**PROPOSAL FOR PILOTING PROACTIVE VACCINATION SAFETY SURVEILLANCE AND MONITORING UNDER USAID RISE TECHNICAL ASSISTANCE FOR COVID-19 VACCINATION PROJECT IN THE STATE OF XXXXXXXXX**

# Background & Rational:

# Global health and development adversely affected by the COVID-19 pandemic, resulted in quick responses leading to the fast-track development of vaccines, and hastened clinical trials with emergency use authorization by the national regulatory authorities. The immediate demand of ‘access to COVID-19 vaccine’ for mass vaccination, now urgently requires health system strengthening focused on ‘safety of the vaccine’. Evidence-generation from post-vaccination proactive safety monitoring and follow-up of the populace, especially the vaccinated high-risk population, is an immediate priority.

# Success in other vaccination programs resulting in high vaccination coverage rate has several lessons for the COVID-19, another Vaccine Preventable Disease (VPD). Enhancing a robust safety monitoring system to support policy making, based on up-to-date safety information timeously available due to Artificial Intelligence / Machine learning (AI/ML) and integration of local and global safety data, is crucial. This sustained and continuous people-safety centred process enhances the decisive vaccine confidence building amongst the population.

# Since January 2021, India has administered more than 124 crore doses of the vaccine. The Adverse Event following Immunization (AEFI) data is captured through passive surveillance, resulting in 44,000 AEFI with only approximately 2000 serious or severe cases. According to the WHO, expected surveillance rate of rare AEFI’s are a minimum of 1 per 10000 vaccination doses. While Australia records 21.7 AEFI per 10,000, USA with 14 and Europe records 9.6 AEFI/10,000, India, has 0.3 AEFI cases per 10000 vaccination doses. This demonstrates the need for a robust proactive vaccination safety surveillance & monitoring system backed by AI/ML.

# Hence, it is critical to address the gaps of the current passive vaccination surveillance by having an innovative, robust, proactive vaccination safety surveillance and monitoring system for COVID-19 vaccination (and routine immunization), based on early forecasting, timely detection and evidence-based response to events, to enhance vaccine acceptance by the population.

# Pilot Coverage:

# Pilot study can be done at selected health facilities, secondary and tertiary level with consensus from the stake holders: State Immunization Officer, MD-State NHM and State JHPIEGO team and further feasibility assessment for implementation of pilot research.

# Aim and objectives:

# This project aims to initiate a unique digital solution with AI/ML and data analytics focused on strengthening proactive vaccination safety surveillance in near real-time by JHPIEGO in RISE Health facilities/ Covid-19 Vaccination Centers. This proactive surveillance and monitoring of beneficiaries, especially the high-risk population is envisioned to enhance post vaccination events detection and reporting to the existing surveillance system with quality data. The objectives are:

# • To improve identification, reporting, investigation of post-vaccination events, follow up and active surveillance for AEFI and facilitate through current reporting mechanism through District Immunization Officer.

# • To deploy real-time digital solutions to strengthen safety surveillance systems by utilizing AI/ML to extend the speed and breadth of advanced data analytics (including but not limited to predictive analytics)

# • To integrate the proposed digital solution with existing surveillance system of AEFI, PvPI platforms through DIO at District level and PvPI associate at medical college facility level and can be configured with technology platforms (CoWIN and SAFE vac), where feasible, for timely investigation through DIO, AEFI verification support through medical colleges and management of AEFI cases at health facility.

# • To enhance use of contextualized and timely surveillance evidence for improved program efforts, including crisis communication.

# • To enhance community participation with interactive communication mechanisms that addresses literacy, health literacy and language barriers as a form of improving AEFI response mechanism

# Proposed Key Activities in the PVSSM:

**Piloting a vaccine-recipient centred proactive safety monitoring**

• Pilot a mobile application system to obtain real-time data on post-vaccination follow-up and adverse events by designated Vaccination Safety Surveillance Associates (VSSA). Additionally, village level surveillance volunteers - field health workers, village volunteers, Accredited Social Health Activists (ASHA), Anganwadi Workers (AWW), school teachers, Gram Panchayath members, etc- will be involved.

• Pilot an Interactive Voice Response (IVR) system, SMS and tele-caller support for obtaining post vaccination feedback and active surveillance of COVID 19 post-vaccination events. Additionally, with SMS follow-up, automated WhatsApp follow-up and other interactive systems focused on vaccine-beneficiaries, it is designed to enhance feedback mechanisms including self-reporting.

• Pilot post-Vaccination person scheduled visits for follow-up with identified village level surveillance volunteers. These volunteers will visit high-risk / identified beneficiaries’ residences on 2nd day, 3rd day, and 8th day after the vaccination.

**Intended benefits of the proposed active vaccination safety surveillance and monitoring:**

• The consenting vaccinated beneficiaries enrolled in the VC-19 digital platform uses AI-driven data analytics and algorithms to support decision making by the state vaccination program authorities.

• VC-19 digital platform can desegregate data on the high-risk population– pregnant women, lactating mothers, paediatrics, geriatrics, people with comorbid conditions, etc.

• This Real-time Adverse Event Active Surveillance Platform is powered by AI analytics engine capable of extracting COVID-19 vaccine data aggregation / extraction from various global data sources, social media etc and identifying the potential signal, risk prediction by using various AI and ML algorithms (Figure 2). The data and the information collected through the platform are processed through VC-19 Analytical platform and can be structured into different file formats, that can be submitted as regulatory reports as part of the GVP and the ICH-GCP guidelines.

• The multi-modal communication module has been designed for pro-active communication and solicitation of AE reporting. The mobile app is coupled with the communication engine that is alerted with the vaccine recipient’s registration and vaccination uploaded on the Co-WIN app. 1) The individual receives a SMS of the vaccine administered and of solicitation of vaccination feedback. 2) A configurable daily / weekly/ monthly SMS is sent to report post vaccination events, if any. 3) A SMS to remind the next dose, as necessary.

**HR support for program**

**Existing HR related to AEFI and medical colleges will be primarily utilized. In addition, field based** Vaccination Safety Surveillance Associates (VSSA) and village level surveillance volunteers will be engaged for this pilot study.

• One State AEFI Consultant/ Program Officer/ Surveillance Officer

• Vaccination Safety Surveillance Associates

• Surveillance volunteers

• Support to District Immunization Officer (DIO) in data verification and validation of reported events through district AEFI committees with support of Medical colleges & RISE Hub & Spokes

• Support in categorizing Adverse events into minor, severe and serious AEFIs

**Training support for program**

• Trainings on proactive vaccination safety surveillance to surveillance volunteers for active follow-up of vaccinated beneficiaries for identification and reporting of events.

• All selected pilot district AEFI committee members, medical colleges staffs involved in AEFI surveillance & management will be supported and where required, trained on AEFI surveillance systems, reporting, investigations from the state selected HUB Medical College hospitals.

• Capacity building for sustainability of COVID-19 and routine immunization programs with front line village volunteers (potential surveillance volunteers) who can actively follow up vaccinated beneficiaries at village level, especially when the beneficiaries do not have individual mobile numbers.

# Expected project Outputs and Outcomes:

• A near real-time signal detection with the mobile app data followed through with language appropriate IVRS, Whatsapp, SMSs, and where required, personal visits by the volunteers to collect events data.

• Unique advantage of positioning the data from India alongside the primary data collected prospectively in designated health facilities. This valuable data can map the progression of behaviour challenges and the potential of technology to track and provide feasible solutions.

• The proposed solution will enhance data use for improving program efforts and policy decision for both minor and Severe/ Serious AEFI cases. Severe/ serious events will be reported through the existing surveillance system to enhance patient safety. This will also help in real time actions and causality assessments by AEFI committees.

**Pilot Project Cost**

Total cost for the pilot project will be borne by JHPIEGO through the USAID RISE funds

# Financial Details:

# The proposed collaboration does not have any financial obligations on the State Health Department or RISE health facility.

# JHPIEGO will implement this project and bear the cost of all learning resources, IEC materials, training manuals, job aids, etc related to this project.

# Scale up & Sustainability:

The proposed solution can be easily scaled up as existing manpower and resources will be used for the pilot project including existing State AEFI consultants & District Pharmacist/ Surveillance Officer for technical support and supervision. The technology of the digital tool, server, Mobile app, etc., can be merged into existing state cloud storage for scale-up and sustainability. Based on the outcome of pilot study evaluation, entire state-wide / national wide implementation and replication in Routine Immunization (RI) programs will enhance proactive vaccination safety surveillance and monitoring.

# Data security & ownership:

The ownership of data belongs to the State. JHPIEGO’s role is to provide supportive supervision & technical support. Once integrated, the proposed system can be part of CoWIN and SAFE Vac on existing CoWIN platform.

**Other technical controls / Security Provisions**

• Secured login through multi-factor authentication process

• Timeout data handling

• Role-based access control for restricted access with strong password encryption

• Data storage, maintenance and optimization in the secured cloud and controlled access

• Compliance with Data Privacy guidelines in hosting of data on Cloud

• Restricted Admin access on the Cloud hosted data

• Ensures a validated and compliant Cloud infrastructure

**Global recognition of Proposed Digital Solution on vaccine safety monitoring**

This proposed digital solution 3 Analytics has been recognized by WHO Geneva team for the drug safety surveillance digital solution, which defined a specific process flow/approach for those who met requirements.

**Appendices**

**Table 1: Comparison of AEFI cases reported from India and other countries**

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| --- | --- | --- | --- | --- |
| Region | No. of doses administered | Total No. of AEFIs reported | AEFI per 10000 | References |
| India | 1240000000 | 44000 | 0.3 | CoWIN portal, accessed 2nd December 2021 |
| US | 461000000 | 664745 | 14 | Bloomberg.com, accessed 2 December 2021; VAERS (CDC)  |
| Europe | 428000000 | 412571 | 9.6 | EMA, accessed 28 October 2021 |
| Canada | 59635768 | 26734 | 4.5 | Health-infobase.canada, accessed 26 November 2021 |
| Australia | 38454860 | 83301 | 21.7 | Tga.gov.au, accessed 21 November 2021 |

**Figure 1: VC-19 Platform**

