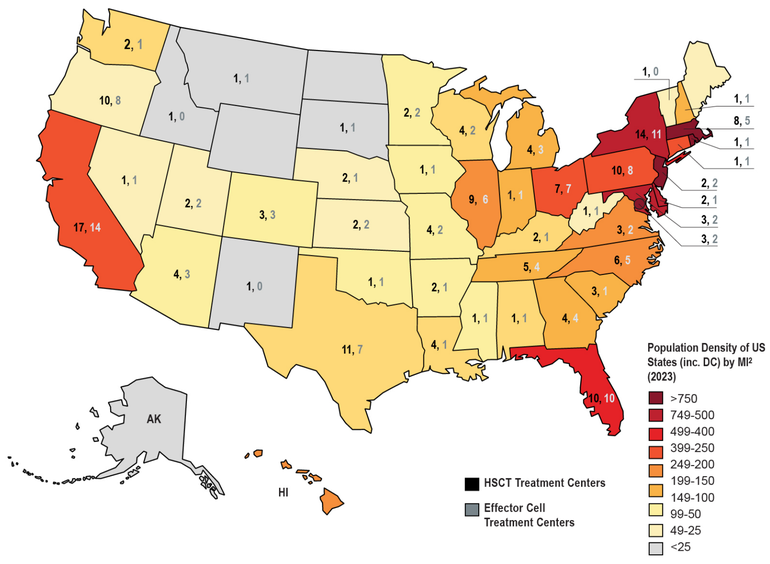
Community Blood Banks as Access Levers for CGT Delivery

Becky Cap [1], Vivienne Marshall, PhD [2], Adrienne Mendoza [2], Emmanuel Casasola[1]
And Rachel Beddard M.D.[1]

[1] BioBridge Global, San Antonio, TX
[2] South Texas Blood & Tissue a subsidiary of BioBridge Global, San Antonio, TX

Distribution of US Treatment Centers



Background

Currently, CAR-T therapy is primarily delivered in a subset of treatment hospitals with specialized infrastructure. Of the 6,129 hospitals in the US, 72 have attained NCI Cancer Center designation. Of those:

- 11 Cancer Centers, recognized for scientific leadership, resources, and depth / breadth of research
- 54 Comprehensive Cancer Centers also bring a substantial transdisciplinary approach to research
- 7 Basic Laboratory Cancer Centers primarily focused on lab research and preclinical translation

For clinical translation, FACT accreditation has become a critical qualification hallmark. Today there are 172 FACT-accredited HSCT treatment centers and 130 FACT-accredited immune effector cell therapy treatment centers.

Current Treatment Rates

	Revenue (E)	Estimated Treatment Population
2022	$2.5B ($2.2-$2.8B)	6,400
2023	$4B ($3.8-4.2B)	10,000

Using an average cost estimate of $400,000 per patient treatment, 2022 and 2023 revenue estimates suggest a maximum treated population of 10,000 total patients in the current system.

Treatment Supply Potential

	FACT-accredited facilities	Monthly capacity	Annual capacity	Modeled capacity	Theoretical maximum treatment volume
HSCT	172	6	12,384	20	41,280
Immune effector cell	130	6	9,360	20	31,200

Anticipated Treatment Demand

Demand for treatment, especially as therapies move into earlier lines, is already outstripped based on current facility qualification norms. US 2023 estimated ***incident*** population for targeted indications:

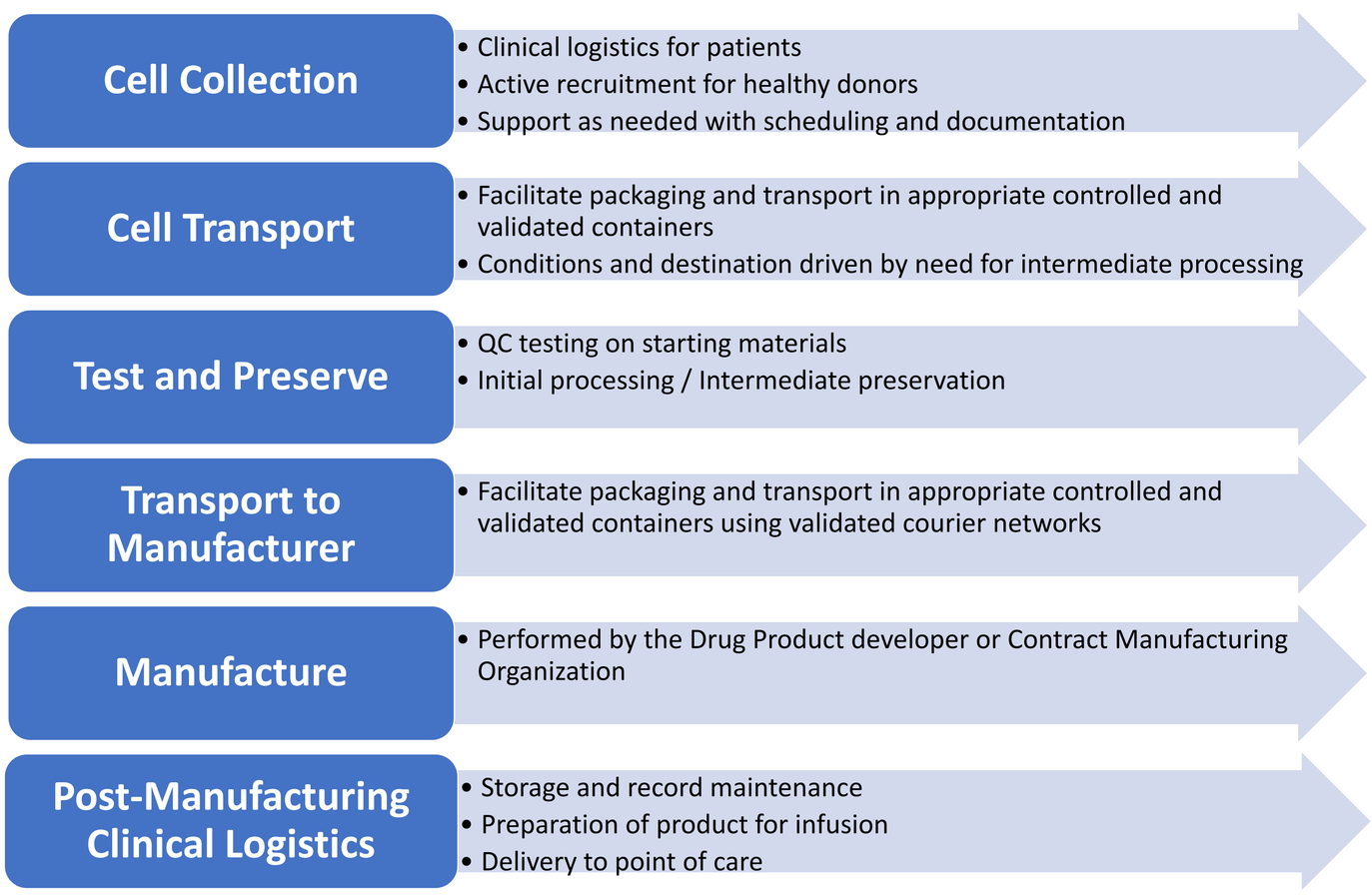
- 59,610 leukemia patients
- 89,380 lymphoma patients
- 35,730 multiple myeloma patients

As survival rates and times increase, the prevalent population is growing for all conditions. Further expansion of the target population will occur as indications are added for other liquid tumors, solid tumors, and non-oncologic conditions.

Discussion

Effective supply chain management relies on optimizing each unit operation, then successfully stitching it together. Challenges to the system are many—including trained physician capacity. Logistical barriers to care, however, can be addressed by positioning treatment preparation activities closer to the patient *and* outside the hospital. A hybrid solution incorporating some critical elements of decentralized manufacturing is likely to be the most effective – balancing regional or centralized control of manufacturing with optimal use of local or decentralized networks for services where expertise already exists.

- Community blood banks developed to ensure access to our earliest cellular therapy–blood.
- Highly regulated organizations with robust quality management systems
- Operate 24/7 with employees are accustomed to managing OSHA risks working with blood products and the impact of human error on themselves and the patient
- Business model relies on donors and hospital relationships, consents and qualifications, and appropriate contracts



Conclusion:

Including blood banks in this supply chain will improve product quality through more timely processing of starting materials and preparation for delivery to the patient. A lower burden on hospitals and manufacturers enables extending therapy to more patients in broader geographic areas, allowing hospitals to focus on delivery of care.