Policy for presentation and publication of results within the PAMAfrica project

Distributed by the PAMAfrica Publications Committee, September 2022

PAMAfrica is a consortium of ten public and private sector research partners across Africa and Europe, led by Medicines for Malaria Venture (MMV), a leading product development partnership (PDP) in antimalarial drug research and development. The consortium has been granted €21.9 million over 5 years by the EDCTP to implement an ambitious drugs development program, with an additional €22m from MMV, Novartis and other partners. (For the list of partners see Annex 1.)

PAMAfrica aims to develop varied novel, efficacious and well tolerated antimalarial medicines in three different sub-clinical areas – severe malaria, malaria in newborns and uncomplicated malaria resistant to artemisinin.

PAMAfrica Publications Committee

The **PAMAfrica Publications Committee** is a decision-making body whose aim includes the approval and endorsement of all publications, congress abstracts, presentations (oral or poster) and symposia based on the PAMAfrica study data, including, but not limited to: study design, primary results, secondary and post-hoc analyses. The PAMAfrica Publications Committee reports to the PSMC.
Refer to the PAMAfrica Publications Committee Charter for more information.

Responsibilities

- **Author** of a publication, a congress abstract, a presentation (oral or poster). or a symposium
    - To be listed as an author at least one of the following 3 conditions must be met such as:
        - Have contributed to protocol development
        - Or have contributed to the development and validation of the CSR
        - Or have been recruiting patients
        - All co-authors will also need to have reviewed and validated the final manuscript

        - In addition:
            - A maximum of 2 authors per institution
            - Special attention should be paid to questions related to sex/gender ratio and geographical location of the authors
            - For the initial publication of study results, the 1st authors must be the recruiting PI/Co-PI
            - Last authors can be the senior KOLs of the supporting institutions

        - Sub-analysis publications should not precede the publication of the main study
    - Acknowledge the support of the PAMAfrica consortium and EDCTP as per Art. 29.4 of the Grant Agreement
    - Follow the International Committee of Medical Journal Editors (ICMJE) guidelines (ICMJE, 2016; http://www.icmje.org) and the Good Publication Practice version 3 (GPP3) guidelines (Battisti et al., 2015; http://annals.org/article.aspx?articleid=2424869)
    - Submit all forms of publication to the Publications Committee for review before submitting them for publication
    - Notify the Publications Committee of the date and time of the proposed publication, presentation or symposium.

- **Publications Committee**
    - Review each submitted publication (15 working days for manuscripts not exceeding two double-spaced pages in length or equivalent and 20 working days for all other manuscripts, presentation and/or congress abstract and final
    - Oral presentation or poster (within 5 working days), primarily focusing on publications based on the primary and key secondary endpoint analyses scheduled within 2 years of study readout. In exceptional cases, e.g. for breaking publications, the time frame may be reduced
    - Assess ideas and proposals for other publications proposed by consortium members or external scientists/groups and provide feedback within 5 working days, if the proposal is valid and publication can be prepared. Review will be done in 15 working days for manuscripts not exceeding two double-spaced pages in length or equivalent and 20 working days for all other manuscripts.
    - Review and endorse authorship qualification criteria and ensure adherence to ICMJE guidelines and GPP3 for all study publications
    - Make the final decision, involving the authors, with regards to publishing, journal or congress selection and the type of publication to be pursued such as abstract or a full manuscript. Open access journals have to be chosen.
    - Ensure that the manuscript and the publication process is in line with EDCTP2 policy on clinical trials registration, publication and data sharing

- **Study Sponsor**
    - Confirm the accuracy of the data and provide relevant supplementary information
    - Verify that intellectual property (IP) is secure and proprietary information is not being inadvertently divulged. Sponsors/ Authors may be asked to hold off on the submission of the abstract/paper for a limited time, as outlined below, to allow for the filing of a patent or in the event of unforeseen circumstances affecting the study conclusions or program outlook
    - Provide information which may not have yet been made available
    - Provide input for consideration regarding the content of the manuscript.
    - Ensure that the publications respect relevant patient and personal data privacy regulations.
    - Inform the Publications Committee of any changes in publication obligations and transparency policies or trials registry requirements that may impact timelines.

- **PAMAfrica Grant Management team (with input from PAMAfricomms)**
    - Update the author and Publications Committee of any logo changes and/or EDCTP requirements
    - Provide support on dissemination of communications on any publication or presentation through all relevant channels including media.

Process and Procedures

- The author should discuss the content of the planned publication, congress abstract oral presentation or poster with the Study Sponsor and only start drafting once approval has been obtained
- During the process of writing, ICMJE guidelines should be followed and EDCTP contribution acknowledged, as per Art. 29.4 of the Grant Agreement
- High impact, peer-reviewed professional journals should be targeted
- PAMAfrica consortium will ensure open access (free-of-charge, online access for any user) to all peer-reviewed scientific publications relating to its results
- The final draft has to be submitted to the Publications Committee for review
- The Publications Committee will review the content of the publication, and check that it follows ICMJE guidelines, the Publications Committee charter, and is within the given timelines

  (see below). Further, the Publications Committee will ensure that the publication is in line with EDCTP2 policy on clinical trials registration, publication and data sharing, including respect to timeframes (summary results within 12 months from primary study completion, the last visit of the last subject for collection of data on the primary outcome) and policy on recognizing the funding from EDCTP and the European Union (see guideline "Acknowledging EDCTP, A guide for grantees", http://www.edctp.org/publication/acknowledging-edctp-a-guide-for-grantees/)
- Publication in a journal is expected within 24 months from study completion
- Logo usage will be reviewed and discussed with PAMAfricomms by the PAMAfrica GMT and be in line with Art. 29.4 of the Grant Agreement
- Once feedback is received, the author may have to adapt the publication and after a final review by the Publications Committee, the submission process can be started.
- Inform PAMAfrica GMT if the plan is for media to be involved.

Annex I: PAMAfrica Consortium members

Coordinator:

1. Medicines for Malaria Venture (MMV), Switzerland

Participants:

2. Eberhard Karls Universität Tübingen (EKUT), Germany
3. Fundación Privada Instituto de Salud Global de Barcelona (ISGlobal), Spain
4. Centre de Recherches Médicales de Lambaréné (CERMEL), Gabon
5. Fundação Manhiça (FM), Mozambique
6. Novartis Pharma AG-Basel, Switzerland
7. Groupe de Recherche Action en Santé (GRAS), Burkina Faso
8. Centre National de la Recherche Scientifique et Technologique (CNRST) - Institut de Recherche en Science de la Santé (IRSS), Burkina Faso
9. Infectious Diseases Research Collaboration (IDRC), Uganda
10. Merck KGaA, Darmstadt, Germany