

Sarah Cannon's Approach to Offering CAR T Therapy in the Community Setting

Disclosure Information

***I have no financial
relationships to disclose***

Agenda

- Overview of HCA Healthcare
- Overview of Sarah Cannon Transplant and Cellular Therapy Network
- Our Experience with CAR T-cell Therapy
- Our Approach to offering CAR T-cell Therapy Safely

Who is HCA Healthcare



HCA Healthcare Statistics

280,000 colleagues

185 Hospitals

2,000+ sites of care

21 states and the **United Kingdom**

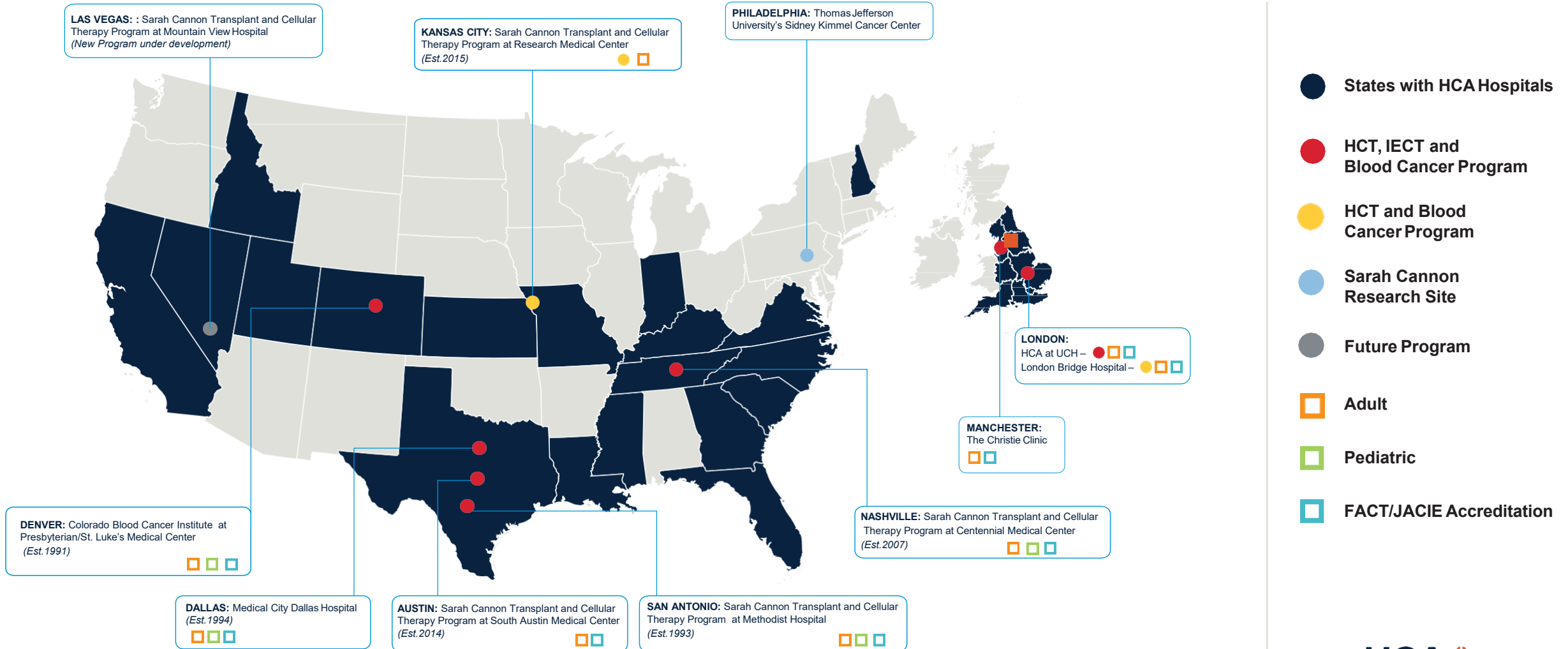
35 million patient encounters annually

2 million inpatient admissions annually

9.4 million outpatient & ASC visits annually

1.6+ million cancer patient encounters annually

Sarah Cannon Transplant & Cellular Therapy Network



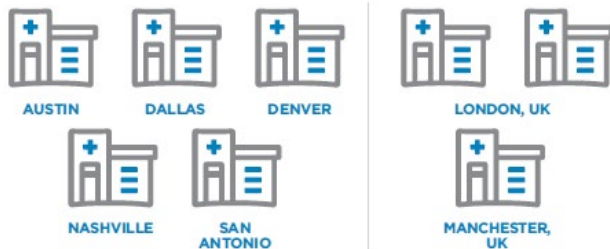
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Sarah Cannon Transplant & Cellular Therapy Network

The Largest Network Providing Transplant and Cellular Therapies

FACT/JACIE Accredited
Hematopoietic Cell
Transplant (HCT) Programs
Across
the U.S. and UK

8



HCTs performed since inception

15,000+



~1,200

HCTs performed each year

1 Comprehensive Network Approach for Patient Care:

- Quality Plan
- Patient Management Technology Platform
- HCT & IECT Patient Eligibility Criteria
- HCT & IECT MD & APP Practicing Privileges
- Standardized Nursing Education
- HCT Clinical Pathways
- HCT & IECT Policies and Procedures
- Corporate-level Vendor/Pharma contracting
- Centralized Payer contracting
- Network HCT/IECT Travel Nurse Program

Immune Effector Cell Therapy Experience

Studies open in:

- DLBCL
- Mantle Cell Lymphoma
- Indolent Non-Hodgkin Lymphoma
- Multiple Myeloma
- Sickle Cell Disease
- B-Cell Non-Hodgkin Lymphoma
- ALL
- CLL/SLL
- AML/MDS
- Sarcoma
- Melanoma
- Non-Small Cell Lung Cancer

Our Presence at ASH 2020

- 53 Abstracts and Presentations
- 21 Oral Presentations

Our Presence at TCT 2021

- 19 Abstracts and Presentations

50+

Immune Effector Cell Therapy
studies
Activated since Dec 2015



300 +

patients who have
received FDA-approved or
research CAR T-Cell
therapy to date

Immune Cell Therapy Committees

- Coordination and standardization of research processes across centers for both blood cancer and solid tumor indications
- Local committees comprised of site transplant, nursing, research staff and physicians meet monthly at each center
- Local committees report to Sarah Cannon Immune Effector Cell Therapy leadership monthly



Commercial CAR T-Cell Therapy

- SC executes Corporate-level Agreements with Pharma
- SC partners with Pharma to streamline the process across the Network

Products Available

- Novartis: DLBCL and P-ALL
- Kite: DLBCL , MCL & FL
- BMS: In process of offering DLBCL & MM
- J&J/Janssen: Working towards offering their MM product when it becomes FDA approved

SCTCTN Requirements To Offer IECT

- ❑ Implementation of SCBCN SOPs to meet Immune Effector Cell Therapy FACT Standards
- ❑ Implementation of SCBCN Annual Competencies for MDs and APPs
- ❑ Implemented local IECT Committee Structure
- ❑ Participate on SCBCN Monthly IECT Committee
- ❑ Adoption of SCTCT Network’s CAR T-cell Patient Eligibility Criteria and Process
- ❑ Appropriate number of staff to handle the complexity of CAR T patients including IECT/HCT Physicians, IECT Coordinators, Research staff, BMT and ICU nursing staff, Oncology Pharm D.
- ❑ All physician specialties involved in the care of CAR T patients have been identified and appropriately trained
- ❑ Full adoption of all 3 modules of StafaCT software by Physicians and Staff
- ❑ Completion of IECT Readiness Assessment by members of the SCBCN team



IECT Program Development Checklist

SARAH CANNON The Cancer Institute of HCA Healthcare				
17	Make the competency completed			
18	Whereas the competency completed			
19	On the competency completed			
20	On the competency completed			

SARAH CANNON The Cancer Institute of HCA Healthcare				
CAR T-Cell Readiness Checklist				
#	Check Item	Complete	Responsible	Notes/Remarks
1	Local IECT Committee formed and active			Review attendance and minutes
2	Physician qualified team education			SBCCN IECT physician training date min
3	Updated SOPs and IECT language updated			SBCCN SOP Template
4	IECT & HCT Facility Management SOP updated			
5	Develop CAR T-Cell Research, clinical & treatment process/algorithm			
6	Develop Immune Cell Test reference & acceptance process/algorithm			
7	Procedure for steps in CAR T-Cell Research process and personnel responsible for each step			
8	Procedure for steps in Commercial CAR T-Cell process and personnel responsible for each step			
9	Develop local patient and cell workflow (SOPs)			
10	Addressed staff training (Research & Commercial)			
11	Staff Learning (Research & Commercial)			
12	Staff Infection Control Training			
13	Staff Home and Clinic Pharmacy Training including OIG identification & Management Agreement to Test?			
14	Commercial CAR T-Cell consent form approved by IRB?			
15	Physician & APP competencies complete			
16	Research kit competency complete			

Patient Eligibility Form

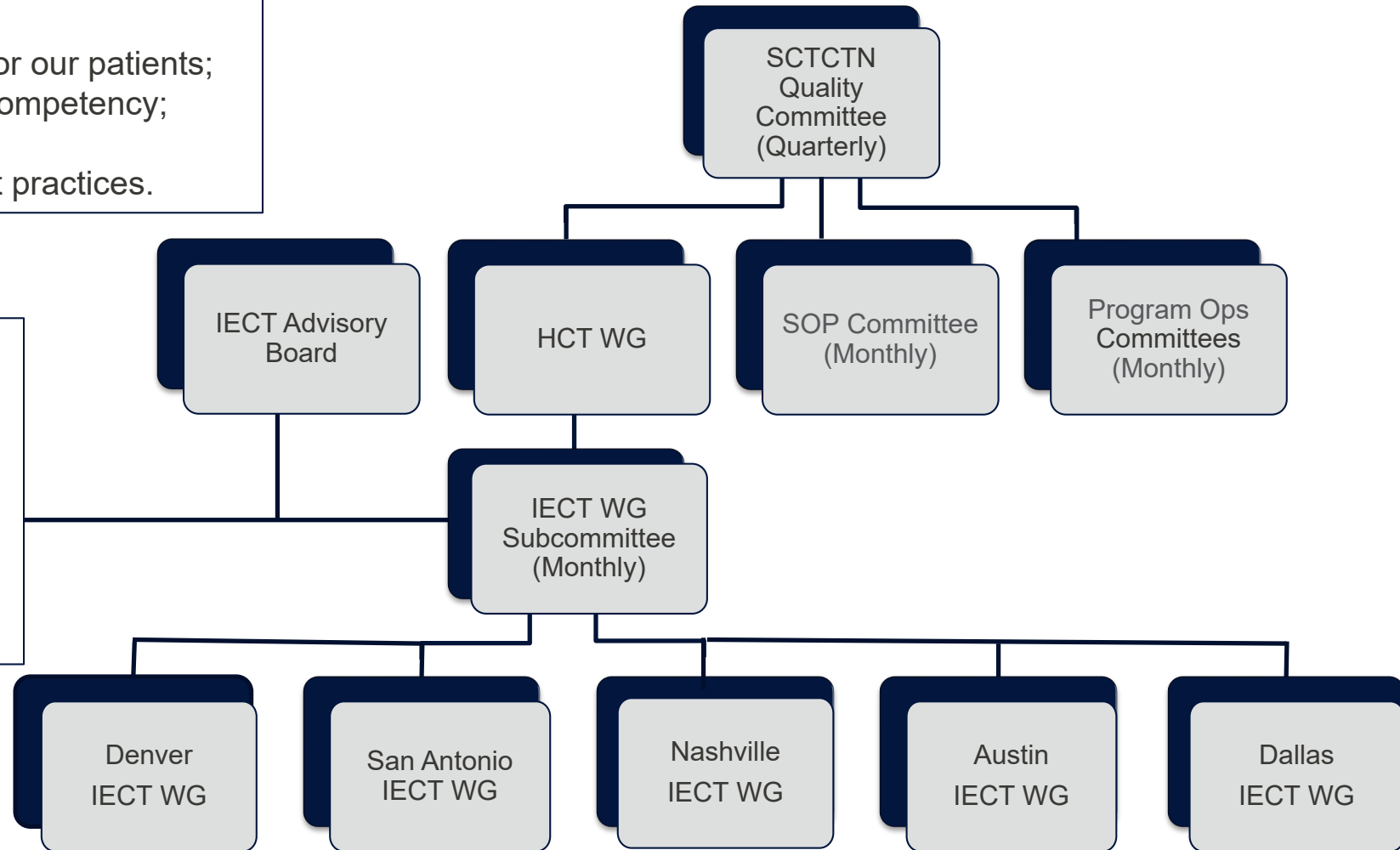
Immune Effector Cell Therapy Committee Structure

Committee Goals

- Ensure safety, consistency and quality for our patients;
- Demonstrate Network capabilities and competency;
- Improve patient outcomes;
- Share lessons learned and develop best practices.

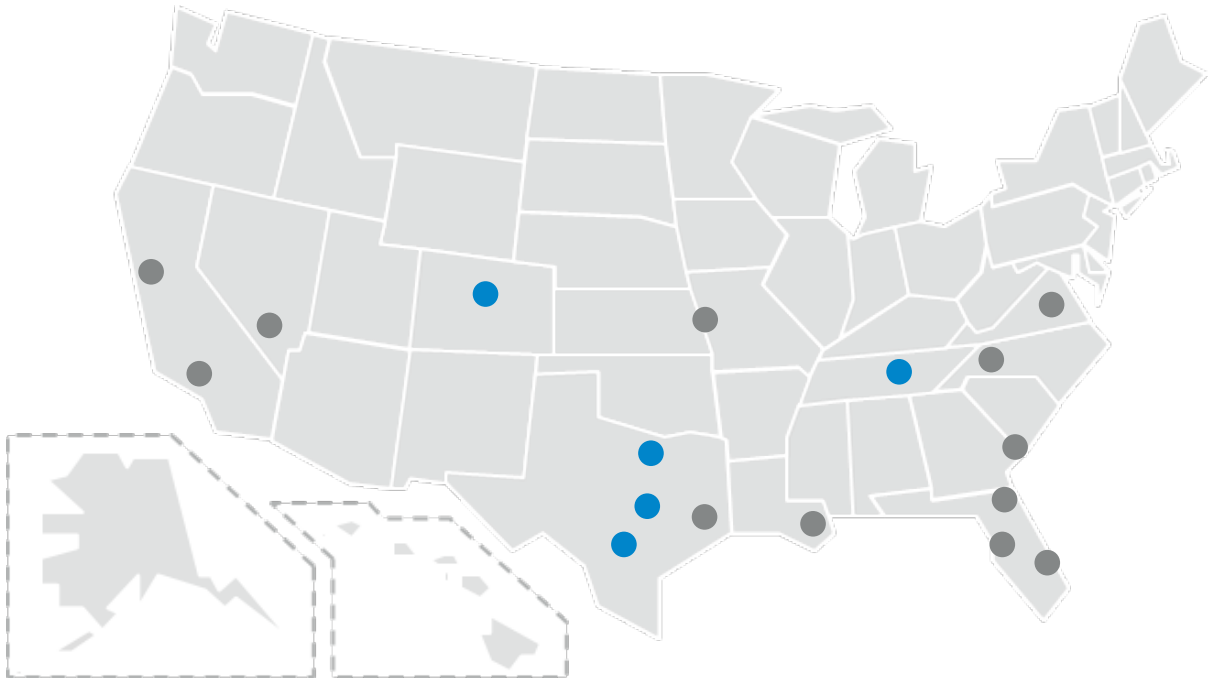
IECT Subcommittee Members

- Fred LeMaistre, MD
- Carlos Bachier, MD
- Peter McSweeney, MD
- Aravind Ramakrishnan, MD
- Paul Shaughnessy, MD
- Vikas Bhushan, MD
- Program Administrators
- SC Support Team



Expanded Access to IECT Is Needed

Patients receive CAR T treatment at SC's five FACT-accredited IECT¹ centers -- 12 additional centers anticipated



- Sarah Cannon IECT Center
- Future Sarah Cannon IECT Center

SC employs a robust, structured process to qualify IECT centers for CAR T therapy administration

IECT Center Site Requirements

- Implement SOPs to meet Immune Effector Cell Therapy FACT Standards
- Implement SCBCN Annual Competencies for MDs and APPs
- Implement local IECT Committee Structure
- Participate in SCBCN IECT Committee
- Staff appropriate volume of HCPs and support (e.g., coordinators, nurses, oncologists, etc.) to support complexity of CAR T patients
- Administer appropriate training to all physician specialties involved in CAR T patient care
- Adopt all modules of StafaCT and provide necessary training to physicians and staff
- Ensure completion of the IECT Assessment across relevant staff

Site Checklist

1) IECT Centers – A Sarah Cannon / HCA facility with current or planned cellular therapy infusion and care capabilities

Barriers and Risks to Expansion

Maintain Patient Safety and Regulatory Compliance, While Increasing Timely Patient Access To Therapy

Healthcare Delivery Infrastructure

- IECT experienced Physician
- Resource-intensive process to become certified and maintain certification with Pharma. (REMS training)
- Committed consulting physicians, such as Neurologists
- Long-term patient monitoring/follow up
- Local Hospital with appropriate infrastructure to support patients
- Collection services
- Maintaining staff competencies

Therapy Delivery Economics

- Government Reimbursement Issues
- Managed Care single-case agreements can delay timelines
- Individualized authorization process
- Experienced individuals to manage CAR T-cell global case rates
- Lack of predictability of cost due to patient's health condition and variability in cost of product

Supply Chain Process

- Coordination of manufacturing and patient treatment timelines
- Lengthy manufacturing time
- Product may not meet FDA specifications for release

Thank You



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