

BACKGROUND

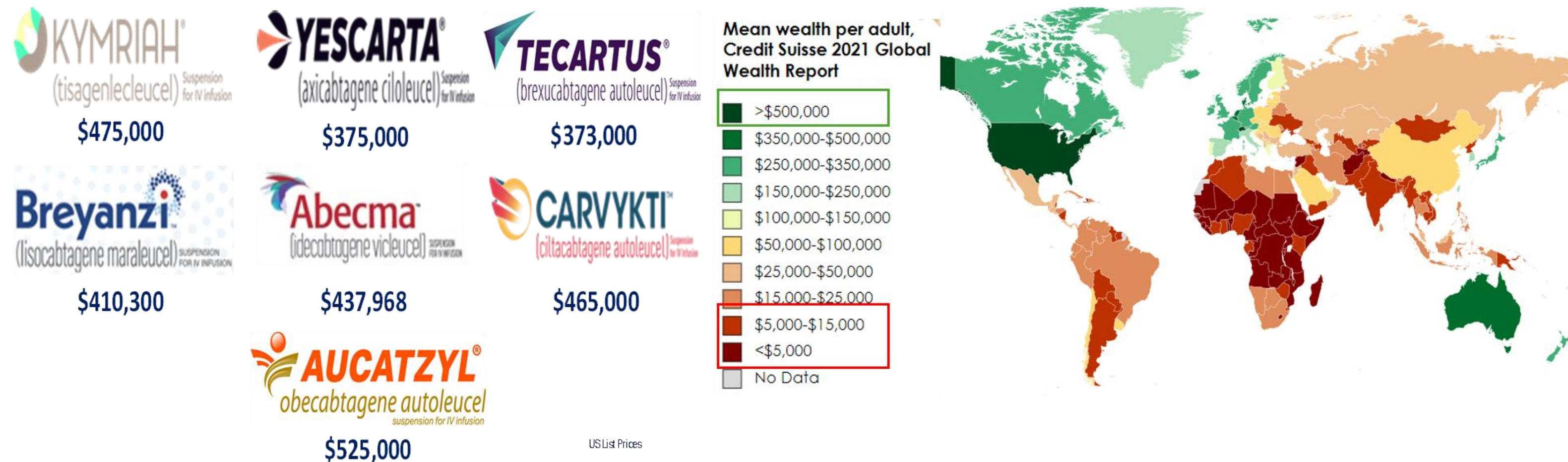
Talicabtagene autoleucel (Tali-cel) is India's first indigenous, affordable and humanized anti-CD19 CAR-T cell therapy.

Commercial authorization was granted by CDSCO (Indian regulatory agency) in October 2023 for relapsed/refractory (r/r) B-cell malignancies.

Barriers to access CAR-T cell therapy in LMICs

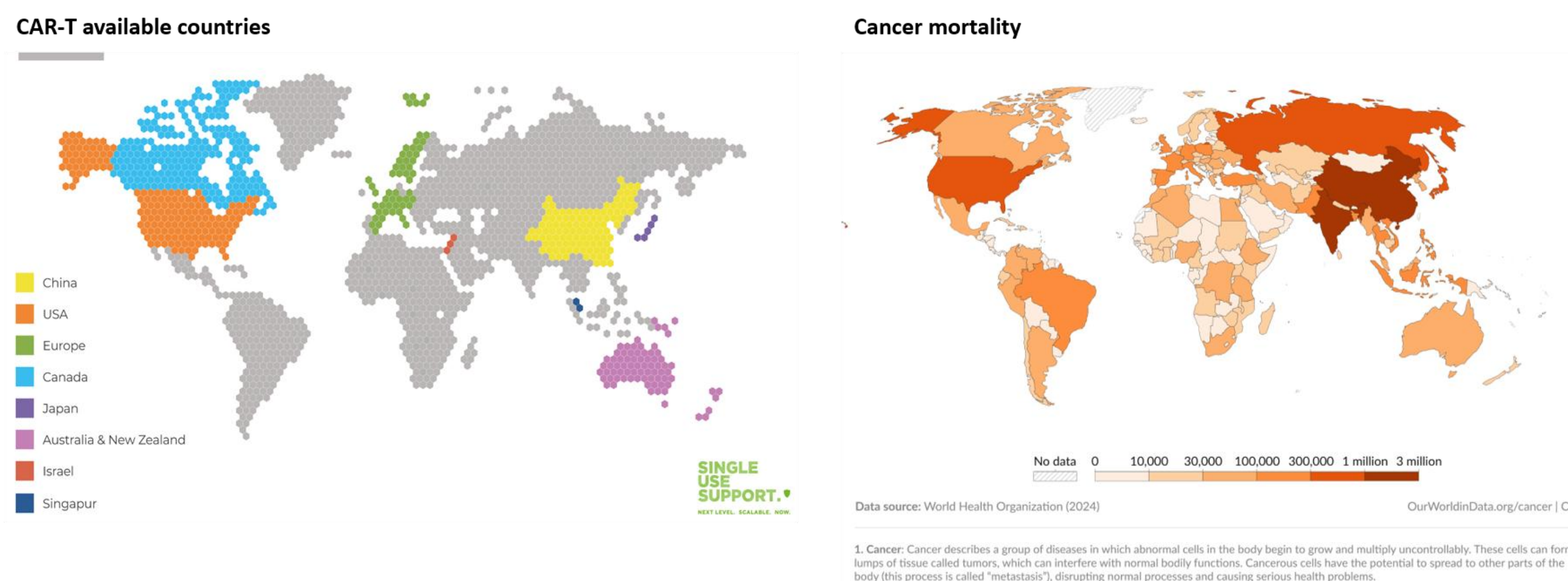
Financial burden and affordability gap

- Exorbitant drug costs
- Lack of income and insurance coverage



Geographic Disparity in LMICs

- Unavailability of CAR-T cell therapy as well as other curative strategies²
- 70% of global cancer deaths in LMICs^{3,4}



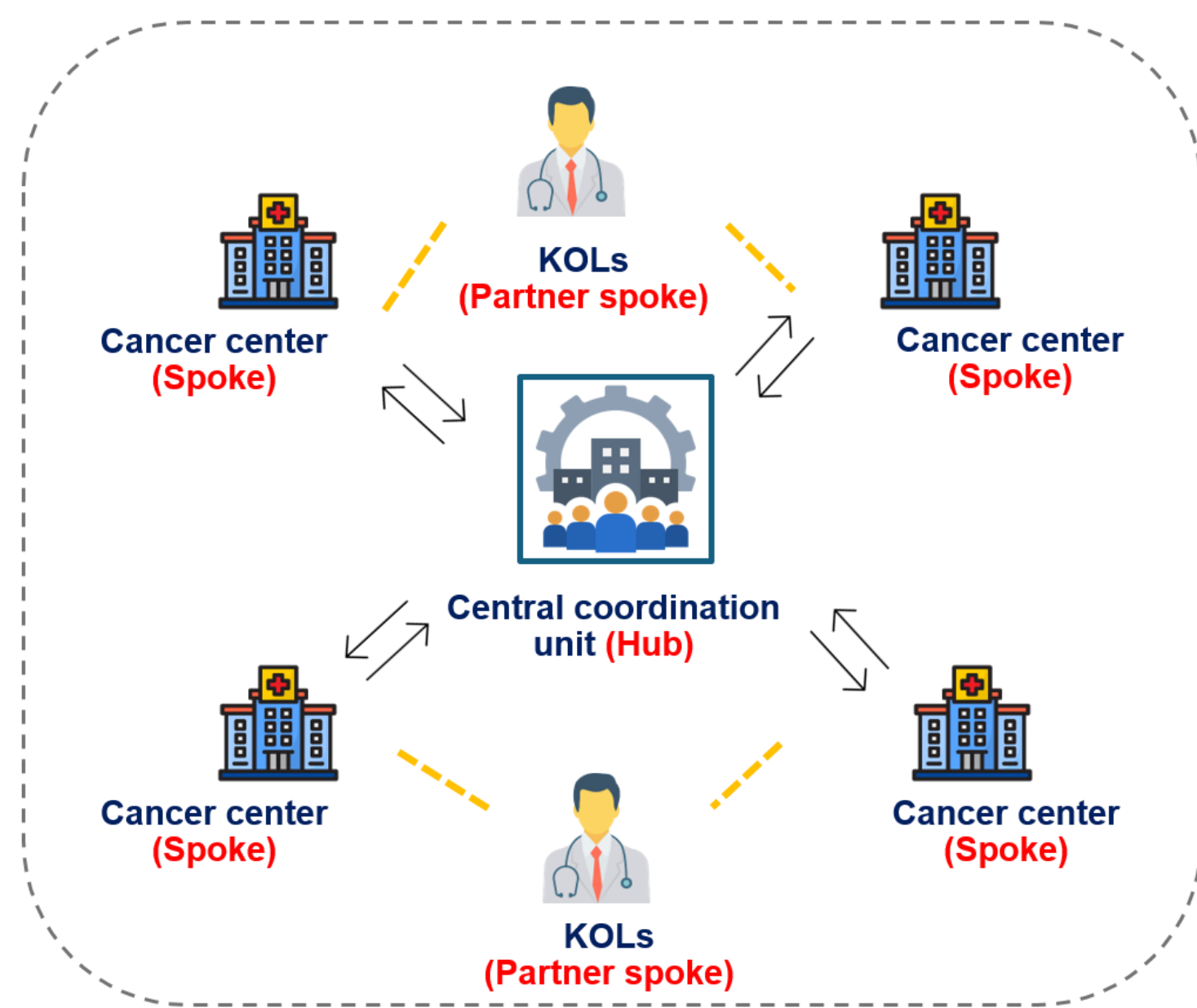
OBJECTIVES

To evaluate the real-world feasibility, access, efficacy, and safety of Tali-cel for relapsed/refractory (r/r) B-cell malignancies.

To develop a sustainable and efficient system for delivering CAR-T therapy in India, especially in limited resource settings.

METHODS

Elements of equitable access model – orchestrated Hub and Spoke model



Hubs: GMP units + CART manufacturing

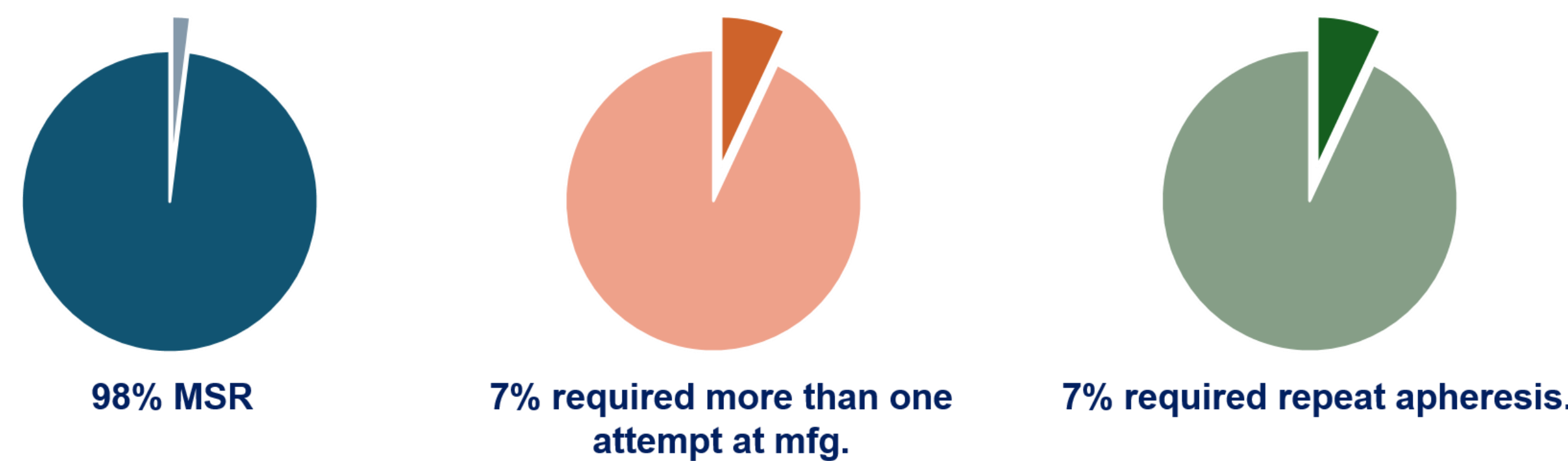
Spokes: Centers for diagnosis, follow-up and monitoring

Central Co-ordination Units fort slot allocation, quality assurance and pharmacovigilance

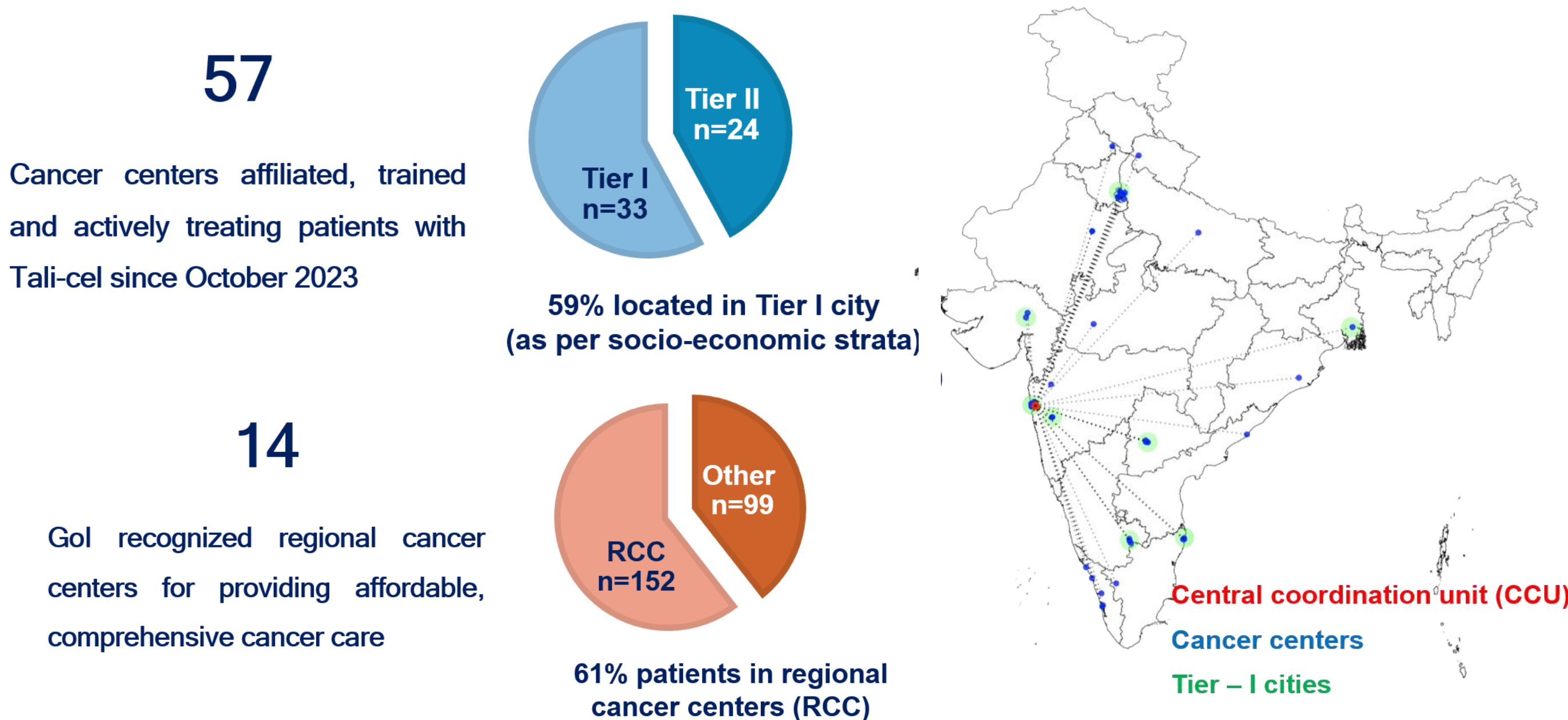
RESULTS

Equitable access model supports centralized manufacturing

- Equitable access model allowed for failure-free logistics independent of tier status
- Overall Manufacturing success rate(MSR) – 98%
- Centralized manufacturing supports better resource management, process control and product quality and can lower manufacturing costs

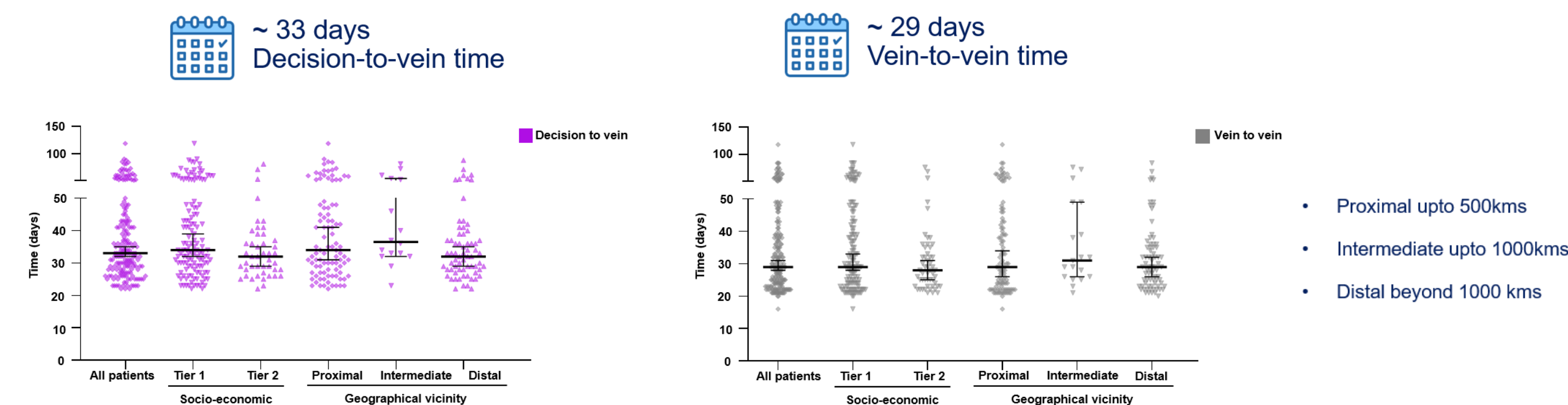


Affiliation and accreditation across diverse geography

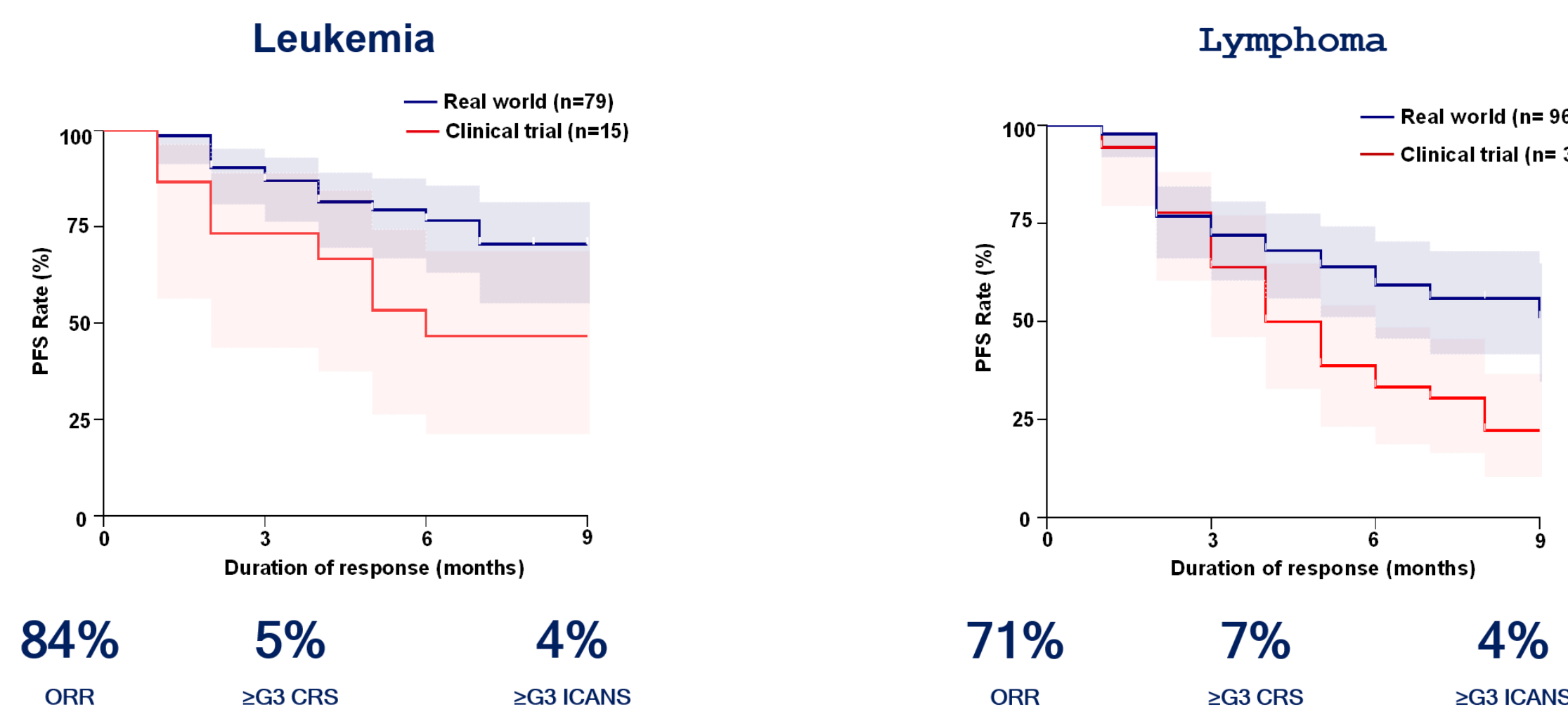


Accessibility of CAR-T cells in timely manner to all

- Equitable access model allowed for access to CAR-T independent of tier status and geographical vicinity to the manufacturing site



Tali-cel – Efficacious and safe as standard of care in real world



Easy to deliver as outpatient like standard of care in real world

Regionally decentralized manufacturing to reach larger masses

Lymphoma

7 days, median hospitalization

7% ICU admission rate

15 days, median ICU stay

Leukemia

12 days, median hospitalization

5% ICU admission rate

4 days, median ICU stay

Current GMP facility

Capacity : 480 patients

Utilization : 400 patients

>80% capacity utilization within two years of market approval

New GMP facility

Capacity : >3000 patients

Utilization : for accessible and affordable CAR-T cell therapy in India and other LMICs

CONCLUSION

- Talicabtagene autoleucel shows favorable balance of efficacy to toxicity.
- Talicabtagene autoleucel is easy to deliver with limited resources in outpatient-like settings
- Equitable access model developed
 - allows access across Tier-I and Tier-II cities.
 - allows access across diverse geographies independent of vicinity to manufacturing site.
 - allows timely delivery to the patients across various large and small cancer centres.

REFERENCES

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