FEBRUARY 2026 Volume 5, Issue 1

VACCINE INSIGHTS

SPOTLIGHT

Bioinformatics and AI/ML tools to streamline vaccine discovery, development, and manufacturing

BIOINFORMATICS AND AI/ML TOOLS ACROSS THE VACCINE LANDSCAPE

SPOTLIGHT

The digital immune 'twin': a new catalyst for vaccine discovery in African swine fever?

Joyce Reimer and Gordon Broderick

VIEWPOINT

"[...] a digital twin of the swine immune system is uniquely positioned to unlock the full potential of such limited data by casting it in the context of our broader knowledge of pig physiology and immunity."

Vaccine Insights 2026; 5(1), 19–24 · DOI: 10.18609/vac.2026.005

The socioeconomic impacts of African swine fever (ASF) date back to the first documented cases in 1921 [1]. Over 100 years later, ASF has now been reported in 83 countries, resulting in widespread economic losses, fractured livelihoods and a compromised global food security network [2,3]. While much work has been done to mitigate the damage, there remains a large gap in ASF defense measures due to the lack of an internationally recognized, safe, and reliable vaccine. Some attempts at

live-attenuated virus vaccines have proven useful for containing local outbreaks, but when examined more closely for global viability, they have been found to be ineffective against multiple strains and, at times, cause harmful side effects [4–6].

The elusiveness of a vaccine is due largely to the highly complex nature of the virus. The ASF virus is a double-stranded DNA virus with over 150 coding regions [7]. Its genetic diversity and immune evasion strategies make it a uniquely tricky virus to outsmart, highlighting the need for innovative and concerted research efforts.

If we are to take on increasingly complex problems like the development of an ASF vaccine, we will need to develop and leverage new *in silico* strategies to not only transform data into information but deliver actionable insight. For some time, data-driven bioinformatics has been the biomedical sciences' primary interface with the computational world. However, purely data-driven analyses are not without their limitations, even in the era of so-called Big Data, with generalizability and explainability remaining key concerns [8]. These issues are only exacerbated under challenging experimental conditions such as the high-containment study of dangerous pathogens, where experimental data are, by necessity, sparsely sampled and very partially observed.

Techniques for formally harnessing prior knowledge of more universally-accepted first principles in biology [9] and incorporating these into the foundational architecture of computational models, including machine learning frameworks [10], are emerging as a promising approach to address these issues.

Ideally suited to data-poor environments, this knowledge-driven paradigm consists in using what little experimental data might be available for model selection and validation rather than *de novo* model construction. Putative maps of cause-and-effect cascades can be translated into dynamic models of biological systems by superimposing logical rules and scheduling schemes for governing the regulatory outcomes and kinetics, such that predicted behaviors may explain experimental observations [11].

With the study of ASF requiring high-containment conditions and the University of Saskatchewan's Vaccine and Infectious Disease Organisation (VIDO) being the only non-government institute in Canada authorized to work with this pathogen, it is no surprise that sample profiling and population size in animal trials will be very limited [12–14]. As such, a digital twin of the swine immune system is uniquely positioned to unlock the full potential of such limited data by casting it in the context of our broader knowledge of pig physiology and immunity.

Building on these concepts, our group is assembling a high-fidelity digital immune twin as a means of acquiring a much deeper understanding of ASF and accelerating vaccine development. We are integrating vast amounts of prior *in vitro* and *in vivo* knowledge of mammalian immune response documented in the peer-reviewed literature with manually curated pathway schema, then using generative AI to suggest putative mechanisms that might address gaps in our knowledge. Potential molecular avenues of infection of our virtual host can be mined from a growing body of pathogen-host protein-protein interaction maps derived from extensive transcriptomic analyses [7,15,16,17,18].

Integrating this myriad of cause-and-effect relationships into a cohesive regulatory network map, we can apply a mathematical framework whereby immune decisions and their timing are captured such that illness progression in our virtual host offers a mechanistic explanation of very partially observed progression in clinically relevant phenotypic groups as well as in individual animals.

There are several examples in the literature of pigs and pig populations that display

significantly different symptom severities and illness progression trajectories, including a complete tolerance of ASF in African wild swine [19]. Knowledge of the potential genetic or epigenetic mechanisms that confer such phenotypic variation in clinical outcomes can be derived from comparing the corresponding digital immune twins, specifically by analyzing the regulatory parameters that supported the accurate mirroring of the corresponding illness progression.

A preliminary computational study being conducted by our group has produced digital twins of two such phenotypes of contrasting severity observed in domestic pigs [14]. By examining differences in the parameter space of each phenotype's twin, we find that certain proteins might be differentially regulated, both in terms of their affinity to upstream mediators and the functional repercussions thereof. Such selectively amplified and muted response elements suggest potential epigenetic modifications that may confer better or worse resistance to disease progression. A similar principle could be applied to explain mechanisms of phenotypic variation at play in other situations, leading to new hypotheses for treatment or vaccine candidates.

Digital twins also serve as useful predictors of how the immune system would respond to certain perturbations, such as adjuvants and immunogenic proteins. This is particularly helpful for exploring vaccine candidates.

It is well-reported in the literature that ASF virus suppresses the IFN-γ response, a canonical indicator of a Th1 immune response [14,20], making it difficult to determine which proteins might recruit adaptive immune response in the context of vaccine formulation. With a representative digital twin, however, we can conduct a high-throughput screening of individual ASF virus proteins to predict and rank which (if any) of these proteins introduced individually might produce a timelier and more amplified IFN-γ response.

Preliminary research from our group shows that the course of infection in our digital twins aligns with published experimental results, namely that an IFN-γ response is not recruited by ASF virus or recruited too late to avoid cytokine-induced death. Nonetheless, perturbation with certain isolated ASF proteins is predicted to hasten this response by several days. Our continuing work with these digital twins will involve the introduction of co-stimulatory agents such as adjuvants as a means of further expediting and amplifying IFN-γ response and ranking on this basis the synergistic effects of adjuvant-antigen pairs.

The search for an ASF vaccine is far from complete, and researchers around the world continue to contribute invaluable insights to this effort. Expanding these efforts to include computational frameworks such as digital twins [21,22] will allow us to mobilize our growing foundation of prior knowledge and will be important in fueling continued discovery.

With the protein regulatory fabric in both human and pig consisting of approximately 15–20,000 proteins linked by over 150,000 interactions [23–25], delivering digital twins with increasing fidelity will continue to challenge our computational capabilities [26]. However, with emerging innovative platforms such as quantum computers [27,28], the scale required to capture an organism's entire proteome, to create a true digital twin, may be within reach much sooner than we may expect.

REFERENCES

1. Penrith ML, Kivaria FM. One hundred years of African swine fever in Africa: where have we been, where are we now, where are we going? *Transbound. Emerg. Dis.* 2022; 69, e1179-e1200.
2. WOAH. The global economic impact of ASF. Jan 2020. https://bulletin.woah.org/?panorama=02–2-2–2020-1-economic (Accessed Jan 2026).
3. WOAH. African swine fever. 2025. https://www.woah.org/en/disease/african-swine-fever/ (Accessed Jan 2026).
4. van den Born E, Olasz F, Mészáros I, *et al*. African swine fever virus vaccine strain Asfv-G-ΔI177l reverts to virulence and negatively affects reproductive performance. *NPJ Vaccines* 2025; 10, 46.
5. Gladue DP, Borca MV. Recombinant ASF live attenuated virus strains as experimental vaccine candidates. *Viruses* 2022; 14, 878.
6. Borca MV, Ramirez-Medina E, Mutisya C, *et al*. Evaluation of cross-protection of African swine fever vaccine ASFV-G-ΔI177L between ASFV biotypes. *Vaccines* 2025; 13, 858.
7. Hao Y, Yang J, Yang B, *et al*. Identification and analysis of the interaction network of African swine fever virus D1133L with host proteins. *Front. Microbiol.* 2022; 13, 1037346.
8. Chekroud AM, Hawrilenko M, Loho H, Bondar J, *et al.* Illusory generalizability of clinical prediction models. *Science* 2024; 383, 164–7.
9. Callahan TJ, Tripodi IJ, Pielke-Lombardo H, Hunter LE. Knowledge-based biomedical data science. *Annu. Rev. Biomed. Data Sci.* 2020; 3, 23–41.
10. Mumuni F, Mumuni A. Improving deep learning with prior knowledge and cognitive models: a survey on enhancing explainability, adversarial robustness and zero-shot learning. *Cogn. Syst. Res.* 2024; 84, 101188.
11. Abou-Jaoudé W, Traynard P, *et al.* Logical modeling and dynamical analysis of cellular networks. *Front. Genet.* 2016; 7, 94.
12. Madden DW, Artiaga BL, Trujillo JD, *et al*. Temporal dynamics of cytokine, leukocyte, and whole blood transcriptome profiles of pigs infected with African swine fever virus. *Pathogens* 2025; 14, 992.
13. Wang S, Zhang J, Zhang Y, *et al*. Cytokine storm in domestic pigs induced by infection of virulent African swine fever virus. *Front. Vet. Sci.* 2021; 7, 601641.
14. Zuo X, Peng G, Zhao J, *et al*. Infection of domestic pigs with a genotype II potent strain of ASFV causes cytokine storm and lymphocyte mass reduction. *Front. Immunol.* 2024; 15, 1361531.
15. Fenster, JA, Azzinaro PA, Dinhobl M, *et al*. African swine fever virus protein–protein interaction prediction. *Viruses* 2024; 16, 1170.
16. Dupré J, Dolata KM, Pei G, *et al*. Exploring virus–host interactions through combined proteomic approaches identifies BANF1 as a new essential factor for African swine fever virus. *Mol. Cell. Proteom.* 2025; 24, 101038.
17. Wu Q, Lei Y, Zuo Y, *et al*. Interactome between ASFV and host immune pathway proteins. *mSystems* 2023; 8, e00471–23.
18. Shi M, Zhou N, Xiu M, *et al*. Identification of host proteins that interact with African swine fever virus pE301R. *Eng. Microbiol.* 2024; 4, 100149.
19. Salguero FJ. Comparative pathology and pathogenesis of African swine fever infection in swine. *Front. Vet. Sci.* 2020; 7, 282.
20. Lv P, Wang Z, Chen H, Chen Y, *et al*. Immunoevasion strategies for African swine fever virus: modulation of antigen presentation pathways. *Virulence* 2025; 16, 2541711.
21. Waight MC, Prakosa A, Li AC, *et al*. Personalized heart digital twins detect substrate abnormalities in scar-dependent ventricular tachycardia. *Circulation* 2025; 151, 521–533.
22. Akbarialiabad H, Pasdar A, Murrell DF, *et al*. Enhancing randomized clinical trials with digital twins. *NPJ Syst. Biol. Appl.* 2025; 11, 110.

23. Groenen M, Archibald, A, Uenishi, H, *et al*. Analyses of pig genomes provide insight into porcine demography and evolution. *Nature* 2012; 491, 393–398.

24. Álvez MB, Bergström S, Kenrick J, *et al*. A human pan-disease blood atlas of the circulating proteome. *Science* 2025; 390, eadx2678.

25. The Human Protein Atlas. Protein interactions. https://www.proteinatlas.org/humanproteome/ interaction/ interaction (Accessed Jan 2026).

26. Reimer J, Saha P, Chen C, Dhar N, Byrns B, Rayan S, Broderick G. GPU-accelerated Modeling of Biological Regulatory Networks. *arXiv* 2025; 2506,19866.

27. Erlandsson-Brisebois A, Broderick J, Khatooni Z, Wilson HL, Rayan S, Broderick G. Identifying protein co-regulatory network logic by solving B-SAT problems through gate-based quantum computing. *arXiv* 2025; 2504, 09365.

28. Jiang J-R, Shu Y-C, Lin Q-Y. Benchmarks and recommendations for quantum, digital, and GPU annealers in combinatorial optimization. *IEEE Access* 2024; 12, 125014–125031.

BIOGRAPHIES

Joyce Reimer holds an undergraduate degree in Physiology and an advanced degree in Biomedical Engineering, both from the University of Saskatchewan, Canada. She is a Senior Research Analyst and High-performance Computing Lead with the Mathematical Immunology and Immunodynamics Lab at the Vaccine and Infectious Disease Organization.

Joyce Reimer, Research Analyst, Vaccine and Infectious Disease Organization, Saskatchewan, Canada

Gordon Broderick currently holds cross-appointments at the University of Saskatchewan, Canada, in mathematics and statistics in the College of Arts and Science and pediatrics in the College of Medicine. He is a principal scientist at the USask's Vaccine and Infectious Disease Organization where he leads their initiative in Mathematical Immunology and Immunodynamics (MIIL), applying network and dynamic systems theory to design novel vaccines and immune therapies.

Gordon Broderick PhD, Principal Scientist, Vaccine and Infectious Disease Organization, Saskatchewan, Canada

AUTHORSHIP & CONFLICT OF INTEREST

Contributions: The named author takes responsibility for the integrity of the work as a whole, and has given their approval for this version to be published.

Acknowledgements: We thank the University of Saskatchewan's Advanced Research Computing (ARC) team, as well as the Centre for Quantum Topology and Its Applications (quanTA) for their support of all computational work. This article is published with the permission of the Director of VIDO.

Disclosure and potential conflicts of interest: The author has no conflicts of interest.

Funding declaration: VIDO receives operational funding from the Canada Foundation for Innovation through the Major Science Initiatives Fund and from the Government of Saskatchewan through Innovation Saskatchewan and the Ministry of Agriculture.

AI process statement: The authors confirm that no AI tools were used in the preparation of this article.

ARTICLE & COPYRIGHT INFORMATION

Article source: This article was written by the named authors and reviewed by BioInsights' Editorial team to ensure clarity and alignment with BioInsights' editorial standards.

Revised manuscript received: Feb 9, 2026.

Publication date: Feb 27, 2026.

BIOINFORMATICS AND AI/ML TOOLS ACROSS THE VACCINE LANDSCAPE

SPOTLIGHT

Applying AI in vaccine clinical development

Demetris N Zambas and Lynne Cesario

Interview

"AI would take on the bureaucratic, operational, and repetitive work, allowing humans to focus their time on creativity, scientific reasoning, and critical thinking."

Charlotte Barker (Editor, *Vaccine Insights*) speaks with **Demetris N Zambas** (Global Head, Clinical Data and Information Sciences, Clinical Development and Operations, Pfizer R&D) and **Lynne Cesario** (Executive Director, Risk-Based Monitoring Program Lead and AI Program Lead, Pfizer) about the role of AI in risk-based management of clinical trials, and their approach to integrating these new tools into established teams and processes.

Vaccine Insights 2026; 5(2), 43–49 · DOI: 10.18609/vac.2026.010

Q What are the key areas in which your team is applying AI in vaccine clinical research?

DZ In most cases we use AI from an operational perspective, to assess data consistency across sites and procedures, helping to identify variability

in how protocols are implemented in the field. This includes detecting signals that suggest certain procedures may be unclear in the protocol or inconsistently executed at specific sites, allowing teams to intervene early. AI tools are also applied to analyze site performance and recruitment, supporting the identification of locations or strategies with a higher probability of success and enabling more efficient operations.

LC I agree – we focus mainly on pattern recognition and anomaly detection. By leveraging large volumes of historical data, AI models are trained to detect unusual patterns that may indicate potential misconduct, fraud, or data quality issues. These approaches support proactive monitoring and help maintain high levels of data integrity.

More recently, the team has expanded into predictive analytics, using AI to forecast trends and find areas of increased risk. We can them look at what mitigations would be good to pair with those risk areas going forward. That works especially well when you have structured data, and the accuracy of those predictions increases with larger amounts of data. Vaccine trials generate a large amount of data, so is a good opportunity to apply these approaches.

Q What have been the hardest organizational or technical bottlenecks to overcome in operationalizing AI at scale?

DZ Technically, the most significant challenge has not been availability of data *per se*, but rather establishing meaningful relationships across different data types and sources. For example, each study has a database, but when we want to compare across studies, we run into problems. This challenge is compounded when trying to combine operational data with clinical data. However, these connections are critical, as operational performance can be predictive of clinical outcomes, such as subject retention during long-term follow-up. High-performing sites tend to engage patients more effectively and retain them longer, whereas poorly performing sites are more likely to lose participants, negatively affecting patients, sites, and overall vaccine development. That is why linking data across operational and clinical domains and across studies is critical.

From an organizational standpoint, the biggest challenge has been adoption and change management. Especially early on, there was significant apprehension around new technologies, including concerns about job security, the need for behavioral change, and upskilling. While many people welcomed opportunities to build new skills, there was also fear that AI would compete directly with their roles. Over time, this perception has begun to shift. It has become clearer that AI is not replacing scientists, but rather that individuals who know how to use AI effectively will outperform those who do not.

LC I would add that change management also requires removing old ways of working as we introduce new ones. As we give our colleagues new tools and ways of working, we have to remove outdated processes to avoid repetition and make their lives more efficient.

> "From an organizational standpoint, the biggest challenge has been adoption and change management."

Vaccine Insights 2026; 5(2), 43–49 · DOI: 10.18609/vac.2026.010

Q What signals has AI been particularly effective at surfacing that traditional monitoring approaches tend to miss?

LC AI has been particularly effective at detecting signals buried within large volumes of operational data, like audit trails. Examples of signals include large volumes of data being entered at unusual times or propagation of similar data points across multiple patients. These signals may point to potential fraud, but more commonly indicate issues such as instrument malfunction, misuse of equipment, or misunderstanding of the clinical protocol.

DZ Audit trails across multiple sources, including third-party laboratories, electronic outcome assessments from mobile devices, and electronic data capture systems, contain massive amounts of data. Regulators have increasingly emphasized the value of these data because of the insights they can provide into study conduct and data integrity. However, without AI support, even highly skilled human reviewers are limited in how much of this information they can realistically assess.

Q How aligned is the industry today on best practices for AI-enabled risk-based management?

DZ There is broad industry alignment that these approaches are beneficial for patients, sites, and the development of vaccines and other therapies.

Because failures related to fraud or poor oversight can damage confidence across the entire field, companies tend to share their approaches openly with peers, focusing on methodologies and principles rather than proprietary algorithms. This type of knowledge sharing has occurred through industry forums and presentations to groups connected with regulators and global health organizations, reinforcing a common understanding of what 'good' looks like.

Companies are largely using AI in similar ways for similar goals. Where fragmentation still exists is primarily in the stage of adoption – some companies are using AI across their work, others are running limited pilots, and still others are at proof-of-concept stage.

Q What have regulators been most interested in or cautious about when it comes to AI-driven monitoring approaches in vaccine clinical research?

DZ We proactively discuss our focus areas with regulators to address concerns, and agencies including the US FDA, the European Medicines Agency (EMA), and Japan's Pharmaceuticals and Medical Devices Agency (PMDA) have been very engaged.

Regulators typically are not prescriptive about where or how companies should use technologies. Rather than directing companies to focus on specific use cases, they have encouraged broader principles such as adopting risk-based approaches. However, one area they have shown particular interest in is audit trail data.

A key expectation from regulators is the presence of a human in the loop. They do not want AI to operate autonomously without oversight. There is more caution when AI is

used in ways that directly influence medical decisions or patient care, such as AI-driven therapeutic devices. In those cases, where AI has a direct impact on patient health and safety, regulators apply a higher level of scrutiny. The more operational the use-case, the lower the regulatory concern.

Q What would be on your 'wish list' for the next generation of AI tools?

LC A clear priority is stronger interoperability and consolidation. We want to interact with fewer tools and centralize insights into one place, so study teams can review and interact with data in a single environment. That would drive efficiency, improve data quality, accelerate insights, and improve decision-making across the trial lifecycle.

DZ Emerging agentic AI approaches are particularly promising in this area. These agents can consume outputs from multiple tools and synthesize them into more digestible summaries for humans.

Reaching that point depends on continued progress in digitalization of clinical trial artifacts, particularly protocols. Digitalization, as opposed to simple digitization, refers to embedding metadata throughout protocols so they can be computationally understood. Word documents are digital but that does not mean they are suitable for computational approaches.

If protocols and their execution data were consistently linked through metadata across many studies, AI could drive much higher levels of automation, allowing us to automate parts of trial execution and predict operational challenges in new studies. At present, this is not available at scale, although drug developers and vendor partners are actively working toward this goal.

LC In practice, several AI-enabled tools are already embedded in day-to-day operations. Examples include tools such as Smart Data Quality that combines machine learning, natural language processing, and rules-based logic to automate discrepancy detection, discrepancy reasoning, and query text generation, as well as Smart Medical Coder, which supports medical coding by suggesting drug names and adverse event terms using standard dictionaries. These tools operate with a human-in-the-loop model and were introduced into routine use during large-scale efforts such as the COVID vaccine trials, representing a major step forward in operational efficiency.

DZ Our Operations team also uses AI to identify potential new study centers for specific indications, as well as predicting procedures or protocol elements that have historically led to higher dropout rates or inconsistent execution. Again, unifying these into a single system would be very beneficial.

Q Is there anything about AI in vaccine development that you think the industry isn't talking about enough?

DZ There is a risk of approaching AI with too much hype and too little purpose. There is a tendency to treat AI as a kind of 'magic fairy dust', without clearly

Vaccine Insights 2026; 5(2), 43–49 · DOI: 10.18609/vac.2026.010

"Rather than pursuing large, multi-year transformation programs with distant payoffs, progress is made through delivering tools that solve concrete problems quickly..."

defined use cases. Organizations often struggle when they cast the net too broadly, trying to apply AI everywhere at once, which can lead to unfocused efforts that fail to deliver meaningful results. In contrast, the most successful implementations start with well-defined problems to solve. Those targeted efforts can then expand into broader applications, but going broad from the outset is far more difficult and often ineffective.

Another underappreciated point is that vaccine trials have characteristics that make them particularly well suited to AI-enabled approaches. Vaccine trials are often very large but short in duration, making it a perfect test bed for AI and automation. In these settings, data arrives extremely quickly, sometimes with thousands of patients enrolling in a single day, making manual review impractical. In a high-volume scenario like this, AI provides value not only by scaling analysis beyond what human teams can manage, but also by delivering consistency.

LC Large numbers of humans reviewing massive data streams increase the likelihood of errors, whereas AI systems apply the same logic consistently across all data. This speed and consistency allow insights to be generated and shared with study teams much earlier, enabling operational adjustments while there is still time to act – for example, keeping enrollment open for longer.

Q What are the most effective ways to build confidence in AI-driven insights, without overpromising?

DZ A key element is proper training and education. New technology can be intimidating when people do not understand how it works or how it fits into their role. With appropriate training and clear examples of how AI can enhance productivity and career development, that fear is reduced. The emphasis needs to be on humans working with AI, not humans being replaced by it. Pharma R&D is a highly skilled and complex job that cannot be replaced by AI.

Equally important is early and sustained stakeholder engagement. Successful initiatives involve the people who do the work from day 1. When users help define the use case, contribute to the design, and participate in testing, the technology feels familiar rather than imposed. Upfront engagement of end users is often the single biggest factor in successful adoption.

LC We've also been successful through the use of a roadmap that prioritizes quick wins. Rather than pursuing large, multi-year transformation programs with distant payoffs, progress is made through delivering tools that solve concrete problems quickly, such as summarizing information, finding hard-to-locate documents, or automating simple tasks. This allows users to experience real benefits early on and these benefits can then be layered on top of one another, building momentum and efficiency over time.

Q In 5–10 years, what would success look like for AI in vaccine clinical development?

DZ For me, successful implementation of AI in vaccine clinical development would be defined by a shift in how human expertise is used. AI would take on the bureaucratic, operational, and repetitive work, allowing humans to focus their time on creativity, scientific reasoning, and critical thinking. Instead of spending hours generating, merging, and reviewing multiple reports just to surface a potential issue, AI would handle that technical groundwork and bring meaningful signals directly to humans, who would then apply judgment, context, and scientific insight.

Importantly, the scientific core of vaccine development will not – and should not – shrink. The time required to observe outcomes, conduct long-term follow-up, and answer scientific questions is dictated by biology and public health needs. What AI would compress is the 'head and tail' of clinical development: the setup activities before a study begins and the summarization, reporting, and submission activities after it ends. If successful, AI would dramatically shorten these phases without compromising rigor.

BIOGRAPHIES

Demetris Zambas presently holds the position of SVP and Global Head Clinical Data and Information Sciences at Pfizer. Since 2017, Demetris has been instrumental in revolutionizing Pfizer's Clinical Data Sciences division by developing and transitioning to an internal operational model spanning multiple global locations to bolster Pfizer's portfolio. Notably, in 2020, he and his team introduced the industry's pioneering ML-based error detection tool, precipitating a strategic pivot within the organization towards analytics, ML, and Gen AI, with the objective of redefining Clinical Data Management as Clinical Data Sciences. Demetris is also at the forefront of steering various cross-functional AI initiatives across Pfizer Research and Development.

Demetris Zambas, SVP and Global Head Clinical Data and Information Sciences, Pfizer

Lynne Cesario is an accomplished Executive Director at Pfizer with over 25 years of experience in clinical research and drug development. She has led the development and implementation of risk-based monitoring methodologies, established global central monitoring and data science teams, and pioneered AI and automation innovations that have notably impacted the industry, including COVID vaccine efforts. Lynne is recognized for her leadership in industry workstreams and co-authored industry papers focused on innovation in technology and the transition from Clinical Data Management to Clinical Data Sciences.

Lynne Cesario, Executive Director, Risk-Based Monitoring Program Lead and AI Program Lead, Pfizer

Vaccine Insights 2026; 5(2), 43–49 · DOI: 10.18609/vac.2026.010

AUTHORSHIP & CONFLICT OF INTEREST

Contributions: The named authors take responsibility for the integrity of the work as a whole, and has given their approval for this version to be published.

Acknowledgements: None.

Disclosure and potential conflicts of interest: The authors are employees of Pfizer. They have no other financial disclosures.

Funding declaration: The author received no financial support for the research, authorship and/or publication of this article.

AI process statement: BioInsights used an AI tool (ChatGPT) to support non-creative editorial tasks such as the initial tidying of interview text material, including removing repetition and non-substantive dialogue from raw transcripts and correcting spelling and grammar. Human editors created the narrative, edited the content and approved the final version.

BioInsights encourages transparent, responsible, and verifiable use of AI as a supporting tool; never a creative substitute. All content ultimately reflects human expertise, ethical rigor, and scientific integrity. See our full AI policy statement for more information.

ARTICLE & COPYRIGHT INFORMATION

Article source: This article was developed by BioInsights' Editorial team using insights shared during an interview with the named authors. It is a reflection of the discussion held that has been edited for clarity and flow. The named authors reviewed and approved the final version prior to publication.

Interview held: Jan 20, 2026.

Publication date: Mar 4, 2026.

Designing durability: T follicular helper cells and the future of vaccine-induced immunity

Nimesh Gupta

INTERVIEW

"...Tfh-based assays will evolve into practical tools for guiding vaccine design and development in the years ahead."

Ashling Cannon (Editor, *Vaccine Insights*) speaks with **Nimesh Gupta** (Chief, Vaccine Immunology Laboratory, National Institute of Immunology, India) about the role of T follicular helper cells in shaping durable antibody responses, emerging correlates of protection, and how advanced immuno-profiling could inform future vaccine development and evaluation.

Vaccine Insights 2026; 5(1), 25–29 · DOI: 10.18609/vac.2026.006

Q You have described T follicular helper (Tfh) cells as central architects of durable antibody responses. How close are we to being able to design vaccines that intentionally tune Tfh responses, and what misconceptions still persist about what makes a protective immune response?

NG Tfh cells are indeed the architects of long-lasting antibody responses. They determine not only the magnitude, but also the quality, durability, and memory of humoral immunity. Over the past several years, we have made substantial

progress in understanding what defines this highly specialized subset of $CD4^+$ T cells, from their transcriptional programs to their metabolic preferences.

Much of this progress has been driven by the ability to study Tfh cells at an antigen-specific level using single-cell and high-resolution profiling technologies. We are now moving well beyond simply measuring Tfh cell frequency and beginning to understand their functional attributes in the context of broadly protective immunity.

Although we are not yet fully able to precisely fine-tune Tfh responses through vaccination, we are getting very close. I believe next-generation vaccines will be built on a deep understanding of how these cellular architects provide help to B cells, allowing us to shape antibody responses that are high quality, long lived, and broadly protective. This T cell-guided approach represents an exciting and rapidly evolving frontier in vaccinology.

Several misconceptions still persist. One is the assumption that higher antibody titers always equate to better protection. In reality, protection depends far more on antibody quality, including breadth, affinity, durability, and function, rather than quantity alone. Another misconception is that all $CD4^+$ T-cell help is equivalent. The specialized help provided by Tfh cells within germinal centers is fundamentally distinct and is essential for the evolution of durable protective humoral immunity. Post-pandemic, the field is increasingly shifting toward these qualitative aspects of immune protection.

Q From your work across diverse pathogens such as dengue and SARS-CoV-2, what has surprised you most about how infection-induced and vaccine-induced Tfh responses differ, and what do those differences reveal about the limits of our current vaccine strategies?

NG One of the most fascinating aspects of our research has been understanding how Tfh cells contribute to lifelong protective immunity, particularly following natural infection. If we can define the attributes of Tfh cells in that setting, we can apply those principles to rational vaccine design.

We have studied this question using Japanese encephalitis virus, a mosquito-borne flavivirus related to dengue, Zika, and yellow fever. Individuals who recover from natural infection are protected for life. In contrast, vaccination with a live attenuated JE vaccine provides protection for only a few years, after which immunity wanes.

This contrast led us to examine how Tfh responses differ between infection and vaccination. We observed that natural infection induces a broader and more potent Tfh response in individuals who recovered successfully. At greater resolution, this appeared to reflect differences in the early signals that establish virus-specific Tfh cells, as well as the diversity of the Tfh repertoire engaged during infection.

These findings highlight a critical limitation of current vaccine strategies. We do not simply want vaccines that generate antibodies; we want vaccines that instruct the immune system to build those responses in a refined and durable way. Insights from human-centric infection models are beginning to reveal which Tfh attributes must be

"We do not simply want vaccines that generate antibodies; we want vaccines that instruct the immune system to build those responses in a refined and durable way."

"While we are not yet at the stage of fully personalized vaccines, stratifying populations based on metabolic health, immune history, and demographic factors is becoming increasingly realistic."

induced and fine-tuned, and I believe this knowledge will fundamentally reshape future vaccine development.

Q Individual variation remains a major unknown. Some people mount extraordinary antibody breadth and durability, others very little. What new immunological or metabolic parameters are emerging as predictive of strong vaccine responses, and how close are we to using these for stratification or tailoring?

NG Individual variation is one of the most intriguing and challenging aspects of human immunology. When the same vaccine is administered to different individuals, the outcomes can vary widely, from broad and durable antibody responses to minimal or no detectable responses.

In our work, we have focused on the biology of Tfh cells in these divergent outcomes. Strong responders often show an early, high-magnitude Tfh response with favorable qualitative features, which can be highly predictive of antibody breadth.

We have also examined metabolic signatures associated with vaccine responsiveness. In individuals who fail to respond to vaccination, we observed elevated levels of specific metabolites at baseline, prior to immunization. One example is the short-chain fatty acid sodium butyrate. Mechanistically, we found that sodium butyrate can directly suppress Tfh cell differentiation and inhibit Tfh-driven germinal center responses, thereby compromising antibody quality and protective immunity.

These findings underscore that immune fitness is not solely genetic, but also metabolic and environmental. While we are not yet at the stage of fully personalized vaccines, stratifying populations based on metabolic health, immune history, and demographic factors is becoming increasingly realistic. This knowledge has important implications not only for vaccine design, but also for vaccine implementation across diverse populations and regions.

Q Your lab uses TB co-culture assays, metabolomics, and single-cell profiling. Are these approaches ready to inform vaccine evaluation pipelines, or are they still mainly discovery tools? What needs to change for regulatory-grade use?

NG Historically, T-cell assays were viewed primarily as discovery tools. This perception has changed significantly during and after the pandemic. While metabolomics and single-cell profiling remain largely discovery-focused approaches, a broad range of T-cell assays are now being integrated into vaccine evaluation. These include quantitative and functional assessments of antigen-specific responses, as well as assessments of the ability of Tfh cells to support B-cell immunity.

At the National Institute of Immunology in India, we have established a Human Immune-Monitoring and T-cell assay platform that supports accelerated evaluation of vaccines and biotherapeutics. Recently, we conducted a Phase 3 immuno-bridging trial for

an intranasal COVID-19 vaccine, demonstrating that a battery of T-cell assays can be used when conventional efficacy trials are not feasible, including for high-risk pathogens.

These assays are increasingly being incorporated into comparator and immuno-bridging trials. While further standardization and scaling are needed, they are rapidly evolving into precision tools that can inform vaccine optimization and regulatory decision-making. We are currently in the process of spinning off this platform to support a larger network of vaccine developers and industry partners.

Q Many current vaccines rely on antibody titers as correlates of protection. What might next-generation correlates look like, and how should developers begin measuring them?

NG Antibody titers provide information about immunogenicity, but they do not fully capture protective immunity. Next-generation correlates will need to be multidimensional, integrating antibody measurements with cellular and functional readouts.

Tfh cells represent a particularly promising biomarker. Their frequency, functional capacity, and ability to provide help to B cells could serve as early indicators of durable humoral immunity. We have developed sensitive T-cell/B-cell co-culture assays that can assess helper capacity using very small numbers of antigen-specific T cells, and we have shared these protocols with the broader community. We continue to refine these assays to enhance usability and scalability for high-throughput applications.

Ultimately, composite signatures that integrate cellular and functional data will be required to predict not only vaccine responsiveness, but long-term protective immunity.

Q What would it take to make advanced immuno-profiling or Tfh-based assays part of routine vaccine evaluation or clinical trial endpoints?

NG The path forward requires simplification, standardization, and validation. Many advanced assays exist, but they must be harmonized, supported by shared reference datasets, and validated across platforms to ensure reproducibility.

Equally important is demonstrating predictive value. If early Tfh or B-cell functional signatures can reliably forecast the durability and quality of antibody responses, they become invaluable tools for prioritizing vaccine candidates early in development. This could accelerate decision-making, reduce translational risk, and lower clinical costs by reducing the reliance on large-scale efficacy trials.

Achieving this will require close collaboration between academic laboratories, industry partners, and regulatory agencies. While antibody titers remain the primary endpoints today, I am confident that Tfh-based assays will evolve into practical tools for guiding vaccine design and development in the years ahead.

BIOGRAPHY

Nimesh Gupta is a virologist and immunologist who leads the Vaccine Immunology Laboratory at the National Institute of Immunology (NII), India. With over two decades

Vaccine Insights 2026; 5(1), 25–29 · DOI: 10.18609/vac.2026.006

of experience in virus immunology, his research has advanced the understanding of how T cells shape durable, protective antibody responses. Dr Gupta's laboratory focuses on the T–B cell collaboration that ultimately defines the quality of humoral immunity, with a particular emphasis on follicular helper T (Tfh) cell biology. By leveraging well-characterized longitudinal human cohorts of viral infection and vaccination including dengue, Japanese encephalitis, and COVID-19, his team seeks to define Tfh-cell correlates of protection and translate these insights into T cell-guided vaccine designs. Bridging discovery with translation, Dr Gupta established the 'Human Immune Monitoring and T-cell Assay' platform, a pioneering resource that supports advanced immunological evaluation of vaccines, especially when conventional efficacy trials are not feasible. He serves on national and international advisory bodies, including India's National Technical Advisory Group on Immunization (NTAGI), contributing to evidence-based vaccine policy and innovation.

Nimesh Gupta, Chief, Vaccine Immunology Laboratory, National Institute of Immunology, India

AUTHORSHIP & CONFLICT OF INTEREST

Contributions: The named author takes responsibility for the integrity of the work as a whole, and has given their approval for this version to be published.

Acknowledgements: None.

Disclosure and potential conflicts of interest: The author has no conflicts of interest.

Funding declaration: The author received no financial support for the research, authorship and/or publication of this article.

AI process statement: AI tools (ChatGPT) were used to support non-creative editorial tasks such as organisation of source material, language tidying, and house style checks.

ARTICLE & COPYRIGHT INFORMATION

Article source: This article was developed by BioInsights' Editorial team using insights shared during an interview with the named author. It is a reflection of the discussion held that has been edited for clarity and flow. The named author reviewed and approved the final version prior to publication.

Interview conducted: Nov 20, 2025.

Revised manuscript received: Feb 10, 2026.

Publication date: Feb 25, 2026.

EVENT PREVIEW

World Vaccine Congress Washington 2026

Vaccine Insights 2026; 5(1), 15–17 · DOI: 10.18609/vac.2026.004

World Vaccine Congress Washington 2026 takes place March 30–April 2 in Washington, DC. The event brings together senior leaders from governments, global health organizations, academia, and pharma to explore how the vaccine landscape must evolve in response to shifting epidemiological, political, and economic realities.

Readers of *Vaccine Insights* can access a **20% discount** on delegate tickets – just use the code **IB20**.

WORLDVACCINE CONGRESS WASHINGTON

GLOBAL HEALTH GOVERNANCE & FINANCING ACROSS THE VACCINE LIFECYCLE

Global health leadership and governance form a core pillar of the program. In a keynote presentation, Senior Leadership from Global Health Institutions will outline how they can adapt to support regional ownership while safeguarding equitable access to vaccines.

The transition of leadership and financing from global institutions to regional and national actors is a recurring focus, with speakers tackling donor alignment, decentralization risks, and the long-term sustainability of immunization systems.

VACCINE INDUSTRY PERSPECTIVES

Industry leaders including Alejandro Cane (Pfizer), Temi Folaranmi (GSK), Holger Kissel (BioNTech), Jean-François Toussaint (Sanofi), and Francesca Ceddia (Moderna) will come together to discuss disease prioritization, next-generation platforms, and partnership models required to sustain innovation and access.

Plus, Rajinder Suri (DCVMN International), Petro Terblanche (Afrigen Biologics & Vaccines), Hun Kim (SK Bioscience), Rosane Cuber Guimarães (Fiocruz), and Sunil Gairola (Serum Institute of India) bring perspectives from across the Global South, including the role of AI, and the push for decentralized and regional production.

Closing the first day, a panel including Peter Hotez (Texas Children's Hospital),

Clarisse Ingabire (World Bank), and Rino Rappuoli (European Vaccine Hub) will place the vaccine field within the context of climate change, food insecurity, and antimicrobial resistance.

PANDEMIC PREPAREDNESS PLATFORMS & BROADLY PROTECTIVE VACCINES

The Pandemic Preparedness and Platforms track includes perspectives from CEPI, regulatory authorities, and public health agencies, with speakers exploring dual-use platforms, R&D gaps, regulatory bottlenecks, and scale-up challenges.

Sessions on broadly protective and next-generation vaccines address scientific and economic barriers to developing durable protection against coronaviruses and other respiratory pathogens. Contributions from Kayvon Modjarrad (Pfizer), Mandeep Singh Dhingra (CEPI), and Derek Fleming (CIDRAP) will examine target product profiles, correlates of protection, and funding mechanisms required to sustain long-term investment.

A plenary panel on pandemic-proofing health systems features panelists including Nicole Lurie (CEPI), and Thomas Waite (UKHSA) examining cross-border coordination and the role of real-world data in future outbreak response.

THREATS NEW & OLD

A panel on tuberculosis, malaria, and HIV will feature contributions from Seth Berkley (Brown University), Richard White (London School of Hygiene and Tropical Medicine), Deborah Atherly (PATH), and Kara Bickham (IAVI). The discussion assesses vaccine pipeline progress, implementation readiness, and the positioning of these diseases within broader global health security strategies.

The emerging and re-emerging Diseases track focuses on vaccine development strategies for chikungunya, mpox, malaria, Nipah virus, and cytomegalovirus, alongside discussions on genomic surveillance and real-time variant tracking.

A dedicated panel on climate change and infectious disease risk brings together voices from global health organizations and research institutions to consider how climate data and disease modeling can inform vaccine prioritization and preparedness planning.

Dedicated sessions on influenza and respiratory vaccines dive into strain selection, combination vaccine strategies, and the ongoing challenge of aligning seasonal immunization schedules across geographies.

Meanwhile, the Veterinary Vaccines track highlights One Health approaches to zoonotic disease prevention and climate-linked risks.

IMMUNE PROFILING, CORRELATES OF PROTECTION, & IMMUNOBRIDGING

The Immune Profiling track brings together immunologists and translational scientists to discuss how advanced immune-profiling tools are reshaping vaccine development and regulatory decision-making. Topics covered include high-resolution antibody profiling, longitudinal immune studies, and defining correlates of protection for pathogens including mpox, malaria, and emerging viral threats.

There is also a focus on immunobridging as a mechanism for accelerating vaccine access, with speakers including Marion Gruber (IAVI) and Anna Honko (CEPI) examining regulatory precedent, assay standardization, and the scientific limitations of extrapolating immune data across populations and platforms.

EVOLVING ROLE OF VACCINES IN CANCER IMMUNOTHERAPY

The Cancer and Immunotherapy Vaccines track explores how the role of vaccination

Vaccine Insights 2026; 5(1), 15–17 · DOI: 10.18609/vac.2026.004

in oncology is evolving. Sessions present strategies to induce robust cytotoxic T cell responses without viral vectors, optimize lipid nanoparticle and nucleic acid delivery systems, and integrate cancer vaccines with checkpoint inhibitors and other immunotherapies.

Senior academic and translational leaders, including David B. Weiner (The Wistar Institute), Simon Van Haren (Harvard Medical School), Peter Demuth (Elicio Therapeutics), and Kyle Holen (Moderna), will discuss progress from bench to bedside.

CLINICAL DEVELOPMENT & SAFETY

The Clinical Development and Trials track looks at how trial design and regulatory flexibility are evolving in response to emerging threats. Sessions explore decentralized trials, recruitment strategies, and the growing role of human challenge models in accelerating efficacy assessment. Representatives from CEPI, IVI, and national regulatory agencies assess ethical considerations, infrastructure requirements, and the integration of immunobridging data into licensure pathways.

The Vaccine Safety track focuses on safety science across development and post-licensure surveillance, including observational data, pharmacovigilance frameworks, and communication challenges in an increasingly fragmented policy environment.

MANUFACTURING & SUPPLY CHAINS

The Bioprocessing and Manufacturing track presents innovations across formulation, fill and finish, adjuvants, and mRNA production, alongside strategies for sustainable and regionally distributed manufacturing. Senior experts from academia, pharma, and international manufacturing networks will address regulatory alignment, quality control, and the integration of digital and AI-enabled manufacturing tools.

Parallel discussions within the Supply and Logistics track focus on vaccine distribution, cold chain resilience, and domestic manufacturing strategies, with particular attention to lessons learned from COVID-19 and their implications for future health security planning.

POLITICS & POLICY

The conference is bookended by reflections on the current political landscape for vaccines. The program opens with a fireside chat with senior US HHS officials on federal priorities for infectious disease research, pandemic preparedness, and regulatory reform.

Meanwhile, the closing session examines how political change and policy uncertainty are reshaping vaccine markets and offers a forward-looking perspective on how pharma, nonprofits, clinicians and regulators can navigate an evolving policy environment.

Overall, the program points to a growing emphasis on the intersection of scientific innovation, policy decisions, and delivery constraints across the vaccine lifecycle.

Further details on the program and registration are available here.
Readers of *Vaccine Insights* can access a **20% discount** on delegate tickets – just use the code **IB20**.
To learn about other events coming up in your field, you can find our online Events Calendars here.

THE BIG QUESTION

What's new and what's next for vaccines in 2026?

As the vaccines field continues to evolve, new technologies, targets, and delivery strategies are reshaping both research priorities and implementation pathways. We asked members of the *Vaccine Insights* Editorial Advisory Board to reflect on the areas shaping their current work and the developments they believe will influence the field in the years ahead.

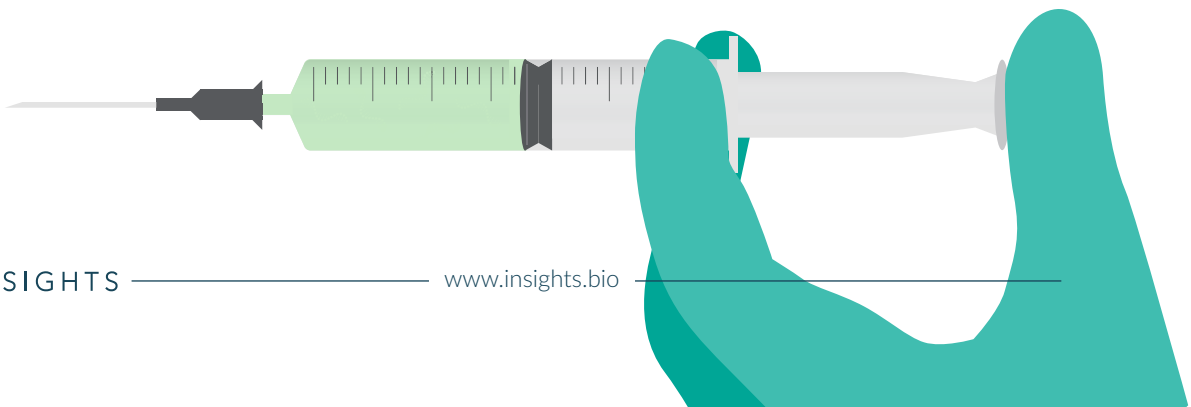
Vaccine Insights 2026; 5(1), 11–14 · DOI: 10.18609/vac.2026.003

WHAT'S NEW: EMERGING PRIORITIES IN VACCINE RESEARCH & INNOVATION

Editorial Advisory Board members highlighted efforts aimed at improving breadth and durability of protection and bringing manufacturing considerations into earlier points in the vaccine lifecycle.

Trina Racine, Director of Vaccine Development at the Vaccine and Infectious Disease Organization (VIDO), Saskatoon, Canada

"Developing vaccines capable of delivering broader and more durable protection is an important aspect of my current work. I am involved in efforts to advance a broadly protective coronavirus vaccine, with the aim of achieving protection that can better withstand viral variation and support future pandemic preparedness."



Cleo Kontoravdi, Professor of Biological Systems Engineering,
Department of Chemical Engineering - Faculty of Engineering,
Imperial College London, UK

"RNA-encoded antibodies for infectious diseases represent a central focus of my research. Alongside this, the establishment of Imperial College's Vaccine Manufacturing Research Hub has been an important development, enabling closer integration of research, process design, and formulation considerations at the outset of programs."

Isis Kanevsky, Director Bacterial Vaccines,
Pfizer, USA

"My current interests include the development of multivalency vaccines and novel carrier systems. These approaches have the potential to address a wider range of diseases within a single platform and to refine immune responses through improved antigen presentation."

Jeffrey Ulmer, President,
TechImmune LLC, USA

"Beyond traditional prophylactic applications, my work extends to immunotherapy approaches for conditions such as long COVID. As our understanding of long-term viral sequelae continues to develop, vaccines and immune-based interventions may begin to play a broader role in disease management as well as prevention."

Vaccine Insights 2026; 5(1), 11–14 · DOI: 10.18609/vac.2026.003

WHAT'S NEXT: TRENDS SHAPING THE FUTURE OF VACCINES

Looking ahead, board members identified digital technologies, improved formulations, and broader disease coverage as key drivers of future progress. There was also an emphasis on the importance of manufacturing innovation, access, and public trust as progress across the vaccines field continues to accelerate.

Tuck Seng Wong, Professor of Biomanufacturing, School of Chemical, Materials, and Biological Engineering (CMBE), University of Sheffield, UK

"I expect AI to become more routinely integrated into the design of highly effective and readily manufacturable vaccines, alongside broader availability of oral vaccines and feed-based vaccines for livestock. In parallel, increasing polarization around vaccine acceptance could present additional challenges, reinforcing the importance of trust and clear communication."

Christopher Ton, Principal Scientist, Vaccines & Advanced Biotechnologies Process Development, Merck & Co., USA

"AI will play a pivotal role in vaccine research, development, and manufacturing, enabling the identification of novel antigens and targets more quickly and accurately. In addition, machine learning will expedite process optimization, maximize productivity, and streamline manufacturing processes."

Cleo Kontoravdi

"Key developments I anticipate include wider adoption of platform manufacturing processes, progress toward heat-stable RNA formulations, and greater use of mathematical models for process optimization. Digital twins and AI-enabled tools could also support real-time product release, provided they achieve broader validation and acceptance."

Rajender Jena, Head Malaria Vaccines (Quality Control), Serum Institute of India Pvt Ltd, India

"Based on current trends, I expect increased focus on vaccine formulations that incorporate multiple antigens or immunogens, potentially addressing several diseases or stages within a

single product. Improving thermostability and strengthening supply-chain resilience will be particularly important for expanding access in resource-limited settings."

Pierre A Morgon, CEO,
MRGN Advisors, Switzerland

"As antimicrobial resistance continues to rise globally, I would like to see vaccines play a greater role in addressing this important threat. Broadening vaccine programs into this space could offer an important preventive strategy alongside existing antimicrobial stewardship efforts and the revival of phage therapy."

THE ROAD AHEAD

Collectively, these insights suggest that the next phase of vaccine innovation will be defined not only by technological advances, but also by how effectively new approaches are translated into durable and accessible solutions. As platforms mature and digital tools become more embedded, the challenge will lie in ensuring that progress in formulation science, manufacturing, and data-driven development is accompanied by practical advances in stability, supply chains, and access – particularly in settings where the need for effective vaccines remains greatest.

AUTHORSHIP & CONFLICT OF INTEREST

Contributions: The named authors take responsibility for the integrity of the work as a whole, and have given their approval for this version to be published.

Acknowledgements: None.

AI process statement: BioInsights used an AI tool (ChatGPT) to support non-creative editorial tasks such as organisation of source material, language tidying, and house style checks. The authors confirm that no AI tools were used in the preparation of this article.

BioInsights encourages transparent, responsible, and verifiable use of AI as a supporting tool; never a creative substitute. All content ultimately reflects human expertise, ethical rigor, and scientific integrity. See our full **AI policy statement** for more information.

ARTICLE & COPYRIGHT INFORMATION

Article source: Invited.

Revised manuscript received: Jan 29, 2026.

Publication date: Feb 4, 2026.

EVENT PREVIEW

NextGen Biomed 2026

Vaccine Insights 2026; 5(1), 7–9 · DOI: 10.18609/vac.2026.002

As part of our ongoing coverage of key gatherings in life sciences, BioInsights presents a preview of NextGen Biomed 2026. Scheduled for March 24–25, 2026, in London, UK, this event will unite the brightest scientific minds and the most disruptive innovations in biomedicine under one roof. The agenda spans advances in biologics, peptide and oligonucleotide therapeutics, immunotherapy strategies, vaccine research and development, and sustainable bioprocessing, featuring a keynote presentation from Andreas Plückthun (Professor of Biochemistry, University of Zurich), who will discuss molecular engineering for the future across therapeutic modalities, alongside contributions from a broad range of academic and industry leaders.

EXPLORING ADVANCES IN ADC ENGINEERING

The Proteins, Antibodies and ADCs program will explore topics ranging from protein and antibody engineering through to advanced bioanalytics, real-world case studies, and innovations in upstream and downstream processing. Senior leaders from pharmaceutical companies, biotechnology firms, and research institutions will share perspectives on antibody discovery, analytical development, and protein purification strategies. Charlotte Deane (Professor, University of Oxford) will examine the application of AI in protein design, while Dan Bach Kristensen (Scientific Director, Servier) will present on characterization of ADCs and next-generation biologics in biological matrices using affinity capture liquid chromatography–mass spectrometry.

OLIGONUCLEOTIDE DESIGN, CMC, & SCALE-UP STRATEGIES

Beyond ADCs, the conference will also include presentations on how computational design approaches, CMC strategies, sustainable process improvements, and advanced analytical controls are being applied to accelerate oligonucleotide-based drug development timelines. A thought leadership panel featuring Anna Perdrix (Chief Executive Officer, Sixfold Bioscience), Sritama Bose (Associate Director of Chemistry, Orfonyx Bio), and Sandor Batkai (Life Science Consultant, formerly Head of Medical Research and Intelligence, Cardior Pharmaceuticals) will explore regulatory considerations, novel technologies, and

scale-up challenges in oligonucleotide drug development.

NOVEL IMMUNOTHERAPY & IMMUNO-ONCOLOGY APPROACHES

Immunotherapy for cancer and autoimmune diseases will be another central theme, with sessions focused on biomarker-guided strategies, next-generation cellular and antibody-based approaches, and personalized treatment paradigms. Alexander Eggermont (Professor, University Medical Center Utrecht) will present on the neoadjuvant immunotherapy revolution across multiple tumor types, discussing why neoadjuvant immuno-oncology strategies may offer advantages over adjuvant approaches. Callum Scott (Senior Vice President and Head of Development, Scancell) will address the role of potency testing across the cancer vaccine development lifecycle, highlighting the intersection of technical feasibility, regulatory expectations, and commercial considerations.

INNOVATIONS IN VACCINE DESIGN & DEVELOPMENT

The vaccines program will examine advances in nucleotide-based vaccine platforms for infectious diseases, AI-driven antigen design, and emerging delivery systems. Daniel Larocque (Innovation Leader, Sanofi) will present a historical and forward-looking perspective in a session titled 'Tracing 200 years of vaccine innovation: from prophylactic to therapeutic vaccines and AI-driven vaccines'. Supriyadi Hafiz (Senior Scientist, Merck) will discuss the growing demand for responsibly sourced alternatives to animal-derived ingredients, with a focus on fermentation-derived, non-animal-origin squalene. Across the program, attendees will gain insights into adjuvant production, clinical development strategies, and translational approaches that support the progression of vaccine candidates from research to real-world application.

WOMEN IN NEXTGEN BIOMED PANEL DISCUSSION

The two-day event will also feature a Women in NextGen Biomed panel discussion. Building on the success of the previous year, this session will bring together leading female scientists and industry professionals for a discussion focused on innovation, career pathways, and addressing barriers in STEM. The panel will highlight achievements, ongoing challenges, and future opportunities for women contributing to the next generation of biomedical research and development.

Vaccine Insights 2026; 5(1), 7–9 · DOI: 10.18609/vac.2026.002

NextGen Biomed 2026 will bring together innovators across biologics, tides, and immunotherapy fields to share real-world case studies spanning novel target discovery and clinical validation, as well as biologics engineering and therapeutic development. Together, these discussions will offer a deep dive into the science and strategy behind the field's most promising breakthroughs.

You can find out more about the NextGen Biomed 2026 events **here**.

To learn about other events coming up in your field, you can find our online Events Calendars here: ***Bioconjugate Insights***, ***Nucleic Acid Insights***, and ***Vaccine Insights***.

INDUSTRY INSIGHTS · JANUARY 2026

Maternal vaccine safety, controversial policy changes, and the surprising link between tattoo ink and vaccine response

Charlotte Barker

Charlotte has over 20 years of experience as a science writer and editor. As Commissioning Editor of *Vaccine Insights*, she works with leading scientists to produce content covering all aspects of vaccine R&D and manufacturing. For this month's Industry Insights, Charlotte shares the news that caught her attention this month – from how tattoos might affect vaccine responses, to mounting evidence that shingles vaccines can prevent dementia.

Vaccine Insights 2026; 5(1), 1–6 · DOI: 10.18609/vac.2026.001

DISCOVERY AND IMMUNOLOGY

Tattoo ink may alter vaccine-induced immune responses [1]

A mouse study investigated how tattoo ink affected immune responses to vaccines. Tattoo ink rapidly drained to nearby lymph nodes, where it was primarily captured by macrophages. When tattoo ink was present, antibody responses to a mRNA-based SARS-CoV-2 vaccine were reduced, correlating with decreased spike protein expression in macrophages, whereas responses to an inactivated influenza vaccine were enhanced.

CXCL10–IFN-γ signaling may drive myocarditis in mRNA vaccine models [2]

A mechanistic study investigated the mechanism behind rare cases of myocarditis observed after SARS-CoV-2 mRNA vaccination, mostly in young men. By analyzing samples from vaccinated individuals, including some who developed myocarditis, the authors identified CXCL10 and IFN-γ as possible biomarkers for vaccine-induced

myocarditis. Neutralizing CXCL10 and IFN-γ during a two-dose vaccination regimen reduced cardiac injury in mice and decreased stress and inflammatory markers in human cardiac cell models.

Reverse vaccinology and AI identify candidate mpox vaccine antigen [3]

A study applied Reverse Vaccinology 2.0 and AI to identify new vaccine and antibody targets against monkeypox virus. Neutralizing monoclonal antibodies were isolated from B cells of individuals with prior MPXV infection or vaccination, and AI-assisted structural modeling and cryo–electron microscopy identified OPG153 as their target. OPG153-directed antibodies neutralized multiple MPXV clades as well as vaccinia virus *in vitro*, and adjuvanted MPXV OPG153 antigen elicited potent neutralizing antibody responses in mice.

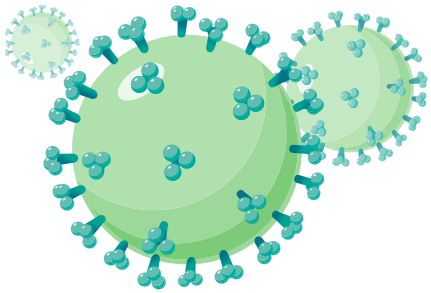
CLINICAL TRIALS

Real-world analysis found no increased pregnancy risks with maternal RSV vaccination after 32 weeks [4]

To address concerns raised in earlier trials, a post-authorization safety analysis evaluated pregnancy outcomes following administration of Pfizer's RSV prefusion F vaccine, Abrysvo, during late pregnancy. The US study examined 54,011 pregnancies during the first RSV season after approval, with 19% of participants vaccinated between 32 and 36 weeks' gestation. The analysis found no statistically significant increase in preterm birth, hypertensive disorders of pregnancy, premature rupture of membranes, or preterm premature rupture of membranes among vaccinated individuals.

Canadian study confirms lower maternal and neonatal risks with COVID-19 vaccination during pregnancy [5]

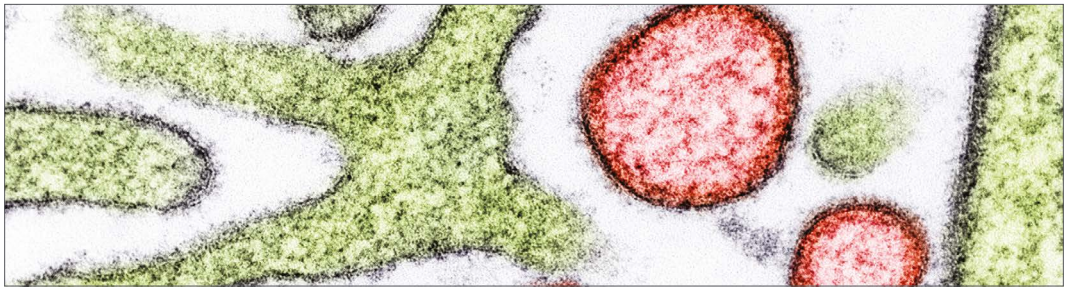
A population-based study examined outcomes among nearly 20,000 pregnant Canadian women who developed COVID-19 and found that vaccinated women were 62% less likely to be hospitalized and 90% less likely to require critical care compared with unvaccinated women. Vaccination was also associated with reduced risk of preterm birth, with a 20% reduction during the Delta wave and a 36% reduction during the Omicron wave. Infants born to vaccinated mothers were less likely to require neonatal intensive care, while rates of stillbirth were similar between groups.



More evidence that shingles vaccination reduces dementia risk – and may slow progression [6,7]

Natural experiments from Canada support previous studies showing that herpes zoster vaccination lowers the risk of developing dementia amongst older adults. Plus, a new analysis of a large cohort in Wales, UK, shows a lower incidence of mild cognitive impairment in vaccinated people without dementia, and fewer deaths from dementia among vaccinated dementia patients.

Vaccine Insights 2026; 5(1), 1–6 · DOI: 10.18609/vac.2026.003



Interim analyses show moderate effectiveness of the 2025–26 influenza vaccine despite strain mismatch [8]

Two interim analyses from France and China assessed the effectiveness of the 2025–26 seasonal influenza vaccine during early circulation of influenza A(H3N2) subclade K viruses, which were not antigenically matched to the vaccine. A French study analyzing 24,267 patients reported an overall vaccine effectiveness of 36.4% against laboratory-confirmed influenza, with higher protection in children (57.2%) than in adults aged 65 years and older (27.7%). A parallel analysis from Beijing reported similar results.

Reduced-dose yellow fever vaccine less effective than standard dose in infants [9]

The WHO recommends fractional dosing of yellow fever vaccine to address shortages during outbreaks. Fractional dosing has been shown to be effective in adults, but a new double-blind randomized trial conducted in Kenya and Uganda found that a fractional dose (500 IU) of live attenuated yellow fever vaccine was inferior to the standard dose (1300 IU) in infants aged 9–12 months.

Phase 1 trial reports safety and immunogenicity of a novel Nipah virus vaccine [10]

A Phase 1 randomized, placebo-controlled clinical trial evaluated the safety and immunogenicity of an investigational Nipah virus vaccine in 192 healthy adults aged 18–49 years. Two doses of the vaccine were well tolerated and induced robust immune responses, with antibodies detected within 1 month after the second dose.

Multistage malaria vaccine shows promising results in controlled human infection study [11]

A Phase 2 randomized controlled trial evaluated the multistage malaria vaccine ProC6C-AlOH/Matrix-M in Malian 34 adults with lifelong exposure to *Plasmodium falciparum*. Participants received either three doses of the malaria vaccine or a rabies vaccine control, followed by controlled human malaria infection 94 days after the final dose. Among participants completing the challenge, there was an estimated vaccine efficacy of 54% and vaccination delayed time to detectable parasitemia by a median of 2 days.

Cohort study reports no increase in mortality 4 years after COVID-19 mRNA vaccination [12]

A national cohort study using French National Health Data System records examined 4-year all-cause mortality in 22.8 million adults who received a COVID-19 mRNA vaccine versus 5.9 million unvaccinated participants. After controlling for sociodemographic factors and comorbidities, vaccinated individuals

showed no increased risk of all-cause mortality and a 74% lower risk of death from severe COVID-19. All-cause mortality was also lower among vaccinated individuals.

MARKET TRENDS

CEPI commits up to $54 million to take Moderna's H5 avian influenza mRNA vaccine into Phase 3 trials [13]

Moderna announced it secured up to $54.3 million in funding from CEPI to advance its H5 avian influenza messenger RNA (mRNA) vaccine candidate, mRNA-1018, into Phase 3 clinical testing. The agreement supports late-stage development after prior US government funding for the program was discontinued earlier in 2025. Under the terms, Moderna will allocate 20% of its production capacity to low- and middle-income countries at affordable pricing in the event of a pandemic, subject to regulatory approval. The Phase 3 trial is expected to begin in early 2026 in the US and UK, building on earlier-stage safety and immunogenicity data in healthy adults.

NIH-funded program advances fungal vaccine VXV-01 toward Phase 1 trials [14]

The Lundquist Institute and its start-up company Vitalex Biosciences announced that its second-generation fungal vaccine candidate VXV-01 is nearing a Phase 1 clinical trial under a NIH/NIAID contract valued at up to $40 million. VXV-01 is a dual-antigen vaccine designed to target invasive Candida infections, with reported broader cross-kingdom protection potential against Gram-negative healthcare-associated pathogens.

Sanofi to acquire Dynavax [15]

Sanofi has entered into an agreement to acquire vaccine biotech Dynavax. Dynavax has a marketed hepatitis B vaccine and a shingles vaccine in clinical trials. Sanofi's EVP for Vaccines, Thomas Triomphe, stated: "Dynavax enhances Sanofi's adult immunization presence by adding differentiated vaccines that complement Sanofi's expertise."

REGULATION AND POLICY

Moderna files global regulatory submissions for seasonal influenza vaccine mRNA-1010 [16]

Moderna has submitted marketing authorization applications for its investigational seasonal influenza mRNA vaccine, mRNA-1010, to regulators in the US, EU, Canada, and Australia for use in adults aged 50 years and older. The company stated that mRNA-1010 demonstrated a relative vaccine efficacy of 26.6% versus licensed comparators, with consistent results across age and risk subgroups, as well as superior immunogenicity across all included influenza strains.

Vaccine Insights 2026; 5(1), 1–6 · DOI: 10.18609/vac.2026.003

Controversial hepatitis B newborn vaccine study in Guinea-Bissau halted over ethical concerns [17]

A US-funded study evaluating hepatitis B vaccination strategies in newborns in Guinea-Bissau was halted by Africa CDC following concerns about its ethical design. The $1.6 million study, supported under the US Department of Health and Human Services, drew criticism for potentially withholding a proven hepatitis B vaccine from a control group in a country with a high disease burden. Africa CDC officials stated the trial was cancelled due to ethical issues and would only proceed if redesigned to meet international research standards.

CDC to revise US childhood immunization schedule [18,19]

Acting CDC Director Jim O'Neill signed a decision memorandum directing the CDC to make changes to the recommended childhood vaccination schedule. The US

Department of Health and Human Services stated this was in response to an assessment comparing US recommendations with those of 20 other nations. Under the revised framework, the number of vaccines recommended for all children will drop from 17 to 11, with vaccines for flu, COVID-19, rotavirus, hepatitis A & B, dengue and meningitis now recommended only for specific high-risk populations or based on shared clinical decision-making. The changes have been called 'dangerous and unnecessary' by the American Academy of Pediatrics.

Have a vaccine story you think we should cover? Contact us: editor@insights.bio

REFERENCES

1. Capucetti A, Falivene J, Pizzichetti C, *et al*. Tattoo ink induces inflammation in the draining lymph node and alters the immune response to vaccination. *Proc. Natl Acad. Sci. USA* 2025; 122, e2510392122.
2. Cao X, Manhas A, Chen Y-I , *et al*. Inhibition of CXCL10 and IFN-γ ameliorates myocarditis in preclinical models of SARS-CoV-2 mRNA vaccination. *Sci. Transl. Med.* 2025; 17, eadq0143.
3. Paciello I, Rundlet EJ, Zhou L, *et al*. Antigen-agnostic identification of poxvirus broadly neutralizing antibodies targeting OPG153. *Sci. Transl. Med.* 2025; 17.
4. Michnick AI, MacDonald SC, Cosgrove A, *et al*. Interim safety of RSVpreF vaccination during pregnancy. *JAMA* 2026; published online Jan 8. https://doi.org/10.1001/jama.2025.23452.
5. McClymont E, Blitz S, Forward L, *et al*. The role of vaccination in maternal and perinatal outcomes associated with COVID-19 in pregnancy. *JAMA* 2026; 335, 154–162.
6. Pomirchy M, Chung S, Bommer C, Strobel S, Geldsetzer P. Herpes zoster vaccination and incident dementia in Canada: an analysis of natural experiments. *Lancet Neurol.* 2026; 25, 170–180.

7. Xie M, Eyting M, Bommer C, Ahmed H, Geldsetzer P. The effect of shingles vaccination at different stages of the dementia disease course. *Cell* 2025; published online Dec 11. https://doi.org/10.1016/j.cell.2025.11.007.
8. De Clercq A, Blanquart F, Vieillefond V, *et al*., on behalf of the RELAB study group. Interim vaccine effectiveness against influenza virus among outpatients, France, October 2025 to January 2026. *Euro. Surveill.* 2026; 31, pii=2500992.
9. Kimathi D, Juan-Giner A, Bob NS, *et al*. Low-dose yellow fever vaccination in infants: a randomised, double-blind, non-inferiority trial. *Lancet* 2026; published online Jan 13. https://doi.org/10.1016/S0140-6736(25)02069-0.
10. Frenck RW, Naficy A, Feser J, *et al*. Safety and immunogenicity of a Nipah virus vaccine (HeV-sG-V) in adults: a single-centre, randomised, observer-blind, placebo-controlled, phase 1 study. *Lancet* 2025; 406, 2792–2803.
11. Kone MK, Plieskatt J, Thienta M, *et al*. Efficacy of ProC6C-AlOH/Matrix-M against Plasmodium falciparum infection and mosquito transmission: a phase 2, randomised, controlled human malaria infection study. *Lancet Infect. Dis.* 2025; published online Dec 16. https://doi.org/10.1016/S1473-3099(25)00664-4
12. Semenzato L, Le Vu S, Botton J, *et al*. COVID-19 mRNA Vaccination and 4-Year All-Cause Mortality Among Adults Aged 18 to 59 Years in France. *JAMA Netw. Open* 2025; 8, e2546822.
13. Moderna. Moderna announces global regulatory submissions for its investigational seasonal influenza vaccine. Jan 5, 2026.
14. The Lundquist Institute. The Lundquist Institute and its start-up company Vitalex Biosciences announces strategic advancement of second-generation fungal vaccine VXV-01 through Phase 1 trials under $40 million competitive contract from NIH/NIAID. Dec 15, 2025.
15. Sanofi. Sanofi to acquire Dynavax, adding a marketed adult hepatitis B vaccine and phase 1/2 shingles candidate to the pipeline. Dec 24, 2025.
16. Moderna. Moderna announces global regulatory submissions for its investigational seasonal influenza vaccine. Jan 5, 2026.
17. Schreiber M. Controversial US study on hepatitis B vaccines in Africa 'cancelled.' *The Guardian* 2026; Jan 16.
18. US Department of Health and Human Services. CDC acts on Presidential memorandum to update childhood immunization schedule. Jan 5, 2026.
19. Jenco M, Schering S, Stangland S. AAP: CDC plan to remove universal childhood vaccine recommendations 'dangerous and unnecessary.' *AAP News*; Jan 5, 2026.