

Data Access and Scientific Publications Policy

MMV recognizes the importance of timely dissemination of research to the scientific community to catalyze the virtuous cycle of research. The sharing of clinical data, both negative and positive, help the development of current and new projects, invigorating and optimizing the drug development process both at MMV and with other research teams. Sharing data leads to the compilation of large data sets optimal for model-based analyses that in turn bring additional benefits. Accordingly, MMV has developed a policy for access and publication of clinical data that reflects current good practice as well as the general expectations of MMV's funders, partners and the wider scientific community.

I. General Principles:

MMV is committed to sharing data and allowing appropriate and rigorous third-party analyses. When assessing funding proposals to support clinical trials, it will consider Principal Investigators' publishing track records. MMV also commits to ensuring the publication and sharing of data generated by MMV-sponsored and MMV-funded clinical trials in the following ways:

1. **Clinical trial registries** – MMV-sponsored and MMV-funded clinical trial data are published on a publicly accessible clinical trials registry, such as www.clinicaltrials.gov. 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** – MMV follows Good Publications Practice 3 (GPP3) as delineated by the International Society for Medical Publication Professionals. MMV assumes the responsibility to:
 - i. Establish a publication strategy, including avoiding premature publication or release of study information and avoiding duplicate publication;
 - ii. Work with its partners to submit results, both positive and negative, of all MMV-sponsored and MMV-funded clinical studies, with the intent of peer-reviewed publication within 24 months of study completion; where relevant, present results by demographic sub-groups or co-variables;
 - iii. Grant all authors (including medical writers) full access to study data before the writing process begins or before first external presentation of the data. This includes study protocols, statistical analysis plans and reports, data tables, and clinical study reports required to support publication of clinical trial results in peer-reviewed journals;

- iv. Review in a timely manner articles and abstracts before these are submitted and share scientific comments with authors;
 - v. Include the trial ID or registry identifier code in all publications.
 - vi. Deposit into ChEMBL (open access database) data relating to publications that disclose chemical structure;
 - vii. Ensure all MMV publications are accessible freely and available in the public domain - MMV will pay the cost of publication to journals for open access should this be required.
3. **Sharing of project and metadata** – MMV supports qualified investigators engaged in rigorous, independent scientific research, such as the [WorldWide Artemisinin Resistance Network](#) (WWARN) that facilitates the sharing of data on clinical efficacy of drugs to track the spread of resistance to artemisinin, by working with its drug development partners to facilitate access to de-identified patient-level data from medicines that are either approved by the regulatory authorities, or will not be developed further.
 4. **Monitoring registration** – MMV 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.

MMV draws primarily upon [guideline ICH E6 \(r2\)](#) and also on [WHO's guidelines for Good Clinical Research Practice](#) to conduct its clinical trials. It also follows national regulations in the country where trials are held. Patient confidentiality and anonymity are paramount and MMV 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.

II. Publication authorship and acknowledgements

MMV follows the current version of **Good Publications Practice (GPP)**. MMV holds the responsibility to:

1. Provide copies of the MMV's publication policy to all authors.
2. Disclose potential conflicts of interest in all articles and presentations.
3. Identify funding sources in all articles and presentations – and acknowledge MMV's financial contribution.
4. Ensure appropriate attribution of authorship - based on contribution and input. Authors should meet all three 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.
5. Ensure all authors agree on the order in which they appear in an article or presentation and any changes on authorship before submission.
6. Take care to ensure appropriate acknowledgement of the contributions made by medical writers and to describe their funding. Depending on the contributions they make professional medical writers may qualify for authorship.

7. Acknowledge in all articles and presentations all significant contributions made by individuals and organizations.