

BOX 2: INVITATION TO COLLABORATION

DEVELOPMENT OF A HEALTH PRODUCT A

Objective

The Public Sector Research Centre (PSRC) is seeking collaborative relationships with one or more organizations capable of completing the following tasks for prototype health products: industrial development, manufacturing, clinical testing, and licensure by national regulatory authorities.

Health Product A can be produced in a number of different ways. The PSRC believes that one or more of these production methods could be viable for commercial scale-up.

The Public Sector Research Centre

[insert a description of the PSRC including governance, funding, research programs, goals, history, capabilities, etc.]

Participating Scientists

The following scientists have played a leading role in the development of methods for synthesizing Health Product A as described in the attached documents. [attach copies of relevant publications]

and their collaborators.

Mode of Operation

The PSRC has the ability to mobilize assistance for the health-product development process by a variety of means including financial, technical, and in-kind support.

Companies should contact the PSRC to initiate an agreement on a development project.

The following issues are open for discussion with respect to a collaboration agreement:

- Product development including consultation on details of manufacture, adjuvanting, packaging, heat stability, etc.
- Cost sharing of the manufacture of sufficient health product for Phase I through Phase III trials.
- Assessment and planning for the introduction of the health product into private-sector markets.
- Assessment and planning for the introduction of the health product into public-sector markets.

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- Development of regulatory standards through interactions with national regulatory authorities and the World Health Organization.
- Conduct of Phase I through Phase III trials in developed and developing countries in a variety of populations.
- Obtaining regulatory approval in developed and developing countries.

Intellectual Property Rights

Details on patent applications will be discussed with interested parties following execution of a suitable confidentiality agreement. The PSRC possesses extensive know-how, which will be essential for the cost-effective implementation of a health-product development program.

Desired Product

The envisaged health product is expected to consist of _____. Further information on specific methods for health product manufacture is provided in the attached documents.

In the developing world, the principal use of the product is expected to be _____. In the developed world, the health product may find use in _____. See the following dossier for further discussion of potential market.

Submission of Expression of Interest

At this time, a letter containing the following information is requested:

- the nature of your interest in this project
- if you wish, a summary of the capabilities and experience of the organization
- names of other collaborators or partners
- an indication of the types of assistance/collaboration desired from the Institute

Interested parties are requested to write to the PSRC _____. Submissions are requested prior to _____.

For further information, contact either [name 1] _____ or [name 2] _____ of the PSRC at telephone _____ or fax _____ or write to them at [e-mail address] _____ or the above address.

Review and Contracting Procedure

Interested parties will be contacted to arrange for meetings and development of collaborative agreements.

Background on Health Product A and Collaborating Scientists

Health Product A is involved in acute, chronic, and _____. Health Product A is widespread in both developing and developed countries and infects _____. Infection persists throughout life. Health Product A transmission is primarily by _____.

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Box 2 (CONTINUED)

Health-Product-A-associated diseases are significant causes of morbidity and mortality. For example, in developing countries _____.
In developed countries, it leads to significant morbidity _____.

Short biographies of collaborating scientists [include as an attachment]

Market Potential for Health Product A

Scientific and other References

Source: Mahoney¹⁰