



science & innovation
Department:
Science and Innovation
REPUBLIC OF SOUTH AFRICA



Implemented by:



**Equipment / Infrastructure Support for the Research,
Development, Testing, Pilot Scale Production and
Regulation of Vaccines in South Africa
Request for Applications (RFA)**

EMAIL AND BRIEFING SESSION

Q&A SUMMARY

26 June 2024

Reference No: SAMRC-RFA-GIPD-06-2024

Release Date: 14 June 2024

Closing Date: 26 July 2024

QUERIES RECEIVED VIA EMAIL AND THE BRIEFING SESSION WITH ANSWERS

- Q. [Startup companies](#) are known to play an important support role in development and production of vaccines. Are startup companies involved in biotech innovation (vaccine R&D) value chain eligible for this call?**
- A. Yes, if they can motivate their role in the vaccine research, development and manufacturing ecosystem in line with the objectives of the program.
- Q. Please provide more details on [budget and maximum value of funding support](#). Is there an [upper limit](#) in terms of the equipment cost?**
- A. The total budget for support areas 1 to 3 is €17 million. There is no upper limit in terms of equipment costs. However, items costing R1 million or less will only be considered in exceptional circumstances.
- Q. The call specifies a focus on vaccine bulk drug substance (APIs) production. While there is a good supply of fill/finish capacity locally, we do need small scale filling for clinical development. Will [small-scale vial filling](#) be supported?**
- A. Yes, small-scale vial filling for pilot production falls within the scope of the RFA under support area 1.
- Q. May [clinical research sites](#) that need to be developed to meet the demand of vaccine clinical trials apply? Currently the laboratory of the site refers samples for analysis and processing to other labs.**
- A. This RFA is not aimed at capacitating clinical trial sites.
- Q. Can [biobank equipment](#) be applied for?**
- A. Yes, provided that there is sufficient motivation regarding the relevance of the equipment to the vaccine research, development, testing and manufacturing activities listed in the RFA and it is preferably linked to a research group involved in such activities.
- Q. May [manufacturers not based in South Africa](#), apply for the RFA through a distributor based in SA? Will the SAMRC assist in procuring such distributors?**
- A. No, the company and equipment must be located / used in South Africa.
- Q. Will [shipping costs](#) of the instrument be covered i.e. can this be included in the quote?**

- A. Yes, this can be included in the quote. The Steering Committee will determine whether such costs can be covered, taking into account available budget.
- Q. **Is the call limited to mRNA vaccines or are protein vaccines eligible?**
- A. No, the RFA is not limited to mRNA vaccines. Support area 1B is for APIs for vaccines that are not mRNA based, hence protein vaccines would be eligible.
- Q. **So there are two categories (support areas) that we are interested in applying for i.e. 1a and 3. We want to know whether a separate application is required for training if we want to use the GMP equipment for training purposes, do we need to submit two applications or can we just submit one application?**
- A. If the primary intention of the equipment is to do pilot-scale manufacturing, then you should apply under support area 1(a). If that same equipment will also be used for training, this should be included under the motivation around the use and value of the equipment.
- If a separate training laboratory is to be set up to train a number of people simultaneously, with different equipment that is not part of the general pilot-scale production plant, that would require a separate application under support area 3.
- If there is overlap between production and training, then the primary purpose of the equipment should be used to determine whether to apply under support area 1 or 3.
- Q. **Regarding the applications for upgrading and modernizing building infrastructure, part of this would require consultation with engineers if it were a complicated project. Can this be built into the application?**
- A. With regard to renovations, the quote may include all aspects from design to construction and commissioning of the infrastructure upgrades. Therefore, if an engineer needs to be consulted this can be included in the request. The Steering Committee will determine which costs will be covered, taking into account available budget.
- Q. **What is the thinking around existing quality systems in the applicants, whether it be GMP, GCLP or GLP? Is that a requirement and what is the view on that from the perspective of the application process? Is it a prerequisite, and if it isn't, is there value in having those quality systems when the applications are reviewed?**
- A. For research equipment, in most cases GLP and ISO standards are not necessarily required for early-stage vaccine R&D. However, if those systems were in place, it would certainly add to the merits of the

application. If the application is to place equipment in a facility that will be providing a service where there is a minimum requirement for certification or qualification or quality management systems, then such requirements should be in place or there should be a plan presented on the steps towards acquiring the necessary certifications. This will be an important consideration when evaluating such applications. IT systems required to support such certification or quality management systems would be eligible for this RFA.

Q. The call does say it also supports [production of reagents](#), but often with these vaccine reagents, you would have to do some level of discovery, and these are supported by specific platforms. Are we then eligible to apply for equipment that supports discovery and also production of reagents that are related to vaccine production?

A. Yes, provided the link to vaccine development and/or manufacture and the overall value chain for this is well motivated.

Q. Are you looking into [upstream and downstream processing](#) for the vaccine manufacturing process? For the pilot scale?

In the industry we refer to upstream as the actual fermentation or the bioreactor processes, and downstream is usually your polishing steps, clarification, purification etc. and then final filling and finish.

A. Yes, the RFA covers the full requirements to produce a pilot-scale batch of any one type of vaccine.

Q. What [volumes do you consider to be pilot-scale](#) and what [volumes do you consider to be R&D](#) because that differs on what equipment we would recommend based on your volumes?

A. Pilot-scale would cover the volumes needed for testing the production process and/or for producing batches for clinical trials.

Q. Regarding the requirement to provide quotations for equipment as part of supporting documents, [who should the quotations be addressed to](#), the SAMRC or the applying entity?

A. Quotations should be addressed to the applying entity. Note that those quotations will not be used for the procurement. The procurement must follow the SAMRC process, however, those quotations are critical to determine the value of the application and for program budgeting purposes. It is important that the equipment specifications included in the quotations are accurate as these will be used for procurement if the application is successful.

Q. Regarding equipment specifications, these would need to be stated before obtaining quotations. How does this relate to the involvement of the SAMRC in developing the specifications with the Implementing Partner at the later stage, post award?

A. The SAMRC will take guidance on the equipment specifications from the successful applicants when procuring the equipment. These specifications must be in the quotations submitted with the applications and therefore need to be determined by the applicant upfront. Awards will be made based on those specifications. The quotations will provide an indication of the current market value of the equipment. If the specifications are to materially change after award, additional approvals and revisions to the awards may be needed. It is therefore critical that those specifications are as accurate as possible when applying. They will be confirmed with the Implementing Partner before commencement of the procurement process and, once bids or quotes are received via the SAMRC procurement processes, the Implementing Partner will play a role in the evaluation thereof.

Q. Can we include a buffer for exchange rates when requesting a specific amount? It would be higher than that amount quoted for the equipment.

A. The quote can be provided in the currency in which it is quoted however, the amount must be converted by the applicant to the South African Rand value using the exchange rate around the date of submission of the application, for the Summary Spreadsheet. Provision will be made for foreign exchange fluctuations at the point of procurement.

Q. How many awards will be made?

A. It cannot be determined at this stage, but it has not been limited. The total budget available for support areas 1 to 3 is up to €17 million. The total amount will only be spent if warranted based on a real need and satisfactory motivation for the equipment and infrastructure. Each support area does have a target amount of allocated funds; however, we have not stipulated this as we would like to reserve some flexibility to reallocate funds between support areas. The number of awards made will be determined by the number and quality of applications received, how they align with each other, and whether they address key gaps in the vaccine research, development and manufacturing ecosystem in line with the objectives of the program. Awards for support areas 1(a) and 1(b) (pilot plants) and support area 3 (training) will be limited. Under support area 2 (research and laboratories), we are likely to make multiple awards.

Q. Has the one health approach been considered or is this just for human vaccines?

A. The call itself does not specify this; however, the merits of the applications will be considered

particularly in respect of how they relate to the complete vaccine value chain. We recognize the importance of a one-health approach. At this point, applications from the animal vaccine arena are not ineligible; however, they will be evaluated against those in the human vaccine arena.

Q. Are applicants to be registered in South Africa for all the components of the project?

A. Yes, to the extent that the components relate to the equipment requested. Any equipment must be placed in a South African entity and used in South Africa. Parts of the work that do not involve the requested equipment may happen outside of the country.

Q. As a supplier of the actual equipment to be used in either pilot-scale production or R&D laboratories, the SAMRC won't be buying equipment from us? We need to work with the institution that has the facilities?

A. Suppliers of equipment would not apply directly to the SAMRC in response to this RFA. They must work with the applicants to provide a quote. The SAMRC is not involved in this process. Once awards are made, the specifications for those awards will be used to procure the equipment from suppliers through an open, fair, equitable, transparent, competitive and cost effective tender or request for quotations process. The only exception is where a specific brand of equipment is required or where the specifications can be met by only one supplier. This will follow a single or sole source supplier route but will have to be well motivated.

Q. Mention is made that the full specifications are required up front. So if the specifications had minor changes through the process but doesn't impact the quote, is that an issue or does one need to have the full specs in place upfront?

A. No, minor changes will not be an issue if they do not have cost implications, but the extent thereof will be evaluated at the time of award and procurement. We do expect the applications to include specifications that are as close as possible to what will be required if awarded.

Q. Will preference be given to previously disadvantaged entities? Entities in the rural areas need this support to improve; however, they may fall short on certain application requirements. They will need assistance to see how to bridge that gap.

A. This is an open competitive call with certain criteria which the independent reviewers will use to evaluate the applications received. The Steering Committee then has the discretion to take into account other considerations such as transformation, diversity, equity, spread of awards between institutions, etc. We recommend that if certain entities do not have adequate capacity at this point to support or to

justify any piece of equipment they may be requesting, they link with a co-applicant who can provide that support. This will strengthen the application if it results in a meaningful collaboration that will build capacity to effectively use that equipment and to achieve the objectives of the program. This is one way during this application process that applicants can address any deficiencies they may have as a result of location, lack of resources or other shortcoming at their institution.

Another example is if there is a collaboration of institutions in any particular area or region that are working together and jointly have the expertise, resources and need for the equipment. Applying as co-applicants may strengthen the application.

Though we have provided for a co-applicant option, it is not necessary to have one. It is for situations like those outlined above that can strengthen the application and bring in the required capacity as well as ensuring broader multi-institutional use of the equipment.

Q. Will having accessibility to [clean room facilities](#) add an advantage as we will be working with vaccines?

A. A reminder that only public institutions and the National Control Laboratory will be considered for renovations and infrastructure upgrades to buildings, including clean rooms. If the request is for equipment for clean rooms and it is directly linked to vaccine development, preclinical testing or pilot-scale production, then it would be eligible for this call but has to be well motivated. If having accessibility to clean rooms is a requirement for the activity under which the request is being made, then having such access will strengthen the application.

Closing remarks to the briefing session:

The objectives of this program, in line with the objectives of the Governments of Germany and South Africa, are to build the vaccine ecosystem in South Africa so that, in future pandemics, we are more resilient and less reliant on external supply. This means we have to build the capacity in South Africa to undertake the full value chain of vaccine research, development and ultimately full commercial manufacture. This program addresses up to pilot-scale manufacture. If potential applicants feel that they can contribute to this and their proposal fits within the value chain and may enable us in future to develop, test, register and produce for clinical trials our own vaccines, then they are eligible to apply and should motivate as such.

We also need to reiterate that this is not a full-cost program. There are numerous commitments expected from the institution, including financial commitments. If your institution cannot make those financial commitments, then please re-consider applying. The program cannot finance equipment that will sit idly and not be used for its intended purpose because there are not any suitably trained and



science & innovation

Department:
Science and Innovation
REPUBLIC OF SOUTH AFRICA



Implemented by:



qualified people to operate it, no backup systems in place, and no running costs to operate the equipment. It is important to consider this upfront before submitting an application.

Late applications will not be accepted. We wish you all the best and look forward to receiving your applications.

Any further enquiries with regard to this funding instrument are still welcome and may be addressed to:

Sumaya Behardien

SAMRC Grants Innovation and Product Development (GIPD)

Email: vaccine.equipmenttrfa@mrc.ac.za