

# Interface Control Document

## Donor Hemovigilance System

Draft Version 4.7

Aug 04, 2009

## **Acknowledgement**

The Interface Control Document contains the data formats and definitions to be used to provide data for the Donor Hemovigilance program. These standards were developed based on inputs from AABB's Donor Hemovigilance Working group (AABB DWG).

## Record of Changes

<i>Revision</i>	<i>Date</i>	<i>Location</i>	<i>Type of Change</i>
V1.0	October 10, 2008	Section <a href="#">1</a>	Created the first draft of ICD.
V 2.0	December 15, 2008	Section <a href="#">3</a>	Second draft. Removed Organizations and Facility identifiers, components by individual, outside medical care, onsite or off site flag. Added “Reaction related to donation” flag.
V 3.0	December 24, 2008	Section <a href="#">4</a>	Added denominator details.
V 3.5	January 15, 2009	Section <a href="#">5</a>	Added CSV Format Specification.
V 4.0	January 30, 2009	<a href="#">Table 5</a> , <a href="#">Table 2</a>	Updated the Signs and Symptoms for Local Injury Related to Needle – Hematoma / Bruise category according to Dr. Mary J. Townsend, M.D. feedback.  Updated the Donation data elements to add Hemoglobin count data element.
V 4.1	March 4, 2009	<a href="#">Table 4</a> , <a href="#">Table 5</a> , <a href="#">Table 6</a> , <a href="#">Table 7</a> <a href="#">Table 2</a>	Updated signs and symptoms as per Dr. Mary J. Townsend, M.D. feedback.  Rearranged the Reaction Types, Categories, Sign and symptoms and Adverse events according to the order in the User Interface.
V4.2	April 4, 2009	<a href="#">Table 1</a> , <a href="#">Table 3</a> and	Changed race code from “BAA” to “AAB”. Updated "recovery more than 30 min"

<i>Revision</i>	<i>Date</i>	<i>Location</i>	<i>Type of Change</i>
		Sections <a href="#">5.3</a> , <a href="#">5.5</a>	and "reaction began more than 30 min" in reaction and CSV details
V4.3	May 18, 2009	Entire document	Ensure consistency with respect to the application
V 4.4	June 10, 2009	<a href="#">Table 3</a> , Section <a href="#">5.4</a>	Added update flag for reactions
V 4.5	July 22, 2009	<a href="#">Table 2</a> , <a href="#">Table 9</a> and Section <a href="#">5.3</a>	Discrepancies in terminology between reaction and denominator resolved
V 4.6	July 31, 2009	Entire document	Replaced "Biovigilance" with "Hemovigilance"
V 4.7	Aug 04, 2009	<a href="#">Table 6</a> , <a href="#">Table 7</a>	Updated few Signs and Symptoms and Other Adverse Events

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# 1 INTRODUCTION

This Interface Control Document (ICD) contains information pertinent to the understanding, definition, format, and interchange of data with the Donor Hemovigilance System.

## 1.1 Background

The focus of the Donor Hemovigilance system is to capture and analyze reaction information from the nation's blood centers. Though the components of a comprehensive hemovigilance system include adverse transfusion events, infectious diseases monitoring, emerging infectious diseases, and hazards of donation, this research effort focuses on the donor aspect of hemovigilance. Hemovigilance includes monitoring, analyzing, and researching the risks involved for a donor at the time of blood donation, or after the donation activity. Innovative approaches that will be implemented in the current Donor Hemovigilance system include:

1. Gather the information related to donor reactions that have occurred during blood donation using Web-based data capture methods;
2. Monitor the key metrics related to the occurrence of reactions, and track them across facilities and regions, nationally;
3. Use the collected information for data mining and GIS-based visualization to analyze changes in trend differences in patterns and identify the underlying causalities;
4. Apply pattern analysis for generating reports related to the early warning of safety issues, application of evidence for practice improvements, and the promotion of educational activities.

## 1.2 Purpose and Scope

The purpose of this document is to capture the format and requirements relevant to the hemovigilance data feed. Consolidating this information into one document, reviewed and agreed upon by both software vendors and hemovigilance system stakeholders, will ensure a greater level of understanding, and facilitate the smooth interchange of data with the Donor Hemovigilance system.

In addition, by keeping this document current and accurate, the time and effort to maintain and modify this process in the future will be reduced for both vendors and the hemovigilance system users. Information contained in this document includes:

- A description of the types of data contained in the CSV file
- A definition of each of the fields in the CSV file.

## 2 POINTS OF CONTACT

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### 3 DATA ELEMENTS IN DONOR HEMOVIGILANCE SYSTEM AND THEIR FORMAT

The system will have the ability to accept files containing donor, donation and reaction information from Blood Establishments and Organizations in the form of CSV on a frequent basis. The table below explains the data elements, their definition and their format for each.

**Table 1: Donor Data Elements**

Data Element	Definition	Data Type	Max Length	Allow Null
ORGANIZATION NAME	An identifier that uniquely defines an organization.	Alpha-Numeric	100	N
REGION	In the case donor identifier is unique within a region (as in the case of ARC), the region ID.	Alpha-Numeric	50	Y
DONOR IDENTIFIER	An identifier that uniquely identifies a donor.	Alpha-Numeric	50	N
DATE OF BIRTH		MM/DD/YYYY	10	N
GENDER	Valid Values: Male, Female	Alpha-Numeric	10	N
ETHNICITY	Valid Values: HISP, NOHISP	Alpha-Numeric	10	Y
RACE	Can specify multiple values separated by semicolon. Valid Values: AMIN, ASIAN, AAB, NH-PI, WHITE	Alpha-Numeric	28	Y

The enumerated values correspond to AMIN (American Indian/Alaska native), AAB (African American or Black), NH-PI (Native Hawaiian/Other Pacific Islander), HISP (Hispanic or Latino) and NOHISP (Not Hispanic or Latino).

**Table 2: Donation Data Elements**

<b>Data Element</b>	<b>Definition</b>	<b>Data Type</b>	<b>Max Length</b>	<b>Allow Null</b>
ORGANIZATION NAME	An identifier that uniquely defines an organization.	Alpha-Numeric	100	N
REGION	In the case donor identifier is unique within a region (as in the case of ARC), the region ID.	Alpha-Numeric	50	Y
DONOR IDENTIFIER	An identifier that uniquely identifies a donor.	Alpha-Numeric	100	N
COLLECTION CENTER	An identifier of the collection center where the donation happened.	Alpha-Numeric	100	N
DONATION IDENTIFIER	An identifier that uniquely identifies a donation.	Alpha-Numeric	50	N
DONATION DATE		MM/DD/YYYY	10	N
DONATION HISTORY	Valid Values: First, Repeat	Alpha-Numeric	10	Y
DONOR HEIGHT	Height in inches	Decimal	10	Y
DONOR WEIGHT	Weight in lbs	Decimal	10	Y
NUMBER OF DONATIONS	Donations made in the past 12 months.	Integer	10	Y
COLLECTION SITE	Valid Values: Fixed site, Mobile inside-set-up, Mobile donor coach	Alpha-Numeric	25	Y
SPONSORING GROUP TYPE	Valid Values: High school, College, Work Place, Military, Other	Alpha-Numeric	12	Y
INTENDED DONATION TYPE	Valid Values: Allogeneic, Autologous, Therapeutic, Directed, Source Plasma, Other	Alpha-Numeric	15	Y
INTENDED PROCEDURE TYPE	Valid Values: Whole Blood, Apheresis Platelets, Apheresis Red Cells, Apheresis Plasma, Apheresis Platelets and Plasma, Apheresis Platelets and Red Cells, Sample only, Apheresis Leukocytes, Apheresis Platelet	Alpha-Numeric	50	Y

	Plasma Red Cells, Apheresis Plasma Red Cells, Apheresis Stem Cells, Apheresis Double Red Cells			
TIME NEEDLE INSERTED		Time in HH:MM	5	Y
TIME NEEDLE WITHDRAWN		Time in HH:MM	5	Y
MANUFACTURER		Alpha-Numeric	50	Y
MODEL		Alpha-Numeric	50	Y
SOFTWARE		Alpha-Numeric	50	Y
VERSION		Alpha-Numeric	25	Y
KIT MANUFACTURER		Alpha-Numeric	50	Y
KIT TYPE		Alpha-Numeric	25	Y
KIT NUMBER		Alpha-Numeric	25	Y
LOT NUMBER		Alpha-Numeric	25	Y
COMPONENTS PRODUCED	Component Produced by total. Can specify multiple combinations of component name and its number of units.  Valid Values: Whole Blood, Platelets, Red Blood Cells, Plasma, Leukocyte, Stem cells. See section 5.3 for details on this field.	Alpha-Numeric	50	Y
VOLUME REMOVED		Integer		Y
FLUID INFUSED		Integer		Y
SUCCESSFUL DONATION	Valid Values: Yes, No	Alpha-Numeric	10	Y
PLATELET COUNT		Decimal	10	Y
DATE OF PLATELET COUNT		MM/DD/YYYY	10	Y
TOTAL PROTEIN		Decimal	10	Y
DATE OF TOTAL PROTEIN		MM/DD/YYYY	10	Y
PULSE		Integer	10	Y
SYSTOLIC PRESSURE		Integer	10	Y
DIASTOLIC PRESSURE		Integer	10	Y
HEMATOCRIT COUNT		Decimal	10	Y
HEMOGLOBIN COUNT		Decimal	10	Y

KIND OF SAMPLE	Valid Values: Capillary, Venous	Alpha-Numeric	10	Y
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**Table 3: Reaction Data Elements**

Data Element	Definition	Data Type	Max Length	Allow Null
ORGANIZATION NAME	An identifier that uniquely defines an organization.	Alpha-Numeric	100	N
REGION	In the case donor identifier is unique within a region (as in the case of ARC), the region ID.	Alpha-Numeric	50	Y
DONOR IDENTIFIER	An identifier that uniquely identifies a donor.	Alpha-Numeric	50	N
COLLECTION CENTER	An identifier of the collection center where the donation happened.	Alpha-Numeric	100	N
DONATION IDENTIFIER	An identifier that uniquely identifies a donation.	Alpha-Numeric	50	N
DATE REACTION BEGAN		MM/DD/YYYY		Y
TIME REACTION BEGAN		Time in HH:MM	5	Y
TIME REACTION ENDED		Time in HH:MM	5	Y
LOCATION REACTION BEGAN	Valid Values: Registration, Screening, Bed, Transit to canteen, Canteen, Other location on site, Off site	Alpha-Numeric	25	Y
REACTION TYPE	Valid Values: Allergic, Apheresis, Local injury related to needle, Vasovagal, Other	Alpha-Numeric	40	N
REACTION CATEGORY	Valid Values: See Table 5 for association between reaction types and categories.	Alpha-Numeric	100	N
REACTION BEGAN MORE THAN 30 MINUTES AFTER NEEDLE WITHDRAWAL	Valid Values: 1 for Yes and 0 for No	Boolean	1	Y
RECOVERY MORE THAN 30 MINS	Valid Values: 1 for Yes and 0 for No	Boolean	1	Y
HIGHEST PULSE		Integer	10	Y
LOWEST PULSE		Integer	10	Y

HIGHEST DIASTOLIC PRESSURE		Integer	10	Y
LOWEST DIASTOLIC PRESSURE		Integer	10	Y
SIGNS AND SYMPTOMS	Can specify multiple values separated by semicolon. Valid Values: See Table 6 for association between Reaction Category and Signs and Symptoms.	Alpha-Numeric	1400	Y
OTHER ADVERSE EVENTS	Can specify multiple values separated by semicolon Valid Values: See Table 7 and Table 8 for association between Reaction Category and Other Adverse Events.	Alpha-Numeric	500	Y
OTHER EVENTS	Any other Events.	Alpha-Numeric	1000	Y
RESOLUTION OF ACUTE REACTION	Valid Values: Released, Released, escorted, Released to outside medical care, N/A	Alpha-Numeric	40	Y
DATE OF RESOLUTION OF PROLONGED REACTION		MM/DD/YYYY	10	Y
OUTCOME	Valid Values: Open, Resolved, Death, Disability.	Alpha-Numeric	15	Y
OUTSIDE MEDICAL CARE	Can specify multiple values separated by semicolon. Valid Values: None, ER, EMT, Outpatient, Hospital Admission, Multiple clinic visits	Alpha-Numeric	75	Y
REACTION RELATED TO DONATION	Indicates whether the reaction is related to donation or not Valid Values: 1 for Yes and 0 for No	Boolean	1	Y
UPDATE_FLAG	Indicates whether the reaction is to be added or updated. Valid Values: 0 for Add; 1 for Update	Integer	1	N

## 4 DENOMINATOR

The system will have the ability to accept denominator from blood establishments and organizations through CSV file inputs. Denominator refers to total number of donations (as measured by needle insertions) at a facility. Denominators are used to calculate rates of reactions and to analyze the demographic and donation procedures that might be associated with donor reactions.

In the donor hemovigilance system, denominators are maintained at both organization and individual collection center level. The table below explains the data elements, their definition and their format.

**Table 4: Denominator Data Elements**

Data Element	Definition	Data Type	Max Length	Allow Null
ORGANIZATION NAME	An identifier that uniquely defines an organization.	Alpha-Numeric	100	N
COLLECTION CENTER	An identifier of the collection center where the donation happened.	Alpha-Numeric	100	N
MONTH	Month ( in number) to indicate the month for which denominator data is being reported	Integer	2	N
YEAR	Year ( in number) to indicate the year for which denominator data is being reported	Integer	4	N
DIMENSION NAME	Name of the Dimension for which denominator data is being reported. See Table 9 in section Denominator Data6.5 to view the valid values.	Alpha-Numeric	100	N
DIMENSION CLASS	Name of the Dimension Class for which denominator data is being reported. See Table 9 in section Denominator Data6.5 to view the valid values.	Alpha-Numeric	100	N
NO OF DONATIONS	Number of donations	Integer	10	N

## 5 COMMA SEPARATED VARIABLE FILE FORMAT SPECIFICATION

Donor Bio-vigilance System accepts reaction data upload using comma separated variable (CSV) files. This section details the format for the CSV files.

### 5.1 Guiding Principles

- 1) Each line in a CSV file corresponds to a row (record) in a table. Within a line, the fields are separated by commas. The last field in a row is not followed by a comma. Each record is located in a separate line, delimited by a line break (CRLF).

```
TEST ORG,TEST REGION ONE,1,6/6/1966,MALE,NOHISP,AABCRLF
```

```
TEST ORG,TEST REGION ONE,12,6/6/1966,FEMALE,NOHISP,WHITECRLF
```

- 2) The last record in the file may or may not have an ending line break.

```
TEST ORG,TEST REGION ONE,1,6/6/1966,MALE,NOHISP,AABCRLF
```

```
TEST ORG,TEST REGION ONE,12,6/6/1966,FEMALE,NOHISP,WHITE
```

- 3) The first line contains the header. The header will contain the field names separated by commas.

```
ORGANIZATION NAME,REGION,DONOR IDENTIFIER,DATE OF BIRTH, GENDER,ETHNICITY,  
RACECRLF
```

```
TEST ORG,TEST REGION ONE,1,6/6/1966,MALE,NOHISP,AABCRLF
```

```
TEST ORG,TEST REGION ONE,12,6/6/1966,FEMALE,NOHISP,WHITECRLF
```

- 4) Each row should contain the same number of fields as specified in the header. If a field is NULL, it can be specified by having immediately the next comma.

```
... TEST REGION ONE,1,6/6/1966, FEMALE,,WHITECRLF
```

- 5) The donor bio-vigilance system supports 3 CSV file formats corresponding to donor, donation and reaction data. The format of these CSV files is detailed in sub-sections 5.2, 5.3, and 5.4. The fields in these files cannot be renamed or re-arranged. If any organization does not have data for any field, the field still has to be included in the file but can be left empty.

- 6) Each field may (optionally) be enclosed in double quotes.

```
... TEST REGION ONE,16/6/1966, "FEMALE", NOHISP,"WHITE"CRLF
```

- 7) Fields containing line breaks (CRLF), commas (,), and double quotes (" or ") should be enclosed in double quotes"

... TEST REGION ONE,1,6/6/1966, "FEMALE", NOHISP,"WHITE, CCC"**CRLF**

- 8) A double-quote appearing inside a field must be escaped by preceding it with another double quote:

... TEST REGION ONE,1,6/6/1966, "FEMALE", NOHISP,"WHITE, ""CCC"""**CRLF**

- 9) Leading and trailing spaces in a field are trimmed:

... TEST REGION ONE , 1, 6/6/1966 , FEMALE , NOHISP , WHITE **CRLF**

Is same as

... TEST REGION ONE,1,6/6/1966, FEMALE, NOHISP,WHITE**CRLF**

If they are a part of the field, the field needs to be enclosed in double quotes:

... TEST REGION ONE,1,6/6/1966,FEMALE,NOHISP," WHITE , CCC "**CRLF**

## 5.2 Donor Data

The donor CSV file contains the following fields:

Organization Name, Region, Donor Identifier, Date of Birth, Gender, Ethnicity, Race

If race has multiple values, they should be separated by a semicolon.

Test Org,Test Region One,6,6/6/1966,Male,Hisp,Amin

Test Org,Test Region One,7,6/6/1966,Male,Hisp,Amin;Asian;Aab;WHITE;Nh-Pi

Test Org,Test Region One,8,6/6/1966,Female,NOHISP,Nh-Pi

## 5.3 Donation Data

The donation CSV file contains the following fields:

Organization Name, Region, Donor identifier, Collection center, Donation identifier, Donation date, Donation history, Donor height, Donor weight, Number of donations, Collection site, Sponsoring group type, Intended donation type, Intended procedure type, Time needle inserted, Time needle withdrawn, Manufacturer, Model, Software, Version, Kit manufacturer, Kit type, Kit number, Lot number, Components produced, Volume removed, Fluid infused, Successful donation, Platelet count, Date of platelet count, Total protein, Date of total protein, Pulse, Systolic pressure, Diastolic pressure, Hematocrit count, Hemoglobin count, Kind of sample

If any of the numeric values have commas (e.g. 20,000), it should be enclosed in double quotes. Components produced should be enclosed in double quotes and should be of the format "Component produced, Qty" (e.g., "Whole blood, 2"). If multiple components are produced, they should be separated by ';' (e.g., "Red Blood Cells, 1; Plasma, 2").

Sample records:

```
TEST ORG,TEST REGION ONE,1,TEST CENTER 1,1,1/1/2009,REPEAT,88,212,
5,Mobile inside-set-up,,Therapeutic,Apheresis Platelets and Red Cells,23:18,23:18,,,,,,
,"Plasma, 1; Red blood Cells, 1; Platelets, 2",3,8,YES,,8/30/1972,,9/23/2004,173,95,
98,,Venous
```

```
TEST ORG,TEST REGION ONE,2,TEST CENTER 1,2,1/1/2009,REPEAT,64,298,5,
Mobile inside-set-up,,Directed, Apheresis Leukocytes,6:29,6:29,,,,,,,"Plasma, 1; Red
blood Cells, 1; Platelets, 2",1,4,YES,,1/19/1993,,8/23/1972,141,141,43,,
```

```
TEST ORG,TEST REGION ONE,3,TEST CENTER 1,3,1/1/2009,REPEAT,60,188,5,
Mobile donor coach,,Therapeutic,Apheresis Leukocytes,21:26,21:26,,,,,,,"Whole Blood,
2",1,8,YES,,4/14/1984,,11/1/1993,147,,,,,
```

## 5.4 Reaction Data

The reaction CSV file contains the following fields:

Organization Name, Region, Donor Identifier, Collection Center, Donation Identifier, Date Reaction Began, Time Reaction Began, Time Reaction Ended, Location Reaction Began, Reaction Type, Reaction Category, Reaction Began More Than 30 Minutes After Needle Withdrawal , Recovery More Than 30 Mins, Highest Pulse, Lowest Pulse, Highest Diastolic Pressure , Lowest Diastolic Pressure , Signs And Symptoms, Other Adverse Events, Other Events, Resolution Of Acute Reaction, Date Of Resolution Of Prolonged Reaction, Outcome, Outside Medical Care, Reaction Related To Donation, Update Flag

Since some of the signs and symptoms have commas this field should be enclosed in double quotes and delimited by semicolon. (e.g. "Redness, Warmth; Pressure, Swelling, Tenderness"). If the reaction category contains comma, it should be enclosed in double quotes (e.g., "Prefaint, no LOC (uncomplicated)").

If multiple values are specified for other adverse events they should be separated by semicolon and enclosed in double quotes (e.g. "Brachial artery pseudoaneurysm; Cardiac arrest; Compartment syndrome")

If multiple values are specified for 'Outside medical Care' they should be separated by semicolon and enclosed in double quotes (e.g., "EMT; Hospital Admission; ER").

Sample records:

TEST ORG,TEST REGION ONE,1,TEST CENTER 1,1,2/2/2009,0:35,0:35,Off site,  
Allergic,Anaphylaxis,1,0,175,68,149,93,"Anxiousness, restlessness; Normal  
Pulse" ,,,Released to outside medical care,3/3/2009,Open,EMT,1,0

TEST ORG,TEST REGION ONE,2,TEST CENTER 1,2,2/2/2009,0:14,0:14,Registration,  
Allergic,Anaphylaxis,0,1,95,60,130,99,"Anxiousness, restlessness; Rapid  
Pulse" ,,,N/A,3/3/2009,Open,Outpatient,0,1

TEST ORG,TEST REGION ONE,3,TEST CENTER 1,3,2/2/2009,22:25,22:25,Screening,  
Allergic,Anaphylaxis,1,0,101,84,124,87,"Anxiousness, restlessness; Normal Pulse;  
Cyanosis" ,,, "Released, escorted",3/3/2009,Disability,EMT,1,0

## 5.5 Denominator Data

The denominator CSV contains following fields:

Organization name, Collection Center, Month, Year, Dimension Name, Dimension Class,  
No of Donations

Sample Records:

TEST ORG, TEST CENTER 1, 1, 2004, Blood Pressure, BP < 60, 234

TEST ORG,, 1,2004,Race,Native American,2

TEST ORG,, 1,2004,total,,12

## 6 APPENDIX

### 6.1 Association between Reaction Types and Reaction Categories

**Table 5: Reaction Types and Categories**

Reaction Type	Reaction Category
Vasovagal	<ul style="list-style-type: none"> <li>• Prefaint, no LOC (uncomplicated or minor)</li> <li>• LOC, any duration (uncomplicated)</li> <li>• LOC, any duration (complicated)</li> <li>• Injury</li> </ul>
Local injury related to needle	<ul style="list-style-type: none"> <li>• Nerve Irritation</li> <li>• Hematoma / Bruise</li> <li>• Arterial Puncture</li> </ul>
Apheresis	<ul style="list-style-type: none"> <li>• Citrate</li> <li>• Hemolysis</li> <li>• Air Embolus</li> </ul>
Allergic	<ul style="list-style-type: none"> <li>• Local</li> <li>• Systemic</li> <li>• Anaphylaxis</li> </ul>
Other	<ul style="list-style-type: none"> <li>• Other</li> </ul>

### 6.2 Association between Reaction Categories and Signs & Symptoms

**Table 6: Signs and Symptoms associated with Reactions**

Reaction Type	Category	Signs & Symptoms
Vasovagal	Prefaint, no LOC (uncomplicated or minor)	<ol style="list-style-type: none"> <li>1. Cold extremities, chills</li> <li>2. Feeling of warmth</li> <li>3. Hypotension</li> <li>4. Lightheaded / Dizziness</li> <li>5. Nausea / vomiting</li> <li>6. Normal pulse</li> <li>7. Pallor, pale skin or lips</li> <li>8. Rapid pulse</li> <li>9. Slow pulse</li> <li>10. Sweating</li> <li>11. Twitching</li> <li>12. Weakness</li> </ol>

Vasovagal	LOC, any duration (uncomplicated)	<ol style="list-style-type: none"> <li>1. Cold extremities, chills</li> <li>2. Feeling of warmth</li> <li>3. Hypotension</li> <li>4. Lightheaded / Dizziness</li> <li>5. Loss of consciousness &lt; 60 seconds</li> <li>6. Nausea / vomiting</li> <li>7. Normal pulse</li> <li>8. Pallor, pale skin or lips</li> <li>9. Rapid pulse</li> <li>10. Slow pulse</li> <li>11. Sweating</li> <li>12. Twitching</li> <li>13. Weakness</li> </ol>
Vasovagal	LOC, any duration (complicated)	<ol style="list-style-type: none"> <li>1. Cold extremities, chills</li> <li>2. Convulsions</li> <li>3. Feeling of warmth</li> <li>4. Hypotension</li> <li>5. Lightheaded / Dizziness</li> <li>6. Loss of bladder, bowel control</li> <li>7. Loss of consciousness &lt; 60 seconds</li> <li>8. Loss of consciousness <math>\geq</math> 60 seconds</li> <li>9. Nausea / vomiting</li> <li>10. Normal pulse</li> <li>11. Pallor, pale skin or lips</li> <li>12. Rapid pulse</li> <li>13. Slow pulse</li> <li>14. Sweating</li> <li>15. Tetany</li> <li>16. Twitching</li> <li>17. Weakness</li> </ol>
Vasovagal	Injury	<ol style="list-style-type: none"> <li>1. Cold extremities, chills</li> <li>2. Convulsions</li> <li>3. Feeling of warmth</li> <li>4. Hypotension</li> <li>5. Lightheaded / Dizziness</li> <li>6. Loss of bladder, bowel control</li> <li>7. Loss of consciousness &lt; 60 seconds</li> <li>8. Loss of consciousness <math>\geq</math> 60 seconds</li> <li>9. Nausea / vomiting</li> <li>10. Normal pulse</li> <li>11. Pallor, pale skin or lips</li> <li>12. Rapid pulse</li> <li>13. Slow pulse</li> <li>14. Sweating</li> </ol>

		<ul style="list-style-type: none"> <li>15. Tetany</li> <li>16. Twitching</li> <li>17. Weakness</li> </ul>
Local injury related to needle	Nerve Irritation	<ul style="list-style-type: none"> <li>1. Immediate intense pain at site,</li> <li>2. Parasthesias, Numbness or tingling of fingers, hand or arm</li> <li>3. Shooting pain down arm</li> <li>4. Weakness of arm</li> </ul>
Local injury related to needle	Hematoma / Bruise	<ul style="list-style-type: none"> <li>1. Pain</li> <li>2. Pressure, swelling, tenderness</li> <li>3. Redness, warmth</li> </ul>
Local injury related to needle	Arterial Puncture	<ul style="list-style-type: none"> <li>1. Bright red blood</li> <li>2. Pulse sensation in tubing</li> <li>3. Pulsing blood flow</li> <li>4. Rapid filling of bag (less than 4 minutes)</li> </ul>
Apheresis	Citrate	<ul style="list-style-type: none"> <li>1. Bluish tint to skin (cyanosis)</li> <li>2. Carpopedal spasms</li> <li>3. Chills / Shivering</li> <li>4. Circumoral paresthesia</li> <li>5. Mental confusion</li> <li>6. Muscle tightness or cramping, tetany</li> <li>7. Nausea / vomiting</li> <li>8. Normal Pulse</li> <li>9. Pallor</li> <li>10. Rapid pulse</li> <li>11. Sharp chest pain</li> <li>12. Shock - Low blood pressure</li> <li>13. Shortness of breath</li> <li>14. Slow Pulse</li> <li>15. Tachycardia, irregular heart beat</li> <li>16. Twitching / tremors (Sensation of vibration)</li> </ul>
Apheresis	Hemolysis	<ul style="list-style-type: none"> <li>1. Back / Flank pain</li> <li>2. Bluish tint to skin (cyanosis)</li> <li>3. Hematuria</li> <li>4. Mental confusion</li> <li>5. Pallor</li> <li>6. Red plasma</li> <li>7. Shock - Low blood pressure</li> <li>8. Shortness of breath</li> <li>9. Tachycardia, irregular heart beat</li> </ul>
Apheresis	Air Embolus	<ul style="list-style-type: none"> <li>1. Back / Flank pain</li> <li>2. Bluish tint to skin (cyanosis)</li> <li>3. Mental confusion</li> </ul>

		<ol style="list-style-type: none"> <li>4. Nausea / vomiting</li> <li>5. Sharp chest pain</li> <li>6. Shock-low blood pressure</li> <li>7. Shortness of breath</li> <li>8. Tachycardia, irregular heart beat</li> </ol>
Allergic	Local	<ol style="list-style-type: none"> <li>1. Itching at insertion or bandage site</li> <li>2. Rash / Hives at insertion or bandage site</li> <li>3. Redness at needle insertion or bandage site</li> </ol>
Allergic	Systemic	<ol style="list-style-type: none"> <li>1. Anxiousness, restlessness</li> <li>2. Arrhythmia</li> <li>3. Cyanosis</li> <li>4. Generalized hives</li> <li>5. Generalized itching</li> <li>6. Generalized rash</li> <li>7. High blood pressure</li> <li>8. Itching at insertion or bandage site</li> <li>9. Laryngeal edema with stridor</li> <li>10. Low blood Pressure</li> <li>11. Normal Pulse</li> <li>12. Pulmonary edema</li> <li>13. Rapid Pulse</li> <li>14. Rash / Hives at insertion or bandage site</li> <li>15. Redness at needle insertion or bandage site</li> <li>16. Scratchy feeling in throat</li> <li>17. Shortness of breath</li> <li>18. Slow Pulse</li> <li>19. Sneezing and nasal congestion</li> <li>20. Wheezing</li> </ol>

Allergic	Anaphylaxis	<ol style="list-style-type: none"> <li>1. Anxiousness, restlessness</li> <li>2. Arrhythmia</li> <li>3. Cyanosis</li> <li>4. Generalized hives</li> <li>5. Generalized itching</li> <li>6. Generalized rash</li> <li>7. High blood pressure</li> <li>8. Itching at insertion or bandage site</li> <li>9. Laryngeal edema with stridor</li> <li>10. Low blood pressure</li> <li>11. Normal Pulse</li> <li>12. Pulmonary edema</li> <li>13. Rapid Pulse</li> <li>14. Rash / Hives at insertion or bandage site</li> <li>15. Redness at needle insertion or bandage site</li> <li>16. Scratchy feeling in throat</li> <li>17. Shortness of breath</li> <li>18. Slow Pulse</li> <li>19. Sneezing and nasal congestion</li> <li>20. Swollen tongue, throat, eyes and face</li> <li>21. Wheezing</li> </ol>
Other	Other	<ol style="list-style-type: none"> <li>1. All signs and symptoms of all reaction types &amp; categories (without duplicates)</li> </ol>

### 6.3 Association between Reaction Categories & Other Adverse Events

**Table 7: Adverse Events Categories Associated With Different Reactions**

Reaction Type	Category	Adverse Event Categories
Vasovagal	Prefaint, no LOC (uncomplicated or minor)	<ol style="list-style-type: none"> <li>1. Major Cardiovascular Event</li> <li>2. Other Adverse Events</li> </ol>
Vasovagal	LOC, any duration (uncomplicated)	<ol style="list-style-type: none"> <li>1. Major Cardiovascular Event</li> <li>2. Other Adverse Events</li> </ol>
Vasovagal	LOC, any duration (complicated)	<ol style="list-style-type: none"> <li>1. Major Cardiovascular Event</li> <li>2. Other Adverse Events</li> </ol>
Vasovagal	Injury	<ol style="list-style-type: none"> <li>1. Injury</li> <li>2. Major Cardiovascular Event</li> </ol>

		3. Other Adverse Events
Local injury, related to needle	Nerve Irritation	1. Infection 2. Major Blood Vessel Injury 3. Major Cardiovascular Event 4. Minor injury 5. Other Adverse Events
Local injury, related to needle	Hematoma / Bruise	1. Infection 2. Major Blood Vessel Injury 3. Major Cardiovascular Event 4. Minor injury 5. Other Adverse Events
Local injury, related to needle	Arterial Puncture	1. Infection 2. Major Blood Vessel Injury 3. Major Cardiovascular Event 4. Minor injury 5. Other Adverse Events
Apheresis	Citrate	1. Major Cardiovascular Event 2. Other Adverse Events
Apheresis	Hemolysis	1. Major Cardiovascular Event 2. Other Adverse Events
Apheresis	Air Embolus	1. Major Cardiovascular Event 2. Other Adverse Events
Allergic	Local	1. Other Adverse Events
Allergic	Systemic	1. Major Blood Vessel Injury 2. Major Cardiovascular Event 3. Other Adverse Events
Allergic	Anaphylaxis	1. Major Blood Vessel Injury 2. Major Cardiovascular Event 3. Other Adverse Events
Other	Other	1. All other adverse events irrespective of reaction types & categories

## 6.4 Adverse Events

**Table 8: Adverse Events in Different Adverse Event Categories**

<b>Adverse Event Category</b>	<b>Events in the adverse event category</b>
Major Blood Vessel Injury	1. Arteriovenous fistula 2. Axillary vein thrombosis 3. Brachial artery pseudoaneurysm 4. Compartment syndrome 5. Deep vein thrombosis 6. Thrombophlebitis

Major Cardiovascular Events	<ol style="list-style-type: none"> <li>1. Angina pectoris within 24 hours</li> <li>2. Cardiac arrest</li> <li>3. Cerebrovascular accident</li> <li>4. Myocardial infarction within 24 hours</li> <li>5. Transient ischemic attack within 24 hours (TIA)</li> </ol>
Injury	<ol style="list-style-type: none"> <li>1. closed head injury</li> <li>2. dental injury</li> <li>3. fracture</li> <li>4. Laceration</li> <li>5. motor vehicle accident with imputability</li> <li>6. other</li> <li>7. soft tissue injury</li> </ol>
Minor Injury	<ol style="list-style-type: none"> <li>1. Abrasion</li> <li>2. Bruise</li> <li>3. Hematoma</li> <li>4. Pain</li> </ol>
Infection	<ol style="list-style-type: none"> <li>1. Local infection - Cellulitis</li> </ol>
Other	<User can enter free-form text>

## 6.5 Denominator Dimensions and their corresponding classes

**Table 9: Dimensions and their classes**

Dimension Name	Dimension Class Name
Age	<ol style="list-style-type: none"> <li>1. 16 – 18</li> <li>2. 19 - 22</li> <li>3. 23 - 29</li> <li>4. 30 - 39</li> <li>5. 40 - 49</li> <li>6. 50 - 59</li> <li>7. 60 - 69</li> <li>8. 70 – 79</li> <li>9. &gt; 80</li> </ol>
Blood Pressure	<ol style="list-style-type: none"> <li>1. BP &lt; 60</li> <li>2. BP 60 – 90</li> <li>3. BP &gt; 90</li> </ol>
Collection Site	<ol style="list-style-type: none"> <li>1. Mobile donor coach</li> <li>2. Fixed site</li> <li>3. Mobile inside-set-up</li> </ol>
Container	<ol style="list-style-type: none"> <li>1. Container F</li> <li>2. Container M</li> <li>3. Container P</li> </ol>

Device	<ol style="list-style-type: none"> <li>1. Device C</li> <li>2. Device F</li> <li>3. Device H</li> </ol>
Donation History	<ol style="list-style-type: none"> <li>1. First</li> <li>2. Repeat</li> </ol>
Donation Type	<ol style="list-style-type: none"> <li>1. Allogeneic</li> <li>2. Autologous</li> <li>3. Directed</li> <li>4. Source Plasma</li> <li>5. Therapeutic</li> <li>6. Other</li> </ol>
Ethnicity	<ol style="list-style-type: none"> <li>1. Hispanic or Latino</li> <li>2. Not Hispanic or Latino</li> </ol>
Gender	<ol style="list-style-type: none"> <li>1. Female</li> <li>2. Male</li> </ol>
Height	<ol style="list-style-type: none"> <li>1. &lt; 60</li> <li>2. 60 - 63</li> <li>3. 64 - 67</li> <li>4. 68 – 72</li> <li>5. &gt; 72</li> </ol>
Procedure Type	<ol style="list-style-type: none"> <li>1. Apheresis Double Red Cells</li> <li>2. Apheresis Leukocytes</li> <li>3. Apheresis Plasma</li> <li>4. Apheresis Platelets</li> <li>5. Apheresis Platelets and Plasma</li> <li>6. Apheresis Platelets and Red Cells</li> <li>7. Apheresis Platelet Plasma Red Cells</li> <li>8. Apheresis Plasma Red Cells</li> <li>9. Apheresis Stem Cells</li> <li>10. Sample Only</li> <li>11. Whole Blood</li> <li>12. Apheresis Red Cells</li> </ol>
Pulse	<ol style="list-style-type: none"> <li>1. &lt; 70</li> <li>2. 70 – 100</li> <li>3. &gt; 100</li> </ol>
Race	<ol style="list-style-type: none"> <li>1. African American or Black</li> <li>2. Asian</li> <li>3. American Indian/Alaska Native</li> <li>4. Native Hawaiian/Other Pacific Islander</li> <li>5. White</li> </ol>
Sponsor Group Type	<ol style="list-style-type: none"> <li>1. College</li> <li>2. High School</li> <li>3. Military</li> <li>4. Work place</li> <li>5. Other</li> <li>6. NA</li> </ol>

Weight	<ol style="list-style-type: none"><li>1. &lt; 110</li><li>2. 110 - 119</li><li>3. 120 - 129</li><li>4. 130 - 139</li><li>5. 140 - 149</li><li>6. 150 - 159</li><li>7. 160 - 169</li><li>8. 170 - 179</li><li>9. 180 - 189</li><li>10. 190 - 199</li><li>11. 200 - 224</li><li>12. 225 - 249</li><li>13. 250 - 274</li><li>14. 275 - 299</li><li>15. &gt; 300</li></ol>
Total	<ol style="list-style-type: none"><li>1. Total Donations</li></ol>