

## CEPI Funding Agreements: Key Terms

This document sets out the key terms which will be included in all CEPI funding agreements. This document is provided to potential CEPI awardees (“**Awardees**”) for information. CEPI will prepare the first draft of its funding agreements; each Party shall meet its own legal costs in completing the funding agreement.

CEPI expects that funding agreements will be executed within three (3) months of the CEPI decision to fund an award. If an agreement is not executed by the end of the three (3) month period, CEPI may elect to withdraw its offer of funding.

**CEPI funds:** The Awardee shall use the funding from CEPI only for the purposes outlined in the Awardee’s application to CEPI and in the Project Milestones (and for no other purpose without CEPI’s prior written consent).

For information about which costs are eligible for CEPI funding and funding currencies, please see the [cost eligibility document link here](#).

The Awardee shall not seek or accept any other support for the costs which are funded by CEPI.

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**Project Milestones:** The Parties shall agree at least 2 Project Milestones. CEPI shall pay the first tranche of the award amount after the execution of the funding agreement. CEPI shall pay further tranches of the award amount to the Awardee only if CEPI determines that the Awardee has successfully achieved the Project Milestones by the agreed dates.

CEPI shall retain up to 10% of the award amount until the Awardee can demonstrate at the end of the Project that it has fully complied with CEPI policies on [open access and data sharing](#).

CEPI funding agreements will also contain financial controls, to ensure that CEPI funds are being used in furtherance of CEPI’s mission.

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**Records and Standards:** The Awardee shall be responsible for the management, monitoring and control of all research work undertaken pursuant to the Project (and compliance with the requirements of all applicable laws and regulatory authorities).

Where CEPI is funding a clinical trial:

1. The Awardee shall establish a Trial Steering Committee which shall have responsibility for managing the trial, and performance against the trial objectives. CEPI shall engage in the Trial Steering Committee and any data safety monitoring board as an observer.
2. The Awardee shall comply with the CEPI’s policies on [data sharing](#) and clinical trials (to be published soon).
3. The Awardee shall be required to take out and maintain appropriate clinical trial insurance.

The Awardee shall keep appropriate scientific, business and financial records relating to the Project and shall make these available to CEPI on request.

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**Project Management and Oversight:**

The Project Lead shall lead the Project. The Awardee shall ensure that a person fulfilling a project manager role shall be appointed to support the Project Lead.

The Parties shall establish a Project Steering Group (“**PSG**”) which shall have responsibility for managing the Project, assessing the progress towards the achievement of Project Milestones and performance against objectives, and considering matters relating to intellectual property. The PSG is a monitoring and advisory group, and it is the Project Lead’s responsibility to prepare and present progress and finance reports to the PSG.

1. Normally the members of the PSG shall comprise the Project Lead, another member of the Awardee’s organisation, an independent member and one CEPI nominee.
2. CEPI shall be entitled to invite further nominees to PSG meetings as observers, as it deems appropriate.
3. Where there are Project co-funders, they will join the PSG commensurate with their funding level.
4. The PSG shall be chaired by the Project Lead.
5. The PSG will take decisions by consensus.
6. The structure and composition of the PSG will reflect the proportion of funding from CEPI, including CEPI taking greater oversight for dedicated programs.

The Awardee shall provide written reports to CEPI at least quarterly during the course of the Award, and shall provide regular reports to CEPI after the completion of the Award in order to allow CEPI to determine the impact of its funding.

CEPI may appoint a Site Visit Group made up of a small team of independent experts and observers from CEPI to evaluate progress, performance and key issues. The Site Visit Group shall have reasonable access to visit the premises where the Project is being conducted to consult informally with those working on the Project, and shall report back to CEPI and the PSG on its findings.

The Awardee shall agree that CEPI shall have full access to dossier submissions, and any related documents and information exchanges between any regulator and the Awardee, including as part of regulatory planning in early stages of development. The Awardee shall invite a CEPI nominee to observe all interactions between the Awardee and any regulator which relate to the award.

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**Intellectual Property – ownership and protection:**

Background Intellectual Property and Foreground Intellectual Property shall normally be owned and protected by the Awardee, in accordance with CEPI’s policies on Equitable Access, Shared risks/shared benefits and IP management, as [available here](#).

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<b>Intellectual Property – management and exploitation:</b>	Background Intellectual Property and Foreground Intellectual Property shall be managed in accordance with CEPI’s policies on Equitable Access, Shared risks/shared benefits and IP management as <a href="#">available here</a> ; where the main objective is to ensure availability of and equitable access to CEPI funded investigational and/or licensed vaccines.
	The Awardee will commit to diligence obligations in relation to the development and exploitation of the Foreground Intellectual Property. The Awardee shall obtain CEPI’s prior written consent in order to exploit Foreground Intellectual Property; CEPI shall only withhold its consent to exploitation if the proposed exploitation is inconsistent with the Awardee’s equitable access obligations.
<b>CEPI Step-In Rights:</b>	In the event that the Awardee does not develop and exploit the Foreground Intellectual Property in accordance with the funding agreement and the Awardee’s agreed development and exploitation plans, CEPI may exercise step-in rights in relation to Background Intellectual Property and Foreground Intellectual Property, as described in CEPI’s policies on Equitable Access, Shared risks/shared benefits and IP management as <a href="#">available here</a> .
	<p>To enable CEPI to fully and rapidly exercise its step-in rights, CEPI may require:</p> <ol style="list-style-type: none"> <li>1. licences to the Foreground Intellectual Property and Background Intellectual Property to be executed concurrently with the funding agreement (albeit that such licences will have conditions precedent that relate to the step-in rights set out in the funding agreement); and</li> <li>2. escrow arrangements to be put in place to enable CEPI to have access and rights of use of Awardee materials. Such escrow arrangements may be established for confidential information, non-patented trade secrets, know-how, biological materials, cell-lines, software, and the like.</li> </ol>
<b>Sharing of Commercial Benefits:</b>	If commercial benefits arise as a result of the exploitation of Foreground Intellectual Property, then CEPI shall be entitled to share in such commercial benefits in a proportionate manner, as described in CEPI’s policies on Equitable Access, Shared risks/shared benefits and IP management as <a href="#">available here</a> .
<b>Publicity, publications and confidentiality:</b>	Except for announcements required by law, the Parties shall consult on all press releases and public announcements regarding the Award. The Parties shall be bound by standard confidentiality obligations.
	<p>Notwithstanding the foregoing:</p> <ol style="list-style-type: none"> <li>1. The Awardee must comply with CEPI’s open access, transparency and data sharing policies as included <a href="#">here</a> including requirements around the publication of clinical trial data; and</li> <li>2. CEPI shall be permitted to publish a summary of the funding agreement, focussing on the agreement’s compliance with CEPI’s policies on Equitable Access, Shared risks/shared benefits and IP management.</li> </ol>
<b>Warranties:</b>	The Awardee shall be required to give customary warranties including warranties relating to intellectual property matters. The Awardee shall repeat these warranties prior to CEPI making payments to the Awardee.

**Term, termination and effects of termination:** The Agreement will commence on its effective date and shall continue for the period that the Project takes to complete.

CEPI will be entitled to terminate the Project if:

- (i) the Awardee is in material breach of the Agreement;
- (ii) the Awardee is in an insolvency situation;
- (iii) the Awardee takes/omits to take any action which would be incompatible with/have an adverse effect (A) on CEPI’s objectives or reputation, or (B) on the ability of the Awardee to comply with its obligations under the Agreement;
- (iv) the Project Lead leaves the Awardee and the Parties are unable to agree a suitable replacement; or
- (v) the Site Visit Group recommends that CEPI terminates the Project.

If CEPI terminates the Project, CEPI shall not be required to make any further payments to the Awardee and the Awardee shall return all funding received from CEPI which is unspent at the time of termination. In case of material breach or insolvency, CEPI may also require spent funds to be returned.

Certain clauses shall survive termination, including provisions relating to Intellectual Property, the Awardee’s equitable access obligations, CEPI step-in rights, the sharing of commercial benefits and confidentiality undertakings.

**Governing law and jurisdiction:** The funding agreement shall be governed by the laws of England and Wales and the courts of English and Wales shall have exclusive jurisdiction for dispute resolution.

The Parties will attempt to resolve disputes in a collegiate way and in a timely manner.

Version number	Approval process	Date
1.0	Prepared by: Secretariat	20 February
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