



VACCINE LICENSURE FOR PHYSICIANS

Summary

- Vaccines require rigorous **(1) safety** and **(2) efficacy** data to be licensed, as they are administered to healthy individuals.
- Approval follows strict regulatory protocols in the **U.S. (FDA)**, **EU (EMA)**, and globally **(WHO PQ)**.
- **Clinical endpoint** trials are preferred; however, correlates or surrogates of protection can accelerate approval in special cases.
- Multiple **regulatory pathways** exist for accelerated licensure during public health emergencies.
- Manufacturing, distribution, and post-marketing surveillance are integral throughout the vaccine **life cycle**.
- Licensure is not equivalent to recommendation or reimbursement—these decisions are made by **NITAGs** and/or financial bodies.

What is Vaccine Licensure?

- Licensure ensures a vaccine meets the highest standards of **safety, efficacy, and quality** before public use.
- Essential due to administration in **healthy populations** and **population-wide implications**.

Core Steps in Vaccine Licensure

• **Development:** Laboratory research, preclinical animal studies, and **phased clinical trials (I, II, III)**.

Regulatory Submission:

- **U.S. pathway:** *Investigational New Drug (IND) → Biologics License Application (BLA)*
- **EU pathway:** *Clinical Trial Application → Marketing Authorisation Application (MAA)*

• **Review:** National/regional agencies (FDA, EMA) assess evidence, manufacturing, and benefit–risk profile.

• **Approval:** Successful products receive licensure (market authorisation).

• **Post-marketing:** Ongoing surveillance for rare adverse events and effectiveness.

Documenting Vaccine Efficacy:



- Randomised, controlled clinical trials with disease endpoints are the gold standard.
- Alternative evidence for efficacy:

- Validated correlate of protection (e.g., specific antibody levels)

- Surrogate of protection (immunogenicity bridging)

- Animal efficacy for pathogens where human studies are not ethical.

Accelerated and Alternative Pathways

- **Accelerated Approval, Fast-Track, Priority Review, and Breakthrough Designation** are pathways available in the **U.S.** to expedite vaccine approval for urgent public health threats.

- The EU has similar processes: **Centralised, Mutual Recognition, Decentralised, and National Procedures**.

- The **WHO prequalification(PQ)** allows broader access to vaccines in countries lacking mature regulatory systems and is essential for **global immunisation programmes**.

Special Considerations and Challenges

- **Manufacturing consistency, site licensure, and quality control checks** are regulatory requirements.

- **EU has similar processes:** Centralised, Mutual Recognition, Decentralised, and National Procedures.

- **WHO prequalification(PQ)** allows broader access to vaccines in countries lacking mature regulatory systems and is essential for global immunisation programmes.

References

1. **Boyce D.** Vaccine licensure. In: Schmitt HJ, ed. *Essentials in Vaccinology*. Singapore: Global Health Press; 2021:chap 15. doi:[10.33442/vt202115](https://doi.org/10.33442/vt202115). Accessed November 9, 2025.
2. **Masignani V, Palacios R, Martin MT, Tibaldi F, Vadivelu VK.** De-risking vaccine development: lessons, challenges, and prospects. *npj Vaccines*. 2025;10:177. doi:[10.1038/s41541-025-01211-z](https://doi.org/10.1038/s41541-025-01211-z). Accessed November 9, 2025.

Select Epidemiology References ~ (as discussed in attached sources)

- **Carter A, et al.** Modeling the impact of vaccination for the Immunization Agenda 2030: deaths averted due to vaccination against 14 pathogens in 194 countries from 2021 to 2030. *Vaccine*. 2024;42(Suppl 1):S28–S37.
- **World Health Organization.** *Immunization Agenda 2030: A Global Strategy to Leave No One Behind*. Geneva: World Health Organization; 2020.

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