Technical Project Summary- SDI

Project title

INFECTORY

Acronym (optional)

Project leader + organisation

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File number:

10920012510018

Key words

Bacteriophage, GMP production, infectious diseases

Domain 4D Map (link)

☐ A. Basic Science & Target Identification
☐ B. Target Pharmacology
☒ C. Lead Identification
☒ D. Lead Optimization
☒ E. Clinical Research & Development
☐ F. Regulatory review
☐ G. Post-marketing
☐ H. Medical Landscape
☐ I. Commercial Manufacturing & Distribution

Theme investmentagenda (if applicable)

Investeringsagenda SDI 2025 (link)

☐ 2025. "Molecular Diagnostics and Imaging"
☐ 2025. “Early Discovery Infrastructure”
☒ 2025. “Small scale (shared) manufacturing facilities, "Bioprocessing and fermentation" and "Sustainable manufacturing"

Aims and objectives

INFECTORY will establish national GMP capacity for small-batch bacteriophage manufacturing for compassionate use and early-phase clinical trials, a capability currently unavailable in the Netherlands. The platform provides non-discriminatory access via a transparent cost-plus model and centralizes QA/QC and biosafety requirements. It enables clinical-grade supply, allowing for systematic evidence generation, while de-risking private investment and SME participation. INFECTORY strengthens Dutch technical capability and closes an infrastructure gap, advancing the AMR response in alignment with PharmaNL’s high-quality infrastructure objectives.

User group and application

The INFECTORY will operate as a fee-for-service manufacturing organisation for GMP grade bacteriophages under the InFECT-NL foundation. Its independence and national character allow for use by any party, private or public. For compassionate use access, the project will facilitate the creation of an expert committee to judge appropriateness and recommend dosage and routes of administration. For clinical research purposes, including systematic clinical trials, INFECTORY can be contracted through subawards or directly. INFECTORY will use a transparent cost-plus funding model, allowing for open and fair access. INFECTORY will provide non-discriminatory technology transfer to any Dutch start-up in the bacteriophage production field.

Impact

INFECTORY will provide clinical-grade, small-batch GMP production of bacteriophages for compassionate use and early-phase trials, targeting delivery of 3–4 QP-released products per year during the project lifetime, with sufficient capacity to expand thereafter. Centralized biobanking, validated processes, and standardized QC/release reduce reliance on foreign/non-GMP sources and

shorten lead times. Evidence generation (safety, potency, stability, workflows) will underpin national indications and guideline development via the expert pathway. The facility reinforces the Dutch pharmaceutical value chain, enabling SME participation through cost-plus access and CDMO-like services, and strengthens national AMR response. The operating model is self-sustaining from first production, ensuring durable impact.

Technical description of the shared infrastructure

The 220m2 facility has a linked class B and class C production suite with an isolator fit for bacteriophage production and is designed to ensure the safety of patients, personnel, and the environment by complying with Biosafety and GMP facility requirements. In Class B areas, a biosafety cabinet primarily supports aseptic operations within a Grade A environment, surrounded by Grade B conditions, ensuring both operator and environmental protection. In Class C areas, aseptic processes are conducted within an isolator suitable for bacteriophage production. The facility will fully comply to GMP standards, as well as MLIII and BSL3 biosafety containment requirements. A VHP (Vaporized Hydrogen Peroxide) pass box is used to maintain a sterile working environment within the GMP facility, preventing contamination. A pressure cascade ensures full containment, including product protection from adventitious agents. All air leaving the facility is HEPA-filtered, and pressure levels are continuously monitored and controlled to maintain negative pressure relative to the external environment. Waste deactivation is performed using a destruction autoclave integrated into the laboratory design. Emergency showers are available for personnel safety. Entrance and exit pathways are separated, one way directionality for both staff and goods are included in the design. A large GMP grade storage area is available in the lab.

Project group and collaborating partners

Project leadership is anchored in a five-partner steering committee: INFECTA, UMC Utrecht (UMCU), LUMC, FAST, and AHAM. INFECTA's CEO, Prof. Dr. Meta Roestenberg, chairs the team; she brings extensive experience in early-phase infectious-disease trials, GMP production of challenge agents, and consortium leadership, and oversees INFECTORY's design and build. Dr. Pieter-Jan Haas (UMCU), medical microbiologist and head of the phage group, has over 20 years' expertise in phage R&D, production/purification, clinical application, and European quality frameworks. Dr. P. Meij (LUMC), QP ATMP and head of the Center for Cell and Gene Therapy, is a leading expert in complex ATMPs and infectious challenge agents, active in Dutch/Belgian ATMP working parties. Dr. S. J. de

Innovation and Distinctiveness

Currently, GMP production of bacteriophages in the Netherlands is impossible. The INFECTORY facility thus fills an important gap in the development chain for bacteriophages as alternative products for the treatment of multi-resistant bacterial infections. The operating model is make-to-order: phages are produced only against confirmed requests. Pricing is transparent and cost-plus with an 8% margin. As a result, the operating budget turns positive once GMP production starts in 2030, and the facility is self-sustaining thereafter.

Alignment PharmaNL programme (optional)

INFECTORY aligns with PharmaNL Human Capital by offering a national training site across post-MBO, post-HBO and post-academic levels, offering hybrid, life-long learning embedded in operations and the demonstrator. It provides supervised placements for lab technicians and modular courses for pharmacists, microbiologists and SME staff. Open access and shared protocols create a knowledge-to-market cycle, strengthen mobility between hospitals, academia and SMEs, and ensure the infectious-disease innovation pipeline is matched by the skills to deliver it.