CEPI Clinical Trials Policy

Objective

The purpose of this policy ("Policy") is to set out the Coalition for Epidemic Preparedness Innovations' (CEPI) expectations with respect to the conduct of Clinical Trials that are funded (partially or in full) by CEPI.

The Policy ensures that all Clinical Trials are conducted in accordance with international and national regulations and standards (including ICH Good Clinical Practice Guidelines), prioritising participant safety, scientific rigour, transparency, and ethical integrity throughout the lifecycle of each Clinical Trial, while advancing CEPI's mission to accelerate development of vaccines and other countermeasures against epidemic and pandemic threats.

Contents

Definitions

ALCOA++	A set of data integrity principles (Attributable, Legible, Contemporaneous, Original, Accurate, Complete, Consistent, Enduring, Available, and Traceable) to ensure records are traceable, readable, timely, primary, and correct through the duration of their life cycle
Associate	An individual who is not a direct employee of CEPI, who is engaged to perform work for CEPI or chosen or appointed to speak on behalf of CEPI, including, for example: consultants, external reviewers or other experts engaged by CEPI, interns and fellows, and members of CEPI's Board of Directors and advisory bodies.
Awardee	Awardee (or "Primary Awardee"): An entity that receives funding from CEPI to carry out specific projects or activities. Awardees are responsible for managing the funds provided by CEPI and ensuring that the projects are completed according to the agreed terms.
Clinical Trial	A Clinical Trial is any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes.
Clinical Research Organisation (CRO)	A person, company, or organisation that contractually assumes one or more of a clinical trial sponsor's obligations, such as trial design, management, monitoring, data analysis, and regulatory submissions
Employee	An individual with an employment contract directly with one of CEPI's three legal entities in Norway, the United Kingdom, or the US.
Good Clinical Practice (GCP)	Good Clinical Practice (GCP) is an international, ethical, scientific and quality standard for the conduct of trials that involve human participants. Clinical trials conducted in accordance with GCP will help to assure that the rights, safety and well-being of trial participants are protected; that the conduct is consistent with the principles that have their origin in the Declaration of Helsinki; and that the clinical trial results are reliable. As referred to in the CEPI GxP Quality and Compliance Expectations and Requirements document, GCP in this context refers to compliance with ICH-GCP, including but not limited to E6 (ICH Requirements for Pharmaceuticals for Human Use Harmonised Guideline: Good Clinical Practice (GCP) and E8 (ICH Harmonised Guideline: General Considerations for Clinical Studies)
Good Practice (GxP)	GxP refers to "Good Practice" quality guidelines and regulations (including GCP (Good Clinical Practice) and related standards in research, lab, manufacturing, etc.)
ICH	International Council for Harmonisation
Quality by Design (QbD).	QbD is a proactive, risk-based approach that integrates quality into the design and execution of activities by defining objectives upfront, understanding critical factors and risks, and implementing appropriate controls to ensure outcomes are fit for purpose and compliant across the lifecycle.
Sponsor	The individual or organisation that takes responsibility for the initiation, management, and /or regulatory oversight of a Clinical Trial. CEPI expects the Awardee or its partner to fulfil this function.

Other key terms (e.g. DSMB, IEC/IRB) are defined in context below.

Scope

The policy applies to all CEPI funding recipients (Awardees) and any sub-awardees or contractors involved in CEPI-funded (in whole or in part) Clinical Trials and covers all phases of Clinical Trials (Phase I–IV and clinical studies in emergencies) worldwide (regardless of location or disease area).

It encompasses all aspects of a Clinical Trial, including the initiation, design, ethical and regulatory review and approval, conduct, monitoring and oversight, Clinical testing and sample control, reporting, revision, extension, and termination.

CEPI also requires that all its Employees and Associates abide by the principles as outlined in this policy.

This policy should be read in conjunction with related CEPI policies and guidelines, including:-

- CEPI's Third-Party Code of Conduct
- The CEPI GxP Quality and Compliance Requirements[1]
- CEPI Scientific Integrity Policy

Policy Statement

Clinical Trials are essential in advancing biomedical innovations into practical healthcare solutions. Scientifically rigorous, well-designed randomised controlled Clinical Trials are regarded as the benchmark for evaluating the safety and efficacy of new vaccines and medical countermeasures intended to prevent illness and reduce mortality. Supporting these trials is a core part of CEPI's mission to accelerate the development of vaccines and other biologic countermeasures targeting epidemic and pandemic threats, with the ultimate aim of making these solutions accessible to everyone in need. This commitment reflects CEPI's vision of a world where epidemics and pandemics no longer pose a threat to humanity.

CEPI-funded Clinical Trials must be conducted in full compliance with all applicable laws and standards within the relevant territories and jurisdictions where CEPI-funded activities are performed.

In circumstances where local legal requirements or standards are less rigorous than those set out in this policy or in referenced international standards, the more stringent CEPI standard as defined in this policy should be followed. However, if any CEPI policy requirement is found to be in conflict with national law—so that complying with CEPI's requirements would contravene local regulations—awardees are expected to implement the highest standard that is permissible under local law.

CEPI also expects that Clinical trial activities conducted during infectious disease outbreaks will be designed and implemented in a manner that also incorporates the effects/impact of those interventions and at least do not interfere with other public health interventions.

To ensure that Clinical Trials are conducted ethically, protect participants' rights, safety, and well-being, and uphold data quality according to international standards, CEPI has defined the following seven (7) principles that awardees and partners should adhere to:

[1] Note the Clinical Trials policy covers all aspects of conducting a clinical trail incluind the assocaited GCP requirements. The specific GCP requirements are expanded upon within the CEPI GXP Quality and Requirements Documents

1. Ethical and Regulatory Approvals

Ethical Approval:
Awardees should obtain all necessary ethics approvals before starting any CEPI-funded Clinical Trial. Ethics committees are expected to follow ICH-GCP principles, and all ethics-related communications should be stored, and any major ethical issues or protocol changes should be reported promptly to both the IEC/IRB and CEPI.

If a site lacks an Independent Ethics Committee (IEC) / Institutional Review Board (IRB) meeting ICH-GCP standards, Awardees should collaborate with CEPI and local authorities to find an appropriate ethics review body.

Regulatory Authority Approval:
All relevant regulatory authorities must approve the protocol before Clinical Trial initiation and subsequently any substantial amendments.

Approval documents should be provided to CEPI upon request and retained in accordance with relevant legislative requirements. Furthermore, all regulatory approvals (ethics, regulatory agency, institutional permissions) must remain in force throughout the trial; if any approval is suspended or expires, the trial at that site must pause participant enrolment and vaccination until the issue is resolved.

2. Adherence to ICH-GCP principles and associated Quality requirements

Adherence to Good Clinical Practice (ICH-GCP) principles and the associated quality requirements is required to ensure that all clinical research activities are conducted ethically, safely, and with scientific integrity. Such compliance protects the rights, safety, and well-being of trial participants and safeguards the reliability and credibility of data used to inform regulatory decision-making and the development of new medical interventions. Upholding ICH-GCP standards reinforces organisational accountability, supports alignment with global regulatory expectations, mitigates operational and compliance risks, and promotes public trust. Consistent application of these requirements ensures high-quality research outcomes, including responsible, transparent, and compliant clinical development. This includes but is not limited to:-

Protocol Compliance
CEPI requires strict adherence to the approved Clinical Trial protocol, with the Awardee responsible for ensuring investigators and CROs fully understand and follow it. Planned protocol deviations are only allowed to prevent immediate harm to a participant and should be promptly reported to the ethics committee, regulators, and CEPI. Inclusion and exclusion criteria should be defined and are intended to be followed as written. Individuals who do not meet these standards can be considered for enrolment only if there is a documented justification and appropriate approval.

Investigator Qualifications and Responsibilities
CEPI requires all funded Clinical Trials to be led by qualified and competent investigators. Each trial should have a Principal Investigator (or co-PIs) with appropriate credentials—typically a licensed physician, or health professional with relevant expertise. Investigators should be in good professional standing, ensure participant safety, maintain data integrity, and dedicate adequate time to the study without being overcommitted. They are also responsible for ensuring that all trial staff are properly qualified and trained. Any delegated duties should be documented in a delegation log and assigned only to individuals qualified for those tasks.

Trial Staff and Facility Qualification
CEPI requires Awardees to select clinical sites with adequate resources, competent staff, and access to any specialised procedures needed for the trial. Staff qualifications, workload, and training needs should be assessed during site selection, with all required training completed before study start. All investigators and research staff should have up-to-date, documented ICH-GCP and relevant ethics training.

Clinical Trial Testing
Clinical trial testing and laboratory investigations should only be conducted if specified in the protocol and approved by the clinical trials ethics committee.

CEPI expects all clinical trial testing to use phase-appropriate, tailored, and reliable methods and or assays to ensure clinical study successes. Assays evolve throughout the vaccine development lifecycle, with increasing expectations for quality, defined purpose, and degree of standardisation as programs progress. A fit-for-purpose approach is essential to support vaccine development from early discovery through regulatory approval.

The intended context of use should drive the analytical principles guiding assay development, optimisation, qualification, and validation, with the context of use encompassing:-

- The intended clinical and/or statistical application of assay results in support of study endpoints (e.g., subject screening, population GMT (Geometric Mean Titre) comparisons for consistency or non-inferiority assessments, or evaluation of seropositivity, seroconversion, or protection rates).
    - The level of the clinical endpoint supported by the assay (exploratory, secondary, or primary), which generally determines the assay's status within a hierarchical framework (characterised, qualified, or validated).
    - Whether assay-generated data are intended to support regulatory decisions or product label claims.
- The stage of the vaccine development program, including sero-epidemiological studies and Phase I–IV clinical trials.

Sample collection, handling, transport, storage, and retention should adhere to internationally recognised quality standards to preserve sample integrity and ensure participant safety. Human biological samples may only be used for the purposes specified in the approved protocol, ethics submissions and informed consent, including any secondary uses such as exploratory analyses, assay development, or broader research activities.

Data Recording and Record Retention
CEPI prioritises data integrity and transparency. Awardees should follow Good Documentation Practices (as defined in the CEPI GXP Quality and Compliance expectations document) to ensure reliable, verifiable data. Written SOPs should address data collection, management, correction tracking, backup procedures and adherence to ALCOA++ principles for all critical records.

Confidentiality and Data Privacy
Awardees should comply with all applicable data privacy laws and apply data minimisation, pseudonymization, and secure storage, sharing only aggregate or deidentified data unless specific consent or strict governance allows otherwise. Secondary use of samples or data without written informed consent is permitted only when ethics approval is in place and conditions such as anonymisation, legal compliance, and clear health benefit are met. Participants should be informed if data or samples will cross borders, especially where privacy standards differ.

Quality Management and Compliance Systems
CEPI requires a comprehensive quality management system (QMS) aligned with ICH-GCP and supported by written SOPs that ensure accurate conduct, documentation, and protocol compliance. Quality by design (QbD) principles should be applied from the outset, and investigational products should meet Good Manufacturing Practices (GMP) standards appropriate to the trial phase, with justification provided for any deviations permitted by local law. Serious breaches of GCP or the Clinical Trial protocol should be reported as required by local legislation and notified to CEPI, including any associated reporting timeline requirements.

3. Benefit–Risk Evaluation

Clinical Trials should proceed only when anticipated benefits clearly outweigh risks, with participant rights, safety, and well-being as the overriding priority and supported by a favourable independent ethics and risk review. The Clinical Trial should offer a meaningful/positive benefit-risk assessment to the involved communities, avoid undue inducement, and fully comply with legal and professional standards while mitigating all foreseeable harms.

Awardees are expected to conduct thorough and ongoing risk assessments, minimise product and procedure-related risks, and apply a risk-based approach to safety and quality oversight. Continuous reassessment of the benefit–risk balance and transparent consent communication are required throughout the trial.

4. Scientific Integrity in Trial Design and Conduct

Ethical Conduct and Scientific Integrity
CEPI-funded research must uphold the highest ethical standards, following principles such as the Declaration of Helsinki, The Council for International Organisations of Medical Sciences (CIOMS) guidelines, and the Nuremberg Code. Even in infectious disease emergencies, ethics remain paramount, with CEPI expecting Awardees to apply WHO outbreak-ethics guidance [2]and integrate robust community engagement. Clinical Trials must be scientifically justified, offer clear public health or societal benefit, and avoid undermining local health responses. Awardees and partners must maintain integrity and transparency, with zero tolerance for misconduct or data falsification and a duty to report concerns promptly.

Protocol and Trial Design
CEPI-supported Clinical Trials should follow ICH-GCP and use robust, scientifically sound protocols that undergo CEPI review before finalisation. Each protocol should include a clear benefit–risk assessment and justify how the research will benefit participants or communities, particularly in public health emergencies. Clinical Trials should be designed to be informative with a focus on the factors that are critical to quality ("quality by design") to generate valid evidence, including comparison to the best available standard of care where appropriate. Protocols should also outline how data will be shared to maximise public health impact.

Informed Consent of Participants
Valid and freely given informed consent is mandatory for all CEPI-funded Clinical Trials and should follow ICH-GCP and local legal requirements, using culturally and literacy-appropriate communication. Participants—or legally acceptable representatives for those unable to consent—should receive clear information on the investigational product, procedures, risks, benefits, alternatives, and confidentiality,

2 https://www.who.int/publications/i/item/guidance-for-managing-ethical-issues-in-infectious-disease-outbreaks

with additional safeguards for paediatric or incapacitated participants. Novel consent approaches may be used only with prior ethical justification and approval, and all processes should be documented and archived. Consent is an ongoing process, participants should be re-consented if new information arises and retain the right to withdraw at any time.

Community consultation

Community engagement is a key element of ethically conducted research. Such engagement shall be proportionate to the scale and impact of the study being undertaken. In low and middle-income countries (LMICs), community consultation and engagement (including the involvement of local researchers) prior to, during and after the course of research is particularly important to build and maintain trust. Building trust is of particular importance if the trial is occurring in an emergency outbreak situation where fear can dominate public perceptions and fair access to potentially effective interventions is in focus. Refer to the WHO guidance on good participatory practices in trials of interventions against emerging pathogens[3] for further guidance in this area.

5. Trial Registration and Public Transparency

CEPI requires all funded Clinical Trials to be prospectively registered in a publicly accessible registry (e.g., Clinical Trials.gov or WHO International Clinical Trials Registry Platform (ICTRP)) and in line with local trial registration before enrolment begins, ensuring transparency and accountability. Awardees should keep registry records accurate and up to date throughout the study. CEPI also mandates timely public disclosure of trial results to support scientific integrity and maximise public health benefit. This commitment to open information sharing applies regardless of whether study outcomes are positive, negative, or inconclusive.

6. Trial oversight, monitoring and safety

CEPI places participant safety as a top priority, requiring Awardees to maintain robust systems for the timely detection, assessment, and reporting of adverse events. An independent Data Safety Monitoring Board (DSMB) or Data Monitoring Committee (DMC), with appropriate regional representation, is a requirement for CEPI-funded Clinical Trials to provide expert oversight except where the investigator or sponsor determines the risk to be low. Awardees should promptly report Serious Adverse Events (SAEs), Serious Unexpected Serious Adverse Reactions (SUSARs), safety-related study holds, and any participant deaths to regulators, ethics committees, and CEPI Project team, along with DSMB summaries and regulatory safety review outcomes. This reporting should be completed in line with associated legislative timelines and to all relevant authorities, including those where there is an ongoing clinical trial and/or an open Investigational New Drug (IND) application, etc. In public health emergencies, any safety findings with urgent implications should be shared immediately with CEPI and, where required, WHO.

Awardees are encouraged to establish and maintain a Good Pharmacovigilance Practice (GVP)–compliant framework and disclose any delegated Pharmacovigilance Practice (PV) activities and associated agreements to CEPI, as appropriate.

7. Results Disclosure and Data Sharing

CEPI requires open-access publication of all CEPI-funded trial findings, with acknowledgement of CEPI support, and expects results—positive, negative, or inconclusive—to be shared responsibly in line with

3 https://www.who.int/publications/m/item/good-participatory-practice-guidelines-for-trials-of-emerging-(and-re-emerging)-pathogens-that-are-likely-to-cause-severe-outbreaks-in-the-near-future-and-for-which-few-or-no-medical-countermeasures-exist-(gpp-ep)

ethical approvals and participant consent. Awardees should publish peer-reviewed results within 12 months of pivotal results being available and within 24 months of study completion. Summary results should also be posted to the relevant trial registry within 12 months of LSLV (Last Subject, Last Visit)for adult Clinical Trials and 6 months for paediatric Clinical Trials. Data sharing should maximise public health benefit while respecting consent and governance requirements.

Policy Monitoring and reporting.

The CEPI Internal Audit function will review the implementation of this policy in accordance with the Annual Internal Audit Plan, as agreed with the CEPI Audit and Risk Committee.

Ongoing monitoring is also carried out during the lifetime of the project by the relevant CEPI project teams. This includes routine oversight of compliance and escalation of issues through the Quality Notification processes defined in partner contracts and the CEPI Third Party Code of Conduct.

Should there be any concerns regarding activities governed by this Policy, CEPI teams should inform the Policy Owner, the CEPI Clinical Development and/or CEPI GXP Quality and Compliance functions or, if appropriate, raise their concerns in accordance with the Whistleblowing Policy.

Policy Violations and Exceptions

Violations of the CEPI Clinical Trials policy or related procedures may be subject to disciplinary action for internal stakeholders and suspension/termination of the relationship, declining to enter into future arrangements, and/or seeking to recover funds for Third Parties. Any exception to this policy or related procedures must be approved by the Policy Owner. Any exception should be clearly justified, judged on a risk basis, and documented formally. The Clinical Trials policy and procedure aim to be as clear and direct as possible, but cannot address every risk or situation that may arise. Individuals are encouraged to bring questions, suggestions and concerns to the attention of the CEPI Clinical Development and/or CEPI GXP Quality and Compliance functions.

Policy Ownership, Implementation and Training

The Director, Clinical Development, is the owner of this Policy and is responsible for its implementation in CEPI's operations and activities.

It is the responsibility of the Policy Owner to ensure that an appropriate level of information, awareness and training is provided to relevant Employees and Associates to ensure compliance with this Policy.

Current version	**2.0**
Approved by CEPI Board	June 2026
Owner	Director, Clinical Development
Linked documents	*GxP Quality Compliance Expectations* *Scientific Integrity Policy* *Third Party Code*
Past versions	1.0
Date of last review	June 2026