Building a Data Management Training Program for Initial Hiring, Onboarding and Ongoing Competency

Claudette Edwards, MSN, RN; Laurian Walters, MPH; Juliana Norat, BSN, RN; Gregory Gibbs, MA; Ann Martin, BHSA, RN; Fiama Reyes, MPH, CCRP
Presenter: Laurian Walters, MPH
University of Miami Sylvester Comprehensive Cancer Center
TCT Clinical Research Professional / Data Management Conference

CIBMTR®
CENTER FOR INTERNATIONAL BLOOD & MARROW TRANSPLANT RESEARCH

The CIBMTR® (Center for International Blood and Marrow Transplant Research®) is a research collaboration between the National Marrow Donor Program® (NMDP)/Be The Match® and the Medical College of Wisconsin (MCW).

Disclosures

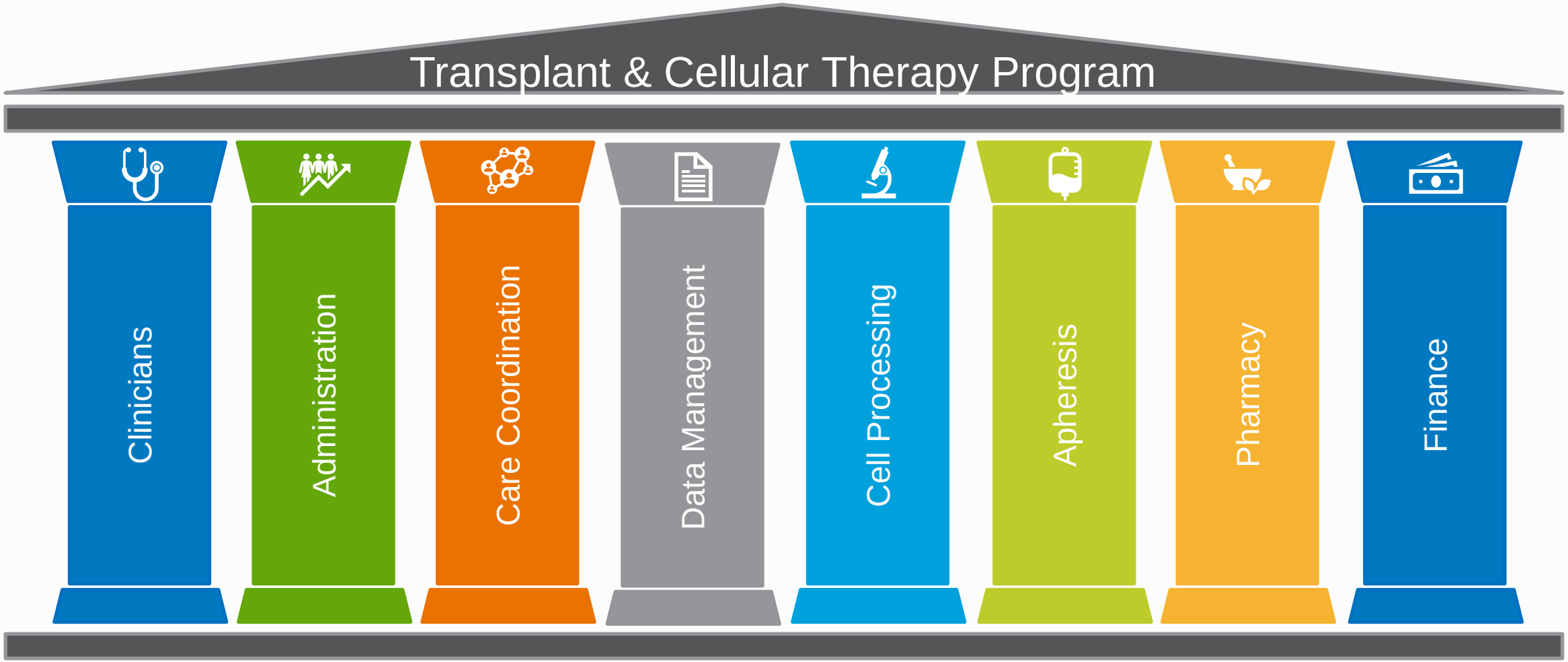
- No relevant disclosures

CIBMTR®
CENTER FOR INTERNATIONAL BLOOD & MARROW TRANSPLANT RESEARCH

Learning Objectives

- Explain the various steps utilized to develop a comprehensive educational plan
- Identify rationale for providing an integrated approach to data management onboarding
- List the benefits of having a comprehensive onboarding plan for data management

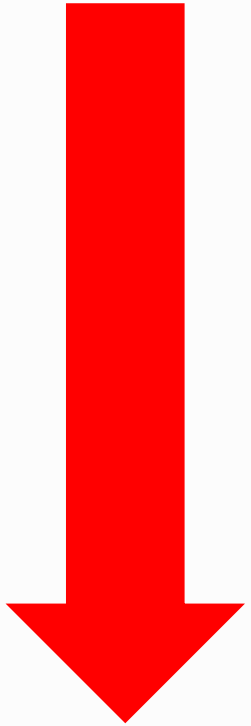
Pillars of Success



CIBMTR®
CENTER FOR INTERNATIONAL BLOOD & MARROW TRANSPLANT RESEARCH

Limited Hiring Pool

<u>Demand</u>
Expansion of TCT
Increased data capture

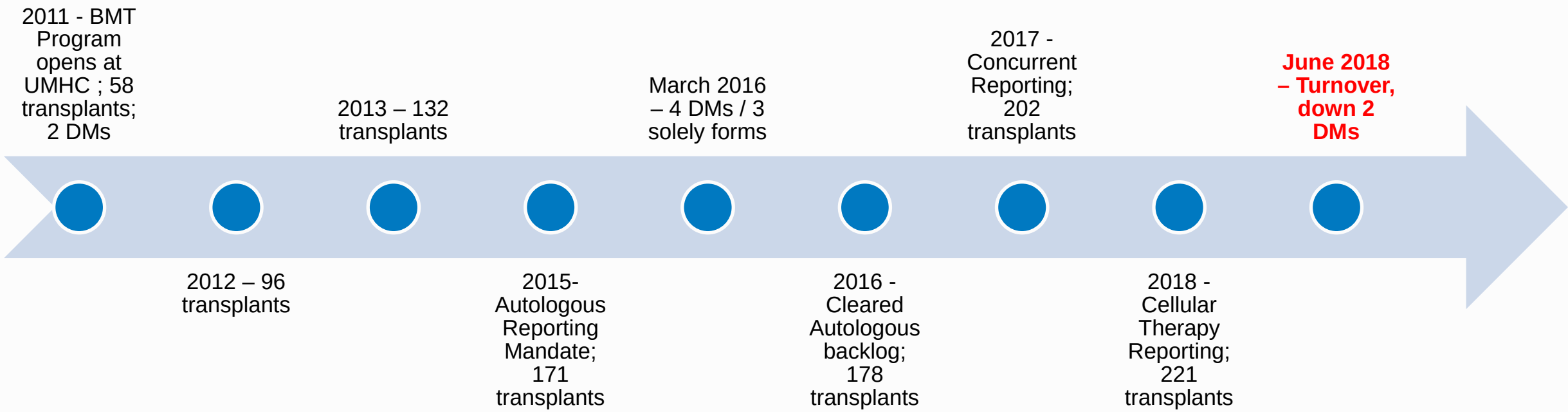


<u>Supply</u>
Qualified DMs

- Qualified TCT Data Manager
  - Comprehensive knowledge of:
    - Transplantation and Cellular Therapy
    - Hematology / Oncology
    - Research
    - Data Collection and Quality
    - Technical knowledge

CIBMTR®
CENTER FOR INTERNATIONAL BLOOD & MARROW TRANSPLANT RESEARCH

Our Journey

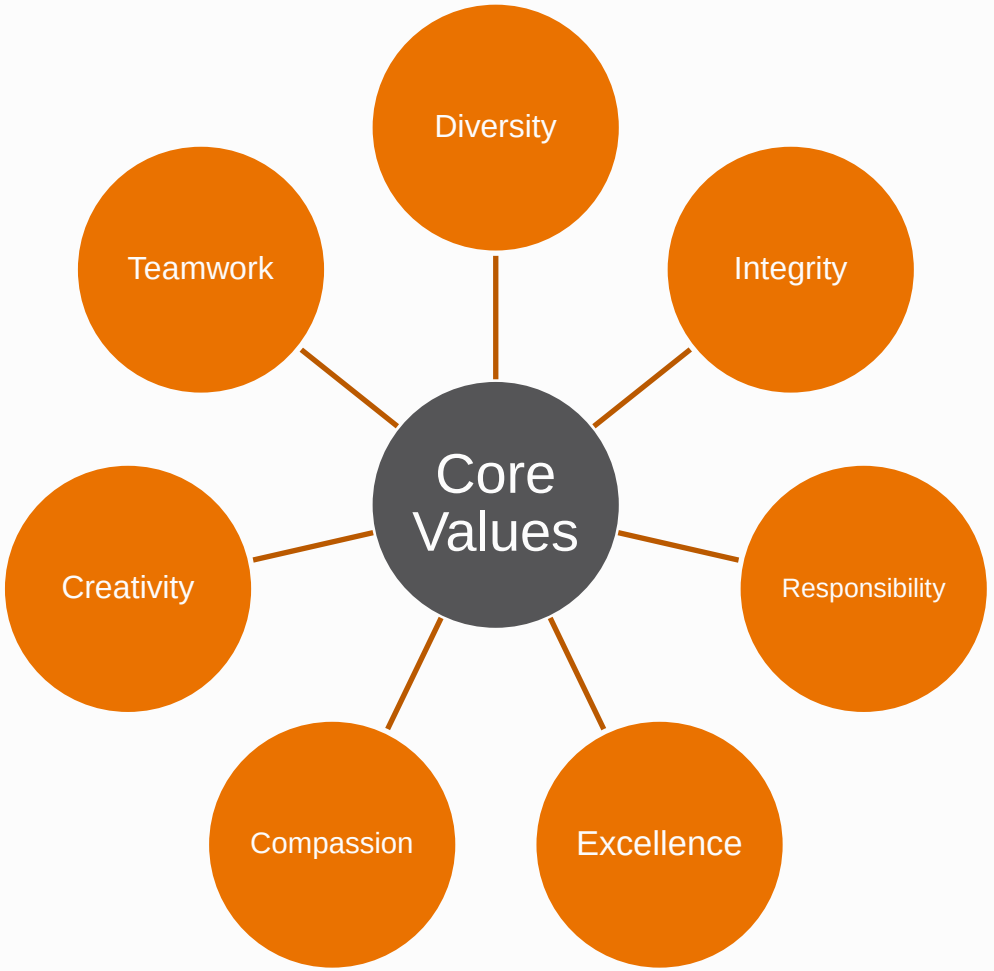


- Rapid Growth
- Turnover/Loss of seasoned DMs
- No centers to poach form
- No formal training programs

CIBMTR®
CENTER FOR INTERNATIONAL BLOOD & MARROW TRANSPLANT RESEARCH

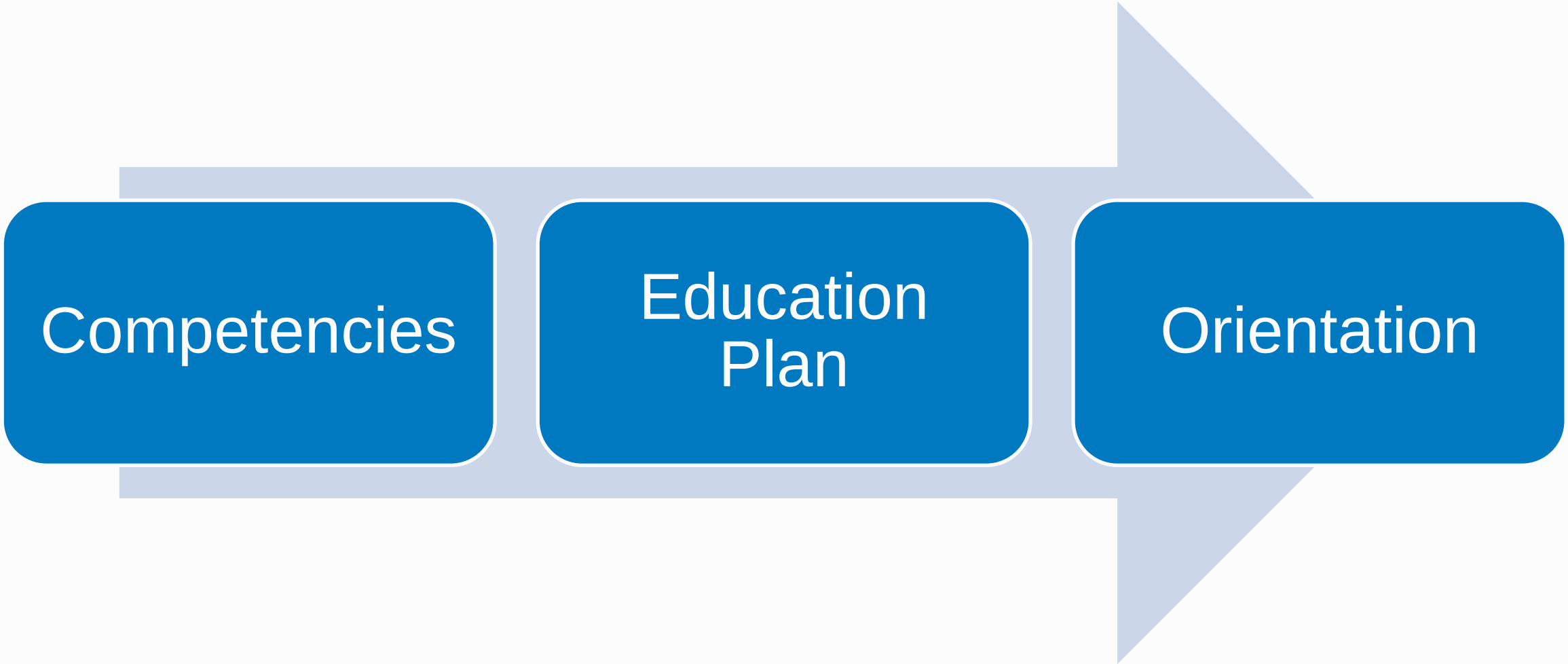
Hiring

- Identified key characteristics for potential hires:
  - Demonstration of the University of Miami Core Values
  - Hard skills: clinical, research, quality, registry or regulatory experience
  - Soft Skills: critical thinking, problem solving, and initiative
  - 2 Year commitment



CIBMTR®
CENTER FOR INTERNATIONAL BLOOD & MARROW TRANSPLANT RESEARCH

Development of Training Program



Competency

- Utilized CIBMTR Data Collection Forms and Forms Manual as a foundation
- Leveraged the experiences of current data managers to determine the content of competencies
- Mapped internal transplant process from a data management perspective
- Adapted format from nursing competency checklist

Competency

SYLVESTER COMPREHENSIVE CANCER CENTER
UNIVERSITY OF MIAMI HEALTH SYSTEM

Adult Stem Cell Transplant Program
Research Data Manager
Initial Competency and Validation

EMPLOYEE NAME:		DATE:	TITLE:
NOTE: This is a representative sampling of the competencies necessary for safe, effective performance.			
K E Y	**SELF ASSESSMENT:** 1 No experience 2 Some experience/ needs practice 3 Can safely perform without supervision Note: This section to be completed by employee	**COMPETENCIES:** The employee will demonstrate the following skill competencies listed below **Note:** Competencies should be written using *measurable verbs* (i.e. demonstrate, comprehends, understands, provides, displays).	**METHOD OF EVALUATION KEY:** A. Post-test B. Return Demonstration C. Observation of Daily Work D. Case Study E. Exemplar F. Discussion/Reflection Group G. Mock Event H. Presentation I. Quality Improvement J. Monitor K. Other	**LEVEL OF COMPETENCE:** 1 Met objective 2 Met objective with minimal assistance 3 Not met (see action plan)

CIBMTR®
CENTER FOR INTERNATIONAL BLOOD & MARROW TRANSPLANT RESEARCH

Department Specific Initial Skill Competencies	Self-Assessment				Date	Measure	Initials	Level of Competence		
	N/A	1	2	3				1	2	3
Transplant Specific or General Objectives										
Basic Knowledge for Hematopoietic Progenitor Cell (HPC) Transplantation										
Understand rationale for type of transplant and the determination process (Autologous vs. Allogeneic) • Indications for autologous transplant and rationale o Disease Indications o Rationale for HSCT after conditioning										
• Indications for allogeneic transplant and rationale o Disease Indications o Types o Rationale for HSCT after conditioning o GVL effect										
Selection of Suitable Recipient (B3.3.4.2)										
Understand selection of suitable recipients • HCT Comorbidity index										
• Donor evaluation and management (B3.3.4.3) o NMDP Registry o Rationale for using MRD vs. MUD vs. MMUD vs. Haploidentical										
• HLA Typing o Basic understanding of the HLA matching process o Rationale for HLA typing o Matched donor vs. Unmatched donor o Minimum HLA Matching Requirement o Understanding of MHC type 1 and type 2 o Locate HLA report ▪										

CIBMTR®
CENTER FOR INTERNATIONAL BLOOD & MARROW TRANSPLANT RESEARCH

Department Specific Initial Skill Competencies	Self-Assessment				Date	Measure	Initials	Level of Competence		
	N/A	1	2	3				1	2	3
• Organ specific toxicities • Infections										
Cellular Therapy (non-HSCT)										
Understand the following concepts associated with CAR-T and other novel cellular therapy treatment modalities: • Cytokine Release Syndrome (CRS) • Neurotoxicity (NT) • Grading and management of CRS • Locate CRS and NT flowsheets										
CIBMTR / Data Management Processes										

Comprehend and perform the following data management processes and tasks:
 	
• Admission Flow
  ○ Accession Log
  ○ Velos
  ○ Forms: 2804, 2814, 2400, 2402, Baseline forms
  ○ Randomization: TED vs. CRF										

• Follow-up Flow
  ○ Forms: 2450, 2100, 211x
  ○ Send fax requests to outside providers										

• Platelet Engraftment										

CIBMTR®
CENTER FOR INTERNATIONAL BLOOD & MARROW TRANSPLANT RESEARCH

Department Specific Initial Skill Competencies	Self-Assessment				Date	Measure	Initials	Level of Competence		
	N/A	1	2	3				1	2	3
Disease Specific Objectives										
Acute Myelogenous Leukemia (AML)										
• Know disease process for AML										
• Distinguish between AML subtypes										
• Understand tests required for diagnosis and management o CBC/Peripheral smear o Bone marrow o Molecular (i.e. BCR-ABL) o Cytogenetics (Karyotype & FISH) o Flow Cytometry										
• Explain testing used to identify minimal residual disease										
• Understand disease staging and response criteria (basic terms of remission)										
• Identify treatments for AML including treatment intent/purpose										
• Review and be familiar with the following forms: o 2402 – AML section o 2010/2110										
Acute Lymphoblastic Leukemia (ALL)										
• Know disease process for ALL										
• Distinguish between ALL subtypes										
• Understand tests required for diagnosis and management o CBC/Peripheral smear o Bone marrow o Molecular o Cytogenetics (Karyotype & FISH) o Flow Cytometry										
• Explain testing used to identify minimal residual disease										
• Understand disease staging and response criteria (basic terms of remission)										

CIBMTR®
CENTER FOR INTERNATIONAL BLOOD & MARROW TRANSPLANT RESEARCH

Education Plan (EP) [Lesson Plan]

- Used competencies as roadmap for lesson plan
- Designed the EP as a stepwise approach with opportunities for discussion, evaluation, and the application of knowledge.
- Reviewed reputable journals, articles, etc. to support the content
- Determined best teaching method as it related to the content
  - Lecture
  - Self-paced modules
  - Case Review (previously completed cases)
- Assigned an experienced DM as a preceptor for each topic

CIBMTR®
CENTER FOR INTERNATIONAL BLOOD & MARROW TRANSPLANT RESEARCH

Education Plan

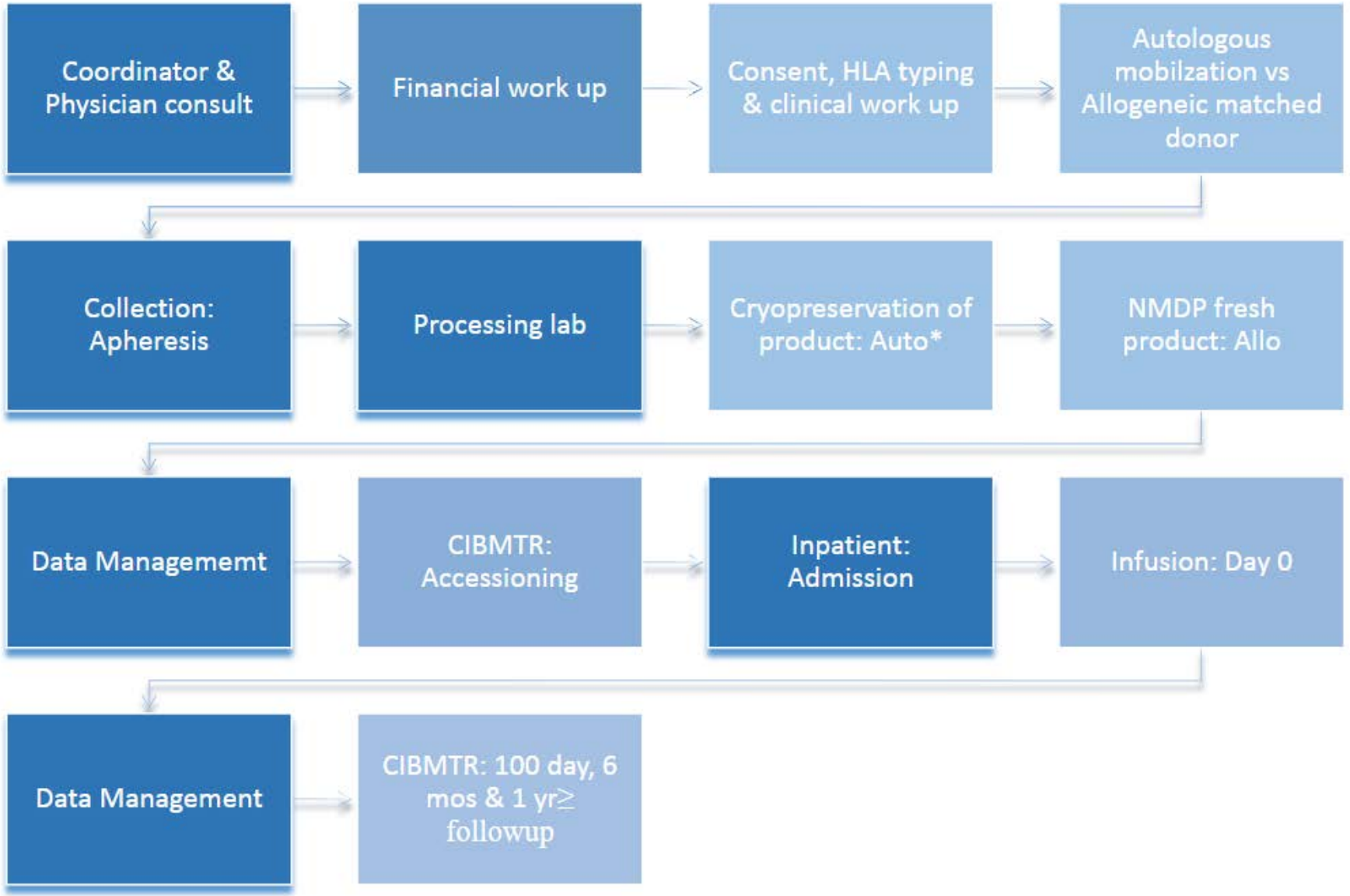
	Start	Monday	Tuesday	Wednesday	Thursday	Friday	End
Week 1	**26-Aug-19**			8 am - 5pm DM Team -Housekeeping -Department Orientation -Staff Meeting 11 am - 12pm Systems DB Engineer -Database Access -Database Reports	9 am -11 am Intro to SCT - DM Staff -Overview (SCT Flowchart) -SCT Tour 1 pm - 5pm -Meet w/ DM Manager -Review Orientation Material -NMDP E-Learning	8 am - 4 pm - Cancer Basics SSB Rooom 160	**30-Aug-19**
Week 2	**2-Sep-19**	HOLIDAY	9:00 am - 11:00 am DM Staff -Protocol Training 1:00 pm - 5:00 pm Web-based Training - Introduction to HLA - Basic Biology of HLA - Advanced Biology - Genetics of HLA - HLA Reporting (Form 2005)	8:30 am - 12:30 pm TCTP Coordinator Manager 1:30 pm - 2:00 pm DM -Telos Training -HLA & Chimerism Application -Final Typing DB -Q&A / Debrief 2:30 pm - 3:30 pm Independent Study	8 am - 12 pm TCTP Coordinator Manager (Competency Sign Off - Need to Highlight on Compentency which ones) 1 pm - 5 pm Web-based Training - FomsNet3 Recipient Training - CRID 2804 - Indication for CRID - Pre-TED Form 2400 - Reporting Prep Regimen on 2400 and Form 2000	8 am - 12 pm DM -Admission Process -Source Document Review (i.e. CMI, PFT, Labs, etc.) -Review Forms 2804, 2814, 2400 12 pm - 4:30 pm Web-based Training -Baseline Form 2000 -Review Completed Baseline Form -Infusion Data (Form 2006)	**6-Sep-19**
Week 3	**9-Sep-19**	**8:00 am - 12:00 pm** off	8:00 am - 10:00 am Apheresis Manager - Collection Center 10:00 am - 5:00 pm Director of CTL -Stem Cell Processing Lab	8:00 am - 10:00 am DM Staff -Admission Process 10:00 am - 11:00 am Finance Manager -Finance Orientation 12:00 pm - 5:00 pm Webinars - Lymphoma Pre-Infusion - Lymphoma Post Infusion - Cellular Therapy	10:00 am -3:30 pm DM Staff -Assess Understanding of Webinars -Didactic training (Lymphoma) -Lymphoma Case Review (CRID XXXX MRN XXXXX, Patient Name- Mantle cell) Reviewed 2400- DM Staff -Assigned to look up LDH (lab) and read on Cytogentetics in the manual	8:00 am - 10:00 am Self Paced Learning -Case Reviews -NMDP Curriculum 1- 3 pm DM Staff - Case Review (Completed 2402) - Didactic Training (Lymphoma) Completed 2018	**13-Sep-19**

CIBMTR®
CENTER FOR INTERNATIONAL BLOOD & MARROW TRANSPLANT RESEARCH

Orientation Plan

- Set an expectation that new hires would have an observational rotation through the clinical and non-clinical areas of the transplant program
- Used transplant flow as the basis of programmatic orientation
- Identified key individuals from each of the departments and set the objectives/key topics they would cover with new hires
- Aligned orientation schedule to coincide with topics in education plan

Stem Cell Transplant Process



CIBMTR
CENTER FOR INTERNATIONAL BLOOD & MARROW TRANSPLANT RESEARCH

Summary

Competencies

Development
- Based on prior DM experience
- CIBMTR data collection forms and manual = foundation
- Format adapted from nursing

Execution
- 10-page (landscape) competency checklist
- 2 main categories:
  - Transplant Specific & General Objectives
  - Disease Specific & General Objectives

Education Plan

Development
- Based on competencies
- Used varied approaches for effective learning
- DM preceptor assigned for each topic

Execution
- Detailed schedule of assigned topics, preceptors, and method of training

Orientation

Development
- Mapped transplant process from data management perspective
- Identified key individuals
- Established objectives for rotation
- Aligned rotation schedule with education (lesson) plan

Execution
- Schedule of clinical and non-clinical areas to be observed
- List of point of contacts for each area in transplant program

CIBMTR®
CENTER FOR INTERNATIONAL BLOOD & MARROW TRANSPLANT RESEARCH

Culmination and Execution of Training Program

- Successfully onboarded 3 novice data managers in the span of 12 months

- Each data manager was given an Orientation Folder containing:
  - Data Management Orientation Checklist
  - Education Plan (calendar of assigned topics)
  - Interdepartmental Orientation Schedule (calendar)
  - Data Management Competencies
  - Organization Chart
  - Phone Rooster
  - Internal Data Management Manual

Culmination and Execution of Training Program

- New hires spent a minimum of 10 weeks in didactic training and 8 weeks of guided forms submission
- Competencies periodically reviewed and checked off by both new hire and preceptor
- Personalized education plans were developed to bridge knowledge gaps uncovered in evaluation phase

Example of Focused Study Guide for a Personalized Education Plan

Allogeneic Patient: Focused Study Guide

Post-Transplant Complications

Complications:

1. **General**

- Identify common complications post-transplant and treatment
- Define and understand each:
  - neutropenia
  - mucositis
  - catheter related complications

2. **Infection**

Transplantation related factors affecting the risk of infection- Refer to Table 1 link

- Define the 3 phases for infection risk:
  - Pre-engraftment: 2-4 weeks post HSCT
  - Post engraftment: 2-3 months post
  - Late phase: beyond 3 months after engraftment

Objectives

- Define each complication.
  - Identify vaccination schedule post-transplant
  - Identify what infections/complications occur in each phase include neutropenia etc and rationale*
  - Identify prophylaxis treatment for each infection or complication, length of tx
  - Identify differences between treatment and prophylaxis (common medications, ex dosages)
  - Identify causes and rationale for prophylaxis and infection risks
  - Identify laboratory tests available for each infection
  - Identify manifestations and/ or presentation of each infection

- Refer to risk stratification and management for further understanding
- Post-transplant care recommendations (NMDP)

1. Infections- vulnerability to infection and immune reconstitution (finalizes 2-3 yrs post)

   a. Fungal (mold) Infections
      i. Aspergillus -PJP
      ii. Non aspergillus

   b. Bacterial Infections
      i. Blood stream infections
      ii. Gut Infections e.g C-Dificile
      iii. Staph infections
      iv. Pseudomonas

CIBMTR®
CENTER FOR INTERNATIONAL BLOOD & MARROW TRANSPLANT RESEARCH

Ongoing Competency

- Continued use of individual education plans beyond onboarding period
- Mandatory annual education in transplantation and cellular therapy
- Performance of data validation audits
- Case discussion and presentation
- Presence in clinical conferences (i.e., Tumor Boards, etc.)

Outcomes / Benefits

- Plan is structured, formal and reproducible
- Ensures consistency in training and knowledge base
- Establishes transparency and clearly outlines job performance and expectations
- Allows the department to be prepared for turnover and growth
- Helps to hard wire internal processes
- Creation of a center specific data management manual

THANK YOU!

Quality and Data Management Team

CIBMTR®
CENTER FOR INTERNATIONAL BLOOD & MARROW TRANSPLANT RESEARCH