Strengthening African National Regulatory Authorities Data Systems to Enhance and Track Performance

Grand Challenges

Request for Proposals

The Opportunity

Insufficient access to quality, safe, efficacious, and affordable medical products in Africa has posed a significant challenge to public health for decades. The establishment of the African Medicines Agency (AMA)[1] will help to facilitate coordination of regulatory activities and further harmonization across Member States and help drive access.

Over the last decade, the Bill & Melinda Gates Foundation (the Foundation) among other funders and stakeholders has supported the harmonization of regulatory technical standards and optimization of regulatory processes in Africa. The Foundation's Africa regulatory systems strategy addresses all aspects of the newly emerging African tri-level regulatory ecosystem – continental, regional (Regional Economic Communities (RECs)), and national. While AMA will be a key catalyst of Africa's new regulatory ecosystem, it is designed to work within a regulatory network drawing on expertise and other resources from the RECs and National Regulatory Authorities (NRAs). Without strong NRAs, this ecosystem cannot function. At the national level, the Foundation is supporting a number of NRAs to reach WHO maturity level 3 (ML3), and ultimately to become WHO listed Authorities (WLA). This important effort is supported by African governments, the African Union, WHO, and several international partners. As part of the process to attain ML3 and WLA, NRAs need to establish clear Key Performance Indicators (KPIs), and to track and publish these in a transparent manner.[2]

The Challenge

While harmonization of technical standards and processes has been ongoing in Africa for more than a decade, there remain disparities between different NRAs and regions. While maturity levels vary, so do processes for managing marketing authorization, clinical trials, and other regulatory applications and services, with many NRAs performing these manually without the support of a robust digital environment. Many NRAs have published public service charters committing to achieve certain levels of performance (based on clearly defined KPIs), but without a structured approach to measuring these KPIs, it is impossible for NRA leadership to track progress, take corrective action, or share performance with stakeholders. The lack of fit-for-purpose tracking systems prevents NRAs from accurately defining and overseeing their end-to-end processes, which in turn impacts their organizational strategic planning and execution.

The ability to track and report these metrics is also important when NRAs seek support from their government and partners in order to improve their environment, as they need to report the impact of these investments to their governments, local stakeholders, and partners.

Most NRAs do not have data systems, nor staff dedicated to the generation and reporting of data on KPIs. Where staff play such a role, in many instances these staff have other responsibilities and only do the data generation, analysis and reporting as additional duties or in their spare time. This has been evident in regional regulatory work-sharing/cooperation with

RECs struggling to obtain data on products submitted to NRAs following regional recommendations and the associated regulatory timelines. This too applies to some NRAs participating in WHO's prequalification collaborative registration procedure, as well as for clinical trial review timelines they are expected to publish.

In summary, we seek to address four problems: i) Lack of clear internal processes to manage different regulatory pathways available at NRAs; ii) Lack of clearly defined KPIs by some NRAs; iii) Lack of, or sub-optimal data systems for capturing and reporting key data and metrics to inform process improvement and demonstrate performance against KPIs and iv) lack of harmonized solutions that are interoperable across multiple NRAs and built to scale.

The funded projects will be part of a larger coordinated program aimed at further strengthening African National Regulatory Authorities data systems to enhance and track performance. The project teams funded through this RFP will be expected to work together on shared areas of interest including, but not limited to, knowledge exchange and harmonization of solutions. This effort, while expected to contribute to NRAs attainment of ML3, will not support wider efforts at attaining ML3, but be limited to data systems, performance measurement, and advancing transparency.

Funded projects will work closely with a coordinating entity (that will provide technical support to NRAs on data systems). An advisory committee comprised of key stakeholders will be constituted to guide this work including representatives from relevant African Union organizations.

Proposals are required to allocate funds for staff time and travel to participate in the cross-project collaborative activities at least once a year agreed upon by the governance committees.

What we are looking for:

Applications are invited from African National Regulatory Agencies (NRAs). Each proposal should be submitted by one primary applicant, but the awards require active collaboration between at least two NRAs per application. In addition, proposals should address at least two (2) of the following categories:

Regulatory review process management:

- Create or improve regulatory digital data management systems and end-to-end processes including structured approaches to data generation, analysis, sharing at the regional level. and reporting of KPIs. Priority will be given to proposals including a solid plan for reporting on KPIs, this includes:
    1. regulatory timelines for national marketing authorization,
    2. clinical trial applications,
    3. facilitated regulatory pathways; we would prioritize proposals including REC products, WHO PQ CRP, global pathway (and AMA pathways in future)
- Design and structure data management systems that contribute to NRAs achieving WHO ML3/WLA status along with other important efforts addressing the rest of the GBT requirement outside of performance management.

Metrics systems and performance indicators improvement:

- Develop data systems and processes and engage in continuous improvement to establish key performance indicators and to assess process effectiveness. These should

be based on the WHO Global Benchmarking Tool (GBT) for Evaluation of National Regulatory Systems of Medical Products.
- Develop best practices for regulatory metrics monitoring and evaluation systems.
- Develop, and/or update key performance indicators, organization client charter and publish on NRA website.

Regulatory Data Standardization and data vocabulary:

- Enable data integration both from various sources within the same agency and beyond including other NRAs, other governmental agencies.
- Develop/improve data structures and vocabularies to enable interoperability across countries and regions and that would support the AMA/continental RIMS development.
- Develop guidelines and Standard Operating Procedures (SOPs) that support data systems at the NRA(s) participating in this call for proposals.

Artificial Intelligence (AI) centered tools:

- Enable/design data systems that would enable the use of AI to facilitate regulatory activities including screening, reviews, and scanning large databases for potential quality and safety signals.

Funding level

We seek to fund up to 5 proposals. Successful proposals will receive an award of up to USD $300,000 with an 18- to 24-month grant duration. Proposals must demonstrate that at least 80% of the funding is going to NRAs. While proposals require the collaborative participation of at least two investigators at different NRAs, proposals should be submitted by one primary applicant/NRA. While restricted to one application per institution as the primary applicant, applicants may participate as collaborators in multiple collaborative applications.

Selected proposals will be part of a coordinated program and will work closely with a coordinating entity (that will provide technical support to NRAs on data systems). An advisory committee comprised of key stakeholders will be constituted to guide this work including representatives from relevant African Union organizations.

Successful proposals to be considered should:

- Involve at least an NRA operating at WHO (Maturity Level) ML3 level.
- Demonstrate at least 80% of the funding is going to NRAs.
- Demonstrate how they would enable other countries to achieve WHO ML3 level.
- Involve substantial collaboration between at least 2 NRAs. The suggested collaboration should be key to advancing the project goals and yield insights that are unlikely in the absence of co-produced approaches. In addition, however, applications could include collaborations with institutions in other geographical areas including from outside Africa.
- Have the potential to demonstrate impact on the areas proposed and within the proposed budget and timeframe of 18 -24 months.
- Explain how resources for the project (including personnel) will be procured within the 1st 3-4 months to ensure that activities take off in time, and the project is completed in time (18-24 months).
- Be driven by a shared commitment for collaboration, protocols and processes sharing and advancing information management systems and processes.

- Plan for change management and implementation of new data systems and processes.
- Demonstrate how sustainability of established systems will be achieved beyond this grant including key personnel like statisticians. An example might be securing written commitment from the agency Board (of all NRAs participating in the project) to fund the continued use of developed systems and personnel at the end of the project. Proposals that commit to start transition of ownership of personnel after 12-15 months of the project will be preferred.

We will not consider for funding:

- Proposals that do not involve an ML3 NRA
- Proposals led by institutions not based in Africa
- Proposals that don't demonstrate a clear commitment to collaborating with other funded proposals/teams and the coordination team
- Proposals that are not accomplishable within the grant term
- Proposals outside the scope of this call even when what is proposed is highly relevant for the regulatory authorities involved.
- Proposals seeking to support efforts at attaining ML3 that go beyond creating and enabling data systems.

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[1] https://joppp.biomedcentral.com/articles/10.1186/s40545-020-00281-9

[2] https://www.who.int/tools/global-benchmarking-tools