

# Be Safe. Be Sure.

ClosedLoop™ Clinical Systems for Safer Healthcare

## Tissue Tracking and Traceability:

## The Evolving Need for Biologics Management

SEABB

March 2008



# Agenda



- The Evolution of New Therapies
  - ◆ The past and present of transplantation
- Who does - or should - manage biologics?
- Why focus on biologics?
  - ◆ Risk and Cost concerns
  - ◆ The rise of Hemovigilance
- Introducing: BiologiCare
- Mediware Credentials
- Questions & Answers

# The Evolution of New Therapies



*Healthcare technologies have historically focused on:*

*Products Infused*

*Products Injected*

*Products Ingested*



*More than 50% of hospitals now transplant 'something else', be it bone, tissue, stem cells or designer cellular therapies.*

# The Beginning of Transplantation...



***The first recorded transplantation was recorded between the years 285 and 305 AD.***



Twin brothers, Saints Cosmas and Damian, studied medicine in Syria and became famous for their healing skills. Their most miraculous exploit was the grafting of a leg from a recently deceased Ethiopian to replace a patient's ulcerated leg.

*They were later cited by Joint Commission for improper storage and their inability to trace the product.*

# We've come a long way...



- Tissue transplants seen as leading edge now represent every day procedures
  - ◆ Heart, liver, kidney and other primary organs
  - ◆ Bone implants
  - ◆ Skin
  - ◆ Cellular therapy products
  - ◆ Other tissues
- More than 10 million tissue transplants in the past 20 years
  - ◆ *Source: AATB*



*The AATB has accredited nearly 100 tissue banks and has over 1100 members.*

# Who Manages Biologic Products?



## *Bones and Tissues are ‘Orphans’ in hospitals without a clear owner.*

- Materials Management
  - ◆ Non-clinical expertise
- Operating Room
  - ◆ Vendors feature ‘latest & greatest’ to surgeons without inventory or quality controls
- Blood Bank
  - ◆ Have the expertise to manage, maintain, report on inventory
  - ◆ Without tools, most use paper logs on freezer doors



*“We’ve been through the FDA, we know what it’s like to have your back against the wall.”*  
- Dr. Lane



# Results of Mismatched Materials



## ***Lack of centralized controls create confusion, inefficiencies and waste.***

- Tracking, monitoring and managing inventory throughout hospital is difficult
- Outdated inventory results in significant cost and loss
- Ordering & vendor qualifications oversight is inconsistent
- Worse case scenario is contamination or product recall



*One customer disposed of \$40,000 of outdated materials.*

***“Hospital’s risk management offices need to know that there is a fairly consistent process to manage all of these moving parts.”***

***- Dr. Kaplan***

# Why Address Biologics Management?



- Sentinel Events are becoming more visible and increasing regulatory pressures
  - ◆ Joint Commission - PC.17.10-30
  - ◆ FDA - 21 CFR 1271
  - ◆ AABB/AATB/EBAA
  - ◆ CAP
- The focus is on Biovigilance
  - ◆ Tracking/Tracing
  - ◆ Vendor Qualification
  - ◆ Adverse Outcome Documentation
  - ◆ Recall awareness and public safety alerts

## Man accused in body-part tissue scandal may tell all

By Adam Goldman  
ASSOCIATED PRESS

NEW YORK — The man accused of scheming to plunder bodies for parts used in thousands of tissue transplants is poised to plead guilty, and authorities and victims' relatives say his testimony could roil the billion-dollar industry.

In an effort to escape a lengthy jail sentence in cases in Philadelphia and New York, Michael Mastromarino has agreed to talk to investigators about the companies that bought the stolen tissue, said his lawyer, Mario Gallucci.

"Let's just say that he is going to assist them and give any information he has about the processors and their role," Gallucci said.

The companies that processed the tissue already face hundreds



**Michael Mastromarino** has agreed to talk about firms that bought stolen tissue, his lawyer says.

the Blood and Tissue Center of Central Texas.

The parts were used in disk replacements, knee operations, dental implants and a variety of other surgical procedures performed by unsuspecting doctors across the United States and in Canada. About 10,000 people received tissue supplied by BTS.

Among the bodies BTS looted was that of "Masterpiece Theatre" host Alistair Cooke, who died in 2004.

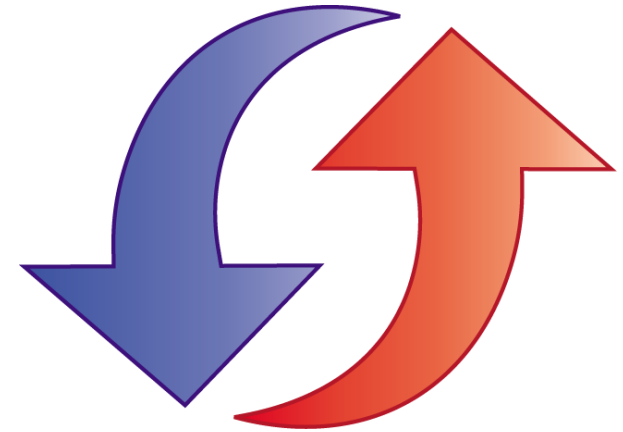


# How Can We Achieve Biovigilance?



*New requirements have focused us on biologics management.*

- What tools are available?
  - ◆ Paper logs
  - ◆ Access database
  - ◆ Tissue vendor provided software for their own materials



*Our approach should address donors and recipients.*

***“The information system functionality a facility needs for a unit of red cells they also need for a frozen femur sitting in a freezer.”***

**- Dr. Ness**

# Introducing... *BiologiCare*™



*Extending Blood Management experience to biologics.*

## ● Bone and Tissue

### ◆ Bone/Tissue Banking

- Utilize existing knowledge and blood management functionality

## ● Cellular Therapy

### ◆ Stem Cells

- Utilize concept of process driven product manufacture

### ◆ Designer Therapies

- A new and uncharted 'world'

A screenshot of the Mediware login interface. At the top left is the Mediware logo, a stylized 'M' with a circular element, followed by the text 'Mediware' and 'ClosedLoop® Clinical Systems For Safer HealthCare.' Below this are four input fields: 'User Name' (text box), 'Password' (text box), 'Facility' (dropdown menu showing 'HOSP'), and 'Domain' (text box showing 'MAHIV-LTXP'). At the bottom right are two buttons: 'Login' and 'Cancel'. The background is a blue gradient with the word 'Biologics' in a large, light blue font at the bottom right.

◆ BiologiCare 1.0 Release Date June 2008

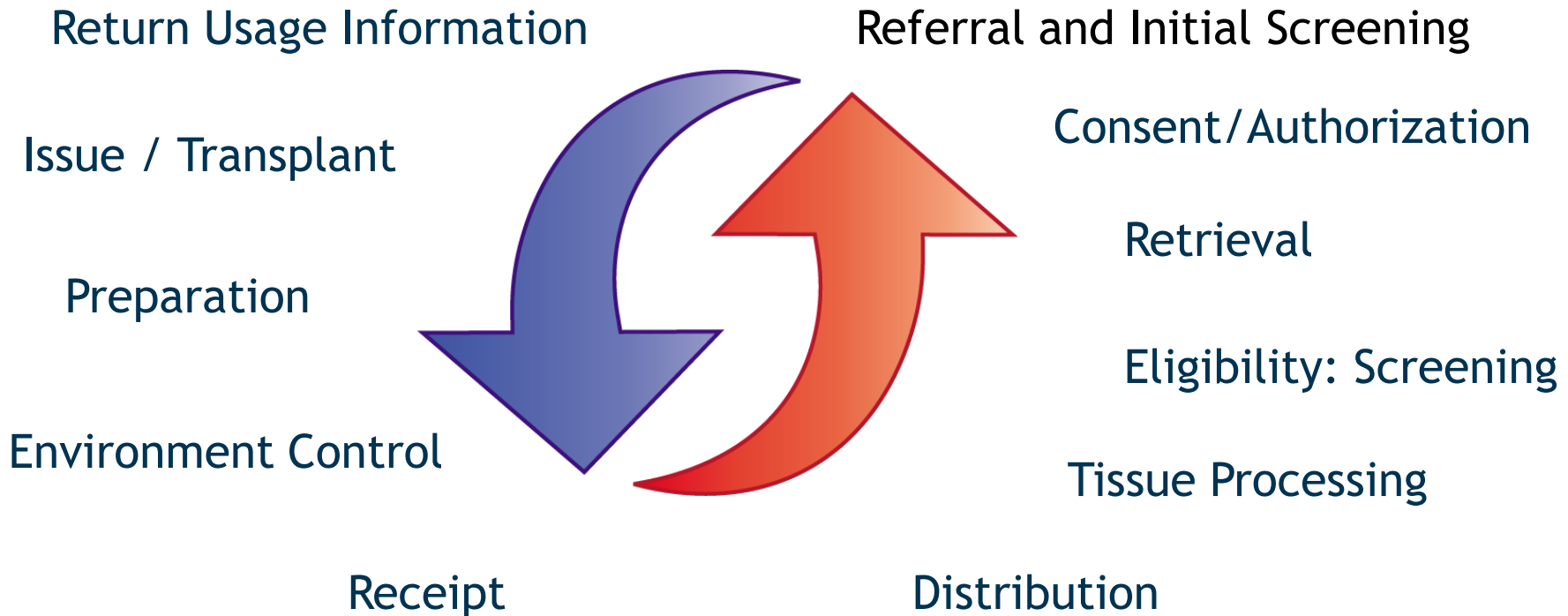
*TJC PC.17.10, PC.17.20,  
and PC.17.30 compliant*

# Biologic Product Continuum



## TRANSPLANT CENTER

## TISSUE BANKS



# Introducing... *BiologiCare*™



- Mediware is creating a **ClosedLoop**™ environment for managing bone and tissues
- Initial functionality:
  - ♦ Electronic Vendor Qualifications
  - ♦ Manage Individual tissues as well as lots and sublots
  - ♦ Scanning of Tissue Donor Cards and Order Requisitions
  - ♦ At-a-Glance Inventory Review
  - ♦ Multi-facility, Multi-site inventory management
  - ♦ Tissue Bank Reconciliation
  - ♦ Recall and Quarantine Management
  - ♦ Adverse Event Alerts
  - ♦ Workflow Management
  - ♦ Management Reporting
  - ♦ HL7 Integration to other systems

A screenshot of the Mediware login interface. At the top left is the Mediware logo and the text "ClosedLoop® Clinical Systems For Safer HealthCare." Below this are four input fields: "User Name" (text box), "Password" (text box), "Facility" (dropdown menu with "HOSP" selected), and "Domain" (text box with "MAHIV-LTXP" entered). There are "Login" and "Cancel" buttons. At the bottom right, the word "Biologics" is displayed in a large, light blue font.

Mediware  
ClosedLoop® Clinical Systems For Safer HealthCare.

User Name  Facility

Password  Domain

Biologics

♦ BiologiCare 1.0 Release Date June 2008

*TJC PC.17.10, PC.17.20,  
and PC.17.30 compliant*



# Rich Inventory



- Details of bone and tissue being stored
- Inventory viewable by storage device and location
- Product level drill down

HCLL Biologics - Hospital's Name - User Demo Logged In - [Biologics Module]

File Module Report Window Help

Room Temperature Biologics History

	15mm	15cc	Thick	Achilles		Distal	4x5		
<b>CStruts</b>	6/25	2/25	10/25	0/25		0/25	0/25	0/25	0/25
0 - 2 mo	6		10						
3 - 12 mo									
> 12 mo									
	17905	17906	17907	17908		17909	17910	17911	17912
<b>CChips</b>	0/25	0/25	0/25	0/25		0/25	0/25	0/25	0/25
0 - 2 mo									
3 - 12 mo									
> 12 mo									
	102003	102007	102009	102010		102012	102020	102021	102022
<b>Alloderm</b>	17/25	0/25	0/25	0/25		0/25	0/25	0/25	0/25
0 - 2 mo	17								
3 - 12 mo									
> 12 mo									
	430034	430036	430200	430300		430310	430335	430340	430350
<b>Tendon</b>	0/25	0/25	0/25	0/25		0/25	0/25	0/25	0/25
0 - 2 mo									
3 - 12 mo									
> 12 mo									
	450100	450300	450310	450316		450360	450370	450376	450377
<b>Fascia</b>	0/25	0/25	0/25	0/25		0/25	0/25	0/25	0/25
0 - 2 mo									
3 - 12 mo									
> 12 mo									
	68014	68021	68029	68030		68031	68032	68033	68034
<b>FGraft</b>	0/25	0/25	0/25	0/25		0/25	0/25	0/25	0/25
0 - 2 mo									
3 - 12 mo									
> 12 mo									

start Microsoft Off... Andrea - Conver... HCLL Biologics - H... 100% 10:41



# Product Level Details in Inventory



- All products included within selected product type on one screen
- Details include:
  - ◆ Expiration dates
  - ◆ Supplier
  - ◆ Tissue parameters
  - ◆ Availability

The screenshot shows the HCLL Biologics software interface. The window title is "HCLL Biologics - Hospital's Name - User Demo Logged In - [Biologics Module]". The interface includes a menu bar (File, Module, Report, Window, Help), a toolbar with various icons, and a main area with tabs for "Biologics Overview", "Biologics", and "Biologics History". The "Biologics" tab is active, showing a search bar and buttons for "Search", "Receive", "Ship", "Update Status", and "Comments". Below this is a summary row with fields for Code (100600), Lot # (998877), Sub Lot# (3), Batch (34), Status (IN), Exp D/T (20-Mar-2), Supplier (ARC), Vol (10.00), Height (10), Width (20), Length (30), Diameter (0), Fac (HOSP), and Storage Dev (BBREF1). A table below the summary row lists product details with columns: Code, Lot #, Sub Lot#, Batch, Status, Exp D/T, Supplier, Vol, Height, Width, Length, Diameter, Fac, Storage Dev, and Shelf. The table contains four rows of data, all with Status "IN" and Exp D/T "21-Mar-2008 23:59".

Code	Lot #	Sub Lot#	Batch	Status	Exp D/T	Supplier	Vol	Height	Width	Length	Diameter	Fac	Storage Dev	Shelf
100600	998877	3	34	IN	20-Mar-2008 23:59	ARC	10.00	10	20	30	0	HOSP	BBREF1	
100600	98765	3	33	IN	21-Mar-2008 23:59	ARC	10.00	10	20	30	0	HOSP	BBFRZ	
100600	98765	2	33	IN	21-Mar-2008 23:59	ARC	10.00	10	20	30	0	HOSP	BBFRZ	
100600	98765	5	33	IN	21-Mar-2008 23:59	ARC	10.00	10	20	30	0	HOSP	BBFRZ	
100600	98765	4	33	IN	21-Mar-2008 23:59	ARC	10.00	10	20	30	0	HOSP	BBFRZ	

# Inventory Receive



- Scan tissue log for permanent record
- Document tissue parameters upon receipt
- Assign storage locations
- Batch / single unit receive capabilities
- Designed specifically for bone and tissues

HCLL Biologics - Hospital's Name - User Demo Logged In - [Biologics Module]

File Module Report Window Help

**Biologics Receive**

Header

Donor ID	Receipt #	Ship D/T	Supplier	Rec D/T	Rec Fclty Cd	Insp	Size (####.###)			
		1/30/2008		1/30/2008			Height	Width	Length	Diameter
Temperature	Lot #	Biologics Cd	Exp D/T	Vol(#####.###)	Device	Shelf	Quantity			
							Upload File...			

Detail

Insp	Lot #	Sub Lot#	Code	Exp D/T	Vol	Height	Width	Length	Diameter	A/D/R	Storage	Shelf	Statu
------	-------	----------	------	---------	-----	--------	-------	--------	----------	-------	---------	-------	-------

Save Edit Clear Print Close

start Z M... Andr... HCLL ... PrintK... Docu... 100% 10:41

# Vendor Qualification



- User defined vendor qualification process & timeline meets JC standards
- System validates tissues upon receipt
- Electronic warnings when vendor quals not met

The screenshot displays the HCLL Biologics software interface. The main window is titled "Biologics Receive" and contains a form with the following fields:

Donor ID	Receipt #	Ship D/T	Supplier	Rec D/T	Rec Fclty Cd	Insp	Size (####.###)
CA999	5	2/28/2008	ARC	2/28/2008			Height Width Length Diameter

Additional fields include Temperature, Lot #, Biologics Cd, Exp D/T, Vol(#####.###), Device, Shelf, and Quantity. An "Upload File..." button is located next to the Quantity field.

Below the form is a "Detail" table with columns: Insp, Lot #, Sub Lot#, Code, Exp D/T, Vol, Height, Width, Length, Diameter, A/D/R, Storage, Shelf, and Statu.

A warning dialog box titled "HCLL Transfusion Service" is overlaid on the screen. It contains a question mark icon and the text: "Supplier qualification has expired, do you wish to continue receiving products?". The dialog has "Yes" and "No" buttons.

At the bottom of the form are buttons for "Save", "Edit", "Clear", "Print", and "Close".

# Vendor Qualification Exceptions



- Exception reasons captured for quality management review

The screenshot shows a software interface for 'HCLL Biologics'. The main window is titled 'Biologics Receive' and contains a form with the following fields:

Donor ID	Receipt #	Ship D/T	Supplier	Rec D/T	Rec Fclty Cd	Insp	Size (###.###)			
CA999	5	2 /28/2008	ARC	2 /28/2008			Height	Width	Length	Diameter

Below this is another set of fields:

Temperature	Lot #	Biologics Cd	Exp D/T	Vol(####.###)	Device	Shelf	Quantity

An 'Exception' dialog box is open in the foreground, titled 'Exception' and containing the text 'Select a reason.' Below this is a text input field with the value 'STAT SURGERY'. The dialog has 'OK' and 'Cancel' buttons.

At the bottom of the 'Biologics Receive' window are buttons for 'Save', 'Edit', 'Clear', 'Print', and 'Close'.



# Trackability

- Track every aspect of each product within your facility
  - Where it has been stored
  - Who handled it
- Minimize waste
- Improve utilization

HCLL Biologics - Hospital's Name - User Demo Logged In - [Biologics Module]

File Module Report Window Help

Biologics Overview Biologics Biologics History

Biologics Search Receive Ship Update Status Comments 00:10:00

Lot #	Sub Lot#	Batch	Statu	Exp D/T	Supplier	Vol	Height	Width	Length	Diameter	Fac	Storage Dev	Shelf
100150	28MG948	3		35	IN	15-Sep-2		25.80	0	0	0	HOSP BBFF	
28MG948	3	35	IN	15-Sep-2009 23:59	BAX	25.80	0	0	0	0	HOSP	BBFRZ	
28MG948	1	35	IS	15-Sep-2009 23:59	BAX	25.80	0	0	0	0	HOSP	BBFRZ	
28MG948	4	35	IN	15-Sep-2009 23:59	BAX	25.80	0	0	0	0	HOSP	BBFRZ	
28MG948	2	35	IN	15-Sep-2009 23:59	BAX	25.80	0	0	0	0	HOSP	BBFRZ	
28MG948	5	35	IN	15-Sep-2009 23:59	BAX	25.80	0	0	0	0	HOSP	BBFRZ	

start | 100% | 12:39



# Order/Issue



- Patient order scan functionality
- Product Order and Issue function on same screen
- Print product transplant tag

**Patient Order Input Form**

Fac	Ente	Account #	Name	A	MR #	Alias	DOB	Sex	Ethnicity	ABO/Rh	ABSC	Ab	PI	Ag	Tx'd	C
HOSP		DP100	Demo, Patient	N	DP100	N	1/19/1978	M		O NEG	NEG	N	N	N	Y	N

Description	Description	Int	Description

Prod	Unit #	Date	Status
100150	28MG948-1	02/11/2008	IS
100600	998877-1	01/10/2008	TR

Ord #	Type	Code	Qty	Pri	Physician	Requested D/T	Received D/T	Biologics Code	Lot #	Su	PF	ABN	Stat	Accept	Upload
080420001	Biologic	CCP	1	AS	D'AMICO	02/11/2008 10:08	02/11/2008 10:08	100150	28MG948	1	IS	N	A	<input checked="" type="checkbox"/>	<input type="checkbox"/>
080220001	Biologic	CCS	1	AS	SABATINI	01/22/2008 12:04	01/22/2008 12:04	100600	998877	2	XM	N	A	<input checked="" type="checkbox"/>	<input type="checkbox"/>
072750001	Biologic	CCS	1	Rou	SAADEH	01/10/2008 11:13	01/10/2008 11:13	100600	998877	1	TR	N	A	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

Filter: None | Sort: Name Ascending

View Requisition | Remove | Edit | Add | Comments | Select Product | Issue | Save | Close | Print slip

# Implant Record



- JC requires documentation of products implanted
- System generates necessary documentation to send to tissue center

## IMPLANT INFORMATION CARD

IMPLANT FACILITY	
Name:	Chicago Hospital
Address:	123 Anywhere St.
City:	Chicago
State:	IL
Zip Code:	60987

IMPLANT INFORMATION	
Supplier:	City Tissue Bank
Identifier:	12430871UO
Lot Number:	
Product Code:	100607
Product Name:	Cortical Cancellous Struts (1x10cm)
Expiration Date:	10/10/2009

PATIENT INFORMATION	
Patient Name:	Smith, Joseph A.
DOB:	01/10/1980
MRN:	12908375
SSN:	435-23-2345
SEX:	M

IMPLANT STATUS	
Physician:	Harold Cowboy, MD
Received:	04/20/2007
Implant Date:	09/30/2007
Surgery Procedure:	Lumbar Fusion

# Full Traceability



- Trace each product from receipt to final disposition
  - When it was received into the facility
  - Supplier
  - Each status change
  - When transplanted
- Fully reportable
  - Inventory management reporting tools

HCLL Biologics - Hospital's Name - User Demo Logged In - [Biologics Module]

File Module Report Window Help

Biologics Overview Biologics Biologics History

00:00:40  
4 Events

Status Change	USER3	10/09/2007 14:2	CCS	100607	1020182	1	TR	01-Mar-2508 23:5	BAX	N	N	Demo, Patient	DP100
Event	Tech ID	Event D/T	Drv Grp	Code	Lot	Sub	Status	Exp D/T	Supplier	AAA	Com	Name	MR #
Status Change	USER3	10/09/2007 14:25	CCS	100607	1020182	1	TR	01-Mar-2508 23:59	BAX	N	N	Demo, Patient	DP100
Issue	USER3	10/02/2007 16:45	CCS	100607	1020182	1	IS	01-Mar-2508 23:59	BAX	N	N	Demo, Patient	DP100
Select	USER3	10/02/2007 16:45	CCS	100607	1020182	1	XM	01-Mar-2508 23:59	BAX	N	N	Demo, Patient	DP100
Receive	USER3	10/02/2007 16:43	CCS	100607	1020182	1	IN	01-Mar-2508 23:59	BAX	N	N	Demo, Patient	DP100

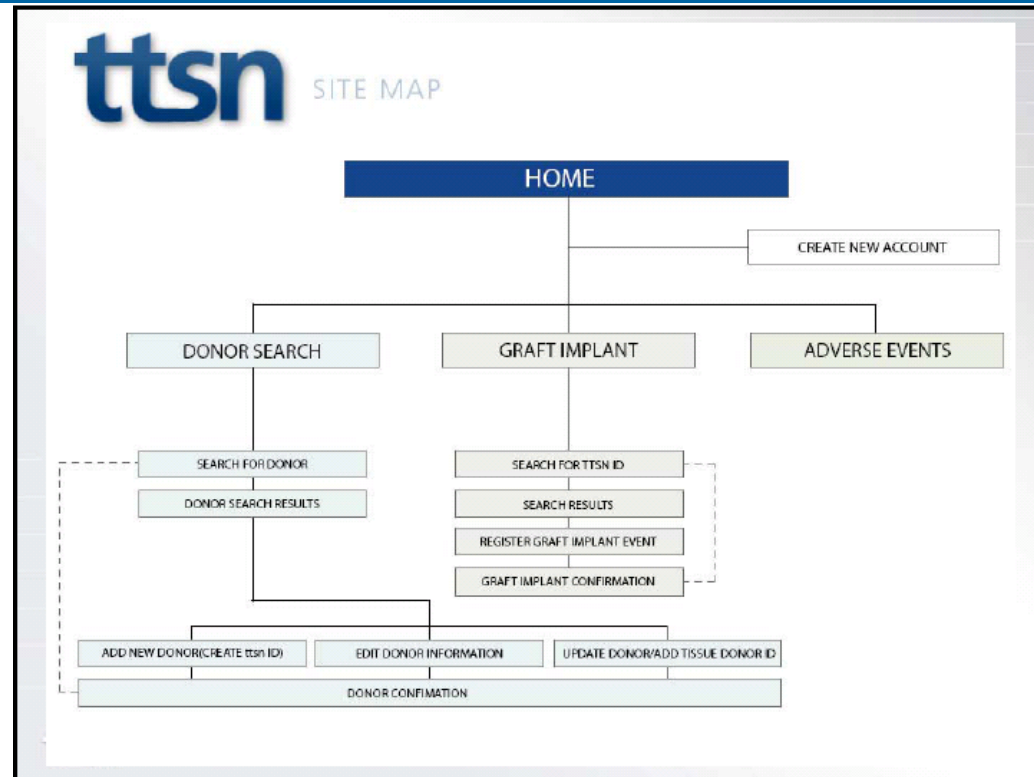
start | Inbox - M... | HCLL Biol... | 100% | 09:31

# From Hemovigilance to Biovigilance



*Experience and success is rapidly driving supporting network for Biovigilance.*

- Transplantation Transmission Sentinel Network
  - ◆ Web based application enabling traceability of allografts
- Headed to:
  - ◆ Industry standard software application will enable electronic notification and alerts with TTSN
  - ◆ Electronic interfaces with tissue centers and hospital based tissue banks



**Mediware is actively monitoring TTSN developments to enable system to system communication.**

# Why Mediware



- 25+ Year Proven Track Record with over 300 Current Transfusion Management Customers
- Solutions Designed by Blood Bankers for Blood Bankers, >10% of staff are SBB certified
- No other company offers the breadth and depth of blood management products
- Extending Commitment & Experience to Biologics Management







***Mediware products close the loop to support every step of the blood management process, from recruitment to final disposition.***

## Key Facts:

- 300+ hospitals licensed HCLL in 4 years
- 60+ blood center facilities use our software / services
- Approximately 75% of U.S. Blood Supply passes through a Mediware System

## Mediware Products

- Donor Center Management
  - ◆ IMS Donor Relationship Management tools
  - ◆ LifeTrak® donor center management
- HCLL™ Donor & Transfusion
  - ◆ Blood therapy and blood bank management
  - ◆ Hospital donor management
- BloodSafe™
  - ◆ Intelligent, distributed storage and point of care technologies
- *and now, BiologiCare™*

# Thank You



## QUESTIONS?

**Tina Keefer, Product Manager**  
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