Global Health
EDCTP3

Global Health EDCTP3 Joint Undertaking

Call for Proposals

Topic title:

Mobilisation of Emergency funding for Mpox outbreak research response

Global Health EDCTP3
Joint Undertaking

WEBSITE
https://globalhealth-edctp3.eu

VISITING ADDRESS
Avenue de la Toison d'Or /
Gulden Vlieslaan 56-60
1060 Brussels (Belgium)

Global Health
EDCTP3

Topic Title: Mobilisation of Emergency funding for Mpox outbreak research response

Expected outcome:

This topic aims at supporting activities that contribute to answering the most pressing questions raised by public health responders to the Mpox Public Health Emergency (PHE), as part of the efforts to manage and prevent the spread of the current epidemic. Proposals should result in new knowledge to manage and prevent future outbreaks and should strengthen the capacities of at-risk countries to respond to epidemics.

To that end, proposals submitted under this topic should aim at delivering results that are contributing to the following expected outcomes:

- Provide novel, critical and timely insights into the Mpox outbreak and/or potential avenues for its management or prevention, focusing on the most affected population, specifically children, pregnant women and immunosuppressed individuals.
- Be timely, with rapid activation, to enable early and valuable outcomes and results to be produced and/or to support access time-dependent resources.
- To contribute to the public health preparedness and response in the context of the ongoing Mpox epidemic.

Scope:

The Global Health EDCTP3 Work Programme 2024[1] foresees funding to be mobilised in case of a Public Health Emergency (PHE). This mechanism allows rapid mobilisation of research funding with or without a call for proposals in exceptional and duly substantiated emergencies. Global Health EDCTP3 considers a situation as an emergency if it is unforeseen and presents a serious and immediate risk to human health.

Following the Mpox outbreak in the Democratic Republic of Congo (DRC), first reported in 2023, the DRC Government, Africa CDC, World Health Organization (WHO) and partners have been closely monitoring it. From 1 January through 12 November 2023, a total of 12 569 suspected Mpox cases, including 581 suspected Mpox deaths (case fatality ratio: 4.6%), had been reported in 156 health zones from 22 out of 26 (85%) provinces of the DRC[2]. In 2024, and as of 29 March, 4 488 cases have been reported, of which 319 have been confirmed. A total of 279 deaths have been reported in the country in 2024 (CFR: 6.7%)[3].

[1] https://globalhealth-edctp3.eu/resources/work-programme-2024
[2] https://www.who.int/emergencies/disease-outbreak-news/item/2023-DON493
[3] https://www.ecdc.europa.eu/en/news-events/outbreak-mpox-caused-monkeypox-virus-clade-i-democratic-republic-congo

Global Health
EDCTP3

On 13 April 2024, a High-Level Emergency Regional Meeting[4] was held in Kinshasa, to discuss the ongoing epidemic of Mpox in DRC and the potential risk of transmission to neighbouring countries and beyond. On the same day, the Ministry of Health (MoH) of DRC assessed the situation and considered the ongoing outbreak as a Public Health Emergency which requires a rapid and efficacious response. Aligning with this statement, the High-Level Meeting ended with a Communiqué (dated 13 April 2024) whereby twelve Ministers of Health and international partners called for a coordinated response to the outbreak and for the establishment of an Africa Taskforce for Mpox Coordination among Member States affected and at-risk of Mpox. These documents include a call to accelerate research and regulatory processes to enable access to vaccines, diagnostics and therapeutics for affected populations including children.

In the light of rising numbers of cases being reported in the DRC and the high public health risk, the Global Health EDCTP3 is activating the emergency funding mechanism to support research and innovation projects and activities as part of the Joint Undertaking's response to the emergency.

The Global Health EDCTP3 invites proposals for Research & Innovation Actions (RIA) to support research activities in DRC and neighbouring or affected countries, to manage and/or prevent the spread of the current Mpox outbreak.

Proposals should address one or more of the following areas:

1. **Vaccines research and development:**
   Trials should focus on both pre-exposure prophylaxis and post-exposure prophylaxis.
2. **Clinical trials for therapeutics:**
   Proposals should include trials on therapeutic products in the context of the Monitored Emergency Use of Unregistered Interventions (MEURI), such as tecovirimat (approved by the European Medicines Agency for use in the European Union) and other promising therapeutic candidates. Research on pain management strategies should integrated in the proposed R&D efforts.
3. **Surveillance strategies, evaluation of rapid diagnostics and epidemiological studies:**
   Proposals should provide data on epidemiological characteristics such as geographical spread, viral genotype, and pathogenicity, clinical information on host susceptibility and host immune responses. This work is foreseen to use and evaluate available diagnostic tools to ensure improved surveillance.

Moreover, proposals should ensure:

- Focus on the most affected population, specifically children, pregnant women and immunosuppressed individuals.
- Alignment with the national priorities of the DRC and neighbouring countries as well as the African Taskforce for Mpox Coordination.
- Partnership with researchers and public health institutions in DRC and neighbouring countries.
- Strengthening of national and local research capacity.
- Coordination and collaboration with other research and/or humanitarian activities operational in the countries affected.

[4] https://www.afro.who.int/media-centre/statements-commentaries/united-fight-against-mpox-africa

- Alignment with the Africa CDC Task Force recommendations for rapid activation of R&D activities to control the outbreak.
- Compliance with International Council on Harmonisation – Good Clinical Practice (ICH-GCP), regulatory and ethical standards.
- Commitment to open access and data sharing principles, including appropriate data management and governance plans.
- Demonstrate alignment/synergy with DRC national government health service delivery policy and plans, where appropriate.

Proposals should provide novel, critical and timely insights into the Mpox outbreak and/or potential avenues for its management or prevention, focusing on the most affected population, specifically children, pregnant women and immunosuppressed individuals.

Proposals must be timely, with rapid activation, to enable early and valuable outcomes to be established and/or to access time-dependent resources.

Proposals funded under this mechanism must share the relevant generated data within 30 days after generation with all parties that need and can use the findings to address the PHE.

Who should apply?

Under this mechanism, the invitation to apply for funding will be open to all eligible entities, and those based in affected countries are particularly encouraged to apply. To be eligible for assessment, proposals must be submitted by consortia that fulfil the eligibility criteria (See further under Eligibility).

Eligibility

The general conditions related to Work Programme 2024 (including Annex 1A, pages 7 to 12)[5] apply.

In particular, a proposal/application will only be considered eligible if:

1. its content corresponds, wholly or in part, to the topic/contest description for which it is submitted;
2. it complies with the eligibility conditions set out below:

Legal entities forming a consortium are eligible to participate in actions under the programme provided that the consortium includes:

- At least three legal entities independent from each other and established in different countries, where legal entities are eligible to receive funding;
- At least one independent legal entity established in a Member State or an associated country; and

[5] https://globalhealth-edctp3.eu/resources/work-programme-2024

- At least one independent legal entity established in a sub-Saharan African (SSA) country that is a member of the EDCTP Association.

Indicative budget and Topic-Specific Conditions

Specific conditions

Indicative timetable	This Call will be open for a maximum period of 2 weeks.
Expected EU contribution per project	The Global Health EDCTP3 JU estimates that a JU contribution of around EUR 1.25 million would allow the outcomes of this topic to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts. The total budget for this call may potentially attract additional funding from interested contributing partners.
Indicative budget	The total indicative budget for the topic is EUR 5 million.
Type of Action	Research and Innovation Actions.
Procedure	The following derogation to the evaluation procedure described in General Annexes F applies to open invitations to submit applications: In order to ensure a balanced portfolio covering responses to different aspects of the public health emergency, grants will be awarded to applications not only in order of ranking, but also to those projects that enhance the quality of the project portfolio through synergies between projects and avoidance of overlaps, provided that the applications attain all thresholds.
Legal and financial set-up of the Grant Agreements - Costs for providing financial support to third parties allowed	The action may also include justified derogations from the standard limits to financial support to third parties (maximum EUR 60 000 unless justified). Where applicable, the relevant grant agreement options will be applied.
Legal and financial set-up of the Grant Agreements - Standard deliverables	Implementing the provision on affordable access as defined in Article 114 of the Council Regulation 2021/2085, grants that implement clinical studies awarded under this topic will have to submit the following deliverables: **1. Stewardship plan** Participants must prepare stewardship plans outlining how to achieve the optimal use of an intervention, including, for example, how to avoid irrational use, overuse or abuse of health technologies (e.g. antimicrobials). A draft plan must be submitted after half the duration of the project has elapsed and a final plan must be submitted with the final report.

	2. Global access plan With the final report, participants must submit an appropriate and proportionate global access plan that covers registration targets, plans to meet demand, flexible approaches to IP and other strategies that reflect ability to pay and ensure that economic barriers to access are low.
Legal and financial set-up of the Grant Agreements - Additional exploitation obligations	Also in line with Article 114 of the Council Regulation 2021/2085, participants will be subject to the following additional exploitation obligations: 1. Participants must – up to four years after the end of the action (see Data Sheet, Point 1) – use their best efforts to ensure that resulting health technologies and services will be broadly available and accessible, as soon as possible and at fair and reasonable conditions. In this respect, if, despite a participants' best efforts, the results are not exploited within one year after the end of the action, participants must (unless otherwise agreed in writing with the granting authority) use the Horizon Results Platform to find interested parties to exploit the results. 2. In case the participants cannot fulfil the preceding obligation, the participants must (if requested by the granting authority) grant non-exclusive licences - under fair and reasonable conditions - to their results to legal entities that commit to rapidly and broadly exploiting the resulting health technologies and services and ensure that they are broadly available and accessible, as soon as possible and at fair and reasonable conditions. 3. In case of transfer of the ownership or licensing of results, participants must pass on such additional exploitation obligations to the legal entities exploiting the results. 4. For up to four years after the action (see Data Sheet, Point 1), the funding body must be informed every year about the status of the development of the product and any other exploitation of the results through an annual report that is due on each anniversary of the end of the grant agreement.