Monday, January 5, 2026

Poster abstract submission

Approval Status Not Started

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Country United Kingdom

Type of organization Academic / research institution

Poster title
MHRA Initiatives for the Advancement of Regulation for Phage Therapeutics

Poster abstract

Antimicrobial resistance (AMR) poses a critical global health threat, driving urgent innovation in alternative therapeutics such as bacteriophage-based products. To address regulatory challenges and accelerate safe deployment of phage therapies, the UK Medicines and Healthcare products Regulatory Agency (MHRA), supported by the Global Antimicrobial Resistance Innovation Fund (GAMRIF), has implemented a multi-faceted programme spanning regulatory science, stakeholder engagement, and international collaboration.

MHRA funded Phages for Global Health workshops in Malaysia and Uganda (March 2025) to build capacity in low- and middle-income countries (LMICs) and address systemic and regulatory barriers to phage adoption. These workshops fostered One Health approaches and strengthened global networks for phage development and governance.

To provide clarity on regulatory pathways, MHRA published Regulatory considerations for therapeutic use of bacteriophages in the UK (June 2025), outlining requirements for both licensed and unlicensed routes from preclinical development through post-licensure pharmacovigilance. A companion interpretation guide, developed with the Innovate UK Phage Innovation Network, supports developers in applying these principles. MHRA also contributed to a review of phage regulation through the TATFAR consortium, promoting international harmonisation.

Recognising the complexity of engineered and synthetic phages, MHRA secured funding from the UK Engineering Biology Sandbox Fund to establish a multi-agency regulatory groundwork initiative. This two-year project, involving MHRA, UKHSA, FSA, VMD, and Defra, aims to explore frameworks for novel phage technologies and inform future policy.

To help standardise critical quality attribute assessment of these products, the MHRA is developing a phage reference material. This resource will enable cross-platform validation of e.g., sequencing, integrity, and proteomic workflows, supporting consistent quality control and regulatory confidence across human, veterinary, and food applications.

Collectively, these activities advance confidence and shape the frameworks for phage therapeutics, reduce barriers to innovation, and promote global alignment, accelerating the delivery of safe and effective phage-based solutions to combat AMR.

Research topic Phage or phage products