

## ABOUT PROVISIONAL ACCREDITATION



### **What is FACT's provisional clinical accreditation?**

A pathway for new cellular therapy programs that haven't yet treated the minimum number of patients for full accreditation.

- Demonstrates compliance with all FACT Standards except for those regarding patient volume and provider experience.
- Intended to increase access to safe, high-quality cellular therapies closer to where patients live and work.
- Once minimum patient numbers are met, programs can pursue full accreditation.



### **Why does FACT offer provisional accreditation?**

To help new programs safely provide cellular therapies while addressing real-world barriers.

- Helps programs overcome the "minimum patient conundrum," especially in community or non-academic settings.
- Reduces financial risk related to treating the minimum patient numbers without guaranteed reimbursement.
- Signals to payers and stakeholders that the program has the necessary training, infrastructure, and quality systems.



### **How are provisionally accredited programs recognized?**

Programs are listed publicly and receive a certificate indicating provisional status.

- Included on FACT's website listing of accredited programs with provisional designation.
- Certificate specifies which services are provisionally accredited.
- Organizations should clearly communicate provisional status to payers and stakeholders.



### **How does provisional accreditation address minimum patient requirements?**

Allows new programs to demonstrate readiness before reaching patient volume thresholds.

- FACT minimum patient volumes ensure experience, competence, and sufficient patient records for inspection.
- Typical minimums: 5 autologous or IEC patients; 10 allogeneic transplant patients.
- Provisional accreditation helps community-based programs start safely without the initial financial burden.



### **Is provisional accreditation as rigorous as full accreditation?**

Yes, the process is equally thorough.

- Same review, reporting, inspection, and correction processes as full accreditation.
- Compliance with all FACT Standards is required, except patient volume and provider experience.
- Inspections verify:
  - Quality management program
  - Personnel education and training
  - Infrastructure for patient care and product handling
  - Patient care guidelines and informed consent
  - Data management

## ABOUT PROVISIONAL ACCREDITATION (CONT.)



### How is provisional accreditation different from full accreditation?

Main differences relate to patient volume, provider experience, and quality implementation.

- Programs have not yet treated minimum patients and/or providers may not meet experience requirements.
- Patient records are not inspected until full accreditation.
- Some quality management activities (audits, improvement projects) may not be fully implemented.
- Provisional accreditation is non-renewable; it's a temporary pathway to full accreditation.

## APPLYING, MAINTAINING, AND ADVANCING ACCREDITATION



### Who is eligible?

New programs planning autologous cellular therapy that haven't treated minimum patient numbers.

- Includes programs and contracted entities providing collection or processing services.
- Requests must be submitted in writing to FACT Headquarters.
- Programs confident they will reach minimum numbers within a year may pursue full accreditation instead.
- Contact FACT: 1-402-920-7001 | [fact@factglobal.org](mailto:fact@factglobal.org)



### How long does provisional accreditation last? What are the requirements?

Provisional accreditation is valid for 3 years and is non-renewable.

- Programs must treat minimum patient numbers before applying for full accreditation (usually ~12 months before provisional expiration).
- Annual report required to demonstrate ongoing compliance and update patient numbers.



### How does a program transition to full accreditation?

After treating minimum patient numbers, the program can apply for full accreditation.

- Transition can occur 6 months after provisional accreditation or at the 2nd anniversary.
- Full accreditation follows standard renewal process:
  - New Compliance Application
  - On-site inspection
  - Correction of deficiencies
- Programs must continue to meet minimum patient #'s annually within the 3-year cycle.
- Each organization is eligible for only one provisional accreditation.