Terms of Reference

This contract is requested by:

Unit:	PRD
Department:	HQ/POL

1. Scope of work

The independent expert (individual / company) will provide the necessary biostatistical /epidemiological / analytical support on safety data, to the Safety Advisory Committee to facilitate their recommendations on nOPV2 use to the GPEI.

2. Background

The Global Polio Eradication Initiative (GPEI) is facing an increasing number of outbreaks globally due to circulating vaccine derived poliovirus type 2. The vaccine currently available to stop these outbreaks is monovalent OPV2 (mOPV2) which unfortunately also carries the rare risk of seeding new outbreaks. In response the GPEI has developed the Novel type 2 Oral Polio Vaccine (nOPV2), a modified more genetically stable version of the current OPV type 2 which can be used in outbreak response without the same risk of seeding new outbreaks. Phase II studies have demonstrated nOPV2 is safe and effective, with Phase III studies planned to commence soon. In the interim, the GPEI is looking to roll out nOPV2 in December 2020 under WHO's Emergency Use Listing (EUL) mechanism which is a risk based procedure to assess and list unlicensed vaccines for use mainly during a Public Health emergency of International Concern (PHEIC). Polio has remained a PHEIC since 2014.

The use of nOPV2 under EUL is anticipated to commence December 2020 and will be ongoing until is the vaccine is prequalified and licensed, which is anticipated not before end of 2022. As this will be the first time the WHO's EUL mechanism is used for a vaccine, safety monitoring is critical. On 6th October 2020, the SAGE endorsed that an independent Safety Advisory Committee be established to review safety data / outcomes for the entire EUL period (~18 months), with particular attention paid to the initial use period (the first ~3-6 months) during which nOPV2 will be used for outbreak response in 1-3 countries.

The decision to transition from initial use of nOPV2 under EUL to wider use of nOPV2 under EUL will be informed by the nOPV2 Safety Advisory Committee contingent on meeting safety criteria. The nOPV2 Safety Advisory Committee will evaluate key safety data and provide recommendations on nOPV2 use to the Global Polio Eradication Initiative.

Given the tight timelines, the GPEI seeks to initiate RFP process as soon as possible, in order to identify / establish an independent expert (individual / company) that can provide the necessary biostatistical /epidemiological / analytical support in the area of vaccine safety evaluation and pharmacovigilance, to enable the Safety Advisory Committee to make their critical recommendations.

3. Planned timelines (subject to confirmation)

- Start date: 1 December 2020
- End date: 31 December 2021

4. Work to be performed / key deliverables

The incumbent will:

1. Develop and maintain a database to record all safety related nOPV2 data
2. Review the safety data from the field, including Adverse Events Following Immunization (AEFI); Adverse Events of Special Interest (AESI), and Vaccine Associated Paralytic Poliomyelitis (VAPP) collected by countries using nOPV2
3. Analyse the safety data from the field
4. Review and analyse observational data from the field related to pregnant women
5. Review and analyse surveillance data from the field (if/when available) related to individuals with primary immunodeficiency
6. Summarize / consolidate the analyses / safety outcomes in a regular report format for review by the Safety Advisory Group, nOPV2 WG and WHO PQ (monthly for the initial use period then quarterly thereafter)
7. Synthesize an in-depth report consolidating analyses after each vaccination campaign (day 72 after completion of each round) for each country individually as well as aggregated for all countries. This will be reviewed by the Safety Advisory Committee, nOPV2 WG
8. Coordinate with US-CDC on any issues related to safety data and data quality
9. Draft the final consolidated report which will reflect the Safety Advisory Committee's key recommendations at the end of the initial use period. This will be finalized by the Safety Advisory Committee for submission to the nOPV2 WG, the Global Vaccine Advisory Committee and SAGE

5. Place of assignment

The incumbent will work from home and will need appropriate functional setup for teleworking, including virtual calls via Microsoft teams and zoom. Given the strong analytical focus of the work the incumbent is expected to already have the necessary statistical platforms / programs to complete the work.

6. Remuneration and payment schedule

The fee for this work will be USD 60,000

- First, second and third payments of USD 6000 each will be made upon receipt of the first, second and third monthly report (USD 18,000)
- Fourth payment of USD 6000 will be made upon receipt of the first report following first vaccination campaign ~following day 75
- Fifth payment of USD 6000 will be made upon receipt of the report following second vaccination campaign ~following day 103
- Sixth, seventh, eighth payments of USD 6000 will be made upon receipt of each quarterly report (USD18,000)
- Ninth payment USD 6000 will be made upon receipt of final consolidated report following the end of the initial use period
- Payment of up to USD 6000 will be made at the end of the contract for additional ad-hoc analyses conducted by the consultant

7. Technical supervision

Responsible officer	Carolyn Sein	polioresearch@who.int
Manager	Carolyn Sein	polioresearch@who.int

8. Specific requirements

Education

- Essential PhD in biostatistics or epidemiology

- Desirable M.D; experience in conducting and analysing vaccine safety assessment, pharmacovigilance studies

Experience

- Essential Minimum 10 years of experience in biostatistics or epidemiology
- Desirable Work experience in analyses/evaluation of polio vaccines including nOPV2; experience working with international organizations and/or in AFRO and EMRO

Skills and competencies

- Essential Ability to consolidate scientific outcomes / analyses into scientific reports
- Desirable Excellent writing, communication and presentation skills; ability to work with multiple agencies, partners, sub-committee members

Language

- Essential Fluency in English
- Desirable Capacity to review and analyze data in French, Portuguese and/or Arabic