



'Off-the-Shelf' Immuno-Cell
Therapies: Manufacturing
Process Development,
Scale-Up and Tech Transfer

ANZ Biologics 2026
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Cartherics at a Glance

Cartherics is a late preclinical stage cell therapy company developing 'off-the-shelf' iPSC-NK treatments for solid cancers and endometriosis.



- Based in Melbourne, Australia
- Commenced operations Jan 2016
- Currently ~30 employees



- >AU\$79M raised to date from private capital, competitive grants and R&D tax incentives.



- Operating from a dedicated 1,800m² purpose-built facility.
- Upgraded clean rooms

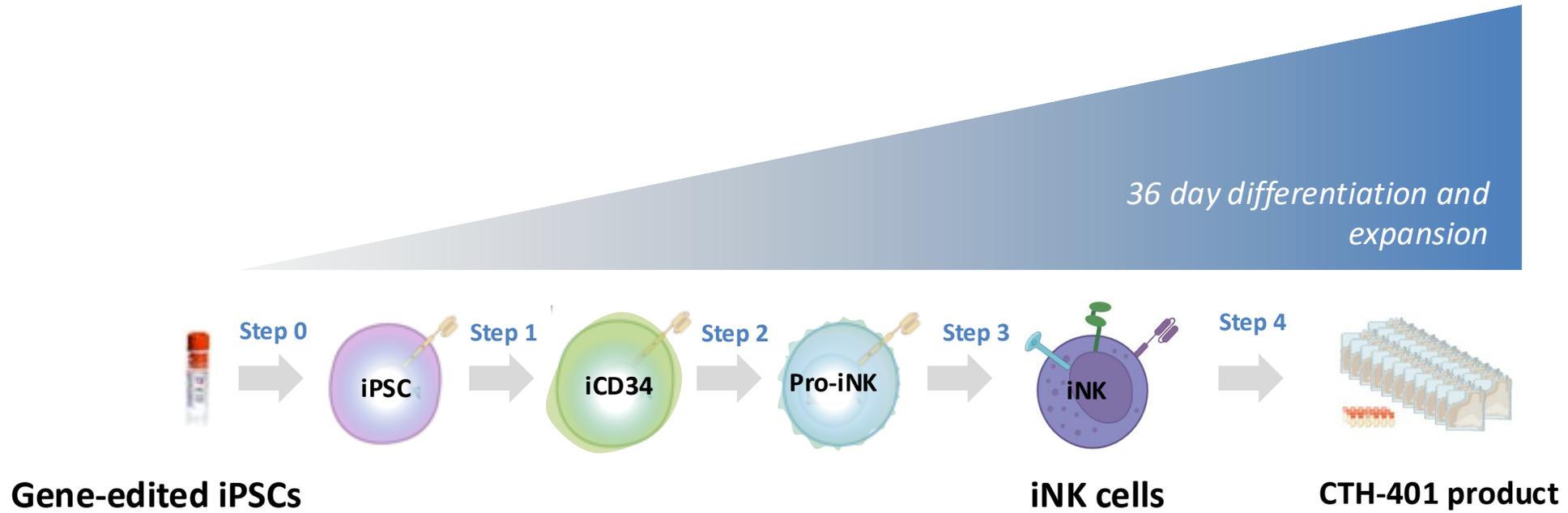


- 'Off-the-shelf' platform, using gene-edited iPSCs to produce immune cells with enhanced function

Process Development & Scale-Up

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Manufacturing Targets

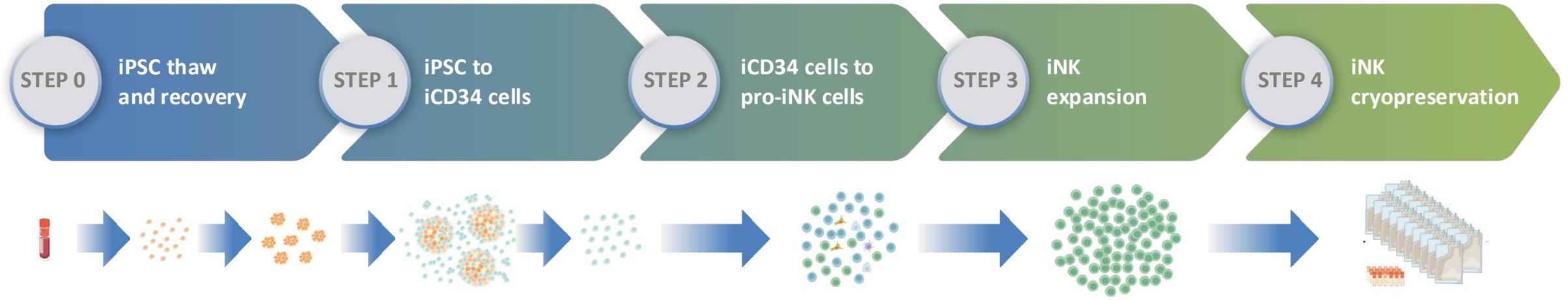


Input
1x10⁶ cells

Output
>20 doses ← FIH
1000+ doses ← Commercialization

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Manufacturing Process Design



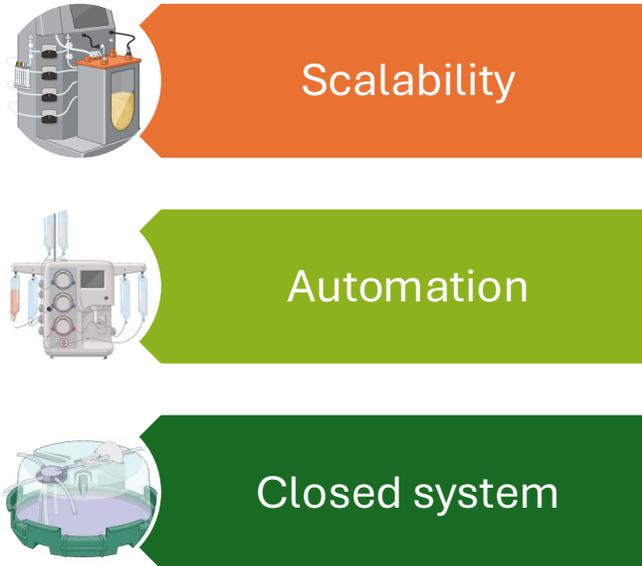
Key Considerations

- Define the **clinical and commercial end** state upfront
- Target **higher manufacturing yields** to compensate for scale-up losses
- Design and establish **control strategies** early in development
- Engage with **regulators** early to align expectations

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Manufacturing Process Design

Three Pillars of advanced cell therapy manufacturing



Risk Management

Quality

- Patient safety
- Product efficacy
- Product quality
- GMP compliance
- Data integrity
- Process robustness



Business

- Timelines
- Budget
- Resources
- Contractors and Vendors
- Product Business Strategy

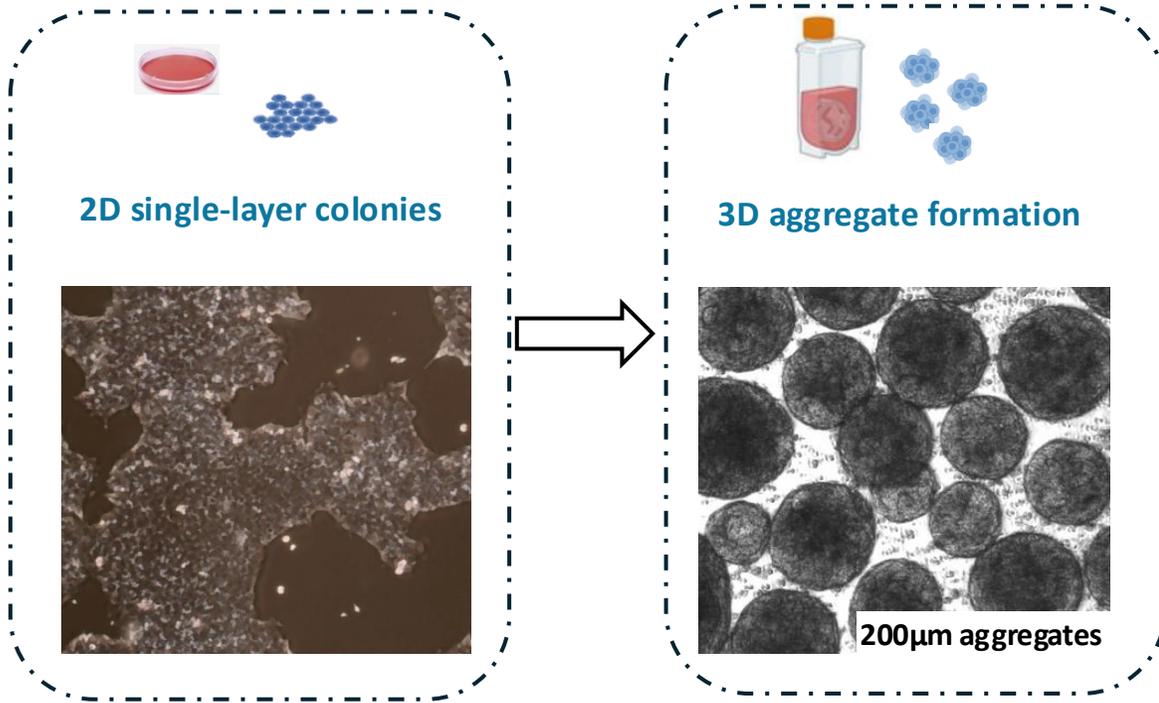
Phase appropriate GMP

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Manufacturing Process Development - Scalability

iPSC single cell seeding

48hrs post- inoculation

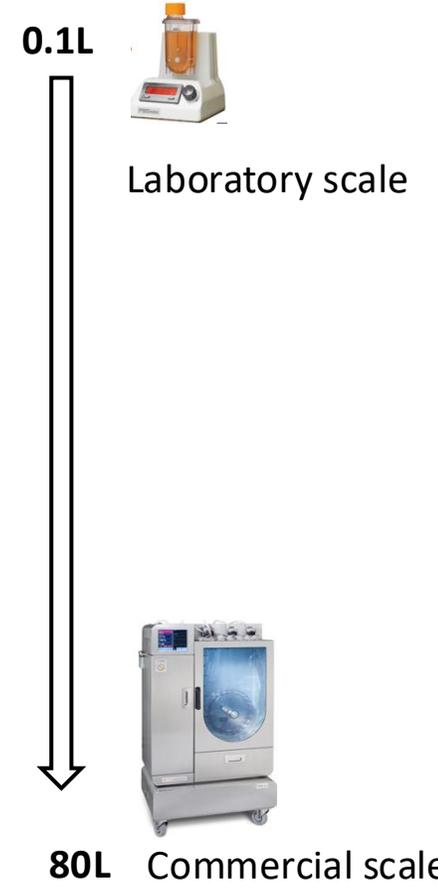


Continue cell differentiation driven by active components in the culture media.

3D Aggregation



Scalability



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Manufacturing Process Development – Closed System & Automation

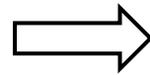
Bench-top centrifuge



28x 500mL centrifuge tubes

Issues

- Multiple vessels required
- High contamination risk
- Yield loss during transfers
- Long processing time
- Poor scalability



Automatic cell wash program



2x 5L storage bags

Address key challenges

- Simplified, closed process
- Reduced manual handling
- Shorter processing time
- Lower contamination risk
- Improved scalability

Highlights

Closure

Closed cell washing procedure

Automation

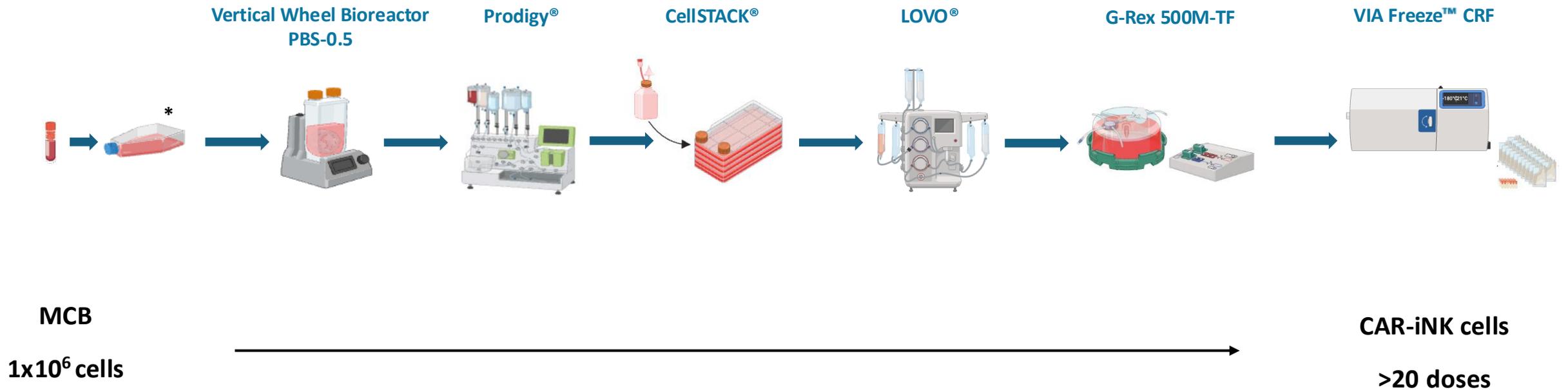
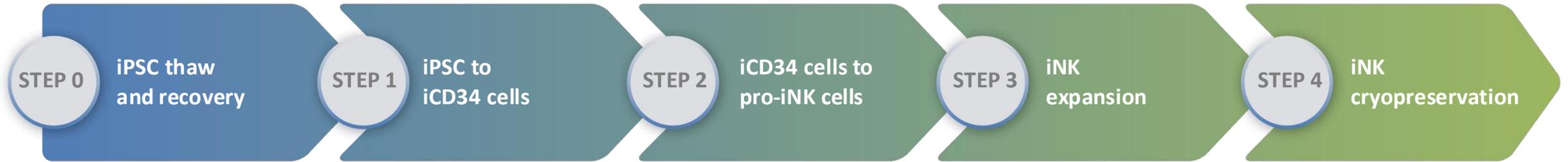
Streamlined workflow
Significant reduction in processing time

Scalability

Built-in capability for future scale-up

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CTH-401 FIH MoM



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Manufacturing Process Development – Control Strategy

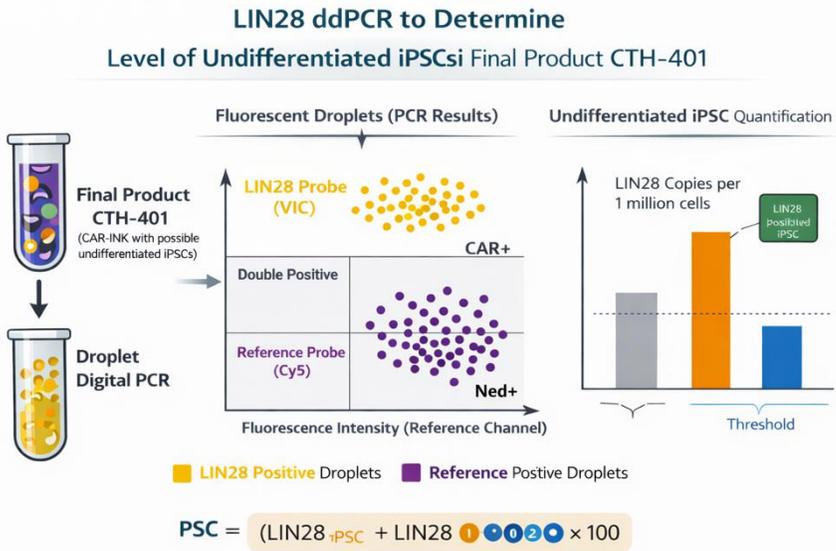
Control Strategy

- Define critical process parameters (CPPs) and critical material attributes (CMAs)
- Ensures in-process and batch-release critical quality attributes (CQAs) are consistently met
- Aligns process monitoring from R&D through manufacturing
- Maintains product activity, potency, and functional performance
- Delivers consistent MoM-scale output and batch-to-batch reproducibility

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Development of Key Release Assays

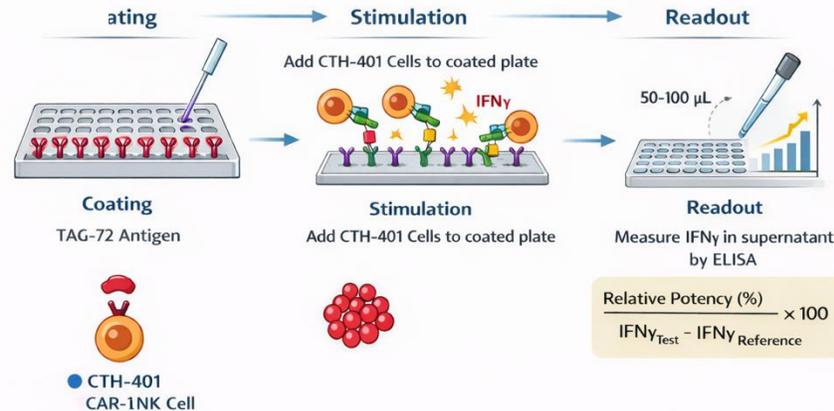
LIN28 Expression ddPCR Assay



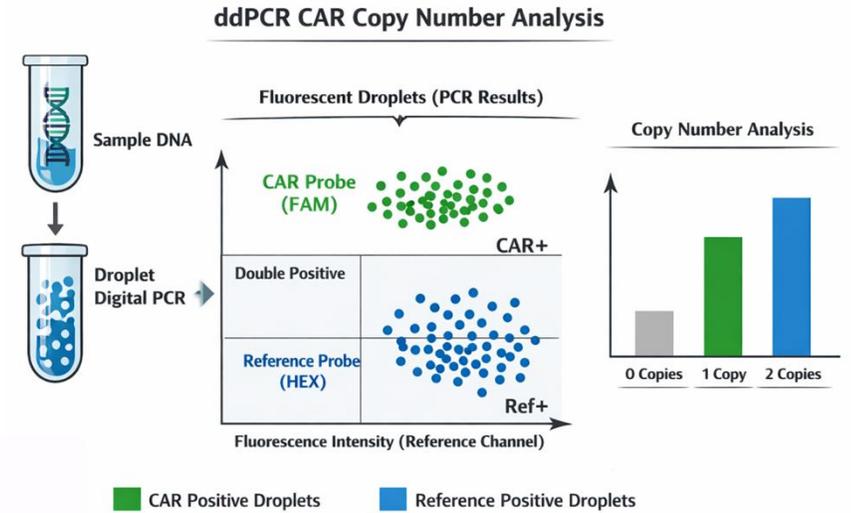
Potency Assay

Plate-Bound TAG-72 CAR-iNK Potency Assay

Measuring IFN γ Release as Surrogate Marker of Potency



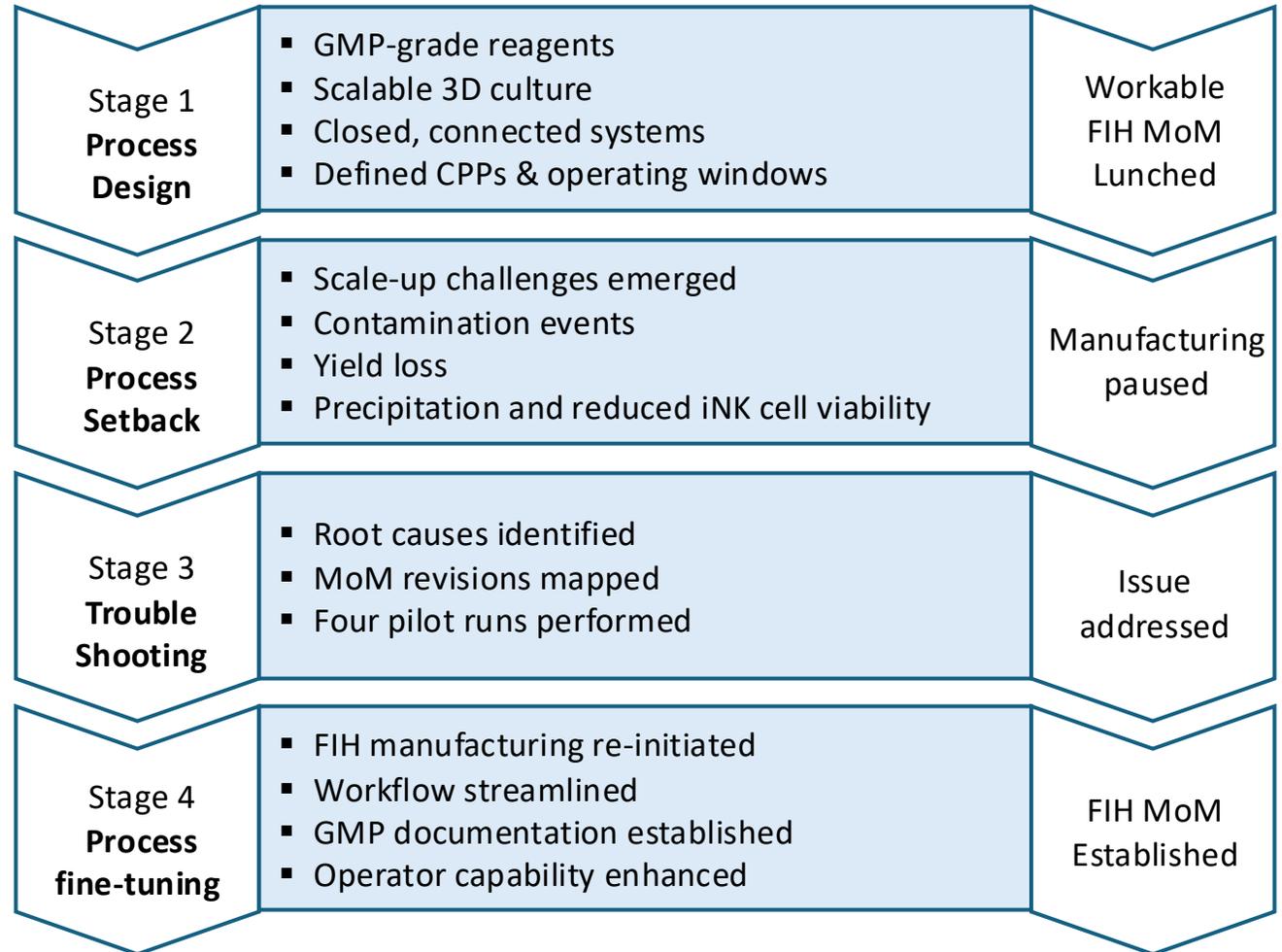
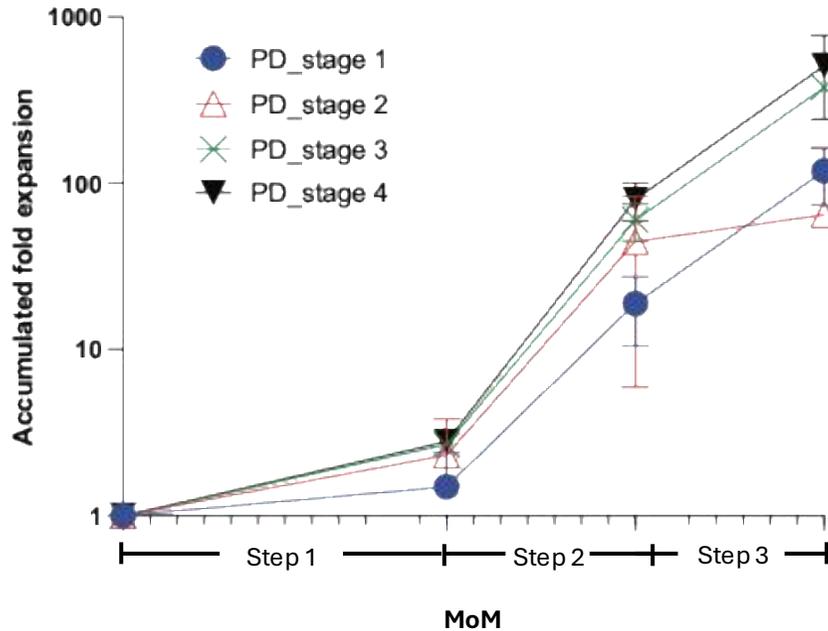
CAR Copy number Assay



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CTH-401 FIH MoM Performance

FIH MoM overall performance



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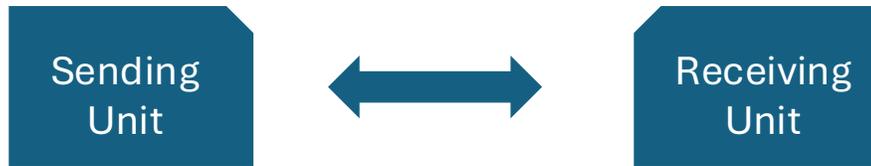
Tech Transfer

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Tech Transfer to GMP Operation

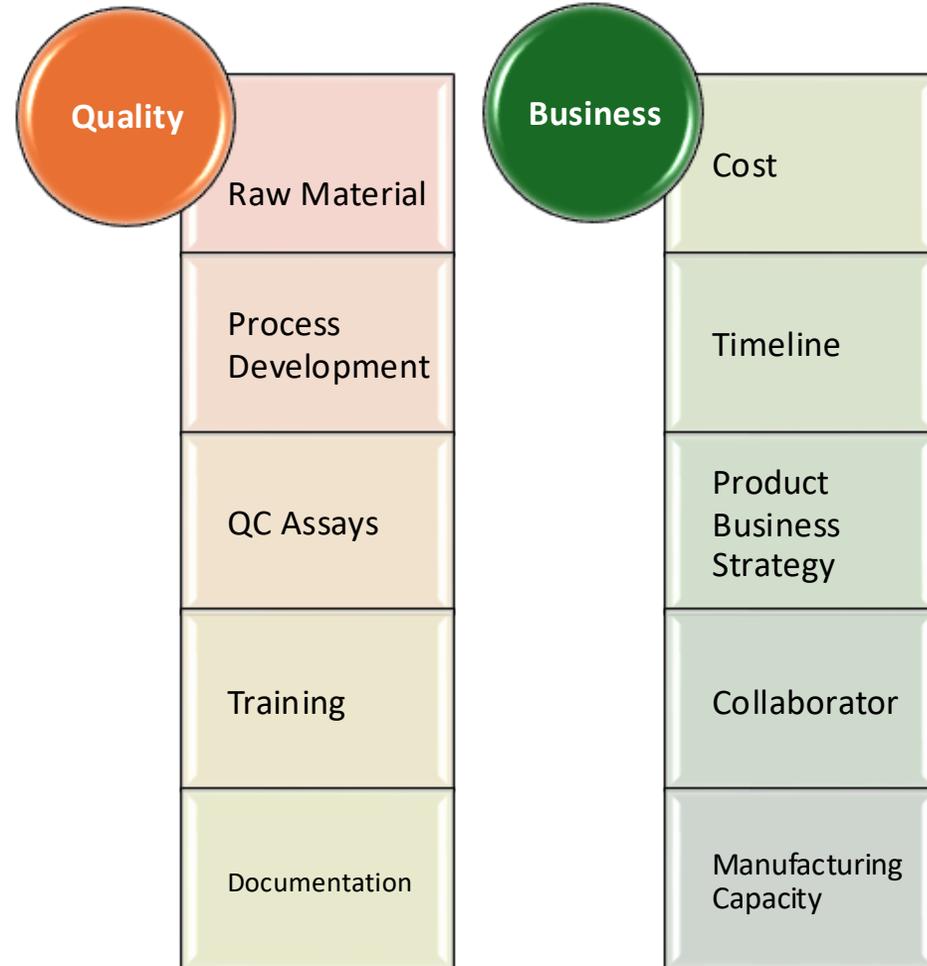
PC2 laboratory

GMP cleanroom



- What is the process?
- What are the control strategies?
- What are the goals at the completion of the transfer?

Lessons Learned



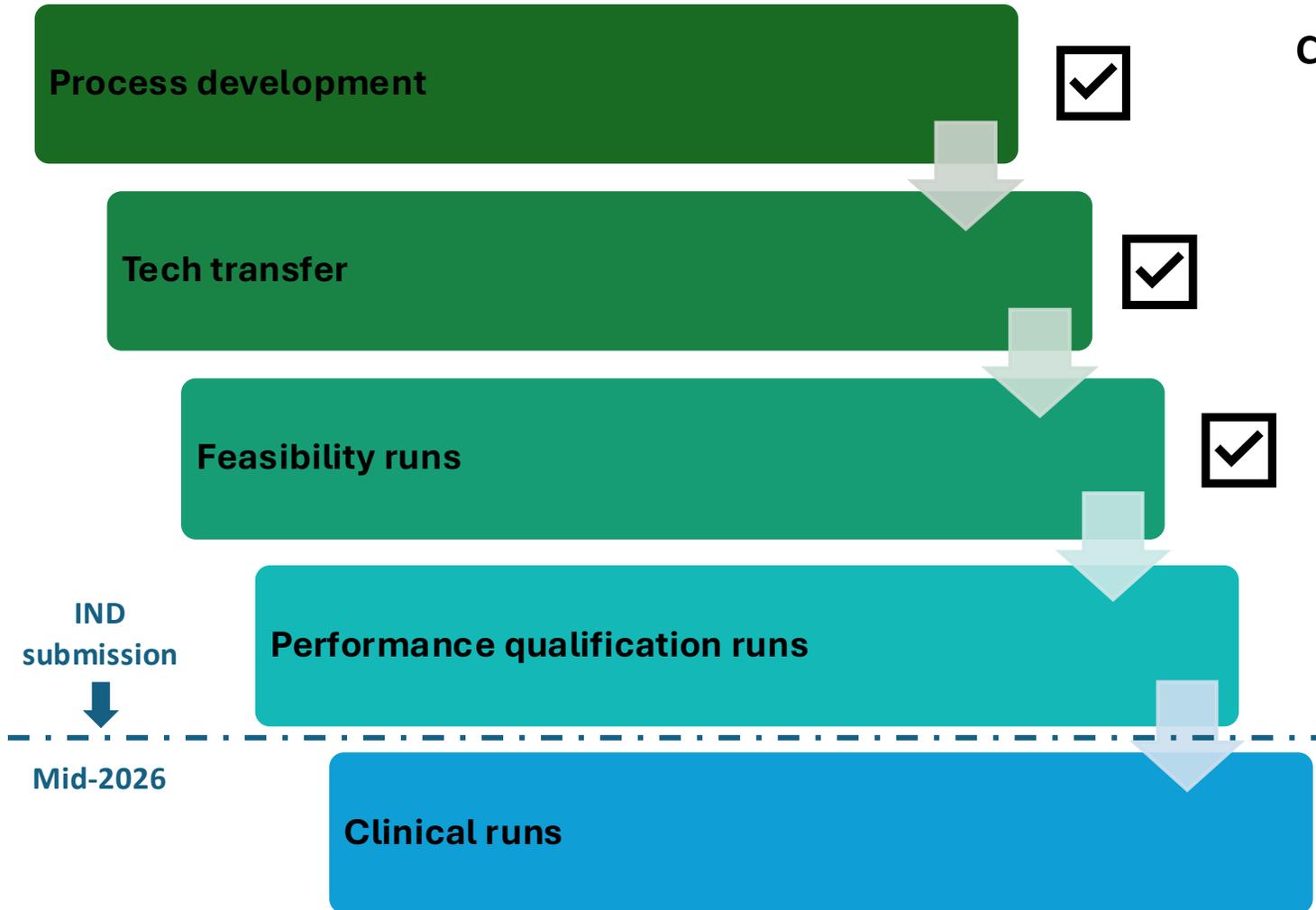
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Take Home Messages

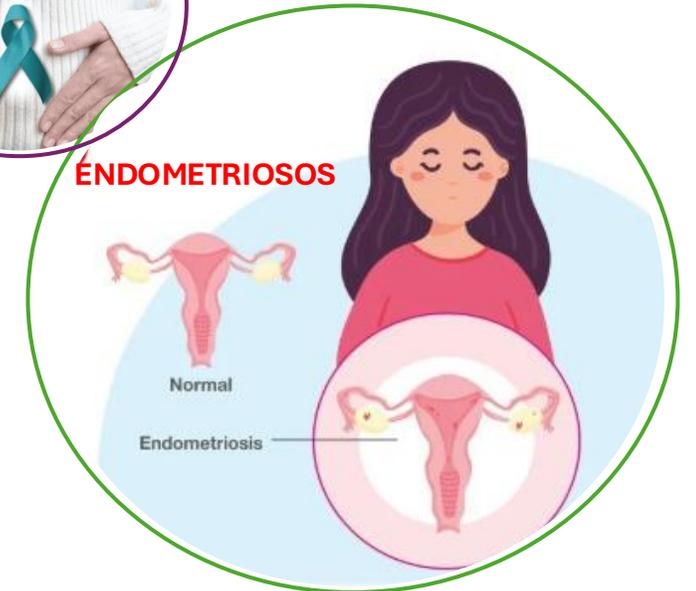
- Cartherics' lead 'off-the-shelf' allogeneic product, CTH-401, is ready for FIH clinical manufacturing.
- Process development and scale-up are critical to successful manufacturing execution.
- Effective planning, risk management, and a well-defined control strategy are key to reliable delivery.
- Phase-appropriate GMP is essential to ensure patient safety, product quality, and manufacturing robustness.

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CTH-401 Future Path into the Clinic



Clinical Applications



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Acknowledgements



2025 Cartherics off-site event

Thank you!



on-site cleanroom

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