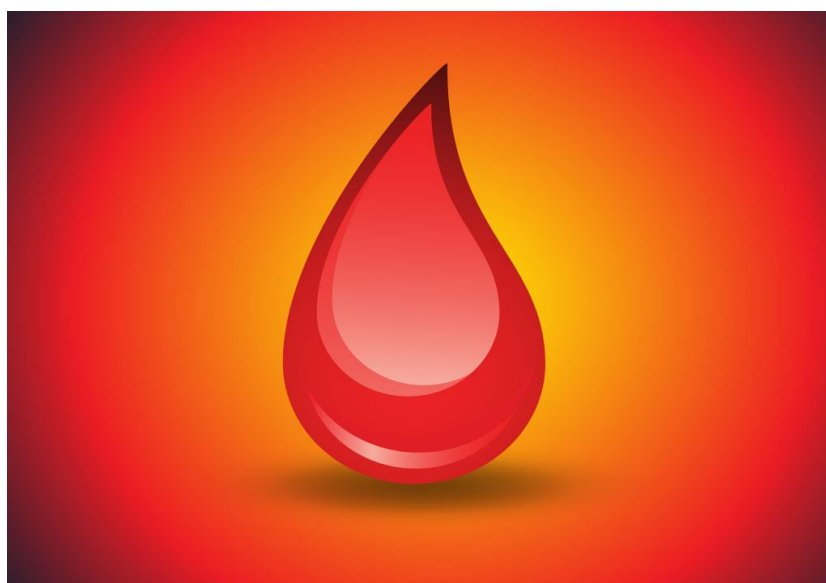




IPC-NIB

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.



(Dr. Surinder Singh)

08/4/2013

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.


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Scientist-III, NIB
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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.

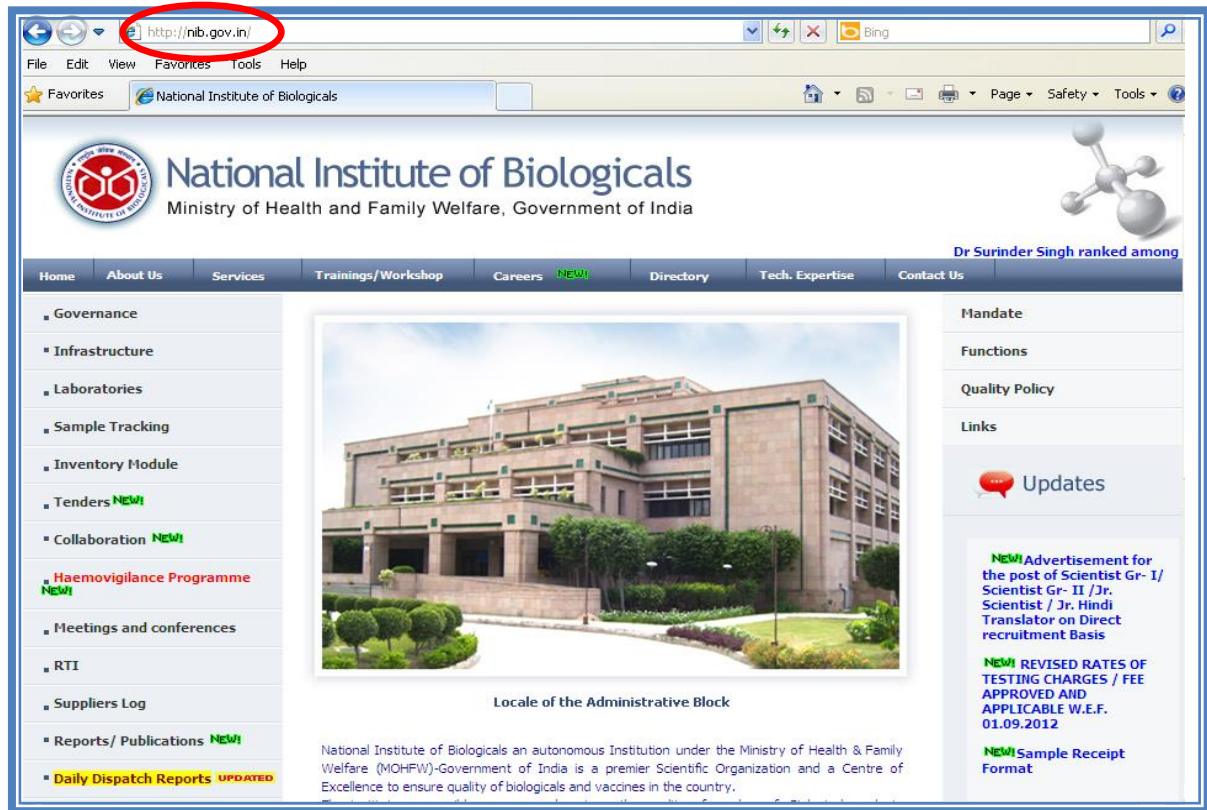

(Dr. Surinder Singh) 08/4/2013
Director In- Charge
National Institute of Biologicals,
Ministry of Health & Family Welfare,
Government of India

I N D E X

**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**

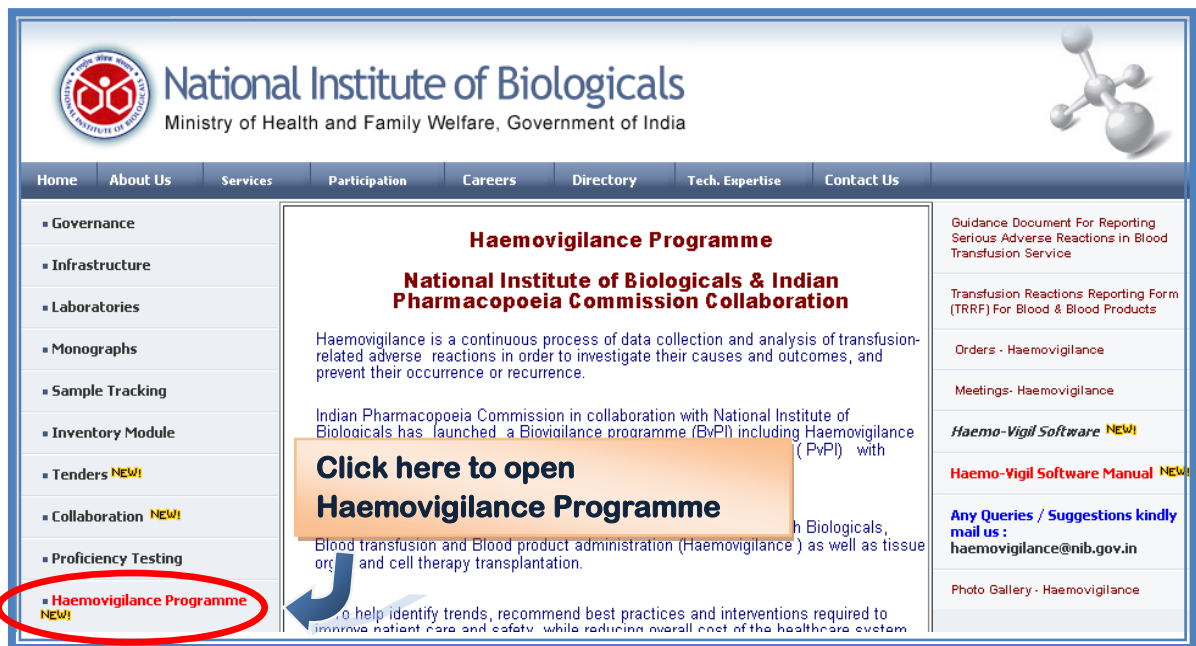
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Step 1:



Link to NIB website- <http://nib.gov.in/>

Step 1(A):



Step 1(B):-

National Institute of Biologicals
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Home About Us Services Participation Careers Directory Tech. Expertise Contact Us

■ Governance
■ Infrastructure
■ Laboratories
■ Monographs
■ Sample Tracking
■ Inventory Module
■ Tenders **NEW!**
■ Collaboration **NEW!**
■ Proficiency Testing
■ Haemovigilance Programme **NEW!**

Haemovigilance Programme
National Institute of Biologicals & Indian Pharmacopoeia Commission Collaboration

Haemovigilance is a continuous process of data collection and analysis of transfusion-related adverse reactions in order to investigate their causes and outcomes, and prevent their occurrence or recurrence.

Indian Pharmacopoeia Commission in collaboration with National Institute of Biologicals has launched a Biovigilance programme (BvPI) including Haemovigilance across the country under its Pharmacovigilance Programme of India (PvPI) with following Terms of References :

1. To track Adverse Blood transfusion organ and cell
2. To help identify trends, recommend best practices and interventions required to improve patient care and safety, while reducing overall cost of the healthcare system

Click here to open Haemo-Vigil Software Manual

Guidance Document For Reporting Serious Adverse Reactions in Blood Transfusion Service
Transfusion Reactions Reporting Form (TRRF) For Blood & Blood Products
Orders - Haemovigilance
Meetings- Haemovigilance
Haemo-Vigil Software NEW!
Haemo-Vigil Software Manual NEW!
Any Queries / suggestions kindly mail us : haemovigilance@nib.gov.in
Photo Gallery - Haemovigilance

Step 1(C):-

National Institute of Biologicals
Ministry of Health and Family Welfare, Government of India

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■ Governance
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1. To track Adverse Blood transfusion organ and cell therapy transplantation.
2. To help identify trends, recommend best practices and interventions required to improve patient care and safety, while reducing overall cost of the healthcare system

Click here to open Haemo-Vigil Software

Guidance Document For Reporting Serious Adverse Reactions in Blood Transfusion Service
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Haemo-Vigil Software Manual NEW!
Any Queries / suggestions kindly mail us : haemovigilance@nib.gov.in
Photo Gallery - Haemovigilance

- 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:-

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

Member Login

Username

Password

Validation code: 
Enter the code above here :
Can't read the image? click [here](#) to refresh

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:-

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](#) ::

Details of Transfusion Reaction Reporting Form

Showing results 1 to 13 of 13

ID	Form No.	Hospital Code No.	Hospital Admission No.	Audit Trail	Date of Report	Centre ID	State	Update
<input type="checkbox"/>	1096	nbn	bmi	Audit_date	12/12/2012	10	Andhra	View
<input type="checkbox"/>	1095	ghgh	ghgh	Audit_date	12/12/2012	10	Andhra	View
<input type="checkbox"/>	1094	vbn	vbn	Audit_date	12/12/2012	10	Andhra	View
<input type="checkbox"/>	1093	ghgh	ghgh	Audit_date	12/12/2012	10	Andhra	View
<input type="checkbox"/>	1092	ghgh	ghgh	Audit_date	12/12/2012	10	Andhra	View
<input type="checkbox"/>	1091	nmhg	ghgh	Audit_date	12/12/2012	10	Andhra	View
<input type="checkbox"/>	1090	ghgh	ghgh	Audit_date	12/12/2012	10	Andhra	View
<input type="checkbox"/>	1089	ghgh	ghgh	Audit_date	12/12/2012	10	Andhra	View


[Add Details](#)


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 Transfusion (No. of Repeats)
Whole Blood	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Red Blood Cells	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Platelets Apheresis	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Platelets Pooled / RDP	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Solvent detergent (SD) Plasma	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
FFP	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Cryoprecipitate	<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

Blood Products (Please Specify)	Manufacturer	Batch Number	Expiry Date	Indications	1st time / Repeat Transfusion (No. of Repeats)
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

C. Nature of Adverse Reactions *


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

D. Outcomes of the Adverse Reactions *

Death following the adverse Reactions	<input type="checkbox"/>
Recovered	<input type="checkbox"/>
Recovered with sequelae	<input type="checkbox"/>
Permanently disabled	<input type="checkbox"/>
Unknown	<input type="checkbox"/>
Any other information	<input type="text"/>

E. Reporter

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

Validation code:  Enter the code above here :
 Can't read the image? click [here](#) to refresh

**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

HAEMOVIGILANCE
(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 Transfusion (No. of Repeats)
Whole Blood	<input type="checkbox"/>						
Red Blood Cells	<input checked="" type="checkbox"/>	1234, 7859, 3456	XYZ	XYZ123	2011-02-11	Low Hb	1
Platelets Apheresis	<input type="checkbox"/>						
Platelets Pooled / RDP	<input type="checkbox"/>						
Solvent detergent(SD) Plasma	<input type="checkbox"/>						
FFP	<input type="checkbox"/>						
Cryoprecipitate	<input type="checkbox"/>						
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
Immunological Haemolysis due to ABO Incompatibility	<input type="checkbox"/>
Immunological Haemolysis due to the allo-antibody	<input type="checkbox"/>
Non Immunological Haemolysis	<input type="checkbox"/>
Transfusion-Transmitted bacterial infection	<input type="checkbox"/>
Anaphylaxis / Hypersensitivity	<input type="checkbox"/>
Transfusion Related Acute Lung Injury (TRALI)	<input type="checkbox"/>
Transfusion Transmitted Viral Infection (HBV)	<input type="checkbox"/>
Transfusion Transmitted Viral Infection (HCV)	<input type="checkbox"/>
Transfusion Transmitted Viral Infection (HIV -1/2)	<input type="checkbox"/>
Transfusion Transmitted Viral Infection, Other (Specify)	<input type="checkbox"/>
Transfusion Transmitted Parasitical Infection (malaria)	<input type="checkbox"/>
Transfusion Transmitted Parasitical Infection, other (Specify)	<input type="checkbox"/>
Post Transfusion Purpura	<input type="checkbox"/>
Transfusion Associated Graft versus Host Disease (TAGvHD)	<input type="checkbox"/>
Febrile Non Haemolytic Reactions (FNHTR)	<input type="checkbox"/>
Transfusion Associated Dyspnea (TAD)	<input type="checkbox"/>
Transfusion Associated Circulatory Overload (TACO)	<input type="checkbox"/>
Other Reaction(s)	<input type="checkbox"/>

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):-

D. Outcomes of the Adverse Reactions*	
Death following the adverse Reactions	<input type="checkbox"/>
Recovered	<input type="checkbox"/>
Recovered with sequelae	<input type="checkbox"/>
Permanently disabled	<input type="checkbox"/>
Unknown	<input checked="" type="checkbox"/>
Any other information	

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):-

E. Reporter
Date of this report (DD/MM/YYYY)

Reporter Information

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

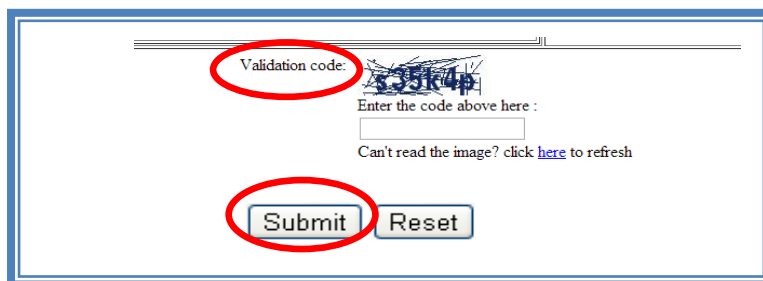
Step 4(F):-

F. Causality Assessment
<div>Unknown</div> <div>Excluded</div> <div>Unlikely</div> <div>Possible</div> <div>Likely</div> <div>Certain</div>

• Causality Assessment

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

Step 4(G):-



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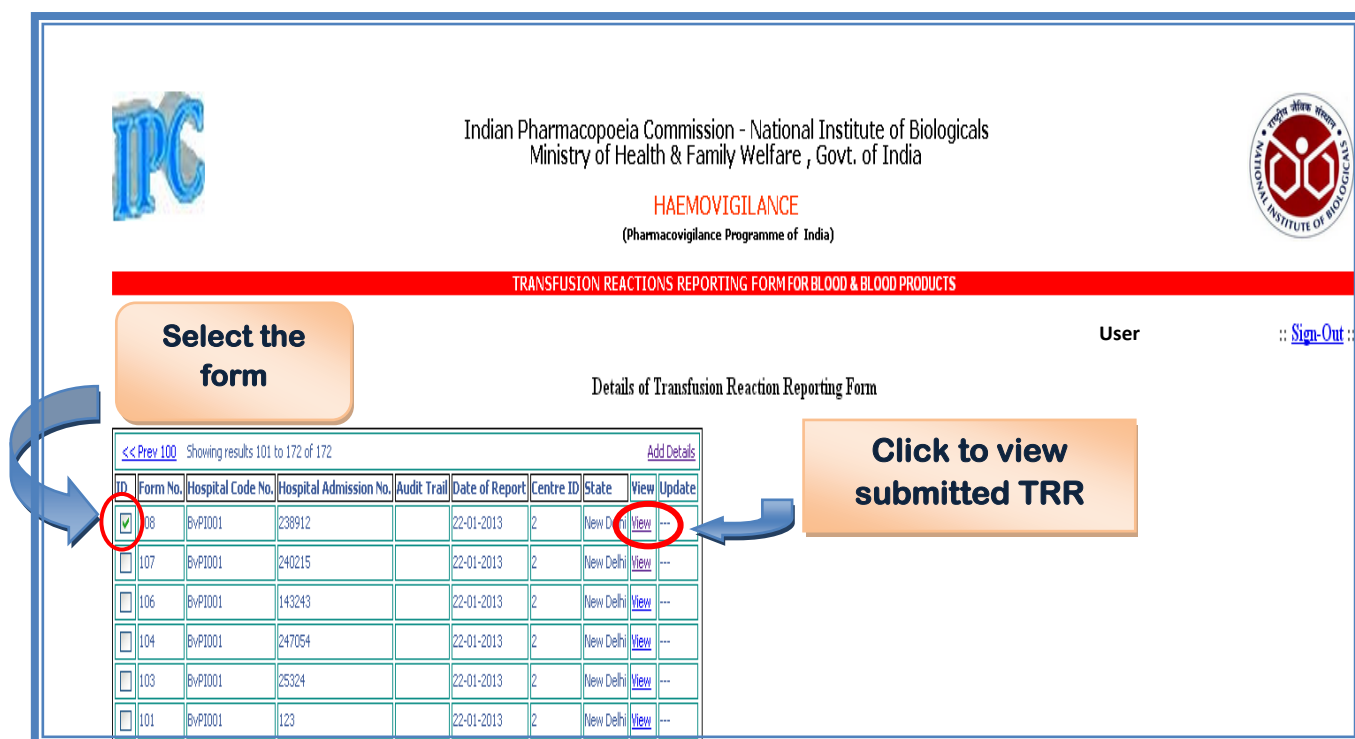
Can't read the image? click [here](#) to refresh

Submit **Reset**

Validation Code & Submission of TRR Form

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

Step 5:-



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HAEMOVIGILANCE
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TRANSFUSION REACTIONS REPORTING FORM FOR BLOOD & BLOOD PRODUCTS

Select the form

User [Sign-Out](#)


Details of Transfusion Reaction Reporting Form

ID	Form No.	Hospital Code No.	Hospital Admission No.	Audit Trail	Date of Report	Centre ID	State	View	Update
<input checked="" type="checkbox"/>	108	BvP1001	238912		22-01-2013	2	New Delhi	View	---
<input type="checkbox"/>	107	BvP1001	240215		22-01-2013	2	New Delhi	View	---
<input type="checkbox"/>	106	BvP1001	143243		22-01-2013	2	New Delhi	View	---
<input type="checkbox"/>	104	BvP1001	247054		22-01-2013	2	New Delhi	View	---
<input type="checkbox"/>	103	BvP1001	25324		22-01-2013	2	New Delhi	View	---
<input type="checkbox"/>	101	BvP1001	123		22-01-2013	2	New Delhi	View	---


Click to view submitted TRR

- “**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 & Family Welfare ♦ Govt. of India
HAEMOVIGILANCE
(Pharmacovigilance Programme of India)



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 Admission 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 Transfusion (No. of Repeats)
Red Blood Cells	<input checked="" type="checkbox"/>	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 Transfusion (No. of Repeats)

C. Nature of Adverse Reactions

Reactions	Please Tick
Feverile Non Haemolytic Reactions (FNHTR)	<input checked="" type="checkbox"/>

D. Outcomes of the Adverse Events

Unknown	<input checked="" type="checkbox"/>
---------	-------------------------------------

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:-



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

Details of Transfusion Reaction Reporting Form

ID	Form No.	Hospital Code No.	Hospital Admission No.	Audit Trail	Date of Report	Centre ID	State	View	Update
<input type="checkbox"/>	251	xyz	123		08-02-2013	1	Uttar Pradesh	View	Edit
<input type="checkbox"/>	250	BvPI001	110828	23-01-2013	01-02-2013	2	New Delhi	View	Edit
<input type="checkbox"/>	249	BvPI001	49767		23-01-2013	2	New Delhi	View	Edit
<input type="checkbox"/>	248	BvPI001	228748		23-01-2013	2	New Delhi	View	Edit

Click to edit the form



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