

Bioprocess Development of Chimeric Antigen Receptor (CAR) T Cells

Institute of Biologics
Development Center for Biotechnology

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Development Center for Biotechnology, DCB



400+ 

RD/BD professionals serving as the innovation hub for early drug development.

36 

Founded in 1984, non-profit RD institution subsidized by the Ministry of Economic Affairs of Taiwan.

1200+ 

The premium drug development entity and connected with 1200+ biotech of TW.

25 

20+ out licensed assets and 5 Spin offs under **out-licensing** and **co-development** model.

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Project Team



Project Team

Unmet Need

Technology

Opportunity

IP/Dev Status

Summary/Contact

T **Principal Investigator**
Hsin-Lin Lu, Ph.D.

Expertise

Molecular biology, Cell biology, Immunology, Virology



E **Team Leader**
Wei-Kuang Chi, Ph.D.

Bioengineering, Chemical engineering



A **Chemistry Leader**
Ching-Jen Yang, Ph.D.

Chemical engineering, Virology



M Pei-Ju Leng
Yu-Hua Su

Cell biology, Immunology

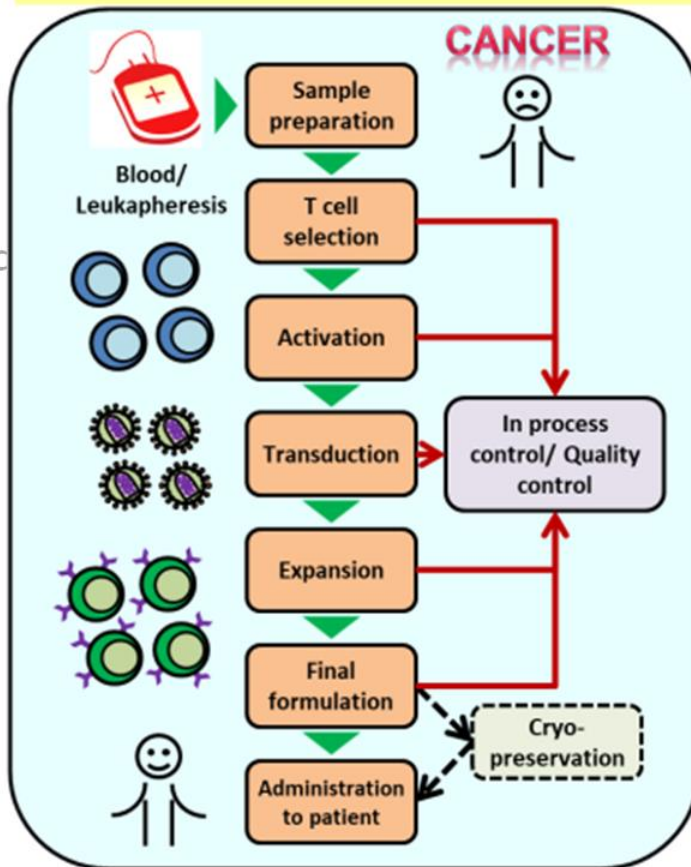


The Bioprocess of CAR-T Cells with Quantity, and Quality Less than 2 Weeks is Required

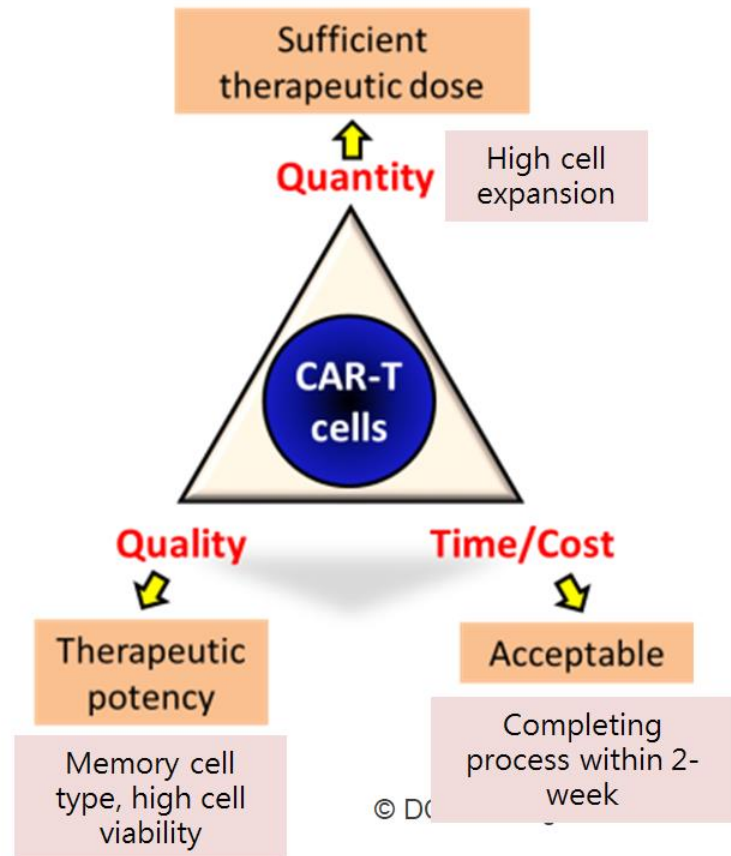
Stable Serum-Free Bioprocess for CAR-T Cell Preparation is Important for CAR-T Cell Development

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Complex Process of CAR-T Cells

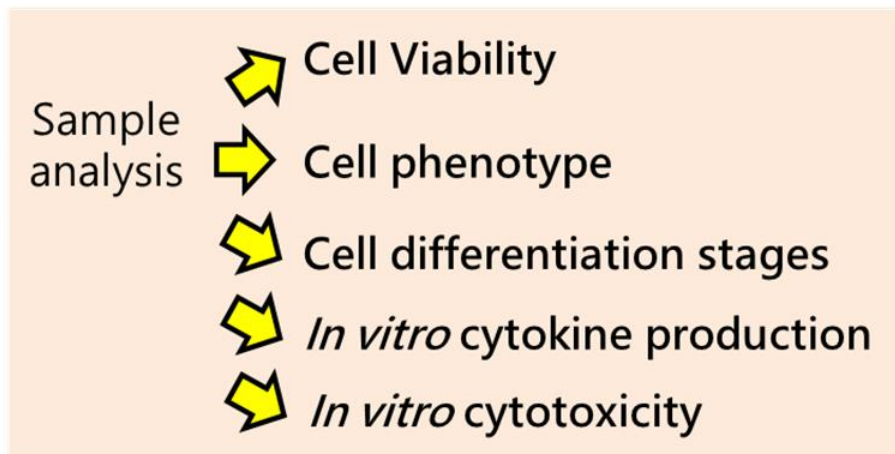
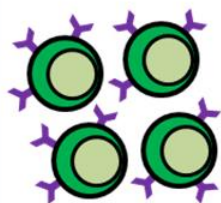
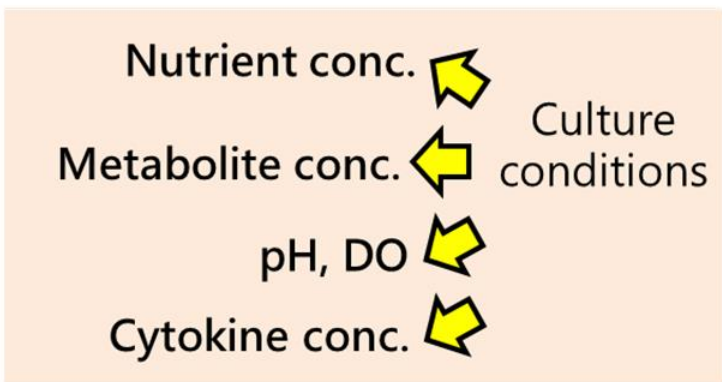
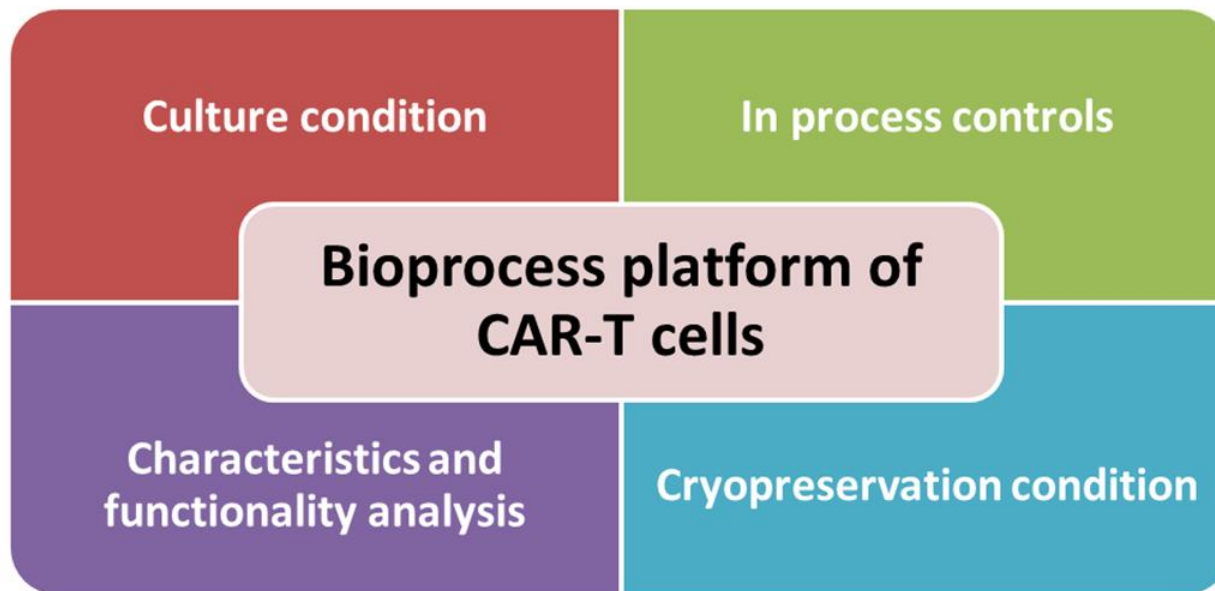


Challenges of Process for Preparing CAR-T Cells



Producing High Quality CAR-T Cells

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DCB Platform Increases CD19 CAR-T Cell Growth Rate and CAR+ Population



Anti-CD19 CAR-T cells expanded to averagely about **188 folds** in a **6-day culture**.

CAR+ population is averagely increased **20%** as compared to initial population.

Project Team

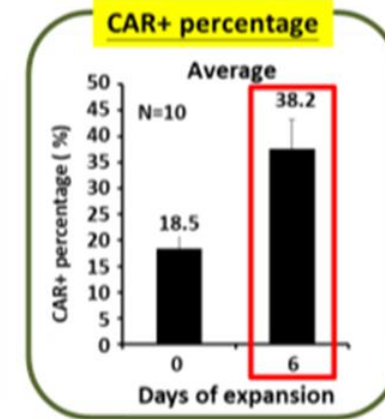
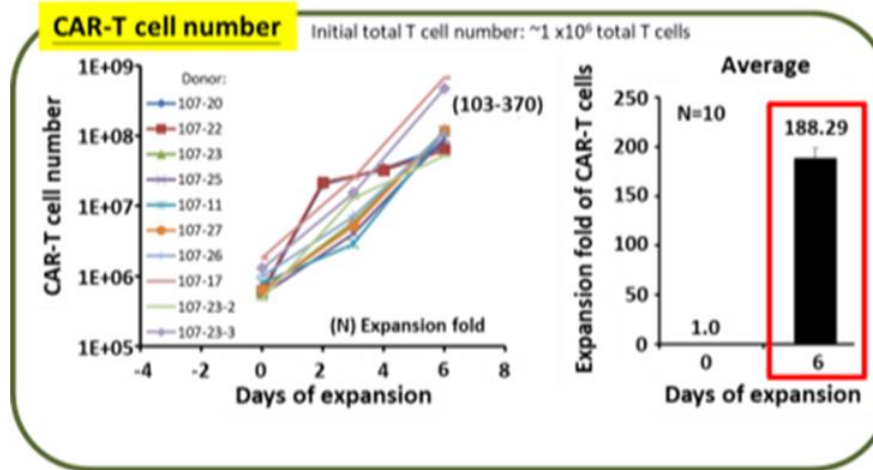
Unmet Need

Technology

Opportunity

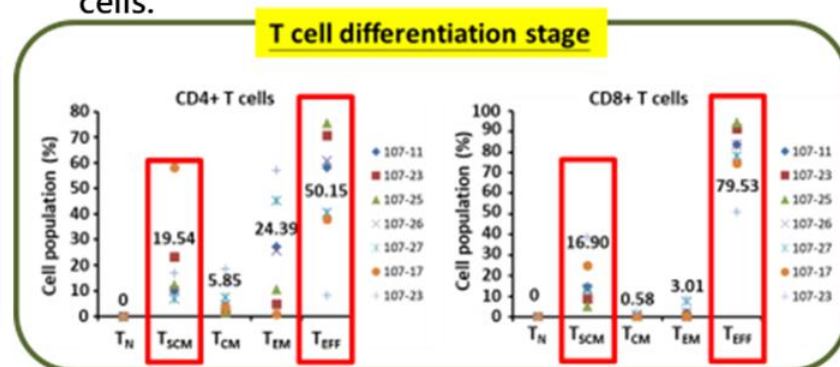
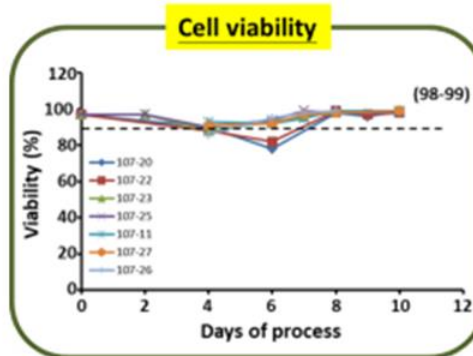
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The cell viability of CAR-T cells is above **98%**.

The differentiation stages of CAR-T cells majorly are **stem cell memory** (T_{SCM}) and **effector** (T_{EFF}) cells.

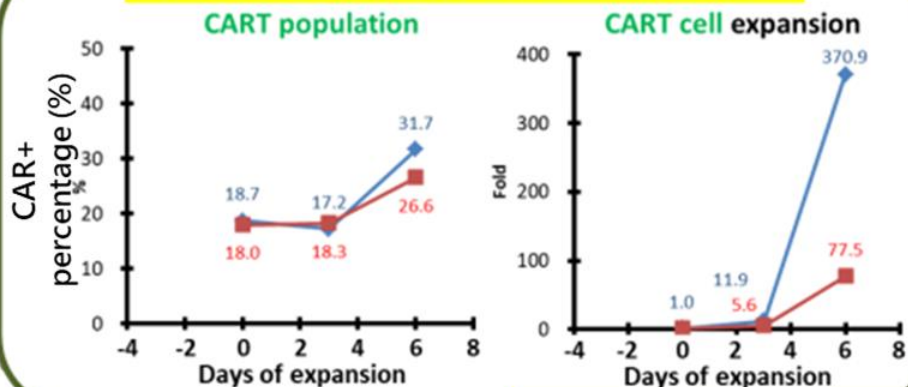


The Expansion and Potencies of CAR-T Cells Are Higher than Those of Benchmark Technology

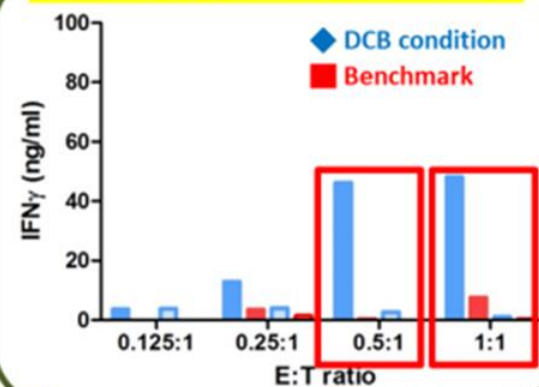


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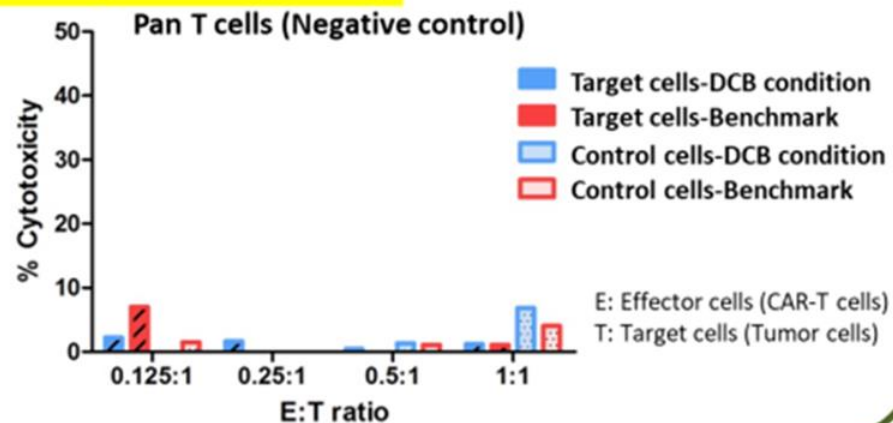
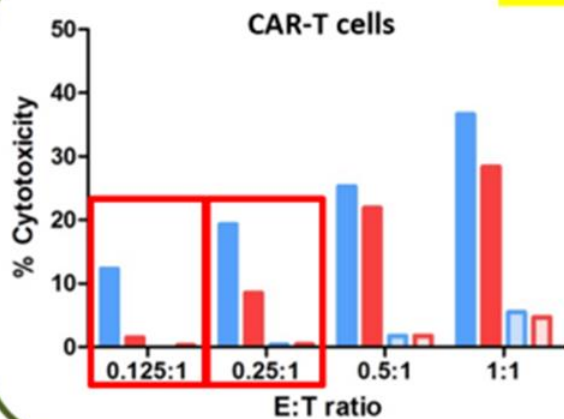
CAR-T Cell population and Expansion



Cytokine production assay



In Vitro cytotoxicity assay



Opportunity

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IP

Trade Secret

Partnership

- Non-exclusive License (Open for Contract Services)
- Other Ways of Partnership

Expect in the Future

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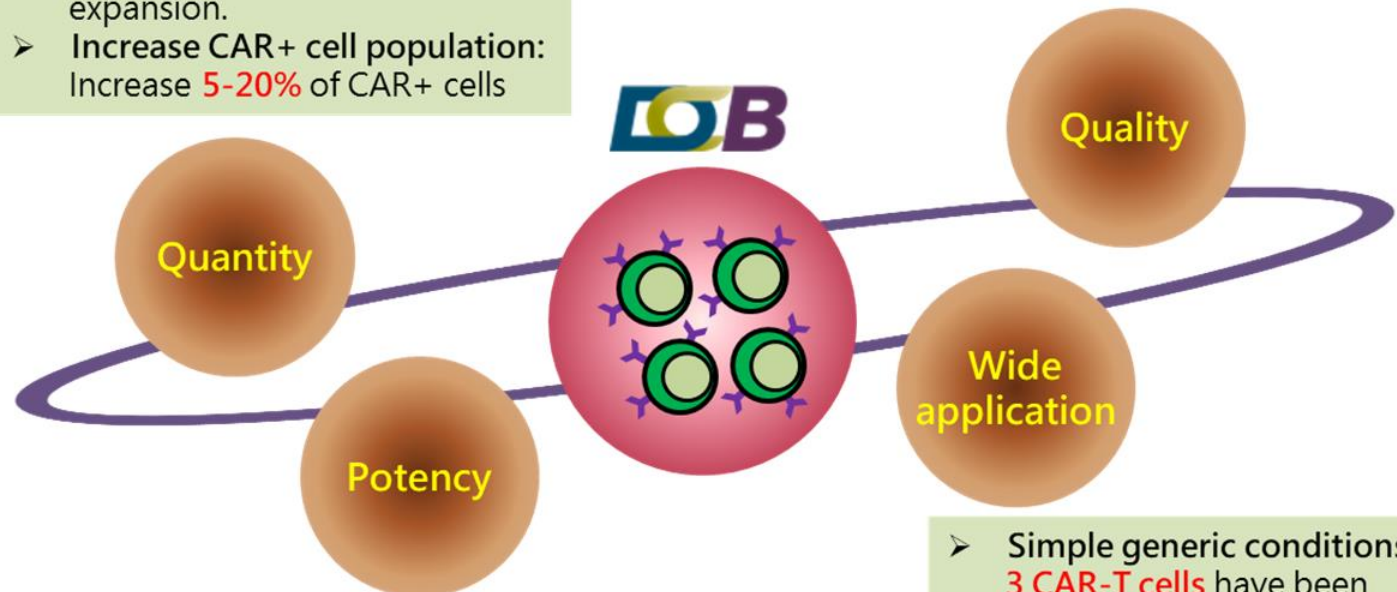
Opportunity

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- **High cell expansion fold:**
Average **60-188 folds** in **6 day**-expansion.
- **Increase CAR+ cell population:**
Increase **5-20%** of CAR+ cells

- **High cell viability:**
Above **98%** in the endpoint.
- **Cellular immunity populations:**
T_{SCM} and **T_{EFF}** are major stages.
Th1 and **CTL** are major subsets.



- **Higher cytotoxicity activity:**
Increase **5-10%** of target cell killing.
- **Higher cytokine production:**
Increase **5-30 ng/mL** of IFN- γ production

- **Simple generic conditions:**
3 CAR-T cells have been applied in the optimized conditions.

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DCB's CAR-T Process

- DCB's process condition **requires lower initial T cell number to 1 to 10 million T cells (dependent on dosage), shortens the operation time to 10 days, cultures at high cell density to 4 million cells/mL**, and leads to the reduction of occupancy of equipment and consumption of materials.
- In DCB's condition, **cell subsets** were maintained at **early differentiation stages**, implying the increase of persistence and potency of CAR-T cells.

BD Contact

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Thank you for your attention