

# nOPV2 Working Group TORs (Feb 2020)

## Purpose

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The nOPV2 Working Group (nOPV2 WG) is a time-limited group that will manage and coordinate GPEI's activities to enable a rapid and effective roll out of nOPV2 as the tool of choice for responding to cVDPV2 outbreaks.

## Duties

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The working group will focus on the following, through the development, implementation and management of workplans and budgets for the following areas of work:

1. **Research:** Support new clinical trials and pilot field-projects through provision of technical guidance, ensuring field operational needs are met; coordinate operations monitoring/studies of initial field use of nOPV2 and dissemination of results and reports across stakeholders.
2. **Regulatory:** Support fast-track submission under WHO's Emergency Use Listing Procedure (EUL), and eventual full licensure, along with WHO prequalification.
3. **Supply:** Ensure the availability of nOPV2, in sufficient quantities, and establish risk mitigation strategies.
4. **Implementation Readiness:** Plan for the deployment of nOPV2, including providing technical guidance for decision making and training, regulatory approvals and continued surveillance and monitoring following use; coordinate laboratory and diagnostics work to enable strain identification.
5. **Communications:** Ensure stakeholders and countries have timely and accurate information about nOPV2 to support its use, including assessing feasibility of conducting behavioral and anthropological research, developing crisis communications strategies and proactive information dissemination
6. **Policy:** Work with SAGE and its polio working group to develop prioritization guidance for the initial use of nOPV2, including priority countries and strategies, provide guidance on candidate selection and manufacturing decisions for nOPV2 as needed.

## Outputs

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- Costed annual workplan, including:
  - The development of a roadmap and timeline for nOPV2 EUL, licensure and use
  - Mapping of critical activities against existing structures / responsibilities and identifying and addressing gaps / bottlenecks
- Risk management plan for nOPV2
- Regular reports on progress to SC (Standing item on SC agenda), POB, and SAGE, as requested
- Minutes of calls, meetings and decisions
- Decision papers, as required, for discussion and approval at SC

## Composition

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### Chairs and Members

- The nOPV2 WG co-Chairs will be appointed by the SC, and work together to lead the group.
- Each GPEI partner nominate one person as their core nOPV2 working group member, along with an alternate who will also function as a member of the core group.
- The nOPV2 WG will establish appropriate sub-groups or identify nOPV2 specific liaisons to oversee each of the critical areas of work. These include sub-groups on clinical/pilot studies, regulatory, implementation readiness, and liaisons to the VSTT for supply and the SCWG on communications.

- In areas where sub-groups have been established, key links have been developed with existing GPEI groups, such as the OPRTT, RRTs, STT, ESIWG, CRTT, GPLN SWG, PACT to ensure alignment and avoid duplication.
- Sub-group leads and liaisons will join core group calls, to ensure the core group has the necessary functional experience to fulfil its duties. Sub-group membership may include individuals who are not part of the working group or part of GPEI (i.e. regional colleagues, PATH, regulators etc)
- The involvement of manufacturers in the group will be assessed and decided on a case by case basis by the co-Chairs, and core members, in consultation with the SC.

## Secretariat

A dedicated secretariat has been established to support the group, with responsibility for scheduling working group and sub-group meetings, as well as tracking workplan outputs and monitoring progress. The secretariat will also include a technical coordinator, who will directly support the core working group members, under the guidance of the co-chairs.

## Operating mode, Rhythm of Business

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### Meetings

- The OPV2 WG will meet bi-weekly by teleconference (TC). Ad hoc TCs will be arranged by the Secretariat as required.
- In-person meetings will be arranged by the Secretariat at least once a year.
- Sub-groups will set up their own operating rhythm but are expected to hold a TC at least once per month.

### Decision making

- Decisions will be made by consensus across core working group agency representatives
- When consensus cannot be reached, decisions will be escalated to the SC at the discretion of the WG co-Chairs.

### Accountability

- The nOPV2 WG will report to the SC.
- The nOPV2 WG will maintain close links with the OPRTT, RRTs, VSTT, Strategic Communications Working group, PACT comms team, the Hub, FMT and other GPEI groups to ensure coordination of activities and avoid duplication.

### Duration

- The nOPV2 WG will cease to function at a time when the EUL is no longer in force. This could be due to i) the nOPV2 achieves prequalification; or ii) the EUL for nOPV2 no longer applies.
- However, depending on the status of nOPV1 and nOPV3 development during this time-frame, a decision might be taken by SC to maintain some of the group's functions to guide development and implementation of these vaccines.

### Limits of authority

By delegation from the SC, the WG is authorized to:

- Appoint the leads/co-leads of its sub-groups.
- Approve sub-group ToRs and annual workplans.
- Develop budgets and funding requests for nOPV2-related activities.
- Approve resource allocation for workplans within approved budget, with the authority to reallocate funding across WG budget lines staying within the approved funding envelope.

## Approval

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These TORs have been approved by the SC on February 6, 2020.