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GMP MANUFACTURING SOLUTIONS FOR SMALL-BATCH AND PERSONALIZED CANCER VACCINES

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PRODUCTION CLEAN ROOMS

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QC AND STORAGE ROOMS

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TECHNOLOGIES

Dendritic cells

lipid nano-particles

In-vitro transcribed RNA

Stromal vascular fraction (SVF)

Multivirus-specific T-cells

Point-of-care CAR-T cells (starting 2024)

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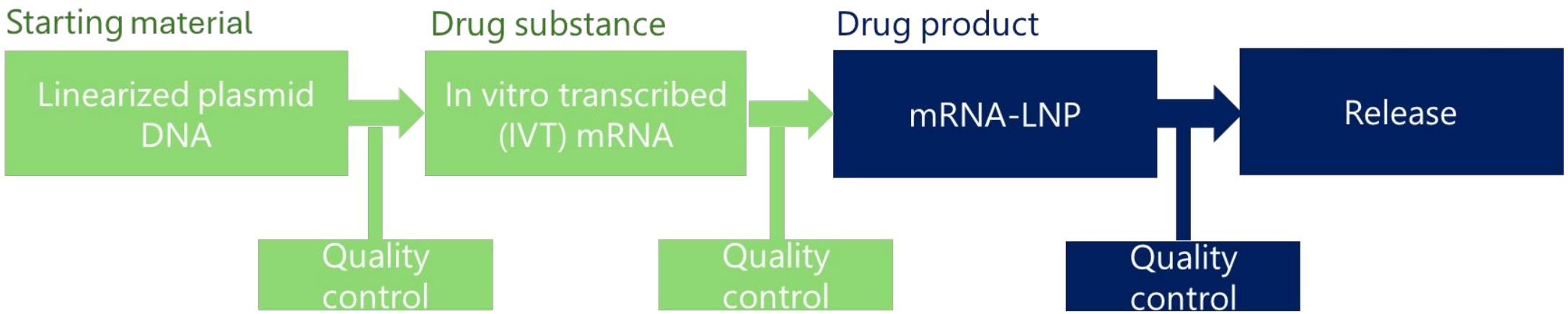
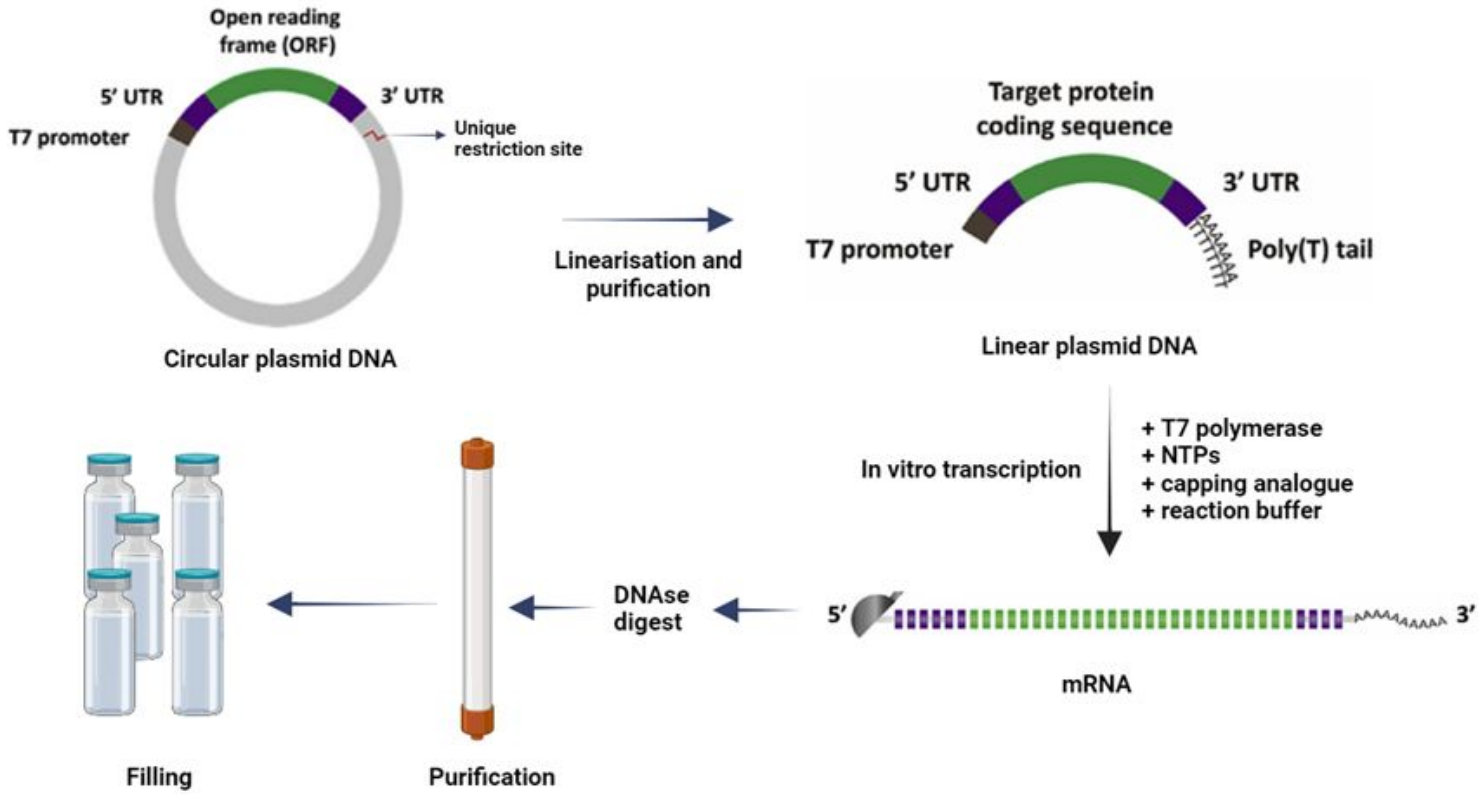
RNA PRODUCTION FLOW



RNA PRODUCTION FLOW



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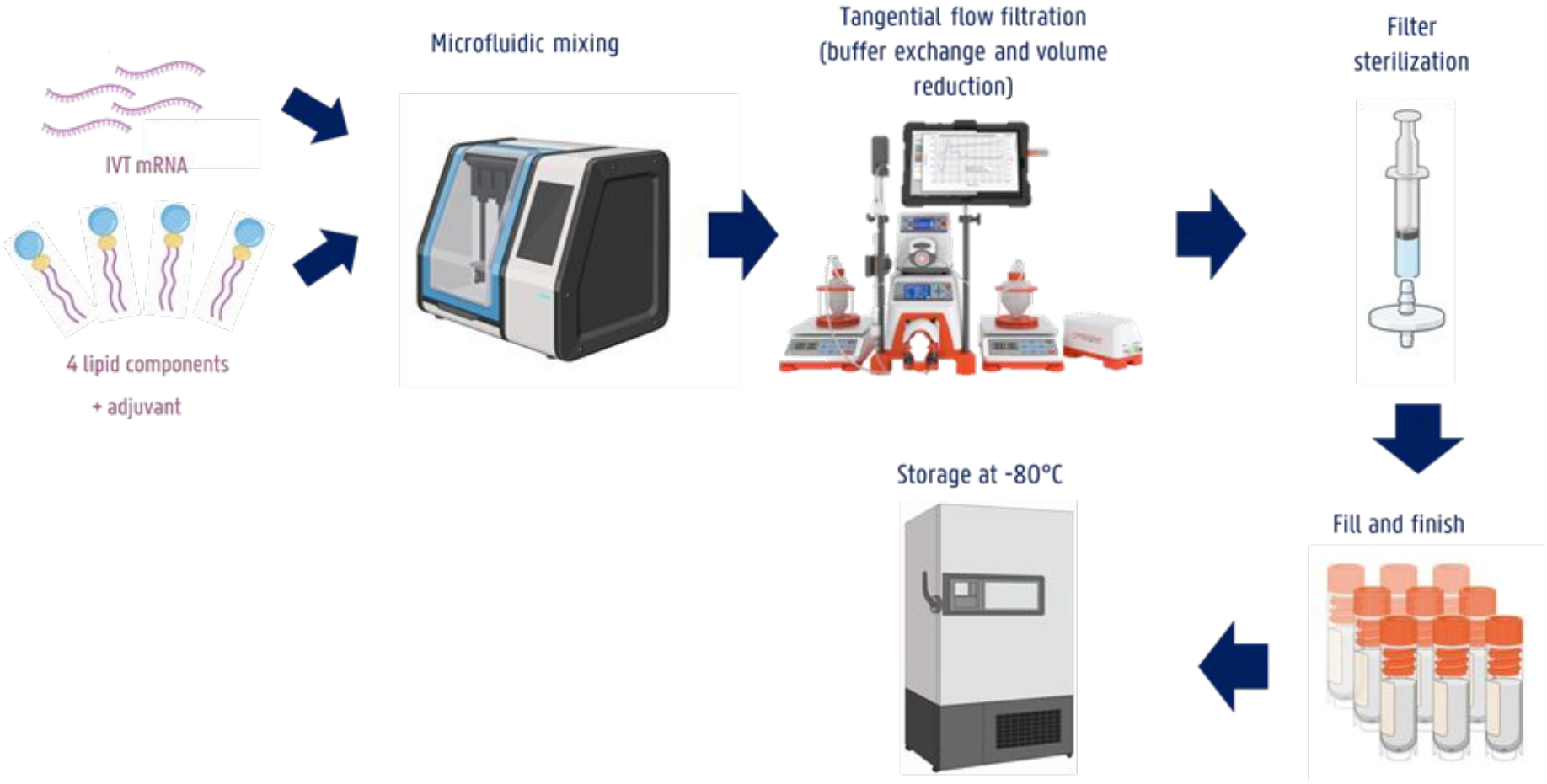
RNA PRODUCTION FLOW



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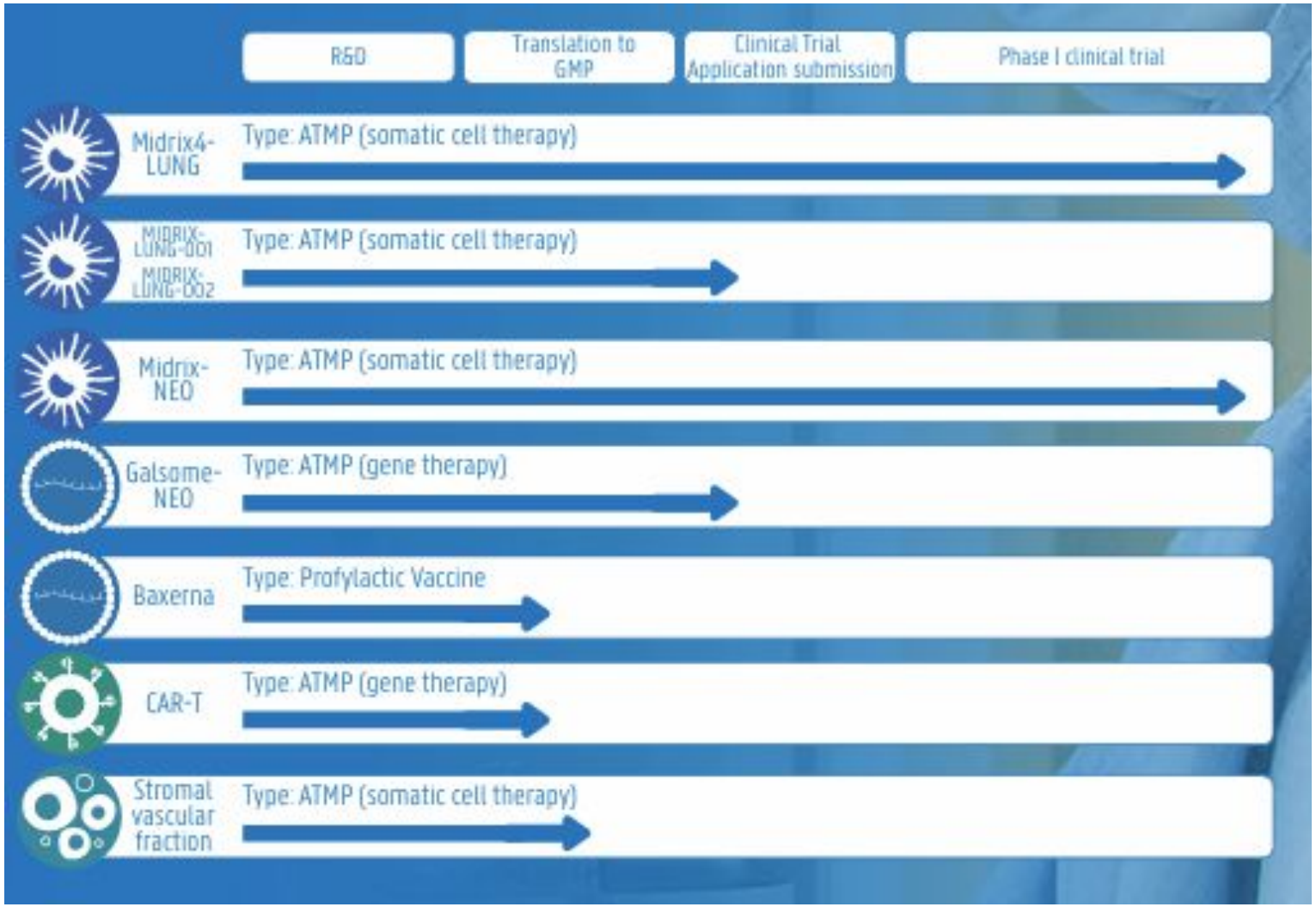

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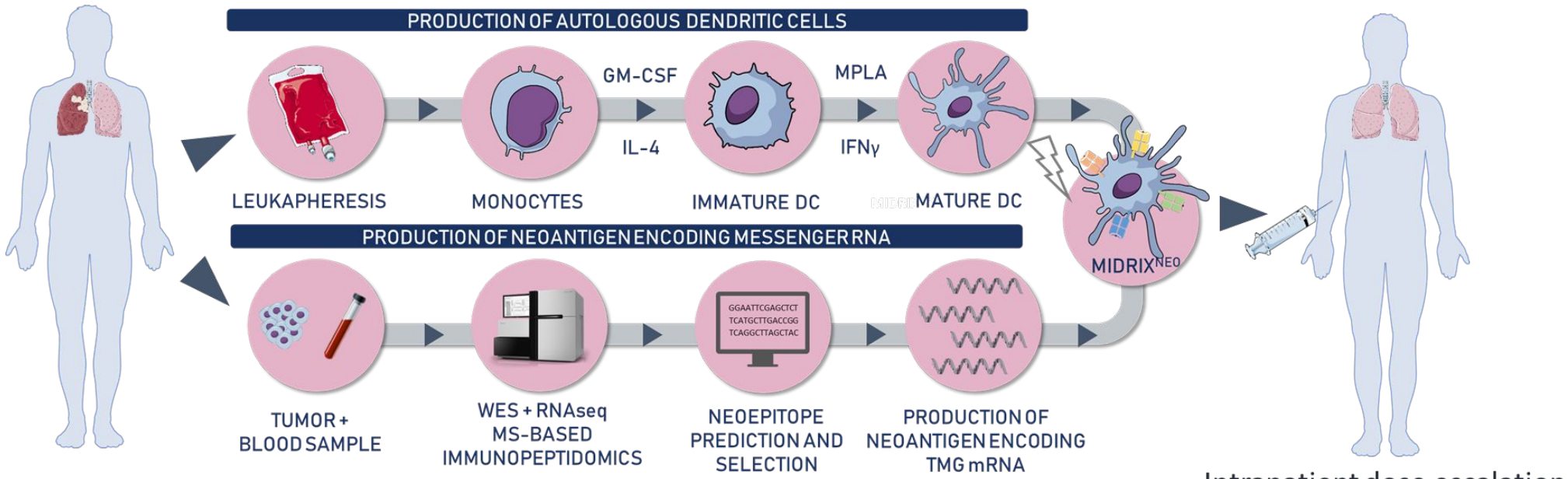
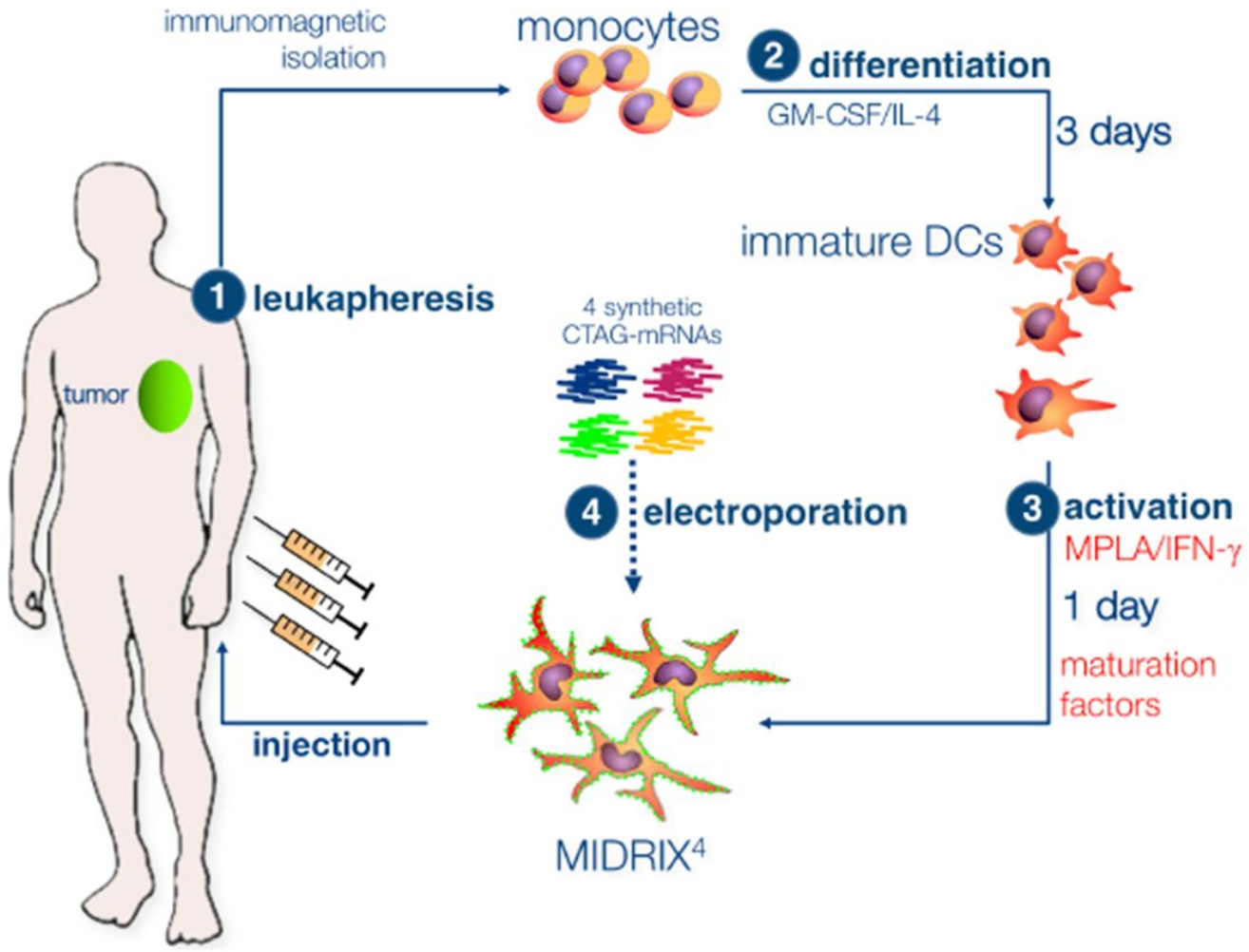
MIDRIX NEO



Brabants *et al.* Cytotherapy 2018

MIDRIX 4 LUNG



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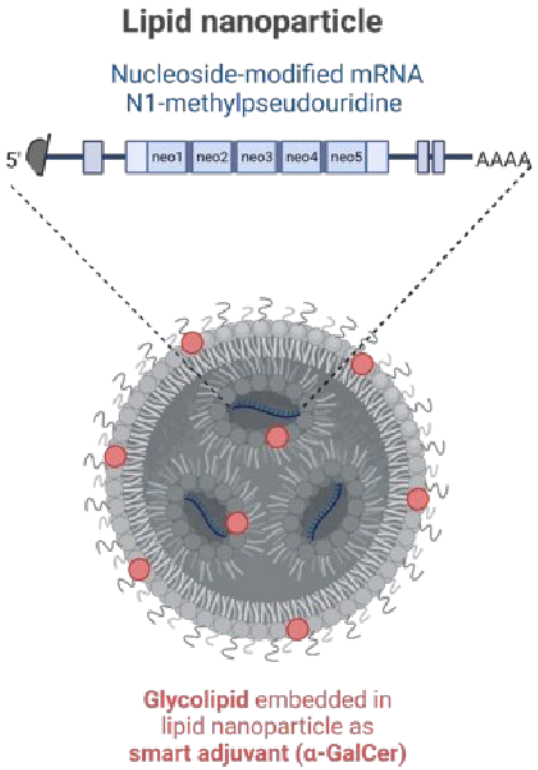
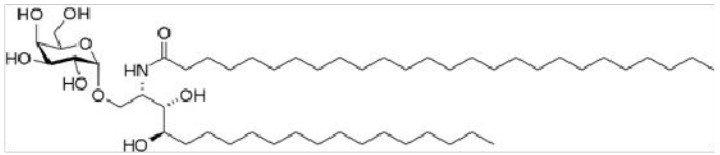
GALSOME-NEO



Lipid nanoparticle (LNP) for co-delivery of:

- **nucleoside modified neo-epitope-encoding mRNA**
  immunosilent -> Limited type I IFN activity
  Increased stability and translation capacity

- **α-galactosylceramide** (adjuvant)
  Glycolipid antigen presented in CD1d pathway
  Recognized by Natural Killer T cells (iNKT cells)



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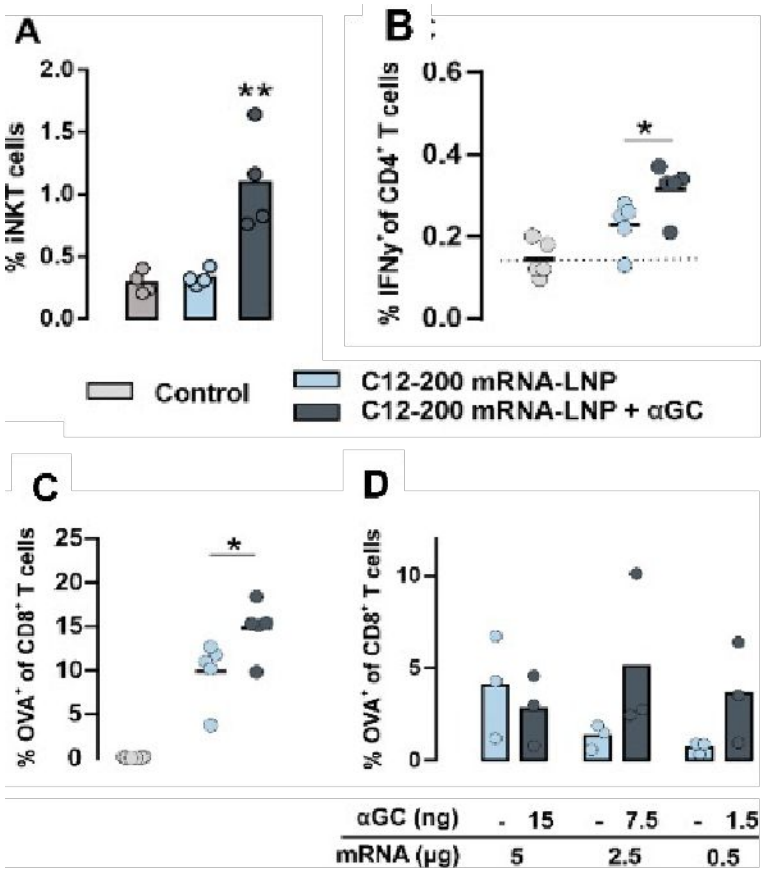
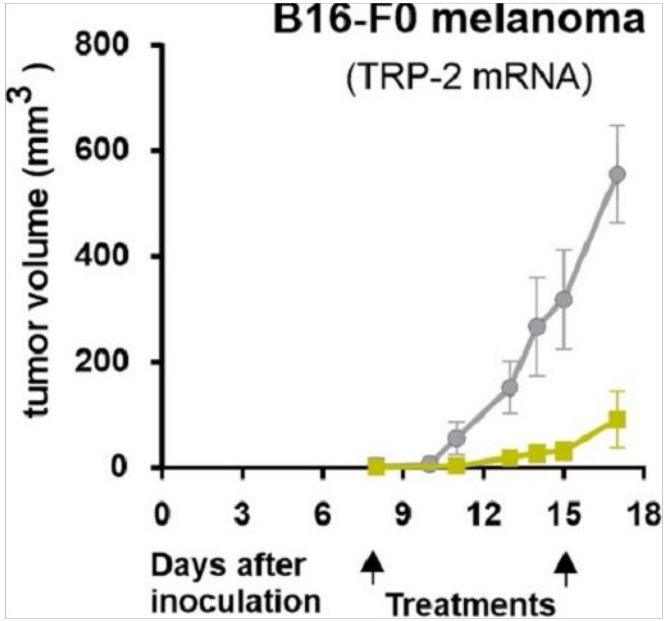
GALSOME-NEO



Dose-sparing effect

Therapeutic vaccination with relevant mRNA encoded antigen (TRP-2) results in strong tumor growth reduction



RNA CAR T

- Academic developed CAR T product
- Ex vivo prepartion of CAR Ts – autologous – but with RNA in LNPs
- The GMP unit produced the RNA / LNP formulation for this partner
- Clinical trial ongoing 2025-2027

VIB-KUL COLLABORATION

See presentation Prof. Dr. Dieter Lambrechts

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ZIPHIUS VACCINES

OncoRNA
PERSONALIZED CANCER VACCINE

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OncoRNA

PERSONALIZED CANCER VACCINE

- IPCEI Med4Cure selected project
- Head and neck cancer
- Synthetic DNA
- RNA production is individualised as a pool (compared to concatenated)
- Because there is no limitation in termes of neoantigens numbers, the patented technology enables the production of more than 100 neoantigens (vs. max 20/30 with Plasmids)
- Phase 1 expected 2026

Cliniques universitaires SAINT-LUC UCL BRUXELLES

SIDE NOTE ON PROPHYLACTIC VACCINES

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BAXERNA

Institut Pasteur

Demangel
Mycobacteria
Tuberculosis & Buruli Ulcer

Van der Henst & Muraille
Acinetobacter baumannii
AMR

VIB

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VIB
Impens
MS Proteomics
Immunopeptidomics

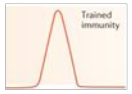
VIB
Martens
MS Bio-IT
Immunopeptidomics

Antigen discovery

mRNA vaccine development

Breckpot
mRNA design
immunotherapy

De Smedt
mRNA vaccines
adjuvantia



Netea
trained immunity
innate immunity

Loré
vaccine mechanisms
In vivo models

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GHENT UNIVERSITY

Radboudumc

Karolinska Institutet

GHENT UNIVERSITY
Vandekerckhove
GMP mRNA-LNP
production

GHENT UNIVERSITY
Vermaelen
Pneumology
Tuberculosis

GHENT UNIVERSITY
Leroux-Roels
Center for Vaccinology
Clinical trials

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clinical trial

VFI VACCINE FORMULATION INSTITUTE — Analytical Methods

RheaVita — Vaccine lyophilization & storage

Quantam Biosciences — Cheaper en local Vaccine production

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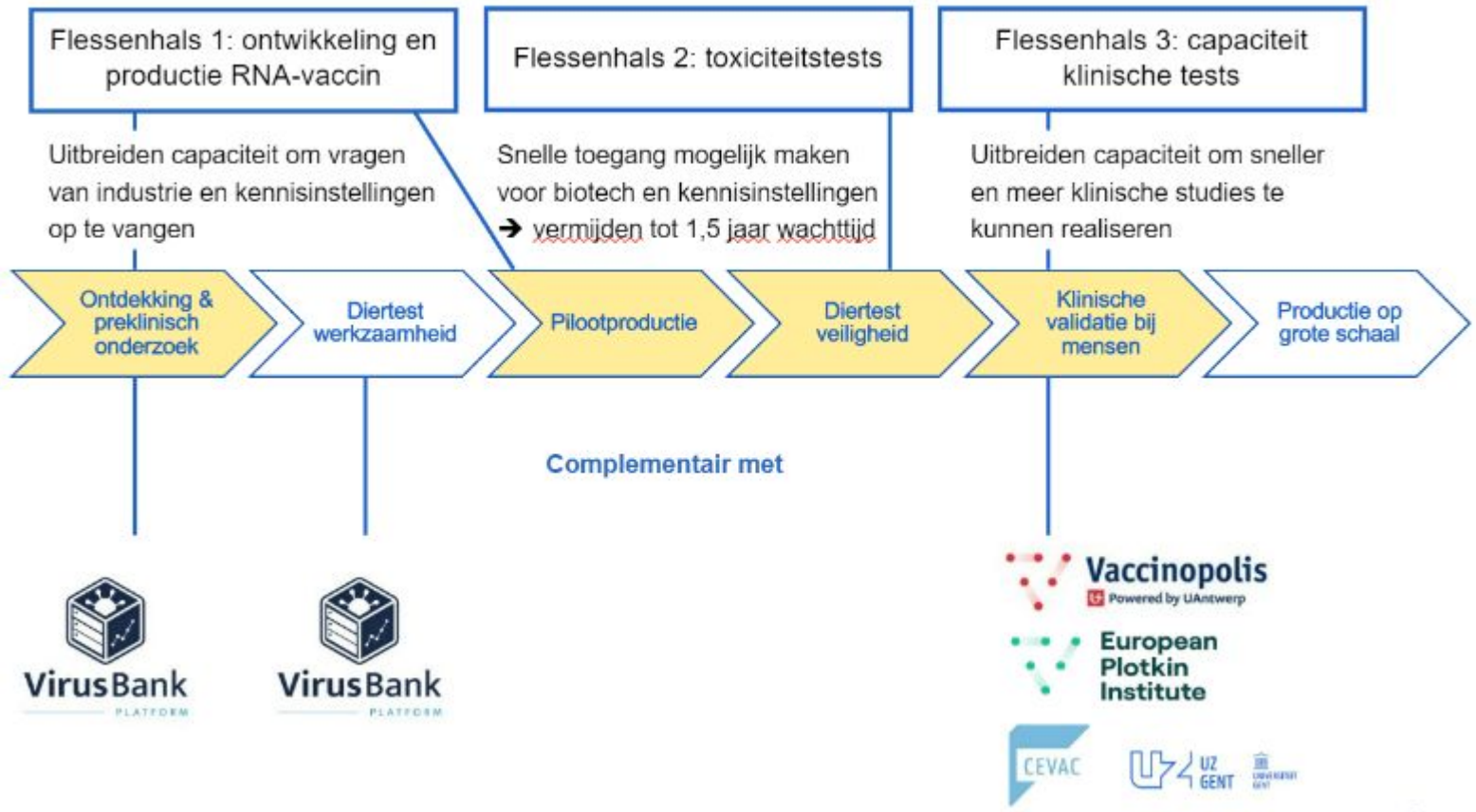
VAXADVANCE



- Enable fast and local vaccine production in case off pandemic situations and bio-safety
- Public setting
- Warm-ready facilities
- Build-on and enforce excisting infrastructures and expertise

https://vaxadvance.com/

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Ecosystem

- cover academic needs
- cover patient needs
- integration in Flemish ecosystem

- UZGent (Prof. Verhasselt and Prof. Rottey)
- External parties

Advisory board






Conclusions

- Small batch GMP production is possible in a hospital setting
- RNA-derived products – vaccines and ATMPs - are a focus on UZ Ghent
- Bringing innovations faster and cost-effective to patients
- On-site production of lentivirus and CAR T in the coming years
- Important expansion of the facility expected by end 2026
- Challenging to do this within the constraints of funding channels

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Collaborators and Team

Business Developer
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Eva Pascal

Eva Van Houtte
Saskia Desmet
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Bjorn Menten
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Sandra Van Lint
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Tessa Kerre

B Depypere
P Blondeel

Linos Vandekerckhove
Wojciech Witkowski

Francis Impens
Rupert Mayer
Lennart Martens

Sponsors
Kom op tegen Kanker KOTK
Stichting tegen Kanker
Horizon 2020
Industrieel Onderzoeksfonds IOF
Innovatiefonds UZ Gent

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Thank you – any questions?

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ACADEMIC COLLABORATIONS IN ATMP

Projectacronym	Project	status	promotor
ATMP-XB	Vlaams-Nederlande competentiecluster	ingediend	
VaxAdvance	Oprichting instituut voor (pre)-klinisch veiligheidsonderzoek van vaccins in het kader van pandemic prepardeness	lopend	
Attract	Europees consortium: CD19 CAR-T (ARI-001) in pediatrische ALL	2de ronde	Susana Rives, Barcelona, Spain
UM-VAC	Therapeutic vaccines targeting multiple shared tumor-specific neoantigens related to the dark transcriptome.	Negotiatie	O Lantz, Institut Curie, Paris France
Mission Europe call 2025	Multinational clinical study targeting Ewing Sarcoma neogenes	negotiatie	Olivier Delattre, Institut Curie
DURACAR	Durability and Upgraded resilience in advanced CAR-T cell Therapies	rebuttal sent	Linos Vandekerckhove
GD2-IL18 CAR-T	GD2 CAR-T Glioblastoma	negotiation	Bart Neyns, Liang Goa Miltenyi, Sandra Tuyaerts
CD19 CAR-T	CD19 CAR-T in pediatric ALL,	negotiation	Locatelli, Rome Italy; Miltenyi
IRI call FWO	Belgian to become part of the European Research Infrastructure EATRIS - focus on translational medicine	in preparation	VUB, UA, KUL, UGent …
NKI - TILs	academic development - uterine cancer	after clinical trial - EMA	Nederlands Kanker Instituut
KUL – VIB Dieter Lambrechts			

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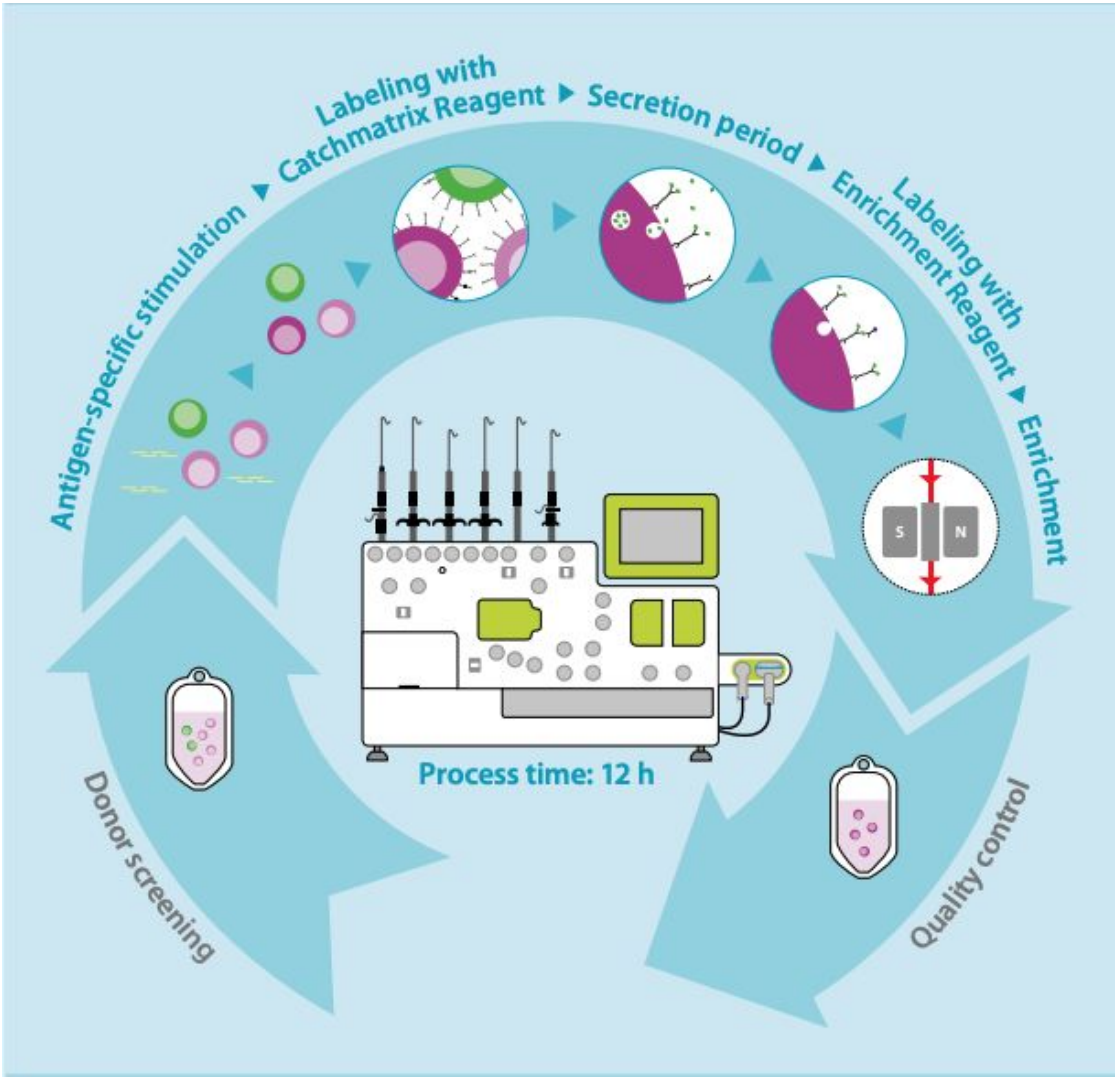
TRACE STUDY



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