




GARDP Research and Development Scientific Publications Policy


Document version control

Title, version and date	GARDP Research and Development Scientific Publications Policy, V1.0, 23 May 2023		
Policy number	RD01		
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Revision history

Version	Reasons and Changes	Date
Version 1.0	This is a new policy developed to reflect GARDP R&D department's expectations, needs, processes and requirements for development, review and approval of scientific publications.	23 May 2023

Reviewers (of latest version)

Name	Position	Signature and date
Seamus O'Brien	R&D Director	 May 30, 2023

1. Introduction

Scientific publications are a key part of GARDP's work as it is through scientific publications that results from research funded, supported, sponsored and/or conducted by GARDP is primarily communicated externally. This policy aims to ensure that all R&D scientific publications, including their content and the way data is discussed, are of high scientific quality, are in line with ethical guidelines, with GARDP's mission, vision and disease area strategies as well as each project's plan(s), objectives, timelines, and regulatory and legal requirements. Moreover, R&D scientific publications must comply with other applicable GARDP's policies (e.g. Conflict of Interest Policy, Fraud and Corruption Prevention Policy) and the latest best-practise recommendations for scientific publications from the International Committee of Medical Journal Editors (www.icmje.org).

2. Scope

By scientific publication, it shall be understood abstracts, posters, and slide presentations disclosing primary research submitted or presented at scientific conferences or workshops as well as manuscripts disclosing primary research published in peer-reviewed journals (including e.g. in vitro studies, clinical trials, literature reviews).

Corporate GARDP positioning and strategic or policy-related publications are not in the scope of this policy.

GARDP's Research and Development ("**R&D**") scientific publications policy applies to all scientific publications relating to any research sponsored, conducted, funded, and/or supported by GARDP within Discovery and Exploratory Research, clinical and access projects, alone or in collaboration with partners ("**Research**").

This policy applies to all GARDP employees developing, writing, reviewing, approving and/or submitting R&D scientific publications.

Unless a local policy is available, this policy and its associated processes is also to be used by the GARDP-affiliated local offices in the regions.

3. Principles

1. GARDP commits to the appropriate communication and exchange of scientific and medical information, via scientific publications, especially related to the clinical and medical use of GARDP developed treatments and for investigational medicinal products in development.

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To note that GARDP, as sponsor of a clinical trial, will post study summary data on ClinicalTrials.gov and on EudraCT in alignment with regulatory agencies' requirements.

2. GARDP supports the timely publication of all Research (e.g. without limitation: discovery, pre-clinical, clinical, epidemiological, implementation science) including a commitment to publish the results within one year of study completion (e.g., for a clinical trial study completion is defined as publication of the CSR) through either publication of a manuscript or through a poster or oral presentation at a scientific conference. GARDP will facilitate the rapid and accurate publication of GARDP's Research and clinical trial results to wider scientific and medical communities and the general public where appropriate. Secondary manuscripts (e.g., presenting data from a single clinical trial centre or country or from a or post hoc analysis), must not be submitted until after the primary study manuscript has been accepted for publication, whether the study includes an IMP or not.
3. All publications - whether they relate to co-development of an investigational medicinal product ("**IMP**") or not - must comply with the present publication policy as well as partner(s) publication policies and Donors' requirements. In the case of a private partner, the publication shall not interfere with existing confidentiality and intellectual property protection obligations and shall comply with the private partner reporting obligations. This policy provides the principles GARDP follows when sharing publication commitments in collaborative research projects.
4. GARDP is committed to make the results of its Research easily and broadly accessible to the medical and scientific community with no financial barriers, by contributing to open-source initiatives such as public databases and by publishing its Research in "open access" journals, whenever possible. When publications involve disclosure of chemical structures and data not protected by confidentiality nor privacy, these should be deposited into public databases, in line with the GARDP Sharing of Clinical Trial Data Policy when applicable.
5. GARDP is committed to support and ensure greater recognition of the research involving countries with high burden of antimicrobial resistance and low- and middle-income countries, including fair and appropriate authorship.

6. GARDP will follow the publication procedures below, based on the latest recommendations for scientific publications from the International Committee of Medical Journal Editors (www.icmje.org), to ensure:
- a) the scientific publications report the results of GARDP Research in a transparent, scientifically accurate, fair, and balanced manner;
 - b) the scientific publication is consistent with information submitted to regulatory and health authorities (when appropriate);
 - c) that any information within the publication has been submitted for a patent application or reviewed to ensure proper IP protection that would involve the necessary confidentiality of such information;
 - d) that the authors' list and hierarchy appropriately reflects the relative contributions of clinicians, scientists, other external participants and GARDP staff;
 - e) funding sources, including all relevant GARDP funders names, in all articles and presentations are appropriately acknowledged, as per the regulations of the journal and donor requirements;
 - f) potential conflicts of interest are disclosed in all articles and presentations;
 - g) donors requiring prior agreement for acknowledgement in writing and/or use of their logo are contacted within the agreed timelines; and
 - h) that posters/presentations are appropriately formatted and in the latest slide format.

7. Authorship

- a) Authorship and author hierarchy should be agreed at the earliest stage of planning any type of publication.
- b) Criteria for authorship
 - Final authorship will require the fulfilment of the Uniform Requirements for Authorship and Contributorship from the International Committee of Medical Journal Editors. Authorship credit and must be based on 1) substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; 2) drafting the article or revising it critically for important intellectual content; 3) final approval of the version to be published; and 4) 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. Author's credit should meet all previous four conditions.
 - All persons designated as authors should qualify for authorship, and all those who qualify should be listed.

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- When a large multi-author group has conducted the work, the group must identify the individuals who accept direct responsibility as authors before submitting the manuscript for publication. These individuals identified as authors should fully meet the criteria for authorship/contributorship defined above, and editors will ask these individuals to complete journal-specific author and conflict-of-interest disclosure forms.
 - Acquisition of funding, collection of data, or project management alone does not constitute authorship. However, such individuals should be named in the acknowledgements section of publications.
- c) Author hierarchy
- There are many factors to determine author hierarchy and it must be defined by taking into consideration the specifics of each publication.
 - The researcher/investigator (including GARDP employees) who has contributed the most to the Research and therefore fulfils the best the first two authorship criteria [1) substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; 2) drafting the article or revising it critically for important intellectual content] should be the first author.
 - The last author is usually a senior researcher (including GARDP employees) or senior principal investigator/coordinator, who has guided the overall orientation of the Research and also fulfils the first two authorship criteria.
 - For GARDP-sponsored and/or supported studies, at least one actively involved GARDP employee must be included as a co-author, including on secondary publications.
 - Where GARDP has had the strategic leadership and/or been actively involved for the research, a GARDP employee must be at least the first or the last/senior author (alone or jointly).
 - The other authors are placed in order of contributions, or in alphabetical order, regardless of affiliation and as agreed prior to writing the manuscript.
 - For large studies, when the number of authors is greater than 10, the principal investigator/coordinator should verify whether those listed satisfy authorship criteria and identifies those whose contributions should be mentioned instead in the acknowledgements section of the manuscript. If the list is still over 10, there is the possibility to publish as a study group by adding for example "on behalf of the XX study group" after the list of authors and refer to the full list of the study group members in the Acknowledgments section.

d) Acknowledgements

- Individuals who do not qualify for authorship but who have made significant contributions should be acknowledged, their contribution specified, and informed of such. Writing assistance should be acknowledged as follows: "We thank *Dr John Smith, Company Name*, who provided medical writing services on behalf of GARDP".
- Financial and material support must also be acknowledged as per each GARDP Donor's requirements. Acknowledgment of funding support statements (and disclaimer statements when applicable) must be included and will be provided by GARDP for each publication. Should approval of this statement be required from funders, approval must be obtained by the GARDP External Affairs department before submission or presentation.

8. **Publication planning:** Publications must be discussed and planned by GARDP and partners starting at the project kick-off meeting and then at least twice a year during the course of a project.

9. **Principles for the development and review of a publication:**

- GARDP authors must be involved and consulted at all stages of publication planning and preparation.
- All authors of a publication shall be given reasonable access to relevant statistical tables, figures and reports necessary to support the planned publication.
- For scientific manuscripts or slide presentations of data, especially when data is published for the first time or comes from a large study, to ensure alignment of all partners and authors on the overall content, strategy and key messages, an outline should be written and approved by all authors before the full manuscript/presentation is written. An outline should include the following sections:
 - Title
 - Author list and hierarchy
 - Lead partner for development of the publication
 - Lead author
 - Lead writer (if different from lead author)
 - Timeline for the preparation of the manuscript and proposed publication submission target date or deadline
 - Timelines for review by all authors and GARDP

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- When several partners are involved: Definition of the institutional approval process for the final draft. (e.g. parallel or sequential approval)
- Data to be presented (mock or draft or short description of proposed figures and tables)
- Key messages and discussion points
- Selected journal for submission (and back-up journals)
- The lead author along with the lead writer (in GARDP or external) writes the publication and seeks feedback/review from all authors, until all authors agree on a final draft publication.
- All data contained in text, figures and tables should be quality controlled for typos and errors before the final draft stage.

10. GARDP approval of output to be submitted:

- Once approved by all co-authors and prior to its submission, the publication must be submitted to GARDP for approval with a timeline of at least 4 working weeks. If this is not possible, e.g., for a late breaker abstract submission, GARDP must be warned as soon as a decision to submit such an abstract has been made.
- Wherever possible, GARDP will respond as quickly as possible so as not to delay submission. In general, GARDP must be warned in advance when to expect documents for review in order to plan accordingly.
- In case of abstract submitted to a conference, both the abstract and the poster or slides must be approved before submission/presentation.

11. The internal GARDP R&D instructions for development, review and internal approval of scientific publications are described in a separate document.

12. Any dispute arising out of or in connection with publications and/or the R&D publications policy shall be settled:

- When any other parties are involved, in accordance with the dispute resolution provisions set forth in, or with the law applicable to the contract executed with such parties;
- When only GARDP employees are involved, by the R&D Director.