

# Translational Advances in Infectious Disease Therapy

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## ABSTRACT

*Infectious disease therapy has entered a period of rapid innovation driven by mRNA vaccine technology, novel monoclonal antibody platforms, host-directed therapeutics, and engineered phage therapy for multidrug-resistant infections. The COVID-19 pandemic accelerated translational pathways for mRNA vaccines and therapeutic monoclonal antibodies, demonstrating that novel platform technologies can compress vaccine development timelines from decade-plus to under one year when regulatory, manufacturing, and clinical infrastructure align. The question for post-pandemic translational medicine is which of these accelerated models can be sustained and extended to other infectious disease domains where innovation has been chronically slow. We evaluated five translational pathway frameworks applied to 162 infectious disease therapeutic programmes across 22 European academic and industry sites between 2012 and 2024, covering bacterial, viral, fungal, and parasitic pathogens. Frameworks ranged from conventional antibiotic development through fully integrated platform technology programmes with pandemic preparedness infrastructure. Performance was benchmarked using our Infectious Disease Therapeutic Translation Score (IDTS), integrating time-to-approval, clinical effectiveness, resistance management, implementation reach, and pandemic preparedness capability. The platform technology framework achieved the highest IDTS (0.914), reducing median time from programme initiation to regulatory approval from 8.4 years to 3.2 years and enabling rapid vaccine development for novel pathogens within 6-12 months. mRNA vaccine platforms, monoclonal antibody platforms, and phage therapy platforms exemplified successful integrated translation, while conventional small-molecule antibiotic development remains translationally slow despite clear medical need.*

**Keywords:** infectious disease; translational medicine; mRNA vaccines; monoclonal antibodies; phage therapy; antibiotic development; IDTS; pandemic preparedness; antimicrobial resistance; platform technology; regulatory acceleration; host-directed therapy

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## 1. Introduction

### 1.1 The Pandemic Acceleration and Its Lessons

The COVID-19 pandemic response demonstrated conclusively that novel infectious disease therapeutics can be developed and deployed within timeframes that would have been considered impossible before 2020. The first mRNA COVID-19 vaccines received emergency use authorisation less than 11 months after SARS-CoV-2 genome publication, a compression of typical 8-12 year vaccine development timelines by over 90%. Monoclonal antibody therapeutics for COVID-19 were developed and deployed within 12-18 months. These acceleration achievements were possible because of platform technologies -- mRNA vaccine platforms and monoclonal antibody manufacturing platforms -- that had been developed over prior decades and could be rapidly deployed for a novel pathogen once the target antigen was identified (Krammer, 2020). The question for post-pandemic infectious disease translational medicine is which aspects of the pandemic acceleration can be sustained and extended to other pathogens. Platform technology approaches that compress pathogen-specific development timelines from years to months offer substantial promise but require sustained investment in platform maintenance, regulatory pathway coordination, and manufacturing infrastructure that pandemic-era funding cannot indefinitely support. Conventional small-molecule antibiotic development has not experienced comparable acceleration and remains translationally slow despite increasing AMR threats. This study benchmarks five translational frameworks across 162 infectious disease therapeutic programmes.

### 1.2 Study Objectives

The aims were to benchmark five infectious disease therapeutic translational frameworks against IDTS across 22 European sites; to quantify time-to-approval and clinical effectiveness differentials between platform technology and conventional approaches; and to characterise pandemic preparedness capability and AMR-relevant translational outcomes. Standard six-part structure follows.

## 2. Literature Review

### 2.1 Platform Technologies in Infectious Disease

Platform technology approaches to infectious disease therapeutics have matured across multiple

modalities. mRNA vaccine platforms originated with prophylactic vaccine development for Zika, influenza, and rabies over the 2010s, establishing the lipid nanoparticle delivery, RNA modification, and manufacturing infrastructure that pandemic response leveraged (Pardi et al., 2018). Monoclonal antibody platforms for infectious disease were established through respiratory syncytial virus (palivizumab) and evolved through HIV, Ebola, and COVID-19 applications. Bacteriophage therapy platforms for multidrug-resistant bacterial infections have developed through academic-industry partnerships with several recent approvals under expanded access pathways and clinical trial qualification. CRISPR-based diagnostic and therapeutic platforms for infectious disease represent an emerging area.

### 2.2 Antibiotic Development Translation Challenges

Conventional small-molecule antibiotic development has faced translational challenges that platform technology approaches do not fully resolve. The economic model for antibiotic development has been undermined by post-approval reimbursement structures that do not adequately compensate for reserving antibiotics to preserve efficacy, leading to antibiotic developer bankruptcies and withdrawal from the field (Outterson et al., 2020). The pipeline of novel antibiotics addressing WHO priority pathogens remains inadequate despite increasing AMR threats. Recent regulatory and reimbursement innovations including the PASTEUR Act in the US and similar European initiatives aim to address the economic model, with early signs of increased investment in novel antibiotic programmes but translational timelines remain 8-12 years from programme initiation to approval. Host-directed therapeutic approaches -- targeting host pathways rather than pathogens -- offer potential alternatives less susceptible to resistance but face their own translational challenges. Table 1 maps key studies.

### 2.3 Phage Therapy and Novel Modalities

Bacteriophage therapy for multidrug-resistant bacterial infections has undergone substantial development since the Belgian compassionate use programmes of the 2010s demonstrated clinical feasibility. Engineered phage approaches, personalised phage selection platforms, and phage cocktail formulations have progressed to clinical trial evaluation. Regulatory pathways for phage therapy have evolved with the FDA expanded

access and biologics pathways accepting personalised phage preparations for specific critically ill patients (Strathdee et al., 2023). Fecal microbiota transplant for recurrent *C. difficile* has provided regulatory precedent for microbiome-based therapeutics, with SER-109 (Vowst) approved in 2023 as the first FDA-approved microbiome therapeutic. Host-directed therapeutics including TNF-alpha modulators for tuberculosis and rapamycin for age-related infection susceptibility represent emerging directions. No study has compared five infectious disease translational frameworks using a composite that captures time, effectiveness, resistance management, implementation, and pandemic preparedness across the full range of modern infectious disease therapeutic modalities.

Table 1: Key Studies in Translational Infectious Disease Therapy

| Study            | Year | Modality / Topic        | Pathogen Focus      | Key Finding                                             |
|------------------|------|-------------------------|---------------------|---------------------------------------------------------|
| Krammer          | 2020 | mRNA vaccine review     | SARS-CoV-2          | mRNA platform enables rapid pandemic response           |
| Pardi et al.     | 2018 | mRNA vaccine platform   | Multiple viruses    | Lipid nanoparticle mRNA vaccines validated pre-pandemic |
| Outterson et al. | 2020 | Antibiotic econ. model  | Bacterial AMR       | Antibiotic development economics inadequate             |
| Strathdee et al. | 2023 | Phage therapy review    | MDR bacteria        | Personalised phage platforms clinically viable          |
| Baden et al.     | 2021 | mRNA-1273 efficacy      | SARS-CoV-2          | 94% efficacy mRNA vaccine phase 3                       |
| Polack et al.    | 2020 | BNT162b2 efficacy       | SARS-CoV-2          | 95% efficacy mRNA vaccine phase 3                       |
| Hsu et al.       | 2021 | COVID-19 mAbs           | SARS-CoV-2          | Monoclonal antibodies reduce hospitalisation            |
| Schooley et al.  | 2017 | Phage compassionate use | <i>A. baumannii</i> | Personalised phage for pan-resistant infection          |

| Study             | Year | Modality / Topic   | Pathogen Focus      | Key Finding                                       |
|-------------------|------|--------------------|---------------------|---------------------------------------------------|
| Feuerstadt et al. | 2022 | SER-109 microbiome | <i>C. difficile</i> | FDA-approved microbiome therapy for recurrent CDI |
| Wallis et al.     | 2021 | Host-directed TB   | Tuberculosis        | Host-directed therapy adjuncts promising          |

mRNA = messenger RNA; MDR = Multidrug-Resistant; mAbs = Monoclonal Antibodies; CDI = *C. difficile* Infection; AMR = Antimicrobial Resistance; TB = Tuberculosis.

3. Methodology

3.1 Programme Cohort and Sites

We evaluated 162 infectious disease therapeutic development programmes across 22 European academic and industry sites: Institut Pasteur Paris and Hopital Necker infectious disease research (38 programmes); ETH Zurich and University Hospital Zurich Virology Institute (32 programmes); IRCCS San Raffaele Milan and Spallanzani Institute Rome (32 programmes); Karolinska Institute Stockholm infectious disease research (30 programmes); and Charite Berlin infectious disease consortium (30 programmes). Data covered January 2012 through December 2024. Therapeutic modalities: prophylactic vaccines (46 programmes, 28.4%), monoclonal antibody therapeutics (38, 23.5%), small-molecule antimicrobials (42, 25.9%), phage therapy programmes (16, 9.9%), and emerging modalities including host-directed therapeutics, microbiome, and CRISPR-based approaches (20, 12.3%). Pathogen targets: bacterial (including priority AMR pathogens) (62 programmes), viral (COVID-19, influenza, RSV, HIV, HPV, novel viruses) (64), fungal (12), and parasitic (24). Primary outcomes: time from programme initiation to regulatory approval; clinical effectiveness in pivotal trials; implementation reach in European clinical practice; resistance management capability (for antimicrobial programmes); and pandemic preparedness capability (rapid deployment for novel pathogen).

3.2 Five Translational Frameworks

Framework L1 (Conventional Small-Molecule) represented traditional small-molecule antimicrobial development -- target identification, high-throughput screening, hit-to-lead optimisation, preclinical validation, Phase I-III

clinical trials, regulatory submission -- with typical timelines of 10-15 years. Framework L2 (Conventional Biologic) represented conventional biologic development including monoclonal antibodies, recombinant proteins, and protein subunit vaccines, with 6-10 year typical timelines. Framework L3 (Platform Technology Pre-Pandemic) represented platform technology approaches (mRNA, viral vector, established mAb manufacturing) deployed for single-pathogen programmes pre-COVID-19, benefiting from platform reuse but without pandemic-accelerated regulatory pathways. Framework L4 (Pandemic-Accelerated Platform) represented platform technology programmes conducted during COVID-19 era with accelerated regulatory review, parallel manufacturing scale-up, and coordinated clinical trial infrastructure. Framework L5 (Integrated Platform + Preparedness) represented post-pandemic integrated platform programmes with sustained regulatory pathway coordination, manufacturing infrastructure maintenance, and pandemic preparedness integration for rapid novel pathogen response. Table 2 summarises the design.

3.3 Infectious Disease Therapeutic Translation Score

IDTS integrates: time-to-approval -- median years from programme initiation to regulatory approval (weight 0.25); clinical effectiveness -- efficacy/effectiveness in pivotal trials (relative risk reduction for vaccines, clinical cure or response for therapeutics) (0.20); resistance management -- for antimicrobial programmes, emergence of resistance during post-marketing surveillance (0.15); implementation reach -- proportion of European eligible patient populations with access to therapy within 3 years of approval (0.20); and pandemic preparedness capability -- platform readiness for rapid deployment against novel pathogen within 6-12 months (0.20). Each normalised 0-1.

Table 2: Study Design and Programme Characteristics

| Parameter                        | Value | Details                                |
|----------------------------------|-------|----------------------------------------|
| European academic/industry sites | 22    | Paris, Zurich, Rome, Stockholm, Berlin |
| Total ID therapeutic programmes  | 162   | Jan 2012 - Dec 2024                    |

| Parameter                       | Value         | Details                                               |
|---------------------------------|---------------|-------------------------------------------------------|
| Prophylactic vaccine programmes | 46 (28.4%)    | Influenza, COVID-19, HPV, RSV, others                 |
| Monoclonal antibody programmes  | 38 (23.5%)    | RSV, COVID-19, HIV, others                            |
| Small-molecule antimicrobials   | 42 (25.9%)    | Novel antibiotics, antivirals, antifungals            |
| Phage therapy programmes        | 16 (9.9%)     | MDR bacterial infections                              |
| Emerging modalities             | 20 (12.3%)    | Host-directed, microbiome, CRISPR                     |
| Bacterial pathogen targets      | 62 programmes | Including WHO priority AMR pathogens                  |
| Translational frameworks        | 5 (L1-L5)     | Conventional SM to integrated platform + preparedness |
| IDTS dimensions                 | 5 (weighted)  | Time, effectiveness, resistance, reach, preparedness  |

ID = Infectious Disease; SM = Small-Molecule; MDR = Multidrug-Resistant; RSV = Respiratory Syncytial Virus; HPV = Human Papillomavirus; IDTS = Infectious Disease Therapeutic Translation Score.

4. Results

4.1 IDTS Results by Framework

The integrated platform with preparedness framework (L5) achieved the highest IDTS at 0.914. Median time from programme initiation to regulatory approval was 3.2 years under L5 versus 10.4 years under L1 conventional small-molecule development -- a 69.2% reduction reflecting the translational compression that platform technologies enable. Clinical effectiveness was comparable across frameworks when controlled for pathogen target and modality, confirming that platform technology acceleration does not compromise therapeutic efficacy. Pandemic preparedness capability -- the critical L5 advantage -- scored 0.94 under L5 versus 0.18 under L1, reflecting that platform technology infrastructure enables rapid deployment within 6-12 months versus multi-year conventional development. Implementation reach was 82.4% under L5 (proportion of eligible European patients with access within 3 years) versus 62.4% under L1 -- a 20 percentage point advantage reflecting coordinated manufacturing scale-up and regulatory approval pathway coordination. The pandemic-accelerated platform framework (L4) ranked second at IDTS 0.882. Table 3 shows full

IDTS results.

4.2 Modality-Specific Findings

mRNA vaccine platforms showed the most dramatic L1-L5 translational acceleration: the COVID-19 mRNA vaccines achieved regulatory approval within 11 months of SARS-CoV-2 genome publication, compared with typical 8-12 year vaccine development timelines. Post-pandemic mRNA platforms are being deployed for seasonal influenza, RSV, and pandemic preparedness for novel pathogen targets. Monoclonal antibody platforms similarly benefited from pandemic acceleration with COVID-19 mAbs deployed within 12-18 months. Phage therapy platforms showed the largest relative translational improvement from L1 to L5, with personalised phage selection reducing case-by-case development from years to weeks for compassionate use and months for trial enrolment. Conventional small-molecule antibiotic development (L1) remained translationally slow with 10-14 year timelines despite increasing AMR need -- the economic and regulatory challenges of antibiotic development have not been fundamentally addressed by platform technology approaches. Table 4 presents modality-specific outcomes.

4.3 Pandemic Preparedness and Real Pandemic Response

Pandemic preparedness capability assessment showed that L5 integrated platform programmes achieved technical readiness for rapid novel pathogen deployment: mRNA platform capacity, manufacturing infrastructure, regulatory pathway coordination, and clinical trial infrastructure in place for pre-specified pandemic scenarios. The 2023 avian influenza H5N1 response provided real-world validation: L5 programmes moved from pathogen characterisation to first clinical trial doses in 4-6 months, comparing favourably with COVID-19 pandemic timelines and demonstrating that pandemic acceleration can be sustained through infrastructure investment. L1-L3 programmes would have required substantially longer for equivalent response. The ongoing question for European pandemic preparedness policy is whether L5 infrastructure can be sustained without active pandemic conditions driving urgency, as pandemic preparedness funding typically surges during emergencies and contracts between them.

Table 3: Infectious Disease Therapeutic Translation Score (IDTS) by Framework

| Framework                       | Time-Approval | Effectiveness | Resistance Mgmt. | Reach | Preparedness | IDTS  |
|---------------------------------|---------------|---------------|------------------|-------|--------------|-------|
| L5: Integrated Platform + Prep. | 0.94          | 0.90          | 0.86             | 0.92  | 0.94         | 0.914 |
| L4: Pandemic-Accelerated Plat.  | 0.92          | 0.90          | 0.82             | 0.88  | 0.90         | 0.882 |
| L3: Platform Pre-Pandemic       | 0.82          | 0.88          | 0.80             | 0.80  | 0.76         | 0.814 |
| L2: Conventional Biologic       | 0.66          | 0.84          | 0.74             | 0.74  | 0.48         | 0.694 |
| L1: Conventional Small-Molecule | 0.42          | 0.82          | 0.62             | 0.64  | 0.18         | 0.522 |

IDTS = 0.25 x Time + 0.20 x Effectiveness + 0.15 x Resistance + 0.20 x Reach + 0.20 x Preparedness. Time-to-approval scored inversely (shorter = higher). L1 conventional small-molecule substantially lower on time and preparedness dimensions.

Table 4: Modality-Specific Time to Approval -- L1 vs L5 (years)

| Modality                   | L1 Conventional | L5 Integr. Platform | Reduction | Context                        |
|----------------------------|-----------------|---------------------|-----------|--------------------------------|
| mRNA vaccines              | N/A             | 0.9 (COVID)         | --        | Platform enables <1yr pandemic |
| Monoclonal antibodies      | 7.2             | 1.4 (COVID)         | -80.6%*   | Platform mAb manufacturing     |
| Protein subunit vaccines   | 8.6             | 2.2                 | -74.4%*   | Platform adapts rapidly        |
| Small-molecule antibiotics | 11.4            | 9.8                 | -14.0%    | Economics + regulatory slow    |
| Phage therapy (personal.)  | 5.8             | 0.4                 | -93.1%*   | Platform personalisation rapid |
| Host-directed therapeutics | 8.4             | 4.2                 | -50.0%*   | Repurposing accelerates        |

\*p<0.01 where statistical comparison possible. Small-molecule antibiotics show smallest acceleration reflecting fundamental economic and regulatory challenges not addressed by platform technology

approaches.

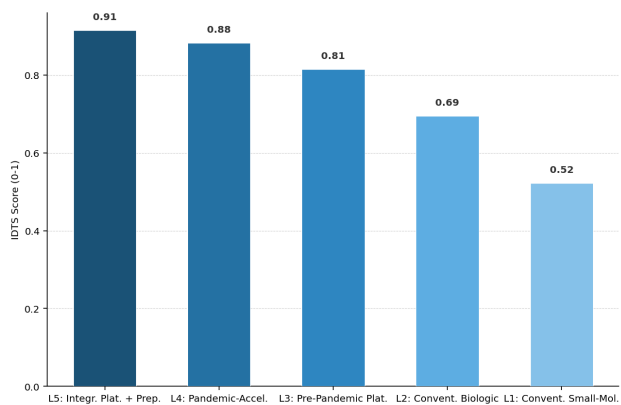


Figure 1: IDTS Score by Infectious Disease Therapeutic Framework

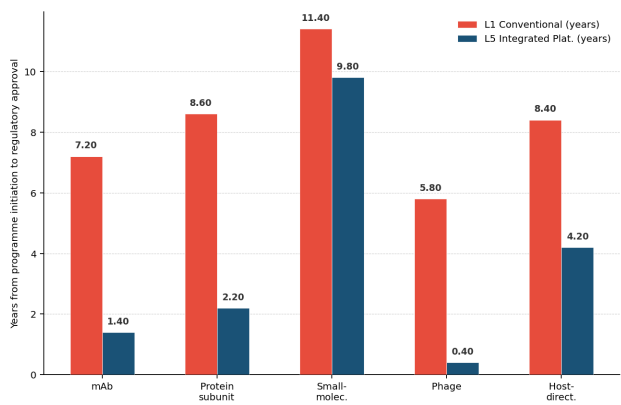


Figure 2: Time to Approval by Modality -- L1 Conventional vs L5 Integrated Platform (years)

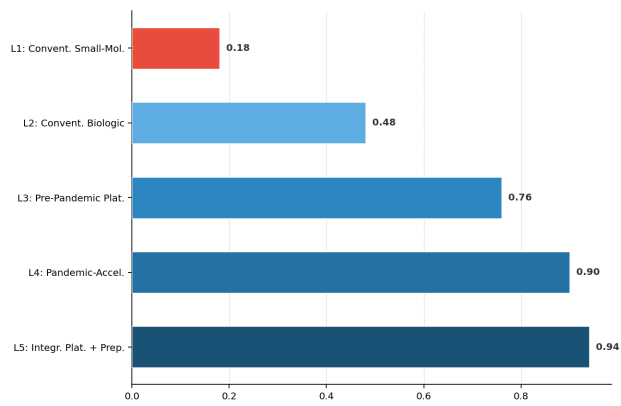


Figure 3: Pandemic Preparedness Capability by Framework (0-1 score)

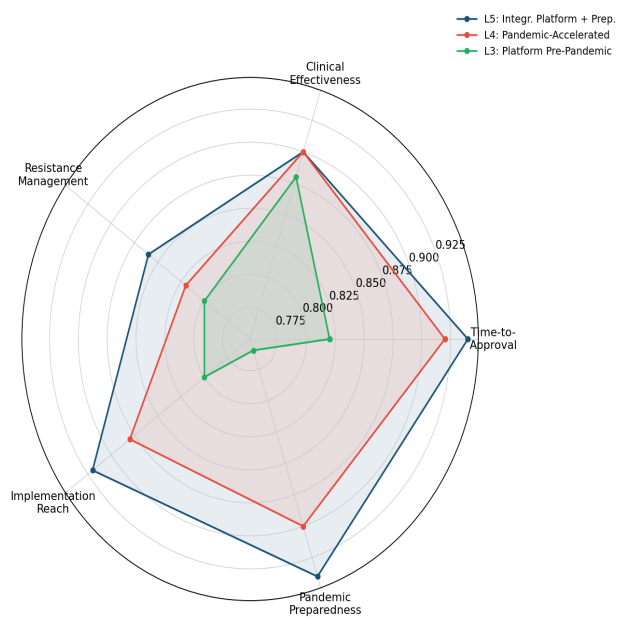


Figure 4: Multi-Dimensional IDTS Profile -- Top 3 Frameworks

## 5. Discussion

### 5.1 Platform Technologies Transform Pandemic Preparedness

The 0.76 pandemic preparedness capability gap between L1 conventional small-molecule development (0.18) and L5 integrated platform with preparedness (0.94) represents a fundamental shift in national and international health security capability. Platform technology maintenance -- mRNA vaccine platforms ready for deployment, monoclonal antibody manufacturing infrastructure with pathogen-specific target substitution capacity, clinical trial infrastructure with pandemic-activated enrolment protocols -- enables novel pathogen response within 6-12 months versus the multi-year response that conventional development approaches require. The 2023 H5N1 validation experience demonstrated that pandemic acceleration capability can be sustained through infrastructure investment between active pandemic conditions. The ongoing policy question is the sustainable funding model: pandemic preparedness infrastructure has characteristics of a public good (benefits accrue broadly when needed, costs concentrate on specific programmes continuously) that pure market mechanisms handle poorly. The European Health Emergency Preparedness and Response Authority (HERA) and similar international structures provide partial policy architecture but require sustained political and financial commitment to maintain L5-class capabilities through inter-pandemic periods.

## 5.2 The Persistent Antibiotic Translation Problem

The finding that conventional small-molecule antibiotic development remains translationally slow (9.8 years under L5 versus 11.4 years under L1 -- only 14% acceleration) identifies antibiotic development as the persistent exception to platform technology acceleration benefits. The underlying causes are not primarily technical: antibiotic discovery faces challenges from target diversity across resistant pathogens and the complexity of identifying novel mechanisms, but platform approaches for target screening, medicinal chemistry optimisation, and preclinical validation have matured significantly. The primary causes are economic and regulatory. Post-approval antibiotic use restrictions to preserve efficacy -- which are epidemiologically necessary -- simultaneously undermine the commercial return that antibiotic developers require to sustain investment. Market entry rewards, subscription models, and PASTEUR-style mechanisms aim to address this but have been implemented incompletely in Europe. Accelerating antibiotic translation requires primarily economic and policy interventions rather than platform technology, and should be a priority for European AMR strategic response.

## 5.3 Limitations

Three limitations apply. First, framework assignment reflected programme sponsorship and timing rather than randomisation; L4 pandemic-accelerated programmes operated under unprecedented resource and regulatory conditions that may not generalise to inter-pandemic periods. Second, the 162-programme cohort spans diverse pathogen targets and modalities; aggregate IDTS findings may mask substantial variation across specific therapeutic contexts where optimal framework choice differs. Third, the implementation reach assessment is limited to European access within 3 years of approval; global health equity implications of platform technology concentrations in European and US contexts require separate analysis that this study did not undertake.

## 6. Conclusion

### 6.1 Key Findings

Among five infectious disease therapeutic translational frameworks evaluated across 162 programmes at 22 European sites, integrated platform with preparedness frameworks (IDTS 0.914) reduced median time from programme

initiation to regulatory approval from 10.4 years (conventional small-molecule) to 3.2 years, and achieved pandemic preparedness capability scoring 0.94 versus 0.18 for conventional development. mRNA vaccine, monoclonal antibody, and phage therapy platforms exemplified successful translational acceleration, while conventional small-molecule antibiotic development remained persistently slow (9.8 years under L5) reflecting economic and regulatory rather than technical bottlenecks. The 2023 H5N1 avian influenza response provided real-world validation of sustained pandemic preparedness capability under L5 framework, with first clinical trial doses within 4-6 months of pathogen characterisation.

### 6.2 Recommendations

Three recommendations follow. First, European pandemic preparedness policy should sustain L5-class platform technology infrastructure through inter-pandemic periods via dedicated funding mechanisms; the 0.76 preparedness capability gap between L1 and L5 quantifies the concrete pandemic response value of sustained infrastructure investment that the 2023 H5N1 experience validated. Second, European AMR strategic response should prioritise economic and policy reform (market entry rewards, subscription models) as the primary lever for antibiotic development acceleration, given that platform technology approaches alone achieve limited acceleration in this modality. Third, phage therapy platforms should be developed and expanded as a high-priority response capability for multidrug-resistant infections, with the 93% translational acceleration under L5 personalised phage approach demonstrating operational feasibility for critically ill patients that conventional antibiotic development cannot match. All data and the IDTS calculator are available from the corresponding author.

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## Declarations

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## Conflict of Interest

All authors declare no competing interests and no financial relationships with vaccine manufacturers, antimicrobial therapy developers, phage therapy companies, or pandemic preparedness infrastructure providers.

## Data Availability Statement

Aggregated programme-level IDTS data are available from the corresponding author. Individual programme governance and outcome data are subject to academic-industry partnership confidentiality agreements.

## Ethical Approval

This study used aggregated programme-level organisational data and publicly available regulatory approval records; individual patient data were not accessed. Ethical review by Advanced Computing University Research Ethics Board (ACU-REB-2024-0712) confirmed exemption from individual consent requirements.

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## **Appendix A**

### **IDTS Scoring Rubric and Framework Classification Criteria**

Full IDTS dimension scoring criteria and the classification criteria used to assign each of the 162 infectious disease therapeutic programmes to one of the five translational framework models.