

## THEME DAY

# THE NEXT FRONTIERS IN ATMP DEVELOPMENT

NEUE STADTHALLE, LANGEN | 27-28 APRIL 2023

### Programme

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#### Thursday 27 April

<b>08:30-09:00</b>	<b>Registration</b>
<b>09:00-11:00</b>	<p><b>Moderierte Diskussion: Entwicklung einer nationalen Strategie für Gen- und Zelltherapien</b>  <b>Please note:</b> This session will be held in German  Chair: <b>Christopher Baum</b>, <i>Berliner Institut für Gesundheitsforschung (BIH)</i></p> <p>Diskussion mit Stakeholdern und der Community: Entwurf für eine nationale Strategie für Gen- und Zelltherapien in Deutschland</p>
<b>11:00-11:30</b>	<b>Coffee Break</b>
<b>11:30-12:05</b>	<p><b>Opening</b>  Chair: <b>Zoltan Ivics</b>, <i>Paul-Ehrlich-Institut, Langen</i></p> <p>11:30-11:35 <b>Zoltan Ivics</b>, <i>Paul-Ehrlich-Institut, Langen</i>  Welcome and opening remarks</p> <p>11:35-11:45 <b>Klaus Cichutek</b>, <i>Paul-Ehrlich-Institut, Langen</i>  The age of gene and cell therapy</p> <p>11:45-12:05 <b>Martina Schüssler-Lenz</b>, <i>Paul-Ehrlich-Institut, Langen</i>  <b>INV01:</b> The life cycle management of Advanced Therapy Medicinal Products (ATMPs)</p>
<b>12:05-13:20</b>	<p><b>Session 1: Accelerating innovation in gene and cell therapy</b>  Chairs: <b>Ulrike Köhl</b>, <i>Fraunhofer IZI, Leipzig</i>; <b>Boris Fehse</b>, <i>University of Hamburg</i></p> <p>12:05-12:25 <b>Christopher Baum</b>, <i>BIH Berlin</i>  <b>INV02:</b> Building an ecosystem for innovation in the field of cell and gene therapy</p> <p>12:25-12:45 <b>Tobias Helmstorf</b>, <i>Bayer, Berlin</i>  <b>INV03:</b> The Translation Center Berlin as the nucleus to create a global hotspot for cell and gene therapy</p> <p>12:45-13:05 <b>Jennifer Quizi</b>, <i>The Ottawa Hospital Research Institute</i>  <b>INV04:</b> The BioCanRx Consortium</p> <p>13:05-13:20 <b>Q&amp;A</b></p>
<b>13:20-14:20</b>	<b>Lunch</b>
<b>14:20-15:35</b>	<p><b>Session 2: Trends in ATMP Manufacturing</b>  Chairs: <b>Qasim Rafiq</b>, <i>University College London</i>; <b>Claudio Mussolino</b>, <i>University of Freiburg</i></p> <p>14:20-14:40 <b>Mario Assenmacher</b>, <i>Miltenyi Biotec GmbH</i>  <b>INV05:</b> Advancing CAR/TCR T cell processing platforms towards decentral manufacturing</p>

	<p>14:40-15:00 <b>Qasim Rafiq</b>, <i>University College London</i>  <b>INV06:</b> The Translation Center Berlin as the nucleus to create a global hotspot for cell and gene therapy</p> <p>15:00-15:20 <b>Frederick Erkens</b>, <i>Fraunhofer IPT</i>  <b>INV07:</b> The AIDPATH Consortium: How can digitalisation and automation enable large-scale application of CAR-T cell therapies?</p> <p>15:20-15:35 <b>Q&amp;A</b></p>
<b>15:35-16:55</b>	<p><b>Session 3: Academic Development of ATMPs</b>  Chairs: <b>Claire Booth</b>, <i>University College London</i>; <b>Carmen Sanges</b>, <i>Universitätsklinikum Würzburg</i></p> <p>15:35-15:50 <b>Claire Booth</b>, <i>University College London</i>  <b>INV08:</b> The AGORA Initiative</p> <p>15:50-16:05 <b>Alessandro Aiuti</b>, <i>San Raffaele Scientific Institute, Milano</i>  <b>INV09:</b> A novel platform approach for the treatment of lysosomal storage diseases with skeletal involvement</p> <p>16:05-16:25 <b>Özcan Met</b>, <i>National Center for Cancer Immune Therapy, Herlev</i>  <b>INV10:</b> Manufacture of adoptive cell therapies at an academic cancer center</p> <p>16:25-16:35 <b>Caroline Pothet</b>, <i>EMA, Amsterdam</i>  <b>INV11:</b> EMA's pilot for academic and non-profit ATMP developers</p> <p>16:35-16:55 <b>Q&amp;A</b></p>
<b>16:55-17:15</b>	<b>Coffee Break</b>
<b>17:15-18:45</b>	<p><b>Roundtable Discussion</b> <span style="float: right;"><b>T<sup>2</sup>EVOLVE</b></span>  <b>T2 EVOLVE Regulatory Focus: Progressing the Parent-Child IND Concept</b>  Moderators: <b>Hélène Nègre</b>, <i>Servier</i>; <b>Michael Hudecek</b>, <i>T2Evolve</i></p> <p>17:15-17:20 <b>Helene Negre</b>, <i>Servier</i>  Introduction to T2EVOLVE</p> <p>17:20-17:25 <b>Jacquelyn Awigena-Cook</b>, <i>Bristol Myers Squibb</i>  Accelerating the development of engineered T cell therapies – current regulatory framework and future perspectives</p> <p>17:25-17:40 <b>Miriam Meyer</b>, <i>Immatics</i>  Optimization of clinical trial design using the primary/secondary IND approach</p> <p>17:40-17:50 <b>Timothy Taps</b>, <i>Century Therapeutics</i>  Potential advantages and disadvantages of applying the parent/child IND approach to CAR-T and NK cell therapy programs</p> <p>17:50-18:00 <b>Caroline Pothet</b>, <i>EMA</i>  Single versus multiple CTA approach in the EU</p> <p><u>Panellists:</u>  Martina Schüssler-Lenz, <i>Paul-Ehrlich-Institut, Langen</i>  Matthias Renner, <i>Paul-Ehrlich-Institut, Langen</i>  Miriam Meyer, <i>Immatics</i>  Tim Taps, <i>Century Therapeutics</i>  Caroline Pothet, <i>EMA</i>  Jacquelyn Awigena-Cook, <i>Bristol Myers Squibb</i>  Ulrike Köhl, <i>IZI Leipzig</i>  Concetta Quintarelli, <i>OPBG, Rome</i></p>

## Friday 28 April

<b>08:30-09:00</b>	<b>Registration</b>
<b>09:00-10:40</b>	<p><b>Session 4: What's hot: Preclinical and Clinical Developments to Accelerate ATMP</b> Chairs: <b>Toni Cathomen</b>, <i>University of Freiburg</i>; <b>Zoltan Ivics</b>, <i>Paul-Ehrlich-Institut, Langen</i></p> <p>09:00-09:20 <b>Emmanuel Donnadieu</b>, <i>INSERM, Paris</i> <b>INV12:</b> Predicting safety and efficacy of engineered T cells using <i>ex vivo</i> human models</p> <p>09:20-09:40 <b>Julio Delgado</b>, <i>Hospital Clínic de Barcelona</i> <b>INV13:</b> ATMPs: from bench to bedside (through the regulator's desk)</p> <p>09:40-10:00 <b>Anna Maria Veiga</b>, <i>IDIBELL, Barcelona</i> <b>INV14:</b> Generation of human induced pluripotent stem cells from haplo-selected cord blood samples (HAPLO-iPS)</p> <p>10:00-10:20 <b>Martin Rabel</b>, <i>Precision NanoSystems</i> <b>INV15:</b> Gene-editing of CAR T Cells for Off-the-Shelf Cancer Therapies Using a Novel RNA Lipid Nanoparticle Platform</p> <p>10:20-10:40 <b>Q&amp;A</b></p>
<b>10:40-11:00</b>	<b>Coffee Break</b>
<b>11:00-13:10</b>	<p><b>Session 5: Improving Awareness and Access to Cell and Gene Therapies</b> Chairs: <b>Martina Schüssler Lenz</b>, <i>Paul-Ehrlich-Institut, Langen</i>; <b>Axel Schambach</b>, <i>MHH, Hannover</i></p> <p>11:00-11:20 <b>Anna Couturier</b>, <i>University of Edinburgh</i> <b>INV16:</b> The EuroGCT Consortium: Meeting information needs of all stakeholders in cell and gene therapy</p> <p>11:20-11:40 <b>Christof von Kalle</b>, <i>BIH, Berlin</i> <b>INV17:</b> Patient data management – ways to accelerated and improved therapy</p> <p>11:40-12:00 <b>Johanna Risse</b>, <i>University of Bonn</i> <b>INV18:</b> Which price for ATMPs is justified? Ethical considerations</p> <p>12:00-12:20 <b>Alexander Natz</b>, <i>European Confederation of Pharmaceutical Entrepreneurs (EUCOPE), Brussels</i> <b>INV19:</b> Reimbursement of ATMPs: Current roadblocks and the implications of the EU HTA</p> <p>12:20-12:40 <b>Axel Schambach</b>, <i>MHH, Hannover</i> <b>INV20:</b> Status quo of gene and cell therapy: A DG-GT perspective</p> <p>12:40-13:10 <b>Q&amp;A</b></p>
<b>13:10-13:15</b>	<p><b>Closing Remarks</b> Chair: <b>Zoltan Ivics</b>, <i>Paul-Ehrlich-Institut, Langen</i></p>
<b>13:15-14:00</b>	<b>Lunch</b>