

CEPI Side Letter - Awardee conditions to include

Successful EDCTP/CEPI Award recipients will be expected to enter the EDCTP Grant Agreement alongside a Side Letter with CEPI which will incorporate CEPI's usual award policies and will include these elements, by way of example. The exact terms of the final Side Letter and the process by which an Equitable Access Plan is developed and agreed with CEPI through the development of the funded project and which will also form part of this Side Letter, will be agreed with the relevant award recipients according to how each might be involved in that Plan.

Data/Results

The joint call will support a policy of transparency that enables availability of information, data, and materials relating to the development and testing of EDCTP/CEPI-funded vaccines while respecting and protecting patient privacy and safety. As a signatory of the [WHO Statement on Public Disclosure of Clinical Trial Results](#), CEPI has affirmed that the prospective registration and timely public disclosure of results from all clinical trials is of critical scientific and ethical importance and will require such registration and public disclosure by its awardees. Approaches to ensuring access to and rights of use of data, materials and transparency while maintaining confidentiality where required, will comprise one or more of the following:

- Requiring awardees to provide EDCTP/CEPI with information and data arising from their EDCTP/CEPI-supported project(s) in as close to real-time as possible.
- Requiring awardees to share data and materials pooled together with other awardees for use by EDCTP/CEPI or their choice of partner to facilitate the conduct of multiple and cross-cutting projects.
- Requiring awardees to share biological materials with other EDCTP and CEPI-funded awardees and with others as necessary and appropriate for the purpose of global-health research.
- Requiring the rapid dissemination of the data and results from EDCTP/CEPI-supported projects (including clinical trials) to the wider scientific community, allowing for measures to protect proprietary interests (where appropriate), and to enable the recognition of academic priority of discovery, while adhering with all elements in the WHO statement on public disclosure of clinical trial results.
- Requiring awardees that publish the results of work funded by EDCTP/CEPI in peer-reviewed journals to do so on an open access basis that enables the unrestricted access and reuse of all peer-reviewed published research funded, in whole or in part, by EDCTP/CEPI, including the underlying data sets.

In implementing these approaches, EDCTP/CEPI and their awardees will take all necessary steps to fully protect rights of personal privacy and to ensure appropriate attribution of the source of data, information, and materials.

Intellectual Property

The specific terms of IP management arising from funded programmes should be negotiated on a case-by-case basis with each awardee. Normally, the default position will be not to seek ownership of background IP or IP developed using EDCTP and CEPI funding ("foreground IP") and to manage IP through the award agreement in a manner that facilitates equitable access to vaccines, while also incentivising innovation, EDCTP/CEPI will:

- Require clear agreement with awardees regarding how relevant IP (both background and foreground IP) will be managed to fulfil the equitable access obligations, including where one awardee company or a pertinent asset is bought by another
- Require awardees to identify relevant background IP (whether these are owned by the awardee or third-parties), that may be used, incorporated, or further developed as part of a

- joint-funded project, and to clarify how such background IP will be managed by the awardee to exploit any foreground IP resulting from a EDCTP/CEPI-supported project
- Actively monitor foreground IP of funded awardees and require awardees to disclose foreground IP to EDCTP/CEPI as part of milestone reports

Equitable Access

Equitable access to epidemic vaccines in the context of an outbreak means that vaccines are available when and where they are needed to end an outbreak or curtail an epidemic, and that they are accessible to all populations that need them, without financial constraints, to achieve that objective. As part of its joint funding agreements, EDCTP/CEPI will pursue the principle that once a vaccine is licensed, price should not limit necessary access to a vaccine they have funded while at the same time ensuring the sustainability of vaccine manufacturing and distribution.

EDCTP/CEPI will work with awardees to jointly develop funding agreements on a case-by-case basis by using customised approaches to ensure that all awardees are aligned at the outset on a plan to achieve equitable access to the developed vaccine. The unpredictable nature of the vaccine development process, especially in the face of an emerging epidemic, calls for flexibility in the agreements and their underlying vaccine development plans. However, customised approaches and flexibility should not detract from the guiding principles and commitments to equitable access.

Step In Rights

In the event an awardee is acquired by another entity, or the awardee cannot or will not deliver on the original vaccine development agreement—particularly in the face of an outbreak or epidemic—EDCTP/CEPI must have an immediate way forward to ensure successful completion of agreed work. The precise approach taken in an award agreement may vary depending on the awardees' strategic focus, capacity, and capabilities. The array of approaches taken to ensure achievement of the joint call's goals will include, but are not limited to, one or more of the following:

- Step-in provisions that enable EDCTP/CEPI to take actions to move a project forward if an awardee steps back from the original agreement.
- Requirement of the awardee and EDCTP/CEPI to agree how relevant manufacturing partners for EDCTP/CEPI-supported vaccines will be contracted, and how licensing of IP, transfer of biological materials, and necessary technology sharing, know-how and assistance will be managed.
- A provision that EDCTP/CEPI and the awardee may choose another mutually agreed development or manufacturing partner to take over those commitments as needed, by agreeing to license/transfer to the chosen company all that is necessary to further develop the vaccine candidate and achieve equitable access obligations, such as required IP, biological materials, relevant technology, know-how, and assistance. In some cases, the awardee and EDCTP/CEPI may consider involving a trusted, mutually agreed, manufacturing partner during the development process so that it can take over if and when the manufacturing need arises.

Benefits

EDCTP and CEPI anticipate that their awardees may derive benefits in working with EDCTP/CEPI to develop vaccines, including the opportunity to benefit from EDCTP/CEPI's expertise in vaccine development and advocacy, and reputational benefits that go along with developing products for critical unmet global-health needs. However, EDCTP/CEPI also recognise the risks undertaken by their

awardees in developing such vaccines, including the uncertainty of timing and level of product demand, the reputational risk of failure or discontinuation of the development program, and the opportunity costs inherent in choosing to partner with EDCTP/CEPI on development of these vaccines. EDCTP/CEPI also recognise that their awardees in the private sector need to derive an acceptable return on investment for the company as a whole and that awardees in the academic sector often seek to find commercial partners for IP they develop.

In addition, awardees may generate revenue or other commercial benefits resulting from EDCTP/CEPI funding in support of their need to derive acceptable returns on investments, including from use or sale of a Priority Review Voucher awarded by the U.S. Food and Drug Administration, sales of a new vaccine or other products based on IP arising from EDCTP/CEPI-funded work, or in some cases royalty income from such IP.

Audit

CEPI will require that awardees allow for CEPI and its nominees to have a right of audit over the award expenditure including having access to the awardees own audit reports as they relate to the award and the passing on of this obligation to any sub-awardee.

Code of Conduct

CEPI will expect awardees to operate under the awards according to CEPI's usual award policies and code of conduct including in particular its Equitable Access Policy.

EDCTP Grant Agreement

EDCTP and CEPI agree - should any of the obligations set out above in this Side Letter in a particular case for an awardee (beneficiary in the EDCTP Grant Agreement) result in a conflict with any of the obligations following from the EDCTP Grant Agreement for this awardee – that the obligations following from the EDCTP Grant Agreement will prevail in such a case.