Standards Development

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Purpose of Presentation

- Describe the Standards Development Process
- Explain the relationship among the FACT Standards
- Provide an overview of the Clinical Standards
  - Immune effector cell-specific standards will be discussed in the next session

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

FACT Standards

- Evidence-based Standards:
  - Published medical literature when available
  - Accepted scientific theory and expert consensus
- Written by world-renown experts in the field, filling a variety of professional roles
  - Clinicians, laboratory scientists, technologists, quality experts
- Each edition published for public comment
  - Opportunity to provide feedback and participate in the Standards development process
- FACT Standards are not best practices
  - Define minimum requirements to reach level of quality worthy of accreditation
  - Allows flexibility in methods/processes to meet requirements

Standards Committee

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

Factors in Standards Revision

- New developments
  - Evidence-based
- Feedback from current processes
  - Standards
  - Accreditation
- Input from related
  - Organizations
  - Individuals

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 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

Precedent-Setting Decisions

- Prevents inconsistent interpretation of Standards
- May require additional information
  - Standards Committee intent
  - Medical literature
  - Commonly accepted practices
- Decision is made at a global level rather than considering only an individual program

Announcements of Accreditation Committee Interpretations

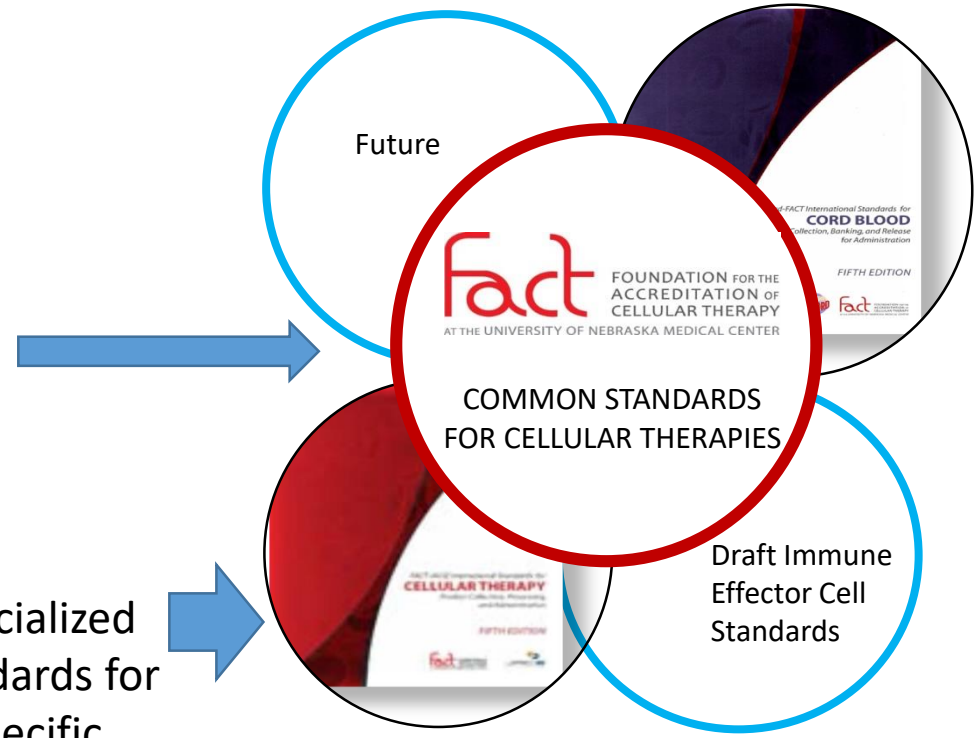
- Newsletter articles
- Guidance updates
- Weekly emails
- Webinars
- Workshops

Leveraging FACT's/HPC Transplant Field's Expertise

- Proven standards and voluntary accreditation program
  - Forum for expert collaboration
  - Experience with drafting minimal standards and applying them to clinical and laboratory sites
  - Knowledge of cell therapy as standard of care and applying lessons learned to other specialties
- Collaboration with experts and professional societies is critical
  - Connect with specialists in various clinical areas as well as facilities manufacturing clinical research products
  - Assess relevance and usefulness of standards in new field
  - Determine necessary requirements; rely on relevant expertise for therapy-specific standards

Relationship Among Standards

Standards that can be applied to any cell type or clinical indication and included in all other sets of Standards



Specialized Standards for specific accreditation goals

Scope of FACT Common Standards

- Includes basic fundamentals applicable to any cell source or therapeutic application
  - Discipline-specific or product-specific standards will be added going forward
  - Immune Effector Cell Standards first specialized requirements originating from Common Standards
- Serves as the basis for accreditation of fundamental quality requirements in cellular therapy
- Collection, processing, and/or administration of cellular therapy products from living donors intended for human administration
- Processes, facilities, personnel, and quality management programs for:
  - Minimally or more than minimally manipulated cells collected from non-hematopoietic sources (see definition at 21 CFR 1271.3(f))
  - Cells collected from hematopoietic sources and processed and administered under approved research protocols for new indications or non-homologous use (e.g., MSCs)
  - A variety of cell types, including pancreatic islets, hepatocytes, and others

Scope of FACT-JACIE Hematopoietic Cellular Therapy Standards

- Hematopoietic progenitor cells (HPC) and donor lymphocyte infusions (DLI)
- Collection of cells from marrow and peripheral blood
- Cellular processing
- Clinical administration of HPCs and DLIs 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

Scope of NetCord-FACT Cord Blood Banking Standards

- Banking of placental and umbilical cord blood for clinical use
- Screening, testing, and eligibility determination of the maternal and infant donor
- Collection of cord blood cells, regardless of methodology or site of collection
- All phases of processing, cryopreservation, storage, and distribution
- Making unit available for administration, either directly or through a registry
- Search, selection, and release processes of specific cord blood units

Clinical Program Standards

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General Requirements

- Integrated medical team in geographically contiguous or proximate space and with common protocols
- Use collection and processing facilities that meet FACT Standards
  - Relationship with manufacturers is discussed in next presentation
- Abide by applicable laws and regulations
- Program Director and one other physician must be in place for at least 12 months prior to accreditation

Minimum Number of Patients

- Demonstrates program experience
- Allows program to audit processes and collect data to:
  - Perform quality management functions
  - Provide evidence of compliance with Standards
- Distinct numbers outlined for hematopoietic cellular therapy related to allogeneic/autologous, adult/pediatric, and single/multiple sites
- Currently drafted at a minimum of five for immune effector cell programs
  - Accreditation process can begin before five is reached
  - Accreditation will be awarded after five

Clinical Unit

- Designated inpatient unit that minimizes airborne microbial contamination
- Designated area for outpatient care that protects patient from transmission of infectious agents and allows for appropriate patient isolation, administration of intravenous fluids, medications, and/or blood products, and confidential examination and evaluation

Personnel Requirements

- Clinical Program Director
  - Appropriately licensed to practice medicine and be specialist certified
  - Have two years of experience as an attending physician
  - Responsible for all aspects of Clinical Program
- Attending Physicians
  - Appropriately licensed to practice medicine and specialist certified
- List of training requirements in this section
- Other requirements for mid-level practitioners, nurses, consulting physicians, and other staff

Donor Selection, Evaluation, and Management

- Applicability to a particular applicant depends on the program's role in selection and evaluation of donors and collection
- Must have written criteria
- Informed consent
- Evaluation of the donor for suitability, or medical fitness to undergo the collection procedure
- Testing requirements
- Allogeneic donor requirements for recipient compatibility

Recipient Care

- Recipient informed consent
- Concurrent recordkeeping
- Safe administration of preparative regimens (chemotherapy and radiation therapy)
- Safe administration of cellular therapy products
- Recipient monitoring for GVHD, post-transplant vaccination schedules, discharges to facilities adequate for post-transplant care (HPC transplant-specific)
- Extracorporeal photopheresis

Clinical Research and Data Management

- Formal review of investigational treatment protocols and patient consent forms as required by applicable laws and regulations
- Disclosure of conflicts of interest in clinical research
- Collect data in CIBMTR data forms

Records

- Specific records must be maintained
  - Listed in Standard B10
- Recipient, donor, and employee records must be maintained in a confidential manner

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
- Subscribe to and read the FACT newsletter and emails
  - Inspector trainees are already subscribed
  - If you are not receiving weekly emails from FACT, please let us know
- Ask the FACT staff questions
  - Contact information is on FACT website

Educational Opportunities

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

Thank You

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