

**FOUNDATION FOR THE ACCREDITATION
OF CELLULAR THERAPY**

**STRATEGIC PLAN
2023-2025**

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MISSION STATEMENT

Our purpose . . .

To improve the quality of cellular therapy through peer-developed standards, education, and accreditation for the benefit of patients.

VALUES STATEMENT

What we believe . . .

A voluntary organization of practicing professionals is best positioned to improve patient care and foster development of the cellular therapy field through quality standards and accreditation.

VISION STATEMENT

What we aspire to be . . .

FACT will be the premier organization setting standards and awarding accreditation to cellular therapy – a dynamic, global organization that is responsive to the evolving field and the needs of patients.

DEFINING OBJECTIVES

The Foundation for the Accreditation of Cellular Therapy (FACT) regularly adopts three-year strategic plans to advance its organizational mission in the context of the evolving field of cellular therapy. On the heels of a worldwide pandemic and in anticipation of a burgeoning list of advanced therapies, this strategic plan for 2023-2025 is intended to strengthen and streamline FACT's infrastructure to support the health care system's ability to offer quality cellular therapy to all patients who could benefit from it.

Following an extensive organizational assessment performed by an external global strategy consulting firm, the FACT Board of Directors held a strategic planning retreat to review the results, evaluate current programs and accomplishments, and prioritize growth opportunities. The result is this strategic plan that includes defining objectives, goals, strategies, and tactics. Responsible committees and staff are assigned timeframes for moving tactics forward to accomplish the defining objectives.

The defining objectives are interdependent and critical to effectively conduct ongoing mission-driven activities. Accomplishing each of these is necessary to perform excellent standards, accreditation, and education services within the next wave of advancements in cellular therapy. The defining objectives are:

Defining Objective #1: INFRASTRUCTURE

Establish an organizational structure sufficient to meet the growing demand for FACT services.

FACT must evolve alongside the field in order to continue fulfilling its mission in the new cellular therapy landscape. There are new stakeholders with different needs and expectations, including additional medical specialties and the pharmaceutical and biotechnology industry. FACT will need to adjust its operating model in order to better serve these markets, while prioritizing the ability of health care institutions to provide cellular therapy in the context of growing regulatory and operational requirements. As the continuum of care becomes increasingly complex and industry stakeholders play a greater role in cellular therapies, there are new potential sources of quality failure.

Defining Objective #2: ACCREDITATION PROCESS

Streamline the FACT accreditation process to increase efficiencies for accredited organizations, volunteer inspectors, and FACT staff.

Accredited organizations and inspectors are satisfied overall with the FACT accreditation process. They identified pain points in the process that, if alleviated, would result in more efficient completion of initial and renewal accreditation, improved retention of inspectors and staff, and enhanced ability to meet the growing demand in number and variety of cellular therapy programs.

Accredited organizations note challenges with the pace and clarity of accreditation requirements, including completion of the compliance application, uploading documents, responding to deficiencies, and overall use of the accreditation portal. Potential solutions include upgraded portal functionality,

assistance with document organization, education regarding the FACT Standards, and quality management templates.

Inspectors understand the value of accreditation, especially to their individual programs. The high demand on these experts as part of their professional careers limits the time they are able to volunteer to prepare for, perform, and report on FACT inspections. Receiving professional time, rather than using personal time off, could increase the number of inspections they can perform. Inspectors also noted the accreditation portal as a pain point, and are interested in ways to streamline the inspection checklists.

A key interdependency of the tactics within this overall strategic plan is the impact they will have on FACT accreditation staff. Clarification and documentation of job roles and responsibilities can help to quickly address a subset of challenges. Improvements made to the accreditation portal will also greatly improve the efficiency of internal FACT processes. Responsibilities related to the accreditation process and growth opportunities need to be monitored to ensure sustainability in the future state.

Defining Objective #3: GROWTH

Implement growth opportunities to advance the FACT mission in the evolving field of cellular therapy.

As the field of cellular therapy expands, there are two major areas of rapid evolution: 1) new indications for cellular therapies that involve an increasing number of medical specialties and a wider variety of health care facilities and 2) a rise in regulatory approved investigational or commercially licensed cellular therapy products manufactured by biotechnology or pharmaceutical companies, or by investigators at sites distant from the intended recipient's treatment.

These additional complexities create greater risks to patient safety and product efficacy, making FACT accreditation even more important for establishing and maintaining quality programs. FACT has also been recognized as a potential contributor to solving significant challenges affecting patient access. Prioritized growth opportunities include auditing services, new program-start up, and modular accreditation.

FACT already has the expertise that makes addition of auditing services a natural extension of its core competency. FACT-performed audits on behalf of industry or accredited programs could reduce the burden on facilities by reducing the number of visits from external parties.

FACT could also leverage its deep expertise to develop a product inclusive of training materials, protocols, and infrastructure requirements to sell to persons and facilities eager to enter the cellular therapy market. The addition of this off-the-shelf offering would reduce burden on FACT's consulting services. Because this would be a purchased product, it is best positioned under FACT Consulting Services to prevent perceived conflicts of interest for programs ultimately applying for accreditation.

The variety of cellular therapies entering the market requires modular accreditation for various functions that industry intends to decentralize to promote patient access. This includes surgical collection of tissue as starting material (e.g., tumors), mobile collection sites, and storage facilities. FACT can leverage its

existing mechanisms for independent accreditation and non-fixed collection sites by evaluating requirements for decentralized sites.

GOALS, STRATEGIES, AND TACTICS

Goals, strategies, and tactics are outlined for each defining objective. There are closely linked interdependencies across multiple strategies. The completion of some tactics is dependent on the completion of other tactics.

The Strategic Planning Administrator will evaluate progress on the strategic plan quarterly, and a quarterly dashboard will be provided to the Board of Directors. If a prerequisite tactic has not been completed, there may be necessary adjustments to the target dates of subsequent tactics. Such adjustments will be reported to the Board.

High-Priority Goals

All of the strategies outlined in this plan are important to fulfilling the FACT mission in the changing landscape of cellular therapy. To effectively implement the plan, the completion dates for tactics have been organized around goals with the highest chronological priorities. These priorities relate to organizational development, and achieving them will dictate the success of all the other goals, strategies, and tactics:

- Create funding mechanisms to invest in additional staffing and initiatives.
- Develop a staffing model that will create a leadership infrastructure, strengthen core services, and support growth initiatives.
- Establish systems to allow FACT Accreditation Services personnel to perform their job duties effectively.

Outline of Goals and Strategies

The following is an outline of goals and strategies for the defining objectives. Subsequent pages list the specific tactics for each.

Defining Objective One: Establish an organizational structure sufficient to meet the growing demand for FACT services.

- *Goal:* Create funding mechanisms to invest in additional staffing and initiatives to support the FACT mission. (High Priority)
Strategy: Obtain contributions and grants from industry partners, governmental agencies, and private foundations.
- *Goal:* Develop a staffing model that will create a leadership infrastructure, strengthen core services, and support growth initiatives. (High Priority)
Strategy: Redesign the FACT organizational structure.
- *Goal:* Implement a succession plan to protect the continuity of FACT services.
Strategy: Identify and groom potential successors for high priority roles.

Defining Objective Two: Streamline the FACT accreditation process to increase efficiencies for accredited organizations, volunteer inspectors, and FACT staff.

- *Goal:* Establish systems to allow FACT Accreditation Services personnel to perform their job duties effectively. (High Priority)
Strategy: Improve and streamline the functionality of the accreditation portal and the staffing model.
- *Goal:* Streamline the accreditation process to reduce the time required of organizations to achieve initial or renewal accreditation.
Strategy: Mitigate pain points identified by organizations.
- *Goal:* Create an environment for performing inspections that reduces the personal time volunteered by inspectors.
Strategies: Streamline inspector-related processes and persuade hospital administrations to allow inspectors professional time to perform FACT inspections.

Defining Objective Three: Implement growth opportunities to advance the FACT mission in the evolving field of cellular therapy.

- *Goal:* Optimize patient care and access to cellular therapy by providing an unbiased, unified auditing system applicable to quality, operational, and regulatory requirements of any stakeholder.
Strategy: Develop an auditing service that can be coordinated with accreditation services and confirm compliance with industry and regulatory requirements.
- *Goal:* Provide a solution for rapid creation of new cellular therapy programs to meet patient demand.
Strategy: Create a New Program Start-Up product to sell to healthcare institutions or professional medical groups.
- *Goal:* Award accreditation for emerging infrastructures intended to decentralize cellular therapy functions.
Strategy: Develop a modular approach to accreditation.

COMMITTEE AND TASK FORCE CHARGES

In addition to strategic assignments, the FACT Board of Directors delegates the conduct of regular business to nine standing committees, seven special committees, and three task forces. Each reports directly to the Board. The charges and related objectives of each are critical to the core business of FACT standards setting, accreditation, and education.

Standing Committees

Executive Committee	The Executive Committee manages the policies and business affairs of FACT, acting on behalf of the Board of Directors when the Board is not in session. The Executive Committee may exercise the full authority of the Board, except it may not (1) amend the Bylaws, (2) elect officers, or (3) adopt the annual budget. The Board of Directors can modify or rescind any action of the Executive Committee.
Cellular Therapy Accreditation Committee	The Cellular Therapy Accreditation Committee maintains oversight of cell therapy program accreditation. It reviews on-site inspection reports in a timely, fair, and consistent manner, and provides recommendations to the FACT Board of Directors regarding applicant program accreditation status.
Cord Blood Bank Accreditation Committee	The Cord Blood Bank Accreditation Committee maintains oversight of cord blood bank accreditation. It reviews on-site inspection reports in a timely, fair, and consistent manner and provides recommendations to the FACT Board of Directors regarding applicant bank accreditation status.
Education Committee	The Education Committee creates, manages, and evaluates education programs that help FACT achieve its mission to improve the quality of cellular therapy through peer-developed standards, education, and accreditation. The committee and its staff serve as a resource for other FACT committees that have constituent education needs.
Standards Committee	The Standards Committee drafts standards and guidance for Common Standards for Cellular Therapies, Hematopoietic Cellular Therapy Standards, Immune Effector Cell Standards, and Cord Blood Standards.
Grievance Committee	The Grievance Committee receives, reviews, and attempts resolution of any challenge to the impartiality, professionalism, or ethical conduct of

	FACT officers, members of the Board of Directors, committee members, and staff.
Leadership and Nominations Committee	The Leadership and Nominations Committee ensures strong, capable, and sustained leadership for FACT, and nominates candidates for office and for membership on the Board of Directors.
Finance Committee	The Finance Committee oversees the fiscal affairs of FACT, assures that there is sufficient capital and resources for operations, develops and administers an investment policy, and reviews internal and external financial audits.
Audit Committee	The Audit Committee reviews the annual financial audit conducted by an outside accounting firm and forwards it to the Board of Directors for approval. [Currently the Finance Committee is acting as the Audit Committee.]

Special Committees

Clinical Outcomes Improvement Committee	The Clinical Outcomes Improvement Committee assists hematopoietic progenitor cell transplant programs with improving patient outcomes by providing resources, creating tools, and reviewing corrective action plans.
FACT-CIBMTR Data Audit Committee	In collaboration with CIBMTR, the FACT-CIBMTR Data Audit Committee evaluates transplant centers' management of the accuracy of data submitted to a national or international database for programs seeking or maintaining FACT accreditation.
Global Affairs Committee <i>Working groups:</i> <ul style="list-style-type: none"> • India Working Group • FACT-JACIE Stepwise Accreditation Task Force • FACT-SBTMO (Brazil) Working Group • China Working Group (TBD) 	The Global Affairs Committee improves the worldwide quality of cellular therapy, including transplant, cord blood banking, and regenerative medicine, through international cooperation and promotion of standards, accreditation, and education. Special emphasis is given to transplant programs in developing countries.
Inspector Development Committee	The Inspector Development Committee promotes the highest level of excellence and consistency in inspections and ensures an adequate core of committed inspectors.
Technology Committee	The Technology Committee enhances, refines, streamlines, and improves the efficiency of the accreditation process and educational programs through the continued development of FACT's information technology systems and website.

Professional Relations Committee

The Professional Relations Committee facilitates communications and cooperation among cellular therapy organizations and encourages timely reports by liaisons to and from the organizations they represent.

Quality Management Committee

The Quality Management Committee develops and administers programs that maintain high quality in FACT operations and in accredited programs.

Task Forces

Immune Effector Cell Task Force

The Immune Effector Cellular Therapy Task Force develops and promotes standards and accreditation for immune effector cellular therapy.

Regenerative Medicine Task Force

The Regenerative Medicine Task Force develops and promotes standards and accreditation for non-HPC cellular therapies.

New Business Development Task Force

The New Business Development Task Force evaluates revenue-generating commercial activities that are fully aligned to the fulfillment of FACT's mission.
