



# Driving Public Banked Cord Blood Inventory Utilization thru Research and Development

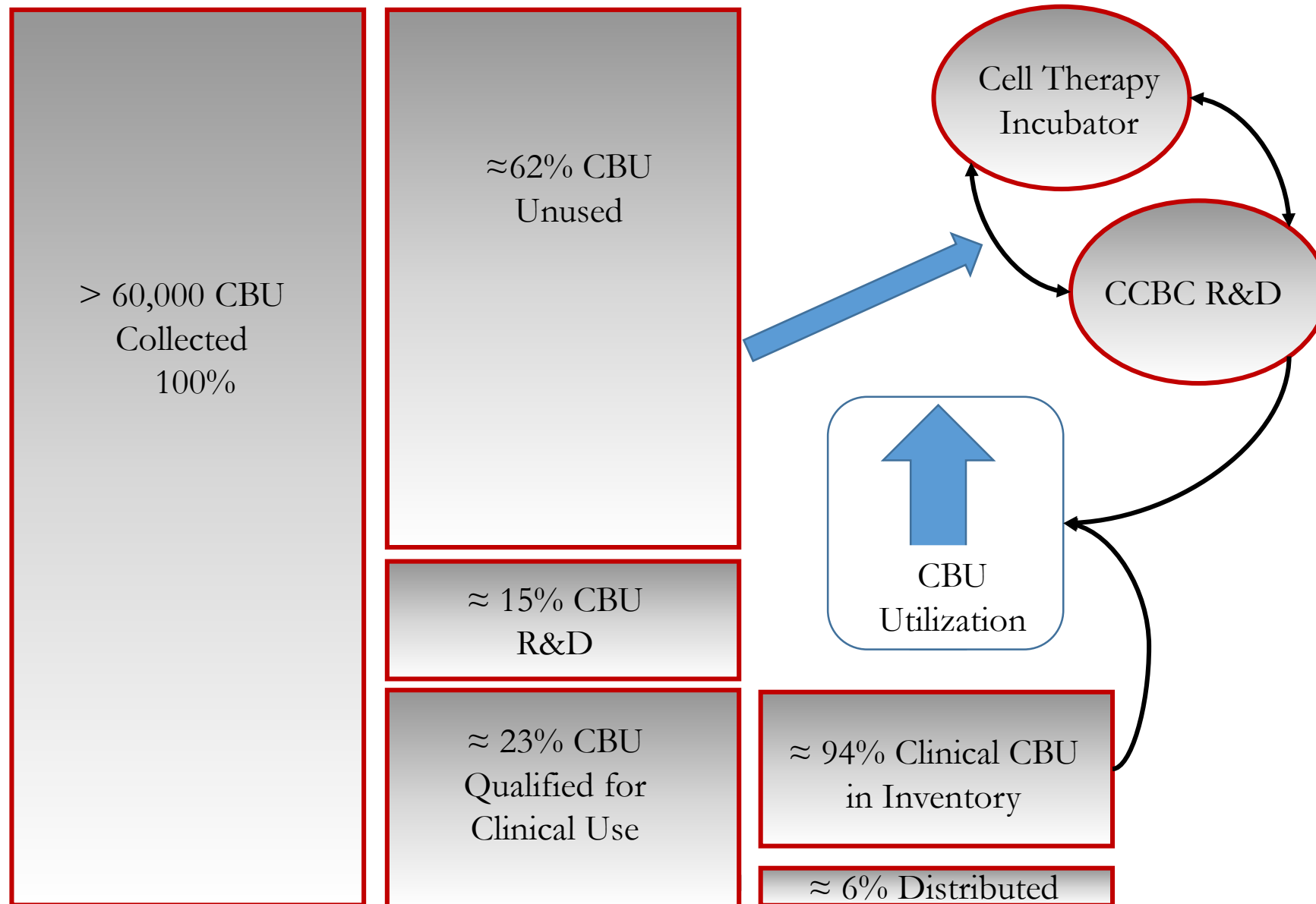
May 17, 2019

# Utilization Drivers

- Optimizing HPC, Cord Blood inventory
- Developing Clinical Pathways & Product Pipelines
- Leveraging Existing Resources to Diversify Utility



# Drive Utilization of CB Inventory

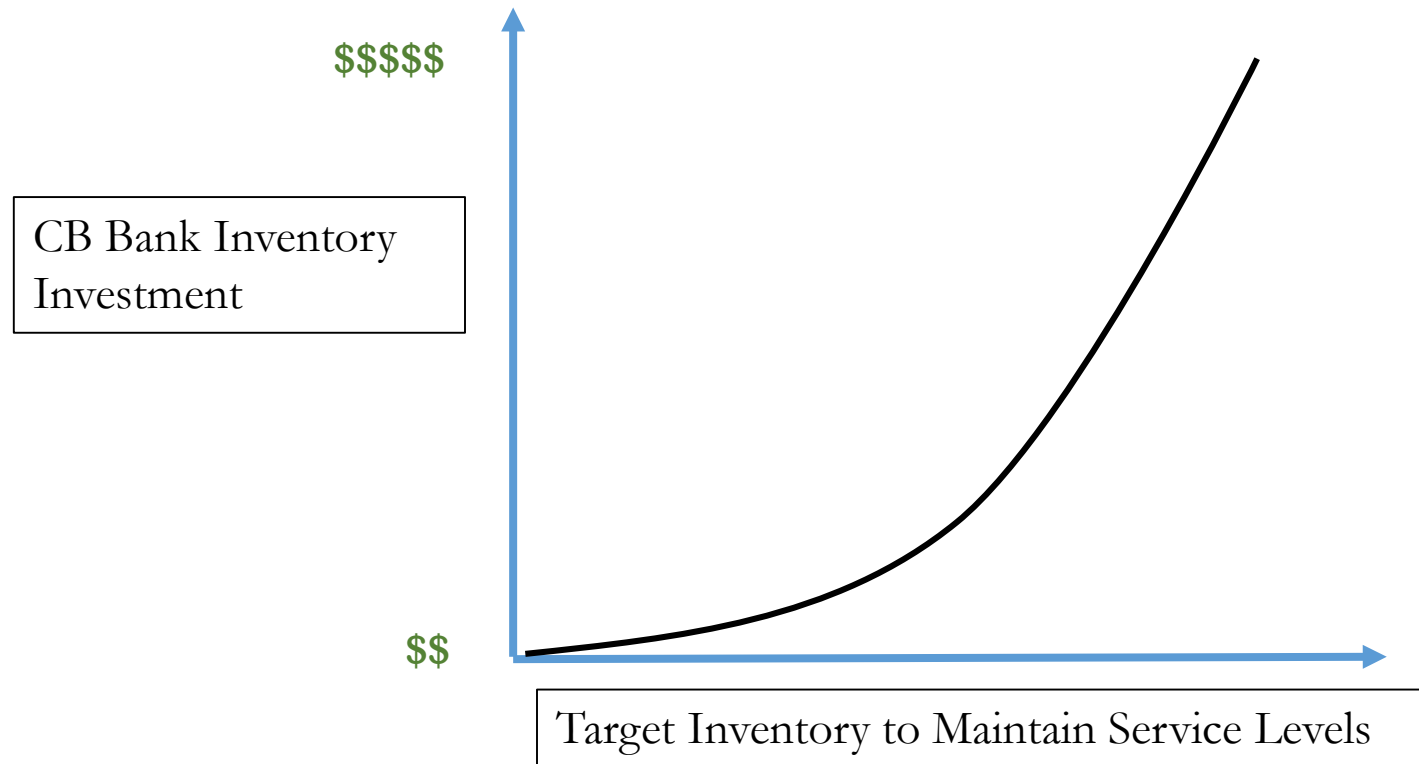


# Utilization Drivers

- Optimizing HPC, Cord Blood Inventory
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# HPC, Cord Blood Inventory Management



BALANCE: Cost with Inventory Needed

# Optimizing HPC, Cord Blood Inventory

## IDENTIFY INDUSTRY DRIVERS

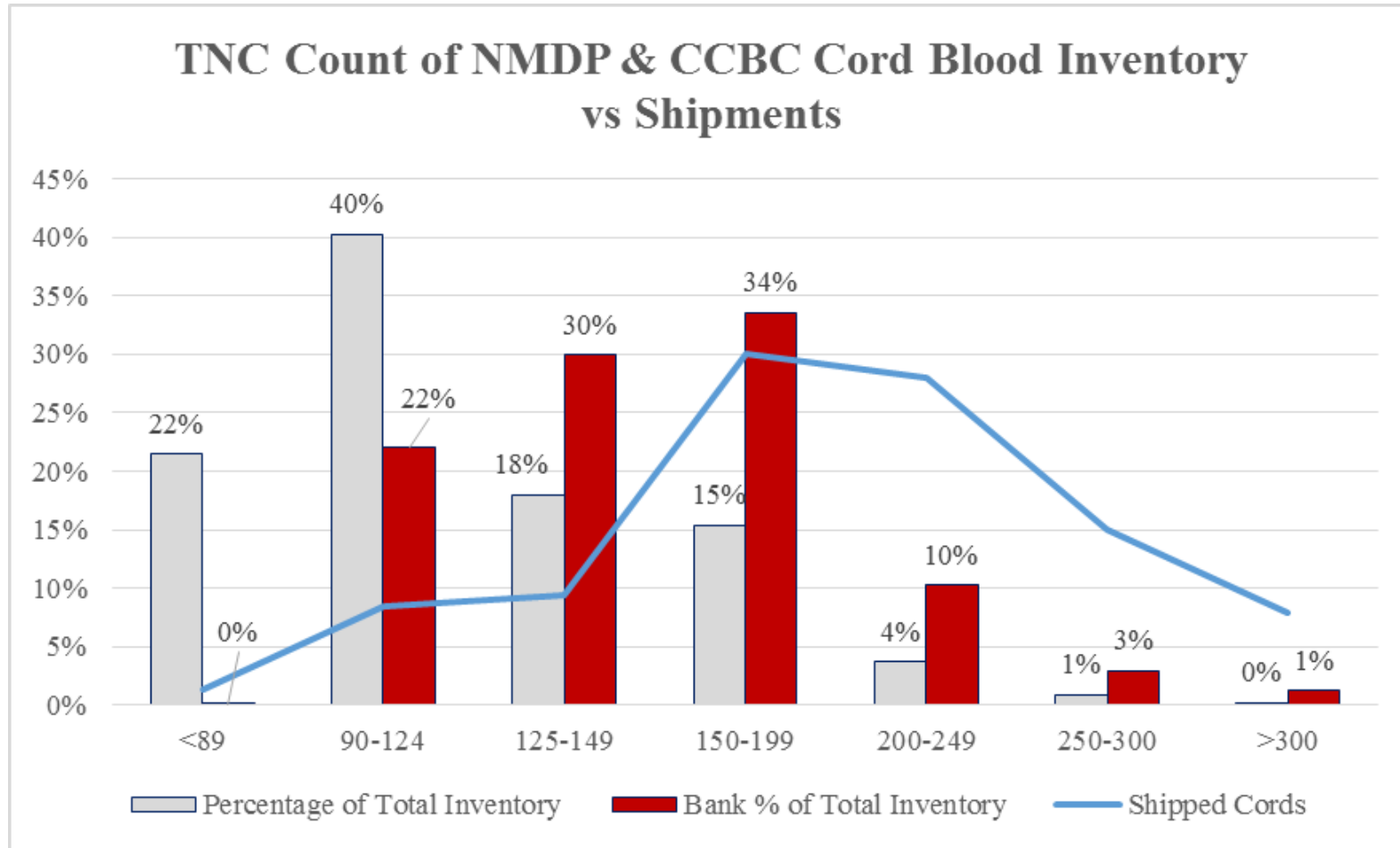
- High TNC Cord Blood Units
- Rare HLA types

## REDUCE COST OF INVENTORY ACQUISITION

- Streamline Processing Procedures
- Optimize Collection



# Optimizing HPC, Cord Blood Inventory



## CONSIDER INVENTORY CLASSIFICATION-A-B-C STRATEGY

- A- most desirable segment of inventory (10-20%)
- B- moderately desirable segment of inventory (20-50%)
- C- lowest desirable segment of inventory (20-50%)

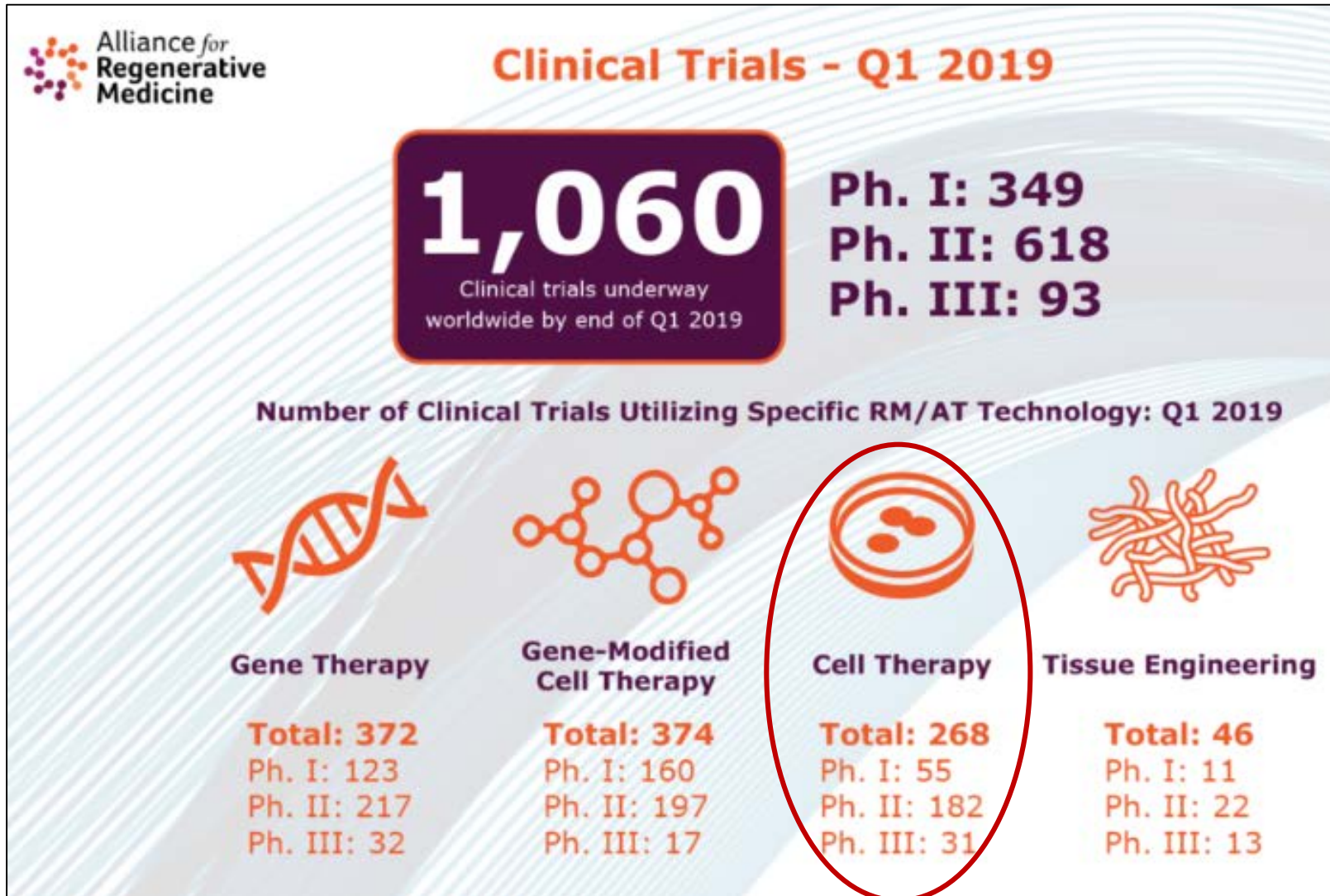
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# Clinical Research- US



# Clinical Research- EU

The screenshot shows the EU Clinical Trials Register interface. At the top, there is a blue header with the European Union flag and the text 'EU Clinical Trials Register' and 'Help'. Below the header is a navigation bar with links for 'Home & Search', 'Joining a trial', 'Contacts', and 'About'. The main content area is titled 'Clinical trials for Cord Blood'. It features a search bar with the text 'Cord Blood' and a 'Search' button. Below the search bar, there are examples of search terms and a link to 'How to search [pdf]'. There is also an 'Advanced Search' section with a 'Search tools' dropdown menu. At the bottom, there are two tabs: 'Trials with a EudraCT protocol (163)' and 'Paediatric studies in scope of Art45 of the Paediatric Regulation (3)'. The text '163 result(s) found for: Cord Blood. Displaying page 1 of 9.' is circled in red.

EU Clinical Trials Register Help

Home & Search Joining a trial Contacts About

## Clinical trials for Cord Blood

Cord Blood X Search

Examples: Cancer AND drug name. Pneumonia AND sponsor name.  
[How to search \[pdf\]](#)

Advanced Search: [Search tools](#) ▾

Trials with a EudraCT protocol (163) Paediatric studies in scope of Art45 of the Paediatric Regulation (3)

**163 result(s) found for: Cord Blood. Displaying page 1 of 9.**

# CCBC Non-clinical R&D Examples

- Generation of regulatory T-cells for Diabetes
- Dual cell approach in Parkinson's Disease
- UCB-derived cells for Chronic, Non-Healing Wounds



# CCBC R&D Examples

Approximately **780,000\*** Publically Banked Cord Blood Worldwide

- **6.5 million people in the U.S** currently have chronic wounds
- **1.25 million American children and adults** have Type 1 Diabetes
- **1 million** Parkinson's disease (PD) patients in the US

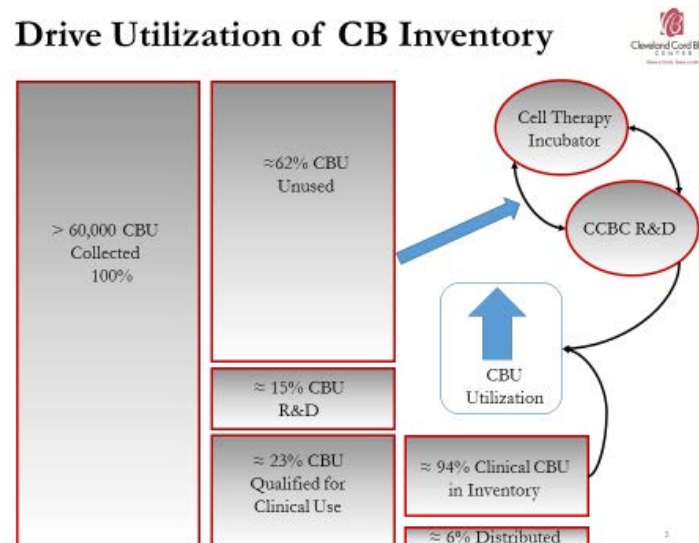
If **ONE** of these research approaches resulted in a safe & efficacious cellular therapy product, the public cord blood inventory could be more fully & effectively utilized.

\*WMDA Website

# Utilization Drivers

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## Drive Utilization of CB Inventory



# Clinical Development Pathway

## Approved Cellular and Gene Therapy Products

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Below is a list of licensed products from the Office of Tissues and Advanced Therapies (OTAT).

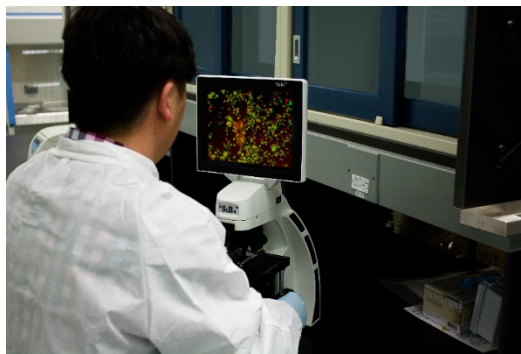
### Approved Products

- [ALLOCORD \(HPC, Cord Blood\)](#)  
SSM Cardinal Glennon Children's Medical Center
- [LAVIV \(Azficel-T\)](#)  
Fibrocell Technologies
- [MACI \(Autologous Cultured Chondrocytes on a Porcine Collagen Membrane\)](#)  
Vericel Corp.
- [CLEVECORD \(HPC Cord Blood\)](#)  
Cleveland Cord Blood Center
- [GINTUIT \(Allogeneic Cultured Keratinocytes and Fibroblasts in Bovine Collagen\)](#)  
Organogenesis Incorporated
- [HEMACORD \(HPC, cord blood\)](#)  
New York Blood Center
- [Ducord, HPC Cord Blood](#)  
Duke University School of Medicine
- [HPC, Cord Blood](#)  
Clinimmune Labs, University of Colorado Cord Blood Bank
- [HPC, Cord Blood - MD Anderson Cord Blood Bank](#)  
MD Anderson Cord Blood Bank
- [HPC, Cord Blood - LifeSouth](#)  
LifeSouth Community Blood Centers, Inc.
- [HPC, Cord Blood - Bloodworks](#)  
Bloodworks
- [IMLYGIC \(talimogene laherparepvec\)](#)  
BioVex, Inc., a subsidiary of Amgen Inc.
- [KYMRIAH \(tisagenlecleucel\)](#)  
Novartis Pharmaceuticals Corporation
- [LUXTURNA](#)  
Spark Therapeutics, Inc.
- [PROVENGE \(sipuleucel-T\)](#)  
Dendreon Corp.
- [YESCARTA \(axicabtagene ciloleucel\)](#)  
Kite Pharma, Incorporated

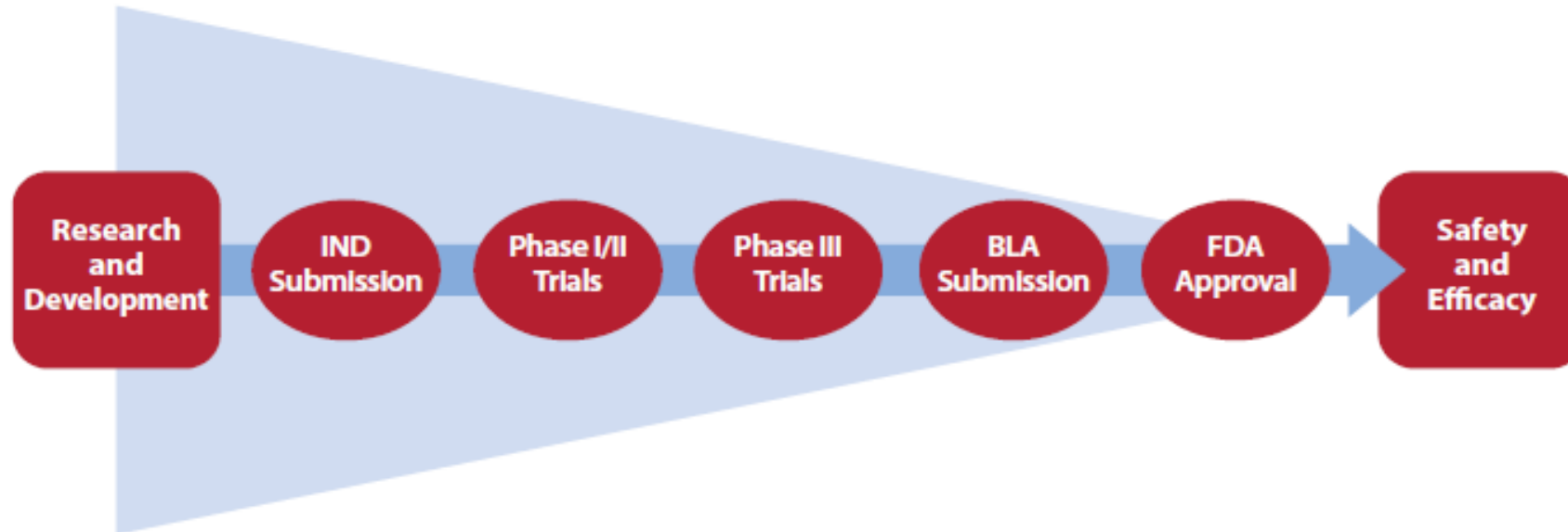
- 16 FDA Approved Cellular and Gene Therapy Products
- 8 HPC, Cord Blood

# CCBC Cell Therapy Incubator (CTI)

- *New* Facility in existing building
- Wet lab and clean room suite
- Diversification of Cord Blood utility
  - Technology evaluation (De-risking)
  - Internal Product Development (Pipeline)
  - Product Development for external partners (Contracting)



# Clinical Development Pathway

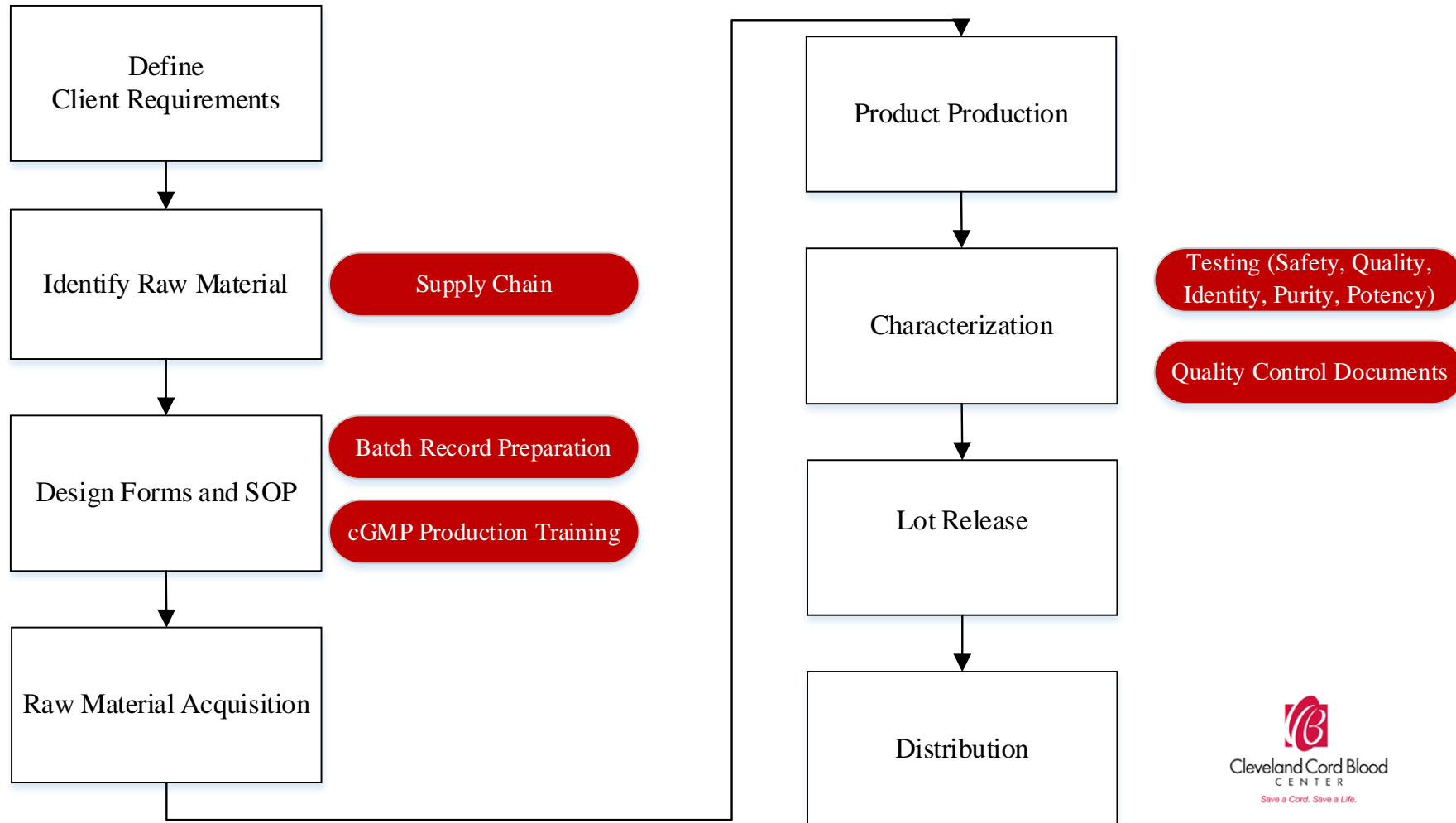


The CCBC Cell Therapy Incubator will add value by:

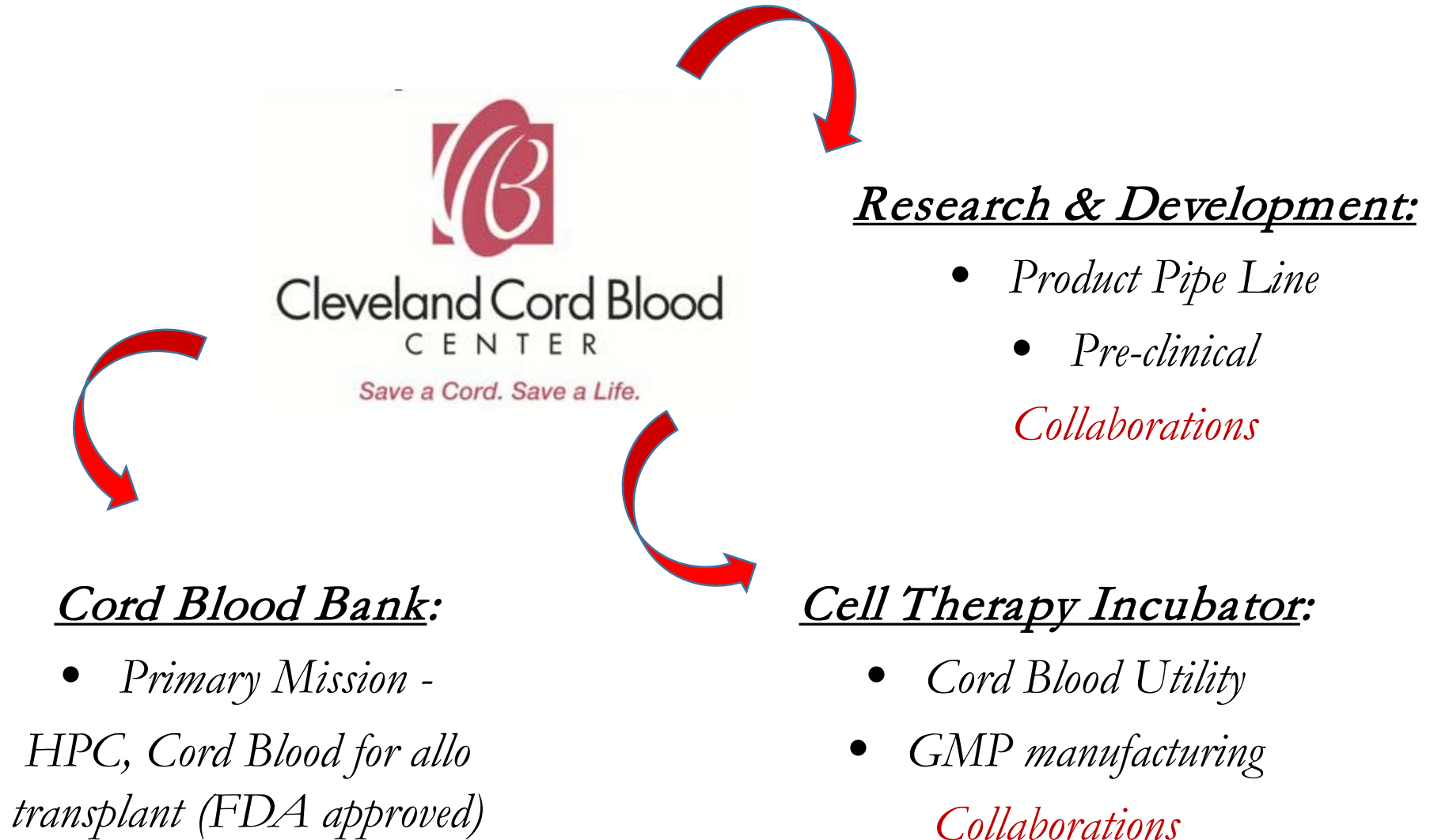
- Decreasing time to market
- Overcoming regulatory hurdles
- Developing quality products by leveraging our **experience** and **diverse partnerships** to support the movement of cellular therapy products from R&D to FDA approval



# CTI – Leveraging Existing Infrastructure and Know-How



# *Driving CCBC Inventory Utilization*

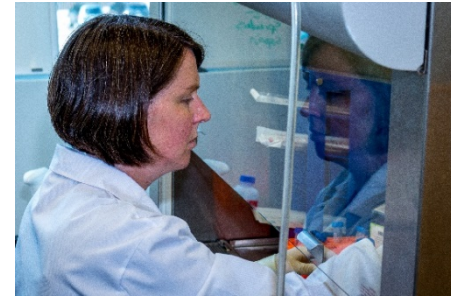
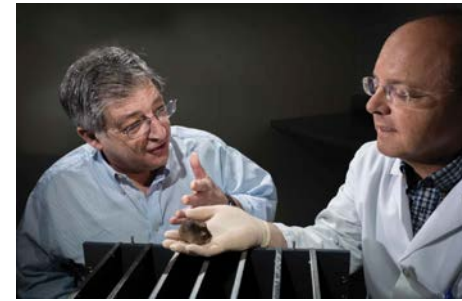


# CCBC Team

- Wouter Van't Hof (CBB Director, Processing Facility Director)
- Marcie Finney (Executive Director)
- Mary Laughlin (Medical Director, Director of Research)
  - Jay Do (Associate Research Staff)
  - Daniel Zwick (Associate Research Staff)
  - Fey Zhong (Research Technician)
- Lisa Phillips Johnson (Director, Quality/Regulatory)
- Dawn Thut (Quality Manager)
  - Faith Dedino (Quality Specialist)
  - Angela Bunnell (Quality Specialist)
- Kathy Bobik-Kurz (Collection Site Manager)
  - Candace Laster (Hospital Collections)
  - JoAnn Chase (Hospital Collections)
  - Sue Boucher (Hospital Collections)
- Sara Shields (Laboratory/ Project Manager)
  - Kim Vincent (Lead Technician)
  - Denise Blanco (Sr Processing Tech)
  - David Starkey (Sr Processing Tech)
  - Kara Evans (Processing Tech)
  - Michelle Patchin (Processing Tech)
  - Molly Walker (Processing Tech)
  - Susan Whitmer (Lab Assistant)
- Doreen Merritt (Finance Manager)
- Sydnie Echols (Administration)
- Sean Nehlson (HR Consultant)
- Marc Meyer (IT Consultant)



# Save a Cord. Save a Life.



  
**586**  
Cord Blood  
Units Distributed

# Questions?

