- If requested by regulators as pre-requisite for clinical studies, in-vivo tests in a non-human primate model.
- Evaluation of Antibody-Dependent Enhancement (ADE) risk where scientifically relevant.
- Production of batches of the most promising antibody candidates according to the Good Manufacturing Practices (GMP)[261].
- 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) [262] 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[263] such as those having contributed to the services developed under the ISIDORe project[264].

Applicants should provide details of their clinical studies[265] 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-08: Development of innovative antimicrobials against pathogens resistant to antimicrobials

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 8.00 and 10.00 million would allow these outcomes to be addressed

261 https://health.ec.europa.eu/medicinal-products/eudralex/eudralex-volume-4_en
262 https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32003H0361
263 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
264 https://isidore-project.eu
265 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.

	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 44.20 million.
Type of Action	Research and Innovation Actions
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 pathogens targeted in this topic[266], 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 pathogens 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:

[266] Pathogen i to vi, as given in the scope of this topic.

- The scientific and clinical communities have a better understanding of and access to new and innovative products for the treatment of antimicrobial resistant bacteria and fungi, as well as for further clinical investigation.

- Candidate therapies are available to treat patients for antimicrobial resistant bacteria and fungi, increasing therapeutic options for clinical deployment in the fight against Antimicrobial Resistance (AMR).

Scope: The rapid rise of AMR presents a formidable threat to public health, challenging our ability to treat infections that were once easily managed with standard antimicrobials. As pathogens continually adapt and develop resistance to existing drugs, the efficacy of these treatments diminishes, leading to more severe and prolonged illnesses, increased healthcare costs and productivity losses, and higher mortality rates. This escalating crisis underscores an urgent need for viable therapeutic alternatives required to reduce the burden of diseases caused by antibiotic resistance. Innovative solutions are crucial to maintaining effective disease management and safeguarding public health.

Proposals should pursue the development of innovative and effective antibacterial and antifungal agents, including antibody-based therapies, which meet at least one of the four World Health Organization (WHO) innovation criteria[267], namely: i) new chemical class, ii) new target, iii) new mode of action and iv) no evidence of cross-resistance.

This topic contributes to strengthening the Research and Innovation ecosystem within the EU and supports the implementation of the European Medical Countermeasures Strategy[268] and the forthcoming Critical Medicines Act[269].

Proposals under this topic should not pursue the development of phage-therapies.

Applicants should explicitly state in their proposal which of the following pathogens is targeted and the proposed work should address only this specific pathogen. The proposed work should pursue the development of existing therapeutic candidates targeting exclusively one of the following pathogens:

i. Carbapenem resistant Acinetobacter baumanii (CRAB)

ii. Carbapenem-resistant Enterobacterales (CRE) and third-generation cephalosporin-resistant Enterobacterales (C3GRE)

iii. Carbapenem resistant Pseudomonas aeruginosa

iv. Methicillin-Resistant Staphylococcus aureus (MRSA)

v. (Drug)-resistant Aspergillus fumigatus

267 https://www.who.int/publications/i/item/9789240093461
268 https://health.ec.europa.eu/health-emergency-preparedness-and-response-hera/preparedness/medical-countermeasures-strategy_en
269 https://health.ec.europa.eu/publications/proposal-critical-medicines-act_en

vi. (Drug)-resistant Candida spp

Identifying a specific pathogen does not preclude the exploration of these candidates' effects on other bacteria or fungi. Proposals should thus aim to accelerate testing of novel candidates in human trials, diversify and accelerate the global prophylactic and therapeutic research and development portfolio for AMR bacterial and fungal infections, and to strengthen the leading role of the EU in prophylactic and therapeutic research and development.

Proposals should address all the following areas:

- If necessary, finalisation of 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 therapeutics deemed sufficient for moving to first clinical trials.
- If requested by regulators as pre-requisite for clinical studies, in-vivo tests in a non-human primate model.
- Production of batches of the most promising antimicrobials candidates according to the Good Manufacturing Practices (GMP)[270].
- In human clinical safety and efficacy studies, demonstrating a clear regulatory pathway for market authorisation. Attention should be paid to critical biological and social factors such as sex, age, ethnicity, disability and vulnerability.

Participation of third countries where AMR bacteria and fungi 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) [271] 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 initiatives such as the co-funded European Partnership on One Health Anti-Microbial Resistance (EUP OHAMR)[272].

Applicants should provide details of their clinical studies[273] 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.

270 https://health.ec.europa.eu/medicinal-products/eudralex/eudralex-volume-4_en
271 https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32003H0361
272 https://cordis.europa.eu/project/id/101217154, https://ohamr.eu
273 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.