

Request for Expressions of Interest (EOI) v10Feb2024**Clinical trial and regulatory technical support for WHO coordinated study****Efficacy of probiotic supplementation in preterm and small for gestational age infants. A WHO coordinated multi-centre, individually-randomised trial (Probiotics in preterm and small for gestational infants, PROPS trial)**

Posting date Tuesday 13th February 2024 Geneva time

Closing date for submissions Monday 4th March 2024 5pm Geneva time

1. Background

The World Health Organization (WHO) Department of Maternal, Newborn, Child, Adolescent Health and Aging (MCA) is coordinating a trial to assess the effect of probiotic supplementation in 14,000 preterm and small for gestational age (SGA) infants in five low- and middle-income countries (LMICs) (Bangladesh, Ethiopia, Nigeria, Pakistan and Kenya).

The overall aim of the trial is to assess the effect of probiotic supplementation on mortality, morbidity, and growth in human milk fed preterm and term SGA infants in the first six months of life in South Asia and Sub-Saharan Africa. The primary objective is to assess the effect of probiotic supplementation on (i) mortality at six months in preterm infants and (ii) underweight (low weight-for-age) at 6 months in term SGA infants. The secondary objective is to assess the effect of probiotic supplementation on mortality at 6 months in infants of low birth weight (LBW). Other secondary outcomes are rates of hospitalization, suspected and confirmed sepsis, and necrotizing enterocolitis.

The trial will be implemented in urban and rural settings in the five sites over four years. It will involve recruitment in hospital in the first two days of life and follow up in the community through home visits. The probiotic supplement will be specially prepared for the trial and given orally or by feeding tube. It will be given to infants by their mothers in hospital or at home from day 2-30 of life. The mothers will be directly observed and supported by specially trained field workers (directly observed therapy, DOT).

WHO/MCA is seeking technical support for regulatory and clinical trial components for the first 12 months of the preparatory phase of the trial.

We invite academic and clinical trialists in institutions experienced in regulatory approvals and the processes and conduct of clinical trials in infants and children to submit an Expression of Interest (EOI). The EOI guidance below should be followed with submission no later than Monday 4th March 2024 5pm Geneva time. EOIs should be sent by email to Karen Edmond and Nigel Rollins (edmondk@who.int rollinsn@who.int). EOIs received after this date will not be considered for selection.

2. Summary of requirements / work to be performed

The work involves providing technical support to the WHO/MCA team for the regulatory and clinical trial components for the first 12 months of the preparatory phase of the trial.

Specific activities are:

- (i) Providing technical support for the preparation of clinical trial applications to regulatory

authorities and ethical review committees for the five sites and WHO.

- (ii) Liaising with the probiotics manufacturer to obtain needed documents and data for the applications
- (iii) Liaising with the sites, WHO and the manufacturer to submit and revise/resubmit applications as needed
- (iv) Providing technical support for the preparation of other materials for clinical trial implementation in the five sites including: informed consent forms (ICFs), information sheets, case record forms (CRFs), protocol updates, monitoring plans

It is anticipated the work will require at least 0.5 full time equivalent (FTE) for 12 months (March 2024 to February 2025) e.g. one team member for 0.5 FTE, two team members for 0.25 FTE each. No work should be outsourced to other providers. There may be an opportunity for additional related work after February 2025. The characteristics of the required provider are presented in section 3 below.

3. Characteristics of the provider

Essential

- Proof of International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Guideline for Good Clinical Practice (GCP) training / accreditation
- Experience in developing and implementing clinical trials of investigational medical products (IMPs) according to ICH-GCP - preferably for infants or children - in LMICs
- Publications as an investigator of clinical trials of IMPs - preferably for infants or children - in LMICs in the last 10 years
- Experience in preparing clinical trial applications to regulators and ethical review committees for IMPs - preferably for infants or children - in LMICs
- Experience in preparing other materials for clinical trial implementation according to ICH-GCP - preferably for infants or children - including informed consent forms (ICFs), information sheets, case record forms (CRFs), protocols, monitoring plans
- Higher degree (masters or PhD) in epidemiology, clinical trials, public health or a related field

Desirable

- Experience in developing and implementing clinical trials of probiotic supplementation- preferably for infants or children - in LMICs
- Experience in preparing clinical trial applications to regulators and ethical review committees for probiotics - preferably for infants or children - in LMICs in the last 10 years

4. Format of the EOI to be submitted (size 11 font, normal margins)

3 pages maximum

- I. Describe your experience and expertise in conducting the four activities listed in section 2 (1 page maximum)
- II. Describe how you meet each of the essential and desirable characteristics in section 3 (1 page maximum)
- III. Illustrative budget outline. In this EOI, we request you to provide an illustrative high-level budget outline (no budget justification required at this stage). Please base your budget on the outline provided in this EOI. While illustrative, the budget should be prepared carefully and reflect actual costs. It is anticipated that the bulk of the budget would be for staff salaries. Please note all administrative costs should be itemised. Travel costs do not need to be included. Travel is not anticipated but if required any travel needs will be covered separately by WHO (1 page maximum).

In addition to the 3-page maximum

- IV. Short CV with academic and professional qualifications, current position and affiliation, most relevant research grants and publications (2 page maximum for each team member).
- V. Completed provider contact information form (Annex A).

5. What will happen after the closing date for submission of Expressions of Interest?

The received Expressions of Interest will be screened and scored by WHO using the criteria set out in section 3 above. The results of selection process will be notified in April 2024.

Disclaimer

Submission of an Expression of Interest does not guarantee that a provider will be selected.

Any and all costs and expenses incurred in relation to, or ensuing from, the submission of an Expression of Interest will exclusively be borne by the applicant. The application and selection process set forth in this document will not be subject to claims for financial compensation of any kind whatsoever. WHO is acting in good faith by issuing this Request for Expression of Interest, however, this Request for Expression of Interest does not entail any commitment on the part of WHO, either financial or otherwise. WHO reserves the right to select research teams identified by WHO through means other than this Request for Expression of Interest; reject any or all Expression(s) of Interest, without incurring any obligation to inform the affected applicant(s) of that decision or the grounds thereof; and/or change or cancel the process at any time.

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Annex A – Provider Information Form

Contact information to be provided by the lead provider expressing interest	
Name and title of lead provider who is submitting the EOI:	[.....]
Signature:	
Institution name:	[.....]
Date:	[.....]
Mailing address:	[.....] [.....] [.....]
Email address:	[.....]