

# Donor Vigilance: Five-Year Journey of Continuous Process Improvement

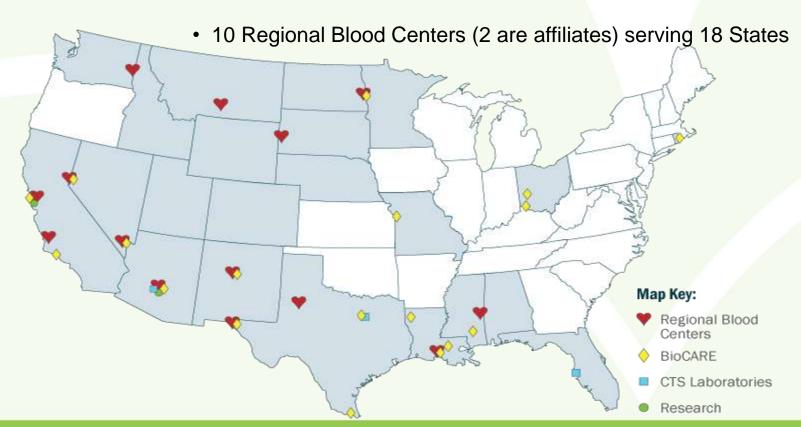
Hany Kamel, MD Marjorie Bravo, MD Brian Custer, PhD Peter Tomasulo, MD

## Background

- Donor Vigilance Program at Blood Systems, Inc. (BSI) began in 2007
- Resulted in multiple refereed publications that have influenced policies
- Led to implementation of intervention measures that reduced vasovagal reactions in donors.

# **Organization Background**

- Established 1943
- Non-profit 501 (c) (3) Organization
- National Headquarters is Blood Systems (Scottsdale, Arizona)





#### Aim

 To describe actions taken in data collection to enhance analysis and reporting on blood donor adverse events (AEs) aimed to inform appropriate intervention strategies.

#### **BSI's Donor VigilanceTimeline**

2007 > 2008 > 2009 > 2010 > 2011 > present

#### **CONTINUOUS PROCESS IMPROVEMENT**

**Data Collection Forms** 

**Database** 

Vasovagal Reactions Classification

**Supplemental Donor Testing** 

BECS changes to accommodate external reporting

- Mild Reactions
- Donor Association
- Intended Collection Type



#### **Data Collection Forms**

2007 > 2008 > 2009 > 2010 > 2011 > present

- Rev 5 (up to 6/3/07)
  - Rev 6 (6/4/07 to 12/2/07)
    - Rev 7 (12/3/07 to 4/24/08)
      - Rev 8 (4/25/08 to 7/27/08)
        - Rev 9 (7/28/08 to 10/26/08)
          - Rev 10 (10/27/08 to 3/29/09)
            - Rev 11 (3/30/09 to 11/27/2011)
              - Rev 12 (11/28/2011 to present)
- Revisions 5 to 12 (2007 to present) periodic reviews allowed inclusion of data elements evaluated as important in donor vigilance
- NOTE: participation in national reporting allowed for stabilization of data collection form, i.e. Rev. 11 (3/30/2009 to 11/27/2011)



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	☐ Weaknes	O Feeling v	☐ Sweating	D Swesting	☐ Hyperventilation		☐ Pain or pressure at nee	die site	☐ Pressure be	
Proges	☐ Tingling/r	C) Maryouse	☐ Feeling warn	☐ Feeling warm	☐ Light-headedness/Dizzi	1415	D Possible arterial punctu		D Breathing in	
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INSTRU	☐ Feet elev	O Weaknes	□ Hyperventila	□ Hyperventiat	☐ Tingling/numbness lips/	lingers.	☐ Rash/ttching/hives at no		☐ Saline infus	
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Repeat	☐ Fluid intal	O Hematen	☐ Nausea	☐ Nausea	☐ Twitching movements (	remors)	the forearm			
Reactio		OHematen	☐ Yomting	□ Vamiting	☐ Muscle tightness or crar	oping (Tetany)	Numbness/tingling of fir hand or arm	igers.		
Time of	Monitoring	O intitration	☐ Twitching mo ☐ Muscle tights	☐ Twitching ma ☐ Muscle tightn	☐ Incontinence ☐ Fainting/loss of conscio		D Weakness of arm or ha	S		
00-7	Pre-donation	O Pan or p	☐ incontinence	☐ incontinence	-Length of Time se		TT AMERICAN OF SUM OF US	100		
If donor	Time	-	☐ Fainting/loss	☐ Fainting/loss	one)	Control (Concre	Pain anywhere in affect	ed arm		
	BP	Treatment	-Length of Tim	-Length of Time	Convulsions		Other incident (see Con			
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Sw	Emesis	Q Advised t	☐ Chest pain	Chest pain	Chest pain		-			
☐ Nes	Postion	O Pressure	☐ Accident/Fall	☐ AccidentiFall	☐ Accident/Fall					
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Pal Sw Nes Hys Ras Ligit	Time	Pre-donation/da	Other reaction	Other reaction	☐ Other reaction (see Co	mments)	19			
-	Pulse	1	100000000000000000000000000000000000000	September of the second				Reaction	Monitoring	
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Addre	Reaction Si	For	Donor Name_	Donor Name_	Donor Name	Reaction/Incident Start D	ate (if different than donat	ion date)		Can	prets at Part 6 for new or
Donor 1	☐ Pallor ☐ Sweating	Day	For minor don	For minor don	Reaction Si	Reaction/Incident Start Ti	me if time i	not known, select 🔲	0601-1200 - 1201-	1800   180	1-2400 0001-060
1000	C Nervousn		Daytime phon	Daytime phone	☐ Pallor ☐ Sweating	Reaction During II P	re-screening/Registration	□ B+d/0	ollection	D Cantien	
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Donatio	☐ Light-hea ☐ Weaknes	O Sweating	☐ Palor	☐ Palice	□ Nervousness/An			12 17404	t to Cameen	TI Cheste	
Proges	☐ Tingling/r	O Feeling v	☐ Sweating ☐ Feeling warn	☐ Swesting ☐ Feeling warm	☐ Hyperventilation ☐ Light-headednes		ther (specify)				
Was oo	Treatment	O Hyperver O Light-hea	□ Nervousness	□ Nervousness	☐ Weakness	Reaction Sign	is/Symptoms		blems/Incidents		Treatment
INSTRU	☐ Feet elev	O Weaknes	☐ Hyperventital	☐ Hyperventiat	☐ Fingling/numbre	□ Paller □ Sweating		☐ Hematoma Siz		D Feet el	evated impress applied
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Repeat	☐ Cool com ☐ Fluid intal	-	☐ Tingling/num	□ TinglingInum	☐ Vomiting	D Feeling warm		Pain or pressur		☐ Advise	t to take slow, deep
15 13 25 5 11	Li Frad Inta	O Hematon	☐ Nausea ☐ Yomlling	☐ Nauses	☐ Twitching mover ☐ Muscle tightness	Chills or shivering	April 10 to	D Possible artero		Breath	
Reactio	-	O intitration	☐ Twitching me	☐ Varieting ☐ Twitching ma	□ Incontinence	☐ Tingling/numbness lps ☐ Muscle tightness_cram		☐ Redness at ne			re bandage ng into paper bag
Time of	Monitoring Pre-denator	9/0	☐ Muscle tights	□ Muscle tightn	☐ Fainting/loss of o	D Hyperventilation	ping, spaams, receny	D Generalized ra			take encouraged
If donor	Time	O Pain or p	☐ incontinence ☐ Fainting/loss	☐ Incontinence ☐ Fainting/loss	-Length of Time	☐ Light-headedness/Dizz	mess	Pain that shoot	s/radiates down	☐ Saline	mfused
-	BP	Treatment	-Length of Tim	-Longth of Time	one)  Convulsions	☐ Weakness		the forearm			tie
При	Pulse	Treatment O Feet elev O Cool com	Convusions Difficulty bre	☐ Convulsions	C Officulty breathing	□ Nauses □ Vomiting		D Numbnessiting hand or arm	ing of fingers,	C Other t	reatment proments)
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Net	Position	O Pressure	☐ Accident/Fall	□ AccidentiFall	☐ Accident/Fall	☐ incontinence/Diamhea		Pain anywhere			
H Ray	Monitoring	1995	☐ No appar	□ No appare	□ No apparent □ With injury (	☐ Fainting/loss of conscio		Other incident	see Comments)		
Pal Sw Nes Hys Ras Ligs Fall	Time	Mo	Other reaction	☐ With Injury	☐ Other reaction (	Length of Time	secimin (circle one)	11-100000000000000000000000000000000000	March 11 Control of the Control of t		
LI Fai	BP	Pre-donatism/fla	Di Other reaction	Other reaction		Difficulty breathing/Sho	ciness of breath			-	
_	Pulse			1		C Cheet pain	Lindson		Reaction A	tonitoring	
	Emesis	Time	During I	During R		☐ Accident/Fall		dayor seri			
Donor	Position Key	Time	(mark as a	(mark as ag		□ No apparent injury		Phiebotomy Start	Time:	-	
	Release fro	Time	☐ Rapid th	☐ Rapid the	200000000000000000000000000000000000000	☐ With injury (see Cor ☐ Other reaction (see Co		A-unenning Stoh	Time: Reaction (Progesa	-	NA .
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1.0-1	☐ Home wit	Time	□ Slow pu	pulse	Time	Pre-donation Vital Signs	BP				
□ Exc	☐ 911, Para		☐ RapidAn	Slow pul	Time	Time	DP	Pulse	Symptoms		Position
	☐ Medical D	Time	pulse	Rapidon	Time	Time	82	Pulse	Symptoms		Position
□ Nor	Procedure	Time		pulse	Time	Time	BP/	Pulse	Symptoms		Position
	☐ Hematom	Time	☐ Hypoten	Hypoten	Time	Time	D+	Pulse			Position
□ tells	☐ Infiltration	Discharge Time	(low blood	(low blood)	Time	Time	BP/	Pulse	Symptoms		Position
Pos	☐ Possible				Time	Time	Bb	Pulse	Symptoms		Position
□ Fall	☐ Other inc	Time ]			Time	Time	BP/	Pulse	Symptoma		Position
-	Treatment				Dincharge Time and	The State of the Control of the Cont		Pulse	Symptoms		Position
Descrip	☐ Pressure	Gp-			Time	Discharge Time and Vital Sign		- Im	gular Pulsa, if note	a .	
120,000	Comments					Time	BP/_ Position Key. R=lying or feet	Pulse			Position
Propert	Completed t	O Rapis threa	Bischarge fire	Discharge Time		The second secon	Fostion Key. Ralying or feet	elevated, 8=sitting wi	n feet on the bed, D=	sitting with fee	of over the side; T=sta
			1		BORD CONTRACT	Completed by					
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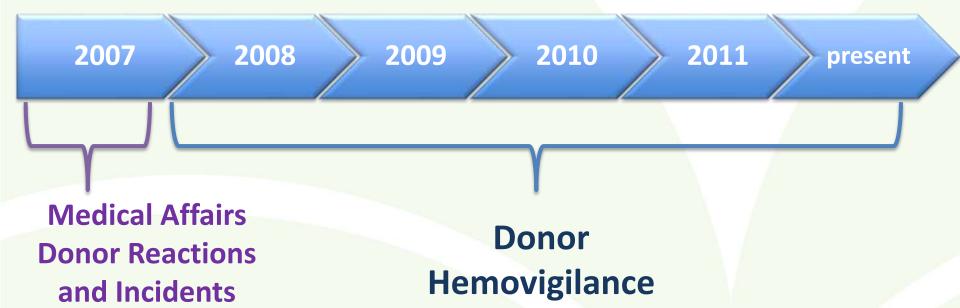
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Y.	•.	Donor					•	Date _ / _ /_	_				
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8 6	☐ Pallor	Day	For minor don	For minor don	Reaction Si	Reaction/Incide							
Donor 1	☐ Sweating ☐ Nervousing	D-M)	Daytime phon	Daytime phon	☐ Pallor	Reaction During	Reaction/incident Start Tim	Pringer by the principle of the					0001-06
Sex:	☐ Hyperven	Reaction Sign	Reaction	Reactio	☐ Sweating ☐ Feeling warm or	Nancture Chilling	Reaction During D Pre				Cante		
Donatio	☐ Light hea ☐ Weaknes	O Pallot O Sweating	□ Palor	☐ Palice	□ Nervousness/An		□ Me	dical Screening	□ Tyans	t to Canteen I	□ Offste		
Proges	☐ Tingling/g	O Feeling v	☐ Sweating	□ Sweating	☐ Hyperventilation	537	D 0#	ver (specify)					
Was oo	Treatment	O Hyparvar	☐ Feeling warn ☐ Nervousness	☐ Feeling warm ☐ Nervousness	☐ Light-headednes ☐ Weakness	Rea	Reaction Signs	Symptoms	Procedure Pre	blems/incidents		Treatmen	
INSTRU	☐ Feet elev	O Light-hea O Weaknes	☐ Hyperventila ☐ Light-headed	☐ Hyperventiat ☐ Light-headed	I Tingling/numbne	☐ Paller ☐ Sweating	☐ Pallor		☐ Hematoma Size		□ Advis	ed to perform A	AMT
	☐ Advised t	- CONTRACTOR (C)	□ Weakness	□ Weakness	□ Nausea	□ Nervousness	☐ Sweating		D < 2 m. D >	2 in.	D Feet	elevated	
Repeat	☐ Cool com ☐ Fluid intal	Procedure Pr	☐ Tingling/num ☐ Nausea	☐ TinglingInum ☐ Nausea	□ Vemiting □ Twitching mover	☐ Feeling warm ☐ Chills or shiv	□ Nerrousness(Anxiety □ Feeling warm		☐ Infiltration ☐ Pain or pressure	st noadle stra		compress appli n compress app	
Reactio	100000000000000000000000000000000000000	O Hematen	☐ Yomting	□ Vamting	□ Muscle tightness	☐ Tinging/num	Ci Chilla or shivening		Possible arteria	puncture Pulse Y N	☐ Advis	ed to take slow	
Time of	Monitoring	O intitration	☐ Twitching me ☐ Muscle rights	☐ Twitching ma ☐ Muscle tights	☐ Incontinence ☐ Fainting/loss of a	Muscle tights	☐ Tingling/numbness lips/fin ☐ Muscle tightness, crampin	gers	☐ Redness at nee ☐ Rest/Itching/hiv		Breat		
If donor	Pre-donation	O Pain or p	☐ incontinence	☐ Incontinence	-Length of Time	☐ Hyperventilat ☐ Light-headed	Muscle lightness, crampin     Hyperventilation	g, spasms, recany	☐ Generalized ras			ture bandage thing into paper	bag
II donos	Time BP	Treatment	-Length of Tim	☐ Fainting/loss -Length of Time	one)	□ Weakness	☐ Light-headedness/Drzzine	85	Pain that shoots		O Fluid	intake encoura	ged
-	Pulse	O Feet elev	☐ Cenyusions	☐ Convulsions	☐ Consulsions ☐ Officulty breathing	□ Nauses	☐ Weakness ☐ Nauses		the forearm  Numbness/tingle	ng of finance		e infused . iume	
Pal	Emesis	O Coot com	C) Difficulty bro	☐ Difficulty brea ☐ Chest pain	☐ Chest pain	☐ Vomiting ☐ Twitching me	☐ Vernting		hand or arm	CONTROL STORY	☐ Other	treatment	
Sw	Position	O Pressure	☐ Accident/Fall	☐ AccidentiFall	☐ Accident/Fall	□ incontinence	☐ Twitching maxements (Tre ☐ Incontinence@iairhea	(mors)	☐ Weakness of at ☐ Pain anywhere	m or hand	(See	Comments)	
Hyp Ray	Monitoring	925	☐ No appar	□ No appare	☐ No apparent ☐ With injury (	☐ FaintingAoss	D FaintingAss of conscious	ness	C Continued vom	ing			
Ligit	Time	Mo	Other reaction	Other reaction	☐ Other reaction (	Length o	Length of Time	sealmin (circle one)	C) Other incident (	see Comments)			
□ Fai	BP	Pre-donator/vita	Ci Other reacon	Court teactor	1-31-51-51-51-51	Difficulty brea	☐ Convulsions ☐ Difficulty breathing/Shortn	also of breath	<u></u>		-		
-	Pulse Emesis	Time	7.5	1		Cheet pain	Chest pain	and the browning		Monito	oring		
	Position	Time	During F	During 9		☐ Accident/Fall ☐ No appare	☐ Acodent/Fall				-		
Donor	Position Key	1000000	(mark as a	(mark as ap	X.C.	☐ With injur	□ No apparent injury □ With injury (see Comm	ants)	Phiebotomy Start	Time:			
Her	Release fro	Time	☐ Rapid th	#apid th	Pre-donation Vita	☐ Other reaction	Commission (see Commission)			Reaction (Propesa		Ontvi	
L. 1	☐ Home wit	Time	pulse	pulse	Time	Pre-donation V	Pre-donation Vital Signs E	8D / (	Pulsa inegala	Fulse,	(circle on	33312	
□ Exc	☐ 911, Para	Time	(3 Slow pu	Slow put	Time	Time			Pulse # nated	Symptoms			
	☐ Medical D	Time	□ RapidAn	Rapidón	Time	Time	Time E		Pulse D	Symptoms			
Nur	Procedure	Time	pulse	pulse	Time	Time			Pulse □	Symptoms			
Carlo Carlo	☐ Hematom ☐ Excessive	Time	☐ Hypoten	Hypoten	Time	Time		3P/	Pulse D	Symptoms			
	☐ Excessive	Discharge Time	(low blood	(low-blood)	Time	Time	Time E	3P/	Pulse D	Symptoms			
□ Pos	☐ Possible				Time	Time			Pulse D			Position.	
□ Fall	☐ Other inc	Time			Time	Time	TimeE	3P/ I	Pulse D	Symptoms	Y N	Position	
3377	Treatment	122			Discharge Time and I	Time	Time E	3P / I	Pulse D	Symptoms	Y N		
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1	Comments	220000000000	Discharge Time	100000000000000000000000000000000000000	1	Time		3P/ / Jaikon Key: Rviving or feet	Pulse Lelizated Senting wi	h feet on the best Own	ettina with	Position:_	
Propert	Completed t	O Rapis three	mestriarge turs	Discharge Time		Charles to the control of the		201000000000000000000000000000000000000	The state of the state of the	CONTRACTOR NO.	and man		20, 10 per
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<b>*</b>	Blood	57521	Blood S	Blood S	Blood Syst	Blood S	Y	DIN Date / /		Center Inform	ration:		
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Addre	Reaction Si	For	Donor Name_	Donot Name	Donor Name	Reaction/Incide	Reaction/Incident Start Date (i					Conglete at Par	E for newed
3 03	☐ Pallor ☐ Sweating	Day	For minor don	For minor don	Reaction Si	Reaction/Incide	Reaction/incident Start Time					TT - 100 - 1 - 100	C 050+ 4
Donor 1	☐ Nervousn	200	Daytime phon	Daytime phon	☐ Pallor	Reaction During	그렇게 얼마같이 되었어? 이 어디어?	THE RESERVE OF THE PERSON OF T					D 0001-6
Sex	☐ Hyperven	Reaction Sig	United States of the States of		☐ Sweating ☐ Feeling warm or	Address Same	Reaction During D Pre-sc	creening/Registration	C) Be	d/Collection	C Can		
Donatio	☐ Light-hea	O Pallot	Reaction Palor	Reactie	☐ Nervousness(An		☐ Medic	al Screening	to Ty	ansit to Canteen	□ Offs	te:	
Proges	☐ Weaknes ☐ Tingling/r	O Sweating O Feeling v	□ Sweating	□ Sweating	☐ Hyperventilation	650	□ Other	(specify)					
Was oo		O Nervousi O Hyperver	☐ Feeling warn ☐ Nervousness	☐ Feeling warm ☐ Nervousness	☐ Light-headednes	Rea	Reaction Signs/Sy		Procedure	Preblems/locident		Treatm	ent
	Treatment	O Light-hea O Weaknes	☐ Hyperventila	☐ Hyperventiat	□ Weakness □ Tingling/numbre	C Paller					ID Ad	vised to perfor	
NSTRU	☐ Advised t	Owearnes	☐ Light-headed	☐ Light-headed	□ Nausea	☐ Sweating	Paltor		☐ Hematoma S			rcises et elevated	
Statement	☐ Cool com		☐ Weakness ☐ Tingling/num	☐ Weakness ☐ Tingling/num	□ Vomiting	D Nervousness D Feeling warn	Sweating Nerrousness/Anxiety		□ < 2 in. 1	2×2m		et elevated al compress as	being
Repeat	☐ Fluid intal	Procedure Pr	☐ Nausea	☐ Nausea	☐ Twitching mover	Chils or ship	☐ Feeling warm		Pain or pres	sure at needle aite	D W	em compress	applied
Reactio		O Hematen	☐ Yomting	□ Vamiting	☐ Muscle tightness ☐ Incontinence	☐ Tingang/num	C Chills or shiveong			mal puncture Pulse		vised to take s	ow, deep
Time of	Monitoring	O intitration	☐ Twitching mo ☐ Muscle fights	☐ Twitching mo ☐ Muscle tightn	☐ FaintingAoss of o	Muscle tights	☐ Tingling/numbness lips/finger ☐ Muscle tightness, cramping, i	manne Tetany	□ Redness at	needle site Anves at needle site		aths Issure bandap	0
f donor	Pre-donation	O Pain or p	☐ incontinence	☐ incontinence	-Length of Time	☐ Hyperventilat ☐ Light-headed	☐ Hyperventilation		☐ Generalized	rash/itching/hives	□ Br	athing into pay	per bag
II GILITICA	BP.	Treatment	☐ Fainting/loss -Length of Tim	☐ Fainting/loss -Length of Time	one)	□ Weakness	☐ Light-headednessi/Dizziness	99		oots/radiates down		id intake enco	pegeru
	Pulsa	O Feet elev	C Cenyusiens	☐ Convulsions	☐ Convulsions	□ Nauses	☐ Weakness ☐ Nauses		the forearm	ingling of fingers.	D 50	line infused Volume	
☐ Pal	Emesis	O Cool com	C Difficulty bree	Difficulty brea	C Officulty breathing Chest pain	☐ Vurniting	☐ Vamiting	97	hand or arm		D 01	her treatment	_
Nes	Position	O Pressure	☐ Chest pain ☐ Accident/Fall	☐ Chest paint ☐ AccidentiFall	C Accident/Fall	☐ Twitching me ☐ Incontinence	Twitching maxements (Tremo	ors).	☐ Weakness o		(S	e Comments)	
□ Hys	Monitoring	500000000000000000000000000000000000000	☐ No appar	☐ No appare	☐ No apparent	☐ Fainting/loss	☐ Incontinence@iairhea ☐ Fainting/less of consciousnes		☐ Pain anywho	ere in affected arm			
C Light	***************************************	Mo	☐ With Injur	☐ With Injury	□ With injury (	Length o	Length of Timese			omiting nt (see Comments)			
Pol Sw Nes Hys Ras Ligs Fai	Time	Pre-donatari/fa	Other reaction	☐ Other reaction	☐ Other reaction.	☐ Convulsions	☐ Convulsions	Secretary Secretary and A	-	or face acquired			
-	Pulse	Prie-donales visual	26-20-000000000	Service and the control of the contr		D Difficulty brea D Cheef pain	Difficulty breathing/Shortness	s of breath					
	Emesis	Time	1	-		☐ Accident/Fall	Chest pain			M	nitoring		
CHORRES	Position.	Time	During f	During P		☐ No appan	☐ Acodent/Fall ☐ No apparent injury		Phlahotomy S	tart Time:			
Donor	Position Key	1000000	(mark as a	(mark as ap		☐ With injury	☐ With injury (see Comment	ts)	Phiebotomy S	top Time			
Her	Release fro	Time	☐ Rapid th	Rapid th	Pre-donation Vita	☐ Other reaction	Cither reaction (see Comman			sing Reaction (Prop		s Only)	
	☐ Home wit	Time	pulse	pulse	Time	Pre-donation V	Pre-donation Wal Signs BP	/ 0	de la lace	gular Fulse, sted	(circle	a med	
[] Exc	☐ 911 Para	Time	☐ Slow pu	Slow pul	Time	Time	Time BP	D. D.	njae a w		ms Y		
LI EXC	☐ Medical D	Time	□ RapidAn	Rapidón	Time	Time	Yima BD	P	uise		ms Y		
	Procedure	Time	pulse	pulse	Time	Time	Time BP						
☐ Nur	☐ Hematom	1.00	☐ Hypoten	Hypoten	Time	Time	Time BP		ulse	Li Sympto	ms Y		
1000	☐ Excessive	Time	flow blood	flow blood	Time	Time		/ P	ulse	□ Sympto	ms Y		
☐ tell	☐ Infiltration	Discharge Time	-		Time	Time		/ P	ulse	□ Symph	Y em		_
☐ Pos	□ Possible	Time			Time	Time			ulse		ms Y		
Fail	☐ Other inc				Discharge Time and	Time		/P	ulse		ma Y		
	Treatment				Time Time	Dischurge Time as		/ P	ulte	□ Sympti	ms Y I	# Position	
	Comments				1 4114	Time	Discharge Time and Vital Signs TimeBP	, P	uise			Position	
Descrip	Comments	REPORT OF THE PARTY OF THE PART	Discharge Time	The state of the second	1	Carro		ion Key: Rwiying or feet o		s with feat on the best	D+sitting w		
Descrip		O Rapid this a	manchings tone	Discharge Time		120000000000000000000000000000000000000			ESTABLISHED TO STREET	Position of the second	op sales g. o	0.0331303100	41459), LC 141
	Completed	a contract of											
Descrip	Completed I		BS 336 (Rev. 8)			Completed by BS 306 (Rev. 11)	Completed by (Signature) _ BS 336 (Rev. 12)						Page 1 c



#### **Database**



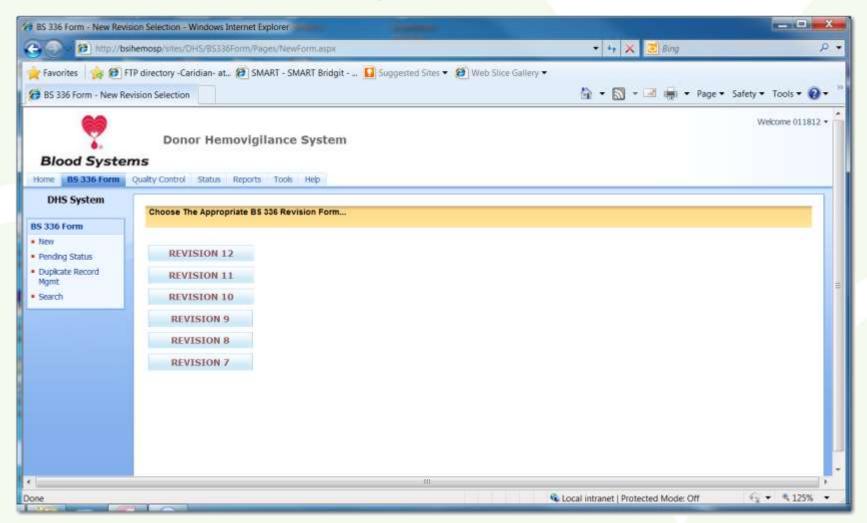
System (DHS)

**Database (MADRID)** 

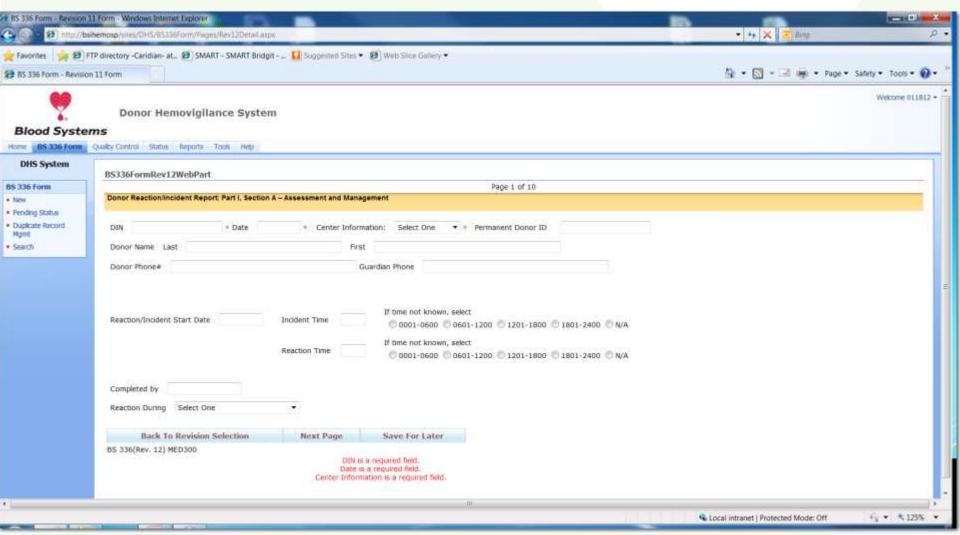
# Medical Affairs Donor Reactions and Incidents Database (MADRID)

views	Clippoard 14 Font	'' KICH TEXT KECOFGS	Sort & Filter Window
	Medical Affairs Donor React	<u>tion and Incident Database (</u>	MADRID)v.2
▶	Center 22	Entry Date:	DRR
	<b>Donation #</b> 6097614	11/20/2007	Donation # on DRR   6097614
	Date on BS 336: 6/20/2007		Donor ID on DRR 2549659
	Reaction Location D		Gender M
	Reaction/ Incident Start Time: 16:40		DOB: 9/29/1944
	<b>Donor ID</b> 2549859	Supervisor/ Designee Review	Donation Date: 6/20/2007
	Reaction Signs/ Symptoms	Class. of Reaction 1 Moderate ▼	Collection Site 22C01
	Fainting/unresponsive Vomiting	Reaction 2	Donation Type B
	to commands Tetany	Reaction 2	Bag Type TC
	0 Sec 0 Min Convulsions	Phlebotomy Type: pls/rbc	Weight (in pounds) 185
	Release from Collection Site		Height (in inches)
	911, Paramedics Called	First time Donor	Blood Pressure
	Time released from site: 17:28	Collection Complete	Systolic 138
		Needle Adjustment	Diastolic 84
	Procedure Problems and Incidents  Hematoma Tingling	Follow-up Treatment	Pulse 64
	Excessive pain at needle Redness	ER Admitted	Donor Reaction Time:
	Infiltration Fall	Risk Management Notified	Phlebotomy
	☐ Possible arterial puncture ☐ No apparent injury	Medical Director May donate	Start Time:
	☐ Pain in arm ☐ Head trauma	Review	End Time:
	☐ Numbness ☐ Other injury		
	Comments:		

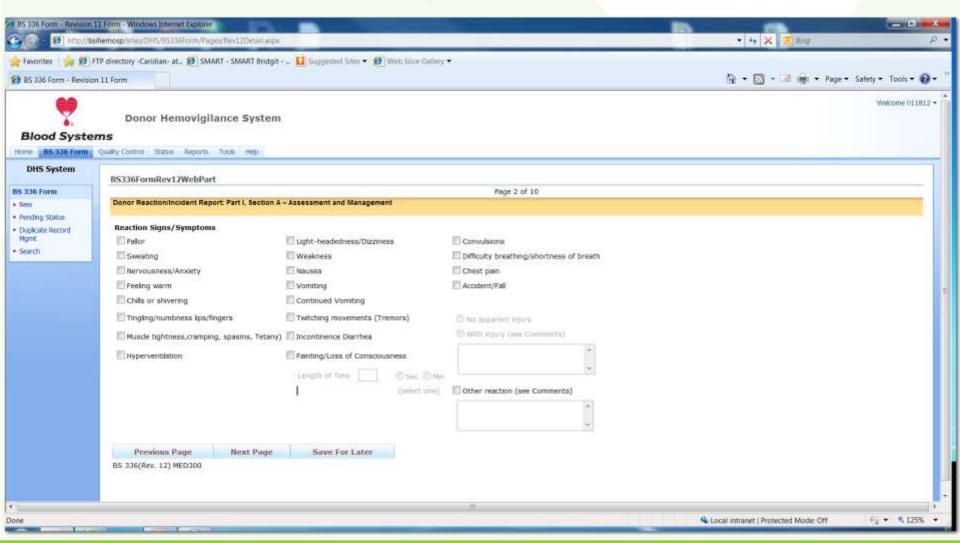




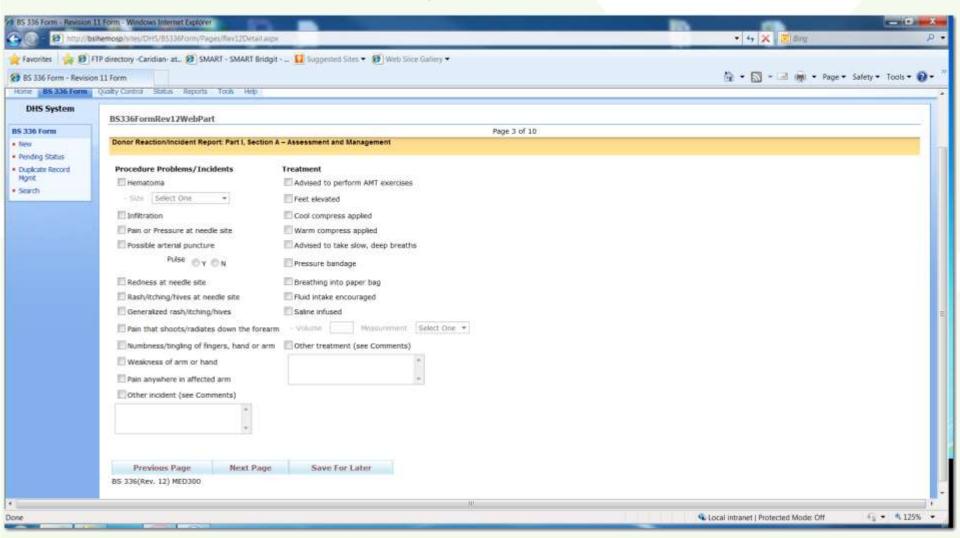






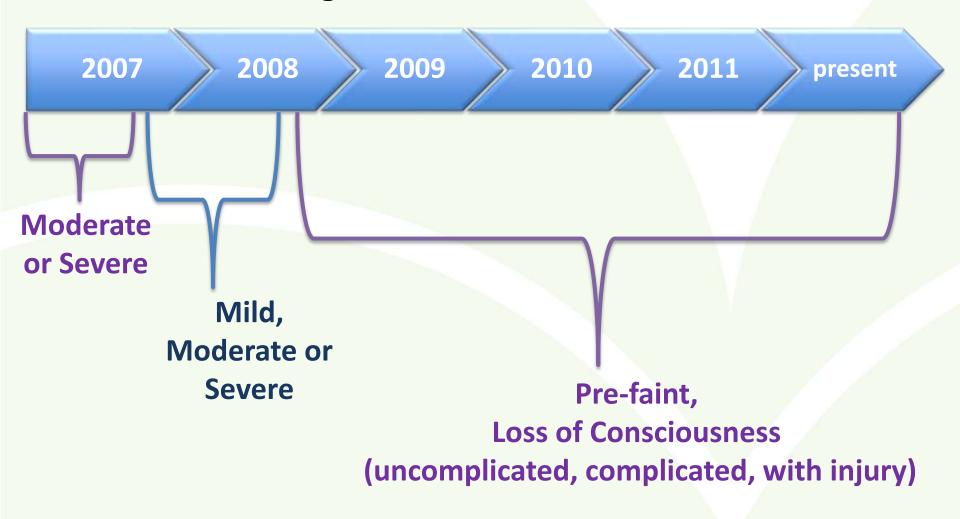






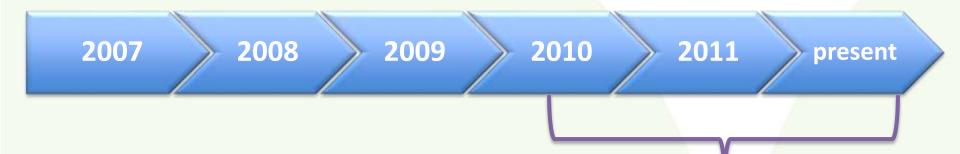


#### **Vasovagal Reactions Classification**





#### BECS changes to accommodate external reporting



#### MILD Reactions

Allergic

Citrate

Hematoma (small)

Infiltration (small)

Multiple

Other

Vasovagal (mild)

#### **Donor Association**

**High School** 

College

Military

Others

as of

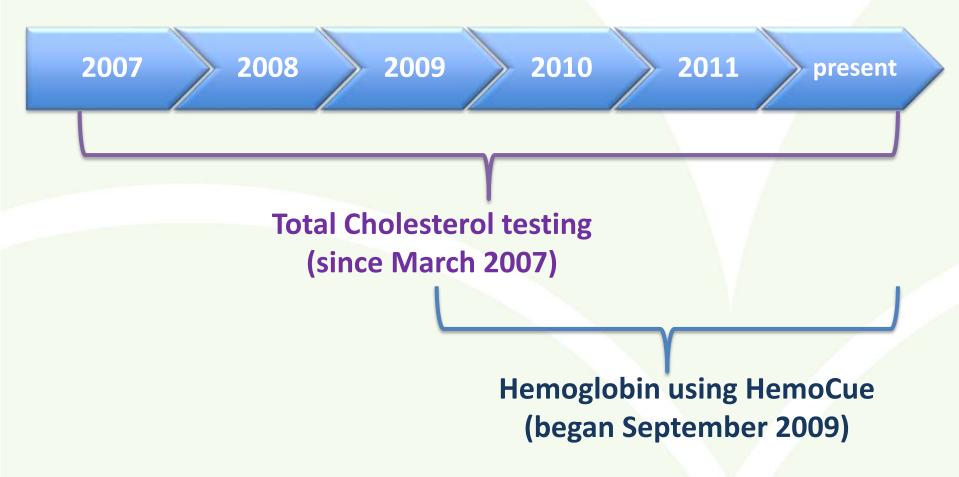
**18 January 2010** 

#### **Intended Collection Type**

Specification of collection type among donors with incomplete or unsuccessful donation



#### **Supplemental Donor Testing**





#### **External Reporting**







### Timeline - Overview

	Bloc	od Systems,	Inc. Dono	r Vigila	nce:	5 years of	centralized donor	reactions and incident	ts data collection			
Year		2007	In a la la la	2008			2009	2010	2011		2012	
Charles Maria I	1 2 3 4 5	THE RESERVE OF THE PERSON NAMED IN		5 6 7 8	8 9 10	11 12 1 2 3	4 5 6 7 8 9 10 11 12 1	1 2 3 4 5 6 7 8 9 10 11 1	2 1 2 3 4 5 6 7 8 9	10 11 12		
1st Intervention		Pre-Intervent	ion					1st Post-Intervention				
2nd Intervention				111			2nd Pre-Intervention			2nd	Post-Intervent	
Donor Survey							none				Donor Survey using Survey	
BS 336 form revisions	Rev 5 (up to 6/3/07)	Rev 6 (6/4/07 to 12/2/07)	Rev 7 (12/3/07 to 4/24/08)	to	Rev 9 (7/28/08 to (0/26/08)	Rev 10 (10/27/08 to 3/29/09)		Rev 11 (5/30/09 to 11/27/2011)		100000000000000000000000000000000000000	(11/28/2011 t present)	
Centralized BS 336 data entry - Data Collection Tools		- Access database S 336 fields entered		(lau	inched in M	Nay 2009, backlog da	me	s - validated in-house developed B5 336 data ost B5 336 fields entered 2008, current SOPs in place for centers to se		DHS )		
BS 336/ Reaction Data Compliance with AAB8 Donor Reaction Requirements			NO				VES (except for Mild reactions)		d reactions - as of 1/18/2010) fue to errors needing resolution)	pending	BS 336 data en	
ISTARE Donor Advers Reactions Data				No		-,		2010 data submitted on March 1, 2012	pending submission once data for 2011 is	completed		
Mild Reactions captured in BECS		MILD reaction is	n BECS to include all t	types, mild vas	sovagal or	other mild procedur	re problems	The second secon	s to match AABB classification (as of 1/18/2 a (small), infiltration (small), Multiple, Other	THE RESERVE OF THE PARTY OF THE	mild)	
BS 336 Vasovagal Reactions Classification	Modera	ate or Severe	Mild, Mode	erate or Severe	•		Vasovag	vagal Categories (pre-faint, LOC, uncomplicated, complicated, with injury)				
BS 336 Incidents Classification		scident	incident (matches category except for		on type/ phylaxis)	AABB Reaction type/ category including Allergic Analphylaxis)	ABB Reaction pe/ category Apheresis Auding Allergic Allergic					
Can be mapped to AABB Reaction Type/ Category	pre-AAB8 Donor Hemovigilance categories can b						AABB reaction types and categories luding MILD reactions)	can be matched to AAB	B reaction types and categories (including N	MILD reaction	0.	
Hemoglobin testing	Rode								lemoCue testing			
Cholesterol Testing	none						Began testing on March	5, 2007				
Donor Association Data		based on use of exter	mal association table	from Hemaspi	here , merg	ged to data using the	e site description	Direct Association fields option available	for staff within BECS: HS, College, Military in the DRR (implemented on 1/18/2010)	and Others ac	ded as a ques	



#### Results

#### Continuous process improvement (CPI) allowed:

- 1. Improved capabilities to classify AEs in a manner that allow comparisons with the national and international standards:
  - U.S. Donor Hemovigilance System, and
  - International Surveillance of Transfusion-Associated Reactions and Events (ISTARE),
- 2. The use of appropriate statistical analyses, e.g. multivariable regression, thus overcoming the limited usefulness of simple rate comparisons or uni-variate analyses, and
- 3. The evaluation of additional factors' contribution to the likelihood of vasovagal reactions and/or needle related injuries in blood donors



# Summary

Donor vigilance is an evolving field.

 Gained knowledge may generate new inquiries.

 Only through a continuous improvement process, an optimum donor vigilance program can be achieved.

# Questions



#### **BSI's Commitment to Quality**

- Quality is providing an uncompromised quality of work life, while continuing to ensure the quality and safety of our products and services to ensure a positive outcome for patients and donors
- Blood Systems is dedicated to quality, continuous performance improvement, and implementation of new quality initiatives.