PediMACS Tutorial:

September 20, 2012

Washington University

St. Louis, Missouri

Welcome

Elizabeth Blume, MD

Chair of the INTERMACS Pediatric Committee

Tim Baldwin, PhD

NHLBI Representative to INTERMACS and PediMACS

Purpose of Today's Tutorial

- **Provide Information on PediMACS**

--AND--

- **Provide Instruction on entering patient data into the web based data entry system for pediatric patients who receive MCSDs**

PediMACS Tutorial: September 20, 2012

I.	Welcome	Drs. Blume & Baldwin
II.	PediMACS	Dr. Kirklin
III.	PediMACS Structure	Dr. Blume
IV.	Hospital Enrollment	Dr. Naftel & ML Clark
V.	Patient Enrollment	Susan Myers
VI.	Data Elements and Definitions	Dr. Rosenthal
VII.	Adverse Events Definitions	Dr. Morales
VIII.	Training and Hands-on Data Entry	Kathryn Hollifield, RN
IX.	Data Quality and Hospital Evaluation	Dr. Naftel
X.	Wrap Up	Dr. Blume

PediMACS

- Overview of INTERMACS
- Genesis of PediMACS
- Goals & Expected Analyses

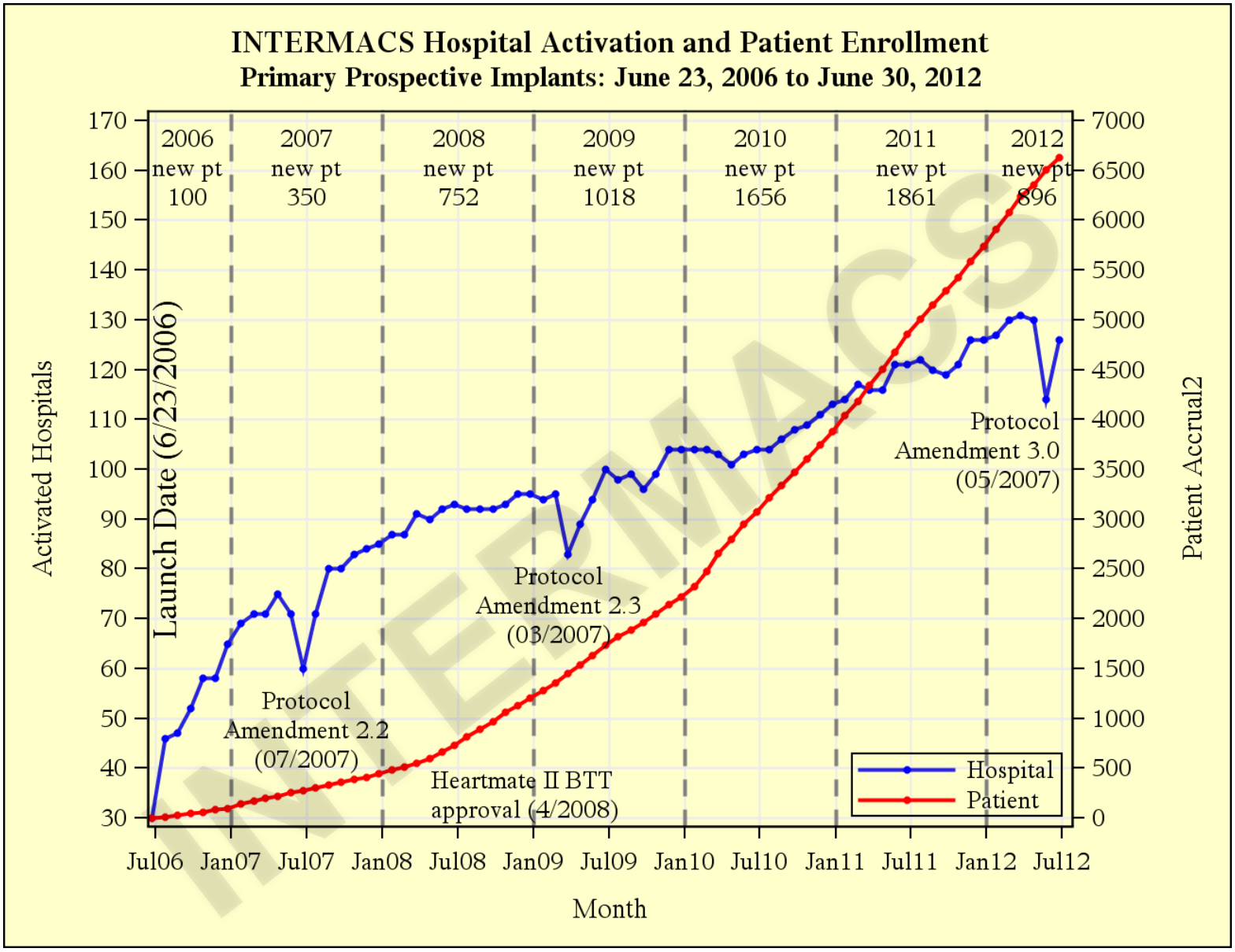
James K. Kirklin, MD

What is INTERMACS ?

INTERMACS is the United States national (North American) registry for patients who are receiving durable, FDA approved mechanical circulatory support device therapy to treat advanced heart failure. This registry was devised as a joint effort of the National Heart, Lung and Blood Institute (NHLBI), the Centers for Medicare and Medicaid Services (CMS), the Food and Drug Administration (FDA), clinicians, scientists and industry representatives.

Goals of the Registry

- **Facilitate the refinement of patient selection to *maximize outcomes* with current and new device options.**
- **Identify predictors of good outcomes as well as risk factors for adverse events after device implantation.**
- **Develop consensus "*best practice*" guidelines to improve clinical management by reducing short and long term complications of MCSD therapy.**
- **Guide clinical application and evolution of next generation devices.**
- **Utilize Registry information to guide improvements in technology, particularly as next generation devices evolve.**



Between June 23, 2006 and June 30, 2012, 145 hospitals participated in INTERMACS and, of these, 131 hospitals actively contributed information on a total of 6633 patients. Cumulative patient accrual and the number of participating hospitals over this time period are displayed above.

INTERMACS: Federal Partners Report
Implants through June 30, 2012

Age Category

AGE GROUP (yr)	Implant Date Period						TOTAL	
	Pre 2011		2011		2012 (Jan-Jun)			
	n	%	n	%	n	%	n	%
0-18	52	1.3 %	17	0.9 %	3	0.3 %	72	1.0 %
19-39	546	14.0 %	222	11.9 %	110	12.2 %	878	13.2 %
40-59	1859	47.9 %	704	37.8 %	342	38.1 %	2905	43.7 %
60-79	1412	36.4 %	903	48.5 %	436	48.6 %	2751	41.4 %
80+	7	0.1 %	15	0.8 %	5	0.5 %	27	0.4 %
TOTAL	3876	100.0 %	1861	100.0 %	896	100.0 %	6633	100.0 %

The Pediatric Component of INTERMACS Prior to PediMACS Launch

- Limited pediatric adverse event definitions
- Limited tailoring for pediatric patients
- Little proactive recruitment of pediatric hospitals
- Essentially no FDA approved durable devices for small children (prior to December 2011)
- No temporary devices as primary device
- Limited pediatric involvement in the INTERMACS committee structure
- Few pediatric patients (n=72) enrolled into INTERMACS (essentially teenagers with adult devices)

What have we learned about pediatric patients from INTERMACS?

Presented at AHA 2011
Manuscript in progress

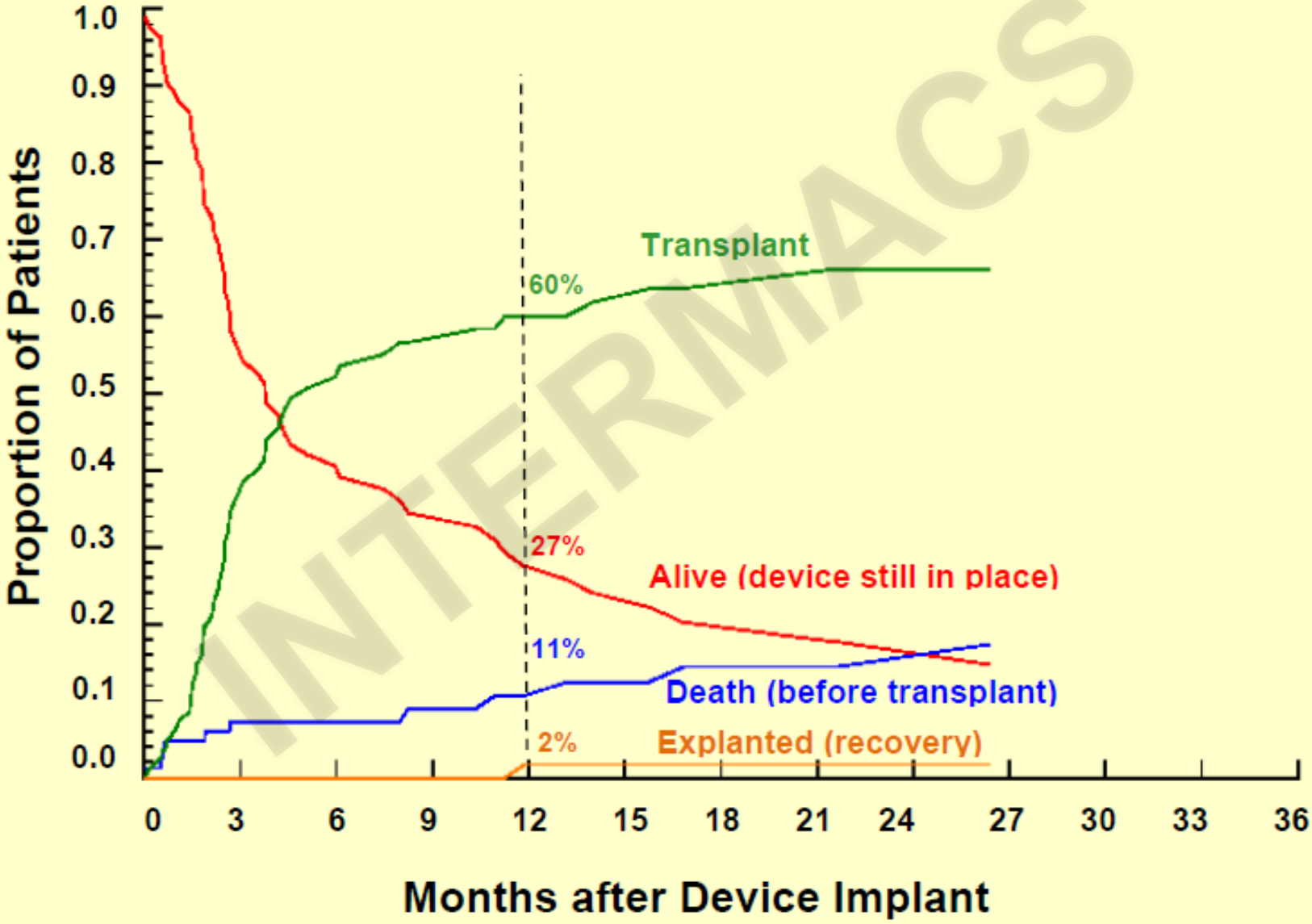
Outcomes of Children Implanted with Ventricular Assist Devices in the United States: Analysis of the Interagency Registry for Mechanical Circulatory Support (INTERMACS)

D Morales, A Lowry, D Epstein, D Rosenthal,
J Chen, C Almond, P Wearden, D Naftel,
J Kirklin, E Blume

intermacs

June 2006 – March 2011: Outcomes of Children with VADs

n=84 patients (age at implant 0-21 years)



June 2006 – March 2011: Outcomes of Children with VADs

Adverse Event Rates after Device Implantation (Events/100 Patient Months) in the First 3 Months post implant and 3 months or more post implant for Pediatric Patients

	Entire Time Period			Adverse Event Rates			
	# of	# of	% of	1st 3 months		≥ 3 months	
Event	events	patients*	patients	n	rate	n	rate
Infection	81	31	37%	56	28.68	25	7.82
Bleeding	74	28	33%	61	31.24	13	4.07
Cardiac Arrhythmia	23	16	19%	18	9.22	5	1.56
Device Malfunction	21	12	14%	2	1.02	19	5.94
Neurological Dysfunction	12	10	12%	7	3.58	5	1.56
Respiratory Failure	10	10	12%	9	4.61	1	0.31
Renal Dysfunction	8	8	10%	8	4.10	--	--
Right Heart Failure	8	7	8%	7	3.58	1	0.31
Hepatic Dysfunction	7	7	8%	7	3.58	--	--
Hypertension	7	7	8%	6	3.07	1	0.31
Pericardial Drainage	7	5	6%	7	3.58	--	--
Hemolysis	6	3	4%	5	2.56	1	0.31
Psychiatric Episode	6	3	4%	3	1.54	3	0.94
Venous Thromboembolism	4	4	5%	4	2.05	--	--
Other*	30	17	20%	20	10.24	10	3.13

* # of patients with one or more events

Table 6: Version 1

Planning PediMACS:

- Pediatric adverse event definitions
- Data element tailoring for pediatric patients
- Proactive recruitment of pediatric hospitals
- Berlin Heart EXCOR approved December 2011
- Includes temporary devices
- Pediatric involvement in the INTERMACS committee structure
- Expect to enroll the majority of pediatric patients in North America

PediMACS

- Planned, created and implemented: August 2011 – August 2012

- Launched: September 19, 2012 !

What devices will be part of PediMACS?

Retrospective information exists in the Pediatric Heart Transplant Study (PHTS)

Outcome of Children Bridged to Transplant with Ventricular Assist Devices: A Multi-Institutional Study

E. D. Blume , D.C. Naftel, H. J. Bastardi,
B.W. Duncan, J.K. Kirklin, and S. A. Webber
for the PHTS Investigators

Children's Hospital Boston, University of Alabama, Cleveland Clinic Foundation, Children's Hospital of Pittsburgh

Patient Characteristics: VAD Type January 1993-December 2003 PHTS

VAD Device	Total	LVAD	L+R VAD
Pulsatile, chronic	70		
Thoratec		29	24
Heartmate		12	1
Novacor		3	-
Berlin		1	-
Pulsatile, temporary	10		
Abiomed		5	5
Continuous flow	16		
Biomedicus		9	5
Biomedicus, Thoratec		-	2
Total		**59**	**37**

Ventricular assist device support as a bridge to pediatric heart transplantation: a practice in evolution.

To be presented at AHA 2012

Anne Dipchand[1], David Naftel[2], Betsy Blume[3], Richard Kirk[4], Bob Morrow[5], David Rosenthal[6], Marc Richmond[7], James Kirklin[2]

1 Hospital for Sick Children, Toronto; 2 University of Alabama at Birmingham; 3 Children's Hospital, Boston; 4 Freeman Hospital, Newcastle Upon

5 Arkansas Children's Hospital, Little Rock; 6 Stanford University Medical Center, Stanford 7 Columbia University – Babies Hospital, New York

PHTS: 1993–2010, Ventricular Assist Devices

All Listing VADs (n=126)

Type VAD	n	%
Berlin Heart EXCOR	34	27%
Thoratec (primarily HMII)	57	45%
All others	35	28%
Total	126	100%

Device Brand List
Pediatrics (< 19 Years of Age)

1. Approved Durable Devices (potential for patient discharge): These devices **SHOULD BE ENTERED** into PediMACS except in rare circumstances where a patient with an approved device is in the control arm of an FDA approval study.

Company	Device	Position
Abiomed, Inc.	AbioCor TAH	TAH
Micromed Technology, Inc.	MicroMed DeBakey VAD – Child	L
SynCardia Systems, Inc.	SynCardia CardioWest	TAH
Thoratec Corporation	HeartMate II LVAS	L
	HeartMate IP	L
	HeartMate VE	L
	HeartMate XVE	L
	Thoratec IVAD	L/R
	Thoratec PVAD	L/R
WorldHeart, Inc.	NovaCor PC	L
	NovaCor PCq	L
Berlin Heart	Berlin Heart EXCOR	L/R

2. Approved Temporary Devices: These devices SHOULD be entered into PediMACS.

Company	Device	Position
Abiomed, Inc.	Abiomed AB5000	L/R
	Abiomed BVS 5000	L/R
	Impella	L
CardiacAssist, Inc.	Tandem Heart	L/R
Levitronix Medical Division	Levitronix Centrimag	L/R
	Levitronix Pedimag	L/R
Medtronic Biomedicus, Inc.	Biomedicus	R
Maquet Cardiovascular	Jostra Rotaflow	

Goals & Expected Analyses from PediMACS

- The goals of PediMACS are the same as the goals of INTERMACS – but, with a focus on pediatric patients and an expansion to temporary devices.

Goals of the Registry

- **Facilitate the refinement of patient selection to *maximize outcomes* with current and new device options.**
- **Identify predictors of good outcomes as well as risk factors for adverse events after device implantation.**
- **Develop consensus "*best practice*" guidelines to improve clinical management by reducing short and long term complications of MCSD therapy.**
- **Guide clinical application and evolution of next generation devices.**
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PediMACS Structure

- Committees
- Benefits to hospitals
- Quality Assurance reports

Elizabeth Blume, MD

pediMACS Launch Status

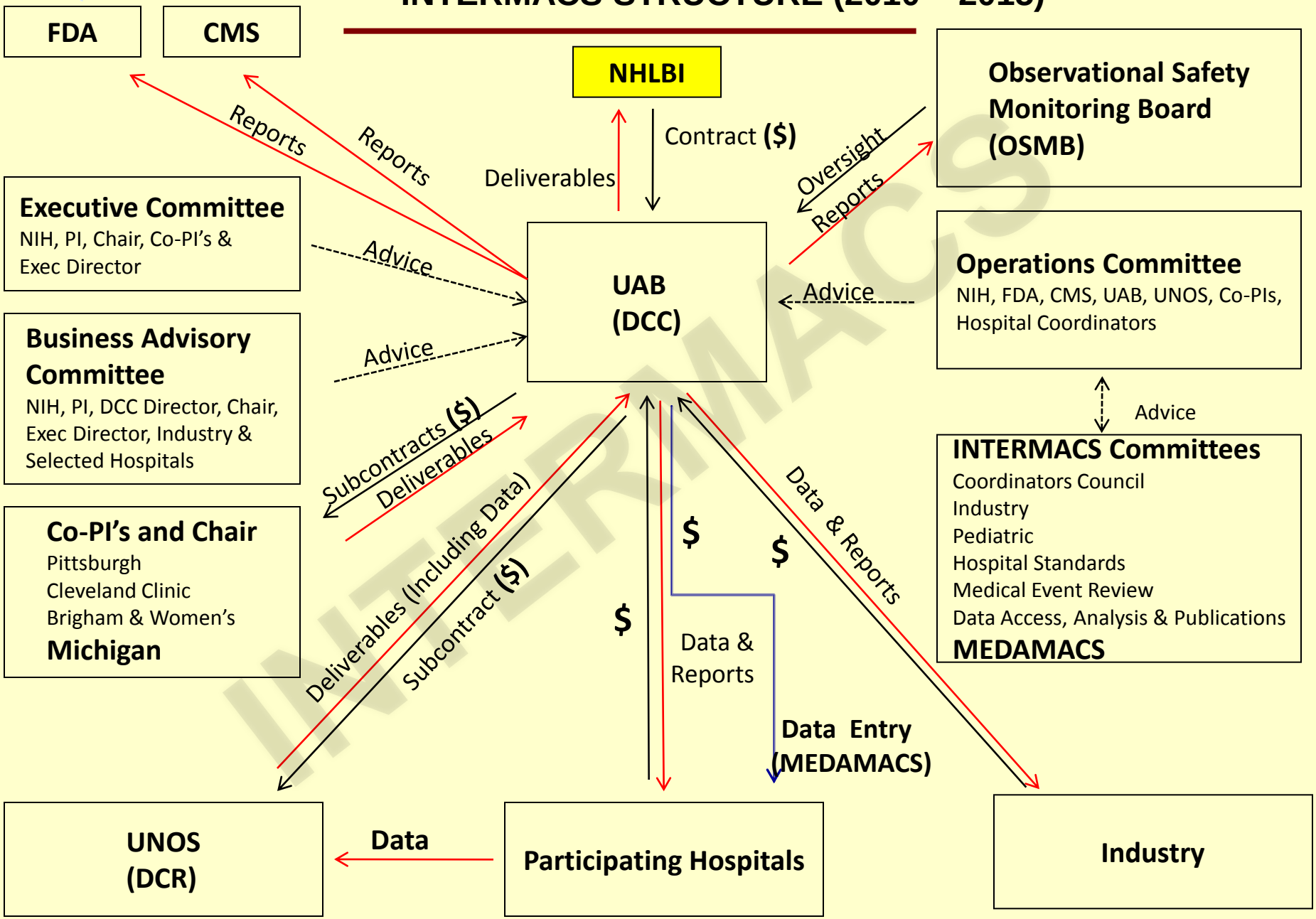
- pediMACS will follow the structure of INTERMACS
- A few important changes from INTERMACS:
  - Pediatric patients (< 19 yrs. at time of implant)
  - Includes both durable and temporary support MCSDs
  - Modifications of AE definitions
  - Possible expansion of quality of life instruments

PediMACS Committees

PediMACS Committees

- Coordinators Council
- Industry
- Operations Committee
- Hospital Standards
- Medical Event Review
- Data Access, Analysis & Publications

INTERMACS STRUCTURE (2010 – 2015)



Benefits to Hospitals

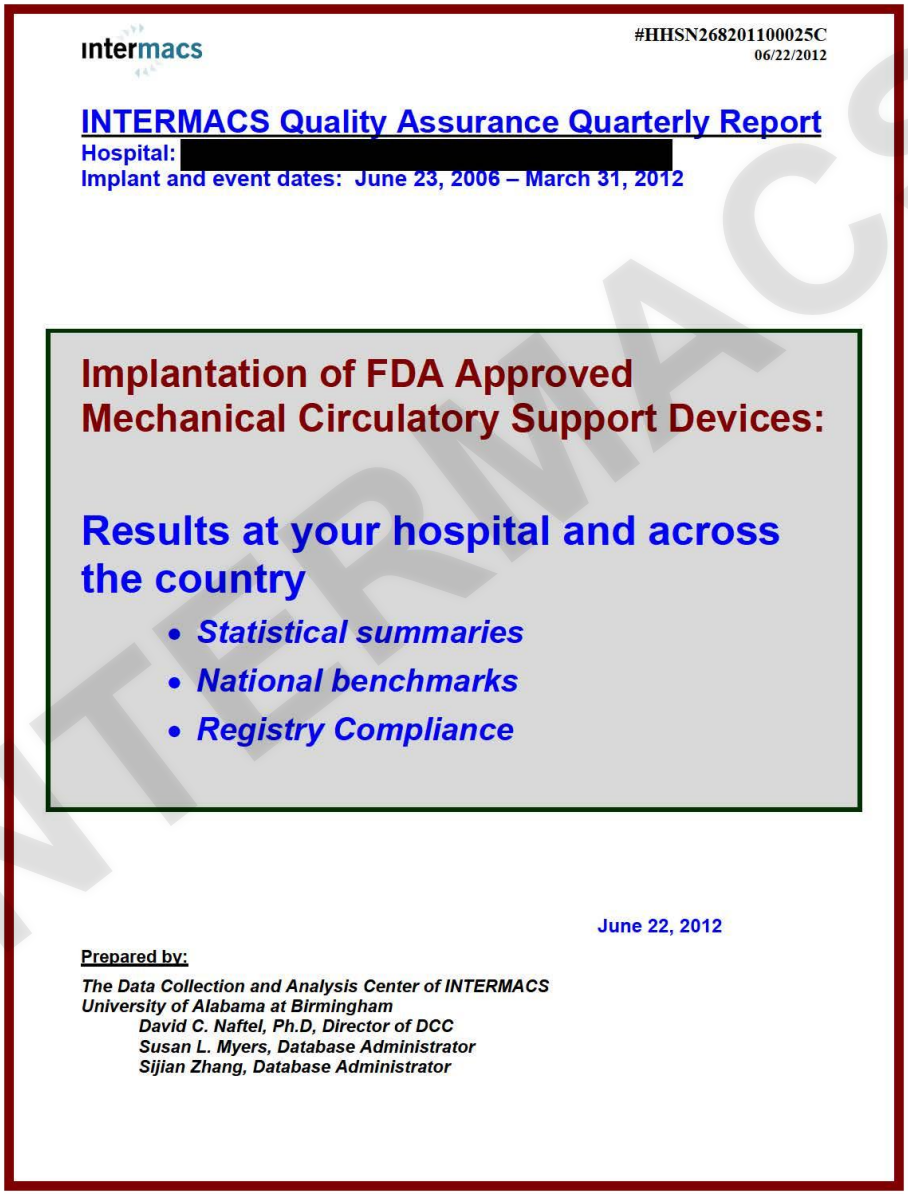
Hospitals

- **What services do the hospitals receive for their participation fee?**
  - Services
    - Meets CMS/Joint Commission requirement for Destination Therapy Certification
    - Meets FDA required submission of Medical Device Reports (MDRs) by hospitals
    - Provides clinical summaries of patients
    - Provides quality assurance reports
    - Provides electronic data transfer
    - Provides standardized datasets
    - Provides benchmarking
    - Provides training and continuing education units

Hospitals (Continued)

- **What benefits do the hospitals receive for their participation fee?**
  - Benefits
    - Fulfills CMS DT Certification requirement
    - Become part of the national dialogue on the evaluation and evolution of MCSDs
    - Invited to participate in the INTERMACS Annual Meeting
    - Invited to join the INTERMACS Committees
      - Coordinators Council and other committees
    - Select Hospital Administrators will have the opportunity to serve on the Business Advisory Committee

Quality Assurance Reports



intermacs

#HHSN268201100025C
06/22/2012

INTERMACS Quality Assurance Quarterly Report
Hospital: [redacted]
Implant and event dates: June 23, 2006 – March 31, 2012

Implantation of FDA Approved Mechanical Circulatory Support Devices:

Results at your hospital and across the country

- *Statistical summaries*
- *National benchmarks*
- *Registry Compliance*

June 22, 2012

Prepared by:

The Data Collection and Analysis Center of INTERMACS
University of Alabama at Birmingham
David C. Naftel, Ph.D, Director of DCC
Susan L. Myers, Database Administrator
Sijian Zhang, Database Administrator

INTERMACS QUARTERLY QUALITY ASSURANCE REPORT
IMPLANTS: June 2006 - March 2012
[redacted]
Patient Demographics

Table 1: Age Group

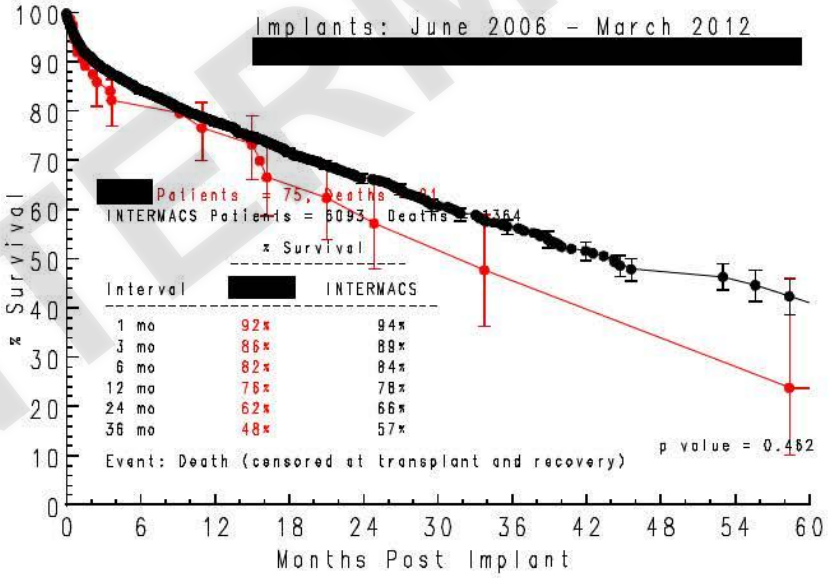
Age Groups	[redacted]		INTERMACS	
	#	Pct %	#	Pct %
A: 0-18	3	4.0 %	69	1.1 %
B: 19-39	13	17.3 %	815	13.3 %
C: 40-59	34	45.3 %	2703	44.3 %
D: 60-79	25	33.3 %	2482	40.7 %
E: 80+	.	.	25	0.4 %
Total Patients	75	100.0 %	6094	100.0 %

Table 2: Gender

Gender	[redacted]		INTERMACS	
	#	Pct %	#	Pct %
F	16	21.3 %	1285	21.0 %
M	59	78.6 %	4808	78.8 %
U	.	.	1	0.0 %
Total Patients	75	100.0 %	6094	100.0 %

INTERMACS Quarterly Quality Assurance Report
Implants: June 2006 - March 2012
[redacted]

Figure 1: Post Implant Survival: Primary Implants



Hospital Enrollment

David C. Naftel, PhD

You too can participate in PediMACS!

Currently Enrolled in INTERMACS

Currently Enrolled	139
Approved for PediMACS Enrollment	56
Stand-alone Pediatric Hospitals	11

Currently enrolled in INTERMACS:

- **Current approval to include pediatrics**

OR

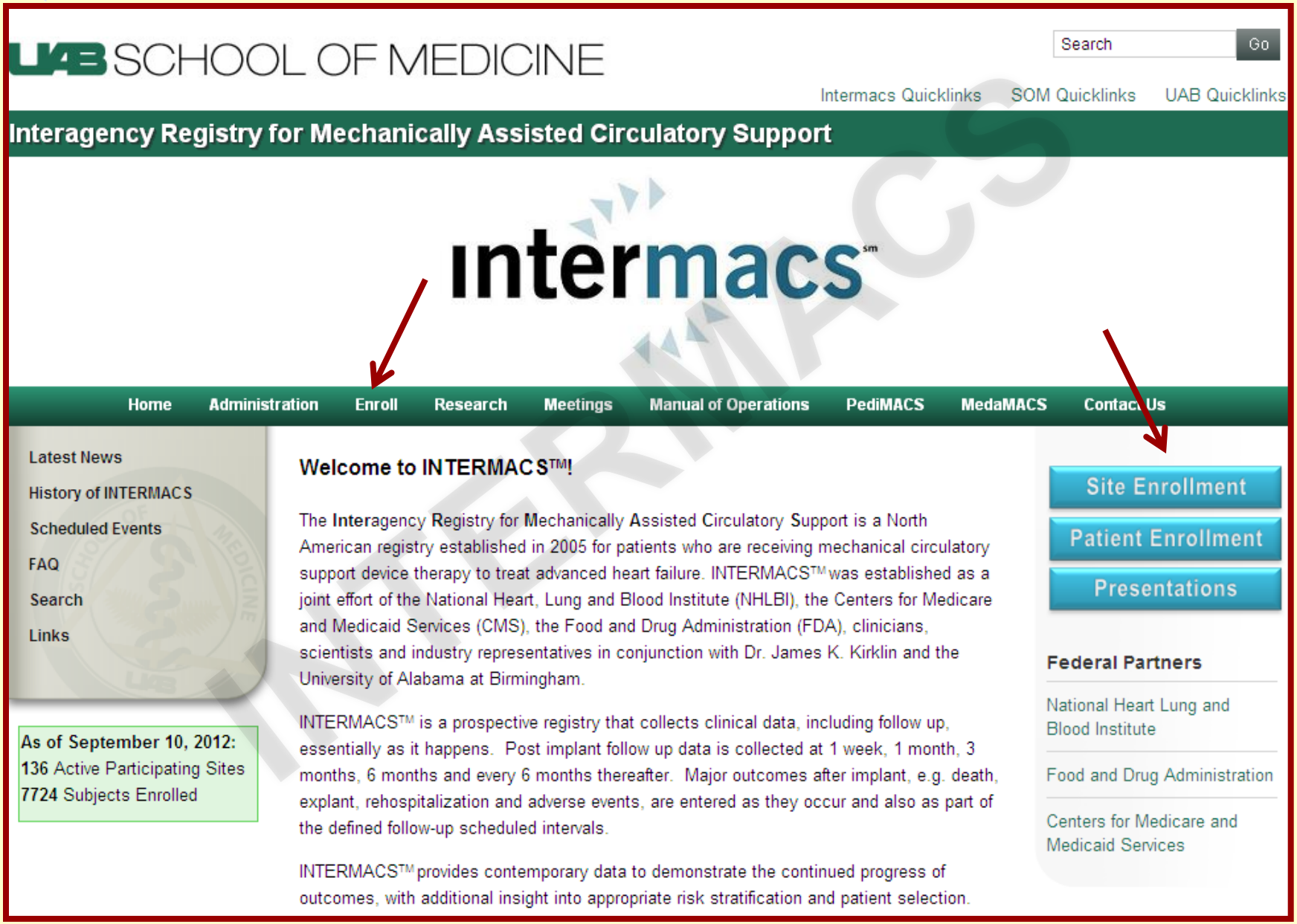
- **Add pediatric patients**

New Sites:

Enroll through the INTERMACS website

www.intermacs.org

PediMACS Training, September 20, 2012



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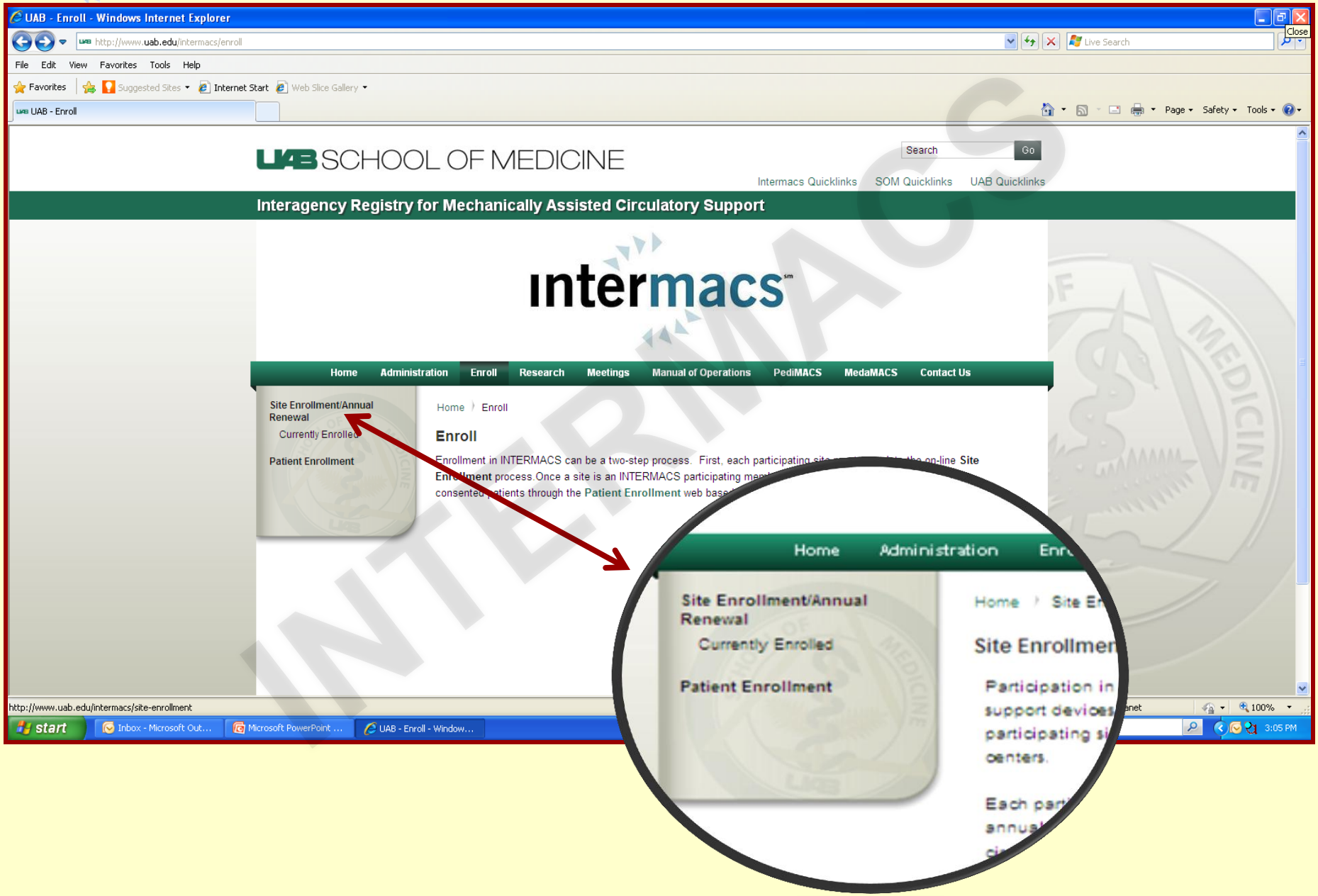

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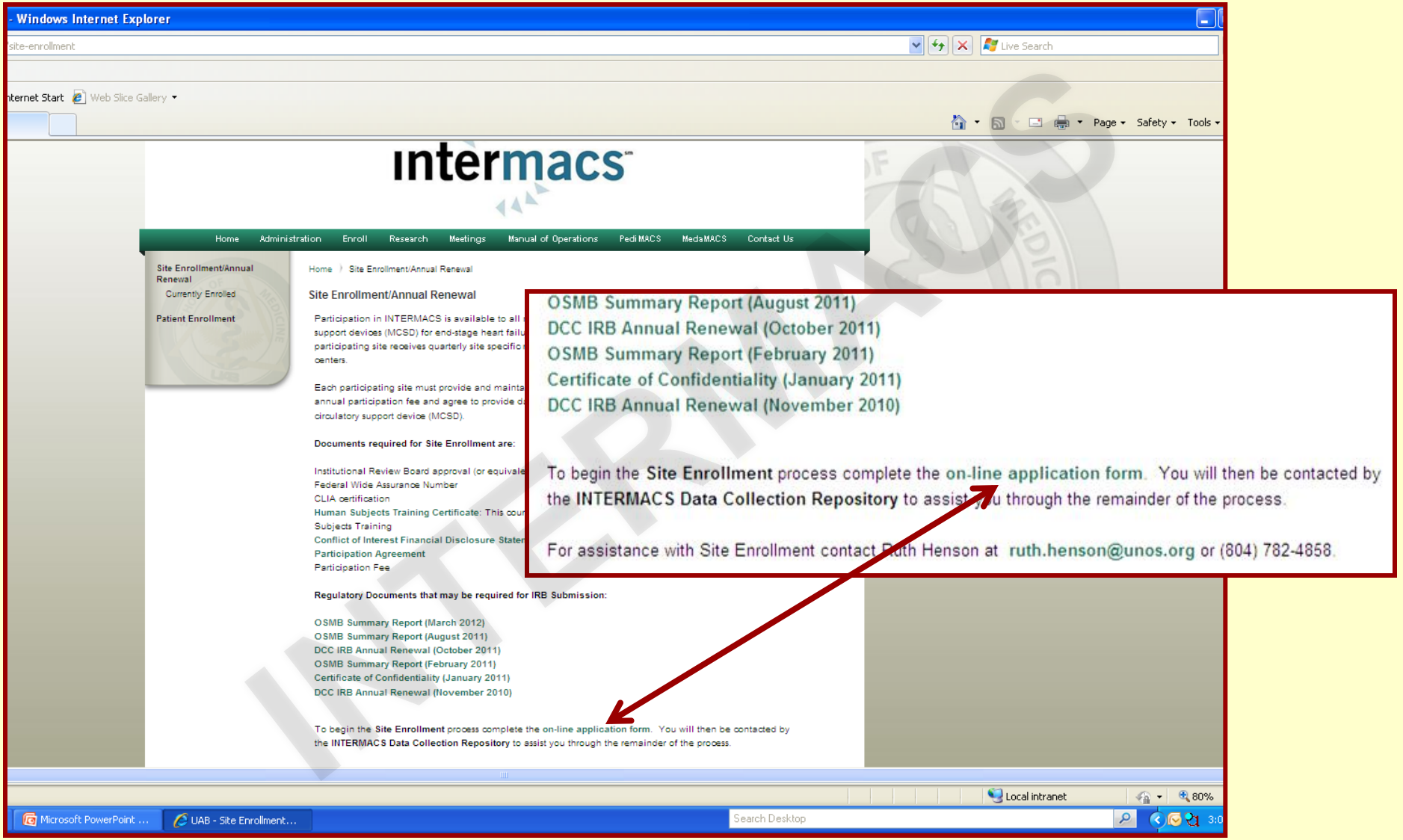

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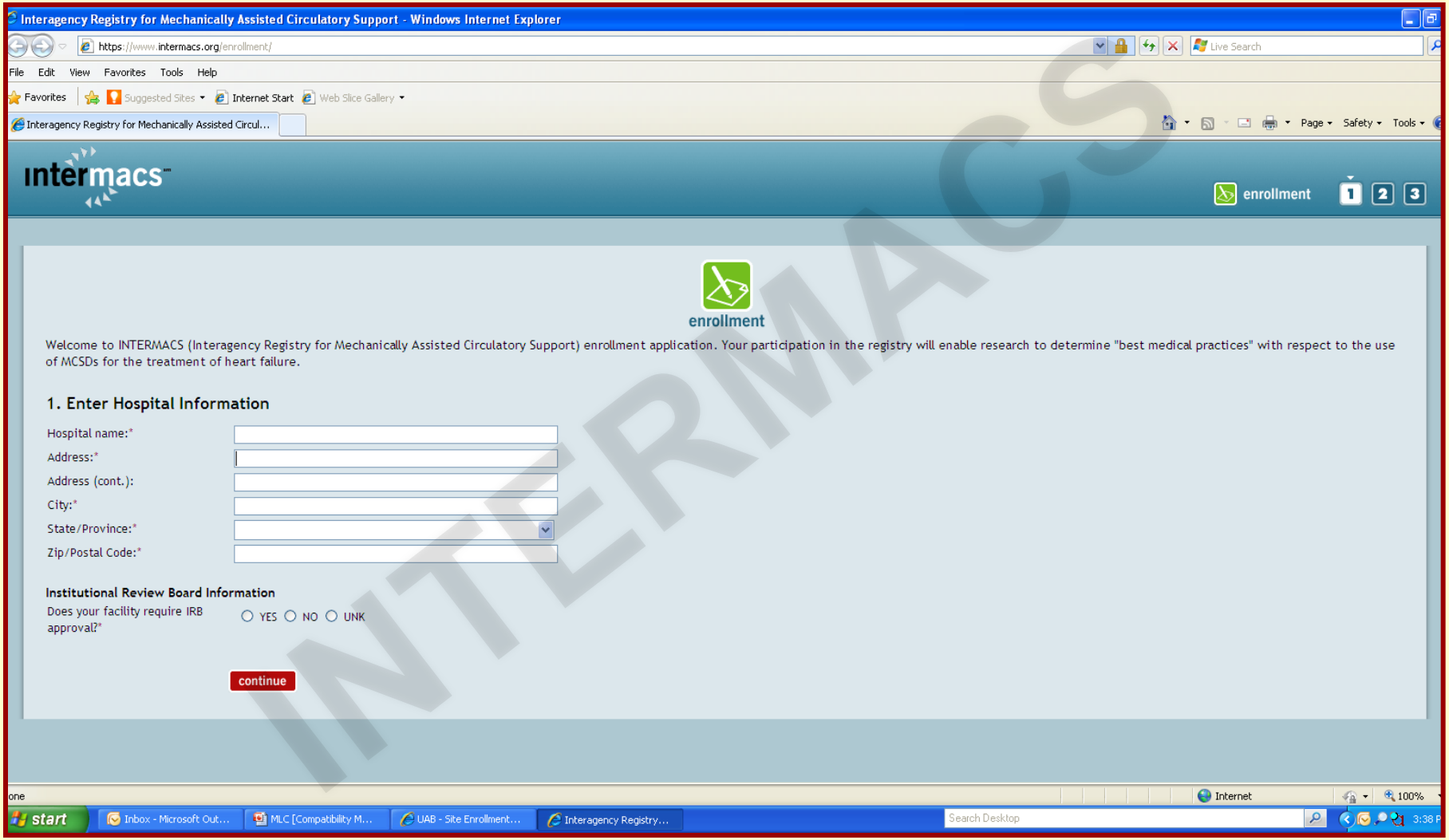

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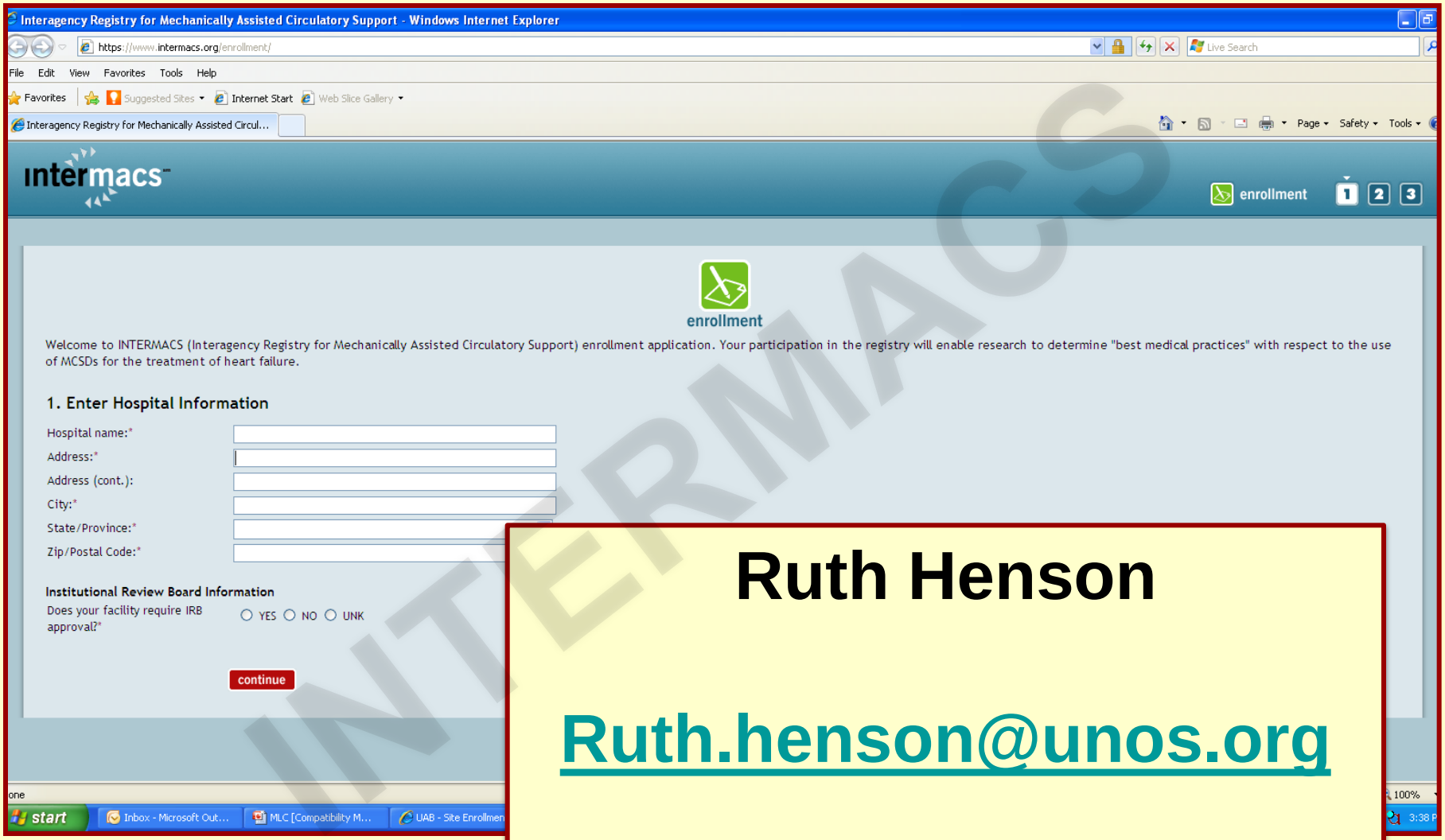


Ruth Henson

Ruth.henson@unos.org

804-782-4858

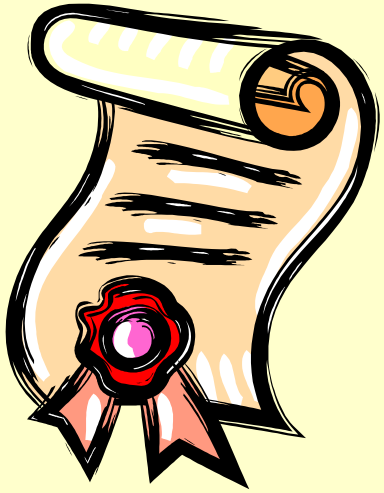
Regulatory Requirements

- Participation Agreement
- Federal Wide Assurance Number
- IRB / Ethics Board Approval
- Approved Consent/Authorization Forms
- Clinical Laboratory Improvement Amendments (CLIA)
- Financial Disclosure / Conflict of Interest
- Human Subjects Training

The final step for activation is

Training

Please make sure you signed the registration sheet. This is our documentation that you received training.



Mary Lynne Clark
Regulatory Director

mlclark@uab.edu
intermacs@uab.edu
205-934-2555

Patient Enrollment

- Inclusion / Exclusion
- Structure of database

Susan Myers

Database Administrator

pediMACS Launch Status

Live Test Site
August 29, 2012

Aug 29 – Sep 19

Target: LAUNCH Date
September 19, 2012

- **Live test site: August 29, 2012**
  - Testing by INTERMACS Nurse Monitors
  - Testing by the DCC Data Managers
  - Testing by the INTERMACS Co-PIs
  - Testing by *3 Hospitals* (Beta Sites)
  - Testing by Pediatric Committee
- **Launch Date: September 19, 2012**
  - Online training will be available
  - Training Session in September 2012

Overview of Data Entry

This is to:

Current members AND

New members

- Inclusion/exclusion criteria
- Devices
- Patient flow

Inclusion / Exclusion

Inclusions

- Patient less than 19 years of age at time of implant
- Patient receives a mechanical circulatory support device (MCSD) which is FDA approved
- Implant on or after September 19, 2012 (The device does not need to be the first implant for a patient)
- Patient/Parent signed informed consent

Exclusions:

- Patient 19 years or older at time of implant (patient should be enrolled into INTERMACS)
- Patient receives a mechanical circulatory support device (MCSD) which is not FDA approved
- Patient is incarcerated (prisoner)
- Patient (legal guardian) did not sign informed consent
  - Too sick pre-implant and died early post implant
  - Missed opportunity to consent
  - Patient or legal guardian refused
  - Patient and/or legal guardian is unable to communicate in English

Device Brand List
Pediatrics (< 19 Years of Age)

1. Approved Durable Devices (potential for patient discharge): These devices **SHOULD BE ENTERED** into PediMACS except in rare circumstances where a patient with an approved device is in the control arm of an FDA approval study.

Company	Device	Position
Abiomed, Inc.	AbioCor TAH	TAH
Micromed Technology, Inc.	MicroMed DeBakey VAD – Child	L
SynCardia Systems, Inc.	SynCardia CardioWest	TAH
Thoratec Corporation	HeartMate II LVAS	L
	HeartMate IP	L
	HeartMate VE	L
	HeartMate XVE	L
	Thoratec IVAD	L/R
	Thoratec PVAD	L/R
WorldHeart, Inc.	NovaCor PC	L
	NovaCor PCq	L
Berlin Heart	Berlin Heart EXCOR	L/R

2. Approved Temporary Devices: These devices SHOULD be entered into PediMACS.

Company	Device	Position
Abiomed, Inc.	Abiomed AB5000	L/R
	Abiomed BVS 5000	L/R
	Impella	L
CardiacAssist, Inc.	Tandem Heart	L/R
Levitronix Medical Division	Levitronix Centrimag	L/R
	Levitronix Pedimag	L/R
Medtronic Biomedicus, Inc.	Biomedicus	R
Maquet Cardiovascular	Jostra Rotaflow	

INTERMACS Printable Forms

- Screening Log
- Patient Demographics Form
- Pre-Implant Form
- Implant Form
- 1 Week/1month Follow-up Form
- 3 month/6month Follow-up Form
- Implant Discharge Form
- Rehospitalization Form
- AE Infection Form
- AE Neurological Dysfunction Form
- AE Device Malfunction Form
- AE Bleeding Form
- Other Adverse Events
- Explant/Transplant Form
- Death Form
- Patient Transfer/Withdrawal Form

INTERMACS Printable Forms

Patient

- Screening Log
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Clinical Course

Data Structure Follow-up

- Follow-up schedule
- Adverse Events
- Adding a device
- Ending patient participation

Clinic (or hospital) Visit time table for follow-up

		Example: Apr 1st implant	
Expected Clinic Visit	Acceptable Time Window for Clinic Visit	Expected Clinic Visit	Acceptable Time Window for Clinic Visit
1 week	4–10 days post implant (+/- 3 days)	Apr 7	Apr 4 - Apr 10
1 month	23–37 days post implant (+/- 7days)	May 1	Apr 24 - May 8
3 month	60–120 days post implant (+/- 30 days)	Jul 1	Jun 1 - Aug 1
6 months	120-240 days post implant (+/- 60 days)	Oct 1	Aug 1 - Dec 1
12 months	300–420 days post implant (+/- 60 days)	Apr 1	Feb 1 – Jun 1
18 months	480–600 days post implant (+/- 60 days)	Oct 1	Aug 1 - Dec 1
24 months	660-780 days post implant (+/- 60 days)	Apr 1	Feb 1 - Jun 1

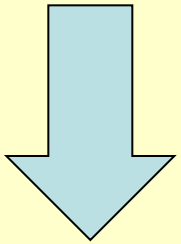
Adding an Adverse Event

- During implant hospitalization
- Outside of hospital
- During re-hospitalization
- Adverse Event “Triggers”

Adding a Device

INTERMACS® allows for entry of multiple implants for an individual patient. The LVAD implantation date will be the "driving force" of the follow up clock. If an LVAD is removed and then replaced with a new LVAD then the follow up clock restarts with the new LVAD. If the initial device implanted is an RVAD alone then the RVAD will 'drive' the follow-up clock and if an LVAD is subsequently implanted then the LVAD will 'restart' the follow-up 'clock'.

There are two possible scenarios.



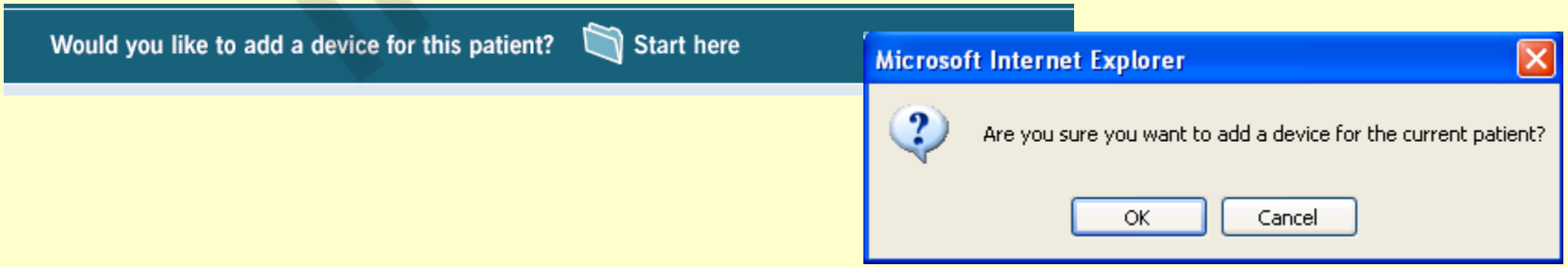
Adding a Device

- **Replacement of an existing device**

If a patient has a device replaced (e.g., a patient with an LVAD receives a replacement LVAD) then the previous implant for the patient must be explanted and all forms related to this implant must be completed and validated. Once the forms for the previous implant have been submitted then the “Add Device” icon is available for the entry of a new implant for the patient.

- **Additional device**

If an additional device is implanted (e.g., a patient with an LVAD subsequently receives an RVAD) then select the “Add Device” icon for the entry of a new implant for the patient.



1.4 Ending Patient Participation

A patient's participation in INTERMACS® may end for clinical or administrative reasons:

Clinical

(1) **Death:**

(2) **Transplant:** Patient will be followed through the OPTN database.

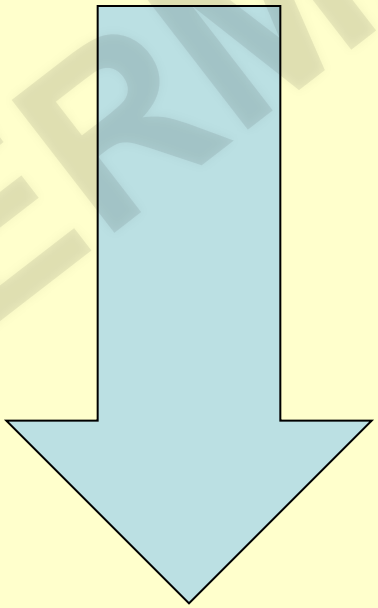
(3) **1 year after removal of a device due to recovery:** Regular follow-up form completion ceases, but the coordinator reports to the registry whether the patient died or was transplanted for a period of 1 year post-explant.

Administrative

(1) **Patient transfers** medical care to another hospital: This will end the patient participation at your hospital. The receiving hospital will then continue following this patient.

(2) **Patient revokes/withdraws his/her informed consent**:

Let's take a look at a couple of sample patients



PediMACS Tutorial: September 20, 2012

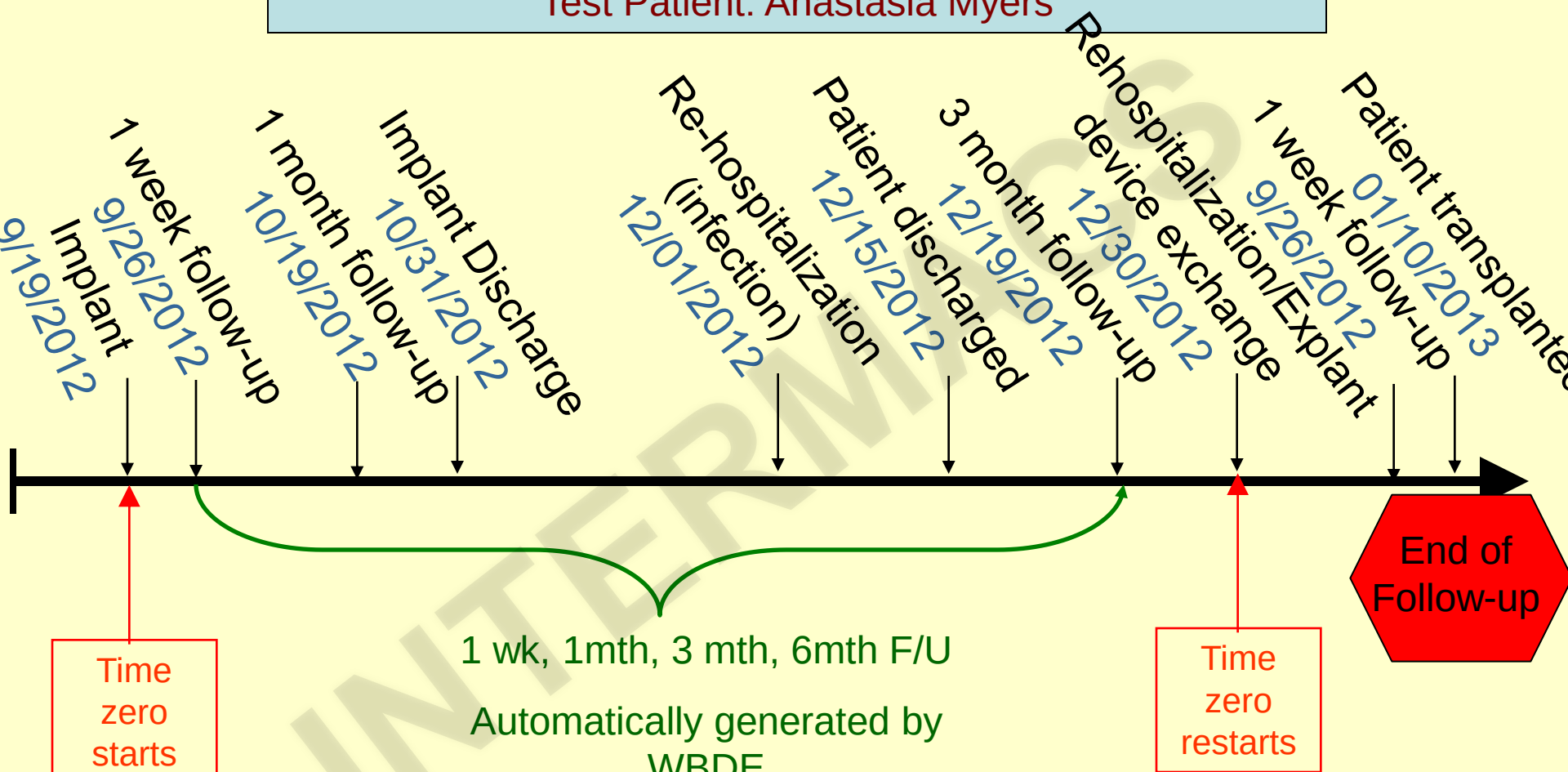
Test Patient: Anastasia Myers

- **12 year old white female**
- **Advanced heart failure**
- **Dilated Cardiomyopathy**
- **PediMACS Level 3 – Stable but inotrope dependent**

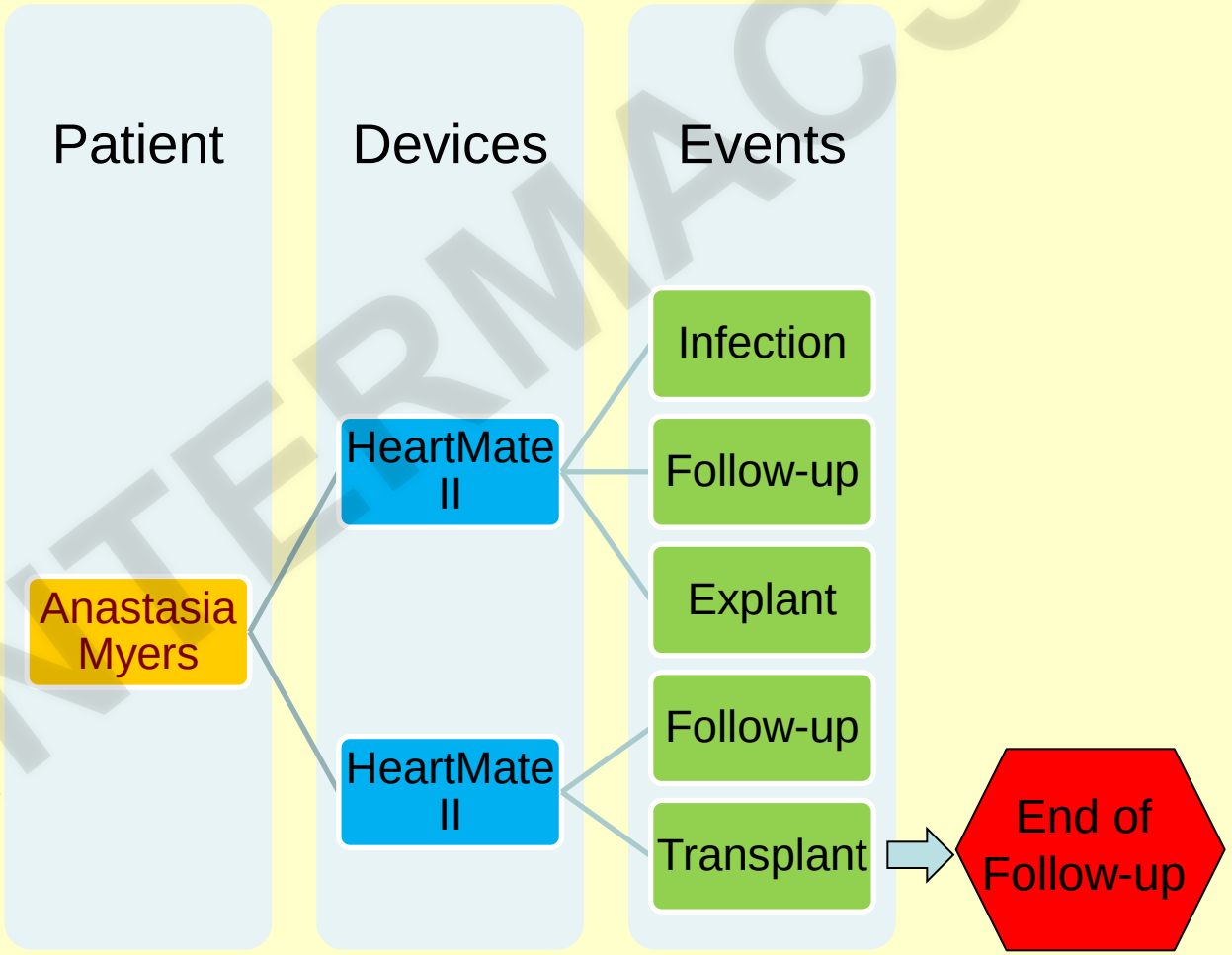
09/19/2012:	HeartMate II
09/26/2012	1 week follow-up
10/19/2012	1 month follow-up
10/31/2012:	Patient discharged home
12/01/2012:	Patient re-hospitalized for infection - sepsis
12/15/2012:	Patient discharged home
12/19/2012	3 month follow-up
12/30/2012	patient re-hospitalized – explant – device exchange
01/10/2013	patient transplanted - End of Follow-up

PediMACS Tutorial: September 20, 2012

Test Patient: Anastasia Myers



Data Structure



PediMACS Tutorial: September 20, 2012

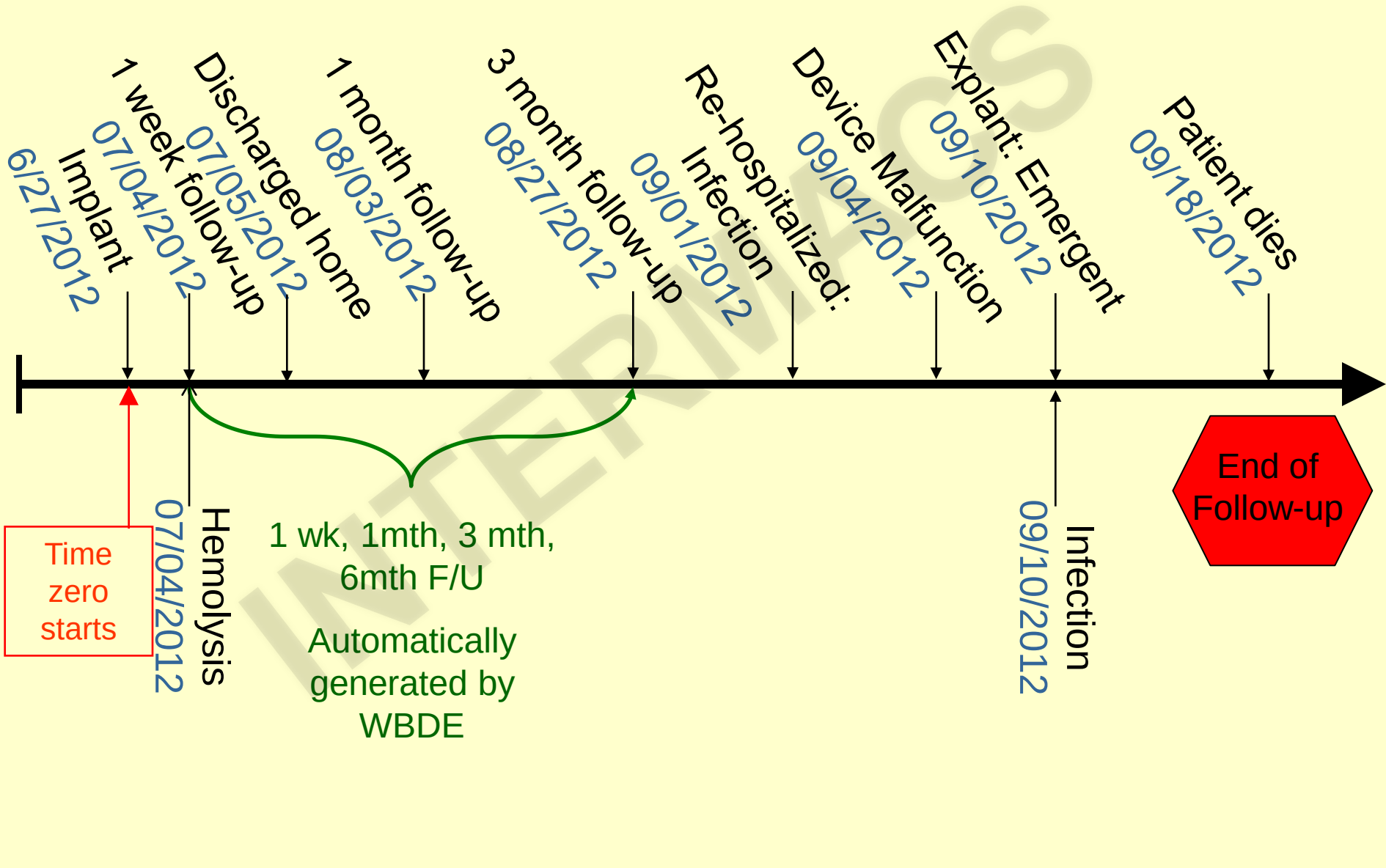
Test Patient: Princess Leai

- **9 year old Hawaiian female**
- **Elective VAD placement**
- **Dilated Cardiomyopathy: Viral**
- **PediMACS Level 2 – Progressive Decline**

06/27/2012	HeartMate II
07/04/2012	1 week follow-up
07/04/2012	Hemolysis
07/05/2012	Patient discharged home
08/03/2012	1 month follow-up
08/27/2012	3 month follow-up (includes QOL)
09/01/2012	Patient re-hospitalized for infection: line sepsis
09/04/2012	Device Malfunction
09/10/2012	Infection: Fungal
09/10/2012	Patient explanted: Emergent: viral infection
09/18/2012	Patient dies

PediMACS Tutorial: September 20, 2012

Test Patient: Princess Leai



Data Elements and Definitions

- Disease Severity, Patient Selection and Potential Risk
- Quality of Life and Functional Capacity

David Rosenthal, MD

PediMACS Levels

PediMACS 1: Critical cardiogenic shock describes a patient who is "crashing and burning", in which a patient has life-threatening hypotension and rapidly escalating inotropic pressor support, with critical organ hypo perfusion often confirmed by worsening acidosis and lactate levels. This patient can have modifier A or TCS (see 'Modifiers' below)

PediMACS 2: Progressive decline describes a patient who has been demonstrated "dependent" on inotropic support but nonetheless shows signs of continuing deterioration in nutrition, renal function, hepatic function, respiratory function, fluid retention, nutrition, tachyarrhythmia**,** or other major status indicator. Patient profile 2 can also describe a patient with refractory volume overload, perhaps with evidence of impaired perfusion, in whom inotropic infusions *cannot be maintained* due to tachyarrhythmia, clinical ischemia, or other intolerance. This patient can have modifiers A or TCS.

PediMACS 3: Stable but inotrope dependent describes a patient who is clinically stable on mild-moderate doses of intravenous inotropes (or has a temporary circulatory support device) after repeated documentation of failure to wean without symptomatic hypotension, worsening symptoms, or progressive organ dysfunction (usually renal). It is critical to monitor nutrition, renal function, fluid balance, and overall status carefully in order to distinguish between a patient who is truly stable at Patient Profile 3 and a patient who has unappreciated decline rendering them Patient Profile 2. This patient may be either at home or in the hospital. Patient Profile 2 can have modifier A, and if in the hospital with circulatory support can have modifier TCS. If patient is at home most of the time on outpatient inotropic infusion, this patient can have a modifier FF if he or she frequently returns to the hospital.

PediMACS 4: Resting symptoms describes a patient who is at home on oral therapy but frequently has symptoms of congestion at rest or with ADL. He or she may have orthopnea, shortness of breath during ADL such as dressing or bathing, gastrointestinal symptoms (abdominal discomfort, nausea, poor appetite), disabling ascites or severe peripheral edema (extremity or facial). This patient should be carefully considered for more intensive management and surveillance programs, by which some may be recognized to have poor compliance that would compromise outcomes with any therapy. This patient can have modifiers A and/or FF.

PediMACS 5: Exertion Intolerant describes a patient who is comfortable at rest but unable to engage in any activity, living predominantly within the house or housebound. This patient has no congestive symptoms, but may have chronically elevated volume status, frequently with renal dysfunction, and may be characterized as exercise intolerant. This patient can have modifiers A and/or FF.

PediMACS 6: Exertion Limited also describes a patient who is comfortable at rest without evidence of fluid overload, but who is able to do some mild activity. Activities of daily living are comfortable and minor activities outside the home such as visiting friends or going to a restaurant can be performed, but fatigue results within a few minutes or any meaningful physical exertion. This patient has occasional episodes of worsening symptoms and is likely to have had a hospitalization for heart failure within the past year. This patient can have modifiers A and/or FF.

PediMACS 7: Advanced NYHA Class 3 describes a patient who is clinically stable with a reasonable level of comfortable activity, despite history of previous decompensation that is not recent. This patient is usually able to walk more than a block. Any decompensation requiring intravenous diuretics or hospitalization within the previous month should make this person a Patient Profile 6 or lower. This patient may have a modifier A only.

PediMACS Quality of Life

2.14 Quality of Life

Introduction

The PediMACS quality of life section will be similar to the core INTERMACS quality of life as far as the time they are collected (pre-implant, 3 mth, 6mth and every 6mth thereafter) and some of the same basic structure of how we have set up quality of life instrument data entry (i.e., EQ-5D and KCCQ) for core INTERMACS. There are several PediMACS quality of life forms (child and parent reports).

- **PEDSQL Toddler 2-4 yrs (Parent Report)**
- **PEDSQL Young Child 5-7 yrs (Child Report)**
- **PEDSQL Young Child 5-7 yrs (Parent Report)**
- **PEDSQL Child 8-12 yrs (Child Report)**
- **PEDSQL Child 8-12 yrs (Parent Report)**
- **PEDSQL Teen 13-18 yrs (Child Report)**
- **PEDSQL Teen 13-18 yrs (Parent Report)**
- **VAD QOL (> 8 yrs) Child Report**
- **VAD QOL (< 2 yrs) Parent Report**
- **VAD QOL (≥ 2 yrs) Parent Report**

PEDSQL: Child

Did the child complete a form? Yes/No/Unknown

If no, please enter the reason the PEDSQL form was not completed:

- **Too Sick**
- **Administrative (check specific reason)**
  - **Urgent implant, no time**
  - **Coordinator too busy or forgot**
  - **Unable to contact patient**
  - **Other reason, specify**

If yes, please select the 'Child' form:

- **PEDSQL Young Child (5-7yrs)**
- **PEDSQL Child (8-12 yrs)**
- **PEDSQL Teen (13-18 yrs)**

The appropriate form 'opens' once the form (along with its instruction/direction page).

Young Child (5-7)

YOUNG CHILD REPORT (ages 5-7)

Instructions for interviewer:

I am going to ask you some questions about things that might be a problem for some children. I want to know how much of a problem any of these things might be for you.

Show the child the template and point to the responses as you read.

If it is <u>not at all</u> a problem for you, point to the smiling face

If it is <u>sometimes</u> a problem for you, point to the middle face

If it is a problem for you <u>a lot</u>, point to the frowning face

I will read each question. Point to the pictures to show me how much of a problem it is for you. Let's try a practice one first.

	Not at all	Sometimes	A lot
Is it hard for you to snap your fingers	☺	😐	☹

Ask the child to demonstrate snapping his or her fingers to determine whether or not the question was answered correctly. Repeat the question if the child demonstrates a response that is different from his or her action.

Young Child (5-7)

PedsQL 2

Think about how you have been doing for the last few weeks. Please listen carefully to each sentence and tell me how much of a problem this is for you.

After reading the item, gesture to the template. If the child hesitates or does not seem to understand how to answer, read the response options while pointing at the faces.

PHYSICAL FUNCTIONING *(problems with…)*	Not at all	Some-times	A lot
1. Is it hard for you to walk	0	2	4
2. Is it hard for you to run	0	2	4
3. Is it hard for you to play sports or exercise	0	2	4
4. Is it hard for you to pick up big things	0	2	4
5. Is it hard for you to take a bath or shower	0	2	4
6. Is it hard for you to do chores (like pick up your toys)	0	2	4
7. Do you have hurts or aches (*Where?*)	0	2	4
8. Do you ever feel too tired to play	0	2	4

Remember, tell me how much of a problem this has been for you for the last few weeks.

EMOTIONAL FUNCTIONING *(problems with…)*	Not at all	Some-times	A lot
1. Do you feel scared	0	2	4
2. Do you feel sad	0	2	4
3. Do you feel mad	0	2	4
4. Do you have trouble sleeping	0	2	4
5. Do you worry about what will happen to you	0	2	4

SOCIAL FUNCTIONING *(problems with…)*	Not at all	Some-times	A lot
1. Is it hard for you to get along with other kids	0	2	4
2. Do other kids say they do not want to play with you	0	2	4
3. Do other kids tease you	0	2	4
4. Can other kids do things that you cannot do	0	2	4
5. Is it hard for you to keep up when you play with other kids	0	2	4

SCHOOL FUNCTIONING *(problems with…)*	Not at all	Some-times	A lot
1. Is it hard for you to pay attention in school	0	2	4
2. Do you forget things	0	2	4
3. Is it hard to keep up with schoolwork	0	2	4
4. Do you miss school because of not feeling good	0	2	4
5. Do you miss school because you have to go to the doctor's or hospital	0	2	4

PEDSQL: Parent

Did the parent complete a form? Yes/No/Unknown

If no, please enter the reason the PEDSQL form was not completed:

- **Too Sick**
- **Administrative (check specific reason)**
  - **Urgent implant, no time**
  - **Coordinator too busy or forgot**
  - **Unable to contact patient**
  - **Other reason, specify _____**

If yes, please select the 'Parent' form:

- **PEDSQL Toddler (2-4 yrs)**
- **PEDSQL Young Child (5-7yrs)**
- **PEDSQL Child (8-12 yrs)**

Parent Report for Toddlers (ages 2-4)

Version 4.0

PARENT REPORT for TODDLERS (ages 2-4)

DIRECTIONS

On the following page is a list of things that might be a problem for **your child**. Please tell us **how much of a problem** each one has been for **your child** during the **past ONE month** by circling:

0 if it is **never** a problem
1 if it is **almost never** a problem
2 if it is **sometimes** a problem
3 if it is **often** a problem
4 if it is **almost always** a problem

There are no right or wrong answers.
If you do not understand a question, please ask for help.

Parent Report for Toddlers (ages 2-4)

PedsQL 2

*In the past **ONE month**, how much of a **problem** has your child had with …*

PHYSICAL FUNCTIONING *(problems with…)*	Never	Almost Never	Some-times	Often	Almost Always
1. Walking	0	1	2	3	4
2. Running	0	1	2	3	4
3. Participating in active play or exercise	0	1	2	3	4
4. Lifting something heavy	0	1	2	3	4
5. Bathing	0	1	2	3	4
6. Helping to pick up his or her toys	0	1	2	3	4
7. Having hurts or aches	0	1	2	3	4
8. Low energy level	0	1	2	3	4

EMOTIONAL FUNCTIONING *(problems with…)*	Never	Almost Never	Some-times	Often	Almost Always
1. Feeling afraid or scared	0	1	2	3	4
2. Feeling sad or blue	0	1	2	3	4
3. Feeling angry	0	1	2	3	4
4. Trouble sleeping	0	1	2	3	4
5. Worrying	0	1	2	3	4

SOCIAL FUNCTIONING *(problems with…)*	Never	Almost Never	Some-times	Often	Almost Always
1. Playing with other children	0	1	2	3	4
2. Other kids not wanting to play with him or her	0	1	2	3	4
3. Getting teased by other children	0	1	2	3	4
4. Not able to do things that other children his or her age can do	0	1	2	3	4
5. Keeping up when playing with other children	0	1	2	3	4

Please complete this section if your child attends school or daycare

SCHOOL FUNCTIONING *(problems with…)*	Never	Almost Never	Some-times	Often	Almost Always
1. Doing the same school activities as peers	0	1	2	3	4
2. Missing school/daycare because of not feeling well	0	1	2	3	4
3. Missing school/daycare to go to the doctor or hospital	0	1	2	3	4

VAD QOL: Child (for children > 8yrs of age)

Did the child complete a form? Yes/No/Unknown

If no, please enter the reason the PEDSQL form was not completed:

- **Too Sick**
- **Administrative (check specific reason)**
  - **Urgent implant, no time**
  - **Coordinator too busy or forgot**
  - **Unable to contact patient**
  - **Other reason, specify _____**

If yes, the VAD QOL (Child form opens – see attached form)

VAD QOL: Child (> 8 years)

ID#_____ Date:_____ *Patient > 8 years*

Directions

Children with heart conditions sometimes need a special device to help their heart function. Please fill in the circle which best describes your feelings about the ventricular assist device (VAD). Feel free to add any additional comments to the text lines.

1. The VAD noise bothers me when I am awake.
   ○ Always ○ Very Often ○ Sometimes ○ Rarely ○ Never _____
2. The VAD noise bothers me when I am trying to sleep.
   ○ Always ○ Very Often ○ Sometimes ○ Rarely ○ Never _____
3. I have pain or discomfort at the driveline or tubing pump exit site.
   ○ Always ○ Very Often ○ Sometimes ○ Rarely ○ Never _____
4. I have difficulty sleeping due to the position of the driveline or tubing pump exit site.
   ○ Always ○ Very Often ○ Sometimes ○ Rarely ○ Never _____
5. I am bothered by how I look with the VAD.
   ○ Always ○ Very Often ○ Sometimes ○ Rarely ○ Never _____
6. I worry about the VAD breaking or malfunctioning.
   ○ Always ○ Very Often ○ Sometimes ○ Rarely ○ Never _____
7. I am bothered that I cannot visit family or friends outside the home or hospital with the VAD.
   ○ Always ○ Very Often ○ Sometimes ○ Rarely ○ Never _____
8. I am bothered that I cannot move easily from place to place with the VAD.
   ○ Always ○ Very Often ○ Sometimes ○ Rarely ○ Never _____
9. I cannot participate in usual play activities with the VAD.
   ○ Always ○ Very Often ○ Sometimes ○ Rarely ○ Never _____
10. I find it difficult to express feelings and talk to others about the VAD.
    ○ Always ○ Very Often ○ Sometimes ○ Rarely ○ Never _____
11. Overall, I would describe my day-to-day level of worry with the VAD to be :
    ○ High ○ Medium ○ Low _____
12. Overall, I would describe my day-to-day level of happiness with the VAD to be:
    ○ High ○ Medium ○ Low _____

PediMACS Functional Capacity

Captured at Follow-up

Functional Capacity for follow-up time period: Answer Yes or No

Sedated	Yes/No
Paralyzed	Yes/No
Intubated	Yes/No
Ambulating	Yes/No
Primary Nutrition orally	Yes/No
Primary Nutrition per feeding tube	Yes/No
Primary Nutrition TPN	Yes/No

Has the patient had any non-medically required excursions off the unit?

If so, where (please select all that apply)

- Playroom
- Cafeteria
- Walk outside
- Sitting room
- General rehab
- None
- Other, specify _____

EXERCISE FUNCTION

All patients ≥ 10 yrs of age at time of implant should attempt to complete these functional capacity measurements especially for those patients classified as PediMACS patient profile levels 4-7.

6 minute walk: This requires an inside hall for which distances (in FEET) should be measured, preferably as long as possible to avoid frequent turns. Patients are instructed to walk steadily to cover as much distance as possible during the 6 minutes. They are advised that they may stop if necessary during the 6 minutes. The staff member performing the test should walk *behind* the patient to avoid undue influence on the pace. The distance covered during the 6 minutes in feet will be recorded here.

All efforts should be made to perform the 6 minute walk test for any patient able to walk more than a few steps. A distance as short as 3 feet may be recorded. If the test is not done, the reason must be indicated as "not done: too sick" or "not done: other", for which an example might be a patient needing to remain supine after a groin puncture for routine catheterization. Any musculoskeletal limitation to walking should be recorded as "not done: too sick".

Gait speed (1st 15 foot walk): ____ **seconds**

Instructions: Record the time (seconds) required for the patient to walk the first 15 feet of the 6 minute walk. The "starting" line and the 15 foot line should be clearly marked. Record the time to the first footfall at 0 feet and ends with the first footfall at 15 feet in the nearest. 0.1 sec with a stopwatch.

Adverse Events

David Morales, MD

June 2006 – March 2011: Outcomes of Children with VADs

Adverse Event Rates after Device Implantation (Events/100 Patient Months) in the First 3 Months post implant and 3 months or more post implant for Pediatric Patients

	Entire Time Period			Adverse Event Rates			
	# of	# of	% of	1st 3 months		≥ 3 months	
Event	events	patients*	patients	n	rate	n	rate
Infection	81	31	37%	56	28.68	25	7.82
Bleeding	74	28	33%	61	31.24	13	4.07
Cardiac Arrhythmia	23	16	19%	18	9.22	5	1.56
Device Malfunction	21	12	14%	2	1.02	19	5.94
Neurological Dysfunction	12	10	12%	7	3.58	5	1.56
Respiratory Failure	10	10	12%	9	4.61	1	0.31
Renal Dysfunction	8	8	10%	8	4.10	--	--
Right Heart Failure	8	7	8%	7	3.58	1	0.31
Hepatic Dysfunction	7	7	8%	7	3.58	--	--
Hypertension	7	7	8%	6	3.07	1	0.31
Pericardial Drainage	7	5	6%	7	3.58	--	--
Hemolysis	6	3	4%	5	2.56	1	0.31
Psychiatric Episode	6	3	4%	3	1.54	3	0.94
Venous Thromboembolism	4	4	5%	4	2.05	--	--
Other*	30	17	20%	20	10.24	10	3.13

* # of patients with one or more events

Table 6: Version 1

June 2006 – March 2011: Outcomes of Children with VADs

Adverse Event Rates after Device Implantation (Events/100 Patient Months) in the First 3 Months post implant and 3 months or more post implant for Pediatric Patients

	Adverse Event Rates			
	1st 3 months		≥ 3 months	
Event	n	rate	n	rate
Infection	56	28.68	25	7.82
Bleeding	61	31.24	13	4.07
Cardiac Arrhythmia	18	9.22	5	1.56
Device Malfunction	2	1.02	19	5.94
Neurological Dysfunction	7	3.58	5	1.56
Respiratory Failure	9	4.61	1	0.31
Renal Dysfunction	8	4.10	--	--
Right Heart Failure	7	3.58	1	0.31
Hepatic Dysfunction	7	3.58	--	--
Hypertension	6	3.07	1	0.31
Pericardial Drainage	7	3.58	--	--
Hemolysis	5	2.56	1	0.31
Psychiatric Episode	3	1.54	3	0.94
Venous Thromboembolism	4	2.05	--	--
Other*	20	10.24	10	3.13

Table 6: Version 2

Adverse Event Definitions:

4 Major Adverse Events

- Device Malfunction
- Bleeding
- Infection
- Neurological Dysfunction

11 Adverse Events

- Cardiac Arrhythmia
- Right Heart Failure
- Arterial Non-CNS Thromboembolic Event
- Hypertension
- Other SAE
- Pericardial Fluid Collection
- Myocardial Infarction
- Venous Thromboembolism
- Psychiatric Episode
- Wound Dehiscence
- Respiratory Failure

3 'Triggered' Adverse Events

- Renal Dysfunction
- Hemolysis
- Hepatic Dysfunction

Device Malfunction

Device malfunction denotes a failure of one or more of the components of the MCSD system which either directly causes or could potentially induce a state of inadequate circulatory support (low cardiac output state) or death. A failure that was iatrogenic or recipient-induced will be classified as an Iatrogenic/Recipient-Induced Failure.

Device failure should be classified according to which components fails as follows:

1) **Pump** failure (blood contacting components of pump and any motor or other pump actuating mechanism that is housed with the blood contacting components). In the special situation of **pump thrombosis,** thrombus is documented to be present within the device or its conduits that result in or could potentially induce circulatory failure.

2) **Non-pump** failure (e.g., external pneumatic drive unit, electric power supply unit, batteries, controller, interconnect cable, compliance chamber)

MAJOR BLEEDING

AN EPISODE OF <u>SUSPECTED INTERNAL OR EXTERNAL BLEEDING</u> THAT RESULTS IN ONE OR MORE OF THE FOLLOWING:

1. **Death,**
2. **Re-intervention,**
3. **Hospitalization**

Neurological Dysfunction

Any new, temporary or permanent, focal or global neurologic deficit ascertained by a standard neurological examination (administered by an neurologist or other qualified physician and documented with appropriate diagnostic tests and consultation note); or an abnormality identified by CNS imaging. The examining physician will distinguish between a transient ischemic attach (TIA), which reverses fully within 24 hours, and a stroke, which lasts longer than 24 hours (or less than 24 hours if there is evidence of infarction). Alternatively, a neurologic event may be recognized by seizure activity or as a clinically silent event detected by CNS imaging alone. Each neurologic event should be subcategorized as:

1. Transient Ischemic Attack (complete resolution of clinical findings within 24 hours, and no infarction seen by imaging if performed).
2. Ischemic or Hemorrhagic Cardiovascular Accident (clinical findings persist beyond 24 hours, or for less than 24 hours with infarction seen on imaging study).
3. Infarction seen by imaging, without clinical findings of TIA/Stroke at the time of event recognition.
4. Extra-axial bleeding seen by imaging study.
5. Clinical seizure activity or EEG demonstrating seizure activity.

For infants less than 6 months of age, head ultrasound is an acceptable imaging modality.

Major Infection

A clinical infection accompanied by pain, fever, drainage and/or leukocytosis that results in either initiation of a new anti-microbial agent, or a surgical exploration/debridement. This will include all presumptive use of antibiotics for periods exceeding 72 hours. The event will be considered resolved when all antibiotics are stopped for 72 hours, with the resolution date considered to be the last day of antibiotic administration. The general categories of infection are listed below:

Localized Non-Device Infection

Infection localized to any organ system or region (e.g. mediastinitis) without evidence of systemic involvement (See sepsis definition), ascertained by standard clinical methods and either associated with evidence of bacterial, viral, fungal or protozoal infection, and/or requiring empirical treatment.

Percutaneous Site and/or Pocket Infection

A positive culture from the skin and/or tissue surrounding the drive line or from the tissue surrounding the external housing of a pump implanted within the body, coupled with the need to treat with antimicrobial therapy when there is clinical evidence of infection such as pain, fever, drainage, or leukocytosis.

Internal Pump Component, Inflow or Outflow Tract Infection

Infection of blood-contacting surfaces of the LVAD documented by positive site culture. (There should be a separate data field for paracorporeal pump that describes infection at the percutaneous cannula site, e.g. Thoratec PVAD).

Bacteremia/Sepsis

Evidence of systemic involvement by infection, manifested by positive blood cultures and/or hypotension OR positive blood culture. There may be more than one site of infection in the event of a positive blood culture in conjunction with a specified site above.

Cardiac Arrhythmias

Any rhythm disturbance requiring initiation of a new anti-arrhythmic medication, electrical cardioversion, or defibrillation. Events shall be classified as ventricular or supraventricular. The treatment event shall be recorded (i.e. cardioversion, defibrillation, or medical therapy with name of medication). Event is resolved when all anti-arrhythmic medications have been discontinued for at least 72 hours. Time of resolution will be the time of discontinuation of the last anti-arrhythmic medication. Cardiac arrhythmias are classified as 1 of 2 types:

1) Sustained ventricular arrhythmia requiring defibrillation or cardioversion, or initiation of medication.
2) Sustained supraventricular arrhythmia requiring drug treatment or cardioversion

Right Heart Failure

Clinical evidence of right heart failure (e.g. elevated CVP, diminished cardiac output, reduced LVAD filling) requiring RVAD implantation, inotropic or inodilator therapy, or inhaled nitric oxide; in the absence of pericardial tamponade, pneumothorax, uncontrolled cardiac arrhythmia, or LVAD dysfunction. OR, persistent requirement for inhaled nitric oxide or inotropic therapy for a duration of more than 1 week, or reinitiation of such therapy at any time after LVAD implantation.

LEVEL OF RIGHT HEART FAILURE

Please select the level of right heart failure severity below:

Severe RHF: RVAD

Moderate RHF: Inotrope or intravenous/inhaled pulmonary vasodilator such as Nitric Oxide

Select all that apply:

IV Inotrope therapy

Inhaled pulmonary vasodilator

Arterial Non-CNS Thromboembolic Event

An acute systemic arterial perfusion deficit in any non-cerebrovascular organ system due to thromboembolism confirmed by one or more of the following:

1) standard clinical and laboratory testing
2) operative findings
3) autopsy findings

This definition excludes neurological events.

Hypertension

New onset blood pressure elevation greater than or equal to 140 mm Hg systolic or 90 mm Hg diastolic (pulsatile pump) or 110 mm Hg mean pressure (rotary pump).

Pediatric patients: for patients under 18 years of age weighing < 50 kg, hypertension is defined as systolic, diastolic, or mean blood pressure greater than the 95th percentile for age which requires the addition of a new iv or oral therapy for management. The event shall be considered resolved upon the discontinuation of the treatment.

Other SAE

An event that causes clinically relevant changes in the patient's health (e.g. cancer). Enter other serious adverse event that occurred since last PediMACS report/last follow-up into the block provided.

Pericardial Fluid Collection

Accumulation of fluid or clot in the pericardial space that requires surgical intervention or percutaneous catheter drainage. This event will be subdivided into those with clinical signs of tamponade (e.g. increased central venous pressure and decreased cardiac/VAD output) and those without signs of tamponade.

Myocardial Infarction

Defined as the presence of troponin or CK > normal range w/ + MB fraction (≥ 3% total CK) & a new regional LV or RV wall motion abnormality by myocardial imaging & 1 of the following 2 criteria being present post-implantion:

- Chest pain characteristic of myocardial ischemia
- ECG pattern or changes consistent with an MI

Pre-implant MI: The clinical suspicion of MI together with CK-MB or Troponin > 10 x ULN, found w/in 7d following implant & acute MI ECG findings.

These events will not be captured in the database.

Venous Thromboembolism

Evidence of venous thromboembolic event (e.g. deep vein thrombosis, pulmonary embolism) by standard clinical and laboratory testing.

Check all that apply:

Deep Vein thrombosis – enter date in MMDDYYYY format
Pulmonary Embolis – enter date in MMDDYYYY format
Other – if selected, enter in block provided
Unknown

Psychiatric Episode

Initiation of a new psychotropic medication, or referral to a mental health professional. Usual causes will be disturbance in thinking, emotion or behavior that impairs functioning, but this definition should be understood to exclude use of medications that are being administered to control post-operative pain or to facilitate withdrawal from such agents.
Suicide is included in this definition.

Wound Dehiscence

Disruption of the apposed surfaces of a surgical incision, excluding infectious etiology, and requiring surgical repair.

Respiratory Failure

Impairment of respiratory function requiring reintubation, tracheostomy or (for patients older than age 5 years) the inability to discontinue ventilatory support within 7 days post-VAD implant, except if the patient had pre-operative tracheostomy. This excludes intubation for re-operation or temporary intubation for diagnostic or therapeutic procedures, provided the total length of such intubation is 48 hours or less. If the intubation is prolonged beyond 48 hours, the start date of the event shall be the time of intubation, not the 48 hour period.

Renal Dysfunction

Two categories of renal dysfunction will be identified:

Acute

Abnormal kidney function requiring renal replacement therapy in patients who did not require it prior to implant.

A serum creatinine increase > 3 x baseline creatinine or > 3 x ULN for age sustained > 48 hours.

Chronic

Requirement for renal replacement therapy for at least 90 days

Hemolysis

A plasma-free hemoglobin value that is greater than 40 mg/dl, in association with clinical signs associated with hemolysis (e.g., anemia, low hematocrit, hyperbilirubinemia) occurring after the first 72 hours post-implant. Hemolysis related to documented non-device-related causes (e.g. transfusion or drug) is excluded from this definition.

Hepatic Dysfunction

An increase in any two hepatic laboratory values (total bilirubin, aspartate aminotransferase/AST and alanine aminotranferease/ALT) to a level > 3x UNL >14 days post-implant. Any case where hepatic dysfunction is the primary cause of death as noted on medical chart and/or death certificate

Training and Hands-on Data Entry

Kathryn Hollifield, RN

Nurse Monitors

- Kathryn Hollifield, BSN, RN
  Phone: 205-996-9290/kathryn@uab.edu
- Gail Mertz, BS, RN, CCRC
  Phone: 205-996-9292/gmertz@uab.edu
- Janella Miller, BSN, RN
  Phone: 205-996-9291/jmiller@uab.edu
- Tammy Davis, RN
  Phone: TBD/trdavis@uab.edu

PediMACS WBDE Forms

- Screening Log
- Demographics
- Pre-Implant
- Implant
- 1 week/1 Month
- Implant Discharge
- 3 Month/6 Month and Thereafter Follow-Up Forms
- Events
- Death/Explant/Recovery/Transplant
- Rehospitalization

FOLLOW UP VISITS AND DATA ENTRY GUIDELINES

- The windows for visits are not the same as the guidelines for form completion.
- The web-based data entry (WBDE) system is prospective and the forms should be filled out as the implant, follow-up dates, and as events occur.
- Forms should generally be completed within seven (7) days of an event, but always within 30 days.

Follow Up Visit	Acceptable Time Window for Visit
1 week	± 3 Days (4 – 10 days post implant)
1 month	± 7 Days (23 – 37 days post implant)
3 month	± 30 Days (2 – 4 months post implant)
6 months and beyond	± 60 Days (4 – 8 months post implant, etc.)

- **Patient Scenarios**
- **How Do I Enter Data?**

Web Based Data Entry

http://test.intermacs.org/registry/login.aspx/

User Name: training1

Password: training1

intermacs

secure login

Please Login

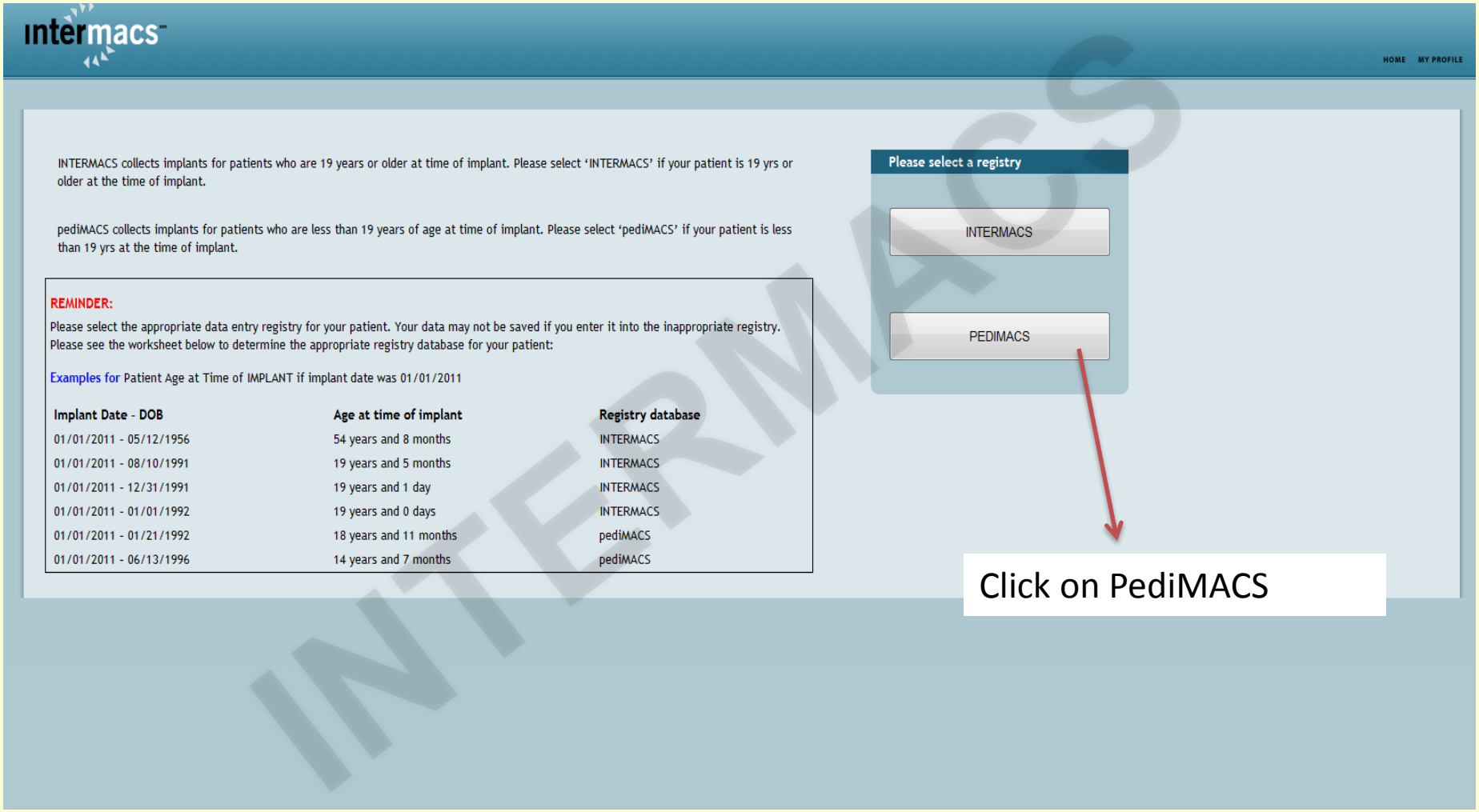
This section is password-protected for secure data entry by authorized centers only. Contact the INTERMACS Registry Manager by e-mail or at (804) 782-4869 or (804) 782-4859 for information on becoming an authorized center.

User name:* training1

Password:* ••••••••••

login

PediMACS Tutorial: September 20, 2012



Click on PediMACS

PediMACS Tutorial: September 20, 2012

edit a patient

Search for an Existing Patient

Search for an existing patient or view the records below.

Screening:* Included Excluded

Institution:* Training

First name:

Last name:

Medical record number:

SSN (last 5 digits):

Date of birth:

Device type:

Device brand:

Implant date: start date end date

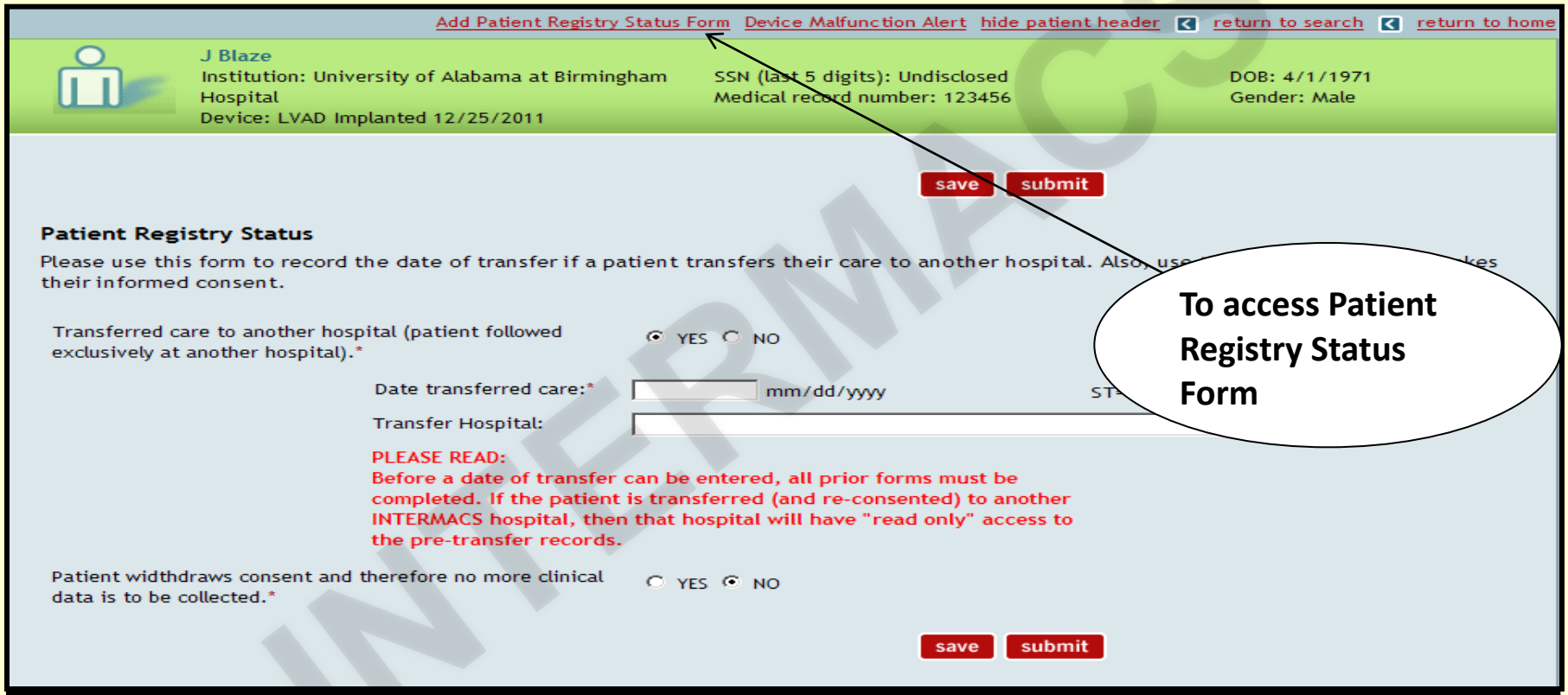
search

Select Patient # according to the number on your laptop

Recent Patients at Training

Pt#	Device#	Name	Hospital	Medical Record Number	SSN (last 5 digits)	Implant Date	Device Type	Brand Name	Status
49	42	Patient 13	Training			02/09/2012	LVAD (Left Ventricular Assist Device)	HeartMate II LVAS	Alive
50	43	Patient 14	Training			02/09/2012	LVAD (Left Ventricular Assist Device)	HeartMate II LVAS	Alive
52	45	Patient 15	Training			02/09/2012	LVAD (Left Ventricular Assist Device)	HeartMate II LVAS	Alive
34	27	Patient 2	Training	3001059130		02/09/2012	LVAD (Left Ventricular Assist Device)	HeartMate II LVAS	Alive
36	29	Patient 3	Training	3001059130		02/09/2012	LVAD (Left Ventricular Assist Device)	HeartMate II LVAS	Alive
39	32	Patient 4	Training	3001059130		02/09/2012	LVAD (Left Ventricular Assist Device)	HeartMate II LVAS	Alive

PATIENT REGISTRY STATUS FORM



To be completed by the sending institution, after all the patients forms and visits have been completed. The Receiving hospital will have 'read only' access to the pre-transfer records.

Patient Transfers

Sending Institution

- Ensure All Forms and Visits Have Been Completed
- Complete Patient Registry Status Form

Receiving Institution

- Patient must agree to continued participation in INTERMACS at the new institution
- Receiving institution must have IRB approval
- Obtain "Authorization to Release Information Consent" at the receiving institution.
- Obtain INTERMACS Registry Consent Form at receiving institution.
- Please forward copies of both consents to Mary Lynne Clark at the INTERMACS DCC

Questions?

Data Quality and Hospital Evaluation

David C. Naftel, PhD

- Audits
- Implant reconciliation
- Medical Event Review
- Hospital Compliance

REGISTRY MONITORING PROCESS

- Screening Log Reconciliation
  - Included patients
  - Excluded patients

  Goal: To capture all MCSD patients at each institution

- Data Resolution via phone
  - Quarterly
  - Pre on-site visit (approximately 14 days prior to on-site visit)

  Goal: To identify and correct data discrepancies efficiently

- Major Events Review
  - Via phone
  - On-site monitoring

  Goal: To discover unreported events and increase data accuracy and quality

REGISTRY MONITORING PROCESS

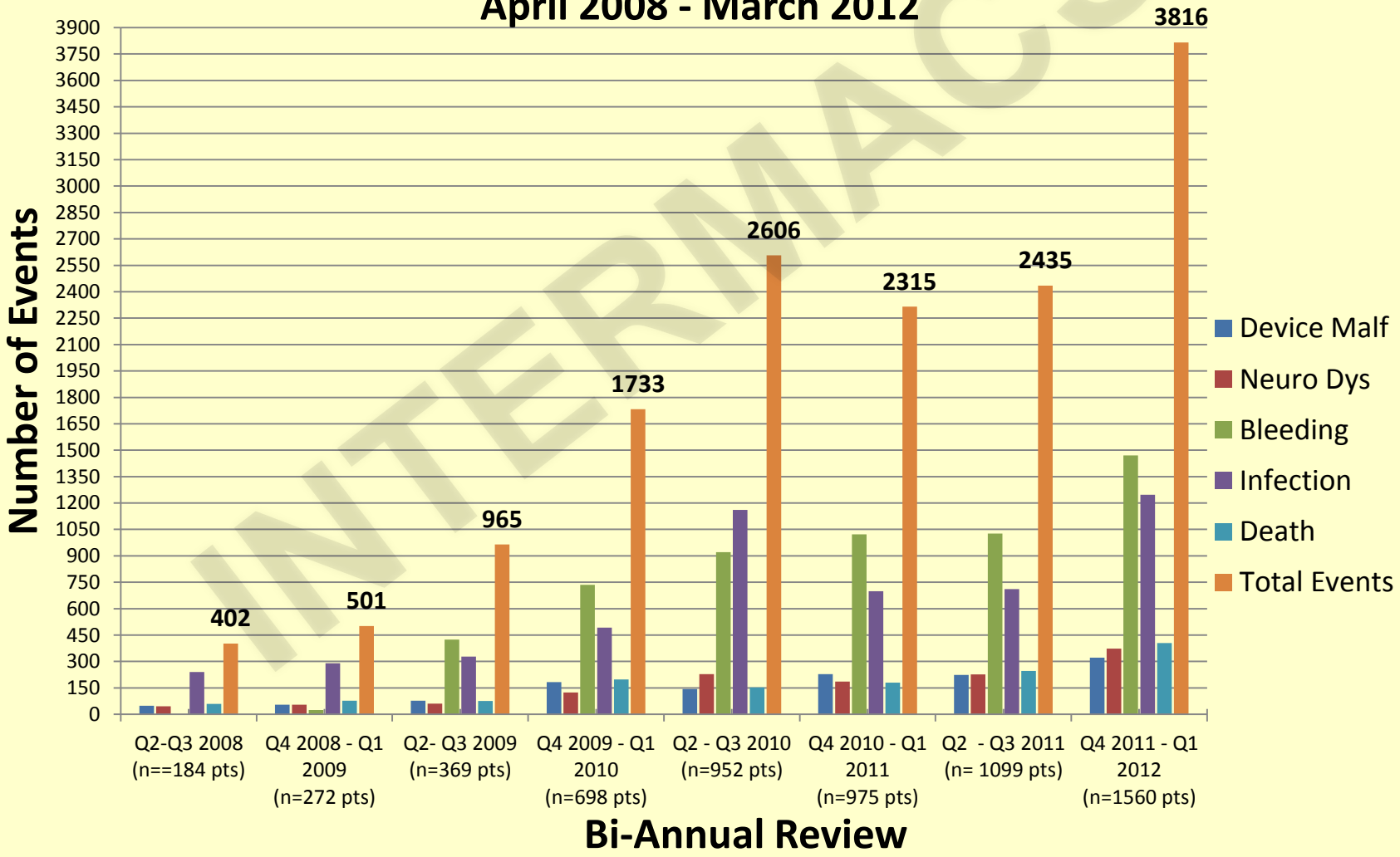
- **For Cause Audits**
  - Hospital Compliance < 70%
- **Scheduled Audits**
  - Each hospital is scheduled to be audited 'on site' once during the 5 year contract period

Implant Reconciliation

- Thoratec implant counts
- Syncardia implant counts

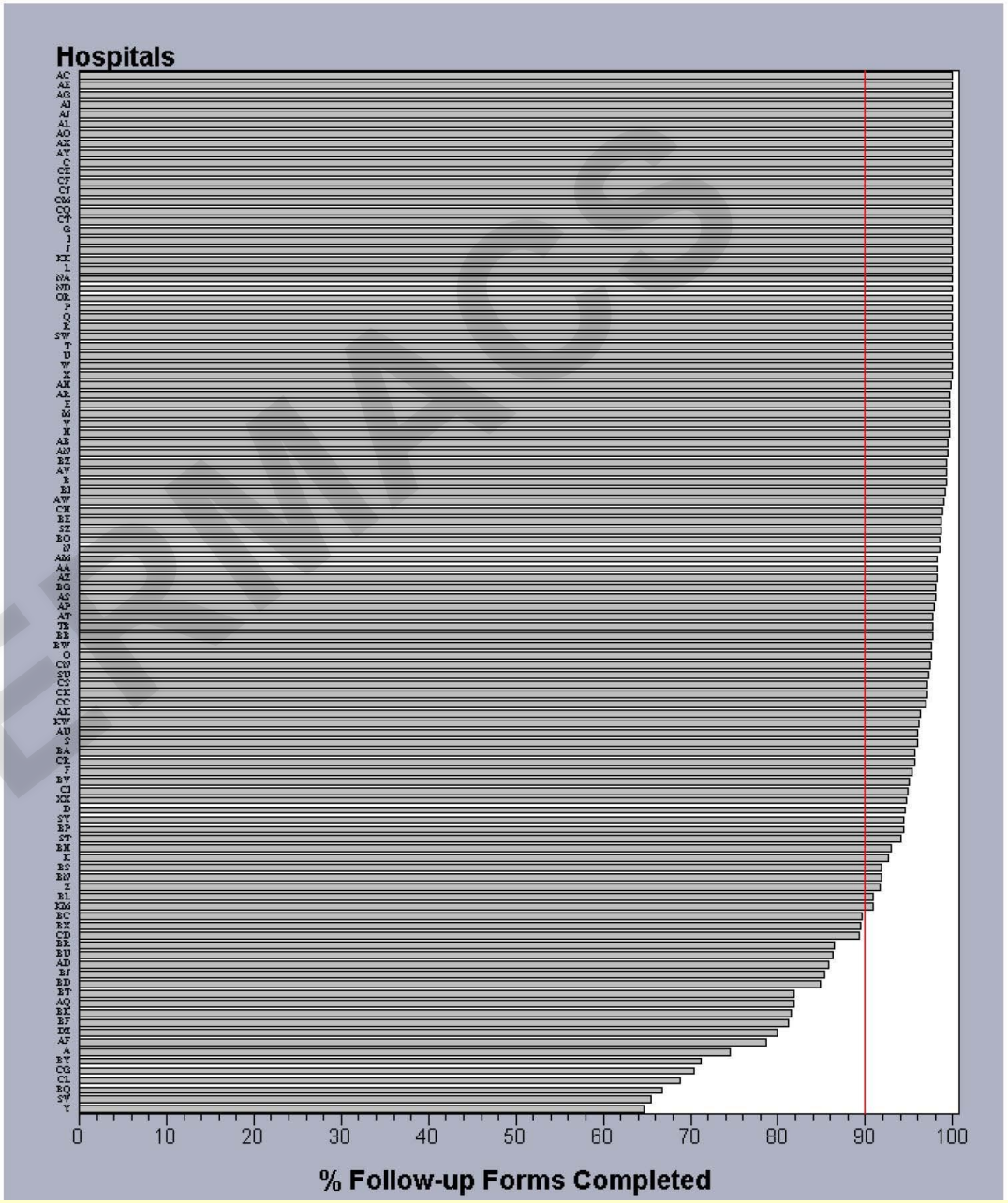
Major Adverse Events Reviewed by MER Committee

April 2008 - March 2012



Hospital Compliance

INTERMACS QUARTERLY DATA QUALITY REPORT
IMPLANTS: JUNE 2006 - March 2012
Registry Compliance



PediMACS Registry brought to you by -- UNOS – *"Robert Todd"*

Fantastic Job!!

Wrap-up

Elizabeth Blume, MD

I.	Welcome	Drs. Blume & Baldwin
II.	PediMACS	Dr. Kirklin
III.	PediMACS Structure	Dr. Blume
IV.	Hospital Enrollment	Dr. Naftel & ML Clark
V.	Patient Enrollment	Susan Myers
VI.	Data Elements and Definitions	Dr. Rosenthal
VII.	Adverse Events Definitions	Dr. Morales
VIII.	Training and Hands-on Data Entry	Kathryn Hollifield, RN
IX.	Data Quality and Hospital Evaluation	Dr. Naftel
X.	Wrap Up	Dr. Blume