



Your content marketing partner for life sciences

MEDIA KIT 2023





Your content
marketing
partner for life
sciences

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ABOUT

Immuno-Oncology Insights

Immuno-Oncology Insights is an online only, independent, peer-reviewed open access journal covering the entire cancer immunotherapy space from preclinical to clinical development. Critical topics include tools and technologies, biomarkers, the TME, combination therapy, platform development trends and safety. Challenges and advances are addressed through publication of original research, reviews, commentary articles, clinical trial reports and so much more.

All content is available free of charge, and the written material is complemented by engaging formats such as webinars, infographics, animations, video and podcasts.

An online only, peer-reviewed, open access journal covering the entire cancer immunotherapy space from pre-clinical to clinical development

Senior Editors: Jon Wigginton

**IMMUNO-
ONCOLOGY**
INSIGHTS



 BIOINSIGHTS

Is it important for **your company to demonstrate its capabilities** to scientists and/or business leaders making key technology platform decisions at an early stage in a product's development?

Do you need to **generate qualified leads** from companies involved in the development of cancer immunotherapies?

Are you looking to **provide educational materials** to individuals focused on analysis, tools, technologies, preclinical and clinical development?

***Immuno-Oncology Insights* provides a unique online content marketing and lead-generation opportunity:**

- ▶ **Active engagement of key stakeholders** from across the global community all year round
- ▶ The chance to **target organizations at varying stages of the R&D pipeline**: Large pharma-mid sized pharma, biotech, spin-outs, research and academic institutions, hospital, investors and analysts
- ▶ **An alternative to the ever-more expensive conference market**
- ▶ A means by which you can access those individuals driving the ongoing translation of safe, effective immuno-oncology therapeutics on a global basis



Immuno-Oncology Insights provides a unique online content marketing and lead-generation opportunity

WHAT CAN WE DO FOR YOU?

We can:

- ▶ Provide support in the **development of your content marketing strategy** and tactics for this sector, partnering with you in the development of your annual marketing plans
- ▶ Work closely with you to **create quality written, video and audio content** of high value to your target audience
- ▶ Offer you opportunities to **re-purpose scientific and educational content** you have already developed and make it available to a global audience
- ▶ **Raise your company's profile**, demonstrate your capabilities, and enhance your reputation as a thought-leader in the sector
- ▶ Play a key role in your **lead-generation activities**
- ▶ Ensure your leading scientists are seen as **Subject Matter Experts** throughout your target market
- ▶ **Create written content from video or audio**, ideal for increasing the reach, longevity and searchability of your data and other technical information

We don't sell off-the-shelf solutions. All the packages we provide are tailored to your precise marketing, educational and business development objectives.

We can partner with you to develop high quality content to demonstrate your thought-leadership:

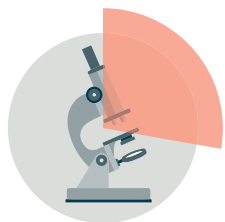
- ▶ Your own special focus issue or ebook on the topic of your choice
- ▶ Client case studies, interviews and co-presentations
- ▶ Peer reviewed articles, as well as editorials and commentaries
- ▶ Video presentations and roundtables
- ▶ Podcasts
- ▶ Infographics and animations
- ▶ Webinars, both live and on demand



USER DEMOGRAPHICS

Data by sector

- ▶ Immunotherapy approaches have transformed cancer treatment. This has resulted in increased investment in the immuno-oncology space to meet the need for both new drugs, and cutting-edge products, technologies to support further innovation
- ▶ *Immuno-Oncology Insights* offers an unparalleled opportunity to target all the key stakeholders involved in driving the ongoing translation of safe, effective I-O therapeutics.
- ▶ Prolific academic institutions and research hospitals, in particular those that generate spin-outs based on cancer immunotherapy candidates and technologies
- ▶ Pharmaceutical companies and large biotechs with a major or growing focus on immuno-oncology
- ▶ Government-funded organizations (such as NIH) and NGOs
- ▶ Investors and analysts



28%

Biotech



27%

Academic/
Hospital



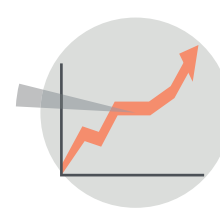
18%

Pharma/
Large Biotech



3%

Government/
NGO



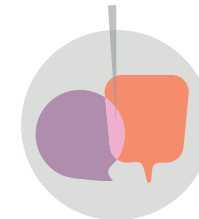
3%

Investor/
Analyst



20%

Solution/Service
Provider



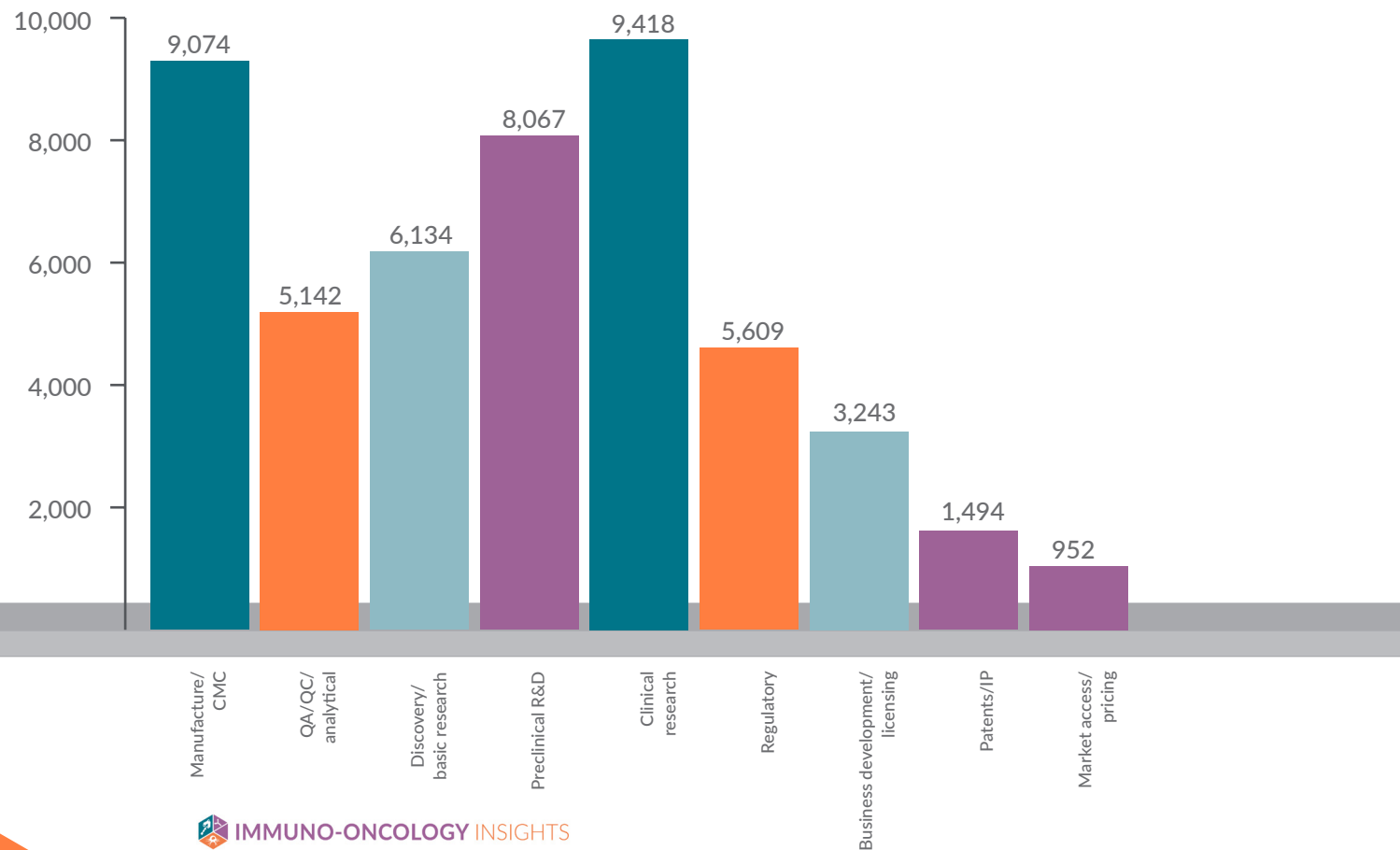
1%

Consultant

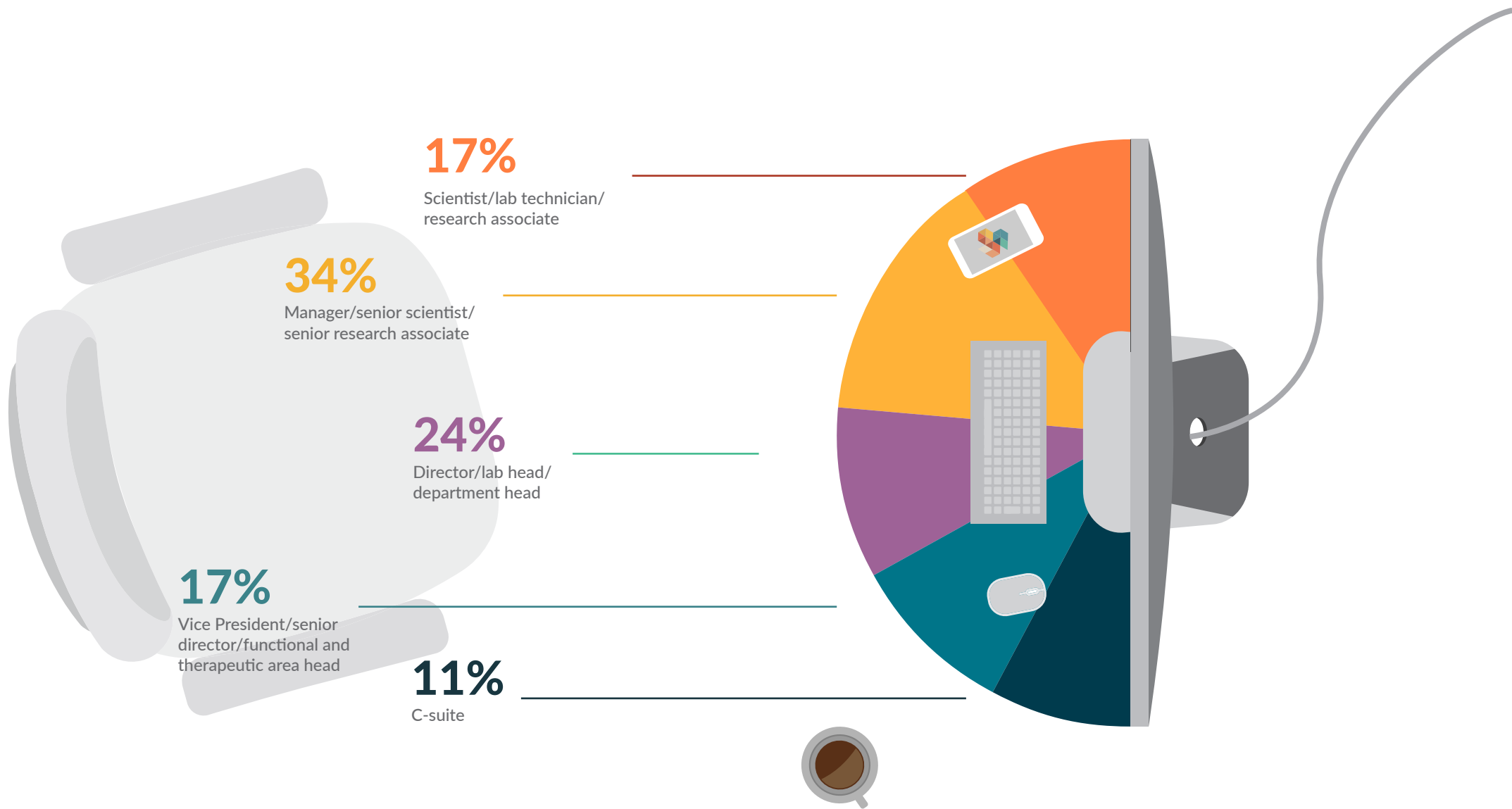
Immuno-Oncology Insights covers the entire cancer immunotherapy space from from preclinical to clinical development and the latest tools and technologies, featuring content of value to individuals along the R&D pipeline

Data by interest area & seniority

- ▶ Discovery and basic research
- ▶ Preclinical development and translational R&D
- ▶ Clinical research
- ▶ Product development, process development, operations, logistics and manufacture
- ▶ Regulatory affairs, QA/QC and validation
- ▶ Business development, corporate management and licensing



Data by interest area & seniority continued



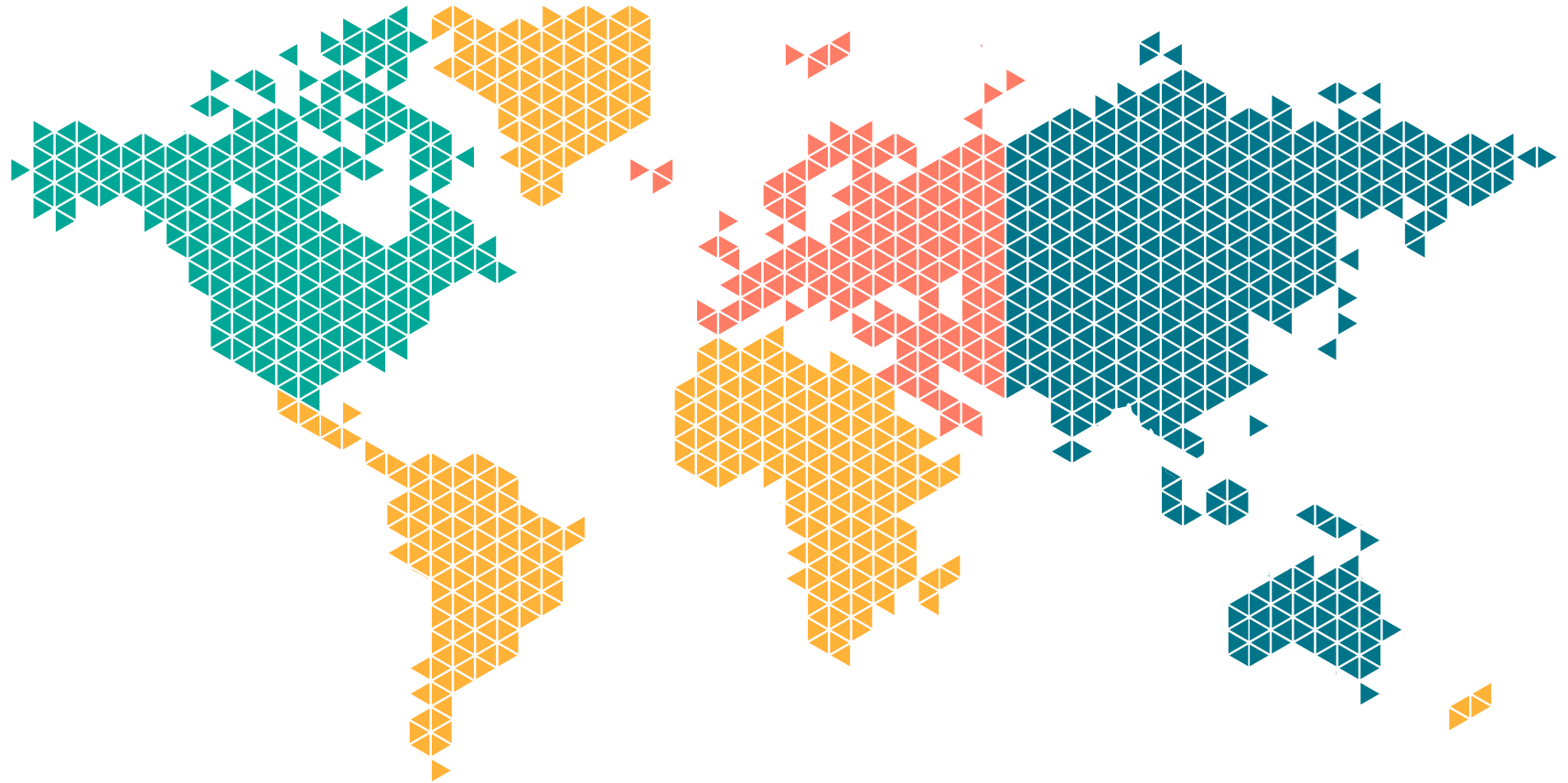
Data by Location

▶ **58%**
North America

▶ **32%**
Europe

▶ **8%**
Asia and Australia

▶ **2%**
Rest of World



EDITORIAL CALENDAR



Spotlights

Each monthly Spotlight focuses BioInsights members' attention on a particular topic or technology area. We leverage an array of formats to provide a comprehensive update on the key trends, challenges and breakthroughs in a given field: Independently peer reviewed Expert Insights, opinion pieces, interviews, webinars, podcasts, FastFacts videos and more...



Channel Editions

Channels allow us to zoom right in on specific aspects that are of special interest to BioInsights members. The Tools & Technologies Channel will cover topics including AI, machine learning, multiomics, imaging and *in vivo* tools



Podcast series

We select a key issue or challenge, then invite a range of stakeholders to proffer their opinions and share related learnings via the ever-popular, easy-to-consume podcast format.

2023 Editorial Calendar



SPOTLIGHT

FEBRUARY

Nonclinical tools update
Guest Editor: Pelin Candarlioglu

MARCH

Clinical development strategy

APRIL

Modality/platform development trends
Guest Editor: David J DiLillo

MAY

Combination therapy



CHANNEL FOCUS Tools & Technologies

Leveraging cutting edge tools and technology to advance I-O: AI and machine learning

Leveraging cutting edge tools and technology to advance I-O: multiomics

JUNE

Overcoming mechanisms of tumor resistance part 1: Breaking into the TME
Guest Editor: Brent Hanks

JULY

Overcoming mechanisms of tumor resistance part 2. What progress is being made in solid tumors?

AUGUST

SEPTEMBER

Novel targets and pathways

Leveraging cutting edge tools and technology to advance I-O: *in vivo* tools for preclinical applications

OCTOBER

Biomarker discovery and patient selection

NOVEMBER



Safety: preclinical and clinical

Leveraging cutting edge tools and technology to advance I-O: tools of tomorrow

Contact Diane McKenna
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Europe: +44 7789035984
diane.mckenna@insights.bio
to discuss thought leadership and lead generation opportunities

NEW for 2023!



Tools and technologies channel

- ▶ Channels allow us to zoom right in on specific aspects of topic areas that are of special interest to BioInsights members.
- ▶ The Tools and Technologies channel will feature four editions in 2023, covering topics such as AI, multiomics and *in vivo* tools.

Each spotlight will comprise:

- ▶ Peer-reviewed Reviews and Expert Insight articles written by leading experts in the field
- ▶ Webinars, featuring industry speakers and sponsors discussing key topics specific to the Spotlight
- ▶ Podcast, written and video interviews with key opinion leaders
- ▶ On demand roundtable discussions

Immuno-Oncology Insights' spotlights provide you with fantastic opportunities to:

- ▶ **Educate your target market** about your company's expertise, capabilities and experience
- ▶ **Share your latest data** with organizations looking for partners and service providers in your field
- ▶ **Profile your executives and scientists** as thought-leaders and KOLs
- ▶ **Generate qualified leads** from across the global sector
- ▶ **Increase awareness** of your company's role in immuno-oncology R&D

For more detail on the planned contents for any of the spotlights and focus issues, please contact Nicola McCall at n.mccall@insights.bio



Spotlights

FEBRUARY

Nonclinical tools update

GUEST EDITOR: Pelin Candarlioglu, GSK

- ▶ Guest Editor: Pelin Candarlioglu
- ▶ Emerging animal models
 - ▶ Humanized mice
- ▶ Cell models and organoids
- ▶ Xenografts/patient-derived xenografts
- ▶ *In vitro* versus *in vivo* models
- ▶ 3D cell technologies
- ▶ Enhancing preclinical predictivity
 - ▶ Addressing the lack of translatability from preclinical activity for various agents and combos

MARCH

Clinical development strategy

- ▶ Expanding the reach of immuno-oncology
 - ▶ Targeting earlier lines of treatment
- ▶ The changing global regulatory landscape
- ▶ Clinical trials:
 - ▶ Logistics and practicalities
 - ▶ Innovation in clinical trial design
- ▶ Addressing the intensifying patient recruitment challenge
- ▶ Modernizing eligibility criteria
 - ▶ Diversity and inclusion
 - ▶ Different patient groups (children, the elderly etc)

APRIL

Modality/platform development trends

GUEST EDITOR: David J DiLillo, Director, Immuno-Oncology Regeneron Pharmaceuticals

- ▶ Checkpoint inhibitors 2.0 – where are we now, and what's next?
- ▶ The rebirth/evolution of cytokine agents
- ▶ The next generation of multipecifics
- ▶ ADCs
- ▶ Intralesional therapy
- ▶ Myeloid-directed therapies
- ▶ mRNA-based therapeutics
- ▶ Cellular immunotherapy
- ▶ Oncolytic virotherapy

MAY

Combination therapy

- ▶ How to further rationalize I-O combination therapy development
 - ▶ Addressing PD1 refractory disease: identifying, characterizing and classifying patients into subgroups to tailor therapy effectively
- ▶ Emerging technologies or trial designs to better elucidate the contribution of different agents in a combination
- ▶ How can we improve the outcome with combination drugs without increasing the costs?
- ▶ Can multispecific I-O drugs replace combination therapies and reduce cost?
- ▶ How to best combine I-O drugs with ADCs?
 - ▶ Safety challenges
- ▶ Translational approaches for IO combination trials

JUNE

Overcoming mechanisms of tumor resistance part 1: Breaking into the TME

GUEST EDITOR: Brent Hanks, Associate Professor of Medical Oncology, Associate Director of Basic and Translational Research, Duke Center for Cancer Immunotherapy; Duke University and Duke Cancer Institute

- ▶ Addressing microenvironmental challenges
- ▶ Overcoming TME issues by targeting monocyte macrophage populations
- ▶ For cell immunotherapy, how can we make cells that address the known immunologic barriers?
- ▶ Key enabling technologies unlocking the secrets of the TME

JULY

Overcoming mechanisms of tumor resistance part 2. What progress is being made in solid tumors?

- ▶ With CAR-Ts approved for blood cancers, how do we translate this success into solid tumor malignancies?
- ▶ Cell therapy approaches: T cells, NK cells, macrophages. What will be successful?
- ▶ Multispecifics vs. CAR Ts in solid tumors – how do they compare and which will come out on top?
- ▶ As various modalities (cytokines, CAR-T, T cell engagers, ADCs, oncolytic virotherapy) make more headway into solid tumours, how can these modalities complement and/or synergize with checkpoint blockade?
- ▶ Combinations in solid tumors

SEPTEMBER

Novel targets and pathways

- ▶ Commercial and academic perspectives on novel target discovery
- ▶ Aligning academic and industry priorities
- ▶ Industry has the money but academia has the novel ideas – who is going to take/fund risks?
- ▶ How can the I-O space move past the low hanging fruit?
- ▶ Optimal selection of tumor antigens (expression patterns, antigen escape, expression on normal tissue)
- ▶ Moving the needle on combinations – what modalities/ approaches will be involved?

OCTOBER

Biomarker discovery and patient selection

- ▶ Clinical biomarker discovery and development
 - ▶ Novel biomarker assays
- ▶ Why hasn't the promise of diagnostic/prognostic biomarkers been fulfilled?
- ▶ Is there a path forward for peripherally available biomarkers (serum, blood based, liquid biopsy) for I-O therapies? Or is it only biopsy driven or *in situ* (i.e. what's happening in the TME) biomarkers that are important?
- ▶ Patient selection and precision medicine
 - ▶ AI/patient data
 - ▶ Optimal patient characteristics
 - ▶ Clinical NGS
- ▶ Are we measuring response the right way?
- ▶ Alternative ways to measure response – cDNA, PET scans, imaging
 - ▶ Applying AI and machine learning tools to make more educated decisions. (furthering the partnership between mathematics, computational biology, big data management, and raw biology)
 - ▶ Harnessing precision medicine for combination therapy decision-making

NOVEMBER

Safety: preclinical and clinical

- ▶ Preclinical safety
 - ▶ Addressing the lack of translatability in preclinical evaluation of immunotoxicity
 - ▶ What tools/platforms are demonstrating potential to aid in the prediction of toxicity?
- ▶ Clinical safety
 - ▶ Balancing toxicity and efficacy
 - ▶ Addressing patients who develop I-O-related toxicity with no response to therapy
 - ▶ Lack of clinical management options for toxicity



Tools & technologies channel focus

MARCH

Leveraging cutting edge tools and technology to advance I-O: AI and machine learning

- ▶ Leveraging AI, machine learning, big data

MAY

Leveraging cutting edge tools and technology to advance I-O: multiomics

- ▶ Multiomics (spatial omics, genomic profiling, proteomics, transcriptomics, etc, combined with histology assessment)

SEPTEMBER

Leveraging cutting edge tools and technology to advance I-O: *in vivo* tools for preclinical applications

- ▶ *In vivo* tools for preclinical applications
- ▶ Exploring the cutting edge in imaging tools (e.g. digital pathology) and their application in preclinical I-O

NOVEMBER

Leveraging cutting edge tools and technology to advance I-O: tools of tomorrow

- ▶ Tools of tomorrow: enabling tools and emerging platforms likely to make a splash in 2024.

Immuno-Oncology Insights provides you with fantastic opportunities to:

- ▶ **Educate your target market** about your company's expertise, capabilities and experience
- ▶ **Share your latest data** with organisations looking for partners and service providers in your field
- ▶ **Profile your executives and scientists** as thought-leaders and KOLs
- ▶ **Generate qualified leads** from across the global sector
- ▶ **Increase awareness** of your company's role in cell and gene therapy R&D and manufacture.

TESTIMONIALS & EDITORIAL BOARD



Testimonials:

- ▶ This is what HUB Organoids had to say about *Immuno-Oncology Insights* after working together on a webinar:

“We are getting good traction on the Immuno-oncology Insights front at HUB. The webinar hosted by *Immuno-Oncology Insights* generated a good number of leads that we are now nurturing, but also gave us the opportunity to assess and re-evaluate our offerings and capabilities.

I feel more confident now and will be seeing assets and promos coming up because of the webinar. We will be using *Immuno-Oncology Insights* throughout this year and in 2023 to help us with our marketing campaign to increase

awareness and lead generation for HUB. I worked with other digital media publications this year, but I find the quality of the *Immuno-Oncology Insights* leads to be better aligned to our current needs at HUB Organoids.”

- ▶ Testimonial from guest editor: Dr Pelin Candarlioglu, Senior Cell Biologist at GSK and Chair of Industry Advisory Board at EUROoCS:

“I had an interest in immuno-oncology and cell therapies long before I could start working with them and during that time I was reading a lot of articles from *BioInsights*. It is very nice to know I might be able to contribute to the next generation’s interest in the field.”

IOI Editorial Advisory Board:

Immuno-Oncology Insights (Sen. Eds.: Dr Jon Wigginton, Dr Renier Brentjens) is an independently peer reviewed, open access journal for debate and discussion by all stakeholders involved in driving the ongoing translation of safe, effective I-O therapeutics.

Our editions are strongly guided by our Editorial Advisory Board, which features a number of high-profile figures within academia and industry that include the following:

- ▶ Fernanda I. Arnaldez, MD, Executive Global Product Leader - Early Development, Oncology Research and Development, AstraZeneca

- ▶ Roy D. Baynes, MD, PhD, Senior Vice President and Head, Global Clinical Development, Chief Medical Officer, Merck Research Laboratories
- ▶ John Desjarlais, PhD, CSO, Xencor
- ▶ David J. DiLillo, PhD, Associate Director, Oncology/Angiogenesis, Regeneron Pharmaceuticals
- ▶ Dr Rakesh Dixit, President & Chief Executive Officer, Bionavigen
- ▶ Dr Jessica Flechtner, CSO, Genocea Biosciences
- ▶ Anurag Khetan, PhD, Senior Director, Global Cell Line Development and Omics, Bristol-Myers Squibb

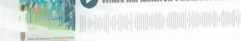
- ▶ Dr Patrice Milos, Co-Founder/President and CEO, Medley Genomics, Inc.
- ▶ Jacques Moisan, PhD, Translational Innovation Platform - Immuno-Oncology Scientific Site Head (USA), - - EMD Serono Research and Development Institute
- ▶ Jill O'Donnell-Tormey, PhD, Chief Executive Officer & Director of Scientific Affairs, Cancer Research Institute
- ▶ Alfredo Perales-Puchalt, MD, PhD, Vice President, Research & Development, Geneo Therapeutics



The Biosights Podcast

Where will tomorrow's workforce come from? PART 4: Who are tomorrow's cell and gene therapy workers?

DATE: 12/15/2023 | 15:00 | 20:00 | 15:00 | 20:00



LISTEN NOW

SHOW NOTES

PART 4: Who are tomorrow's cell and gene therapy workers?

Welcome to a 4-part series exploring a question that the cell and gene therapy community is struggling with at the moment: "Where will tomorrow's workforce come from?"

The cell and gene therapy field has been abuzzing at a breakneck speed for the last part of a decade now, fueled by long medical histories, commercial investments, and a skilled workforce. In addition to long medical histories and big programs, the cell and gene therapy field is also seeing a lot of growth and innovation comes from a combination of developing a sufficiently large and skilled workforce to support and maintain the field.

In this final episode, we look to the future of the cell and gene therapy workforce exploring the implications, skills, goals, and priorities of the individuals who are at various early stages of their careers in the sector. **Host: Dr. Jeffrey Wood, co-owner, Medley Genomics, Inc. and Lecturer in the sector. Guest: Dr. Jeffrey Wood, co-owner, Medley Genomics, Inc. and Lecturer in the sector. Host: Dr. Jeffrey Wood, co-owner, Medley Genomics, Inc. and Lecturer in the sector. Guest: Dr. Jeffrey Wood, co-owner, Medley Genomics, Inc. and Lecturer in the sector.**

ThermoFisher SCIENTIFIC

CELL & GENE THERAPY INSIGHTS

VECTOR Purification

The CAR toolkit: progress and challenges in CAR T/NK cell R-D and manufacture

H Diemme, T Manning, S Steiner

15 DECEMBER 2023

ThermoFisher SCIENTIFIC

CELL & GENE THERAPY INSIGHTS

VECTOR Purification

CONTENTS

1. Introduction

2. The CAR toolkit: progress and challenges in CAR T/NK cell R-D and manufacture

3. The cell and gene therapy workforce: implications, skills, goals, and priorities

4. The future of the cell and gene therapy workforce

5. Conclusion

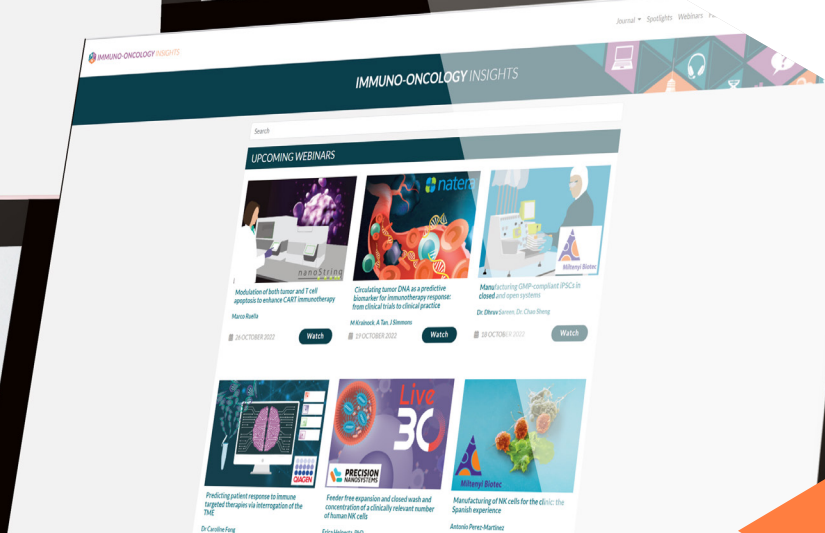
WEBINARS

Presenting a webinar with *Immuno-Oncology Insights* gives you an efficient and cost-effective way to:

- ▶ Generate qualified leads from amongst the global immuno-oncology community
- ▶ Demonstrate your company's expertise and capabilities
- ▶ Stimulate discussion around a topic of significant importance to your customers
- ▶ Educate individuals on crucial regulatory, scientific or technical issues
- ▶ Make a noise around a new product or service offering launch

Download our webinar guide here

Webinars can stand alone or can be included in a Spotlight, depending on the topic and timing fit.



Our
2023
webinar
schedule is now
starting to fill up.
Contact diane.mckenna@insights.bio to discuss options & availability.

Presenting a webinar with us is an efficient and cost-effective way to generate qualified leads.

Our webinar packages include:

- ▶ As much support as you need in terms of topic selection and agenda development, format selection, and speaker panel identification and invitation
- ▶ Full hosting and technical support, including planning calls with panellists and rehearsals as needed
- ▶ A comprehensive promotional plan, including multiple email shots to our database, website and newsletter marketing, and social media
- ▶ A host from our editorial team to ensure the webinar runs smoothly on the day
- ▶ Registration and attendee lists for the webinar
- ▶ A report on the questions submitted during the live webinar so you can follow up directly with individuals afterwards and continue the discussion
- ▶ Hosting of the webinar recording on an indefinite basis with ongoing lead generation
- ▶ Webinar recording provided to you for hosting on your own site
- ▶ The option for us to publish an article based on the transcript of the webinar, repurposing your presentation into written format and making it search engine friendly

We don't sell off-the-shelf solutions. All the packages we provide are tailored to your precise marketing, educational and business development objectives.

Examples of previous webinars for our clients:

Panel-style webinar with accompanying transcript-based article for Sartorius

Aug 5 2021 ON-DEMAND
Cell-based therapies for cancer treatment: leveraging advanced flow cytometry for greater clinical insight
Sponsor: **SARTORIUS**

IMMUNO-ONCOLOGY INSIGHTS
LEVERAGING CUTTING EDGE TOOLS TO CONVERT I-G DATA INTO KNOWLEDGE
SPOTLIGHT

INNOVATOR INSIGHT
Cell-based therapies for cancer treatment: leveraging advanced flow cytometry for greater clinical insight
Rong Fan, Tamara J Lukowski & Nick Semelitsch

The revolution of antibody cell and targeted protein analysis methods, which are now becoming critical to antibody research and development, will open up clinical treatment and diagnostic avenues previously unexplored. In this article, we report on our discussion the practical application of advanced flow cytometry and antibody research and development of T cell and CAR-MR therapies.

Dr. Nick Semelitsch
Product Manager
Sartorius, Göttingen, Germany
Office: +49 551 3939-1000
E-mail: nick.semelitsch@sartorius.com

1 year ago, antibodies in the particular context of technology and its clinical application?

Expanded Topics: The New Era of Cell-based Therapies: Next-Gen Flow Cytometry

As we begin to adopt T cell transfer therapy, we must consider the cell-based therapies that are already in use. In addition, we must consider the cell-based therapies that are already in use. In addition, we must consider the cell-based therapies that are already in use. In addition, we must consider the cell-based therapies that are already in use.

257

258

Presentation-style webinar with Q&A for Miltenyi Biotec

Apr 20 2021 ON-DEMAND
Ultrahigh-content imaging helps to identify CAR target candidates against pancreatic adenocarcinoma
Sponsor: **Miltenyi Biotec**

Watch now

SPEAKERS
Dr. Daniel Schäfer
Team Coordinator R&D, Miltenyi Biotec

Live30 webinar: a 30 minute webinar focused on new technologies and their applications for HUB Organoids

Jun 15 2022 ON-DEMAND
Overcoming current challenges in immunotherapy drug development with patient-derived organoids
Sponsor: **HUB ORGANOIDS**

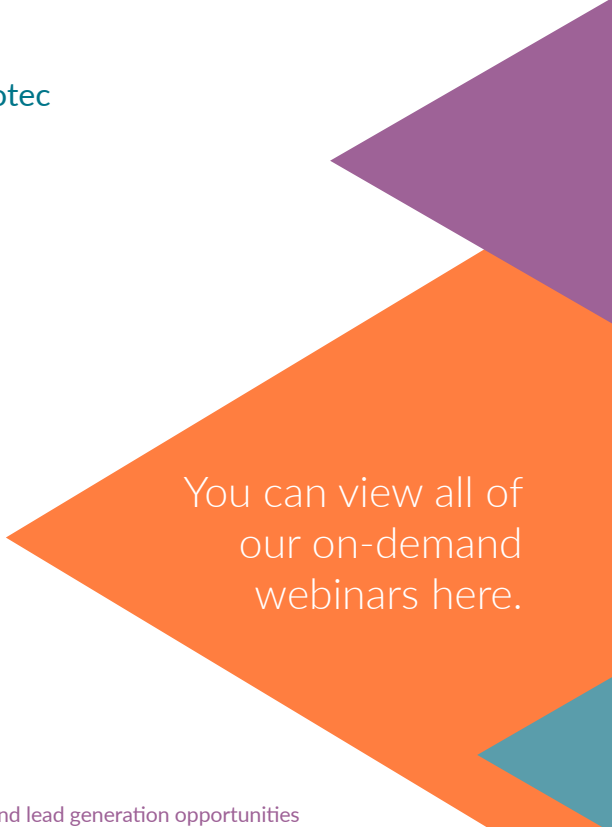
Live 30

Watch now

SPEAKERS
Sylvia F. Boj
Chief Scientific Officer at HUB Organoids

You might also like

ThermoFisher

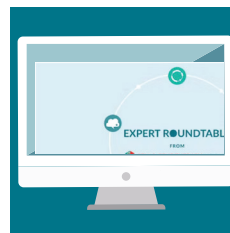


You can view all of our on-demand webinars here.

EXPERT ROUNDTABLES

On-demand video expert roundtables provide powerful tools for you to generate qualified leads and/or position your thought-leader(s) at the heart of the debate around a topic of key importance to your company. Our editorial team works closely with you to identify over-arching topics and discussion points, and to convene a panel of KOLs. We then liaise with the panel to define the final list of questions for discussion, video and edit the roundtable itself, and then produce a full article based on the transcript.

Video roundtable examples:



Video

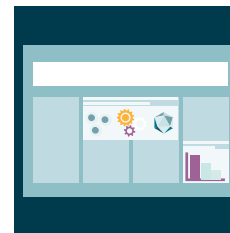


Article

Expert Roundtable: leveraging cutting edge tools to convert I-O data into knowledge



Video & article



Poster summarising key learning points

Strategies for scaling up and out in gene therapy manufacturing: addressing AAV's growing pains (for Corning)

ARTICLES

Free access publication of submitted articles remains the gold standard for sharing data with scientists across the sector.

Our sponsored article publication package includes full peer review, a license for you to reproduce the article on your own website, and a comprehensive 2-month promotional package to maximise readership.

Examples of articles for BioInsights' clients:

VECTOR BIOPROCESSING

Clarification of recombinant adeno-associated virus (rAAV) adherent culture

Cell & Gene Therapy Insights 2022; 8(3): 483–493
DOI: 10.18609/cgti.2022.070
PUBLISHED: 30 APRIL 2022

RESEARCH ARTICLE

Rajeshwar Chinawar, Nicholas Marchand

In recent years the cell and gene therapy industries have been rapidly expanding, with two adeno-associated virus (AAV) and lentivirus. With clinical success comes the need to develop processes. As both of these vectors are produced in cells, the first step in their purification many technologies traditionally used for cell culture clarification but given the projected consumables a combination of depth and membrane filtration is a logical fit for batch proce

CELL & GENE THERAPY INSIGHTS

488 DOI: 10.18609/cgti.2022.070

ANALYTICS: Enhancing accuracy & throughput

Accelerating AAV capsid analysis using a new multi-capillary platform

Cell & Gene Therapy Insights 2022; 8(2): 231–240
DOI: 10.18609/cgti.2022.039
PUBLISHED: 16 MARCH 2022

INNOVATOR INSIGHT

Susan Darling

Adeno-associated viral (AAV) vectors, while offering numerous advantages over other viruses (non-pathogenic, low immunogenicity, and can readily enter a variety of cell types), are highly complex molecules that present significant manufacturing challenges. There are a large number of serotypes to choose from, and the need to implement transfection processes that afford high yields of capsids containing the gene of interest and purification hurdles to overcome. From an analytical perspective, samples are getting more complex, more numerous, and require more complex analytical methods that involve complex method set ups, but results are needed in less time. Despite these challenges, developers of gene therapies must be able to understand the molecular liabilities of AAV vectors as soon as possible in the

CELL & GENE THERAPY INSIGHTS

440 DOI: 10.18609/cgti.2022.070

CELL THERAPY CMC AND QUALITY CONTROL

Characterization of a novel high-throughput, high-speed based image cytometric cell counting method

Cell & Gene Therapy Insights 2021; 7(4): 427–447
DOI: 10.18609/cgti.2021.070
PUBLISHED: 14 MAY 2021

RESEARCH ARTICLE

Jordan Bell, Yongyang Huang, Henry Qazi, Dmitry Kuksin, Jean Qiu, Bo Lin, Leo L

Bioprocessing applications for cells and biologics have dramatically increased the number immunotherapy. The cell counting time is a major bottleneck for traditional counting methods, high-speed, and high-precision systems. Here we characterize and demonstrate throughput cell center in bright field and fluorescence imaging modes. The system was utilizing microbeads, Jurkat and CHO-S cells. We investigated the bead/cell counting con

Method	Accuracy (%)	Throughput (cells/min)
Flow cytometry	99.9	100
Image cytometry	99.9	1000
Image cytometry	99.9	1000

CELL & GENE THERAPY INSIGHTS

440 DOI: 10.18609/cgti.2021.070

Clarification of recombinant adeno-associated virus (rAAV) & lentivirus from adherent culture (for Pall Biotech)

Accelerating AAV capsid analysis using a new multi-capillary electrophoresis platform (for SCIEX)

Characterization of a novel high-throughput, high-speed and high-precision plate-based image cytometric cell counting method (for Nexcelom)

Podcasts
in a variety
of formats and
lengths can also be
produced, either in
series or as
one-offs



Key factors to consider for successful cell therapy manufacturing: a case study

Cell & Gene Therapy Insights 2022; 8(2): 241-249
10.18609/cgti.2022.039
PUBLISHED: 2 MARCH 2022

Valentina Becherucci, Øystein Åmellem, Xavier de Mollerat du Jeu

You can listen to the [podcast at the bottom of this page](#) or read the interview below

[View pdf](#)



PODCAST INTERVIEW

QA: That makes sense. When you have a four-week manufacturing time, that means that the cells are undergoing several passages. Do you have criteria for how many passages you run in your manufacturing process, in order to not lose the cells' characteristics? Do you count the number of passages or the way you get to the desired end point of your drug?

VB: The data of all cultures comes out after process validation. The goal is to reach the therapeutic design. The culture can be shorter - you can stop it at three weeks and use four weeks. It can be more than four weeks because, according to the literature, if you culture for more than four or five weeks, you can get some unwanted effects on cells. For example, you can get genetic variation that is not good for the patient. The four weeks come from our process validation, where we produced five batches of MSCs, and in four batches we saw that the variability was low in terms of the number of cells after four weeks of culture. We also checked other parameters of MSCs, for example the antigen expression of specific markers that must be positive or negative according to International Society of Cell Therapy.

XMJ: Valentina, in this four-week process, how do you ensure you maintain sterility? Do you do weekly QC monitoring on your process?

VB: In our process, we perform initial sterility before starting the culture directly on the bioreactor. Then, we perform an in-process control of sterility after two weeks of culture, and at the end of the culture, before freezing. In our process, cells will be frozen after four weeks of culture and then stored in liquid nitrogen until you get the patient. In this case, the sterility is performed both on cells and on the cell culture media, on the equipment.

QDH: What are the QC or analytical tests you implement in your process to ensure the safety and quality of the product?

VB: According to the regulatory specification, the testing methods must be validated, and mandatory regular testing includes testing of the sterility, endotoxin, mycoplasmas, and hermesites, and in our case we also perform cell identification with flow cytometry. All these tests are performed as in-process control at different steps of the process, and also for the final release or the end of the process.

QA: Valentina - as you are using flasks, you operate in Class A and culture conditions. I see you used bags, or a more closed system that you could operate in a hood?

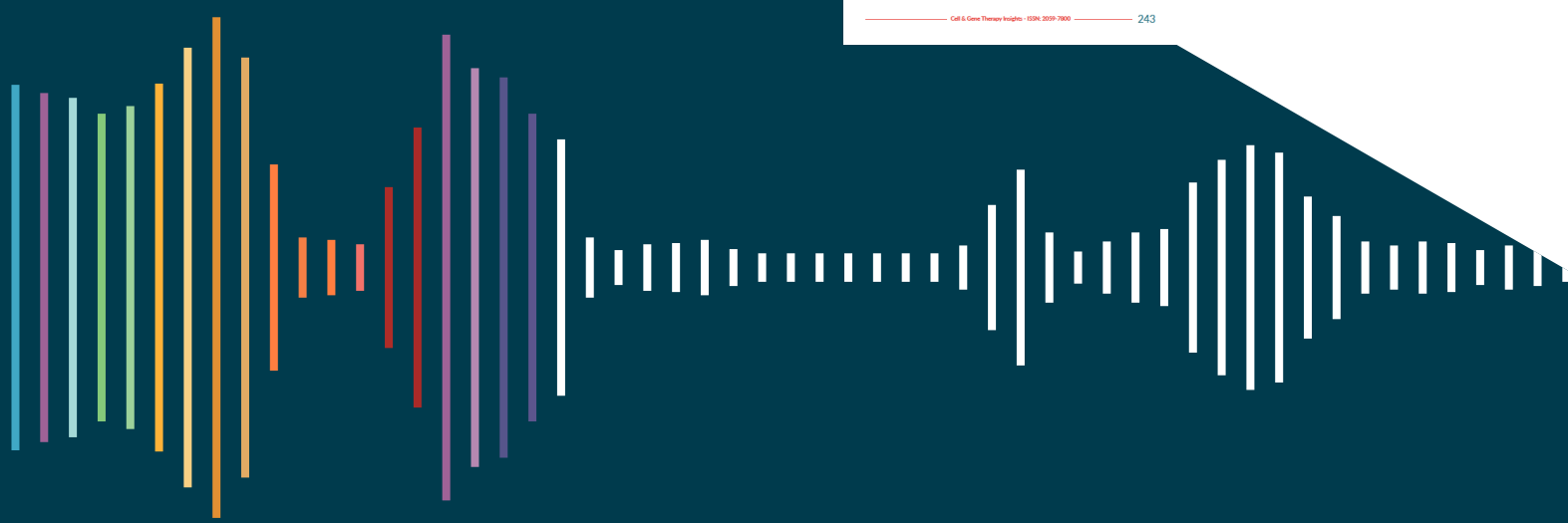
VB: We have tested different kinds of flasks with more surface for culture. However, we do not use bags. Bags are only used in the final step for freezing and storage in liquid nitrogen. We only use open systems and flasks.

XMJ: You mentioned it is a Phase 2 process. As you move to Phase 3 and commercial, you will need to scale this process. How are you thinking about doing that?



For example:

[Key factors to consider for successful cell therapy manufacturing: a case study \(for Thermo Fisher Scientific\)](#)



VIDEO PRESENTATIONS

Our FastFacts videos are 10-15 minute edited presentations, accompanied by a poster summarising the key learning points. They are designed for the presentation of app notes, validation data, case studies, scientific posters or product demonstrations, and work well both for educational purposes and for lead generation.



Here are some examples:



FASTFACTS

A demonstration of the Cocoon® platform: a bespoke solution to minimize manual touchpoints in cell therapy manufacturing

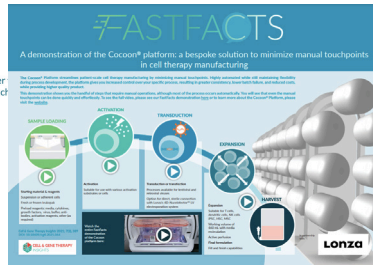
Cell & Gene Therapy Insights 2021;7(10), 369
 DOI: 10.1186/s12929-021-0064
 PUBLISHED: 21 APRIL 2021

FASTFACTS

Joseph O'Connor

Watch the demonstration video or read the poster for cell therapy manufacturing by minimizing manual touch

- ▶ Sample loading
- ▶ Activation
- ▶ Transduction or transfection
- ▶ Expansion
- ▶ Harvest



A demonstration of the Cocoon® platform: a bespoke solution to minimize manual touchpoints in cell therapy manufacturing (for Lonza)



FASTFACTS

Driving CAR-T from early-stage development to clinical filing and lot release

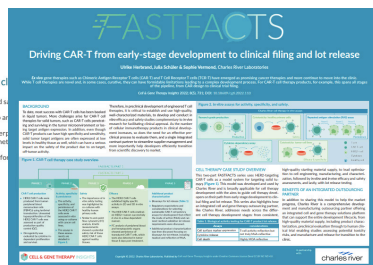
Cell & Gene Therapy Insights 2022; 6(5), 731
 DOI: 10.1186/s12929-022-110
 PUBLISHED: 11 JULY 2022

FASTFACTS

Ulrike Herbrand, Julia Schueler, Sophie Vermond

Driving CAR-T from early-stage development to clinical filing and lot release

- ▶ Approach to assess the efficacy, potency, persistence, and safety of CAR-T
- ▶ Evaluating the efficacy and safety profile of CAR T in vivo
- ▶ Share regulatory expectations (guidelines and how to interpret development) that reflect the MoA and are able to meet needs
- ▶ Discuss biological activity assays at play for CAR-T and how they play a key role in defining the quality of the product.



Driving CAR-T from early-stage development to clinical filing and lot release (for Charles River Laboratories)



Leveraging oncology gene expression signatures to accelerate research

Immuno-Oncology Insights 2022; 3(7), 357
 DOI: 10.1186/s12929-022-037
 PUBLISHED: 7 JULY 2022

FASTFACTS

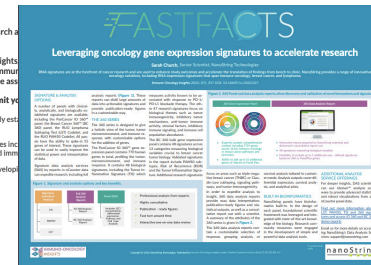
Sarah Church

RNA signatures are at the forefront of cancer research as a bench to the clinic.

In this video and poster from Immuno-oncology Insights total, profiling the tumor, microenvironment, and Immune Signature (TIS) which measures activity known to be associated with cancer progression.

Watch the video, read the scientific poster, or submit your own research.

- ▶ Patents with clinically, analytically, and biologically essential interpretation of data
- ▶ Research signatures focusing on biological themes including transcription factors, inhibitory immune signaling, and immune response
- ▶ The framework and processes that went into development



Leveraging oncology gene expression signatures to accelerate research (for NanoString)



T cell characterization in 3D cell models using advanced flow cytometry

Immuno-Oncology Insights 2021; 2(4), 207
 DOI: 10.1186/s12929-021-0228
 PUBLISHED: 12 JULY 2021

FASTFACTS

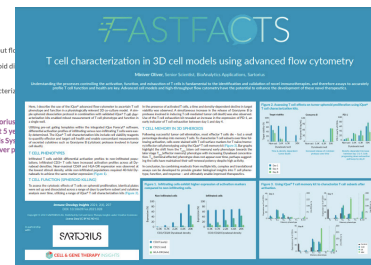
Miniver Oliver

Watch the video or read the poster to learn:

- ▶ Why advanced cell models and advanced high throughput flow cytometry are essential for the development of 3D spheroids
- ▶ How the IQure® platform, kits and fully validated spheroid development workflow can be used to study T cell characterization in 3D spheroids
- ▶ How multiparametric analysis using IQure® T cell characterization can be used to study T cell characterization in 3D spheroids



Miniver Oliver is a Senior Scientist at Sartorius Bio Analytics research team. Over the past 5 years, she has been instrumental in the development of the IQure® Live Cell Analysis System Advanced Flow Cytometry Platform. Miniver's research focuses on T cell characterization and compound screening.



T cell characterization in 3D cell models using advanced flow cytometry (for Sartorius)

Our FastFacts work well for educational and lead-generation purposes

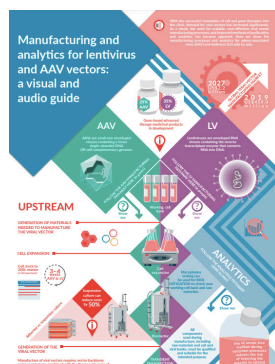
INFOGRAPHICS

Our team are experts in communicating complex scientific information via visual formats, including infographics (static, voiced and animated), PPT presentations and illustrations. They work closely with your team to define contents and style, and the resulting content can be published in *Immuno-Oncology Insights* or simply provided to you for your own use.

Examples include:

Voiced infographic

[Manufacturing and analytics for lentivirus and AAV vectors: a visual and audio guide \(for Thermo Fisher Scientific\)](#)

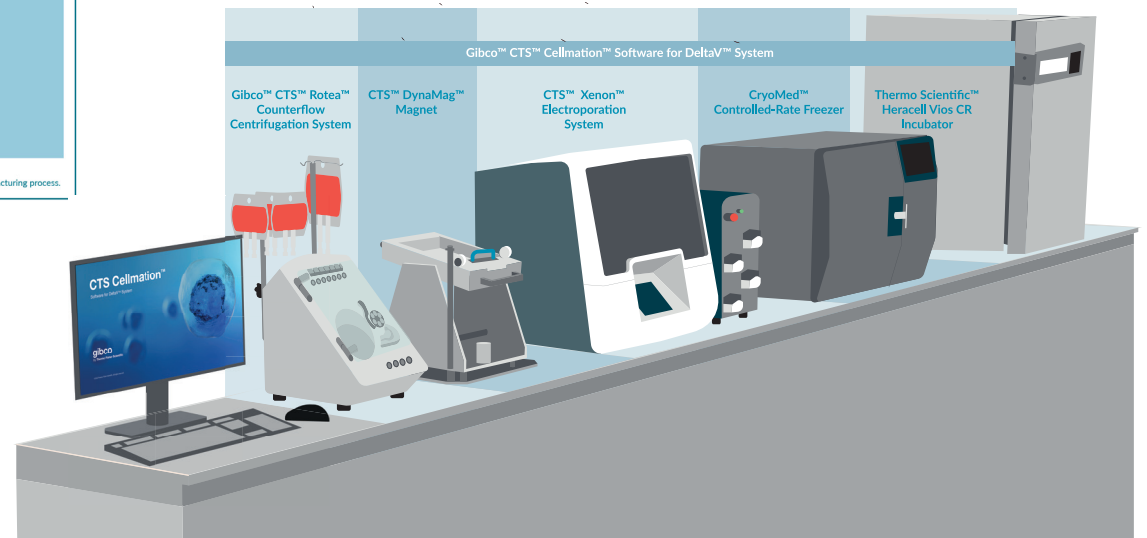
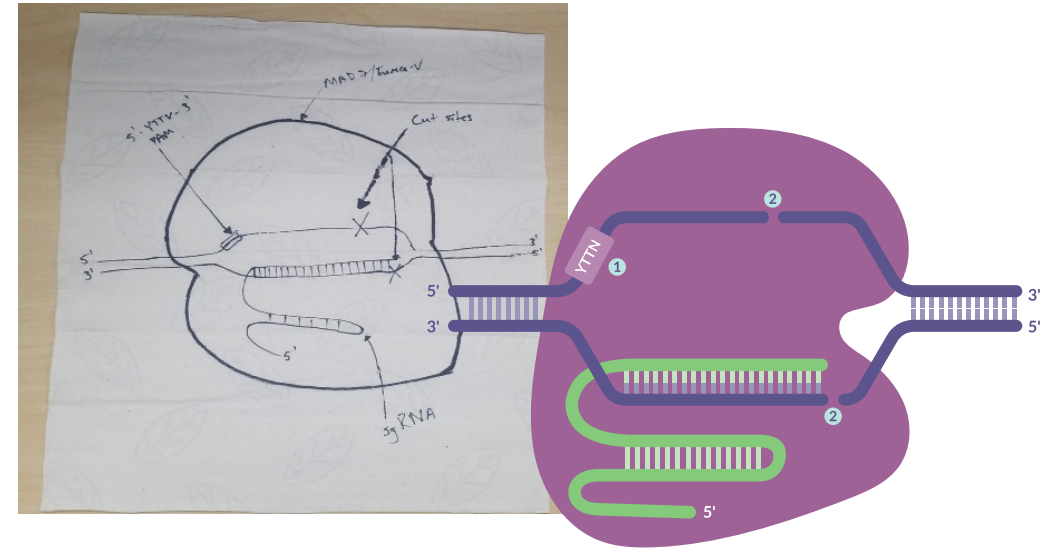
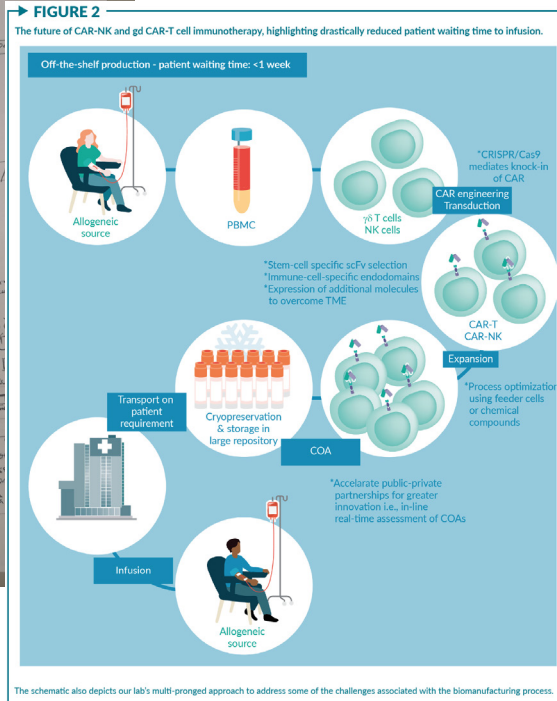
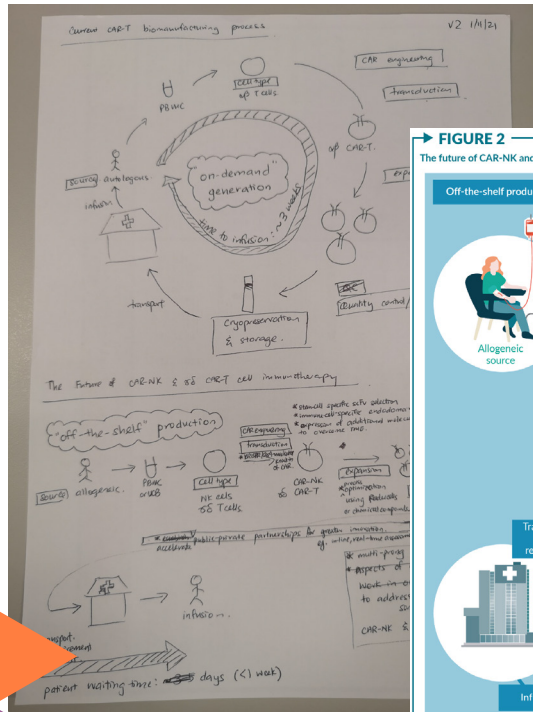


Animated infographic

[Animated infographic - Regulatory FAQs & common concerns for cell & gene therapy raw and starting materials \(for Thermo Fisher Scientific\)](#)



SCIENTIFIC ILLUSTRATIONS



We work from your sketch or concept to create schematics or illustrations of your products or services

eBLASTS

We offer a strictly limited number of 3rd party eblasts to our registered users.

To discuss opportunities for 2023, please contact Diane McKenna at diane.mckenna@insights.bio

OUR OTHER PUBLICATIONS

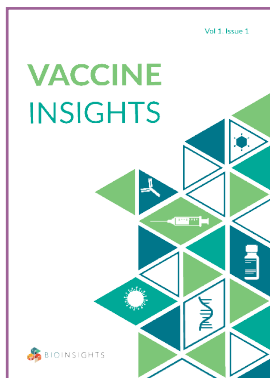
In addition to *Cell & Gene Therapy Insights*, BioInsights also publishes:



Cell and Gene Therapy Insights

Launched in 2014, *Cell & Gene Therapy Insights* is our inaugural online, open access, peer-reviewed journal with a translational focus.

Cell & Gene Therapy Insights addresses the important challenges and advances in the field of cell and gene therapy, publishing original research, reviews, commentary articles, clinical trial reports and much more.



Vaccine Insights

Launched in 2022, *Vaccine Insights* is a peer-reviewed, open-access journal providing insights into development and manufacture of prophylactic and therapeutic vaccines. The journal brings together leading experts from pharma, biotech, academia and other key stakeholders to address critical issues and put the latest developments into context. Guided by an expert advisory board, the journal covers the most important advances in vaccine development and manufacture across all disease areas.

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