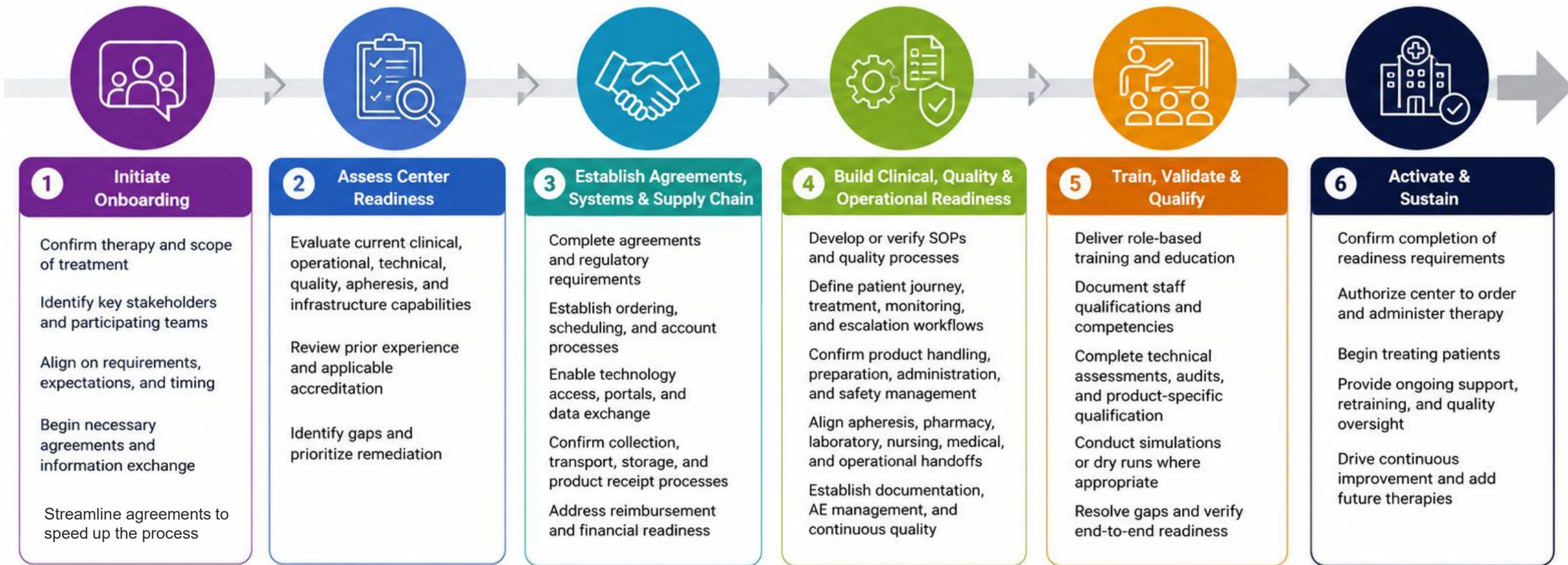


The Cell Therapy Treatment-Center Onboarding Journey

A common path to center readiness across manufacturers and therapies

While each manufacturer and therapy has unique requirements, treatment centers move through a largely common journey to become ready to deliver cell therapy safely and effectively.



MULTIPLE FUNCTIONS. ONE JOURNEY. Manufacturers engage cross-functional teams across medical, operations, quality, pharmacy, apheresis, supply chain, finance, IT, and more—working in parallel to achieve a common goal: safe, high-quality patient care.



● Start the Journey ● Understand & Plan ● Build the Foundation ● Prepare & Align ● Validate Readiness ● Go Live & Grow



➤ Each stage can be explored in more detail on the following slides

Common Cell Therapy Treatment-Center Onboarding Journey (Time-Agnostic Model)

Major workstreams progress in parallel as centers advance through a common readiness and activation journey



This model shows how common workstreams overlap and progress in parallel across the onboarding journey. The duration of each stage and workstream will vary based on therapy, manufacturer, center readiness, existing infrastructure, regulatory environment, and local processes.

LEGEND

- Primary focus
- Continued as needed



THE GOAL

A treatment-ready center delivering safe, high-quality cell therapy to more patients

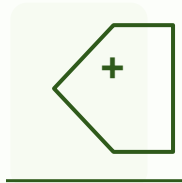
Most Treatment Center Onboarding Is Shared Across Cell Therapies

Build the universal foundation once. Then add what is unique to each manufacturer or therapy.



THE SHARED FOUNDATION

Common capabilities required for all cell therapy programs



Facility & Operational Readiness

Infrastructure, equipment, and processes in place



Staff Training & Qualifications

Trained, competent staff and role clarity



Pharmacy, Lab & Storage

Compounding, testing, and secure storage



Quality, Safety & Compliance

Policies, SOPs, risk management, and readiness



Technology & Data Systems

Systems, data exchange, security, and reporting



Financial & Reimbursement

Payer needs, coding, authorization, and payment, Cost to serve



This foundation is reused for every cell therapy program. It saves time, cost, and resources.



THE UNIQUE LAYER

Product- and manufacturer-specific requirements



Product Handling & Storage

Specific handling, storage, and administration requirements



Logistics, Packaging & Shipping

Shipping requirements, temperature controls, packaging requirements and kitting, and storage parameters



Ordering Systems & Portals

Manufacturer portals, ordering processes, and scheduling tools



Product-Specific Training

Training content and competencies unique to the product



Contracts & Manufacturer Setup

Contracts, terms, account setup, and program enrollment



Once the foundation is in place, onboarding new therapies becomes faster and more efficient.

Build strong. Build once. Build for the future.



STAGE 1: INITIATE ONBOARDING

Establish the foundation for a successful partnership by aligning on purpose, scope, key contacts, and initial requirements to launch the onboarding process.



KEY ACTIVITIES IN THIS STAGE

1. Align on Purpose & Scope - Confirm intent to partner and treat patients - Define initial scope of services and therapies - Discuss patient populations and volume expectations - Clarify shared goals and success criteria	2. Identify Key Contacts & Governance - Exchange primary points of contact - Identify decision makers and champions - Establish communication channels - Define initial governance and escalation path	3. Share Initial Information - Provide overview of therapies and program requirements - Share overview of center capabilities and services - Exchange initial forms and documentation - Review confidentiality and data sharing expectations
4. Align on Timing & Milestones - Discuss desired target activation window - Agree on preliminary timeline and key milestones - Confirm resource commitments and availability - Establish cadence for follow-up and next steps	5. Understand Initial Requirements - Review high-level program and operational expectations - Identify critical capabilities and prerequisites - Discuss payer and reimbursement considerations - Clarify information that will be needed in Stage 2	6. Launch the Onboarding Process - Confirm intent and mutual commitment - Open onboarding case or engagement - Document agreed-upon next steps and owners - Schedule kickoff for Stage 2 activities



OUTPUT OF THIS STAGE

A strong foundation and mutual alignment to begin assessing center readiness.



Confirmed intent, scope, and goals for partnership



Key contacts and governance structure established



Initial information exchanged and documentation collected



Preliminary timeline and milestones agreed upon



Understanding of initial requirements and expectations



Onboarding case opened and next steps confirmed



KEY STAKEHOLDERS INVOLVED

Center leadership, program management, nursing, pharmacy, lab, apheresis (if applicable), quality, finance/reimbursement, IT, operations, and patient access teams.



FOCUS

Build alignment, establish relationships, and set the foundation to move efficiently into readiness assessment.

STAGE 2: ASSESS CENTER READINESS

Evaluate the center's existing capabilities across the key domains required to safely and effectively deliver cell therapy and identify any gaps requiring action.



READINESS DOMAINS TO EVALUATE

1. Clinical Capabilities - Multidisciplinary team expertise (hematology/oncology, nursing, pharmacy, etc.) - Patient evaluation and eligibility assessment - Treatment administration and monitoring - Toxicity management and emergency response (e.g., CRS/ICANS) - Access to critical care and consulting specialties	2. Apheresis & Collection (where applicable) - Apheresis equipment and capacity - Qualified staff and training - Donor/patient eligibility and screening processes - Collection protocols and documentation - Facility space and patient flow	3. Pharmacy, Laboratory & Storage - Receiving and chain of custody capabilities - Cryostorage capacity and temperature monitoring - Compounding/handling readiness - Laboratory testing and support services - Inventory management and product tracking
4. Quality & Regulatory - Quality management system and governance - Accreditation status and compliance requirements - Standard operating procedures (SOPs) and documentation practices - Change control and deviation management - Regulatory, safety, and reporting requirements	5. Operational & Technology - Staffing model and role definitions - Scheduling, bed availability, and capacity management - IT systems and EHR readiness - Data exchange and interoperability - Manufacturer portals and system access - Cybersecurity and data privacy readiness	6. Access & Financial Readiness - Payer mix and contract coverage - Prior authorization and utilization management processes - Coding, billing, and claims infrastructure - Patient financial assistance processes - Revenue cycle and reimbursement readiness



OUTPUT OF THIS STAGE

A clear understanding of the center's current state to guide planning and remediation.



Documented baseline of existing capabilities across key domains



Identified gaps, risks, and readiness limitations



Prioritized remediation needs and required resources



Readiness action plan with timelines and accountabilities



Alignment on next steps to establish agreements, systems, and supply chain



KEY STAKEHOLDERS INVOLVED

Center leadership, clinical and nursing leadership, pharmacy, laboratory, quality, IT, operations, finance/reimbursement, apheresis (if applicable), and patient access teams.



FOCUS

Understand current capabilities, confirm what is in place, and identify what is needed to be ready for cell therapy.

STAGE 3: ESTABLISH AGREEMENTS, SYSTEMS & SUPPLY CHAIN

Put in place the agreements, systems, and supply chain infrastructure needed to support safe and reliable cell therapy delivery.



KEY ACTIVITIES IN THIS STAGE

1. Execute Agreements & Contracts - Review and execute legal agreements and contracts - Confirm terms, pricing, and service commitments - Establish data use, privacy, and compliance agreements - Document roles and responsibilities	2. Set Up Systems & Access - Create accounts in manufacturer portals and ordering systems - Establish system access and user roles - Enable data exchange and interoperability - Confirm EHR and technology integrations	3. Establish Supply Chain & Logistics - Confirm collection and shipping processes - Establish courier and transportation partners - Define packaging, labeling, and documentation requirements - Confirm turnaround time expectations and tracking
4. Plan Inventory & Product Management - Define inventory management processes - Confirm product ordering procedures - Establish storage and handling requirements - Validate traceability and lot management processes	5. Confirm Financial & Reimbursement Systems - Validate billing and coding requirements - Confirm payer authorizations and approval pathways - Establish financial assistance pathways - Align on payment terms and processes	6. Finalize Documentation & Policies - Establish document management and retention processes - Review and align on required forms and templates - Define escalation and issue resolution process - Confirm compliance with regulatory and accreditation requirements



OUTPUT OF THIS STAGE

All agreements, systems, and supply chain components are in place and operational to support readiness and activation.



Executed agreements and contracts in place



Systems, portals, and user access established



Supply chain and logistics processes defined and confirmed



Inventory and storage processes established



Financial, billing, and reimbursement systems aligned



Policies, documentation, and escalation processes finalized



KEY STAKEHOLDERS INVOLVED

Legal, contracts, IT, supply chain/logistics, pharmacy, finance/reimbursement, quality/compliance, operations, laboratory, and program management.



FOCUS

Put in place the foundational infrastructure, systems, and agreements that enable safe, compliant, and efficient treatment center operations.

STAGE 4: BUILD CLINICAL, QUALITY & OPERATIONAL READINESS

Prepare people, processes, facilities, and quality systems to deliver cell therapy safely, consistently, and in compliance with standards.



KEY ACTIVITIES IN THIS STAGE

1. Prepare People & Teams - Define roles and responsibilities - Confirm staffing and coverage - Build multidisciplinary team collaboration - Assess competency needs - Plan ongoing education and development	2. Build Clinical Processes & Workflows - Develop patient pathway and workflows - Establish admission and scheduling processes - Define order sets and protocols - Establish escalation and after-hours processes - Integrate with specialty services	3. Strengthen Quality & Compliance - Implement quality management system and governance - Confirm accreditation and regulatory compliance - Develop policies and standard operating procedures - Establish adverse event reporting and CAPA process
4. Prepare Facilities & Infrastructure - Ensure space and environmental requirements - Confirm clean room and engineering controls - Set up equipment and technology - Verify emergency equipment and crash cart readiness - Ensure IT and network readiness	5. Ready Support Services & Ancillary Functions - Align pharmacy preparation processes - Confirm lab testing and result turnaround - Validate blood bank and transfusion support - Coordinate with apheresis (where applicable) - Confirm nutrition, social work, and supportive care resources	6. Validate Documentation & Data Readiness - Finalize clinical documentation and forms - Configure EHR documentation and templates - Define data capture and reporting requirements - Test data exchange and system integrations - Ensure privacy, security, and audit readiness



OUTPUT OF THIS STAGE

Clinical, quality, and operational infrastructure and processes are established and validated to support safe and compliant cell therapy delivery.



Multidisciplinary team roles, staffing, and competencies defined



Clinical workflows, protocols, and escalation processes in place



Quality system and policies implemented



Facilities and infrastructure ready and validated



Pharmacy, lab, and support services aligned and prepared



Documentation, data systems, and reporting configured



KEY STAKEHOLDERS INVOLVED

Clinical leadership, nursing, pharmacy, laboratory, quality, IT, operations, facilities, blood bank, apheresis (if applicable), compliance, and support services.



FOCUS

Build and validate the systems, processes, infrastructure, and quality foundation needed to deliver cell therapy safely and consistently.

STAGE 5: TRAIN, VALIDATE & QUALIFY

Ensure people, processes, and systems are trained, validated, and qualified to perform safely and consistently according to required standards.



KEY ACTIVITIES IN THIS STAGE

1. Develop Training Plans & Materials - Define required training for all roles - Align training content with manufacturer and regulatory requirements - Develop materials and job aids - Plan training delivery method and schedule	2. Train People & Assess Competency - Deliver role-based training - Provide product- and process-specific training - Assess knowledge and skills - Document training completion and competency	3. Validate Processes & Systems - Validate clinical workflows and protocols - Validate information systems and data capture - Perform test transactions and end-to-end process checks - Document validation results
4. Qualify Equipment & Facilities - Verify equipment installation and configuration - Conduct operational qualification and performance checks - Confirm facility readiness - Document qualification results and approvals	5. Qualify Center & Obtain Approvals - Perform internal readiness assessment - Complete required self-assessments - Submit documentation for manufacturer review - Address questions and provide additional evidence - Obtain formal center qualification and approval	6. Finalize Go-Live Readiness - Confirm all training, validation, and qualification complete - Verify all corrective actions are resolved - Confirm go-live plan and communication - Obtain go-live clearance and authorization



OUTPUT OF THIS STAGE

People, processes, and systems are trained, validated, and qualified to deliver cell therapy safely and in compliance.



All required training completed and competencies documented



Processes and systems validated and performing as intended



Equipment and facilities qualified and approved



Center qualification completed and approval received



Go-live readiness confirmed and authorization granted



Center approved and ready to activate



KEY STAKEHOLDERS INVOLVED

Education & training, clinical leadership, nursing, pharmacy, quality, IT, operations, compliance, facilities, and manufacturer training teams.



FOCUS

Build capability, confirm performance, and demonstrate that the center meets all requirements to safely and effectively deliver cell therapy.

STAGE 6: ACTIVATE & SUSTAIN

Go live with confidence, deliver successfully, and continuously improve to sustain long-term performance and patient impact.



KEY ACTIVITIES IN THIS STAGE

 1. Go Live & Deliver Patient Care - Launch patient services and treatment delivery - Monitor initial cases and patient experience - Ensure real-time problem solving and support - Communicate early wins and lessons learned	 2. Monitor Performance & Outcomes - Track clinical, operational, and patient outcomes - Monitor KPIs and service levels - Use data to identify issues and opportunities - Report performance to stakeholders	 3. Sustain Communication & Engagement - Maintain regular communication with all stakeholders - Share updates, insights, and evolving requirements - Strengthen relationships and partnerships - Address questions and emerging needs proactively
 4. Drive Continuous Improvement - Review processes and outcomes regularly - Identify improvement opportunities and root causes - Implement corrective and preventive actions - Standardize best practices and innovations	 5. Expand Capability & Capacity - Onboard additional services, therapies, or sites - Scale capacity and resources as needed - Update systems, processes, and training - Integrate new capabilities seamlessly	 6. Ensure Compliance & Readiness - Maintain accreditation and regulatory compliance - Conduct audits and internal reviews - Update documentation and policies - Ensure ongoing readiness for inspections and growth



OUTPUT OF THIS STAGE

Sustained performance, continuous improvement, and long-term value delivery for patients and the center.



Successful go-live and consistent patient care delivery



Performance monitored and outcomes reported



Strong stakeholder engagement and communication



Continuous improvement process in place



Capability and capacity scaled for future needs



Compliance maintained and readiness sustained



KEY STAKEHOLDERS INVOLVED

Center leadership, clinical and nursing teams, pharmacy, laboratory, quality, IT, operations, finance/reimbursement, marketing, patients, and ongoing support partners.



FOCUS

Deliver excellent patient care, achieve and sustain performance, and continuously improve to create long-term impact and growth.