

## Partner Organization Report

<b>Partner Organization:</b>	FACT
<b>Committee Name (if applicable):</b>	
<b>ISCT Representative(s):</b>	Ngaire Elwood, PhD Joseph Schwartz, MD, MPH Abba Zubair, MD, PhD Ian McNiece, PhD Catherine Bollard, MBChB, MD Elizabeth J Shpall, MD
<b>Role of ISCT Representative:</b>	
<b>Last Committee Report Submitted on:</b>	October 17, 2017
<b>Date of Upcoming Board of Directors Meeting for Submission:</b>	June 20, 2018

**1. How often has this committee met during the last 12 months?**

The FACT Board of Directors meets quarterly, including ISCT-appointed Board members. The President-elect and Executive Director of ISCT are also invited to attend the September teleconference and in-person meeting in December (in conjunction with ASH). In addition to these meetings, 17 FACT committees and additional subcommittees meet on a regular basis to drive the activities of the foundation.

**2. What was accomplished during the meeting(s)? (To answer this question, you may attach conference call reports or meeting minutes.)**

Accreditation

The voluntary accreditation program continues to grow in number of accredited entities and types of services accredited.

- *Summary of activities*

In 2017, FACT awarded initial and renewal accreditation to 102 entities, including hematopoietic progenitor cell transplant programs, immune effector cellular therapy programs, cell collection and processing facilities, and cord blood banks. In the first quarter of 2018, FACT awarded accreditation to 25 entities. The full [accreditation report](#) for the first quarter of 2018 and a [list of all accredited organizations](#) are available on the FACT website.

- *FACT Immune Effector Cellular Therapy Accreditation Program*

As of May 21, 2018, FACT has performed 48 on-site immune effector cell (IEC) inspections and accredited 31 programs. All but one of these are at blood and marrow transplant programs that

were already FACT-accredited for hematopoietic progenitor cell transplantation. The first accreditation of a stand-alone IEC program under the new *FACT Immune Effector Cell Standards* was awarded to The University of Texas MD Anderson CARTOX Program, directed by Drs. Elizabeth Shpall and Sattva Neelapu, on April 19, 2018.

The most common issues identified via inspection citations, questions to FACT, and workshop discussions include:

- Defining responsibilities for working with third-party manufacturers
- Developing an infrastructure to accommodate different study/commercial requirements
- Chain of custody and labeling
- Data and adverse event reporting

Several manufacturers have displayed a vested interest in the administration of their IEC products and require (or plan to require) FACT accreditation as part of their center certification processes. Several manufacturers have approached FACT with questions and requests for assistance with educating programs and anticipating challenges. FACT has been encouraged by manufacturers' willingness to work with programs and learn from others' experiences in order to design processes that will ensure successful implementation of IEC administration.

### Standards

Two sets of Standards were updated in March 2018. The new requirements became effective on May 30, 2018.

- *Seventh edition FACT-JACIE International Standards for Hematopoietic Cellular Therapy Product Collection, Processing, and Administration*

Several resources are available to assist with the transition to the new requirements:

- [FACT-JACIE Hematopoietic Cell Therapy Standards, Seventh Edition](#)
- [FACT-JACIE Accreditation Manual, Seventh Edition](#)
- [Purchase Printed Copies](#)
- [Changes to Seventh Edition FACT-JACIE Standards](#)
- [FACT-JACIE Cellular Therapy Standards Crosswalk 6th to 7th Edition](#)
- [FACT-JACIE Cellular Therapy Standards Crosswalk 7th to 6th Edition](#)

- *First edition, Version 1.1 FACT Standards for Immune Effector Cells*

Interim requirements were added to these Standards to harmonize immune effector cellular therapy-specific standards with those changed in the seventh edition Hematopoietic Cell Therapy Standards. These changes will be permanent for the duration of the effective time period of the first edition Immune Effector Cell Standards. Going forward, the two sets of Standards will be edited and published at the same time to continue harmonization. A list of [changes to the first edition](#) is available on the FACT website.

### Global Affairs

FACT continues its global expansion efforts through participation in educational events.

- *Reception for International Delegates at BMT Tandem Meetings*  
Special invitations were extended to all international delegates attending the BMT Tandem Meetings for a wine and cheese reception on February 22, 2018. Members of the FACT Global Affairs Committee were available to provide attendees with information about the new

International Accreditation program. This program assists transplant centers in developing economies who may require additional assistance and education in developing quality systems and adhering to global accreditation requirements.

- *WBMT/AFBMT*  
The African Blood & Marrow Transplantation Group (AFBMT), in conjunction with the Worldwide Network for Blood and Marrow Transplantation (WBMT), organized the first annual meeting in Morocco in January 2018. In conjunction with this meeting, FACT and JACIE coordinated a quality and accreditation workshop attracting 35 attendees. Special time was dedicated to explaining that Standards are not prescriptive but are rooted in Quality Management concepts and descriptive of systems, processes and procedures that must be in place. Thus allowing for programs to adjust their specifics to their local needs and limited resources.
- *FACT-JACIE Stepwise Accreditation Program*  
FACT and JACIE continue to pilot the joint international accreditation program intended to assist transplant programs with the development of their quality systems by offering a stepwise approach to accreditation. In addition to the initial three pilot centers in Mexico and Argentina, 12 more centers in Latin America who have expressed interest in initiating the process have been provided with applications to begin the process.

### **3. What are the key goals and initiatives for the next 6 months to 1 year?**

#### Updates to FACT Standards

The FACT Standards Committees continue to incorporate new developments in cellular therapy into several different sets of Standards.

- *FACT Common Standards for Cellular Therapies*  
The draft second edition will be available for review and comment in June 2018. The Common Standards Committee includes a variety of expertise to ensure the standards included are relevant to *any type of cellular therapy*. ISCT is encouraged to distribute the draft to its membership so that the Standards are considered by professionals working with a wide variety of cellular therapy products.
- *NetCord-FACT Cord Blood Standards*  
The Cord Blood Standards Committee has begun drafting the seventh edition Cord Blood Standards. A survey was distributed to stakeholders to solicit feedback for potential changes. The public comment period for this draft is anticipated to begin in September 2018.

#### Regenerative Medicine Initiatives

As cellular therapies for regenerative medicine continue to advance in scientific discoveries and regulatory reviews, FACT continues to leverage its experience in standards setting and voluntary accreditation to assist with bringing new therapies to patients.

- *Regenerative Medicine InterCHANGE Scheduled for September 17*  
As illustrated by recent developments and successes in cellular therapies, proactive change management is key to advancing regenerative medicine.

FACT invited nearly 30 organizations with complementary missions to participate in the **Regenerative Medicine InterCHANGE** on September 17, 2018, to share their visions and objectives for advancing regenerative medicine therapies. The purpose of this meeting is to discuss specific challenges identified during the recent commercialization of cellular therapies, list current efforts to address these challenges, and identify any existing gaps. ISCT was invited to participate in this meeting, which will take place immediately after the Cord Blood Connect meeting in Miami Beach, Florida.

- *Development of Cardiovascular Cellular Therapy Standards*

The FACT Regenerative Medicine Task Force, which includes several cardiologists representing the Cardiovascular Cell Therapy Research Network (CCTRN), is evaluating the FACT Common Standards for Cellular Therapies for applicability to cardiovascular cellular therapy. Additional specific requirements that may be required of such programs are also under consideration.

#### New Accreditation Portal to be Launched in 2018

In 2015, the FACT Technology Committee committed to replacing the FACTWeb Portal. This April, after three years, the first users logged into the new FACT Accreditation Portal. Ten different organizations were selected to serve as beta testers and complete their applications in the new portal. Feedback on the new portal has been positive, confirming increased speed and enhanced user interfaces. With a successful beta test underway, the new portal is scheduled for launch this August. Online training opportunities will be available throughout 2018. See the complete list on the [FACT Event Calendar](#).

#### **4. Are there any activities within this time period that ISCT should be aware of or take part in? Specifically, are there activities that any ISCT Committees can comment on?**

FACT invites ISCT to participate in the following:

1. Comment on the draft second edition of the *FACT Common Standards for Cellular Therapies*, which will be available in June 2018.
2. Participate in the Regenerative Medicine InterCHANGE on September 17, 2018.
3. Encourage programs in India, Latin America, Africa, and Asia to pursue FACT accreditation.
4. Promote the benefits of FACT Standards and its voluntary accreditation program for immune effector cellular therapy.

#### **5. Additional comments or feedback:**

FACT congratulates ISCT on a successful annual meeting in Montréal.