

SYSTEM TRAINING DOCUMENT
For
VACCINE ADVERSE EVENTS INFORMATION
MANAGEMENT SYSTEM

Submitted by:

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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**

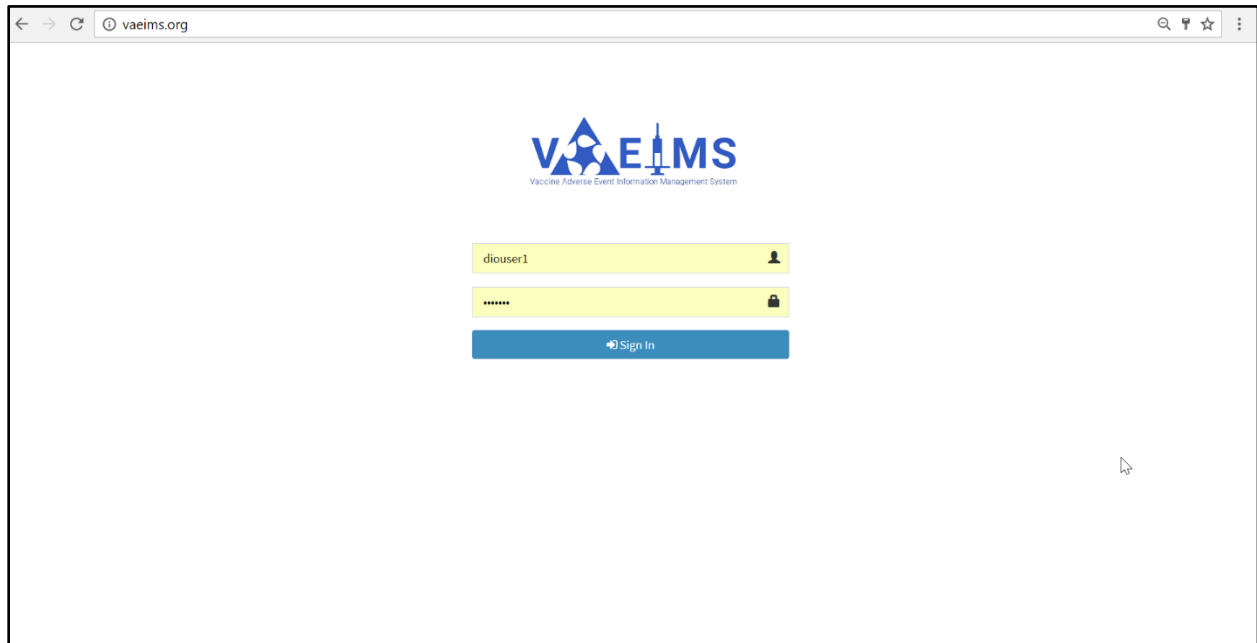
Informative Dashboard designed for Monitoring and Assessing the Cases that have been reported , Submissions and Period.

- **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.

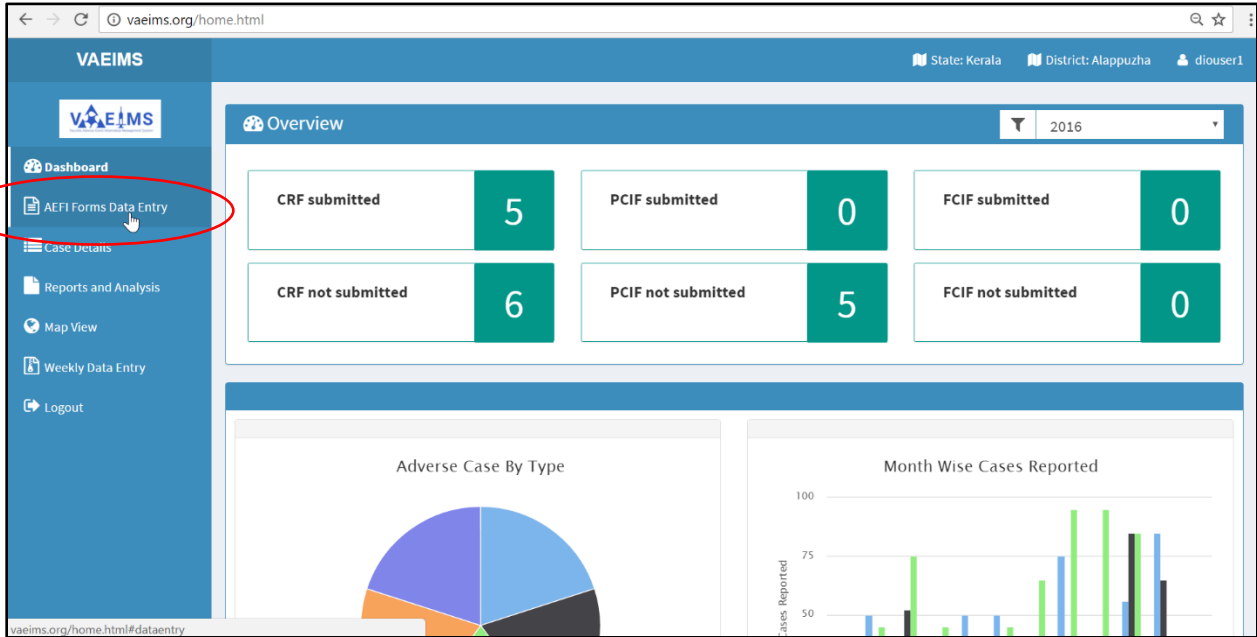


Based on the user details given the system will direct the user to the restricted access to the system based on the roles / rights allocated.

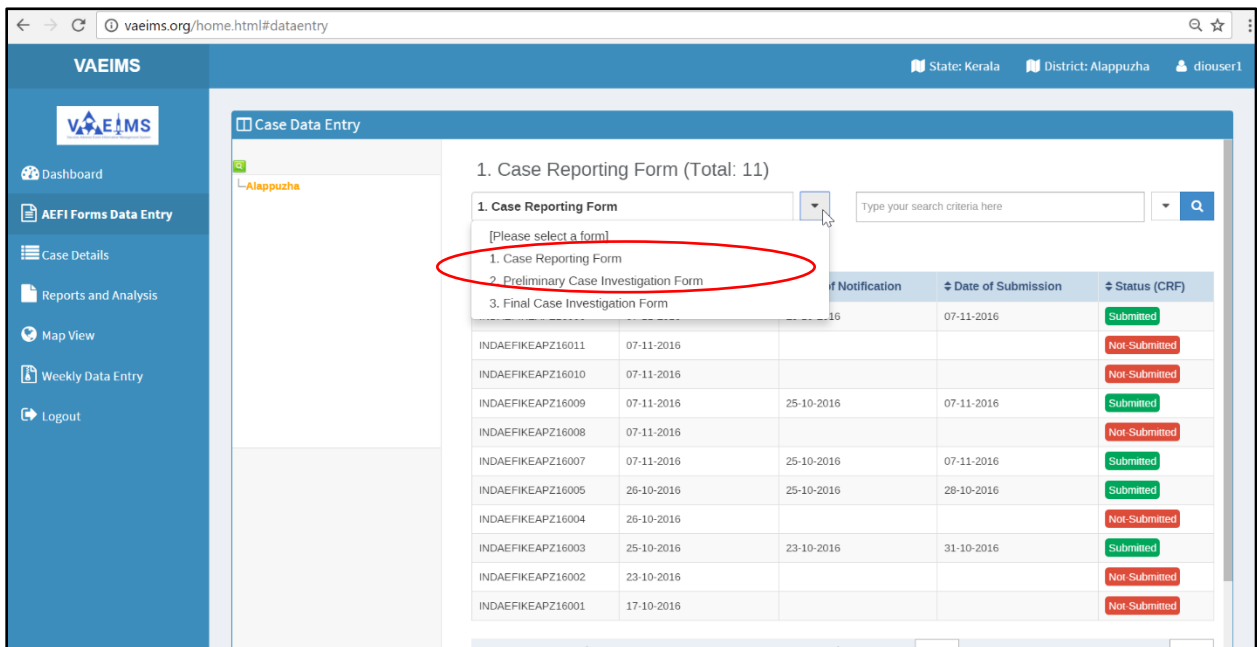
Case Reporting

Step by Step Process for CRF Entry

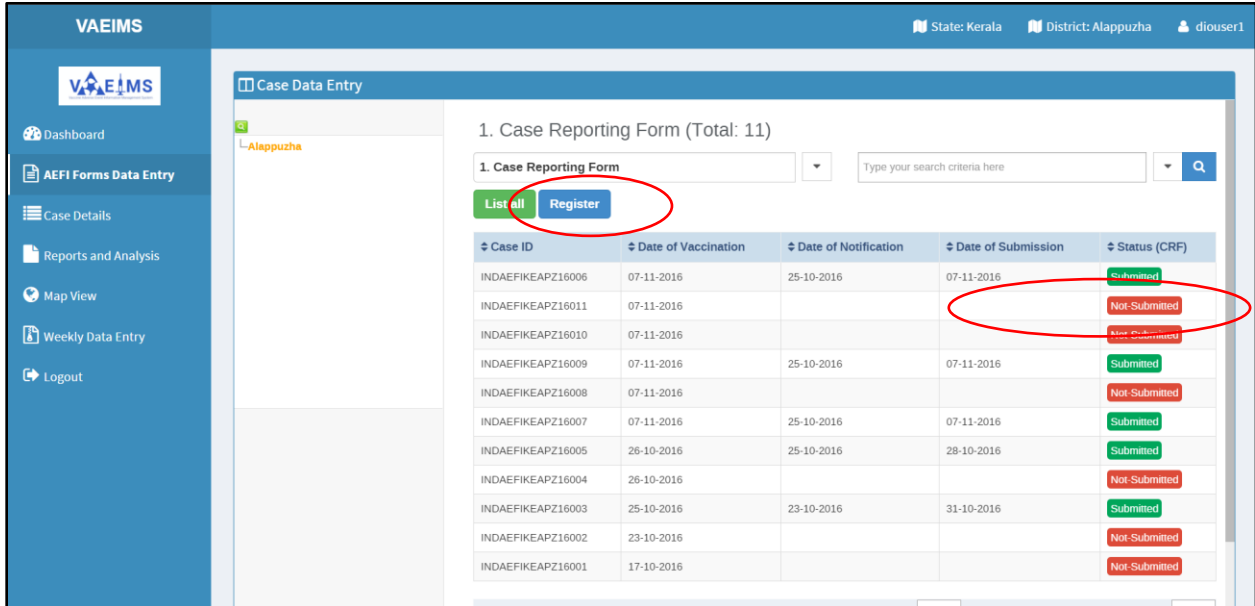
1) From the Menu choose AEFI forms data entry.



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.



The screenshot displays the VAEIMS Case Data Entry interface. The left sidebar contains navigation options: Dashboard, AEFI Forms Data Entry, Case Details, Reports and Analysis, Map View, Weekly Data Entry, and Logout. The main content area is titled "Case Data Entry" and shows "1. Case Reporting Form (Total: 11)". Below this, there is a search bar and two buttons: "List all" and "Register". The "Register" button is circled in red. Below the buttons is a table with the following columns: Case ID, Date of Vaccination, Date of Notification, Date of Submission, and Status (CRF). The table contains 11 rows of data. The second row, with Case ID INDAEFIKEAPZ16011, has a "Not-Submitted" status, which is also circled in red.

Case ID	Date of Vaccination	Date of Notification	Date of Submission	Status (CRF)
INDAEFIKEAPZ16006	07-11-2016	25-10-2016	07-11-2016	Submitted
INDAEFIKEAPZ16011	07-11-2016			Not-Submitted
INDAEFIKEAPZ16010	07-11-2016			Not-Submitted
INDAEFIKEAPZ16009	07-11-2016	25-10-2016	07-11-2016	Submitted
INDAEFIKEAPZ16008	07-11-2016			Not-Submitted
INDAEFIKEAPZ16007	07-11-2016	25-10-2016	07-11-2016	Submitted
INDAEFIKEAPZ16005	26-10-2016	25-10-2016	28-10-2016	Submitted
INDAEFIKEAPZ16004	26-10-2016			Not-Submitted
INDAEFIKEAPZ16003	25-10-2016	23-10-2016	31-10-2016	Submitted
INDAEFIKEAPZ16002	23-10-2016			Not-Submitted
INDAEFIKEAPZ16001	17-10-2016			Not-Submitted

- 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 ▼ ▼

Today's Date

Profile

Case ID

Date of Vaccination*

Case Data Entry

Back ◀ ▶ 1. Case Reporting Form ⚙

Case ID

Date of Vaccination*

AEFI CASE REPORTING FORM (CRF)

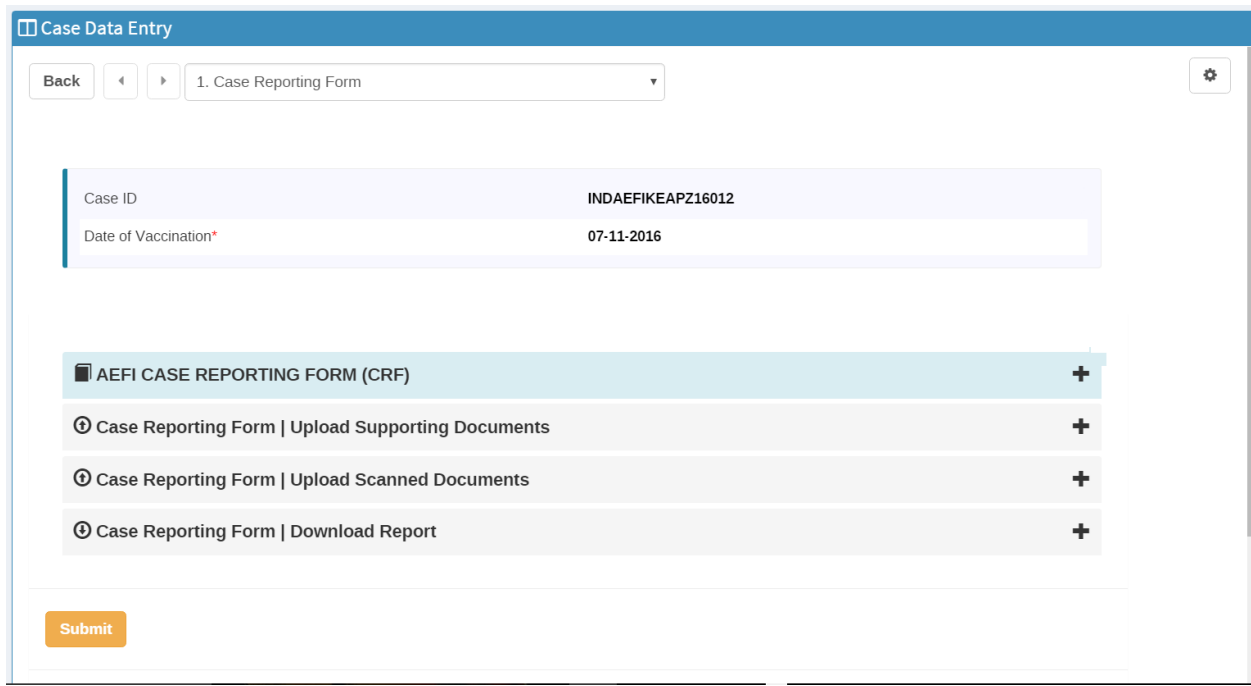
+

+

+

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.



The screenshot shows a web interface titled "Case Data Entry". At the top, there is a navigation bar with a "Back" button, left and right arrow buttons, and a dropdown menu currently showing "1. Case Reporting Form". A settings gear icon is located in the top right corner. Below the navigation bar, there is a table with two rows of data:

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

Below the table, there is a list of four expandable sections, each with a plus sign (+) on the right:

- AEFI CASE REPORTING FORM (CRF) +
- Case Reporting Form | Upload Supporting Documents +
- Case Reporting Form | Upload Scanned Documents +
- Case Reporting Form | Download Report +

At the bottom left of the form, there is an orange "Submit" button.

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

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: [Posted At] **Designation:** [Designation] **Time of preparing this form (hh:mm AM/PM):** [Time of preparing this form]

Phone # *Should be 10 digits* (845)555-1212 **Reviewed:** [Reviewed]

Notified by: [Notified by]

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

Page 2

Current status: --Select--

If died, Date of death: dd-MM-yyyy **Time of death (hh:mm AM/PM):** --Select-- --Select-- --Select--

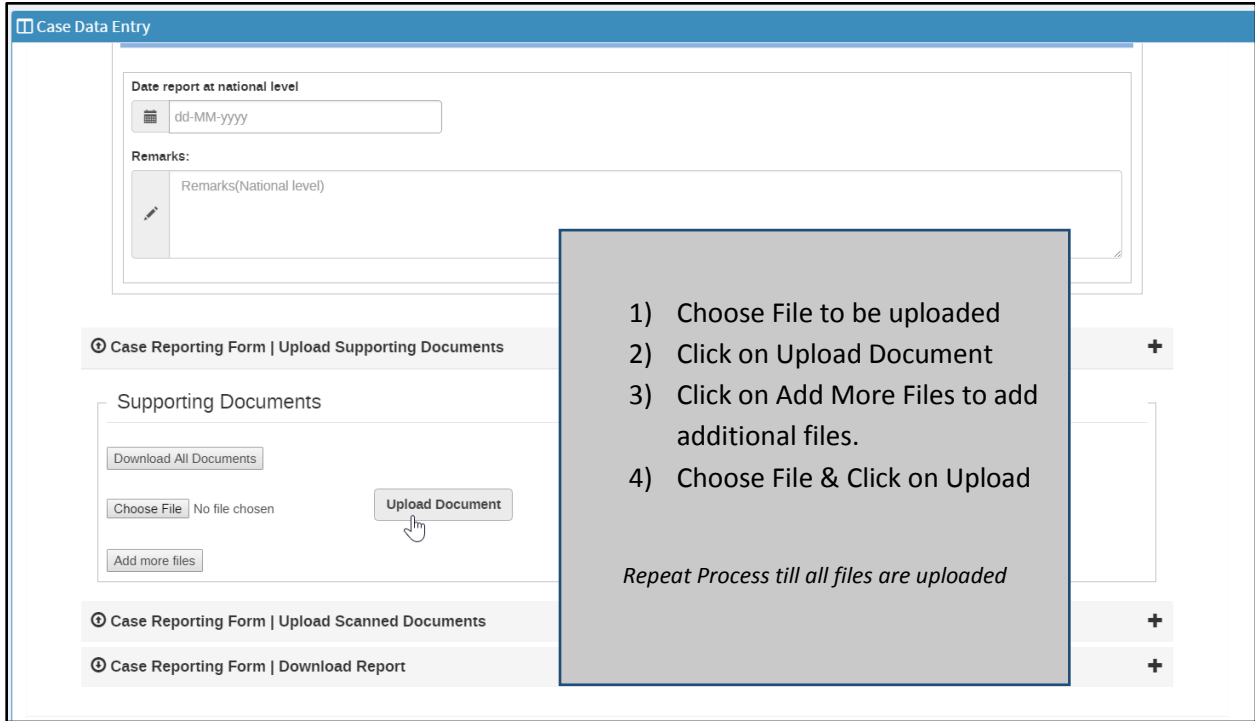
Post mortem done ? --Select-- **if Yes, Then date of post mortem done:** dd-MM-yyyy **If not done, but planned, Planned Date:** dd-MM-yyyy

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

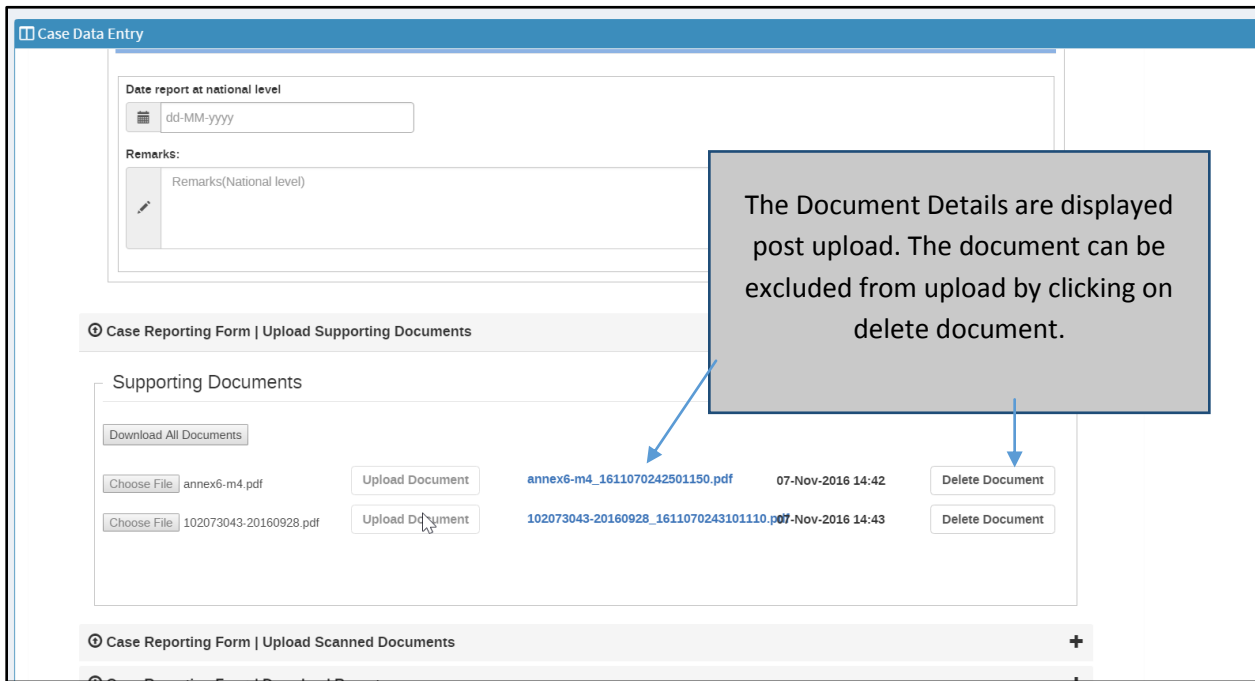
Add more files

Case Reporting Form | Upload Scanned Documents

Case Reporting Form | Download Report

- 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 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

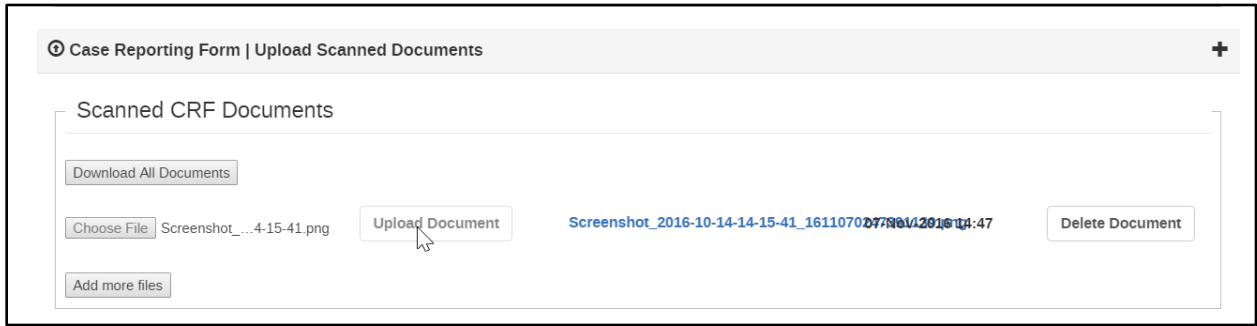
Choose File annex6-m4.pdf Upload Document annex6-m4_1611070242501150.pdf 07-Nov-2016 14:42 Delete Document

Choose File 102073043-20160928.pdf Upload Document 102073043-20160928_1611070243101110.pdf 07-Nov-2016 14:43 Delete Document

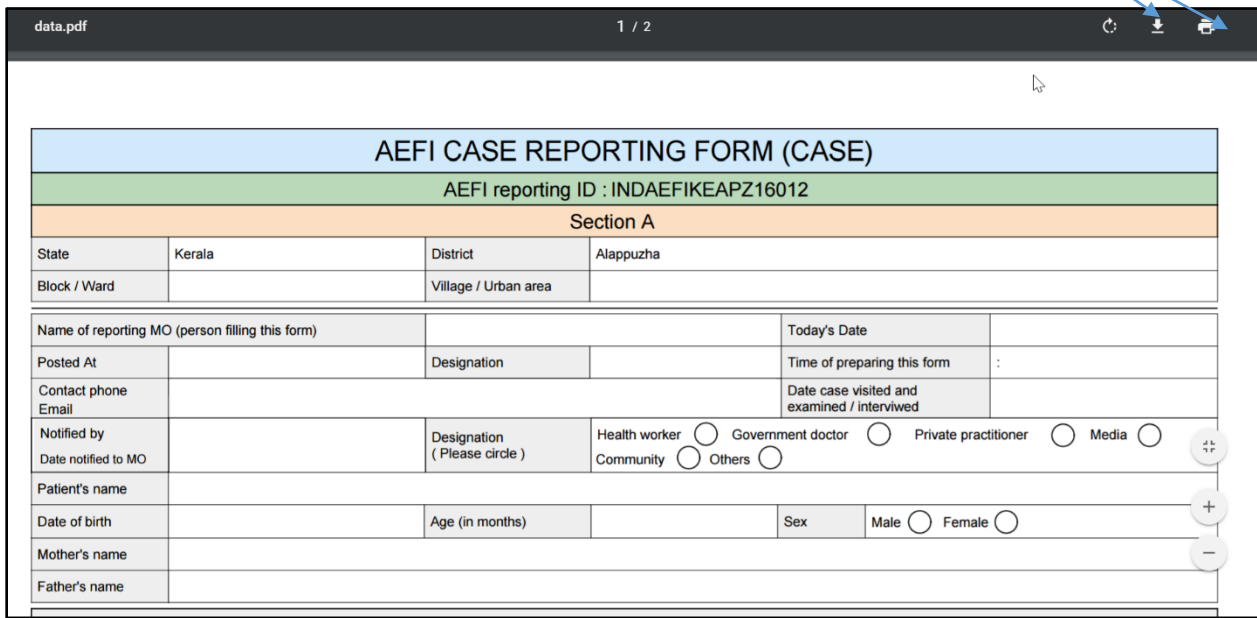
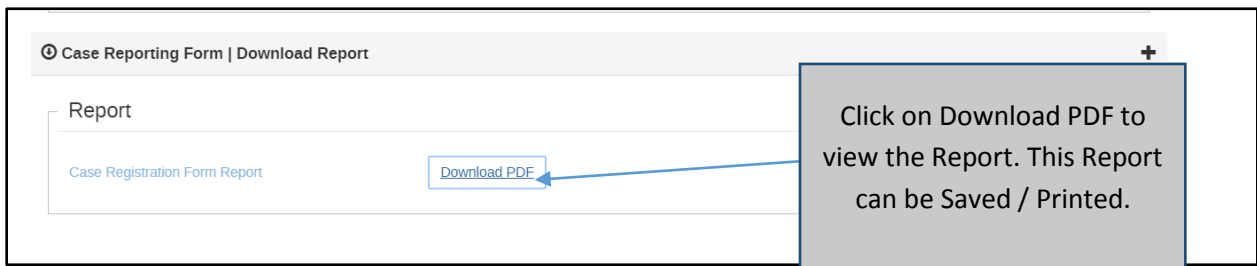
Case Reporting Form | Upload Scanned Documents

The Document Details are displayed post upload. The document can be excluded from upload by clicking on delete document.

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



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



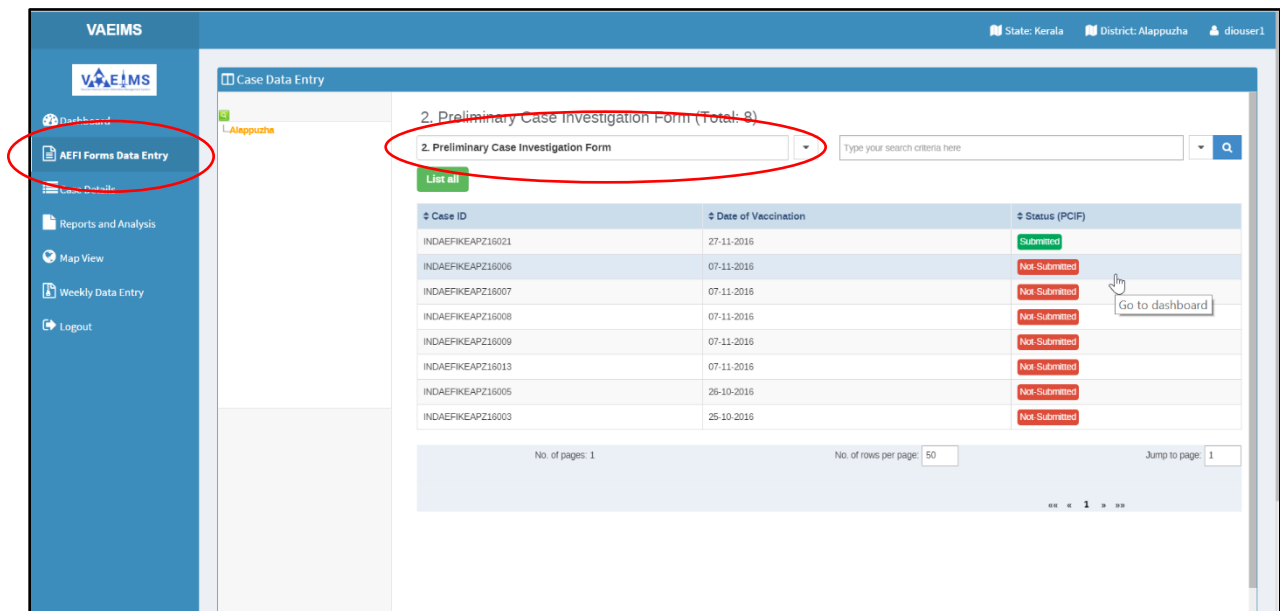
- On Click of the Submit Button the CRF is submitted and ready for review for the zonal / state officers. An auto email is send to the required designated users notifying the users regarding the reporting of a case.



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.

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



Case ID	Date of Vaccination	Status (PCIF)
INDAEFIKEAPZ16021	27-11-2016	Submitted
INDAEFIKEAPZ16006	07-11-2016	Not Submitted
INDAEFIKEAPZ16007	07-11-2016	Not Submitted
INDAEFIKEAPZ16008	07-11-2016	Not Submitted
INDAEFIKEAPZ16009	07-11-2016	Not Submitted
INDAEFIKEAPZ16013	07-11-2016	Not Submitted
INDAEFIKEAPZ16005	26-10-2016	Not Submitted
INDAEFIKEAPZ16003	25-10-2016	Not Submitted

- 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.

Casr Data Entry

Name of investigator: Date case visited and investigated:

Posted At: Designation:

Date preparing this form:
Time of preparing this form(hh:mm AM/PM):
This report is: Preliminary Final

Contact phone number: E-Mail:

Patient's name:

Sex: Date of birth: Age (in days): Age (in months): Age (in years):

Mother's name:

Father's name:

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

PRELIMINARY CASE INVESTIGATION FORM

- Page 1 +
- Page 2 +
- Page 3 +
- Page 4 +
- Page 5 +
- Page 6 +
- Page 7 +
- Page 8 +

- PRELIMINARY CASE INVESTIGATION FORM | Upload Supporting Documents +
- PRELIMINARY CASE INVESTIGATION FORM | Upload Scanned Documents +
- PRELIMINARY CASE INVESTIGATION FORM | Download Report +

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

Case Data Entry

Date of Vaccination 07-11-2016

PRELIMINARY CASE INVESTIGATION FORM

Page 1 +

Page 2 -

Date of first symptom 26-10-2016

Time of first symptom (hh:mm AM/PM) 07 x 45 x PM x

Date of key symptom dd-MM-yyyy

Time of key symptom --Select-- --Select-- --Select--

Hospitalization Yes

Date of hospitalization 26-10-2016

Time of hospitalization (hh:mm AM/PM) 07 x 25 x AM x

Name of hospital Apollo Geneagies Hospital

Address of hospital

Current status left against medical advice (LAMA) x

If died, Date of death

Time of death --Select-- 30 x AM x

wo1

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

Supporting Documents

Download All Documents

Choose File +monitor-pos...-english.jpg Upload Document

Choose File +monitor-poster-Hindi.jpg Upload Document

Add more files

PRELIMINARY CASE INVESTIGATION FORM | Upload Scanned Documents

Scanned CRF Documents

Download All Documents

Choose File +monitor-poster-Hindi.jpg Upload Document

Add more files

PRELIMINARY CASE INVESTIGATION FORM | Download Report

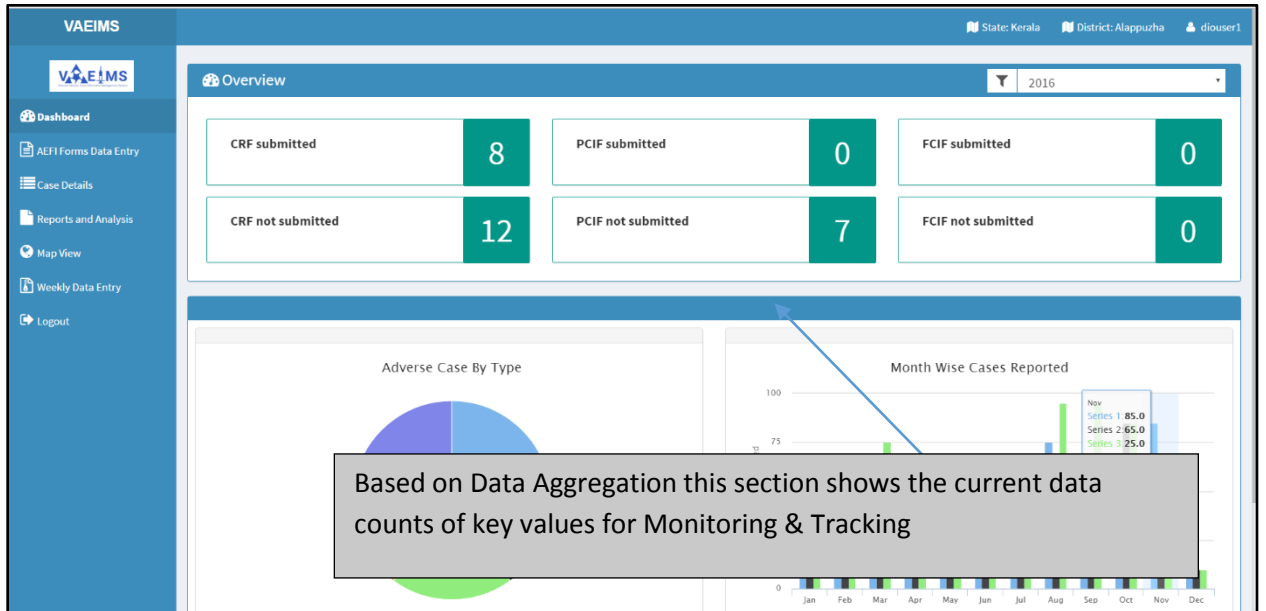
Submit

Feedback

cker-capture/index.html

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

VAEIMS

Country: India State: Kerala Slouser2

Real Time Monitor

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

Alappuzha
Number of Cases: 20

3. Case Details

VAEIMS

State: Kerala District: Alappuzha diouser1

Case Detail

Show 5 entries Search:

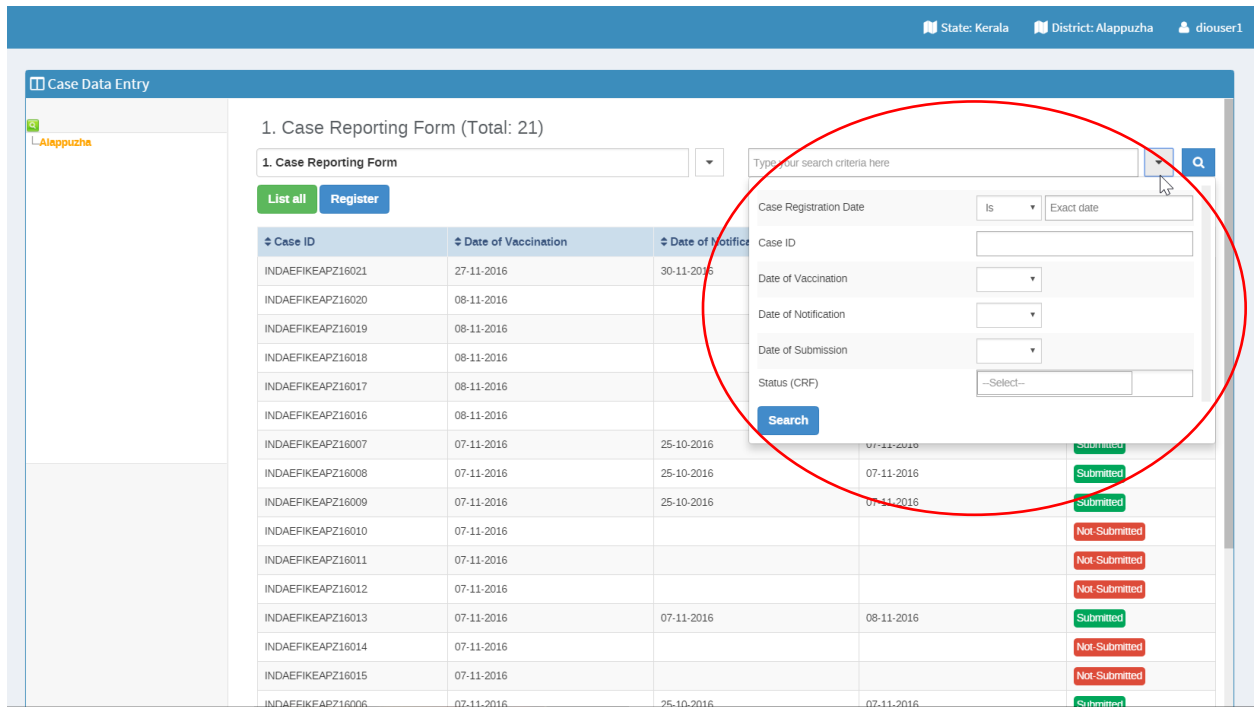
Case id	CRF	PCIF	FCIF	Notifications
INDAEFIKEAPZ16001	Not-Submitted	-	-	
INDAEFIKEAPZ16002	Not-Submitted	-	-	
	mitted	Not-Submitted	-	
	Submitted	-	-	
	mitted	Not-Submitted	-	

Previous 1 2 3 4 5 Next

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.



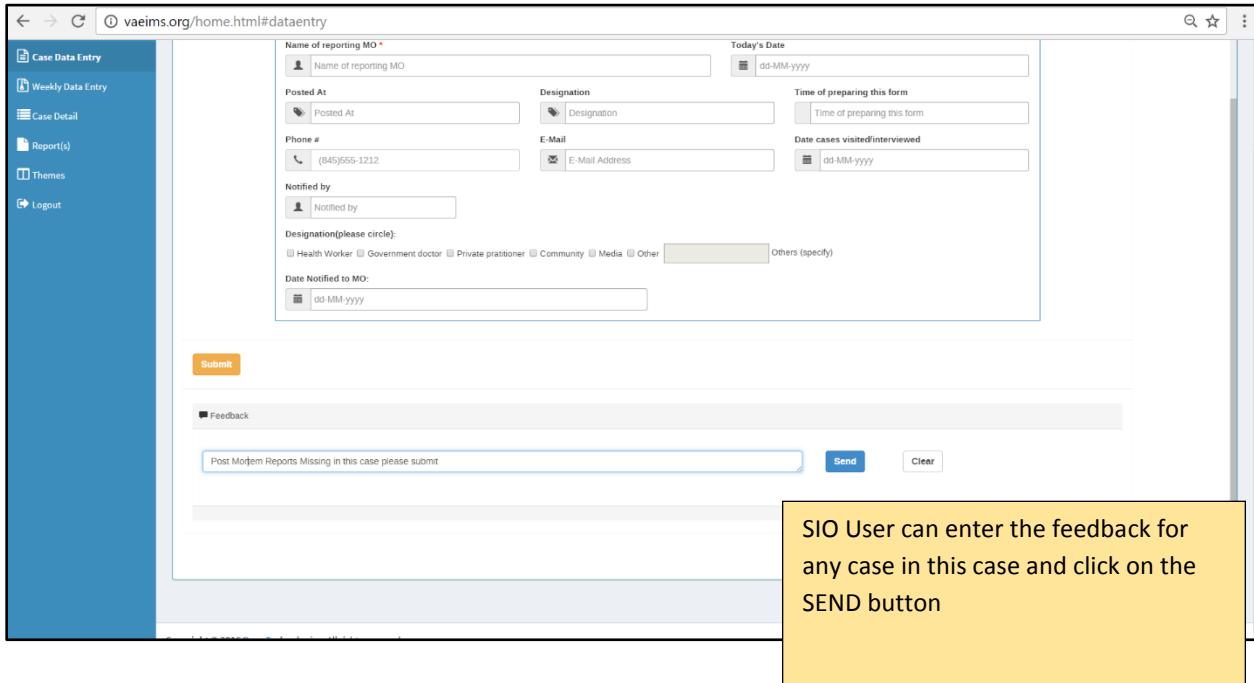
The screenshot displays the 'Case Data Entry' interface for Kerala, Alappuzha. It features a table of case reporting forms and a search overlay. The search overlay is circled in red and includes a search input field, a dropdown menu for 'Case Registration Date' (set to 'Is'), an 'Exact date' input, and fields for 'Case ID', 'Date of Vaccination', 'Date of Notification', and 'Date of Submission'. A 'Search' button is located at the bottom of the overlay.

Case ID	Date of Vaccination	Date of Notification	Date of Submission	Status (CRF)
INDAEFIKEAPZ16021	27-11-2016	30-11-2016		
INDAEFIKEAPZ16020	08-11-2016			
INDAEFIKEAPZ16019	08-11-2016			
INDAEFIKEAPZ16018	08-11-2016			
INDAEFIKEAPZ16017	08-11-2016			
INDAEFIKEAPZ16016	08-11-2016			
INDAEFIKEAPZ16007	07-11-2016	25-10-2016	07-11-2016	Submitted
INDAEFIKEAPZ16008	07-11-2016	25-10-2016	07-11-2016	Submitted
INDAEFIKEAPZ16009	07-11-2016	25-10-2016	07-11-2016	Submitted
INDAEFIKEAPZ16010	07-11-2016			Not-Submitted
INDAEFIKEAPZ16011	07-11-2016			Not-Submitted
INDAEFIKEAPZ16012	07-11-2016			Not-Submitted
INDAEFIKEAPZ16013	07-11-2016	07-11-2016	08-11-2016	Submitted
INDAEFIKEAPZ16014	07-11-2016			Not-Submitted
INDAEFIKEAPZ16015	07-11-2016			Not-Submitted
INDAEFIKEAPZ16006	07-11-2016	25-10-2016	07-11-2016	Submitted

- 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

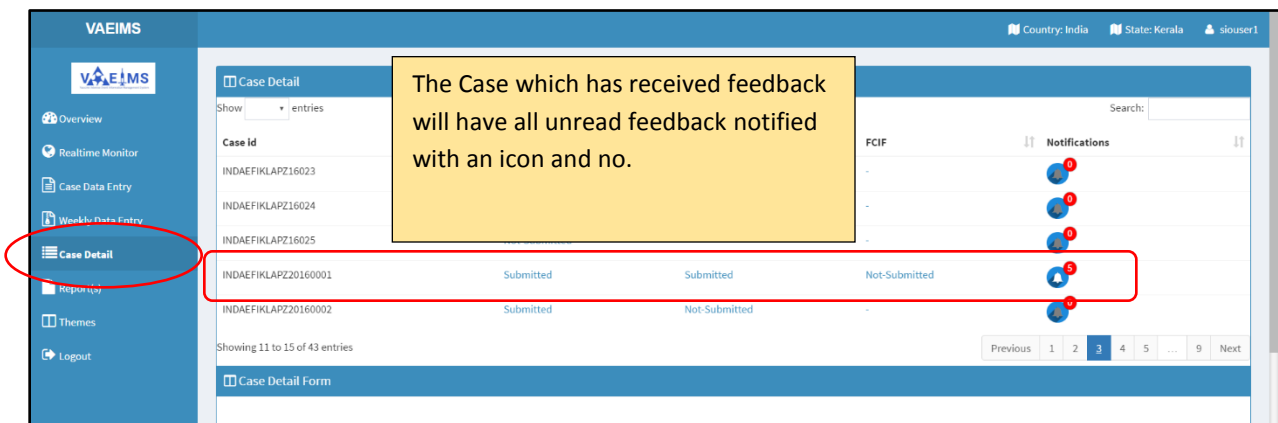
Feedback Feature

There is feature in the system where the State User can notify the District user on Missing Information or any other feedback on the case on a real time basis.



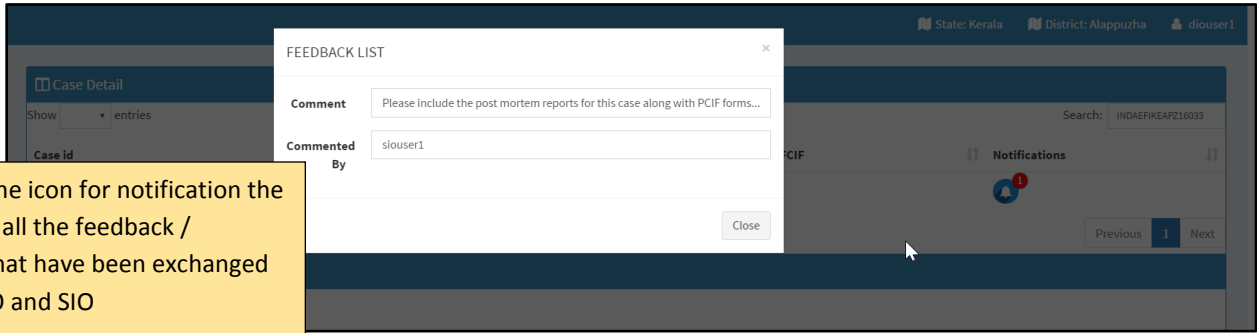
SIO User can enter the feedback for any case in this case and click on the SEND button

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.

Case Id	Submitted	Submitted	Not-Submitted	Notifications
INDAEFIKLAPZ16023				
INDAEFIKLAPZ16024				
INDAEFIKLAPZ16025				
INDAEFIKLAPZ20160001	Submitted	Submitted	Not-Submitted	5
INDAEFIKLAPZ20160002	Submitted	Not-Submitted		



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

