European Vaccine Initiative

www.euvaccine.eu
+49 6221 565373
contact.us@euvaccine.eu

UniversitätsKlinikum Heidelberg
Voßstraße 2, Geb. 4040
69115 Heidelberg, Germany

EVI Policies

Data sharing and Communication Policy

EVI recognises the importance of timely dissemination of research to the scientific community to catalyse the virtuous cycle of research. The sharing of data, both negative and positive, help the development of current and new projects, invigorating and optimising the vaccine development process both at EVI and with other research teams. Accordingly, EVI has developed a policy for data access and publication of results that reflects current good practice as well as the general expectations of EVI's funders, partners and the wider scientific community.

A. General Principles: EVI is committed to sharing data and allowing appropriate and rigorous third-party analyses. When assessing funding proposals, it will consider Principal Investigators' publishing track records. EVI also commits to ensuring the publication and sharing of data generated by projects in which EVI is leading or involved in, in the following ways:

1. **Clinical trial registries:** clinical trial data is published on a publicly accessible clinical trials registry, such as www.clinicaltrials.gov and/or the Pan African Clinical Trials Registry (PACTR; https://pactr.samrc.ac.za/). Studies will be registered in advance of initiation and updated when any substantial amendments are made to the study status and design. In addition, information on the site will be updated to include final enrolment, and completion data, as well as results. Summary results will be made publicly available in a timely manner on a clinical trial registry after primary study completion (within 12 months, if possible). If a study is not completed, updates will include information regarding study termination. Disaggregated demographic characteristics of the population enrolled in each trial, with regards to age and sex, will be reported.

2. **Peer-reviewed publications:** unless it goes against legitimate interests, EVI and/or EVI partners will - as soon as possible- disseminate results by disclosing them to the public by appropriate means (other than those resulting from protecting or exploiting the results). Results are defined as any tangible or intangible outputs that can create an impact during and after the funded activity is finished. Thus, EVI assumes the responsibility to the following:
    a. Work with its partners to ensure the dissemination of results as soon as feasible, in a freely and publicly available format (open access), subject to any restrictions due to the protection of intellectual property, security rules or legitimate interests. This includes depositing a machine-readable electronic copy of the published or final version in a repository for scientific publications.
    b. Grant all authors full access to study data before first external presentation of the data.

www.euvaccine.eu
+49 6221 565373
contact.us@euvaccine.eu

UniversitätsKlinikum Heidelberg
Voßstraße 2, Geb. 4040
69115 Heidelberg, Germany

c. Review in a timely manner articles and abstracts before these are submitted and share scientific comments with authors.
d. Include the trial ID or registry identifier code in all publications when applicable.
e. Ensure that the proper funding acknowledgement is included in all publications.

3. **Data access:** EVI supports qualified investigators engaged in rigorous, independent scientific research and take measures to deposit generated data in open research data repositories, such as the BY-COVID portal (https://by-covid.org/). This facilitates the sharing of data, making it possible for third parties to access, mine, exploit, reproduce and disseminate data, for example to address public health emergencies.
   By working alongside with its partners EVI aims to deposit the research data needed to validate results presented in the deposited scientific publication.
   Metadata of deposited publications must be open under a Creative Common Public Domain Dedication (CC 0) or equivalent, in line with the FAIR principles.
   Details of the data management and how and where data will be deposited in, within the scope of each funded activity, is set out in detail in data management plan (DMP) for individual projects if applicable.

4. **Monitoring registration** – EVI endorses the development of systems to monitor reporting of results on an on-going basis and supports the notion that the outputs from the monitoring process will be publicly available.

EVI shall comply with applicable laws and regulations when collecting, obtaining, or using any personal data for communication and dissemination that is conducted, sponsored, supported or funded pursuant to the action. The processing and handling of personal data is to be fully compliant with the General Data Protection Regulation (GDPR) that entered into force in the European Union in May 2018 [Regulation (EU) 2016/679-680].
Specifically for clinical research, EVI draws primarily upon WHO's guidelines for Good Clinical Research Practice to conduct its clinical trials, together with the World Medical Association's Declaration of Helsinki, and the Council on International Organizations of Medical Sciences' (CIOMS) International ethical guidelines from 2016 on biomedical research involving human subjects. It also follows any local, national and regional regulations in the country where trials are held. Patient confidentiality and anonymity are paramount and EVI takes all precautions to minimize risk to patient privacy, such as appropriately anonymizing or de-identifying raw data and removing direct identifiers such as patient names.

B. **Publication authorship and acknowledgements:** EVI follows the current version of Good Publications Practice (GPP). In doing so, particular care is taking to involve and acknowledge adequately any contribution from researchers, organisations and communities in LMIC in accordance with the Global Code of Conduct for Research in Resource-Poor Settings. EVI holds the responsibility to:

European Vaccine Initiative

www.euvaccine.eu
+49 6221 565373
contact.us@euvaccine.eu

UniversitätsKlinikum Heidelberg
Voßstraße 2, Geb. 4040
69115 Heidelberg, Germany

a. Share its publication policy with all authors.
b. Disclose potential conflicts of interest in all articles and presentations.
c. Identify and acknowledge funding sources in all articles and presentations.
d. Ensure appropriate attribution of authorship - based on contribution and input - Uniform Requirements for Authorship and Contributorship from the International Committee of Medical Journal Editors (https://icmje.org/recommendations/). Authors should meet all four of the following conditions: have made substantial contributions to conception and design, acquisition of data or analysis and interpretation of data; drafting the article or revising it critically for important intellectual content and final approval of the version to be published and agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.
e. Ensure all authors agree on the order in which they appear in an article or presentation and any changes on authorship before submission.
f. Acknowledge in all articles and presentations all significant contributions made by individuals and organisations.