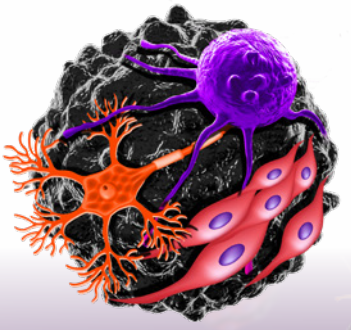
7-9 May 2019 | Boston

www.allogeneic-cell-therapies.com

Allogeneic Cell Therapies Summit



Optimize Persistence, Large-Scale Manufacturing and Production Time to Deliver Safe, Commercially Viable and Effective Allogeneic Cell Therapies to Patients Worldwide

Expert Speakers Include:

Andre Choulika
CEO
Cellectis

Alison Moore
CTO
Allogene Therapeutics

Xiaokui Zhang
CSO
Celularity

Bob Valamehr
CDO
Fate Therapeutics

Robert Igarashi
CSO
CytoSen Therapeutics

Jean-Pierre Latere
COO
Celyad

Partners: ACEA Biosciences, Inc. | Lonza Pharma & Biotech

Tel: +1 415 735 3289 Mail: info@hansonwade.com Cell Immunotherapy

hansonwade

Welcome to the Allogeneic Cell Therapies Summit

Advancing the Next Generation of Cost Effective Cell Therapies at Scale

Although there has been success with autologous cell therapies, there are challenges commercially in scaling, manufacturing and meeting patient demand.

The Allogeneic Cell Therapy Summit is focused on optimizing the clinical and commercial development of engineered allogeneic cell therapies with improved manufacturing and commercialization strategies to reach patients in need at a better cost.

Bringing together the pioneers of allogeneic cell therapy development we will discuss how to ensure **efficacy and clinical proof of concept** to **improve the trafficking and persistence** of allogeneic cell therapies, and ultimately **overcome rejection** providing patients with the best standard of care.

Join us, and leading experts from **Cellectis, Servier, Fate Therapeutics** and **Celyad** as we drive towards the future of cell therapies. Discover methods to create allogeneic cell therapies that are enhanced through engineering to boast simpler and more cost effective manufacturing strategies with improved commercial benefits.

Hear what past attendees have to say:

"Very well organized meeting with top researchers in this field: great overview of a dynamic subject area"

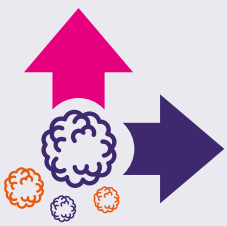
"Intimate setting where scientists and clinicians can have focused discussions around cell biology and clinical translation"
Fate Therapeutics

Your Checklist to Delivering Allogeneic Cell Therapies to Patients

1.

Evaluating Methods to Commercialize Cell Therapies with Effective Scale Up & Scale Out

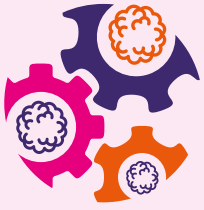
Examine how well-defined and uniform "off-the-shelf" sources of therapeutic cells can make cell-based therapies available to a wide range of patients with **Bob Valamehr of Fate Therapeutics**



2.

Addressing Automation as a Means to Reducing Cost and Increasing Efficiency of Allogeneic Cell Therapies

Learn how employing novel engineering and manufacturing technologies can aid in consistency of manufacture and how **CytoSen Therapeutics** have incorporated semi-automated methods for manufacture of therapeutics cells



3.

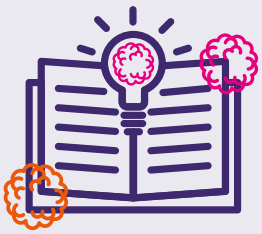
Investigate the Regulatory Checkpoints Allogeneic Cell Therapies Need to Meet to Ensure Safety and Efficacy

Gain an in-depth understanding of the regulatory landscape as allogeneic cell therapies move into clinical investigation to ensure that safety is of the highest standards with **Shaun Stapleton of ReNeuron**

4.

Understanding Persistence Shortcomings in Allogeneic Cell Therapies to Optimize Clinical Development

Learn how to improve persistence in allogeneic cell therapies whilst ensuring products are pure, consistent and affordable with **Cellectis** experts to streamline clinical trials



5.

Discussing the Value of Effective Cold Chain Supply Chain to Deliver Therapies Without Losing Key Characteristics

Hear and discuss novel techniques to rigorously maintain products within specific temperature specifications in order to create commercial cold chains for cell therapies

YOUR EXPERT SPEAKERS

Anne Altmeyer
CBO
Adicet Bio Inc.

Stewart Abbot
SVP & CSO
Adicet Bio Inc.

Alison Moore
CTO
Allogene Therapeutics

Greg Liposky
SVP, Commercial Manufacturing
Athersys

David Sourdive
EVP, Technical Operations
Cellectis

Andre Choulika
Chairman & CEO
Cellectis

Ross Durland
SVP Product Development
Cell Medica

Xiaokui Zhang
CSO
Celularity

Jean-Pierre Latere
COO
Celyad

Robert Igarashi
CSO
CytoSen Therapeutics

Bob Valamehr
CDO
Fate Therapeutics

Harpreet Singh
CEO
Immatics

Yannick Bulliard
Director, Off-the-Shelf Therapies
Immatics

Michael Har-Noy
Founder, CEO & CSO
Immunovative Therapies

Lawrence Lamb
CSO
Incysus

Minh Hong
Head of Allogeneic Cell Therapy Commercial Development
Lonza

Ralph Bradenberger
VP, Development & Manufacturing
Nkarta Therapeutics

Shaun Stapleton
Head of Regulatory Affairs
ReNeuron

Sophie Amsellem-Bosq
CAR-T Program Director
Servier

Lan Cao
Senior Director of Product Development and Clinical Manufacturing
Takeda

Angela Scott
COO
TCBiopharm

Michael Leek
CEO
TCBiopharm

Evren Alici
CEO
Vycellix

Christopher Haqq
CSO
Atara Biotherapeutics

CONFERENCE DAY ONE
WEDNESDAY 8TH MAY 2019

Bob Valamehr CDO **Fate Therapeutics**	**8.15**	**Chair's Opening Remarks**

Advancing Allogeneic Cell Therapies to Commercial Scale Production

Andre Choulika Chairman & CEO **Cellectis**	**8.30**	**Allogeneic Cell Therapies as the Future of CAR-T** Exact talk details to be confirmed
Bob Valamehr CDO **Fate Therapeutics**	**9.00**	**Pluripotent Stem Cell Product Platform as a Unique Means to Mass Produce Off-the-Shelf Allogeneic Cell Products** • Examining how pluripotent stem cell technology represents a unique and powerful approach to make cell-based therapies available to a wide range of patients through the generation of a well-defined and uniform "off-the-shelf" source of therapeutic cells • Highlighting that engineered clonal master iPSC lines can be developed to manufacture hundreds to thousands of doses of the drug product in a cost-effective manner • As a case study, describing the development of off-the-shelf CAR-NK and CAR-T cell products manufactured from a clonal engineered master iPSC line
Alison Moore CTO **Allogene Therapeutics**	**9.30**	**The Use of QTPP as a Tool in the Development of an Allogeneic Cell Therapy** • The creation of a Quality Target Product Profile (QTPP) can be an important tool in biologics manufacturing • Comparisons of the opportunities and challenges in QTPP construction between cell therapies and recombinant proteins • The importance of making progress in robust product understanding to enable manufacturing advances
Xiaokui Zhang CSO **Celularity**	**10.00**	**An Allogeneic, Off-the-shelf NK Cell Product Derived from Placental Hematopoietic Progenitor Cells** • Clinical studies suggest that adoptive transfer of allogeneic natural killer (NK) cells represent a promising treatment for patients with hematological malignancies and solid tumors • Celularity is developing an allogeneic, off-the-shelf NK cell product that is derived from placental hematopoietic stem cells and exhibits substantial cytolytic activity against various cancer cell lines, primary AML and primary MM cells • Clinical and translational development of Celularity NK cell product will be discussed
	10.30	**Morning Refreshments & Speed Networking**
Ralph Bradenberger VP, Development & Manufacturing **Nkarta Therapeutics**	**11.30**	**Development of a Scalable Manufacturing Platform for Off-the-Shelf Genetically Engineered, Allogeneic Natural Killer (NK) Cell Products** • Overview of Nkarta's NK cell platform • Scalability of the platform • Path to commercialization
Evren Alici CEO **Vycellix**	**12.00**	**Genetically Modified NK Cells, Promises, Pitfalls and Potentials** • Elucidating critical factors for long term NK cell engraftment • Decreasing vein to vein time • Bottlenecks in NK cell gene modification
	12.30	**Lunch & Networking**
David Sourdive EVP, Technical Operations **Cellectis**	**1.30**	**Transforming Adoptive T-cell Therapy with Gene-editing** • TALEN®-based gene-editing enables making off-the-shelf allogeneic T-cells • It also enables designing next generation T-cells with engineered attributes and programmed to fulfill chosen immunological scenarios

Exploring Automation as a Means to Reducing Cost and Increasing Efficacy

Robert Igarashi
CSO
CytoSen Therapeutics

2.00 Incorporation of Semi-Automated Methods for Manufacture of High Dose NK Cells Using the PM21 Platform

- PM21 allows for high scale expansion of high potency NK cells to therapeutically relevant high dosages for oncology
- CytoSen has incorporated semi-automated methods for manufacture of therapeutic NK cells
- Automated methods are likely to aid in consistency of manufacture

Jean-Pierre Latere
COO
Celyad

2.30 Perspectives on Developing Non-gene Edited Allogeneic CAR T Therapies

- NKG2D is now a clinically validated target for AML/MDS patients
- CYAD-101: A clinical stage NKG2D CAR T cells therapy built on TCR Inhibitory Molecule (TIM)
- Introducing our proprietary non-gene edited shRNA platform for allogeneic CAR T therapies

Harpreet Singh
CEO
Immatics

3.00 Novel Allogeneic Cell Therapies for Treatment of Solid Cancers

- What are the success factors for clinically and commercially successful treatment of solid cancers?
- XPRESIDENT® antigen discovery platform for novel tumor targets and T-cell receptors
- ACTallo® allogeneic gamma-delta T cell platform
- Outlook: warehouse-based off-the-shelf and fully tailored immunotherapies attacking multiple tumor targets

Examining the Regulatory Landscape for Allogeneic Cell Therapies

Shaun Stapleton
Head of Regulatory Affairs
ReNeuron

3.30 Regulatory Challenges and Opportunities for Allogeneic Cell Therapies: Theory and Real World Experiences

- Regulatory control of allogenic cell therapies – global similarities and differences
- Key regulatory challenges facing allogeneic cell therapies – CMC, nonclinical and clinical aspects
- Opportunities for expedited development and approval – global regulatory programmes and standards

4.00 Afternoon Refreshments & Poster Session

Addressing the Logistical Needs of Allogeneic Cell Therapies

4.30 Roundtable Discussion: Examining Logistical Challenges Specific to Allogeneic Cell Therapies

More practical and highly interactive breakout roundtables where attendees can crowd-source solutions and share opinions around pre-assigned topic areas. A valuable chance for attendees to unite around hot topics and debate best practice. No more sitting quietly, this is a dedicated opportunity for you to voice your experience and identify unique solutions.

1 Addressing the Need for Effective Cold Chain Supply

- Developing robust cryopreservation protocols for the supply and transport of cell therapies
- What are the supply chain modifications needed for allogeneic cell therapies as opposed to autologous cell therapies?
- Exploring efficient ways to thaw and wash cryopreserved products whilst reducing costs
- Evaluating the exposure time to potentially detrimental cryoprotectants

2 Optimizing Transport and Logistical Protocols

- What are the challenges when internationally delivering cell therapies?
- Addressing means to reduce the costs of transport and logistics
- Exploring the tracking systems and procedures that could be implemented to prevent product mix-up
- Examining the value of clinical site data

3 Outlining the Means to Increase Preservation and Shelf Life

- Exploring compatible storage medium for cell therapies that maintain therapy functionality after thawing
- Evaluating the ease of effective distribution of cell therapies with increased shelf life
- Will allogeneic therapies one day become much like a conventional drug?

Bob Valamehr
CDO
Fate Therapeutics

5.30 Chair's Closing Remarks

5.35 End of Day One

CONFERENCE DAY TWO
THURSDAY 9TH MAY 2019

Greg Liposky SVP, Commercial Manufacturing **Athersys**	**8.45 Chair's Opening Remarks**

Allogeneic Cell Therapies Beyond T Cells

Lawrence Lamb CSO **Incysus**	**9.00 Driving the Road to Off-the-Shelf Allogeneic γδT Cell Therapies** **Allogeneic Cell Therapies Beyond T Cells** • Incysus Therapeutics is currently in clinical trials of allogeneic haploidentical γδ T cell therapy for leukemia. • This is in the setting of hematopoietic cell transplant and the autologous Drug Resistant Immunotherapy of glioblastoma multiforme as a combination • We will evaluate allogeneic and off-the-shelf T cell therapies for consolidation of therapy-resistant malignancies
Ross Durland SVP, Product Development **Cell Medica**	**9.30 Allogeneic Natural Killer T (NKT) Cells for CAR-Mediated Cancer Therapy** • Advantages of NKT cells for allogeneic CAR cell therapy • Optimizing the CAR to fit the cell type • Co-expressing IL-15 to improve persistence and activity • Down-regulating MHC to minimize rejection • Future directions
Greg Liposky SVP, Commercial Manufacturing **Athersys**	**10.00 Establishing Long-Term Strategic Plans for Commercial Manufacturing of Allogeneic Cell Therapies** Exact talk details to be confirmed
Yannick Bulliard Director, Off-the-Shelf Therapies **Immatics**	**10.30 ACTallo®: Off-the-Shelf γδ T Cell Therapy Engineered Against Novel Tumor Targets** • γδ T cells are ideally suited for an allogeneic cell therapy, due to their intrinsic antitumor activity, inherent ability to infiltrate tumors and an MHC-independent TCR unlikely to cause GvHD • With ACTallo®, we are leveraging the intrinsic properties of γδ T cells with the addition of a tumor-specific moiety (TCR, CAR,...), in a fully GMP-compatible, 14-days process • With this process, we can generate hundreds to thousands of therapeutic doses from a single healthy donor leukapheresis, with appropriate tumor killing properties • While a first-generation ACTallo® product has great potential in hematologic malignancies, in solid tumors the persistence of an allogeneic product may become a limiting factor. γδ T cell-specific in vivo activation, disruption of the HLA complex, or overexpression of checkpoints could help address this issue
	11.00 Morning Refreshments & Speed Networking
Stewart Abbot SVP & CSO **Adicet Bio Inc.**	**11.30 Development of Chimeric Antigen Receptor-Modified γδ T Cell Therapies for Solid and Liquid Tumors** • Commercial-scale, cGMP-compliant manufacture of gamma delta T cell therapies • Optimization of allogeneic gamma delta cell therapeutics • Preclinical efficacy in solid and liquid tumors

Understanding the Clinical Development of Allogeneic Cell Therapies

Michael Leek
CEO
TCBiopharm

12.00 Step-wise Clinical Development of Allogeneic γδ CAR-T Based Products

- TC BioPharm is developing a range of allogeneic γδ based CAR-T products. Our step-wise clinical development pathway has allowed us to move rapidly from autologous, to allogeneic, to CAR modified variants.
- Our first clinical studies (TCB001) revealed that high doses of autologous γδ T cells (up to 10 billion cells per dose) were well tolerated, with evidence of tumor shrinkage in some patients. TCB is currently evaluating increasing doses of allogeneic cells in AML patients (TCB002); with the aim of commencing clinical studies of CAR-T modified γδ variants later this year (TCB003).
- Over the last five years TCB has taken an integrated approach to product development – having built dedicated in-house infrastructure, including GMP manufacture of cellular product and lentivirus, QC facilities plus clinical/ regulatory expertise.

12.30 Lunch & Networking

Innovative Solutions to Allogeneic's Bottlenecks

1.30 Panel Discussion: Allogeneic Innovation and Collaboration

- Cell therapies are an expensive and resource intense proposition. How can the industry work in a way to most efficiently achieve commercial allogeneic cell therapies?
- How can we bring together everyone from investors to CMOs to collaborate efficiently?
- What is the best business model for allogeneic cell therapies?

Anne Altmeyer
CBO
Adicet Bio Inc.

Greg Liposky
SVP, Commercial Manufacturing
Athersys

Sophie Amsellem-Bosq
CAR-T Program Director
Servier

Minh Hong
Head of Allogeneic Cell Therapy Commercial Development
Lonza

2.30 Afternoon Refreshments & Networking

Lan Cao
Senior Director of Product Development and Clinical Manufacturing
Takeda

3.00 Scientific and Manufacturing Challenges for Allogeneic T Cell Therapy Products

- Unknown scientific questions for allogeneic T cell therapy products
- Manufacturing considerations for allogeneic T cell therapy products

Michael Har-Noy
Founder, CEO & CSO
Immunovative Therapies

3.30 Next Generation Immunotherapy

- Living T-cells differentiated and expanded from healthy donors "off-the-shelf" allogeneic cell therapy
- Non-genetically manipulated, administered in out-patient setting, no chemotherapy conditioning and applicable to solid tumors
- Consistently converts 'cold' tumors to 'hot' tumors to expand checkpoint inhibition applications
- Harnesses the power of the graft vs. tumor effect of non-myeloablative allogeneic stem cell transplant, while eliminating GVHD toxicity, matched donor requirement and need for engraftment
- Artificial lymph node high density bioreactor potential to produce 500 to 1000 treatments per donor creating unprecedented economy of scale
- Phase I and Phase II clinical data documenting tumor debulking immunity and long term survival

Sophie Amsellem-Bosq
CAR-T Program Director
Servier

4.00 Allogeneic CAR-Ts: Effective Therapies to Cure Cancer?
- Update on UCART19, the 1st allogeneic CART product
- Lessons learnt so far
- Future roadmap

Christopher Haqq
CSO
Atara Biotherapeutics

4.30 Pioneering an Off-the-Shelf, Allogeneic T-cell Platform for Epstein-Barr Virus (EBV)-Associated Cancers and MS
- Epstein-Barr virus (EBV) infects B cells and epithelial cells, and is implicated in cancers and autoimmune diseases including post transplant lymphoproliferative disease (PTLD) and multiple sclerosis (MS). EBV-associated PTLD (EBV+ PTLD) is currently treated with chemotherapy and rituximab
- Atara has developed an off-the-shelf, allogeneic T-cell platform which enables rapid delivery of a T-cell immunotherapy manufactured in advance and stored in inventory, with each manufactured lot of cells providing therapy for numerous potential patients
- tab-cel® (tabelecleucel) is Atara's most advanced T-cell immunotherapy; it is in Phase 3 for patients with EBV+ PTLD, who have failed rituximab or rituximab plus chemotherapy
- Atara is also developing T-cell immunotherapies targeting EBV antigens for the potential treatment of MS
- Atara is also engineering EBV-specific T cells by leveraging next-generation CAR technologies, to support further development of an off-the-shelf, allogeneic CAR T immunotherapy platform

Greg Liposky
SVP, Commercial Manufacturing
Athersys

5.00 Chair's Closing Remarks

5.15 End of Day 2

WORKSHOP DAY TUESDAY 7TH MAY

Workshop A

Effective Scale-Up to Achieve Commercialization of Allogeneic Cell Therapies

9:00am – 12:00pm

Allogeneic cell therapy products are displaying encouraging clinical and pre-clinical results. As therapeutic technologies mature, it is essential for the cell manufacturing industry to correspondingly develop to adequately support commercial scale production. Consequently, there is much that can be learned and adapted from traditional manufacturing fields.

Attend this workshop to:

- Identify current gaps in cell therapy manufacturing
- Discuss strategies for integrating new solutions into allogeneic cell therapy manufacturing
- Address the need for a highly controlled, robust and standardized manufacturing engineering strategy

Workshop Leaders

Evren Alici
CEO
Vycellix

Robert Igarashi
CSO
CytoSen Therapeutics

Workshop B

Building Your Own GMP Infrastructure for CAR-T - Commercial, Clinical and Regulatory Considerations

1:00pm – 4:00pm

TC BioPharm (TCB) has elected to bring cell and lentiviral vector (LVV) manufacture in-house to guarantee supply of materials for our CAR-T programmes. This decision has been taken primarily to address key concerns facing our future business in the CAR-T space. This is because there continues to be limited availability of GMP-grade LVV from CDMO's. Subcontractor bottlenecks can lead to significant delay in the manufacturing process and clinical timelines. There also is a high cost with regard LVV manufacturing (this has increased significantly with ongoing interest in CAR-T sector).

Aims of the workshop:

- To address some key considerations facing CAR-T manufacture with regard to γδ T cells
- Gain insight into de-risking strategies for developing allogeneic treatment platforms

GMP manufacture
- In-house vs contracted manufacture
- Regulatory considerations
- Shipment, starting material & end product, validation, shelf-life

LVV manufacture
- Facility design – MHRA review
- QA systems
- Platform considerations
- Release tests

Cell manufacture
- Facility design
- Cell banking - autologous vs allogeneic
- Donor recruitment
- Storage and contingency
- Media optimisation
- Release tests (auto/allogeneic)

Workshop Leaders

Michael Leek
CEO
TCBiopharm

Angela Scott
COO
TCBiopharm

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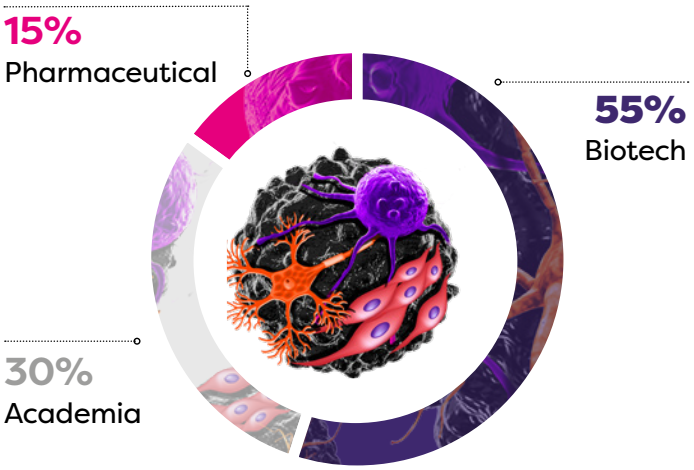
Exhibitor

ACEA Biosciences, Inc.

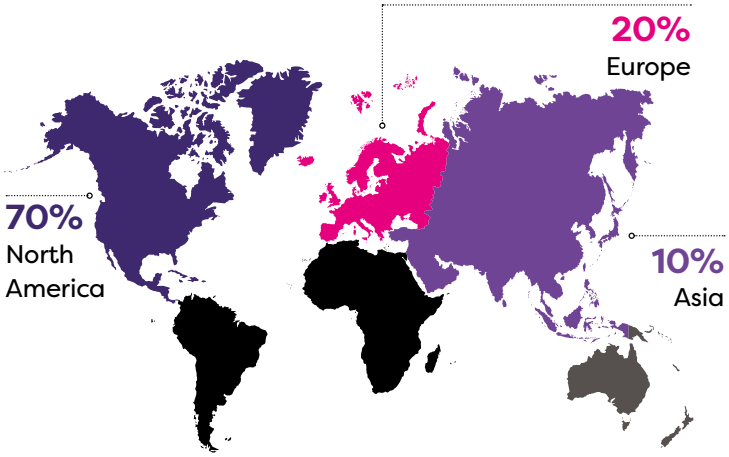
ACEA Biosciences pioneers the development and commercialization of cutting edge cell analysis instruments. Employing noninvasive impedance microelectrodes in automated high-throughput plate formats, our xCELLigence®Real-Time Cell Analysis instruments enable label-free, real-time monitoring of cell proliferation, cell size/morphology, cell-substrate attachment quality, and cell invasion/migration. Salient applications include cancer drug discovery and immunotherapy cell killing assays. ACEA is also helping to revolutionize the field of flow cytometry by producing high performance, customizable benchtop cytometers at accessible price points. Our NovoCyte™ flow cytometers include up to 13 fluorescence detection channels with 3 lasers, direct volumetric-based cell counting, and a versatile high throughput walkaway autosampler.

www.aceabio.com

Attendance by Company Type



Attendance by Geo



GET INVOLVED

Luke O'Neill
Partnerships Director
Tel: +44 203 8541 823
Email: sponsor@hansonwade.com

READY TO REGISTER?

3 EASY WAYS TO BOOK

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Tel: +1 415 735 3289

Email: register@hansonwade.com

Network with the experts and leaders of the Allogeneic Cell Therapy Community and take this opportunity to make collaborative partnerships for future clinical prospects.

Hear the novel clinical data from trials and apply the lessons learnt to future pipelines to ensure future efficacy.

Learn from the leaders in the space and join the communal discussion finding solutions to limiting manufacture and regulatory issues.

Team Discounts*

- **10% discount – 3 delegates**
- **15% discount – 4 delegates**
- **20% discount – 5 or more delegates**

Please note that discounts are only valid when three or more delegates from one company book and pay at the same time.
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