to poor practice are addressed, and overseas work is conducted to standards equivalent to those in the UK (<https://www.nc3rs.org.uk/integrating-3rs-publicly-funded-research>).

In CEPI's call for vaccine development, the NC3Rs will only evaluate **proposals entering due diligence/negotiation processes** and that include projects involving the use of animals highlighted by NC3R (i.e. mice, non-human primates (NHPs), cattle, dogs, cats, pigs and equines). Based on the review, the NC3Rs will provide recommendations to CEPI, including advice on opportunities to implement the 3Rs, raise specific animal welfare concerns, highlight where good practice is not being adopted, and monitor the implementation of specific policies and guidance. This advice will be used during decisions on funding and when drafting the terms and conditions of grant awards.

To prepare your proposal for this review process, please take into account the following guidelines:

- NC3Rs Guidelines: [Non-human primate accommodation, care and use](#)
- [Responsibility in the Use of Animals in Bioscience Research](#), which applies to use of any vertebrate species
- [ARRIVE Guidelines](#) on the reporting of *in vivo* studies

Implementation of the principles in these guidelines is a condition of receiving funds from CEPI.

Other information that will be considered during the review can be found on the NC3Rs website:

- [Directive 2010/63/EU](#)
- [Scientific literature](#) on applying the 3Rs in drug development
- [NC3Rs resources on best practice](#) – including those on improving non-human primate welfare (such as the Macaque Website)

In addition, the NC3Rs has produced a [PDF presentation](#) to remind applicants of the required animal welfare standards and to provide advice on choosing appropriate contractors. Applicants contracting out animal research or collaborating with other laboratories (regardless of species) are advised to view the presentation well in advance of submitting their application.

10. Technical and administrative questions

Technical and administrative questions about CfP3i should be directed to CEPI Secretariat (cfp@cepi.net). A summary of frequently asked questions and answers (FAQs) will be posted on CEPI's website.