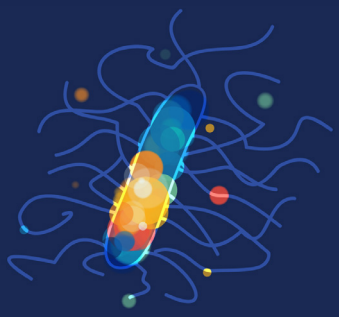

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# REDEFINING ID&V CLINICAL DEVELOPMENT: KEY TRENDS AND INNOVATIONS SHAPING 2026 AND BEYOND

The infectious diseases (ID) landscape is rapidly evolving. Beyond the traditional focus on clinical management and epidemiology, there is an accelerating convergence of artificial intelligence (AI), antimicrobial resistance (AMR) strategy, and next-generation anti-viral development. ID therapeutics is no longer a reactive field; it is becoming a proactive, technology-enabled ecosystem central to global health preparedness and sustainable drug development.

*Here are five key trends gaining momentum and what they suggest for 2026.*

1. **AMR Drug Development is an R&D Opportunity Rather than Just a Stewardship Problem**

   One of the recent shifts in the ID space is how we think about drug-resistant infections. Where once the narrative mainly focused on stewardship, there is now a focus on R&D opportunities. For example, leveraging RWE to justify earlier use of newer Gram-negative agents and targeting multidrug-resistant organisms in high-risk, complex patients (e.g., transplant, ICU, ventilated pneumonia, etc.) rather than just for salvage use.

   This is important for drug development for several reasons:

   - Payors and hospital P&T committees are still the main bottleneck for novel anti-infectives. High quality RWE is being positioned as an alternative to massive, traditional Phase 3 trials for market uptake in severe, resistant infections.
   - Regulators have already signaled openness to pathogen-focused and site-agnostic trial designs in AMR trials. The field is now adding pragmatic post-market data to argue for broader label use and reimbursement sooner.

   Compelling RWE to support guidelines and earlier empiric use of novel antibacterials is a strategy shift, and it affects how AMR assets are being developed and de-risked, which will hopefully encourage stakeholders in AMR R&D to keep the fire lit.

2. **Broad-Spectrum Direct-Acting Antivirals are Gaining Traction**

   Another major shift is the rise of direct-acting, broad-spectrum antivirals. For example, MDL-001, described as an orally available, direct-acting, broad-spectrum antiviral. The drug was developed from an array of AI models within Model Medicines' proprietary platform, targets a conserved "Thumb-1" domain in viral polymerases, and is presented as a novel, cross-family antiviral mechanism validated across respiratory and hepatic viruses. MDL-001 is framed as potentially the first in-class small molecule that can be deployed broadly across multiple, unrelated viral infections.

   Why this matters:

   - The COVID era proved that governments will stockpile pan-respiratory countermeasures. If you can credibly pitch one oral agent as deployable for multiple viral threats (flu, RSV-like viruses, coronaviruses, and hepatic viruses), you become a biodefense-pandemic-preparedness asset, not just a single-indication antiviral.

- Mechanistically, going after a deeply conserved viral polymerase motif is a key development strategy that goes beyond the classic, single-virus, single-protein model of antiviral drug development.
- These broad-spectrum programs are increasingly using AI-driven comparative virology and protein structure modeling to identify conserved pockets that are both druggable and mutation-resistant. That is the same logic that was driving AI-designed pan-variant SARS-CoV-2 inhibitors over the last 2-3 years, now applied to multi-family antivirals.
- This has pipeline strategy implications. We're witnessing the emergence of a new approach to antiviral drug development.

### 3. AI has Come of Age in ID R&D

AI is no longer a buzzword in ID development and has become relevant for clinicians, epidemiologists, and translational researchers. Use cases span from target discovery to trial design, site selection, and real-time resistance surveillance.

How AI is enabling translational research and drug development:

- Target discovery and hit finding: AI multi-agent systems can mine pathogen genomes and resistance plasmids for novel essential targets, generate first-pass inhibitor scaffolds, and evaluate pharmacologic liabilities in silico before any wet-lab spend. Drug hunters and drug discoverers are using these AI tools to prioritize anti-infectives that hit resistance-proof bacterial pathways and antivirals that bind pockets that are slow to mutate. This results in fewer, but more strategic and cost-effective attempts, which is crucial in ID where traditional ROI is weak.
- Trial design and site selection: Using AI and large language models (LLMs) on top of hospital EHR data to predict which hospitals will enroll the right resistant isolates and to simulate inclusion/exclusion criteria against historical patient populations to avoid overly restrictive trials. Additionally, using AI and LLMs to streamline workflows and support expedited document generation, while also generating adaptive trial schemes tuned to the dynamics of outbreaks rather than static timelines developed months before a study starts. This can shorten the path from preclinical to first-in-human and then to pivotal data, as you are less likely to design an underpowered, un-enrollable ID trial.
- Real-time resistance surveillance as a development input: AI-driven resistance dashboard models that continuously learn from antibiograms, culture data, and prescribing patterns to flag emerging resistance clusters inside and across institutions.

### 4. Vaccines and Prophylaxis: Durability, Access, and Combination Strategies

There is a focus on durability and positioning of adult respiratory vaccines (e.g., RSV, flu, COVID) and shingles vaccination in older adults. Respiratory vaccines are being repositioned from seasonal public health tools to chronic risk modifiers in older patients with comorbidities, which supports combination products, long acting monoclonals, and year-round prophylaxis strategies. This kind of framing changes how companies think about trial endpoints and commercial lifetime value.

Again, AI is present in immunogen design and epitope mapping. Structural vaccinology has already leaned on protein-folding AI, but now LLM models trained on immunology literature are being used to propose which epitopes are most likely to drive durable neutralization without antibody-dependent enhancement (ADE) surprises. There is discussion around this optimizing next-gen RSV and pan-flu immunogens.

5. **Public Health Stressors are Directly Impacting ID Clinical Trials**

   One underlying, but increasingly visible trend is public health stressors, including government shutdowns and resource constraints. The CDC normally supplies critical epidemiology, genomic surveillance, and outbreak analytics that feed biotech pipeline decisions. With recent public health stressors, industry and academic groups are stepping into their own surveillance, modelling, and preparedness narratives. When biopharma and academics start doing the epidemiology traditionally done by federal agencies, they unofficially also start setting the "priority threat list." The assets they're already building naturally bubble to the top of that list. This privatized prioritization accelerates certain antiviral/antibacterial programs and may starve others.

## WHAT'S NEXT FOR ID DRUG DEVELOPMENT IN 2026

The trajectory of ID&V drug development appears to be shifting as we enter 2026. AI-native discovery and triage are no longer theoretical—multi-agent LLM systems are being openly taught to clinicians, which design, score, and iteratively improve leads for resistant organisms and emerging threats before a single mouse study is run. Additionally, pan-pathogen/pan-family antivirals are real programs with named molecules that will move forward.

Meanwhile, AMR economics are being attacked with RWE, not just policy lobbying. Companies are generating outcomes data that argue for earlier-line use of advanced agents, reframing them from niche "salvage drugs" to "standard tools" to prevent mortality in high-risk patients. That's how you justify premium pricing and formulary inclusion, which in turn justifies keeping AMR discovery alive.

Clinical trial ops are getting "precision-ID". Generative AI is being used to pre-map enrollment sites, predict resistant isolate flow, and auto-generate adaptive trail designs. This could cut months—and millions of dollars—between preclinical signal and registrational data in ID, which is historically a slow, expensive area to prove benefit because events are sporadic and resistant patterns move.

Finally, preparedness/biodefense framing is now backed into mainstream ID pipelines. Between pan-respiratory antivirals, adult respiratory vaccine durability data, and climate-driven vector-borne threat sessions, the message is clear: these are not niche outbreak tools, they are infrastructure.

As we reflect on the latest trends in ID&V clinical development, we also look forward, preparing for the next wave of innovations in the industry. New innovations, advancements in technology, and the growing ID&V clinical development market offer the community renewed hope for advancing global health.

## MAKING THE COMPLEX SEAMLESS IN ID&V CLINICAL DEVELOPMENT

The complex and dynamic nature of infectious diseases demands an experienced CRO partner with deep medical expertise across various indications and an understanding of the constantly evolving landscape to effectively conduct global ID&V clinical trials. Our thorough medical, operational, and regulatory understanding of the complexities of infectious diseases trials allows us to identify potential pitfalls early and implement strategies to avoid them, helping to minimize risk and accelerate bringing new therapies to market.

Interested in learning more? We welcome the opportunity to discuss your upcoming clinical development plans. Contact our ID&V experts today.