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SaxoCell®

CLUSTERS 4 FUTURE
Innovationsnetzwerke für unsere Zukunft

Welcome to

SaxoCell
Kick-off Meeting

16th November 2021 | online

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KLINIKUM CHEMNITZ gGmbH

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Our partner

Initial industry partners (11)

External Advisory Board

- Prof. Ute Modlich (Paul Ehrlich Institut, Langen)
- Dr. Lorenz Mayr (Vector BioPharma AG / Basel)
- Prof. Axel Schambach (MHH, Hannover)
- Dr. Jessica Morison (CRISPR Therapeutics, Boston)
- Jan Geissler (Patient, München)
- Nadine Winter (Patient, Dresden)

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Chatterfall

Please complete this sentence in your chat window, but wait for the start signal to press enter:

- I expect from this kick off …

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Chatterfall

I expect from this kick off …

…to get an overview on the whole concortium

…to learn more about the individual parts of the SaxoCell project

…to learn about the overall structure and plans of SaxoCell

…an overwiew about synergistic potential laying in the SaxoCell Cluster

…to connect with the partners and learn about all the different SaxoCell projects

…a good overview about the different projects and the people behind these

…to get to know projects and transfer strategies

…to understand which competences are bundled within this unique consortium

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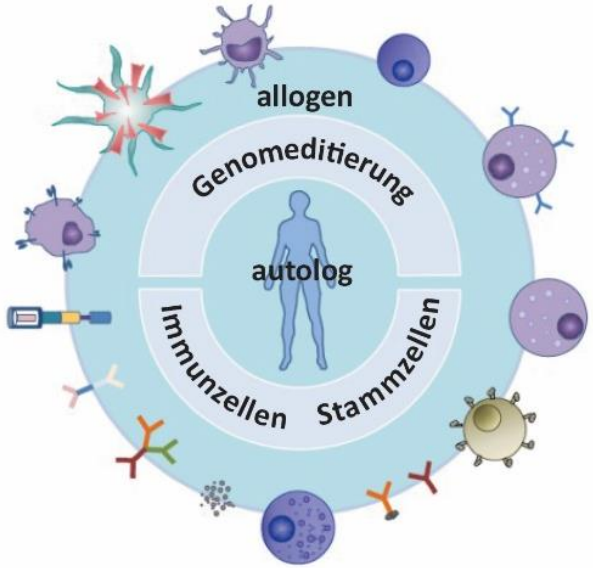
Vision & Mission

Affordable and safe cure of patients who suffer from incurable disease with **cell and gene therapy**

Saxony as **European hub**

Clusters4Future as **Accelerator** of R&D **transfer**

Industry



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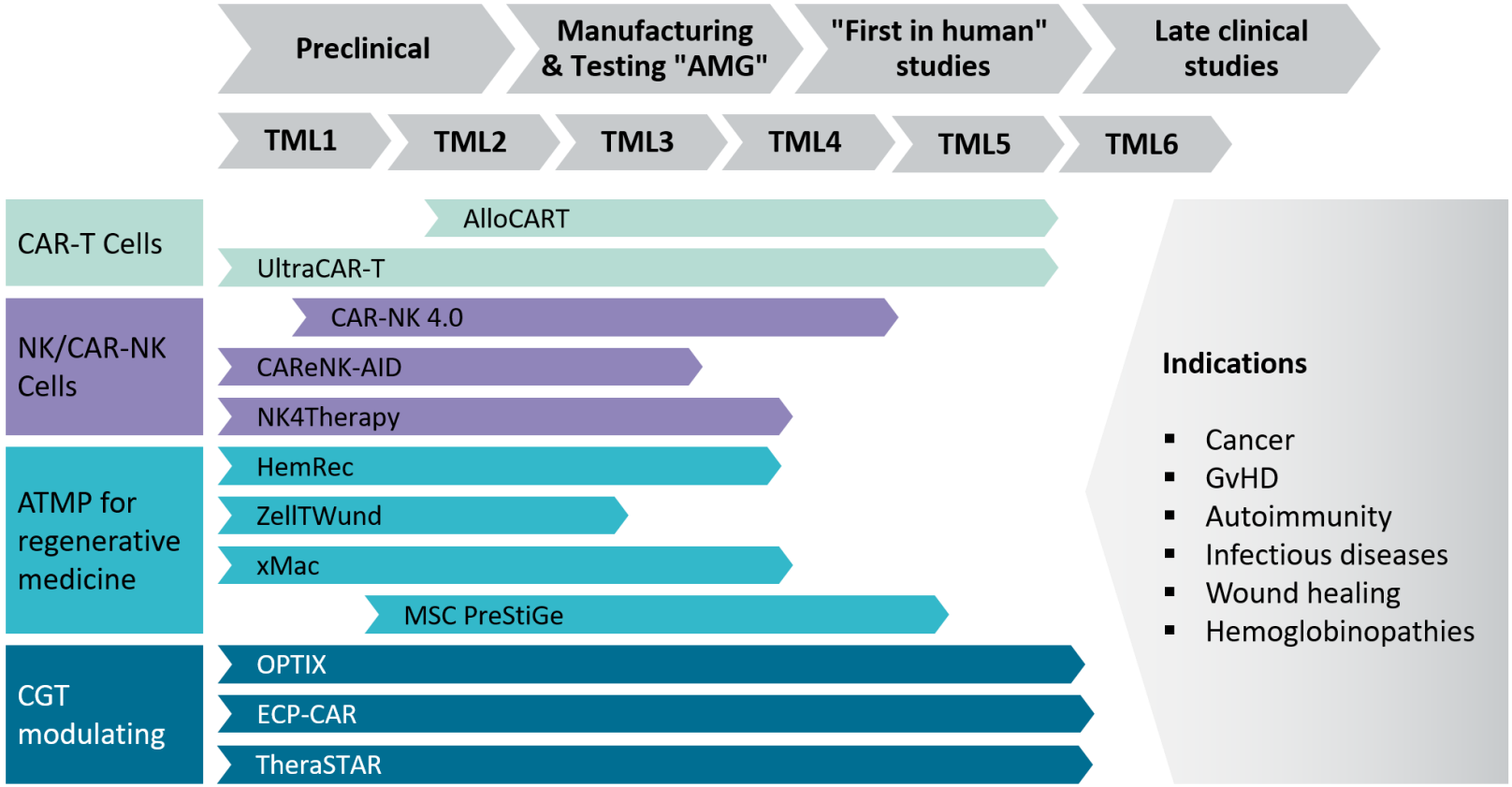
Overview

Complete Value Chain – Early Translation - Network



TRL: Technology Readiness Level; ZGT: Cell and Gene Therapy; GvHD: Graft versus Host Disease

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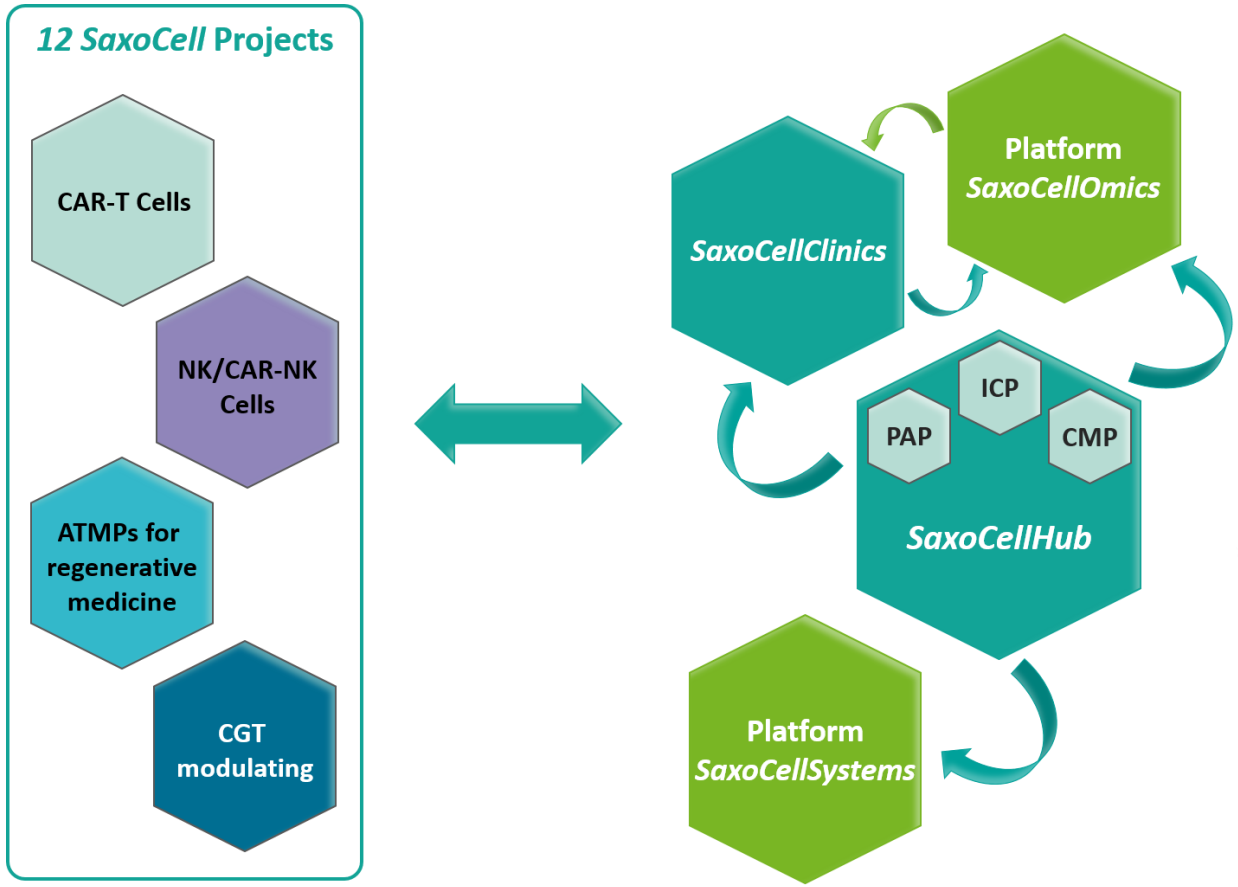
Overview

More than Innovative Research
Added Value through Inter- and Transdisciplinarity



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Optimierte GMP-Herstellung und First-in-Man Phase 1 Studie von Palintra® als ATMP für die allogene Stammzelltransplantation

PI: Lilly Stahl (Tcell Tolerance GmbH)

Partner: Dr. G. Schmiedeknecht/PD Dr. S. Fricke (Fraunhofer IZI), Prof. Dr. U. Platzbecker (Uniklinik Leipzig), PD Dr. M. Hänel (Klinikum Chemnitz), Prof. Dr. M. Bornhäuser (Uniklinik Dresden)

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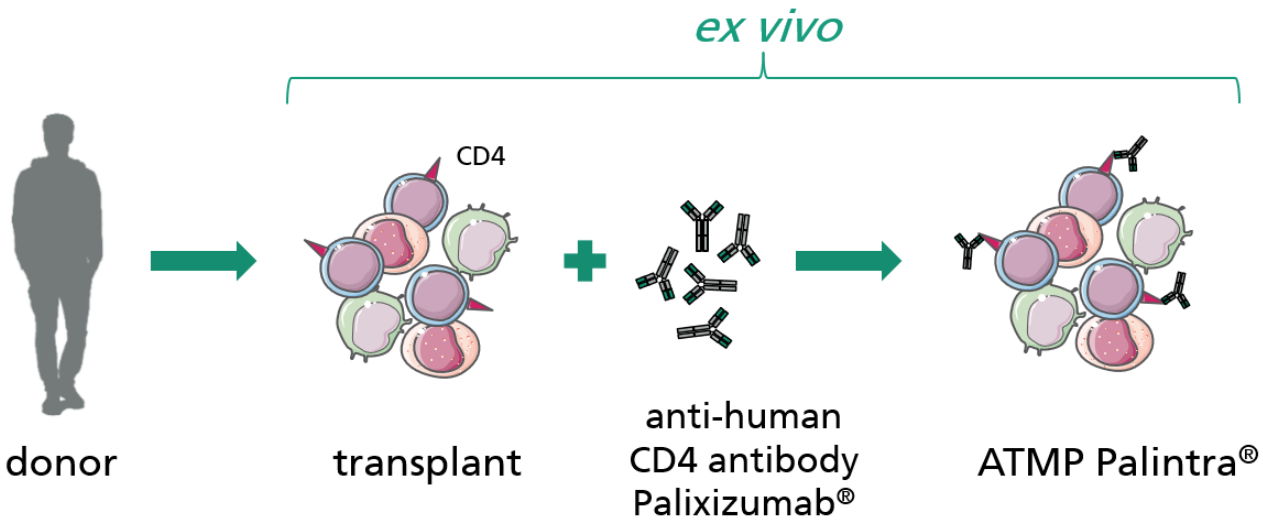
Vision and core competences



Vision: Towards automated manufacturing of Palintra® ATMP

Core competences:
- preclinical ATMP characterization
- ATMP GMP process development
- ATMP GMP manufacturing
- GvHD treatment
- hematopoietic stem cell transplantation

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Topic and unique selling point

Goal

Transfer of promising research results on GvHD prevention by *ex vivo* incubation of a stem cell graft with the anti-CD4 antibody Palixizumab® to clinical use of the antibody-incubated graft Palintra®

Approach

- Basic research: further elucidation of the mechanism of action of Palixizumab®
- Applied research: improvement of the efficacy of allogeneic stem cell transplants
- Development: transfer to GMP manufacturing and automation of cell therapeutics

USP

Extracorporeal treatment of allogeneic cell transplants is an innovative therapeutic approach for GvHD treatment.

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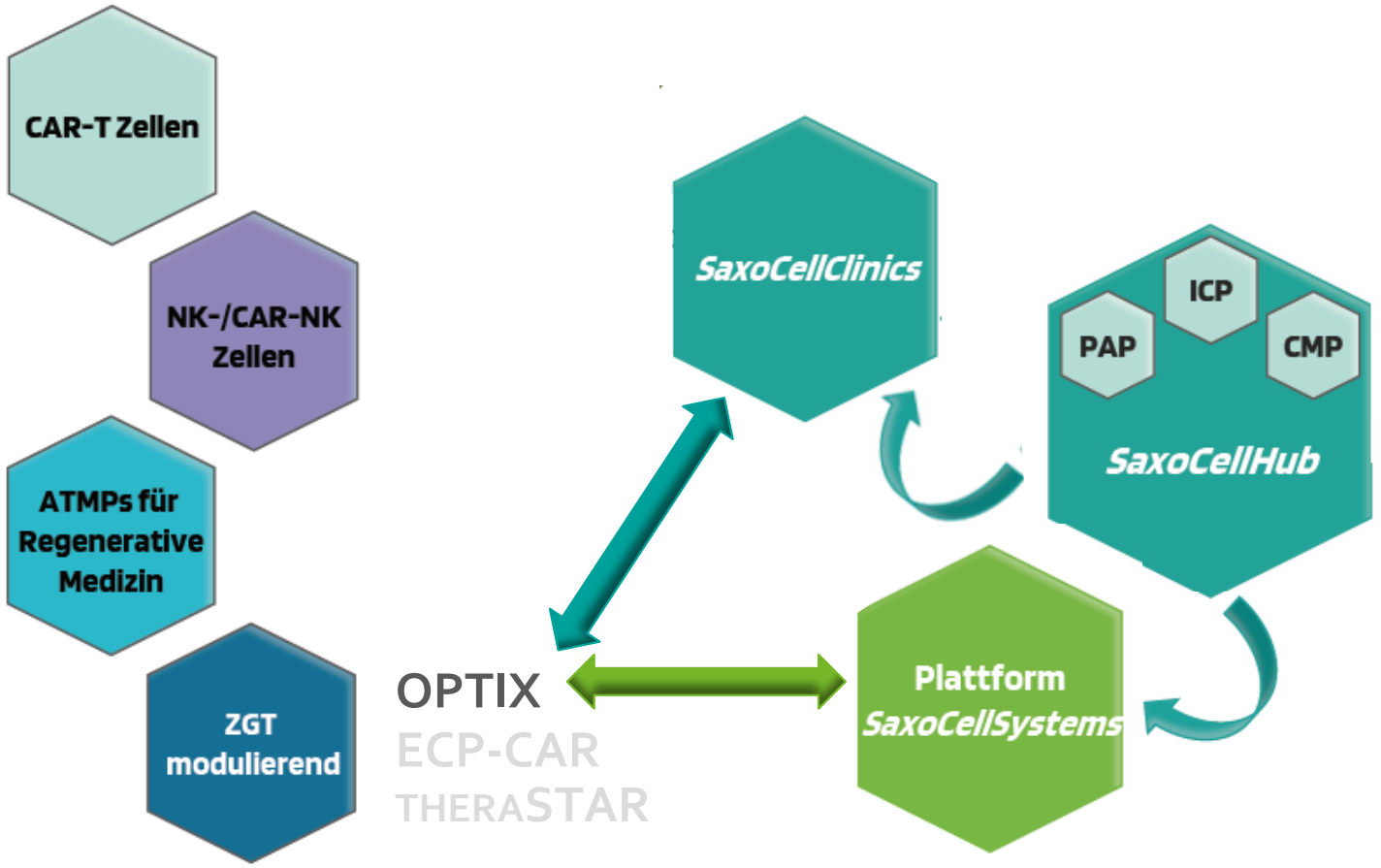
Expectations towards SaxoCell - Required links to SaxoCell

SaxoCell Projects



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ECP CAR

Coordinator: Dr. Vladan Vucinic, University Clinic Leipzig, Medical Clinic I, Hematology and Celltherapy

Partner: Prof. Dr. Uwe Platzbecker, University Clinic Leipzig, Medical Clinic I, Hematology and Celltherapy

Prof. Dr. Ulrich Sack, Institute for Clinical Immunology

PD Dr. Marco Herling, University Clinic Leipzig, Medical Clinic I, Hematology and Celltherapy

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Vision and core competences

- Implementation of ECP in lymphodepletion (immunomodulation) prior to application of CAR T-cells

Analyses of:

- patients‘ CAR T-cells (quantitative and qualitative)
- ECP induced modulation of cellular and humoral microenvironment
- dynamics of cytotoxic effector functions and transcriptome-profiles

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Topic and unique selling point

- Positive effects on in-vivo expansion, persistence and funcionality of CAR T- cells

- Implementation of immunomodulation with ECP on other entities treated with CAR T-cells
- Definition of parameters influencing the efficacy of CAR T-cells
- Determination of strategies for „pharmacological" modulation of target-cell populations or target-signalling molecules

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Expectations towards SaxoCell - Required links to SaxoCell

- Expert utilization of Multiomics Platform as basis for further development
- implementation of „pharmacological" strategies for immunomodulation
- Towards development of new ATMPs „made in Saxony"

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TheraSTAR

Development of theranostic targeting modules for diagnosis and therapy

PI: Dr. Anja Feldmann,
Helmholtz-Zentrum Dresden-Rossendorf (HZDR)

Partner: Prof. Dr. Michael Bachmann, HZDR, TU Dresden

Prof. Dr. Marc Schmitz, TU Dresden

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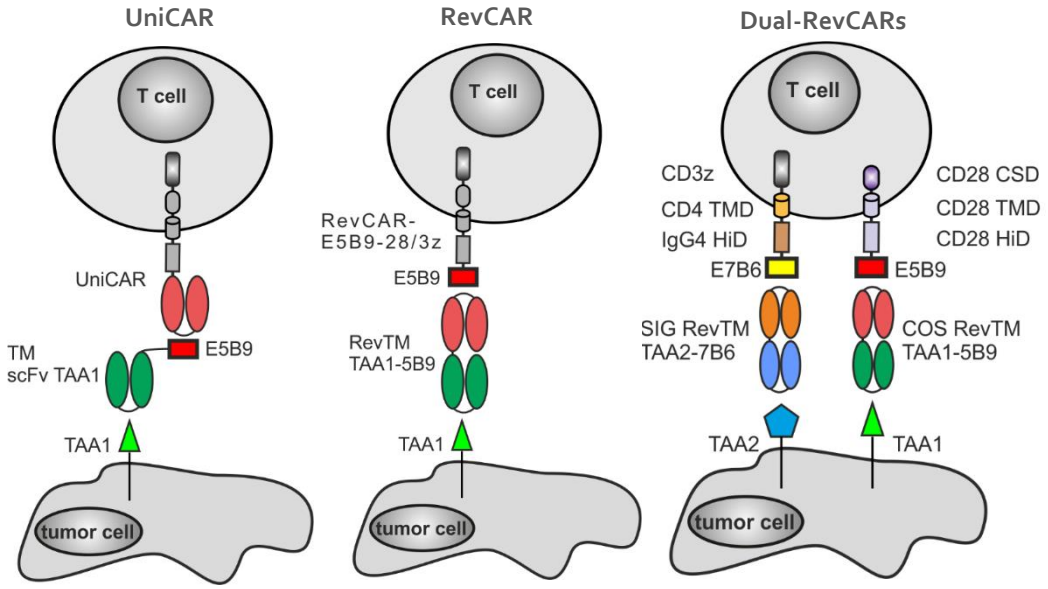
Vision and core competences

theranostic and immunomodulating platform technology based on adaptor universal CARs and targeting modules

immunotherapy



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Vision and core competences

theranostic and immunomodulating platform technology based on adaptor universal CARs and targeting modules

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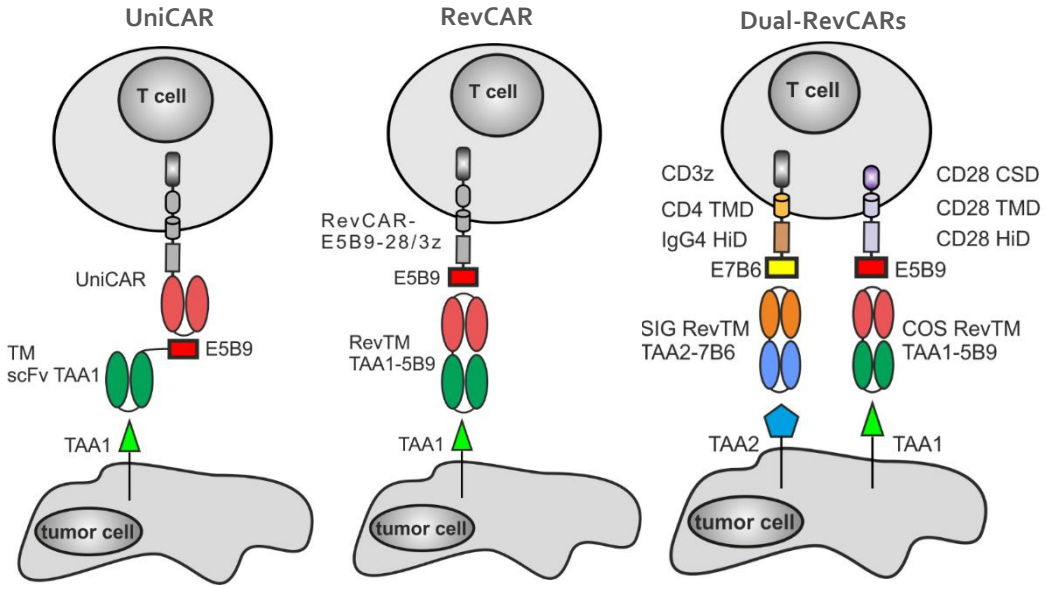
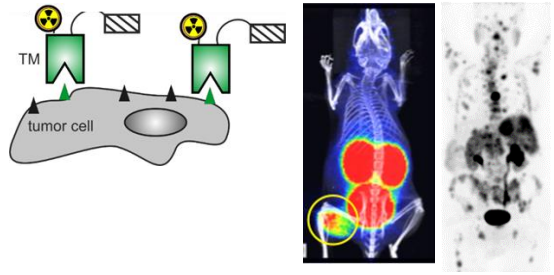


diagnostic imaging



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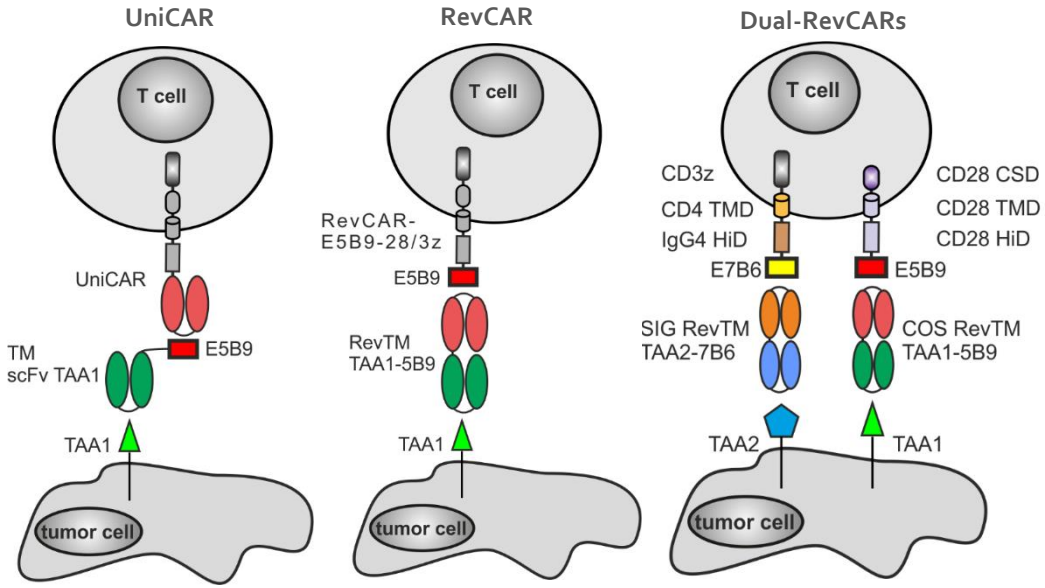
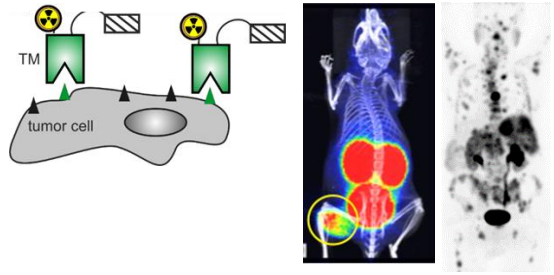
Vision and core competences

theranostic and immunomodulating platform technology based on adaptor universal CARs and targeting modules

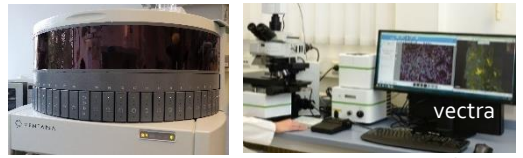
immunotherapy



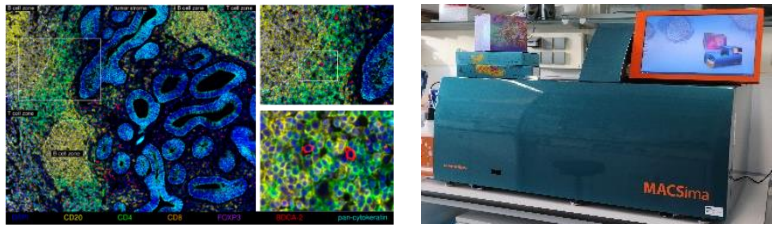
diagnostic imaging



tumor microenvironment



automated staining and imaging platforms



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Topic and unique selling point

theranostic and immunomodulating platform technology based on adaptor universal CARs and targeting modules

- versatile
- effective
- safe / switchable / programmable
- broadly applicable
  - for therapy, diagnosis, monitoring and immunomodulation
- universal / flexible / adaptable
  - targeting of different antigens without reengineering of CAR-modified immune cells
  - targeting of different diseases
  - engineering of different immune cells
  - engineering of targeting modules with different specificities, formats and pharmacokinetic properties

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Expectations towards SaxoCell - Required links to SaxoCell

- new contact and fruitful collaborations with scientists, clinicians and industry
- access to innovative ideas, know-how and infrastructure (e.g. bioinformatic analysis and design)
- sharing of materials and tools
- invention and establishment of novel unique products
- large-scale GMP (industrial) manufacturing of drugs
- support for clinical translation of products, for technology transfer, generation of IP and founding of start-up companies

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AlloCART*reg*

PI: Martin Bornhäuser Anke Fuchs Frank Buchholz

Partners: Anja Feldmann Michael Bachmann

Universitätsklinikum Carl Gustav Carus

CRTD Center for Regenerative Therapies TU Dresden

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AlloCART*reg*

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CLUSTERS 4 FUTURE Innovationsnetzwerke für unsere Zukunft

Vision and core competences

Martin Bornhäuser

Anke Fuchs

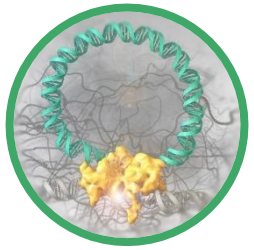
Frank Buchholz

Anja Feldmann

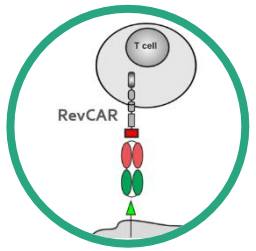
Michael Bachmann

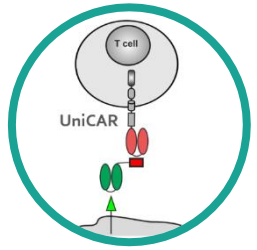
Hematology
Cell therapy incl. Treg

Treg manufacture
GMP / ATMPs

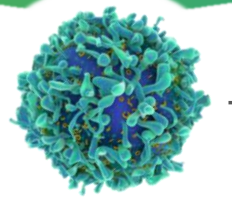


Gene editing
Designer recombinases





Flexible unique adapter CAR technology

Off-the-shelf suppressive  targeted T cells for aGvHD

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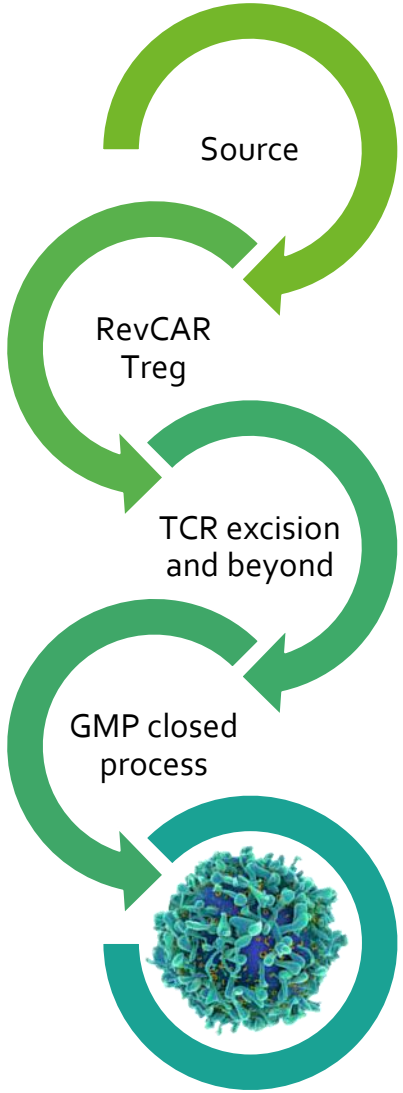
Topic and unique selling point



DKMS WIR BESIEGEN BLUTKREBS DKMS Stem Cell Bank Selected donors

Engrafting human regulatory T cells with a flexible modular chimeric antigen receptor technology

Stefanie Koristka [a, 1], Alexandra Kegler [a, 1], Ralf Bergmann [a], Claudia Arndt [a], Anja Feldmann [a], Susann Albert [b], Marc Cartellieri [c], Armin Ehninger [d], Gerhard Ehninger [e, f, g, h, i], Jan Moritz Middeke [e], Martin Bornhäuser [e, f, g, h, i], Marc Schmitz [f, g, h, j], Jens Pietzsch [a, k], Katja Akgün [l], Tjalf Ziemssen [l], Jörg Steinbach [a, f, g, h, k], Michael P. Bachmann [a, b, f, g, h, i, *]

→ RevCAR as **advanced CAR**

Advanced gene editing (designer recombinases)

Automated Clinical Grade Expansion of Regulatory T Cells in a Fully Closed System

José Manuel Marin Morales [1], Nadine Münch [1], Katja Peter [1], Daniel Freund [1], Uta Oelschlägel [2], Kristina Hölig [2], Thea Böhm [3], Anne-Christine Flach [3], Jörg Keßler [3], Ezio Bonifacio [4], Martin Bornhäuser [2,5] and Anke Fuchs [1,2,4]*

→ RevCAR Miltenyi Biotec ScaleReady™

→ AlloCART*reg*

Off-the-shelf availability for 30% of patients
Not restricted to target
? Autoimmune diseases and beyond

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AlloCART reg

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Expectations towards SaxoCell - Required links to SaxoCell

- Exploit alternative automated closed-system approaches
- Bundle IZI and CRTD Treg manufacturing experiences and activities
- Early development of a roadmap towards the clinic
- Support in exploiting additional funding sources
- Know-how in IP and commercial liaisons

- **Team spirit** and corporate identity:

  SaxoCell students, postdocs, PIs, …

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UltraCAR-T: Cancer immunotherapy with next generation CAR-T cells

Coordinator:
Prof. Dr. Michael Hudecek, Fraunhofer IZI Leipzig and Universitätsklinikum Würzburg

Partner:
Prof. Dr. Dr. Ulrike Köhl, Fraunhofer IZI Leipzig
Dr. Jan Van den Brulle, T-CURX Würzburg

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Vision and core competences

Vision

Generation of a high-quality value chain along the translational and commercial development of gene-engineered cellular immunotherapies

Core competences

- Established GMP manufacturing and product release for CAR-T cells (Fraunhofer IZI)
- Preclinical models to analyze safety and efficacy under GLP (Fraunhofer IZI)
- Innovative target and product pipeline for hematology and oncology (T-CURX)
- Proprietary CAR-T cell technologies (T-CURX)
  - Novel ultramodular CAR format
  - Novel virus-free gene transfer technology
  - Novel safety control switch

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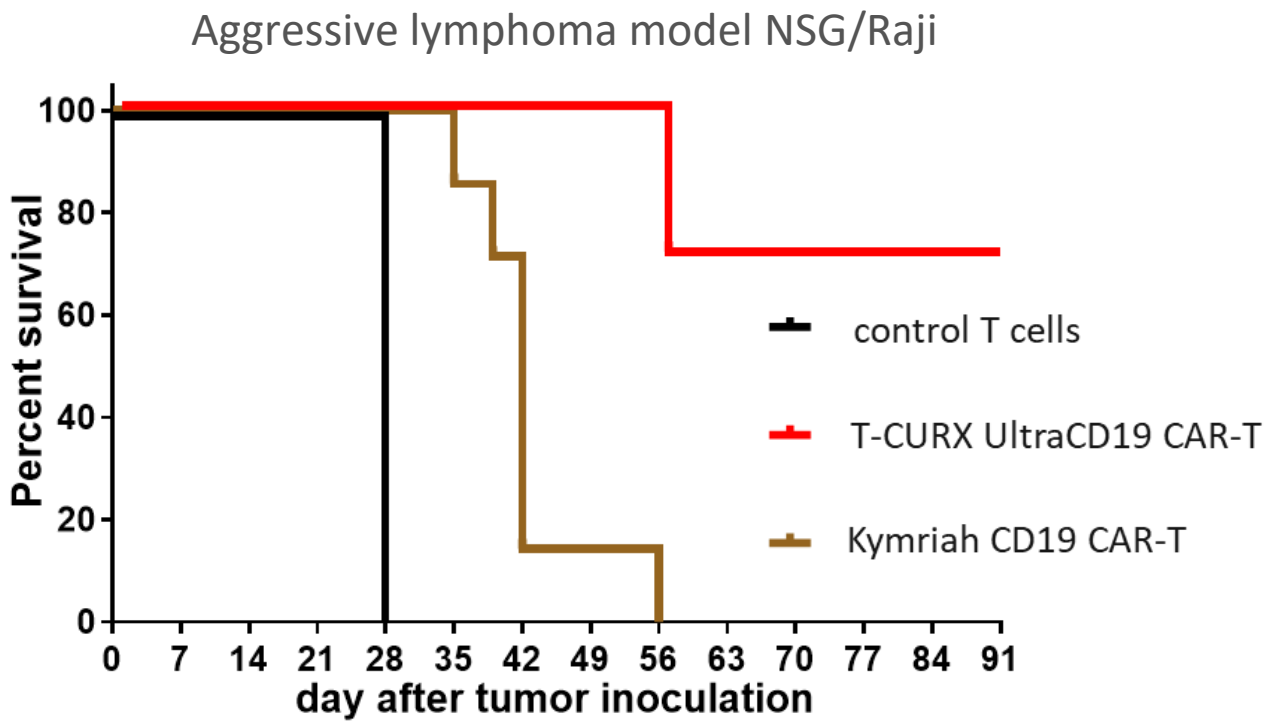
Topic and unique selling point

- Unique Selling Point: T-CURX UltraCAR Technology



[1]NSG immunodeficient mice, inoculated with Raji lymphoma and treated with single dose of T-CURX' MatchMaker CD19 CAR-T vs. Kymriah vs. mock control T cells. Kaplan-Meier analysis shows superior survival in T-CURX vs. Kymriah cohort ($p<0.05$).

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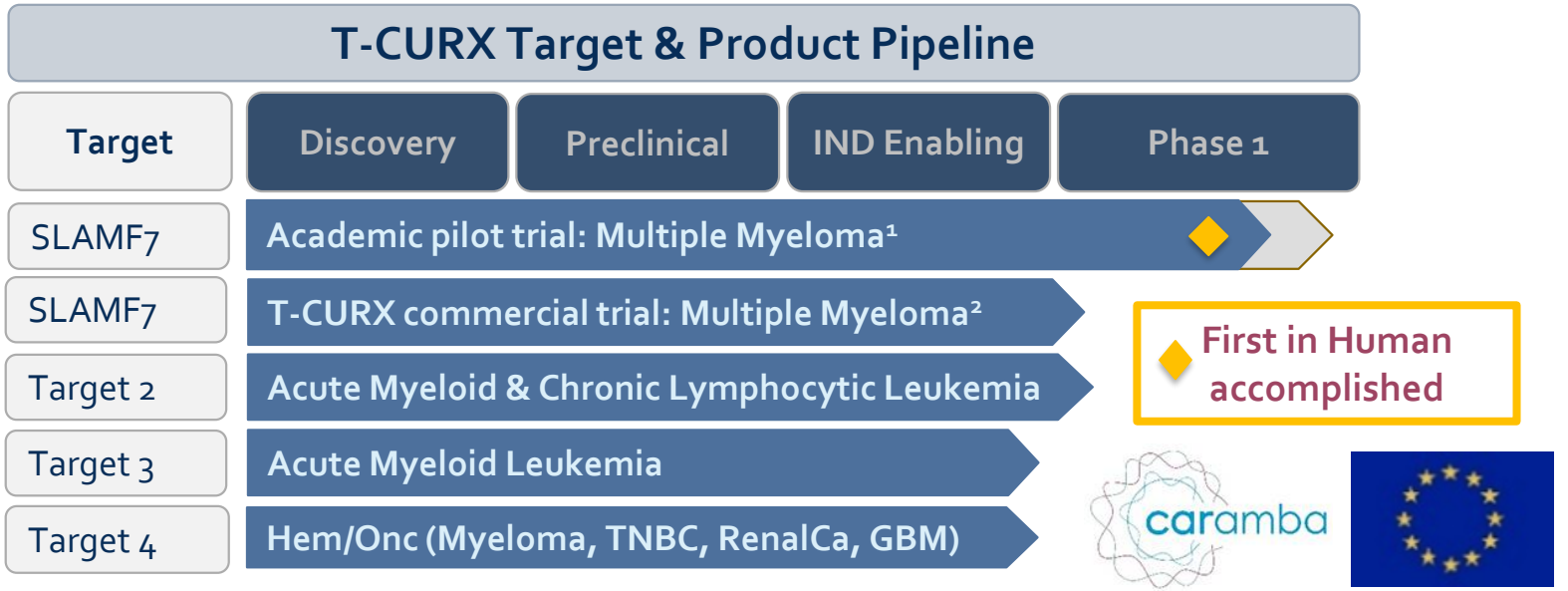
Topic and unique selling point

- Unique Selling Point: T-CURX Target & Product Pipeline



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Topic and unique selling point

- Validation and application of an optimized scalable manufacturing process to shorten development and delivery timelines
- Preclinical and clinical validation of first T-CURX targets and corresponding CAR-T products with optimal anti-tumor efficacy
- Optimization of novel pre-clinical models to assess safety and efficacy of proprietary CAR-T cell products (e.g. by 3D tissue models or high resolution microscopy)
- Standardization of data collection and management to allow for the deployment of machine learning and artificial intelligence to further accelerate and scale the development of novel CAR-T cell products

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Expectations towards SaxoCell - Required links to SaxoCell

UltraCAR-T will deliver the first clinical product and trial in SaxoCell.

- Establishment of optimized CAR-T cell product manufacturing and release platforms at Fraunhofer IZI (SaxoCellOmics)
- Establishment of an optimal infrastructure for clinical trials at SaxoCellClinics
- Generation of an attractive „Innovation Ecosystem" for cellular immunotherapies for partnering activities within and outside of SaxoCell

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Break

Please choose your break out room:

- meet member of area 4
- meet member of area 1
- at the coffee room (small talk)
- quiet break (no interaction)

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CAR NK-4.0

Establishment of a platform for the automated production of allogeneic CAR-NK cell therapeutics for the treatment of specific cancers

Coordinator:	**Prof. Dr. Dr. Ulrike Köhl (Fraunhofer IZI)**	
Project lead:	**Fraunhofer IZI**	**- Dr. Anna Dünkel & Dr. Paul Franz**
Partners:	Klinikum Chemnitz gGmbH	- PD Dr. Mathias Hänel
	Universität Leipzig	- Prof. Dr. Ulrich Hacker
	Affimed GmbH	- Prof. Dr. Joachim Koch
	Miltenyi Biotec B.V. & Co. KG	- Dr. Nina Möker

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Vision and core competences

Vision: Towards optimized **automated manufacturing of CAR NK cells**

Goal 1: Development of an automated CAR-NK cell manufacturing platform

Goal 2: Preclinical testing of CAR NK cells and design of a study plan for the therapeutic use of CAR NK cells in MDS

Goal 3: Enhancement of NK cell cytotoxic activity

- Bispecific CARs for the treatment of EMM
- AVV vector-mediated gene delivery into primary NK cells
- Combination of CAR NK cells and multi-specific ICEs
- Gene engineering for optimized CAR NK cell functionality

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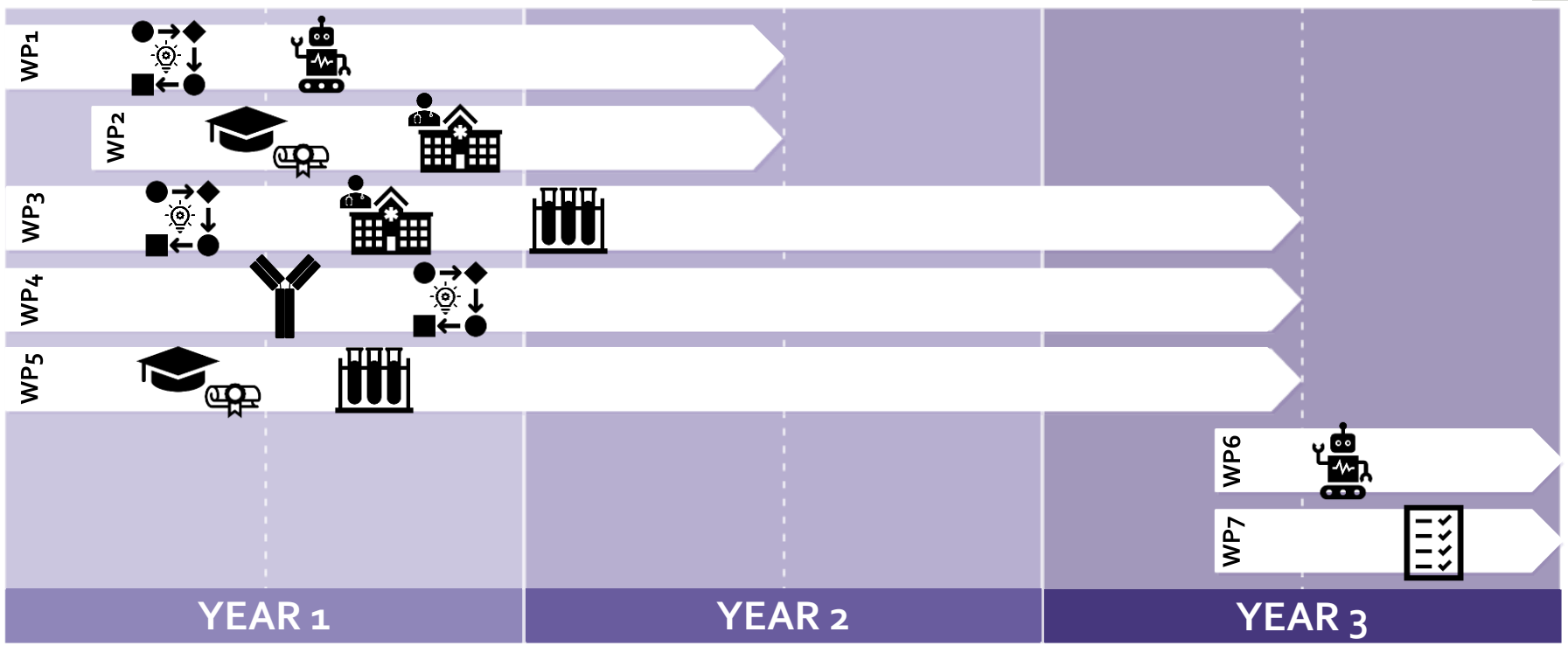
Topic and unique selling point

USP Solutions are enabled within the multidisciplinary consortium:

1 Platform technology for automated CAR NK cell manufacturing

2 Research program for the enhanced anti-tumor activity of effector cells



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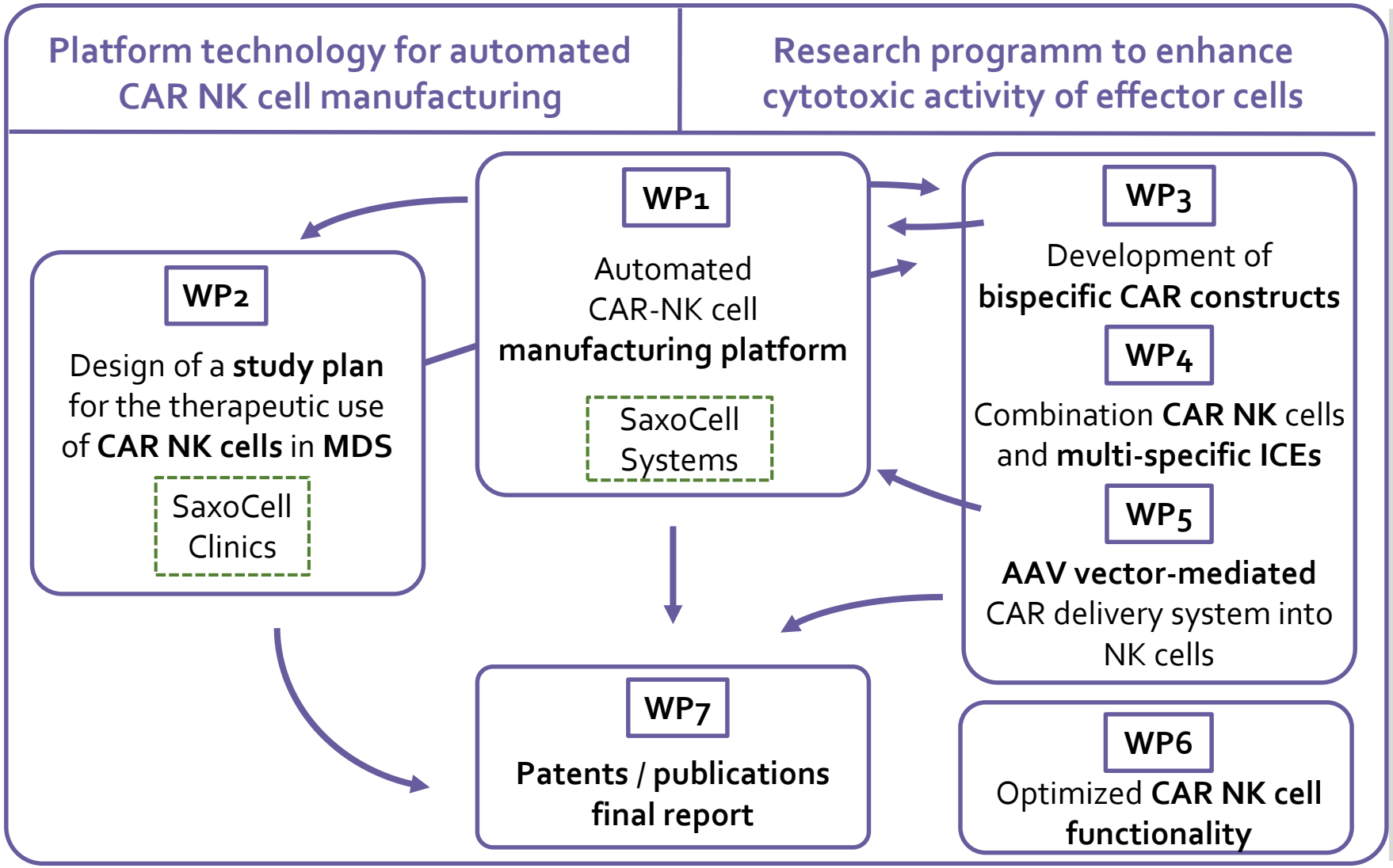
Topic and unique selling point



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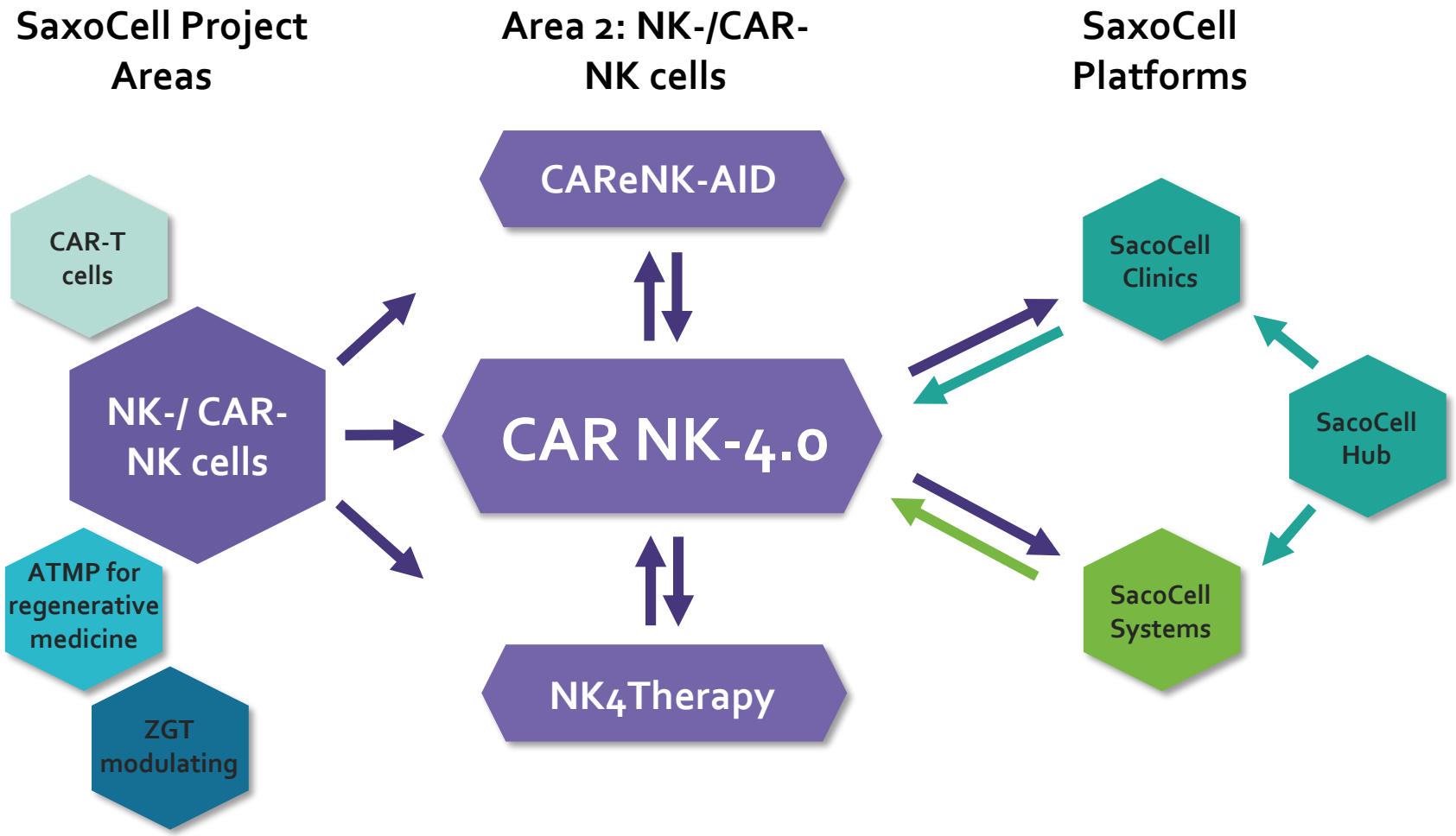
Expectations towards SaxoCell - Required links to SaxoCell



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CAReNK-AID

Chimeric **A**ntigen **R**eceptor **e**ngineered **N**atural **K**iller cells for **A**uto**i**mmune **D**iseases

Torsten Tonn; Jiri Eitler (ETM, MF, TU Dresden, TT coordinator)

Achim Temme (NCH-FOR, MF TUD)

Stefan R. Bornstein (MK III, MF TUD)

Ezio Bonifacio; Anne Eugster (CRTD, TUD)

Achim Aigner (Med. Fakultät, Universität Leipzig)

Heiko von der Leyen (Orgenesis Germany GmbH)

Graves Disease; NEJM

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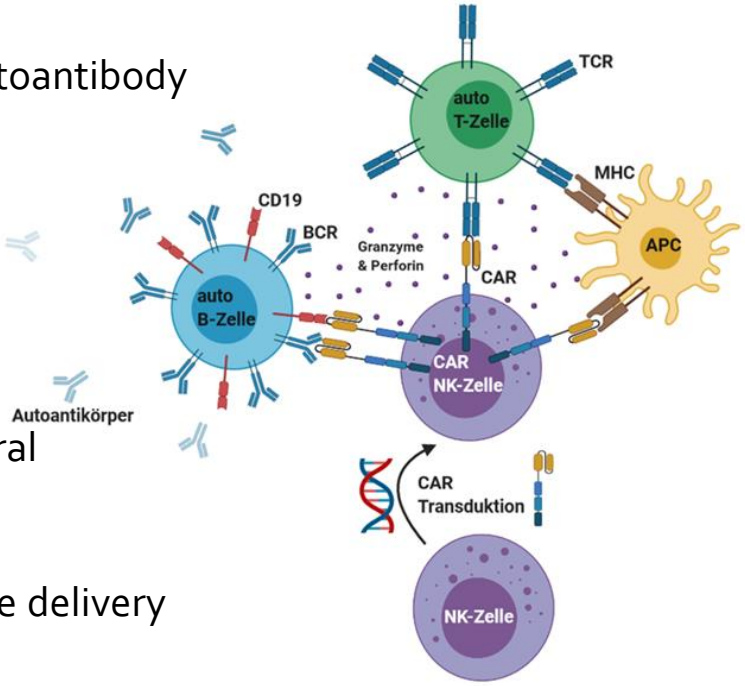
Vision and core competences

➢ Expand CAR cell therapies into non malignant diseases such as autoimmune diseases: Myasthenia Gravis, T1D, Graves disease.

- >20 years experience in clinical translation of NK based cell therapies
- Expertise in national and international regulatory landscape for ATMP
- Research infrastructure for in autoimmunity and autoantibody targets
- Leading clinical centre for metabolic diseases and T1D providing broad patient base
- Humanized animal models in autoimmune diseases
- Genetic engineering of NK cells using viral & non-viral methods
- Nanoparticle technologies for gene / oligonucleotide delivery
- NK cell expansion and characterization
- Automated cell manufacturing processes



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Topic and unique selling point

- Developing Natural Killer cells as carriers for CAR targeting autoreactive B-Lymphocytes in Myasthenia Gravis and T1D
  - NK cells have improved risk/benefit ratio over CAR-T cells - mandatory for non malignant indications.
  - NK cells suited for off-the-shelf approaches - cost effective
- Combining B cell targeting (CD19) with autoantibody targeting (epitopes)
  - specific eradication of autoreactive cells with less Off-Autoreactive cell effects
- Integrated and automated manufacturing process for CAR-NK cells
- Nanoparticle-based gene delivery methods into NK cells

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Expectations towards SaxoCell - Required links to SaxoCell

- Enhance visibility regionally, nationally and internationally
- Support in contracting (collaboration agreements, in- and out-licensing, intellectual property)
- An environment/culture, which facilitates commercialisation, start-up and more investment
- Guide the path to commercialisation/spin-off

- Access to SaxoCellomics facilities (sequencing & Bioinformatics)
- Networking, interactions and competence expansion that increase our competitiveness

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NK4Therapy

Entwicklung eines GMP-konformen Herstellungsprozesses für adaptive NK – Zellen mit artifiziellen Feeder-Zellen und der CC-TOP-Zellisolations-Technologie

Prof. Dr. Achim Temme (MF, TU Dresden, coordinator)

Prof. Dr. Torsten Tonn (MF, TU Dresden)

Prof. Dr. Martin Bornhäuser (MF, TU Dresden)

Dr. Willi Gerdes, Dr. Herbert Stadler (Cell.Copedia GmbH,Leipzig)

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Vision and core competences

- New NK cells therapeutics for treatment of cancer – from bench to bedside

- Proprietary platforms for fully-automatic purification (CC-TOP-Technology*) and expansion of specific NK cell subsets and CAR-NK cells*
- Complementary NK-CAR concept system based on DAP12 signaling
- Experience in pre-clinical tumor models
- Expertise in establishing GMP conform processes for production of „advanced therapeutic medicinal products" (ATMPs)
- Long-standing expertise in clinical studies

*patent pending

Michaelis SU et al., Ann Hematol. 2014 Sep;93(9):1579-86.
Töpfer et al., J Immunol. 2015 Apr 1;194(7):3201-12.
Müller et al., J Immunother. 2015 Jun;38(5):197-210
Fasslrinner F. et al., Lancet Haematol. 2018 Apr;5(4):e161-e169.
Nowakowska P. Cancer Immunol Immunother. 2018 Jan;67(1):25-38.
Michen et al., Cytotherapy. 2020 Jul;22(7):354-368.

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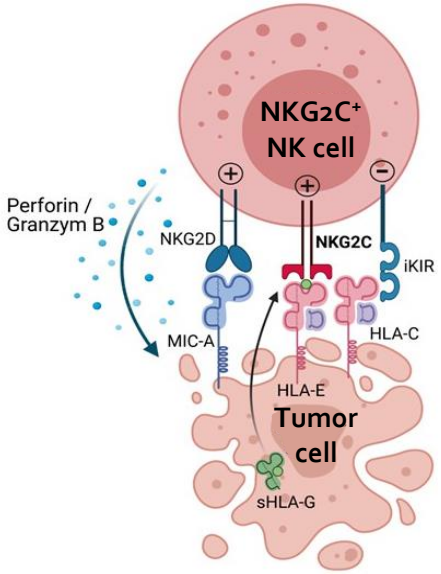
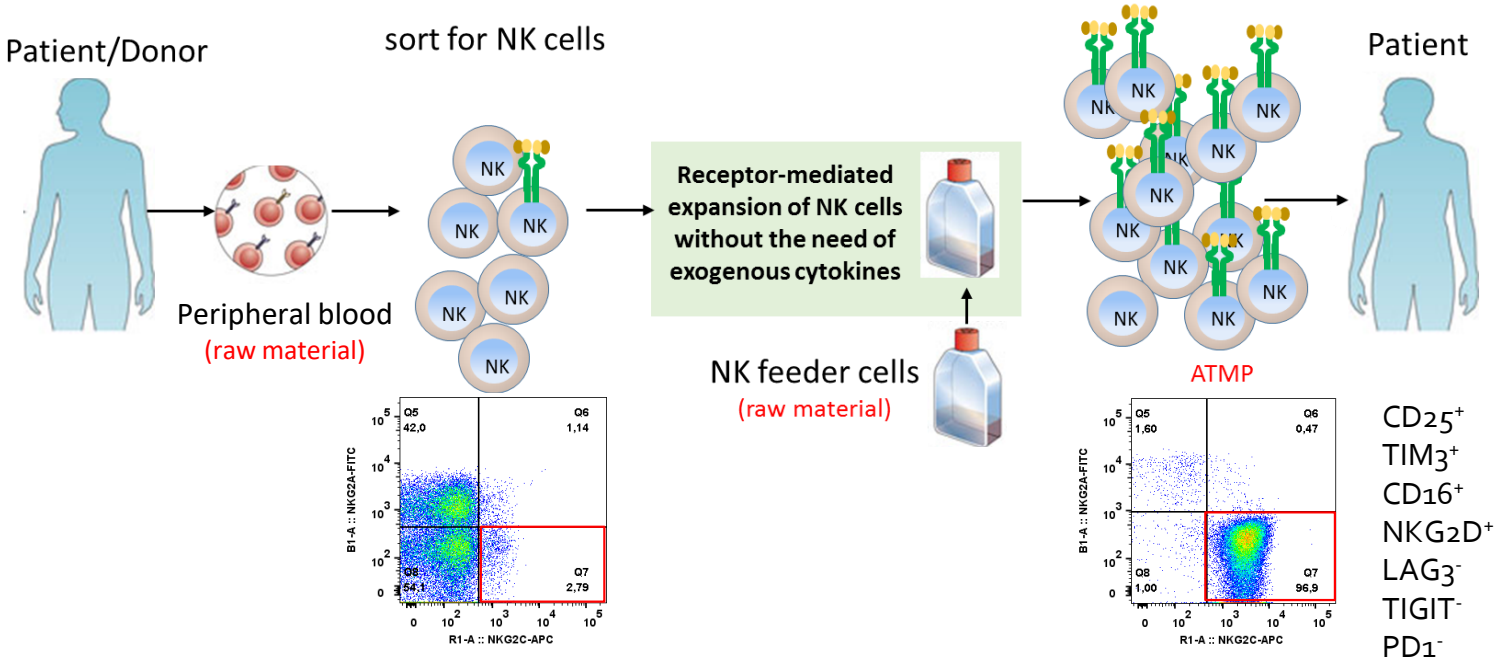
Topic and unique selling point

- Focus on differentiated CD56dim/NKG2C+/KIR+ NK cells
- Combinatorial „induced self" and „modified self" mechanisms of tumor cell killing
- ...in combination with ADCC





CD25+
TIM3+
CD16+
NKG2D+
LAG3-
TIGIT-
PD1-

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Expectations towards SaxoCell - Required links to SaxoCell

- Administrative support
- Support for regulatory issues concernig production of ATMPs and clinical studies
- Providing infrastructure and expertise for GMP
- Implementation of automatic purification protocols, hardware and tools
- Counceling and networking to enable market entry for products

- SaxoCellHub
- SaxoCellClinics

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HemRec:
Reactivating Fetal Globin for ß-Hemoglobinopathies

Prof. Dr. Frank Buchholz / Dr. Duran Sürün (TUD)

Thomas Schäfer / Dr. Philine Bergmann (DKMS)

Universitätsklinikum Carl Gustav Carus

TECHNISCHE UNIVERSITÄT DRESDEN

DKMS Life Science Lab

BIOTEC Biotechnology Center TU Dresden

CRTD Center for Regenerative Therapies TU Dresden

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Vision and core competences

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Universitätsklinikum Carl Gustav Carus

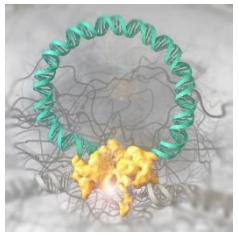
DKMS Life Science Lab

Duran Sürün

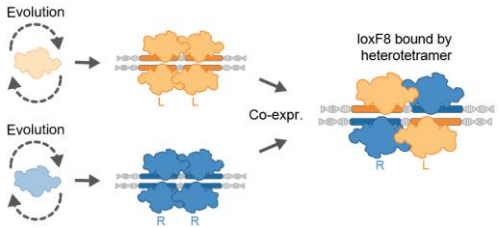
Frank Buchholz

Thomas Schäfer

Philine Bergmann

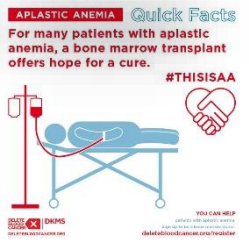


Genome editing



SLiDE of Designer-Recombinases

World's largest HLA genotyping laboratory



Supporting DKMS, the world leading stem cell donor registry

Sickle red blood cell

HemRec

Normal red blood cell

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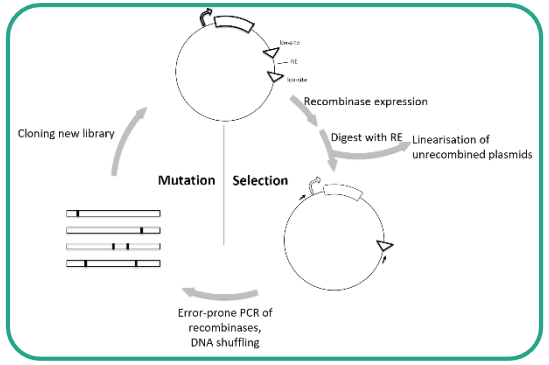
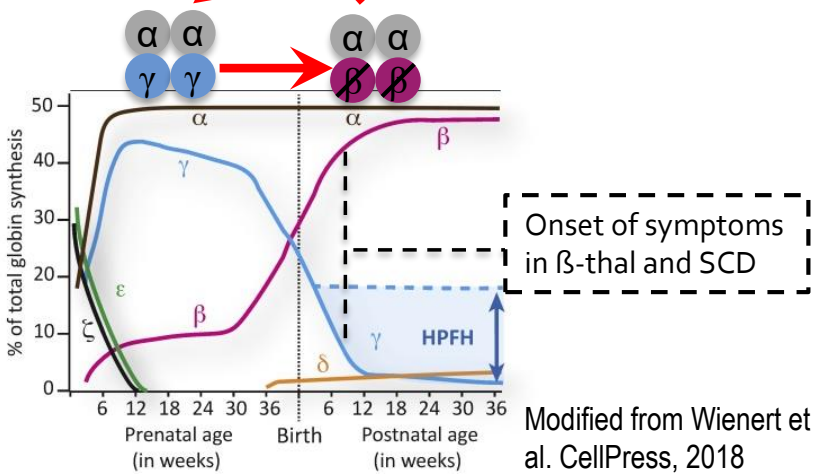
Topic and unique selling point

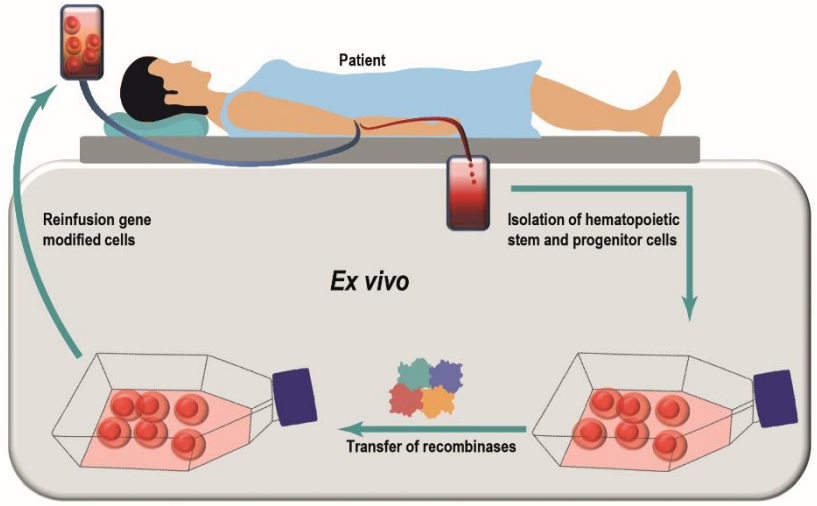


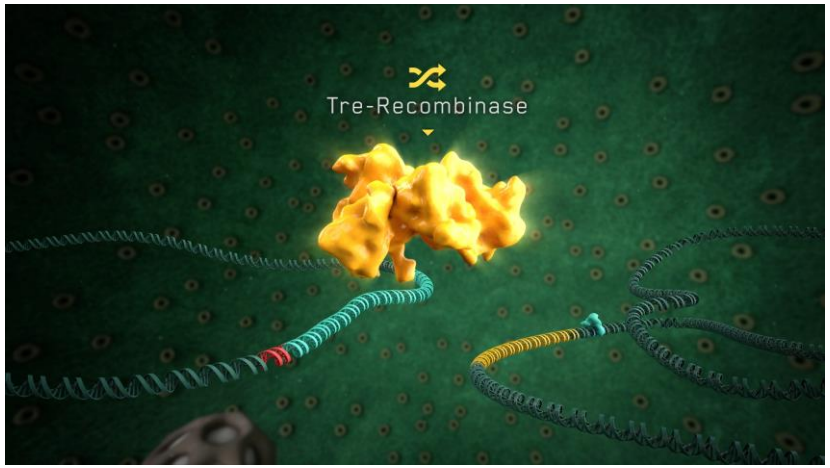
Efficient and Safe



Onset of symptoms in ß-thal and SCD

Modified from Wienert et al. CellPress, 2018





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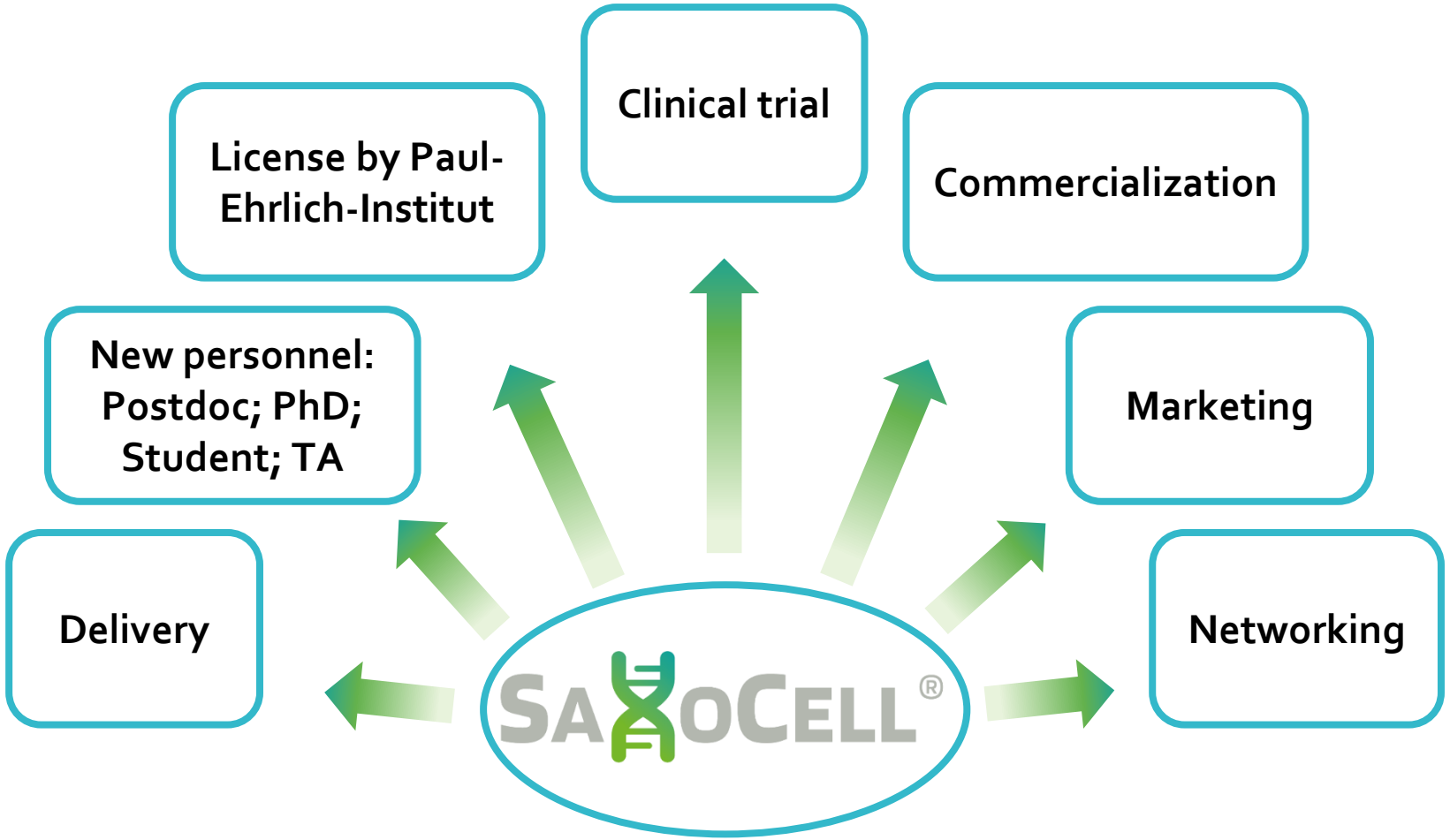
Expectations towards SaxoCell - Required links to SaxoCell



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Innovative cell therapy for enhanced human skin regeneration

- Prof. Dr. Jan C. Simon (University of Leipzig, UKL)
- Dr. Yuval Rinkevich (HelmholtzZentrum Muenchen)

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Vision core competences

- **The vision:** to develop a cellular therapy for hard to heal wounds
- **The problem**: Hard-to-heal wounds represent a huge clinical burden with unmet medical need and with a growing elderly and diabetic population.
- **The solution**: We propose to combine core competencies in wound regeneration (Simon group) and human stromal cells (Rinkevich group), in order to develop an innovative wound dressing that delivers cell-based therapy for enhancing non healing chronic or diabetic wounds.

Zitate JCs and Yuval

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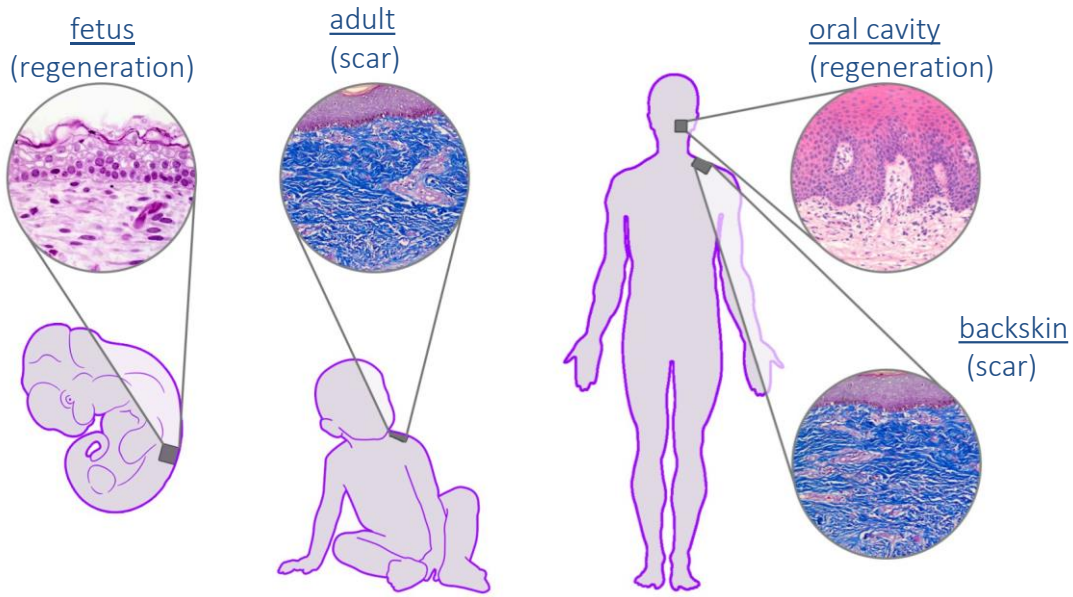
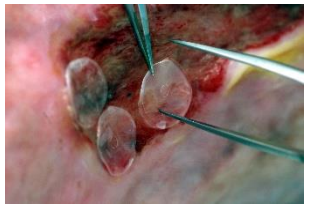
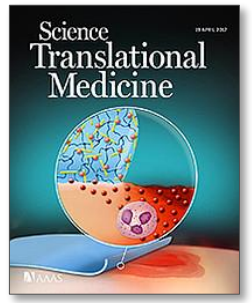
Previous findings and core competences



Cell transplantation



Novel wound dressing



- We have discovered distinct fibroblastic cells that induce tissue regeneration and enhanced wound healing upon cell transplantation.
- Pro-regenerative stromal cells have been discvered in murine skin across anatomic skin locations and across ontogeny
- We were one of the first clinicians to apply transplantion of autologous purified cell populations to patients with chronic, non healing wounds
- We have developed novel immunomodulatory wound dressings that form a protective niche for the transplantation of cells and provide a unique pro-regenerative environment

- Renner et al., Simon Int. Wound J 2009
- Lohmann et al.Simon Science Translational Medicine 2017
- Correa-Gallegos et al Rinkevich, Nature 2019
- Jiang et al. Rinkevich, Nature Cell Biology 2018
- Tsai et al. Rinkevich, Science Translational Medicine 2018
- Jiang et al. Rinkevich, Nature communications 2020

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Topic and unique selling point

- Topic : cellular therapy for hard to heal wounds
- Synopsis: Hard to heal wounds (which include chronic wounds and ulcerations) can be fatal or lead to amputations. Despite the enormous clinical consequences, these wounds are merely 'managed', as there is no cure.
- Our program aims to develop an advanced cell based wound dressing (ATMP) that would be used to cure hard-to-heal wounds in patients.
- USPs include: complementary expertise from cell biologists, stem cell researchers, immunologists, clinicians, GMP-manufacturers, R&D experts, material scientists and engineers will allow a rapid and successful completion of the preclinical phase

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Work programme

Our three specific aims are:

Aim 1: Cellular characterization of human dermal fibroblasts

Aim 2: Transplantation models of purified human fibroblast populations.

Aim 3: To develop a wound dressing inclusive of defined human fibroblasts.

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Expectations towards SaxoCell – Required links to SaxoCell

- Access to Fraunhofer IZI GMP-labs for production of human cellular products.
- Funding requested: Stage 1 initial 3 year funding (preclinical) UKL/IZI/HMZ 544 k€/3 years for personell (2 PostDoc), consumables, animal costs, GMP-lab fees
- Stage 2 after completion of preclinical phase: Proof of concept study together with Industry: approx. 7 Mio €
- Together we shall take advantage of the unique expertise in customization of human cellular products at the GMP facility of Fraunhofer IZI Leipzig, and longstanding collaboration with material scientist from Dresden.

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xMAC

Macophage cellular therapy

Michael Sieweke, CRTD

with Frank Buchholz, UCC

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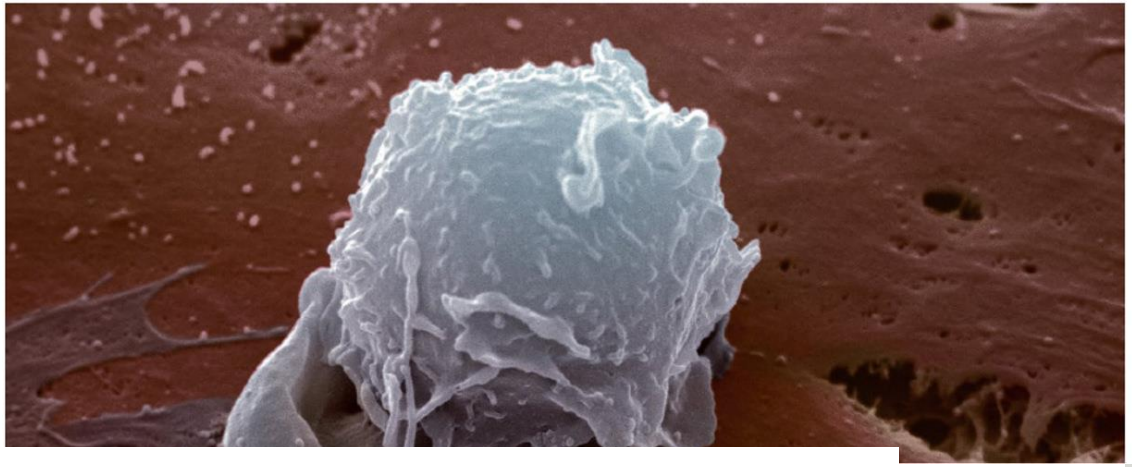
Vision and core competences

Macrophage Cell Therapy: CAR macrophages as just one example

Cancer-eating immune cells kitted out with CARs

Immunotherapy startups look to engineer macrophages to fight solid tumors.

The scientific founders of Carisma Therapeutics, a startup aiming to equip phagocytes with a chimeric antigen receptor (CAR), reported in March that their engineered macrophages could infiltrate solid cancers, ingest malignant cells and stimulate a robust anti-tumor immune response in mice. By the end of the year, Carisma aims to launch first-in-human trials with an autologous CAR-macrophage therapy directed against tumors expressing human epidermal growth factor receptor 2 (HER2).



NATURE BIOTECHNOLOGY | VOL 38 | MAY 2020 | 509–522 | www.nature.com/naturebiotechnology

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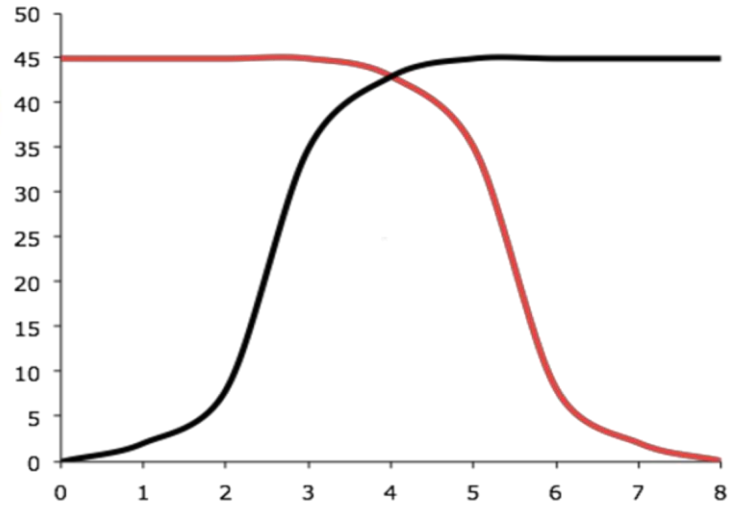
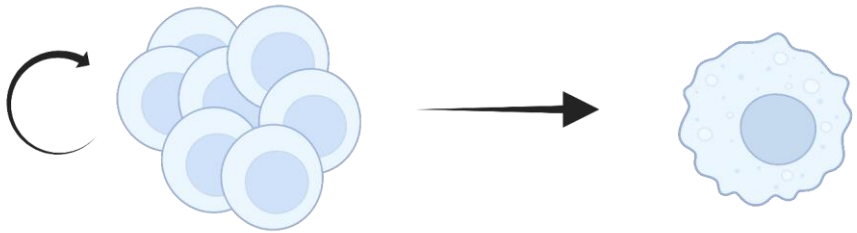
Vision and core competences

Macrophage Cell Therapy: What is the problem?

Weiskopf. Unlike T cells, which undergo massive clonal expansion in laboratory culture, monocyte-derived macrophages do not proliferate ex vivo. "So, what you put in is basically what you get out," he says.

[…monocyte-derived macrophages do not proliferate ex vivo. "So what you put in is basically what you get out"]





Differentiation is associated with cell cycle withdrawal

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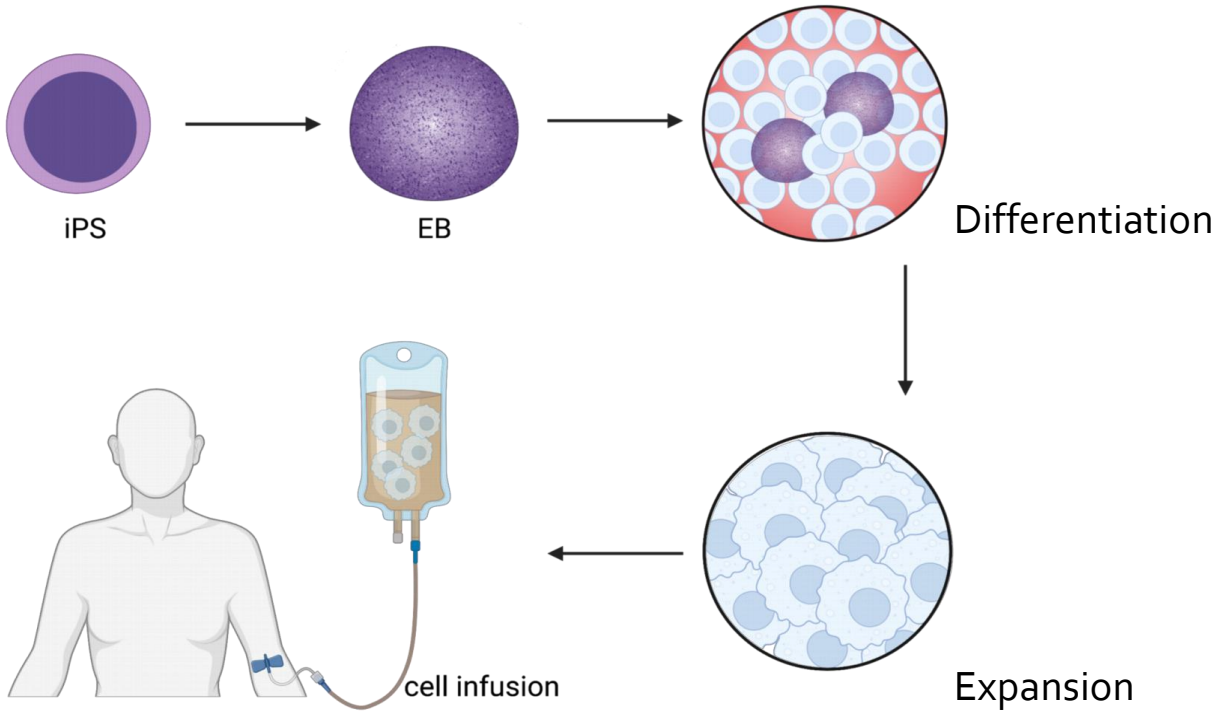
Vision and core competences

Human macrophages from iPS cells



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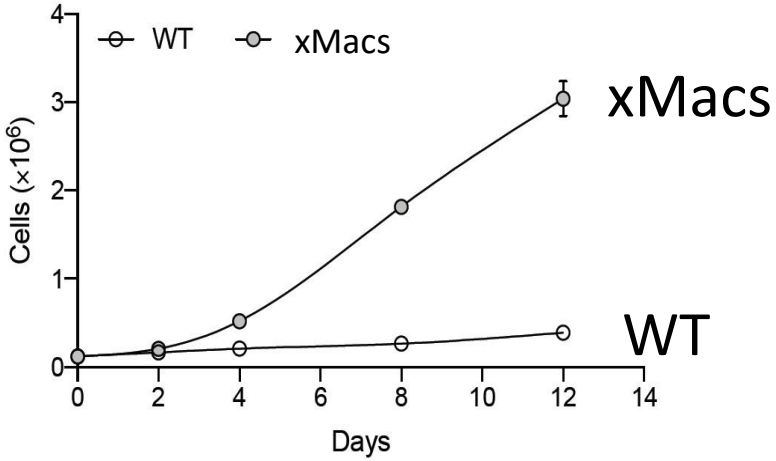
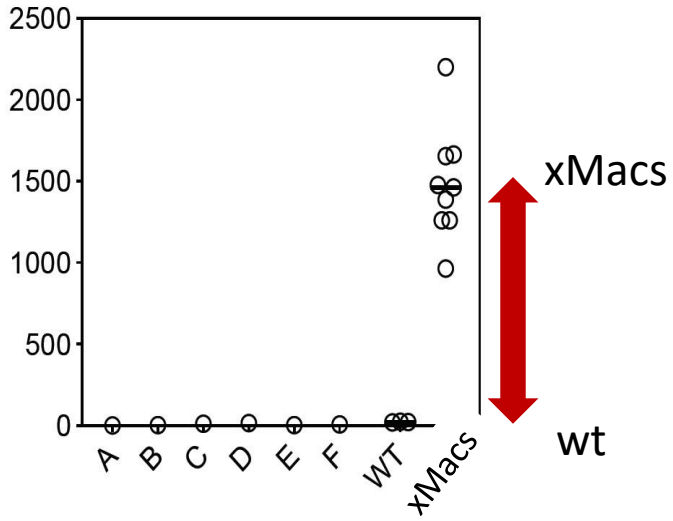
Topic and unique selling point

xMAC
Dissociation of differentiation and cell cycle arrest

Growth curve after differentiation



Yield comparison



A-F: other protocols

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Expectations towards SaxoCell - Required links to SaxoCell

Foster collaboration and translation!

- Solid cancer cell therapy – Martin Bornhäuser
- Allogenic macrophage therapy – Anke Fuchs (GMP), IZI
- Off-the-shelf universal macrophages – Frank Buchholz
- Fixed macrophage activities (M1, M2) – M. Bornhäuser, M. Rüdiger
- Macrophage / NK cell interaction – Thorsten Tonn
- Tailored macrophage banks (haplotypes, activities) - Thorsten Tonn

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Break

Please choose your break out room:

- meet member of area 2
- meet member of area 3
- at the coffee room (small talk)
- quiet break (no interaction)

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SaxoCellOmics

Ezio Bonifacio (CRTD, Dresden); Kristin Reiche (Uni Leipzig, Leipzig)

Scads.AI, ecSeq Bioinformatics Gmbh, Fraunhofer IZI

ScaDS.AI DRESDEN LEIPZIG

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ECSEQ BIOINFORMATICS

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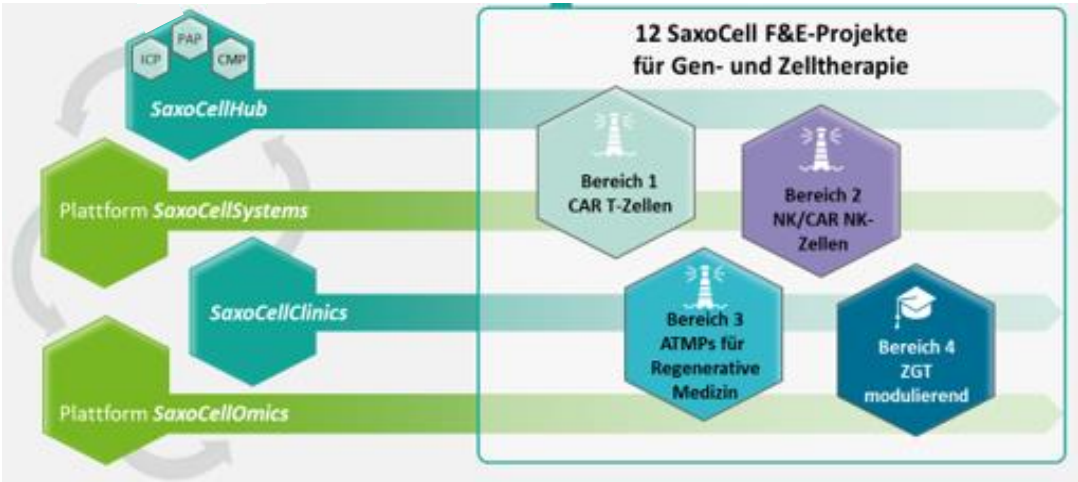
SaxoCellOmics

Through SaxoCellOmics, SaxoCell projects receive access to:

- advanced **diagnostics,** medical **bioinformatics** and **data science** tailored to the needs of the project
- efficient and harmonized processes for **diagnostics, patient stratification, monitoring, companion diagnostic**
- **existing value chain in Saxony** for the development of biomarkers
- evaluation of gene and cell therapies by utilizing standardized **high-dimensional and high-throughput measurements**



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SaxoCellOmics

Vision

SaxoCellOmics as platform for investigator-& project-tailored high-dimensional measurements and analyses that will:

- Understand mechanisms of action & resistance
- Identify novel targets
- Increase competitiveness in gene and cell therapies, biomarkers, bioanalytical tools, methods and technology

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SaxoCellOmics

Core competencies

- State-of-the-art NGS services[1] (single-cell MultiOmics, varied short- and long-read sequencing, spatial transcriptomics)
- Adaptive Immune Receptor Repertoire community partner
- Comprehensive range of cell flow and cytometry capacity
- Highest quality lipidomic and metabolic profiling
- Integrated tools for bioinformatic and AI data analyses
- Tailored bioinformatics courses & service

[1]DRESDEN-concept Genome Center (DFG NGS Competence Center); Biomarker Center Fraunhofer IZI

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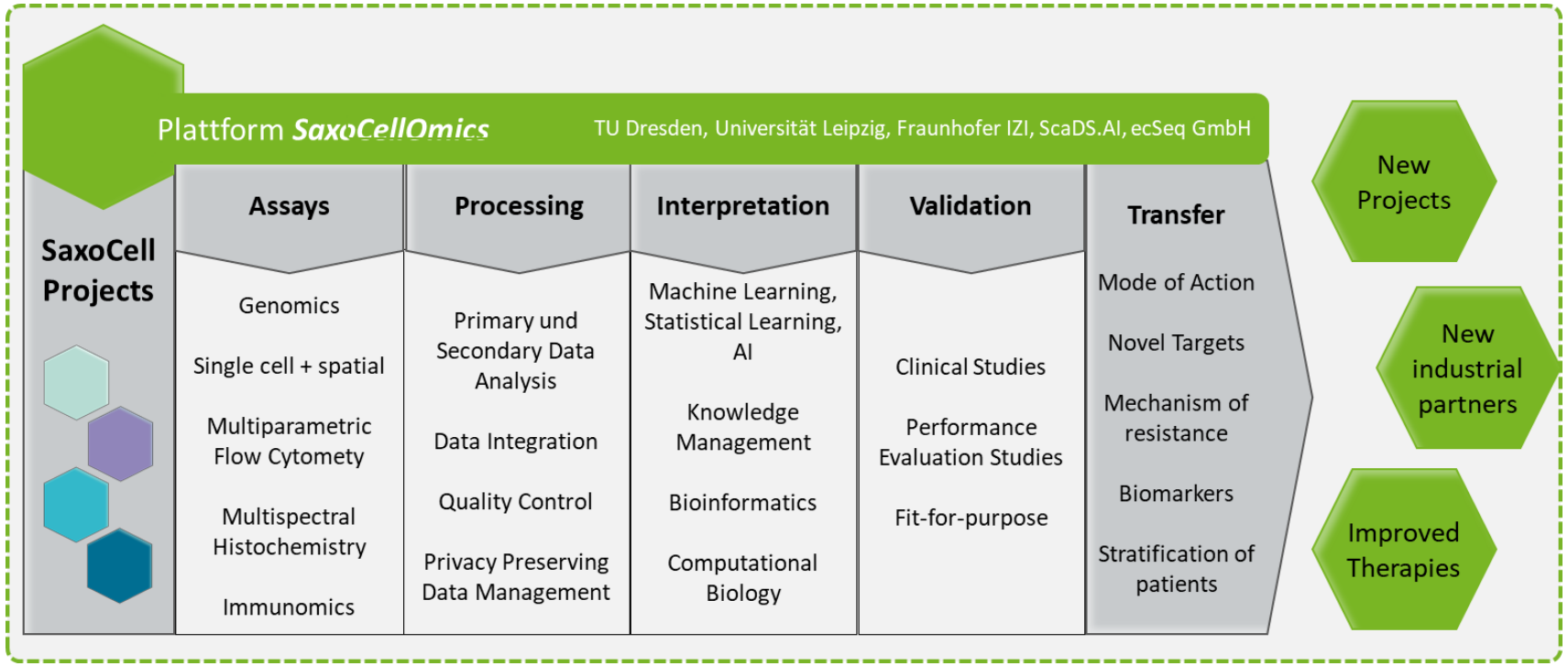
SaxoCellOmics

Role and interaction within SaxoCell



- Crosstalk with SaxoCell Clinics & SaxoCellBio biobank
- Accompanying Clinical SaxoCell projects (e.g. ECP-CAR, UltraCAR-T, MSC-PreSTiGe), cell and product characterization

SaxoCellOmics

The Team

SaxoCell®

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Ezio Bonifacio,
Juliana Gusson Roscito

UNIVERSITÄT LEIPZIG


Kristin Reiche,
Alexander Scholz

Fraunhofer IZI


Conny Blumert,
Ulrike Weirauch

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Christian Martin,
Jan Ewald

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David Langenberger,
Mario Fasold

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Aufbau von KI-gesteuerten Technologien zur Unterstützung von automatisierten ATMP- Herstellungsprozessen Made in Sachsen (SaxoCellSystems)

PI: PD Dr. Fricke (Fraunhofer IZI) & Dr. Blache (Fraunhofer IZI)

Partner: Prof. Dr. Rüdiger & Dr. Freund (TU Dresden); Prof. Dr. Neumuth, Prof. Dr. Henschler, Prof. Dr. Rahm, Prof. Dr. Pompe & Dr. Jahnke (Universität Leipzig)

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Vision and core competences

Vision: Towards automated manufacturing of ATMPs

Core competences:
- Biomanufacturing
- GMP process development & training
- Artificial intelligence
- Data science & management
- Smart sensor systems

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Topic and unique selling point

Goal

Building an automation platform for the intelligent manufacturing of ATMPs (from the SaxoCell Cluster and beyond)

Approach

- Concepts and protocols for automated ATMP manufacturing
- Development of next-generation quality controls
- Intelligent quality management and process control via artificial intelligence (AI) methods
- Good Manufacturing Practice (GMP) compatibility
- GMP training courses for personnel in the field of ATMP and automation

USP

Uniquely suited consortium of biologist, physicians, engineers and data scientists with relevant qualifications

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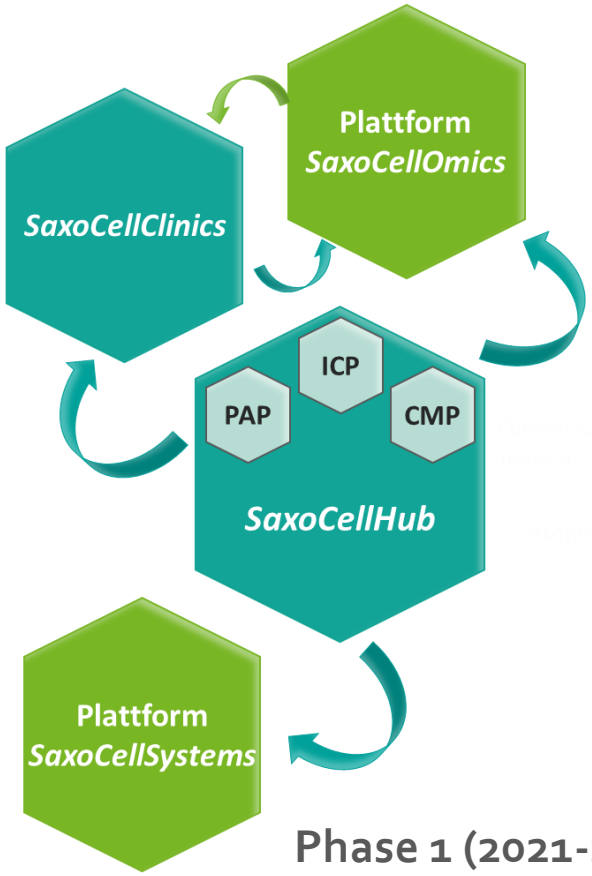
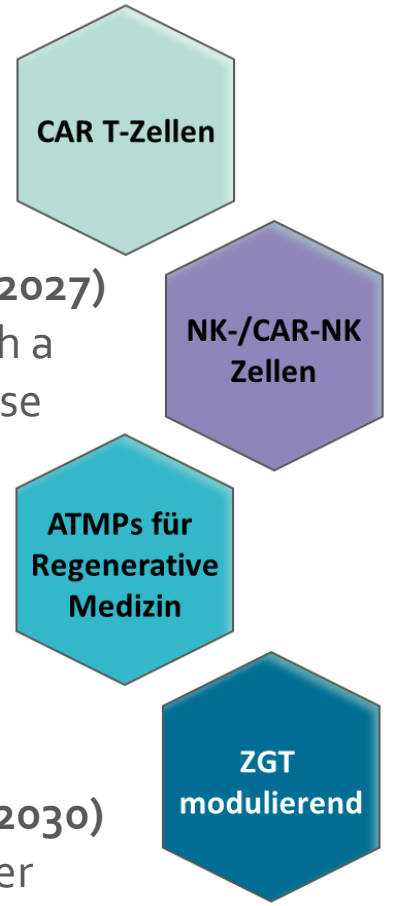
Expectations towards SaxoCell - Required links to SaxoCell



Phase 1 (2021-2024)
SaxoCellSystems platform concept

Phase 2 (2024-2027)
Application with a SaxoCell Usecase

Phase 3 (2027-2030)
Transfer to other SaxoCell ATMPs



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SAXOCELLCLINICS

YOUR CONTACT PARTNER FOR CLINICAL TRIALS

Prof. Dr. med. Uwe Platzbecker (ULE)

Prof. Dr. med. Martin Bornhäuser (UKD)

PD Dr. med. Mathias Hänel (KC)

Coordination: Lysann Tietze, Nicole Schütz

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Vision and core competences

SAXOCELLCLINICS

- clinical contact for project partners
- provider of resources and services to support innovative research projects with direct clinical relevance
- communicator between research institutes, authorities (e.g. PEI, country directorate, ethics committees) and industry
- cooperation with other partners and platforms
  - **SaxoCellHub**, **SaxoCellOmics** and **SaxoCellSystems**

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Topic and unique selling point

SAXOCELLCLINICS

- establishment of a central coordinating structure for clinical and regulatory aspects
- optimization of the translation of phase 1-3 clinical studies
- advice and network building with all partners and platforms
- development of a registry and harmonization of biobanking

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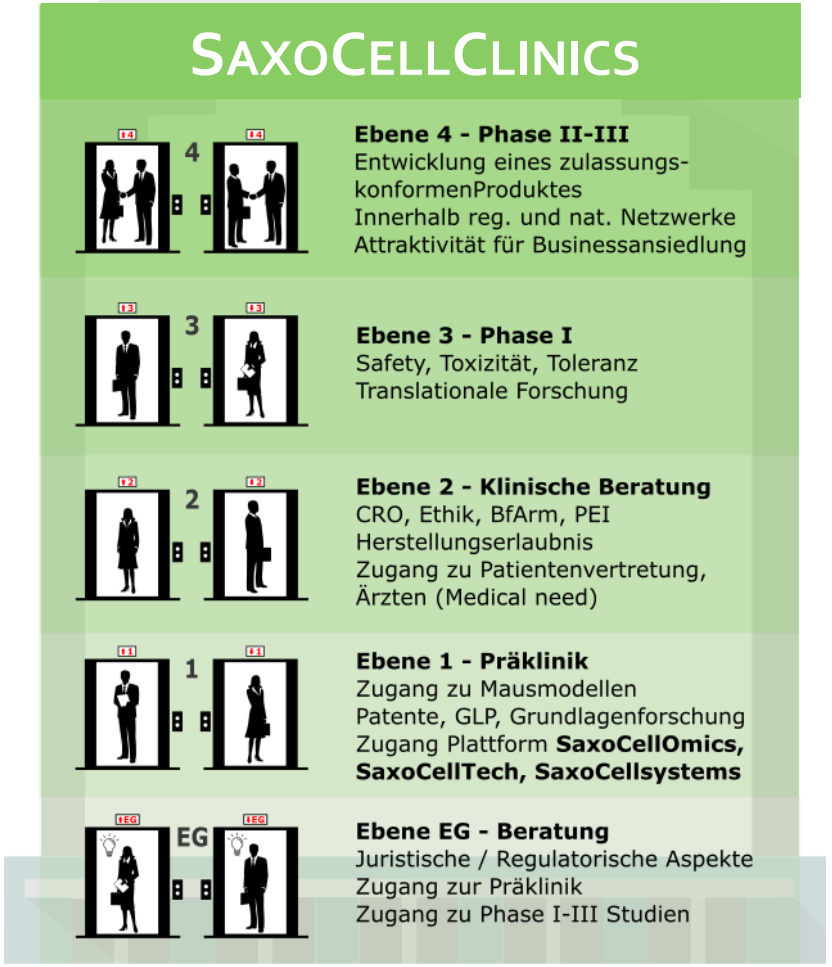
Expectations towards SaxoCell - Required links to SaxoCell



- ECP-CAR
- CAR-NK4.0
- SHIMMER Registry
- OPTIX
- TheraStar
- HemRec
- MSC-Prestige
- UltraCART

- SaxoCellHub
- SaxoCellOmics
- SaxoCellSystems

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Innovation Hub

PIs: Dipl-Kffr Dorit Teichmann (TUD), Dr. Thomas Tradler, MBA (FhG IZI)

Partner: University of Leipzig

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Introduction

Vision and core competences

- **SaxoCell** will establish an innovative R&D- and industry cluster in the field of cell- and gene-therapy in Saxony with a focus on local value creation
- **SaxoCell's Innovation Hub** is our interdisciplinary approach to support cluster development and R&D activites, having a particular focus on fostering an innovation-friendly cluster culture
- The Hub is organized and managed in **three programs** that are in close exchange and interaction:
  - **PAP - Pipeline Acceleration Program** → Project management
  - **ICP - Innovation Culture Program** → PR, transfer, marketing
  - **CMP - Cluster Matching Program** → Strategy development

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PAP

Pipeline Acceleration Program

- **Project management** to ensure realization of a focused development approach and optimal support for all development activities
- **Dedicated project manager** for each project
  - Dresden projects – at the start Dorit Teichmann; recruitment of further resources currently ongoing
  - Leipzig projects – Ilka Henze, Anette Bartsch
- Identification of open needs within the projects (additional expertise, instruments, further specific support) → **Support to address gaps**
- **Preparation of projects for next step in value creation chain**, close interaction with the other programs within the Hub

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CMP

Cluster Matching Program

- Jointly conducted by PAP and ICP
- **Strategy development** for further cluster development
- Scouting for **new R&D projects**
- Development of **joint R&D infrastructures**

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ICP

Innovation Culture Program

- High visibility
- Innovation culture
- Efficient transfer
- Optimal R&D support
- Broad expertise distribution

- **Press and public affairs, internal & external communication** → Press releases, social media, web presence, SaxoCell newsletter (*1st edition coming soon*), annual report etc.
- **Cluster & location marketing** → Active participation at relevant conferences, participation in ARM/ISCT activities, internationalization
  - Saxony as a „place to be" for cell- and gene therapy innovators
- **Transfer & BD** → Global marketing support for SaxoCell R&D results and relevant partner technologies spin-off support, VC network
- **Market intelligence** → Market surveys and strategy development
- **Contract and patent management support** → In close collaboration with structures at the partners
- **SaxoCell events, training and further education** → Establishment and conduct of several event series
- **Stakeholder management** → Maintaining and expanding close ties

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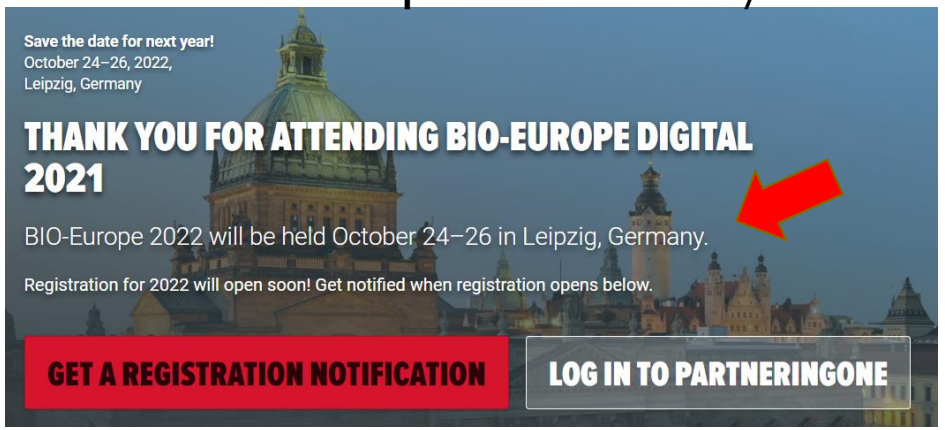
ICP

Innovation Culture Program

Activity area examples

BIO Europe 2022 in Saxony!



DG-GT
Deutsche Gesellschaft für Gentherapie e.V.

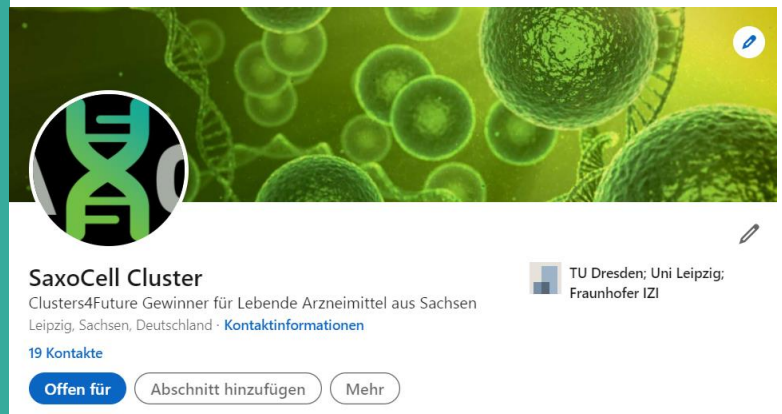
International Society ISCT Cell & Gene Therapy®

Alliance for Regenerative Medicine

LinkedIn presence – we`ll be happy to have you joining!

Instagram

Deutsche Biotechnologietage



Web presence (www.saxocell.de)

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SaxoCell HUB

Expectations towards SaxoCell - Required links to SaxoCell

- We are SaxoCell`s central communication, knowledge distribution, R&D support and transfer hub
- We are looking forward to:
  - Efficient and transparent communication
  - Close interaction with the scientists, regular exchange and bilateral support
  - New ways for knowledge and expertise distribution
  - Realization of SaxoCell as a truly Saxony-wide endavour

We are happy to start a close collaboration with all people, groups, institutions and partners in our cluster!

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Chatterfall

Please complete this sentence in your chat window, but wait for the start signal to press enter:

- What was new for me was …

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Chatterfall

What was new for me was …

… the diversity and excellence of cell-based therapies covered by SaxoCell

…the people and projects in Leipzig. Would have loved to get to know you all in person

…so many potential synergies between projects

…the different types of SaxoCell projects and how they are connected

…the huge amount and high Level of projects involved in SaxoCell

…great focus on GvHD topic

…the diversity of the projects and the possiblities for networking

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Break out sessions

- Break out sessions should be a first start of exchange
- regular meeting should be organized In the next 3 years
- What should be done in the break out sessions is to address:

(1) exchange project topics

(2) what are the expectations from SaxoCell?

(3) what are the contributions of the projects/area?

(4) what is missing/needs?

(5) identify a speaker for today's summary and future representation

(6) organizational things (eg meetings, communication with Hub)

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Break out sessions

Project Title	Partner / Contacts
AlloCART	TUD: M. Bornhäuser, A. Fuchs, F. Buchholz
ROR1CAR-T	IZI: M. Hudecek, U. Köhl, T-Curx: C. Söllner

Project Title	Partner / Contacts
CAR-NK4.0	IZI: U. Köhl, S. Fricke; UL: U. Platzbecker, U. Hacker; KC: M. Hänel; Affimed: J. Koch; Miltenyi: N. Möker
CAReNK-AID	TUD: T. Tonn, A. Temme, R. Bornstein; CRTD: Bonifacio; UL: A. Aigner
NK4Therapy	TUD: T. Tonn, A. Temme, M. Bornhäuser; Cell.Copedia GmbH :H. Stadler

Project Title	Partner / Contacts
HemRec	TUD: F. Buchholz; DKMS: T. Schäfer, V. Lange
ZellTWund	UL: C. Simon; Y. Rinkevich
xMAC	TUD: M. Sieweke; F. Buchholz
MSC-PRESTIGE	TUD: M. Rüdiger, MDTB: T. Hammer; DKMS A. Platz

Project Title	Partner / Contacts
OPTIX	Tcell: L. Stahl; IZI: S. Fricke; UL: U. Platzbecker; KC: M. Hänel; TUD: M. Bornhäuser
ECP-CAR	UL: V. Vucinic; U. Platzbecker; Therakos: C. Hirt
TheraStar	HZDR: A. Feldmann; M. Bachmann; TUD: M. Schmitz

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Break out sessions: Area 1 CAR T Cells

Area 1: CAR T Cells

Our key aspects - Required links to other areas and SaxoCell

- think about other diseases beside cancer as further steps
- acceptance from regulatory authorities?
- close contact to patients and patient organization
- workshops and meetings
- promote clinical development of CAR-T (make it cheaper, better) as those that are on the market now
- Support from SaxoCellClinics for establishing first clinical studies
- learning from other projects on cell manufacturing processes as early

Expectations towards SaxoCell

- learn from each other
- regulatory aspects were similar across the areas
- important question how can we protect the technologies
- CRISPR Technology from regulatory perspective can give guidance
- Contact to T2EVOLVE IMI project

Organisational (meetings: rate, format; speaker) ...

- think tank meeting
- also important exchange with the platforms
- Anke Fuchs and Michael Hudecek

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Break out sessions: Area 2 NK-CAR-NK Cells

Area 2: NK-CAR-NK Cells

Our key aspects - Required links to other areas and SaxoCell

- NK cells for AID + cancer
- multiple application in cancer
- good preclinical models for NK cells are pitfall
- different in vivo models tumor tissue bank (PDX or fresh)
- best strategy to develop the best NK product
- no comments yet from industry
- consider different delivery technologies
- ethical permission still available

Expectations towards SaxoCell

- proactively reach out to AID industry (use visibility from Saxocell)
- be prepared for next wave from pharma - closely monitor activities
- collect different manufacturing protocols
- reach out to and align with patients
- cost considerations early on in projects
- more networking with Clinics
- enlarge perspectives beyond SaxoCell (SaxoCell is not a nutshell)
- organisation of interproject talks and exchange

Organisational (meetings: rate, format; speaker) ...

- Speaker: Achim Temme
- Meeting every 8 weeks
- Reach out to xmac
- connect via cloud

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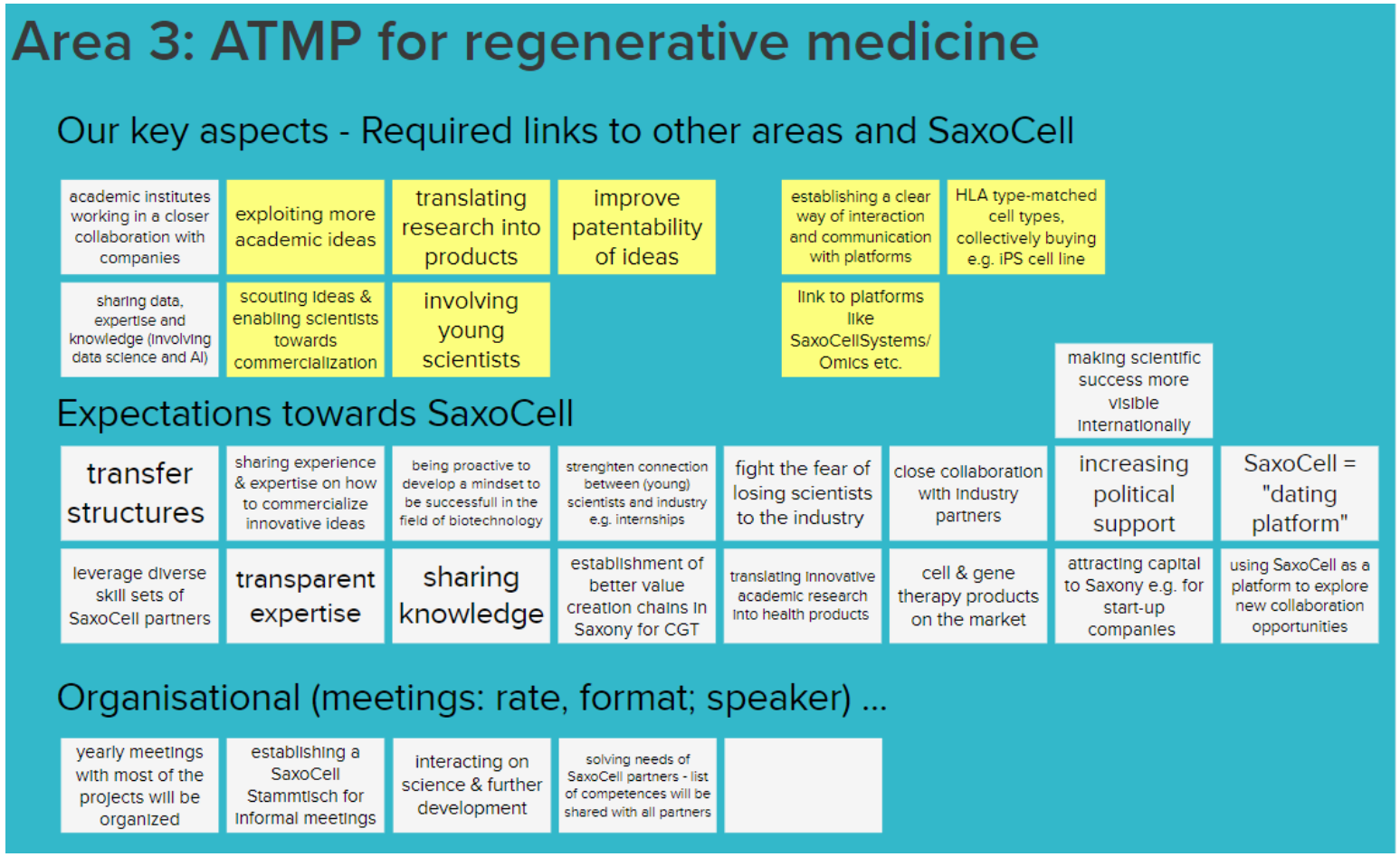
Break out sessions: Area 3 ATMPs for regenerative medicine



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Break out sessions: Area 4 ZGT-modulating

Area 4: ZGT-modulating

Speaker: Stephan Fricke

Our key aspects - Required links to other areas and SaxoCell

- stabilise our projects
- clinics is most important aspect

- decide on certain processes and products, instead of trying too many different things (focus!)

- interim evaluation necessary

- bioinformatics, remodulation

- it's great that such a structure exists - very much appreciated

Expectations towards SaxoCell

- improve communication within our cluster
- be open, there must be a benefit for project participants

- management of clinical protocols / using existing resources

- interact with industry (spin-off? new partners?)

- establish synergies, learn from one another

- transnational continuation

- flex funds, mobility grants for players worldwide (to and from)

Organisational (meetings: rate, format; speaker) ...

- regular meetings wanted, every 3 months

- some presentations did not state exactly what partners are doing (non-disclosure reasons) -> we should be open to one another

- project mgmt tools, milestones and deliverables, do's and don'ts

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Closing

- Summary of the day
- Forecast (meeting in this constellation every year

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wishes

Internship program of interest as well for the economic partners

Mobility grant for exchange

Internal area with capacity board of partners, „dating platform"

Cluster Wiki

Think tank meetings

Informal meetings

Inter-project talks

Regulatory, ethical aspects, exchange of protocols

Include more industry – it is not a SFB

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Thank‘s

- For your participation
- Your talk
- The discussions

- Please give us feedback at the poll

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end

Please stay and join us at wonder.me

https://www.wonder.me/r?id=4c6e1299-5c37-4de6-aecb-df83e0837d3b

Please use Explorer or Chrome

Leave zoom session or mute your selves and take your camera off in zoom

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Scientific Advisory Board

- Please use the chance for some minutes of exchange with speaker in the break out room

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