

# CAR-TCR Summit



*Engineering a Cancer-Free World*

**Dedicated to the durable, safe and cost-effective, clinical and commercial development of CAR-T and TCR based cell therapies for patients globally.**

***September 10-13<sup>th</sup>, Boston***

The CAR-TCR Summit bring over 1000 industry leaders developing CAR-TCR based therapies from across pharma, biotech, regulatory bodies, academia and solution and service providers at the world's only end-to-end summit focused on the development of CAR-TCR therapies from early basic research through to commercialization and into the lives of patients in need.

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## **Confirmed speakers include:**

*Sadik Kassim, CSO, **Mustang Bio***

*Ali Mohamed, Vice President of CMC, **Immatix***

*Katy Rezvani, Professor - Melanoma Medical Oncology, Chief of Section Cellular Therapy, **MD Anderson Cancer Center***

*Bob Valamehr, Chief Development Officer & Vice President - Cancer Immunotherapy, **Fate Therapeutics***

*Peter Hoang, CEO, **Marker Therapeutics***

*Steve Shamah, Head of Research, **Obsidian Therapeutics***

*Mario Marcondes, Senior Director - Clinical Development, **Nektar Therapeutics***

*Kirstin Powel, Director – Product Quality, **Novartis***

*Claire White, Nurse Navigator for the Cancer Immunotherapy Program, **The Children’s Hospital of Philadelphia***

*Steven Kanner, Chief Scientific Officer, **Caribou Bio***

*Saul Priceman, Assistant Research Professor, **City of Hope National Medical Center***

*Maksim Mamonkin, Assistant Professor, **Baylor College of Medicine***

*Miguel Forte, Chief Executive Officer, **Zelluna Immunotherapy***

*Aiman Shalabi, Vice President R&D, **GlaxoSmithKline***

*Paul Rennert, Chief Scientific Officer, **Aleta Biotherapeutics***

*Scott Shoemaker, Senior Director of Operations, **bluebird bio***

*David Spencer, Chief Scientific Officer, **Bellicum Pharmaceuticals***

*Hanspeter Gerber, Senior Vice President & Chief Scientific Officer, **3T Biosciences***

*Eric von Hofe, President, **AffyImmune Therapeutics***

*Adrian Bot, Vice President of Translation, **Kite, a Gilead Company***

*Junxia Wang, Director of Analytical Development, **Mustang Bio***

*Bijan Nejadnik, Chief Medical Officer, **Eureka Therapeutics***

*Doug Danison, Vice President - Market Access, Value & Evidence Strategy, **bluebird bio - TBC***

*Gwendolyn Binder, EVP of Science & Technology, **Cabaletta Bio***

*Rick Morgan, Senior Vice President of Immunogenetics, **Editas Medicine***

*Steven Kelly, Chief Executive Officer, **Carisma Therapeutics***

*Thomas Andresen, Chief Scientific Officer, **Torque Therapeutics***

*Angela Scott, Chief Operating Officer, **TCBiopharm***

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# Why You Should Attend the CAR-TCR Summit

Well organized conference that brought the leading researchers and sponsors together to discuss topics highly relevant to the field. Well done.

abbvie

This meeting enables us to know what is happening and what to care in the real world. It is extremely informative to consider what to do when we apply CAR or TCR to patients in Japan.

TakaRa

A nice blend of academic, biotech, and pharmaceutical attendance in an environment that encourages cross-fertilization of ideas within CAR-T therapy.

C4 Therapeutics

I can't speak highly enough about this conference. This conference allowed me to keep informed of the latest research and development on T cell therapies. I was also able to network with some of the leaders in T cell immunotherapies from both academia and the industry.



Memorial Sloan Kettering  
Cancer Center

As a newcomer to the CAR-T space, I felt this meeting to be extremely valuable as it provided me the opportunity to meet many of the movers and shakers in the space. Great education and information!

AURORA BIOPHARMA

This meeting was very informative and focused on cell therapies. You're able to learn a lot from the presentations whilst meet leaders of the field. We have already confirmed sponsorship for next year.

ProMab  
Biotechnologies, Inc.

Where science, translation, clinical trial, and commercialization of new therapies meet.

Penn  
UNIVERSITY OF PENNSYLVANIA

Great opportunity to interact with both academic and industry leaders in the field of CAR T cell therapy.

JUNO  
THERAPEUTICS

The technology showcase was excellent. Being able to engage new vendors and see new devices and technology was outstanding. As always, the scientific program was exceptional - very high calibre, very well organized. Very well done! Another outstanding conference. Thank you for everything.

NOVARTIS

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## Your Roadmap to CAR-T and TCR Drug Development – Pre-conference Workshop Day

| Time | Discovery   | Translation  | Manufacturing  | Logistics   | Commercialisation   |
|------|---|--|--|---|---|
| 9am  | <b>A - Armoured CAR and TCR Constructs to Create Better Killers</b> <ul style="list-style-type: none"> <li>- Explore novel gene engineered CAR-T and TCR constructs which enhance their potency and overcome suppressive nature of the tumor microenvironment</li> <li>- Strip inhibitory receptors to create anti-T-cell CAR-T's</li> <li>- Identify accessory proteins which help enhance efficacy</li> </ul> | <b>B- Identify Biological Features of an Optimal CAR-T Cell</b> <ul style="list-style-type: none"> <li>- Understand the functional difference between a cell that infiltrates and kills tumor cells against those that do not</li> <li>- Explore the underlying features of biology that prevents T-cells from working efficiently and how to overcome it</li> <li>- Review clinical data to support findings</li> </ul>     | <b>C- Data Processing to Calculate Optimal Conditions for Cell Growth</b> <ul style="list-style-type: none"> <li>- Calculate how metabolite turnover, pH and media content can affect culture growth</li> <li>- Review potential changes in the manufacturing process to optimise these conditions and increase the functionality of cells</li> </ul>  | <b>D. How to Manage an Ecosystem of Multiple Clinical and/or Commercial Products</b> <ul style="list-style-type: none"> <li>- Identify the challenges faced when manufacturing and running multiple clinical trials at one time in the same centre</li> <li>- Highlight strategies to make best use of the facility and suite capacity to ensure patient specific products are tracked and labelled consistently</li> </ul>                                 | <b>E. Bridge the Gap between Patient Support and Marketing Programs</b> <ul style="list-style-type: none"> <li>- Explore the strategy and operations behind managing a CAR-T program that is an industry first</li> <li>- Manage patient support when coordinating with different teams</li> <li>- Market education to prepare and quantify an appropriate patient</li> </ul> |
| 11am | <b>Morning Refreshments</b>   |  |  |   |   |
| 12pm | <b>F- Antigen Identification for Clean Targets</b> <ul style="list-style-type: none"> <li>- Explore innovative platforms to identify and validate novel targets beyond CD19 to reduce the toxic effects of on-target-off-tumor reactivity</li> <li>- How to identify clean targets to increase the efficacy of CAR and TCR therapy in solid tumor indications</li> </ul>  | <b>G. Clarity in IND Submission Requirements</b> <ul style="list-style-type: none"> <li>- Gain clarity on which studies are necessary to carry out prior to IND submission to be able to plan effectively and recognise what to anticipate</li> <li>- Understand current requirements to move into clinic and what doses are expected</li> <li>- Review animal model data that have received IND approval and why</li> </ul> | <b>H- Analytics to Measure Potency</b> <ul style="list-style-type: none"> <li>- Explore the use of analytics to produce a viable, stable CAR and TCR product consistently</li> <li>- Recognise the importance of understanding how the product works, the cell biology and t cell biology</li> <li>- Use analytics to define cell attributes that results in strong potency to enable targeting of difficult tumors</li> </ul> | <b>I. Labelling to Secure Tracking and Monitor Movement</b> <ul style="list-style-type: none"> <li>- Understand the need for a standardized labelling process for academic and commercial entities to support chain of identity</li> <li>- Discuss moving all manufacturing of cell therapy products to the ISBT128 labelling system, to identify products in a universal information system ensuring directional traceability of these products</li> </ul> | <b>J- Drug Labelling to Drive Operating Strategy</b> <ul style="list-style-type: none"> <li>- Identify the importance of product labels and how they determine your product strategy</li> <li>- Managing specifications to ensure standards are met in a commercial setting</li> </ul>  |
| 2pm  | <b>Afternoon Refreshments</b>   |  |  |   |   |

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| 3pm | <p><b>K- Optimal Binding Qualities to Enhance Product Safety</b></p> <ul style="list-style-type: none"> <li>- Explore the developments of conventional IDG binders to create compounds that are conditionally active therefore can only bind when in the presence of the tumor microenvironment</li> <li>- Controlled activation to allow higher dosing in the clinic and better responses</li> <li>- Discuss the optimal selectivity and sensitivity of binders and how this differs in solid and liquid tumor indications</li> </ul> | <p><b>L- Animal Models to Represent Translation</b></p> <ul style="list-style-type: none"> <li>- Characterization of safety is not pertinent in current animal models</li> <li>- Explore new ways to model tumor burden to gain a realistic representation of translation in humans</li> </ul> | <p><b>M- New Gene Editing for an Industrial Reality</b></p> <ul style="list-style-type: none"> <li>- Explore current gene editing platforms which are able to create allogeneic tumor reactive cells which are compatible with current standards</li> <li>- Utilize novel gene editing platforms to make CAR-T and TCR cells better killers with a broader spectrum of targets</li> <li>- Explore manufacturing strategies which can support this at an industrial level</li> </ul> | <p><b>N. Optimize the Process of Transport and Shipping Frozen and Fresh Products</b></p> <ul style="list-style-type: none"> <li>- Explore the different challenges around transporting frozen and fresh products</li> <li>- How does frozen or fresh products effect your release criteria?</li> <li>- Discuss ways to prepare for global delivery of CAR-T and TCR therapy</li> </ul> | <p><b>O. Explore Payment Systems for Next Generation CAR and TCR Therapies</b></p> <ul style="list-style-type: none"> <li>- Explore how to design and support patient centric or outcome based contracts</li> <li>- How to design the operating frameworks and develop financial models to support the contract</li> <li>- Understand how to operationalize and administer this contract internally and externally</li> </ul> |
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# Conference Day One, September 11<sup>th</sup> 2019

## 8.30am Opening Remarks

## 9.00am Industry Leader's Fireside Chat

With two approved CAR-T therapies seeking global approval, what are the next steps, where do we go now? With the excitement in allogeneic therapy, will autologous therapy become a thing of the past? How can we enhance the efficacy when targeting solid tumors and meet this unmet need?

Take this opportunity to ask the leaders what their future plans are and what we can expect from the CAR-TCR space over the next few years.

## 9.30am Sponsor Talk

## 10.30am Speed Networking and Morning Refreshments

| Time  | Discovery   | Translation  | Clinical Management   | Manufacturing  | Logistics   | Commercialisation  |
|-------|---|--|---|--|---|--|
| 11.30 | <b>Novel CAR Constructs</b><br>Review innovative construct design that has the potential to enhance the targeting of CAR cells. Explore multi-targeting technology alongside the use of accessory proteins to enhance potency and engagement. | <b>Clinical Translation and Trial Experience for Autologous Therapy</b><br>Review clinical data from autologous therapy and industry experience in bringing autologous trials through the clinic.<br><br>Outline release criteria tests performed to ensure right attributes are selected. Discuss which tests make sense to support findings. | <b>Measuring Minimal Residual Disease with CAR-T therapy</b><br>Strategies to measure and identify high risk patients.                    | <b>Manage Heterogeneity and Process Variation in Autologous Manufacture</b><br>Explore the need for a manufacturing process that's tailored for each patient due to variability in autologous starting material.<br><br>Outline the need to manage heterogeneous starting materials to improve the non-predictable therapeutic dose which results in significantly varied toxicity, efficacy and safety profile. | <b>Standardisation of Cell Collection and Apheresis</b><br>Reduce product variability among incoming donor material through a standardised process of collection.<br><br>Discuss strategies to overcome insufficient collection, contamination and strain on apheresis centres. | <b>Regulatory Guidelines on Setting up and Running Clinical Trials</b><br>Optimize the planning of regulatory applications and outline the requirements from different tiers of approvals to ensure standards are anticipated and planned for. |
| 12.00 | <b>CAR-T Beyond Oncology</b><br>Explore how modified chimeric autoantibody receptor T cells (CAAR-T) cells demonstrate potency and specific   |  | <b>Enhance Success Rates of Patients with MRD</b><br>Review methods of converting MRD positive patients into MRD negative to increase the | <b>Expansion Techniques for Heterogeneous Cell Populations</b><br>Characterise heterogeneity of growing cultures comparing   | <b>Consistency among Product Labelling to Ensure Traceability</b><br>Recognise how inconsistent documentation and   | <b>Experience Initiating US Trials Globally</b><br>Understand the different requirements from US, EU and ROW.  |

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|              | cytotoxicity to overcome autoimmune disorders.  |   | chances of successful therapy.  | different starting material percentages. Explore expansion techniques and outline what different reagents, activators or media accelerate the process of transfection and expansion.   | labelling over different trials can cause challenges in trial management.<br><br>Discuss the need for standardized labelling to ensure directional traceability to reduce the risk of mixing up patient products and ensure chain of identity is secure.   | Optimize the planning process to ensure a submissions are sent in a timely process.   |
| <b>12.30</b> | <i>Sponsored talk</i>   | <i>Sponsored talk</i>   | <i>Sponsored talk</i>   | <i>Sponsored talk</i>  | <i>Sponsored talk</i>  | <i>Sponsored talk</i>   |
| <b>13.00</b> | <b>Lunch</b>  |   |   |  |  |   |
| <b>14.00</b> | <p><b>Panel: TCR vs CAR</b><br/>Discuss the strengths and weaknesses of each cell product.<br/>What are the challenges faced in bringing engineered TCRs successfully through clinic?</p> | <p><b>Panel: What is the Optimal T Cell from Clinical Experience?</b><br/>Review clinical trial experience to identify what attributes a good functioning T cell has.<br/>Question how to monitor these qualities including persistence and exhaustion and how to select those in future.</p> | <p><b>Panel: CAR-T Therapy to Replace Transplants</b><br/>Explore the potential of CAR-T providing a functional cure and replacing the need for stem cell transplants.<br/><br/>Discuss how the one given therapy of CAR-T can be a better alternative to socio economic burden of transplant.<br/><br/>Highlighting the change of thought process needed for clinicians to choose CAR-T as first line treatment.</p> | <p><b>Panel: What Manufacturing Techniques can Support the Heterogeneous and Patient-specific Material of Autologous Therapy?</b><br/><br/>Review manufacturing practices to manage the heterogeneous starting material of autologous therapy.<br/>Optimize and streamline manufacturing processes to reduce turn-around time.</p> | <p><b>Panel: Optimize Supply Chain Coordination to Ensure Control and Security of Products</b><br/>Discuss methods to improve the communication between different areas of logistics to ensure timeframes are met.<br/>Optimize communication to ensure the chain of custody is clear which is important for personalized therapies.</p> | <p><b>Panel: How do Regulatory Guidelines Compare Around the World to Prepare for Global Clinical Trials?</b><br/>What do non US regulators identify as risks and concerns in the commercialisation of CAR TCR therapy.<br/>Understand what to present in initial applications.</p> |

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| <b>14.30</b>                 | <b>Innovative TCR Cell Design</b><br>Explore pioneering TCR construct design to target multiple antigens and overcome the need for co-stimulatory signals in the tumor environment. Review novel construct designs which improve the regulation and control of binding to target sites. | <b>Dosing and the Effect on Persistence</b><br>Analyse dosing trials to benchmark the best dosing practice to gain maximum potency and overcome exhaustion. Reflect on what the optimum persistence is to maintain resistance and monitor long term safety.       | <b>Toxicity Management</b><br>Predictive biomarkers to identify early signs of toxicity.<br>Discuss the training needed by clinical trial staff to manage patient toxicity.   | <b>Strategies to Automate Autologous Therapy</b><br>To make CAR and TCR therapies accessible, the first step is to reduce cost of manufacture. These sessions will review current strategies to automate the autologous process, reducing human operator variation, intensive labor, turn-around time and cost. | <b>Novel In-Time Tracking Technology to Support Controlled Transport</b><br>Analyse strategies to track personalised therapies throughout logistics to ensure control is maintained throughout product journey. | <b>Industry Experience Bringing a CAR-T Therapy through to Commercialisation</b><br>Outline the challenges faced when bringing a first of its kind therapy through to the market.   |
| <b>15.00</b>                 |   | <b>Dosing Strategies to Reduce Toxicity</b><br>Discuss dosing trials which have tried to mitigate the risk of cytokine release syndrome through splitting doses over a series of time frames to stabilise the increase in CRS and alter dosing based on outcomes. | <b>Biomarkers to Identify Patient Eligibility</b><br>Outline the biomarkers and eligibility tests that should be carried out during patient selection. Optimize patient stratification to identify traits of patients most likely to respond. | Explore the need to streamline manufacture, reduce challenges of maintaining cell viability and deliver for critically ill patients waiting on delivery, with a more de-centralized application.  | <b>Logistical Considerations for International Shipping</b><br>Experience in transporting products internationally to prepare and support and global supply chain.  | <b>Mitigate Post Approval Specification Changes</b><br>Explore the need to set wider specification parameters to allow for greater variability in commercial, large scale trials.<br><br>Optimize the regulatory navigation of changes to prevent disruption of manufacture.<br><br>Discuss experience with setting specification to prevent late stage failures. |
| <b>15.30</b>                 | <i>Sponsored talk</i>   | <i>Sponsored talk</i>   | <i>Sponsored talk</i>   | <i>Sponsored talk</i>   | <i>Sponsored talk</i>   | <i>Sponsored talk</i>   |
| <b>16.00 Afternoon Break</b> |   |   |   |   |   |   |
| <b>16.30</b>                 | <i>Sponsored talk</i>   | <i>Sponsored talk</i>   | <i>Sponsored talk</i>   | <i>Sponsored talk</i>   | <i>Sponsored talk</i>   | <i>Sponsored talk</i>   |
| <b>17.00</b>                 | <b>Engineering Strategies to Overcome Patient Relapse</b><br>How to overcome tumor resistance and antigen loss through construct design and multiple  | <b>Biomarker Validation and Discovery to Identify Patients best suited for CAR-T Therapies</b><br>Explore the use of early stage biomarkers that are able to predict patient  | <b>Standardise CAR-T Cell Algorithms to Manage Toxicity</b><br>Understand the different procedures for identifying and managing toxicity for CAR-T trials and discuss   | <b>Engineering Perspective on Manufacturing CAR-TCR</b><br>Analyse the recoveries of cells in different patient populations, alongside the levels of viable cell  | <b>Allogeneic Banking and Storage</b><br>Characterise the conditions required to store allogeneic cells in banks. Discuss how long  | <b>Overcoming Market Access Challenges with CAR-T</b><br>Optimize health-economic models and valuing of the new personalised therapies.   |

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|              | antigen targeting. Outline methods to target antigen negative disease and increase response rate.   | success to aid in recruitment.   | the need for standardisation.  | production, after infusion to understand how culture conditions can affect expansion.  | these cells will be viable in storage.  | Discuss evidence generation to meet requirements of market access stakeholders.  |
| <b>17.30</b> | <p><b>Biomarkers for Patient Relapse or Resistance</b><br/>Explore research on genomic transcriptional factors within the tumor which could cause resistance to T cell therapy.</p> | <p><b>Combination Trials to Enhance Efficacy in Autologous Trials</b><br/>Explore the trial design of combination therapy. Understand the regulators view on trials with old and novel targets and what tests are necessary to prove safety and function in combination to move into clinic.</p> | <p><b>Setting Up CAR-T Infrastructure in Hospital Settings</b><br/>Explore what kind of training has to be carried out to ensure the setting is registration ready. Understand what Standard Operating Procedures have to be in place before dosing begins.</p> <p>Experience on scheduling training plans to ensure a successful CAR-T trial.</p> | <p><b>What is the Optimal Cell Culture?</b><br/>Explore analytical tools for cell characterisation to identify the optimal phenotype for expansion <i>in vivo</i>.</p> | <p><b>Frozen Supply Chain for Ease of Management</b><br/>Compare and contrast the transport of fresh or frozen products. How does allogeneic compare to autologous when transporting larger batches of cells.</p> | <p><b>Data Monitoring Long Term Effects to Support Value of CAR-T</b><br/>Review long term data of CAR-T and TCR therapy. Discover what data analysis is being carried out to understand the long term effects of these novel therapies on patient's health.</p> |

**18.00 Drinks reception**

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## Conference Day Two, September 12<sup>th</sup> 2019

8.30 Opening remarks

9.00 Sponsored talk

9.30 Late Breaking Abstracts

Key companies will present new data for the first time at the CAR-TCR Summit. Be sure not to miss the session of the year and be the first to hear these new clinical trial read outs.

10.00 Sponsored talk

10.30 Sponsored talk

11.00 Morning Refreshments and Tech Slam

| Time  | Discovery   | Translation   | Clinical Operations  | Manufacture  | Logistics   | Commercialisation  |
|-------|---|---|--|--|---|--|
| 12.00 | <p><b>Panel: How to improve the safety modelling of CAR and TCR therapy in preclinical studies?</b><br/>Explore the need for translatable, preclinical models and early stage biomarkers that would suggest safety challenges and toxicity.</p> | <p><b>Panel: Is Genetic Engineering Ethical and Safe?</b><br/>With controversy in the press in 2018 regarding CRISPR edited babies, it is important to discuss the ethics of genetic engineering in clinical research and the responsibility the industry has to preserve the safety of patients in CAR and TCR trials.</p> | <p><b>Panel: What Do You Need to Run a Successful CAR-T Trial?</b><br/>Discuss what is required to set up the infrastructure of a successful CAR-T trial. Outline what training and qualifications are required to support infrastructure. Optimize practice of managing high risk patients and how to prepare and monitor toxicities.</p> | <p><b>Panel: The Need to Streamline Manufacture to Reduce CoG and Ensure a Timely Delivery to Patients in Need</b><br/>Discuss the need to reduce the current turn-around time and laborious manufacture processes of autologous therapy. Is the future in off-the-shelf manufacture? Discuss the challenges in genetically engineering an allogeneic product to reduce rejection.</p> | <p><b>Panel: Logistical Considerations of Autologous Vs Allogeneic Therapy</b><br/>Outline challenges in transporting patient specific autologous therapy and the importance of chain of identity. Review the challenges in bulk expansion and storage of allogeneic therapy, considering the conditions needed to keep cells viable.</p> | <p><b>Panel: Ensuring CAR-TCR Therapies Are Accessible Through Reduced Pricing and Reimbursements</b><br/>Discuss the challenges faced when finalising CAR-T reimbursement models. How will future allogeneic therapies compare in reimbursement strategies?</p> |

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| <b>12.30</b>       | <b>Regulation of CAR and TCR Products to Enhance Safety, Control and Monitor Toxicity</b><br>Review new switch technology that is able to regulate the activity of CAR and TCR cells after administration.                     | <b>Clinical Trial and Translational Experience with Allogeneic CAR and TCR Therapy</b><br>Outline the most up-to-date off-the-shelf clinical trial data to gain a comprehensive understanding of the state of play in this area of clinical development. | <b>Management of Patients and Care Givers</b><br>Explore best practice for managing patients in the community and the information which should be provided for care givers.<br>Review a detailed site management plan.   | <b>Overcoming Challenges of Manufacturing Allogeneic Therapies</b><br>Manufacturing strategies to overcome the potential immunogenicity that exists when transferring cells between donor and patients.  | <b>Managing Logistics of Multiple Products</b><br>When managing multiple clinical trials and commercial products, review best practice for managing logistics of all products in one suite.   | <b>Pricing Models to Make CAR-T Therapy Affordable</b><br>Review current pricing models, including value based pricing and outcome based pricing, to discuss strategies to make these potentially curative therapies accessible for patients.<br>Discuss considerations of models like relapse and the effect on the price. |
| <b>13.00</b>       | <i>Sponsored talk</i>  | <i>Sponsored talk</i>  | <i>Sponsored talk</i>  | <i>Sponsored talk</i>  | <i>Sponsored talk</i>   | <i>Sponsored talk</i>   |
| <b>13.30 Lunch</b> |  |  |  |  |   |   |
| <b>14.30</b>       | <i>Sponsored talk</i>  | <i>Sponsored talk</i>  | <i>Sponsored talk</i>  | <i>Sponsored talk</i>  | <i>Sponsored talk</i>   | <i>Sponsored talk</i>   |
| <b>15.00</b>       | <b>Safety Switch Technology to Enhance Safety</b><br>Analyse how long it takes to shut down, what the threshold is to decide to turn it off and how much is needed to demonstrate to move into clinical trials.                | <b>Clinical Trial and Translational Experience with Allogeneic CAR and TCR Therapy</b><br>Compare and contrast different technology available including genetically engineered vs non-genetically engineered CARs and their translational advantages.    | <b>Scheduling a Patient Specific Therapy</b><br>Share experience on how to manage a schedule when a patient falls sick and autologous products are unstable to delay delivery.<br>Optimize staff scheduling including data managers and clinicians to ensure support is available. | <b>Overcoming Challenges of Manufacturing Allogeneic Therapies</b><br>Explore methods to carry out large scale expansion whilst preserving efficacy and potency.<br><br>Manufacturing experience with genetically engineering cells to overcome rejection. | <b>Digital Platforms to Support an Efficient Operation System</b><br>Optimise order intake through digital platforms to ensure customer journey is seamless and easy to manage.<br><br>Review digital analytics that can be used to track and control movement and delivery of specific products. | <b>Reimbursement and Payer Perspectives</b><br>Identify the view of payers to understand their expectations and overcome their reimbursement barrier limiting the adoption of this therapy by healthcare providers.   |
| <b>15.30</b>       | <b>Optimal signalling strength of CAR and TCR to reduce toxicity risk</b><br>This session will compare different strategies to manage the toxicity risk of CAR-T by altering the density of the receptor and binding affinity. | <b>NK Cells and their Clinical Advantage in Allogeneic Therapy</b><br>Review CAR-NK data in allogeneic trials and discuss their advantages compared to t cells including short lifespan, ease of expansion and   | <b>Patient Education to Prepare and Understand Risk and Benefits</b><br>Highlight tools and best practice used to educate patients and carers on the therapy.  | <b>Scaling Out Within GMP Facilities</b><br>Optimize the manufacturing operations of multiple individual projects whilst using the same floor space and suite capacity for higher throughput.  | <b>Effective Patient Scheduling to Ensure Streamlined Delivery</b><br>Optimize scheduling management to ensure the timeline of delivery is planned and met.   | <b>Ethical Considerations on the Price of Curative Therapies</b><br>When reviewing the pricing of CAR-T, what can be done to ensure all patients needs are met.   |

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|                              |  | their antigen non-specific nature.   | Outline the important risks that should be understood and how to support the family throughout the process. | Experience in running a quality system that can permit multiple patient products at the same time. Ensure manufacturing capacity matches clinical.  | Discuss contingency plans when patients are sick delaying treatment. |  |
| <b>16.00</b>                 | <b>The Use of Neo-antigens to enhance the targeting of CAR and TCR to Tumor Specific Tissue</b><br>Learn how the specific targeting to neo-antigens can prevent off-target toxicity. | <b>Clinical Experience of Gamma-Delta T Cells in Allogeneic Trials</b><br>Evaluate the clinical translation of gamma delta t cells to understand the clinical success of this cell type and identify the potential for combination strategies. |   | <b>Appropriate Comparability Tests Required for Manufacturing Changes</b><br>Outline the comparability tests necessary for small changes in CMC. Anticipate the scale of analytical and clinical data required to ensure timely review. |  | <b>Meeting Patient Needs with Broader Recruitment Criteria</b><br>Discuss how the patient recruitment of CAR and TCR therapies can be expanded to ensure patients of different ethnicities can be included in clinical trials. |
| <b>16.30 Afternoon Break</b> |  |  |   |   |  |  |

17.00 Plenary

17.30 Closing remarks

17.45 End of Summit

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## Post-Conference Focus Day, September 13<sup>th</sup> 2019

| Time  | Targeting Solid Tumor  | Manufacturing   | TCR-T Cell Drug Development   |
|-------|--|---|---|
| 9.00  | <b>Genetically Engineered Constructs to Overcome the Tumor Microenvironment</b><br>Equip the CAR and TCR product with additional accessory proteins to counteract the suppressive tumor microenvironment including checkpoint blockade, tumor infiltration support and regulated factors to support antigen binding.   | <b>Lenti-Viral Vector Production</b><br>Focus on new technology in lenti-viral vector production to overcome the biggest manufacturing bottleneck which is the adequate and timely delivery of viral vector.<br><br>Clarification on vector copy number to data to support risk benefit ratio.<br><br>Considerations on how to manage service providers timings to ensure patients receive product in a timely process. | <b>Expansion Techniques for TCR-T Therapies</b><br>Outline best performing expansion techniques which correlates with best persistence in vivo and functional capacity of TCR-T cells.  |
| 9.30  | <b>Understanding Suppressive Nature of the TME</b><br>Understand how the PD1 profile and TGF beta profile affects T cell function in the tumor and innovative strategies to overcome this.   | <b>Adeno-associated Virus as an Accessible Alternative to Viral Vector</b><br>Explore the use of AAV to genetically engineer CAR and TCR. Highlight challenges in the stable transduction of <i>in vivo</i> gene delivery and methods to improve this.  | <b>Is TCR Therapy Scalable?</b><br>Due to the lengthy and tailored manufacturing process of TCR therapies, outline strategies to streamline and scale up this type of therapy for late stage trials.  |
| 10.00 | <i>Sponsored talk</i>  | <i>Sponsored talk</i>   | <i>Sponsored talk</i>   |
| 10.30 | <b>Morning Refreshments</b>  |   |   |
| 11.30 | <b>Expansion Strategies in the Tumor Microenvironment</b><br>Manage expansion in solid tumors with the use of homeostatic cytokines for directional support. Explore strategies to enhance the current lack of expansion due to rare antigen specific clonal cells.<br>Review methods to ensure target identification to enhance proliferation of t cells and durability within the site of the tumor. | <b>CRISPR Gene Editing Technology to Prevent Off-target Toxicity</b><br>Discuss how CRISPR gene editing can improve safety and toxicity concerns by improving the targeting of CAR-T's.   | <b>Can TCR be Universal?</b><br>Discuss the limitation of downregulated HLA in cancers which prevents the detection of the cancer cell by TCR-T cells. Outline strategies to also overcome the specific HLA matching to patients which limits the universal applicability of this approach. |
| 12.30 |  | <b>Non-viral Sleeping Beauty Technology to Reduce Cost of Manufacture</b><br>Understand the role of DNA plasmids which have the potential to provide a cheaper method of gene transfer.   | <b>Allogeneic TCR Approach TCR</b><br>With the future moving towards an allogeneic approach, outline the specific challenges with creating an allogeneic TCR therapy.   |
| 13.00 | <i>Sponsored talk</i>  | <i>Sponsored talk</i>   | <i>Sponsored talk</i>   |
| 13.30 | <b>Lunchtime refreshments</b>  |   |   |
| 14.30 | <b>Verification of Clean Targets</b><br>Overcome on-tumor-off-target toxicity with the identification of novel tumor specific antigens.  | <b>Non-viral PiggyBac DNA Modifications to Improve Toxicity</b><br>Explore the piggyback platform and it's potential to elicit more consistent and durable responses with lower manufacturing costs and timelines.  | <b>Overcoming the Reduced Co-Stimulatory Signals in Tumors</b><br>Explore the strategies used to block co-inhibitory molecules and/or stimulation of the co-stimulatory molecules to prevent T cell exhaustion.   |

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|       |   |   |   |
|-------|---|---|---|
| 15.00 | <b>Binder Technology to Restrict Targeting to Tumor Sites</b><br>Review binder technology that ensures binding and activation only occurs when multiple antigens are expressed within the tumor microenvironment as a strategy to combat off tumor binding. | <b>Electroporation for CAR-T Engineering</b><br>Review the advantages and disadvantages of electroporation including the simplicity and speed of the procedure compared to its ability to cause cell death. | <b>TCR Selection to Overcome Toxicity</b><br>Review key assays which can improve the selection of TCRs to reduce the current risk of on-target and off-target toxicities. |
| 15.30 | <b>End of Summit</b>  |   |   |

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