Day 2: Tuesday 12.9.23, Biocity

9:00 – 9:05 Welcome

Day 2	With SAB until Lunch break	
9:00 – 10:30	Project pitches: AlloCART*reg*. CAReNKAID, ECP-CAR, Thera Star, ZellTWund, MSCPrestige	6 Projects pitches 5 min.+ 7 min. discussion
10:30 – 10:50	**Break**	**All**
10:50 – 12:30	Break-out session 2 -> each group hands in report/slides**+ SAB Meeting**	All
12:30 – 13:30	**Lunch Break Parallel Meeting SAB & Speaker**	**All**
13:30 – 14:00	Report Break-out sessions & Action planning	Reporters of each break out group
14:00 – 14:30	Outlook to the next phase, Thank you and good bye	Speakers 30 Min
14:30	**End of the meeting and Vereinsgründung**	**Founding members**

Project pitches #3: 5 min + 7 min

Day 2: Tuesday 12.9.23
9:00-10:30

AlloCART*reg* Anke Fuchs (CRTD, MSNZ), Anke.Fuchs1@tu-dresden.de

CAReNKAID Jiri Eitler (DRK Blutspendedienst), j.eitler@blutspende.de

ECP-CAR Vladan Vucinic (UKL), vladan.vucinic@medizin.uni-leipzig.de

Thera Star Anja Feldmann (HZDR), a.feldmann@hzdr.de

ZellTWund Marta Torregossa (UKL), Marta.Torregrossa@medizin.uni-leipzig.de

MSCPrestige Tino Hammer (MDTB) & Simone Sonnenberg (DKMS SCB),
tino.hammer@mdtbcells.com ; sonnenberg@dkms-stemcellbank.de

AlloCART*reg* – Project Overview

SAXOCELL®

Universitätsklinikum Carl Gustav Carus

CRTD Center for Regenerative Therapies TU Dresden

TECHNISCHE UNIVERSITÄT DRESDEN

HZDR HELMHOLTZ ZENTRUM DRESDEN ROSSENDORF

Martin Bornhäuser

Anke Fuchs

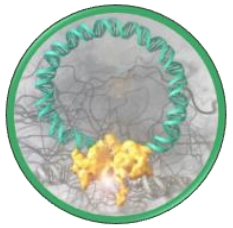
Frank Buchholz

Anja Feldmann

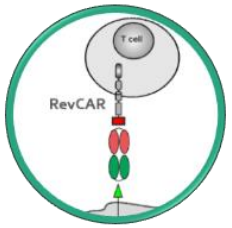
Michael Bachmann

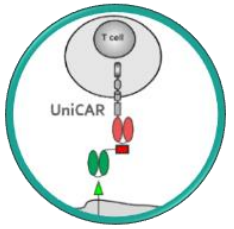
Hematology
Cell therapy incl. Treg

Treg manufacture
GMP / ATMPs

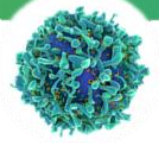


Gene editing
Designer recombinases



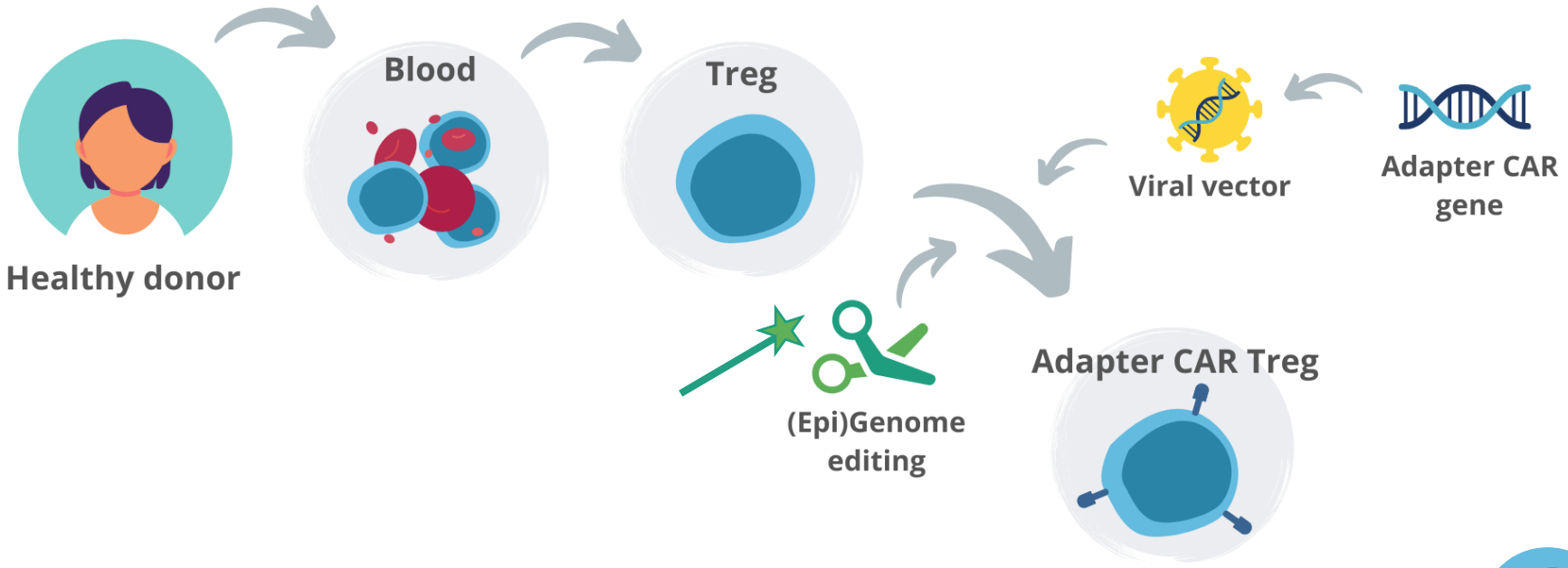


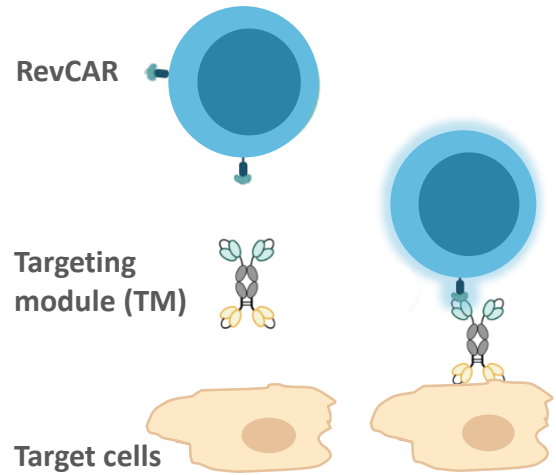
Flexible unique adapter CAR technology

Next generation  Treg cell therapy

AREA 1 – CAR-T

AlloCART*reg* – Project Overview





AREA 1 – CAR-T

AlloCART*reg* – Project Overview

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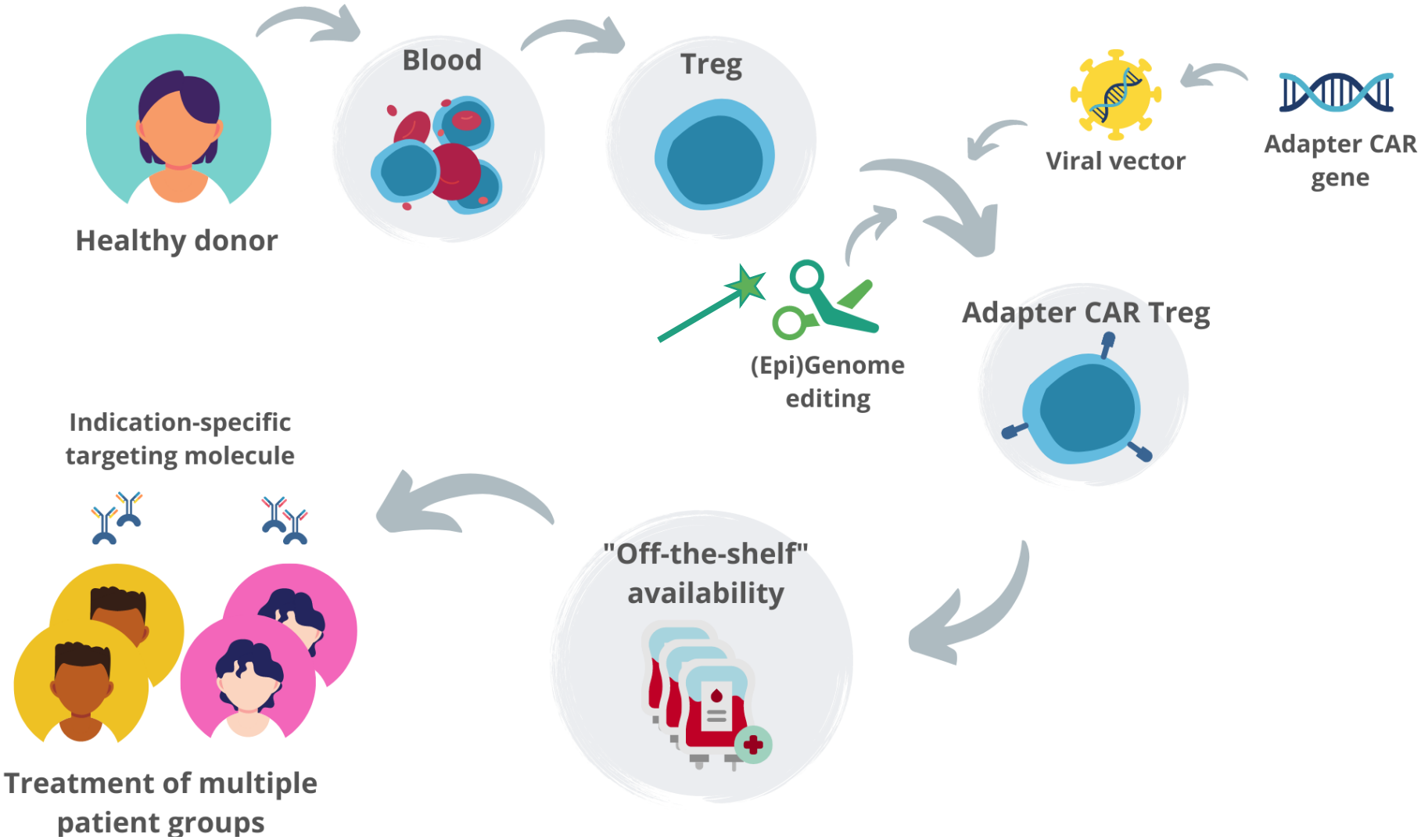
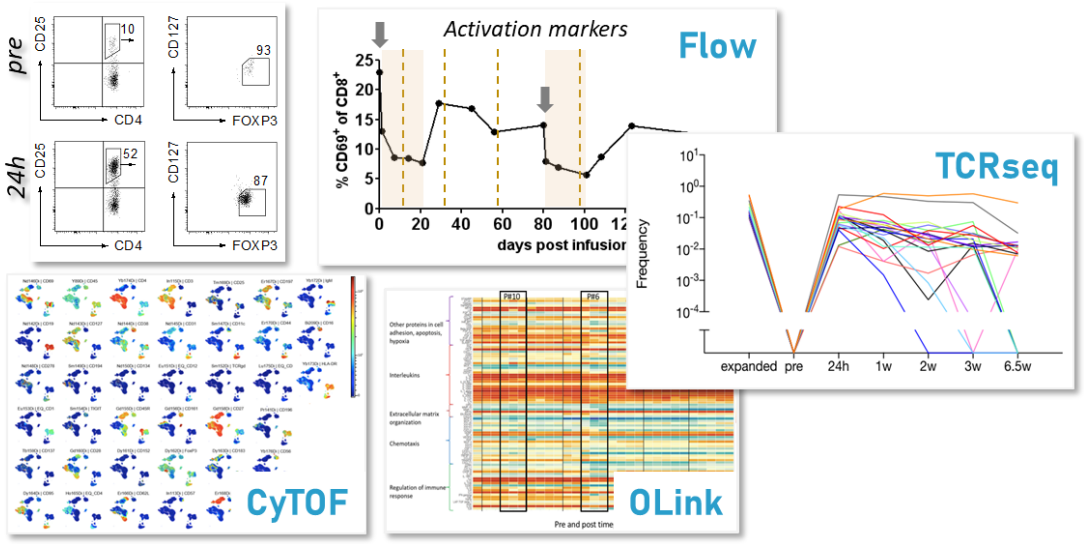


AREA 1 – CAR-T

AlloCART*reg* – Objectives

Polyclonal Treg therapy for cGvHD ✔ **Automation** ✔ **Immunomonitoring** ✔



Transient response / late treatment

Systemic

Theil(Fuchs) et al. 2015, Theil(Fuchs) et al. 2017, Marín Morales et al. 2019

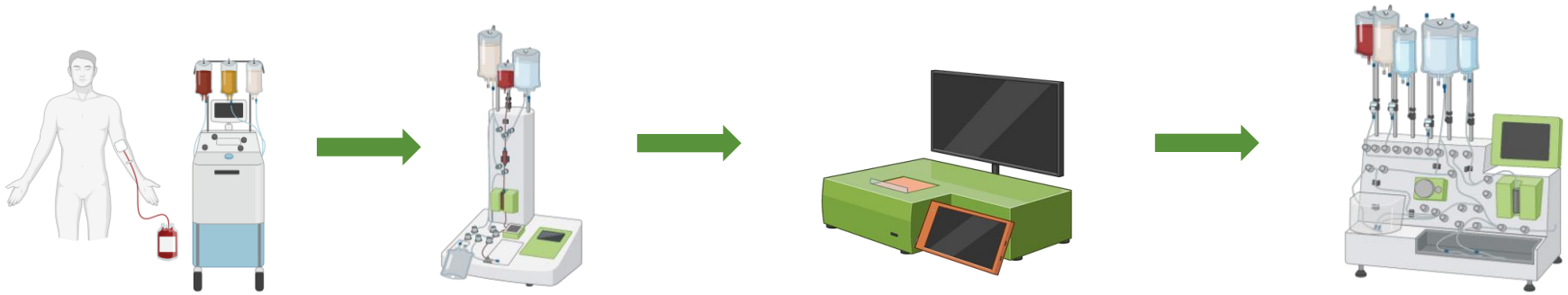
AREA 1 – CAR-T

- **„Off-the-shelf“** product allowing early treatment, multiple doses, cost effectivenss
- **Targeted** suppression, **multiple indications** in inflammatory and autoimmune disease

AlloCART*reg* – Results so far

SAXOCELL®

Clinical Scale RevCAR Treg manufacturing process ✔



Apheresis → Pre-enrichment → GMP compatible sorting → Transduction, expansion

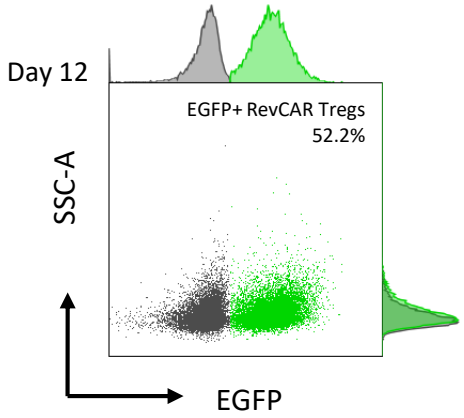
AREA 1 – CAR-T

Kavitha L K Krishnakumar (Fuchs lab), José M Marín Morales (Fuchs lab), CRTD GMP facility, Liliana R Loureiro (Feldmann lab), Alexandra Kegler (Feldmann lab)

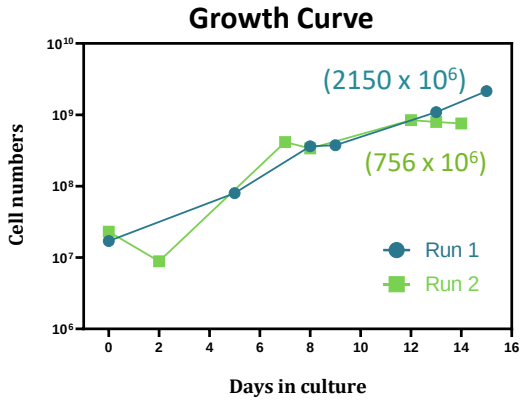
AlloCART*reg* – Results so far

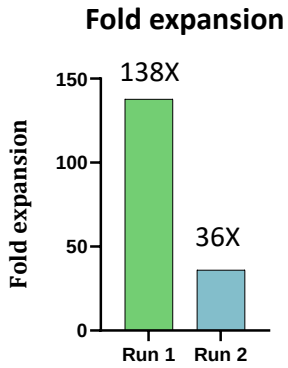
SAXOCELL®

Good RevCAR transduction efficiency



High yield after expansion

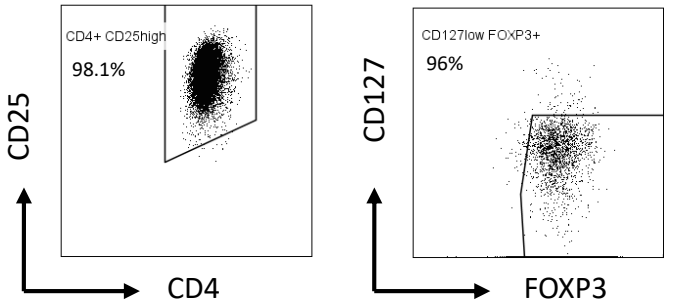




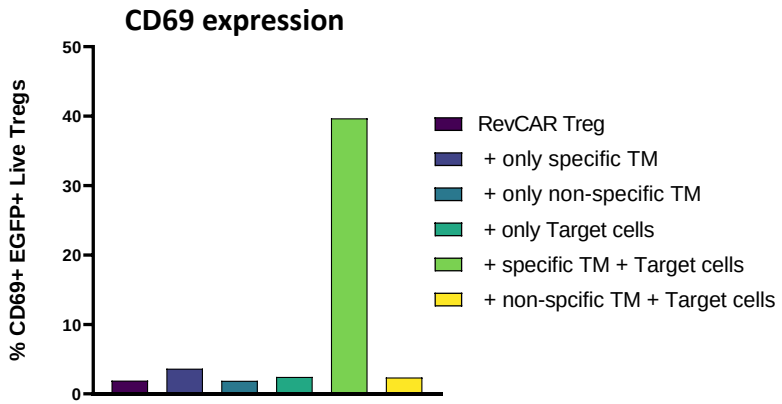
High purity after expansion

Pre-gated on: Viable CD3⁺ CD4⁺ CD25^{high}

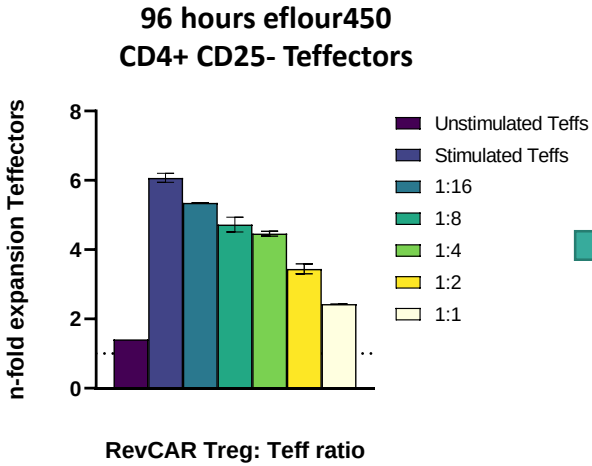
Purity: 96% of viable cells



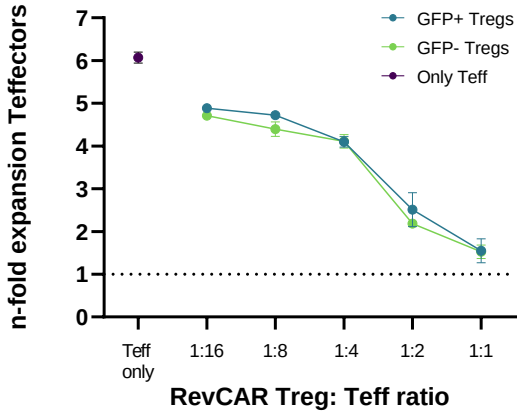
RevCAR Tregs are specifically activated



Retain suppressive function



Sorting
EGFP+/-



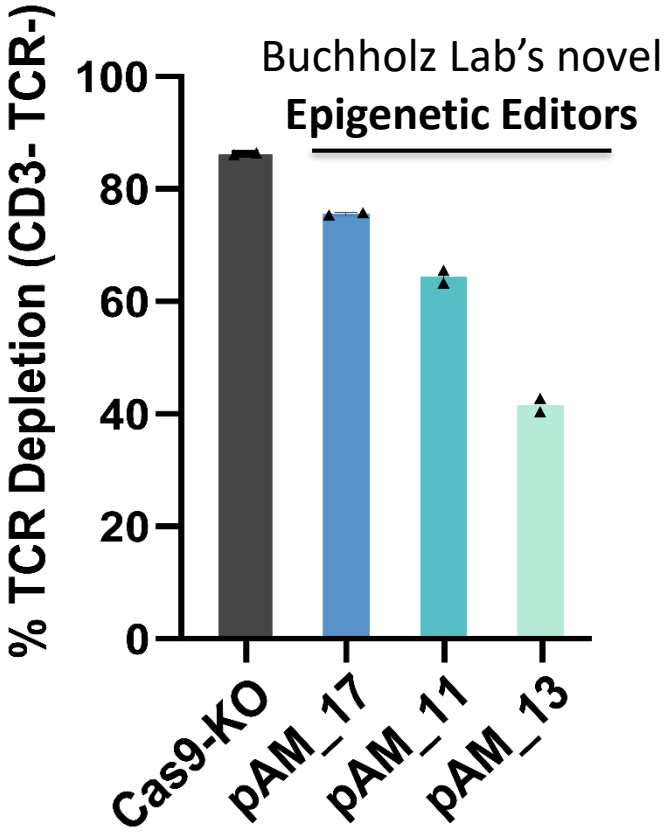
AREA 1 – CAR-T

Kavitha L K Krishnakumar (Fuchs lab), Alexandra Kegler (Feldmann lab)

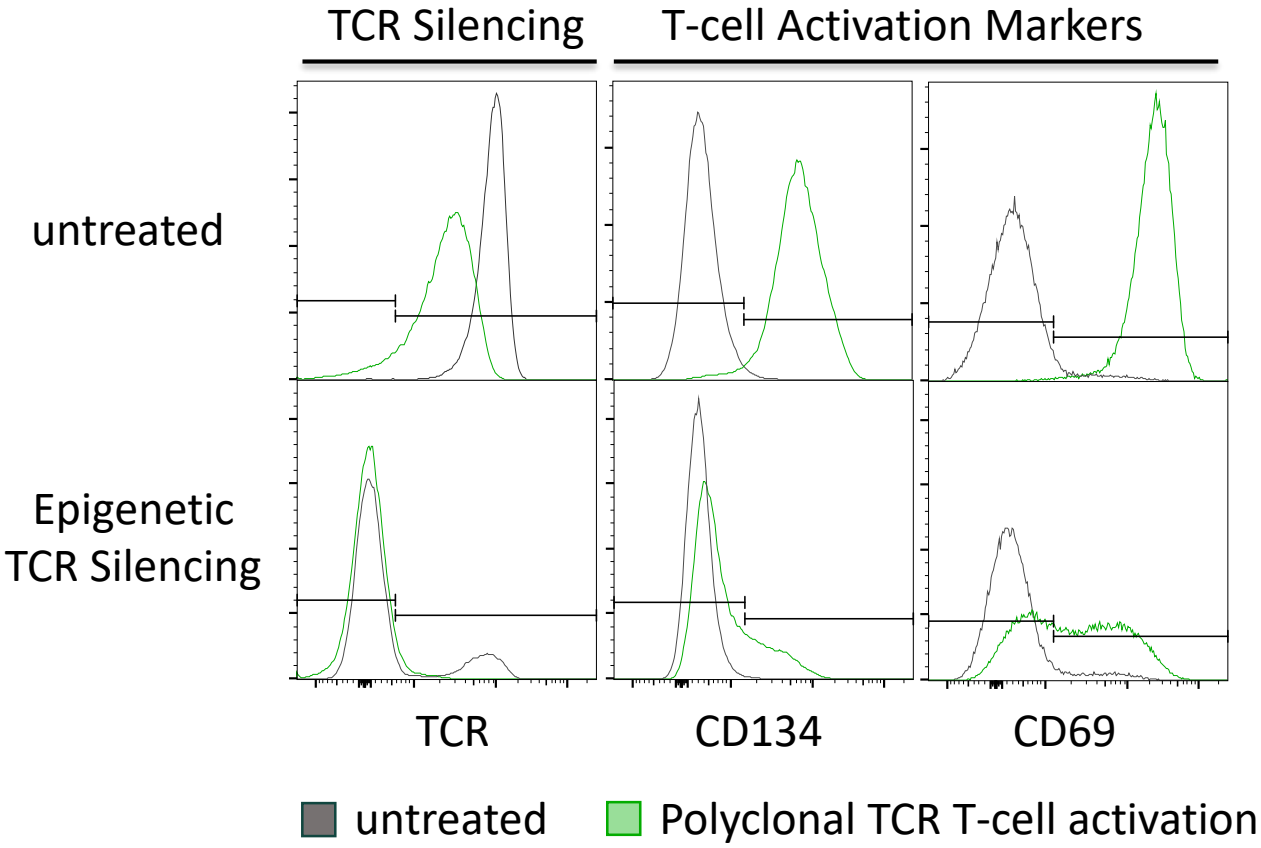
AlloCART*reg* – Results so far

SAXOCELL®

Epigenetic TCR Silencing



Phenotypic Analysis

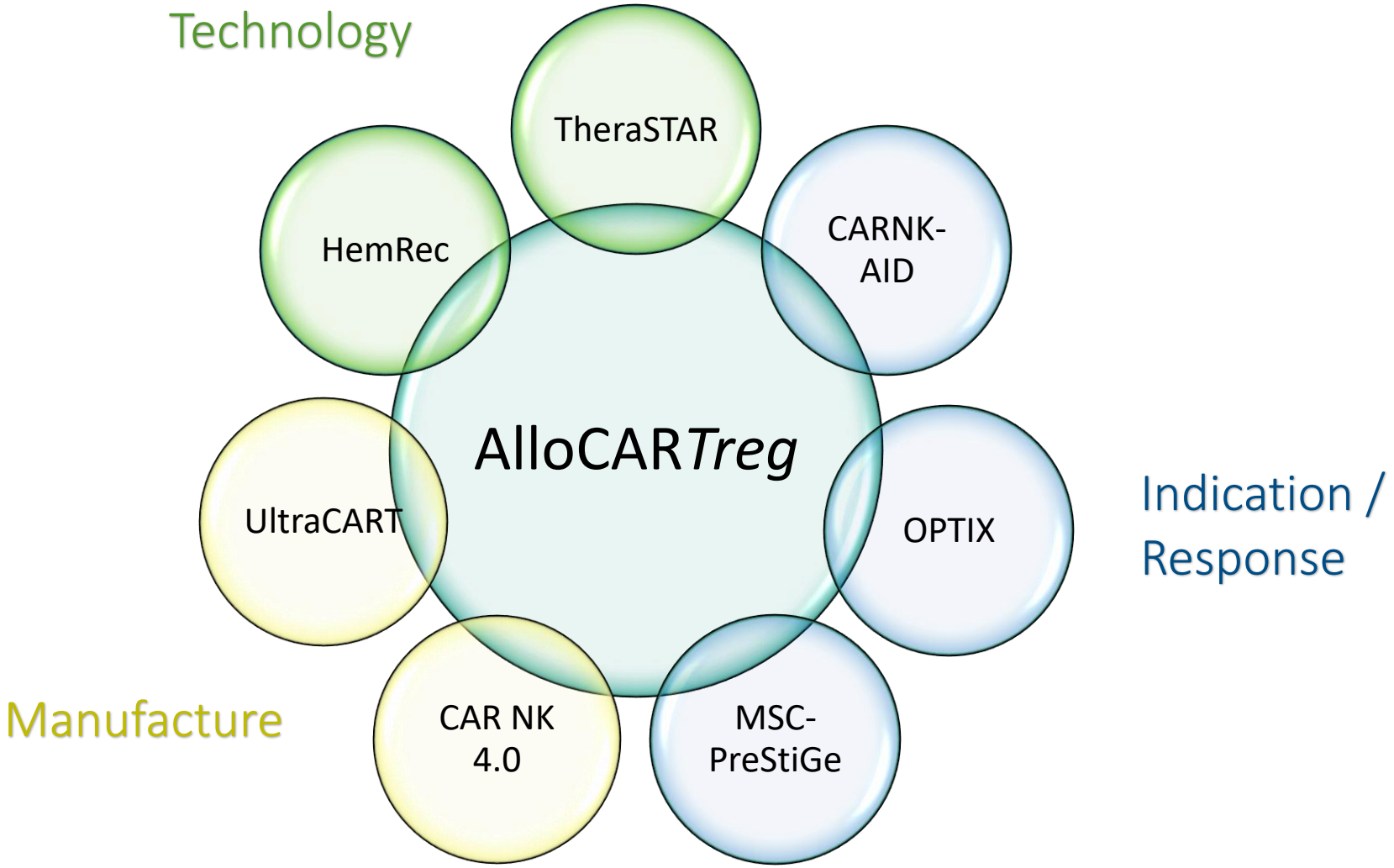


AREA 1 – CAR-T

Pascal Schönberg (Buchholz lab), Samikshya Santosh Nirmala (Fuchs lab)

*Results from Primary CD4⁺ T-Effector cells

AlloCART*reg* – Synergies to other SC Projects



AlloCART*reg* – Outlook

SAXOCELL®

Short-term

- Optimizing antigen-specific functional assays
- Optimizing epigenetic TCR silencing, impact on phenotype and expansion potential

Medium-term

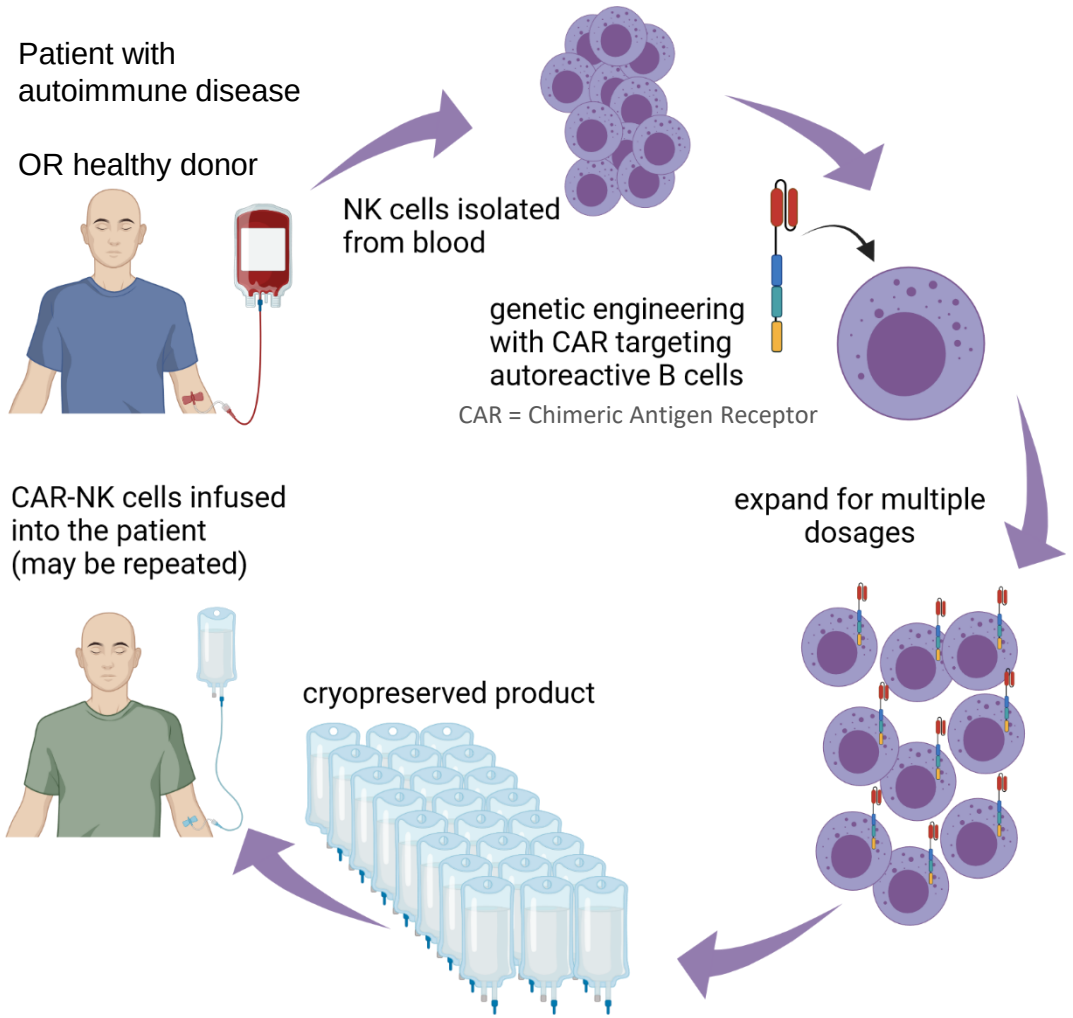
- Integration of epigenetic TCR silencing to the automated manufacturing process
- Upscaling of umbilical cord blood Treg manufacturing DKMS Stem Cell Bank

Long-term

- Novel targeting modules for autoimmune indications including dual targeting
- TCR excision with designer recombinases seamless

CAReNK-AID – Project Overview

CAR engineered NK cells for the targeting of severe AutoImmune Diseases



Torsten Tonn
(ETM, MF, TUD)

Stefan R. Bornstein
(MK III, MF TUD)

Ezio Bonifacio
(CRTD, TUD)

Achim Aigner
(MF, Uni Leipzig)

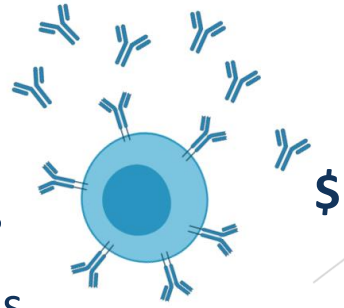
Achim Temme
(NCH-FOR, MF TUD)

AREA 2 – NK & CAR-NK

CAReNK-AID – Objectives

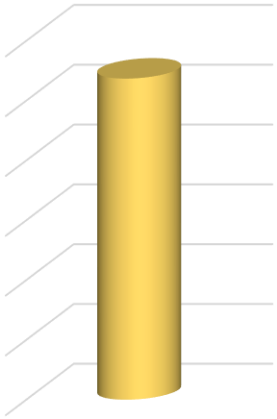
- >100 distinct autoimmune diseases identified
- estimated **10% of world population** is affected (~70 Mio Europe, 4-6 Mio Germany, 23 Mio USA,…)

B cell-mediated:

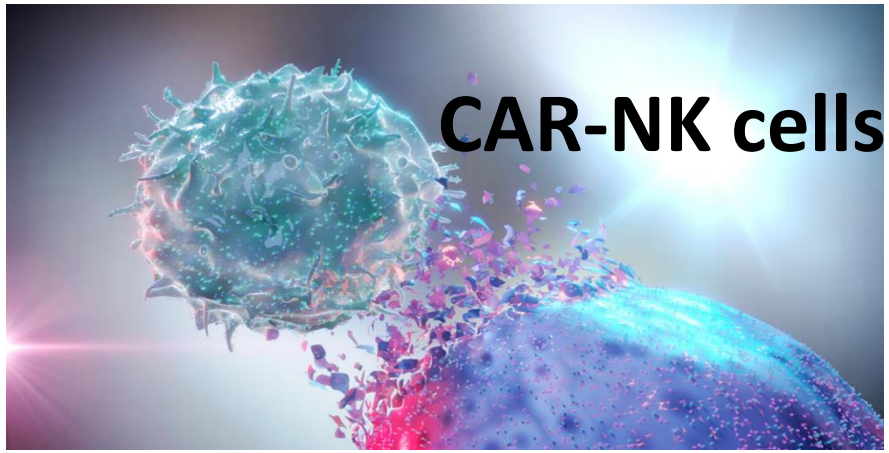


- SLE
- Multiple Sclerosis
- Myasthenia Gravis
- … **3.4 Million patients Europe & USA**

$ 3.4 Billion



1%   **$ 100k**



Safety
(no severe side effects vs. CAR T cells)

Cost effective
(1 product = multiple patients)

Fast transfer from cancer

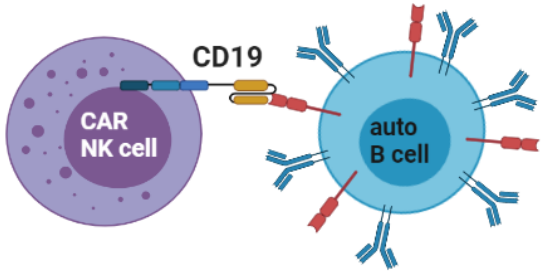
AREA 2 – NK & CAR-NK

CAReNK-AID – Results so far

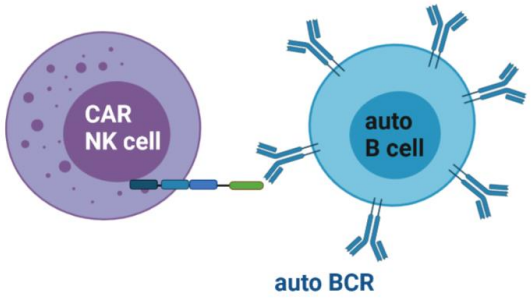
SAXOCELL®

AREA 2 – NK & CAR-NK

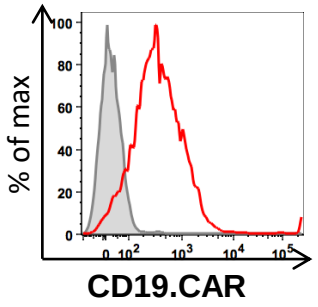
CAR-NK anti-Pan B cells



CAR-NK anti-autoreactive BCR

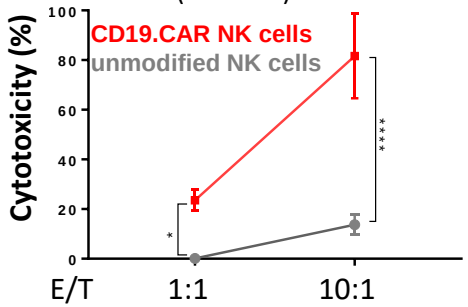


Blood-derived CAR-NK cells

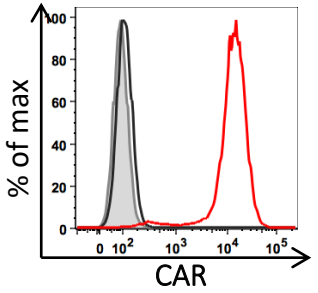


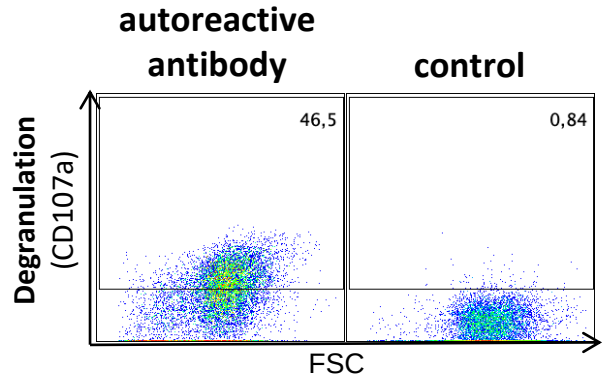
CD19-positive B cell line

(NALM-6)

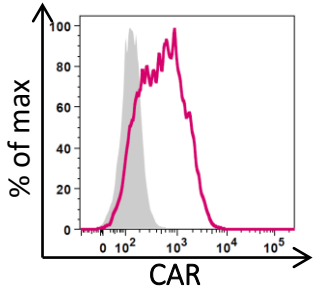


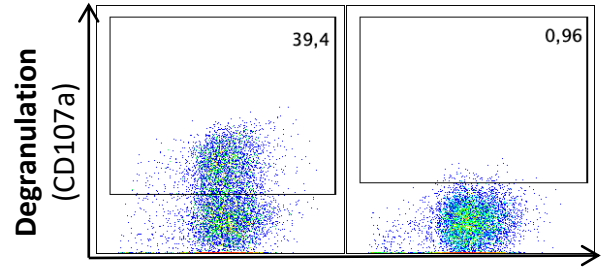
PV.CAR NK-92



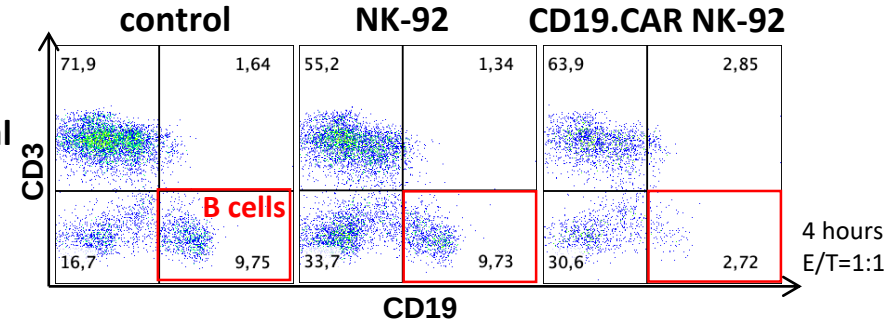


T1D.CAR NK-92





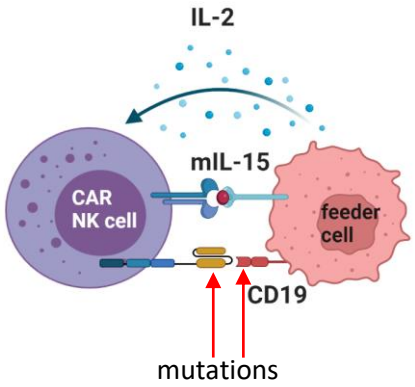
Peripheral blood

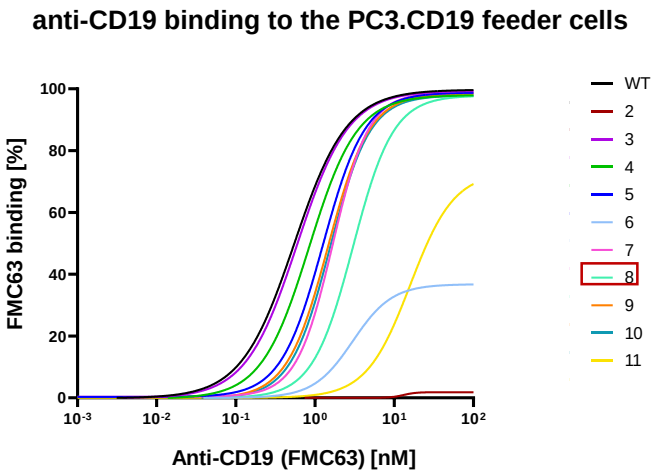


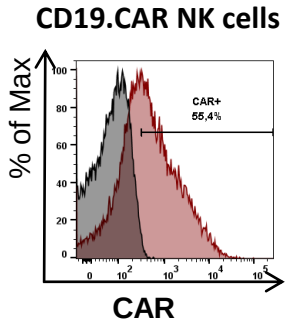
CAReNK-AID – Results so far

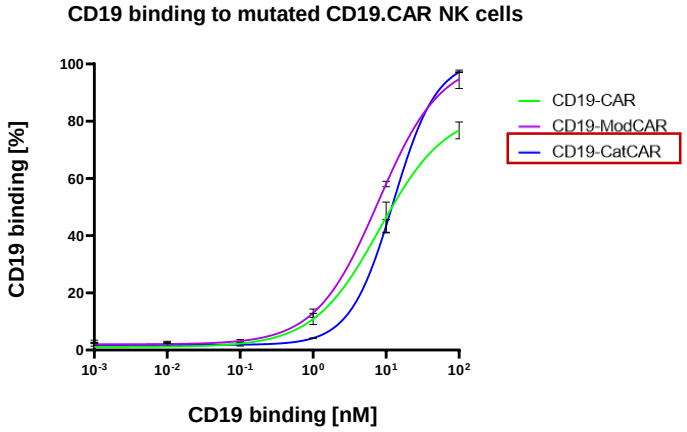
SAXOCELL®

Feeder cells for specific CAR-NK cell expansion





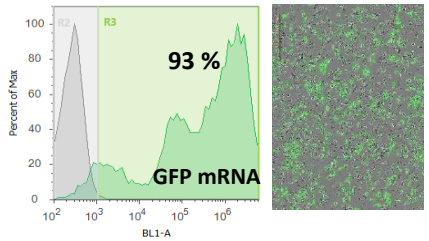


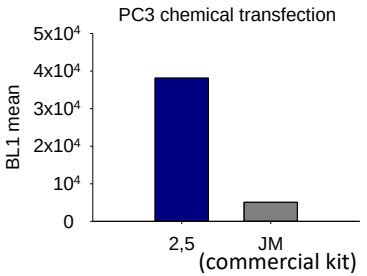


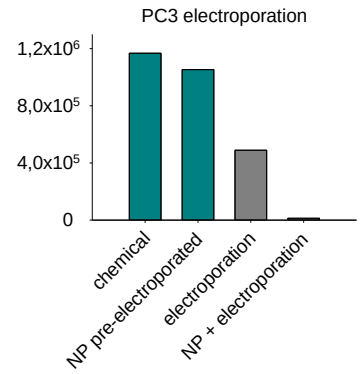
Virus-free NK cell transfection

nanoparticles

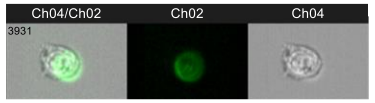
PC3 cells

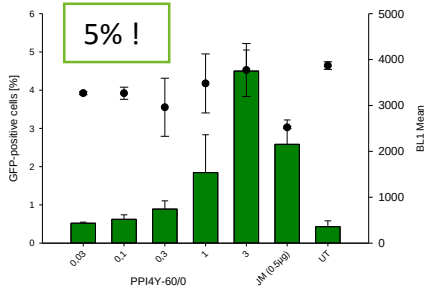




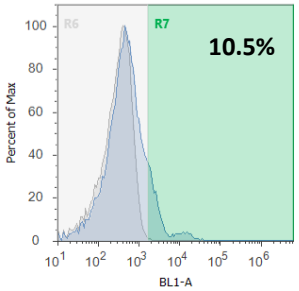


Primary NK cells



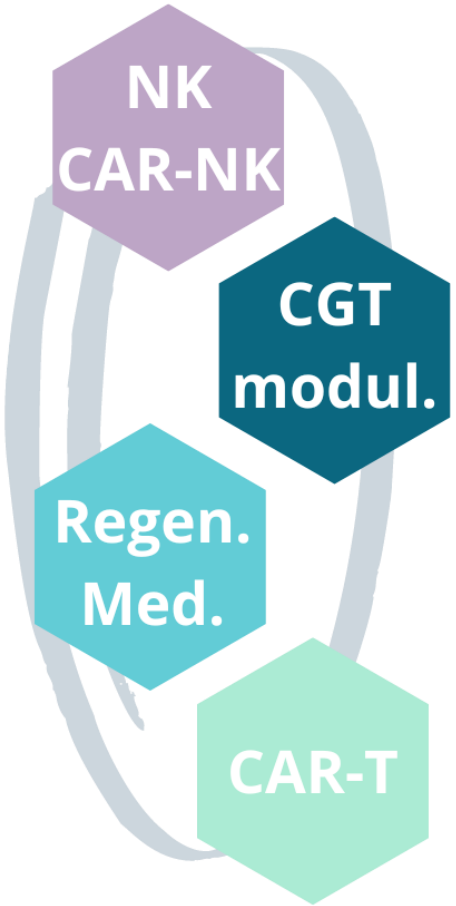


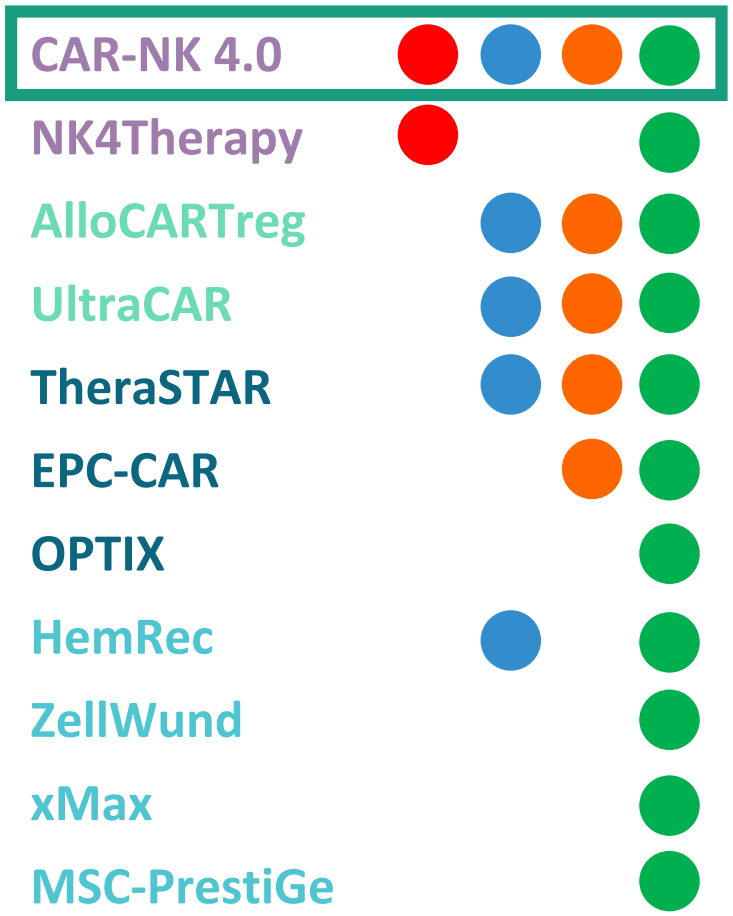
saRNA-GFP



AREA 2 – NK & CAR-NK

CAReNK-AID – Synergies to other SaxoCell Projects





Fraunhofer IZI

- SaxoCell Systems, Clinics, Omics
- Transgenic GMP cell products
- (CAR) gene transfer
- NK cell expansion and production

AREA 2 – NK & CAR-NK

CAReNK-AID – Outlook

SAXOCELL®

	2023	2024	2025	2026	2027
CD19.CAR NK cels	IND enabling studies				
SLE			Phase I/II (27 patients)		
Pemphigus				Phase II	

Orphan Drug Designation

EMA PRIME

FDA fast track

VIROCELL BIOLOGICS

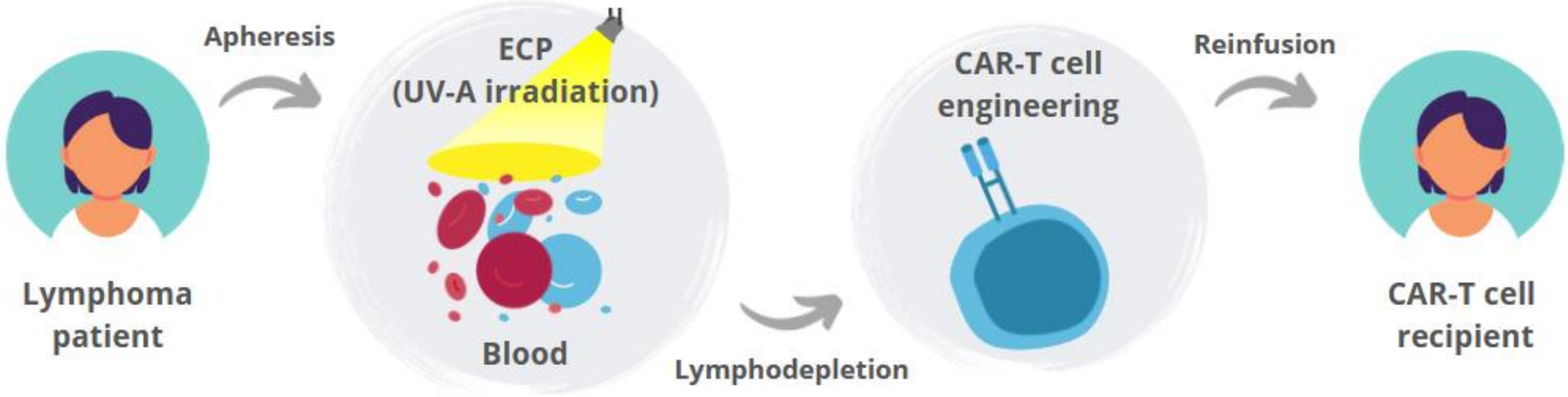
Deutsches Rotes Kreuz DRK-Blutspendedienste

MaxCyte®

Auto-BCR CAR-NK cells	R&D	IND ES	Phase I/II	
iPS CAR-NK cells	R&D	IND enabling studies	Phase I	

AREA 2 – NK & CAR-NK

ECP-CAR – Project Overview

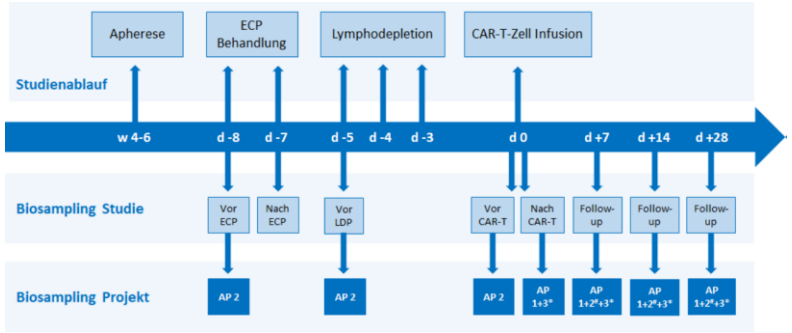


AREA 4 – CGT

ECP-CAR – Objectives

original objectives:

-analysis of samples **PhotoCAR trial**



- patients CAR
- ECP induced
- dynamics of

nature medicine

Article

https://doi.org/10.1038/s41591-023-02404-6

CD19 CAR T-cell therapy and prophylactic anakinra in relapsed or refractory lymphoma: phase 2 trial interim results

Received: 26 February 2023

Accepted: 17 May 2023

Published online: 03 July 2023

Check for updates

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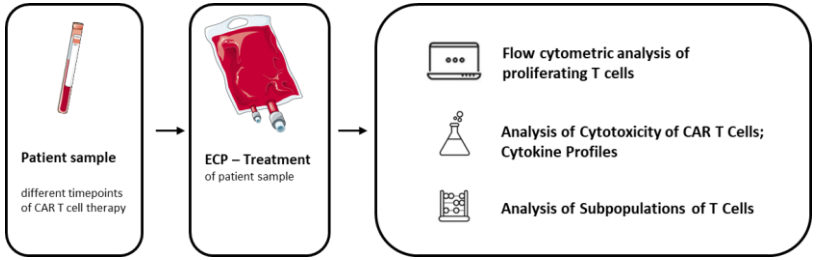
PhotoCAR trial will not be performed (PEI concerns)
- **lack of data on the actual mode of action**
- **impact on CAR T cell efficacy?**

current objectives after project amendment:

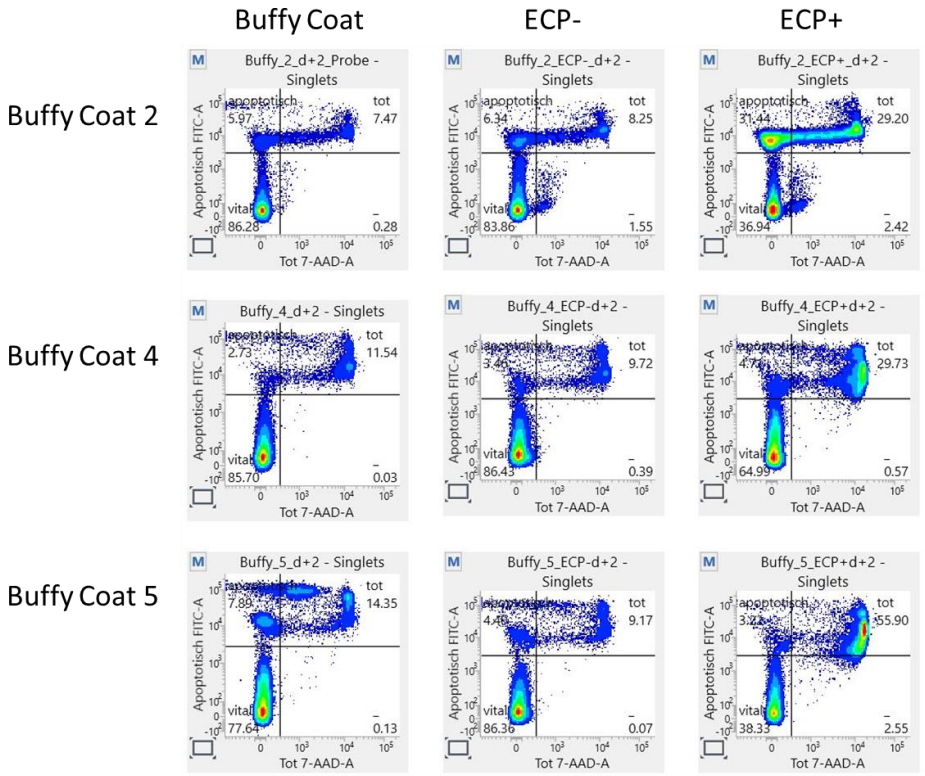
-analysis of 15 ECP treated peripheral blood samples of lymphoma patients after treatment with CAR-T cells



- patients CAR T cells after ECP treatment
- evidence of apoptosis/reduced proliferation
- dynamics of cytotoxic effector functions and cytokine-profiles
- translational research regarding incorporation in current treatment concepts (management of inflammatory complications…)

ECP-CAR – Results so far

Understanding the mechanism of action of ECP - validation of apoptosis using buffy coats:



- 25% - 56% of cells exhibited apoptosis

Proliferation capacity of the T lymphocytes after ECP treatment:

BC2	ECP-	88,7 %
	ECP+	0.2 %
BC4	ECP-	90.9 %
	ECP+	32,4 %
BC5	ECP-	90,3 %
	ECP+	0 %

ECP-CAR – Synergies

- Understanding the role of ECP in immunomodulation prior to lymphodepletion therapy
- Incorporation of ECP in management of inflammatory complications of cellular therapies
- Synergies with current ECP indications as well as with expanding indications for treatment with CAR-T cells

AREA 4 – CGT

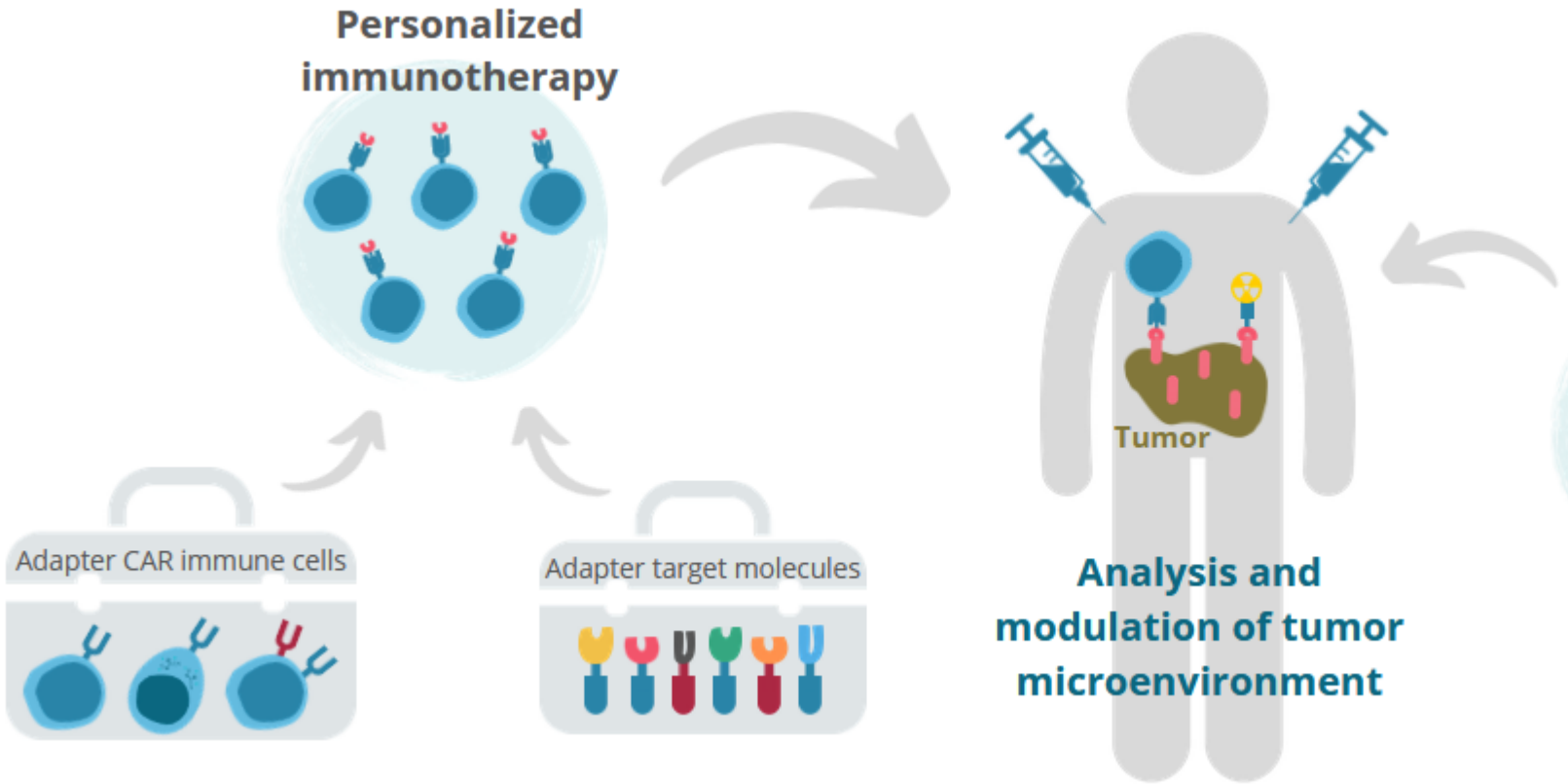
ECP-CAR – Outlook

Till September 2024: analysis of 15 ECP treated peripheral blood samples of lymphoma patients after treatment with CAR T cells (tisagen lecleucel, axicabtagene ciloleucel)

- Provide insights into the potential synergistic effects of immunomodulation by ECP and lymphodepletion
- Deepening the knowledge of the mechanism of action of ECP in CAR T cell therapy
- Defining the role of ECP-immunomodulation in the context of CAR T treatment
- Basis for further concepts of clinical trials

AREA 4 – CGT

TheraSTAR – Project Overview



Michael Bachmann, HZDR, TUD

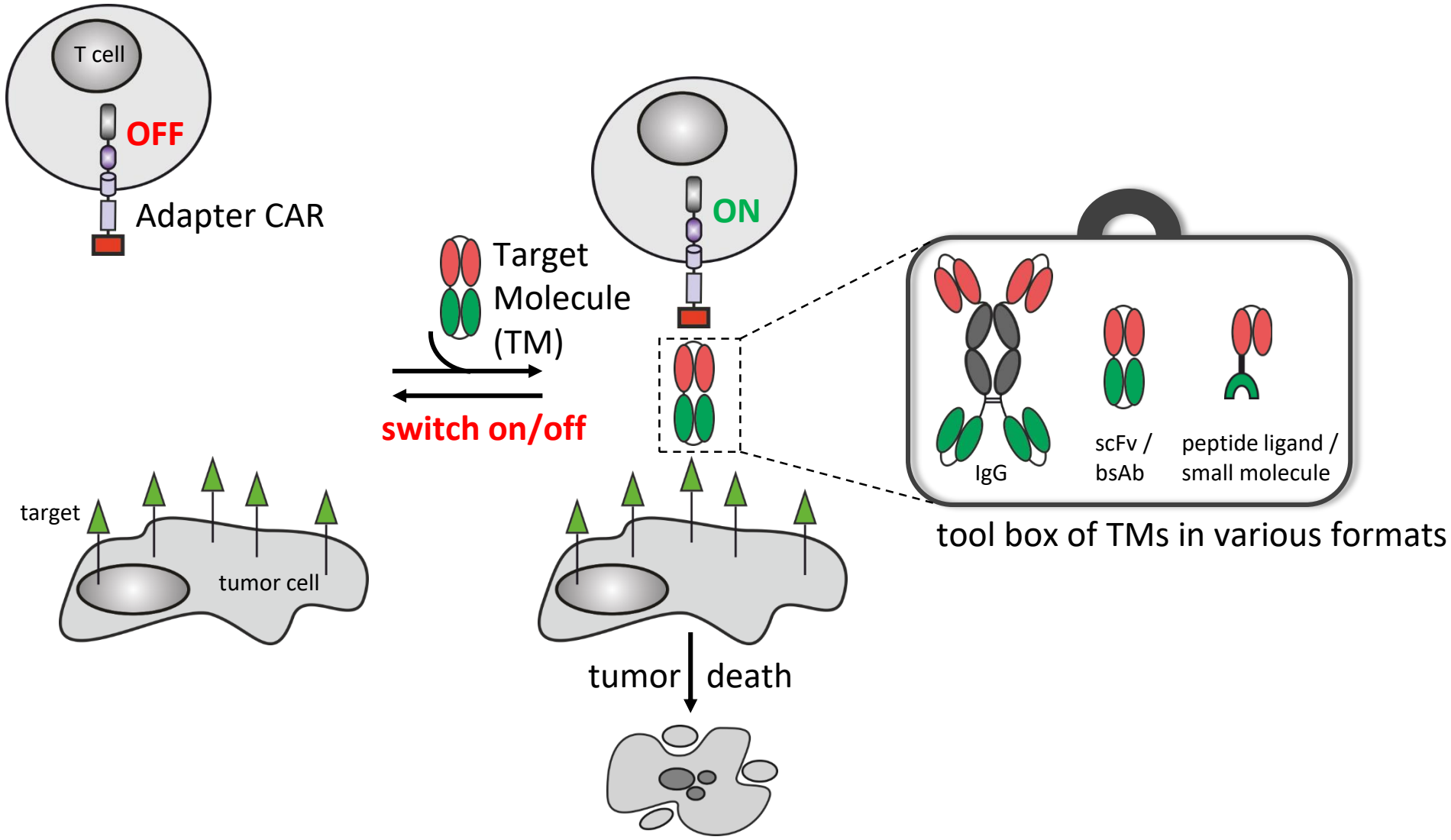
Anja Feldmann, HZDR

Marc Schmitz, TUD

AREA 4 – CGT

TheraSTAR – Project Overview

switchable Adapter CAR platform

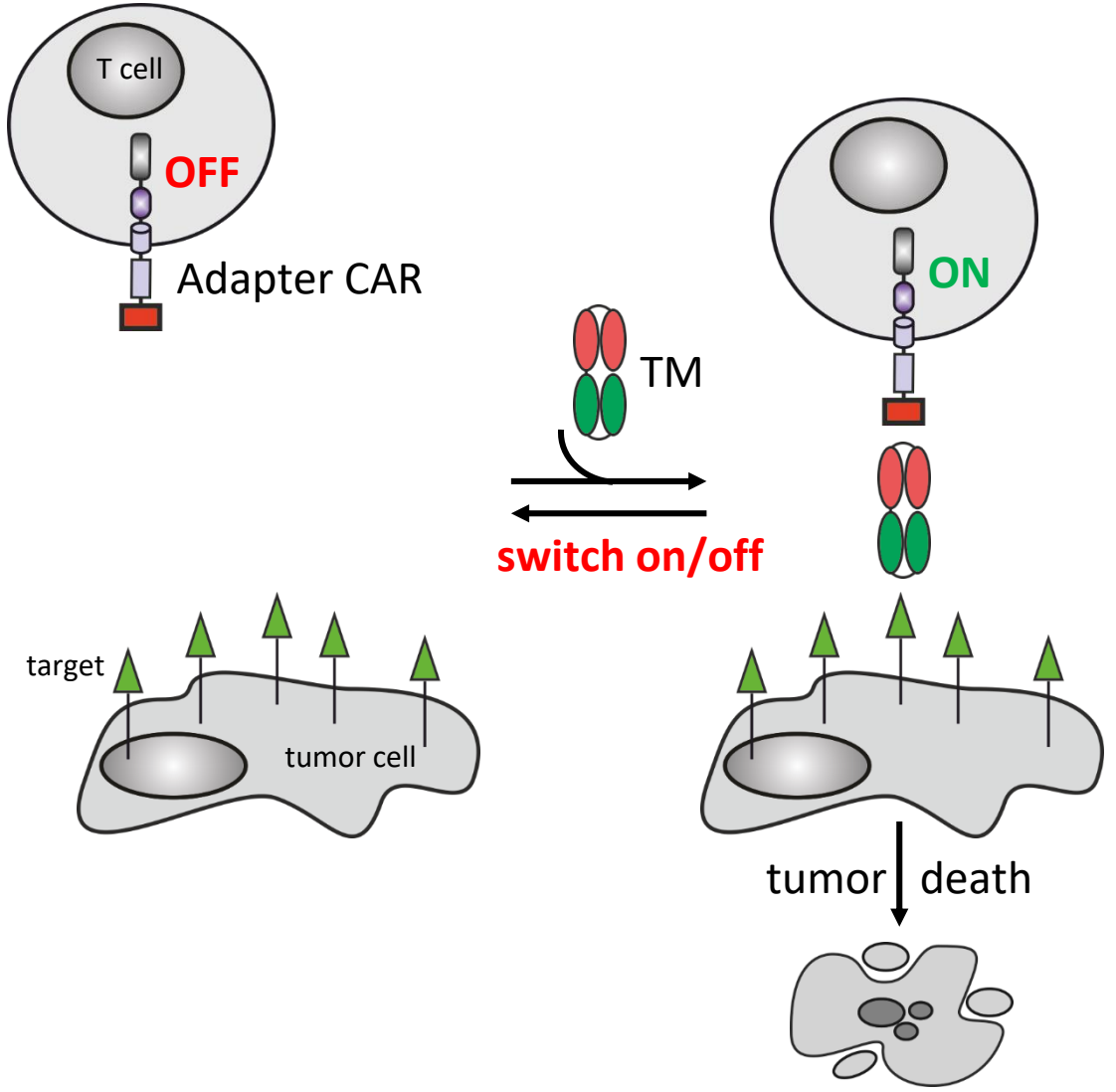


AREA 4 – CGT

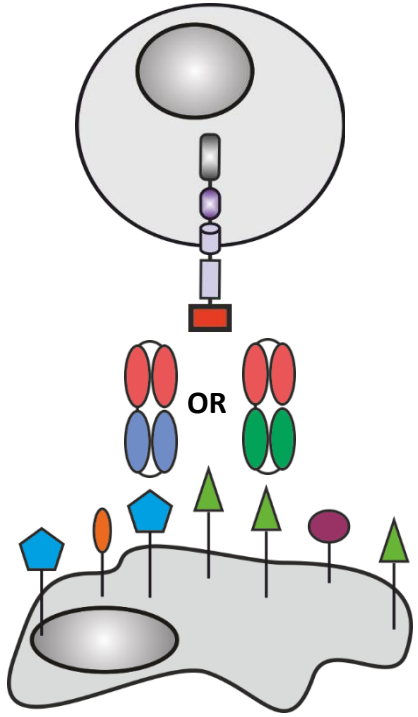
TheraSTAR – Project Overview

SAXOCELL®

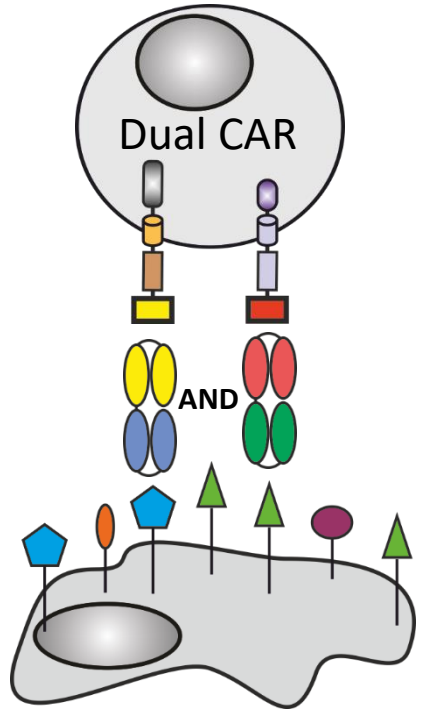
switchable Adapter CAR platform



flexible, multiple tumor targeting



precise tumor targeting



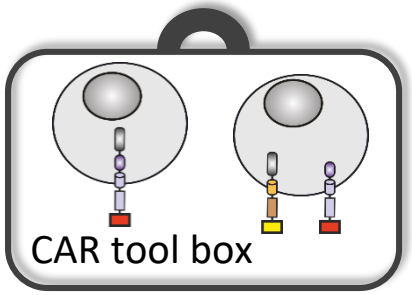
AREA 4 – CGT

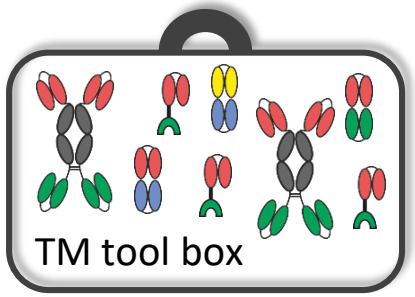
TheraSTAR – Objectives

SAXOCELL®

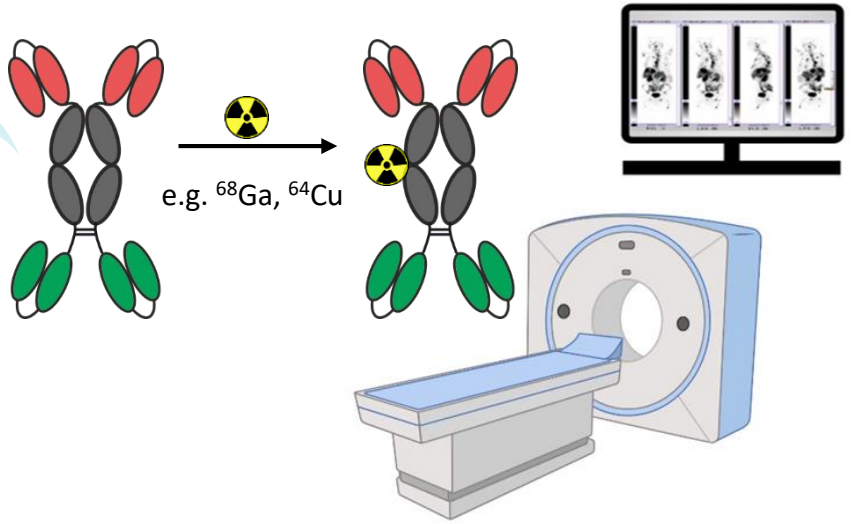
Development of theranostic target molecules for

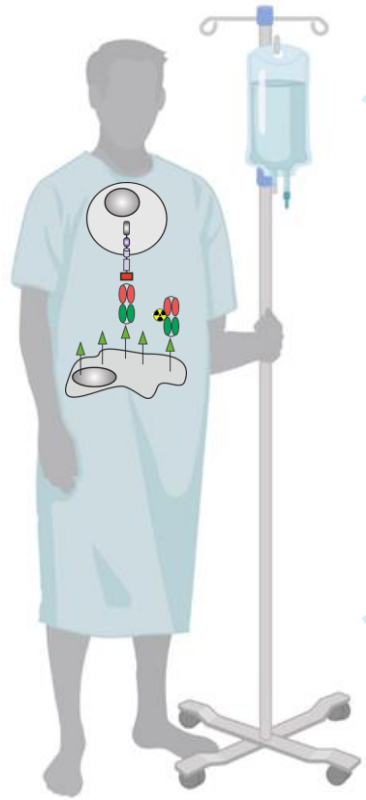
Adapter CAR-based immunotherapy



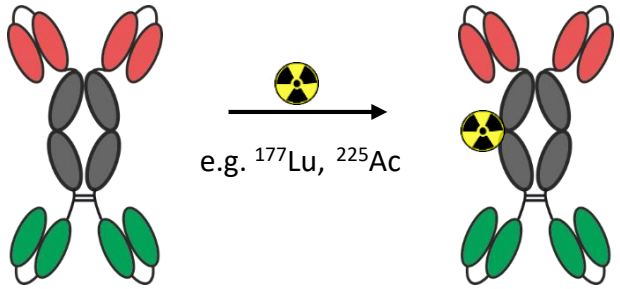


diagnostic imaging

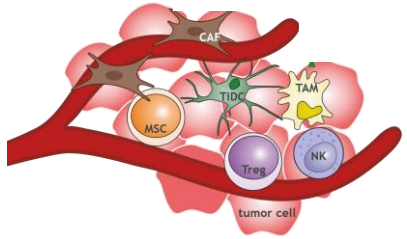




endoradiotherapy



TME and immunomodulation

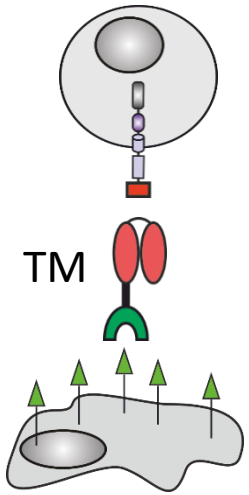


Strengthening of (lokal) industry
Technology transfer
Clinical translation

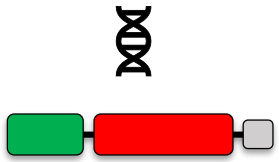
AREA 4 – CGT

TheraSTAR – Results so far

Development of novel Target Molecules (TMs) targeting immune checkpoint molecules (e.g. PD-L1)

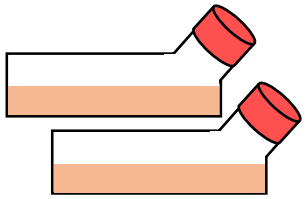


Design



PD-L1 TM cloning

Expression

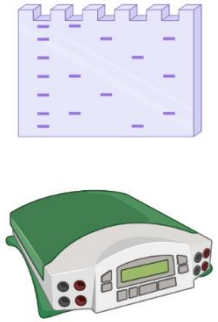


eukaryotic cell line

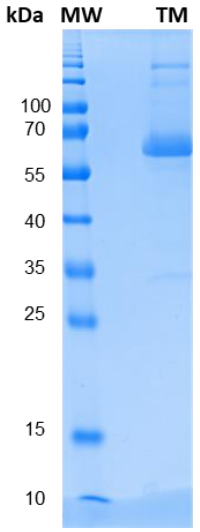
Purification

affinity chromatography

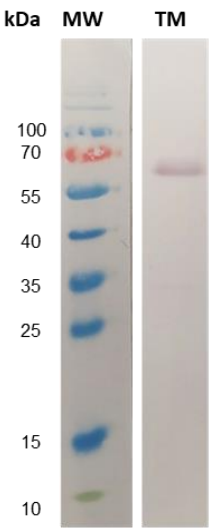
Characterization



SDS-PAGE



Coomassie Blue staining



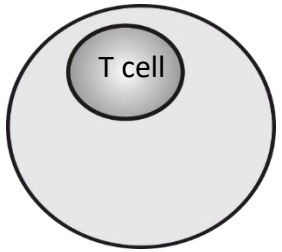
Western Blot

AREA 4 – CGT

TheraSTAR – Results so far

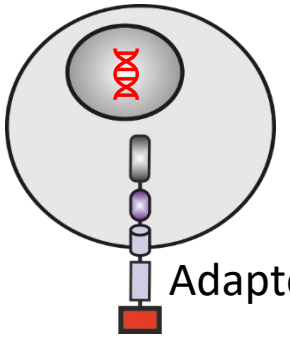
Generation of Adapter CAR T cells

T cell isolation



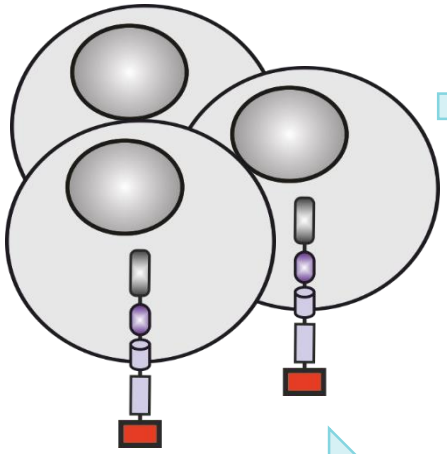
Genetical Modification

lentiviral particle

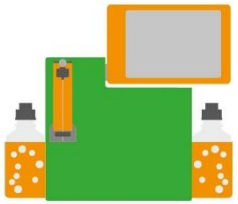


Adapter CAR

Expansion



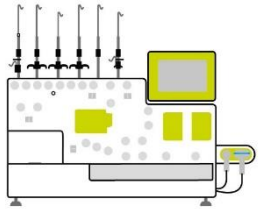
Characterization



Flow cytometry using MACSQuant® Analyzer 10

manual or automated GMP-compliant large scale

cell culture

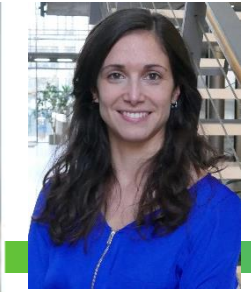


CliniMACS Prodigy®

AREA 4 – CGT

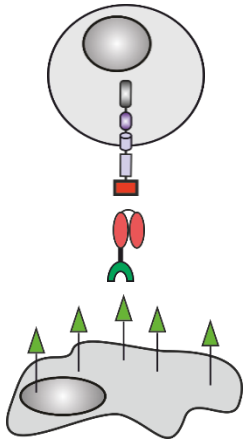
TheraSTAR – Results so far


Eugenia Crespo

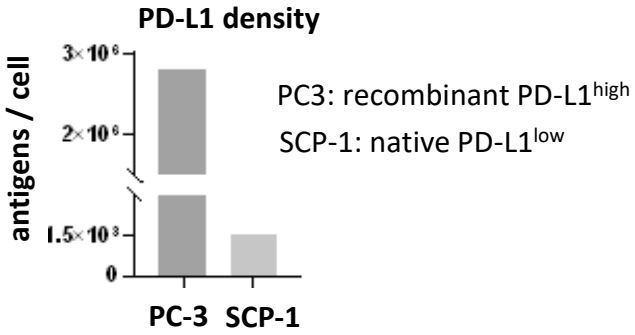

Liliana Loureiro

SAXOCELL®

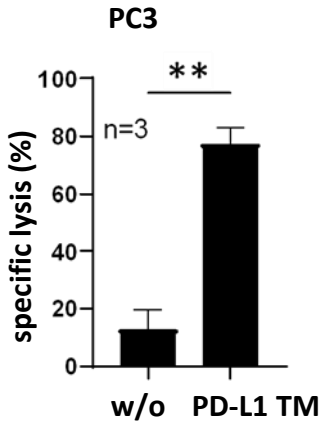
Therapeutic functionality of Adapter CAR platform in-vitro

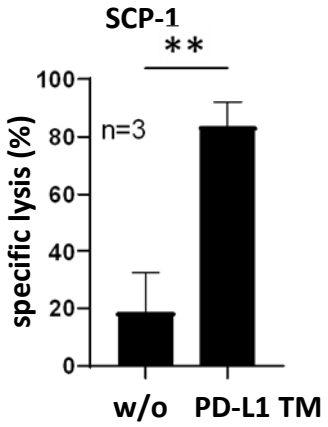


PD-L1⁺ target cell models

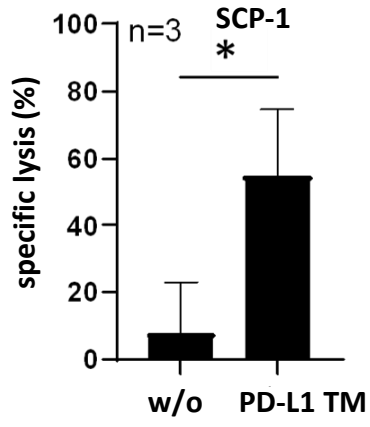


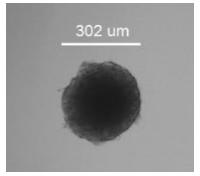
Killing of PD-L1⁺ monolayer target cells



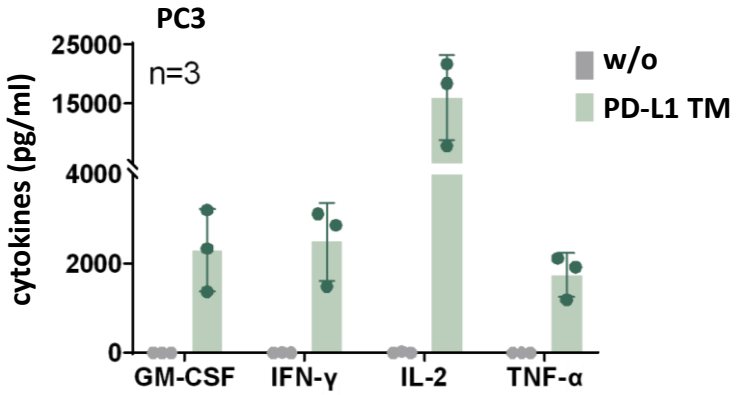


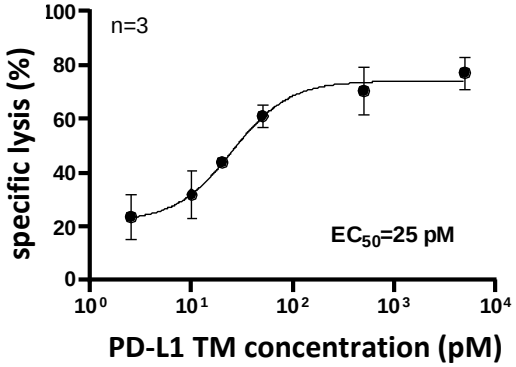
Killing of PD-L1⁺ spheroids

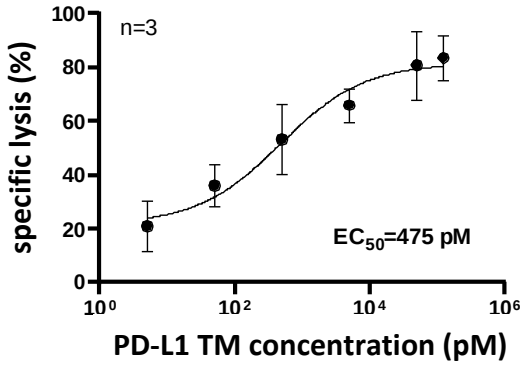




Cytokine release from Adapter CAR T cells







AREA 4 – CGT

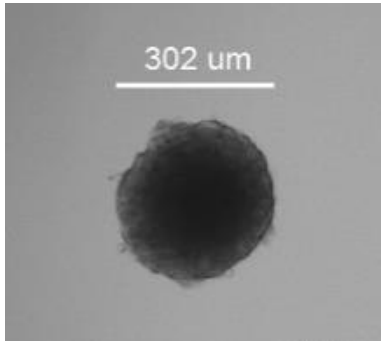
TheraSTAR – Results so far


Luise Rupp

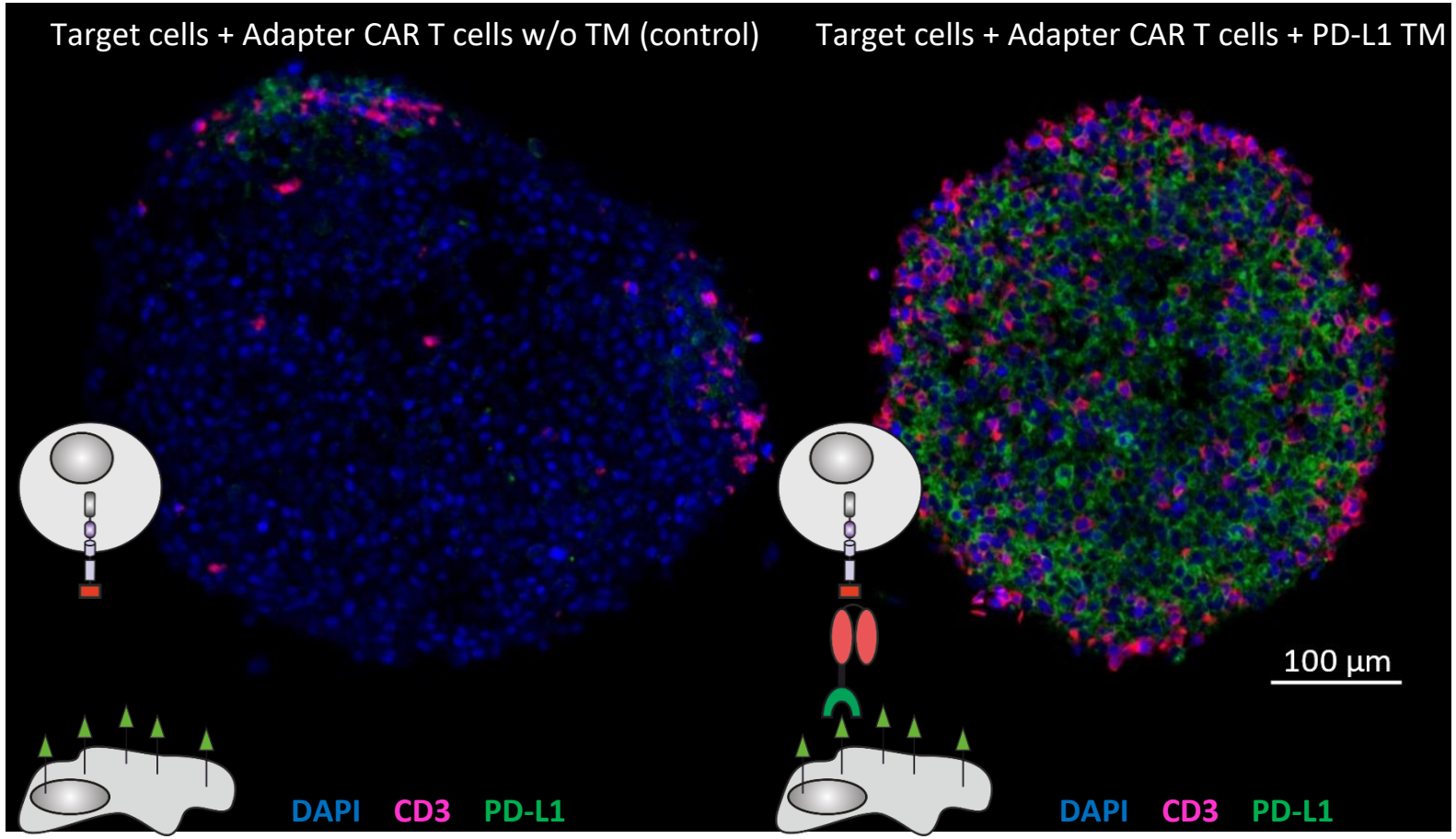

Antonia Stammberger

Infiltration of Adapter CAR T cells in PD-L1^{+} spheroids, TME analysis and modulation

spheroid formation



Vectra automated quantitative immunofluorescence imaging system



AREA 4 – CGT

TheraSTAR – Results and Outlook

SAXOCELL®

AREA 4 – CGT

12 months | 24 months | 36 months

Generation of **Adapter CAR T cells**

Development of **novel target molecules** (TMs)

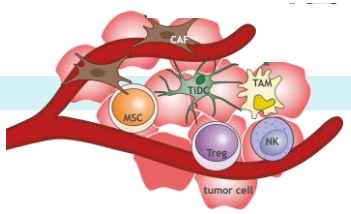
OR

AND

Therapeutic functionality in-vitro

Therapeutic functionality in-vivo

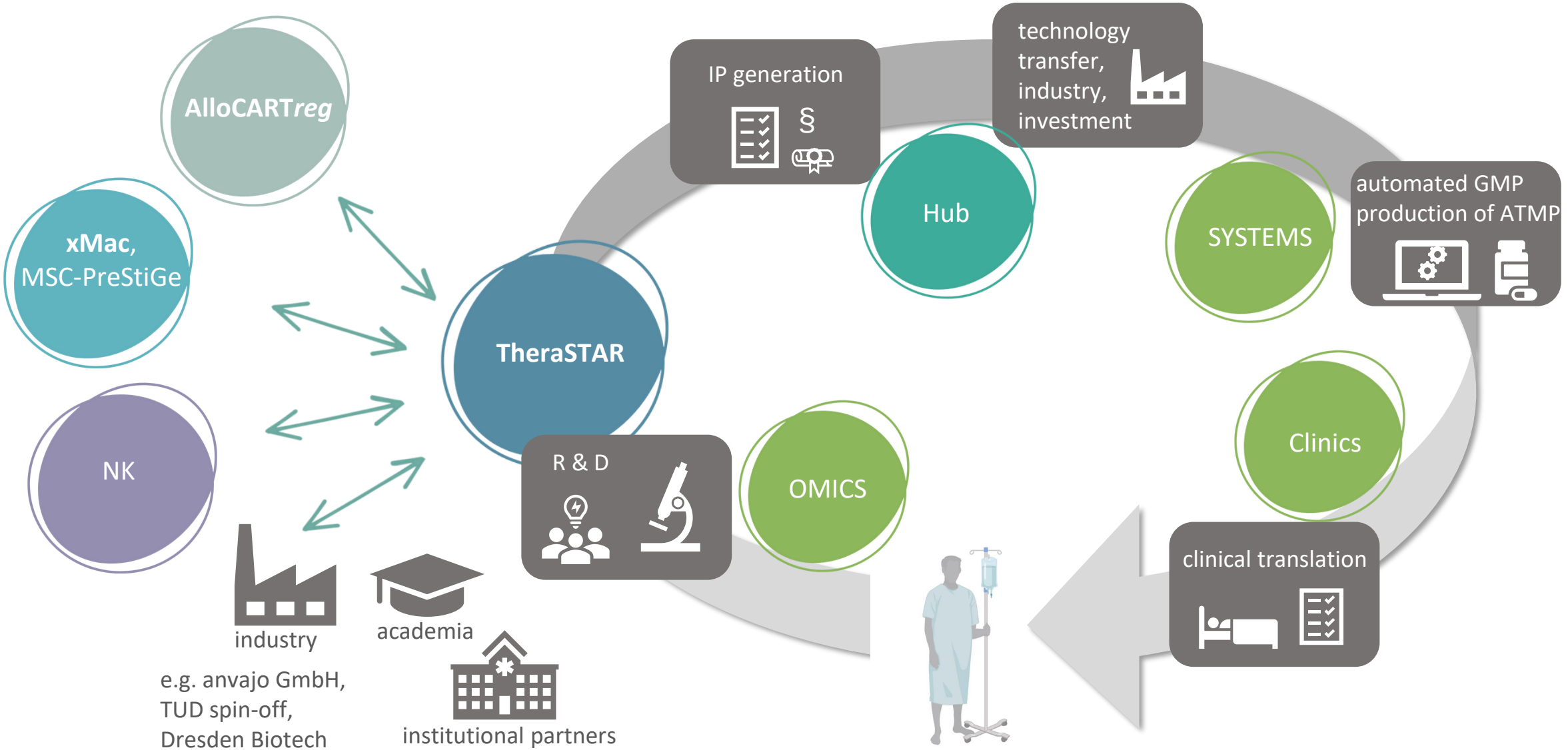
Analysis and modulation of **tumor microenvironment** (TME)



Diagnostic potential in-vivo

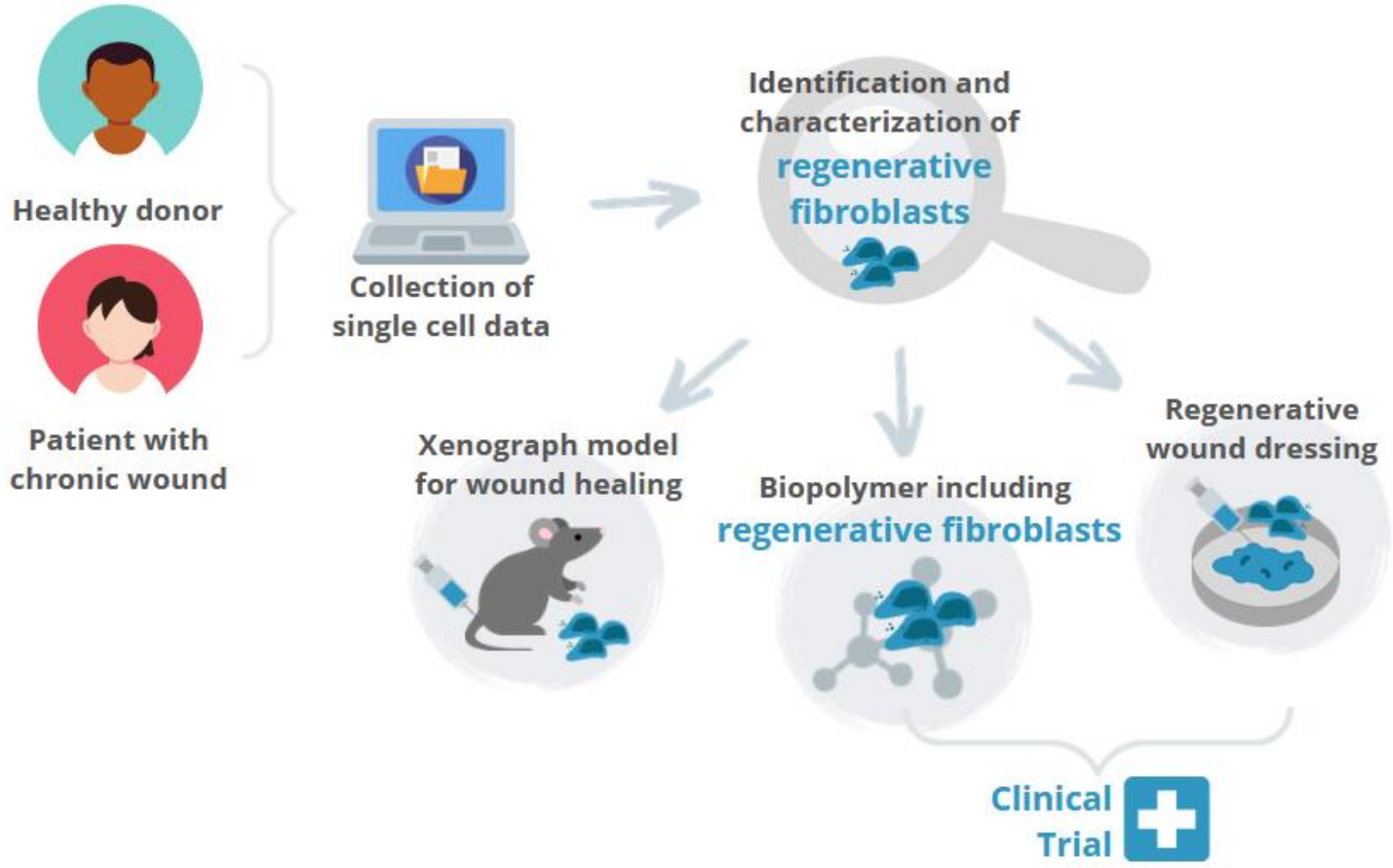
Preparation of clinical translation, **IP** protection, **technology transfer**

TheraSTAR – Synergies and Outlook



AREA 4 – CGT

ZellTWund – Project Overview

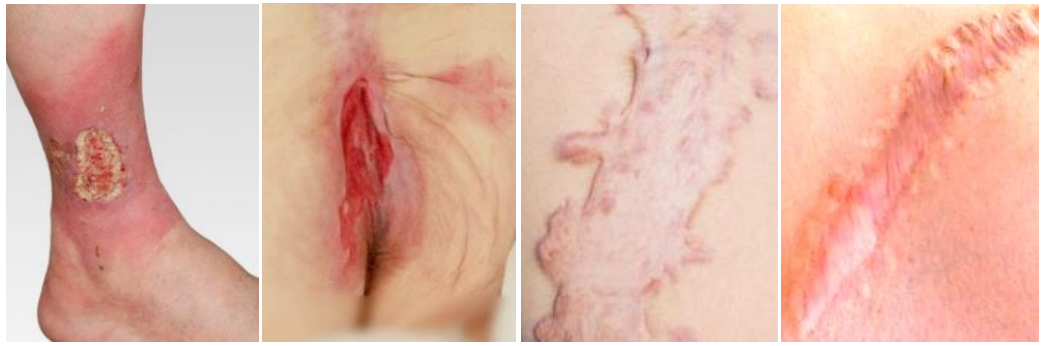


AREA 3 – ATMPs

ZellTWund – Objectives

Innovative cell therapy to promote skin regeneration

Wound healing disorders



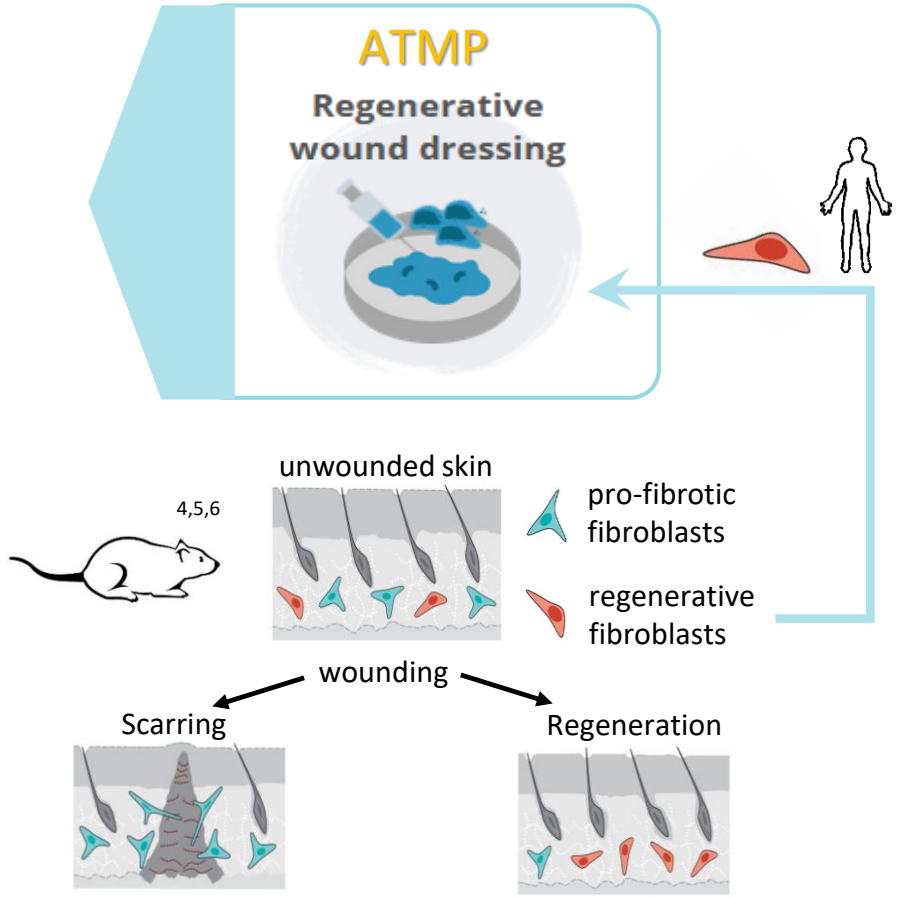
Incidence chronic wounds in Germany[1]: 2018 **0,24%**

Prevalence chronic wounds in Germany[2]: 2012- 2018 **7.8%**

Aging population / Comorbidities

Direct treatment costs[3] : 9000 € / patient / year

Insufficient therapeutic success



AREA 3 – ATMPs

[1] *Heyer et al., WoundRepairRegen, 2016*

[2] *Raeder et al., Int wound J., 2020*

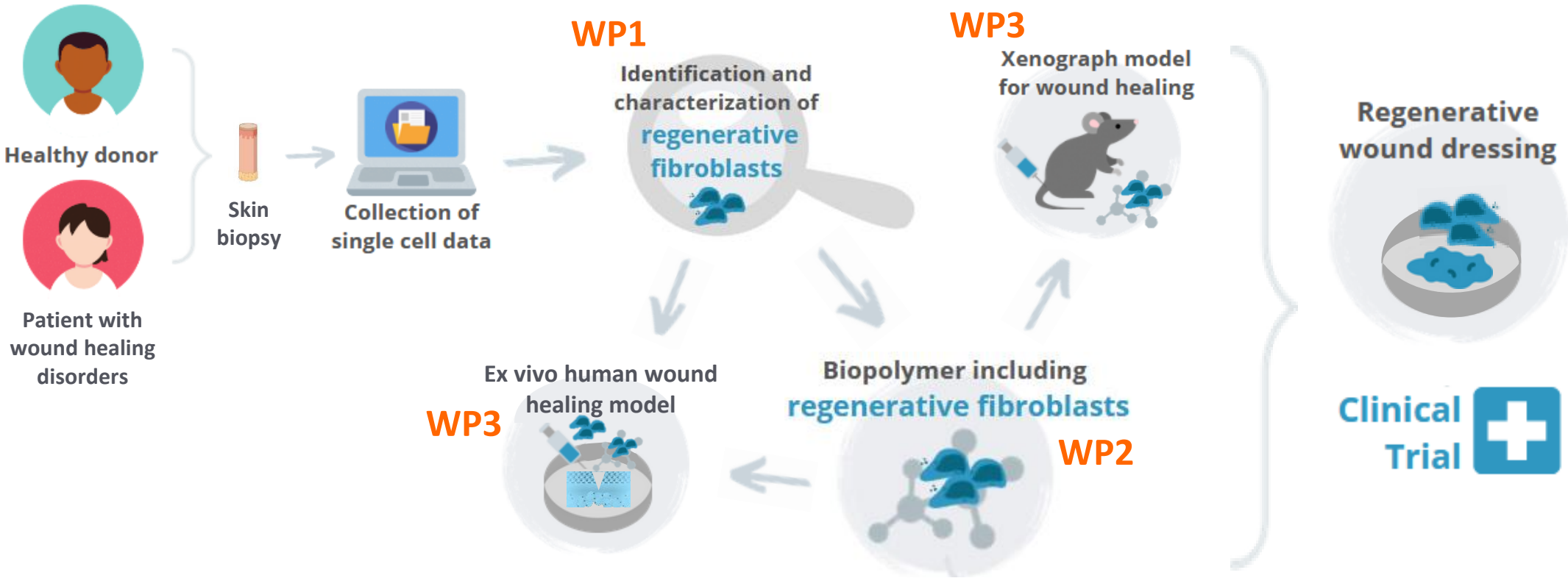
[3] *Augustin et al.; IntWoundJ, 2014*

[4] Shamik et al., *Science*, 2021

[45] Rinkevich et al., *Science*, 2015

[6] Correa-Gallegos et al., *Nature*, 2019

ZellTWund – Project Plan



AREA 3 – ATMPs

WP1: Identification and characterization of human pro-regenerative fibroblast populations

WP2: Development of a transplantable wound dressing

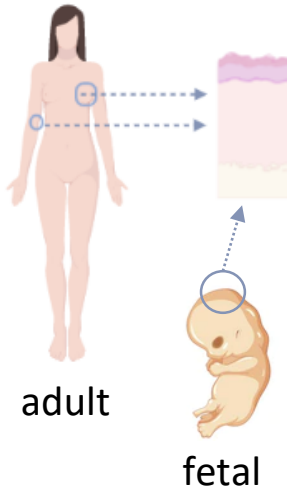
WP3: Establishment of preclinical wound healing models

Identification and characterization of regenerative fibroblasts

ZellTWund – Results WP1

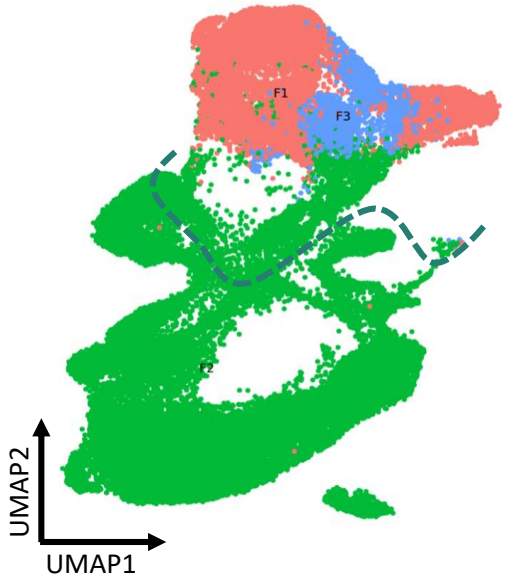
SAXOCELL®

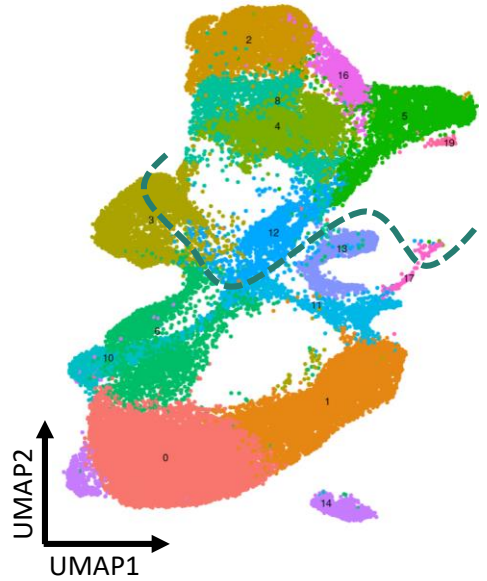
Defining of human fibroblast subtypes



2022 Gur et al., Cell
2021 Reynolds et al., Science

Integrated data: fibroblasts



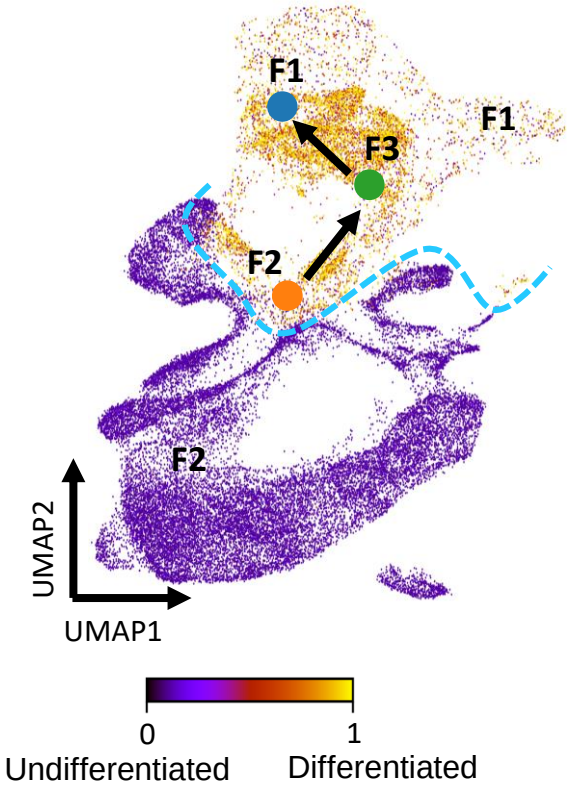


AREA 3 – ATMPS

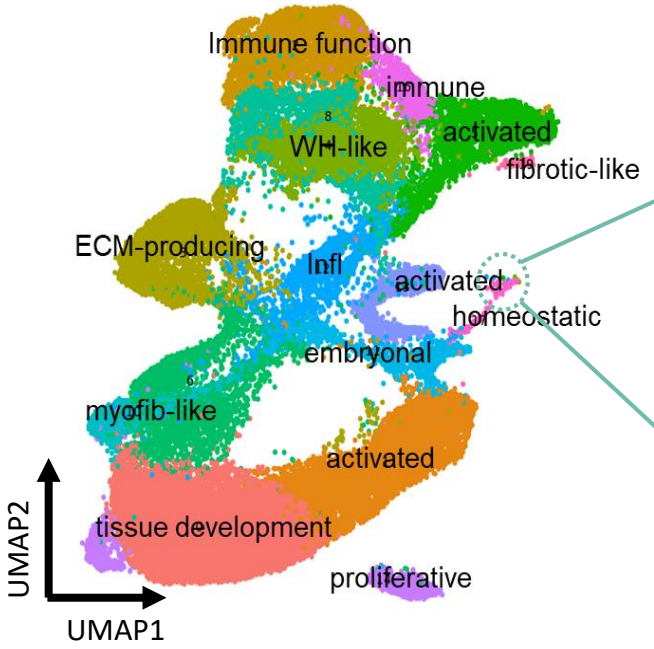
ZellTWund – Results WP1

Defining of pro-regenerative human fibroblast subtypes

Integrated:
Velocity pseudotime



Clusters' annotation



Subcluster 17

Top pro-regenerative genes:

- *IGFBP6*
- *IGFBP7*
- *CD63 (surface marker)*
- *NGFR (surface marker)*
- *CD200 (surface marker)*

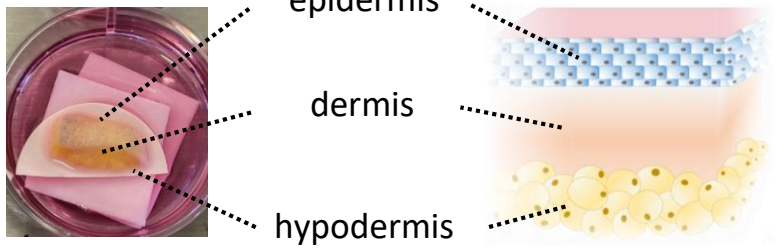
AREA 3 – ATMPs

Disclaimer: confidential data

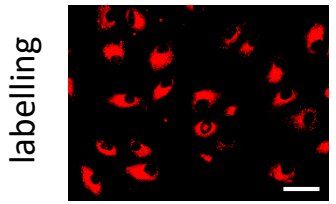
ZellTWund – Results WP3

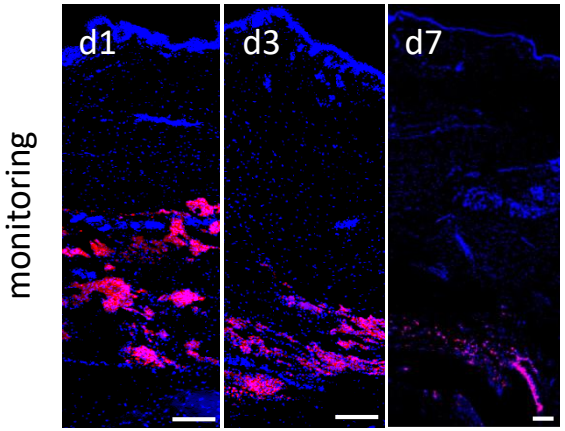
SAXOCELL®

Preclinincal model: Ex vivo human skin model

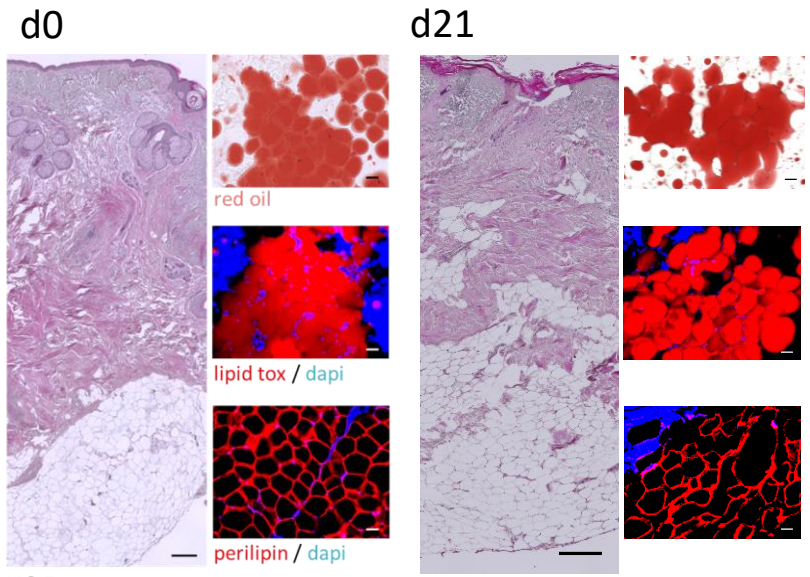


Fibroblast injection and tracing

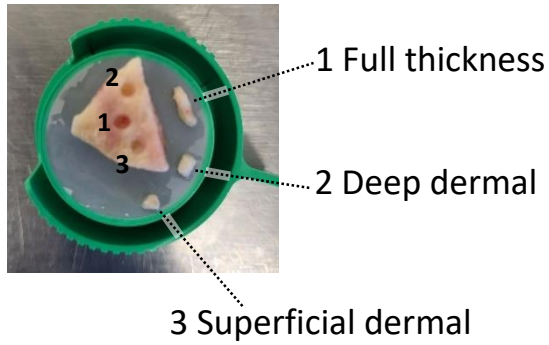


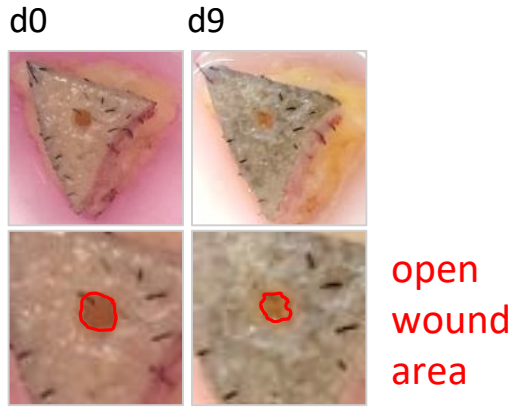


Long-term culture



Wounding



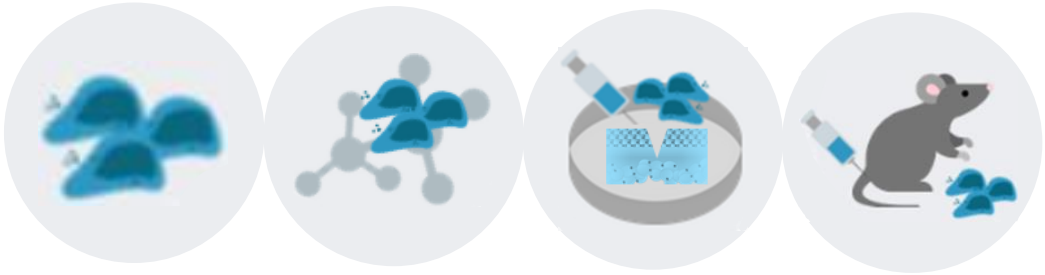


AREA 3 – ATMPs

ZellTWund – Outlook

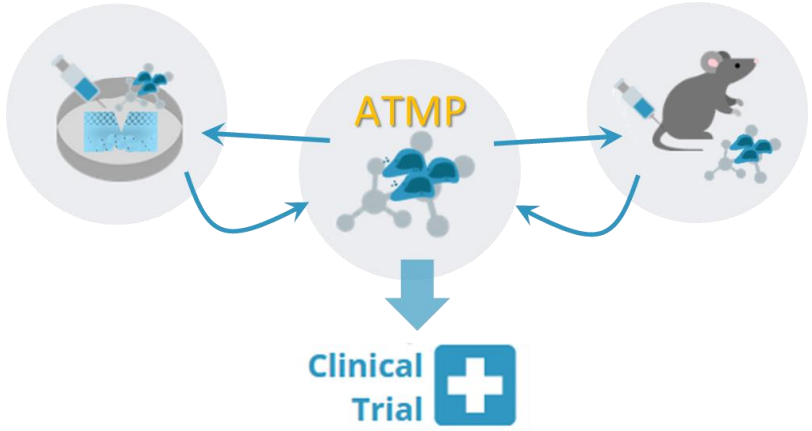
Current funding period

- Isolation, expansion, and functional characterization of regenerative fibroblasts
- Incorporation in transplantable wound dressing
- Testing in preclinical models
- Review under revision (*Nature Cell Biology*)



Future funding period

- Design of regenerative wound dressing (ATMP)
- Testing of ATMP in preclinical models
- Optimization of ATMP
- Clinical trial



AREA 3 – ATMPs

Thanks for your attention!

ZellTWund – Partners

SAXOCELL®

ZellTWund-Team

Universitätsklinikum Leipzig – Medizin ist unsere Berufung.

HELMHOLTZ MUNICH – iRBM Institute of Regenerative Biology and Medicine


Marta Torregrossa


Ravinder Kandi


Sandra Franz


Jan C. Simon


Yuval Rinkevich

Collaborations

ABI

Susie Avagyan

Arpi Grigoryan

Melina Tamazyan

IZBI

Hans Binder

Maria Schmidt

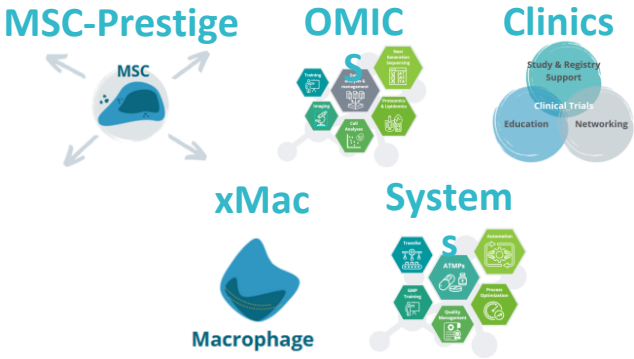
Universitätsklinikum Leipzig – Medizin ist unsere Berufung.

Julia Zarnowski

Sonja Grunewald

Rima Nuwayhid

Synergies



Industry

HAN BIOMEDICAL INC.

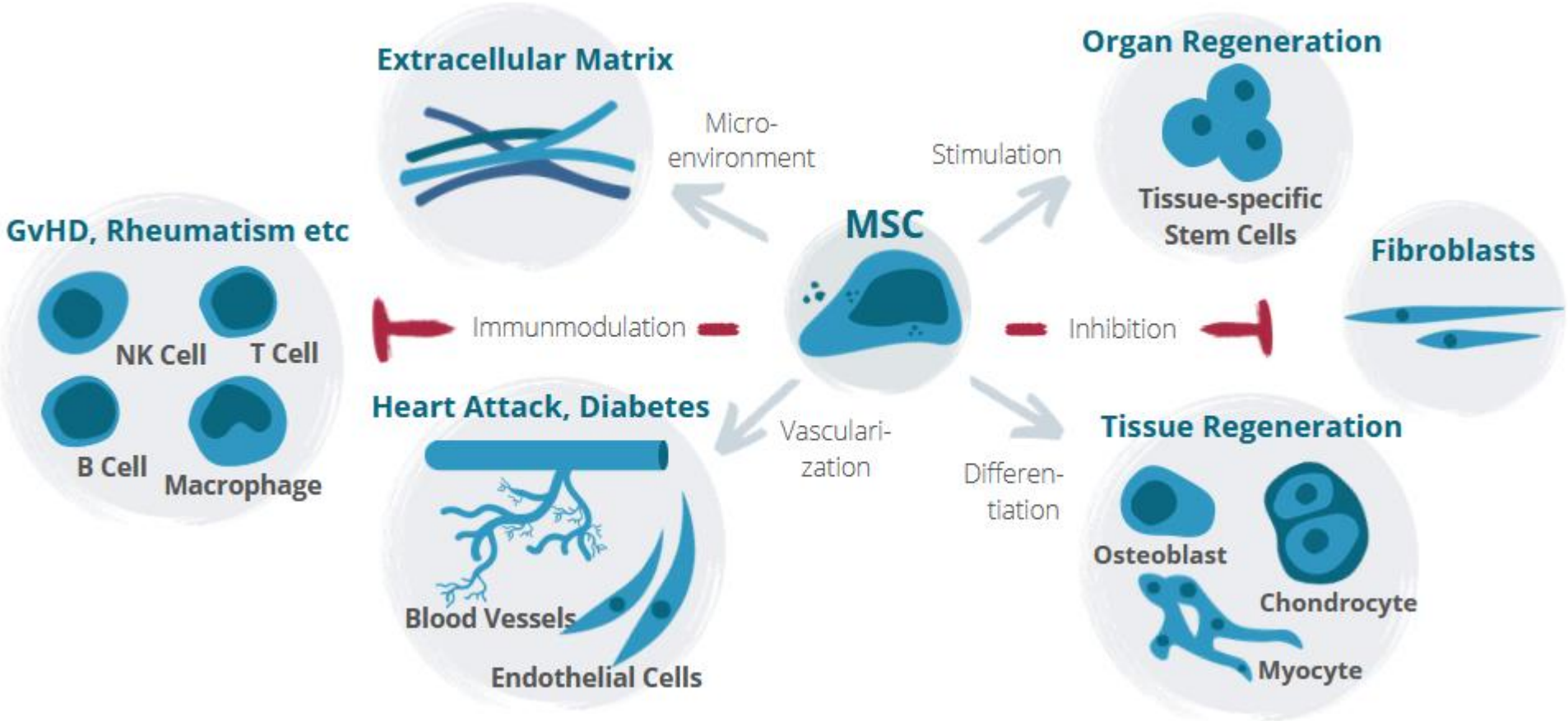
medical forge

nextcell

Nordmark
Wir gestalten gesunde Zukunft.

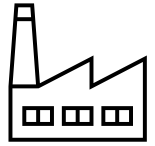
AREA 3 – ATMPs

MSC-Prestige – Project Overview



AREA 3 – ATMPs

MSC-Prestige – Objectives



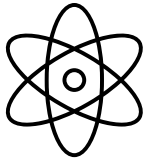
✓ industrial

✓ establish an **industrial pharmaceutical** MSC **Cell Manufacturing**

✓ clinical

✓ produce **Investigational Medicinal Products** (Prüfpräparate)

✓ prepare a Phase I/II Trial



✓ scientific

✓ further characterization

> active profile of the drug substance

> immune profile of patients

✓ international

✓ set up a base in North America

AREA 3 – ATMPs

MSC-Prestige – Results so far

SAXOCELL®

✓ intensive cooperation

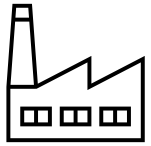
✓ Academic/Clinical Partner

TECHNISCHE UNIVERSITÄT DRESDEN

CRTD Center for Regenerative Therapies TU Dresden

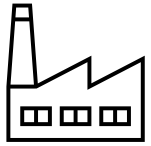
Universitätsklinikum Carl Gustav Carus DIE DRESDNER.

Prof. Rüdiger, Prof. Bornhäuser



✓ Industrial Partner

MDTB CELLS



✓ Industrial Partner (associated)

DKMS Stem Cell Bank

AREA 3 – ATMPs

MSC-Prestige – Results so far

SAXOCELL®

✓ on schedule, objectives will be achieved

WP 1

WP 2

✓ Industrial Process Transfer from CRTD/TUD to DKMS ongoing

✓ specification and SOPs

✓ investments at associated Industrial partner

see next slides – Simone Sonnenberg DKMS

WP 3

✓ Accompanying scientific research in progress

next meeting

✓ characterization drug substance, immune profiles

WP 4

✓ Spin-off of a subsidiary in preparation

✓ will be in Canada, province of Ontario

AREA 3 – ATMPs

MSC-Prestige – focus: DKMS facility

DKMS Stem Cell Bank:

- Banking of allogeneic haematopoietic stem cell transplants
- Quality control
- Cryopreservation and storage
- cGMP manufacturing of cell-based therapeutics (process development, production, testing)

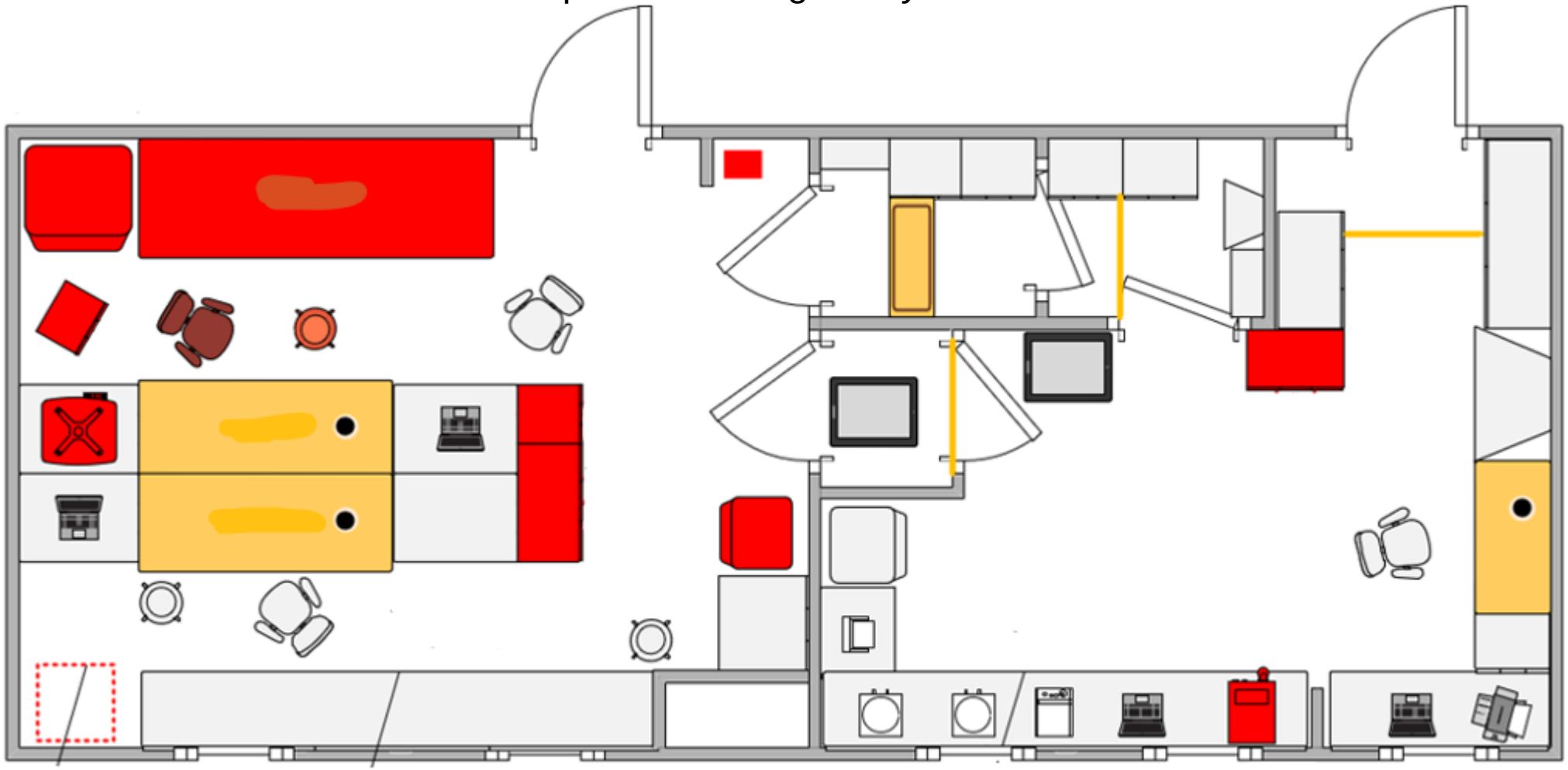
=> associated industrial partner für MSC-Prestige

AREA 3 – ATMPs

MSC-Prestige – result: GMP investments

SAXOCELL®

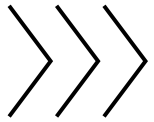
- GMP investments done
- Process transfer induces comprehensive regulatory tasks



AREA 3 – ATMPs

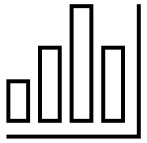
MSC-Prestige – Synergies

AREA 3 – ATMPs



✓ **Systems**

✓ MSC-Prestige is an initial use case for Systems

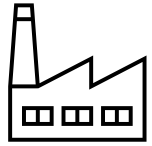


✓ **Omics**

✓ a 1st work package (sequencing) to be initiated (end of 2023)

MSC-Prestige – Outlook Phase I

SAXOCELL®



✓ industrial infrastructure

✓ DKMS is an **industrial partner** for **MSC Manufacturing**

✓ clinical impact

✓ an **ATMP-Therapy** is in clinical testing

DESACELL®

✓ unique 1st product

✓ **Desacell®** is a MSC drug substance for an allogeneic, off-the-shelf, ready-to-use cellular **drug product** at **reasonable costs**

✓ international impact

✓ **Transatlantic** long-term cooperation is prepared

AREA 3 – ATMPs

MSC-Prestige – Outlook Phase II

SAXOCELL®

⇒ **Goal Phase II**

Development of the MSC drug substance Desacell into a **product platform**

for different drug products **for further international clinical studies**

➢ **Vision: World leading MSC-drugs for international trials**

➢ **Targeted Therapies**
➢ **Product Diversification**
➢ **Internationalization**

✓ **Programme Phase II: proposed**

✓ **industrial contribution: confirmed**

AREA 3 – ATMPs

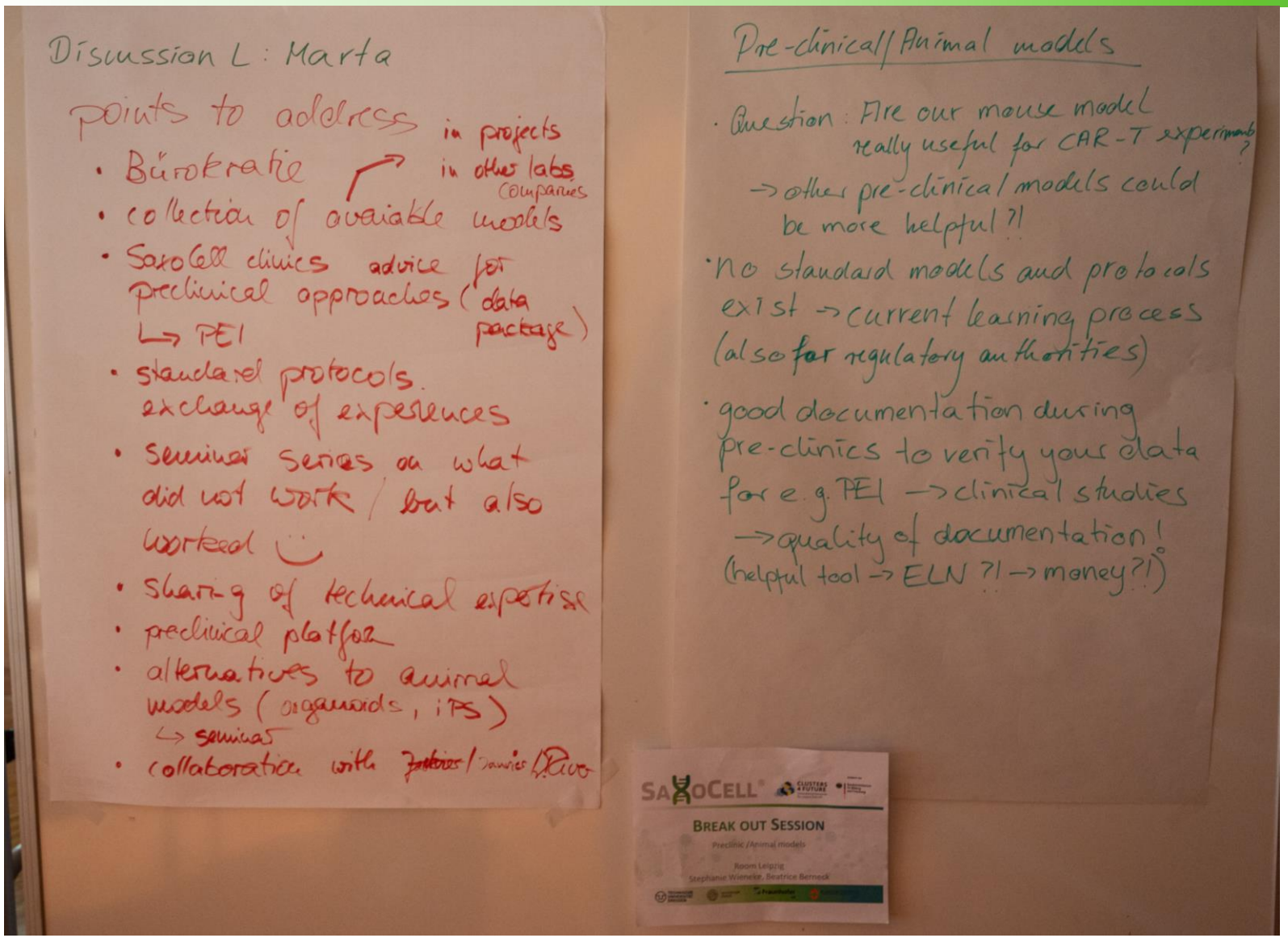
MSC-Prestige – Backup Phase II

⇒ **Programme Phase II**

- **Use clinical data** from the SaxoCell MSC-product Desacell
- Develop a more **targeted therapy** concept based on the clinical data
- Further **diverse the MSC-drug substance platform** using further cell characterization criteria
- Develop **internationalization concept** (develop the “Last Mile” = the international “bedside-value chain” to the patient)
- Develop **regulatory modules** for the future marketing authorisation

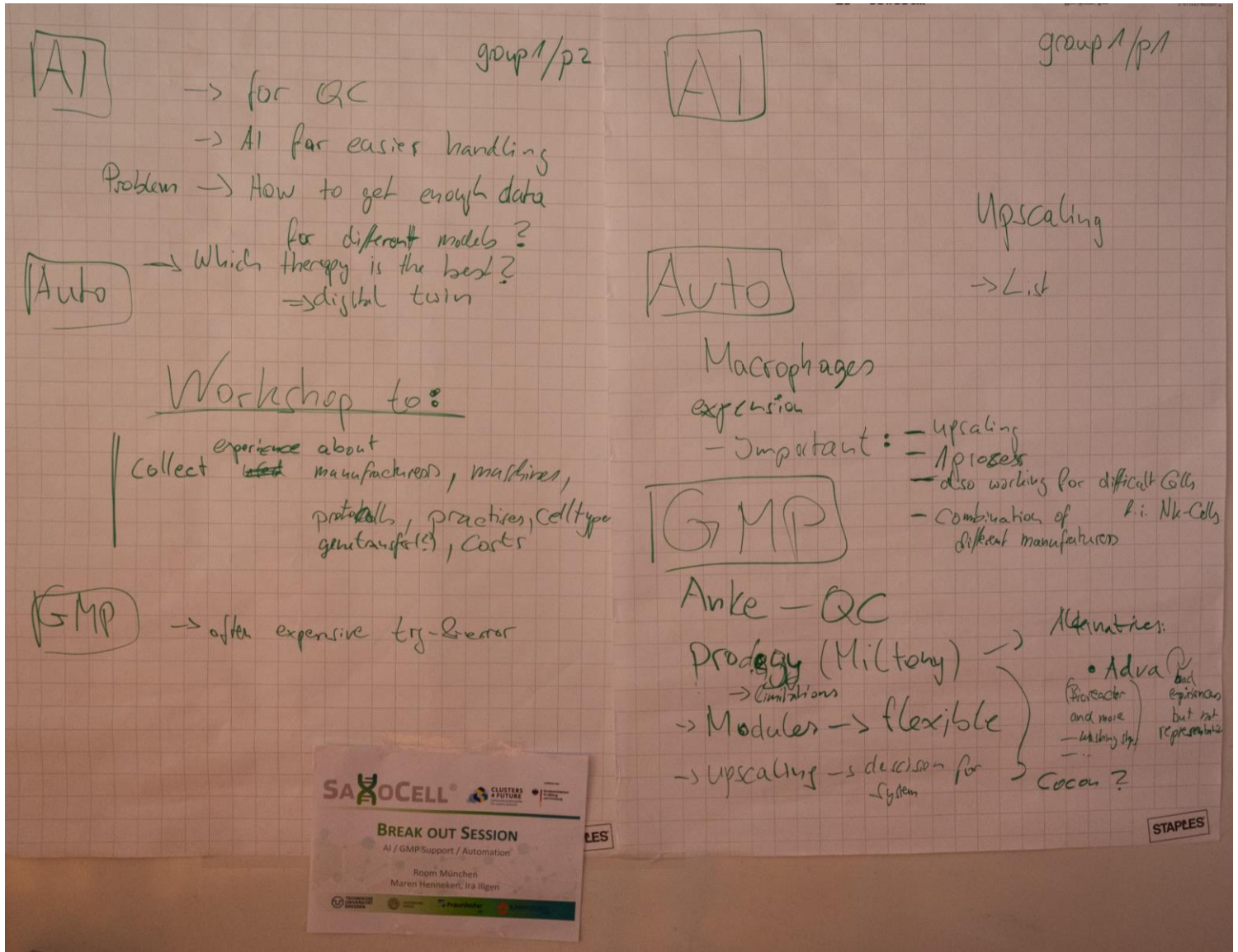
AREA 3 – ATMPs

Break out session: Preclinic /Animal models



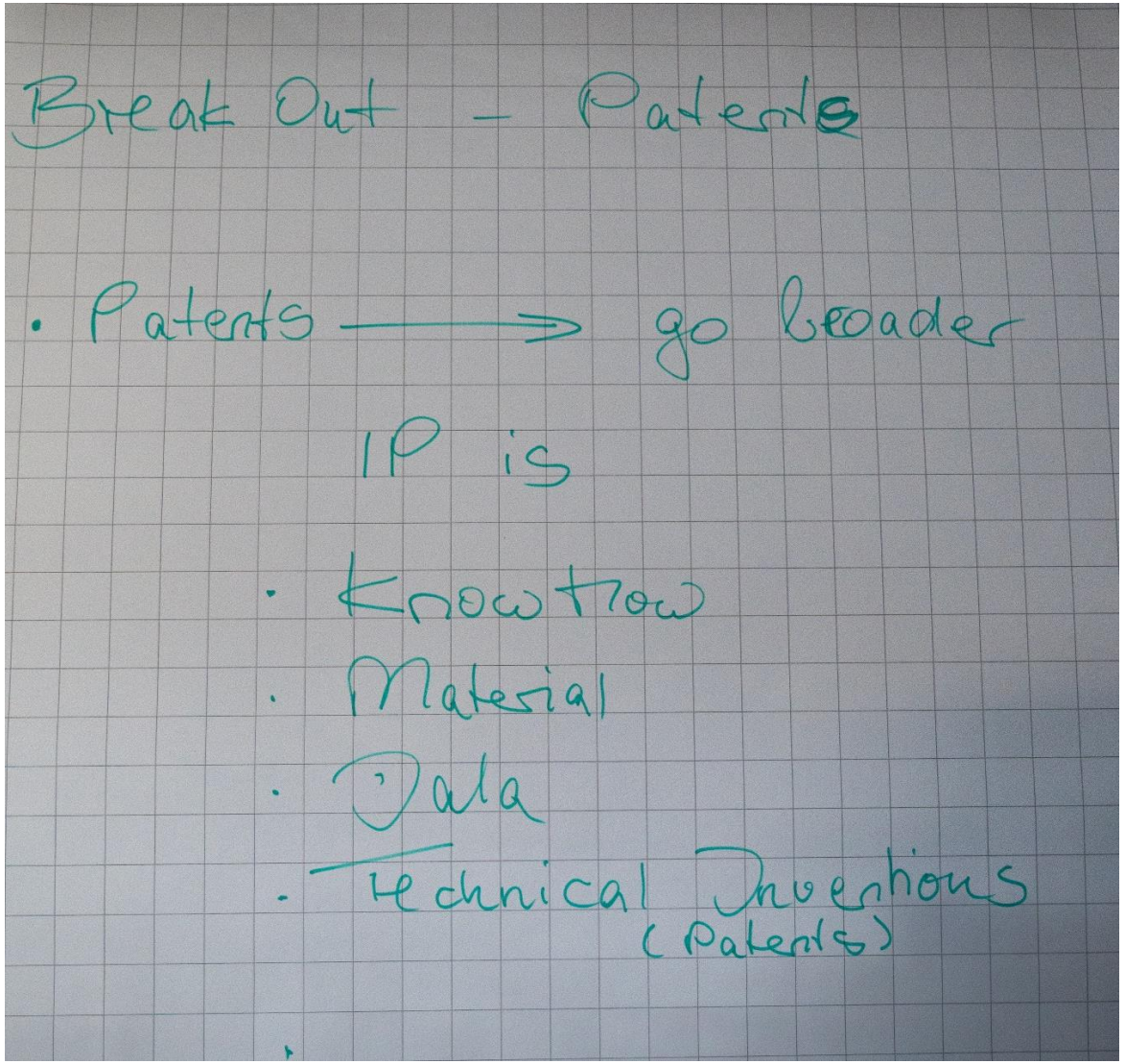
Reporter:
Sandra Franz & Ulrike Weirauch

Break out session: AI / GMP Support / Automation



Reporter: Alexander Scholz

Break out session: Patents



Reporter:
Dorit Teichmann

Break out session: Clusterdevelopment

Reporter: Stefanie Binder

Clusters4future transfer spirit

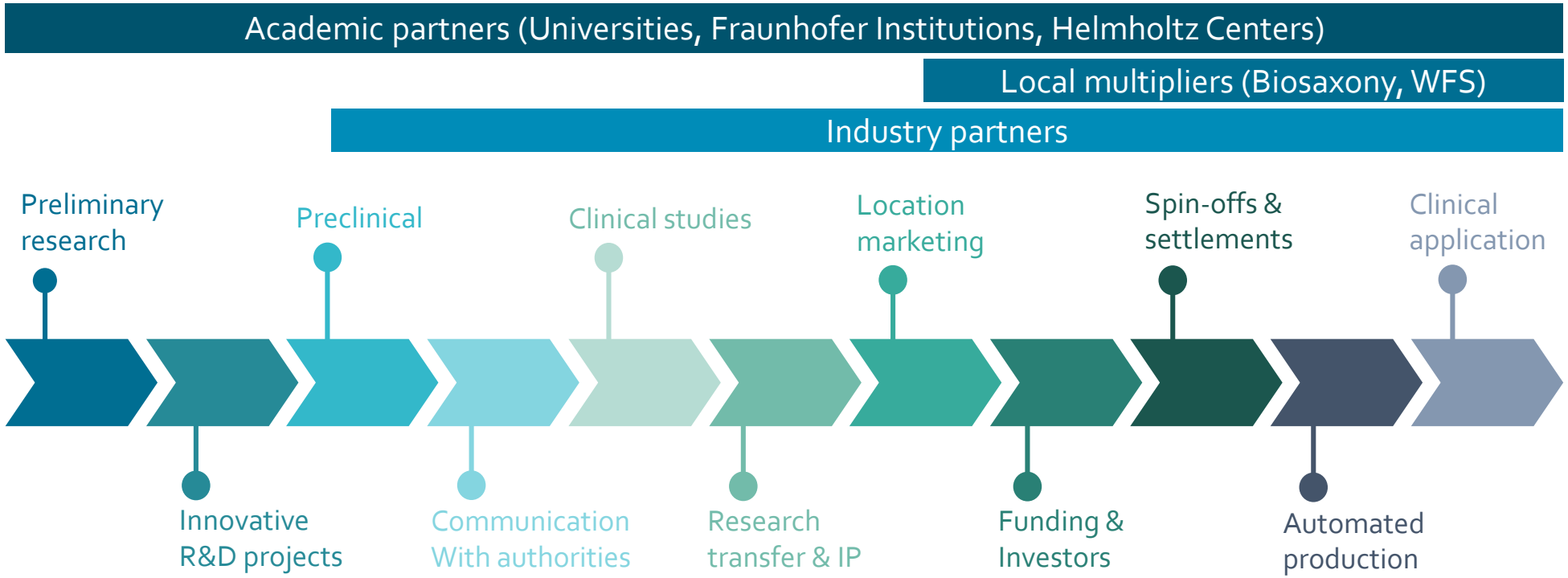
SAXOCELL®

A strong cluster is more than the sum of its individual players

- pursuing regional development approach
- network of local and supra-regional partners
- establishing the complete value chains in Saxony

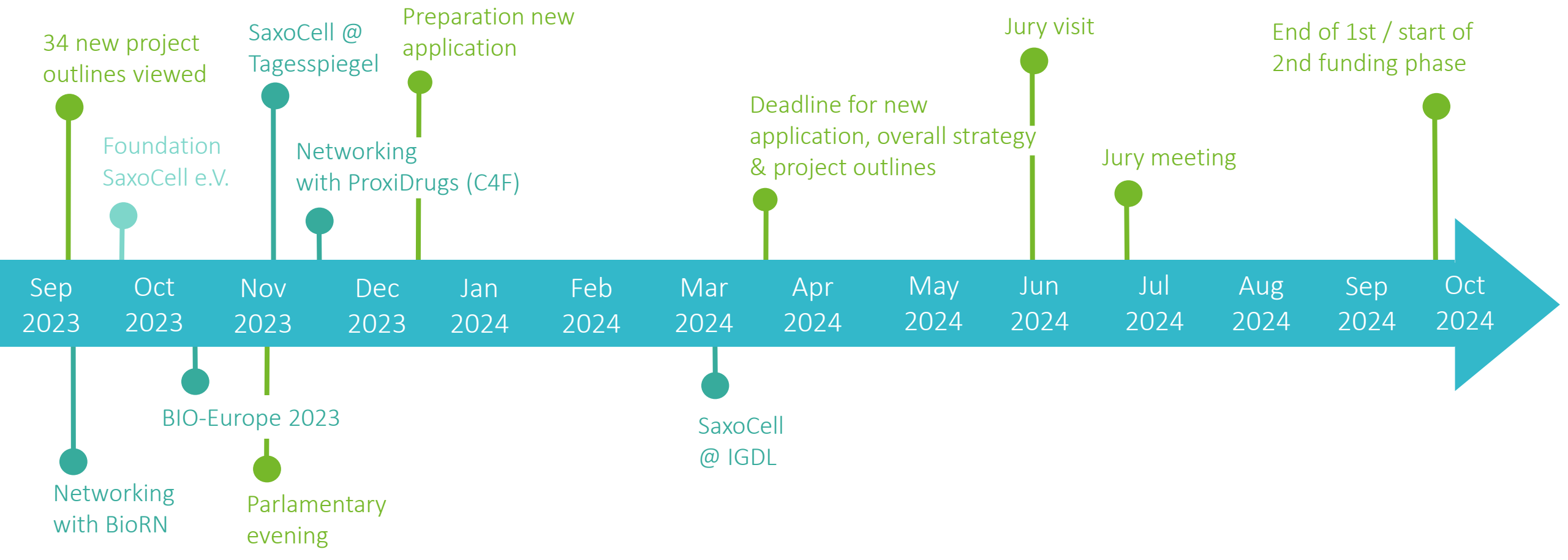
CLUSTERS 4 FUTURE
Innovationsnetzwerke für unsere Zukunft

GEFÖRDERT VOM
Bundesministerium für Bildung und Forschung



Outlook

Transfer | Conferences / Meetings | Cluster-internal



Project outlines for 2nd funding phase

- 34 outlines were submitted
- First categorization was made by the speakers
  - ✓ with concrete industry contribution and innovative
  - ✓ with little to no industry contribution but innovative
  - ✓ new professorships or start up projects and interesting technologies

Discussion between PIs and speakers will begin in the next few days

SaxoCell e.V.

Connect, Innovate, Heal - Together into the future of therapy

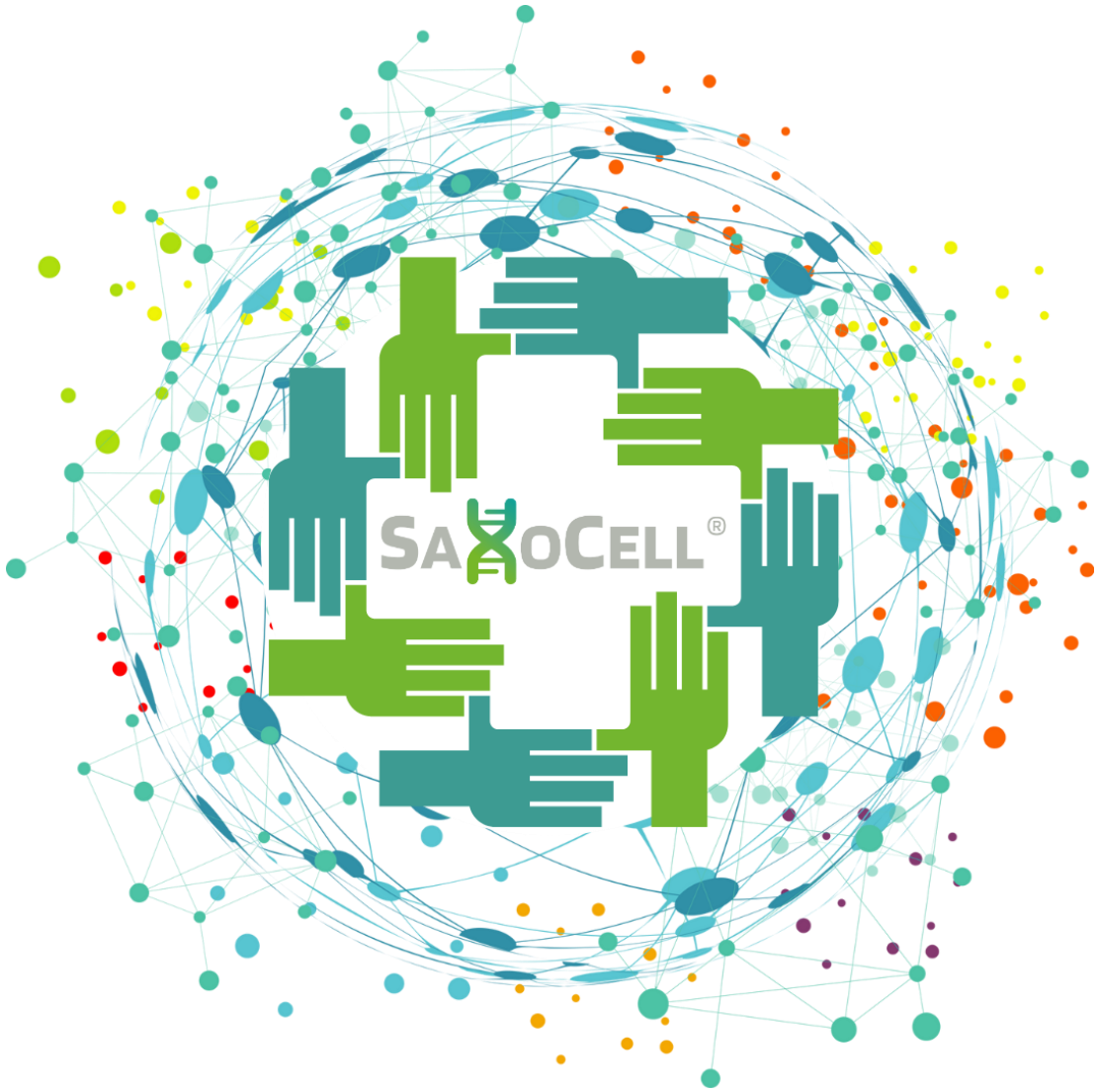
SaxoCell e.V. is to involve (new) partners and strengthen our network

Current status of SaxoCell e.V.

- By-Laws approved by TUD, Uni Leipzig & Fraunhofer IZI
- Founding on September 12, 2023
- Will be open to SaxoCell partners and non-partners
- Attract finances for gene and cell therapy
- Increases flexibility and response to needs

So stay tuned…

Thank you…



…for being part of our sustainably growing network ♥

Day 2: Tuesday 12.9.23, Biocity

SAXOCELL®

Thank you for your participation!

It was nice seeing you!

You can fill out the survey about the meeting here