Medicines for Malaria Venture

Request for Information (RfI)

Clinical development AI landscaping

1. INTRODUCTION AND BACKGROUND

Founded in 1999, MMV is a not-for-profit product development partnership (PDP). We work "end-to-end" to discover, develop and deliver accessible and affordable medicines to treat, prevent and eliminate malaria. Starting where the need is greatest – with children and pregnant women – we collaborate equitably with partners across sectors and geographies, ensuring innovation reflects local realities and reaches those most at risk.
It's working. As of 2026, we have brought 19 medicines that have treated or protected more than 1.48 billion people worldwide. We cannot stop now.

Founded in 2003, DNDi is a not-for-profit product development partnership (PDP) that discovers, develops and delivers safe, effective and affordable treatments for people affected by neglected diseases, including leishmaniasis, sleeping sickness (human African trypanosomiasis), Chagas disease, filarial diseases, mycetoma, paediatric HIV, hepatitis C, dengue, and snakebite envenoming. We work hand in hand with partners in low- and middle-income countries to strengthen research capacity and ensure treatments are adapted to the communities who need them most. The model is delivering results for neglected diseases too. Since 2003, DNDi and partners have delivered 14 new treatments for neglected diseases, saving millions of lives, working with more than 200 partners across nearly 50 countries. We cannot stop now.

The Global Antibiotic Research & Development Partnership (GARDP) is a not-for-profit global health organization based in Geneva, Switzerland. GARDP's mission is to accelerate the development and access of treatments for drug-resistant bacterial infections. It does so by forging public-private partnerships all over the world to develop and expand access to treatments for serious bacterial infections and sepsis in adults, children and newborns, as well as sexually transmitted infections. GARDP was created by WHO and DNDi in 2016, and was legally established as an independent entity in 2018, the GARDP Foundation. Since then, GARDP has developed a portfolio of antibiotic treatments that targets WHO priority pathogens, priority diseases and key populations/regions that are especially affected by drug resistance.

MMV, DNDi and GARDP are part of an ecosystem of partners determined to eliminate malaria and neglected tropical diseases (NTDs) and fight antimicrobial resistance. As product development partnerships (PDPs), we bring the public and private sectors together to promote the equitable development of breakthrough solutions to help end these diseases and advance health for all.

MMV, DNDi and GARDP are jointly conducting landscaping of Artificial Intelligence (AI) solutions applicable to clinical development focusing on study design and protocol optimization, and medical writing. These use case areas are prioritized for potential impact on common product development bottlenecks in the clinical and operational space.

Operating in complex, resource-limited settings to develop critically needed treatments and preventative medicines for malaria, neglected tropical diseases and drug-resistant bacterial infections, MMV, DNDi and GARDP are seeking to landscape the AI tools available to offer maximum impact for our missions through gains in speed, cost efficiency and quality; and to evaluate potential use cases and providers for future proposals.

2. PURPOSE OF THE RfI

MMV, DNDi and GARDP are jointly issuing this RfI to identify providers with existing or under development AI tools that assist in key clinical operations use cases. The tools should facilitate both protocol design and study simulation, operations and writing from concept through final protocol and its implementation and reporting. Potential areas of support may include, but are not limited to:

1) **Protocol Design and Optimization:**
   Development of trial-specific endpoints, inclusion and exclusion criteria, visit schedule optimization to reduce burden on patients and investigators, and identification of risks that may lead to protocol amendments.

2) **Clinical Operations:**
   Development of CDISC TMF-compliant study manuals and other operational documentation to support protocol implementation in both high and low- and middle-income settings, including, but not limited to CRF design, monitoring plan with risk based monitoring, resource forecasting, feasibility questionnaires (site and country level), recruitment forecasting, study startup optimization, validated translations of participants' study materials, e.g. informed consent forms (ICFs), into European and non-European languages.

3) **Medical Writing:**
   Drafting of key study documents (such as protocols, informed consent and assent forms adapted to country-specific terminology and language, participant diaries, and regulatory-compliant clinical study reports), Drug Safety Update Reports (DSURs), eCTD Modules and scientific publications.

4) **Product Development Documents:**
   Drafting and revising of key documents such as Investigator Brochures, integrated Development Plans, development Risk Management Plans

5) **Other Relevant AI Capabilities:**
   MMV, DNDi and GARDP also welcome information on other AI-enabled solutions or approaches that may address any other clinical operations' needs in ways not explicitly described above.

3. ELIGIBILITY CRITERIA

Responding organizations should demonstrate:

1. An existing AI-based solution, rather than a manual-only service.
2. A solution that has progressed beyond the prototype stage.
3. At least one real-world application in clinical development.
4. Experience working with sponsors, CROs, biotechnology companies, and/or pharmaceutical companies.
5. Compatibility with GxP and GCP requirements.
6. An available audit trail.

7. Compliance with GDPR or equivalent data protection requirements.
8. A clear understanding of regulatory expectations for sponsor oversight.
9. A validated and supported system that meets applicable regulatory requirements.
10. Availability of a product demonstration or walkthrough.
11. A solution that can be readily adapted to the malaria and not-for-profit context, where efficiency, equitable access, and sustainability are essential.

4. EXPECTED OUTCOMES

MMV, DNDi and GARDP intend to use the responses received to:

- Build a database of qualified providers that may be considered for future procurement processes or other potential engagements;
- Facilitate efficient identification of suitable providers for future AI Clinical Operations tools and services;
- Strengthen engagement with providers that bring AI expertise and knowledge.

5. SUBMISSION INSTRUCTIONS

Interested organizations should submit RfI responses via Microsoft Forms questionnaire (HERE).

- Please provide clear, concise, and structured responses to the questionnaire.
- Free-text responses should be up to 500 words per question.

Interested organizations may submit the questionnaire and by email a PDF (up to 4 pages) to provide further information on your company, experience, technical capabilities, team expertise, and/or other relevant topics.

- **Issue date:** 9 September 2026
- **Deadline for questions:** 15 September 2026
- **Closing date:** 7 October 2026

Please send any questions about the RfI and any supplementary PDF submissions by email to:

- Helen Demarest, Senior Director Clinical Operations, demaresth@mmv.org and Arthur Masurel, Business Development Manager, masurela@mmv.org,

6. DISCLAIMER

This RfI is issued solely for information-gathering purposes. It does not constitute a solicitation for proposals, an obligation to conduct a procurement process, or a commitment by MMV, DNDi and GARDP to award any contract or fund any activity. Inclusion in any database or network established by us does not guarantee future invitations, selection, funding or contracting. We reserve the right to modify, cancel, or follow up on this RfI at our sole discretion.

Information which the responder considers to be proprietary should be clearly marked as such. All such information will be treated as confidential, unless it is already known to MMV, DNDi or GARDP, publicly available, or independently developed by us respectively. Responses and related information may be used for the purposes of reviewing and assessing responses to this RfI, including, where appropriate, with external reviewers or advisors involved in the RfI process, establishing and maintaining our databases or networks of potential service providers, and considering potential future engagements.

MMV, DNDi and GARDP may also share aggregated, anonymized or non-confidential findings, outcomes and market intelligence arising from this RfI with other product development partnerships or not-for-profit global health organizations for non-commercial landscaping, benchmarking, knowledge-sharing and collaboration purposes. Proprietary or confidential information identified by responders will not be disclosed to such third parties without the responder's prior written consent, unless such disclosure is required by applicable law.