

Valneva Clinical Trials Policy

1 Purpose

The purpose of this policy is to express Valneva's commitment to applying the highest standards of ethics, respecting human rights, ensuring participant safety, and scientific rigor for clinical trials sponsored by Valneva. This policy applies to all employees involved in the clinical development of vaccines. Valneva commits to applying these principles also at contributing to external parties including clinical research teams, contract research organizations (CROs), and collaborating partners.

2 Scope

This policy applies to all clinical trials sponsored or conducted by Valneva, from Phase 1 through Phase 4 clinical trials. It covers all stages of the clinical development process, protocol development, participant recruitment, data collection, monitoring, reporting, and compliance with regulatory and ethical guidelines.

3 Abbreviations

AE: Adverse Event

CRO: Contract Research Organization

GCP: Good Clinical Practice

GCLP: Good Clinical Laboratory Practice

GMP: Good Manufacturing Practice

EC: Ethics Committee

EMA: European Medicines Agency

FDA: Food and Drug Administration

SAE: Serious Adverse Event

4 Policy Statements

1.1 Compliance with Ethical and Regulatory Standards

All clinical trials are conducted in compliance with Valneva's respective Global Quality Standard, which aligns with international ethical and regulatory principles.

1.2 Human Rights

Valneva commits that all clinical trials, irrespective of their geographic location, will adhere to internationally recognized human rights standards. Valneva's commitment to human rights includes:

- Ensuring voluntary and informed consent from all participants.
- Upholding the rights of individuals to withdraw from a trial at any time without penalty or reprisal.
- Protecting vulnerable populations and respecting cultural and social contexts.

Recognizing the importance of community engagement, Valneva will work with local communities to understand and address concerns about Clinical Trial processes. Where possible, Valneva will:

- Seek opportunities for benefit-sharing that contribute positively to local healthcare infrastructure.
- Engage with community leaders and representatives to ensure that our work aligns with community values and needs.

Please also refer to Valneva's Human Rights Policy.

1.3 Informed Consent

Valneva is committed to conducting ethical clinical research in line with its Global Quality Standard, which ensures adherence to the principles of informed consent, participant protection, and data confidentiality. These standard outlines the processes for providing clear information to participants, safeguarding their rights and well-being, and ensuring that consent is obtained in an ethical and transparent manner.

1.4 Inclusivity in Clinical Trials

There are regulatory, medical and/ or scientific reasons to investigate vaccines in diverse trial populations. In addition, some diseases for which we aim to develop prophylactic vaccines to protect humans may be found in specific geographic regions or populations.

We strive to follow inclusivity principles in all stages of our Phase 3 clinical trials. This means that during feasibility assessments and participant recruitment, Valneva is committed to ensuring that clinical trial populations are representative of the intended vaccine recipients and relevant to the settings in which the vaccines will be used.

1.5 Participant Safety and Well-being

All Valneva clinical trials are conducted in accordance with the principles set out in Valneva's respective Global Quality Standard. This standard ensures that diligent benefit/risk assessments are applied throughout all phases of clinical development. The safety, rights, and well-being of clinical trial participants are treated as the highest priority, with oversight and protection embedded in all trial activities. Adverse events (AE) including serious adverse events (SAE) are reported promptly and accurately to regulatory authorities and ethics committees, as needed.

1.6 Investigator/ Institution Fees, Participant Stipends and other Compensation

Any participant stipends or other compensation to participants participating in a Clinical Trial sponsored by Valneva must be appropriate for the local setting and require IRB/EC approval. Participation in clinical trials is voluntary. Undue influence on a participant's decision to participate in a Clinical Trial due to financial compensation must be avoided.

Investigators/ Institutions may be compensated in line with local practices for their time and expertise in contributing to good quality clinical trials. Payments will meet "fair market value", ensuring investigators/institutions are compensated according to their local markets.

1.7 Scientific Integrity

Clinical trial protocols are developed in accordance with Valneva's respective Global Quality Standard to ensure scientific rigor and the generation of reliable and valid results. All data are collected and reported transparently and objectively. Clinical trials are registered on approved registries, such as ClinicalTrials.gov, in line with internal procedures.

1.8 Data Collection and Management, confidentiality, and data protection

Clinical trial data are managed in accordance with Valneva's respective Global Quality Standard to ensure accuracy, completeness, and verifiability from source documentation. Data are stored securely in data management systems according to relevant regulations (e.g., 21 CFR Part 11), and access is restricted to authorized personnel, with confidentiality maintained in line with applicable data protection laws (e.g., GDPR, HIPAA). All personal participant information is handled in a de-identified form whenever possible, and data retention complies with regulatory requirements.

Given that our vendors may handle sensitive data, Valneva places strong emphasis on data protection during the vendor review and qualification process. Any data transfers from vendors to Valneva are conducted securely, in accordance with our internal data protection protocols.

1.9 Monitoring and Audits

All clinical trials must be monitored to ensure compliance with the protocol, GCP, and regulatory requirements. Independent GCP auditors conduct audits of clinical trials to assess trial quality and compliance in line with Valneva's internal procedures.

1.10 Training and Education

Valneva's staff involved in clinical trials and/or assigned vendors (e.g., CROs) must undergo regular training in GCP and project-specific training, as applicable, according to internal Valneva's procedures. Valneva commits to ensuring that investigators and clinical teams maintain certifications and to supporting professional development opportunities to ensure adherence to evolving best practices in clinical research.

1.11 Trial Termination

A Clinical Trial may be prematurely terminated by Valneva, the regulatory authorities, or the IRB/EC if participant safety is compromised or if data suggests the vaccine is unlikely to meet its specified endpoints. In the event of premature termination, all participants must be informed, and IRB/ EC and regulatory bodies must be notified.

1.12 Reporting and Communication

Valneva commits to reporting clinical trial results, regardless of outcome, in publicly available and accessible Clinical Trial databases in line with Valneva's internal procedures.

We believe that making clinical trial data available to the research and scientific community, trial participants, and regulators, builds knowledge, earns trust and advances medical

understanding and progress. Thus, Valneva is committed to publishing manuscripts describing the results of Valneva's clinical trials and submitting journals that provide Open Access.

We fully respect the rights and privacy of the individuals who participate in our clinical trials; thus, measures are applied to minimize the risk of trial participant re-identification for all published data and manuscripts.

Significant findings that impact participants' safety or public health will be communicated to regulatory authorities and the public in a timely manner. Sharing individual trial participants' health-relevant data collected during the clinical trial, as applicable, is described in the Informed Consent Form.

5 Roles and Responsibilities

Valneva's Chief Medical Officer has overall responsibility for ensuring this Policy complies with all legal and ethical obligations.

The Corporate Compliance Officer and Clinical Development Teams have day-to-day responsibility for implementing the Policy and for monitoring its use and effectiveness as well as answering any questions regarding its meaning and interpretation.

Managers at all levels have a specific responsibility to operate within the boundaries of this Policy, take effective steps so that all employees who report to them understand the standards of behavior expected of them, and to take action when behavior falls below its requirements.

Any Clinical Research Organization (CRO) or other vendors must operate under the same standards and guidelines as Valneva. Valneva remains ultimately responsible for the overall Clinical Trial quality, safety and data integrity.

6 Communication, Engagement and Transparency

Valneva's Code of Conduct for Business Partners sets forth Valneva's expectation that its business partners uphold the highest standards and comply with all applicable laws and regulations in that respect. The Code is actively being communicated to the Company's business partners and available on Valneva's website.

Furthermore, Clinical Research Organizations' and vendor selection follow a specific process for qualification of suppliers and customers to ensure they provide Valneva with materials, products, or services in compliance with current GCP/ GMP/ GCLP requirements.

Any feedback received from Valneva's personnel or from external parties—including clinical research teams, contract research organizations (CROs), and collaborating partners— which is relevant to the application of the highest standards of ethics, respect for human rights, participant safety, and scientific rigor in Valneva-sponsored clinical Trials will be carefully reviewed and taken into account when adjusting related processes and procedures.

This policy will be available on the company's intranet and website and communicated via email to our employees.

7 Policy Reviews and Updates

This policy will be reviewed and updated yearly to reflect new regulations, industry standards, and internal company changes. Updates must be approved by Valneva's Chief Medical Officer and VP Clinical Development and communicated to all relevant personnel.

8 References

- ICH E6 (R3) Good Clinical Practice Guidelines
- Respective Global Quality Standards (internal)
- World Medical Association's Declaration of Helsinki
- FDA Code of Federal Regulations 21 CFR Parts 50, 56, 312
- European Medicines Agency (EMA) Guidelines on Clinical Trials
- World Health Organization (WHO) Guidelines on Vaccine Clinical Trials
- Data protection regulations (GDPR, HIPAA, etc.)
- Valneva's Human Rights Policy
- Diversity Action Plans to Improve Enrollment of Participants from Underrepresented Populations in Clinical Studies – FDA Guidance for Industry; draft (June 2024)