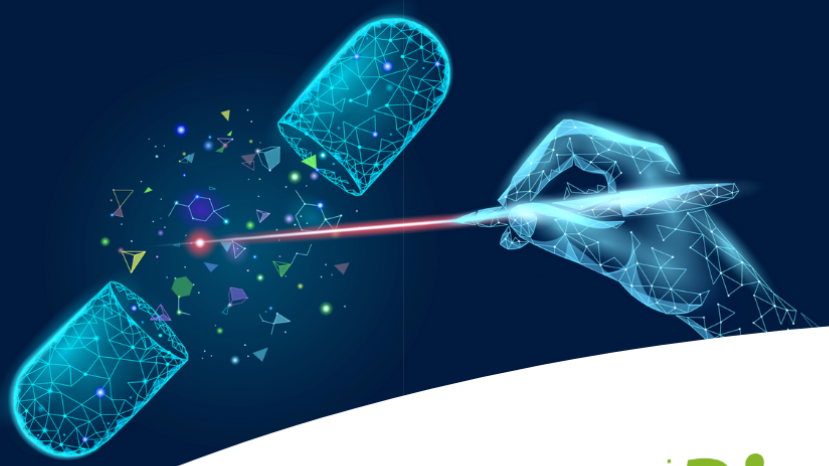

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BioRN Annual Conference 2021

Novel therapeutics: Biotechnology leading the way into the future

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Programme

08:30	Registration & Dial-in
09:00	**Welcome & Introduction**
09:15	Keynote: "Next generation Immunotherapy" **Holger Kissel, BioNTech SE, Vice President Business Alliances**
09:50	**Dirk Grimm, University of Heidelberg, Professor and Group Leader** "The fast and the curious – high-throughput in vitro and in vivo interrogation of AAV capsid libraries" **Christiane Kofink, Boehringer Ingelheim RCV GmbH & Co KG, Vienna, Principal Scientist** "The discovery of the first selective and orally bioavailable SMARCA2 degrader BI-0284"
10:30	Break & Poster Session
11:00	**Ivan Đikić, Goethe University Frankfurt, Professor** "PROXIDRUGS: new therapeutic options for numerous diseases" **Claus Kremoser, WMT Therapeutics AG, Co-Founder and Chairman of the Board** "Targeting Cancer Metabolism to foster Immune Attack on Solid Tumours" **Michael Zimmermann, EMBL, Group Leader** "Identifying microbiome contributions to drug metabolism and toxicity"
12:00	Lunch, Networking & Poster Session

13:00 – 14:00 **Parallel Workshops**		
"Futureproofing your Process Development" by Cytiva. You will learn about novel downstream solutions tailored for ATMPs and the impact on Process Development. Plus, how Mechanistic modelling can Improve process understanding and performance for novel therapies	**"Innovative technologies and statistical methods for successful drug development" by Cytel.** Explore technological solutions which enables cross-functional teams to optimize speed, cost and probability of success in drug development. And discover which Bayesian approaches can be used from preclinical to post-authorization to support orphan drug development.	**"Emerging Biotechnology Venture Capital" by MVentures** Discuss the state of the Biotechnology funding and investing landscape and explore how the recent pandemic has boosted investor interest in innovative biotech startups and driven the sector beyond its already strong projections.

14:10	Keynote: "Development of Bulevirtide/Hepcludex®, the first approved medication to treat chronic Hepatitis D infections." **Stephan Urban, Heidelberg University Hospital, Head of the Translational Virology Unit**
14:40	**Thomas Hanke, Evotec, EVP Head of Academic Partnerships** "Building BRIDGEs across the Rhine, Main, Neckar and other rivers"
15:00	**Happy Hour & Speed-Networking**
17:00	Closing

Welcome

Dear BioRN Members and Friends,

On behalf of the BioRN Cluster, we would like to welcome you to the BioRN Annual Conference 2021.

With the title “Novel Therapeutics: Biotechnology leading the way into the future”, this year’s Annual Conference focuses on new biotechnology-driven therapeutic approaches and partnership models for successful drug development. The biotech industry has recently demonstrated its full potential, with its crucial role for vaccine and therapies development. In addition, collaboration among industry, academia, regulatory, clinician, patient communities, and investment are essential to bring these solutions to the patients.

A big ‘Thank You’ goes to all speakers, who accepted our invitation to share their exciting results and are at the heart of the meeting, as well as to the workshops organisers for addressing crucial topics in the field of drug development. We also would like to thank our sponsors for their dedication and financial support which allowed us to organize an outstanding program.

This year’s conference is also the occasion to celebrate the 25th Anniversary of BioRN. On the 21st of October 1996, the association BioRegion Rhein-Neckar-Dreieck e.V., was founded by the City of Heidelberg, IHK, Arbeitskreis Rhein-Neckar-Dreieick e.V. (now Zukunft Metropolregion Rhein-Neckar e.V.), DKFZ, Heidelberg University, EMBL Heidelberg, Boehringer Mannheim (now Roche Diagnostics), Knoll (now AbbVie), Merck, BASF, Orpegen (now Celonic), Biomeva (now AGC Biologics) and (Schitag-)Ernst & Young.
This has been the founding stone of today’s BioRN Cluster.

But now: let’s enjoy the BioRN Annual Conference 2021 and catch up in person (& digitally) through this great networking opportunity!

To the past and next 25 Years of BioRN!

Gitte Neubauer	**Michael Boutros**	**Julia Schaft**
Chair	Vice Chair	Managing Director
BioRN	BioRN	BioRN

Moderation

Julia Schaft

Managing Director
BioRN Network e.V., Germany

After completing her PhD in molecular and developmental biology at the University of Giessen and the European Molecular Biology Laboratory in Heidelberg (Germany) in 2002, Julia continued her scientific research on the differentiation of human embryonic stem cells at Genea Ltd in Sydney Australia, an IVF clinic with a strong focus on research and innovation in the IVF and human stem cell field. Julia then took over leadership responsibilities in scientific project management and the supervision of all of Genea's embryo research licences. In 2014 Julia relocated back to Germany and took on an administrative role at the European Molecular Biology Laboratory in Heidelberg (Germany) building up the philanthropic fundraising program, the Friends of EMBL. She then joined BioRN as a project manager for international R&D and translational initiatives in the life sciences sector. Since October 2018 Julia is Managing Director of BioRN where she is also taking on BioRN strategic business development and partnering responsibilities.

Welcome and Wrap-up

Gitte Neubauer

Chair
BioRN Network e.V., Germany

Gitte Neubauer is a scientific founder of Cellzome. She graduated from Imperial College, London in Biochemistry and completed her PhD thesis with Matthias Mann at the European Molecular Biology Laboratory. After the acquisition of Cellzome by GSK in May 2012, Gitte Neubauer took over leadership of the company. She is Director of the Board of BioPro Baden-Württemberg, Director of the Board of the Centre for European Economic Research (Mannheim), a member of the industrial advisory board of the Biotechnology faculty of the University of Applied Sciences in Mannheim and member of the BioRN board since 2014 and chair of the BioRN executive board since 2018.

Michael Boutros

Vice Chair
BioRN Network e.V., Germany

Michael Boutros is the Head of the Division Signaling and Functional Genomics and Coordinator of the Functional and Structural Genomics Program at the German Cancer Research Center (DKFZ). He is also Professor for Cell and Molecular Biology at Heidelberg University. After his PhD at the European Molecular Biology Laboratory (EMBL), he joined Harvard Medical School in Boston as a postdoctoral fellow. In 2003, he started his independent group at the DKFZ in Heidelberg funded by an Emmy-Noether Grant of the German Research Foundation (DFG). He was also supported by the EMBO Young Investigator Program. He later became Head of Division and full Professor at Heidelberg University. Michael Boutros' research interests include functional genomic approaches to understand the regulation of cellular signaling in normal and cancer cells. His laboratory further develops and applies high-throughput screening and multi-omic data integration methodologies to dissect genetic networks and genotype-specific vulnerabilities in cancer. He is supported by the European Research Council (ERC) and is an elected member of the European Molecular Biology Organisation (EMBO). He is a member of the BioRN executive board since 2018.

Opening Keynote

Holger Kissel

Vice President Business Alliances, BioNTech SE

Holger Kissel joined BioNTech in 2013. Prior to joining BioNTech he worked at Artemis Pharmaceuticals (now Taconic) in Cologne, Germany, in various project management and business development roles, building a portfolio of preclinical oncology services for the company. After joining BioNTech he was driving the company's business development strategy, building several partnerships with pharmaceutical and biotech companies, as well as academic institutions. In his role as Vice President Business Alliances he is heading BioNTech's alliance management activities. Holger has an undergraduate degree from the University of Hamburg, Germany, conducted his PhD thesis at the Memorial Sloan Kettering Cancer Center, NY and postdoctoral studies at the Rockefeller University, NY.

Next generation Immunotherapy

The recent convergence of breakthrough technologies in life sciences has enabled innovative concepts to address the immunobiology of cancer at its core. One of these breakthroughs has been the establishment of cancer immunotherapy in the armamentarium of cancer treatments. Another has been the emerging progress towards individualized medicine. Technologies such as next-generation sequencing, or NGS, have confirmed beyond doubt the problematic diversity of tumors on the inter-patient level. At the same time, NGS enables fast, cost-efficient and precise high-resolution mapping of each patient's individual disease.

The application of these breakthrough technologies and the combination of innovative immuno-oncology products has the potential to change drug development and profoundly alter the oncology treatment landscape. The ability to translate a comprehensive molecular map of an individual tumor into treatment decisions, and make individually tailored therapeutics available, have become the focus of the next generation of cancer therapy.

The talk will focus on BioNTech's approach towards individualized cancer therapy and will provide an overview of BioNTech cancer therapy portfolio.

Plenary

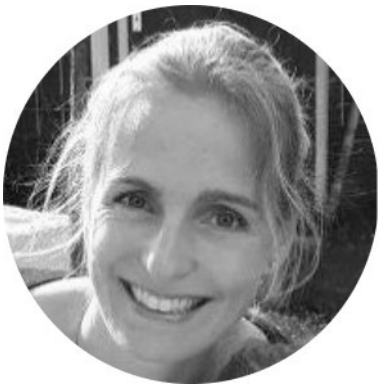
Dirk Grimm

Professor / Group leader, University of Heidelberg, Medical Faculty, Department of Infectious Diseases/Virology

For over 25 years, Prof. Grimm has devoted his scientific career to the design, engineering and optimization of recombinant Adeno-associated viral (AAV) vectors for safe, efficient and targeted human gene therapy. Major contributions include the pioneering development of a helper-free 2-plasmid strategy for AAV vector production and comparisons of AAV isolates as vectors for human gene delivery. In 2008, he introduced DNA shuffling technology into the AAV field as a novel means to select tissue-specific viral vectors, culminating in the isolation of the first chimeric capsid, AAV-DJ. For the past 10 years, Prof. Grimm's lab has particularly focused on the design and use of synthetic AAV vectors for in vitro and in vivo delivery of small RNAs as triggers of DNA engineering (CRISPR) and gene knockdown (RNAi) in mammalian cells, targeting viral pathogens including HIV-1 and SARS-CoV-2. Recently, his team has morover implemented and validated novel wet- and dry-lab technology pipelines for the creation of complex AAV capsid libraries and for their massively parallel in vitro or in vivo screening, enabling the latest identification of an original AAV capsid with unprecedented specificity for the musculature and hence significant potential for muscle gene therapy.

The fast and the curious – high-throughput in vitro and in vivo interrogation of AAV capsid libraries

Adeno-associated virus (AAV) forms the basis for one of the most promising, most versatile and most successful recombinant viral vectors for therapeutic human gene delivery. A major reason for the attractiveness of therapeutics based on AAV vectors is the ability to engineer the viral capsid in order to create new cell type-specificities, to reduce antibody reactivity and/or to enhance the efficiency of gene transfer. To this end, a large variety of capsid engineering technologies have been devised over the past two decades and have been extensively validated in cultured cells or in animals of different species. This presentation will first give a short overview over a selection of key AAV capsid engineering technologies, before focusing on latest developments that now enable the high-throughput interrogation of the resulting complex AAV libraries in vitro and in vivo. This includes our establishment of a robust screening platform based on pre-arrayed, pan-AAV peptide display libraries for rapid capsid identification in cultured cells, as well as our most recent implementation of a combined DNA/RNA barcoding methodology that facilitates the massively parallel screening of wild-type and synthetic AAV capsid variants in all major organs and cell types of animals. To exemplify the power and potential of these technologies, data will be presented on a peptide-displaying AAV9 variant called AAVMYO that displays unprecedented efficiency and specificity of muscle gene transfer in adult mice following systemic administration, including skeletal muscle, heart and diaphragm. While this capsid holds particular potential for muscle gene therapy in humans, the techniques and pipelines presented here are compatible with any target or species, and thus promise to accelerate the isolation of ideal AAV vectors for a wide range of human gene therapy applications.



Christiane Kofink

Principal Scientist, Boehringer-Ingelheim RCV GmbH & Co KG, Vienna

2004 - 2006: PhD in organic Chemistry
Ludwig-Maximilians Universität Munich, Group: Prof. Paul Knochel
"Transition metal catalyzed cross coupling reactions using functionalized organomagnesium reagents"
2007 - 2008: Postdoctoral Research Assistant
University of California Irvine, Group: Prof. Larry E. Overman
"Asymmetric Construction of Rings A-D of Daphnicyclidin-Type Alkaloids"
2008 – present: Principal Scientist – Research Laboratory Head in Medicinal Chemistry
Boehringer – Ingelheim RCV & CoKG, Vienna
Department: Oncology

- Leading oncology projects on PPIs and protein degradation

The discovery of the first selective and orally bioavailable SMARCA2 degrader BI-0284

Targeting subunits of BAF/PBAF chromatin remodeling complexes has been proposed as a therapeutic approach to exploit cancer vulnerabilities. Protein Targeting Chimeras (PROTACs) of the BAF ATPase subunits SMARCA2 and SMARCA4 using a bromodomain ligand linked to an E3 ubiquitin ligase VHL recruitment binder were investigated. Herein, we describe how we achieved PROTAC induced selective degradation of SMARCA2 over SMARCA4 supported by ternary x-ray structures. The structure of BI-0284, a selective and orally bioavailable SMARCA2 PROTAC showing robust in vivo target modulation in mice will be disclosed for the first time.

Ivan Đikić

Director and Professor, Institute of Biochemistry II, Goethe University Frankfurt Medical Faculty

Ivan Đikić is Professor of biochemistry at Goethe University Frankfurt and a Fellow of Max Planck Institute for Biophysics. He leads a multidisciplinary team of students and postdoctoral fellows to study molecular principles of life and explore pathological alterations in human diseases such as cancer, neurodegeneration and infection. He provided structural and molecular basis for insights of how ubiquitin signaling controls diverse cellular functions and how cells maintain homeostasis by digesting organelles or aggregated proteins of pathogens via selective autophagy pathways.
Ivan is an elected member of the American Academy of Arts and Sciences, the German National Academy of Sciences Leopoldina, the European Molecular Biology Organization and the Academia Europaea. He is also a senior editor of eLife and serves on the editorial boards of numerous renowned scientific journals. His scientific achievements were honored with multiple awards, amongst them the Gottfried Wilhelm Leibniz Prize, Ernst Jung Prize for Medicine, the AACR Award for Outstanding Achievement in Cancer Research, and the Ernst Jung Prize for Medicine. He won two of the prestigious European Research Council (ERC) Advanced Grants.

PROXIDRUGS: new therapeutic options for numerous diseases

The new class of proximity-inducing drugs allows for the degradation of disease-relevant target structures (proteins, nucleic acids, organelles) thus opening up new therapeutic options in numerous diseases. The respective drugs usually are small, bifunctional molecules which direct target structures straight towards the cellular waste system. Whilst 80% of proteins are still deemed to be undruggable, a large proportion of these is thought to be targetable by the new strategy. Together with the Fraunhofer Institute for Translational Medicine and Pharmacology (ITMP), Technical University Darmstadt and several other academic as well as industrial partners, Goethe University Frankfurt has established the BMBF-funded Cluster4Future PROXIDRUGS. Key piece of the Cluster is a technology platform for drug discovery and preclinical development. The Cluster aims at systematically improving the new class of proxidrugs and establishing a toolbox that can be quickly adapted to different target structures and disease settings. The Cluster comprises ten different research projects focusing on cutting-edge challenges, such as the development of novel degradation strategies, the solubility enhancement of target proteins, the validation of molecular degraders in neuronal models, the creation of proximity-based agents against bacterial and viral pathogens, of novel E3 ligands and structured linkers and the development of versatile assays, screening and molecular profiling platforms for the identification and characterization of molecular degraders; and targeted trapping of drugs in cells or cell compartments. The research projects are accompanied by an integrative roof project testing and implementing efficient innovation and data processing structures. The Cluster will especially benefit from the knowhow of all partners, including several big pharma companies, and from the facilities and available screening libraries at the newly established Frankfurt Center for Innovation and Technologies and at the Fraunhofer ITMP.

Claus Kremoser

Founder and Chairman of the Board, WM Therapeutics AG

Dr. Kremoser studied biochemistry at the Universities of Tübingen and Munich. He performed his PhD thesis work at the Max-Planck-Institute for Developmental Neurobiology in Tübingen in the highly recognized group of Prof. Dr. Friedrich Bonhoeffer. Part of his work was published in "Cell" and "EMBO Journal". To complement his scientific training with hands-on business experience, he became a founding member of the German Life Science practice of Ernst & Young. During this 2 years period as a consultant at EY he organized and contributed to the European and initiated and wrote major parts of the German EY biotech report. In 1998 he joined the startup bioinformatics company LION bioscience to become its VP Corporate Development. In this position he was instrumental in closing the 100 M Euro BAYER-LION bioinformatics alliance and in preparing LION for its 220 M € IPO in 2000. In 2002, he co-founded Phenex AG together with Thomas Hoffmann and five other cofounders. Dr. Kremoser became CEO from Phenex´ inception on and also coordinated internal drug discovery efforts. In 2014, he closed a 465 M USD deal with Gilead by selling all of the company´s FXR assets including the clinical candidate Cilofexor which is now in phase 3 clinical development. In 2020, Dr. Kremoser, together with Yves Guillermet and 8 other confounders started WMT AG as a small molecule oncology-focussed drug discovery company.

Targeting Cancer Metabolism to foster Immune Attack on Solid Tumors

It is long known and well established that most cancer cells and most tumors in vivo employ a certain form of metabolism, called "Warburg" metabolism after its discoverer Otto Warburg. Warburg metabolism means the shutdown of oxidative phosphorylation to favour glycolysis (or alternatively glutaminolysis), the uptake of glucose and the production of lactate for the generation of ATP. Warburg initially assumed that it is the limited oxygen supply that force cancer cells into this extreme metabolic niche but in fact it turned out that cancer cells pursue these metabolic routes even under normal oxygen supply. Warburg metabolism is not only limited to cancer cells but is actively engaged by nearly all proliferating cell types because it satisfies their demand for the de novo synthesis of nucleotides and lipids. This is why targeting the Warburg metabolism for cancer therapy is a double-edged sword. As with classical chemotherapeutic regimen, inhibiting expanding cells based on their proliferative demands will eradicate tumours and those immune cells that should be stimulated for an anti-cancer immune attack equally alike. WMT scientists have discovered a drug candidate which downregulates cancer metabolism in cell culture and in vivo but does not kill cells within a wide therapeutic window. From single digit nanomolar to micromolar concentrations cells turn down their ATP and lactate production without dying. This results in a striking stimulation of immune surveillance of solid cancers in that e.g. 4T1 solid tumours in syngeneic mouse models, which are largely "immune deserts", see a massive infiltration of Natural Killer and T-cells resulting in a comprehensive immune attack on the tumour. This is a highly desired effect since it allows to combine this new approach with checkpoint inhibitor treatment which largely fails in solid tumours because of the immune shielding effects of Warburg metabolism.

Michael Zimmermann

Group Leader, European Molecular Biology Laboratory (EMBL) Heidelberg

Michael Zimmermann is a group leader at the European Molecular Biology Laboratory (EMBL) in Heidelberg. Michael received his Bachelor's degree in Pharmaceutical Sciences from Basel University and his Master's degree in Biotechnology from the Ecole Supérieure de Biotechnologie (ESBS) in Strasbourg. After research internships at Harvard University and at UCSF, he performed his PhD work at ETH Zurich in metabolomics and Systems Biology and he pursued his postdoctoral training at Yale University to investigate metabolic host-microbiome interactions. His research group at EMBL employs bacterial genetics, metabolomics, gnotobiotic mouse work, and mathematical modeling to systematically map microbial drug transformations and to separate microbial and host drug metabolism. Among several honors and scholarships, Michael was awarded the Daimler Benz Scholarship, Agilent's Steve Berger Award and the 2021 FEBS Anniversary Prize.

Identifying microbiome contributions to drug metabolism and toxicity

Individuals vary widely in their drug responses, which can be dangerous and expensive due to significant treatment delays and adverse effects. Growing evidence implicates the gut microbiome in this variability, however the molecular mechanisms remain mostly unknown. Using antiviral nucleoside analogues and clonazepam as examples, we recently reported experimental and computational approaches to separate host and gut microbiota contributions to drug metabolism. The resulting pharmacokinetic models identified measurable physiological, microbial and chemical parameters that dictate host and microbiome contributions to the metabolism of xenobiotics. To systematically map the drug metabolizing capacity of the gut microbiota and assess its potential contribution to drug metabolism, we further measured the ability of 76 diverse human gut bacteria to metabolize each of 271 oral drugs. We found that two thirds of these drugs are chemically modified by at least one of the tested microbes. Through combination of high-throughput bacterial genetics with mass spectrometry, we systematically identified drug-metabolizing microbial enzymes. These proteins better explain the drug-metabolizing capacity of bacterial strains than their phylogenetic classification. We further demonstrate that the abundance of homologs of these proteins predict the capacity of complete human gut communities to metabolize the targeted drugs. These causal links between microbiota gene content and metabolic activities connect inter-individual microbiome variability to interpersonal differences in drug metabolism, which has translatable potential on medical therapy and drug development across multiple disease indications.

Thomas Hanke

Executive Vice President - Head of Academic Partnerships, Evotec

At Evotec, Thomas is responsible for a growing portfolio of strategic academic partnerships, pre-seed incubators and investments into spin-out companies.
From 2013 to 2016, Thomas was overseeing Evotec's drug discovery portfolio in inflammation and immuno-oncology, generating and building on high-value, performance based alliances with academia and pharma.
From 2007 to 2013, Thomas was Sourcing Director at the Biopharmaceuticals Research Unit of Novo Nordisk where he identified, evaluated and initiated global partnering opportunities for first-in-class therapeutics within haemophilia, autoimmune/inflammatory diseases, growth disorders and protein technologies.
From 2000 to 2007, Thomas was co-founder and Chief Scientific Officer of TeGenero, heading its R&D efforts to develop first-in-class immunomodulatory monoclonal antibodies.
Until 2000, Thomas was group leader and Assistant Professor for Immunobiology at the University of Würzburg following a PostDoc at the University of California in Berkeley where he studied the immune response of lymphocytes. Thomas received his Ph.D. in Biology from the University of Würzburg in 1995.
Today, Thomas has 25+ years of experience in research and drug discovery across academia, biotech and pharma. Fostering innovation and continuous improvement, Thomas manages cross-functional teams as an assessor / developer, sets directions and builds trust in companies.

Building BRIDGEs across the Rhine, Main, Neckar and other rivers

Biotech business models are rapidly evolving to cope inter alia with challenges in accessing first-in-class science, collaborating successfully with academia and securing funding for translational research and drug discovery. Evotec is a global drug discovery company with a full range of technology platforms from target validation to late-stage preclinical development across therapeutic areas and formats. To improve quality and speed of innovation at the interphase of academia and biotech, Evotec developed a novel risk-share paradigm of collaboration with academic centers of excellence –termed BRIDGES- to significantly shorten the time from drug discovery concepts to commercially viable preclinical projects. Today, Evotec has successfully implemented eight BRIDGES jointly accelerating more than 60 first-in-class therapeutics projects across Europe and North America. beLAB2122 is the first BRIDGE in Germany.

Closing Keynote

Stephan Urban

Head of the Translational Virology Unit, Department of Infectious Diseases, Molecular Virology at Heidelberg University Hospital

Professor Stephan Urban is the Head of the Translational Virology unit at the Department of Infectious Diseases at Heidelberg University Hospital. Between 2008 and 2012 he was Coordinator of the BMBF-network "Innovative Therapies" and is now coordinating the Hepatitis D Cure project within the German Centre of infectious diseases (DZIF). He completed a Diploma in Biochemistry at the University of Tübingen and received his Ph.D. under Prof. Dr. Peter Hans Hofschneider at the Max-Planck-Institut für Biochemie in Martinsried. After postdoctoral research at the Centre for Molecular Biology (ZMBH) at the Heidelberg University with Prof. Dr. Heinz Schaller, he received an independent group leader position at the University Hospital Heidelberg and was awarded the first DZIF full professorship for Translational Virology associated with the Department of Molecular Virology.
Professor Urban's research interests include molecular mechanisms of Hepatitis B- and D Virus/host interactions with a focus on early and late events of viral infections, identification of hepadnaviral receptors and structural analyses of virus receptor interactions, development of novel cell culture systems and animal models for HBV and HDV, clinical development of entry inhibitors (Bulevirtide/Hepcludex) for HBV and HDV infection, innate Immune response on HBV and HDV viruses and the development of hepatotropic drugs for the therapy of liver diseases. Professor Urban has published in numerous peer reviewed journals on Hepatitis B, C and D. He is the recipient of the Pettenkofer Price by the Pettenkofer Foundation and was awarded with the 1. DZIF Research Award in 2014.

Development of Bulevirtide/Hepcludex®, the first approved medication to treat chronic Hepatitis D infections.

According to the WHO, about 257 million people are chronically infected with the human Hepatitis B virus (HBV). At least 12 Million people are co-infected with the human Hepatitis Delta Virus (HDV), the causative agent of the most severe form of viral liver disease. Since 2002 my research group is investigating the entry mechanism of Hepatitis B and D viruses into hepatocytes. In the course of our studies, we and others identified the commonly used cellular receptor for both viruses and characterized a highly potent peptidic entry inhibitor that blocks the establishment of infection. This first in class molecule was developed into clinics here at the university hospital Heidelberg. The drug, at that time called Myrcludex B, (now Hepcludex/bulevirtide) successfully passed two pivotal phase II clinical trials in chronically infected HDV patients, one as monotherapy and one in combination with IFN. Hepcludex/bulevirtide has been clinically developed in close collaboration with the German Biotech company Myr-Pharmaceuticals (Bad Homburg), which licensed the drug already early during development and cooperated with us during the preclinical and the clinical phases. Based on the very successful outcomes of both phase II studies regarding safety and efficacy, Hepcludex/bulevirtide received conditionally approved in July 2020 within the "orphan drug" and

"prime eligibility" programs of the European Medicines Agency (EMA). It is available to patients as the first drug to treat chronic Hepatitis D since September 2020 in Germany, France and Austria. On December 10th 2020 Gilead-Sciences acquired Myr-Pharmaceuticals and further develop the drug on a broad international basis.
This development raises the justified hope, that efficient treatment for millions of HDV/HBV co-infected patients world-wide becomes a realistic option in the near future.

Parallel Workshops

“Future-proofing your Process Development” by cytiva

You will learn about novel downstream solutions tailored for ATMPs and the impact on Process Development. Plus, how Mechanistic modelling can Improve process understanding and performance for novel therapies.

Peter Guterstam - Product Manager, Next Generation Resins & Technologies, Cytiva

Peter is Global Product Manager at Cytiva with responsibility for products tailored for downstream processing of Advanced Therapy Medicinal Products. He is based in Uppsala, Sweden. Peter earned is PhD in Neurochemistry from Stockholm University in 2009 based in research regarding delivery of oligo-therapeutics utilizing nanoparticles and conjugation to cell-penetrating peptides.

Peter has been with Cytiva since 2003, primarily working in roles associated with oligonucleotide synthesis and purification. Since Cytiva’s acquisition of Puridify, Peter has the business responsibility to develop products based on the Fibro technology to complement Cytiva’s portfolio of chromatography resins. He has a passion to develop Cytiva’s downstream product portfolio and generate tailored solutions for the manufacture of Advanced Therapy Medicinal Products.

Nick Whitelock - Sales Specialist at GoSilico, part of Cytiva

Nick uses his extensive background in DSP development and operations, from microscale to pilot-scale processing of mAbs, fabs and viral vectors to understand the issues facing the industry. His wide expertise in simulating biopharmaceuticals, including developing structural, economic and mechanistic models, helps him bring sophisticated mathematical solutions to bioprocesses. He has studied for a BSc in Chemistry with Pharmacology, a scholarship-funded MRes in Structural Biology and an EngD in Biopharmaceutical Process Development.

Nick lives to accelerate the adoption of mechanistic model-based process development to enable more efficient, robust and scalable processes across the industry, and therefore more accessible medicines.

"Innovative technologies and statistical methods for successful drug development" by Cytel

Learn from Cytel experts Ursula Garczarek and Martin Kappler on how innovative technology and statistical methods help towards successful drug development. Martin will discuss challenges in the race to bring a new drug into the market with the various constraints and present a technological solution which enables cross-functional teams to explore expansive design space and identify options which optimize speed, cost and probability of success. Ursula will discuss the two main challenges orphan drug development has to tackle and which Bayesian approaches can be used from preclinical to post-authorization to support orphan drug development.

"Re-imagining clinical trial design optimization – A case study" by Martin Kappler, Research Principal in Strategic Consulting

Martin has over 20 years of experience as a statistician and has been working as a trial or lead statistician for more than 15 years. During this time, he gained extensive experience in all statistical tasks related to the planning and designing, conduct and reporting of clinical trials. He contributed to the optimal design of clinical programs for regulatory submission and commercialization and was the study statistician for several late-phase submission projects. Martin participated and represented statistics in interactions with regulatory authorities (US, Europe, and national agencies). He participated in studies from all development phases as well as observational, real-world evidence, post authorization safety studies and registries. He gained experience in a variety of therapeutic areas (Oncology, Immuno-Oncology, Immunology, Hematology, Endocrinology, Hereditary disorders, Neurology, Gastroenterology, Cardiovascular) with a special experience of around 20 studies in the context of rare diseases and small populations.

"Bayesian approaches to support orphan drug development" by Ursula Garczarek, Principal in Strategic Consulting

Ursula has extensive experience in providing statistical support for clinical and non-clinical aspects of product development within both pharmaceutical and consumer companies. As a member of Cytel's Strategic Consulting team, Ursula provides guidance to trial sponsors on optimizing their development strategy, and successfully implementing trial design innovations. She applies new and pragmatic methodologies to address the needs and requirements of the sponsor within the regulatory environment. She is experienced with interactions with the FDA and the EMA for general drug development, medical devices and in rare diseases.

“Emerging Biotechnology Venture Capital” by M. VENTURES

Discuss the state of the Biotechnology funding and investing landscape and explore how the recent pandemic has boosted investor interest in innovative biotech startups and driven the sector beyond its already strong projections.

Christian Uhrich

Head of Strategy, M Ventures

Christian joined M Ventures in August 2019 as Head of Strategy and currently is a Principal within the Biotechnology investment team. Previously, he worked at Merck KGaA, Darmstadt, Germany as a Senior Consultant in the corporate Inhouse Consulting practice where he focused on impactful strategy related projects across all three business sectors of Merck KGaA, Darmstadt, Germany (Healthcare, Life Science, Electronics), such as the Healthcare R&D Strategy, the Life Science Process Solutions Bioprocessing Strategy or the cross-sector Innovation Strategy. Prior to that, Christian spent over ten years in the external consulting space, previously working for Accenture as Manager in its DACH region Strategy practice where he successfully consulted key biotechnology industry players across Europe on strategic challenges and management decisions in the areas of business strategy, digital strategy, marketing & sales strategy, organizational development, and post-merger integration & carve-outs. Prior to joining Accenture, Christian worked for Seeburger Inc., a leading global technology company, where, as a consultant, he built a rich understanding of digital transformation, technology-design, -implementation and -sales and technology-driven optimization of business processes. Christian holds an MBA from Mannheim Business School, Germany and a Diploma in Computer Science and Business Administration (Business Informatics) from Cooperative State University Karlsruhe, Germany.

Industry Poster Gallery

Posters are displayed during the entire time in the networking areas. Please use the breaks as opportunity to meet the poster presenters.

Digital posters are available in the “Lobby” on the dedicated conference digital platform, including contact details to set up 1:1 meeting with the poster presenter(s).

#1 - Alternative pre-mRNA Splicing as a Source of Cancer Neoepitopes

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BioMed X Institute

BioMed X Institute https://bio.mx/research-teams/oncology/team-rsc/

Current approaches to identify neoepitopes have provided limited numbers of immunogenic and cancer-specific targets, thus preventing the broad application of immunotherapy. A potential new source for neoepitopes is alternative pre-mRNA splicing, a process which is dysregulated in several cancer subtypes. Thus, we aimed to investigate how alternative splicing can contribute to the neoepitope repertoire in cancer.

To explore alternative splicing-derived neoepitopes, we determined the HLA-I-bound immunopeptidome of various cancer cell lines. By developing custom bioinformatical workflows, we generated sample-specific reference databases suitable for detecting non-canonical splicing-derived peptides from mass spectrometry data. In parallel, we performed transcriptome-wide splicing analyses to obtain thousands of aberrant splice events. We then mapped our candidate peptides to the identified splice events and were able to identify several alternative splicing-derived peptides that will be further explored as potential neoepitope candidates.

Following this strategy, we demonstrated that aberrant splicing has the potential to promote HLA-I presentation of novel peptides derived from alternative splice junctions and exons as well as retained introns. Our findings have potential implications for immunotherapy of cancer types with low tumor mutational burden, where exploration of the splicing-derived neopeptidome could reveal novel therapeutic approaches.

#2 Re-imagining clinical trial design optimization – A case study

Martin Kappler
Cytel Inc, https://www.cytel.com/

Development teams are under pressure to deliver more, faster and with less. Unfortunately, in the race to bring a new drug to the market, they often lack the time, tools, and organizational support to fully investigate the potential design space for the planned clinical trials. Most of the time a design is optimized out of handful of preselected options.
But current technology combined with high performance machines enable cross-functional teams to explore an exponentially larger design space in a short time frame to identify alternatives that optimize speed, savings, and probability of success. The design exploration, optimization and decision process are illustrated based on a recent oncology phase 3 study on patients with acute myeloid leukemia.

#3 Emulating the MAIN Outcomes of Randomised Controlled Studies through Statistical Analysis of Real World DATA Directly Extracted from Electronic Medical Records

Drake D[1], **Van Wouwe L[2]**, El Rhali A, Abdi R[2], Kouki M[3]
[1]Clinerion Ltd, Basel, BS, Switzerland, [2]datametrix AG, Neuchatel, Switzerland, [3]Higher School of Statisticsand Information Analysis, University of Carthage (ESSAI), Tunis, Tunisia
Datametrix AG (www.datametrix.ch)

OBJECTIVES
To demonstrate that analysis of EMR can be used effectively to emulate patient and response patterns, reflecting the results observed in randomized controlled trials (RCT).
METHODS
For this evaluation, we looked at the outcomes for Chemotherapy and Checkpoint Inhibitor treatments in Advanced Melanoma patients, evaluating results from an RCT and comparing it against an analysis of data extracted from deidentifed EMR from 13 sites in 6 countries.
We have reviewed the data in context of patient care, treatment outcomes. The approach included the review and assessment of RCT endpoints against available RWD datapoints, and identification of the relevant data points in the RWD to match/approximate the data underpinning the RCT endpoint definition, to allow for a meaningful comparison.
RCT data set:
The reference study is an RCT extracted from clinicaltrials.gov, "Study of Pembrolizumab (MK-3475) Versus Chemotherapy in Participants with Advanced Melanoma"
RWD data set:
Our database was built using data from Clinerion's hospital network following the same inclusion and exclusion criteria as the RCT study.
We analysed overall survival (OS) and progression-free survival (PFS) using the weighted Cox regression model with Bayesian approach. The inverse probability of treatment weighted (IPTW) method based on the propensity score was performed to adjust for selection bias. A Bayesian analysis was done to improve survival results.
RESULTS
The analysis showed that, with the weighted Bayesian approach, the checkpoint inhibitor (Pembrolizumab) performed better in terms of OS (HR=0.45 [95% confidence interval [CI] 0.25, 0.82], p=0.0023) and PFS(HR=0.16 [95% confidence interval [CI] 0.08, 0.25], p<0.0001) compared to Chemotherapy.
CONCLUSIONS
We have been able to emulate some results of the RCT in RWD, comparing the treatment effect of Chemotherapy and Checkpoint Inhibitor treatments in Advanced Melanoma Patients. Most notably we have been able to confirm the overall outcome of RCT in terms of OS and PFS.

#4 Innovative synthetic materials for reliable cell culture systems

Annamarija Raic[1], Nadine Kaiser[2], Véronique Schwartz[1]
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Chemovator GmbH www.facellitate.com

Reliable cell culture systems are urgently needed for the development of predictable models in stem cell- and cancer research as well as in drug development or toxicological screening. To achieve this goal, cells require an in vivo similar environment for maintenance of their native character. We developed a new polymer platform which allows 3-dimensional cell growth and provides specific biochemical signals. Our complete inert coating BIOFLOATTM prevents unspecific binding of cells and proteins leading to 3D cell spheroid formation –which allow cell-cell contact in all dimensions for more precise validation of cell based assays. Further, advancement of our polymer platform revealed a new polymer-peptide combination – called BIOINSTRUCTTM. This fully synthetic cell culture substrate allows the expansion of induced pluripotent stem cell (iPSC). Our chemically defined, animal-free coating solutions can be easily applied to create a robust and homogeneous coating by simply rinsing the culture surface of choice. We have benchmarked our surface modifications and analysed morphology and cells functionality. Our new cell repellent technology shows a reproducible, rapid generation of round spheroids within 24 h whereas our cell-instructive surface supports stem cell maintenance of iPSCs. These reliable systems facilitate the establishment of model-based assays applicable in basic research, regenerative medicine or drug development.

#5 A blood-based miRNA signature predicts immunotherapy response

Timothy Rajakumar, Rastislav Horos, Julia Jehn, Judith Schenz, Thomas Muley, Oana Pelea, Sarah Hoffmann, Paul Kittner, Mustafa Kahraman, Marco Heuvelman, Tobias Sikosek, Jennifer Feufel, Jasmin Skottke, Dennis Nötzel, Alberto Daniel-Moreno, Jessica Zeiler, Nathanial Mercaldo, Florian Uhle, Sandra Tamulyte, Markus Weigand, Fabienne Lusky, Hannah Schindler, Tatjana Sauka-Spengler, Qianxin Wu, Klaus Rabe, Martin Reck, Michael Thomas, Petros Christopoulos, Bruno R Steinkraus

Hummingbird Diagnostics https://www.hummingbird-diagnostics.com/

Immunotherapies have recently gained traction as highly effective therapies in a subset of late-stage cancers. These work by blocking the mechanisms by which tumours commonly evolve to evade detection and unleashing the immune system to fight the cancer. Unfortunately, only a minority of patients will experience these remarkable benefits, whilst others fail to respond or worse still, come to harm through immune related adverse events. For this reason, it is vital to administer immunotherapies only to those patients in which the benefits are predicted to outweigh the risks. For immunotherapies within the PD-1/PD-L1 inhibitor class, this patient stratification is currently performed using tumour PD-L1 expression. PD-L1 is an effective predictor in ~30% of cases, despite its status as the gold standard biomarker to guide clinical decisions. There is pressing need for more accurate biomarkers for immunotherapy response prediction.
We have sought to identify peripheral biomarkers, predictive of response to immunotherapies in stage IV NSCLC using the Hummingbird Dx whole blood, small RNA profiling platform and a total of 319 PAX-gene samples. We have defined a miRisk score based on the expression of a 5-miRNA signature that is predictive of immunotherapy response in training and independent validation cohorts. Finally, we have used pathway analysis and miRNA target prediction to make a direct mechanistic link between our miRNA signature, the PD-L1 signaling pathway and PD-L1 itself.

#6 Protecting Life's Most Precious Cargo

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#7 Modelling neuroinflammation with iPSC-derived neurons and microglia

Ricarda Breitmeyer, Sabrina Vogel, Johanna Heider, Hansjürgen Volkmer

NMI Natural and Medical Sciences Institute at the University of Tübingen, Reutlingen, Germany
www.nmi.de

Neuroinflammation appears as a central hallmark of a wide range of neuropsychiatric and neurodegenerative disorders. During brain development and maturation, microglia eliminate weak, inactive synapses while active synapses are strengthened. A substantial deregulation of this process is understood as a direct consequence of uncontrolled neuroinflammation and is considered a major factor in the development and progression of mental health disorders, such as schizophrenia. Robust human model systems to better understand the reciprocal interplay between microglia and neurons at the synapse are however still lacking.
Here, we present fully characterized 2D and 3D schizophrenia patient-derived model systems based on induced pluripotent stem cells to model neuronal and inflammatory phenotypes in vitro. We found a significant reduction of pre-synaptic density in schizophrenia neurons and increased synapse elimination by overactivated patient-derived microglia. Interestingly, anti-inflammatory pre-treatment of microglia prevented pathological pruning of synapses, highlighting the potential use of anti-inflammatory adjunctive therapy for schizophrenia patients. In an electrophysiologically active brain organoid model, microglia-neuron interplay was shown by a functional integration of microglia.
These model systems provide unique tools to study microglia-neuron communication in neurobiological research and for the development of novel drug candidates.

#8 The EQIPD Quality System: a new way to boost innovation

Björn Gerlach, Anton Bespalov, Christoph H. Emmerich, Martin C. Michel, on behalf of the EQIPD consortium

PAASP GmbH https://paasp.net

Risk of failure is an inherent part of developing innovative therapies which can be reduced by adherence to evidence-based rigorous research practices. Supported through the EUs Innovative Medicines Initiative, the Enhancing Quality in Preclinical Research (EQIPD) consortium has developed a preclinical research quality system (QS) that can be applied in both public and private sectors and is free for everyone to use.
The EQIPD QS was designed to boost innovation by ensuring the generation of robust and reliable preclinical data while being lean, effective and user-friendly. Consequently, the QS should not be a burden impacting the freedom to explore scientific questions.
The system was developed by consortium partners from academia, industry, small to midsize companies and non-profit organizations. As a result, the QS has been based on 18 core requirements defining common best practices and are supplemented with 6 requirements needed to make a “formal knowledge claim”. The requirements can be addressed flexibly, according to user-specific needs and following a user-defined trajectory. Additionally, the consortium has developed tools for optional use, a formal accreditation process and is preparing a registered society in Heidelberg which is named “Guarantors of EQIPD”.
Building upon feedback from users, the QS will serve the global community of scientists conducting non-regulated preclinical research and will help them to generate reliable data that are fit for the intended use.

#9 Phialogics - a platform technology to restore immune tolerance in autoimmune diseases

Andreas Ernst, Andreas von Knethen, Andreas Weigert, Michael Parnham and Pascal Oromi

Phialogics GmbH https://www.phialogics.com/

Phialogics is a spin-off company from Fraunhofer ITMP in Frankfurt, founded by researchers who were exploring novel biologics for treatment of autoimmune tissue injury. Although the specific molecular targets vary between different autoimmune diseases, the basic immune mechanisms involved overlap. Autoimmunity often results from loss of tolerance of the immune system to molecules present in the body, leading to immune attack on organs and tissues. To prevent such autoimmune reactions, the immune system has evolved several feedback loops that induce immune tolerance. At Phialogics, we intend to utilize these feedback loops to trigger immune tolerance at the cellular level by developing a platform of immune modulatory biologics. Our approach has wide-spread impact on a number of different autoimmune disorders, ranging from psoriasis arthritis, multiple sclerosis to ulcerative colitis.
In a preliminary study, we demonstrated that our lead molecule, an engineered IgV-domain with improved binding properties, averted immune mediated liver damage in a murine model of acute inflammation. Our lead molecule reduced pro-inflammatory cytokines accompanying the attenuation of immune responses. Excited by these promising results, we are developing this molecule to prevent graft vs. host disease (GvHD) in patients that have received an allogenic hematopoietic stem cell transplant. Phialogics' approach promises to lower the high mortality of GvHD patients by addressing an unmet medical need.

#10 Using Single Cell Multi-omics to Monitor CAR-T Therapy Response Identifies Potential Therapeutic Escape Mechanism in a Multiple Myeloma Patient

Jonathan Scolnick, Patrick Schmidt, Andreas Schmidt, Xiaojing Huo, Stacy Xu, Michael Lovci, Shawn Hoon

Proteona https://proteona.com/

Multiple Myeloma (MM) is an incurable cancer characterized by highly heterogeneous and evolving tumor clones. Chimeric antigen receptor T-cells (CAR T), a rapidly emerging therapy, has shown remarkable success rates in clinical trials. However, it is not clear which patient will respond to a specific CAR T therapy, which myeloma clone may be responsible for relapse, or, after relapse, how to select the next treatment. We used the enhanced single cell analysis with protein expression (ESCAPE) RNA-Seq platform to simultaneously measure cell surface protein expression and gene expression at the single cell level at different timepoints for a relapsed MM patient after CAR T therapy. Combining ESCAPE RNA-Seq with Proteona's MapSuite™ of analysis tools, we were able to identify changes in the cell types present within these longitudinal samples. Subsequent analysis identified discordance between the expression levels of the protein and RNA of therapeutic targets, showing the importance of measuring both protein and RNA in tumor samples and hinting at a CAR T escape mechanism evolved by those cells. Going forward, proteogenomic analysis should become a standard tool for understanding blood cancers and stratifying patient populations for more precise treatments.

#11 A high throughput RNA-seq method to enable efficient drug screening

Samantha Langer, Wenqi Zhu, Yiqi Zhou, Nan Fang

Singleron Biotechnologies GmbH https://www.singleronbio.com/

High-throughput screen is an essential part of drug discovery and development. RNA-seq can be used to generate comprehensive information on drug effects on the transcriptome, which could be used to determine the mechanism as well as effectiveness of various drug compounds. However, the RNA-seq library preparation procedure is costly and tedious, making it difficult to use large-scale RNA-seq in drug screening. To overcome these challenges, we have developed AccuraCode, a high-throughput RNA-seq library construction method that reduces hours and costs compared to traditional RNA-seq. Cell cultures from 384-well plates are barcoded in-plate, followed by a one-step whole transcriptome amplification (WTA) to yield the cDNA with unique sample barcodes. Since only one library preparation reaction is carried out using the pooled cDNA from up to 384 samples, hands-on time and expenses are reduced by 90%. Thus, AccuraCode provides a fast, cost-effective high throughput method which could greatly facilitate the drug discovery process.

#12 Generation of Functional Monoclonal Antibodies by Single B Cell Cloning

Bin Hu

Sino Biological Europe GmbH https://www.sinobiological.com/

Multiple technology platforms are available to support high-quality antibody development in both research and drug discovery. Single B cell sorting has been widely used for antibody screening with advantages in allowing the isolation of native and functional antibodies within a higher chance. Sino Biological Inc. uses this platform to develop rabbit and mouse monoclonal antibodies by coupling antigen-specific single B cell sorting followed by antibody sequence PCR or B cell culture. We successfully obtained rabbit monoclonal antibodies targeting SARS-CoV-2 key antigen, spike protein, with blocking functions.

#13 VectorBuilder: From Discovery to Therapeutic Application

Justin Mirus, PhD Yasmin Emamgholi, PhD

VectorBuilder GmbH www.vectorbuilder.com

VectorBuilder is a rapidly growing biotechnology company specializing in advanced genetic engineering solutions for research and medicine. In particular, VectorBuilder has established itself as the global leader in a range of products and services related to gene delivery, including vector design and optimization, vector cloning, virus packaging, library construction and screening, stable cell line generation, and GMP manufacturing of clinical-grade plasmids, mRNAs, proteins and viruses. One highlight of VectorBuilder's innovative solutions is its award-winning revolutionary online platform.

About the Organiser

BioRN is the science and industry cluster of the Rhine-Main-Neckar region around Heidelberg, one of Germany's strongest biotech hubs. It is a non-profit network fostering health innovations and serving its members by creating a rich translational ecosystem as well as promoting, representing and connecting the regional innovation stakeholders.

Our vision is to develop the region into a world-leading life science cluster attracting international investments and top global talent.

BioRN has about 100 institutional members, including the top academic and research institutions, 7 global pharmaceutical companies, a large range of small and medium-sized enterprises bolstering the life science ecosystem as well as local government organizations and interest groups.

Founded in 1996 BioRN has since raised more than 70 million € of public funding for its members. It was instrumental in the successful bid for the European Institute of Technology (EIT) KIC Healthy Living and Ageing in 2014 with a total grant of 700 million €

BioRN Cluster management establishes initiatives to nurture and extend networks between its members - the key regional innovation stakeholders. It stands for the promotion and visibility of the Life Science region and fosters connections to other regions of innovation worldwide.

BioRN is founding member of the Health Axis Europe (HAE), a strategic alliance between the leading life science hubs of BioRN, Leuven (Belgium), Maastricht (Netherlands) and Copenhagen (Denmark). The alliance aims to bundle and cross leverage the members' innovation resources and thus jointly increase international competitiveness.

The cluster is internationally recognized as an academic center of excellence in the field of cancer, immunology, cutting edge imaging and omics, holding an enormous potential for translation into health applications. By leveraging the unique combination of global pharma and leading academic institutions amongst its members, BioRN drives a range of translational initiatives in order to create an entrepreneurial ecosystem that can compete with other centers of excellence on an international level. These initiatives include tailored technology scouting activities between industry and academia (BioRN Scout), paving the way towards a fully equipped and professionally run life science startup incubator (BioLabs Heidelberg), and the implementation of funding instruments to finance the conversion of academic projects into industry ready assets (beLAB2122).

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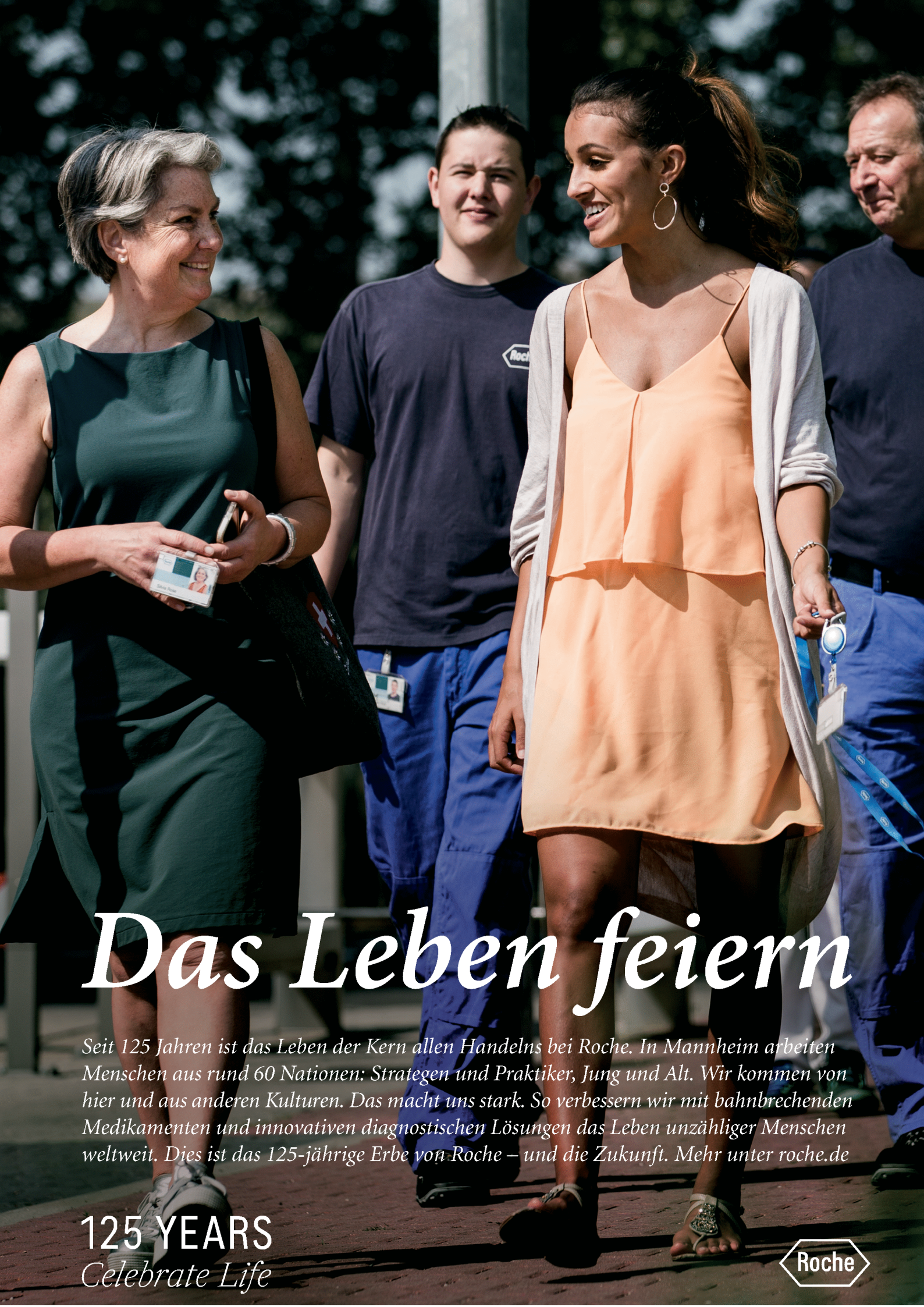
Notes



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