General

This session will unveil NMDP’s multi-phased plan to implement ISBT 128 throughout its network of collection centers.
What is ISBT 128?

ISBT 128 is the global standard for the terminology, identification, coding and labeling of medical products of human origin

– It is used in more than 75 countries across six continents
– It is widely endorsed by the professional community
– Designed to ensure the highest levels of accuracy, safety and efficiency
– Provides international consistency to support the transfer, traceability and transfusion/transplantation of blood, cells, tissues and organs
Learning Objectives

1. Present NMDP’s multi-phased project plan to implement ISBT 128 throughout its network of collection centers.
2. Explain project intent, rationale and value.
3. Provide a high level summary of NMDP’s ISBT 128 Implementation Plan.
4. Describe project challenges, progress and milestones.
### Why Implement ISBT 128?

<table>
<thead>
<tr>
<th>Problem</th>
<th>Solution</th>
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</thead>
<tbody>
<tr>
<td>Current practices for labeling NMDP’s cellular therapy products:</td>
<td>ISBT 128 provides:</td>
</tr>
<tr>
<td>1) Do not include a “globally” single, unique donation identifier for traceability</td>
<td>Globally unique donation identification for product traceability throughout the world</td>
</tr>
<tr>
<td>2) Are inconsistent throughout the NMDP network</td>
<td>A tool to achieve standardization of product labeling and internationally-accepted terminology/definitions</td>
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<tr>
<td>3) Rely on handwritten data entry for each label</td>
<td>Electronic product labeling, coding, and bar code technology</td>
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<tr>
<td>4) Rely on product labels in English language; not suitable for international exchange</td>
<td>Unambiguous communication of product label information in electronically readable format to overcome language barriers</td>
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</table>
Why Implement ISBT 128?

AND...a growing consensus of world leaders in cellular therapy are driving toward required adoption of ISBT 128

**AABB and FACT** require facilities to have a plan for implementation of ISBT 128 coding and labeling
Project Goal

Enable NMDP and Network partners to move

From *Handwritten* label data entry for NMDP products

To *Electronic* label generation that includes a unique donation identification number in accordance with regulatory requirements and that utilizes internationally-accepted standard terminology and bar coding technology
Project Goal:
Single, Unique Donation Identifier

NMDP’s Current Donation Identification
1. Product Name
   +
2. Donor ID # *
   +
3. Date of Collection*
   *

* handwritten

ISBT 128 Donation Identification
1. DIN

Donation Identification Number + Flag Characters + Check Character

A9999 11 123456

Facility ID Number Year Sequence Number Flag Check Character

Donation Identification Number
NMDP’s Approach to ISBT 128 Implementation

- A Collaborative Approach
- A Multi-Phased Approach
- A Simple Approach
A Collaborative Approach

- It takes an ENORMOUS effort to implement ISBT 128 by an individual center on an independent basis *

- A team approach allows for collaboration between NMDP and Network partners

  plus

  sharing of knowledge + resources, that will result in more efficient implementation →

* ~ 190 collection sites in NMDP network

Together we can make it happen
## A Multi-Phased Approach

<table>
<thead>
<tr>
<th>Year</th>
<th>Phase</th>
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<tbody>
<tr>
<td>2011</td>
<td>Preliminary Project Team (learning phase)</td>
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<tr>
<td>2012</td>
<td>Phase 1: Analysis (impact, strategy) and Scope</td>
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<tr>
<td>2013</td>
<td>Phase 2: Planning, requirements identification, vendor qualification, needs assessment, and agreements with vendor and subset of collection sites (pilot sites)</td>
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<tr>
<td>2014</td>
<td>Phase 3: Preparation, development of resources (procedures, validation, training, other), and first wave of full implementation with pilot sites</td>
</tr>
<tr>
<td>2015</td>
<td>Phase 4: Continue implementation throughout network</td>
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A Simple Approach

Standalone ISBT 128 Labeling System: Software and Equipment

- Standalone Labeling System
  - Non-interfaced software
  - Thermal Transfer Printer
  - Bar Code Scanner
  - Label Stock and Ribbons

- Minimum NMDP-specific software configuration
  - Allows centers to use for Non-NMDP products
Project Collaboration: NMDP’s Role

- Overall project management
- Define label requirements
- Execute center participation agreements
- Vendor qualification and service agreement with NMDP
- Software and equipment needs assessment with center
- Develop procedures and training
- Design validation plan
- Liaison with ICCBBA regarding interpretation of the ISBT 128 standard
- Ongoing center support throughout entire implementation process
Project Collaboration: Center’s Role

- Develop site-specific ISBT 128 Implementation Plan
- Coordinate and communicate with NMDP project staff and all site stakeholders throughout project
- Perform implementation activities within site, such as:
  - Install and validate software and equipment
  - Update internal procedures
  - Deliver training
## ISBT 128 Pilot Sites

<table>
<thead>
<tr>
<th>Hospital Name</th>
<th>Blood Center Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alta Bates Medical Center</td>
<td>The Methodist Hospital</td>
</tr>
<tr>
<td>Apheresis Assoc of Northern Virginia</td>
<td>Michigan Blood Center</td>
</tr>
<tr>
<td>Arthur G. James Cancer Hospital</td>
<td>New York Presbyterian Hosp at Cornell</td>
</tr>
<tr>
<td>Carter BloodCare</td>
<td>Presbyterian St. Lukes Medical Center</td>
</tr>
<tr>
<td>City of Hope National Medical Center</td>
<td>Puget Sound Blood Center</td>
</tr>
<tr>
<td>Cook Children Hospital</td>
<td>Rhode Island Blood Center</td>
</tr>
<tr>
<td>Dana Farber Cancer Institute</td>
<td>Scripps Green Hospital</td>
</tr>
<tr>
<td>Dartmouth-Hitchcock Medical Center</td>
<td>South Texas Blood &amp; Tissue Center</td>
</tr>
<tr>
<td>Duke University Medical Center</td>
<td>Stanford Hospital and Clinics</td>
</tr>
<tr>
<td>Georgetown University Hospital</td>
<td>UCLA Medical Center</td>
</tr>
<tr>
<td>Hackensack University Medical Center</td>
<td>UCSF Medical Center</td>
</tr>
<tr>
<td>Karmanos Cancer Center</td>
<td>University of Minnesota-Fairview</td>
</tr>
<tr>
<td>Massachusetts General Hospital</td>
<td>Vanderbilt University Medical Center</td>
</tr>
<tr>
<td>Memorial Blood Centers</td>
<td></td>
</tr>
</tbody>
</table>
Impact, Scope, and Strategy

**Scope**
Products collected in the US
- HPC, Apheresis – HPC(A)
- Concurrent Plasma, Apheresis – CP(A)
- MNC, Apheresis – MNC(A)
- HPC, Marrow – HPC(M)

Participating Centers
- US collection sites (Apheresis Centers and Collection Centers)

**Impact**
- **US and Non-US Transplant Centers (TC)**
  - Products from US collection sites may be delivered to any NMDP TC in the world
- **Other impacted items (agreements, procedures)** to be discussed in more detail later in the presentation

**Strategy**
- Staggered implementation
- Standalone software option selected
Labeling Requirements

Factors Considered

- Regulatory and accreditation requirements
  - FDA, FACT-JACIE, and AABB
- ISBT 128 Standards requirements
- HRSA contract requirements
  - Donor and Recipient Confidential Information
- NMDP specific requirements
Vendor Selection and Qualification

Factors Considered

• Vendor selection
  – Sole supplier: standalone software option

• Vendor Qualification
  – Requirements
  – Registered with ICCBBA
  – Experience
  – References
  – Testing of software
Pilot Sites and Participation Agreements

• Site Selection Criteria
  – Voluntary participation
  – Collection volume
  – Type of center
  – ISBT 128 experience

• Agreement with site
  – Regarding site commitment to participate in project
  – Site ownership of NMDP provided software/equipment

• A total of 27 sites are participating in the pilot
Site Visits and Assessment

Purpose

• Meet site staff responsible for ISBT 128 implementation; build trust
• Opportunity for site staff to learn details of the project, see software demo, and ask questions;
• Opportunity for NMDP representatives to observe and understand site’s current labeling environment and process;
• Mutually evaluate site-specific labeling software and equipment needs
Purchasing/Ordering Software, Equipment, Supplies and ICCBBA Registration

- **Registration with ICCBBA**
  - Determine site registration status
  - If registered, assess need for additional separate FIN
- **Facilitate software/equipment ordering process**
  - Provide financial compensation for software/equipment
  - Collaborate with vendor to create order form
- **Facilitate supplies ordering process**
  - Provide stipend
  - Collaborate with vendor to create order form
- **Serve as a liaison with vendor to resolve ordering issues, as needed**
Product Codes

• NMDP collaboration with ICCBBA to develop education sessions
  – Product code selection
  – Use of Product Code Lookup tool
• Product Codes to be used for products collected for the NMDP
  – Identify
  – Communicate to sites
Validation

• Validation plan (software/equipment) development (IQ, OQ, PQ)
  – Template that site may update
• Installation and validation of software/equipment
  – By NMDP before release to sites
• Installation and validation of software/equipment
  – Beta sites
  – Other pilot sites
• Validation of product labels material (stock) for adhesion and integrity
Procedures: 
Final product labeling for distribution

- NMDP procedures purpose
  - Define each label element
  - Outline labeling process
- Factors considered: site visits findings, feedback from users (pilot sites), labeling requirements
- Multiple new/updated NMDP procedures/Forms/Aids/Manual of Operations
  - Manual labeling procedures
    - Staggered implementation; dual labeling methods
    - Update manual labels to align with ISBT 128 labels
  - ISBT 128 labeling procedures
Training and Education

• Education sessions by ICCBBA
  – Label design
  – Product Code Selection

• Training development by NMDP
  – Collection Centers and Apheresis Centers (US)
  – Donor Centers (US)
  – Transplant Centers (US and International)
  – Couriers
The checklist serves as a method for participating centers and the NMDP to:

- Track/monitor and document completion of key activities at center
- Communicate status of project at center to the NMDP
- Document readiness and approval by center to proceed with implementation
- Document release and approval by the NMDP to proceed with implementation
Support and Resources for Participating Sites

Support and Communication
- Site Visits
- One-on-one consultation with NMDP ISBT-128 project team
- Project updates (at least monthly by e-mail)
- Conference Calls
- Project Webpage (updates, information and resources)
- Product Code identification and selection
- Needs assessment and coordination of software, equipment, supplies ordering

Resources and Tools
- Financial compensation for software/equipment
- ISBT 128 Implementation Plan Template
- Education sessions – ICCBBA
- Liaison with ICCBBA and vendor
- Readiness Checklist
- Validation Plan - Labeling Software/Equipment
- Validation Plan Template – label material (stock)
- ISBT 128 Procedures and Training
Project Challenges - Sites

- Agreements
  - Complexity of approval process varies from site to site
  - Support from other departments at site (IT, contracts, other)
- Diversity of processes and environment at participating sites
  - Who performs and where labeling occurs?
- Decentralized project activities
  - Participating sites are part of different institutions/locations in the US
- Resources and competing priorities at sites
  - Availability of resources needed for project varies from site to site
- Experience and skills
  - ISBT 128 knowledge and skills needed to complete project activities (such as validation) varies from site to site
Project Challenges - NMDP

- Project coordination with release of ISBT 128 new product terminology
- Agreements/Contractual
  - Negotiations with collection sites regarding participation in pilot project
- Definition of labeling elements
  - Not previously defined for NMDP labels
- Align and maintain dual system
  - Manual labels and ISBT 128 labels
- Software customization and configuration
  - Meet NMDP specific needs; maintain usability for sites
- Communicating and capturing DIN
  - Standalone software; no interface/integration
  - How? Who? Where?
- Industry situation
  - Some network centers are farther along in ISBT 128 implementation than the NMDP
Progress and Milestones

- Pilot Sites selected
- Participation agreements
- Label and software user requirements
- Vendor qualification and vendor agreement
- Configuration of label software
  - Includes latest terminology changes
- Site Visits (27 sites)
- Hardware/software assessment and ordering
- Validation plan (software/equipment) development (IQ, OQ, PQ)
- Installation/validation of software/equipment by NMDP before release to sites
- Validation of product labels material (stock) for adhesion and integrity by NMDP
- Definition of each label element
- Labeling process development in collaboration with sites
Next Steps:
Short term

- Site updates/approval of NMDP Validation plan (software/equipment) template
- Site Installation/validation of software/equipment
- Site Validation of product labels material (stock) for adhesion and integrity
- ISBT 128 procedures development by NMDP
- Procedure development by site, as needed

- ISBT 128 training development by NMDP
- Site training development, as needed
- ISBT 128 training delivery
- Fully implement ISBT 128 coding and labeling at pilot sites
- Effectiveness assessment of results; refine plan as needed
Next Steps: Long Term

- Ongoing: Continued planning for next phase of implementation
- Define process to capture DIN at NMDP
- Fully implement ISBT 128 coding and labeling at all NMDP Network sites
Acknowledgments

- Participating Centers
- ICCBBA
- NMDP ISBT 128 Project Team

Thank You!
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Questions?