SYSTEM TRAINING DOCUMENT
For
VACCCINE ADVERSE EVENTS INFORMATION
MANAGEMENT SYSTEM

Submitted by:

Dure Technologies Private Limited, India

Contents

Introduction and User Roles

The Document / User Manual contains all essential information for the user to make full use of the information system. This manual includes a description of the system functions and capabilities, and step-by-step procedures for system access and use.

There are three types of system users in VAEIMS system :

DIOUSER : District Officer who uses the system to key in information about the adverse case reported with CRF / PCIF forms.

The DIO can

- ✓ Register cases only for the district he is mapped to. *Cross Reporting of Cases is currently not supported in the system.*
- ✓ Data Entry of the Case Reported with CRF , PCIF forms Do Complete Data Entry of the Case Reported . The form has been designed
- ✓ Use system for Weekly Data Entry (NIL REPORTING)
- ✓ Attach the soft / scanned original copy of the case
- ✓ Attach documents (soft copies) as Supporting Data (FIR / Hospital Reports etc)
- ✓ Save the details in CRF / PCIF forms before final review and submission.
- ✓ Once Case is Submitted the DIO cannot edit / change the details of the form.
- ✓ Interact / Provide feedback on case issues with Zonal / State officer and take corrective action on data gaps if any.
- ✓ Have Access to a personalised district dashboard which gives details of the cases reported , submitted.

State / National Users : Review and Correct data submitted by DIO.

SIO / National User can

- ✓ Review and Override details entered by DIO for CRF / PCIF forms
- ✓ Provide Feedback on details entered by DIO user
- ✓ Do data entry for the Final Case Data Entry for the case reported
- ✓ Attach documents (soft copies) as Supporting Data (FIR / Hospital Reports etc)

System Modules

- ## Authentication / User Access :

The System Hierarchy has been defined as National – State – District Level. Each user will be given specific user rights and levels in which data can be accessed.

User Role / Matrix for VAEIMS System			
Document / Forms	**DIO**	**State**	**National**
CRF	Add	Edit	Edit
PCIF	Add	Edit	Edit
FCIF	Read	Read	Add / Edit

* DIO user will be allowed to add / edit data for the specific district only. State User can view / edit data only for that state and for districts under that state. All Rights are post Submission.

- ## Case Reporting

VAEIMS system has been primarily designed to digitize and support data entry for CRF , PCIF and FCIF forms with features to upload documents of the scanned copies of the original hard copies of the forms.

- ## Uploading of Documents

For every case reported the user can upload the scanned copy of the original document , supporting documents like the Post Mortem Reports , Hospital Records and any other relevant document for the Case Reported. The Documents will be stored in a central repository to ensure Nil Loss of Data and Quick & Easy Access for State / National Users.

- ## Accessing Case Information

On Submission of a case in the System through CRF the State / National users automatically receive an email / notification of the case. On Accessing the system they can view all the data / support documents that have been submitted. The Case can be reviewed instantaneously and also quick feedback can be provided.

- ## Reports / MIS

Specific Reports / MIS will be generated based on the information / data collected. This information will be useful to derive at Key Indicators and easy view of aggregated data to take corrective action.

- ## Feedback / Notification

Easy method to give online feedback and chat with user for missing information / details on any case that has been submitted. On Feedback the user receives an email and a notification which helps in taking corrective action on data updating required.

- ## Dashboard

Informative Dashboard designed for Monitoring and Assessing the Cases that have been reported , Submissions and Period.

- ## Weekly Data Entry

Feature to update the Weekly Entries for Nil Reporting for DIO Users. This information can be extracted as report and evaluated as against cases reported.

Authentication

Every user will be user id and password details based on the role / access given in the organisation hierarchy.
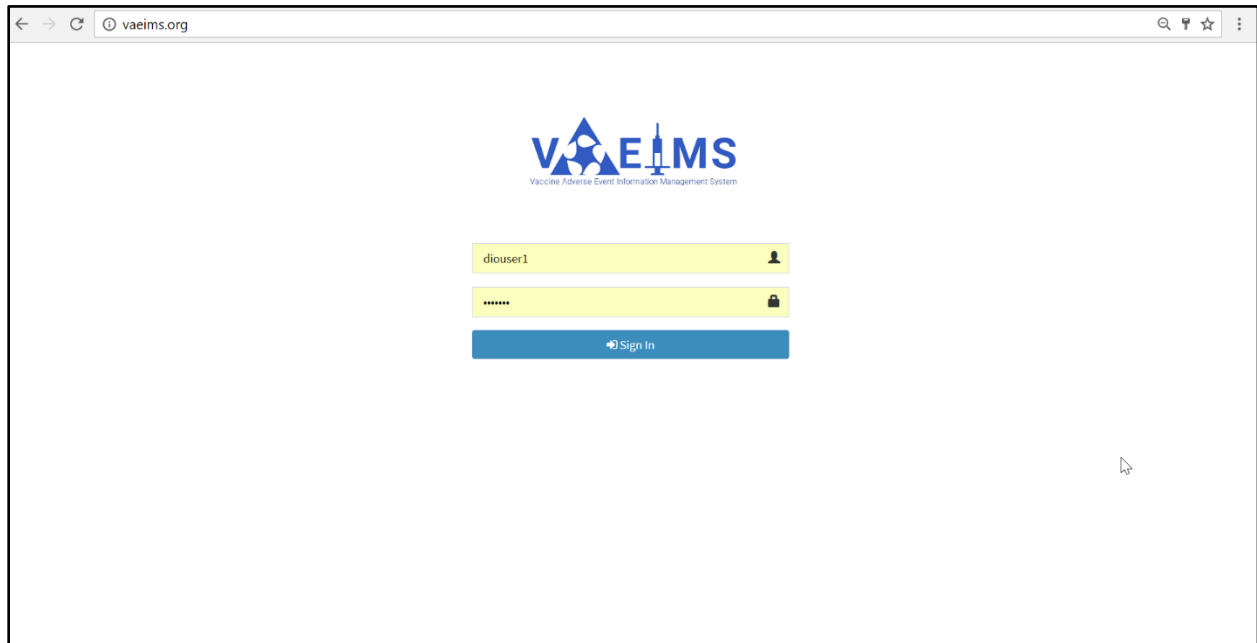
Based on the user details given the system will direct the user to the restricted access to the system based on the roles / rights allocated.

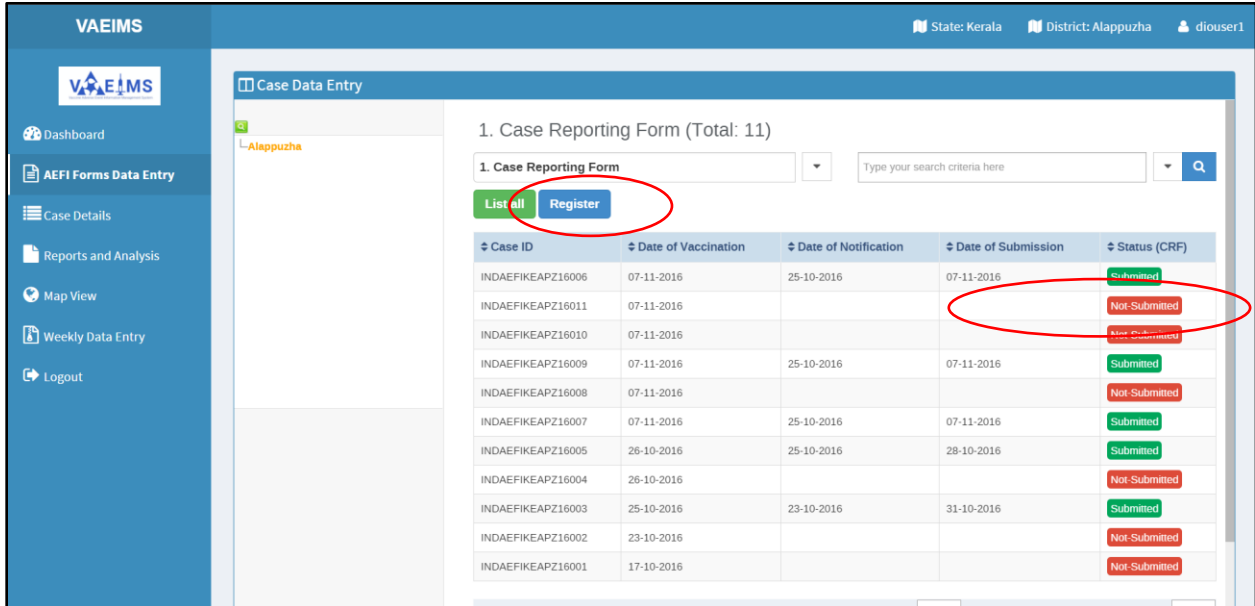# Case Reporting

Step by Step Process for CRF Entry

1) From the Menu choose AEFI forms data entry.
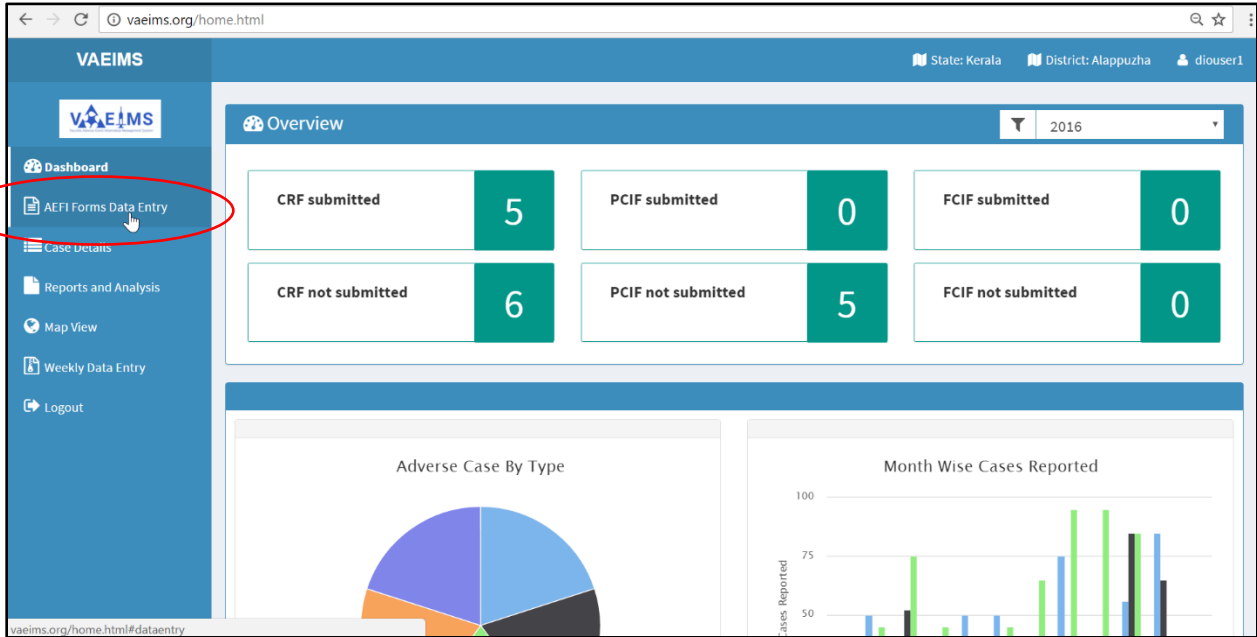
2) Choose the Relevant form from the options provided.
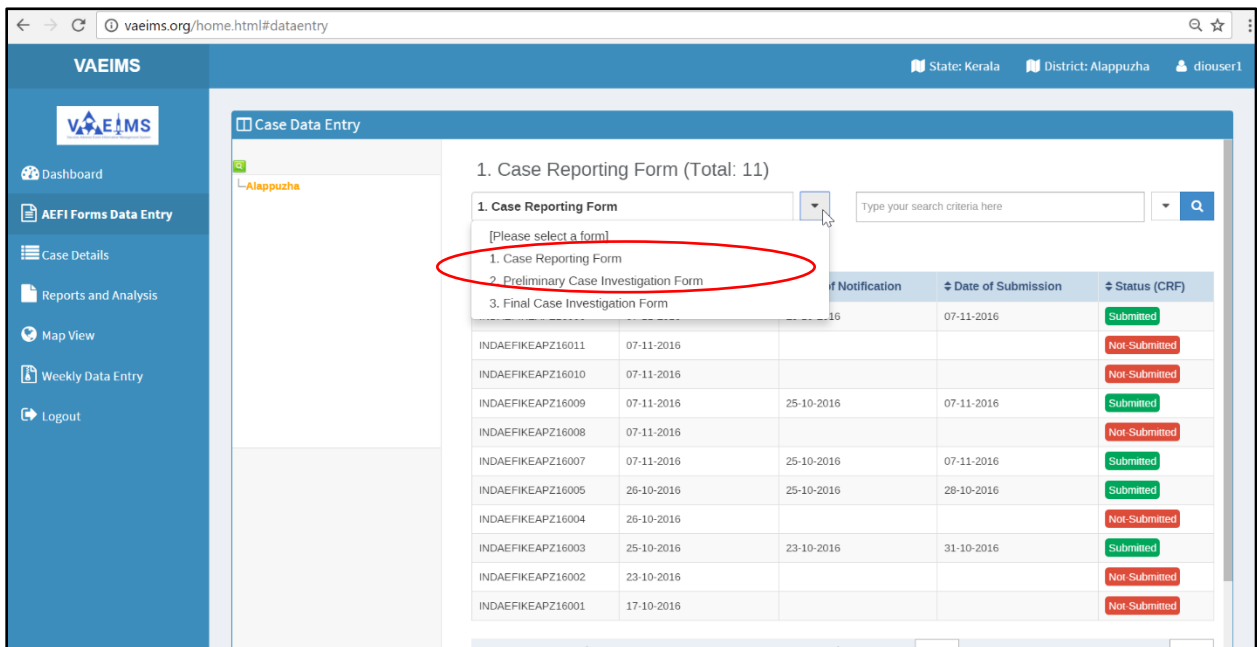
3) Click on Register for New Form Entry OR Click on Non-Submitted for updating the details of an existing case.

4) On click of REGISTER , fill in the **"Date of Vaccination "**and click on Save and Continue , based on the District of the User and other details a unique AEFI id is generated.

Case Register

| 1. Case Reporting Form | ▼ | Type your search criteria here | ▼ | 🔍 |

List all **Register**

| Today's Date | 07-11-2016 |

Profile

Case ID

Date of Vaccination*   **07-11-2016**

Save and continue **Cancel**

🔲 Case Data Entry

Back ◄ ► 1. Case Reporting Form   ▼   ⚙

| Case ID | **INDAEFIKEAPZ16012** |
| Date of Vaccination* | **07-11-2016** |

📖 **AEFI CASE REPORTING FORM (CRF)**

📄 **Page 1**

📄 **Page 2**

⊕ **Case Reporting Form | Upload Supporting Documents**   ✚

⊕ **Case Reporting Form | Upload Scanned Documents**   ✚
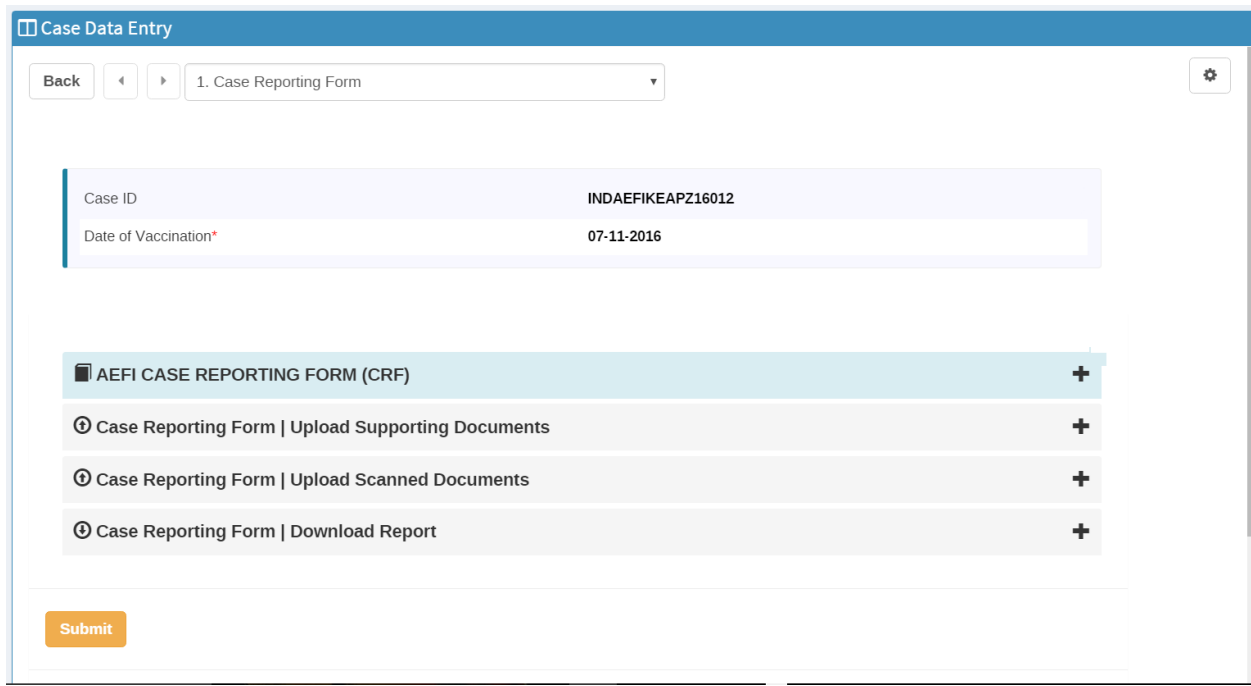
⊕ **Case Reporting Form | Download Report**   ✚

> Unique Case ID is generated based on the State / District, Year & Sequence no

5) The CRF form is divided into multiple sections for easy access and data fill. On click of the "+" sign the relevant section is displayed.

Each section can be viewed by clicking on the "+" sign.

Dure Technologies
UNLOCKING REAL VALUE OF DATA

📋 AEFI CASE REPORTING FORM (CRF)   ✚

📄 Page 1   ✚

Section A (To be submitted by MO within 24 hours of case notification to DIO)

State
☰ Kerala   ✕ ▾

District
☰ Alappuzha   ✕ ▾

Block/Ward:
☐ Block ☐ Ward

Village/Urban Area
☐ Village ☐ Urban Area

Name of reporting MO *
👤 Name of reporting MO

Today's Date
📅 dd-MM-yyyy

Posted At   **Designation**
🏷 Posted At

Time of preparing this form (hh:mm AM/PM)
--Select-- --Select-- ▾

> Validations at relevant and required fields have been provided to ensure quality data entry.

Phone # Should be 10 digits ◄
📞 (845)555-1212

Notified by
👤 Notified by

📄 Page 2   ✚

Current status
--Select--   ▾

If died, Date of death
📅 dd-MM-yyyy

Time of death (hh:mm AM/PM)
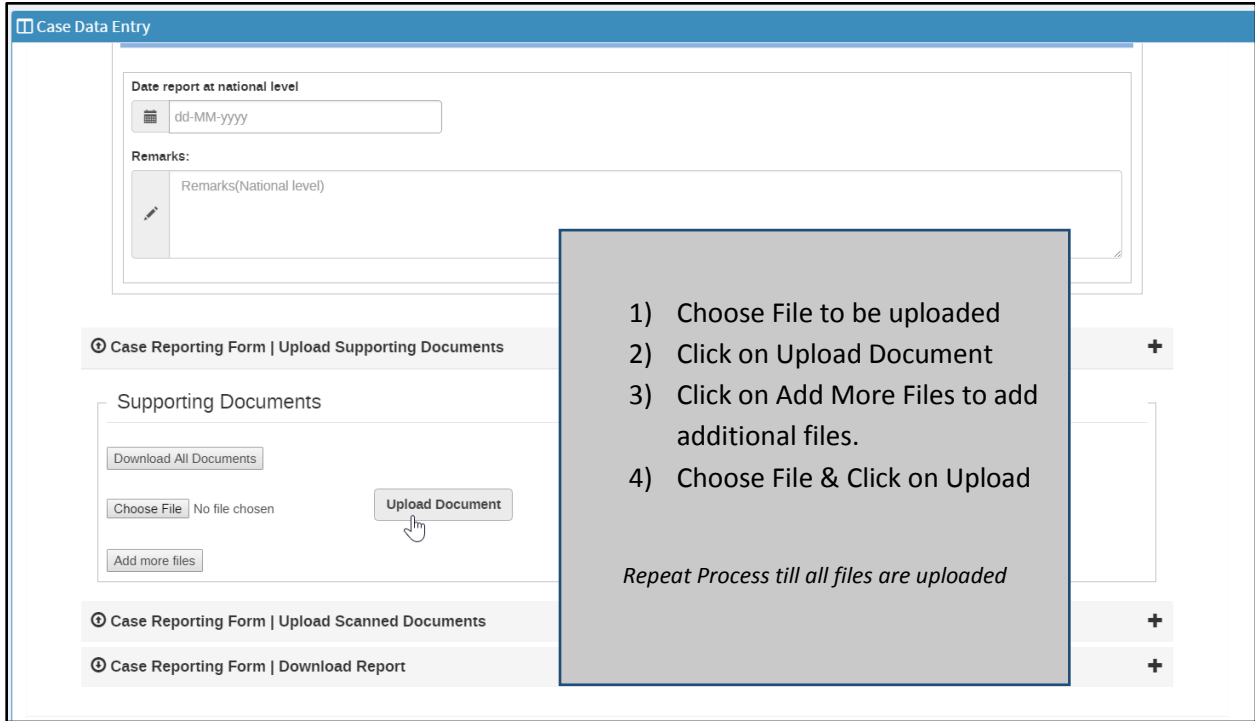--Select-- --Select-- --Select-- ▾

Post mortem done ?
--Select--   ▾

if Yes, Then date of post mortem done
📅 dd-MM-yyyy

If not done, but planned, Planned Date
📅 dd-MM-yyyy

Describe AEFI *(sign and symptoms)*
✏ Sign and Symptoms

ⓘ Suspected adverse event(s) (tick at least one)

☐ **Severe local reaction** *
   ☐ >3 days
   ☐ beyond nearest joint

☐ **Seizures**
   ☐ febrile
   ☐ afebrile

☐ Abscess ☐ Sepsis ☐ Encephalopathy ☐ Toxix shock syndrome ☐ Thrombocytopenia ☐ Anaphylaxis ☐ Intussusception

☐ Fever >=39 C(102 F) ☐ Hyptonic hyporesponsive episode (HHE) ☐ Acute flaccid paralysis ☐ Sudden unexplained death syndrome

6) There is section to upload the support documents like scanned copy of the hospital reports / xrays etc along with the CRF data submission.

Case Data Entry

Date report at national level

dd-MM-yyyy

Remarks:

Remarks(National level)

⊕ Case Reporting Form | Upload Supporting Documents   +

Supporting Documents

Download All Documents
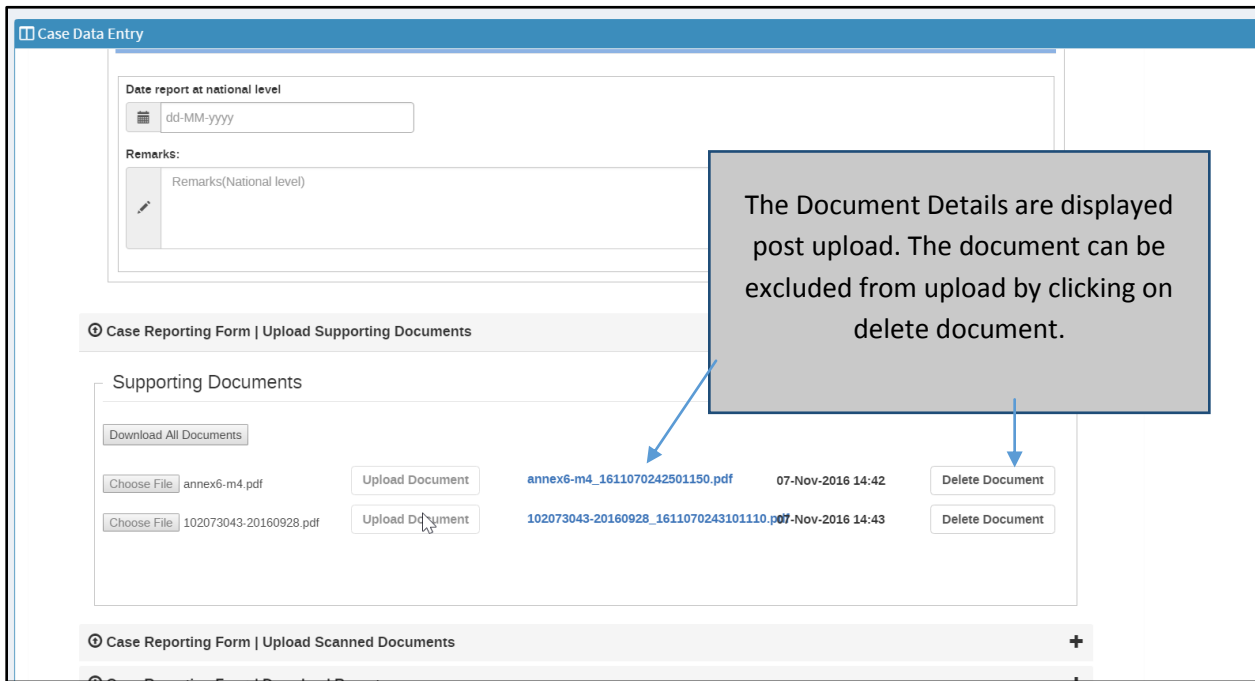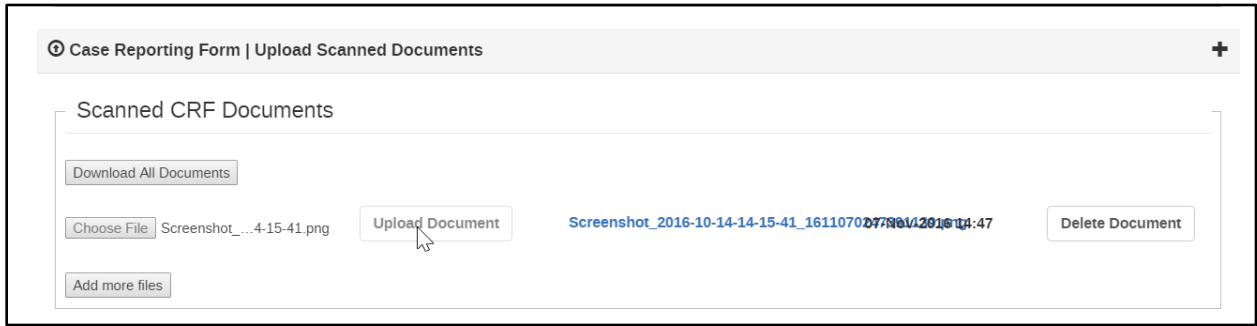
Choose File No file chosen   Upload Document

Add more files

1) Choose File to be uploaded
2) Click on Upload Document
3) Click on Add More Files to add additional files.
4) Choose File & Click on Upload

Repeat Process till all files are uploaded

⊕ Case Reporting Form | Upload Scanned Documents   +
⊕ Case Reporting Form | Download Report   +

Case Data Entry

Date report at national level

dd-MM-yyyy

Remarks:

Remarks(National level)

⊕ Case Reporting Form | Upload Supporting Documents

Supporting Documents

Download All Documents

Choose File annex6-m4.pdf   Upload Document   annex6-m4_1611070242501150.pdf   07-Nov-2016 14:42   Delete Document

Choose File 102073043-20160928.pdf Upload Document   102073043-20160928_1611070243101110.pdf 07-Nov-2016 14:43 Delete Document
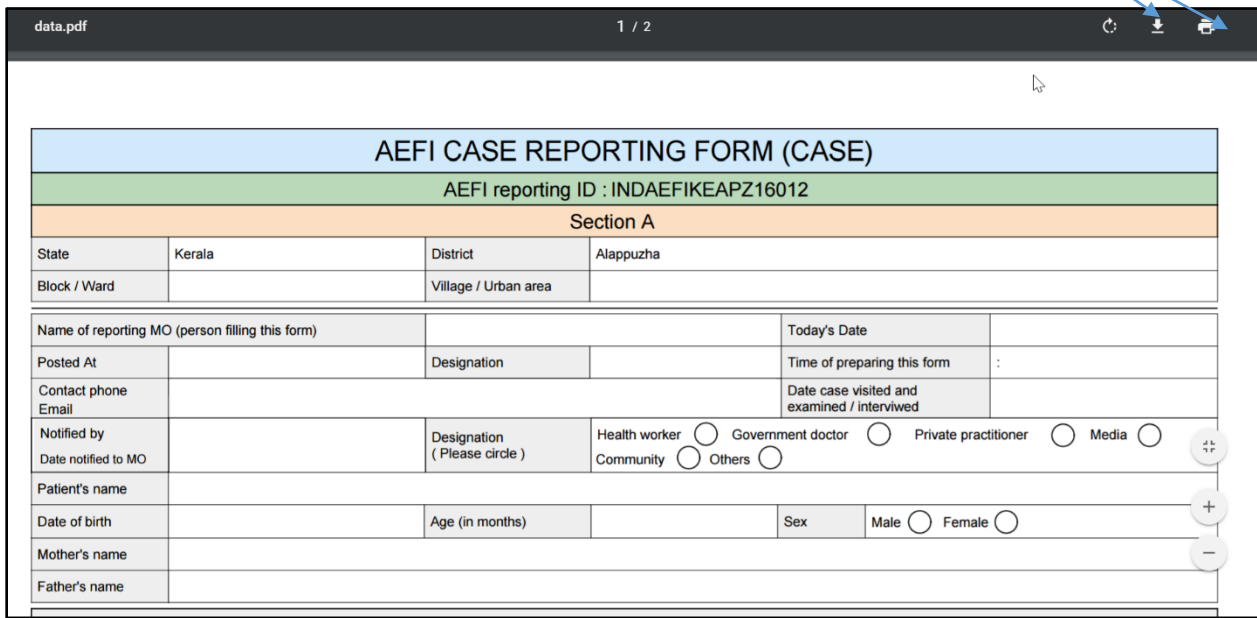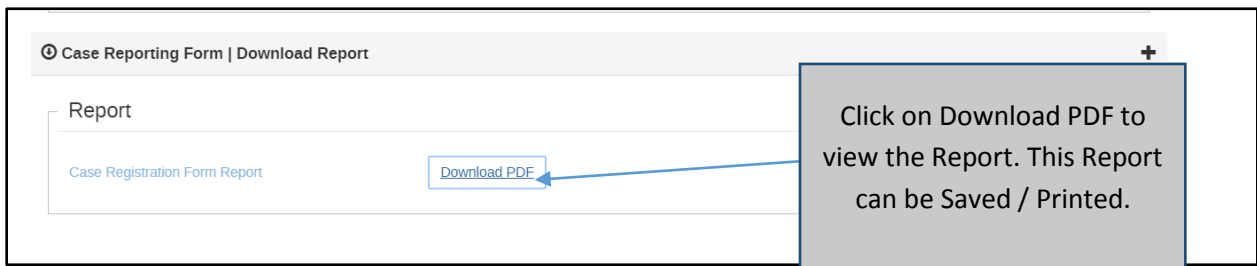
The Document Details are displayed post upload. The document can be excluded from upload by clicking on delete document.

⊕ Case Reporting Form | Upload Scanned Documents   +

7) The CRF scanned copy can be attached through the CRF upload Scanned Documents section.

ⓘ **Case Reporting Form | Upload Scanned Documents**   **+**

Scanned CRF Documents

[Download All Documents]

[Choose File] Screenshot_...4-15-41.png   [Upload Document]   **Screenshot_2016-10-14-14-15-41_16110702NNov/12018 14:47**   [Delete Document]

[Add more files]

---

8) The Details of the CRF case can be viewed through the CRF report for review before submission.

ⓘ **Case Reporting Form | Download Report**   **+**

Report

Case Registration Form Report   [Download PDF]

> Click on Download PDF to view the Report. This Report can be Saved / Printed.

---

data.pdf   1 / 2

AEFI CASE REPORTING FORM (CASE)

AEFI reporting ID : INDAEFIKEAPZ16012

Section A

State	Kerala	District	Alappuzha		
Block / Ward		Village / Urban area			

Name of reporting MO (person filling this form)			Today's Date	
Posted At		Designation	Time of preparing this form	:
Contact phone Email			Date case visited and examined / interviwed	
Notified by Date notified to MO		Designation (Please circle)	Health worker ◯ Government doctor ◯ Private practitioner ◯ Media ◯ Community ◯ Others ◯	
Patient's name				
Date of birth		Age (in months)		Sex	Male ◯ Female ◯
Mother's name				
Father's name				

9) On Click of the Submit Button the CRF is submitted and ready for review for the zonal / state officers. An auto email is send to the required designated users notifying the users regarding the reporting of a case.

Step by Step Process for PCIF Entry

The PCIF can be filled for Submitted CRFs only. Once the CRF is submitted for a case the data automatically gets prepopulated for a PCIF form.

1) To fill PCIF form click on the AEFI Data Entry and Choose PCIF Option. All the CRFs that have been submitted are listed.

2) Click on the CASE for which the PCIF needs to be submitted. The details filled in CRF will be pre populated to avoid entry duplication. The user can update the details entered.

3) The PCIF has been designed in sections for easy entry

4) On Click of the "+" the page details will be displayed.

5) Click on the submit button after all the details have been entered and documents have been attached as part of PCIF.

![Dure Technologies - UNLOCKING REAL VALUE OF DATA]

Components Of Dashboard

1. Indicators
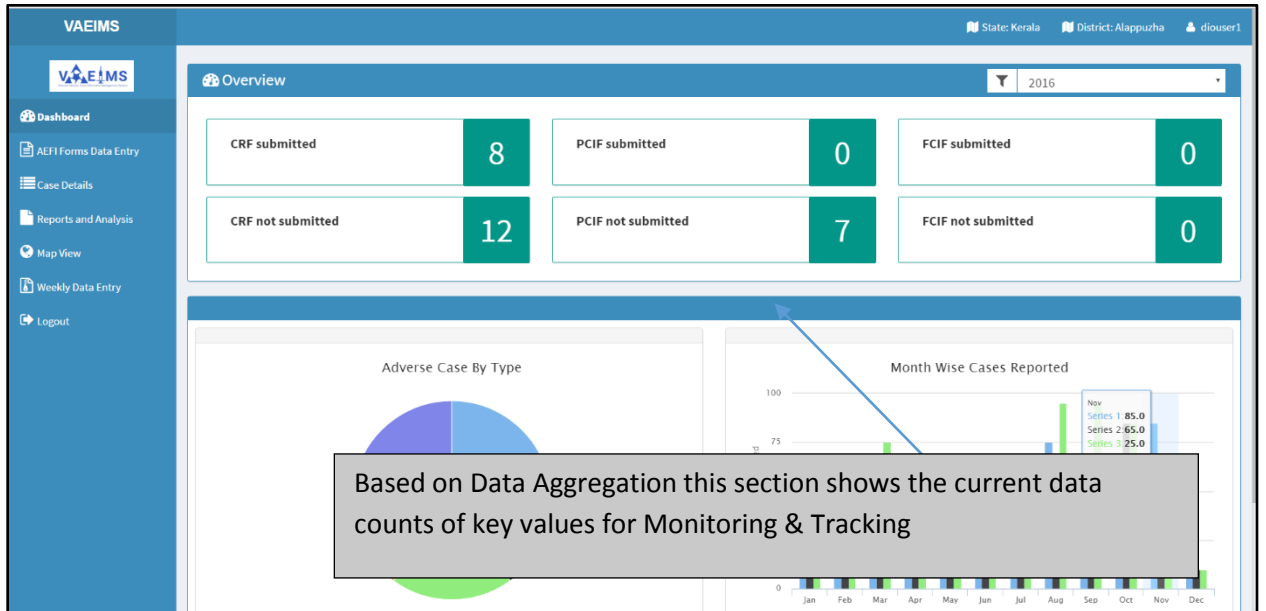
The Values are calculated as per data that is entered on a real-time basis and are restricted to the user id. For e.g The DIOUSER can view the data for his specific district only. Similarly the state user will be able to view the data for only that state.

2. Real-time Monitor

Gives an overview of the cases Submitted under that District for a quick review

3. Case Details
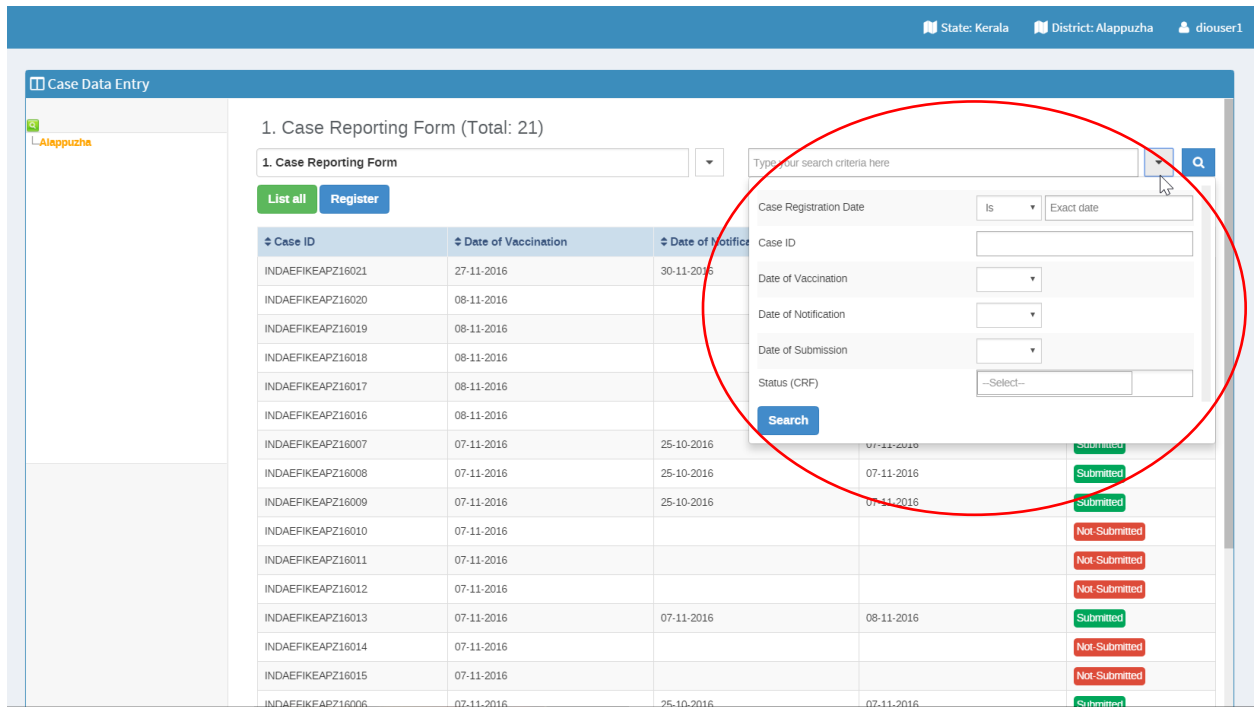
Displays the Summary for all the forms that have been entered for that district and their status (Submitted / Non – Submitted)

It gives the Case ID , Status and Date of Vaccination.

Easy Search

A specific case can also be viewed using the easy search option.

- Search can be based on Case Id , Date of Vaccination , Submission and Notification.
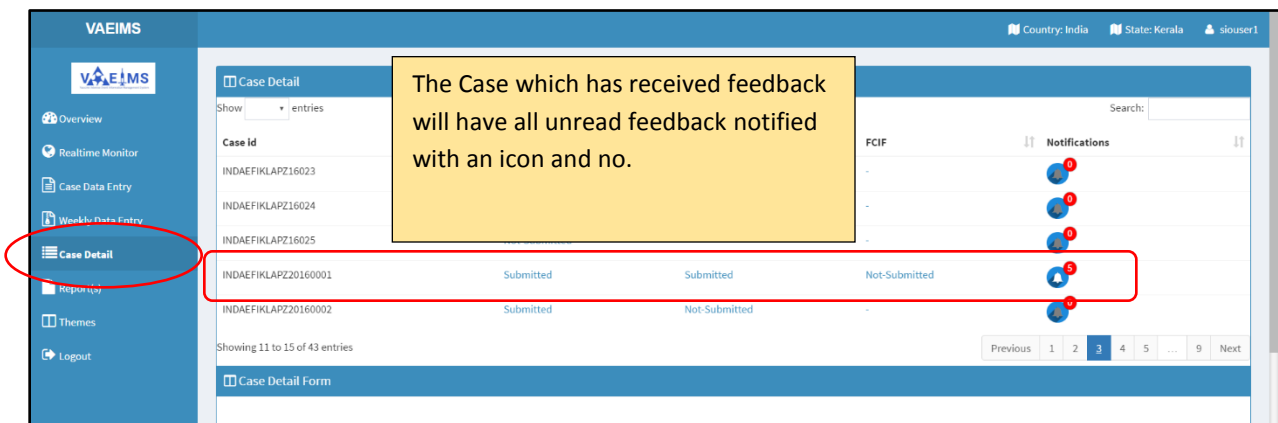- List All is an option to view the default list of all the cases

Feedback Feature

There is feature in the system where the State User can notifiy the District user on Missing Informaton Or any other feedback on the case on a real time basis.
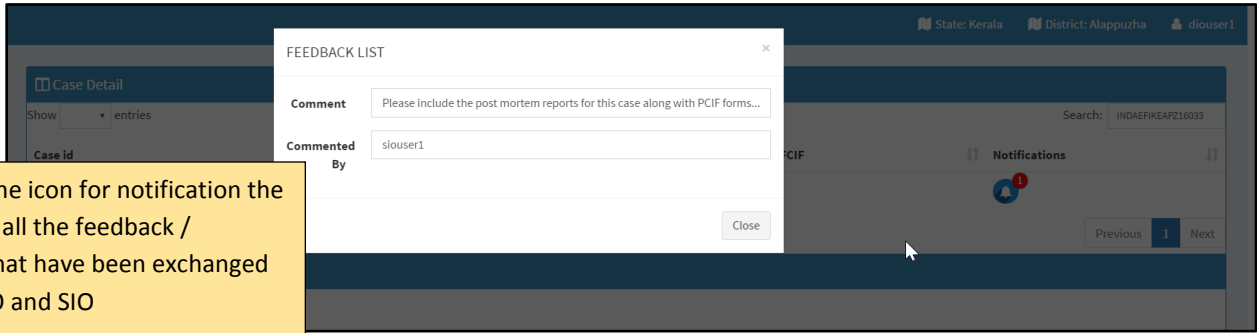

SIO User can enter the feedback for any case in this case and click on the SEND button

Once the comments are submitted the DIO user will receive an email and also an alert in the system. The feedback can be viewed by clicking on the Case Detail option in the Left Menu Bar.

The Case which has received feedback will have all unread feedback notified with an icon and no.

On clicking the icon for notification the user can see all the feedback / comments that have been exchanged between DIO and SIO

Weekly Data Entry

For Nil Reporting Cases the User can enter data by choosing *"Weekly Data Entry"* Menu option. The Weeks for which the data needs to be filled has to be chosen