



# IMMUNO-ONCOLOGY INSIGHTS

Your content marketing partner for life sciences

# MEDIA KIT 2024



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Multi-stakeholder insights and commentary  
Accessible, comprehensive coverage - sharable and concise  
Rapid analysis of cutting-edge technological advances and clinical breakthroughs





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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.

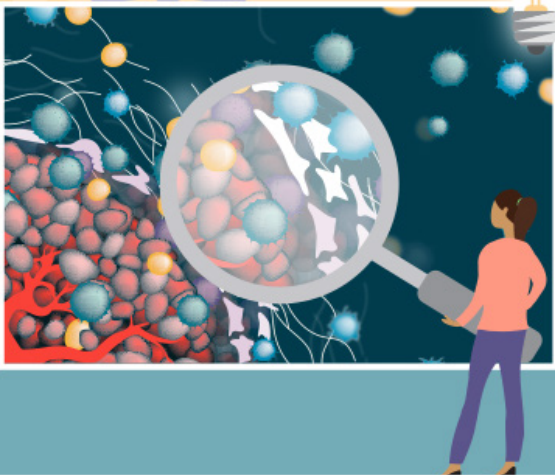
An online only, peer reviewed, open access journal covering the entire cancer immunotherapy space from pre-clinical to clinical development

2023



**SPOTLIGHT ON**  
Overcoming mechanisms of tumor resistance part 2:  
what progress is being made in solid tumors?

**Guest Editor**  
Brent Hanks, William Dalton, Family Assistant Professor of Medical Oncology at Duke University with  
a dual appointment with the Duke Cancer Institute




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:

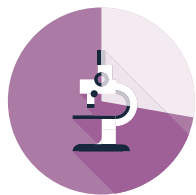
- ▶ Your own special focus issue or ebook on the topic of your choice
- ▶ Client case studies, interviews, and co-presentations
- ▶ Peer reviewed articles, as well as editorials and commentaries
- ▶ Video presentations and roundtables
- ▶ Podcasts
- ▶ Infographics and animations
- ▶ Webinars, both live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



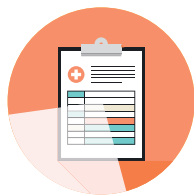
# USER DEMOGRAPHICS

## 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



**29%**  
Biotech



**22%**  
Academic/  
Hospital



**21%**  
Pharma/  
Large Biotech



**3%**  
Government/  
NGO



**2%**  
Investor/  
Analyst



**22%**  
Solution/  
Service Provider,  
including CROs



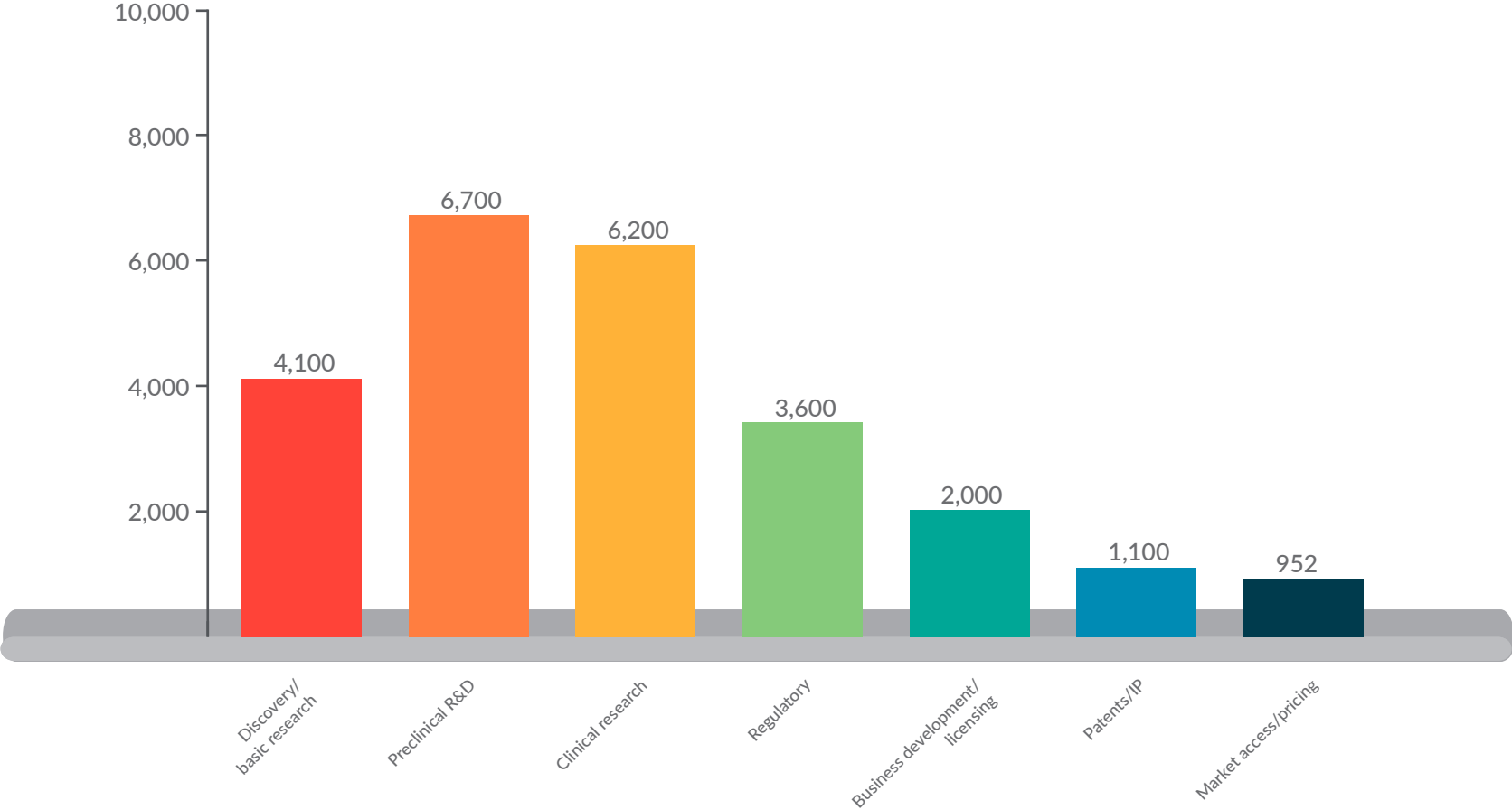
**1%**  
Consultant

We  
currently  
have 13,000  
registered  
users

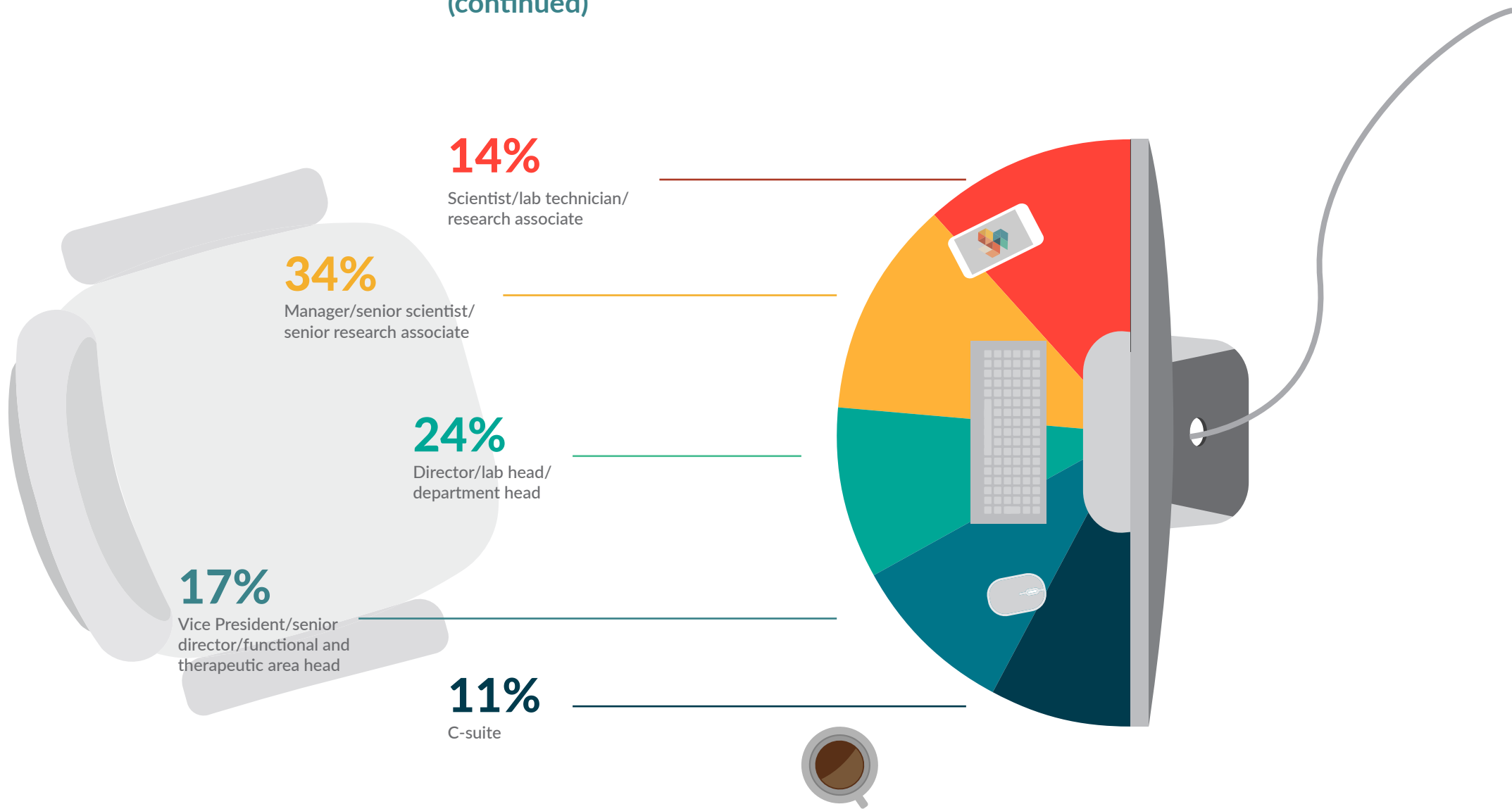
# Data by interest area & seniority

*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

- ▶ 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





# 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...



## 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.

You are able to sponsor any of the Spotlights and/or select an issue for the content we develop together.

We also feature a Tools & Technologies channel on our website where your content can be featured.

## SPOTLIGHT DETAILS

| FEBRUARY  | MARCH   | APRIL   | MAY  |
|---|---|---|--|
| <p><b>Assessing the evolving I-O landscape: key challenges and opportunities for 2024</b></p> <ul style="list-style-type: none"> <li>▶ Progress being made in solid tumors</li> <li>▶ Are cancer vaccines back from the dead?</li> <li>▶ What's next for checkpoints?</li> <li>▶ What will the development of biosimilars mean for the field?</li> <li>▶ Investor, financial, and market access trends</li> </ul>       | <p><b>Combination therapy development</b></p> <ul style="list-style-type: none"> <li>▶ Are multimodality approaches the future of the field?</li> <li>▶ With combination trials proving complex and expensive, how can resources best be deployed/trial design be optimized?</li> <li>▶ Combinations in solid tumors—opportunities and challenges</li> <li>▶ Safety considerations: will synergistic effect also result in synergistic toxicity?</li> </ul>           | <p><b>Solving the challenges of solid tumors</b></p> <ul style="list-style-type: none"> <li>▶ Translating successes in blood cancer into the solid tumor space</li> <li>▶ Understanding and addressing mechanisms of tumor resistance</li> <li>▶ Understanding and overcoming barriers posed by the TME</li> </ul>  | <p><b>Translational insights: bridging the gap from preclinical R&amp;D to the clinic</b></p> <ul style="list-style-type: none"> <li>▶ What is going wrong between preclinical <i>in vitro/in vivo</i> settings and clinical <i>in vivo</i> settings?</li> <li>▶ What model systems can predict patient response to investigational molecules in practice?</li> <li>▶ How can current <i>in vitro</i> models be improved to better represent the complexity of the tumor, immune system, and surrounding tissue?</li> <li>▶ What lessons can be drawn from previous negative outcomes from preclinical studies?</li> </ul> |
| JULY  | SEPTEMBER   | OCTOBER   | NOVEMBER   |
| <p><b>Clinical development strategy</b></p> <ul style="list-style-type: none"> <li>▶ Clinical trial design innovation</li> <li>▶ Dose selection and optimization</li> <li>▶ Assessing the shifting regulatory landscape</li> <li>▶ How can the I-O community work to increase global patient access?</li> <li>▶ Increasing diversity and including the patient voice in clinical trial strategy and planning</li> </ul> | <p><b>Improving patient selection and stratification</b></p> <ul style="list-style-type: none"> <li>▶ Monitoring response and predicting outcome—how can different streams of data (pathology, ctDNA, radiology, etc.) be better harnessed and combined?</li> <li>▶ Novel biomarker discovery and development</li> <li>▶ Patient selection and precision medicine strategies</li> <li>▶ Improved methods of early detection and early detection of relapse</li> </ul> | <p><b>Addressing ongoing safety and toxicity issues</b></p> <ul style="list-style-type: none"> <li>▶ Achieving the greatest benefit with the least toxicity</li> <li>▶ How can we target tumor cells more accurately?</li> <li>▶ Most solid tumor antigens are not restricted—are there subsets of targets that can be more specific?</li> <li>▶ Mechanisms of anti-tumor activity and toxicity in I-O</li> <li>▶ Does the field need to better manage toxicity with existing therapies, or find new targets and approaches?</li> </ul> | <p><b>Tools and trends of tomorrow</b></p> <ul style="list-style-type: none"> <li>▶ Exploring key enabling technology and platform innovation trends and advances for the year(s) to come</li> </ul>   |

## TOOLS & TECHNOLOGIES FOCUS

| MARCH   | JUNE   | DECEMBER  |
|---|--|---|
| <p><b>Practical considerations for cutting edge tech</b></p> <ul style="list-style-type: none"> <li>▶ How can tools such as AI be embedded into prospective ongoing clinical trials?</li> <li>▶ As data science becomes increasingly important, how can we integrate/educate data scientists and cancer immunologists?</li> <li>▶ Are tools like spatial omics practical and usable yet?</li> </ul> | <p><b>Turning data into knowledge</b></p> <ul style="list-style-type: none"> <li>▶ How can emerging tools help to integrate and combine information from different sources and spanning different scales?</li> </ul> | <p><b>Preclinical tools update</b></p> <ul style="list-style-type: none"> <li>▶ Addressing lack of translatability from preclinical activity</li> <li>▶ How can the field pick out the best candidates earlier and save crucial time and resources?</li> <li>▶ Making models more applicable for safety and efficacy</li> </ul> |

# TESTIMONIALS



## 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 BiInsights. 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* (Senior Editors: **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:
- ▶ **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

# OPPORTUNITIES

We offer a broad range of options to help you reach your target audience, any of which can be tailored to match your current marketing and business development priorities. These include interviews, expert roundtables, podcasts, webinars, articles, video presentations, infographics, eblasts, and more.

Any of our options can be tailored to match your current marketing and business development priorities.



# WEBINARS

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

- ▶ Generate qualified leads 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

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

Our  
2024  
webinar  
schedule is  
filling up fast.

Contact [jamie.cox@insights.bio](mailto:jamie.cox@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 moderator 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:

Jul 27 2023  
ON DEMAND  
Targeting EGFR to enhance NKT cell-mediated killing of lung cancer cells  
Thursday 08:00 PDT / 11:00 EDT / 16:00 BST / 17:00 CEST  
Sponsor  
AXION BIOSYSTEMS  
YOUR EMAIL ADDRESS  
Watch now  
SPEAKERS  
Tonya J Webb  
Associate Professor, Department of Microbiology and Immunology at University of Maryland School of Medicine  
David Ferrick  
Chief Scientific Officer at Axion BioSystems

Panel-style webinar for Axion BioSystems

Oct 26 2022  
ON DEMAND  
Modulation of both tumor and T cell apoptosis to enhance CART immunotherapy  
Wednesday 08:00 PDT / 11:00 EDT / 16:00 BST / 17:00 CEST  
Sponsor  
nanoString  
YOUR EMAIL ADDRESS  
Watch now  
SPEAKERS  
Marco Ruella  
Assistant Professor of Medicine, Scientific Director, Lymphoma Program, Division of Hematology and Oncology and Center for Cellular Immunotherapies, University of Pennsylvania

Presentation-style webinar with Q&A for NanoString

Mar 2 2023  
ON DEMAND  
Patient-derived organoids: an emerging platform to de-risk immunotherapy development  
Thursday 08:00 PST / 11:00 EST / 16:00 GMT / 17:00 CET  
Sponsor  
HUB ORGANOIDS  
YOUR EMAIL ADDRESS  
Watch now  
SPEAKERS  
Sylvia F Boj  
Chief Scientific Officer, HUB Organoids  
Andrea Bisso  
Associate Director of Pharmacology & Pre-Clinical Development, Gadeta BV

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

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

How to increase I-O manufacturing efficiency, flexibility, and productivity in line with expected future trends in supply and demand



Video and 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 two-month promotional package to maximise readership.

## Examples of articles for our clients:

**VECTOR BIOPROCESSING**

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

Cell & Gene Therapy Insights 2022; 8(2): 483–493  
DOI: 10.18609/igt.2022.8.2

**RESEARCH ARTICLE**

Rajeshwar Chinnawar, 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 pro-

**CELL & GENE THERAPY INSIGHTS**

**FIGURE 2**  
Performance metrics across different cell types.

**LEGEND**  
Lentivirus and AAV purification metrics.

488 DOI: 10.18609/igt.2022.8.2

**ANALYTICS: Enhancing accuracy & throughput**

### Accelerating AAV capsid analysis using a new multi-capillary platform for SCIEX

Cell & Gene Therapy Insights 2022; 8(2): 231–240  
DOI: 10.18609/igt.2022.8.2

**INNOVATOR INSIGHT**

Susan Darling

Adeno-associated viral (AAV) vectors, while offering numerous advantages over other viruses can readily enter a variety of cell types, are highly complex molecules that present significant number of serotypes to choose from, and the need to implement transfection processes that are of interest and purification hurdles to overcome. From an analytical perspective, samples and require more complex analytical methods that involve complex method set ups, but results challenges, developers of gene therapies must be able to understand the molecular liabilities of

**FIGURE 4**  
Comparison of AAV capsid analysis methods.

**FIGURE 7**  
Performance metrics of the multi-capillary platform.

235 DOI: 10.18609/igt.2022.8.2

**CELL & GENE THERAPY INSIGHTS**

### Walking on thin ice: controlled freezing & thawing of pharmaceutical active molecules for Single Use Support

Cell & Gene Therapy Insights 2022; 8(11): 1457–1464  
DOI: 10.18609/igt.2022.8.11

**INNOVATOR INSIGHT**

Barbara Fischer

Cryopreservation of active pharmaceutical ingredients, cells, or tissues is fundamental to formation, re-crystallization, and other phenomena that occur during the freezing and thawing-induced injuries can be minimized by appropriate molecule design and the use of combination with suitable equipment and physical conditions during the freezing and thawing processes to the characteristics of the protein or active pharmaceutical maintain its biological and chemical stability during storage and shipment. Controlled free-

**FIGURE 1**  
Diagram of controlled freezing and thawing process.

**FIGURE 2**  
Graph showing stability metrics over time.

1458 DOI: 10.18609/igt.2022.8.11

**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**

**Walking on thin ice: controlled freezing & thawing of pharmaceutical active molecules for Single Use Support**

# INTERVIEWS & PODCASTS

Interviews are a great way to raise awareness within the immuno-oncology community, with minimal resource requirements from your team.

We can interview up to three of your scientists, executives, partners or clients, with the resulting video, podcast and/or written version included in an issue of the online journal.

## Examples of previous interviews for our clients:

### Video and written

[Stepping foot into a successful partnership to support your viral vector therapy through commercialization for Merck](#)

**VECTORS: Downstream Bioprocessing**

### Stepping foot into a successful partnership to support your viral vector therapy through commercialization for Merck

Cell & Gene Therapy Insights 2021; 7(11): 1706–1710  
DOI: 10.18609/cgti.2021.225  
PUBLISHED: 12 JANUARY 2022

**Minh Hong, Marc Gaal**

Charlotte Barker, Editor, Cell and Gene Therapy Insights, speaks to Minh Hong, Head of Commercialization at Merck, about the challenges of commercializing viral vector therapies. Minh Hong leads the commercial team for Viral Gene Therapy contract Business Sector of Merck. He is responsible for account management, business development, and regulatory affairs.

**INTERVIEW**

**Q:** How do you see the commercialization of viral vector therapies? Minh Hong: "A robust manufacturing process requires process development insights at every stage of the product lifecycle."  
**Minh Hong**

**Q:** Once you understand the customer's needs, how do you support them through the manufacturing process?  
**MC:** Once the manufacturing process is confirmed, as Minh already stated, we engage a Project Manager to partner with the customer and the Contract Manufacturing Organization. The Project Manager helps guide the customer through the range of options available. By working in combination with Project Manager, we provide a comprehensive solution for the customer. We also provide the operational delivery of a wide range of options, including the design and construction of a new manufacturing plant, the scale-up of existing manufacturing plants, the scale-up of existing manufacturing plants, and the scale-up of existing manufacturing plants.

**Q:** How do you see the commercialization of viral vector therapies?  
**MC:** The new large-scale gene therapy manufacturing facility is composed of state-of-the-art facilities for the production and purification of viral vectors, storage, transport, and delivery. All of the manufacturing steps are done in a cleanroom environment. We do have a range of options available that provide our clients with stable long-term results from process development through manufacturing. These facilities enable us to provide a comprehensive solution for the customer. We also provide the operational delivery of a wide range of options, including the design and construction of a new manufacturing plant, the scale-up of existing manufacturing plants, and the scale-up of existing manufacturing plants.

**Q:** What led your organization to determine that this was the right time to invest in a new gene therapy manufacturing facility?  
**MC:** The new large-scale gene therapy manufacturing facility is composed of state-of-the-art facilities for the production and purification of viral vectors, storage, transport, and delivery. All of the manufacturing steps are done in a cleanroom environment. We do have a range of options available that provide our clients with stable long-term results from process development through manufacturing. These facilities enable us to provide a comprehensive solution for the customer. We also provide the operational delivery of a wide range of options, including the design and construction of a new manufacturing plant, the scale-up of existing manufacturing plants, and the scale-up of existing manufacturing plants.

Cell & Gene Therapy Insights | ISSN 2099-3900 | 1707

### Podcast and written

[Solving challenges in cell therapy clinical trials & effectively delivering complex studies in advanced therapeutics for PPD \(part of Thermo Fisher Scientific\)](#)

**CLINICAL DEVELOPMENT STRATEGY**

### Solving challenges in cell therapy clinical trials & effectively delivering complex studies in advanced therapeutics for PPD (part of Thermo Fisher Scientific)

Immuno-Oncology Insights 2023; 4(2): 79–87  
DOI: 10.18609/oi.2023.012  
PUBLISHED: 5 APRIL  
PODCAST

**Jai Balkisson, Vito Romita**

Cell therapy clinical trials pose a variety of complex challenges. Logistics with cell harvesting, patient safety, changing standard-of-care treatments, and patient enrolment due to competitive pricing are some of the key challenges. Jai Balkisson and Vito Romita outline key obstacles for developing cell therapies in order to increase patient access and design safer trials.

**IMMUNO-ONCOLOGY INSIGHTS**

**CLINICAL DEVELOPMENT STRATEGY**

**SPOTLIGHT**

**INTERVIEW**

### Solving challenges in cell therapy clinical trials & effectively delivering complex studies in advanced therapeutics

**Jai Balkisson, Vito Romita**

Cell therapy clinical trials pose a variety of complex challenges. Logistics with cell harvesting, patient safety, changing standard-of-care treatments, and patient enrolment due to competitive pricing are some of the key challenges. Jai Balkisson and Vito Romita outline key obstacles for developing cell therapies in order to increase patient access and design safer trials.

Jai Balkisson, Assistant Editor, Immuno-Oncology Insights, speaks to Vito Romita, Director of Cell Therapy Clinical Development at PPD, about the challenges of commercializing cell therapy products. Vito Romita is the Director of Cell Therapy Clinical Development at PPD, a part of Thermo Fisher Scientific. He is responsible for account management, business development, and regulatory affairs.

Vito Romita, Director of Cell Therapy Clinical Development at PPD, speaks to Jai Balkisson, Assistant Editor, Immuno-Oncology Insights, about the challenges of commercializing cell therapy products. Vito Romita is the Director of Cell Therapy Clinical Development at PPD, a part of Thermo Fisher Scientific. He is responsible for account management, business development, and regulatory affairs.

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DOI: 10.18609/oi.2023.012  
www.tandfonline.com

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 time 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 longer than that, four weeks because, according to the literature, if you culture for more than that 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 comes 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.

**Q DH:** 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 cell culture conditions. I see you used bags, or a more closed system that you could operate in a hood?

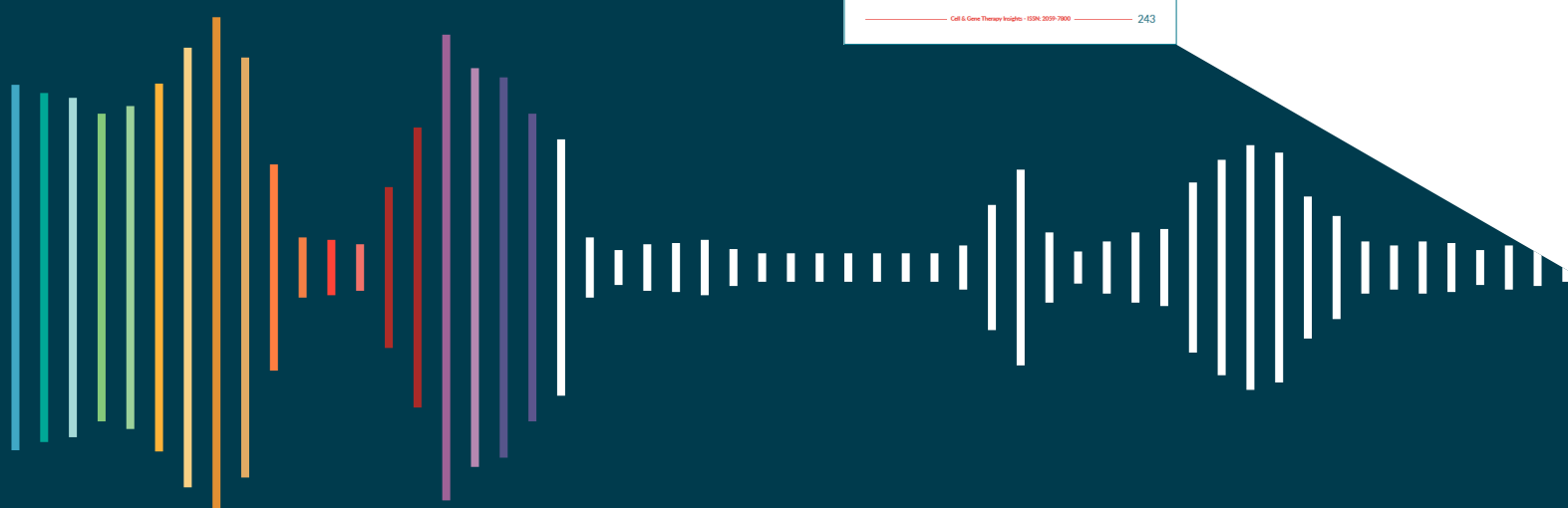
**VB:** We have tested different kinds of flasks with more surface for culture. However, we do not use bags. Bags are only used in the final step for freezing and storage in liquid nitrogen. We only use open systems and flasks.

**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?

Cell & Gene Therapy Insights | ISSN 2029-7900 | 243

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**

Evaluating organoid culture using live-cell analysis & RUO growth factors

Immunology Insights 2023; 4(8):254  
DOI: 10.18609/ins.2023.036  
PUBLISHED: 27 SEPTEMBER

FASTFACTS  
Natacha Lewis

**FASTFACTS**  
Evaluating organoid culture using live-cell analysis & RUO growth factors

Research Lead: Senior Scientific Services

The organoid culture is a 3D model of tissue that mimics the structure and function of the original tissue. It is used to study the biology of the tissue and to test the effects of drugs and treatments. This poster presents a new method for evaluating organoid culture using live-cell analysis and RUO growth factors. The method involves using a high-throughput screening platform to measure the growth and viability of organoids in response to different growth factors. The results show that the method is highly sensitive and specific, and can be used to identify the optimal growth factors for organoid culture. This method is a significant advance in the field of organoid culture and will be used to study the biology of various tissues and to test the effects of drugs and treatments.

Evaluating organoid culture using live-cell analysis & RUO growth factors for Sartorius

**FASTFACTS**

AI pathology in immuno-oncology research

Immunology Insights 2023; 4(8): 193  
DOI: 10.18609/ins.2023.024  
PUBLISHED: 3 JUNE

FASTFACTS  
Marjia Pezer

**FASTFACTS**  
AI pathology in immuno-oncology research

Health Lead: Senior Scientific Support Services

The integration of artificial intelligence (AI) and pathology is revolutionizing the field of immuno-oncology research. This poster presents a new method for using AI to analyze pathology images and identify biomarkers for immuno-oncology. The method involves using a deep learning algorithm to analyze pathology images and identify biomarkers that are associated with immuno-oncology. The results show that the method is highly sensitive and specific, and can be used to identify biomarkers that are associated with immuno-oncology. This method is a significant advance in the field of immuno-oncology research and will be used to identify biomarkers that are associated with immuno-oncology.

AI pathology in immuno-oncology research for Aignostics

**FASTFACTS**

Reducing risk for cell therapy manufacturing with a battle-tested electroporation platform

Cell and Gene Therapy Insights 2023; 9(5): 809  
DOI: 10.18609/ins.2023.130  
PUBLISHED: 26 AUGUST

FASTFACTS  
Andrew Mancini

**FASTFACTS**  
Reducing risk for cell therapy manufacturing with a battle-tested electroporation platform

Research Lead: Senior Technical Specialist, MaxCyte

The development of cell therapy manufacturing is a complex and costly process. This poster presents a new method for reducing the risk of cell therapy manufacturing using a battle-tested electroporation platform. The method involves using a high-throughput screening platform to identify the optimal electroporation parameters for cell therapy manufacturing. The results show that the method is highly sensitive and specific, and can be used to identify the optimal electroporation parameters for cell therapy manufacturing. This method is a significant advance in the field of cell therapy manufacturing and will be used to reduce the risk of cell therapy manufacturing.

Reducing risk for cell therapy manufacturing with a battle-tested electroporation platform for MaxCyte

**FASTFACTS**

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

Immunology Insights 2021; 2(4): 207  
DOI: 10.18609/ins.2021.028  
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 T cell characterization in 3D spheroids
- How the IQure® platform, kits and fully validated spheroid dishes are used for T cell characterization in 3D spheroids
- How multiparametric analysis using IQure® T cell characterization kits is used for 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 and validation of the IQure® Live Cell Analysis System Advanced Flow Cytometry Platform. Miniver is currently focused on the development and validation of the IQure® T cell characterization kits for T cell characterization in 3D spheroids.

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

Research Lead: Senior Scientific Specialist, Operations, Sartorius

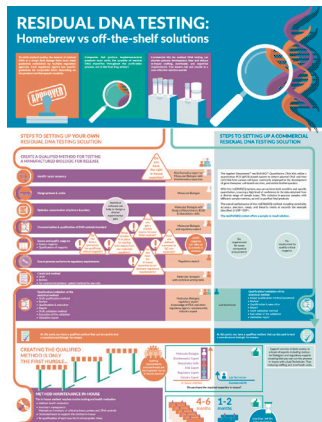
The development of T cell characterization in 3D cell models is a complex and costly process. This poster presents a new method for T cell characterization in 3D cell models using advanced flow cytometry. The method involves using a high-throughput screening platform to identify the optimal T cell characterization parameters for 3D cell models. The results show that the method is highly sensitive and specific, and can be used to identify the optimal T cell characterization parameters for 3D cell models. This method is a significant advance in the field of T cell characterization in 3D cell models and will be used to identify the optimal T cell characterization parameters for 3D cell models.

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

Residual DNA testing: Homebrew vs off-the-shelf solutions for Thermo Fisher Scientific

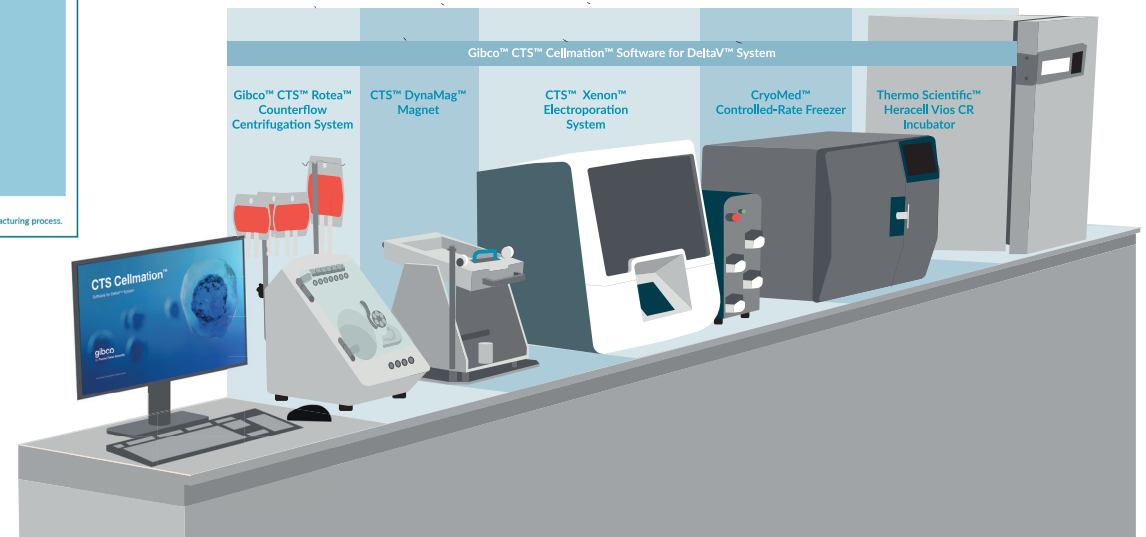
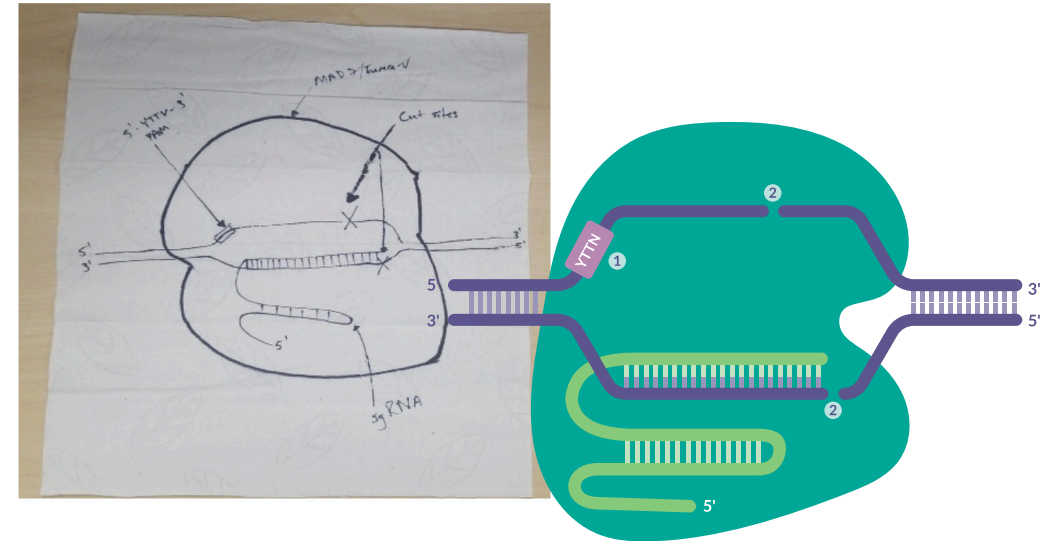
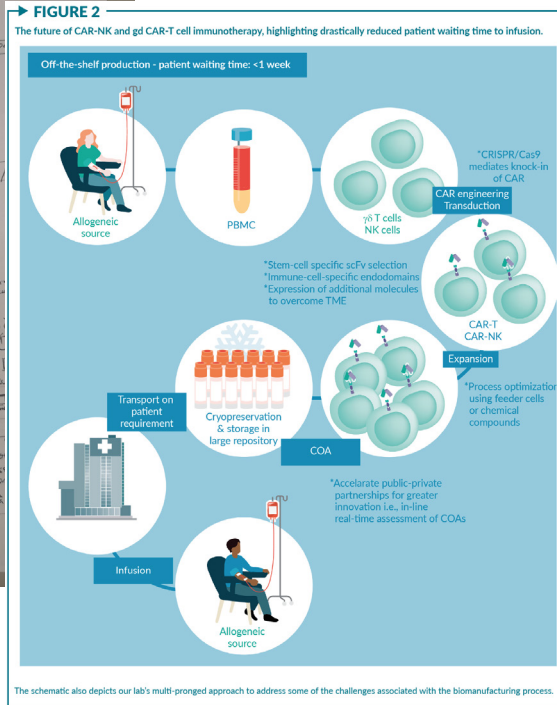
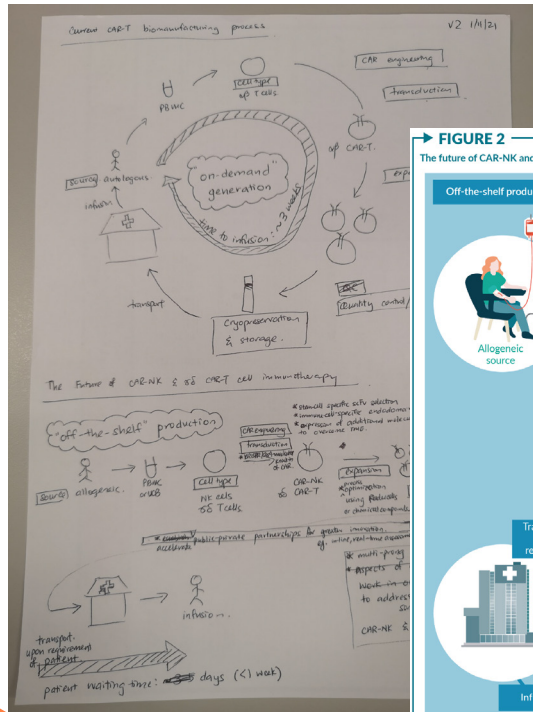


Animated infographic

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 third-party eblasts to our registered users.

Our 2024 schedule is open for bookings. Please contact **Jamie Cox** at [jamie.cox@insights.bio](mailto:jamie.cox@insights.bio).

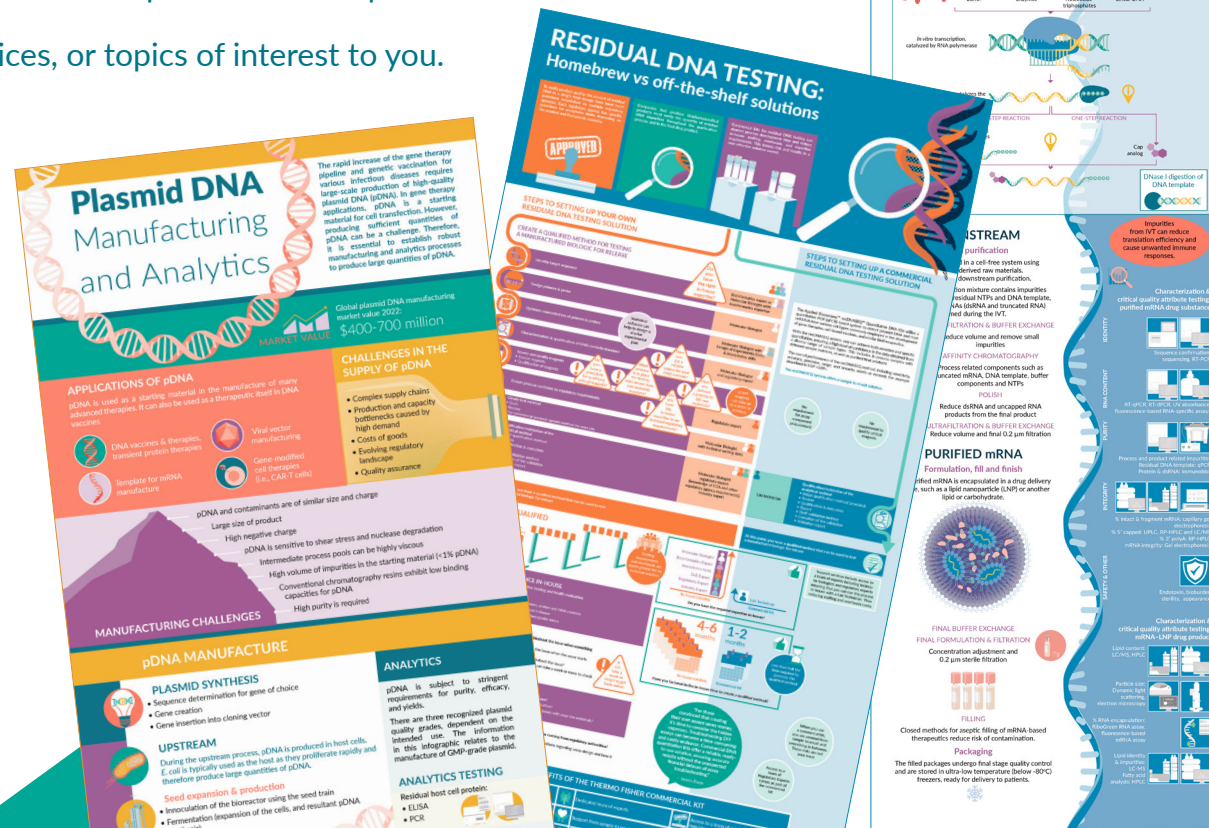




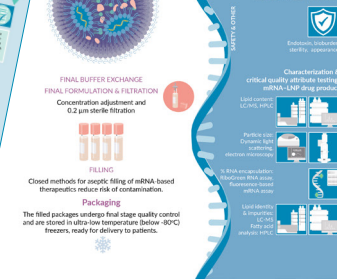
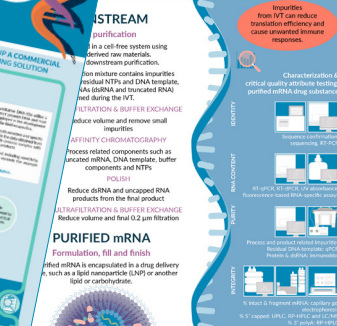
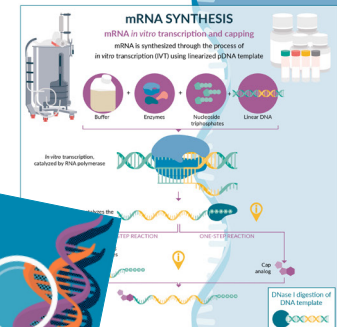
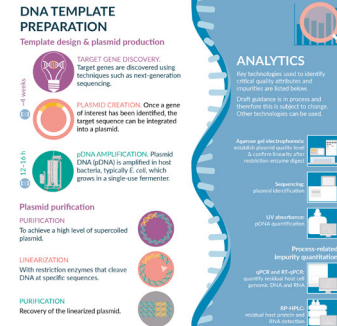
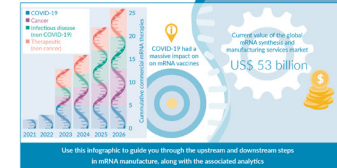
# PREMIUM SERVICES

We offer a number of premium options, both for content creation and for market research. These include:

- ▶ Bringing together KOL panels to discuss the topics of your choice, publishing the output as an ebook, video, and written roundtable, or other suitable content format
- ▶ Designing infographics, which can be animated and/or voiced, ideal for communicating complex technical or scientific information in an easily digestible format
- ▶ Inviting industry or academic Subject Matter Experts to join your live webinars to add their opinions to the discussion
- ▶ Building and deploying surveys amongst our users, providing detailed reports on the responses
- ▶ Bringing together focus groups to discuss your products/services, or topics of interest to you.

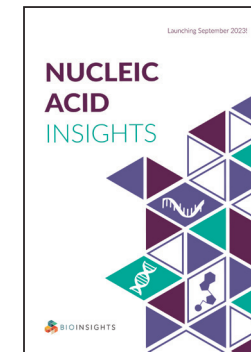


## mRNA manufacturing and analytics



# OUR OTHER PUBLICATIONS

In addition to *Immuno-Oncology Insights*, BioInsights also publishes:



## Cell & 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.

If you would like to distribute content to more than one of the cell & gene therapy, immuno-oncology and vaccine communities, we can promote it across multiple journals and market it to more than one set of users.

## Nucleic Acid Insights

The latest addition to our publication portfolio, *Nucleic Acid Insights* provides online, peer-reviewed, open access content with a translational focus.

*Nucleic Acid Insights* is specifically designed to provide the need-to-know information required to successfully navigate this rapidly evolving space, covering all the major RNA and DNA technologies and modalities, including but not limited to: messenger RNA (mRNA); plasmid DNA; antisense oligonucleotides (ASO); phosphorodiamidate morpholino oligonucleotides (PMO); RNA interference (RNAi); small interfering RNA (siRNA); aptamers; micro RNA (miRNA); and guide RNA (gRNA).