SAXOCELL®

LIVING DRUGS

Saxonian Precision Therapy Cluster

Annual Report 2023/24

Contents

The year 2023/24

SaxoCell recorded several significant successes and milestones during the period from 2023 to 2024, marking a year of dynamic growth and innovation for the cluster. We want to start with the founding of SaxoCell e.V. in September 2023 by 13 founding members in Leipzig. The association will help us to bind interested industry partners and stakeholders and contribute to the cluster's sustainability. Then, one of the key highlights in early 2024 was the submission of the cluster's **application** to BMBF for the **second funding period.** This proposal included a comprehensive restructuring of ongoing projects and a sharpened focus on the cluster's profile, aimed at optimizing its future direction and increasing overall efficiency. In May 2024, SaxoCell underwent an extensive **review by an external panel of experts** at the CRTD in Dresden, a crucial step in assessing the project's progress and laying the foundation for future developments.

Another major milestone was achieved on July 2, 2024, when the **defense of the strategy of the second phase** took place at the BMBF in Berlin. This positive evaluation paved the way for SaxoCell to secure its second funding phase, ensuring an additional three years of support from the BMBF starting at the end of 2024.

In parallel with these core developments, SaxoCell hosted a range of key events that fostered collaboration, public engagement, and scientific excellence. In June 2024, our consortium meeting in Chemnitz was complemented by an SAB meeting, providing a platform for in-depth discussions on project progress and future strategies. Building on this, September 2024 saw the **Cross-cluster meeting with PROXIDRUGS**, a Cluster4Future from Frankfurt, further strengthening the bonds between SaxoCell and other innovative clusters.

SaxoCell also focused on expanding its public outreach and stakeholder engagement. The **SaxoCell Investors Club** brought together key players from industry and finance to explore investment opportunities in cell and gene therapies. **SaxoCell meets Politics** fostered dialogue between our researchers and political representatives, helping to shape the future

regulatory and funding landscape. In parallel, further SaxoCell workshops and trainings provided a platform for technical discussions, while a series of popular science lectures on cell and gene therapy aimed to make these cutting-edge technologies accessible to the wider public. We also focused on engaging the next generation of scientists and raising awareness of career opportunities in biotechnology. Our **Patient Day** offered a unique opportunity for patients to learn more about the latest advances in cell and gene therapies, while the **Student Information Day** aimed to inspire young minds and offer insights into the educational pathways leading to careers in science and innovation.

On the scientific front, SaxoCell's presence in the academic world continued to grow, with countless **publications** in renowned journals and numerous new **patent applications** reflecting the cutting-edge research taking place within the cluster. Our researchers were also recognized with prestigious **awards** for their groundbreaking work, further solidifying our reputation as a leader in the field.

Additional funding sources were secured through newly acquired grants, enabling us to expand the scope of our research projects. Furthermore, the SaxoCell ecosystem continues to thrive with two **new industrial settlements** and three **spin-offs**, underscoring our success in translating academic research into real-world applications.

Finally, SaxoCell was proud to participate in **SPIN2030 events** and the **COSMO Science Festival**, where we showcased our innovations and connected with a broader audience, emphasizing the societal impact of our work.

SaxoCell's journey over the past year has been one of remarkable progress and achievement, positioning the cluster at the forefront of biotechnology in Germany and beyond. We look forward to continuing this momentum as we enter the second funding phase and build on our successes to create a lasting impact on the future of cell and gene therapy.

Saxocell speakers

Ulrike Köhl - Speaker

Director of Fraunhofer Institute for Cell Therapy and Immunology Leipzig; Head of Clinical Immunology at the University of Leipzig

Ezio Bonifacio - Speaker

Professor for Preclinical Stem Cell Therapy & Diabetes at the Center for Regenerative Therapies Dresden, TUD Dresden University of Technology

Uwe Platzbecker - Co-speaker

Director of the Clinic and Polyclinic for Hematology, Cell Therapy and Hemostaseology, Leipzig University Hospital

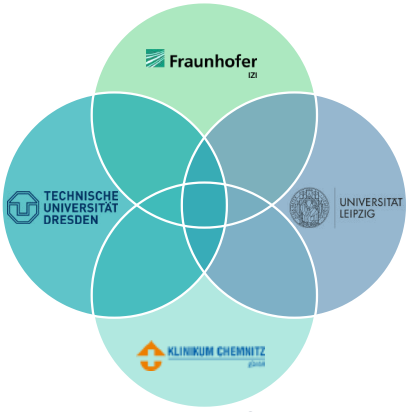
Martin Bornhäuser - Co-speaker

Director of the Medical Clinic I, University Hospital Carl Gustav Carus Dresden

SaxoCell in portrait

SaxoCell - the Saxon precision therapy cluster aims to provide effective, safe and affordable autologous and allogeneic cell and gene therapies to patients suffering from difficult-to-treat diseases.

Our **core partners** are the TUD Dresden University of Techno-logy, the University of Leipzig, the Fraunhofer Institute for Cell Therapy and Immunology and the Chemnitz Hospital. In addition, eight **industrial partners** are already working closely with SaxoCell.



Core institutions of SaxoCell

SaxoCell's core competencies

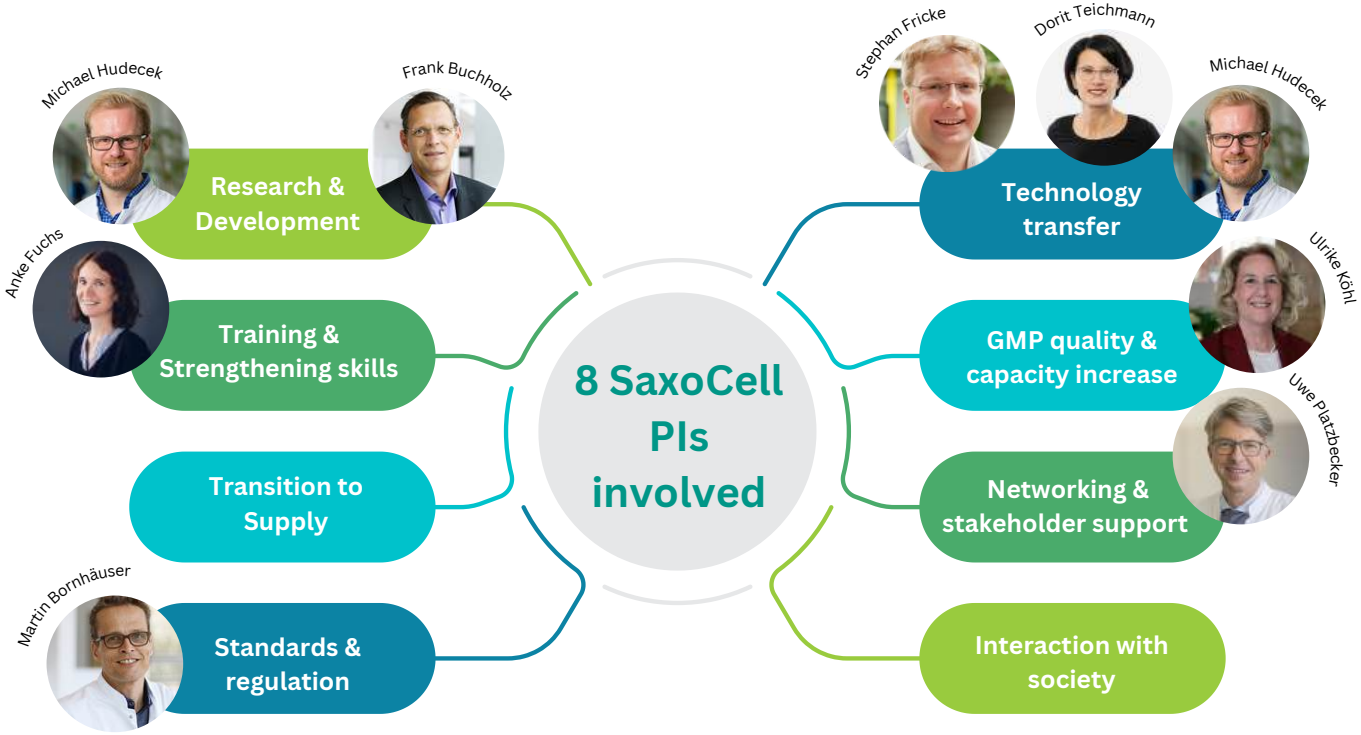
SaxoCell is one of seven winners of the **Clusters4Future initiative of the BMBF** and is funded with EUR 15 million for the first implementation phase 2021 - 2024.

With its 12 innovative research projects on **CAR-T** and **NK** cell therapies as well as gene therapies based on **designer recombinases**, SaxoCell offers a broad spectrum of therapies that are tailored to the needs of patients.

National Strategy

for gene and cell-based therapies

On June 12, 2024, the national strategy for gene- and cell-based therapies was presented to the **BMBF**. Around 150 experts from various interest groups contributed to this eight-point paper in order to develop a plan to improve healthcare and strengthen Germany in the field of gene- and cell-based therapies. As a Germany-wide pioneer cluster in this field, SaxoCell has also contributed its experience and played a key role in shaping this process through the **participation of eight of our PIs**. The National Strategy incorporates perspectives from science, industry, politics, society and patients to define concrete goals and measures in eight fields of action.



Vision and objectives

SaxoCell will continue to substantially improve **regional networking in Saxony** in the field of cell and gene therapy, integrate further partners and initiatives nationwide - and close corresponding gaps in the **value chains**. In this way, **synergy potentials** are to be raised and realized.

Long term goals


Development of new ATMPs & expansion of their existing areas of application


Increasing tolerability and efficacy of new ATMPs


Efficient production of ATMPs through automation


Optimal environment for the development of the CGT industry in Saxony


Strengthening regional technology transfer through investments & settlements

In addition, the cluster will massively increase the **visibility** of the activities of Saxonian and nationwide partners in the field of cell and gene therapy - both at the level of research and with regard to the R&D activities of industrial partners. In this way, access to funding for the players is to be facilitated and expanded, and structures are to be created to **accelerate clinical translation** (network of clinical players and cooperation with regulatory authorities).

Through these and other activities, SaxoCell will significantly increase the attractiveness for investments of national and international companies in the industry and contribute significantly to the development and further strengthening of an innovative cell and gene therapy industry in Saxony and Germany.

A look into the future

5 years

Establishment of the brand SaxoCell®

New jobs, specialist staff and GMP training center

Accelerated translation of ATMPs & designer recombinases for approval

10 years

Global visibility with new spin-offs and relocations

Healing of other diseases

Adaptable technologies for personalized medicine (in vivo & ex vivo therapies - Industry 4.0)

Full automation

ATMP study phase III/IV

20 years

Universally applicable genome surgery and “off the shelf” therapies

Cost-effective cure for many diseases

SaxoCell as a new leading industry in Saxony and Europe

ATMP network

Increased quality of life

DHL Hub Halle/Leipzig

Why cell & gene therapy

Today
Treatment of diseases

Precision medicine

Tomorrow
Cure of diseases

Chemical substances
Regular intake
Relief of symptoms

Immunotherapies
Cell and gene therapies (CGT)

One-off treatment
Elimination of the cause
Long-lasting effect

SAXOCELL®

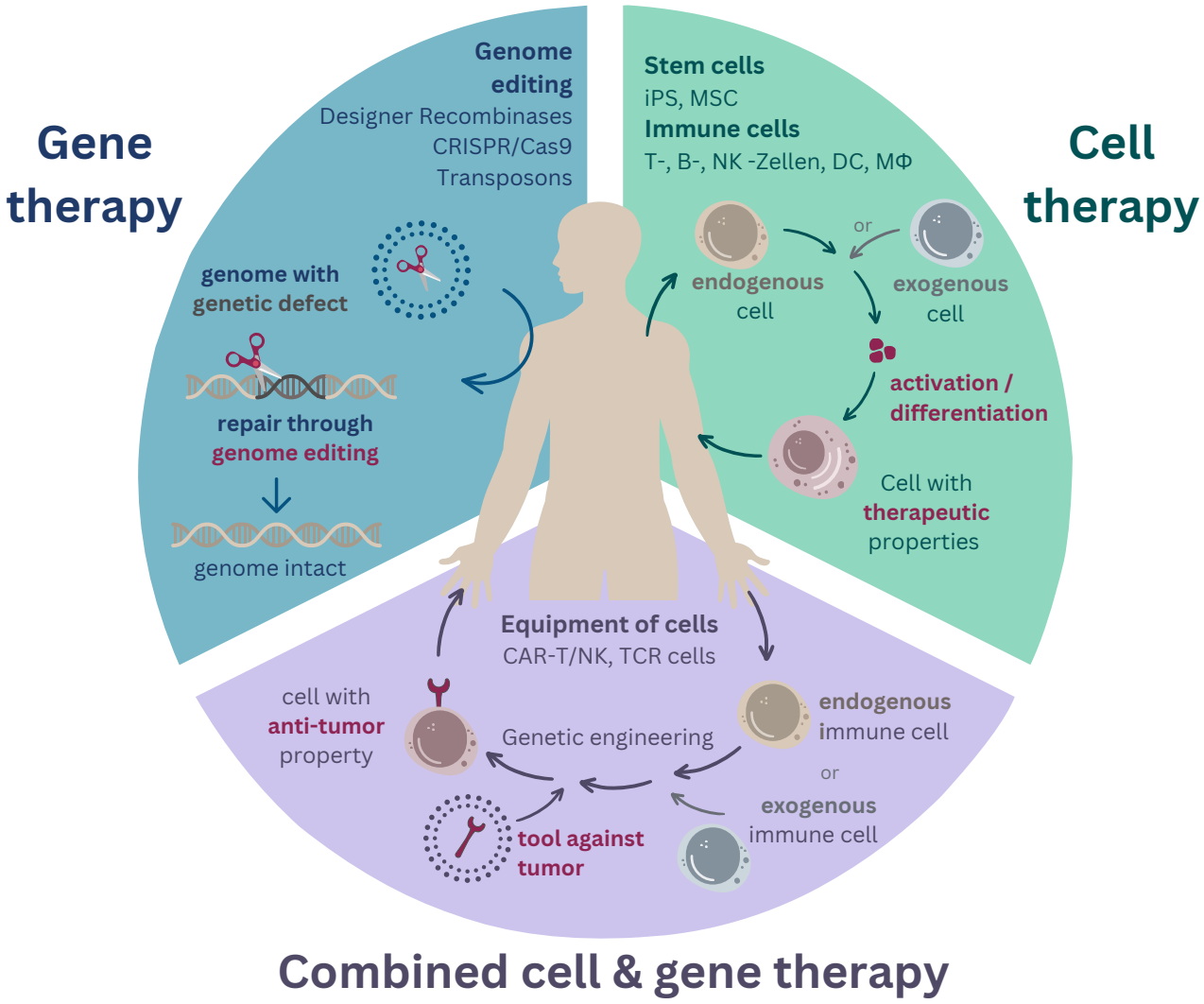
Mission and vision

Affordable & safe treatment
of patients suffering from untreatable diseases with cell & gene therapeutics

LIVING DRUGS

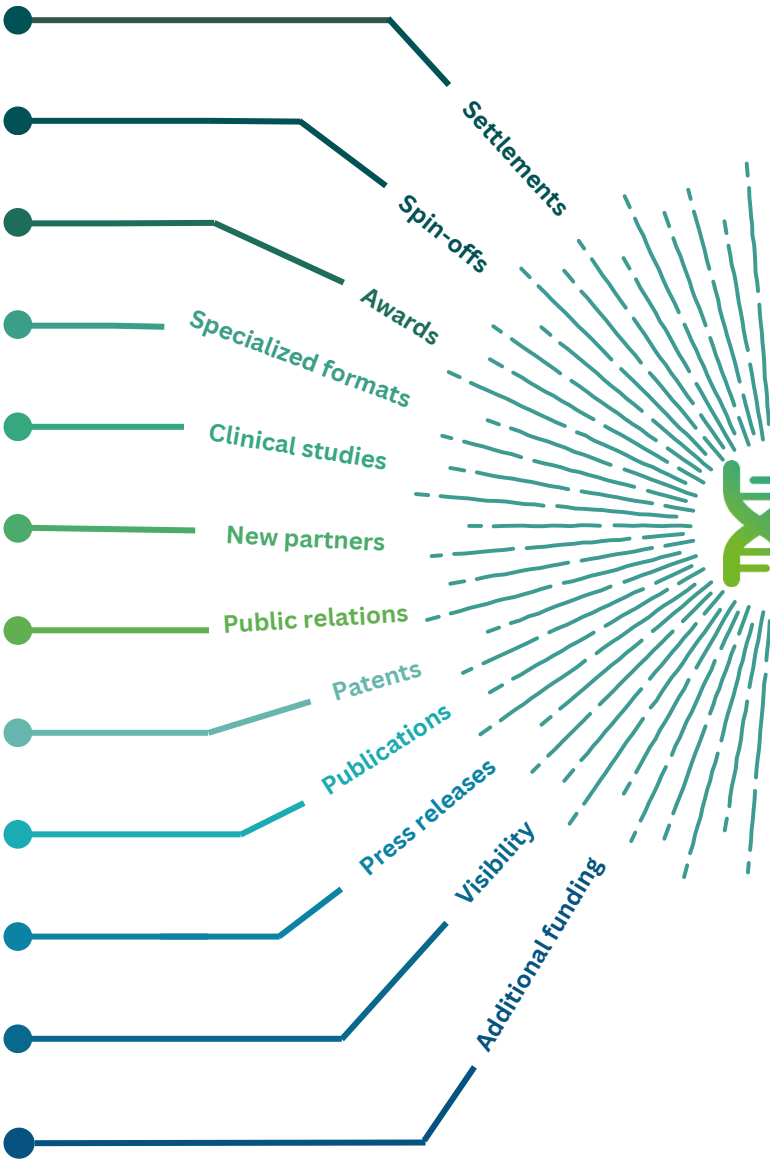
Cell & gene therapy

An overview



Important successes

Review of the first funding phase 2021-2024



Important successes

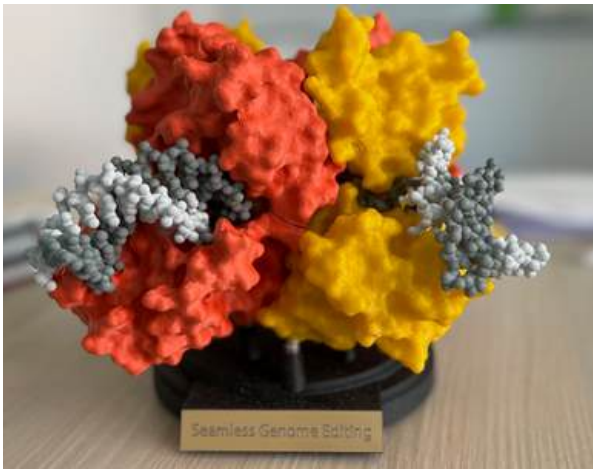
Review of the first funding phase 2021-2024

Scientific

First successful antibody production at Fraunhofer IZI (S1 GMP facility) in 2024

- Antibody MAX.16H5 (Tcell Tolerance, OPTIX)
- High antibody yield
- Prerequisite for the production of Palintra®

Further development of the designer recombinase technology



- Nat Biotechnol.
- First zinc-finger conditioned recombinase system
- IP exclusively licensed to SeamlessTx

Important successes

Review of the first funding phase 2021-2024

Awards

Science4Life Award
Michael Sieweke
xMac

Schelling Award
Michael Hudecek
UltraCART

Unipreneurs Award
Frank Buchholz
HemRec

Clinical Research Certificate Harvard
Paul Warncke
Klinikum Chemnitz

Important successes

Review of the first funding phase 2021-2024

SaxoCell specialized formats

SAXOCELL® meets politics

Networking of representatives from politics, medicine, healthcare & industry

SAXOCELL® Investors Club

Pitching Saxon business ideas to investors & business angels

Important successes

Review of the first funding phase 2021-2024

Clinical studies

> € 10 million funding

ROR2 CAR-T

Clinical trial with ROR2-specific CAR-T cells in patients with ROR2+ cancers

Ulrike Köhl & Michael Hudecek
UltraCART

UC-CISSII

Mesenchymal stromal cells from the umbilical cord as cellular immunotherapy for septic shock

Mario Rüdiger
MSC-PreStiGe

Important successes

Review of the first funding phase 2021-2024

Public realtions

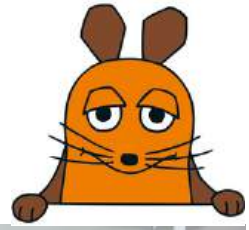
DRESDNER LANGE NACHT DER WISSENSCHAFTEN

Popular science event held annually in Dresden and every two years in Leipzig, at which SaxoCell provides information on innovative forms of therapy with games and illustrative material.





“Türen auf mit der Maus” takes place annually on October 3. Here, companies and organizations can present themselves to an interested audience in a kind of open day and are featured on the Maus/WDR website, and SaxoCell has already taken part.





Important successes

Review of the first funding phase 2021-2024

Patents

xMac
6 patents

NK4Therapy
1 patent

HemRec
5 patents

OPTIX
1 patent

CAR-NK 4.0
1 patent

Under SaxoCell umbrella
3 patents

Important successes

Review of the first funding phase 2021-2024

Publications

Currently, over 20 joint publications with SaxoCell citations have been published in top-class journals, as well as many others with SaxoCell references.

Important successes

Review of the first funding phase 2021-2024

Additional funding

Michael Sieweke &
Anke Fuchs
xMac
GO-Bio BMBF (1Mio€)

Bundesministerium für Bildung und Forschung

GO-Bio initial | next

Horizon Europe

CREATIC - CZ
Total 15Mio€
ULEI + FhIZI 3.2Mio€

Ulrike Köhl &
Michael Hudecek
UltraCART
BMBF (9Mio€)

Bundesministerium für Bildung und Forschung

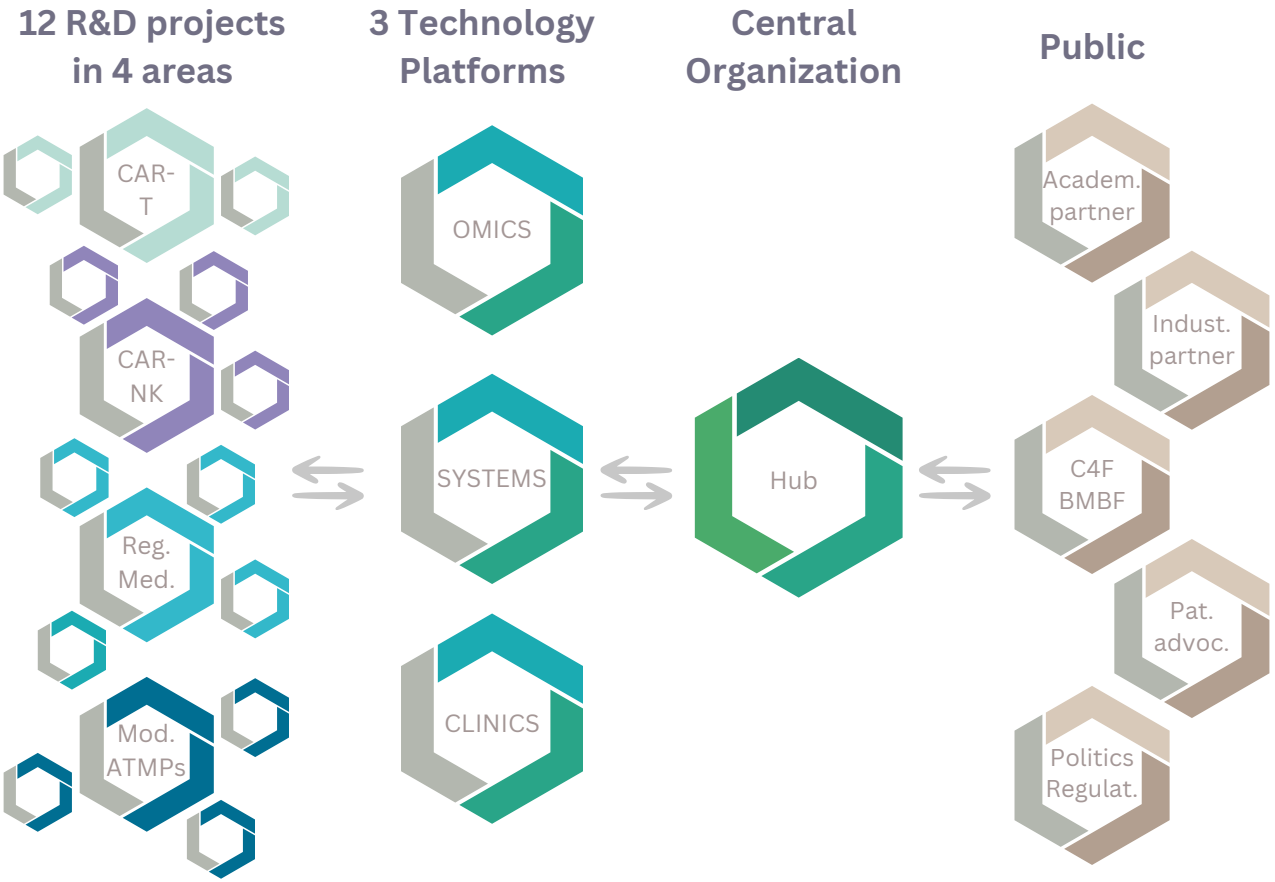
Horizon Europe

CTGCT - SLO
Total 14Mio€
TUD 103T€

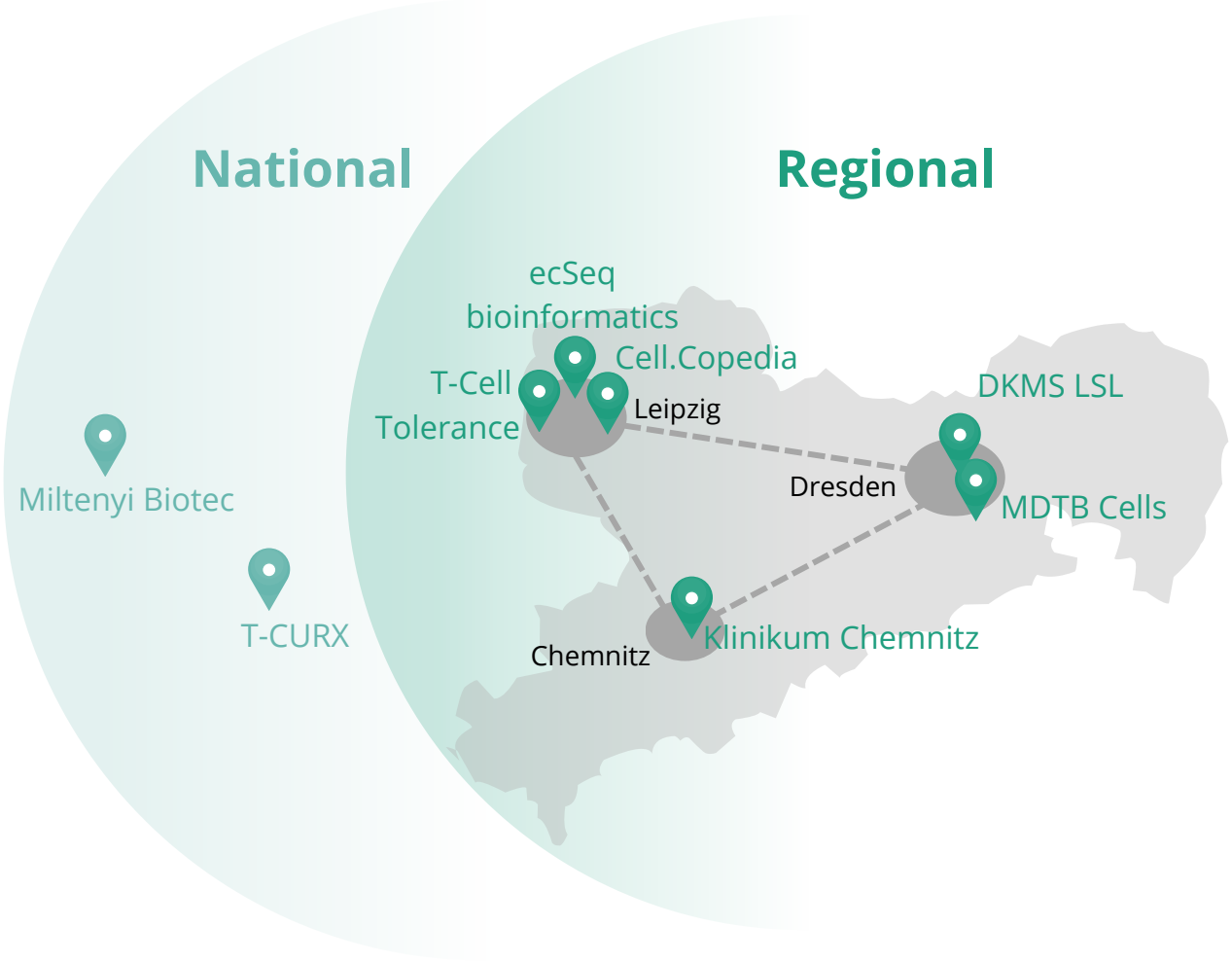
Cluster profile

Linking science and industry

SaxoCell consists of several mutually supporting entities. The **12 research projects** are organized into **four areas** around the overarching foci of CAR T cell therapies, (CAR) NK cell therapies, Regenerative Medicine and Modulated Cell and Gene Therapies. These projects are supported by **three adjacent technology platforms** OMICS (data collection and analysis), SYSTEMS (automation, AI) and CLINICS (clinical trials, consulting). Assistance in project management, transfer and marketing is provided by the Hub, which also represents the **central interface** to the public.



SaxoCell partners



Within the first funding period, we were able to significantly expand our partner network with new industry, cluster and press partners. In the first funding phase, 8 industry partners were involved, whereas in the second period there will be a total of 23.

We were also able to exchange ideas and learn from each other with other clusters in the sector, such as the Cluster4 Future PROXIDRUGS from Frankfurt or BioRN. Press partners such as SPIN2030 and the Tagesspiegel with its annual health event accompanied us on our journey.

Benefits for new partners

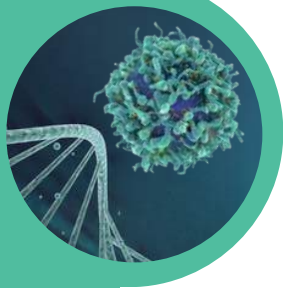
INNOVATE, COLLABORATE, ELEVATE

YOUR GATEWAY TO CELL & GENE THERAPY EXCELLENCE

SaxoCell is the science and industry cluster for cell and gene therapies (CGT) in Saxony with the aim of becoming one of the strongest biotech centers for precision medicine in Germany. It promotes health innovations and acts as a hub for members and stakeholders. Together we are creating a rich translational ecosystem that creates the conditions for researching and launching new applications.

INNOVATIVE CELL AND GENE THERAPIES

- CAR T / NK cell therapies targeting cancer and autoimmune diseases
- Macrophages / MSCs for solid tumors and as regenerative approaches
- Designer-recombinases & transposons for precise & safe genome engineering



CGT LOUNGE – JOIN THE COMMUNITY

- SaxoCell e.V. for connection & exchange of new partners
- Access to a network of platform technologies, infrastructure, patients & comprehensive ATMP expertise
- Access to a network of potential users as well as highly trained talents & know-how

BENEFIT FROM THE LOCAL ECOSYSTEM

- Rich academic and translational ecosystem
- Attraction of top global talents
- Opening up new markets
- Strong region dedicated to CGT development

CGT ANGELS – FIND THE RIGHT INVESTORS

- Early access to VC funding opportunities
- Increased spin-off activities of SaxoCell partners including project funding
- Support with public funding application

CGT KNOWLEDGE – ENABLING INNOVATIONS

- State of the art developments in cell production
- Expanding your knowledge & filling the gaps
- Offering contacts for requirements, training courses, specialist training, workshops, seminars etc.

MORE FROM THE SAXOCELL UNIVERSE

- CGT start-up creation – Validate your business model
- CGT expertise – Learn from experts
- SaxoCell cluster conference
- Collaboration with Saxon stakeholders to accelerate the life science industry

SaxoCell e.V.

Saxocell e.V.

The SaxoCell Association was founded to give interested industry partners and stakeholders the opportunity to join the cluster during the current funding periods and benefit from the SaxoCell network. The non-profit association aims to grow our SaxoCell community steadily but sustainably, which ultimately also contributes to the continuity of the cluster. We look forward to welcoming new, interested partners, who are welcome to contact us at any time at info@saxocell.de.

Foundation: September 2023 in Leipzig

Founding members: 13

Frank Buchholz, Stephan Fricke, Maren Henneken, Ulrikle Köhl, Martin Bornhäuser, Ezio Bonifacio, Uwe Platzbecker, Stfeanie Binder, Ilka Henze, Dorit Teichmann, Anette Bartsch, Alexander Funkner, Stephanie Wieneke (photo from left to right)

SaxoCell projects

CAR T cells	AlloCARTreg
	UltraCART
NK & CAR NK-cells	CAR-NK 4.0
	CAReNK-Aid
	NK4Therapy
ATMPs regen. medicine	HemRec
	ZellTWund
	xMac
	MSC-PreStiGe
CGT modul.	TheraSTAR
	OPTIX
	ECP-CAR

SaxoCell Hub

Genetically modified regulatory T cells for the treatment of autoimmune diseases

CAR-T cell approach with novel target molecules and innovative technology

AI-assisted CAR-NK cell platform with fully automated manufacturing process

CAR-NKs for the treatment of severe autoimmune diseases

Memory NK cell subset for tumor immunotherapy

Designer recombinases for regenerative therapy of hemoglobinopathies

Regenerative wound dressing from fibroblasts & biopolymers for chronic wounds

Macrophages for allogeneic transplantation in solid tumors

Immunomodulatory mesenchymal stromal cells against GvHD after transplantation

Antibody-modified stem cell trans-plantation for the prevention of GvHD

Extracorporeal photophoresis as a modulatory adjunct in CAR-T cell therapy

Switchable Uni-CAR receptors for therapy & diagnostics

Central management interface within the cluster

AlloCARTreg

Preclinical development of allogeneic switchable universal regulatory CAR-T-cells

AlloCARTreg is developing an universal immunosuppressive cell product for the treatment of autoimmune and inflammatory diseases through innovative site-specific adapter CAR technologies. The project bundles expertise with clinical scale fully automated polyclonal regulatory T cell (Treg) manufacturing (Fuchs), Treg cell therapy (Bornhäuser), state-of-the-art universal adaptor RevCAR technology (Feldmann) and pioneering genetic engineering methodology (Buchholz).

Significant progress was made last year in the following project parts:

Source of Regulatory T cells (Tregs): Tregs from adult peripheral blood (apheresis) and umbilical cord blood were comprehensively characterized and compared for their expansion potential and function.

Isolation process: A GMP (Good Manufacturing Practice)-compliant process for the isolation of Tregs from apheresis and umbilical cord blood with significantly improved purity was developed.

Manufacturing process for RevCAR Tregs: A scalable manufacturing process for RevCAR-transduced Tregs from adult apheresis was established according to GMP


standards. This process has been successfully tested in several automated runs, achieving clinically relevant yields.

Organ-specific targeting: In preclinical studies, a protein overexpressed in the inflamed gastrointestinal tract was identified as a first target for RevCAR-Treg therapy in acute graft-versus-host disease (aGvHD). Specific targeting modules were developed in the Feldmann lab. Specific target-dependent activation of universal RevCAR-Tregs was demonstrated.

T cell receptor (TCR) deletion and silencing: The widely used CRISPR/Cas technology works effectively to delete the TCR. However, nucleases bear risks under therapeutical applications. We therefore developed innovative technologies to allow safe depletion of the endogenous TCR using epigenetic silencing (Buchholz). We now have a tool to silence the TCR with very high efficiency to decrease immunogenicity of allogeneic T cells and increase the specific targeting of AlloCARTreg.

Overall, substantial progess was made towards AlloCARTreg´s vision of a cost-effective off-the-shelf living medicine addressing the unmet medical need for targeted immunosuppression in inflammatory and autoimmune disorders.

UltraCART

Cancer immunotherapy with next-generation CAR-T cells

As part of the collaboration between the Fraunhofer Institute for Cell Therapy and Immunology (IZI) and the company T-CURX, various work steps are being carried out in parallel in order to make effective use of synergies and achieve rapid progress.

A central element of the joint research work is the development of CAR-T cells that specifically target a receptor of the lectin family. In the confirmatory experiments performed, the most promising receptor-CAR construct proved to be highly functional. These CAR T cells showed a strong and antigen-specific response to the corresponding target cells. In collaboration with Fraunhofer IZI, the manufacturing process of these CAR T cells was optimized according to GMP (Good Manufacturing Practice) standards. The previous 12-day manual process was successfully shortened to 7 days.

The CAR-T cells produced during this process were comprehensively phenotyped, their expansion rates were analysed and characterized in detail at the transcriptome level using omics analysis. In addition, the efficacy of both CD4+ and CD8+ CAR T cells against the receptor-expressing target cells was extensively functionally tested and confirmed.

Michael Hudecek

The Prodigy platform proved to be extremely suitable for the fully automated and closed production of CAR T cells. For the first time, it was shown that CAR T cells can be produced within 12 days using the Sleeping-Beauty transposon system and T-cell electroporation in this fully automated device (Lock et al., JITC 2022). In addition, a protocol has been developed to shorten the manufacturing process to 7 days using the Prodigy platform.

Furthermore, progress has been made in the analysis of surface molecules on target cells and CAR molecules on CAR T cells. Using the high-resolution dSTORM microscopy technique, protocols were established that make it possible to measure the simultaneous expression of several antigens on the surface of target cells. In addition, the expression of CAR molecules on CAR-T cells was detected using this technique.

These advances pave the way for the next generation of CAR-T cell therapy and open up promising prospects for the treatment of cancer.

CAR-NK4.0

AI-assisted CAR-NK cell platform with fully automated manufacturing process

In this project the academic partners Fraunhofer IZI, Leipzig University and the University Hospital as well as the Chemnitz Hospital team up with Affimed GmbH and Miltenyi Biotec B.V. & Co. KG to develop an AI-assisted CAR-NK cell platform (CAR-NK4.0) and a fully automated manufacturing process for the phase I trial of an allogeneic target-specific CAR-NK approach for the treatment of myeloid neoplasms. Innovative technologies such as biospecific targeting, AAV and lentiviral gene transfer, and novel cell activation are used in this ambitious project.

In a proof-of-concept study, a digitally controlled, automated process for the manufacturing of chimeric antigen receptor (CAR)-carrying primary Natural Killer (NK) cells was established. The Natural Killer Cell Transduction (NKCT) process and associated quality controls were transferred and successfully implemented, resulting in the successful planning and execution of CAR NK cell manufacturing runs using a preclinical vector.

In addition, primary NK cells were isolated from blood products to provide SaxoCell CAR-NK4.0 project partners with standardized laboratory-scale expanded NK cells for their respective scientific studies.


Anna Dünkel & Ulrike Köhl

A protocol for a prospective clinical trial in patients with myeloid diseases and unfavorable prognosis has been developed. In a phase I trial, a dose escalation strategy for patients using target-specific CAR-NK cells is planned. The study includes design, endpoints, patient selection, statistics and monitoring. Biobanking will support the research during and before the study. The clinical implementation of CAR T-cell therapy in the participating hospitals has created a suitable infrastructure for ATMP testing for clinical trials. In addition, the cell therapy expertise of all project partners will strengthen the planned study quality.

The exploration of treatment options for multiple myeloma patients led to the development of bi-specific CAR designs based on antibody fragments targeting MM markers. The production of CAR NK cells was optimised using retroviral vectors for genetic modification, and bispecific targeting of MM-specific tumor markers was successfully tested on tumor cell lines.

For the first time, efficient AAV vector-mediated transgene expression in primary human NK cells was shown. A broad range of AAV vectors were tested for uptake and transgene expression in NK cells. Optimised transduction conditions increased eGFP transgene expression up to 80%. This could also be applied to NK-92 cells. AAV-CAR vectors against CD4 and CD19 are being tested and initial experiments showed increased cytotoxicity. Analyses to define the essential interactions between AAV capsid and NK cells are in progress.

CAReNK-AID

Developing a safe and affordable therapy to cure autoimmune diseases with CAR-NK Cells

Significant progress has been made in the development of chimeric antigen receptor natural killer (CAR-NK) cells for the treatment of severe autoimmune diseases. This research focuses on the targeted depletion of autoimmune-specific B lymphocytes, which has high potential to be used therapeutically to cure autoimmune diseases. Key findings include:

Generation of novel CAR-NK cells: We generated modified innovative CD19-specific CAR-NK cells engineered to efficiently eliminate human B cells, with the goal of resetting the human B cell repertoire. We demonstrated killing of CD19-positive cell lines as well as depletion of B cells from human blood in vitro. For more specific cytotoxicity, we have also generated CAR-NK cells exclusively targeting autoreactive B cells associated with selected diseases and demonstrated their functionality *in vitro*.

Development of efficient gene transfer methods: Genetic engineering of NK cells is challenging mainly due to inefficient gene transfer methods. Here, we compared viral and non-viral transfer methods for CAR gene transfer into blood-derived primary NK cells. For the lentiviral system, we identified an optimal envelope system leading to optimal clinically applicable CAR transduction efficiencies at low


viral load. Because non-viral systems are safer and more cost-effective, we have been working to develop nanoparticle-based and electroporation-based gene delivery systems. We have selected nanoparticle candidates that have been characterized and tested in standard cell line models. Initial studies on mRNA-based electroporation of transgenes in NK cells were successfully performed to test their efficiency.

Generation of feeder cells for expansion of CAR-NK cells: NK cell expansion is another critical hurdle to reach clinically relevant doses of allogenic NK cells for off-the-shelf production. Therefore, we have generated expansion cell line for selective expansion of CD19-CAR-NK cells. The feeder cell line was characterized and tested for NK cell expansion.

GMP conform generation of CAR-NK cells: We have tested optimal GMP-compliant media, supplements and transduction reagents for optimal NK cell culturing and expansion. Finally, we have optimized upscale production of unmodified activated NK cells and validated in three runs under GMP conditions at clinical.

NK4Therapy

Development of a GMP-compliant manufacturing process for adaptive NK cells using artificial feeder cells and CC top cell isolation technology

As part of the NK4Therapy project, a GMP-compliant manufacturing process was developed for a subpopulation of tumor-reactive, so-called “memory-like” NK cells. These cells are characterized by the expression of the surface marker NKG2C and show promising potential for the immunotherapy of leukaemias and solid tumors. NKG2C-positive NK cells are found in higher frequency in the blood of people who have previously been infected with the human cytomegalovirus (HCMV).

To expand these cells, a specially developed feeder cell line was used, which was genetically modified with a transgene for interleukin 2 (IL-2) as well as activating and costimulatory NK ligands. This modified feeder cell line enables selective expansion of NKG2C+ NK cells. The following scientific and technical milestones were achieved in the project:

Identity testing of the Master Cell Bank (MCB): A cell-based testing system was successfully established to detect the protein expression of the transgenic IL-2. This system is used for identity testing of the MCB as well as the Working Cell Bank (WCB) and the End of Production Cell Bank (EoPCB).

Achim Temme

GMP-compliant SOPs: Standard operating procedures (SOPs) for the production of the MCB and EoPCBs and for a GMP-compliant manufacturing process NKG2C+ NK cells have been established.

Selective expansion of NKG2C+ NK cells: The selective expansion of NKG2C+ NK cells from isolated NK-cells from peripheral blood was validated using a special feeder cell clone. A master cell bank (MCB) was successfully generated and tested for identity. The mandatory sterility, mycoplasma and adventitious virus testing of the MCB were completed.

Efficient NK cell expansion after CD3 depletion: By depleting CD3-positive T and NKT cells from the PBMCs using anti-CD3 beads, a selective expansion of NK cells was accomplished, even if monocytes and B cells were still present. A purity of over 80 % of NK cells was achieved. These results suggest that simple CD3 depletion may be sufficient for the NK cell production process.

Animal application: First data of in vivo testing of the NKG2C+ NK cell product showed significant anti-leukemia responses and no adverse effects of treatment. These advances provide a promising basis for the further development of CAR-NK cell therapies, particularly with regard to the treatment of leukemia and solid tumors.

HemRec

Development, testing and preparation for commercialization of a universal cure strategy for β-chain hemoglobinopathies

This project has made significant progress in the development of a universally applicable therapy for β-chain hemoglobinopathies. These diseases include genetic disorders such as sickle cell anemia and β-thalassemias, in which the hemoglobin in red blood cells does not function properly. The aim of the project is to develop innovative gene therapy approaches that enable correction of the hematologic and pathologic defects associated with β-chain hemoglobinopathies. The most important results include:

Development of the HemRec recombinase library: Directed evolution was used to generate and then further optimize HemRec recombinase libraries. Two novel recombinases libraries targeting different target sites have been developed. These recombinases work together as a heterodimer to specifically excise regions within the BCL11A gene, which is of central importance for the reactivation of gamma-globin.

High-throughput screening: High-throughput sequencing was carried out to analyze the efficiency of the developed recombinases. Both the on-target site in the genome and three potential human off-target sites were examined.

Validation of recombinase activity: The activity of the developed recombinases was first validated in bacteria and then tested in human cell lines.

Testing in HeLa and HUDEP cells: HemRec recombinases were successfully tested in HeLa-BCL11A reporter cell lines and HUDEP cells. The precise targeted excision within BCL11A was demonstrated.

Frank Buchholz

Optimization of recombinase activity: Three recombinases with an activity of more than 5 % were identified in HeLa reporter cells. Targeted optimization strategies, such as the use of codon optimization and electroporation, increased the activity up to 35 %.

Off-target analyses and toxicity studies: Comprehensive off-target analyses and toxicity studies were carried out to ensure the safety of the recombinases. These studies are crucial for the development of safe gene therapy approaches.

I**mproving specificity and tolerance:** Strategies to increase the specificity and tolerance of recombinases in mammalian cells have been successfully performed and are ongoing to minimize potential side effects.

Establishing work with primary human stem and progenitor cells (HSPCs): All necessary procedures and technologies for processing primary HSPCs have been successfully established.

Humanized mouse model NBSGW: The NBSGW mouse model was identified as a suitable model for further testing.

Approvals for animal testing and ethics application: The necessary approvals for animal testing and the use of primary donor material were granted, allowing preclinical studies to be carried out.

Business case analysis and GMP process: Initial analyses for a possible market entry have been carried out. A preliminary GMP-compliant manufacturing process has been designed and calculated, which represents important steps towards commercialization. These results show significant progress in the development of a potential cure strategy for β-chain hemoglobinopathies and pave the way for clinical trials and future commercialization of the therapy.

ZellTWund

Innovative cell therapy to promote skin regeneration

The ZellTWund project aims to develop an innovative cell therapy approach (ATMP) for the treatment of patients with chronic, non-healing wounds. The therapeutic approach consists of a wound dressing made of degradable biopolymers into which the body's own pre-regenerative stromal cells (fibroblasts) are integrated. These cells promote wound healing and support skin regeneration. In the current project phase, work is focusing on basic research and preclinical development.

The first part of the project involves the identification and characterization of pro-regenerative fibroblasts in human skin. Fibroblasts are a heterogeneous cell population with diverse functions such as the production of extracellular matrix and the regulation of immune functions. Through single cell sequencing and comparative analyses with murine models, specific fibroblast subtypes with pro-regenerative properties have been identified. These subtypes will be further investigated and defined by surface markers to enable targeted isolation.

The second part focuses on the development of a transplantable wound dressing. This involves investigating how pro-regenerative fibroblasts can be integrated into the biopolymer in order to efficiently support wound healing. Initial results show that both autologous and allogeneic fibroblasts can be successfully integrated in vitro.


Sandra Franz & Jan-Christoph Simon

In addition, the aim is to establish preclinical models for testing the wound dressings developed. In an ex-vivo wound healing model with human skin, a long-term culture approach was developed that simulates wound healing and tests the effectiveness of cell therapy. In addition, a xenograft wound healing model is being established in immunodeficient mice to evaluate the regenerative effect of fibroblasts under real conditions.

Overall, the results to date show that pro-regenerative fibroblasts could represent a promising basis for the cell therapy of chronic wounds. Further investigations to optimize cell isolation and integration as well as preclinical tests are planned in the next project phase.

xMac

Mass production of universal macrophages

Macrophages can adopt a pro-inflammatory polarization state with tumor fighting potential that in principle could make them an ideal anticancer therapeutic. Unfortunately, normal macrophages are rapidly converted by the tumor microenvironment into a tumor-promoting polarization state that helps the tumor grow. We identified mechanism that play a crucial role in regulating these different states. Using these findings, we could genetically manipulate macrophages to remain fixed in a tumor fighting modus.

A further limitation to macrophage cellular therapy has been the inability to grow these cells in culture. We have overcome this problem by activating self-renewal mechanism that enables massive expansion of macrophages ex vivo. With our technology we already achieve 100-200fold higher yields than standard protocols of macrophage production from iPS cells, without having exhausted optimization and scale up options.

This large-scale production potential makes our macrophage cell therapy product highly suitable for allogenic of-the-shelf applications. Further insight into allogenic use of macrophages lead to the filing of a new patent application. This marks a significant step in the further development of our technology.

Michael Sieweke

In the reporting period we also made significant progress towards establishing a GMP-compliant production process. We now identified suitable GMP-compliant media and reagents that enable us to work in xeno-free conditions. We also established highly sensitive assays that confirm that our cell product is safe and has effective tumoricidal activity.

In 2023, we successfully participated in the Science4Life competition, the largest business plan contest for the life sciences in Germany. Coming in fourth place of over 90 initial participants, this highlights the economic potential of our technology.

MSC-PreStiGe

Industrial production of MSC cell products and clinical testing in acute graft-versus-host disease

The aim of the MSC-PreStiGe project is to develop an industrial value chain for mesenchymal stromal cells (MSCs), encompassing drug production and clinical application. The project centers around Desacell®, a newly developed active ingredient that utilizes the immunomodulatory capabilities of MSCs derived from umbilical cord tissue. Due to the significant expansion potential of these cells, a single umbilical cord can generate cell products sufficient to treat multiple patients. The initial clinical focus is on treating severe acute graft-versus-host disease (GvHD) following allogeneic stem cell transplantation.

To establish Desacell® as a novel MSC-based therapeutic, the project began by outlining the entire target process based on an established proof-of-concept. Any deviations from future manufacturing requirements were identified, and GMP-compliant solutions were developed to address these gaps. Additionally, specifications for industrial scaling and an implementation plan for process transfer were formulated and executed, including necessary investments for successful process transfer.

Beyond production, the project also laid the groundwork for targeted clinical intervention with Desacell®. Supplementary activities aimed at further stages of value creation and the development of additional products were initiated to prepare for large-scale international studies. These studies will support future approval applications for indications with high unmet medical needs. Research and development


Tino Hammer & Mario Rüdiger

efforts have been focused on predicting the clinical success of Desacell® and characterizing its mode of action. This has been achieved by establishing and validating an effector cell-free, standardized, automatable quality control test based on Fas-ligand stimulation, which measures the anti-inflammatory capacity of MSCs from umbilical cord tissue (UC-MSC).

The MSC-PreStiGe project leverages the immunomodulatory potential of these juvenile MSCs, which are particularly notable for their immense expansion capacity. This enables the treatment of up to 25 patients from a single cell product. MSCs are seen as highly promising candidates for treating many inflammation-associated diseases, which currently lack satisfactory therapies and are often linked to high mortality or long-term morbidity.

Despite over 20 years of global research and more than 100,000 publications supporting the therapeutic potential of MSCs, their large-scale industrial production under pharmaceutical conditions has not yet been fully realized. The MSC-PreStiGe project addresses this gap by developing an industrial value chain for Desacell® in Saxony, making it possible to produce MSCs in large quantities under GMP conditions at a low cost. This will ensure that allogeneic MSCs with high therapeutic potential are available off-the-shelf, enabling rapid and cost-effective clinical application within the SaxoCell cluster.

OPTIX

Optimized GMP manufacturing and first-in-man phase 1 study of Palintra® as an ATMP for allogeneic stem cell transplantation

Significant progress was made as part of the project for optimized GMP production and the first-in-man phase 1 study of Palintra® as an ATMP for allogeneic stem cell transplantation.

Clarification of the mechanism of action of the anti-CD4 antibody: The mechanism of action of the MAX.16H5 antibody, previously known as Palixizumab® and used in the drug Palintra®, was elucidated through a detailed transcriptome analysis. This analysis enabled the identification of differentially expressed genes that provide a deeper insight into the mode of action of the antibody. A publication and a doctoral thesis on this topic was also prepared.

GMP process transfer and extended quality control: Various manufacturing processes were evaluated in the area of GMP production of Palintra® , with a preference for dispensing with a washing step. This approach was positively evaluated as part of a Scientific Consultation at the Paul Ehrlich Institute.
Implementation of automation concepts: A software demonstrator for the automated evaluation of flow cytometric measurements, the so-called “AI Flow Software Algorithm”, was successfully developed and applied. This progress was documented in two publications: An article in Cytometry Part A is under revision,

Lilly Stahl

and a preprint on “Uncertainty Wrapper in the medical domain” has been published on arXiv.

These developments are important steps towards the clinical application of Palintra® and the expansion of the therapeutic potential of the anti-CD4 antibody.

ECP-CAR

Cellular population dynamics and functional alterations in the wake of immunomodulatory extracorporeal photopheresis (ECP) prior to chimeric antigen receptor (CAR) T-cell therapy

The original aim of the project was to carry out a comprehensive analysis of cellular subpopulations and their molecular profiles and effector functions. The aim was to investigate the effects of an extracorporeal photopheresis (ECP) treatment implemented with lymphodepletion prior to chimeric antigen receptor (CAR) T-cell therapy. The innovative intervention envisaged that the ECP treatment would be carried out as a preparative, immunomodulatory measure prior to the CAR T-cell infusion. This novel clinical procedure was to be part of the “PhotoCAR” study, a prospective phase I/II intervention study. This trial was designed to evaluate the efficacy and safety of ECP treatment in patients with aggressive B-cell lymphoma prior to CAR T-cell therapy and was planned for the fourth quarter of 2021.

Unfortunately, the PhotoCAR study could not start until April 2023. The reason for this was that the ECP procedure was classified as an advanced therapy medicinal product (ATMP) by the Paul Ehrlich Institute (PEI) and was to be considered an investigational medicinal product in combination with CAR-T cells. To clarify the situation, two scientific consultations were held with the PEI on November 1, 2022 and May 16, 2023. In the first consultation, the influence of the ECP procedure on the efficacy of CAR T-cells was questioned and it was requested that data on the safety of the procedure for these patients be provided. A delay in the project was therefore reported to the project sponsor on November 30, 2022 and a cost-neutral transfer of funds was requested.

Vladan Vucinic

In the second consultation, the required safety data for the procedure as well as evidence of apoptosis of the ECP-treated peripheral blood mononuclear cells (PBMCs) were presented, which enabled a positive assessment. However, the PEI clarified that a blinded, two-arm study with 100 participants, which must include all CAR-T manufacturers, is required for a positive assessment of the procedure. As these requirements are not feasible in an academic setting, it was decided to discontinue the study.

In order to gain new insights into the effect of the ECP procedure, and to follow the recommendations of PEI scientific advices, we requested a project change from the sponsor. The project is designed to analyze the ECP-derived cellular and humoral changes in the blood samples of patients undergoing treatment with CAR T-cells. Furthermore, the analyses will include the reduction of proliferative capacity, proportion of apoptosis after ECP and comparison of results with previously performed experiments on commercially available lymphocyte concentrates or healthy donors.

Since May 2023, samples from CAR T-cell patients from Leipzig University Hospital are being treated with ECP at various timepoints. The results wird provide novel conclusions about the effect of the originally planned ECP treatment on CAR-T cells and enable translation in clinical setting. The samples obtained will be treated and then the immune status will be determined and proliferation and apoptosis analyzed in established assays.

TheraStar

Development of theranostic target molecules for diagnosis and therapy

As part of the project to develop theranostic target molecules, significant progress was made in the diagnosis and therapy of tumor diseases. The focus was on the development of the “gated positive” GP-CAR platform, which consists of two components: novel target molecules (TMs) and dual GP-CAR T cells. This platform aims to specifically combat tumor cells.

A decisive step was the successful production of bispecific target molecules (bsTMs), including RevTM PD-1-scFv5B9, which targets the checkpoint molecule PD-L1. Preclinical studies have demonstrated the ability of RevTM to bind to PD-L1-expressing tumor cells and the successful production of GP-CAR-T cells through lentiviral transduction. The specific activation and targeted killing of PD-L1-expressing tumor cells was demonstrated both in 2D cell culture models and in a 3D spheroid model. By utilizing multiplex immunohistochemistry, a significant number of RevCAR T cells infiltrated PD-L1-expressing SCP-1 spheroids in the presence of PD-L1 RevTM and showed an improved cytotoxic activity and cytokine release. In addition, the use of GP-CAR-T cells in combination with RevTM led to significant production and release of pro-inflammatory cytokines such as GM-CSF, IFN-gamma, IL-2 and TNF-alpha.

Anja Feldmann

The efficacy of this system was also tested in vivo in further preclinical studies. Significant tumor cell lysis was observed in immunodeficient mice when the tumor cells were injected together with RevCAR-T cells and RevTM PD-1-scFv5B9. A further advance was the development of a dual GP-CAR-T cell system that enables combinatorial targeting (“AND gate”) of tumor cells with PD-L1 and PSCA expression. Here, too, significant tumor cell rejection and the release of cytokines were demonstrated in vitro.

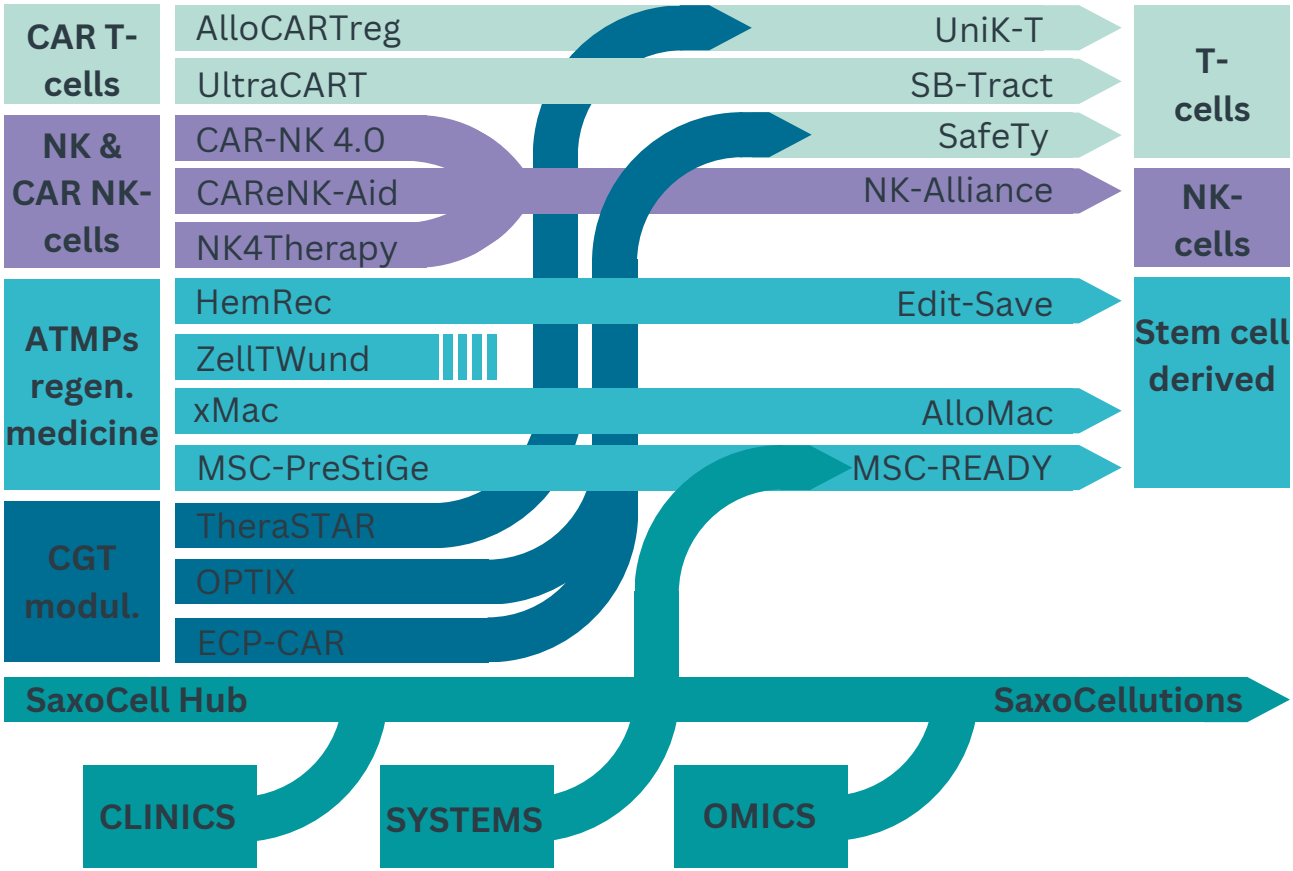
In addition, the proof-of-concept (PoC) for the anti-tumor efficacy of the dual RevCAR T-cell system was confirmed in vivo. The successful labeling of diagnostic target molecules with NODAGA and copper-64 represents further progress in the development of theranostic solutions.

Overall, all the milestones set were achieved: the successful production of GP-CAR and dual GP-CAR components, the validation of their immunotherapeutic efficacy in vitro and the PoC in vivo.

Transition of R&D projects

from the 1st to the 2nd funding phase

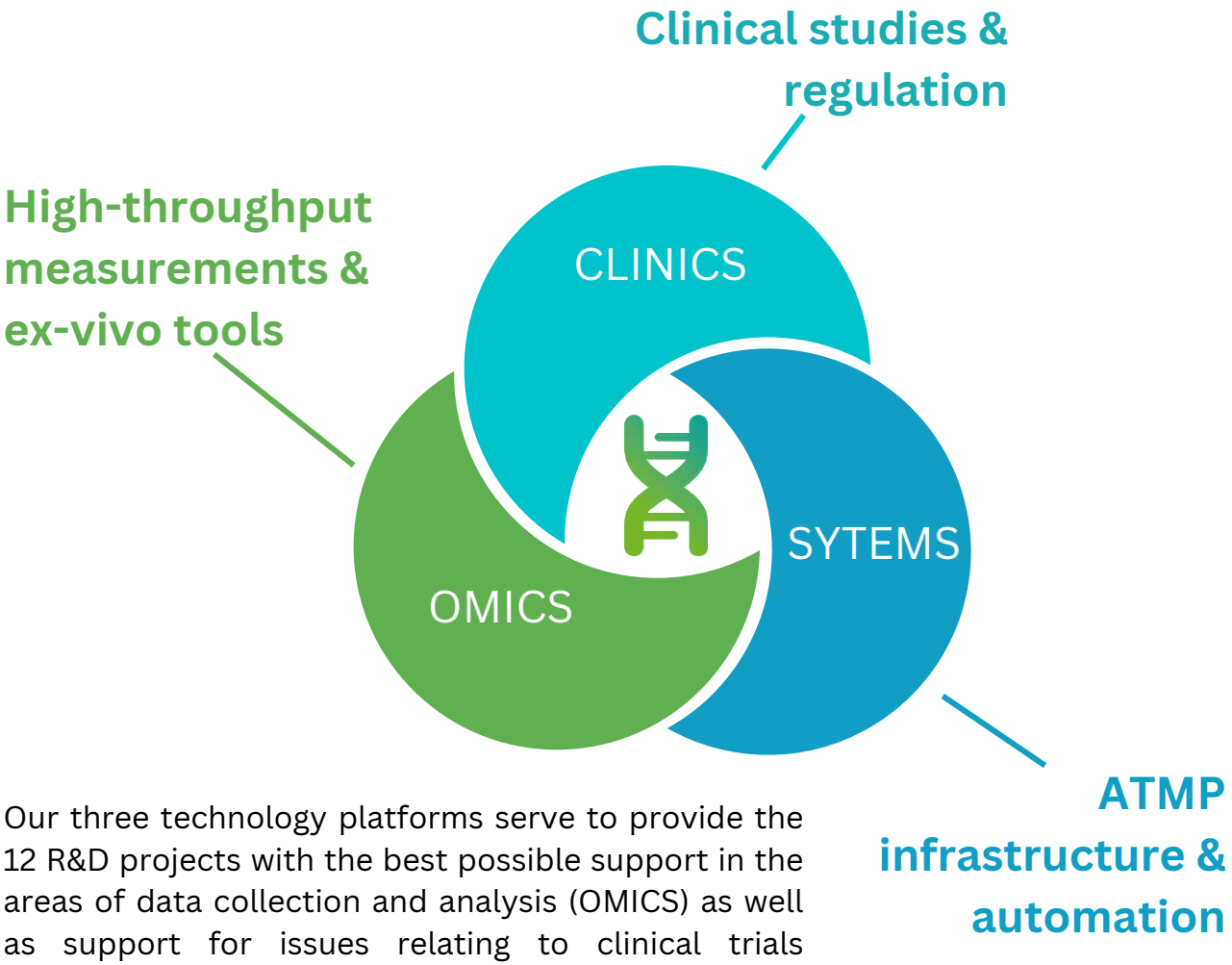
In the first SaxoCell funding phase, we started with 12 R&D projects clustered in four areas (T and NK cells, as well as regenerative approaches and modulated CGTs), three adjacent technology platforms (OMICS, SYSTEMS, CLINICS) and the central management interface - the SaxoCell Hub.



During the transition to the second funding phase, we tried to pursue promising approaches in line with the cluster strategy. To bundle existing resources, certain projects were merged and one project was discontinued. Furthermore, we have assigned the three technology platforms to existing projects according to their fit, thus bundling synergies and making the cluster leaner and more precise.

As a result, there are now 7 R&D projects in three areas (T, NK and stem cells), as well as SaxoCellutions as a combination of the former hub with the integrated technology platforms OMICS and CLINICS. The SYSTEMS platform was combined with the MSC-PreStiGe project to form MSC-READY due to previous close collaboration.

SaxoCell platforms



Our three technology platforms serve to provide the 12 R&D projects with the best possible support in the areas of data collection and analysis (OMICS) as well as support for issues relating to clinical trials (CLINICS) and GMP processes, automated production and AI (SYSTEMS).

CLINICS

- Central coordination office for clinical & regulatory aspects
- Optimization of the implementation of clinical trials (phases 1-3)
- Provision of advice and networking
- Process & biosample harmonization at the three sites Leipzig, Dresden, Chemnitz
- CLINICS workshop on ATMPs (03/2023)
- Close cooperation with ECP-CAR & CAR-NK4.0

OMICS

- CAR-T cell detection by Single-cell-Seq
- Overview of available infrastructure & expertise and method harmonization in Saxony
- Customized pipelines & workflows
- Integration of OMICs data into national human database
- Strategic partnership with industry
- SPARK meeting on data analysis with the Galaxy Server (09/2023)
- Workshops of ecSeq (04+08/2023)
- Close collaboration ECP-CAR, CAR-NK4.0 & UltraCART

SYSTEMS

- GMP automation concept with 3D bioreactors
- Artificial intelligence concept using sensors
- GMP quality management concept with supply chain management
- Workshops & GMP training concept
- Close cooperation with MSC-PreStiGe

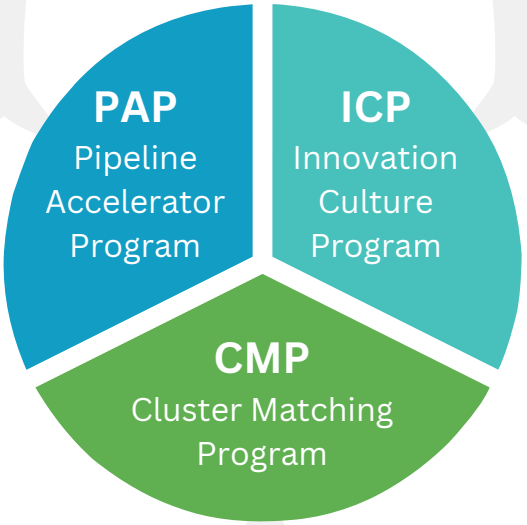
SaxoCell Hub

Project support

- Project management & monitoring
- Support with reporting
- Workshops & trainings

Marketing & transfer

- Tech transfer & commercialization
- Press & PR work
- Network meetings



Strategy development

- Development of cluster strategy
- Cluster sustainability

Many qualifications - one team

Scientific Advisory Board

The SaxoCell Scientific Advisory Board (SAB) is a scientific advisory board and consists of **experts from the fields of research and industry as well as representatives from patient advocacy** who advise the SaxoCell cluster in general and support the projects with their experience.

Discussions are currently underway to **include further members** on the SaxoCell Scientific Advisory Board.

The SAB meets once a year with the project leaders of the SaxoCell projects and technology platforms and provides valuable advice based on its individual expertise from different areas.

Consortia & SAB meeting 2024

In June 2024, our two-day SaxoCell consortia and SAB meeting was a resounding success, offering a perfect blend of productive discussions and engaging activities. PIs and scientists from our projects and platforms, members from the SaxoCell hub as well as our Scientific Advisory Board representatives gathered at Congress Hotel Chemnitz.

Our agenda was packed with insightful discussions, innovative pitches, and a comprehensive outlook on our future projects and perspectives.

One highlight of our retreat was the team challenge aiming for the highest spaghetti tower, fostering creativity and teamwork.

This year's SaxoCell consortia meeting not only strengthened our professional bonds but also provided valuable insights and renewed enthusiasm for our collective goals.

Jury visit

May 2024 - Preparation of the 2nd funding phase

On May 23, 2024, a jury of experts with members from BMBF & PtJ thoroughly reviewed and evaluated our strategy concept for the development of innovative cell and gene therapies.

The assessment by the Federal Ministry of Education and Research and the project management organization Jülich is a decisive step in the further development of SaxoCell. A positive evaluation would not only confirm the scientific excellence and innovative strength of our cluster, but would also pave the way for the next phase of funding and implementation.

Our team, consisting of experienced scientists, junior researchers, physicians and industry partners, has worked

with great commitment and passion to represent our cluster. We had great project pitches! Our PIs and industry partners answered the reviewers' questions precisely and confidently. Excellent posters illustrated the goals and potential of our projects!

In the meantime, we can say that the effort and good preparation has paid off and SaxoCell has been positively evaluated and will start the second funding phase from October 2024, which will take us another step towards becoming a cell and gene bacon in Saxony. We would like to take this opportunity to thank everyone involved for their commitment and support!

Greetings

on the jury visit

Prof. Dr. Eva Inés Obergfell

Rector of the University of Leipzig

SCAN HERE
for video message
(in German)

Ladies and Gentlemen,
it is a great pleasure for me to welcome you to this momentous occasion as we celebrate together a crucial milestone in the development and application of cell and gene therapies. As Rector of Leipzig University, I would like to express to you, albeit in the form of a video message, my sincere pleasure and pride that we are coming together today to pave the way for SaxoCell from the first to the second funding phase.
SaxoCell is an outstanding example of successful collaboration between 38 PIs from Saxony's leading universities, the associated university hospitals from Leipzig and Dresden, the Chemnitz University Hospital and research institutions such as the Fraunhofer IZI and five regional and three national companies. Together, we have committed ourselves to the goal of advancing the development and application of cell and gene therapies. A network of this kind is unique in Germany. These innovative immunotherapies are being developed in Saxony, with SaxoCell playing a central role as a cooperation platform for our partner institutions.

As one of SaxoCell's core partner institutions, Leipzig University is proud to put its expertise and resources at the service of this pioneering network. The support of the Clusters4Future initiative of the Federal Ministry of Education and Research is of crucial importance. It enables us to create synergies, pool resources and provide our researchers with fertile ground for conducting high-level scientific studies.

By sharing knowledge, technology and expertise, SaxoCell will not only advance research at our facilities, but will also be firmly anchored in the National Strategy for Gene and Cell Therapy. In addition, SaxoCell will make a significant contribution to international cutting-edge research. Building on SaxoCell's achievements, new international alliances in the field of cell and gene therapy have been created, most notably the EU consortium CREATIC of the University of Leipzig and Fraunhofer IZI with the Czech Republic and the EU consortium CTGCT of TU Dresden with Slovenia.

It is important to note that SaxoCell is not only of great importance for Leipzig University, but also for our partner institutions and the entire research community. By creating an interdisciplinary network, we will be able to tackle challenges that individual institutions could not solve on their own. This joint effort will help to develop new treatments, combat diseases and ultimately improve the well-being of society.

With this in mind, I would like to express my sincere gratitude to everyone involved in SaxoCell. Your dedication, expertise and passion are the key to our shared success. May SaxoCell continue to be a shining example of the power of collaboration and tireless dedication to science.

Thank you.

Yours sincerely,
Prof. Dr. Eva Inés Obergfell

Greetings

on the jury visit

Prof. Dr. Angela Rösen-Wolff

Vice Rector Research representing the Rector of Technical University Dresden

Ladies and Gentlemen,
to become better in order to remain excellent. Interdisciplinary and cross-sectoral alliances create an environment for excellence and development. In such an environment, projects thrive that will benefit the entire region over bridges. I am therefore delighted to welcome the representatives of the BMBF, the jury, experts and the representatives of the PtJ here at TU Dresden today. Because the SaxoCell future cluster builds bridges! Bridges between academic research in the field of cell and gene therapy and industry, between science and politics, between developers and users, but also between the universities in Saxony and non-university partners. All of this is important for us and for our region.

As an excellent university, TU Dresden is also one of the most patent-rich universities in Germany, but with SaxoCell we now also have the opportunity to promote transfer, especially in the field of cell and gene therapy, and to support potential new spin-offs on their way. Why is this so important?

I am a doctor myself and deal with rare diseases. I am therefore aware of how much potential there is in the field of ZGT and how important it is to drive forward innovative research in this area. However, in order for this research to benefit people, you need partners. After all, you can't take the step of applying and marketing these innovations alone. In the best case scenario, you have numerous competent supporters at your side with an interdisciplinary and active network.

We at the TUD support the SaxoCell future cluster with additional positions and are pleased about the integration into the TUD's transfer activities. SaxoCell also serves as a role model for other potential cluster structures and innovation nuclei in other research areas. The TUD considers it essential to set new accents here, to enrich and supplement the existing offers without creating parallel structures.

Greetings

on the jury visit

Holger Hanselka

President of the Fraunhofer Society

Dear representatives of the BMBF, the Free State of Free State of Saxony, the University of Leipzig, the Technical University of Dresden, ladies and gentlemen,
it is a pleasure for me, on behalf of the Fraunhofer-Gesellschaft my thoughts on the future cluster SaxoCell on behalf of the Fraunhofer-Gesellschaft. This cluster is dedicated to cell and gene therapeutics, a topic of immense social relevance. In recent years, this field has experienced an unprecedented upswing, driven by scientific breakthroughs and the breakthroughs and the resulting approvals. The Fraunhofer-Gesellschaft is proud to have made a significant contribution to these developments, in particular through the Fraunhofer IZI. Since 2006, it has been cell-based therapeutics have been developed and manufactured for clinical for clinical trials. One outstanding example is the approval study for the first approved CAR-T cell therapy Kymriah® by Novartis, which was realized together with the Fraunhofer IZI. This milestone triggered an enormous increase in research activities in this field worldwide. As a research location, however, we are now faced with the task of closing the gap that has grown in recent years the USA and China, where the majority of clinical trials in this area are currently of clinical studies in this area are currently being is currently being conducted in this area.

From a global perspective, we must ensure that the highly complex and therefore expensive drugs are accessible to an increasing number of patients and indications. Close cooperation and strong national networks that work together towards a common goal are essential for overcoming these challenges. The SaxoCell cluster is an outstanding example of this. It combines excellent basic research with applied research and clinical expertise to form a dynamic network. The resulting synergies are not only reflected in increased visibility, publications or better use of resources, but also in concrete successes with direct benefits for patients. One example is the production of an antibody
under pharmaceutical standards at the Fraunhofer IZI. This antibody, developed by the University of Leipzig and the Fraunhofer IZI, is used to produce the ATMP Palintra® to prevent complications in stem cell transplants. This success paves the way for clinical applications and demonstrates the potential of our collaboration in the SaxoCell Cluster.
My special thanks go to the spokespersons of the SaxoCell Cluster, Prof. Dr. Ulrike Köhl, Prof. Dr. Ezio Bonifacio, Prof. Dr. Martin Bornhäuser and Prof. Dr. Uwe Platzbecker. I am confident that we will continue to make significant progress through joint efforts and cooperation. With great enthusiasm for Saxony as a location, I assure you that I will do my utmost to promote the well-being and progress of the location.

Holger Hanselka
President of the Fraunhofer-Gesellschaft

Greetings

on the jury visit

Prof. Dr. med. Ralf Steinmeier

Managing Director Klinikum Chemnitz gGmbH

Dear jury of the Federal Ministry of Education and Research, dear representatives of the Jülich project management organization, ladies and gentlemen,

It is a great honor for me, as Medical Director of Klinikum Chemnitz gGmbH, to be able to welcome you all here as well.

My special greetings go to the jury of the Federal Ministry of Education and Research and to all the representatives of Project Management Jülich, the Free State of Saxony, the Universities of Leipzig and Dresden and the Fraunhofer Institute for Cell Therapy and Immunology IZI.

For three years now, the SaxoCell cluster of young scientists has been making a decisive contribution to the development of innovative, cell-based cell and gene therapies. During this time, we have conducted intensive research, generated knowledge and strengthened networks, and are now facing the important phase of further developing and implementing our results in clinical practice.

Your presence here today, dear members of the BMBF jury, reflects the confidence you have in the quality and potential of our cluster. We are proud to be able to show you how far we have come and what steps we plan to take next. Your feedback and expert assessment are invaluable in helping us to continue to successfully drive our vision forward and achieve our goals together.

Klinikum Chemnitz gGmbH sees its role in this cluster not just as a participant, but as an active contributor. We are convinced that our joint work will not only benefit medical research in Saxony, but that it will also have a national and international impact.

I would like to thank you for your support so far and look forward to continuing this fruitful collaboration. Together we can continue to push the boundaries of what is possible and create real added value for patients worldwide.

Thank you for your attention and commitment. I wish us all an inspiring exchange and successful further collaboration within the SaxoCell Cluster.

Prof. Dr. med. Ralf Steinmeier
Managing Director Klinikum Chemnitz gGmbH

Greetings

on the jury visit

The state capital Dresden is delighted to be able to host the successful cell and gene therapy cluster SaxoCell as a Saxon joint project. At the Technische Universität Dresden (TUD), a pioneer in academic excellence, research is carried out at the highest level every day. The translation of these research results into local applications is of outstanding importance and gives the future cluster particular added value. The transfer of research results, the founding of start-ups and the establishment of new companies represent a significant **enrichment for the life sciences sector**. Last but not least, the citizens of Dresden also benefit from a flourishing labor market and a diversified supply infrastructure. SaxoCell is committed to a future that has the well-being of our city in mind to the highest degree.

Steffen Rietzschel

Office for Economic Development of the City of Dresden

Dr. Ronny Schulz

Office for Economic Development of the City of Leipzig

"Strengthen the strengths" - under this motto, the City of Leipzig is working specifically on maintaining and expanding the growth conditions for an internationally competitive and sustainable development of business, education and research in Leipzig.

In order to effectively increase the economic performance of the city of Leipzig, economic policy is bundling a wide range of activities in the direction of active cluster development.

The City of Leipzig therefore expressly welcomes and supports the further expansion of the precision therapy cluster for “living drugs” of the “SaxoCell” consortium as part of the BMBF's “Future Cluster Initiative” and would be delighted if the “SaxoCell” consortium, with its successful first funding phase, could provide further impetus to the region in the coming years - it would be an important step for applied cutting-edge research in the new federal states.

Greetings

on the jury visit

André Hofmann
Managing director of
biosaxony

With SaxoCell, we are delighted to be able to support a cluster that focuses entirely on living drugs in the cell and gene therapy sector. The cross-regional association of individual institutions in Saxony in particular offers the entire industry significant added value across all stages of the value chain. **SaxoCell enriches Saxony as a location!**

SaxoCell is a pioneering example of the pooling of Saxon expertise in the field of precision therapy and benefits in particular from the broad-based innovation ecosystem that provides all the necessary technologies, especially biotechnology, software and AI. The establishment of a lighthouse cluster with an international reputation has enormous potential to increase the interest of partners in cell and gene therapy and to initiate new cooperation projects. SaxoCell makes an important contribution to strengthening the innovative power of Saxony as a business location with excellent cutting-edge research, which is driven forward by international experts, as well as offering life-prolonging and life-saving cell therapies at affordable prices. We look forward to supporting the network in its further development and technology transfer with regional companies.

Wirtschaftsförderung Sachsen

More information can be found on

www.saxocell.de/en

www.linkedin.com/company/saxocell-cluster

www.x.com/SaxoCell

www.instagram.com/saxocell/