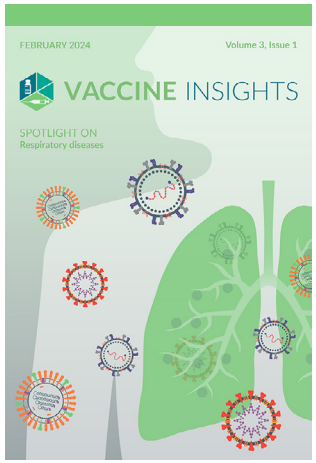
EDITORIAL CALENDAR **2025**

VACCINE INSIGHTS



FEBRUARY	MARCH	APRIL	MAY	JUNE
Combination vaccines	RNA vaccine R&D	Pandemic preparedness	Vaccine manufacturing: upstream processing and raw materials	Analytical innovation
Immune Response Update	Vaccine Clinical Update	Immune Response Update		Vaccine Clinical Update

JULY	AUGUST	SEPTEMBER	OCTOBER	NOVEMBER	DECEMBER
Sustainability in vaccine development and production		Vaccine manufacturing: downstream processing and supply chain	mRNA-LNP vaccine production	How close are we to meeting the 100 days target to produce a vaccine?	
Immune Response Update		Vaccine Clinical Update	Immune Response Update	Vaccine Clinical Update	

SPOTLIGHTS

Peer-reviewed articles
Webinars
Podcasts, written and video interviews
On-demand roundtable discussions

CHANNEL EDITIONS

Immune Response Update

Vaccine Clinical Update

Vaccine Insights provides you with fantastic opportunities to:

- Educate your target market about your company's expertise, capabilities, and experience
- Share your latest data with organizations looking for partners and service providers in your field
- Profile your executives and scientists as thought-leaders and KOLs
- Generate qualified leads from across the global sector
- Increase awareness of your company's role in vaccines R&D

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EDITORIAL CALENDAR **2025**

VACCINE INSIGHTS

JOURNAL SPOTLIGHTS

Combination vaccines — FEB

As immunization schedules grow more crowded, multipathogen combination vaccines are increasingly attractive. What are the immunological, regulatory, manufacturing/formulation, supply chain, and analytical hurdles for new combination vaccines?

- Rationalizing adult and infant vaccine schedules with new combination vaccines to improve uptake and coverage
- Policy interventions to incentivize combination vaccine development
- Optimizing policy and regulatory pathways for monopathogen combination vaccines and applying learnings to multipathogen combinations
- Applications of combination vaccines in LMIC and for neglected diseases
- Identifying priority combination vaccine targets, taking into account syndromic approaches, existing vaccine schedules, and technical challenges
- Achieving good protection with a low volume in combination vaccines
- Assessing and overcoming the risk of immune interference due to antigenic competition, epitope-specific suppression, or adverse adjuvant interactions
- Clinical development challenges for and regulatory approaches to combination vaccines
- Addressing analytical challenges for combination drug products: stability, characterization, interactions
  - Are risk-based approaches available?
  - Choosing the right technological approaches for combination vaccine analysis
- New opportunities for combination vaccines with RNA
- Maintaining stability and shelf life for combined formulations

RNA vaccine R&D — MAR

What's next for RNA vaccines? How can we better understand and optimize the durability, reactogenicity, and stability of RNA vaccines at large scale?

- How applicable are mRNA-LNP vaccines to a variety of unmet vaccine needs and how will they fit into the wider vaccine landscape?
- What are the limitations of a multi-modality approach, and to what extent is it needed?
- Improving antigen design with emerging AI/ML and sequencing tools
- Learning more about immune responses to mRNA vaccines vs other vaccine platforms
  - Balancing immunogenicity and reactogenicity
  - Increasing durability of immune response—the role of antigen vs platform
- How to generate long-term data to better understand rare adverse effects (e.g., myocarditis)?
- To what extent can a specific mRNA-LNP formulation be considered a platform technology to simplify or fast-track the regulatory pathway to approval for next-gen products?
- How close are we to refrigerated or room temperature formulations (e.g., using lyophilization or alternative nanoparticle formulations)?
- Development of novel lipid nanoparticles or alternatives to lipids (e.g., polymers) for effective RNA delivery
- Challenges and advances in next-gen RNA vaccines (e.g., saRNA, circRNA)

Pandemic preparedness — APR

In a changing world, pandemics are an increasing threat to global security. How can policy intervention, new technology, and global cooperation ensure an effective response to a potential pandemic?

- Strengthening national and international collaboration and policy frameworks (e.g., The Pandemic Accord)
- Preparing for emerging threats: the WHO priority pathogen list and beyond
- Quantifying and reducing the threat of avian influenzas
- Understanding and mitigating the impact of climate change and the threat of vector-borne diseases
- Strengthening surveillance and diagnostics (e.g., by leveraging next-generation sequencing tools and global data sharing)
- Harnessing computational tools and AI to model outbreaks and optimize vaccine clinical trials
- Taking a pathogen family approach to vaccine development, rather than focusing on individual pathogens, to generate broadly protective vaccines
- Will RNA be the platform of choice for future pandemic vaccines and how can it be optimized as such?
- Defining the role of animal and human challenge studies in approval of vaccines for diseases with pandemic potential
- Veterinary vaccine development: latest advances and meeting the need for a holistic, global approach
- Addressing hurdles to building localized vaccine production infrastructure in LMIC

Vaccine manufacturing: upstream processing and raw materials — MAY

With new platforms and indications hitting the market, manufacturers need to meet demand in a cost-effective manner. How are new technologies changing how vaccines are produced?

- Predicting productivity and capacity needs to meet future demand
- Achieving a resilient raw materials supply chain:
  - using modeling tools to identify weak links of the chain
  - building in redundancy
  - identifying sustainable sources for finite materials

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EDITORIAL CALENDAR **2025**

JOURNAL SPOTLIGHTS

VACCINE INSIGHTS

- Developing new production platforms for faster, more cost-effective manufacturing of all vaccine platforms, from VLPs to RNA
- Scaling up or scaling out? Overcoming scalability challenges for vaccine manufacturing
- Overcoming regulatory and cost challenges to implement chemically derived media and cell-free manufacturing processes
- Towards closed processes from cell bank onwards for aseptic process control
- Future of process optimization—pursuing automation via AI/ML
- Examining the challenges and benefits of combined facilities
- Harnessing digital twin technology for decentralized manufacturing

Analytical innovation — JUN

New modalities and a drive for faster clinical and commercial translation of vaccines is bringing fresh challenges for vaccine analytics and CMC. How can potency, safety, and characterization of vaccines be optimized?

- Defining quality expectations earlier in development to speed up clinical translation and overcome bottlenecks in assay development
- Overcoming hurdles to implementation of PAT in vaccine manufacturing
- Leveraging computational fluid dynamics and other *in silico* tools to accelerate process and product development
- Harnessing flow-based, individual cell-based assays for faster potency testing
- Expanding the use of mass spectrometry for structural characterization, glycosylation profiling, and antigen quantitation during vaccine development
  - Could it also be applied in the QC lab?
- Meeting increasingly stringent regulatory requirements for host cell protein and host cell DNA testing
- Clearing hurdles to the implementation of NGS for adventitious agent testing for live vaccines
- Evolving analytical strategies for emerging vaccine platforms—beyond mRNA
- How and where specifically are AI/ML being applied to streamline vaccine analytical processes?

Vaccine Insights Spotlights

Each spotlight will comprise:

- Peer-reviewed Expert Insight articles written by leading experts in the field
- Webinars, featuring industry speakers and sponsors discussing key topics specific to the Spotlight
- Podcast, written and video interviews with key opinion leaders
- On demand roundtable discussions

Sustainability in vaccine development and production — JUL

Environmental and economic sustainability is particularly important for vaccines, due to their large-scale manufacturing and long lifecycle. How can we ensure global access to vaccines, while minimizing the impact on the planet?

- Integrating *in vitro* alternatives to animal models—quality of data and regulatory implications
- To what extent can computational modeling augment or even replace preclinical/clinical studies, and reduce waste?
- Reducing environmental impact of vaccine production
  - Applying green chemistry principles
  - Addressing single-use plastics—what are the solutions/alternatives?
  - Overcoming regulatory barriers to implementing more sustainable processes
- Towards sustainably sourced raw materials
- Building long-term vaccine manufacturing capacity for the world
  - Localized vaccine manufacturing in LMIC—what number, size, and type of facilities are sustainable?
  - What local, continental, and global policy interventions are needed in the short and long term to support LMIC countries entering the vaccine manufacturing market?
- How can policy and regulatory frameworks best support sustainable practices?
- What is the optimal model to maintain manufacturing capacity for a pandemic response?

Vaccine manufacturing: downstream processing — SEP

Downstream processing, fill/finish, and supply chain remain common bottlenecks for vaccine manufacturing. How are advances in these areas improving vaccine manufacturing?

- Optimizing downstream processes with new tools and technologies
- Expanding Design of Experiments to include more factors using AI/ML
- Embracing diversity—developing purification approaches for multiple different platforms
- How to scale-up production in a cost-effective manner? Sharing lessons learned
- Automating manufacturing and visual control elements for improved efficiency and process control
- What new considerations and opportunities for downstream processing accompany recent advances in lyophilization technology and its application?
- Towards smoother tech transfer between manufacturing partners for faster, more efficient production
- Building manufacturing capacity in LMIC—is working backwards from drug product manufacturing the right approach?
- Digitization of supply chain and use of AI to optimize processes and maintain the controlled temperature chain
- Improving access to vaccines with fridge-free formulations and pre-filled injectables

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EDITORIAL CALENDAR **2025**

VACCINE INSIGHTS

JOURNAL SPOTLIGHTS

mRNA-LNP vaccine production — OCT

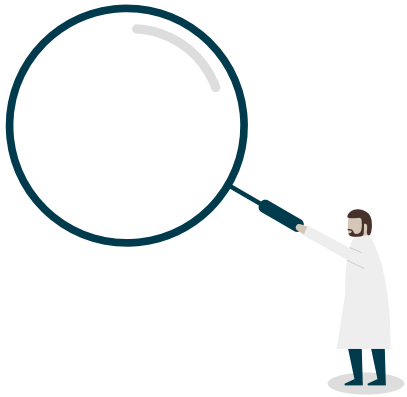
Four years on from approval of the first COVID-19 mRNA-LNP vaccines, what have we learned about how to optimize process development, manufacturing, and analytics?

- Addressing cost and availability of raw and starting materials for mRNA-LNPs
- Optimizing and scaling up IVT with advanced automation and synthetic DNA templates
- Efficient purification at scale—what progress in improving the removal of impurities such as dsRNA, proteins, and enzymes?
- Enhancing sustainability of RNA facilities as demand increases
  - How to predict future demand for RNA vaccine manufacturing capacity?
- Understanding mechanism of action of mRNA-LNPs and how impurities (e.g., dsRNA) affect mRNA vaccine immune responses
- Is emerging mRNA-LNP analytical technology delivering the requisite improvements in the way of higher resolution/sensitivity and reduced sample volume? (e.g., purity profiles, poly-A tail characterization, encapsulation efficiency, stability)
- Reducing sterility testing bottlenecks
- Overcoming analytical challenges posed by multivalent mRNA vaccines
- Understanding the evolving regulatory landscape for mRNA-LNP products to streamline development and mitigate risk
- Advances and considerations in the development and implementation of platform approaches for lot release testing

How close are we to meeting the 100 days target to produce a vaccine? — NOV

CEPI's mission to shrink the timeline from recognition of a threat to a vaccine ready for initial authorization and large-scale manufacturing within 100 days has captured the imagination of the field. What policy, technological, and regulatory advances are needed to make the goal a reality?

- What needs to happen before day 0, in terms of policy and technology?
  - Scalable technology and process
  - Establishing assays to characterize product
  - Rapidly programmable platform technologies
- How can we ensure sustainable R&D funding for comprehensive diagnostic, therapeutic, and vaccine solutions?
- Harnessing AI/ML to accelerate vaccine R&D
- Establishing sustainable international clinical trial infrastructure
- Working towards regulatory convergence for streamlined product and process development
  - Assessing progress to date towards preparatory regulatory approaches, such as pre-agreed correlates of protection and shared risk-benefit profiles
- How can we strengthen post-approval studies?
- Can protein-based vaccines narrow the gap on production speed by moving toward a platform/plug and play approach and optimizing cell culture?
  - Lessons from the antibody therapeutics field
- Can mRNA-LNP vaccines be produced even faster with platform approaches for release testing?



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QUARTERLY CHANNEL CONTENT & NEWSLETTERS

VACCINE INSIGHTS

FEB APR JUL OCT

Immune Response Update

Can we unravel the complexity of immune responses to vaccines?

- Harnessing new tools and technology to better understand all aspects of immune responses to vaccines
- How is single cell analysis changing our understanding of immune responses?
- Understanding cell-based immune responses, including high-throughput methods for T cell analysis
- Analysing multifactorial immune responses to develop more sophisticated correlates of protection
- Systems serology approaches for profiling vaccine-induced antibody responses
- Understanding variation in immune responses
- New strategies to overcome or harness immune imprinting
- How can in vitro models of the immune system best be applied?
- Standardizing protocols between labs (e.g., measuring antibodies) to ensure comparability
- AI/ML approaches to analyzing immunological big data to allow more rational antigen design, understand variation, and identify correlates of protection
- New frontiers for vaccinology—from antimicrobial resistance to latent viruses

MAR JUN SEP NOV

Vaccine Clinical Update

How can we meet the clinical challenge of increasingly complex vaccines? Can we improve confidence in and acceptability of vaccines?

- Using human challenge models to provide early data on efficacy and as a possible alternative where Phase 3 studies are impractical
- Building infrastructure worldwide for large-scale, informative post-approval studies to ensure long-term safety and efficacy
- Toward more efficient and streamlined clinical testing/serology in vaccine clinical trials
- Recruiting and maintaining diverse clinical trial participants
- The role of AI/ML in analyzing clinical trial data and accelerating the clinical trial process
- As vaccine schedules become busier, is now the time for non-needle delivery systems (MAPS, intranasal, oral, etc.)?
  - Understanding mucosal immune responses and reducing reactogenicity
  - Scaling up non-needle delivery technologies for large-scale clinical use
  - Designing vaccines with the delivery method in mind
- Developing more effective vaccine adjuvants
  - Balancing immunogenicity and reactogenicity
  - Availability and sustainability of adjuvants
  - Understanding mechanisms of action
  - Using adjuvants to tailor vaccines to specific populations
- Addressing vaccine hesitancy and improving uptake
- The role of public-private collaboration in vaccine development—key factors for success

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