

FACT – Strategic Plan 2017-2020

Defining Objective #1: Inspections

FACT standards and accreditation have attributes that elevate them above any others in cellular therapy. Chief among those attributes is the role of volunteer professionals. FACT is of the firm belief that skilled and experienced practicing professionals are best positioned to determine standards and help peers meet those standards.

All decisions about FACT accreditation are made by committees of highly qualified volunteers, based on information that is submitted by the applicant programs and verified through periodic inspections by teams of peers. The volunteer inspectors are trained to observe and gather information that helps the accreditation committees make informed decisions. The inspectors, themselves, are not empowered to make accreditation decisions. Rather, they observe how programs and facilities compare to FACT

Standards, and report findings to an accreditation committee.

Since volunteer inspectors are a vital, distinguishing feature of FACT accreditation, the processes for identifying, recruiting, training and retaining inspectors must be excellent. Volunteer inspectors need to be not only individually qualified, but also supported by systems that assure accuracy and consistency within and among the inspector teams.

Over the years, FACT has continually improved its systems for inspector recruitment, training and administration. A strategic objective for the next several years is to take the excellence of those systems to the highest possible level.

GOAL	STRATEGY	TACTIC
The highest possible level of excellence and consistency in inspections of programs and facilities.	Create an Inspector Committee to promote quality inspections and assure an adequate core of committed inspectors.	Develop a charter that defines the duties and responsibilities of an Inspector Committee. Determine the qualifications of persons appointed to the committee, and how the Inspector Committee will relate to other committees responsible for standards and accreditation.
		Appoint a chair for the new Inspector Committee and, together with the chair, nominate committee members from among the best inspectors.
		Approve the charter, qualifications for committee members, and the chair and member appointments for the Inspector Committee.
		Provide the Inspector Committee with the many suggestions for recruitment, training, retention and performance that were offered during the Board of Directors strategic planning retreat.
		Conduct at least one focus-group interview at the BMT Tandem Meetings with inspectors to gather their opinions and ideas about recruitment, training, retention and performance.
		Submit to the Board of Directors a plan and corresponding budget for inspector recruitment, training, retaining and performance.

Defining Objective #2: Immune Effector Cells

FACT Standards for Immune Effector Cells provides minimum requirements for programs, facilities and personnel performing immune effector cell therapies that are intended to modulate immune response for therapeutic effect. The standards address collection, processing and clinical administration.

Immune effector cell therapy is an emerging field, and a demand for accreditation is anticipated over the next several years. FACT committees and staff have been forward-thinking

in moving the immune effector cell standards forward, ahead of the development of other regenerative medicine and cellular therapy standards.

The demand for immune effector cell accreditation is expected among programs that already are FACT-accredited for hematopoietic cell therapies, as well as among non-accredited programs. FACT must rapidly mobilize to accommodate the anticipated demand.

GOAL	STRATEGY	TACTIC
Rapid mobilization of an accreditation service for immune effector cell programs.	Create and implement a plan that offers and promotes an immune effector cell accreditation service.	Develop and submit to the Executive Committee a comprehensive plan for accrediting immune effector cell programs. The plan should address standards-setting and accreditation procedures, reporting relationships, inspector recruitment and training, educational resources, pricing, promotion and other pertinent issues
		Conduct training for immune effector cell inspectors adjacent to the annual meetings of the Society for Immunotherapy of Cancer (SITC), the American Society of Hematology (ASH), and the BMT Tandem Meetings.
		Develop a target market list of 20-30 non-transplant programs that are not FACT-accredited but might be expected to soon offer immune effector cell therapies.
		If the timing is right, launch a promotion of immune effector cell accreditation.

Defining Objective #3: Finances

In recent years and currently, FACT has been financially stable. Income has met operational needs and modestly added to reserves. However, future income may not cover expenses. Waiting until there is a financial crisis to re-structure

FACT finances is not a reasonable strategy. Now, while finances are stable, is the best time to develop a plan for long-range financial sustainability.

GOAL	STRATEGY	TACTIC
Sufficient financial resources to sustain operations and build reserves for the development of mission-directed products and services and for surviving an economic downturn.	Adjust accreditation fees and consider other revenue sources based on a thorough analysis of program needs for the next three years.	Re-structure or augment the Finance Committee for an analysis of FACT's resource needs for the next three years.
		Appoint a chair for the re-structured Finance Committee and, together with the chair, nominate committee members.
		Conduct a thorough analysis of FACT program needs for 2018-2020. Submit a report to the Executive Committee that includes recommendations for accreditation fees, new products and services that might be sold, and any policy changes regarding revenues from commercial organizations.
		Submit to the Board of Directors an implementation plan for revenue and expenditures, based on policies that have been approved by the Board.

Strategic Objective #4: Regenerative Medicine

GOAL	STRATEGY	TACTIC
Continued promotion of the <i>FACT Common Standards for Cellular Therapies</i> , and readiness to introduce disease- or medical specialty-specific standards when appropriate.	Achieve wide stakeholder support for standards and accreditation within the regenerative medicine community.	Continue the pilot efforts toward standards and accreditation for cardiac cellular therapies, but don't press into other diseases or medical specialties before there is evidence of a readiness for standards and accreditation.
		Submit to the Board of Directors a plan for FACT interaction and collaboration with organizations related to regenerative medicine, such as the Alliance for Regenerative Medicine (ARM), the Regenerative Medicine Foundation (RMF), the International Society for Cellular Therapy (ISCT), the Cord Blood Association (CBA) and others.
		Submit an annual report to the Board of Directors on the readiness of various diseases and medical specialties for standards and accreditation that are more specific than the <i>Common Standards</i> .
		Annually evaluate and recommend to the Board of Directors whether the timing is right for a one-day conference on voluntary standards and accreditation, sponsored by FACT in cooperation with ARM, RMF, ISCT, CBA, the International Society for Stem Cell Research (ISSCR), the California Institute for Regenerative Medicine (CIRM) and other stakeholder organizations.

Strategic Objective #5: Clinical Outcomes Improvement

GOAL	STRATEGY	TACTIC
<p>Cellular therapy programs that know how to prevent, investigate and correct deficiencies in clinical outcomes.</p>	<p>Provide education and tools to enable cell therapy programs to be prospective and predictive about clinical outcomes.</p>	<p>Submit to the Board of Directors a plan for educating cellular therapy programs about how to develop an effective corrective action program, including methods for conducting a root-cause investigation and analysis. This may include a white paper, journal article, one or more webinars, a chapter in the accreditation manual and other tactics in cooperation with the Education Committee. Include in the plan information about why denying treatment to high-risk patients is unlikely to improve SCTOD scores.</p>
		<p>Specify in the next edition of <i>FACT-JACIE International Standards for Hematopoietic Cellular Therapy Product Collection, Processing and Administration</i> a requirement that a corrective action plan must meet FACT or JACIE specifications.</p>
		<p>Submit to the Board of Directors a plan for educating cellular therapy programs about how to conduct an audit that identifies potential deficiencies that could lead to metrics that suggest a problem with clinical outcomes.</p>
		<p>Discuss with the FACT Consulting Services Board of Managers a possible role for its consultants in helping cellular therapy programs prepare corrective action plans.</p>
		<p>Collaborate with ASBMT on a strategy for educating transplant programs and clinicians about the three major causes of lower-than-expected clinical outcomes: GVHD, infection, and disease progression. Submit a plan to the Board of Directors of the two organizations for a joint educational effort that addresses the three problems.</p>

Strategic Objective #6: Standards

GOAL	STRATEGY	TACTIC
<p>Clear and user-friendly FACT standards and effective transition between editions of standards.</p>	<p>Wherever practical, FACT standards will avoid requirements that are redundant or don't necessarily affect treatment quality or patient safety.</p>	<p>Conduct and submit to the Board of Directors a comprehensive review of all FACT standards. Include in the review: improvements in the development process, harmonization, re-structuring of standards committees if appropriate, recruitment of and qualifications for standards committee members, intervals between editions, transitions between editions, and any other relevant matters for a comprehensive review.</p>
		<p>Submit to the Board of Directors a policy on interim standards including the criteria for determining the need for an interim standard, how they should be announced and publicized, and when they should take effect.</p>

		Submit to the Executive Committee a proposal to implement an electronic system to manage the standards development process, to minimize time spent on formatting documents for publication, and to effectively track, manage, and update core standards throughout all standards sets.
		Make all FACT standards as relevant and user-friendly as possible by simplifying the language, streamlining the organization, eliminating redundancies, and deleting requirements that do not necessarily enhance quality.

Strategic Objective #7: Accreditation

GOAL	STRATEGY	TACTIC
Consistency in the awarding of FACT accreditation.	Accreditation decisions will be based on consistent interpretation and application of FACT standards and policies	Provide the Inspector Committee a list of the standards for which inspector consistency is especially important.
		Publish precedent-setting interpretations of standards for the benefit of inspectors and accredited facilities via the FACT newsletter and accreditation manuals.
		Together with the Immune Effector Cell Task Force, report to the Board of Directors findings from inspections of immune effector cell programs, including any recommendations based on those findings such as interpretations of standards, supplementary information requested of programs and educational needs for applicant and accredited facilities.
		Continue to encourage inspection team members to participate in accreditation committee meetings.

Strategic Objective #8: Cord Blood Banking

GOAL	STRATEGY	TACTIC
Recognition of FACT as the premier accreditation for both public and private cord blood banks.	Promote FACT-NetCord accreditation to private banks.	Recommend to the Executive Committee a method by which cord blood banks can have official representation on the Board of Directors.
		Invite a representative group of private bankers to participate in an analysis of the current edition of <i>NetCord-FACT International Standards for Cord Blood Collection, Banking and Release for Administration</i> to provide private banking expertise and perspective to the committee. Submit a report of the analysis to the Board of Directors.
		Submit to the Board of Directors a plan for a promotional campaign that invites and encourages private or family cord blood banks to meet NetCord-FACT Standards and apply for FACT-NetCord accreditation.
		Continue to encourage inspection team members to participate in accreditation committee meetings.

Strategic Objective #9: Education

GOAL	STRATEGY	TACTIC
<p>Recognition that education is as important as standards and accreditation within FACT’s mission to promote quality in cellular therapy.</p>	<p>Enhance the visibility of FACT educational offerings.</p>	<p>Submit to the Executive Committee an evaluation of whether an app can be created with links to FACT’s online resources such as standards, announcements, newsletter, webinars, workshops, tips and other materials and information.</p>
		<p>Submit to the Executive Committee a recommendation on whether FACT should publish an annual report that is distributed to accredited facilities, third-party payers, ASBMT and ISCT members, and others to promote awareness of FACT accomplishments. If an annual report is recommended, include recommendations on content, audiences, distribution methods, cost and benefits.</p>
		<p>Submit to the Board of Directors a report on educational programs that address quality in cellular therapy services and products. Include in the report (a) an inventory of programs offered by FACT and other organizations such as ASBMT, ISCT, AABB, CBA, NetCord and similar groups, (b) a gap analysis, (c) recommended strategies for FACT educational programs and (d) ways FACT can collaborate with other organizations.</p>

Strategic Objective #10: Organizational Effectiveness

GOAL	STRATEGY	TACTIC
<p>Organizational health is one of FACT’s greatest strengths.</p>	<p>Maintain adequate skilled staff in the headquarters office to manage new and expanded responsibilities.</p>	<p>Submit to the Executive Committee a three-year staffing plan that includes job descriptions, organizational chart, succession planning for key executives, in-service training for current employees and orientation for new hires.</p>
		<p>Submit recommendations to the Board of Directors on whether performance measurements should be established for FACT committee members. The measurements might include participation in committee activities and attendance at committee meetings.</p>
		<p>Continue to strive for a committee membership turnover of about 20% per year to achieve a healthy balance between experienced members and newcomers with fresh ideas.</p>