CEPI

Call for Proposals:

Broadening protection against SARS-COV-2 and new broadly protective Betacoronavirus candidate vaccines

CEPI is pleased to announce a new funding opportunity for the development of vaccines with one of the following attributes:

1. A **broadly protective vaccine against new emerging variants and variants of concern of the SARS-CoV-2 virus (BPCoV2),** with funding up to 18-24 months to achieve clinical proof of concept (POC).
2. A **broadly protective Betacoronavirus (BPBC) vaccine** with funding potentially awarded for up to 4 years to demonstrate clinical POC.

This document describes the scope, requirements and process for submission, review, and selection for funding. Further details can be found at https://cepi.net/get_involved/cfps/

The main focus of this Call for Proposals (CfP) is the research and development of novel immunogens for vaccine constructs able to elicit durable broadly protective responses.

The CfP is divided into two parts with varying timelines. The **broadly protective vaccine against SARS-CoV-2 variants (BPCoV2)** should have a minimal Target Product Profile (TPP) that aims to prevent disease[1] caused by circulating SARS-COV-2 variants of concern and emergent variants of interest (in aggregate referred to as 'variants' herein). The BPCoV2 application will require one step, the submission of an Expression of Interest (EOI). As these vaccines have the potential to help tackle the ongoing pandemic, as well as avoid costly and time-consuming strain adaptation, a more aggressive timeline for their development will be sought. Established and proven vaccine platforms are desired that facilitate rapid development and offer significant manufacturing scale up potential and access to vulnerable populations with potential Lower and Middle Income Country (LMIC) manufacturing. The BPCoV2 call is open from **April 1st to May 31st, 2021.**

The **broadly protective Betacoronavirus (BPBC) vaccine** will involve the research and development of novel immunogens and platform technologies and should have a minimal TPP that aims to protect against disease[2] caused by the known Betacoronaviruses that already pose a significant epidemic or pandemic risk. An optimal TPP may additionally protect against novel Betacoronaviruses that pose a significant risk of spill over zoonoses[3] and subsequent human transmission that results in new outbreaks. The BPBC application will require two steps: firstly, an EOI and secondly, an invitation to submit a full proposal for funding based on the peer review evaluation of the EOI. The BPBC call is open for EOIs from **April 1st to October 1st, 2021.** The call may be extended or amended depending on programmatic needs.

An EOI may be submitted at any time and reviews will occur on a bi-monthly rolling basis. It should be indicated in the application which program the proposal is for.

CEPI reviews and evaluates proposals based on their merits and in the context of stated eligibility criteria and CEPI's overall project portfolio. For novel strategies and technologies applying to the BPBC vaccine CfP, seed funding could potentially be awarded. Please note that this call for proposal does not seek direct applications for seed funding. The nomination for seed funding will be decided by CEPI after proposal review and aim to support a limited number of advancements, one or two years, when applications don't meet all the required criteria for full funding. Regardless of eligibility at any stage of a funding call, CEPI reserves the right to consider and to decline proposals at its sole discretion.

[1] Ideally, this minimal TPP should also prevent infection and transmission.
[2] Ideally, this minimal TPP should also prevent infection and transmission.
[3] Defined as an event when a reservoir population with a prevalent pathogen comes into contact with a novel host population. The pathogen is transmitted from the reservoir population and may or may not be transmitted within the host population. Please refer to USAID's PREDICT program for specific examples (http://data.predict.global/)

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1. Introduction

Emerging infectious diseases (EIDs), with epidemic or pandemic potential[4], are a significant and growing threat to individual life, societies, and prosperity. At CEPI we envision a world in which epidemics are no longer a threat to humanity. Our contribution to this vision is to accelerate the development of vaccines against EIDs and enable equitable access to these vaccines during outbreaks.

To accomplish its mission, CEPI will:

1. **Prepare** for known epidemic and pandemic threats. Build upon prior achievements to rapidly develop vaccines and promising biologics against the most prominent known threats.
2. **Transform** the response to the next novel threat. Leverage innovations in technology and systems to significantly reduce global vulnerability to emerging infectious diseases.
3. **Connect** and enhance global collaboration. Support the development of a post-pandemic consensus and a more robust and effective global preparedness and response architecture.

The ongoing SARS-CoV-2 pandemic is a public health crisis that has resulted, to date, in the loss of over 2.7 million lives and caused an unprecedented disruption to humanity. Previous epidemics caused by other Betacoronaviruses, SARS-CoV-1 and MERS, have also resulted in significant morbidity, mortality and adverse socio-economic consequences. It is clear that only widely available, safe and effective vaccines, in conjunction with other public health measures, will help prevent further loss of life and economic disruption caused by Betacoronaviruses and their variant forms.

This CfP is a funding opportunity for the development of state-of-the-art vaccines that are broadly protective in two measurable ways; firstly, breadth of protection against variants of SARS-CoV2 and secondly, protection against Betacoronaviruses as a genus. Regarding the former, multiple new SARS-COV-2 mutant variants are being detected as the first immunization campaigns commence. Single-stranded RNA viruses mutate rapidly, and first estimates indicate that SARS-CoV-2 lineages accumulate nucleotide mutations at a rate of around one to two per month. Nomenclature for these variants is not yet uniform and scientists are working with the WHO to propose a common nomenclature that doesn't rely on geographical origin. Nevertheless, variants of concern (VOC) have been designated that exhibit different virological and epidemiological characteristics, and field vaccine efficacy data suggests that protection against all-severity disease is diminished (corroborated by neutralization data). The vaccine field has responded with the generation of new vaccine constructs using Spike protein immunogens based on variant strains. Of particular interest, monoclonal antibodies have been identified that broadly and potently neutralize variants based on specific paratope-epitope interactions. Therefore, given the importance of antigen design, particular emphasis for funding will be placed on novel immunogens able to elicit broad and potent protection against variants. The strategy and scientific approach to demonstrate preclinical and clinical POC will also be crucial for a successful project. The fast-moving nature of the pandemic requires that these activities must have milestone driven, short development timelines, that allow rapid demonstration of clinical proof of concept (POC).

Regarding protection against Betacoronaviruses as a genus, this could include viruses that have already emerged with epidemic and pandemic potential such as SARS-CoV-1, MERS and SARS-CoV-2; as well as other potentially threatening viruses within the genus that are yet to cause disease in humans that could emerge on an epidemic or pandemic scale. The USAID PREDICT 1 program (2009-2019) identified 113 novel coronaviruses in animals and people in ecological hotspots with intensive spill over interfaces, such as live animal markets, caves where bat guano are harvested and communities that border wildlife habitats. Given the importance here for antigen design, particular emphasis will be placed on immunogen strategies and how proof-of-concept will be claimed. From a vaccine platform perspective, to align with CEPI's mission, we seek ideally rapid response technologies using already proven and established platforms, with parameters suitable for distribution in LMICs. Accelerated timelines to demonstrate clinical Proof of Concept (POC) are preferable but we recognize in the case of BPBC candidate vaccines that iterative work may be required based on translational research.

[4] As an example, please refer to the World Health Organization (WHO) "R&D Blueprint for Action to Prevent Epidemics".

2. Objectives

2.1 Objectives for Broad Protective SARS-CoV-2 vaccines

Example BPCoV2 ideal Target Product Profile:

- 80% or more efficacy against moderate-to-severe disease caused by variants;
- Prevention of viral infection and transmission
- Thermostable at 4-8° C
- Use in all ages and pregnant women
- Use in the immunocompromised
- Potential as booster vaccine

The main objective of the first part of this CfP is to support the research and development of broadly protective SARS-CoV-2 vaccines (BPCoV2) to meet the need for protection against variants. Emphasis is again on antigen design to elicit durable, potent and broad protection against variants. Both novel Spike antigens and other relevant viral antigens will be considered. The TPP for a BPCoV2 vaccine should aim for the following indication(s): active immunization of at-risk individuals who remain susceptible to moderate-to-severe disease and mortality caused by variants, regardless of prior SARS-CoV-2 vaccination status; used in a primary vaccination series, or as a booster following primary vaccination against ancestral strains of SARS-CoV-2, to prevent disease and mortality, and ideally to prevent infection and viral transmission. Such vaccines may also be used as a booster following clinical recovery from disease due to ancestral SARS-CoV-2 in high-risk individuals, based on specific risk factors. In the long term: active immunization of at-risk persons to prevent disease and infection.

The main focus of the call is:

1. Immunogen design and selection, based on Spike protein, and other relevant immunogens where applicable to induce a broader protective immune response against variants.
2. Design that considers existing VOC, emergent variants of interest and potentially future variants predicted computational or experimentally.
3. Safe and already proven, rapid response vaccine technology platforms; well suited to use and distribution in LMICs.
4. Technology platforms that can be accelerated through development, drive the breadth of responses and offer large volume production potential for equitable access to vulnerable populations.

Attention should be given to the path to licensure with such BPCov2 vaccines and how to accelerate all avenues of development. For example, if non-S immunogens are included, the justification for inclusion from a regulatory perspective will be essential, related to biomarkers or correlate(s) of protection.

Adjuvants able to promote a broader immune response should be considered, where appropriate.

2.2 Objectives for Broad Protective Betacoronavirus vaccines

Example of a BPBC ideal Target Product Profile:

- Active immunization of at-risk individuals, based on specific risk factors, to prevent disease and mortality (proxy - robust [80%] neutralization against a panel of Betacoronaviuses predictive of protection against disease).
- Prevention of virus infection and transmission
- Thermostable at 4-8° C
- Use in all age groups and pregnant women
- Use in the immunocompromised
- Suitable for use in outbreak situation

The primary objective of this call is the research and development of novel immunogens and platform technologies with the demonstration of preclinical and clinical POC, taking into account prerequisite regulatory requirements. Given that field efficacy trials against certain known Betacoronaviruses (e.g. MERS) and novel threatening lineages are not feasible, and a correlate of protection likely impossible across the genus, clinical POC is provisionally defined as follows;

- Safety demonstrated in phase 1 / 2 trials in vaccinees applicable for the TPP.
- Robust neutralization titers in a high proportion of vaccinees (e.g. 80% or more) against a panel of viruses applicable for the TPP with supportive additional immunological read-outs.
- An overall clinical package confirming that the concept of the new vaccine is feasible and that further late development is warranted and supportive of any subsequent steps towards regulatory approval.

Such clinical POC studies would necessitate the prior conduct and demonstration of pre-clinical POC in relevant animal models, indicative of broad protection rather than single pathogen-specific protection. Preclinical POC should ideally be based on an overall translational science strategy and the concept supportive of Exceptional pathways to licensure. Thus, thorough planning and appropriate regulated studies/quality systems undertaken for animal challenge/protection studies will be important.

The TPP for a BPBC vaccine seeks the following indications: in outbreaks, the active immunization of at-risk individuals, based on specific risk factors, to prevent disease and mortality, and ideally to prevent infection and viral transmission. In the long-term, active immunization of at-risk persons to prevent disease and infection.

The CfP seeks novel immunogen design based, for example, on one or more of the following scientific approaches:

1. Appropriate platform technology to deliver the vaccine immunogen(s) in a manner that elicits a broad immune response.
2. Multivalent immunogens.
3. Computationally designed immunogens using state-of-the-art methods to derive consensus sequences and/or the identification of highly conserved epitopes. Here, additionally, iterative design supported by machine learning tools could inform a translational science approach to optimal immunogen design [5] .
4. Monoclonal antibody driven immunogen design to direct antigen selection in terms of identifying broadly protective conserved / cryptic epitopes across the Betacoronavirus genus[5]
5. Any other vaccine and immunogen design approaches that address the objectives of the CfP.

Ideally, the novel immunogen(s) should be advanced using proven and established rapid response vaccine platform technologies, although novel platform technologies that meet the goals of the CfP will be considered. CEPI also aims to ensure that associated manufacturing capabilities and capacities will enable stockpiling of BPBC vaccines on a global scale as quickly as possible. Applicant's plans or ideas on their platform might be accelerated through development and offer large volume production potential and/or technology transfer to developing country vaccine manufacturers for equitable access to vulnerable populations will be beneficial to the application.

Adjuvants able to promote a broader immune response should be considered, where appropriate.

Although not the focus of this CfP, CEPI recognizes that human disease is also caused by Alphacoronaviruses, such as the 229E and NL63 lineages. These strains cause upper respiratory tract disease, but rarely severe lower respiratory tract complications and the epidemiological understanding of these alphaviruses is poorly documented. An application could additionally test for cross-genus protection, but this would not be considered a current priority.

In summary, the ultimate approach for this CfP is to develop broadly protective Betacoronavirus vaccines to help control the current pandemic and prepare for potential future epidemics and pandemics. It is recognized that a diverse spectrum of approaches can be tackled to address the challenges of broad protection, with overlapping scientific goals, necessitating a unified appraisal of all applications by CEPI. Figure 1 illustrates the spectrum of approaches and the desired timelines to achieve clinical proof of concept.

[5] This call is open to collaborative centres of excellence, with a partnership, that advance computational structural biology approaches for prediction and design of relevant Betacoronaviral immunogens.

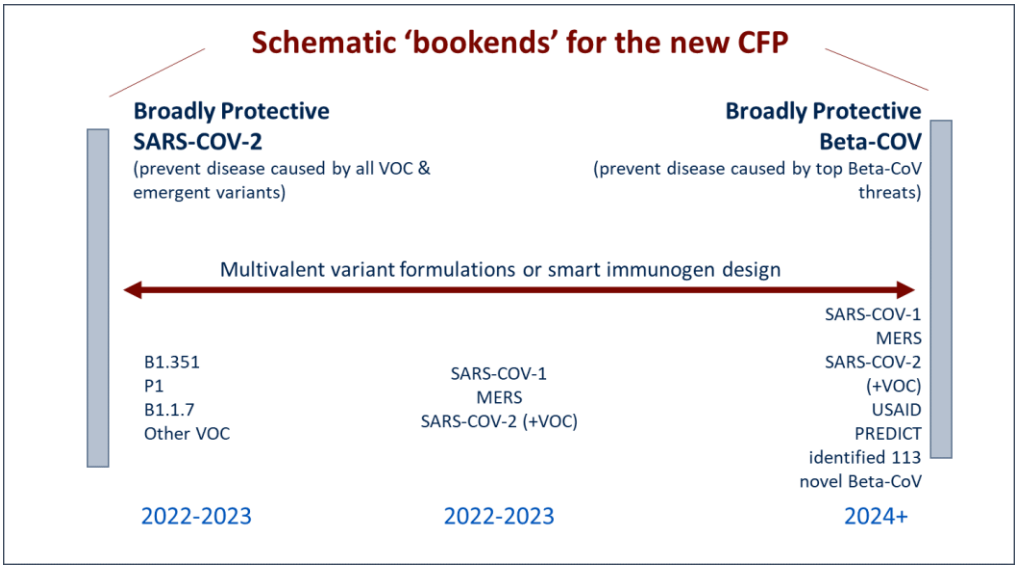

Figure 1: Schematic 'Bookends' illustrating the scope of the CfP with indications of suggested timelines to achieve clinical proof of concept.

3. Scope of the Call and eligibility criteria

The common scope of this CfP is the immunogen design inducing broadly protective and lasting immunogenicity against Betacoronaviruses and/or the emerging variants of SARS-CoV-2. It is recognized that a BPBC vaccine may also function as a BPCov2 vaccine.

The vaccine technology platform utilized should be suitable for rapid response application based on a proven and established technology, or a novel platform technology that meets the goals of the CfP.

The CEPI Secretariat will screen the eligibility of the EOIs according to the criteria described above. Applications that do not meet eligibility criteria will be excluded from further review.

3.1 Eligibility criteria for BPCoV2:

To be eligible the applicants need to fulfil the following criteria:

1. Applicants must be legal entities, or consortia comprised of legal entities.
2. 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 5 years.
3. Have a Target Product Profile (TPP) clearly stipulating the intended indication that drives subsequent immunogen design and R&D plans. Accompanying the TPP, have rationale that justifies the desired breadth of protection being sought.
4. Have access to an established or licensed vaccine technology platform that needs to have mid-stage clinical data on safety and immunity and has ideally rapid response attributes, as well as parameters suitable for LMICs
5. Scientific and operational plans for the design and selection of antigen(s) aiming to provide a sufficient breadth of protection against variants.
6. Definition for a successful preclinical and clinical POC.
7. Have plans for preclinical immunogenicity, safety and toxicology studies in relevant small animal models and NHPs.
8. Clinical and development plans that align with CEPI's targets timelines for this part of the call.
9. Present plans to produce Good Manufacturing Practice (GMP) batch for clinical trial materials and subsequent full-scale production.
10. A regulatory strategy articulated that includes the pathway to licensure of a BPCoV2 vaccine.
11. Present plans to integrate Phase I immunological testing which would utilize CEPI's available Centralised Laboratory network, and apply for sample testing, by completing and submitting the Sample Analysis Request Form.

12. Indicate willingness for data sharing, use of common assays and particularly the use of international reagent standards that must be utilized.
13. Indicate willingness to commit to CEPI's Equitable Access principles including the supply of vaccine doses through the COVAX Facility.

3.2 Eligibility criteria for BPBC:

To be eligible the applicants need to fulfil the following criteria:

1. Applicants must be legal entities, or consortia comprised of legal entities.
2. 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 5 years.
3. Have a Target Product Profile (TPP) clearly stipulating the intended indication that drives subsequent immunogen design and R&D plans. Accompanying the TPP, have rationale that justifies the desired breadth of protection being sought.
4. Have access to an established or licensed vaccine technology platform that has at least early-stage clinical experience, or propose novel vaccine technology platforms that support development of broadly protective vaccines.
5. Propose rationale and pathway for antigen design and selection such as a) multivalent immunogen, b) computational, and/or c) monoclonal antibody driven approaches.
6. Appropriate R&D plans that support the immunogen strategy, including POC plans.
7. Where applicable, leverage immunology biomarker understandings from SARS-COV-1/2 and MERS vaccine development to enable and support preclinical and clinical development
8. Definition for a successful preclinical and clinical POC. Special attention is needed towards the panel of viruses that will be used to establish POC.
9. Present plans to produce Good Manufacturing Practice (GMP) batch for clinical trial materials.
10. Present plans to integrate preclinical and Phase I immunological testing which would utilize CEPI's available central resources and Centralised Laboratory network, and apply for sample testing, by completing and submitting the Sample Analysis Request Form.
11. Indicate willingness for data sharing and use of common assays
12. Indicate willingness to commit to CEPI's Equitable Access principles.
13. Timelines: BPBC proposals should aim to demonstrate clinical proof of concept (POC) within 3-4 years

Solely based on CEPI's peer review process and secretariat recommendations, a limited number of proposals with novel approaches to immunogen design, but with shortcomings against certain criteria, may be be awarded Seed funding to enable the generation of additional supportive data. This seed funding would be for one or two years.

4. Applicant guidelines

EOIs must include essential evidence as required in the EOI template, meet the presented timeline requirements for completion, contain sufficient detail for review of the proposed product development process. Any claims made within the proposal must be supported by evidence.

The EOI template is accessible via www.cepi.net. To respond to this Call for Proposals Step 1, entities must submit their EOI to CEPI via a secure portal. Please send an email to cfp@cepi.net to be provided with a secure link to upload your EOI to the secure portal. The EOI should be uploaded in pdf format. No additional documents should be submitted. Personal data included in proposals will be handled according to CEPI's Privacy Notice on www.cepi.net/terms/.

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

- Indicate what part of the CfP is being preferred (BPBC or BPCoV2)
- requirements in section 3 (applicant eligibility criteria) met
- communication of information and documents in English
- budget figures submitted in US Dollars
- the EOI should not exceed 10 pages

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

In case of questions in relation to the submission system, access to the EOI template, or any other issue related to this Call for EOIs, please contact cfp@cepi.net. The CEPI Secretariat will address your questions within the shortest possible timeframe. Any questions submitted, along with answers, will be anonymised and made public.

No costs incurred by the applicants for the development and submission of EOIs will be covered by CEPI. Furthermore, CEPI will not provide funding retroactively for activities carried out prior to an award.

4.1 Submission and review process BPCoV2

For BPCoV2 EOI will serve as the application for the call for proposals, in accordance with the need of moving these candidates faster to the clinic. Applicants will submit their EOIs via the process outlined above. The review process will start on the **15th and 30th of each month** or the following business day. A review team composed of CEPI staff and external experts will assess compliance with the eligibility criteria (section 3). EOIs not meeting those criteria will not be further reviewed.

CEPI staff and external experts (as needed) will evaluate the eligible EOIs against the review criteria outlined in section 5. CEPI call core team will provide notice to the applicant of either an invitation to proceed to Due Diligence and negotiations or that the application was unsuccessful.

Applicants may resubmit with different or substantially modified EOIs at any time.
The call will be open from April 1 2021 and closes on May 31 2021, 1500 CEST.

4.2 Submission and review process BPBC

For BPBC the application process starts with an EOI and is not in itself an application for CEPI funding. CEPI will review the EOIs and issue an invitation to submit a full proposal for funding to a limited number of applicants. Applicants should submit their EOIs according to the process outlined above. The review process will start on the **15th of each month** or the following business day. A review team composed of CEPI staff and external experts will assess compliance with the eligibility criteria (section 3). EOIs not meeting eligibility will not be further reviewed.

CEPI staff and external experts (as needed) will subsequently evaluate the eligible EOIs against the review criteria outlined in section 5. CEPI call core team will provide notice to the applicant of either an invitation to a full proposal or that the application was unsuccessful. Novel approached may be suggested for Seed Funding and applicants will be notified accordingly.

If invited to submit a full proposal, the applicant will be provided with further direction and the application templates and will have up to 6 weeks to submit a full funding proposal. An invitation to submit a full proposal does not indicate an obligation on the part of CEPI to fund the applicant's work.

Applicants may resubmit with different or substantially modified EOIs at any time.
The call will be open from April 1 2021 and closes on October 1 2021, 1500 CEST.

4.3 Expression of Interest Documents

All documents related to this Call can be found on the CEPI website.
The Expression of Interest template must be used for the submission. Headers for each section and the italicised text explain the information required in that section. Failure to follow the directions of the template will result in the EOI being ineligible for review.

5. Review criteria

EOIs that have met the eligibility criteria described under section 4 will be assessed against the following criteria:

5.1 Review criteria BPBC and BPCoV2:

Please note that the definition criteria for BPCoV2 follow BPBC, but with addition or specification in the separate column.

Criterion	Assessment levels	Definition	
		BPBC	**BCoV2**
1. Immunogen & innovation	• Immunogen selection • Immunogen design • Immune response • Specific innovative approaches to tackle the challenges.	• Relevance of immunogen design and selection according to the Target Product Profile intended indication. • Scientific rationale and the technologies to be utilized for immunogen design for a broadly protective Beta-CoV vaccine approach. • Down-selection process to identify optimal immunogen(s) • Extent to which the technology will rapidly solicit immune responses providing protection/clinical benefit, with the likelihood of offering broad protection. • Immunological strategy (such as virus panels) that will allow the demonstration of breadth • Overall approach to innovative methods and solutions for the challenges.	• Extent to which the technology will rapidly solicit immune responses providing protection/clinical benefit, with the likelihood of improvement or differentiation from existing COVID-19 vaccine candidates in clinical development or granted EUL. • Immunological analytic strategy (such as virus panels) that will allow the demonstration of breadth and leverage existing biomarker experience from other COVID-19 candidate vaccines or those granted EUL.
2. Vaccine technology platform	• Platform safety and proven efficacy • Dosing regimen • Delivery system • Clinical database • Regulatory experience	• Documentation or plans for access to proven and/or licensed vaccine technology platform; or novel platforms well suited for BPBC vaccines • Understanding of platform safety and immunogenicity potential based on early-stage clinical data; in the case of novel platforms suited to BPBC vaccines provide evidence of suitability • Potential need of adjuvant and the complexity this adds to development / supply. • Description and characterisation of the proposed route of delivery and/or system. • Feasibility of securing licensure. • Estimated probability of technical and regulatory success (PTRS).	• Documentation for access to proven and/or licensed vaccine • Understanding of platform safety and immunogenicity potential based minimally on mid stage clinical experience. • Objectives to secure licensure and label claims.
3. Safety potential	• Non-clinical • Clinical	• Safety profile of the platform in animal models Safety profile in humans	• Safety profile for vulnerable population

Criterion	Assessment levels	Definition	
		BPBC	**BCoV2**
4. Speed of development	• Preclinical POC • First in Human • Clinical POC • Manufacturing strategy • Infrastructure	• Rigorous milestone-driven development approach • Translational science strategy to advance candidate vaccine development. • Use of animal models being conducted by regulated studies or quality systems • Extent to which the vaccine candidate will be ready for clinical testing within a defined period after contract signature • Potential for manufacturing scale up • Plans for manufacturing scale-up and/or scale-out during clinical development. • Complexity of technology transfer plans. • Infrastructure, internally or through partnerships, to rapidly advance development.	• Extent to which the vaccine candidate will be ready for clinical testing within 6 months after contract signature • Willingness to utilize CEPI centralized laboratories service for standardized testing of clinical material • Critical use of international standards • Plans for manufacturing scale-up and/or scale-out during clinical development and evidence of a suitable manufacturing partner. • Path to licensure (overarching regulatory strategy & late development expedited plans to licensure).
5. Technical/ Manufacturing scalability	• Quality • Formulation • Speed of production and scale • Scale of production	• Extent to which the technology and plans are expected to enable fast production in very large volumes. • Adjuvant access and supply (if applicable) • Likelihood of lower costs.	• Late development quality and manufacturing plans. • FTE resources able to support any scale-up / scale-out plans, tech transfers, and experience doing so.
6. Equitable access	• Storage and delivery • Sustainability of supply • Access	• Extent to which the technology can be delivered easily in LMICs. • Willingness to supply that ensures equitable access.	• Possibility of formulations and presentations with suitable storage conditions and stability for LMICs. • Extent to which the technology can be delivered easily in LMICs. • Extent of variant vaccine or formulation enabling global equitable access by providing protection against variants occurring more globally • Willingness to supply through the COVAX Facility

Criterion	Assessment levels	Definition	
		BPBC	**BCoV2**
7. Partnership	• Competency, experience, and track-record • Willingness to collaborate with other partners to enable global scale out and affordable manufacturing	• Extent to which the partnership, its plans and procedures are viable and of sufficient quality to deliver on the proposed activities of the project. The potential involvement of Developing Country Vaccine Manufacturer(s). Openness to additional funding from CEPI to include additional work packages and partnerships to progress the project towards realisation of vaccine doses in exchange for enhanced share of doses at affordable prices	• Extent to which the partnership, its plans and procedures are viable and of sufficient quality to deliver on the proposed activities of the project. The potential involvement of Developing Country Vaccine Manufacturer(s). • Partnerships that will secure access to data, samples and reagents necessary to demonstrate preclinical and clinical POC. • Openness to additional funding from CEPI to include additional work packages and partnerships to progress the project towards realisation of vaccine doses in exchange for enhanced share of doses at affordable prices.

6. Note on vaccine access

Any Awardee must have rights in order to develop, use, manufacture, and sell the vaccine proposed here for funding. CEPI will not take ownership of patents arising from its funded projects. CEPI will not seek a share of any commercial return from the vaccine manufacture during the pandemic period, focusing instead on ensuring global allocation needs are met. CEPI has a common interest with Awardees to ensure that project results are quickly and broadly made available to further scientific research on COVID-19 and that publications are 'open access'. CEPI will work with Awardees to develop a plan to ensure that CEPI's investments result in vaccines which are approved for use (during pandemic period) or are licensed, including a clear pathway to successful conclusion of the development of vaccines, their manufacture and global distribution.

CEPI is committed to the principle of universal, equitable and affordable access to vaccines, especially for the most vulnerable countries, as expressed in its Equitable Access Policy. CEPI's access policy requires that vaccines are allocated fairly based on public health need rather than ability to pay. Any Awardee receiving funds through this Call for Proposals, will be required to make commitments to CEPI's Equitable Access Policy and enter into an Award Agreement which will include a plan, appropriate to development stage, to enable that equitable access. CEPI is a co-lead on the vaccine pillar (COVAX) of the Access to COVID-19 Tools (ACT) Accelerator which has established a global mechanism to procure and fairly allocate COVID-19 vaccines (the COVAX Facility) during the current pandemic. Gavi also has established the COVAX AMC, a facility to fund the procurement of COVID-19 vaccines for up to ten (10) years for LMICs. BPCoV2 Awardees may ultimately be required to supply and sell vaccines through the COVAX Facility and the AMC Facility in quantities reflective of the funding received and at fair, affordable prices that are sustainable to the manufacturer as part of their plan for equitable access. One of the benefits of this mechanism is that CEPI has also worked with international partners to establish an appropriate liability and indemnification mechanism, recognising the importance to developers that such issues be addressed comprehensively prior to supplying vaccine.

7. Award conditions

Before submitting an application, Applicants should take note of two Award conditions. The first is that each Awardee recognises CEPI's governance, which can be found on CEPI's website. The second is that any funding is dependent on the signing of an Award Agreement, which provides the terms and conditions under which the Award will be made, in line with CEPI's Third Party Code, which can be found on CEPI's website

Contractual terms and conditions will need to be rapidly concluded in days or weeks and Awardees must be able to meet these pressing timelines given the urgency of the pandemic and the desire to start funding projects as quickly as possible.

Applicants unable or unwilling to meet these requirements should not submit an application.

8. Technical and administrative questions

Technical and administrative questions about this Call should be directed to the CEPI Secretariat (cfp@cepi.net).