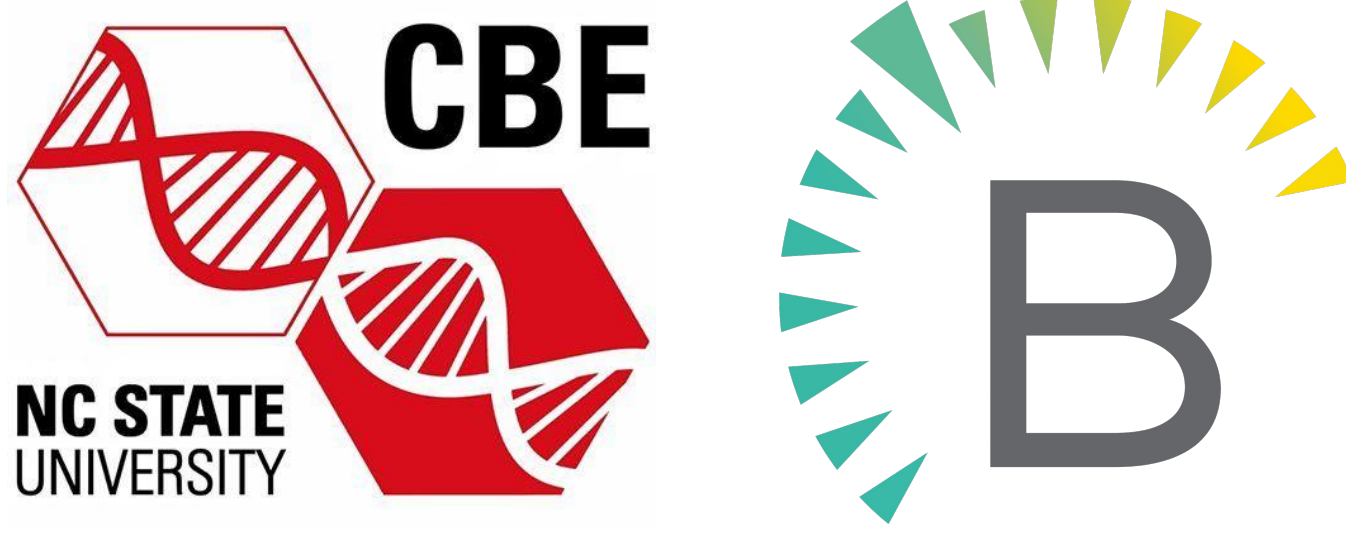


Commercial Autologous Cell Therapy Cleanroom Facility Design



Naomi Bouedo, Zac Gill, Claire Hodges, Duaa Jalal, Lauren Kielty, Jayde Markley
Mentors: Mike Perkins & Meghan Howard – Beam Therapeutics



Purpose

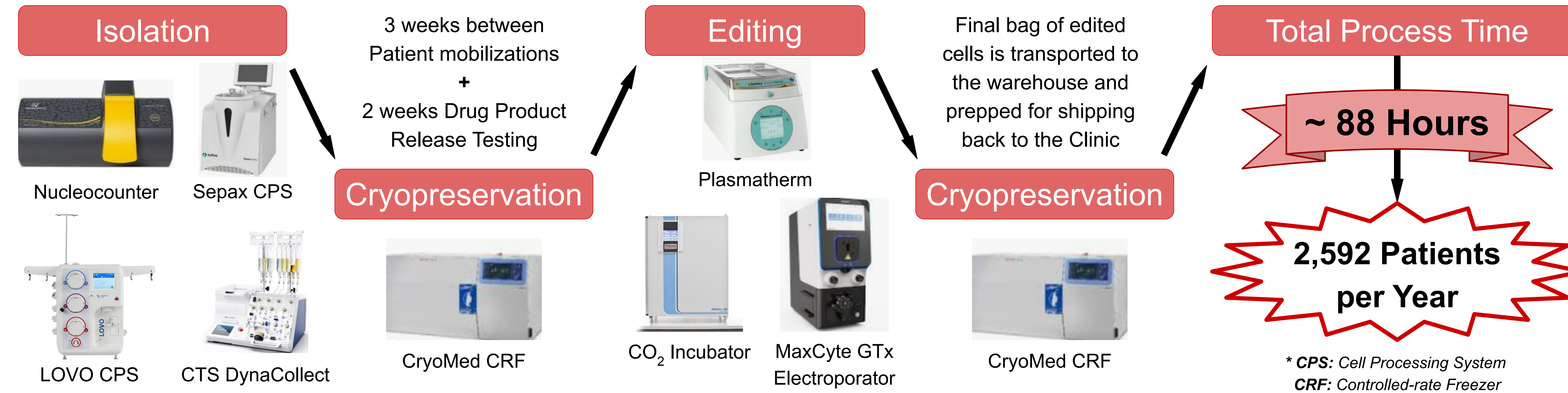
Global Significance:

- Sickle cell disease affects 20 million patients worldwide with 100,000 patients located in the United States.
- The final cell product is a risky but life-altering treatment.
- Facility accessibility determines how many patients can receive treatment.

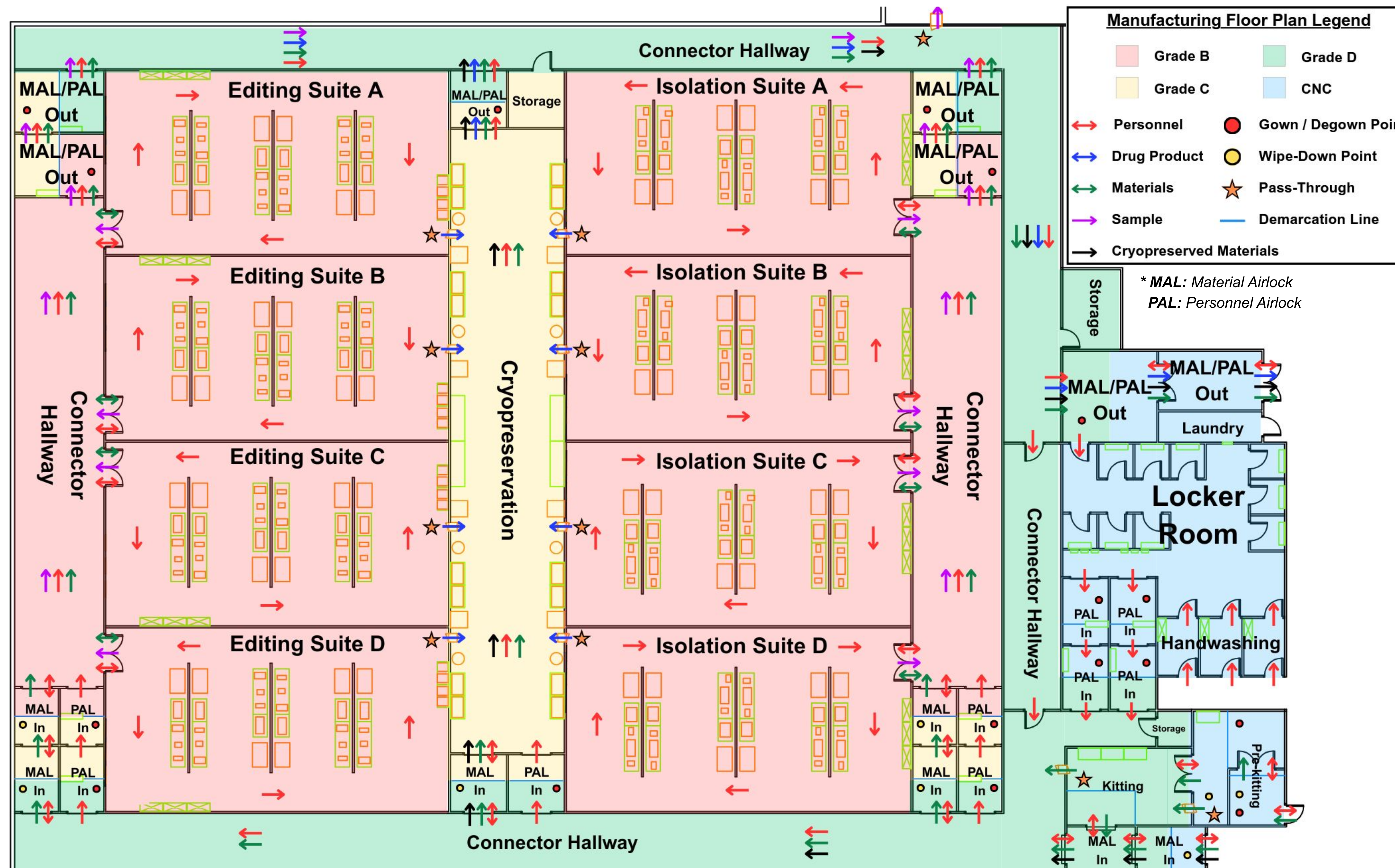
Challenges of this Project:

- A commercial-scale autologous facility presently does not exist.
- Autologous processes have stringent regulatory requirements.
- Balancing increasing capacity with cost-effectiveness and regulatory compliance is essential.

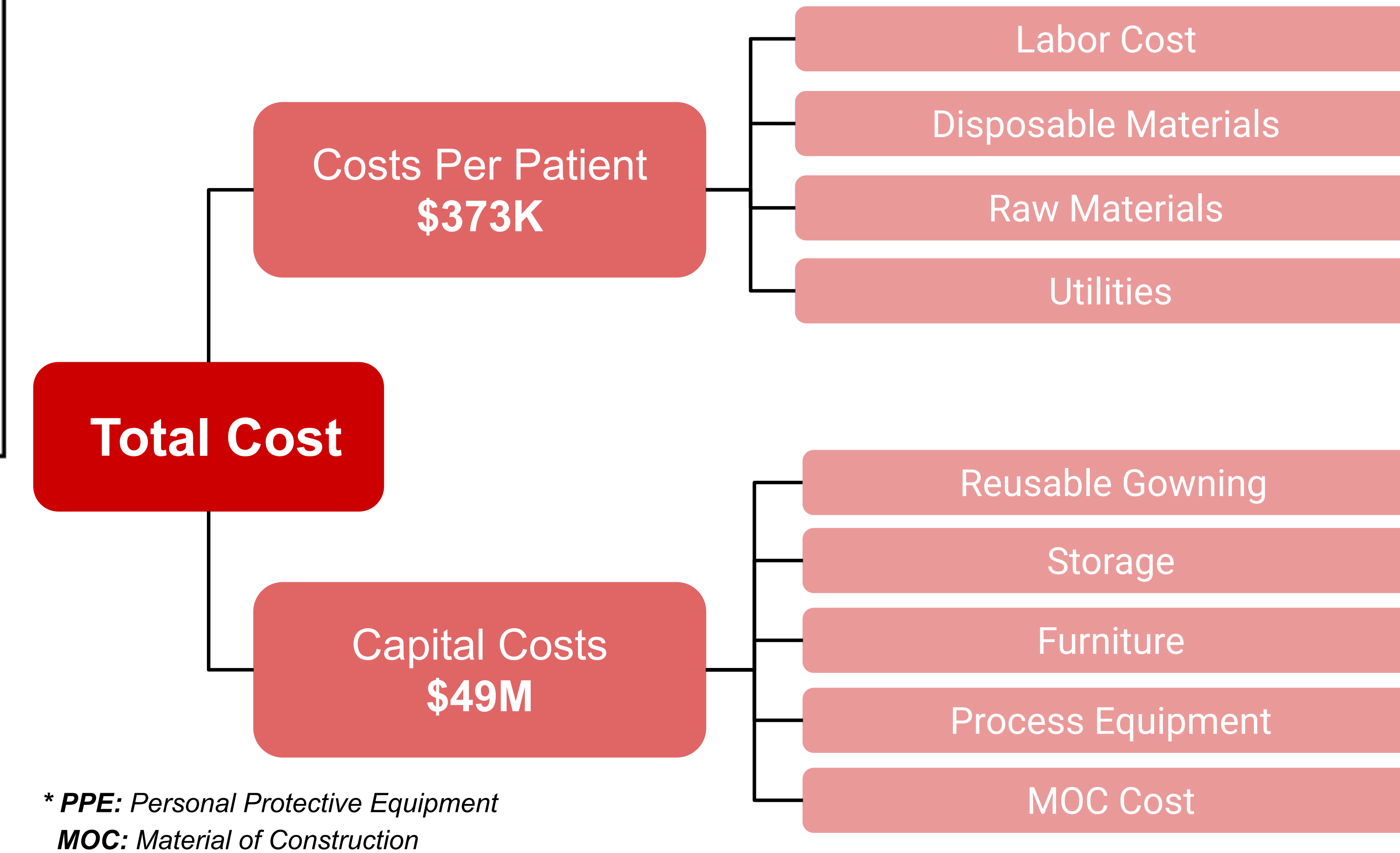
General Process Information



Traditional Floor Plan



Financial Analysis



Innovative Design

The innovative floor plan aimed to maximize the Patient throughput while considering the regulations, time, and financials involved.

- Capital costs were **38%** higher than the traditional design.
- The amount of Grade B space was reduced by **84%**.
- Manufacturing labor was reduced by **21%**.
- Yearly patient throughput increased by **166.67%**.

