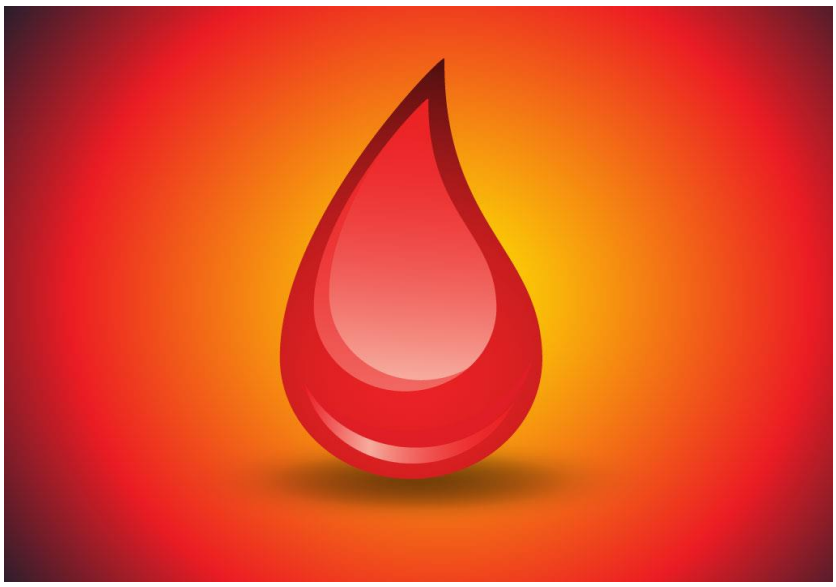
IPC-NIB

Haemovigilance Programme



Instruction Manual

For

HAEMO-VIGIL SOFTWARE

National Institute of Biologicals

Ministry of Health & Family Welfare,

Government of India

A-32, Sector- 62, Noida,

Uttar Pradesh

Foreword

A centralized Haemovigilance system was launched across the country on 10th Dec, 2012 with an objective to track Adverse Reactions/ Events and incidence associated with Biologicals, Blood transfusion and Blood Product administration (Haemovigilance) and to help identify trends, recommend best practices and interventions required to improve patient care and safety. In order to analyse the data pertaining to Haemovigilance coming from all over the country, there was a need to have an indigenous software. **Haemo- Vigil**, a software developed by IT Division of National Institute of Biologicals to collate & analyse the Haemovigilance data was launched on 24th Jan 2013.

I am happy that the members of Core Group – Haemovigilance & IT Division of National Institute of Biologicals have done a commendable job in preparing & launching of Haemo- Vigil Software and Instruction Manual for Haemo- Vigil Software.

I sincerely believe that the Instruction Manual for Haemo-Vigil Software will be useful and an essential tool to enable the user to enter the data in Haemo- Vigil Software which will aid in collation & analysis of the Adverse Reactions related to Blood Transfusion & Blood Product Administration as reported from all across the country.

08/4/2013

(**Dr. Surinder Singh**)
Director In- Charge,
National Institute of Biologicals,
Ministry of Health & Family Welfare,
Government of India

Acknowledgements

The contributions of the members of Core Group- Haemovigilance & IT Division of National Institute of Biologicals in preparing the Haemo- Vigil Software and Instruction Manual for Haemo- Vigil Software are acknowledged and appreciated.

Core Group- Haemovigilance :

1. Dr. J. P. Prasad,
   Scientist-II & Head, NIB

2. Ms. Sudha V. Gopinath,
   Scientist-III, NIB

3. Ms. Akanksha Bisht,
   Scientific Assistant,IPC
   Member Secretary- Haemovigilance Programme

IT Division (National Institute of Biologicals)

1. Mr. Deepak Mahajan,
   Computer Officer

2. Mr. Sunish Singhal,
   Technical Associate

Their endeavour has added value to the Haemovigilance Programme.

(**Dr. Surinder Singh**) 08/4/2013
Director In- Charge
National Institute of Biologicals,
Ministry of Health & Family Welfare,
Government of India

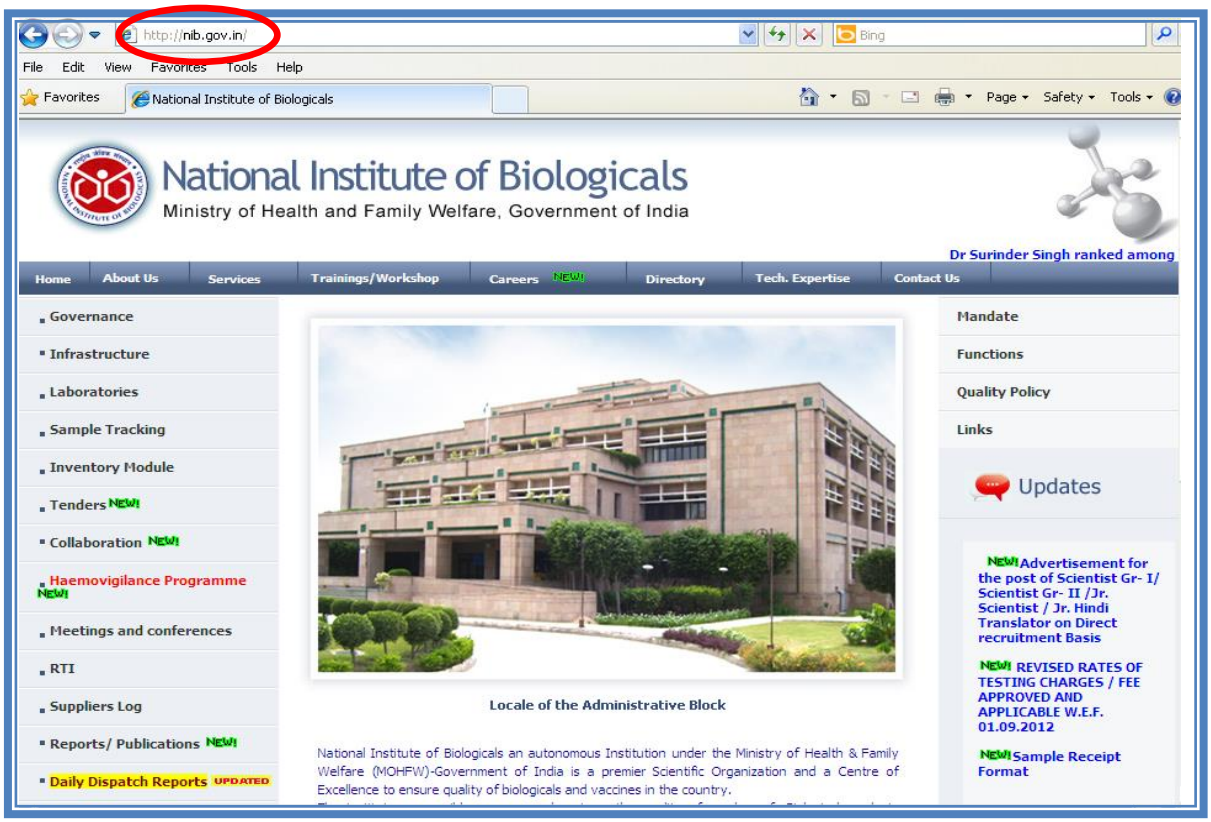
INDEX

Note: - In case of any problems in user operation kindly Contact or E-mail us at

haemovigilance@nib.gov.in

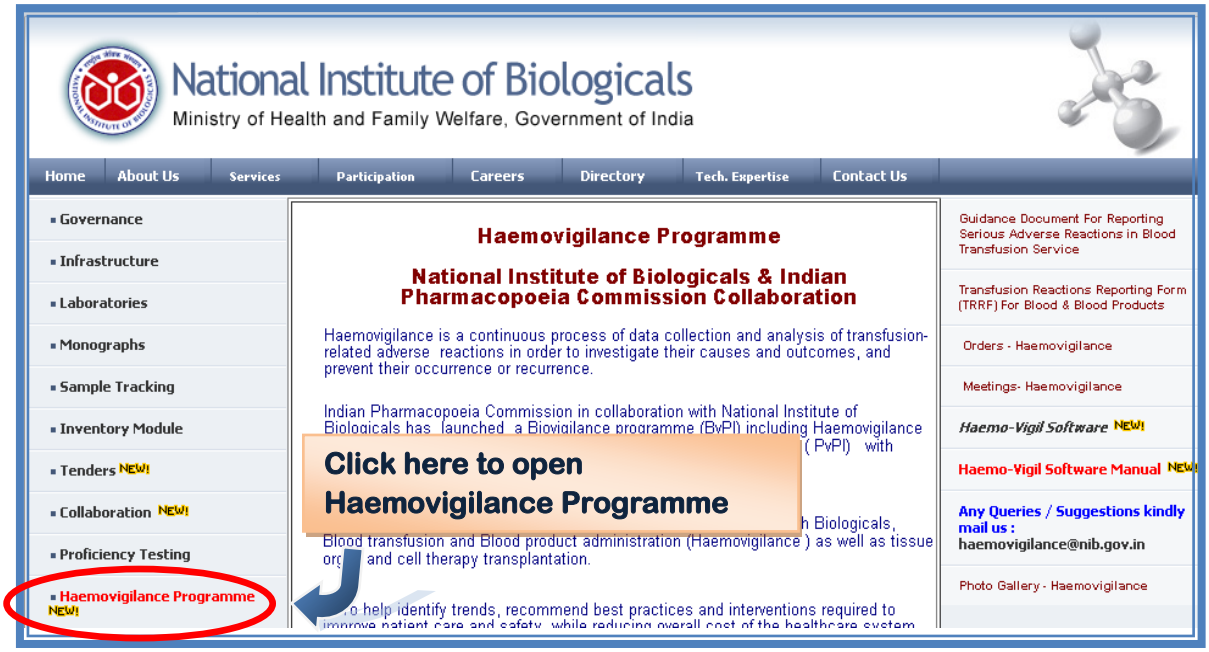
Contact No. 0120-2400022,72

Step 1:



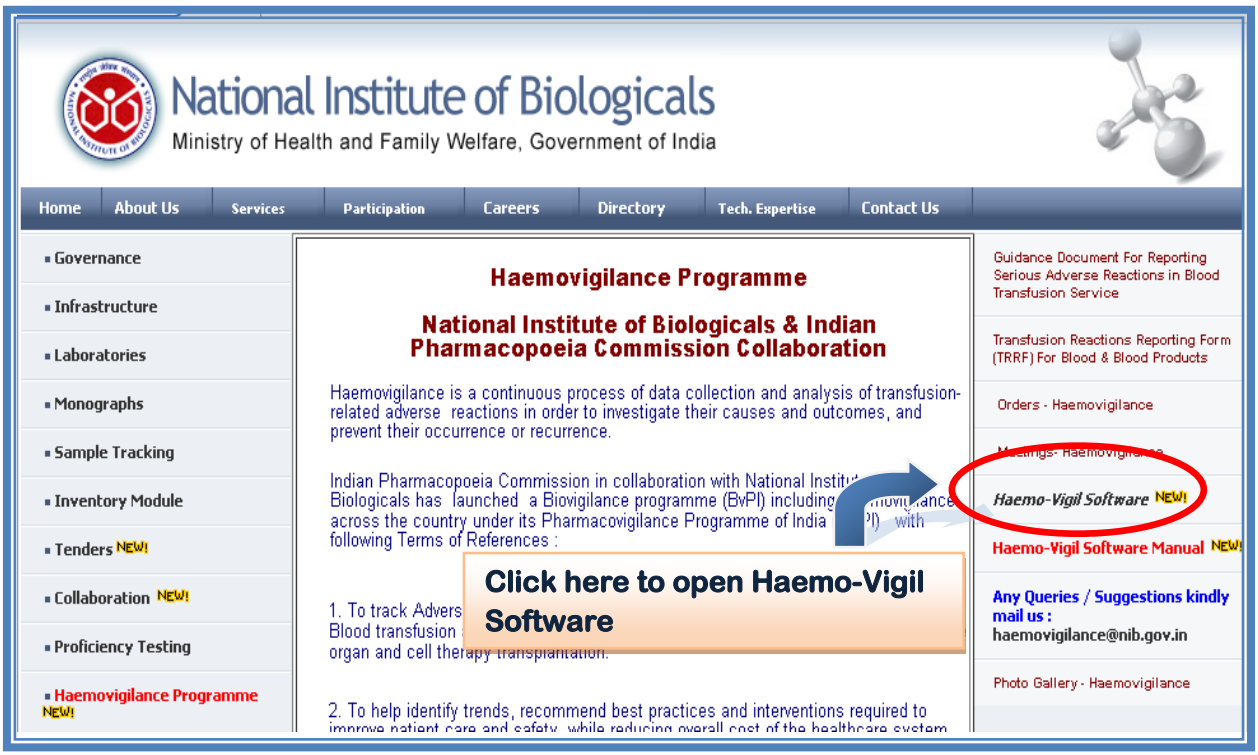
Link to NIB website– http://nib.gov.in/

Step 1(A):-



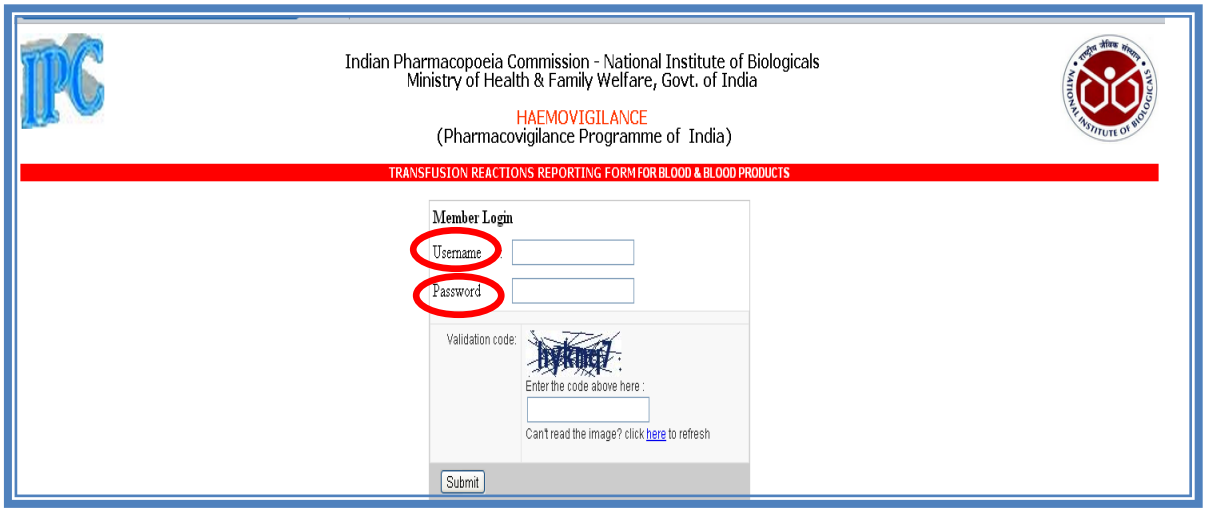
Step 1(B):-

Step 1(C):-



- **Link to Haemovigilance Software:**
- Go to **http://nib.gov.in/** – the homepage of National Institute of Biologicals (NIB) .
- Click on the "Haemovigilance Programme" tab.
- On the right hand side of the page click on the " Haemo-Vigil Software Manual" tab which contains instructions to use software.
- On the right hand side of the page click on the "Haemo-Vigil software" for Login Page.

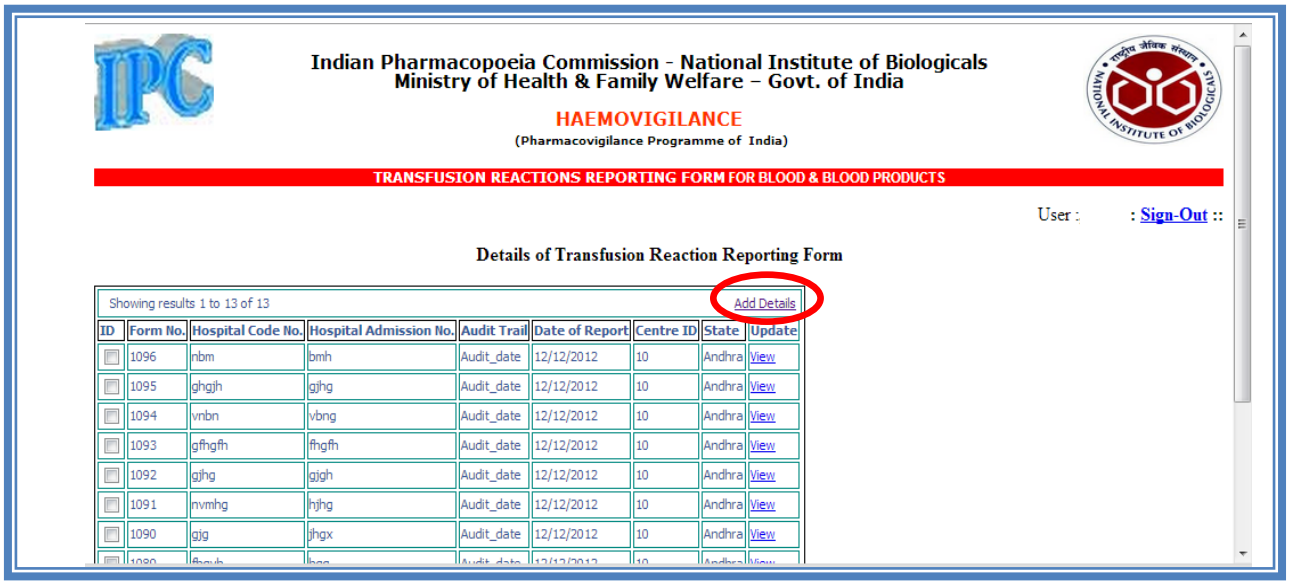
Step 2:-



Login Page

- Enter "Username" and the "Password" in the required fields.
- Enter the "Validation Code" and click submit.
- Don't use special characters like (! @ # $ % ^ & * ( ) _ + = < > ? " : { } \) in the form.

Step 3:-

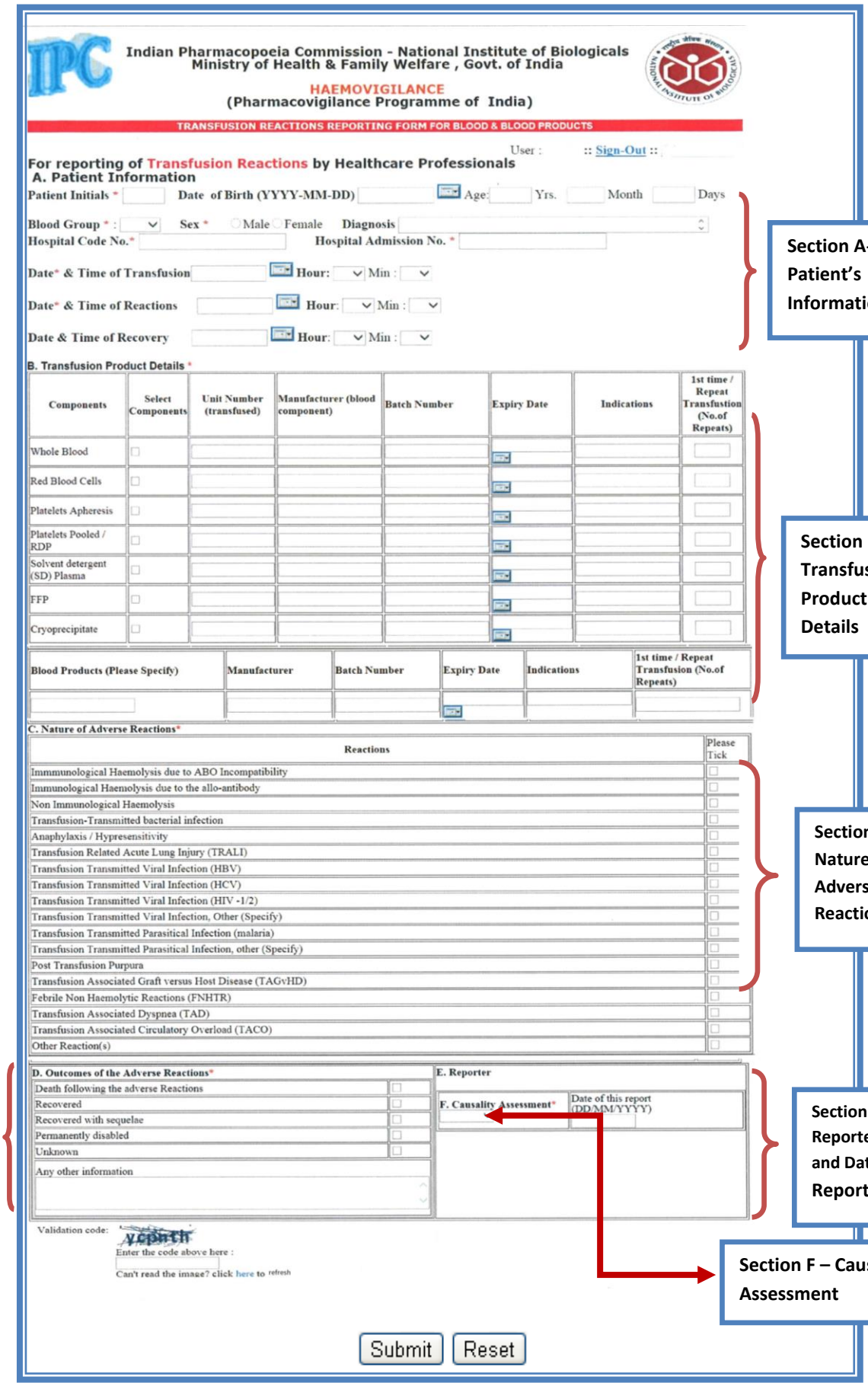


Transfusion Reaction Reporting Form Details

- This page contains TRR Form reports.
- To add a new TRR form, click on "Add Details" tab present on the top-right side of the table. Once the "Add Details" Tab is clicked it displays a blank TRRF as depicted in Step 4 wherein data can be filled.

Step 4:-

*Mandatory Fields



Indian Pharmacopoeia Commission - National Institute of Biologicals
Ministry of Health & Family Welfare , Govt. of India

HAEMOVIGILANCE
(Pharmacovigilance Programme of India)

TRANSFUSION REACTIONS REPORTING FORM FOR BLOOD & BLOOD PRODUCTS

User : :: Sign-Out ::

For reporting of Transfusion Reactions by Healthcare Professionals

A. Patient Information

Patient Initials * Date of Birth (YYYY-MM-DD) Age: Yrs. Month Days

Blood Group * : Sex * Male Female Diagnosis

Hospital Code No.* Hospital Admission No. *

Date* & Time of Transfusion Hour: Min :

Date* & Time of Reactions Hour: Min :

Date & Time of Recovery Hour: Min :

B. Transfusion Product Details *

Components	Select Components	Unit Number (transfused)	Manufacturer (blood component)	Batch Number	Expiry Date	Indications	1st time / Repeat Transfustion (No.of Repeats)
Whole Blood							
Red Blood Cells							
Platelets Apheresis							
Platelets Pooled / RDP							
Solvent detergent (SD) Plasma							
FFP							
Cryoprecipitate							

Blood Products (Please Specify)	Manufacturer	Batch Number	Expiry Date	Indications	1st time / Repeat Transfusion (No.of Repeats)

C. Nature of Adverse Reactions*

Reactions	Please Tick
Immmunological Haemolysis due to ABO Incompatibility	
Immunological Haemolysis due to the allo-antibody	
Non Immunological Haemolysis	
Transfusion-Transmitted bacterial infection	
Anaphylaxis / Hypresensitivity	
Transfusion Related Acute Lung Injury (TRALI)	
Transfusion Transmitted Viral Infection (HBV)	
Transfusion Transmitted Viral Infection (HCV)	
Transfusion Transmitted Viral Infection (HIV -1/2)	
Transfusion Transmitted Viral Infection, Other (Specify)	
Transfusion Transmitted Parasitical Infection (malaria)	
Transfusion Transmitted Parasitical Infection, other (Specify)	
Post Transfusion Purpura	
Transfusion Associated Graft versus Host Disease (TAGvHD)	
Febrile Non Haemolytic Reactions (FNHTR)	
Transfusion Associated Dyspnea (TAD)	
Transfusion Associated Circulatory Overload (TACO)	
Other Reaction(s)	

D. Outcomes of the Adverse Reactions*

- Death following the adverse Reactions
- Recovered
- Recovered with sequelae
- Permanently disabled
- Unknown

Any other information

E. Reporter

F. Causality Assessment* Date of this report (DD/MM/YYYY)

Validation code: ycpnth

Enter the code above here :

Can't read the image? click here to refresh

Submit Reset

Section A- Patient's Information

Section B- Transfusion Product Details

Section C- Nature of Adverse Reactions

Section D – Outcomes of the Adverse Reactions

Section E – Reporter Details and Date of Report

Section F – Causality Assessment

*Don't Use Special characters (! @ # $ % ^ & * ( ) _ += { }: "< >? / []) in the form.

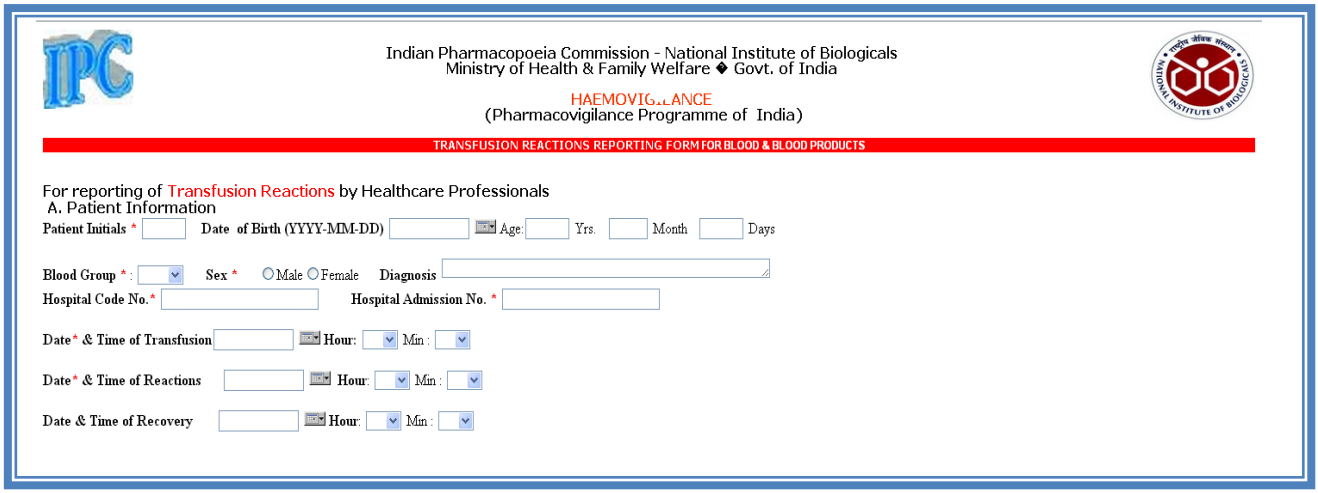
Transfusion Reaction Reporting Form (TRRF)

This page displays blank TRR form where data is to be filled.

The TRR Form is divided in to 6 sections:

A. Patient Information
B. Transfusion Product Details
C. Nature of Adverse Reactions
D. Outcomes of the Adverse Reactions
E. Reporter
F. Causality Assessment

Step 4(A):-


Indian Pharmacopoeia Commission - National Institute of Biologicals
Ministry of Health & Family Welfare ◆ Govt. of India

HAEMOVIG..ANCE
(Pharmacovigilance Programme of India)

TRANSFUSION REACTIONS REPORTING FORM FOR BLOOD & BLOOD PRODUCTS

For reporting of Transfusion Reactions by Healthcare Professionals
A. Patient Information

Patient Initials * Date of Birth (YYYY-MM-DD) Age: Yrs. Month Days

Blood Group * : Sex * Male Female Diagnosis

Hospital Code No.* Hospital Admission No. *

Date* & Time of Transfusion Hour: Min :

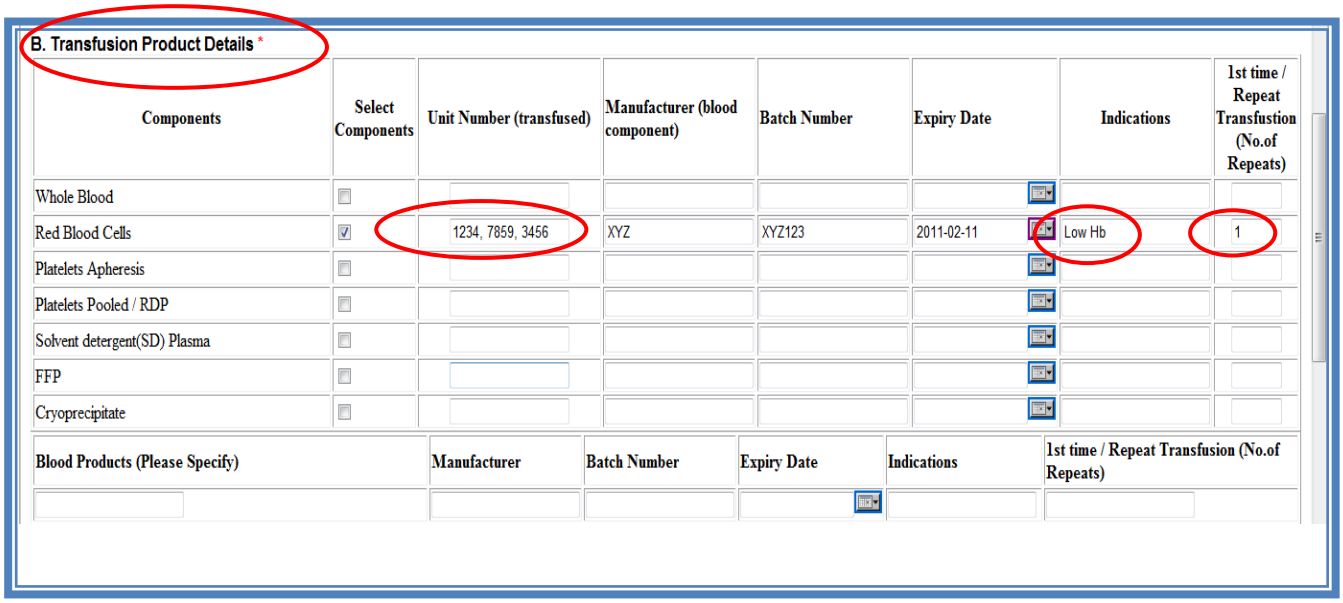
Date* & Time of Reactions Hour: Min :

Date & Time of Recovery Hour: Min :

Patient Information:

- *Enter the Patient's initial. Special characters aren't allowed.
- *Enter the Age in numerical form (Year, Month and Days) **Or** Select the Date of Birth from the Calendar  click on the Calendar tab.
- *Select Blood Group from drop down menu.
- * Select the gender.
- *Enter the Hospital Code Number.
- Enter the Diagnosis .
- *Enter the Hospital Admission Number
- *Select the Date of Transfusion.
- Select the Time of transfusion.
- *Select Date of Reaction using the calendar.
- Select Time of Reaction.
- Select the Date and Time of Recovery.

Step 4(B):-



B. Transfusion Product Details *

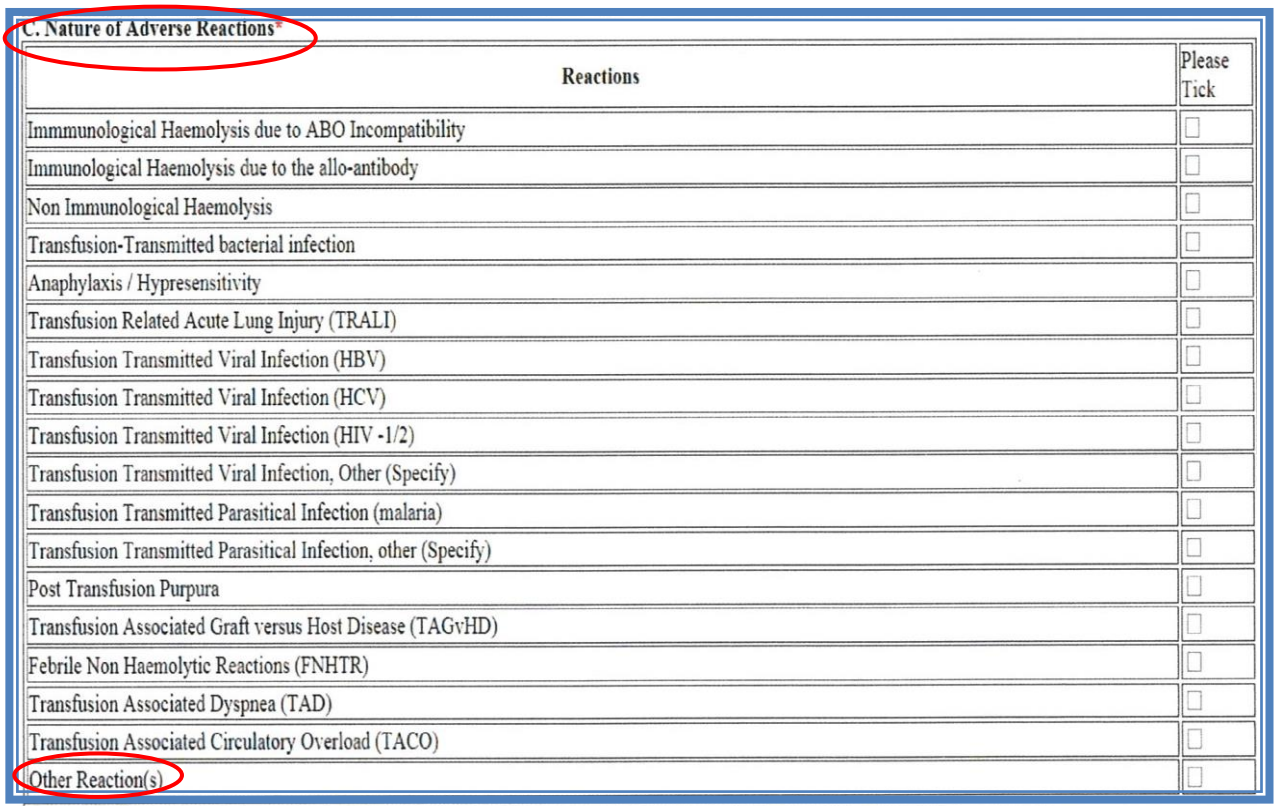
Components	Select Components	Unit Number (transfused)	Manufacturer (blood component)	Batch Number	Expiry Date	Indications	1st time / Repeat Transfustion (No.of Repeats)
Whole Blood	☐						
Red Blood Cells	☑	1234, 7859, 3456	XYZ	XYZ123	2011-02-11	Low Hb	1
Platelets Apheresis	☐						
Platelets Pooled / RDP	☐						
Solvent detergent(SD) Plasma	☐						
FFP	☐						
Cryoprecipitate	☐						

Blood Products (Please Specify)	Manufacturer	Batch Number	Expiry Date	Indications	1st time / Repeat Transfusion (No.of Repeats)

Transfusion Product Details

- Select one or more components from the list.
- Enter the hospital assigned unit number code. [**Note**: If there are more than one unit number then separate them using comma i.e , as shown above in the box]
- Enter the manufacturer's name, batch number of the product, Indications and number of repeats.
- Select the Expiry Date of the Product.
- In case the blood product is not in the given list, enter the details of the product in the last row of the section which includes Manufacturer, Batch Number, Expiry date of the product , Indications and Number of repeats.
- Don't use special characters like (! @ # $ % ^ & * ( ) _ + = < > ? " : { } \)

Step 4(C):-



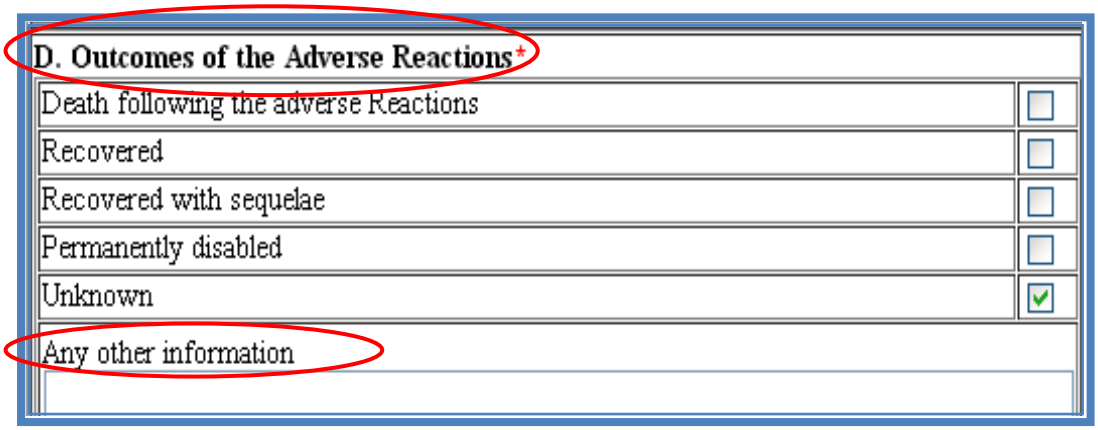
C. Nature of Adverse Reactions*

Reactions	Please Tick
Immmunological Haemolysis due to ABO Incompatibility	☐
Immunological Haemolysis due to the allo-antibody	☐
Non Immunological Haemolysis	☐
Transfusion-Transmitted bacterial infection	☐
Anaphylaxis / Hypresensitivity	☐
Transfusion Related Acute Lung Injury (TRALI)	☐
Transfusion Transmitted Viral Infection (HBV)	☐
Transfusion Transmitted Viral Infection (HCV)	☐
Transfusion Transmitted Viral Infection (HIV -1/2)	☐
Transfusion Transmitted Viral Infection, Other (Specify)	☐
Transfusion Transmitted Parasitical Infection (malaria)	☐
Transfusion Transmitted Parasitical Infection, other (Specify)	☐
Post Transfusion Purpura	☐
Transfusion Associated Graft versus Host Disease (TAGvHD)	☐
Febrile Non Haemolytic Reactions (FNHTR)	☐
Transfusion Associated Dyspnea (TAD)	☐
Transfusion Associated Circulatory Overload (TACO)	☐
Other Reaction(s)	☐

Nature of Adverse Reactions

- Select Adverse Reaction/Reactions.
- If the adverse reaction is other than the reactions listed, then click on "Other Reaction(s)" and mention the details in the "Any other Information" tab at the end of Section D.

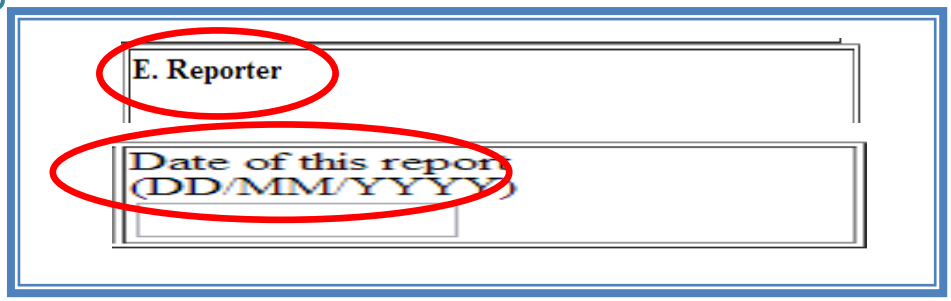
Step 4(D):-



Outcomes of the Adverse Reactions

- Select Outcome of the Adverse Reaction/Reactions.
- Any other information may be provided by the user in the tab "Any other information".

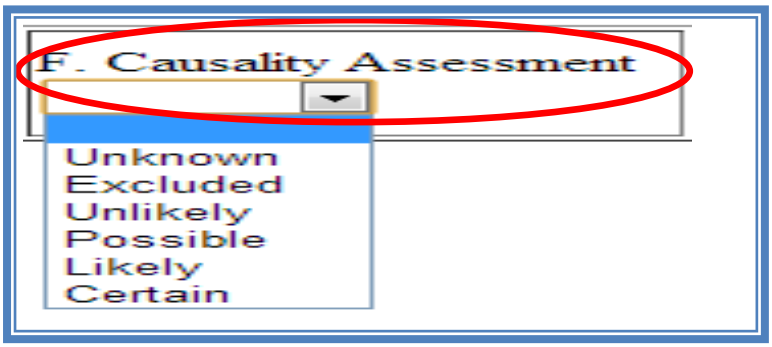
Step 4(E):-



Reporter Information

- Reporter information & Date of this report fields are auto generated.

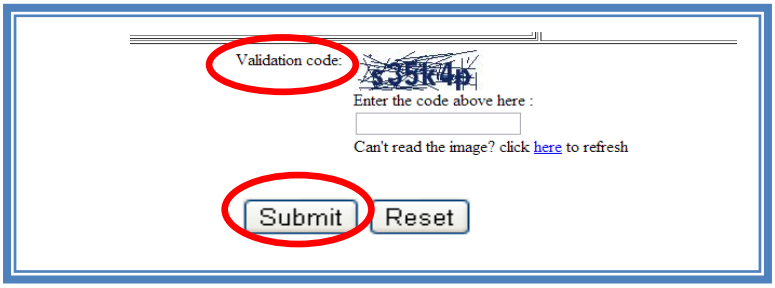
Step 4(F):-



*Causality Assessment

- Select one of the Causality Assessment from the drop down menu.

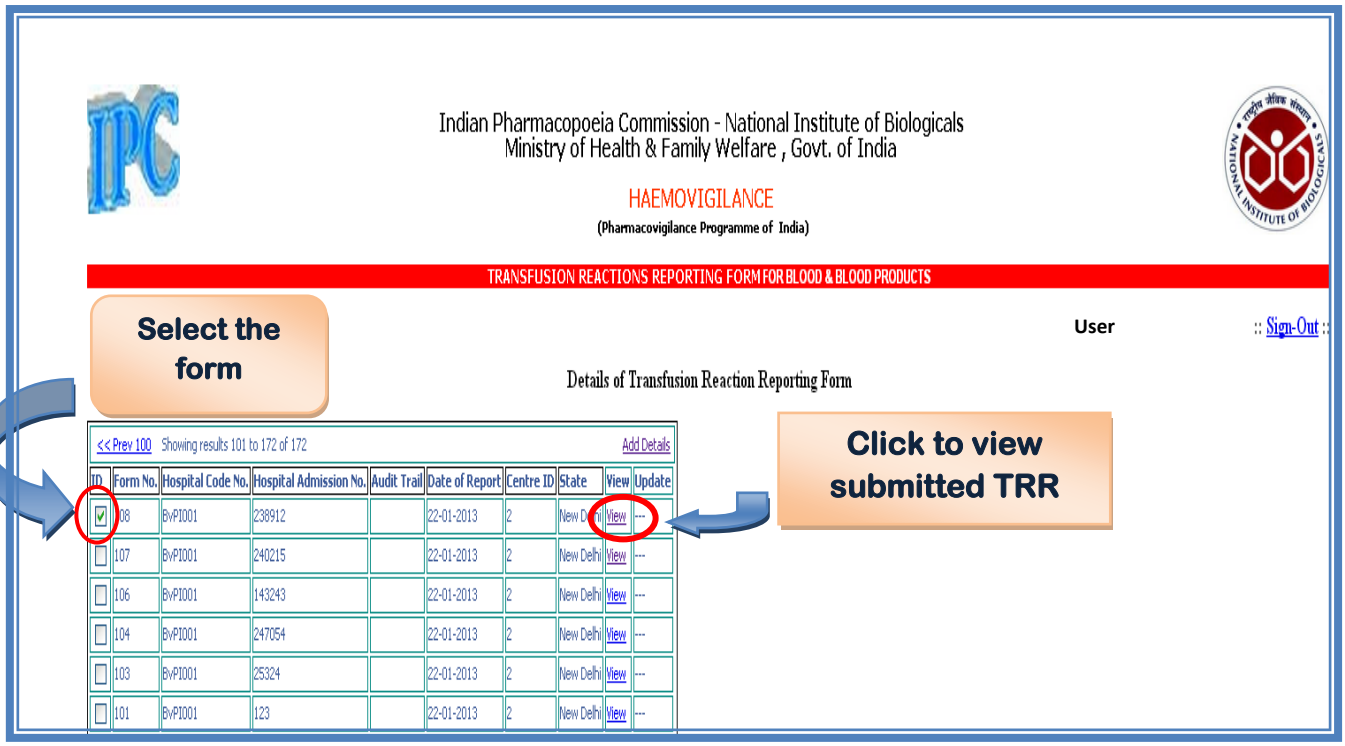
Step 4(G):-



Validation Code & Submission of TRR Form

- Once data is filled, enter the "**Validation Code**" and submit the form

Step 5:-



- "View Data"
- To view the submitted TRRF, select the form and click on "View".

Step 5A:-

Indian Pharmacopoeia Commission - National Institute of Biologicals
Ministry of Health & Fam..., .Velfare ◆ Govt. of India
HAEMOVIGILANCE
(Pharmacovigilance Programme of India)

TRANSFUSION REACTIONS REPORTING FORM FOR BLOOD & BLOOD PRODUCTS

Form No. : 252

For reporting of Transfusion Reactions by Healthcare Professionals

A. Patient Information

Patient Initials :- xyz Date of Birth :- 00-00-0000 Age :- 52 Yrs. 0 Month 0 Days

Blood Group :- A+ Sex : male

Diagnosis :- anaemia

Hospital Code No.	:	1234	Hospital Adminission No.	:	1234
Date & Time of Transfusion	:	11-02-2011	Time	:	0:Hrs : 0 Mins
Date & Time of Reaction	:	11-02-2011	Time	:	0 : Hrs: 0 Mins
Date & Time of Recovery	:	00-00-0000	Time	:	0 :Hrs:0 Mins

B . Transfusion Product Details

Components	Select Components	Unit Number (transfused)	Manufacturer (blood component)	Batch Number	Expiry Date	Indications	1st time / Repeat Transfustion (No.of Repeats)
Red Blood Cells	√	1234,3456,7890,1220	xyz	xyz123	25-03-2011	Low Hb	4

Blood Products (Please Specify)	Manufacturer	Batch Number	Expiry Date	Indications	1st time / Repeat Transfustion (No.of Repeats)

C. Nature of Adverse Reactions

Reactions	Please Tick
Febrile Non Haemolytic Reactions (FNHTR)	√

D. Outcomes of the Adverse Events

Unknown	√

E. Reporter

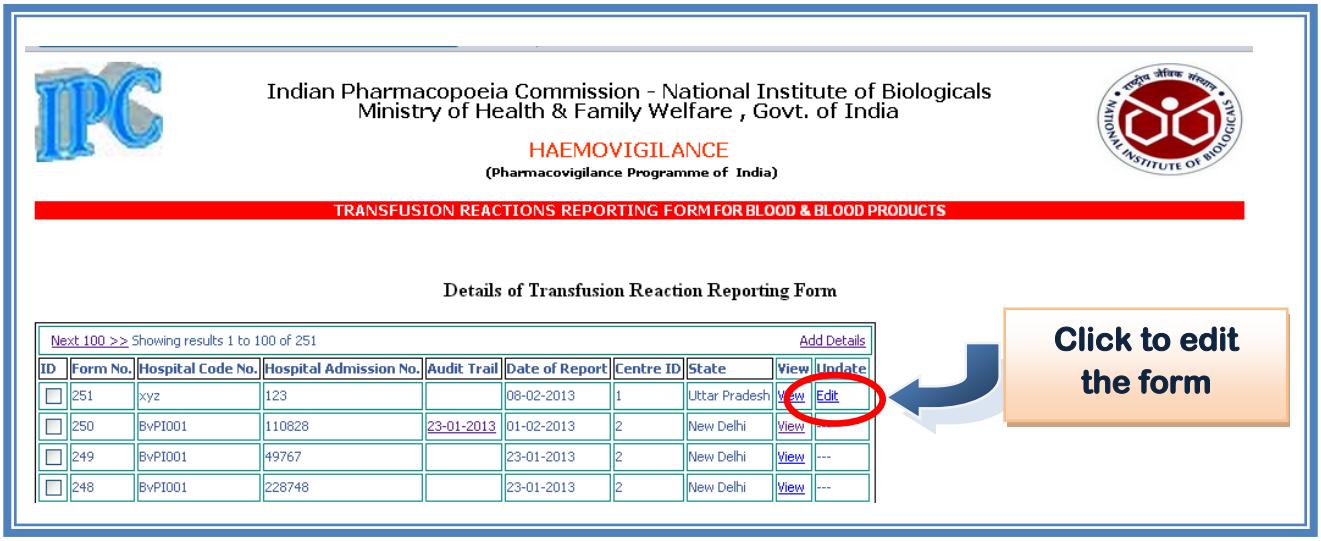
Name :- NIB Coordinating Centre
Address :-NIB, Noida,
State:- Uttar Pradesh Pin:- 0

Causality Assessment : Unknown	Date of this report : 20-02-2013

"Submitted TRR Form"

- Form number is auto generated once the TRR Form is submitted by the user.

Step 6:-



Edit TRR Form:–

- Once a TRR Form is submitted, it cannot be changed. If required, send a request to the Coordinating Centre at NIB, Noida via email to the following email id :

  Haemovigilance@nib.gov.in

- **The email should give a detail about:**
  - ★ *TRR Form number displayed on the top-right side of the TRR form (Refer Step No. 5A)*
  - ★ *Reason to edit the form*
- Once the mail is received, the specific TRR Form will be made editable by the Coordinating Centre at NIB.
- When the form is editable, user can see an option "Edit" for the selected form
- Click on "Edit" to edit the form and then submit.

National Institute of Biologicals

Ministry of Health & Family Welfare,
Government of India
A-32, Sector- 62, Noida,
Uttar Pradesh
Email : Haemovigilance@nib.gov.in
Tel: 0120-2400072,2400022
Fax : 0120-2403014