- Production of batches of the most promising antibody candidates according to the Good Manufacturing Practices (GMP)[254].

- First in human clinical safety studies demonstrating a clear regulatory pathway for market authorisation. Attention should be paid to critical biological and social factors such as sex, age, ethnicity and disability.

Participation of third countries where viruses addressed in the proposal are endemic or where outbreaks have occurred or are ongoing is encouraged.

The participation of start-ups, micro, small and medium-sized enterprises (SMEs) [255] is encouraged with the aim of strengthening their scientific and technological foundations, enhancing their innovation potential, and exploring possibilities for commercial exploitation.

All projects funded under this topic are expected to engage with regulatory bodies in a timely manner to ensure adequacy of the actions from a regulatory point of view.

Proposals should advance research by leveraging already existing and emerging state-of-the-art research infrastructures[256] such as those having contributed to the services developed under the ISIDORe project[257].

Applicants should provide details of their clinical studies[258] in the dedicated annex using the template provided in the submission system. As proposals under this topic are expected to include clinical studies, the use of the template is strongly encouraged.

HORIZON-HLTH-2027-01-DISEASE-07: Development of monoclonal antibodies to prevent and treat infections from Filo-, Nairo-, Phenui-, Picorna- and Toga viruses

Call: Cluster 1 - Health (Single stage - 2027/1)	
Specific conditions	
Expected EU contribution per project	The Commission estimates that an EU contribution of between EUR 9.00 and 10.00 million would allow these outcomes to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.
Indicative budget	The total indicative budget for the topic is EUR 37.30 million.
Type of Action	Research and Innovation Actions

254 https://health.ec.europa.eu/medicinal-products/eudralex/eudralex-volume-4_en

255 https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32003H0361

256 The catalogue of European Strategy Forum on Research Infrastructures (ESFRI) research infrastructures portfolio can be browsed on the ESFRI website: https://ri-portfolio.esfri.eu

257 https://isidore-project.eu

258 Please note that the definition of clinical studies (see introduction to this Work Programme part) is broad and it is recommended that you review it thoroughly before submitting your application.

Eligibility conditions	The conditions are described in General Annex B. The following exceptions apply: In recognition of the opening of the US National Institutes of Health's programmes to European researchers, any legal entity established in the United States of America is eligible to receive Union funding. If projects use satellite-based earth observation, positioning, navigation and/or related timing data and services, beneficiaries must make use of Copernicus and/or Galileo/EGNOS (other data and services may additionally be used).
Award criteria	The criteria are described in General Annex D. The following exceptions apply: The thresholds for each criterion will be 4 (Excellence), 4 (Impact) and 4 (Implementation). The cumulative threshold will be 12.
Procedure	The procedure is described in General Annex F. The following exceptions apply: To ensure a balanced project portfolio covering the viruses targeted in this topic [259], grants will be awarded (within available budget) to proposals not only in order of ranking but at least also to those proposals that are the highest ranked within different viruses targeted, provided that the proposals attain all thresholds.
Legal and financial set-up of the Grant Agreements	The rules are described in General Annex G. The following exceptions apply: The granting authority may, up to 4 years after the end of the action, object to a transfer of ownership or to the exclusive licensing of results, as set out in the specific provision of Annex 5.

Expected Outcome: This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination "Tackling diseases and reducing disease burden". To that end, proposals under this topic should aim to deliver results that are directed at, tailored towards and contributing to all the following expected outcomes:

- The scientific and clinical communities have a better understanding of and access to experimental monoclonal antibodies for the prevention and treatment of emerging or re-emerging viral infections, as well as for further clinical investigation.
- Candidate monoclonal antibody therapies are available to treat patients for emerging and re-emerging viral infections, increasing therapeutic options for clinical deployment in case of an epidemic or pandemic.

[259] Virus i to vi, as given in the scope of this topic.

Scope: Infectious diseases remain a major threat to health and health security in the EU and globally. Viral disease emergence is already being accelerated by climate change, and thus a proactive approach to the development of antiviral prophylactics and therapeutics in preparedness for future infectious disease outbreaks is needed. The capacity to produce antibodies that can target new variants and rapidly increase production would serve as an essential preparedness strategy against future health threats, whether from infectious disease epidemics or pandemics.

This topic contributes to strengthening the Research and Innovation ecosystem within the EU and supports the implementation of the European Medical Countermeasures Strategy[260].

Applicants should explicitly state in their proposal which of the following viruses is targeted and the proposed work should address only this specific virus. The proposed work should aim to advance the development of existing prophylactic and therapeutic monoclonal antibody candidates targeting exclusively one of the following viruses:

i. Ebola Virus

ii. Marburg Virus

iii. Crimean-Congo Hemorrhagic Fever Virus

iv. Rift Valley Fever Virus

v. Enterovirus D68

vi. Chikungunya Virus

Proposals should focus on antibodies produced or derived from a single cell clone through recombinant expression, such as B-cell derived antibodies, hybridoma derived antibodies and nanobodies.

Proposals should thus aim to diversify and accelerate the global prophylactic and therapeutic research and development portfolio for emerging and re-emerging viral infections, and to strengthen the leading role of the EU in prophylactic and therapeutic research and development.

Proposals should address all the following research areas:

- If necessary, finalisation of the in-vitro characterisation of existing monoclonal antibody candidates with regard to target specificity, epitope recognised, and their ability to impair or inactivate viral functions.

- In-vivo tests in at least one animal model or, if available in humanised immune system animal models, to demonstrate the protective function of the monoclonal antibodies deemed sufficient for moving to first clinical trials.

260 https://health.ec.europa.eu/health-emergency-preparedness-and-response-hera/preparedness/medical-countermeasures-strategy_en