



Foundation for the Accreditation of Cellular Therapy

Inspection and Accreditation

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FOUNDATION FOR THE
ACCREDITATION OF
CELLULAR THERAPY

Presenter

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Chair, FACT Standards Development Committee



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Facts about FACT

- Non-profit corporation co-founded in 1996 by the International Society for Cellular Therapy and the American Society for Blood and Marrow Transplantation
- Establishes standards for high quality medical and laboratory practice in cellular therapies
- Conducts voluntary inspection and accreditation in the field of cellular therapy

The FACT Mission

The Foundation for the Accreditation of Cellular Therapy promotes quality medical and laboratory practice of cellular therapy through its peer-developed standards and voluntary inspection and accreditation program.

- Unique perspective of cellular therapy
 - Emphasizes relationship between technical laboratory practices and the clinical use of cells

FACT's Values

An organization comprised of practicing professionals, encompassing all aspects of cellular therapy, is best positioned to set standards and provide an accreditation process that promotes quality patient care, improves treatment outcomes, and fosters continued development of the field.

- Promote quality patient care
- Improve treatment outcomes
- Foster continued development of the field

FACT's Vision

A dynamic organization that is responsive to the evolving field of cellular therapy and regenerative medicine.

- Dynamic organization
 - Flexible as the field of cellular therapy evolves over time
- Responsive
 - Seeks the opinions and needs of cellular therapy professionals and organizations and acts to address those issues
- Optimistic
 - Realizes the potential of new and exciting cellular therapies and has a vested interest in bringing those therapies to patients
 - Believes in international collaboration to allow patients access to quality cellular therapies worldwide

Support to Cell Therapy Programs and Cord Blood Banks

- Collegial
- Dynamic and flexible to adapt to evolving needs
- Evidence-based Standards development every three years
- Updated guidance information as needed
- Comprehensive educational opportunities
- Assistance throughout the accreditation process and between cycles
- Liaison to parent organizations ASBMT and ISCT and to partner organizations such as NetCord

Excellence in Cellular Therapy, including Cord Blood Banking

- Requirement by health insurance companies, managed care organizations, and governments
- Resource for patients making health care decisions
- Regulatory compliance tool with cost savings
- Ranking measurement by *US News & World Report*

Purpose of Presentation

- Outline the scope of the FACT-JACIE Cellular Therapy Standards and the NetCord-FACT Cord Blood Standards
- Discuss the Standards Committee membership
- Explain the flexibility of the Standards
- List resources for studying the Standards

Advantage of FACT Standards

- Cornerstone of FACT accreditation program
 - Clear list of requirements cellular therapy programs must meet
 - Accreditation activities are based upon the Standards
- Only set of requirements that include both clinical and laboratory practices

Scope of Cellular Therapy Standards

- Hematopoietic progenitor cells (HPC) and Therapeutic Cells (TC)
- Collection of cells from marrow and peripheral blood
- Cellular processing
- Clinical administration of HPCs and TCs from marrow, peripheral blood, and placenta/umbilical cord blood
- Requires all cellular therapy programs to:
 - Maintain a comprehensive Quality Management Program
 - Utilize validated methods, supplies, reagents, and equipment

Evidenced-Based Requirements

- Published medical evidence
 - When not available, requirements based upon accepted scientific theory
- Public review and comment
 - Public given 90 days to review draft Standards and submit comments
 - Opportunity to provide feedback and participate in the Standards development process

Collaboration with JACIE

- Joint Accreditation Committee of ISCT-EBMT formed to create voluntary accreditation program in Europe
 - JACIE first adopted FACT Standards
 - Standards development evolved into a joint process
- Standards are now referred to as the FACT-JACIE Cellular Therapy Standards

Accreditation Activity- Cellular Therapy Programs

- Accreditation activity FACT
 - 187 facilities currently accredited, Includes:

Adult		Pediatric		Collection		
Auto	Allo	Auto	Allo	Marrow	PBPC	Processing
137	109	81	79	128	176	184

- Accreditation activity JACIE
 - 101 facilities currently accredited, Includes:

Adult		Pediatric		Collection		
Auto	Allo	Auto	Allo	Marrow	PBPC	Processing
74	67	22	24	67	76	74

Collaboration with NetCord

- The International NetCord Foundation (NetCord)
 - NetCord adopted FACT Standards in 2000
 - Second edition of Cord Blood Standards published jointly in 2002
- Standards are referred to as the NetCord - FACT Cord Blood Standards

Accreditation Activity- Cord Blood Banks

- Accreditation activity NetCord/FACT
 - 31 currently accredited (9 USA)

Donations		
Unrelated Allogenic	Directed Allogenic	Autologous
27 (13 UR Allo only)	16	6 (1 auto only)

Standards Development Process



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Standards Committee

- International representation
 - Cellular Therapy Committee currently consists of members from 10 different countries
- World-renowned experts
- Variety of professional roles
 - Clinicians, scientists, technologists, quality experts, etc.

Organization of Cellular Therapy Standards

- Introduction
- Part A: Terminology, Abbreviations, and Definitions
 - Useful for determining intent of Standards Committee
- Part B: Clinical Program Standards
- Part C: Collection Facility Standards
 - Proposed 5th edition draft separates marrow and apheresis into different sections (Parts CM and C)
- Part D: Processing Facility Standards
- Appendices, Index, Contact Information

Organization of Cord Blood Standards

- Introduction
- Part A: Terminology, Abbreviations, and Definitions
- Part B: Cord Blood Bank Operational Standards
- Part C: Cord Blood Donor Management and Collection Standards
- Part D: Cord Blood Processing Standards
- Part E: Cord Blood Listing, Search, Selection, Reservation, Release, and Distribution Standards
- Appendices, Index, Contact Information

Minimum Requirements = Flexibility

- FACT Standards are not best practices
 - Outline only minimum requirements
 - Allows flexibility of how to meet requirements
- Quote from Accreditation Manual, which provides explanation of the Standards and examples of compliance:

“This is not an exhaustive list of possible ways to meet the Standards, and the intent is to provide examples only since there are many effective mechanisms by which to achieve compliance with FACT Standards.”

Example of Different Methods to Comply with a Standard

- Standard: B1.2 The Clinical Program shall use cell collection and processing facilities that meet FACT-JACIE Standards with respect to their interactions with the Clinical Program.
- Ways in which this requirement could be met:
 - Clinical program is integrated with collection and processing facilities
 - Clinical program contracts services with external collection and processing facilities that are FACT-accredited
 - Many more variations exist in FACT-accredited programs

Accreditation Process



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FACT's Accreditation Program

- Voluntary
 - Cellular therapy programs choose to increase their quality for the betterment of patients, reimbursement from insurance companies, etc.
- International
 - Currently, cellular therapy programs from USA, Canada, and Australia are FACT accredited
 - Mutual interest in accreditation of programs in Latin America and South America

Becoming Familiar with the Standards

- Review the information on the FACT website at www.factwebsite.org
 - Read the Standards
 - Consult the Accreditation Manual for explanations and examples
 - Create a personal profile in FACTWeb to access helpful documents and guidelines
- Subscribe to and read the FACT newsletter and emails
 - To subscribe, contact FACT at fact@unmc.edu
- Ask the FACT staff questions
 - Contact information is on FACT website

Accreditation Process-Overview

- Applicant submits application to confirm eligibility
- Applicant submits document checklist and inspection checklist
- Applicant and inspectors plan on-site inspection
 - FACT Coordinators assist programs and banks with submitting documentation and assist inspectors with travel arrangements
- Inspectors conduct on-site inspection and submit report
- Accreditation Committee determines outcome
 - Applicant submits response; once all standards are met, accreditation is awarded

FACT Initiatives: Maintaining Momentum



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New FACT Website

- www.factwebsite.org *Award Winning
 - Public information
 - Facility information
 - FACTWeb
 - Profiles
 - Store
 - Inspector Application
 - Case studies

Online Accreditation Portal

- Development process
 - FACTWeb Oversight Committee
 - Meetings open to programs and inspectors to provide feedback
- Functions of the portal
 - Hosts all demographics, communication, submissions, and results related to inspection and accreditation process
- Benefits of the portal
 - Streamlined accreditation process
 - Paperless system = \$\$ savings
 - Reporting

Educational Opportunities

- Live events (calendar found on FACT website)
 - Workshops
 - Webinars
- Recorded events (found in Store on FACT website)
 - Recordings of past webinars
 - Tutorials

Facebook

- Type of information posted
 - Pertinent journal articles
 - Tips on the inspection process
 - IT advancements
 - Regulatory Announcements
 - Much more!
- Link is on home page of
www.factwebsite.org
 - www.facebook.com/FACTonFB

International Affiliations Task Force

- FACT is an international organization
 - Cord blood banks around the world are either accredited or in process of accreditation
 - Cellular therapy programs outside of North America and Australia are increasingly requesting approval of accreditation applications
 - For cellular therapy accreditation, a formal request must be submitted to the FACT Board of Directors
- Goal is to expand accreditation opportunities throughout the world
 - In response to requests from organizations in several countries
 - Conducts outreach to increase awareness of FACT
 - Determining and resolving any barriers to accreditation
 - Introductory workshop at Mexican Society of Hematology congress

Regenerative Medicine Task Force

- Exploring how to apply FACT's voluntary accreditation program to cellular therapy for the purpose of regenerative medicine
- Seeking to partner with experts in the field to promote peer-driven quality improvement
- Currently collecting information on the types of cellular therapy products for regenerative medicine being processed

Thank You



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