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ENGLISH | 中文

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GLOBAL HEALTHCARE & BIOMEDICAL INTELLIGENCE

MLJC EXCLUSIVE | Global Oncology & Cell-Therapy Intelligence

NK CELLS

From the Body's Natural Defenders to the Next Generation of Living Cancer Medicine

Immunology • Oncology • CAR-NK • iPSC-NK • Cell Therapy • Precision Medicine
• Biomedical Engineering

Executive Perspective

Cancer medicine is entering a different technological era.

For decades, the principal weapons against cancer were:

**Surgery → Radiation → Chemotherapy
→ Targeted Therapy → Immunotherapy**

The next transition may be:

Living Cells as Medicine

Among the most closely watched candidates are **Natural Killer cells** — NK cells, a major component of the innate immune system.

NK cells can recognise and destroy certain infected or malignant cells through a combination of activating and inhibitory signals, cytotoxic mechanisms and antibody-dependent cellular cytotoxicity. Their biology has therefore become an important foundation for next-generation cellular immunotherapy.

But the real scientific question is not:

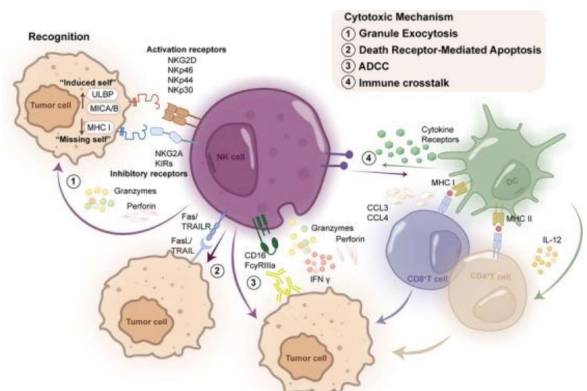
“Can NK cells kill cancer cells?”

That has already been demonstrated biologically.

The more important question is:

Can NK cells be engineered, manufactured and delivered as a safe, scalable and durable cancer medicine?

That is where the strategic importance of **CAR-NK** and **iPSC-derived NK** technologies begins.



NK CELLS

1. What Are NK Cells?

Natural Killer Cells

NK cells are innate lymphocytes that form part of the body's early immune defence.

Unlike conventional antigen-specific T-cell responses, NK cells integrate multiple signals from a target cell before deciding whether to activate.

They can respond to:

- abnormal cellular stress;
- altered expression of surface molecules;
- reduced inhibitory signalling;
- antibody-coated target cells.

Once activated, NK cells can deploy mechanisms including:

Perforin

→ membrane disruption

Granzymes

→ intracellular apoptotic pathways and:

CD16-mediated ADCC

→ antibody-dependent cellular cytotoxicity.

This makes NK cells biologically different from simply being a “natural version of CAR-T.”

They are an independent immune-cell platform with their own recognition and killing mechanisms.

2. Why CAR-NK Matters

The next step was obvious to researchers:

What if we could give an NK cell a programmable tumour-recognition system?

That concept produced:

CAR-NK

Chimeric Antigen Receptor + Natural Killer Cell

The CAR provides a more defined target-recognition mechanism, while the NK cell retains elements of its natural cytotoxic machinery.

The resulting concept is:

Natural Immune Function

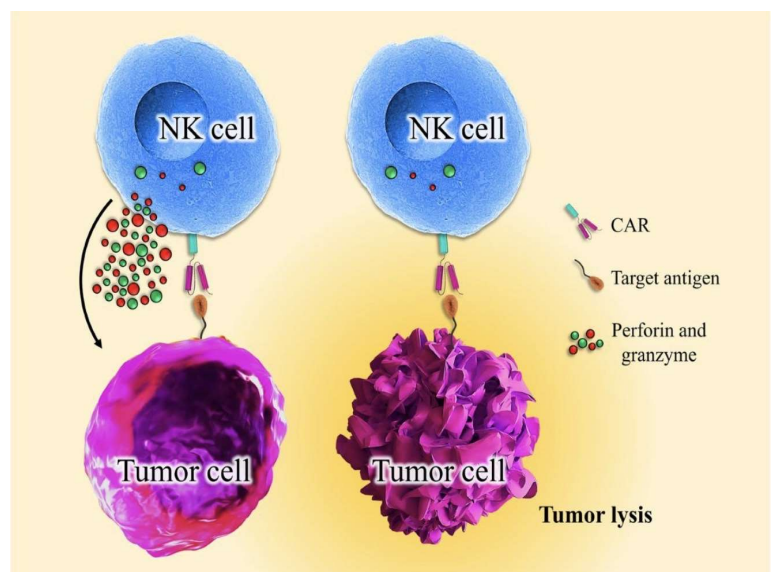
Genetic Engineering

Targeted Recognition

=

Engineered Living Therapeutic

CAR-NK is therefore part of a much broader transition from conventional pharmacology toward **cell engineering**.



3. The Clinical Evidence That Changed the Conversation

One of the most important clinical datasets was published in **Nature Medicine in January 2024**.

The study evaluated **cord-blood-derived CD19-specific CAR-NK cells expressing IL-15** in patients with CD19-positive B-cell malignancies.

Phase 1/2 Clinical Trial

37 patients

with relapsed or refractory CD19-positive B-cell malignancies.

The reported results included:

Clinical endpoint	Reported result
Patients	37
Day-30 overall response	48.6%
Day-100 overall response	48.6%
1-year overall survival	68%
1-year progression-free survival	32%

Importantly, the investigators reported **no notable cytokine release syndrome, neurotoxicity or graft-versus-host disease** in this study.

These are encouraging findings.

But MLJC emphasises an essential distinction:

A promising Phase 1/2 signal is not the same as proof of superiority over established therapies.

The study involved only 37 patients and was not a definitive Phase 3 comparison. That distinction matters.

4. One of the Most Interesting Findings Was Not the Response Rate

The study identified something much deeper.

The quality of the **cord-blood starting material** appeared to influence clinical outcomes.

The investigators found that two characteristics were particularly associated with superior outcomes:

Collection-to-cryopreservation time ≤ 24 hours and

Nucleated red blood cells $\leq 8 \times 10^7$

Patients receiving CAR-NK products from cord-blood units with these characteristics had better outcomes.

This is strategically important because it demonstrates that:

Cell Therapy Is Also a Manufacturing Science.

It is not simply:

“Find NK cells and give them to the patient.”

The real production chain is:

Cell Source

↓

Cell Quality

↓

Genetic Engineering

↓

Expansion

↓

Cryopreservation

↓

Potency Testing

↓

Clinical Delivery

↓

Patient Response

NK CELLS

The manufacturing platform can therefore become as important as the biological concept itself.

5. The “Off-the-Shelf” Opportunity

Traditional autologous CAR-T generally involves:

Patient

- cell collection
- genetic modification
- expansion
- quality control
- return to the same patient.

This is a highly personalised manufacturing process.

CAR-NK offers a different possibility:

Allogeneic Cell Therapy

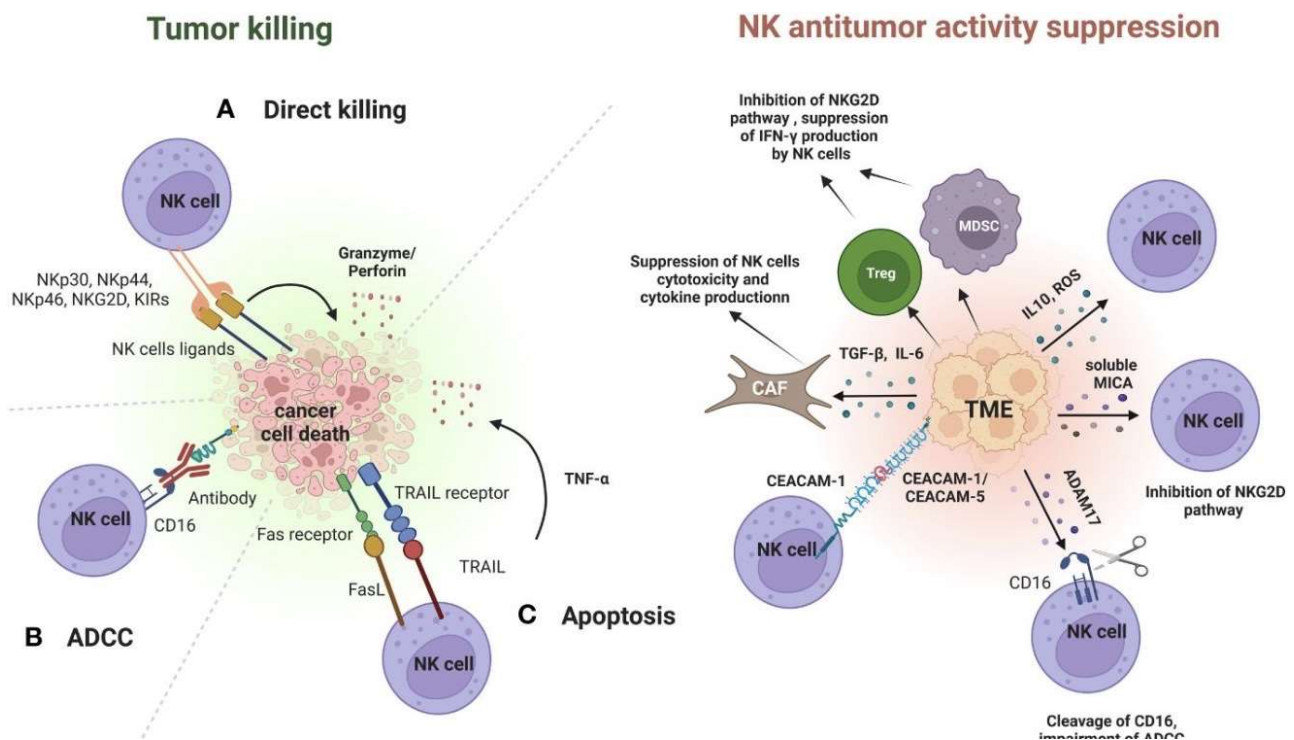
A suitable donor-derived cell product could potentially be manufactured in advance, cryopreserved and administered to multiple patients.

This creates the possibility of:

Off-the-Shelf Cellular Medicine

Nature’s reporting on the 2024 clinical work noted that a single cord-blood unit could potentially generate **more than 100 doses** of CAR-NK cells in the researchers’ manufacturing model.

If such manufacturing efficiency can be reproduced consistently under commercial GMP conditions, the implications for access, logistics and cost could be significant.



6. CAR-NK vs CAR-T

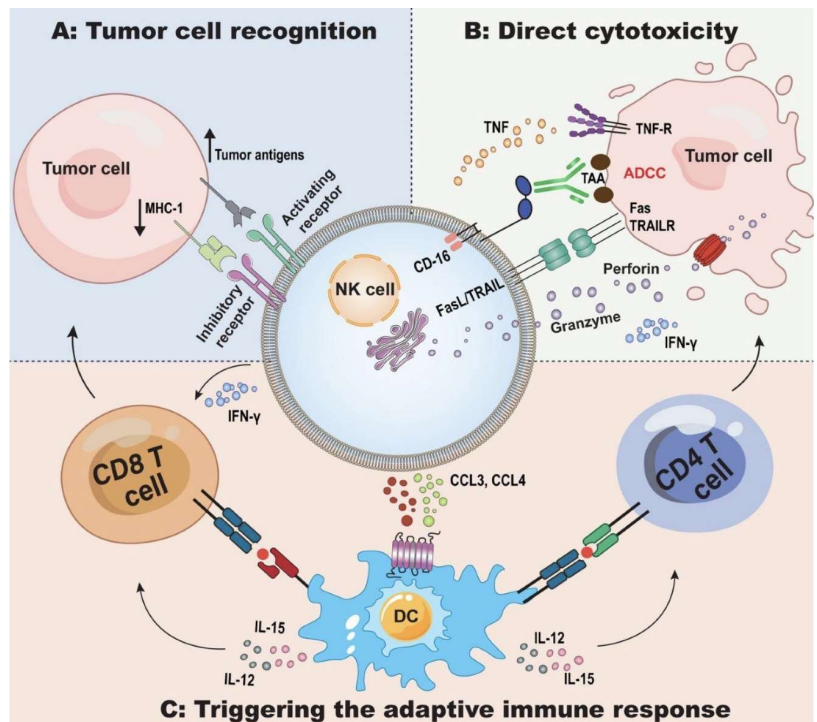
It is tempting to ask:

Will CAR-NK replace CAR-T?

MLJC's answer is:

Not yet.

The two platforms should currently be viewed as complementary rather than mutually exclusive.



Dimension	CAR-T	CAR-NK
Cellular basis	T cell	Natural Killer cell
Targeted recognition	CAR	CAR + native NK receptors
Autologous manufacturing	Established	Possible
Allogeneic development	More challenging	Major research focus
Off-the-shelf potential	Developing	Significant potential
CRS / neurotoxicity	Important clinical considerations	Appears potentially lower in some early studies
Solid tumours	Major challenge	Major challenge
Clinical maturity	More advanced	Earlier-stage
Long-term evidence	Substantially broader	Still developing

A 2024 review in *Cellular & Molecular Immunology* highlighted the potential advantages of CAR-NK for allogeneic and off-the-shelf therapy while also emphasising major barriers in solid tumours, particularly tumour trafficking, infiltration and the immunosuppressive microenvironment.

7. The Next Frontier: iPSC-Derived NK Cells

Another potentially transformative technology is:

iPSC-NK

Induced Pluripotent Stem Cell-derived Natural Killer Cells

The conceptual manufacturing model becomes:

iPSC Master Cell Bank



NK Differentiation



Expansion



Genetic Engineering



Quality Control



Cryopreservation



Ready-to-Use Cellular Product

This could theoretically address some of the variability associated with donor-derived cell products.

But again:

Manufacturing potential is not clinical proof.

The field still has to demonstrate consistent potency, safety, persistence and meaningful patient outcomes at scale.

8. The Biggest Challenge May Be the Tumour Itself

For blood cancers, the therapeutic environment can be comparatively accessible.

Solid tumours are different.

A solid tumour can create:

Hypoxia

Metabolic stress

Immunosuppressive cytokines

Physical barriers

Suppressive immune-cell populations

and other mechanisms that impair immune-cell function.

A 2024 Nature review of CAR-T and CAR-NK therapies in solid tumours identified limited trafficking and infiltration, together with the immunosuppressive tumour microenvironment, as major obstacles.

Therefore:

The challenge is not merely making NK cells stronger.

The challenge is:

Getting the right cells to the right tumour, keeping them functional, and allowing them to remain effective.

9. Where the Field Is Going

The technological evolution can be visualised as:

Generation 1

Natural NK Cells



Generation 2

Expanded / Activated NK Cells



Generation 3

CAR-NK



Generation 4

CAR-NK + Cytokine Engineering



Generation 5

iPSC-derived NK



Generation 6

Multi-target / Armoured / Precision CAR-NK

The field is increasingly exploring ways to improve:

Persistence

Tumour trafficking

Target recognition

Resistance to immune suppression

Antigen coverage

Manufacturing consistency

Safety

This is no longer simply immunology.

It is becoming:

Cell Engineering + Genomics +

Manufacturing + Precision Oncology

10. The Solid-Tumour Question

This may ultimately determine whether NK-cell technology becomes a major commercial platform.

Blood cancers have already produced encouraging clinical signals.

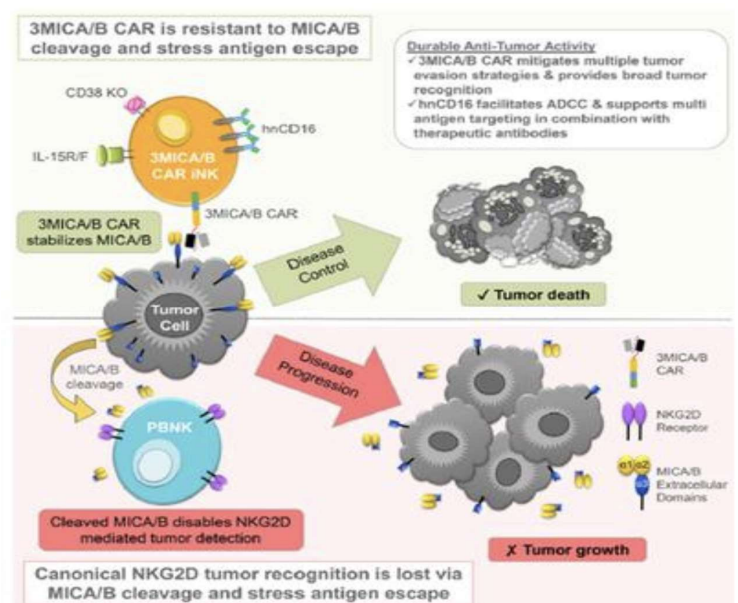
Solid tumours remain much harder.

Current research is investigating CAR-NK approaches against multiple tumour types and targets, including approaches designed to address the biological barriers within solid tumours.

The central question is:

Can engineered NK cells function inside the hostile biological environment of a solid tumour?

If that problem can be solved, the addressable clinical opportunity becomes dramatically larger.



11. MLJC Strategic Intelligence

MLJC identifies **six critical layers** for evaluating the future NK-cell industry.

01 | Cell Source

Where does the cell come from?

02 | Cell Engineering

How precisely can it be modified?

03 | Persistence

How long can it remain functional?

04 | Tumour Trafficking

Can it reach the tumour?

05 | Manufacturing

Can it be produced consistently at GMP scale?

06 | Clinical Evidence

Does it improve meaningful patient outcomes?

A company may possess excellent biology but weak manufacturing.

Another may possess sophisticated manufacturing but inadequate clinical efficacy.

Therefore:

The winner will not necessarily have the strongest NK cell.

It may have the strongest **end-to-end platform**.

12. MLJC Evidence Position

Category	MLJC Assessment
Basic NK biology	Well established
NK anti-tumour activity	Established biological principle
NK-cell therapy	Active clinical field
CAR-NK	Promising early clinical development
iPSC-NK	High strategic potential / emerging clinical field
Off-the-shelf model	Technically attractive; still developing clinically
Haematological malignancies	More mature evidence base
Solid tumours	Major opportunity, major challenge
Long-term persistence	Important unresolved issue
Manufacturing scalability	Critical development bottleneck
Regulatory maturity	Still substantially behind approved CAR-T platforms
Universal cancer treatment	No
Proven cancer cure	No

This distinction is fundamental.

Promising ≠ Proven

Clinical Trial ≠ Approved Therapy

Response ≠ Cure

Biological Potential ≠ Clinical Standard of Care

13. MLJC's Five Questions for the Next Decade

Q1

Can NK cells become a truly scalable **off-the-shelf cancer medicine**?

Q2

Can iPSC technology reduce donor-to-donor variability?

Q3

Can CAR-NK overcome the immunosuppressive tumour microenvironment?

Q4

Can multi-target engineering reduce antigen escape?

Q5

Can large randomised trials demonstrate durable survival benefits? These questions will determine whether NK-cell therapy moves from:

Scientific Promise

to

Clinical Standard

and ultimately to:

Global Healthcare Infrastructure

14. MLJC's Broader Strategic View

The deeper story is not simply about NK cells.

It is about the evolution of medicine itself.

Traditional pharmaceutical model

Chemical Molecule → Patient

Biologic model

Protein / Antibody → Patient

First-generation cellular medicine

Patient Cells → Engineering → Patient

Next-generation cellular medicine

Engineered Living Cell →

Standardised Manufacturing → Patient

The ultimate concept is:

Biology as a Manufacturing Platform

This is why MLJC considers NK-cell technology strategically relevant not only to oncology, but also to:

Biotechnology

Cell Manufacturing

Genetic Engineering

Precision Medicine

Pharmaceutical Investment

Healthcare Infrastructure

and Global Biomedical Policy.

15. MLJC Final Assessment

We would not write:

“NK cells will replace CAR-T.”

The evidence does not justify that statement.

We would write:

NK-cell therapies are progressing from an established area of immunobiology toward an increasingly sophisticated clinical and manufacturing platform.

The 2024 *Nature Medicine* Phase 1/2 study provides an important early clinical signal for allogeneic CD19-directed CAR-NK therapy, including a 48.6% response rate at both day 30 and day 100 and encouraging safety observations in the 37-patient cohort.

But the next stage requires:

larger cohorts

→ **controlled comparative trials**

→ **long-term follow-up**

→ **better manufacturing**

→ **stronger persistence**

→ **improved solid-tumour**

penetration

→ **regulatory validation**

Only then can the field establish its ultimate clinical position.

16. MLJC Conclusion

The next generation of cancer medicine may not simply be designed in a laboratory.

It may be engineered as a living system.

NK cells already exist within the human immune system.

Modern biotechnology is attempting to:

understand them

expand them

engineer them

program them

manufacture them

and ultimately:

turn them into medicine.

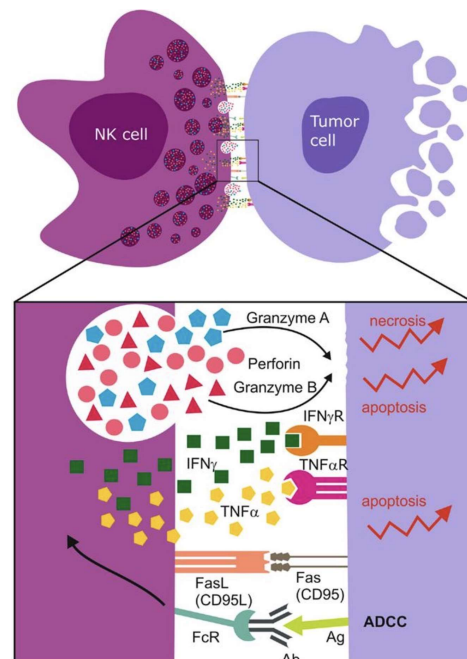
This is not simply:

“boosting immunity.”

It is something much more precise:

ENGINEERING IMMUNITY.

And that is why MLJC believes NK-cell technology deserves serious attention from the global medical, biotechnology, investment and healthcare-policy communities.



<https://www.nature.com/articles/s41591-023-02785-8>

<https://www.nejm.org/doi/full/10.1056/NEJMoa1910607>

<https://www.nature.com/articles/s41568-022-00491-0>

<https://www.nature.com/articles/s41577-022-00732-1>

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Safety, efficacy and determinants of response of allogeneic CD19-specific CAR-NK cells in CD19⁺ B cell tumors: a phase 1/2 trial

David Marin, Ye Li, ... [Katayoun Rezvani](#)

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Nature Medicine **30**, 772–784 (2024) | [Cite this article](#)

This Week Find out what's new in *NEJM Evidence*

ORIGINAL ARTICLE



Use of CAR-Transduced Natural Killer Cells in CD19-Positive Lymphoid Tumors

Authors: Enli Liu, M.D., David Marin, M.D., Pinaki Banerjee, Ph.D., Homer A. Macapinlac, M.D., Philip Thompson, M.B., B.S., Rafet Basar, M.D., Lucila Nassif Kerbaui, M.D., ⁺¹⁹, and Katayoun Rezvani, M.D., Ph.D. [Author Info & Affiliations](#)

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全球医疗与生物学战略情报

NK细胞

从人体天然免疫防线，到下一代“活细胞药物”

MLJC独家 | 全球肿瘤与细胞治疗情报报告

免疫学 • 肿瘤学 • CAR-NK • iPSC-NK • 细胞治疗 • 精准医学 • 生物学工程

一、MLJC执行摘要

癌症治疗正在进入一个新的技术阶段。

过去几十年，肿瘤治疗的主要武器是：

手术 → 放疗 → 化疗 → 靶向治疗 → 免疫治疗

而下一阶段，一个更加重要的方向正在形成：

让“活细胞”本身成为药物。

其中受到全球科研机构、癌症中心、生物科技企业及投资机构高度关注的，就是：

NK Cells | Natural Killer Cells

自然杀伤细胞

NK细胞是人体先天免疫系统的重要组成部分，可以识别并杀伤部分病毒感染细胞以及异常、恶性细胞。

但真正值得关注的问题并不是：

“NK细胞能不能杀死癌细胞？”

这一点在基础免疫学中早已得到证明。

真正具有战略意义的问题是：

我们能否把NK细胞工程化、规模化制造，并转化为安全、稳定、可重复使用的癌症治疗产品？

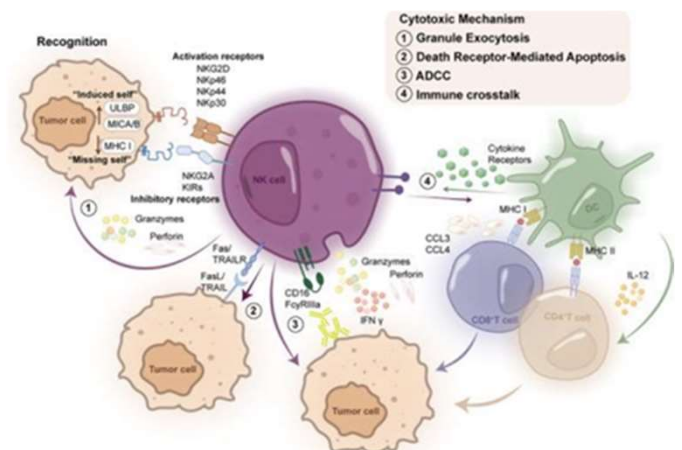
这正是：

CAR-NK

以及

iPSC-NK

等下一代技术真正受到全球关注的原因。



二、什么是NK细胞？

Natural Killer Cells | 自然杀伤细胞

NK细胞属于先天淋巴细胞，是人体早期免疫防御体系的重要组成部分。

与传统T细胞依赖特定抗原识别的方式不同，NK细胞会综合判断目标细胞表面的多种：

激活信号

与

抑制信号

从而决定是否发动攻击。

NK细胞能够对部分：

- 异常细胞
- 病毒感染细胞
- 肿瘤细胞
- 抗体包被的靶细胞

产生免疫反应。

其主要杀伤机制包括：

Perforin | 穿孔素

帮助破坏目标细胞膜结构。

Granzymes | 颗粒酶

进一步启动目标细胞的程序性死亡机制。

ADCC | 抗体依赖的细胞介导细胞毒作用

通过NK细胞表面的CD16等受体识别抗体包被的目标细胞。

因此：

NK细胞并不是简单意义上的“天然CAR-T”。

它拥有独立的天然免疫识别和杀伤机制。

三、为什么CAR-NK如此重要？

科学家进一步提出了一个非常关键的问题：

如果NK细胞天然具有杀伤能力，那么能否给它安装一个更加精准的“导航系统”？

由此形成：

CAR-NK

即：

Chimeric Antigen Receptor
Natural Killer Cell

简单理解：

天然NK细胞

+

基因工程

+

肿瘤靶向受体

=

工程化活细胞治疗产品

CAR可以帮助NK细胞更加明确地识别某些肿瘤相关靶点，同时保留部分NK细胞天然的杀伤机制。

这使CAR-NK成为下一代细胞免疫治疗的重要研究方向。

四、改变行业认知的重要临床数据

Nature Medicine | 2024

目前最值得关注的临床研究之一，是发表于 Nature Medicine 的一项Phase 1/2研究。

研究对象：

37名患者

均为复发或难治性：

CD19阳性B细胞恶性肿瘤

研究使用：

脐带血来源的CD19 CAR-NK细胞

并加入：

IL-15

以增强细胞功能和持续性。

并且严重细胞因子释放综合征（CRS）并不是该研究中的主要问题。Nature Medicine — CAR-NK Phase 1/2 Clinical Trial 这些数据令人鼓舞。

但MLJC必须强调：

Phase 1/2的积极信号，不等于已经证明CAR-NK优于CAR-T。

37例患者的研究规模仍然有限，也不是最终性的Phase 3随机对照试验。

因此：

这是“重要的临床信号”，而不是“最终临床结论”。

临床结果

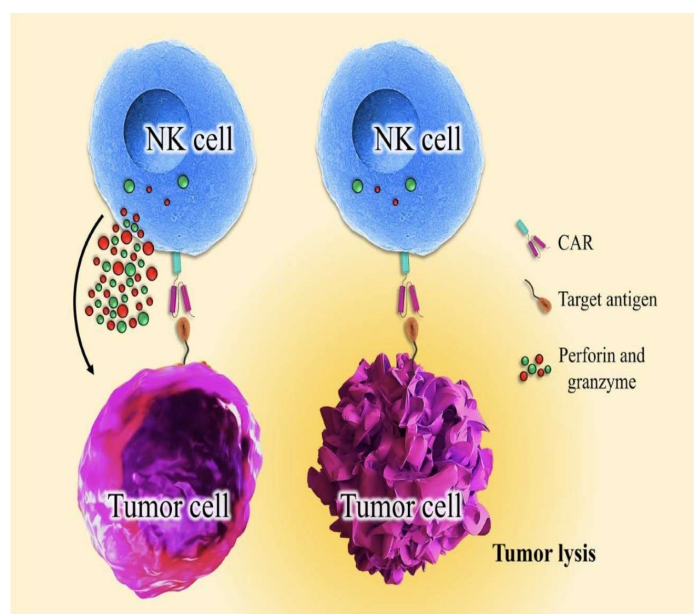
临床指标	研究报告结果
患者数量	37例
第30天总体缓解率	48.6%
第100天总体缓解率	48.6%
1年总体生存率	68%
1年无进展生存率	32%

研究同时报告：

未观察到明显的神经毒性

以及

移植物抗宿主病（GVHD）



NK细胞

五、真正值得注意的，不只是缓解率
这项研究还有一个非常具有产业意义的发现：

细胞来源的质量可能影响治疗结果。

研究人员发现，脐带血样本的一些质量指标与CAR-NK治疗表现存在关联。

其中包括：

采集至冷冻保存时间 ≤ 24 小时

以及：

有核红细胞数量 $\leq 8 \times 10^7$

与更好的细胞功能和临床结果相关。

Nature Medicine — Original Study Data

这告诉我们一个非常重要的事实：

细胞治疗不仅是医学问题，更是制造科学问题。

不是：

找到NK细胞 → 给患者。

真正的产业链是：

Cell Source



Cell Quality



Genetic Engineering



Expansion



Cryopreservation



Potency Testing



Clinical Delivery



Patient Response

因此：

**Cell Therapy = Biology + Engineering +
Manufacturing + Medicine**

六、“现货型”细胞治疗的巨大潜力

传统自体CAR-T通常需要：

患者



采集细胞



基因改造



扩增



质量检测



重新输回患者

这属于：

Autologous Model | 自体细胞治疗模式

而CAR-NK的重要战略价值之一，是探索：

Allogeneic Model | 异体细胞治疗模式

即：

健康供者



NK细胞



基因工程



规模扩增



质量控制



冷冻保存



多个患者使用

最终目标：

Off-the-Shelf Cell Therapy

即：

像传统药物一样，可以提前生产、储存，并在患者需要时使用的“现货型细胞药物”。

Nature相关报道指出，在研究团队的生产模式下，一个脐带血单位理论上可以产生超过100剂CAR-NK细胞产品。

Nature — CAR-NK Manufacturing Research

如果这一制造效率能够在商业化GMP体系中稳定复制，其意义将不仅是医学上的，也包括：

成本

供应链

生产效率

全球可及性

以及：

医疗资源公平性

七、CAR-NK与CAR-T：不是简单的“谁取代谁”

一个非常容易出现错误是：

“CAR-NK马上要取代CAR-T。”

目前没有足够证据支持这一结论。

更专业的理解应该是：

维度	CAR-T	CAR-NK
基础细胞	T细胞	NK细胞
CAR靶向能力	✓	✓
天然免疫杀伤机制	有限	✓
异体治疗潜力	研究中	重要研究方向
Off-the-shelf潜力	发展中	较高战略潜力
CRS	已知重要风险	早期研究显示可能较低
神经毒性	已知风险	早期研究较少
血液肿瘤证据	更成熟	正在快速积累
实体瘤	重大挑战	重大挑战
临床成熟度	较高	较早期

NK细胞

因此MLJC的判断是：
CAR-T与CAR-NK目前更适合被视为
互补技术，而不是替代关系。

八、iPSC-NK：可能更加重要的下
一步

另一条值得长期关注的技术路线是：
iPSC-derived NK

即：

诱导多能干细胞来源的NK细胞

其概念性生产流程为：

iPSC Master Cell Bank



NK细胞分化



扩增



基因工程



质量控制



冷冻保存



标准化细胞产品

如果这一技术最终能够实现高度稳定的产品一致性，那么它可能解决传统供者来源细胞存在的部分：

供者差异

细胞数量

质量波动

生产规模

等问题。

但是：

生产潜力不等于临床疗效已经得到证明。

iPSC-NK仍然需要更多临床数据验证：

安全性

持久性

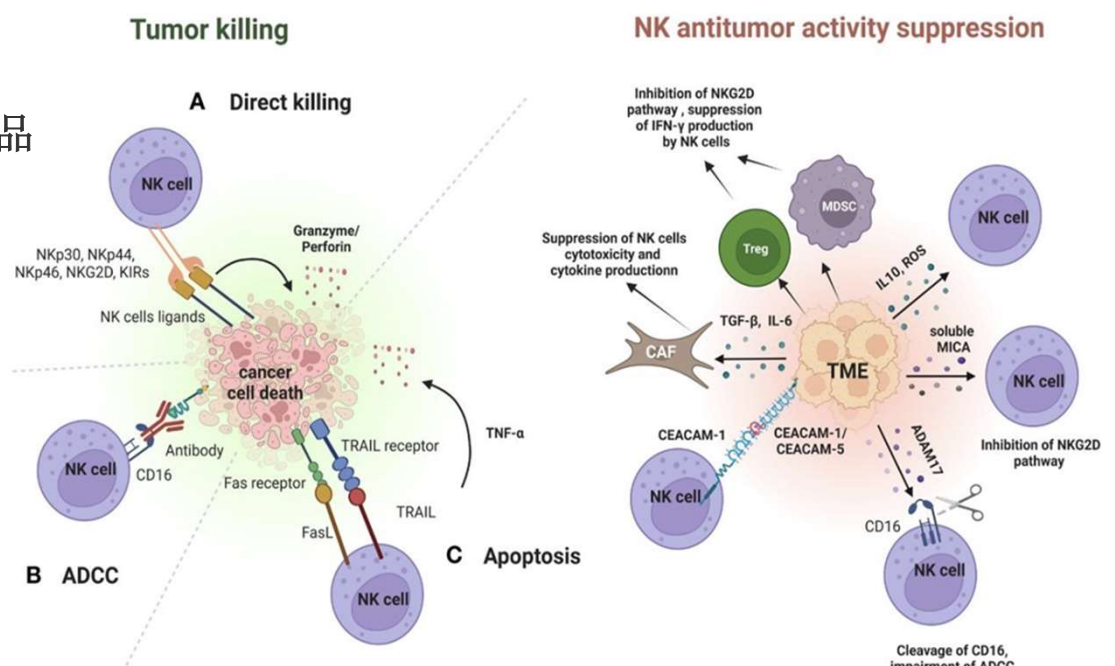
细胞功能

剂量

疗效

以及：

长期生存获益。



九、NK细胞最大的敌人可能不是癌细胞本身

而是：

Tumour Microenvironment | 肿瘤微环境

实体瘤远远不是一个简单的“癌细胞团”。

它可以形成：

- 缺氧环境
- 代谢压力
- 免疫抑制
- 细胞因子抑制
- 物理屏障
- 免疫抑制细胞群

这些因素都可能降低NK细胞的：

进入能力

存活能力

扩增能力

以及：

持续杀伤能力

因此，真正的挑战不是：

Can we make NK cells stronger?

而是：

Can we make NK cells reach the tumour, survive inside it, and remain functional?

这可能是CAR-NK未来最关键的技术战争。

十、从血液肿瘤走向实体瘤

目前NK细胞治疗在血液系统恶性肿瘤方面积累的临床经验相对更多。

但全球真正巨大的市场空间，在：

肺癌

肝癌

胰腺癌

卵巢癌

结直肠癌

以及其他实体瘤。

问题是：

实体瘤拥有更加复杂的免疫抑制环境。

因此未来研发重点可能集中在：

Tumour Homing

Tumour Infiltration

Persistence

Multi-target Recognition

Resistance to

Immunosuppression

以及：

Combination Therapy

NK细胞

十一、未来的NK细胞可能是什么样？

MLJC观察到的技术演进大致可以分为：

第一代

Natural NK Cells



第二代

Expanded / Activated NK



第三代

CAR-NK



第四代

CAR-NK + Cytokine Engineering



第五代

iPSC-NK



第六代

Multi-target / Armoured / Precision CAR-NK

未来甚至可能进一步进入：

AI-Assisted Cell Engineering

即：

肿瘤分子分析



抗原图谱



AI辅助靶点选择



细胞工程设计



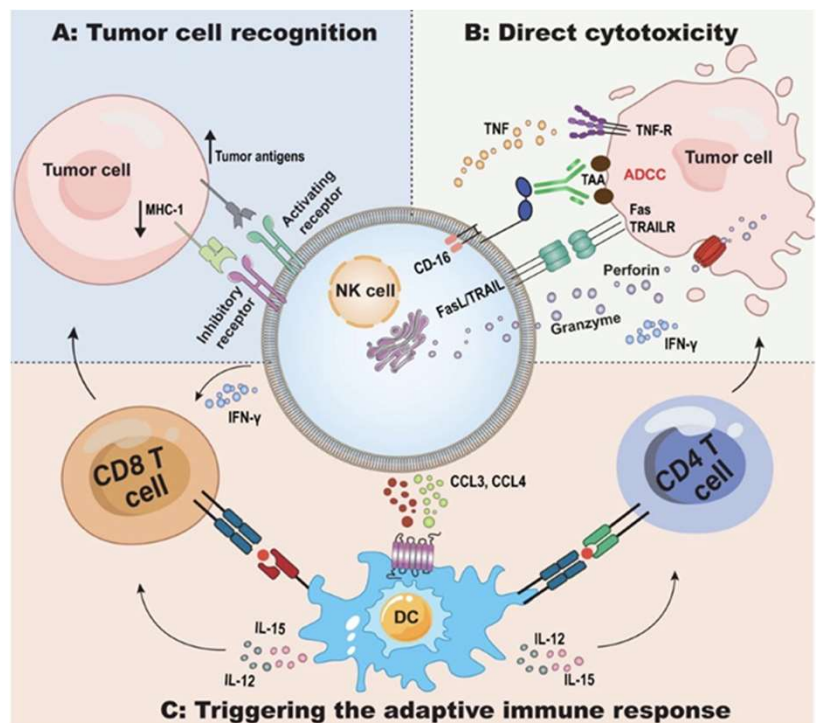
患者匹配



精准细胞治疗

这意味着：

AI + Genomics + Cell Engineering + Manufacturing
可能最终形成下一代细胞治疗产业体系。



十二、MLJC全球战略判断

我们认为，未来NK产业的竞争将集中在六个核心能力。

01 | Cell Source

细胞从哪里来？

02 | Cell Engineering

如何进行精准基因工程？

03 | Persistence

如何让细胞在人体内保持更长时间的功能？

04 | Tumour Trafficking

如何让细胞进入肿瘤？

05 | Manufacturing

如何实现稳定、标准化、GMP规模生产？

06 | Clinical Evidence

最终能否通过大型临床试验证明真正的患者获益？

因此：

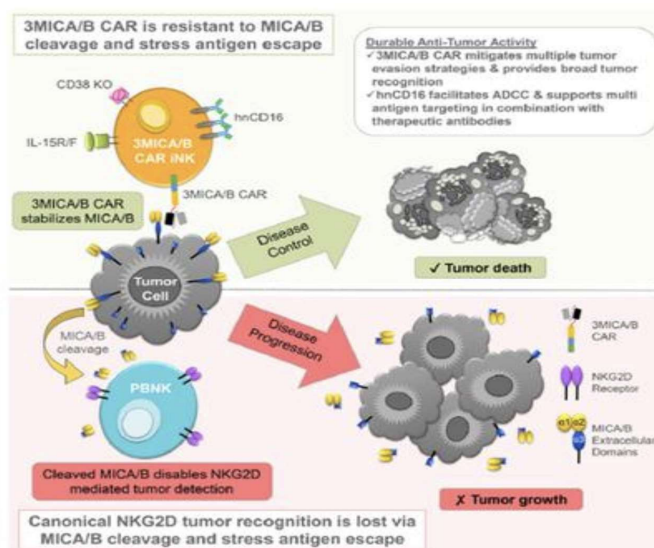
真正的竞争不是“谁的NK细胞最强”。

而可能是：

谁拥有最完整的NK治疗平台。

十三、MLJC证据矩阵

项目	MLJC评估
NK基础生物学	成熟
NK抗肿瘤机制	已有充分基础研究支持
NK细胞治疗	积极发展中的临床领域
CAR-NK	具有潜力的早期临床领域
iPSC-NK	高战略潜力的新兴领域
Off-the-shelf	技术吸引力高，临床仍在发展
血液肿瘤	目前证据相对较强
实体瘤	巨大机会，同时具有重大挑战
长期持久性	仍是重要问题
规模化生产	关键产业瓶颈
全球监管成熟度	仍处发展阶段
已证实为通用癌症疗法	否
已证实治愈癌症	否



十四、MLJC特别强调的医学边界

我们必须避免以下表达：

- ✗ “NK细胞可以治愈癌症”
- ✗ “NK细胞可以杀死所有癌细胞”
- ✗ “NK细胞一定比化疗好”
- ✗ “CAR-NK已经取代CAR-T”
- ✗ “NK细胞治疗已经成为成熟的通用癌症治疗”

更加专业的表达应该是：

NK-cell-based immunotherapy is an actively developing field of cancer research, with encouraging clinical signals in selected malignancies but important unresolved questions regarding persistence, tumour trafficking, manufacturing, safety and long-term efficacy.
即：

NK细胞免疫治疗是目前积极发展的癌症治疗研究领域，在部分恶性肿瘤中已经出现令人鼓舞的临床信号，但其持久性、肿瘤浸润、规模化生产、安全性及长期疗效仍需要进一步验证。

这才是国际医疗机构可以接受的表达。

十五、MLJC未来十年的五个问题

Q1

NK细胞能否真正成为规模化的现货型癌症药物？

Q2

iPSC技术能否解决供者之间的细胞差异？

Q3

CAR-NK能否突破肿瘤免疫抑制微环境？

Q4

多靶点CAR-NK能否降低肿瘤抗原逃逸？

Q5

大型随机对照临床试验能否证明NK治疗带来持久的生存获益？

这些问题将决定NK细胞最终能否从：

科学潜力

进入：

临床标准

再进一步进入：

全球医疗产业平台

十六、MLJC更深层的战略观察

真正值得关注的，并不只是NK细胞。

而是医学产业正在发生的结构变化。

第一阶段

Chemical Molecule → Patient

化学分子 → 患者

第二阶段

Biologic → Patient

蛋白质 / 抗体 → 患者

第三阶段

Patient Cell → Engineering → Patient

患者细胞 → 工程改造 → 患者

第四阶段

Engineered Living Cell →

Manufacturing Platform →

Patient

工程化活细胞 → 规模制造 → 患者

最终可能形成：

Biology as a Manufacturing Platform

这也是MLJC认为NK细胞值得全球医疗、生命科学、投资机构及政策制定者长期观察的根本原因。

十七、MLJC独家结论

我们不会简单地写：

“NK细胞将取代CAR-T。”

目前的科学证据还没有走到这一步。我们更愿意给出一个更加严谨的判断：

NK细胞正在从成熟的基础免疫学概念，逐渐进入工程化、临床化和产业化的平台阶段。

2024年发表于 *Nature Medicine* 的 Phase 1/2 研究，为异体CD19 CAR-NK提供了重要的早期临床证据：

37例患者

48.6% Day-30 Overall Response

48.6% Day-100 Overall Response

68% 1-year Overall Survival

同时出现较为有利的安全性信号。

Nature Medicine — Original Clinical Study

但是，下一阶段必须回答：

更大样本

→ 随机对照研究

→ 长期随访

→ 更稳定的制造体系

→ 更强的细胞持久性

→ 更好的实体瘤浸润能力

→ 监管验证

只有这样，NK细胞才能真正确定自己在未来癌症治疗体系中的位置。

十八、MLJC最终观点

未来一代癌症治疗，可能不再只是实验室里设计出来的一种分子。它可能是一种被工程化设计出来的“生命系统”。

NK细胞本来就存在于人体免疫系统之中。

今天，现代生物科技正在尝试：

理解它



培养它



增强它



工程化它



重新编程它



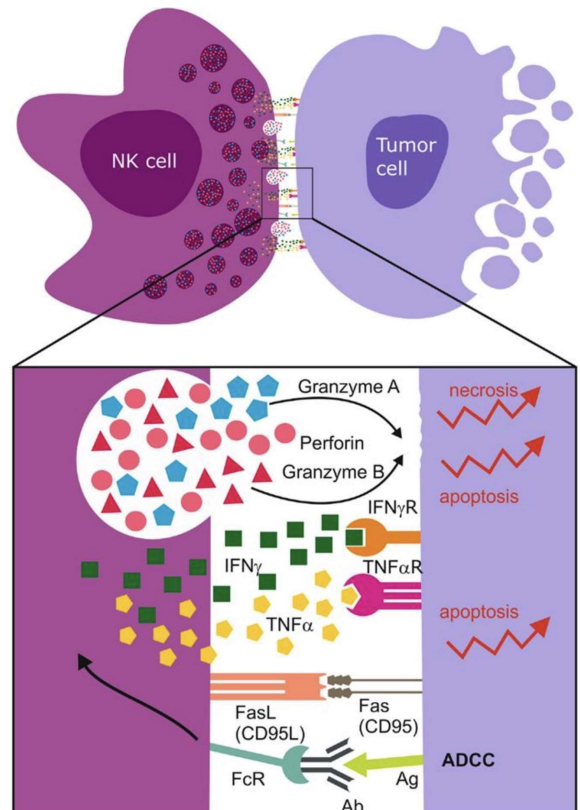
规模化制造它



让它成为药物。

这并不是简单的：

“增强免疫力”。



它真正代表的是：

ENGINEERING IMMUNITY | 工程化免疫

而这，正是MLJC认为NK细胞值得全球医疗机构、生物科技产业、投资机构以及公共卫生政策制定者长期关注的原因。

<https://www.nature.com/articles/s41591-023-02785-8>

<https://www.nejm.org/doi/full/10.1056/NEJMoa1910607>

<https://www.nature.com/articles/s41568-022-00491-0>

<https://www.nature.com/articles/s41577-022-00732-1>

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Authors: Enli Liu, M.D., David Marin, M.D., Pinaki Banerjee, Ph.D., Homer A. Macapinlac, M.D., Philip Thompson, M.B., B.S., Rafet Basar, M.D., Lucila Nassif Kerbaui, M.D., ⁺¹⁹, and Katayoun Rezvani, M.D., Ph.D. [Author Info & Affiliations](#)

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