**Scope Summary Document**

**For**

**PPB - PvERS Project:**

**Pharmacovigilance Electronic Reporting System**

*Version 1.0*

*Prepared By IntelliSOFT Consulting Limited*

*June 2020*

**Revision History**

| **Date** | **Version** | **Description** | **Author** |
| --- | --- | --- | --- |
| July 2020 | 1.1 | Updated system modules/features | Jacqueline Njeri |
| June 2020 | 1.0 | First Draft of the Scope document | Jacqueline Njeri |
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# 1 Background

The pharmacovigilance reporting tools (initially known as Suspected Adverse Drug Reactions form and the Poor Quality Medicinal Products form) were originally available only as hard copies or downloadable PDF-copies from the PPB website. In the year 2012, IntelliSOFT Consulting Limited was contracted to develop the first version of the Pharmacovigilance Electronic Reporting System(PvERS). The system went live in the year 2013. The initiative to transform the paper-based pharmacovigilance data system was supported by USAID through the Management Sciences for Health (MSH).

The PvERS application supported reporting of Suspected Adverse Drug reactions form also known as the “Yellow” form and the Poor Quality Medicinal Products form also known as the “Pink '' form. The digital health technology application was built to be easily accessible via a mobile device, a desktop computer and on the Web. This application was recognized by the World Health Organisation (WHO) Uppsala Monitoring Center (UMC) as the first Vigiflow compatible e-reporting system in Africa.

The agreed upon scope of work is as follows:

1. Incorporate AEFI module for reporting of adverse events from vaccines.
2. Link PVERs system with Clinical Trials Registry.
3. Improve data use, reporting and feedback and user management of the online reporting systems.
4. Institutionalize standards-based interoperability as guided by the Kenya Health Enterprise Architecture blueprint that is guiding the establishment of Kenya’s Health Information Exchange (HIE).
5. Enable Ministry of Health vertical programs like Malaria, HIV, Vaccines and Immunisation to submit ADR to the PvERS. The PvERS will then submit collective reports to DHIS2 powered Kenya Health Information System.

**Project Documentation**

| **Project source code documentation** | <https://github.com/IntelliSOFT-Consulting/pvers/blob/master/README.md> |
| --- | --- |
| **A description of the mechanism for extracting or importing non-personally identifiable information from the system in a non-proprietary format** | Currently data is extracted via PDF/PNG/CSV for individual indicators (e.g gender)  To have all the PII data extractable at once, we can have a provision for the following formats:   1. Directly within the system as a CSV/XML format or 2. Via a RESTful API as JSON |

## 1.2 Definitions, Acronyms and Abbreviations

| **Acronym and Abbreviation** | **Definition** |
| --- | --- |
| ADR | Adverse Drug Reaction |
| AEFI | Adverse Event Following Immunization |
| DHIS2 | District Health Information Software |
| HIE | Health Information Exchange |
| KHIS | Kenya Health Information System |
| MSH | Management Sciences for Health |
| PPB | Pharmacy and Poisons Board |
| PvERS | Pharmacovigilance Electronic Reporting System |
| UMC | Uppsala Monitoring Center |
| USAID | United States Agency for International Development |
| WHO | World Health Organisation |

## 

## 1.3 References Documents

| **No.** | **Title** | **Link** |
| --- | --- | --- |
|  | PvERS Check-in Call\_29th June 2020 | <https://docs.google.com/document/d/1pG1a0JQsPk44qV-DwMMEvNaYv_su6EACdNS4XANqVOI/edit?usp=sharing> |
|  | PvERS<>KHIS Integration meeting 12th June 2020 | <https://docs.google.com/document/d/1RP725r6zwpe2hONubqvMVvEKlFAV-vGNcL7FVeO4dbk/edit?usp=sharing> |
|  | PvERS Check-in Call\_5th June 2020 | <https://docs.google.com/document/d/1EJrmc_l0VqtR0jjMLfyksfarI9A94LAxubZW_642_gg/edit?usp=sharing> |
|  | PvERS Check-in Call\_22nd May 2020 | <https://docs.google.com/document/d/1c2vet-QEDCuzuZ4wV2GSTsYLko7gjB3ApwfpMSgMV8U/edit?usp=sharing> |
|  | PvERS Check-in Call\_15th May 2020 | <https://docs.google.com/document/d/1hIIRdwKOwsXgcgvoD-XL_m1SJIhaW8-f5kR2pJ_qSbY/edit?usp=sharing> |
|  | PvERS Check in Call\_8th May 2020 | <https://docs.google.com/document/d/1D8A-zeQqadCipknOJLRRJXiL9KfwqYJdAlCgJfOPYQk/edit?usp=sharing> |

# 2 System Overview.

## 2.1 Technical Specs.

The system will be an upgrade of the current [Pharmacovigilance Electronic System](http://45.79.161.190/). The database in use is MySQL database which is a relational database and will be maintained as is. The database is password protected ensuring that the data stored in the database is secure.

## 2.2 Applications.

The PvERS system will have additional 4 modules build in addition to the existing modules which include:

* AEFI
* Medical Devices
* Medication Errors
* Transfusion Reaction

Further improvements will be made to the existing modules such as registration.

## 2.3 Deployment.

The current system is designed to be web-based and hence can be accessed remotely using a web browser from any location, as long as the web server is accessible via the internet. This will still be maintained.

## 2.4 Security.

The system is password protected and hence it requires all users of the system to have log-in credentials. Login credentials will be provided by the system administrator.

## 2.5 Scalability.

The system should be scalable and flexible. The system should be designed to handle a large amount of data as long as it is running on the right hardware according to specifications provided.

## 2.6 Integration ready.

The system is expected to be interoperable ready by use of Application Programming Interfaces.

# 3 System Features

This section provides a detailed description of the expected system features.

## 3.1 AEFI

The module will be developed to accommodate the reporting and evaluations of Adverse Events Following Immunization. The process flow for the module will be as follows:

1. The reporter (a facility, individual or health practitioner) logs in into the PvERS.
2. The reporter selects the AEFI module/form and clicks on the Report AEFI button to create a new AEFI form.
3. A pop-up is displayed asking the reporter to confirm they want to start a new AEFI form.
4. The report receives an email notification to complete the report.
5. Once the form is displayed, the reporter is required to fill in the fields as necessary.
6. The reporter receives an email notification once the report is submitted.
7. Any feedback will be viewed in the Feedback tab.
8. The status of the report is displayed on the modules’ dashboard. For example, if the report is not complete, it is displayed as unsubmitted.

## 3.2 Medical Devices

The module will be used for Medical Devices Incident Reporting. The process flow for the module will be as follows;

1. The reporter (a facility, individual or health practitioner) logs in into the PvERS.
2. The reporter selects the Medical Devices module/form and clicks on the Report Medical Devices button to create a new Medical Devices form.
3. A pop-up is displayed asking the reporter to confirm they want to start a new Medical Devices form.
4. The report receives an email notification to complete the report.
5. Once the form is displayed, the reporter is required to fill in the fields as necessary.
6. The reporter receives an email notification once the report is submitted.
7. Any feedback will be viewed in the Feedback tab.
8. The report can be downloaded as a PDF document.
9. The status of the report is displayed on the modules’ dashboard. For example, if the report is not complete, it is displayed as unsubmitted.

## 3.3 Medication Errors

The module will be used for Medication Error Reporting Form. The process flow for the module will be as follows;

1. The reporter (a facility, individual or health practitioner) logs in into the PvERS.
2. The reporter selects the Medication Errors module/form and clicks on the Report Medication Errors button to create a new Medication Errors form.
3. A pop-up is displayed asking the reporter to confirm they want to start a new Medication Errors form.
4. The report receives an email notification to complete the report.
5. Once the form is displayed, the reporter is required to fill in the fields as necessary.
6. The reporter receives an email notification once the report is submitted.
7. Any feedback will be viewed in the Feedback tab.
8. The status of the report is displayed on the modules’ dashboard. For example, if the report is not complete, it is displayed as unsubmitted.

## 3.4 Transfusion Reaction

The module will be used for Adverse Transfusion Reaction reporting. The process flow for the module will be as follows;

1. The reporter (a facility, individual or health practitioner) logs in into the PvERS.
2. The reporter selects the Transfusions Reactions module/form and clicks on the Report Transfusions button to create a new Medication Errors form.
3. A pop-up is displayed asking the reporter to confirm they want to start a new Transfusions Reactions form.
4. The report receives an email notification to complete the report.
5. Once the form is displayed, the reporter is required to fill in the fields as necessary.
6. The reporter receives an email notification once the report is submitted.
7. Any feedback will be viewed in the Feedback tab.
8. The public are able to report on this form on the Reports tab without logging into the system.
9. The status of the report is displayed on the modules’ dashboard. For example, if the report is not complete, it is displayed as unsubmitted.