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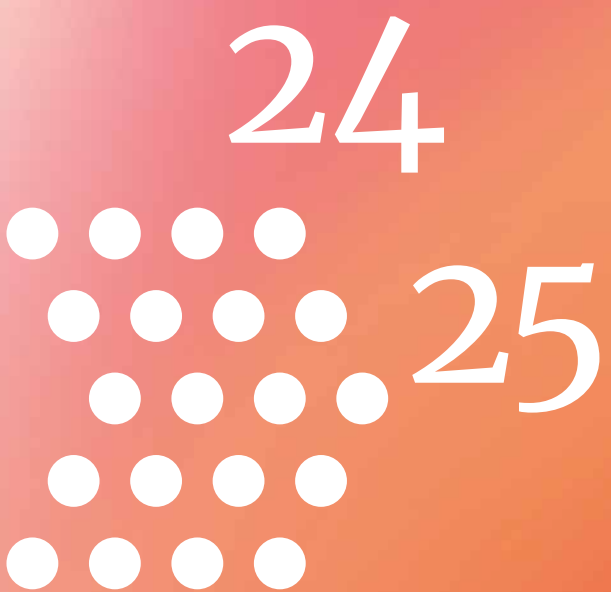
IMMUNO-ONCOLOGY RESEARCH – IOZK FOUNDATION ANNUAL REPORT



The IOZK Foundation: People and their Expertise.

COLOGNE, OCTOBER 2025

Dear readers,

Even with significant advances, cancer treatment remains a challenge for everyone. Behind every research idea, every clinical decision and every therapeutic advance are dedicated individuals who contribute their knowledge, experience and conviction to enable new approaches. This annual report is dedicated to those who, through our foundation's work, are helping to shape the medical development of immuno-oncological therapies.

Our translational research continues to strengthen the bridge between laboratory and clinic – as shown by the optimisation of existing therapies, the expansion of diagnostic possibilities and the growing understanding of immunological communication. Procedures such as hyperthermia are also being further explored to better understand their mechanisms of action. These findings flow directly into new treatment approaches.

As a foundation, we want to provide information about innovations and contribute to better understanding about immuno-oncological therapies. My sincere thanks go to everyone who walks this path with us – in their work for patients, in scientific exchange or through their support of our foundation.

Yours sincerely,

Dr. Wilfried Stücker

Tumour immunologist and member of the management board of the IOZK Foundation

Since every tumour is different, the best results are achieved by using the patient‘s own dendritic cells to target the unique set of tumour cells.

Stefaan Van Gool, MD, PhD

Stefaan Van Gool, MD, PhD, specialises in paediatric haematology and oncology, with a focus on brain tumours. At the IOZK, he serves as Medical Director, responsible for planning and implementing IOZK immunotherapy, and as a Qualified Person in drug manufacturing (GMP). Stefaan Van Gool, MD, PhD, is Co-Director of the IOZK Foundation.

INDIVIDUALISED MULTIMODAL IMMUNOTHERAPY (IMI)

As an expert in brain tumours and as Medical Director, Dr Van Gool played a key role in establishing and implementing the methods standardised in 2024 under the SIOPE HGG-01 protocol. These concern the methods included within Individualised multimodal immunotherapy, and its application to paediatric brain tumours.

New developments are particularly important in glioblastoma (GB), as standard therapy has hardly changed over the past 20 years and the prognosis remains very poor. Conventional therapeutic approaches usually focus on a single causal factor and treat all patients alike, which has limited success given the dynamics and plasticity of GB.

Against this background, new treatment strategies also take other factors in tumour growth into account: not only the tumour cells themselves are addressed but also the tumour microenvironment. The latter comprises a large variety of different cell types that promote tumour progression.

The new standardised treatment protocol at the IOZK therefore identifies six key characteristics, also known as key “hallmarks of cancer”: glioma stem cells, hypoxia, metabolic reprogramming, immune dysregulation with inflammation, neuron-glioma interaction and the gut-brain axis.

SCIENTIFIC INFORMATION

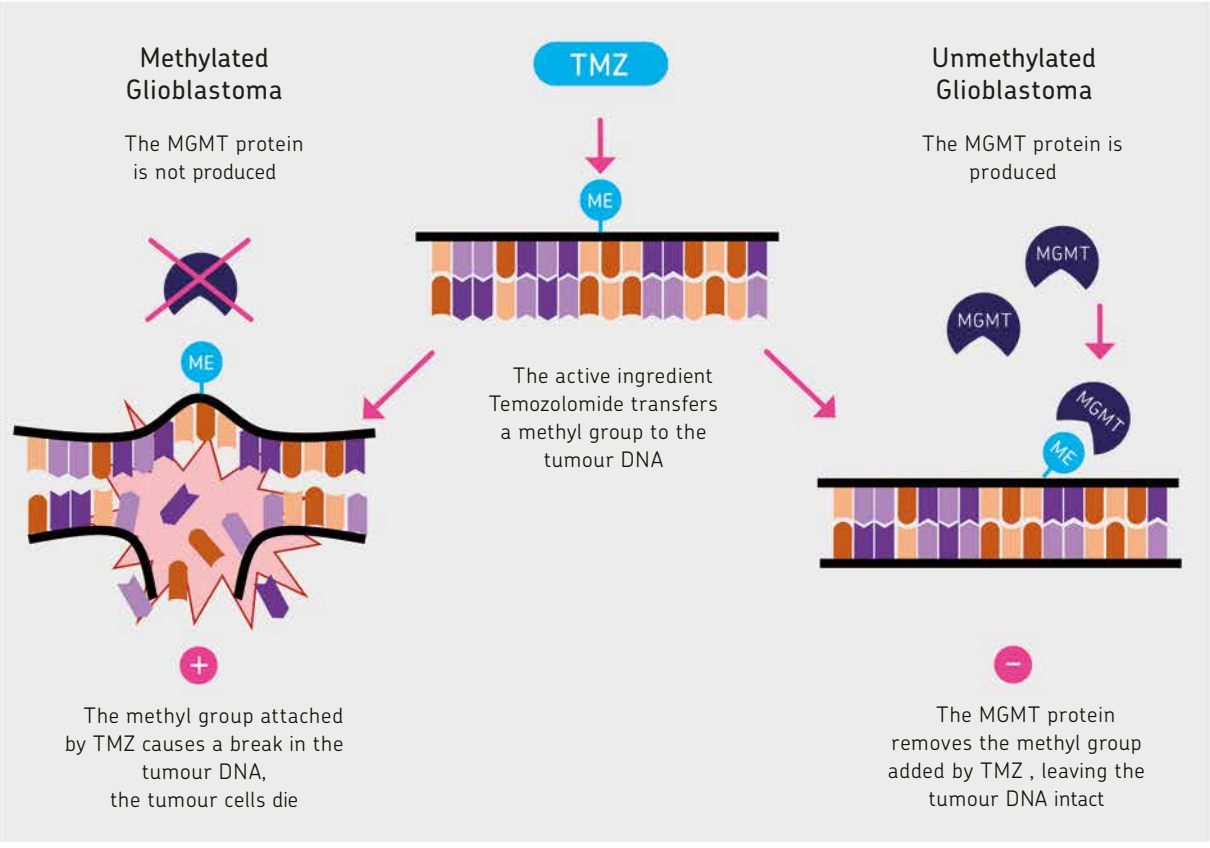
The methylation status and its significance in the treatment of glioblastoma

In order to identify the best treatment method, it is important to understand the tumour in detail. There are roughly two types of glioblastoma: each responds differently to treatment with temozolomide.

Temozolomide (TMZ) is a chemotherapeutic agent marketed under the trade name Temodal that is used in the standard treatment of brain tumours. It works by damaging the DNA of tumour cells, leading to their destruction. TMZ adds a methyl group to specific sites in the tumour DNA, causing breaks in the DNA strands. This damage cannot be repaired by the cells, and the tumour cells die. Healthy cells possess a protective mechanism: the enzyme methylguanine-DNA methyltransferase (MGMT). This mechanism removes these methyl groups and thereby "rescues" the cells from destruction by temozolomide.

The MGMT promoter is a DNA region that controls the production of the MGMT protein. If this promoter is methylated, the production of MGMT is suppressed. Methylation of the promoter therefore disables the tumour cells' protective mechanism, increasing the effectiveness of TMZ. If the promoter is not methylated, the MGMT protein remains active and the tumour cells can protect themselves against the chemotherapeutic agent. The key difference between the two types of glioblastoma thus lies in if and how well this protective mechanism functions.

In patients with glioblastoma, methylation of the MGMT promoter region leads to greater efficacy of TMZ therapy and, consequently, to an improved prognosis.



In MGMT promoter-methylated glioblastomas (left), MGMT cannot be properly formed and the tumour cells die. In MGMT promoter–unmethylated glioblastomas (right), the MGMT protein is sufficiently present, allowing the cancer cells to mount a defence against TMZ, reducing its effectiveness.

The key to defeating cancer lies in individualised therapy adapted over time to the tumour's continuous changes.

Dr. Linde Kampers

Dr Linde Kampers was born in the Netherlands and studied medical biotechnology at Wageningen University. She completed her MSc thesis on vaccine development at a high-containment facility at Merial (now Boehringer Ingelheim). She earned her PhD *summa cum laude* in systems and synthetic biology and now heads the Department of Translational Medicine at the IOZK.

TRANSLATIONAL MEDICINE

The Department of Translational Medicine is dedicated to the continuous optimisation of existing manufacturing processes and the translation of new therapeutic approaches into clinical practice. These developments are based on established procedures described in scientific literature. The department serves as a scientific interface, supporting both the manufacturing unit and the immuno-oncology clinic.

In a paper recently published in *Cancers* entitled *"The Complexity of Malignant Glioma Treatment",* Dr. Linde Kampers analyses the complex interactions between malignant brain tumours – particularly glioblastoma – and their microenvironment. The publication describes five key "hallmarks of cancer":

1. Cancer and glioma stem cells – cells that can easily mutate and so evade treatment
2. Hypoxia – oxygen deficiency within the tumour
3. Metabolic reprogramming – changes in cellular energy metabolism
4. Immunosuppression and inflammation – whereby the immune system is suppressed
5. Neuron-glioma interaction – communication between cancer and brain cells

In the meantime, a sixth hallmark of cancer was included as vital to treat:

6. Gut-brain axis – interaction between the gut microbiome and the nervous system

These characteristics evolve over time as the tumour progresses. Individual differences between patients, tumour microenvironment and tumour structure have far-reaching implications for the effectiveness of therapy.

A deep understanding of tumour biology is deemed essential for effective treatment. Regular review and adjustment of the treatment plan is equally important to ensure optimal individual care.

SCIENTIFIC INFORMATION

The tumour and its microenvironment

When we think of a tumour, we often imagine a dense, solid mass of tissue – something clearly distinct from the rest of the body and seemingly easy to identify. In reality, however, tumours are far more complex. They consist of various cell types with different functions and are interwoven with their healthy surroundings and a network of blood vessels.

A biopsy allows the analysis of the cellular composition of a tumour to be analysed. However, not all cell types are always detected, as only a small number of cells can be taken via biopsy. As a result, treatment is often directed at the most common cell types. Once these have been eliminated, the cell types that were initially less prevalent get the opportunity to grow. The tumour is therefore not only complex but also highly dynamic. For this reason, treatment must be adapted over time..

The tumour as a complex and communicative structure

A tumour is not only composed of different cell types; it also communicates with the surrounding healthy tissue, known as the tumour microenvironment. Cancer cells possess fundamental abilities that healthy cells share: they can form connections and interact with other cells, whether these belong to the tumour or not. The tumour makes strategic use of these connections to influence its microenvironment in a way that protects it from the immune system.

As a result, the body cannot eliminate the tumour as it would other threats, because the tumour actively manipulates its environment to evade the body's defences. This complicates many therapeutic options: if immune cells cannot approach the tumour, they cannot combat it.

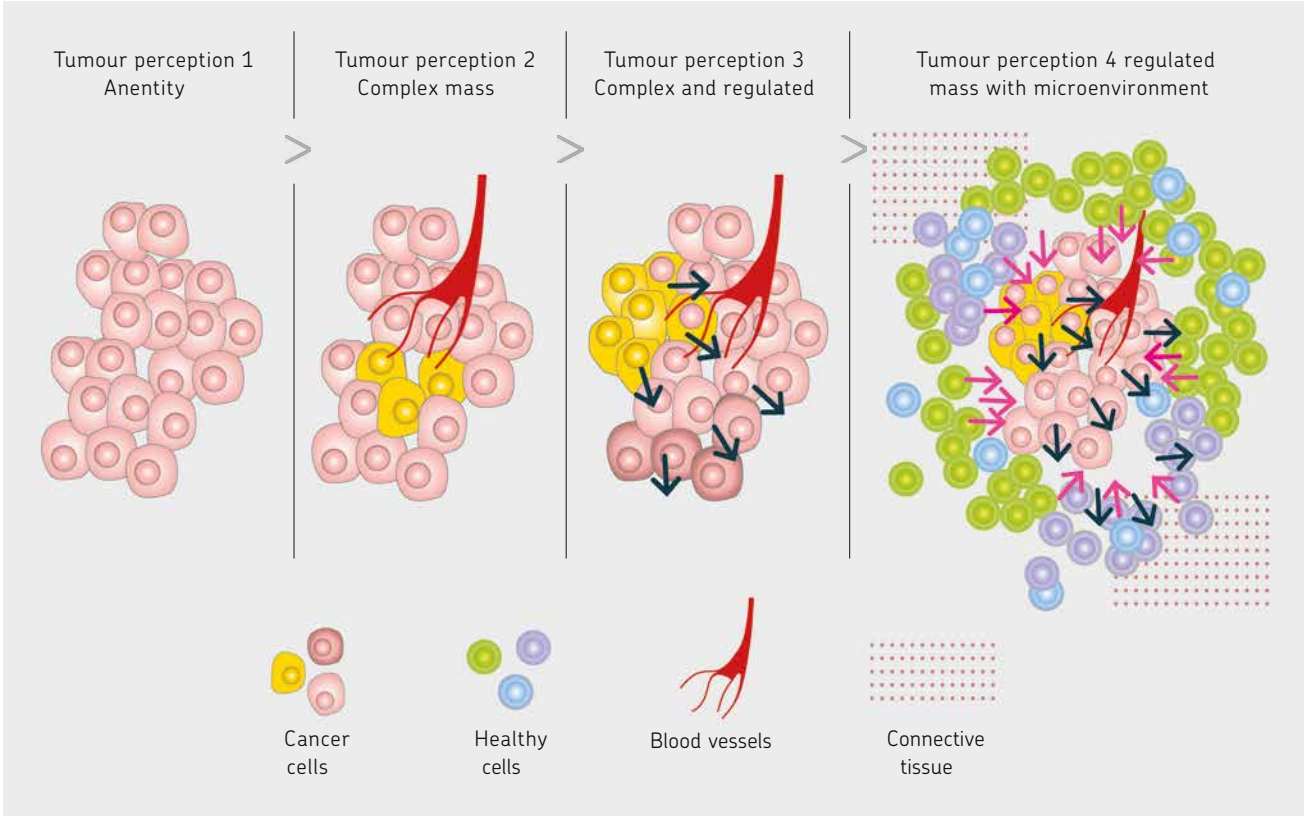
Targeted activation of immune cells

The dendritic cell therapy used at the IOZK provides an answer to this problem. We take immune cells and expose them directly to tumour antigens. In this way, dendritic cells can teach other immune cells precisely what to target, without being influenced by the tumour and its microenvironment.

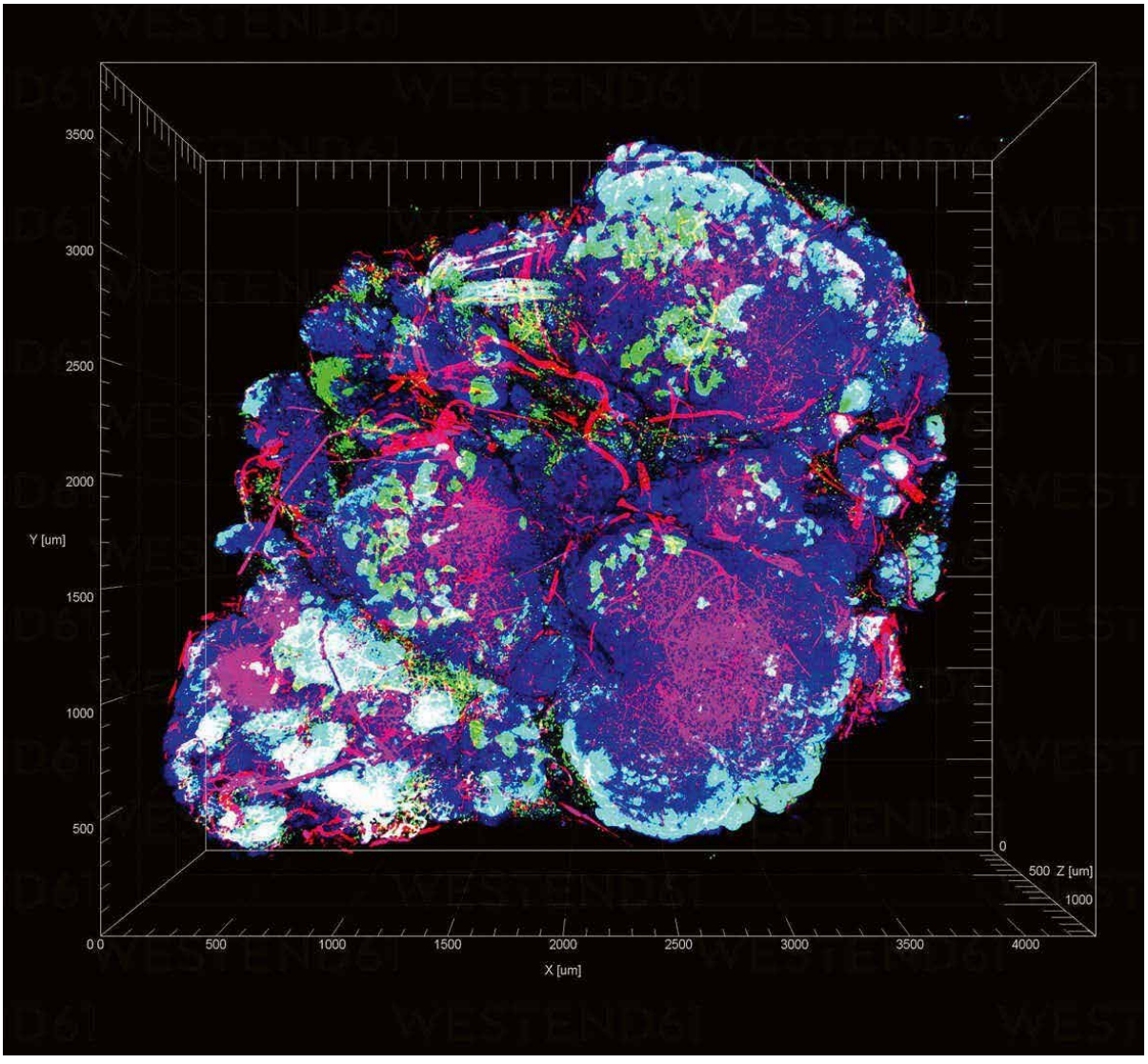
Instead of viewing the tumour as an isolated mass, it should be understood as part of an organ hidden within healthy tissue – a complex network of interacting elements that must be considered and, if necessary, modified over the course of treatment.

SCIENTIFIC INFORMATION

The tumour and its microenvironment



Instead of viewing the tumour as isolated tissue, it should be seen as a complex organ embedded within healthy tissue – an intricate combination of different elements that must be taken into account during the course of therapy. Therapy must be modified where necessary to match the tumor complexity



Transparent tumour tomography visualises the microenvironment of a tumour – shown here using a mouse model of HER2-positive breast cancer, with hypoxic areas of cancer cells highlighted in green.
Image: Westend61 / Connect Images / Callista Image.

Healing occurs where scientific progress and the body's natural self-healing powers go hand in hand.

Dr. Michael Bitar

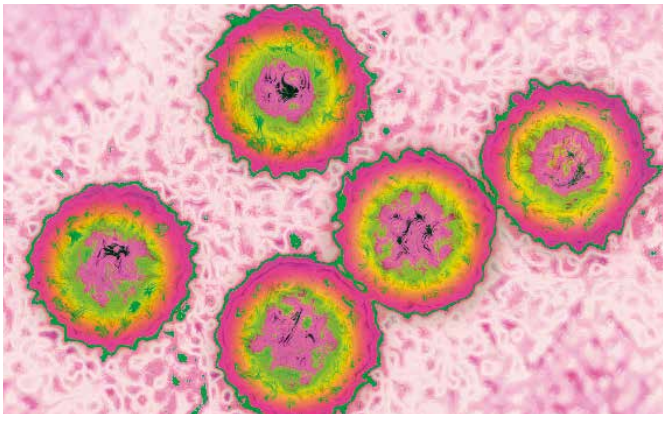
Michael Bitar studied pharmacy and obtained his master's degree in laboratory diagnostics in 2014, followed by a doctorate in clinical immunology in 2020 from the Faculty of Medicine at the University of Leipzig. At the IOZK, he heads the immunodiagnostic laboratory and also serves as a Qualified Person in accordance with GMP guidelines.

OPTIMISATION OF IMMUNO-ONCOLOGICAL THERAPIES

Dr Bitar's current research focuses on the use of human cytomegalovirus-specific T cells to optimise immuno-oncological therapies. Numerous studies suggest that human cytomegalovirus (CMV) can promote tumour progression, making the virus a promising therapeutic target.

The presence of CMV antigens in the tissue of cancer patients makes the virus an attractive target for adoptive cell therapy *(Schuessler et al., 2014; Smith et al., 2020)*. In this approach, CMV-specific memory T cells are used to induce a targeted immune response.

Dr Bitar is working to translate this promising theory into a clinical form of therapy with the aim of opening up new treatment options for cancer patients. If the immune system is specifically made aware of the cytomegalovirus, it can also recognise the tumour and fight it.



By specifically activating the immune response against cytomegalovirus, the aim is to make the glioblastoma visible to the body. If successful, the body's own immune system could control tumour growth in the long term.

Image of cytomegalovirus created from a transmission electron micrograph. Viral diameter approximately 200 nm. Image: BSIP / Universal Images Group via Getty Images.

SCIENTIFIC INFORMATION

About viruses in cancer therapy

Over the past 40 years, the treatment of malignant solid tumours has changed significantly. Although traditional methods such as surgery, chemotherapy and radiation can be effective, they often cause severe side effects and do not always achieve lasting results. Researchers are therefore looking for new, complementary forms of therapy. Virotherapy with oncolytic viruses represents an additional approach in which cancer cells are specifically infected with viruses. This activates the immune system, making the tumour cells immunogenic, allowing them to be recognised and ultimately fought by the immune system. In this way, immunological tolerance is overcome.

Virotherapy with the Newcastle disease virus (NDV)

One of the longest known viruses is the Newcastle disease virus (NDV), which has been used in tumour therapy in humans since the 1960s. Originally applied in veterinary medicine, it is pathogenic to poultry but harmless to humans and does not cause any health problems. Another advantage of NDV is that it does not trigger an intense immune response like human pathogenic viruses. It can therefore be administered systemically at defined intervals and in an immunomodulatory setting.

In the case of human pathogenic viruses such as herpes, adeno, measles, smallpox, reo, coxsackie and polioviruses, inactivating antibodies are formed upon first contact or as a result of previous infections. For this reason, local intratumoural application is preferred.

The aim of oncolytic virotherapy is to selectively destroy tumour cells and make them visible to the immune system for targeted attack.

Cytomegalovirus (CMV) in tumour therapy

Viruses can also be used in other ways, such as the cytomegalovirus, which belongs to the herpesvirus family. After an initial infection – usually unnoticed and often occurring in childhood – the virus remains in the body for life in a dormant state. It is estimated that around 70 to 80 percent of the adult world population carries this virus.

A healthy immune system generally keeps the virus under control, preventing disease. However, if the immune system becomes weakened – for example through chemotherapy or immunosuppression – the virus may reactivate and cause life-threatening complications.

CMV is normally controlled by specialised T cells. In tumour tissue, however, the T-cell response is suppressed, allowing tumour cells to grow undisturbed. This loss of immune competence promotes CMV activation in immunosuppressed tumour tissue. At the same time, CMV contributes to the spread and progression of malignant tumours, particularly in patients with breast, colon, and prostate cancer, as well as glioblastoma. Our working group at the IOZK has developed a method to expand specific cytotoxic CMV T cells outside the body in the laboratory. For this purpose, immune cells are isolated from the blood, "trained" with viral components, and "fed" with defined messenger substances to stimulate their proliferation. The results have been promising: hundreds of millions of functional CMV-specific T cells can be produced that react precisely to the virus – both from healthy individuals and from cancer patients.

The aim of this research is to develop a safe and standardised procedure for producing these cells, with the long-term goal of making the method available to patients under GMP conditions in a clinical setting.

Liquid biopsy is a central component of modern diagnostics – a prerequisite for targeted therapies and improved patient care.

Dr. Simon von Ameln

Simon von Ameln is a biologist specialising in molecular diagnostics and human genetics. He studied biology at the Universities of Aachen and Cologne and subsequently earned his doctorate in human genetics. At the IOZK, he develops liquid biopsy-based diagnostic methods for the clinical implementation of targeted cancer therapies.

LIQUID BIOPSY

At the IOZK, Dr von Ameln has established liquid biopsy as an essential diagnostic method that makes a significant contribution to cancer monitoring and treatment.

By analysing circulating tumour DNA (ctDNA) from a simple blood sample, liquid biopsy offers a minimally invasive alternative to conventional tissue biopsy.

The patient-specific gene panel used at the IOZK focuses on 19 therapy-relevant genes that play a crucial role in determining personalised treatment strategies. Detecting mutations is particularly important for tailoring therapies to the individual needs of patients and for monitoring treatment effectiveness.

One advantage of liquid biopsy is its minimally invasive nature, which allows regular testing without the need for repeated surgical procedures. This approach makes it possible to track genetic changes in the tumour, such as *ESR1* mutations in breast cancer that indicate resistance to aromatase inhibitors. Another example is activating *EGFR* mutations in non-small cell lung cancer, which enable the use of tyrosine kinase inhibitors. With liquid biopsy, physicians can tailor treatment strategies to individual patients, thereby optimising therapeutic outcomes.

Work is currently underway to expand the liquid biopsy panel to include more than 70 genes. This will broaden the possibilities for offering targeted therapies to a greater number of patients. For example, analysing the *BRCA1* and *BRCA2* genes can identify target structures for PARP inhibitors, which are used in the treatment of breast and prostate cancer, among others.

Q&A WITH DR SIMON VON AMELN

What are the advantages of liquid biopsy?

Healthy body cells and tumour cells die continuously, releasing their components – including DNA – into the bloodstream. This cell-free DNA can provide information about both healthy and malignant cells. Liquid biopsy enables the analysis of tumour-derived information from a simple blood sample, which can be repeated as often as needed. In this way, the course of the disease can be continuously monitored, allowing early detection of whether a therapy is effective or whether there are signs of recurrence. Regular monitoring makes it possible to respond quickly and individually to changes – a decisive advantage in personalised cancer medicine.

How does this innovative technology work in the laboratory?

First, cell-free DNA is isolated from the blood plasma, followed by "library prep," a specialised preparation process that makes the DNA ready for sequencing. All the material – from both healthy and cancer cells – is then sequenced intensively, up to 50,000 fold coverage. Within about 24 hours, vast amounts of data are generated and analysed using bioinformatics. The real challenge lies in reliably filtering out the few tumour-associated fragments from the mass of healthy DNA – it's truly like searching for a needle in a haystack.

What is your job?

My responsibilities include interpreting the results and, of course, investigating what the identified genetic changes mean for the patient's clinical situation. Among other things, this involves determining whether a mutation requires an adjustment to therapy – for example, by using a drug developed specifically for that genetic alteration.

This is where the inhibitors come into play...

Exactly. These are specific classes of active substances that are only effective if the corresponding genetic prerequisite is present – that's what makes the therapy so targeted. At the same time, however, the analysis can also reveal resistance mechanisms. Our main goal is to avoid situations in which a drug is ineffective yet still causes side effects. If the molecular target structure is absent, administering the drug would not only fail to help but could also place unnecessary stress on the patient. On a positive note, the number of targeted drugs is steadily increasing, with new discoveries and active substances being added almost every month.

What progress do you expect in this field?

Currently, the focus is still on tumour DNA, as it has been studied most extensively and has already proven its value in clinical practice. However, proteins, RNA and so-called extracellular vesicles – tiny bubbles released by tumour cells that carry important information – also circulate in the blood. These analytes are being intensively researched and could in future be integrated into diagnostics and new therapeutic approaches.

Research into whole-body hyperthermia aims to deepen our understanding of the interactions between temperature and the immune response.

Timo Huber

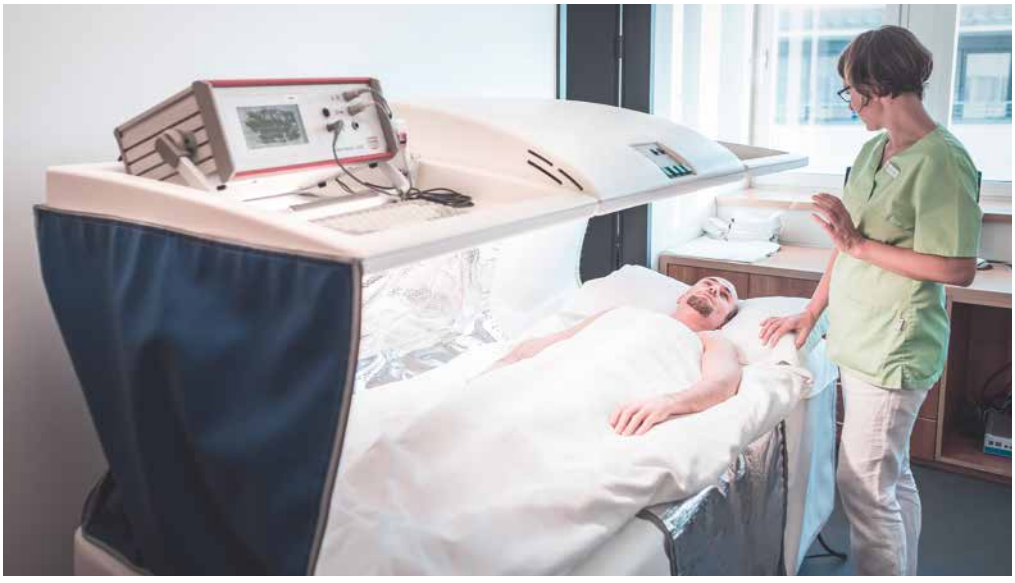
Timo Huber completed his medical degree at the Medical University of Varna in 2021. He has been working at the IOZK since 2022 and specialises in the treatment of oncology patients, with a focus on immuno-oncological therapy approaches, personalised treatment planning, imaging procedures, and the implementation of therapeutic interventions.

HYPERTHERMIA IN IMMUNOTHERAPY

As part of his doctoral thesis, Timo Huber is investigating the immunomodulatory effects of moderate whole-body hyperthermia in close collaboration with the German Sport University Cologne, under the supervision of Prof. Dr Bloch.

To this end, he is conducting a pilot study to investigate the immunological changes induced by a controlled increase in core body temperature. This mechanism, which resembles fever but is specifically triggered without the presence of a pathogen, may have promising effects on the immune response.

The aim of the study is to establish reference values for future research, develop new guidelines for the use of whole-body hyperthermia before or in combination with dendritic cell vaccination, identify immunological patterns in patients who could particularly benefit from heat treatment, and determine factors that may predict individual therapeutic success.



Outpatient application of moderate whole-body hyperthermia

SCIENTIFIC INFORMATION

Hyperthermia as an activating force

Hyperthermia procedures make an important contribution as a key component of immunomodulation. They help activate the immune system, place tumour cells under stress, and destroy them with the support of immune mechanisms.

Over a hundred years ago, physicians observed that some patients overcame cancer after experiencing high-fever infections. In recent years, scientific evidence has increasingly confirmed the impact of "overheating" on the immune system and tumour cells.

Loco-regional modulated electro-hyperthermia

There are now various forms of this treatment used in modern cancer therapy. Loco-regional modulated electro-hyperthermia is applied for local tumour treatment. During the procedure, the patient lies on a water bed with a counter electrode placed underneath, while the affected area is exposed to radio waves of a specific frequency via a probe. This technique takes advantage of the fact that the properties of tumour cells differ from those of healthy cells. Unlike healthy cells, tumour cells are selectively disrupted and damaged by the radio waves, which generate an electric field. Among other effects, this induces the formation of heat shock proteins, enabling the immune system to recognise and attack the tumour cells.

The heating also increases blood flow to the tumour, which can enhance the effectiveness of radiotherapy and/or chemotherapy, as well as antibody, vaccine, or virotherapy.

Passive moderate whole-body hyperthermia

This form of whole-body hyperthermia uses infrared radiation to raise the core body temperature to between 38.5 °C and 40.5 °C, thereby inducing a natural fever response that activates immune cells. The patient lies in a tent-like cabin lined with heat-insulating foil. The radiation creates a layer of warm air around the body that prevents evaporative cooling, further increasing core body temperature. Throughout the procedure, parameters such as body temperature, blood pressure, heart rate, and blood oxygen levels are continuously monitored, followed by a rest phase. A treatment session typically lasts up to four hours. The purpose of the heating is to place the immune system on high alert.

The activating effects of hyperthermia on immune cells can be visualised in the body using modern optical methods. Recent evaluations show favourable effects on prolonged survival of cancer patients in individualised therapy settings.

The activating effects of hyperthermia on immune cells can be visualised in the body using modern imaging techniques. Recent evaluations have shown favourable effects on the long-term survival of cancer patients in individualised therapy settings.

Rejoice in the wonders of nature and the joy of discovery. Nurture your curiosity and your willingness to learn throughout life.

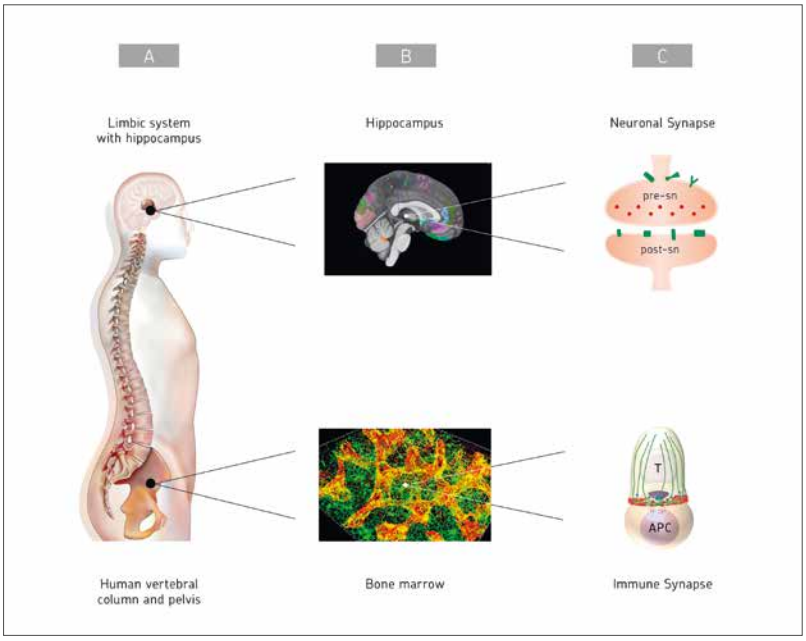
Prof. Dr Volker Schirrmacher

Volker Schirrmacher studied biochemistry in Hamburg and Tübingen and received his doctorate in immunology from the University of Cologne in 1970. After research stays in Stockholm and London, he joined the German Cancer Research Center in Heidelberg as Head of the Division Cellular Immunology from 1976 until 2008. In 1986, he was appointed professor at the University of Heidelberg. He has been the Scientific Director of the IOZK since 2009.

DEVELOPMENTS IN NEURO-ONCOLOGY

Read publication online

Prof. Schirrmacher's current research focuses on comparing the mechanisms of the immune system and the brain. Both systems have evolved in vertebrates over the past 500 million years and are characterised by stability founded on their ability to adapt flexibly to changing environmental conditions. Despite their differences, both possess the ability to learn and to store acquired information in memory.



Both systems rely on communication between specialised cells and have synapses that serve to transmit information. In addition, there are specific interfaces that enable direct interaction between the immune system and the brain, allowing mutual monitoring and providing essential prerequisites for their function in a healthy body.

But what happens when this balance is disturbed? In such cases, diseases may develop that affect both systems, such as multiple sclerosis or brain tumours. These neuroimmunological conditions can be therapeutically influenced through neuroimmunomodulatory approaches. A central area of research in this field is neuro-oncology, which is also being intensively pursued at the IOZK.

Immunotherapy is both a medical innovation and a holistic approach – with the potential to transform structures within the healthcare system

Arnd Slegers, lic.rer.pol. CFA

Arnd Slegers is responsible for the financial affairs of the foundation. He has more than 20 years of international experience in financial management. In addition, he is active in research, focusing on the field of health economics.

Shaping a forward-looking health policy

The IOZK Foundation is committed to researching immunological therapy options and ensuring their timely implementation in patient care – including addressing health economic aspects related to the design of future healthcare measures..

One major challenge in oncological care is the slow transfer of scientific findings into clinical practice. Therapies whose effectiveness has been scientifically proven often enter standard care only after a trial phase of 10 to 15 years – rarely sooner, and often later. The development of new cancer therapies has so far been too heavily focused on drug-based approaches. Holistic strategies – such as combination therapies, digital health solutions, and lifestyle interventions – are not sufficiently considered in approval procedures and clinical studies. In terms of health policy frameworks, there is also a lack of structured economic discussion on how incentive systems and financing models can be designed to achieve better treatment outcomes for cancer patients. Current health technology assessment (HTA) processes represent a significant bottleneck for the introduction of innovative therapies.

Immunotherapy offers great potential: as an individualised treatment tailored to the immune system, it integrates molecular tumour profiles, lifestyle factors, and the microbiome. It can also serve as a model for new approaches in healthcare. It is important to examine whether immunotherapies with long-lasting effects are more economically sustainable than short-term standard medications. A key factor in accelerating innovation is a strong, interoperable data infrastructure. The IOZK Foundation therefore sees immunotherapy not only as a medical innovation but also as a catalyst for structural transformation in the healthcare system.

immuno therapy insights

Nearly every Monday, the IOZK team meets under the motto “Monday Knowledge” to discuss and explore research topics in depth – an important opportunity for continued learning and professional exchange. The topics on this page represent only a small selection of the events that took place at the IOZK between January 2023 and December 2024.

Are CARs the New Perspective in Cancer Therapy?

Targeting Regulated Cell Death

Cytokine Measurement by Flow Cytometry

Bone marrow-derived Adoptive T cell Therapy

PARP Inhibitors: Mechanism and Resistance

Tunable Resistive Pulse Sensing Technology

Genetically Engineered T cells

Natural Killer Cell-mediated Cytotoxicity

Peptide Vaccination Overview

Individualized vs. Population-based Medicine

Temporal Tumor Microenvironment Treatment

Anti-inflammatory Diet against Cancer

Liquid Biopsy: NGS&UMIs

Survivin qPCR&Interlaboatory tests

Gut Microbiome and Therapy

Cannabis in Oncology

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Stiftung für immunologisch-onkologische Forschung
IOZK gemeinnützige GmbH

Hohenstaufenring 30–32
50674 Cologne, Germany

Phone: +49 (0)221 420 399 90

E-Mail: info@iozk-stiftung.org

Donations account:
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Immun-Onkologische Forschung

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