

# Calling All Super Heroes

## Beyond transplantation: Creating standardization across the cell and gene therapy industry

Amy Hines, B.S.N., R.N.

Be The Match BioTherapies®

Nov. 10, 2018

NATIONAL  
MARROW  
DONOR  
PROGRAM®

BE  THE MATCH®



# Disclosures

The following faculty and planning committee staff have the following financial disclosures:

Name	Institution	Disclosure
Amy Hines, B.S.N., R.N.	Be The Match BioTherapies	None
Dawn Henke, Ph.D.	Standards Coordinating Body	None
Hope Guidry-Groves, B.S.	Gulf Coast Regional Blood Center	None
Heather Steinmetz, M.P.H.	UCLA Health	None
Ann Kemp, M.T. (A.S.C.P.), C.Q.A., R.A.C.	Be The Match BioTherapies	None
Julie Smolich, M.B.A.	Be The Match BioTherapies	None
Chris McClain, M.B.A.	Be The Match BioTherapies	None
Jamie Margolis, Ph.D.	Be The Match BioTherapies	None
Janelle Roghair	Be The Match BioTherapies	None
Evan Babekuhl	Be The Match BioTherapies	None
Lauren Maxam	Be The Match BioTherapies	None

# Learning objectives

- Identify two or more ways to prepare their institution for requirements of cell and gene therapy activities
- Access Be The Match BioTherapies support resources available when implementing new protocols or cell and gene therapy requirements
- Describe how to participate in developing standards for cell and gene therapy

# Our panelists



Amy Hines  
Director, Collection  
Network Management  
Be The Match BioTherapies



Heather Steinmetz  
Quality Assurance Manager  
UCLA Health



Hope Guidry-Groves  
Director, Cellular, Apheresis  
and Transfusion Services  
Gulf Coast Regional Blood Center



Dawn Henke  
Senior Technical Program Manager  
Standards Coordinating Body



Ann Kemp  
Senior Manager,  
Regulatory Compliance  
Be The Match BioTherapies

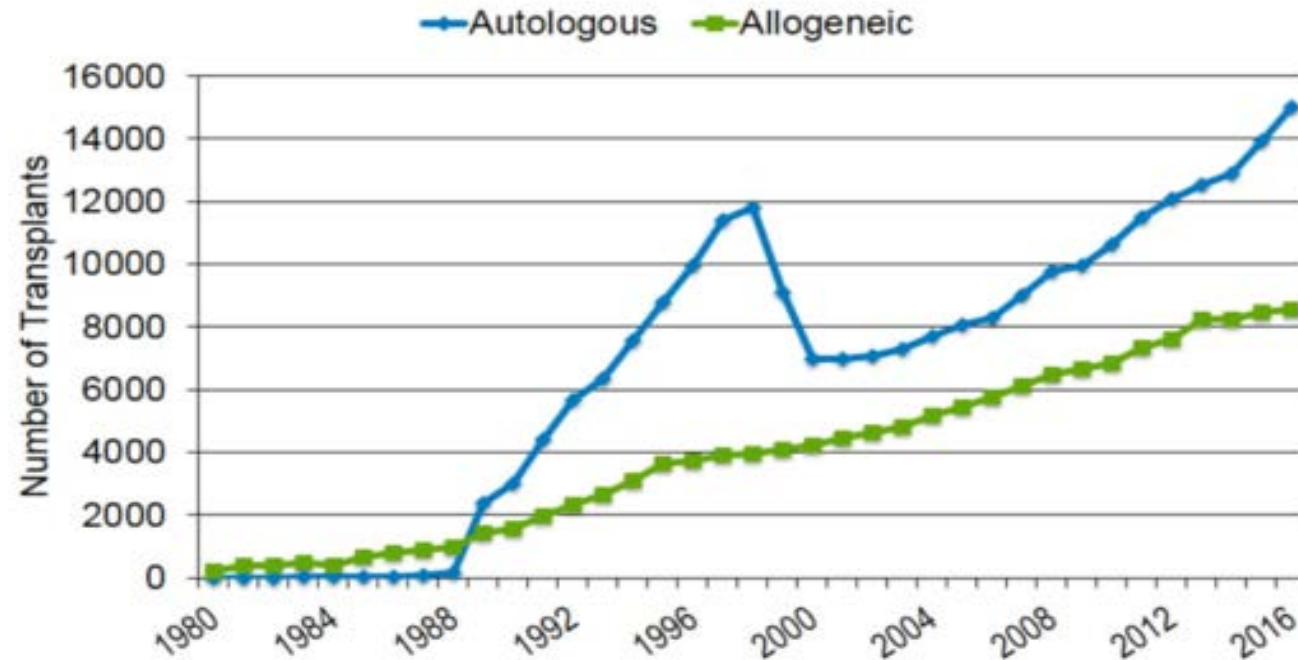


*Grab your cape.*



# History of hematopoietic cell transplantation

## Annual Number of HCT Recipients in the US by Transplant Type



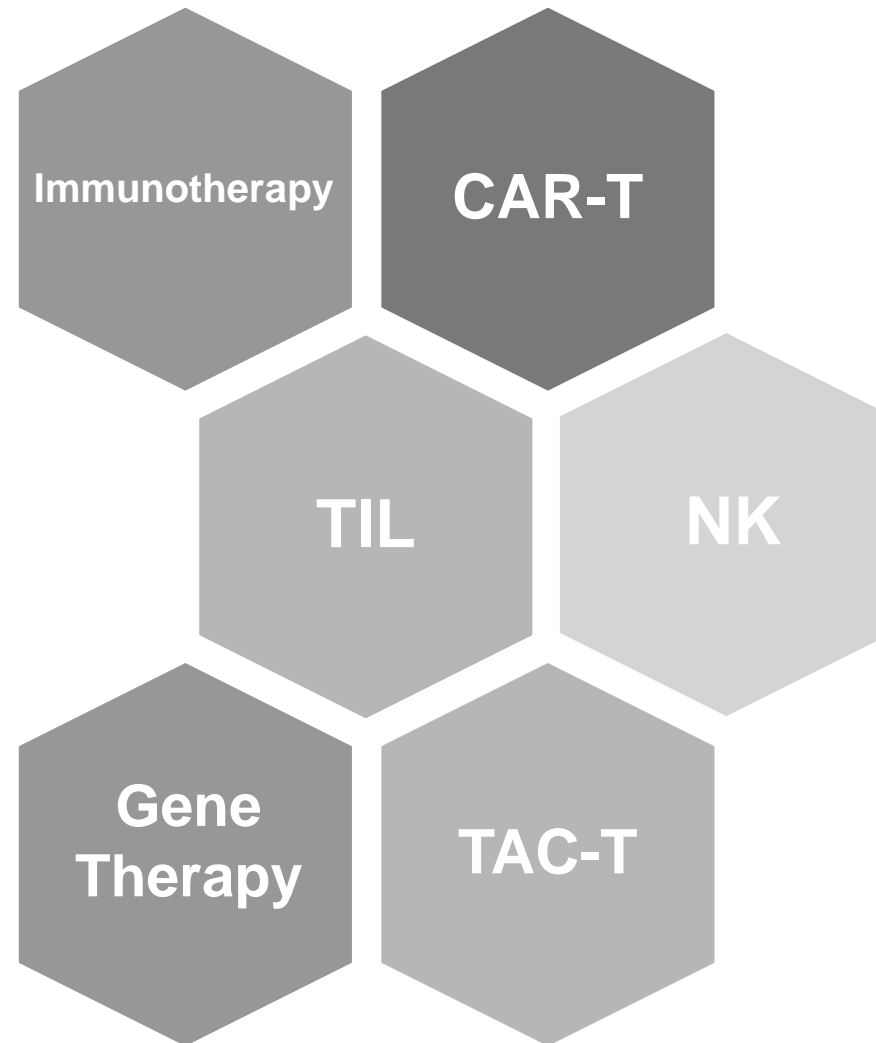
D'Souza A, Fretham C. Current Uses and Outcomes of Hematopoietic Cell Transplantation (HCT): CIBMTR Summary Slides, 2017. Available at: <http://www.cibmtr.org>



Grab your cape.



# Cell and gene therapy clinical trials and commercialized protocols





# Managing a **global cell therapy supply chain**

**30** years of expertise and global leadership

**86,000** total stem cell transplants managed

**112** contracted apheresis and collection centers

**22,000** cell and blood shipments annually

**6,000** annual stem cell transplants

**19 million** donors on the world's largest registry

**220** research studies underway

**900** employees strong



NATIONAL  
MARROW  
DONOR  
PROGRAM®

BE  THE MATCH®

*Grab your cape.*



# Standardization is essential as more cell therapies near commercialization

IN THE LAB

STAT+

## A CAR-T bottleneck: Centers that collect patient cells feel crunch from growing demand

By ANDREW JOSEPH @DrewQJoseph / JULY 17, 2018

Adding to the burden, center directors say, is that **each company with a product or experimental therapy insists on performing its own audit** to ensure its collection protocols are followed.

“We’re auditing the same process again and again,” said Heather Steinmetz, the quality assurance manager for UCLA’s program.



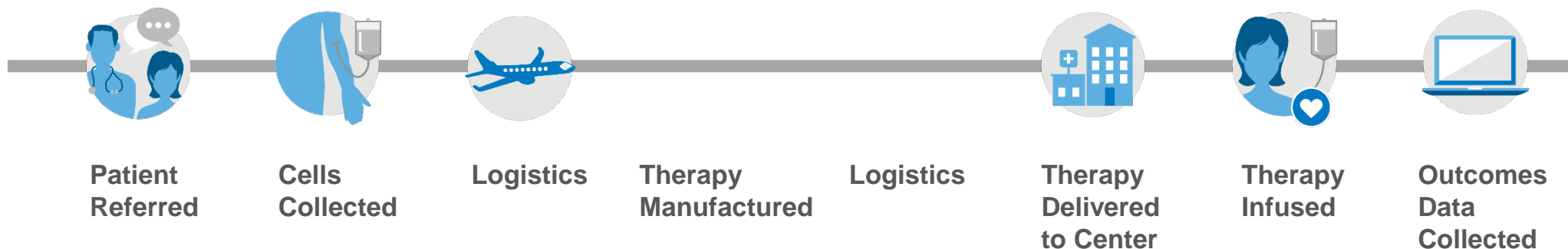
*Grab your cape.*



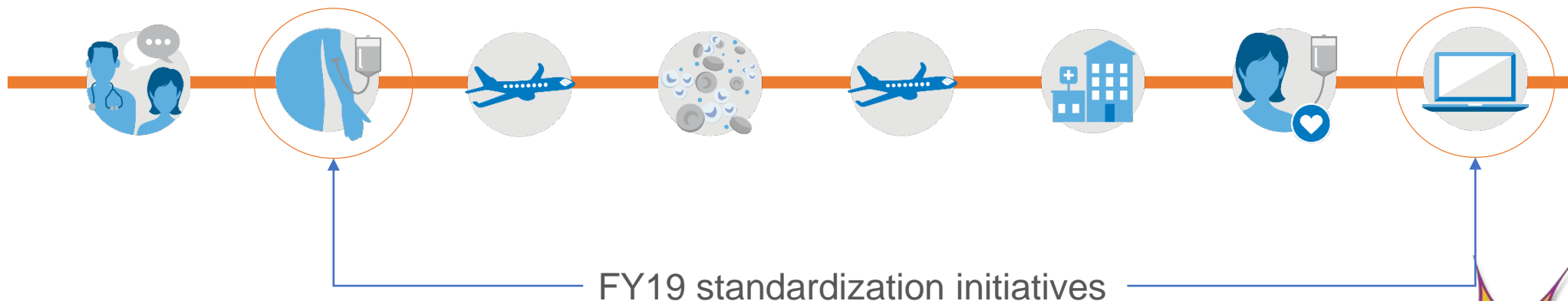


# Opportunities exist for standardization throughout the cell therapy supply chain

## Allogeneic transplant



## Auto/allo cell therapy



# Supporting our **Collection Center Network** and clients

- **Be The Match BioTherapies** promotes consistency and quality by:
  - Understanding client collection and processing requirements, and developing a network of centers to meet those needs
  - Providing training for centers based on client specifications and requirements
  - Ensuring sites meet critical accountabilities, milestones and deliverables
  - Delivering prompt, ongoing customer service and technical support to Network centers
  - Helping centers identify inefficiencies in operations and implement solutions
  - Monitoring and reporting site performance and quality indicators



# Adding industry efficiencies through **Quality System Audit Program**

- **Cell and gene therapy companies can license quality system audit results**
  - Evaluates apheresis center and cell therapy lab compliance with FDA Good Tissue Practice and Good Manufacturing Practice regulations
  - All auditors certified by the American Society for Quality
  - Audits and re-audits performed on a two-year rolling cycle
  - Ensures quality compliance across broad collection center networks, while saving costs and minimizing audit burden
- **Audit results include:**
  - Audit report
  - Audit checklist
  - Audit findings response
  - Audit closure letter



*Grab your cape.*



***Thank you!***



NATIONAL  
MARROW  
DONOR  
PROGRAM®

BE  THE MATCH®