

C O N F I D E N T I A L

Prevention of transfusion-transmitted CMV in low birth-weight infants
TT-CMV Study

Monthly Report *October 1, 2010*

Includes patients enrolled and data received as of 9/31/10

TTCMV Monthly Report

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Table 1: Cumulative Patient Screening and Enrollment

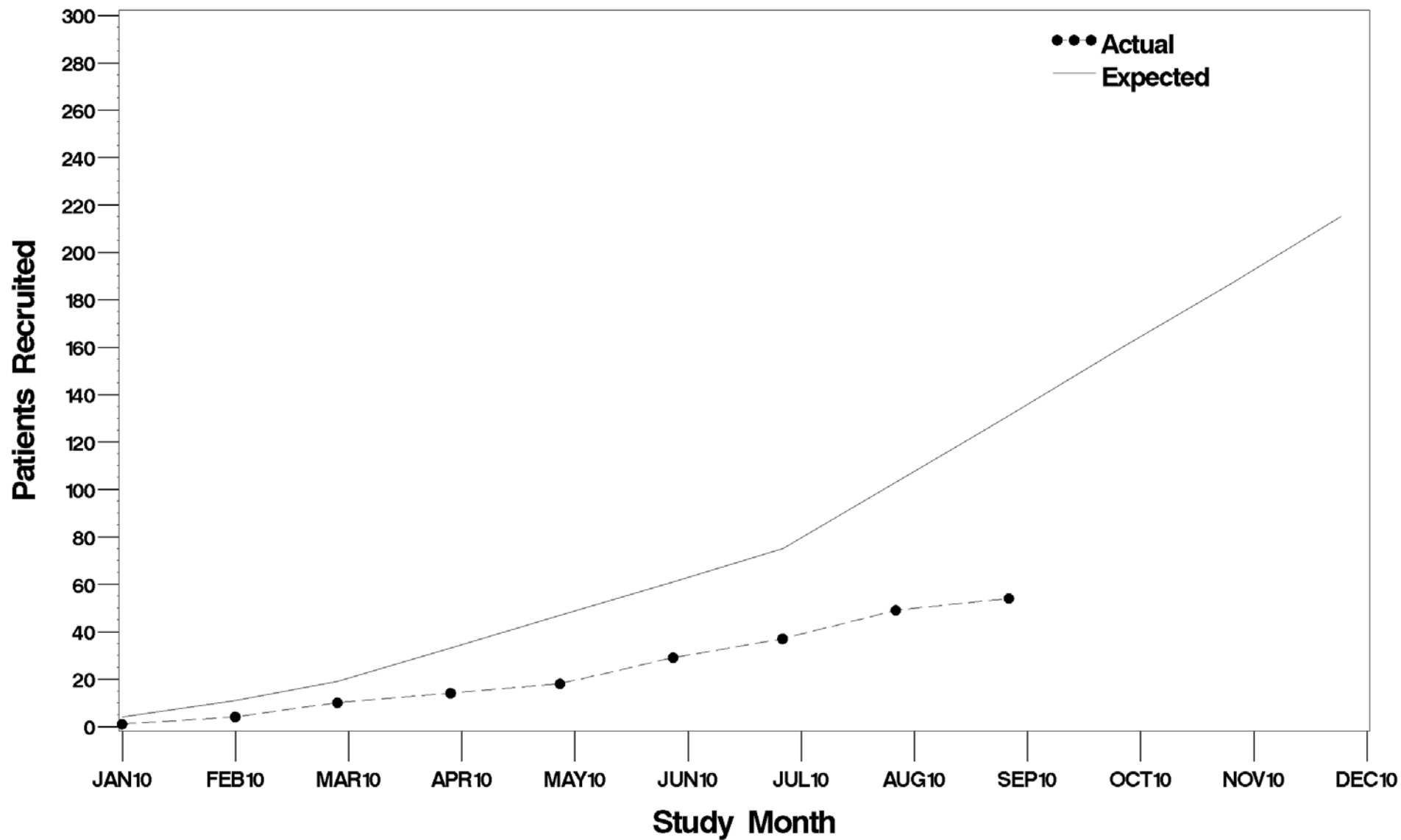
<i>Hospital</i>	<i>No. Screened</i>	<i>No. Eligible (% of screened)</i>	<i>No. Enrolled (% of eligible)</i>
Midtown	47	34/47 (72.3%)	19/34 (55.9%)
Grady	53	36/53 (67.9%)	23/36 (63.9%)
Northside	30	21/30 (70.0%)	12/21 (57.1%)
OVERALL	130	91/130 (70.0%)	54/91 (59.3%)

Table 2: Patients Recruited by Month, 2010

<i>Month</i>	<i>Patients Recruited</i>	<i>Total Recruited</i>
January	1	1
February	3	4
March	6	10
April	4	14
May	4	18
June	11	29
July	9	38
August	11	49
September	5	54

Figure 1: Recruitment Summary through 10/01/2010

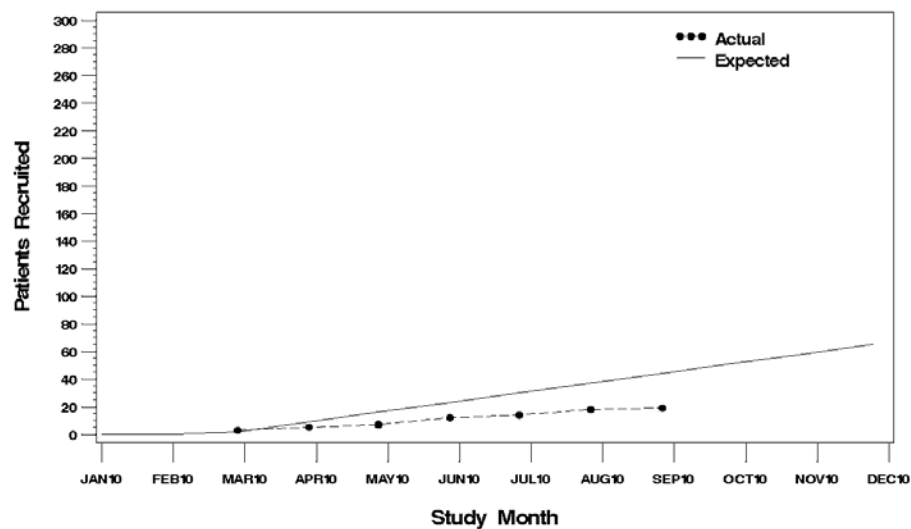
54 patients recruited of 131 expected (41%).



* Expected recruitment per month: Grady: 7; EUHM: 7; Northside: 14.

TT—CMV Patient Recruitment Summary — EUHM

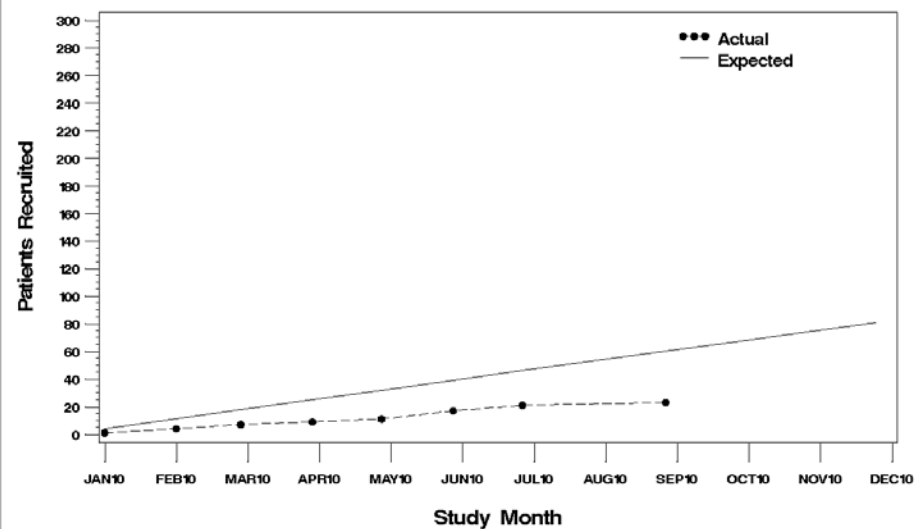
19 patients recruited of 44 expected (43%).



* Expected recruitment per month at EUHM: 7.

TT—CMV Patient Recruitment Summary — Grady

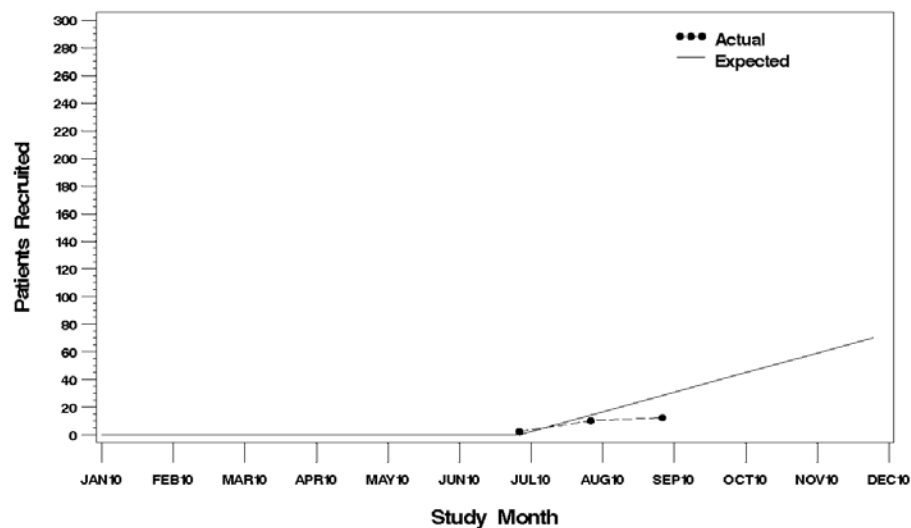
23 patients recruited of 60 expected (38%).



* Expected recruitment per month at Grady: 7.

TT—CMV Patient Recruitment Summary — Northside

12 patients recruited of 28 expected (43%).



* Expected recruitment per month at Northside: 14.

Table 3: Patient Screening and Enrollment by Month, 2010

<i>Month</i>	<i>Hospital</i>	<i>No. Screened</i>	<i>No. Eligible (% of screened)</i>	<i>No. Enrolled (% of eligible)</i>	<i>No. Enrolled as % of monthly target</i>
<i>January</i>	Grady	7	4/7 (57.1%)	1/4 (25.0%)	14%
<i>February</i>	Grady	7	6/7 (85.7%)	3/6 (50.0%)	43%
<i>March</i>	Midtown	3	3/3 (100%)	3/3 (100%)	43%
	Grady	5	3/5 (60.0%)	3/3 (100%)	43%
<i>April</i>	Midtown	9	2/9 (22.2%)	2/2 (100%)	29%
	Grady	6	3/6 (50.0%)	2/3 (66.7%)	29%
<i>May</i>	Midtown	7	7/7 (100%)	2/7 (28.6%)	29%
	Grady	3	2/3 (66.7%)	2/2 (100%)	29%
<i>June</i>	Midtown	9	7/9 (77.8%)	5/7 (71.4%)	71%
	Grady	7	6/7 (85.7%)	6/6 (100%)	86%
<i>July</i>	Midtown	8	6/8 (75.0%)	2/6 (33.3%)	29%
	Grady	5	4/5 (80.0%)	4/4 (100%)	57%
	Northside	3	3/3 (100%)	3/3 (100%)	21%
<i>August</i>	Midtown	8	6/8 (75.0%)	3/6 (50.0%)	43%
	Grady	3	1/3 (33.3%)	0/1 (0.0%)	0%
	Northside	13	10/13 (76.9%)	7/10 (70.0%)	50%
<i>September</i>	Midtown	3	3/3 (100%)	3/3 (100%)	43%
	Grady	10	7/10 (70.0%)	2/7 (28.6%)	29%
	Northside	14	8/14 (57.1%)	4/8 (50.0%)	29%

Table 4: Reasons patients ineligible at screening

<i>Reason not eligible</i>	<i>Total number</i>	<i>Percent of total</i>
1250g < Birthweight < 1500g	30	77
LBWI not within first 5 days of life	3	8
LBWI not expected to live past 7 days of life	5	13

Table 5: Reasons patients eligible at screening were not enrolled

<i>Hospital</i>	<i>Patient ID</i>	<i>Reasons not enrolled</i>
Grady	2000119	Mother not available
Grady	2000219	Mom refuses blood draw
Grady	2000619	Too much going on
Grady	2001119	Scared to participate in research
Grady	2001129	Scared to participate in research
Grady	2001219	No reason given
Grady	2002019	Mom does not read or understand English
Midtown	1001319	overwhelmed with triplets & 2 other children
Midtown	1001329	overwhelmed with triplets & 2 other children
Midtown	1001339	overwhelmed with triplets & 2 other children
Midtown	1001519	mother schizophrenic baby in dfacs custody
Midtown	1001529	mother schizophrenic baby in dfacs custody
Midtown	1001919	Mother not available
Midtown	1002119	No reason given
Midtown	1002219	too much going on
Midtown	1002419	uncomfortable w/blood test; already in one study
Midtown	1002429	uncomfortable w/blood test; already in one study
Midtown	1002519	Mother not available
Midtown	1002319	Too many research trials
Midtown	1003219	Mother not available
Midtown	1003319	Too many research trials
Grady	2003811	Mom unable to make medical decisions
Northside	3001719	Mother not available
Northside	3002119	No reason given
Northside	3002219	No reason given
Grady	2003919	Scared to participate in research
Grady	2004219	Mother does not read English, only French.
Grady	2004529	too much going on in life
Grady	2004619	No reason given
Northside	3002819	No reason given
Northside	3002919	No reason given
Northside	3003219	No reason given
Northside	3003319	No reason given

Table 6: MOC CMV Serology Status Overall and by Site

Site	IgG/IgM Combo Test			/	IgM Test *			/
	Positive	Negative	% Positive		Positive	Negative	% Positive	
Overall	32	15	68.1%		1	31	3.1%	
EUHM	13	5	72.2%		0	13	0.0%	
Grady	13	7	65.0%		1	12	3.1%	
Northside	6	3	66.7%		0	6	0.0%	

*Done only if combo test is positive

Table 7: Study Status Overall and by Site

Site	LBWI On Study n/N(%)	LBWI Completed Study n/N(%)	Number of MOC/LBWI Withdrawn n	All CRFs Received n/N(%)
Overall	15/54(28)	39/54(72)	2	29/39 (74)
EUHM	3/19(16)	16/19(84)	1	10/16 (63)
Grady	3/23(13)	20/23(87)		17/20 (85)
Northside	9/12(75)	3/12(25)	1	2/3 (67)

Table 8: Weekly Summary Status Update for Discharged LBWIs

Site	LBWI Any pRBC TX n/N(%)	LBWI Breast Milk Collected n/N(%)	LBWI Ever on Mechanical Vent n/N(%)	LBWI Transferred To Another Hospital n/N(%)	LBWI with Tx Reaction n/N(%)	LBWI with Unexpected SAEs n/N(%)
Overall	23/37(62)	30/37(81)	29/37(78)	4/37(11)	0/37(0)	0/37(0)
EUHM	7/15(47)	14/15(93)	9/15(60)	1/15(7)	0/15(0)	0/15(0)
Grady	16/20(80)	14/20(70)	18/20(90)	3/20(15)	0/20(0)	0/20(0)
Northside	.2(.)	2/2(100)	2/2(100)	0/2(0)	0/2(0)	0/2(0)

Table 9 a: Expected and Received forms (CRFs) by Site and Overall

<i>CRF Name</i>	<i>Expected CRF</i>	<i>Received CRF</i>	<i>Percent Received CRF</i>	<i>>25% Data Missing(%)</i>	<i>Out-of-window n(%)</i>	<i>Sample not Collected n(%)</i>
MOC Demographics	50	48	96	n/a	n/a	n/a
MOC Blood Collection DOL 0	49	47	96	n/a	n/a	0(0)
MOC Sero Status	49	47	96	n/a	2(4.3)	n/a
MOC Blood Collection (end of study, seroneg)	13	11	85	n/a	n/a	2(18.2)
MOC NAT result (end of study, seroneg)	11	9	82	n/a	n/a	n/a
LBWI Demographics	58	55	95	n/a	n/a	n/a
LBWI Medical Review and Lab Results (Longitudinal)	399	374	94	n/a	22(5.9)	n/a
--- Anthropometric section	.	.	.	2	n/a	n/a
--- Lab section	.	.	.	5	n/a	n/a
LBWI SNAP on DOL 0	58	55	95	29	0(0)	n/a
LBWI SNAP II (Longitudinal)	339	316	93	6	1(0.3)	n/a
LBWI Urine Collection DOL 0	58	54	93	n/a	7(13.0)	1(1.9)
LBWI Urine NAT result DOL 0	57	53	93	n/a	n/a	n/a
LBWI Blood Collection DOL 0	58	55	95	n/a	0(0)	2(3.6)
LBWI Blood NAT result DOL 0	56	51	91	n/a	n/a	n/a
LBWI Blood Collection DOL 21	52	48	92	n/a	2(4.2)	12(25.0)
LBWI Blood NAT result DOL 21	40	37	90	n/a	n/a	n/a
LBWI Blood Collection DOL 40	44	41	93	n/a	1(2.4)	10(24.4)
LBWI Blood NAT result DOL 40	34	34	89	n/a	n/a	n/a
LBWI Blood Collection DOL 60	29	26	90	n/a	2(7.7)	6(23.1)
LBWI Blood NAT result DOL 60	23	23	88	n/a	n/a	n/a
LBWI Blood/Urine Collection DOL 90/EOS	38	35	92	n/a	0(0)	5(14.3)
LBWI Blood/Urine NAT result DOL 90/EOS	33	27	90	n/a	n/a	n/a
Concomitant Meds Log*	38	29	76	n/a	n/a	n/a
Mechanical Vent Log**	33	28	85	n/a	n/a	n/a

***: Only for LBWI who completed study**

****: Only for LBWI who completed study and indicated use of ventilator on summary form.**

Outside target window definitions: blood collection(>+/- 4days); SNAP-DOB (> 5days); SNAP2 (>+/- 2days); Lab review (>+/- 2days);MOC sero(>+/- 5 days) Urine Collection (>+/- 4 days)

Table 9 b: Expected and Received forms (CRFs) for EUHM Hospital

<i>CRF Name</i>	<i>Expected CRF</i>	<i>Received CRF</i>	<i>Percent Received CRF</i>	<i>>25% Data Missing(%)</i>	<i>Out-of-window n(%)</i>	<i>Sample not Collected n(%)</i>
MOC Demographics	18	18	100	n/a	n/a	n/a
MOC Blood Collection DOL 0	18	17	94	n/a	n/a	0(0)
MOC Sero Status	18	18	100	n/a	1(5.6)	n/a
MOC Blood Collection (end of study, seroneg)	6	5	83	n/a	n/a	1(20.0)
MOC NAT result (end of study, seroneg)	11	4	36	n/a	n/a	n/a
LBWI Demographics	21	20	95	n/a	n/a	n/a
LBWI Medical Review and Lab Results (Longitudinal)	145	141	97	n/a	0(0)	n/a
--- Anthropometric section	.	.	.	3	n/a	n/a
--- Lab section	.	.	.	3	n/a	n/a
LBWI SNAP on DOL 0	21	20	95	39	0(0)	n/a
LBWI SNAP II (Longitudinal)	122	118	97	2	1(0.8)	n/a
LBWI Urine Collection DOL 0	21	20	95	n/a	4(20.0)	1(5.0)
LBWI Urine NAT result DOL 0	57	19	33	n/a	n/a	n/a
LBWI Blood Collection DOL 0	21	20	95	n/a	0(0)	2(10.0)
LBWI Blood NAT result DOL 0	56	17	89	n/a	n/a	n/a
LBWI Blood Collection DOL 21	18	16	89	n/a	1(6.3)	12(75.0)
LBWI Blood NAT result DOL 21	40	7	78	n/a	n/a	n/a
LBWI Blood Collection DOL 40	17	16	94	n/a	0(0)	10(62.5)
LBWI Blood NAT result DOL 40	34	9	82	n/a	n/a	n/a
LBWI Blood Collection DOL 60	10	9	90	n/a	0(0)	6(66.7)
LBWI Blood NAT result DOL 60	23	7	88	n/a	n/a	n/a
LBWI Blood/Urine Collection DOL 90/EOS	16	15	94	n/a	0(0)	0(0)
LBWI Blood/Urine NAT result DOL 90/EOS	33	13	93	n/a	n/a	n/a
Concomitant Meds Log*	16	9	56	n/a	n/a	n/a
Mechanical Vent Log**	12	9	75	n/a	n/a	n/a

***: Only for LBWI who completed study**

****: Only for LBWI who completed study and indicated use of ventilator on summary form.**

Outside target window definitions: blood collection(>+/- 4days); SNAP-DOB (> 5days); SNAP2 (>+/- 2days); Lab review (>+/- 2days);MOC sero(>+/- 5 days) Urine Collection (>+/- 4 days)

Table 9 c: Expected and Received forms (CRFs) for Grady Hospital

<i>CRF Name</i>	<i>Expected CRF</i>	<i>Received CRF</i>	<i>Percent Received CRF</i>	<i>>25% Data Missing(%)</i>	<i>Out-of-window n(%)</i>	<i>Sample not Collected n(%)</i>
MOC Demographics	20	19	95	n/a	n/a	n/a
MOC Blood Collection DOL 0	20	20	100	n/a	n/a	0(0)
MOC Sero Status	20	20	100	n/a	0(0)	n/a
MOC Blood Collection (end of study, seroneg)	6	6	100	n/a	n/a	1(16.7)
MOC NAT result (end of study, seroneg)	11	5	45	n/a	n/a	n/a
LBWI Demographics	23	23	100	n/a	n/a	n/a
LBWI Medical Review and Lab Results (Longitudinal)	168	168	100	n/a	4(2.4)	n/a
--- Anthropometric section	.	.	.	0	n/a	n/a
--- Lab section	.	.	.	7	n/a	n/a
LBWI SNAP on DOL 0	23	23	100	4	0(0)	n/a
LBWI SNAP II (Longitudinal)	145	145	100	2	0(0)	n/a
LBWI Urine Collection DOL 0	23	23	100	n/a	2(8.7)	0(0)
LBWI Urine NAT result DOL 0	57	23	40	n/a	n/a	n/a
LBWI Blood Collection DOL 0	23	23	100	n/a	0(0)	0(0)
LBWI Blood NAT result DOL 0	56	23	100	n/a	n/a	n/a
LBWI Blood Collection DOL 21	22	22	100	n/a	1(4.5)	0(0)
LBWI Blood NAT result DOL 21	40	21	100	n/a	n/a	n/a
LBWI Blood Collection DOL 40	20	20	100	n/a	1(5.0)	0(0)
LBWI Blood NAT result DOL 40	34	20	100	n/a	n/a	n/a
LBWI Blood Collection DOL 60	14	14	100	n/a	2(14.3)	0(0)
LBWI Blood NAT result DOL 60	23	16	100	n/a	n/a	n/a
LBWI Blood/Urine Collection DOL 90/EOS	18	18	100	n/a	0(0)	3(16.7)
LBWI Blood/Urine NAT result DOL 90/EOS	33	14	100	n/a	n/a	n/a
Concomitant Meds Log*	19	18	95	n/a	n/a	n/a
Mechanical Vent Log**	18	17	94	n/a	n/a	n/a

***: Only for LBWI who completed study**

**** : Only for LBWI who completed study and indicated use of ventilator on summary form.**

Outside target window definitions: blood collection(>+/- 4days); SNAP-DOB (> 5days); SNAP2 (>+/- 2days); Lab review (>+/- 2days);MOC sero(>+/- 5 days) Urine Collection (>+/- 4 days)

Table 9 d: Expected and Received forms (CRFs) for Northside hospital

<i>CRF Name</i>	<i>Expected CRF</i>	<i>Received CRF</i>	<i>Percent Received CRF</i>	<i>>25% Data Missing(%)</i>	<i>Out-of-window n(%)</i>	<i>Sample not Collected n(%)</i>
MOC Demographics	12	11	92	n/a	n/a	n/a
MOC Blood Collection DOL 0	11	10	91	n/a	n/a	0(0)
MOC Sero Status	11	9	82	n/a	1(11.1)	n/a
MOC Blood Collection (end of study, seroneg)	1	.	.	n/a	n/a	n/a
MOC NAT result (end of study, seroneg)	11	.	.	n/a	n/a	n/a
LBWI Demographics	14	12	86	n/a	n/a	n/a
LBWI Medical Review and Lab Results (Longitudinal)	86	65	76	n/a	18(27.7)	n/a
--- Anthropometric section	.	.	.	3	n/a	n/a
--- Lab section	.	.	.	5	n/a	n/a
LBWI SNAP on DOL 0	14	12	86	58	0(0)	n/a
LBWI SNAP II (Longitudinal)	72	53	74	28	0(0)	n/a
LBWI Urine Collection DOL 0	14	11	79	n/a	1(9.1)	0(0)
LBWI Urine NAT result DOL 0	57	11	19	n/a	n/a	n/a
LBWI Blood Collection DOL 0	14	12	86	n/a	0(0)	0(0)
LBWI Blood NAT result DOL 0	56	11	79	n/a	n/a	n/a
LBWI Blood Collection DOL 21	12	10	83	n/a	0(0)	0(0)
LBWI Blood NAT result DOL 21	40	9	82	n/a	n/a	n/a
LBWI Blood Collection DOL 40	7	5	71	n/a	0(0)	0(0)
LBWI Blood NAT result DOL 40	34	5	71	n/a	n/a	n/a
LBWI Blood Collection DOL 60	5	3	60	n/a	0(0)	0(0)
LBWI Blood NAT result DOL 60	23	.	.	n/a	n/a	n/a
LBWI Blood/Urine Collection DOL 90/EOS	4	2	50	n/a	0(0)	2(100)
LBWI Blood/Urine NAT result DOL 90/EOS	33	.	.	n/a	n/a	n/a
Concomitant Meds Log*	3	2	67	n/a	n/a	n/a
Mechanical Vent Log**	3	2	67	n/a	n/a	n/a

***: Only for LBWI who completed study**

Outside target window definitions: blood collection(>+/- 4days); SNAP-DOB (> 5days); SNAP2 (>+/- 2days); Lab review (>+/- 2days); MOC sero(>+/- 5 days) Urine Collection (>+/- 4 days)

Table 10: LBWI Race/Ethnic Characteristics by Center

Is LBWI Hispanic=No

[illegible]

Is LBWI Hispanic=Yes

[illegible]

Table 11: pRBC Transfusions for LBWI who completed study

	Overall (N = 39)	EUHM (N = 16)	Grady (N = 20)	Northside (N = 3)
<i>Num of pRBC Tx</i>				
No red-cell transfusion - num of LBWI (%)	16 / 39(41.0)	9 / 16(56.3)	4 / 20(20.0)	3 / 3(100.0)
1 or more Tx - num of LBWI (%)	23 / 39(59.0)	7 / 16(43.8)	16 / 20(80.0)	
1 Tx - num of LBWI (%)	5 / 39(12.8)	3 / 16(18.8)	2 / 20(10.0)	
2 Tx - num of LBWI (%)	3 / 39(7.7)	2 / 16(12.5)	1 / 20(5.0)	
3 Tx - num of LBWI (%)	3 / 39(7.7)	1 / 16(6.3)	2 / 20(10.0)	
4 Tx - num of LBWI (%)	2 / 39(5.1)		2 / 20(10.0)	
5-6 Tx - num of LBWI (%)	3 / 39(7.7)		3 / 20(15.0)	
7-10 Tx - num of LBWI (%)	4 / 39(10.3)	1 / 16(6.3)	3 / 20(15.0)	
>10 Tx - num of LBWI (%)	3 / 39(7.7)		3 / 20(15.0)	

Table 12: Platelet Transfusions for LBWI who completed study

	Overall (N = 39)	EUHM (N = 16)	Grady (N = 20)	Northside (N = 3)
<i>Num of Platelet Tx</i>				
No platelet transfusion - num of LBWI (%)	36 / 39(92.3)	15 / 16(93.8)	18 / 20(90.0)	3 / 3(100.0)
1 or more Platelet Tx - num of LBWI (%)	3 / 39(7.7)	1 / 16(6.3)	2 / 20(10.0)	
1 - 2 Platelet Tx - num of LBWI (%)	1 / 39(2.6)		1 / 20(5.0)	
3 - 5 Platelet Tx - num of LBWI (%)	1 / 39(2.6)	1 / 16(6.3)		
6 - 10 Platelet Tx - num of LBWI (%)	1 / 39(2.6)		1 / 20(5.0)	

Table 13: FFP Transfusions for LBWI who completed study

	Overall (N = 39)	EUHM (N = 16)	Grady (N = 20)	Northside (N = 3)
<i>Num of FFP Tx</i>				
No FFP transfusion - num of LBWI (%)	34 / 39(87.2)	15 / 16(93.8)	16 / 20(80.0)	3 / 3(100.0)
1 or more FFP Tx - num of LBWI (%)	5 / 39(12.8)	1 / 16(6.3)	4 / 20(20.0)	
1 - 2 FFP Tx - num of LBWI (%)	3 / 39(7.7)	1 / 16(6.3)	2 / 20(10.0)	
3 - 5 FFP Tx - num of LBWI (%)	1 / 39(2.6)		1 / 20(5.0)	
>10 FFP Tx - num of LBWI (%)	1 / 39(2.6)		1 / 20(5.0)	