

**COUNCIL MEETING***Sharing Our Passion for Life*

# HPC(A) Manufacturing Feasibility Study Conclusions Sharing Council Meeting 2016



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## Disclosures

The following faculty and planning committee staff have no financial disclosures:

Name	Institution
Katherine St. Martin	NMDP/Be The Match
Amy Hines	NMDP/Be The Match
Jennifer Rabin	Georgetown University Hospital
Anita Hove	Memorial Blood Centers
Stephanie Dormesy	New York Blood Center



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## Learning objectives

At the conclusion of this session, attendees will be able to:

- Discuss the study objectives and their associated data results
- Share the key logistical issues related to HPC(A) product sample testing



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## Study Design

- The Manufacturing Feasibility Study was apheresis center (AC) focused, including a subset of 5 NMDP Network ACs
- Each participating AC performed testing for sterility, identity and potency and participated in a lot release process
- AC test results were received and reviewed by the NMDP Quality Unit



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## Site Selection

- There are three types of centers in the Network:
  - Hospital-based
  - Blood Center-based
  - Independent

Type of center	# in Network	% of Collections*
Hospital Based	58	58%
Blood Center	24	33%
Independent	1	9%
* % based on 2015 collections		



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## Site Selection



- Five sites selected through a standard Request for Proposal (RFP) process

Participating Center	% of total NMDP Collections*
Memorial Blood Centers	2
Georgetown University Hospital	9.4
NY Blood Centers	2.9
Carter BloodCare	3.2
Apheresis Associated of Northern Virginia (AANoVA)	8.9
*% based on 2015 collections	



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# Study Objectives



- **Primary Objective**
  - To determine if it is feasible to have test results for sterility, identity and potency completed and reviewed prior to release of the product to the courier for distribution to the transplant center (TC)
- **Secondary Objective**
  - To determine if it is feasible to have test results for sterility, identity and potency completed and reviewed prior to release to the TC

# Sample Testing

- **Sterility**
  - Gram Stain
  - Bacterial culture
- **Identity & Potency**
  - MNC count



# Lot Release



- Tests for sterility (Gram stain only), potency and identity should be completed prior to release of the product to the courier for distribution to the transplant center
- Test results sent between AC and centralized Quality Unit at NMDP



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## Primary Objective Results



Eligible Data Sets	Successful Lot Release (n)	Successful Lot Release (%)
227	32	14.1

Participating Center	Eligible Data Sets	Successful Lot Release (n)	Successful Lot Release (%)
Memorial Blood Centers	43	6	13.9
Georgetown University Hospital	93	22	23.6
New York Blood Center	36	3	8.3
Carter BloodCare	16	0	0
Apheresis Associated of Northern Virginia (AANoVA)	39	1	2.6



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## Secondary Objective Results

Eligible Data Sets	Successful Lot Release n (%)	International TC Receipt n (%)	Mean (hours)	Median (hours)
123	95 (77.2%)	9 (7.3%)	3.3	4.7



## Logistical Challenges

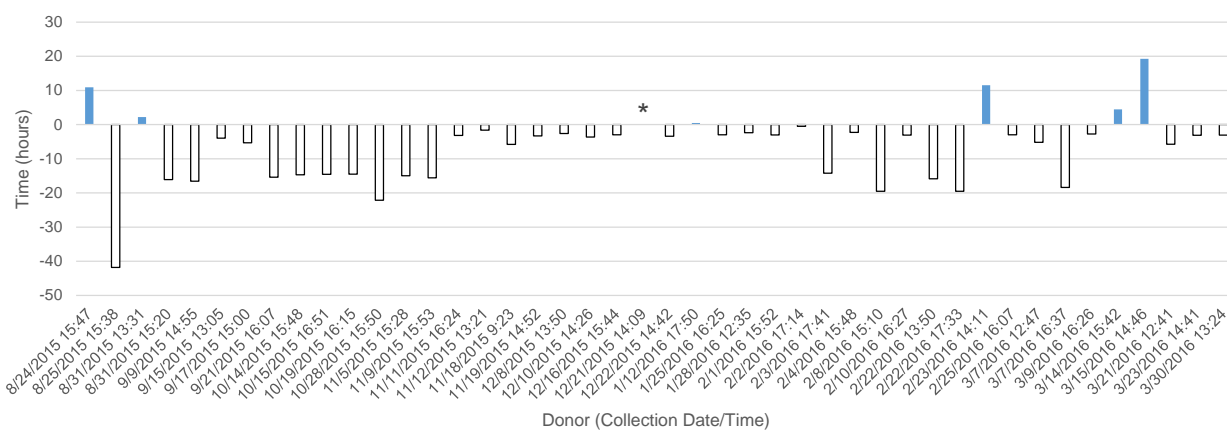


- Proximity/Availability of laboratory services
  - Cellular Therapy testing equipment
  - Sterility equipment
- Staffing availability and experience

# Panel Discussion Introduction

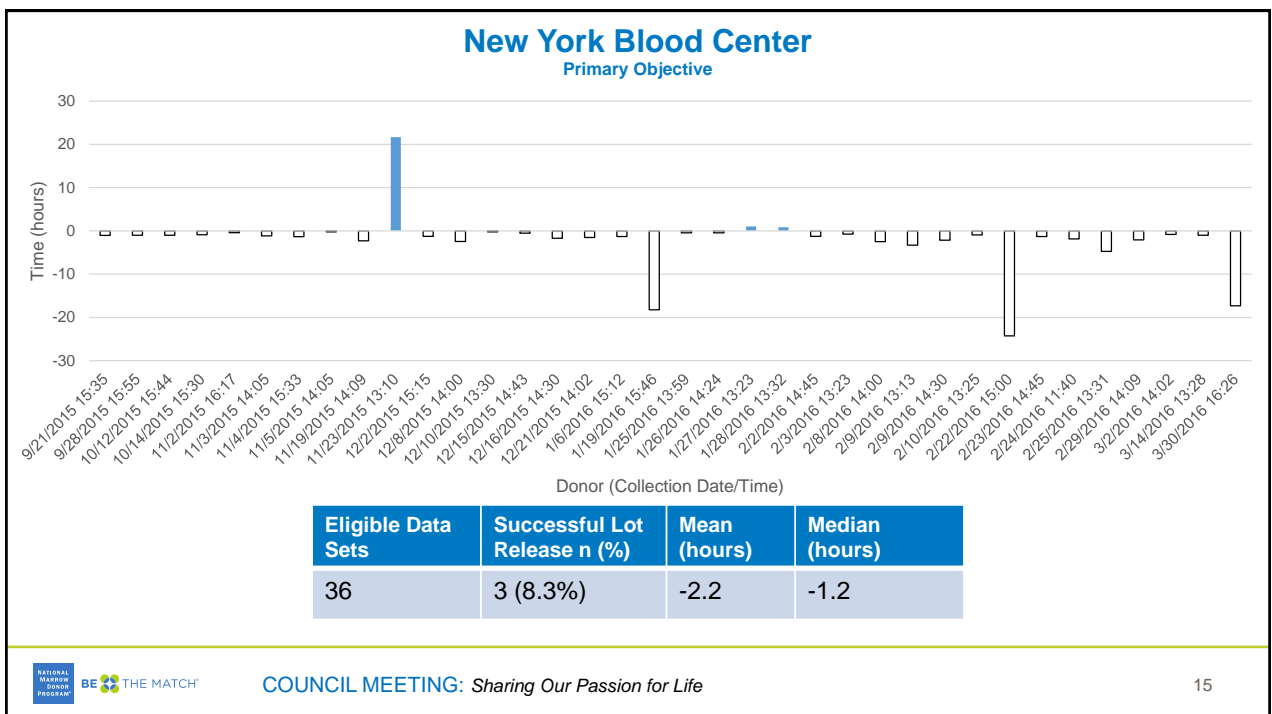
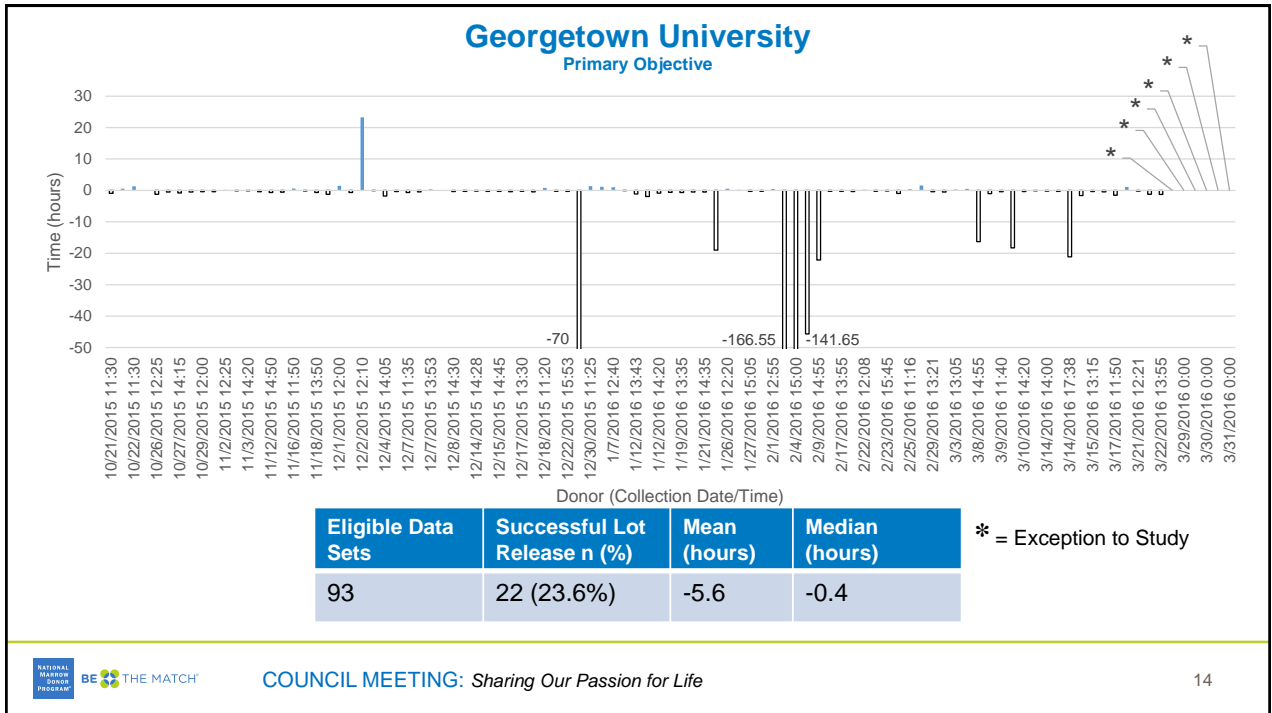


## Memorial Blood Centers Primary Objective



Eligible Data Sets	Successful Lot Release n (%)	Mean (hours)	Median (hours)
43	6 (13.9%)	-6.9	-3.4

\* = Exception to Study





# Discussion & Discovery



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