Annual Review 2023

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Media Partner

BUSINESSWEEKLY

Contents

A Warm Welcome from Tony Jones

It's my pleasure to pen the introduction to this year's One Nucleus Annual Review 2023, our opportunity to introduce One Nucleus, showcase our members and their excellence and update you on our own journey.

In this publication, you will find a thorough introduction to One Nucleus along with a high-level summary of our offer and delivered activities. One Nucleus is primarily about its members and the expertise they share. I am delighted, therefore, that a significant percentage of our Annual Review is dedicated to key insight articles authored by our members that exemplify the types of insight and expertise that can be accessed through engagement.

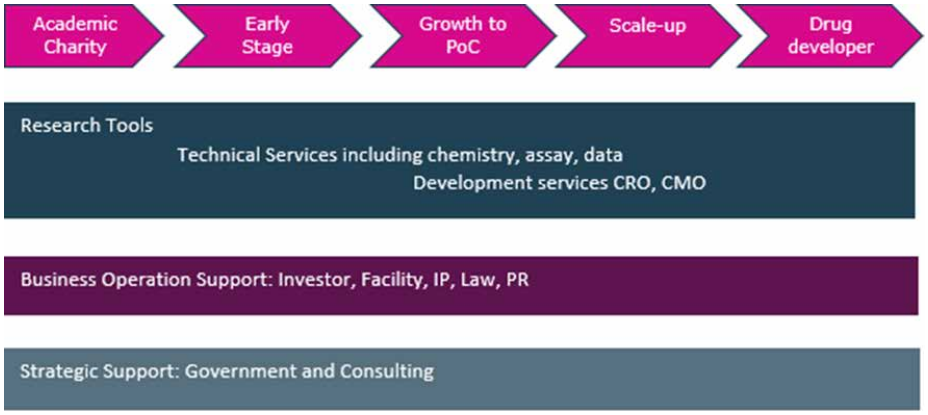
About One Nucleus

Established as Eastern Region Biotechnology Initiative (ERBI) in 1997 then merged with the London Biotechnology Network (LBN) in 2010 to form One Nucleus Ltd, the organisation is headquartered in Cambridge, UK. One Nucleus provides support and services to life science companies by way of access to learning & development resources, savings, events and peer-to-peer networking. We advocate the strengths (and needs) of our members to ensure potential partners, investors, employees and policy makers are aware of the collective life science asset our members represent.

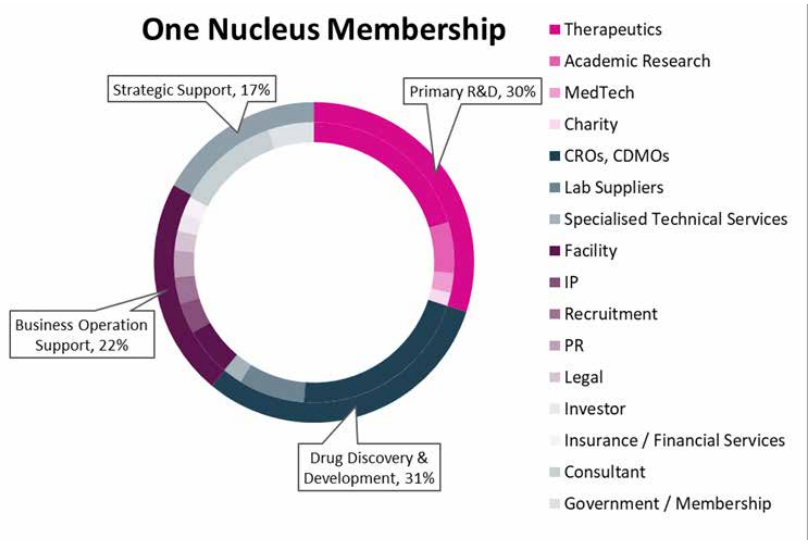
A not-for-profit entity funded by member annual subscriptions, event-derived income and administration fees on services such as our Group Purchasing Scheme and Training Courses, One Nucleus continually evolves its offer to respond to the changing external operating environment encountered by its members. The key drivers of bringing together the best innovation, best people and smart investment do not change and hence the core membership offer has remained focused on these pillars. Providing local, UK-wide and international connectivity, complemented by practical support on operational, investment and technology trends, One Nucleus seeks to enable our members to maximise their performance. In contrast to many of our peer organisations, One Nucleus does not subscribe to the approach of differentiating excellence on the basis of business model when it comes to membership fee structure and thus engagement.

The One Nucleus Membership Base

One Nucleus membership is drawn from the across the diverse life science sector, all playing vital roles in the creation, protection, investment, infrastructure and accommodation of a Life Science ecosystem responsible for translating world class invention and innovation into patient benefit, economic development and returns on investment. Accelerating the speed and efficiency of traversing the process from ideation to patient, as represented here, is the mutual goal of both One Nucleus and our members.



The distribution of membership by primary business focus is illustrated below. The diversity reflects the breadth of the One Nucleus ecosystem and the attraction of the value propositoion to a wide variety of business types.



Being inclusive of excellence, irrespective of business model, stage and area of expertise is an important message to communicate, particularly for a sector that needs to compete with other attractive sectors for the best people as the nature of R&D and the sector diversifies in the required skills.

One Nucleus Geography:

The historic footprint of the merged groups has meant membership has been concentrated (~70%) in the Greater Cambridge (EoE) and Greater London clusters, including key clusters such as Stevenage and Norwich. That said, membership from outside that region continues to grow.

Making the Right Connections

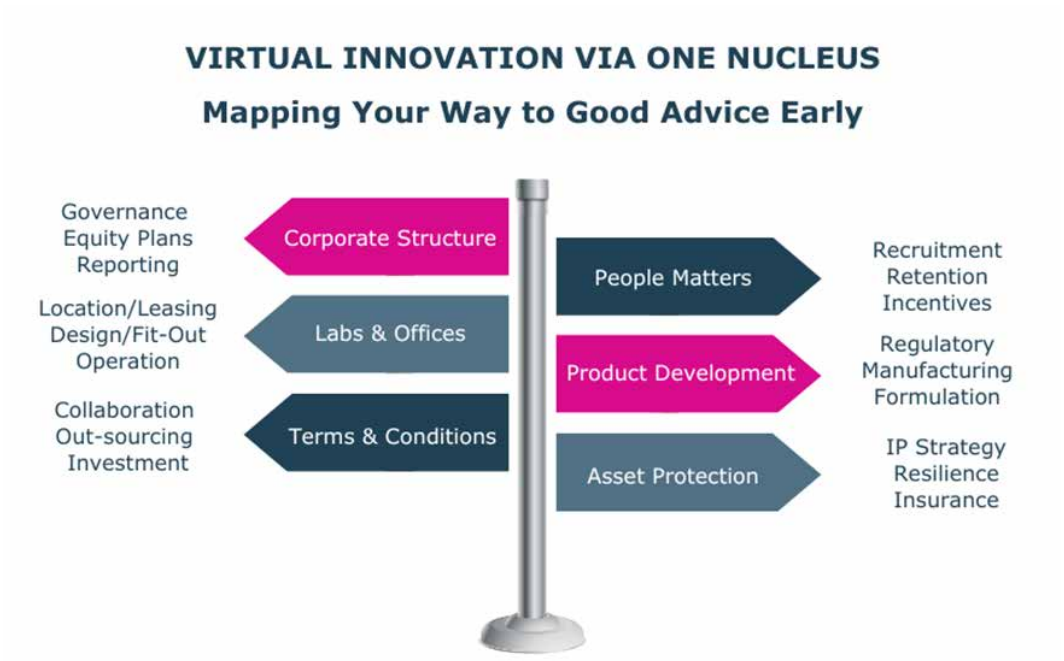
A key advantage to any company joining One Nucleus is the ability to connect to potential partners, investors, service providers, clients and their peers for knowledge-sharing. Along with the evolution of R&D strategies as technologies evolve, there is also a gradual transition that happens within any nascent industry sector when it comes to connectivity with peers. In the beginning, clusters resemble a close-knit community where the majority of people know the majority of others. With growth of the industry, and hence cluster, the stitches of that knitting become vastly more numerous and thus looser, since it is not possible to have such close relationships with the majority.

The role of a membership group such as One Nucleus transitions from one of nurturing a community to enabling an environment for deal flow. Those serendipitous conversations and knowledge sharing that happen frequently in a very familiar community can become less frequent in a larger environment, which can ultimately hinder the speed and success rate of translating ideas to products and start-ups to operational high-growth businesses. The manner in which One Nucleus supports innovation has a clear focus on peer-to-peer engagement that increases the probability of those key conversations and meetings through our Virtual Innovation Centre approach, our Events portfolio and our global collaborations.

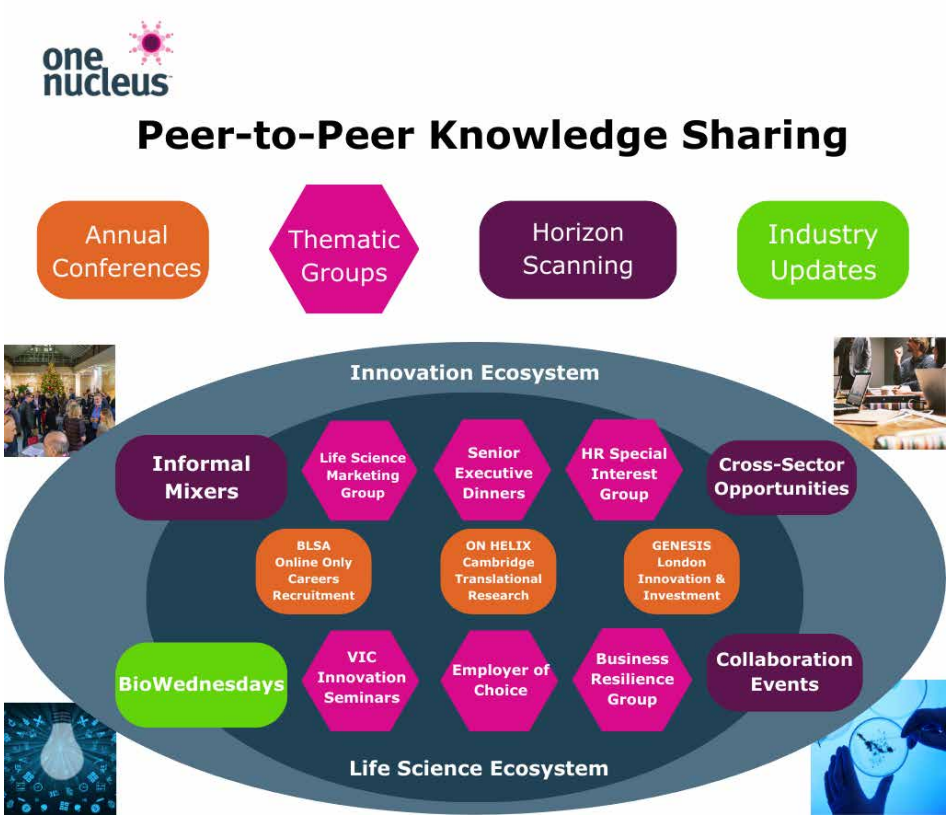
Virtual Innovation Centre (VIC)

The Virtual Innovation Centre approach is a means to conceptualise the One Nucleus support for innovation being translated into successful businesses, products and services. Unlike a traditional innovation centre, where physical capacity is a factor, viewing One Nucleus as an innovation centre without walls encapsulates the immense breadth of excellence One Nucleus is able to facilitate access to for innovators.

For those starting and growing life science business, new challenges continually arise irrespective of business model and often previous experience since external factors are very dynamic. It is valuable to get sage advice early in the planning process. One Nucleus acts as an efficient Map & Sat Nav to the expert and peer connections who can provide such advice.



One Nucleus Events:



The portfolio of One Nucleus events is completely structured around encouraging those key conversations, meetings and knowledge-sharing that enables deal flow.

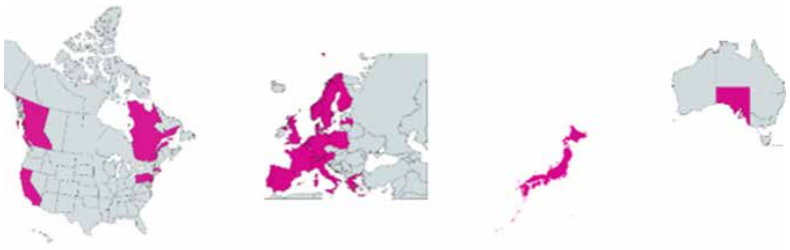
Whether the 'deal' is about R&D collaborations, investment, recruitment, advisory services, contract research provision or other, our aim is to create that environment for transactions to follow.

It's also not all about members talking to members, of course. Much like no single company undertakes all the biomedical research they need to know about, a membership group needs to be a magnet for non-members to find its members and to that end, where possible One Nucleus allows non-members to participate in activities and for that inclusive reason, the One Nucleus network is far wider and comprehensive than the core membership.

Thinking Globally:

Whilst this is vital locally, the ability to connect to other regions, especially internationally, is also valued. To support our members in their growth aspirations, One Nucleus maintains strong relationships with like-minded support groups across Europe, North America and Asia. The collaborator coverage is illustrated here.

One Nucleus' international connectivity is maintained through membership of the Council for European BioRegions (CEBR); supporting inward and outward trade visits; collaboration with UK Department for Business & Trade; Collaboration with peer groups in N America, Asia and Australasia; and attendance and exhibiting at international events, including Bio-Europe Spring, BIO International Convention and Bio-Europe.



Best wishes,

Tony Jones, CEO

Learning and Development

One Nucleus recognises that a company's employees are its most valuable asset and the competition for talented and skilled employees has never been more fierce in the region's life science sector.

During the past 12 months it has been encouraging to see companies increase their appetite for training courses, engaging in sessions discussing best practice in areas such as Equality, Diversity and Inclusion and promoting the career opportunities the sector offers. It is now evident that employee engagement is key to reputation, recruitment and retention for all businesses.

Learning & Development:

To support members, individuals and the wider sector One Nucleus has developed a range of learning and development support opportunities based on the needs of our member companies and their staff. We are constantly introducing courses on new subjects as our members' needs change.

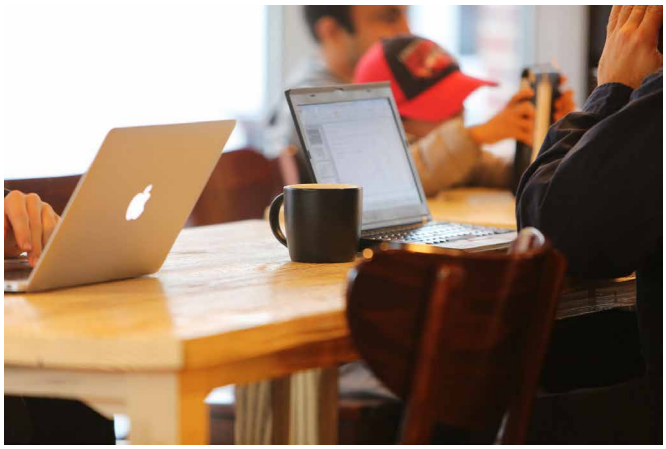
Our training course portfolio can be delivered:

- Face-to-face or online to meet member companies' needs
- In-house for a single company or
- Via open courses, for delegates from multiple companies.
- Via free on-demand content from our events and conferences to fill knowledge gaps.

Recruitment & Careers Support:

To support recruitment, One Nucleus operates:

- A jobs page on the One Nucleus website.
- A LinkedIn 'One Nucleus Member Jobs' Group
- Employer of Choice webinar series providing real world insights, guidance, and best practices on becoming an employer of choice to attract and develop the best team.
- Annual on-line Building Life Science Adventures conference. This One Nucleus careers conference is free to attend and a chance to fill knowledge gaps, debate best practice and connect to enable success.



Learning and Development

The **One Nucleus Mentoring Initiative** is for those already in employment as well as students seeking to develop in the sector. The initiative is an opportunity for One Nucleus to play a full role in connecting the expertise and know-how of our network to those that need it and thereby collectively enhancing the success of the cluster.

Contact training@onenucleus.com with details about what you currently do, the type of mentor you seek and the area of expertise on which you seek their guidance. Free of charge, we'll advertise your mentor vacancy on our LinkedIn, Twitter and website and monthly People Pathways newsletter.

People Pathways Newsletter:

- Monthly e-publication disseminated to our network
- Learning & Development insight articles
- Recent appointments at member companies
- Current vacancies
- Upcoming training courses.


one nucleus

People Pathways | January

Your Monthly Round-up of Employee Engagement Opportunities

Welcome to the First Pathways Newsletter of 2023

Inside this month's newsletter we're serving you the key ingredients to enhance your Employee Value Proposition and support your organisation with a successful year ahead.

One Nucleus Training Courses

We recognise that a company's employees are its most valuable asset. Our range of training courses, delivered both face to face and online, are based on the needs of our member companies and their employees.

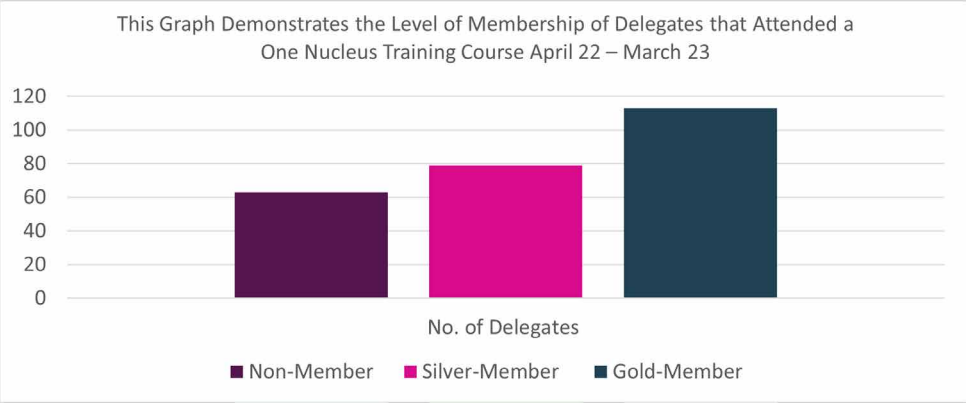
You can view our upcoming courses and for more information about our in-house course offering, please contact training@onenucleus.com.

Join us at Building Life Science Adventures on 28-29 March 2023 Read More...

This two-day online careers conference attracts an international audience of exceptional employers, students, early career seekers and universities.

Learning and Development in Review

During the past 12 months we have seen a continued uptake in training courses amongst member companies with both open and in-house delivery. There has been a steady move away from online in favour of in-person course delivery.



In June 2022, One Nucleus and My Green Lab collaborated to help drive a meaningful and sustainable change within Laboratories. One Nucleus members can receive an exclusive discount on the My Green Lab Accredited Professional training courses.

my green lab.

Babraham Research Campus

start-up to scale-up

Babraham Research Campus supports the scientific discoveries of tomorrow by nurturing and supporting people, companies and ideas at every stage of the development cycle, making it one of the best places in the world to start, scale and grow a bioscience company.

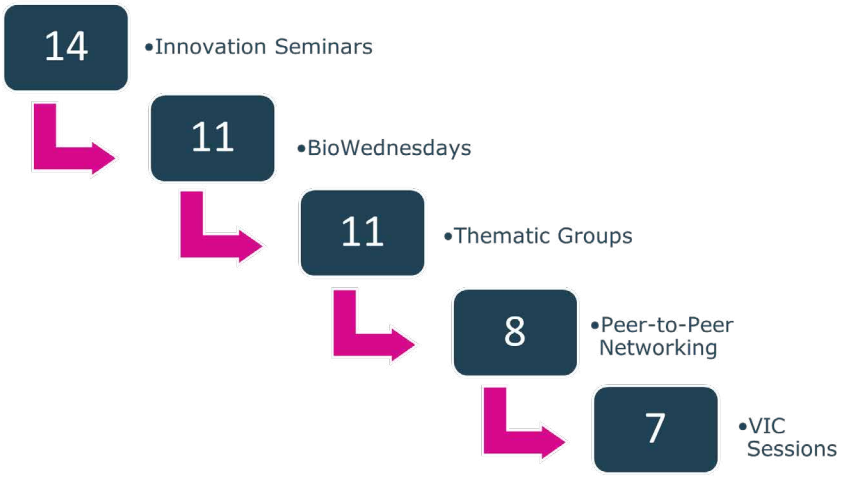
Impactful science and entrepreneurship activities are developed here which make a tangible difference not only to those on Campus but also beyond.

www.babraham.com

One Nucleus Events Wrap-Up

As a people-centric organisation, events are an essential part of the One Nucleus offer. We want to help our members maximise their opportunities for networking, partnering and knowledge exchange with both members and non-members, which is key for mutual and collective success. Our portfolio of events is designed to meet the needs of our network in terms of content, format, timing, peer-to-peer engagements and modes of delivery.

The stats over the past year for non-conference events...



Events Delivered in a Range of Formats:

- 27 In-Person
- 20 Virtual
- 4 Hybrid

Our Events Have Been Buzzing with Excitement…

The past year has seen us return back to more in-person events with this being a clear preference amongst the network. It's been great to meet everyone and our events have been buzzing with excitement! There have also been key lessons learned including, leveraging technology where practicable and reliable to help bring together a greater diversity of delegates and speakers and to help keep our conversations going. A great example of this has been delivery of some of our BioWednesdays in a hybrid format enabling a live panel and networking onsite whilst those remote can still listen in. Or perhaps, one of our more technical Innovation Sessions online where the virtual format is perfectly acceptable for delivering the key learnings. Having a virtual or hybrid option across event categories, aside from the peer-to-peer networking, is continuing to develop the One Nucleus on-demand content hosted on our YouTube channel that contains ample resources for viewing and catching up on content.

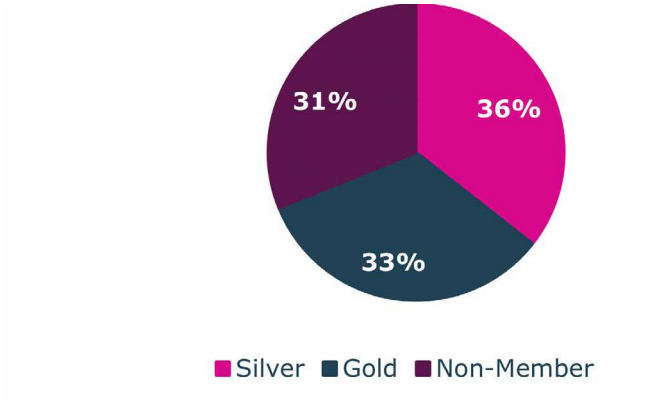
Visit the One Nucleus YouTube channel

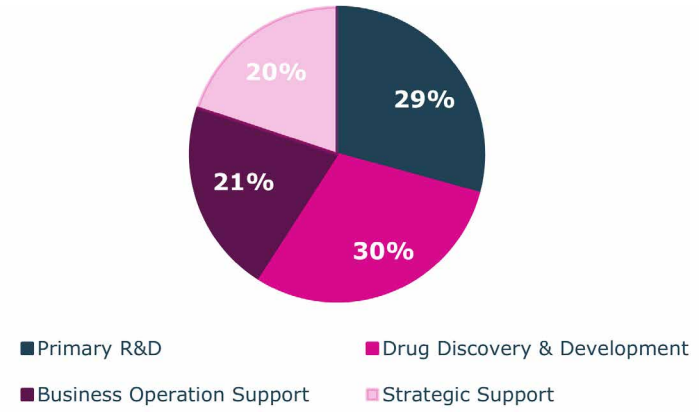
We delivered new activities in the form of our first Business Resilience Session…

The past year saw us enhance the range of Thematic Groups to include Business Resilience, alongside our HR SIG, Life Science Marketing Group and Employer of Choice Sessions. We are delighted to collaborate with Partners& as headline sponsor of the Business Resilience Group.

The Power of a Network…

As the charts below illustrate, One Nucleus events over the past year have been balanced in terms of the members and non-members they attract, whilst attendees can also expect to meet with a range of professionals in the industry. With this wider audience, the opportunities for sharing valuable insights are enhanced. Members gain free and discounted access to some events, while others are open and free to all.





Let's get talking…

Our events cover a wide breadth of topics that are relevant to the local Life Science community. Below are some of the stand our topics our speakers have been discussing and offering their insights on over the past year:

- **Innovation Seminar: Does Cambridge Go Beyond Prototype**

  A session in collaboration with One Nucleus Partner PCML Group that discussed the challenges and opportunities of moving from prototype to development in a region such as Cambridge, which is a hotbed of innovation and ultimately what will help the Cambridge Life Science cluster to grow locally and internationally. The recording of this session can be accessed here.

- **Employer of Choice Webinar: Creating a Destination Workplace**

  A session in collaboration with Future of Work Institute that discussed the key principles needed to become an employer of choice in a noisy market. The recording of this session can be accessed here.

- **BioWednesday: Creating and Defending Sustainable Value in Life Science IP**

  A session in collaboration with One Nucleus Corporate Sponsor Fish & Richardson on how to be compliant and avoid falling foul of IP due diligence, and in cases where you do fall short, then how to survive. The recording of this session can be accessed here.

- **Tech-Bio Beyond the Hype: Contributing to Life Science Companies' Sustainability**

  A sponsored session in collaboration with One Nucleus member Bruntwood SciTech. This event featured a panel discussion around the growing interest in 'Tech-Bio' and how this can help with delivering a more sustainable approach to Life Science companies. The discussion helped to set the scene for the networking that followed.

- **VIC Session - Dealing with the Rising Cost of Living in our Life Sciences Sector: From Supply Chain to Operation Costs**

  A session in collaboration with One Nucleus Corporate Sponsor Thermo Fisher Scientific and One Nucleus Partner EY providing an update on the trends in macro economics impacting businesses and how to ensure security of supply chain. The recording of this session can be accessed here.

We look forward to connecting with you at our future events!

Focus on One Nucleus' Core Events

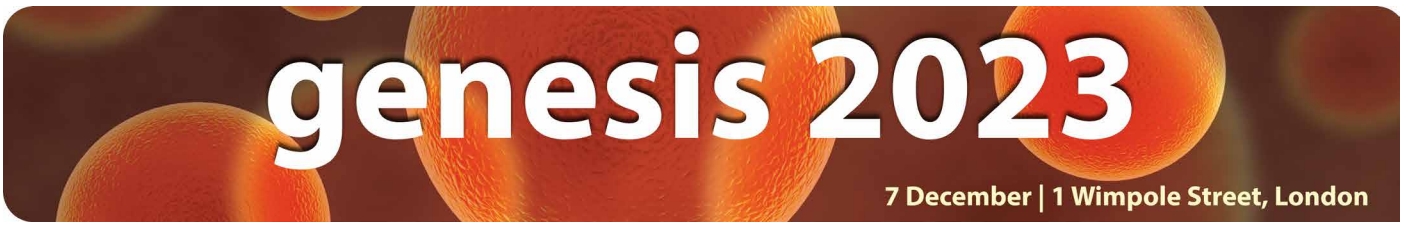
Creating careers not just jobs is a two-way process between those seeking to build their adventures in science and those seeking to employ them with academia a critical enabler.

This two-day free to attend digital careers conference is a chance to fill knowledge gaps, debate best practice and connect to enable success. Not your standard job fair, this is an event bringing panels of students, early career seekers, employers and universities together to engage in lively discussions over the course of two days.

This one-day conference will address key bio innovation trends, from developments in life science and technology research to their translation into new diagnostics, prevention tools or treatments.

Delegates and Supporters will connect with the One Nucleus network to explore New Horizons for Bio Innovation.

ON Helix 2023 offers: • a high content mix of plenary talks and panels from key opinion leaders • networking with 250+ delegates on the day • Option to arrange 1-to-1 virtual meetings with in-person and digital only delegates • The ON Helix Fringe events including digital Innovation Workshops for further technical and business insights and additional in-person networking opportunities • The Innovation Support Hub Exhibition, to showcase the most innovative early-stage life science companies as well as the innovation supporters from the network



The annual Genesis conference has been a pillar of the Life Science sector for over two decades. Bringing together key opinion leaders, investors and innovators from across the sector to share insight, debate key trends and generate deals.

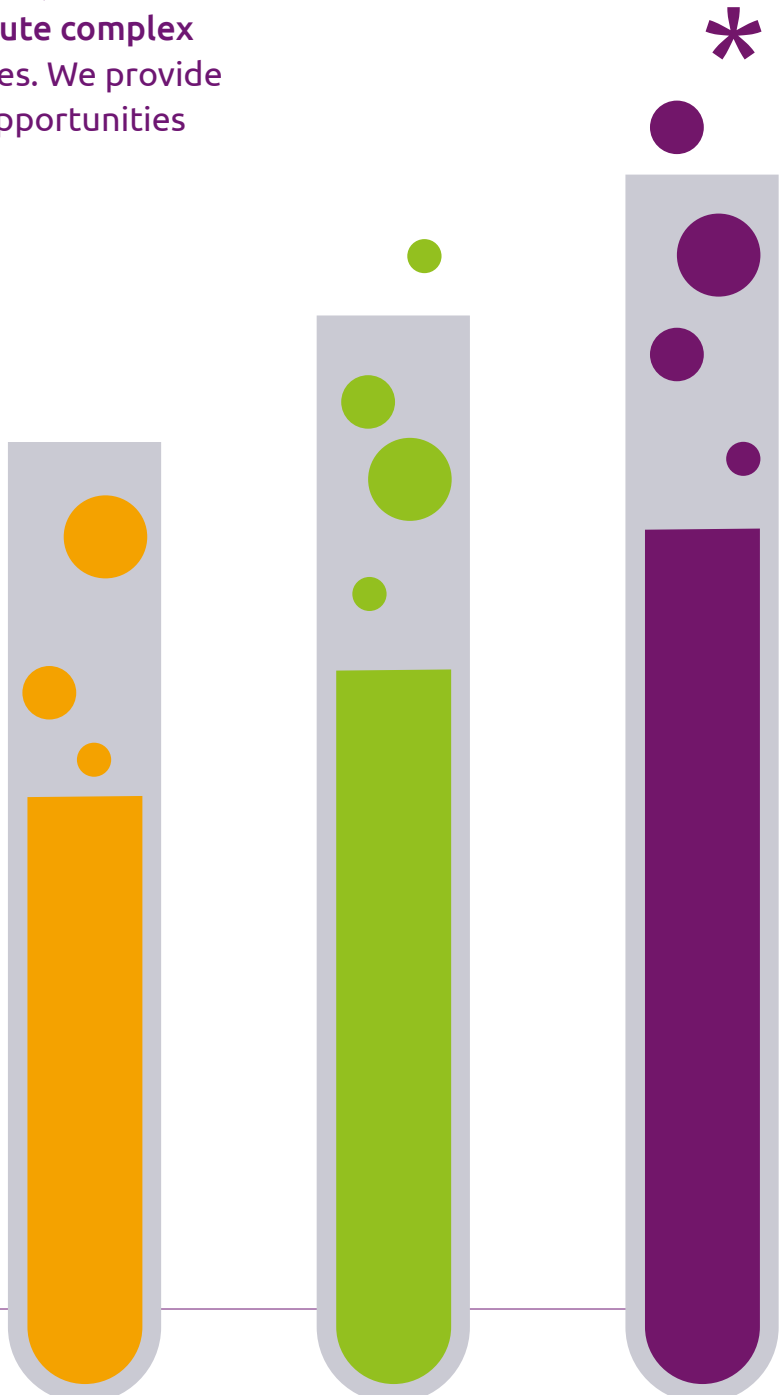
Genesis offers: • a high content mix of plenary talks and panels from key opinion leaders • Innovation Workshops for further technical and business insights • Face to face networking and digital 1-2-1 meetings with 300+ delegates from across the international Life Science and Healthcare industry • popular Fringe Events.

MILLS & REEVE

Achieve more. Together.

Success is our science

The life sciences sector is hugely innovative but also highly complex and regulated. Our renowned multi-disciplinary team of lawyers have **deep sector knowledge** and can help wherever you need, whether that is to protect your latest idea, **to execute complex transactions** or deal with compliance issues. We provide the solutions to enable you to seize the opportunities open to you.



To find out more, please contact:
James Fry
Partner and Head of Life sciences
james.fry@mills-reeve.com

Meet the Team

Tony Jones
Chief Executive Officer

Richard Dickinson
Chief Technical Specialist

Jean
Chief Operating Officer

Debbie Flicos
Finance & Systems Administrator

Laura Bacchus
Events & Data Administrator

Monalisa Breazu
Learning & Development Administrator

Alicia Gailliez
Business Development Manager

Claire Abrams
Director of Events & Communications

Jasmin Bannister
Member Engagement Manager

Natalie Keuroghlian
Marketing Manager

Andrew Bickerton
CRM Systems Manager

Corporate Patron

AstraZeneca

Corporate Sponsors

CHARLES STANLEY
Wealth Managers

CHESTERFORD RESEARCH PARK

FISH
FISH & RICHARDSON

MSD
INVENTING FOR LIFE

ThermoFisher SCIENTIFIC

TaylorWessing

Our Corporate Patron

AstraZeneca
What science can do

With increased interest and curiosity following the pandemic, we have a golden opportunity to inspire the next generation, encouraging them to think about a career within STEM (Science, Technology, Engineering and Maths).

AstraZeneca supports over 500 early career scientists in the UK, offering opportunities to school leavers, undergraduates, graduates, PhD students and postdoctoral researchers. Gaining experience in the biopharmaceutical industry helps to kickstart early careers and will ensure a bright future for the UK's life science sector, benefitting both patients and society as a whole.

Supporting the development of a diverse and inclusive talent pipeline for the future is an area we facilitate at One Nucleus. The breadth of this engagement means we have formed a strong and productive relationship with AstraZeneca, based on our shared ambitions for the Cambridge and wider UK life sciences community.

It is our pleasure to have the continued support of Penny James, Chief Operating Officer, Biopharmaceuticals, as a Non-Executive Director. One Nucleus strives to enable knowledge sharing on the latest innovations in the scientific, business and investment aspects of the sector. AstraZeneca's willingness to dedicate resource to us, such as event speakers and updates, significantly enhances our ability to share and debate content across areas including R&D, deal making and sustainability. Their engagement provides insight to the nascent companies, their founding entrepreneurs and investors, on how exceptional scientific innovation can be translated into patient benefit globally.

Tony Jones, CEO

One Nucleus Partners

Partner Programme

The One Nucleus Partner Programme offers a fully integrated value proposition to organisations seeking to play an influential and visible role in the development of the One Nucleus life science community.

Relationship Management:
Each Partner has a tailored Annual Engagement Plan, developed to ensure a good strategic fit with the Partner's goals for the year ahead and against which performance can be managed. There is an allocated One Nucleus account manager for each relationship to ensure regular reviews and discuss desired adjustments as the year progresses. Engagement may include benefits from the menu below, but the agreed package is designed with flexibility in mind.

Partner Benefits:

- One Nucleus Gold Membership.
- Company logo displayed with advised url hyperlink on the One Nucleus website.
- Company logo and url hyperlink in the One Nucleus Annual Review.
- Opportunity to speak at One Nucleus events (based on relevance and experience).
- Contribution of thought leadership articles to One Nucleus publications.
- Placement of a banner advertisement and article in an edition of One Nucleus eNews.
- Option to develop bespoke event(s) or workshop(s) to be delivered with One Nucleus.
- One in-person delegate pass to any One Nucleus conference offering such an option.
- Annual 1-2-1 meeting with the CEO of One Nucleus to discuss issues facing the life science sector and possible One Nucleus interventions.
- Priority invitation to any VIP-only events hosted by One Nucleus.

*** To become a One Nucleus Partner the cost is £8,810 +VAT per annum**

For information: +44(0)1223 896450 info@onenucleus.com www.onenucleus.com

CHESTERFORD RESEARCH PARK

Where Life Meets Science

Chesterford Research Park offers state of the art laboratory and office space alongside superb central facilities - a community perfectly positioned for today's thriving pharmaceutical and biotech companies.

www.chesterfordresearchpark.com

AVIVA INVESTORS

CHURCHMANOR ESTATES

CHEFFINS
01223 213666

savills.co.uk savills
01223 347 000

Chesterford Research Park: A Prestigious Location Which Ticks All the Boxes

The Science Village Building, Chesterford Research Park

The race for life science space within the cluster has bought with it a heightened awareness of the considerations which are intrinsically important when making the 'where to locate' decision, and ranking high on that list of considerations is staff expectation – both current and future. Today, this group expects much more than just a job and considerations around location, accessibility, amenity and work/life balance all rank just as highly, if not higher, than the immediate office environment, salary, potential for swift career progression and benefits package when evaluating who to work for.

This forensic analysis by current staff and potential recruits is causing organisations to re-evaluate the criteria when it comes to choosing the environment within which they choose to start or scale their ventures.

An Exceptionally Attractive Workplace Which Prioritises Staff Wellbeing
Set within 250 acres of idyllic parkland near Cambridge, Chesterford Research Park is a low-density development of state-of-the-art R&D laboratories and office spaces all set within a wonderful, natural landscape - providing the very best flexible and future-proofed environment for innovative, world class pharmaceutical, biotechnology, diagnostics and technology R&D companies – from startups to multi-nationals - and their highly skilled staff.

Greenspace
Ideal for moments of downtime and contemplation during the working day or a brisk walk or run during lunch break, Chesterford Research Park's superb green spaces, complete with beautiful arboretum and lakes are hard to surpass. The Park even has its own 7-hole, par 3, golf course, which is free to use by all those working on site.

A Central Space for Community, Fitness and Collaboration
At the heart of the Park sits The Nucleus, the Park's exceptional central facilities building. Home to a restaurant and café, fitness centre and range of meeting and conferencing spaces, The Nucleus is a vibrant, communal meeting and social space regularly used by both Park occupiers and visitors.

Ease of Commute
Daily coach services to and from central Cambridge, a shuttle bus service from Great Chesterford train station, Liftshare scheme and Park taxi service are available to all Park occupiers. These services not only reduce road and parking congestion and improve sustainability, but also ensure ease of commute for all staff regularly travelling to and from the Park.

It is this combination of 'work, rest and play' facilities all expertly managed by the Park's dedicated team which proves a winning formula time and again for occupier's who recognise and value the benefits this combination of facilities brings to current (and future) employees' mental and physical wellbeing.

Future Vision
In answer to the high demand for life science space in the Cambridge Cluster, the next phase of development at Chesterford is also now in train. The new, multi-occupier, three-storey 60,000 sq ft Sidney Sussex Building - fitted with a mix of flexible laboratory and write up office space from approximately 2,228 sq ft (207 sq m) to 8,292 sq ft (770 sq m) - will be built on a plot to the east of the Park. Designed to not only enable new occupiers to join the Park community the Sidney Sussex Building will also provide existing occupiers with the opportunity to scale up within the Park setting they already call home.

Discover more about the Park here: www.chesterfordresearchpark.com

Did You Know as a Member You Can...?

Connect via groups in the EU, North America, Australasia & Asia

Save more than your membership fee via member discounts

Post job vacancies online

Be seen as an employer of choice

Access the on-demand library of debates and information

Raise your company's profile

Access the Learning & Development centre for your team

Network with investors, collaborators and customers

Do get in touch to learn more about membership benefits and how to maximise the return on your investment.

Membership Benefits

Benefit	Gold	Silver	Non-member
Listed in online membership directory	Yes	Yes	No
Listed in One Nucleus Annual Review	Yes	Yes	No
Post news to website and social media	Free	Free	£75 + VAT
Advertise jobs on web site	Free	Free	£75 + VAT
Advertise events on web site	Free	Free	£75 + VAT
ON Helix Delegate 2023	£325 + VAT	£435 + VAT	£545 + VAT
Genesis Delegate 2023	£325 + VAT	£435 + VAT	£545 + VAT
BioWednesdays	Free	Free	£50 + VAT
Banner Advert in eNews	£500 + VAT	£500 + VAT	£800 + VAT
Innovation Seminars	Free	Free	Invitation Only
Training	30% discount	15% discount	List Price
Facilities Management Consultancy Day Rate	£770 plus expenses + VAT	£935 plus expenses + VAT	£1,100 plus expenses + VAT
Preferred Supplier Discounts	Yes	Yes**	No
Access M2M Marketplace discounts	Yes	Yes	No
Access to Thematic Interest Groups	Yes	£30 + VAT	No
Employer of Choice Sessions	Free	Free	Invitation Only
Access to on-demand library	Yes	Yes	Restricted

**Access to some but not all

Member Savings

Members can take advantage of discounts on a wide range of products and services to maximise their return on the member subscription, often recovering multiples of the fees paid. One Nucleus negotiates savings and discounts for members by leveraging the critical mass of our membership, providing members with the purchasing power of a large entity. **Receive discounted rates on laboratory supplies, services, key industry events and more.**

Make Even More Savings with the One Nucleus Group Purchasing Scheme

- 9 Preferred Supplier contracts.
- Saving members over £5 million per annum on a combined spend of £7.5 million per annum.
- Member retains full control over their own procurement, which is key to R&D operations.
- Member has direct relationships with the suppliers, including access to services which are customised to their needs.
- Gold Members using Fisher Scientific receive a growth rebate on their annual spending at the end of the year - rebate in 2022 was 3% plus an e-commerce rebate of up to 5% of total spend online. The overall savings made often more than cover the cost of a Gold Membership.
- All Preferred Suppliers have published sustainability plans and policies to protect customers' environmental footprint.
- Four out of the 9 Preferred Suppliers are now available to **all Silver Members**.

Retain Control

We fully understand that Life Science procurement is not a 'one size fits all' approach – with One Nucleus' savings options, you keep control of your own procurement, supplier relationships and get the best possible price.

Member Savings

Member to Member Marketplace:

- Convenient destination to find an array of discounted products and services.
- 11 Support Suppliers offering discounts to One Nucleus members.

Events:

- A free Digital Delegate Pass for each One Nucleus member company to ON Helix and Genesis. A combined saving of £150 + VAT over non-members.
- Discounted delegate rates at ON Helix and Genesis for in-person or additional digital delegates.
- A range of discounts at international and national industry partnering events and conferences such as BIO-Europe Spring, BioTrinity, AngloNordic Conference, Bio Integrates, BIO Convention, Medi Integrates, NLSDays and BIO-Europe.

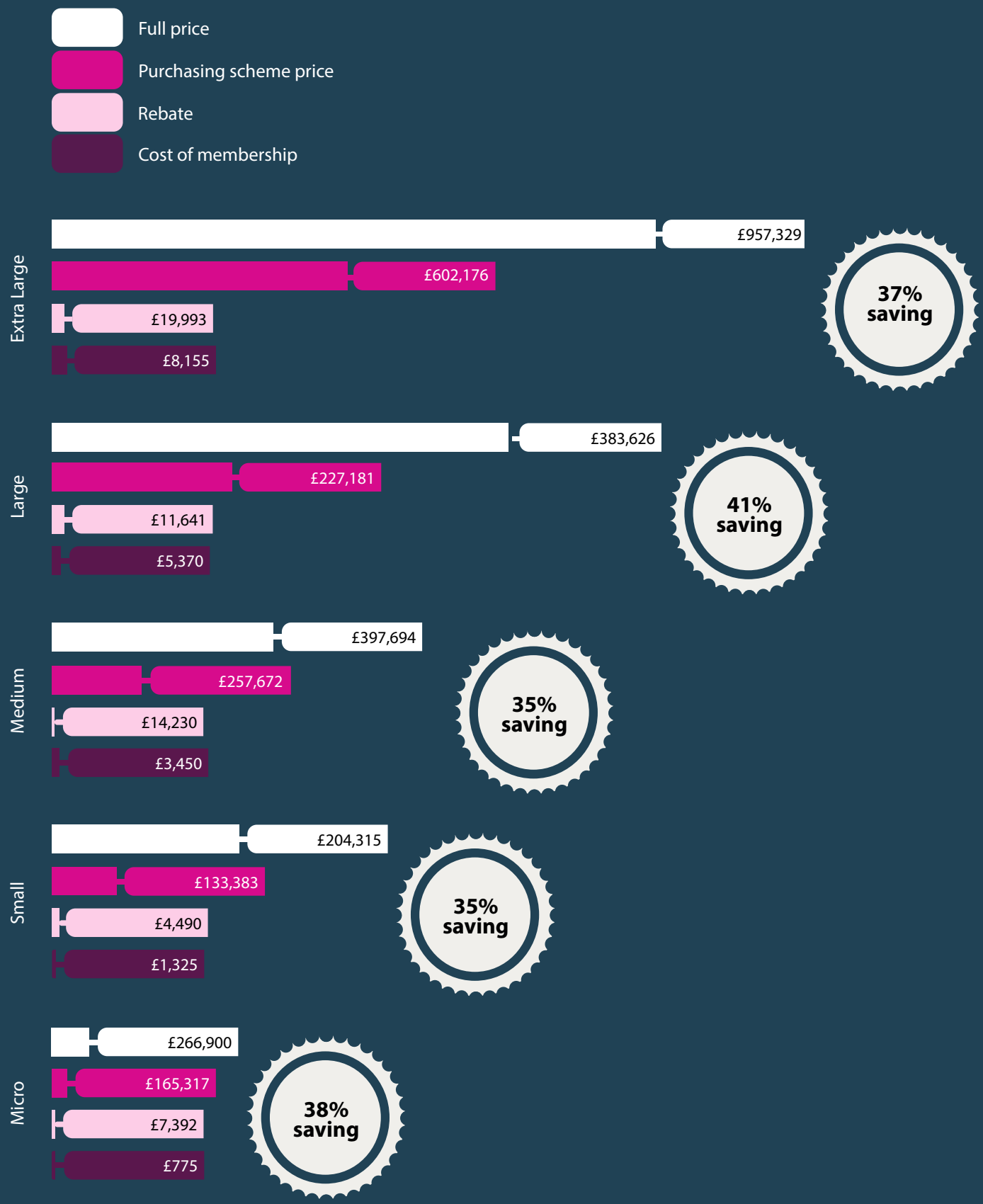
Facilities Management:

- Accessing expertise - Our Chief Technical Specialist, Richard Dickinson, has over 25 years' experience as a Facilities Manager.
- Provision of project management for office and laboratory fit-outs and can assist with laboratory service contracts, maintenance contracts, cleaning contracts, utility bills, insurance, purchasing and budgeting.
- Daily Rates (excluding VAT) – Gold members £770 plus expenses; Silver £935 plus expenses; Non-member £1,100 plus expenses.
- View case studies.

Contact Richard Dickinson to discuss your needs and secure a quote.

Member Savings in 2022

The chart below is a snapshot of our members, ranging from extra large to micro and demonstrates the savings made by them using the Purchasing Scheme.
For some, the rebate alone **covered the cost** of membership.



Facilities Management

Facilities management can be a real problem for small technology companies with challenging demands for laboratory, workshop and office space. One Nucleus provides a range of Facilities Management Services to help our member companies to expand or relocate.

We provide project management for office and laboratory fit-outs (no job too small), and can help with laboratory service contracts, maintenance contracts, cleaning contracts, utility bills, insurance, purchasing and budgeting. As with all our services, these are provided at discounted rates to our members.

Our Facilities Management Services and Purchasing Scheme are managed by Richard Dickinson, One Nucleus' Chief Technical Specialist, who has more than 25 years' experience in laboratory and facilities management. Richard has extensive local contacts and is also NEBOSH certified in health and safety.

Recent projects and clients include:

- Cambridge Science Park
- Charm Therapeutics Ltd
- Clover BioPharmaceuticals UK Ltd
- Domainex
- Healx
- Howard Group
- Ladder Therapeutics
- Superdielectrics Ltd
- VaxEquity Ltd

Companies Richard has helped this year have a total of 200,000 sq. ft. of space.

Looking for space to start or grow your business?

Ask me about our Facilities Management services. We can provide project management for all your laboratory fit-out needs.

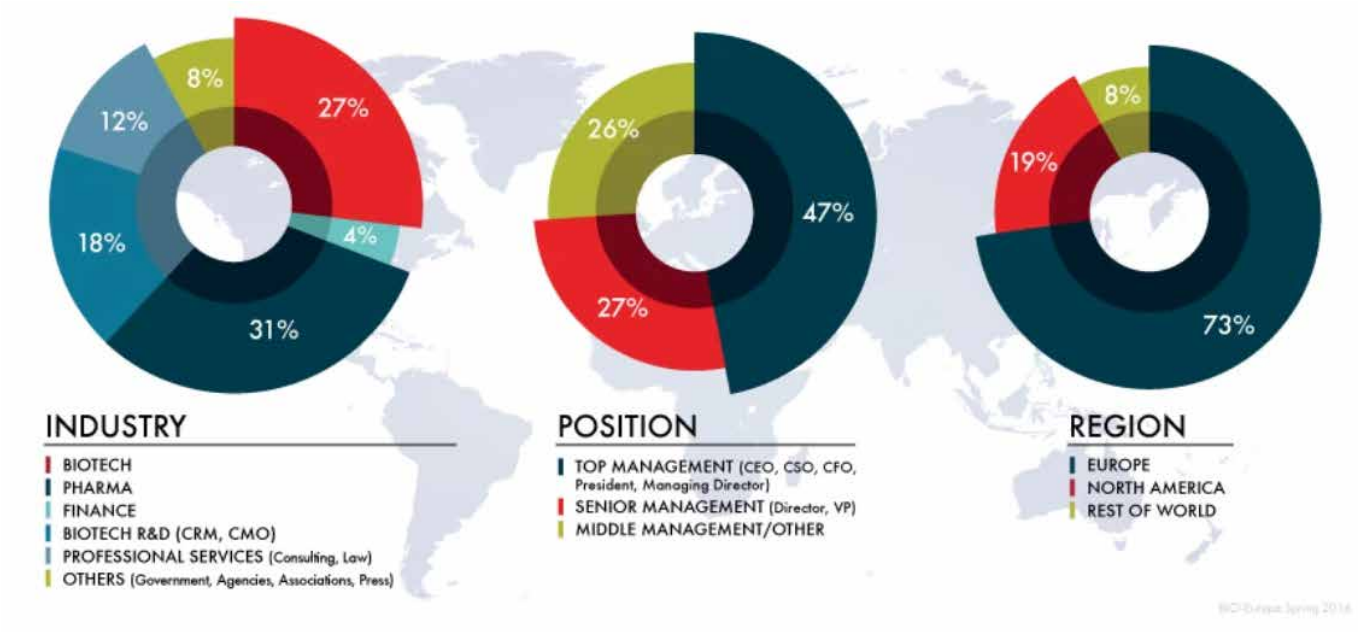
Richard@onenucleus.com | 01223 896453

one nucleus

Our Network at BIO-Europe Spring 2023

BIO-EUROPE SPRING®
MARCH 20–22, 2023 // BASEL, SWITZERLAND

We are returning to BIO-Europe Spring with an enhanced profiling opportunity for our members to help showcase them at this event in Basel, Switzerland on 20-22 March 2023. Meeting dealmakers, the global Bio Pharma community.



Who Attends?
Over the years, BIO-Europe Spring has become Europe's largest springtime partnering event. Its international reach makes it a one of a kind offering and gateway to the global life science community.

The event caters to the entire value chain, start-up and innovator educational programmes, industry trends and outlooks from KOLs, company pitches, partnering meetings as well as various networking opportunities. Read more on the BIO-Europe Spring website.

One Nucleus is proud to represent the following organisations at BIO-Europe Spring: Domainex, Pharmidex, Precision for Medicine, VasoDynamics, Riverlabs, tranScrip, Mursla, Sphere Fluidics, Simbec Orion, Isogenica, ValiRx Inaphaea BioLabs, Sygnature Discovery.

One Nucleus Members attending BIO-Europe Spring this year include: Actigen Ltd, Adrestia Therapeutics Ltd, Alchemab Therapeutics, Aptamer Group, Astellas Pharma Europe, Autolus, BenevolentAI, BioPartner UK, bit.bio, Charm Therapeutics, Curileum Discovery, DLRC Ltd, Domainex, Ergomed PLC, Fusion Antibodies, Healx, Isomerase Therapeutics Ltd, Johnson & Johnson Innovation, LiliumX, Monument Tx, ONO Pharmaceutical, Phaim Pharma, PharmaVentures Ltd, Phoremost Ltd, PrecisionLife, Quotient Sciences, Scendea Ltd, Storm Therapeutics Ltd, WuXi AppTec.

Read on to find out more about the companies we are profiling on Stand 46!

Our Network at BIO-Europe Spring 2023

pharmidex
world-leading translational research

Pharmidex is a UK-based CRO founded in 2002 providing high quality, cost-effective and rapid solutions to clients in in vitro ADME, Pharmacokinetics (DMPK), bioanalysis (non-GLP, GLP/GCP) and toxicology (non-GLP, GLP).

Pharmidex also offer in silico modelling and efficacy models supporting oncology, CNS, respiratory, stroke and auto-immune disease programmes. Pharmidex team are highly experienced in designing, executing, reporting and discussing results of studies to help advance client projects successfully. The client base includes medical charities, academic groups, biotech and pharma companies globally. In addition to fee-for-service offering, Pharmidex are always seeking opportunities to collaborate in grant funded projects.

https://www.pharmidex.com/

SIMBEC-ORION

Simbec-Orion is a full-service international contract research organisation with comprehensive capabilities at every stage of Clinical Development, from first in human through to multinational patient trials. Headquartered in South Wales and with deep expertise in oncology, and rare disease therapeutics, Simbec-Orion employs over 450 staff who are based across Europe and the United States.

Simbec-Orion provides small to mid-size pharmaceutical and biotech clients with an extensive portfolio of services, expertly supported by an in-house dedicated Central Laboratory Facility (Bioanalytical & Pathology) for rapid, accurate and reliable sample analysis as well as Investigational Medicinal Products (IMP) Management.

Learn more at www.simbecorion.com

Our Network at BIO-Europe Spring 2023

SYGNATURE DISCOVERY

Sygnature Discovery is a leading independent provider of integrated drug discovery and pre-clinical resource and expertise, offering fully integrated discovery project support, as well as discipline specific support in medicinal chemistry, computational sciences, bioscience, DMPK or physical sciences as needed.

Sygnature undertake target validation, hit identification, hit-to-lead and lead optimisation projects as well as complete drug discovery programs.

Since 2011, 37 compounds discovered by Sygnature for clients have entered pre-clinical development and, so far, 20 of these have progressed to clinical trials (Phases I, II and III).

For more info: www.sygnaturediscovery.com

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- Genomics Services
- Bioanalysis of Large Molecules, Complex Biologics, and Advanced Therapies
- Biomarker Data Management

Trial Services Include:

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- Biomarker-driven Clinical Trial Strategy and Execution
- Design of Analytical and Clinical Studies
- Companion Diagnostic Development and Go-To-Market Strategy
- Regulatory Affairs Strategy and Consultancy
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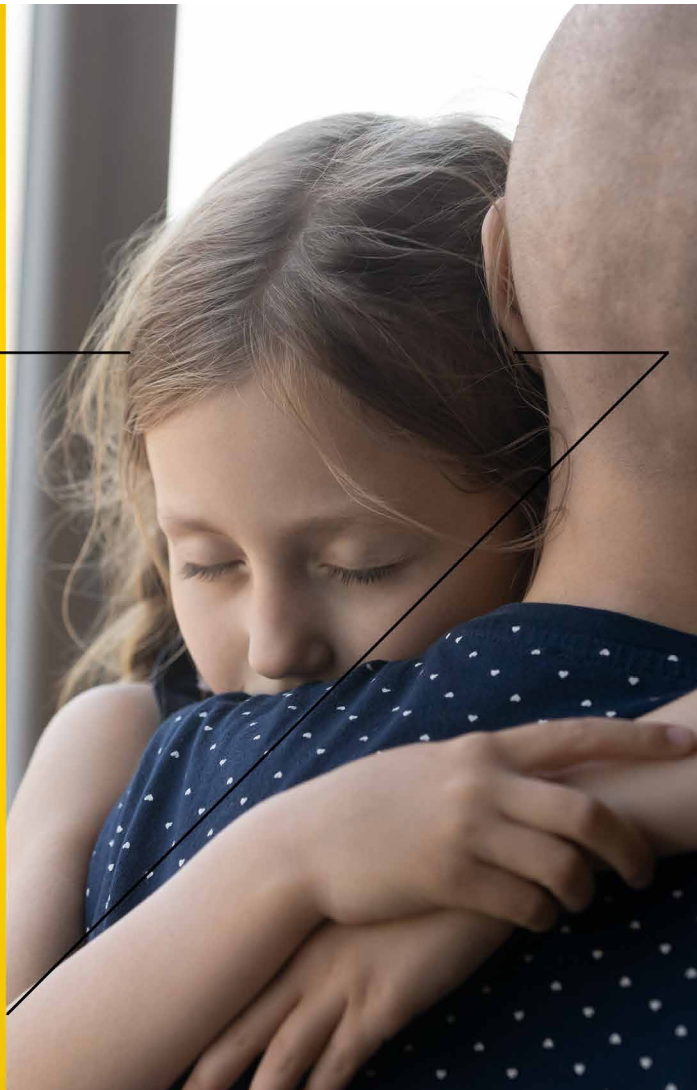

Our Network at BIO-Europe Spring 2023

Domainex
Enrich your medicines pipeline

Domainex is a multi-award winning drug discovery service company that works collaboratively with clients from a variety of sectors (including pharmaceutical, biotechnology, academic and patient foundations) around the world.

We have a headcount of >100 employees and our approach to drug discovery is truly integrated. We offer the full range of pre-clinical drug discovery services supporting our clients at every stage of the journey, from disease target to candidate drug selection including protein production, assay development and screening, structural biology, medicinal, synthetic and analytical chemistry, hit-to-lead and lead optimisation.

Contact us at enquiries@domainex.co.uk to speak to one of our experts.

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Our Network at BIO-Europe Spring 2023

Sphere Fluidics

Sphere Fluidics is an established tools company based near Cambridge (UK). Sphere Fluidics has a range of novel single-cell encapsulation products that perform high-throughput single-cell analysis.

Our main platform (Cyto-Mine®) is protected by a comprehensive patent portfolio and, within several hours, can automatically screen up to 40 million single cells in miniaturised aqueous picolitre volume compartments called picodroplets. These are assayed for single cells that secrete valuable proteins (e.g., antibodies) and imaged (for monoclonality assurance) during subsequent dispensing of "hits". Cyto-Mine® is enabling, increases throughput and reduces costs and time for biopharmaceutical discovery and development, cell therapy and synthetic biology.

https://spherefluidics.com/

tranScrip

tranScrip is a leading contract drug development organisation which supports the development and lifecycle of medicines, medical devices and combination products. From early development through to registration and post licencing, we deliver both strategic leadership and operational execution of development programmes, covering clinical, regulatory, drug safety, and commercial elements, across a wide range of therapeutic areas.

Our teams of experts help clients select the most promising drug candidates and bring them to the market. We guide our clients through their decision making from first in man studies to proof of concept and pivotal trials, regulatory submissions and product launches.

https://www.transcrip-partners.com/

Our Network at BIO-Europe Spring 2023

VasoDynamics

We focus on developing patient-friendly, cost-effective and preventative therapies to prevent the common complications of cancer therapies, including severe mouth ulceration, skin damage, and hair-loss, thereby improving both cancer treatment outcomes and patients' quality of life.

All our programs are being developed for topical administration, both before and during cancer treatment, for optimal topical protection and patient convenience to achieve optimal cost effectiveness of cancer supportive care.

CONTACT US

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VasoDynamics Ltd | Tel: +44 (0) 1438-300 880 | www.vasodynamics.co.uk

Our Network at BIO-Europe Spring 2023

A Spin out from ValiRx PLC, Inaphaea BioLabs, Nottingham (UK), is a new pharmaceutical services company specialising in oncology and women's health. Offering a range of cell-based assays, including efficacy and selectivity of activity against cancer cells; mechanistic and binding assays; and measurements of production of cell markers and hormones.

The Inaphaea team have a strong background of preclinical and clinical drug development, and of understanding both the commercial and scientific needs of the service users from both sides of the table.

Inaphaea will provide testing services that generate the necessary data, analysis, and insights to aid decision making in translational drug development.

For more information please visit our website

Mursla (Cambridge, UK) is an emergent techbio startup, leveraging extracellular vesicle biology to deliver nextgen multi-omics liquid biopsy tests.

Its first product is a blood test to significantly improve the early detection of liver cancer among high risk populations so that more patients can benefit from curative treatments (surgery/transplant).

Its test is first-in-class and is differentiated from first generation liquid biopsy blood tests using circulating free DNA since it is tissue-specific, multi-omics and offers real time snapshot of disease biology.

Mursla was selected as UK Life Sciences Innovator 2023 in the Diagnostics and Precision Medicine category.

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Formulating the Future: Accelerating Oral Drug Development & Manufacturing

Oral solid dosage remains the gold standard for most patients, and hence drug developers. Yet opportunities to improve the processes for the development and manufacture of these mainstay dosage forms are often missed, and finished products may be compromised.

At a recent seminar held at the Royal Society of Chemistry's prestigious Burlington House in London, Catalent and One Nucleus hosted 40 industry experts in oral formulation and development, to discuss ways of improving bioavailability, how the application of drug delivery technologies could improve dose form design, and how to scale supply efficiently so that programs reach the clinic faster and foster market success.

Considering the various pressures on developers such as time, resources, and funding, it is important to make the right R&D choices. Short term thinking can lead to long term problems leading to missed timelines, escalating costs, and even regulatory issues in later phases. By deploying data-driven scientific approaches early, innovators can make better key development decisions. The aim of the workshop was to shed light on the many parameters that innovators should consider when designing and planning for the scale-up and manufacture of oral dosage forms.

Bringing perspectives from his experiences of working closely with many early-stage companies and startups, Tony Jones, Ph.D., CEO of One Nucleus, a not-for-profit life sciences and healthcare membership organization, introduced the speakers and facilitated discussions and Q&A sessions throughout the day.

Setting the scene of seminar, David Elder, principal of David P Elder Consultancy, in his presentation titled, 'Sustaining Accelerated Product Development', discussed the various approaches taken to accelerate drug development, including advanced preparation of a candidate's Target Product Profile (TPP), consideration of alternative administration routes via reformulation approaches, repurposing molecules by leveraging data from previous research more effectively, and utilizing regulatory authorities' expedited approval pathways.

Sharing his thoughts on the use of artificial intelligence, or AI, in accelerating drug development, Elder commented, "The use of AI has enabled innovators to develop and discover novel antibiotics, which would not have been possible using the classical techniques from the past. I believe that in the field of the oral drug product development, AI could one day be used for API synthesis."

James M. Butler, Ph.D., Senior Fellow, GSK, highlighted in his talk the importance of the Developability Classification System (DCS) as a valuable framework for developing an oral formulation to enable pharmaceutical scientists in oral formulation selection.

In the next session, one of Catalent's leading formulation experts, Stephen Tindal, Director, Science & Technology, advocated for flexible solutions for formulation and manufacturing that use elements of quality by design, manufacturing on demand, and the best scientific practices to help expedite pre-clinical and Phase 1 development. Tindal also shared a three-step process for smooth transition from early development to late-stage manufacturing.

Kendal Pitt, Ph.D., Pharmaceutical Consultant and Honorary Professor at the Leicester School of Pharmacy of De Montfort University, followed by presenting the concept of the Manufacturing Classification System (MCS), which, he said, could aid in defining the right particles for the best process in oral drug product manufacturing.

Formulating the Future: Accelerating Oral Drug Development & Manufacturing

"My top recommendation is to store the information from the first batch of API," responded Pitt when asked about the about quantities required to run tests on the first batch of APIs. "Depending on the results of the tests, we can typically expect to recover about 2 grammes of the material that can be reused at a later stage."

The event concluded with a panel discussion on 'Transforming Formulation & Manufacturing of Oral Solid Dosage Medicine', which pulled together the various themes and concepts presented through the seminar. Panelists David Elder, James Butler, Stephen Tindal, and Kendal Pitt were joined by Susan Banbury, Ph.D., Head for Formulation at Catalent, to discuss the future of oral solid dosage forms, and the importance of maximizing efficiency to increase productivity to deliver future solid dosage medicines to patients.

Catalent's vision is to share insights that are not only appropriate for the stage of development, but that also take into account the future needs of the program. Through its broad capabilities and experience of working on hundreds of programs with pharma companies of all sizes, including many emerging biotechs, Catalent is a catalyst for innovation and tailors solutions to accelerate timelines, from pre-clinical and first-in-human studies to developing CMC strategies to seamlessly scale-up for a successful launch.

To learn more about Catalent's capabilities and how it helps bring more molecules and better treatments to market, faster please contact solutions@catalent.com or visit Catalent.com for more information.

Catalent's European Development and Manufacturing Facilities - Haverhill, U.K. | Nottingham, U.K.| Swindon, U.K. | Schorndorf, Germany | Eberbach, Germany | Agnani, Italy | Beinheim, France

ABOUT CATALENT

Catalent is the global leader in enabling pharma, biotech, and consumer health partners to optimize product development, launch, and full life-cycle supply for patients around the world. With broad and deep scale and expertise in development sciences, delivery technologies, and multi-modality manufacturing, Catalent is a preferred industry partner for personalized medicines, consumer health brand extensions, and blockbuster drugs.

Catalent helps accelerate over 1,000 partner programs and launch over 150 new products every year. Its flexible manufacturing platforms at over 50 global sites supply around 80 billion doses of nearly 8,000 products annually. Catalent's expert workforce of approximately 18,000 includes more than 3,000 scientists and technicians.

Headquartered in Somerset, New Jersey, the company generated nearly $5 billion in revenue in its 2022 fiscal year. For more information, visit www.catalent.com.

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Three Steps Early-Stage Companies Can Take to Prepare for IP Due Diligence

Intellectual property due diligence is an essential tool for assessing the risks associated with investment, licensing, partnering, and acquisition. In the patent context, diligence aims to identify and de-risk potential issues with the ownership, validity, enforceability, of a company's patents, as well as evaluate potential infringement issues arising from third party IP. These are particularly important issues for early-stage companies, and there are three steps they can take to prepare themselves for the scrutiny of patent due diligence.

The lowest-hanging fruit for early-stage companies in preparing for diligence is to ensure that they are in possession of and can readily access the relevant documents. These documents generally include copies of patents and pending applications, inventor/company assignment documents to show proper chain of title to the IP, and agreements related to IP, such as employment and license agreements. While organizing patent documents sounds easy in theory, it often gets overlooked in practice, and gaps in the record or challenges in accessing or locating the documents can cause delays during diligence. Outsourcing the tracking and management of these documents to a patent attorney is a common solution for companies to be diligence-ready at any time.

Moving up the scale of complexity, early-stage companies must also pay close attention to inventorship and ownership issues. Both are a significant focus of every diligence regardless of the size of the company or the technology at issue, and getting either wrong can have serious downstream consequences. Inventorship should be determined as close to the patent application filing date as possible. Key questions to ask include (i) were any inventors non-employees, and (ii) did any employee inventor bring the invention with them from a previous employer? To establish ownership of the invention, assignments should be promptly executed and recorded. Prolonging this process can make it harder to locate the inventors and/or gain their timely cooperation.

A more challenging aspect of patent due diligence for many companies is analyzing patentability and freedom to operate ("FTO"), which require a nuanced evaluation of the relevant facts and law. Potential investors and partners will universally inquire about patentability and FTO during diligence, and target companies should be well-prepared to address related questions. This approach minimizes the risk of surprises derailing a potential deal. If there is an issue with the patentability of an asset or the company's freedom to operate, it is better for the company to know about it first, as buyers can more readily accept risk when they can see that the target company has thoughtfully considered the issue. However, companies should not share internal opinions on patentability or FTO with the other side or put any related statements writing

Following these steps to prepare for IP due diligence makes for a smooth diligence process. Demonstrating this sophistication during diligence garners goodwill from the other side and lends additional credibility to a target company's approach to IP.

Authors:
Principal Anita Meiklejohn, Ph.D. - Anita focuses her practice on patent prosecution, validity and infringement opinions, and litigation in the area of biotechnology. From 2019-2022, she was named a "Leading Patent Professional" by IAM Patent 1000

Principal Caleb Bates, Ph.D. - Caleb manages the worldwide prosecution strategy for several pre-clinical and clinical-stage biopharmaceutical companies and routinely counsels clients in licensing, buy- and sell-side due diligence, and freedom-to-operate and patentability analyses.

Growing and Developing your Life Sciences Spin-out – the Key Commercial Areas You Need to Get Right

PENNINGTONS MANCHES COOPER

There are a myriad of different aspects to setting up and running a new company particularly in the life sciences sector. All have to be managed for the company to be successful, and including in the very early stages where there are only a handful of people to do the work.

Rachel Bradley, IP/IT Commercial Partner at Penningtons Manches Cooper looks at some of the key areas for spin-outs to consider when entering into legal agreements that relate to their intellectual property (IP).

Protecting your most valuable asset

The IP owned by a new life sciences company will be its most valuable asset and needs to be protected. New companies are likely to embark on collaboration or co-development projects either with industry or academia or both. In these projects, it is vital for the company to ensure that it has the right to own IP that it generates or that arises from the collaboration that is related to its technology and that it has full rights to commercialise that IP, including access to any background IP of other parties. These collaborations can be incredibly complex legal agreements and it is crucial to ensure that the IP in the company's technology is not in any way diluted or contaminated by the project and the company remains free to commercialise its technology and assets.

Managing your out-sourcing agreements

The other common agreements for a new life sciences company are contract research agreements to assist with the development of the company's technology. Agreements with Contract Research Organisations (CROs) for research support such as preclinical studies or assay development must ensure that the IP that arises, and any data and results generated related to the technology, are always owned by the company. Some CRO standard terms and conditions do not, as an automatic position, assign all IP generated to a biotech company that is paying for this work, and some CROs also seek to retain rights in any background IP owned by the CRO. It is important to review these clauses carefully to ensure they give the company the rights they need to use the results of the research being performed on their behalf by the CRO.

Preparing for future funding and due diligence

A consistent position on ownership and access to IP in a company's contracts is also important, since all of these contracts will form part of the due diligence assessment of the company by a future investor. Raising funds from external investors will of course be a crucial part of a biotech company's development. It will be important to ensure that any IP created by employees, consultants and other sub-contractors are assigned to the company under the applicable agreements (i.e. employment agreement, consultancy agreement). Investors will want to see that IP ownership is clear and well defined, and that all of the legal agreements are consistent in that regard.

Introducing PennStart from Penningtons Manches Cooper

PennStart is our legal support package designed specifically for start-ups and spin-outs across the life sciences and technology sectors – delivering value where you need it most and giving you the freedom to focus on what matters most to you – making your vision a reality.

Our expert team has supported hundreds of life sciences and technology companies through every stage of their growth – you'll get the benefits of our expertise and decades of sector experience, as well as great value and cost certainty.

For more information about how we can support your life sciences company please contact Rachel Bradley.

Rachel Bradley, Partner - IP/IT Commercial, Penningtons Manches Cooper
Email: rachel.bradley@penningtonslaw.com - Tel: +44 (0)1223 465427

Pricing and Market Access

A strong Pricing and Market Access strategy is integral to what it takes to bring a product to market and is, therefore, integral to deal making. Pricing assumptions can have an enormous impact on the valuation of an asset and are frequently a cause of misalignment with potential partners. A strong pricing narrative and a solid data generation plan to support it, is essential for success.

PharmaVentures provides expert validation of recommendations for price assumptions and ensures there is a robust plan in place to achieve market access and reimbursement consistent with the development stage of an asset. We aim to give certainty in pricing and market access assumptions, to increase confidence in development plans, and to strengthen their position in deal making.

Our core methodology is a modular landscape, strategy definition, and validation technique that can be adapted to assets at any development stage:

- **A comprehensive or basic pricing and market access landscape assessment** from a global or sub-global perspective that helps clients understand the market and develop strategies
- **Pricing, data generation, HTA and contracting strategy and assumption development** that strengthens our clients' valuations and improves their market access narrative
- **Validation** through primary payer research, economic modelling and secondary quantitative validation techniques will add robustness to our clients' assumptions and strategy

Our pricing and market access service is tailored towards development stage and deal making and complements our other deal making capabilities.

PharmaVentures can provide clients with exactly what they need, as an addition to an existing project or as a stand-alone pricing and market access study.

How can we help you?

- ☑ Understand the payer and policy landscape in key geographies
- ☑ Create and validate core pricing assumptions for valuation
- ☑ Validate other market access related assumptions
- ☑ Support with the development of a robust HEOR and RW data generation plan
- ☑ Develop models to understand and communicate the economic case for your asset
- ☑ Develop your market access strategy in language your deal partners will understand

Let's Talk

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PharmaVentures
the deal experts

The Importance of Pricing and Market Access in Licensing, Partnering and Early-stage Development

by Ralph Hughes, Vice President, PharmaVentures.

A prominent biotech Venture Capital (VC) firm recently told me: "Insurance companies are the real movers and shakers in health care at the moment, they are the sharp end of the spear." And he went on to say that we need to understand what they are thinking if we are going to develop drugs that are marketable.

Drug developers sometimes struggle to see the value that pricing and market access insights will bring at an early stage. Many believe it is too early, that the deal partner will do their own analysis, or they simply don't understand it.

The VC I spoke to reflected this sentiment, but put a different spin on it: "It's not us or even the small biotech who has to deal with pricing and access; it's the larger partner; they get it right in the teeth." He went on to say it is incumbent on VCs and biotech developers to do the work as it can "pave the way if they do or build barriers if they don't."

This was mirrored by a comment from a pharmaceutical exec who said, "We will only look at assets where we can see the path to market for and that includes market access."

With all this in mind, we spoke to several US payers to try to understand how payer perspectives can impact early development decisions in key areas of development from across the innovative spectrum from gene therapies to repurposed drugs. In these discussions there were some clear lessons that drug developers can learn from payers, even at the very early stage, such as:

- Understanding incentives, perspectives and funding flows can lead to better pricing and development strategies.
- Creating a cost offset narrative is essential for assets with infrastructure issues.
- Understanding payer perspectives can help you define market positioning and pricing.
- Targeting drug development at payers, as well as the regulators, can ensure adoption.
- Payers can become advocates, not blockers, given the right data and narrative.

I have developed a series of short articles from these insights to help early-stage drug developers understand the value that payer insights can bring to early development and deal making.

Understanding the payer perspectives and incentives can lead to a more commercially viable development strategy across the innovative spectrum from gene therapies to value-add therapies

In his book, The Price of Global Health, Ed Schoonveld provides a brilliant analogy of what a payer is. He describes a dinner party in which one person orders the meal (the physician), another person eats the meal (the patient) and a third person picks up the cheque (the payer). This analogy does a great job of capturing the essence of the health system and enables us to see the how perverse incentives and behaviours might emerge from such a setup.

In reality, the payer system is orders of magnitude more complicated and so are the incentives and behaviours. Understanding what drives different types of payers and the different funding flows that they must contend with, helps us to build a picture of how an asset might be paid for or reimbursed. This can have a big impact on the value and price of a development asset.

Payers are not a homogeneous group:
There are many ways of characterising payers, e.g., by the regions they cover, or the populations they cover or the perspectives they take. There are so many different types of payers in the US as it is such a fragmented health system, but what is important is the risk that payers take, what they can do about that risk and therefore the view they take on drug coverage:

- **The insurer view**: Payers like managed care organisations, manage the risk of a patient primarily in the outpatient setting through a pharmacy benefit manager and will leave the management of an inpatient up to the hospital and fund them through fixed fee payments.
- **The value-based view**: Payers like Integrated Delivery Networks or Accountable Care Organisations, own the total risk of the patient from end to end as they manage a network of providers. Through this network, they can deliver care as inpatients and outpatients in the most efficient way possible, this enables them to think about the total cost of care.
- **The provider view**: The provider will only be responsible for their own centre or hospital; this means that they will be focussed on the value coming from reimbursement via the insurer versus how much they must spend to deliver care.

Understanding the difference between these key groups helps us understand the incentives at play and how they might impact on a drug in development.

Different payers have different views:

A payer conveyed to me a compelling illustration of the significance of getting different views. One of the major challenges with gene therapies in the US is the portability of patients under outcome-based or amortisation schemes. This means that an arrangement for spreading the high, one-time cost of a gene therapy over several years with one insurance company may be made, but in the US, people typically switch insurance companies every 1-2 years, making it difficult for the scheme to follow them to the new insurance provider. However, with the prevalence of accountable care organisations, the frequency of switching is much less, occurring only every 4-5 years, which makes patient portability a lesser concern and makes these types of payers more willing to enter into amortisation agreements.

Another instance that showcases all three perspectives well is the recent launch of an antibiotic that requires weekly dosing, eliminating the need for daily IV administration of vancomycin by a nurse through Outpatient Parenteral Antibiotic Therapy (OPAT) and demonstrating similar effectiveness for severe infections. When speaking with payers, I encountered three vastly different views on the value of this product and how the incentives are structured:

1. **A hospital payer** stated that they wouldn't prescribe it for inpatients because its efficacy is the same as a daily generic and they'd rather have the patient return to the outpatient clinic the day after discharge to receive the drug, passing the cost onto the insurer and avoiding adding to their fixed fee episode cost.
2. **A Pharmacy Benefit Manager (PBM)** informed me that they would only approve the prescription if it was a continuation from the hospital, and if it was a new script, they would apply a prior authorisation if the price was too high. The price could also factor in the cost savings from avoiding OPAT.
3. **An Accountable Care Organization (ACO)** payer stated that there was a massive potential for system efficiencies as it could facilitate early discharge, decrease the need for skilled nursing facilities, and OPAT. Taking a value-based approach, they were able to consider inpatient and outpatient as a seamless continuum.

It's not to say that payers always disagree. There are many aspects that payers consistently agree on, and this applies across the innovative spectrum from gene therapies and 505(b)(2) products and across the geographical spectrum from Australia to the USA. One such issue is the importance of choosing the right comparator for an asset: what is your price and efficacy compared to?

A good example of this is with the gene therapies for muscular dystrophy compared with those for haemophilia. An insurer explained that for muscular dystrophy; certain assets have been launched with weak data on surrogate endpoints with no comparator "only adding new costs". These are contrasted with assets launching for haemophilia that will replace the extremely expensive blood clotting factors, which can cost up to $1 million annually. "Ultimately, you can divide gene therapies into two categories: those that bring new costs and those that can offset costs." It was clear that there was a much higher willingness to pay for assets that avoid significant existing cost. This is highly relevant for drug developers, as the comparison and offset costs are crucial for the acceptance of a price by payers and potential partners.

Why is this important to do early?

Whether you're developing a gene therapy or a value-added drug, it's crucial to consider the various payer perspectives as it can help you evaluate the significance of these issues to your asset, the potential blockers to progress and the ways to overcome them. From these examples alone we can see:

- The ability to add certain cost-offsets to our price to drive value with specific payer types.
- The likelihood of getting value-based contracts and spreading the price.
- The importance of developing the right endpoints.
- The importance of considering the right comparators in your trials.

It is certain that major pharmaceutical partners will understand these barriers. For early developers looking to get deals with those pharmaceutical companies, taking steps early on to reveal obstacles and the method for overcoming them can result in better-than-expected pricing outcomes. It enables smaller biotechs to enter important negotiations on a more equal footing with larger pharmaceutical partners and add value to their asset in the mutual valuation.

Read more - Creating a Cost Offset Narrative Early is Essential for Deal Making in Assets with Infrastructure Issues such as Psychedelics and Cell Therapies.

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Leading the Way with Lab Space Provision

By Lucy Garnsworthy

The UK's life science 'golden triangle' of London-Oxford-Cambridge is looking rather full. Demand for lab space in London increased 400% from 2016-2021, according to MedCity's 2021 Demand Report[1]. Meanwhile, the Times recently reported that "a lack of laboratory space in Oxford and Cambridge threatens to thwart Rishi Sunak's dream of making Britain a 'science superpower'[2] . On the ground, the London BioScience Innovation Centre (LBIC), London's original bioscience incubator founded over 23 years ago, continues to operate year on year at full capacity. Its successful growing biotech companies struggle to find high-quality lab space to graduate to in the capital.

To address this high demand and help the UK on its trajectory to become a 'science superpower', LBIC will open its new 37,127ft^2 state-of-the-art facility at the Apex building, adjacent to its existing facilities at King's Cross, London. Scheduled to open in early 2024, Apex is part of the new canal-side 'Tribeca London' mixed-use development by Reef Group and Blackrock Alternatives.

Over the years, LBIC, a subsidiary company of the Royal Veterinary College (RVC), has supported over 200 companies, creating over 5,000 jobs. There have been 27 mergers, acquisitions and flotations and an estimated £2.5 billion of financing raised. The new Apex facility will build on LBIC's current provision for life science companies, allowing existing clients to grow and new clients to come on board, benefiting from the support of LBIC's expert team.

LBIC facilitates collaboration opportunities with other companies and with world-leading academic researchers at its parent institution the RVC, opening up possibilities for industry-academia grant awards and tapping into the animal health market as well as human healthcare.

LBIC gives companies the edge by offering access to specialist equipment and services, plus introductions to a host of industry experts and an initial membership of One Nucleus – an essential for success, of course!

Companies can even take available lab space anywhere and still have a central London base, with LBIC's virtual tenancy giving companies a low-risk option of access to reception services, networking opportunities and meeting room space without the need to be physically based at the Centre. In offering this flexibility, LBIC helps clients build their London network and access vital services and funding while making use of what is available elsewhere. By supporting companies according to their individual needs, the UK can indeed become a 'science superpower' by 2030.

Find our more about LBIC

[1] 'London Life Sciences Demand Report', MedCity and Creative Places, 2021

[2] The Times, 14 Feb 2023

Big Changes Coming for R&D in the Life Sciences Sector

With the most significant changes to research and development (R&D) since 2000 on the way, R&D tax reliefs are no longer a given. Life sciences and biotech businesses need to prepare now to avoid missing out on vital reliefs.

R&D tax relief has always been seen by the life sciences sector as a well-established and reliable tax incentive that fulfils its purpose by encouraging innovation. Spin-outs and start-ups in the sector have relied on the relief since its introduction in 2000, and it's a valued support to cash flow in the early years before commercialisation.

Why is this happening?

21 years on from the introduction of R&D tax relief, changes are afoot. HMRC and HM Treasury are increasingly concerned that the regimes are open to abuse and need refocusing.

In a recent discussion with senior HMRC members, the proposed change to the status quo was described as, 'one of the most fundamental policy shifts since the introduction of the regime'. Clearly, we are approaching a turning point.

While we support the underlying drivers for these changes – namely, to encourage businesses to 'buy British' and invest further in UK businesses, and end abuse of the system – we also have very real concerns about the consequences of restricting access to a tax relief that has been the lifeblood of early-stage businesses in the UK.

How can life sciences businesses prepare?

In this series of dedicated insights for the life sciences sector from our Innovation Relief specialists, we explain what is already known to be changing, what is intended to change in the next few years and, importantly, how this might affect your business.

PAYE cap for R&D claims – the impact for life sciences

How will the PAYE cap reintroduction for R&D claims impact cashflow for life sciences and biotech businesses? And will it be a significant funding limitation for life sciences SMEs and start-ups? Read more

Restricting R&D relief for expenditure incurred overseas – the impact for life sciences

How will HM Treasury's proposed restrictions for R&D relief for expenditure incurred overseas impact life sciences businesses? Read on to find out the impacts. Read more

Tackling R&D abuse – Will your claims still be compliant?

HMRC proposes several changes to the R&D claims submission process. Read on to find out how this will impact the life sciences sector.

How RSM can help

To discuss the impact of these changes in more detail, please contact our specialists:

James Tetley - Partner, Innovation reliefs

Lizzie Gosling - Director, Innovation reliefs

Laragh Jeanroy - Office Managing Partner Cambridge and Bury St Edmunds, Co-Head of Life Sciences

Graham Bond - Office Managing Partner, Chester and Liverpool, Co-Head of Life Sciences

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CONTACT

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The Early Life of a Bio-Innovation Centre

It is now 4 years since the Bio-Innovation Centre on the Cambridge Science Park opened. It has certainly been an interesting time: the Brexit deal; a global pandemic; changes in work patterns; a boom in biotech start-ups and scale-ups; easier access to funding; and a significant shortage of laboratory space for rent.

The Bio-Innovation Centre was envisioned as a building to incubate the next generation of biotech companies. It forms part of a landmark joint venture between Trinity College and TusPark that redeveloped the south-east corner of the Cambridge Science Park. The building is designed for multi-tenant occupancy by companies of different sizes, from the very earliest start-ups of perhaps just one or two people in a co-working laboratory through to those that are becoming more established and need their own space.

The building filled up rapidly and has been fully let for two and a half years. Interestingly, the last spaces filled during the Covid pandemic: the ability to stay open made the building an attractive home to companies. The number of people in the building continues to increase as companies fill their spaces. Whilst there are recruitment challenges, businesses in the building are finding it possible to get high quality staff in the numbers they need.

As an incubator building, it is expected that there will be turnover of companies: the ideal model might be for a company to start in the co-working lab; grow and move into their own lab unit; add another unit or two; and then move to larger premises as their development demands yet more space. The dilemma for companies at this stage is when to look for new space. Their outlook must be short-term focused, as raising the next round of funding depends on meeting key milestones.

Once funding is in place, the next set of targets can require significant recruitment to enable rapid progress to the next milestones. This is fine if there is plenty of laboratory space but the well publicised shortage in the Cambridge area presents real challenges. Without these companies moving, the expansion of those behind them is constrained; and behind them, those looking for their first bench space have nowhere to go.

Typically, the premises they require will not be built for them as there is insufficient time; that has to wait for a later date. However, customization is likely to be needed to fit their work; allow scale-up of processes; and potentially construct pilot facilities. To fit the development/funding cycle, even with good foresight from these companies, there will need to be more mid-sized flexible laboratory buildings. It is encouraging to see new developments proposed in this area. Hopefully, creative repurposing of buildings will tide companies through until this next wave comes to fruition.

For further details visit our website Tuspark UK or contact us

启迪英国
TUSPARK UK

Turning Therapeutic Innovation on its Head: Deep Science Ventures Drives Forward a New Model for Venture Creation

Deep Science Ventures

Whether it is curing cancer or addressing rare genetic disease, humanity's most complex therapeutic problems are reliant on ground-breaking scientific solutions. But while science has driven momentous improvements in many areas, in others it lags woefully behind: the more complex challenges - the ones that require networks or systems of new solutions - persist, and we lack the innovation infrastructure to take them on. Consider the areas of health and climate change: a third of us will still die of cancer despite $45bn in exits in 2021, while a quarter of the global population will be displaced in the next 50 years due to global warming.

At the root of these challenges is not necessarily a lack of scientific knowledge but a failure to combine that knowledge into coherent sets of viable, scalable and sustainable solutions. So, Deep Science Ventures (DSV) is pioneering an alternative approach to finding the most impactful solutions, capable of delivering ideas that are unlikely to emerge via the traditional routes of tech-push translation and ground-up R&D.

At DSV, we take a solution-pull approach to solving the world's largest problems, starting with the desired outcome for an area i.e., the ultimate change we need to drive, and the potential paths to get there. Together with the Founders-in-Residence that we recruit, we determine from first-principles, often through many iterations, the optimal technical solution to that state; one that is agnostic to the technology required to deliver it.

We do not do this alone - we collaborate with some of the world's leading institutions, corporates and charities. Partnership is crucial to the success of our endeavours, contributing both tangible benefits such as lab space and finance, but also deep technical expertise and engaged networks of researchers and patients. DSV counts Cancer Research Horizons, Cell and Gene Therapy Catapult, Cystic Fibrosis Foundation and AbbVie amongst it's valued venture-building partners in therapeutics.

Uniting diverse partners with DSV's unique ideation methodology has proven a fertile soil for the generation of a cohort of next-gen ventures – including 10 companies in the therapeutics arena and a total of 35 across DSV's areas of operation. Companies such as Antiverse, pioneering state-of-the-art machine learning to predict antibody sequences and provide drug candidates in weeks not months; Reflection Therapeutics, developing a new wave of Treg therapies addressing inflammatory disorders; and Neobe, designing unique live programmable bacteria for tackling the tumour matrix barriers that prevent efficacy of many other oncology therapies.

DSV is committed to using our outcomes-focused methodology to create transformative therapies in as many unsolved diseases as possible, and will next turn our sights to new areas including cardiovascular disease, neurodegeneration, female health and paediatric oncology.

We are always seeking forward-thinking impact driven partners to join us in our mission – if you are interested please email Laura Fletcher, Head of Business Development and Venture Portfolio at laura@deepscienceventures.com.

Visit our Website

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Delivering Value to Antibody Therapy Developers

Since the first monoclonal antibody (mAb) product was approved in the United States, mAb-based therapy has become the largest drug class, measured by the total sales of all biopharmaceutical products.[1] The growing prevalence of chronic diseases such as cancer and autoimmune disease is one of the major drivers of mAb market growth. Increasingly, emerging biotech and pharma companies are becoming key players in innovating new biologics, like mAbs, against chronic diseases.[2]

$450B+ Forecasted therapeutic mAb market size in 2028[3]

>50% Market owned by Human mAbs[4]

48% of the market is attributed to North America region[3]

Industry Challenges

Emerging biopharma companies usually work with lean teams, limited resources, and minimal infrastructure, which creates a unique set of challenges throughout the drug development process. Based on our conversations with emerging companies, the biggest challenges they face are slowdowns and ineffectiveness related to the completion of IND-enabling preclinical studies, regulatory submissions, and commercial scale-up.

How Thermo Fisher Scientific Can Help Overcome Challenges

More than ever, emerging mAb developers are seeking holistic support to quickly and efficiently develop and produce a wide variety of antibody-based therapies to meet the growing population's needs. Striving to enable and complement the customers' goals, Thermo Fisher Scientific is leveraging its comprehensive portfolio and services to help simplify and accelerate mAb development with our expertise, innovative technology, and proven solutions. Though speed is a key for serving emerging mAb developers, quality, reliability, and traceability are baked into many aspects of our offerings to help our customers mitigate risks.

- **Target discovery**: We help early-stage mAb developers get to key milestones faster and reduce failure through proven systems such as protein expression systems, proteomics, cryo-EM, and screening services, and award-winning technical support.
- **Pre-clinical development and production**: Our flexible approach based on world-class expertise and experience will help to successfully take a mAb program to IND. For example, Quick to Clinic™ is an integrated early development offering designed for biotech companies looking for a dependable solution to scale up recombinant antibodies from discovery to first-in-human trials. On the other hand, using our single-use technologies (SUT) for in-house production can reduce risk and increase operational efficiency.
- **Clinical Phase**: We guide customers on to the fast and efficient route to a successful BLA filing with our comprehensive suite of mAb services. Our offerings span CRO and CDMO services for clinical trials and supplies to global supply chain logistics including transportation management services.
- **Commercialization**: We enable our customers to rapidly grow, scale, and reach full global potential through our robust supply chain, manufacturing, and logistics network. Our global footprint in the supply chain can support the customers irrespective of their location. For scaling up commercial production, we have tech transfer and CDMO capabilities and fit-for-purpose SUT in various sizes.

1 https://bioprocessintl.com/business/economics/the-market-for-therapeutic-mab-products
2 https://www.iqvia.com/insights/the-iqvia-institute/reports/emerging-biopharmas-contribution-to-innovation
3 https://www.fortunebusinessinsights.com/monoclonal-antibody-therapy-market-102734
4 https://www.gminsights.com/industry-analysis/monoclonal-antibodies-market

Why emerging biopharma can benefit from working with Thermo Fisher?

78% of our clinical phase customers are emerging to mid-size

71% of total biologics approved by FDA in 2021 were supported by us

57 Number of mAbs developed in 2017-2021 that were supported by us

Thermo Fisher provides comprehensive solutions that support the development pipeline from antibody discovery to commercialization. For this article, we have focused on our capabilities in process development, production, and scale-up during the preclinical and clinical phases of therapeutic mAb development. The areas of our capabilities for each key step in the preclinical and clinical development phases are summarized in the tables below.

Pre-Clinical Production & Development

Development Phase	Sub-Phase	Key Step*	Service**	Product***	Platform Solutions****
Pre-Clinical Production and Development	Bioproduction and Process Development	Plasmid vector system design and development	•	•	•
		Vendor Qualification for Raw Material	•		•
		Cell line development	•	•	•
		Cell bank construction	•		•
		Cell culture development	•	•	•
		Reference standard material qualification	•		•
		Dose ranging studies	•		•
		Scale up to reach scalability for pre-toxicity and toxicity studies	•	•	•
		DS-DP Characterization	•		•
		Purification, formulation and stability studies	•	•	•
	Pre-Clinical Animal Experiments	Pharmacokinetic and pharmacodynamic analysis	•	•	
		Safety assessments	•		
		Antibody-drug conjugate (ADC) assays	•	•	
		Quantitation of biotherapeutics and biomarkers	•	•	
	IND Filing	Regulatory and Administrative Components	•		•
		Non-clinical components	•		•
		Clinical Components	•		•

Clinical Phase

Development Phase	Sub-Phase	Key Step	Service	Product	Platform Solutions
Clinical Phase*	Study Design, Site Selection and Study initiation	Protocol Development and Maintenance	•		
		Quality Risk Management	•		
		Study Country and Site Selection	•		
		Investigative Site Initiation, Monitoring and Closure	•		
	Clinical Manufacturing and Supply Chain	Obtain mAb related supplies and raw material	•		•
		Set Up mAb Distribution and Shipping Systems	•		•
		Pack, Label and Release Site Drug and Related Supplies	•		•
		On-going analytical characterization and method development	•		•
	Quality Management	Quality Management Systems	•		•
	Vendor Oversight and Management	Plan and Manage Study Execution	•		
		Study Vendor Oversight and Management	•		
		Clinical Trial Registry	•		
		TMF/ISF	•		

*Continues on following page

Clinical Phase
Continued

Development Phase	Sub-Phase	Key Step	Service	Tool/ Product	Platform Solutions
Clinical Phase	Clinical, Medical and Scientific Oversight	Protocol Management	•		
		Clinical Trial Safety Review	•		
		Oversight of Study Scientific Inquiry	•		
	Study Data Management Analysis and Reporting	Design, Develop, and Release Database	•		
		Statistical Analysis Plan	•		
		Interim and or Final Data Presentations / Analyses	•		
		Clinical Study Report (CSR)	•		
	Process Performance Qualification	Process Performance Analysis	•		
	BLA Submission and Approval	Biologics License Application (BLA) and Pre Approval Inspection (PAI)	•		

*Key Step: General workflow steps mAb developers take to accomplish an objective of each mAb drug development sub-phase

*Service: Our in-house experts and specialists support your team in the form of research and development services or other logistic management services outsourced on a contract basis

**Product: Instrument, reagents, or tools that fit your workflow

****Platform Solutions: Integrated drug development solutions optimized for a particular objective, such as speed, on a contract basis

QUALITY RELIABILITY TRACEABILITY

To meet regulatory requirements and ensure public safety, drug developers are under pressure to deliver quality goods while achieving efficiency. To balance these requirements, companies turn to automation, technology, and collaboration. One area that could greatly impact future-proofing in scale-up is supply chain management. As emerging mAb developers pursue aggressive timelines, striving for completeness when gathering process knowledge can be tempting to overlook. And shortcuts could result in costly problems when scaling. Therefore, it is essential to plan in advance to secure the appropriate supply chain and gain visibility on its quality, reliability, and traceability. Thermo Fisher empowers customers with multiple solutions for successful supply chain management and quality assurance.

- SureTRACE – a program that helps ensure traceability and quality when buying products from our Fisher Scientific eCommerce site
- Production Chemicals and Sourcing Services – a dedicated bioprocessing service for production chemical sourcing, supplier management, and second sourcing assistance
- MySupply Platform- a digital supply chain platform for clinical supply that helps provide visibility and collaboration across the full product lifecycle

Partnering with our customers is very much part of our mission. Not only does this better prepare the supply chain, but it also helps us stay a step ahead of our customers' needs and facilitate their processes – both now and in the future.

Contact Us
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BioTech, MedTech and Pharma Feature Regularly in Annual #21toWatch Programme

The annual **#21toWatch** programme delivered by Cofinitive heralds the next generation of entrepreneurs and innovators from across Cambridge and the East of England, and celebrates those who are building on the legacy of the famed Cambridge cluster by setting fresh standards in innovation and entrepreneurship across the globe.

The people, companies and innovations making the **#21toWatch** list cover all sectors - but commonly highlight the buoyancy of this region's life sciences, biotech and medtech sectors.

This year's Top21.2023 reads like a Who's Who of innovation and includes:

Ama Frimpong, who manages the **52 North Health** engineering team developing NeutroCheck, an innovative device to rapidly identify chemotherapy patients who are at risk of a life-threatening complication called neutropenic sepsis.

Neuroscientist Coco Newton, Co-Founder of Fathom Cognition, whose goal is to create new cognitive markers which can help detect Alzheimer's disease earlier, and certainly years before dementia onset.

Dr Hannah Sore, Founder and CEO of PharmEnable, a company combining AI and medicinal chemistry expertise to develop the next generation of complex 3D small molecule drugs.

Lucy Jung, CEO and Founder of Charco Neurotech, a medtech startup working on an innovative system for people with Parkinson's Disease to improve the quality of their lives.

Broken String Biosciences - a genomics tools company leveraging a state-of-the-art platform with a mission to bring gene editing therapies safely to all who need it.

Qkine – a UK manufacturer driving innovation in growth factor proteins, essential reagents used in transformative technologies such as stem-cell disease models, organoids, cell therapy, bioinks and cultivated meat.

Spirea – a biotech company spun out of the University of Cambridge and using its innovative technology to advance a new generation of antibody drug conjugates for the treatment of a range of solid tumours with significantly better efficacy and safety profiles.

SomaServe - a biotech company exploiting the proprietary technology, PolyNaut®, a polymer nanoparticle platform which is enabling intracellular, targeted delivery of next-gen genetic therapeutics, including siRNA and mRNA, to the brain and other hard-to-reach tissues and cell types.

Those mentioned above follow in the footsteps of so many more people and companies, who received a **#21toWatch** award at the start of their journey – **CMR Surgical, BIOS, Mursla, Cydar Medical, Exonate, Cambridge Cancer Genomics** (acquired)**, Reflection Therapeutics, Chronomics, Semarion, Cyted, Psyomics, Sano Genetics** and **DIOSynVax**, to name just a few.

If you haven't submitted to **#21toWatch** before, maybe it's time you did? You can find out more information about **#21toWatch 2024** at cofinitive.com/21toWatch.

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Centralised European Patent Protection and Enforcement is Coming at Last

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Intellectual property law

After years of uncertainty, both the Unitary Patent (UP) and the Unified Patent Court (UPC) will be live from 1 June 2023. These new systems will centralise patent protection and enforcement within many EU countries. Moreover, the new systems will impact all existing granted EP patents and pending EP applications, such that patent proprietors need to make strategic decisions now.

The Unitary Patent

Currently patents granted by the European Patent Office (EPO) must be validated in all of the countries in which the patent proprietor wants to obtain patents. The validation procedure yields individual patents in the countries of interest, which must then be enforced and/or invalidated individually at the national courts.

The UP will provide an option to have a single patent covering multiple EU member states (presently 17 but likely to be more in the future) as an alternative to the current validation route (which will continue).

Some Key Features of the UP are:

- provides protection in Austria, Belgium, Bulgaria, Denmark, Estonia, Finland, France, Germany, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Portugal, Slovenia, and Sweden (at present)
- requires payment of a single renewal fee
- must meet new translation requirements
- falls under the jurisdiction of the UPC
- requires limitation, transfer, revocation or lapse in all UP member states

Is a UP an Option?

To file a request for a UP, the EP patent must:

- have the same claims for each UP member state; and
- have and retain designations for all UP member states (no designations withdrawn)

Requirements and Timing of UP Request

A request for a UP must be filed within one month of the date of grant of an EP patent. There is no associated official fee. For currently pending EP patent applications it is possible to delay grant to keep the option of a UP open and it is now possible to file an early request for a UP at the EPO.
During a transition period, the patent proprietor will be required to file appropriate translations. For example, if the patent is in English, a translation into any other EU language will be required.

Jurisdiction of the UPC

The UPC is a new centralised court through which:

- a patent proprietor can enforce their European patent against an infringer and
- a third party can seek central revocation of a European patent

Decisions by the UPC will be effective in all UPC member states. Infringement and revocation decisions for non-UPC countries (such as the UK, Spain, Norway and Switzerland) will continue to be made by the national courts. The UPC brings unknown opportunities and risks and there will thus be a transitional period of at least seven years to provide better certainty for users.

Transitional Period

During this period, the national courts of UPC member states will also have jurisdiction over EP patents which are effective in these countries. A patent proprietor can thus choose between centralised patent enforcement before the UPC or enforcement in individual national courts. Similarly, a third party can choose whether to revoke a patent before the UPC or a national court.

During transition, a patent proprietor can request an opt out to remove their EP patents from the jurisdiction of the UPC. The patent proprietor can withdraw this request at a later stage, for example if they wish to initiate a pan-European infringement action. The period for requesting an opt out began on 1 March 2023 and so decisions are needed now.

Ownership may need to be verified before filing an opt out request because the true owner(s) must file the request. There are various factors to consider when deciding whether to request a UP and whether to opt out existing EP patents from the jurisdiction of the UPC. Different decisions may be appropriate for different patents in a portfolio.

For more information on the UP and the UPC, contact Kate Hickinson, Partner, Appleyard Lees


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Harnessing the Enterprise Value of Research Excellence

In life science clusters where there is a long-established entrepreneurial community, it can easily be forgotten that these cultures are not ingrained everywhere that excellence in scientific research exists, often at scale. This may be a timing matter, when different sub-sectors of the life science space have been in vogue with investors and markets. Perhaps there has been an absence of success stories around spin-out company formation. Equally, there may not have been a simultaneous presence of all parties to make it happen. Norwich Research Park is a great example of how their focus areas, appetite for enterprise and a growing support strategy are all aligning.

There are over 100 science parks in the UK and only five are BBSRC Research and Innovation Campuses, Norwich Research Park is one of those five parks. BBSRC funds eight separate research institutes in the UK and Norwich Research Park is the only campus with more than one of these BBSRC funded research institutes. In fact, it is home to three specialist facilities:

- the John Innes Centre
- the Earlham Institute
- and the Quadram Institute

As well as this, the research campus is also home to:

- The Sainsbury Laboratory, which is funded by the Gatsby Charitable foundation
- a top 20 university: the University of East Anglia (UEA)
- and the Norfolk and Norwich University Hospital (NNUH)

Joining the research community and benefiting from the proximity of skills, expertise and technology platforms are 40 businesses currently leasing just over 100,000 sq. ft of office and laboratory accommodation, managed by Anglia Innovation Partnership (AIP), the science park management company based on campus. There are many examples of powerful collaborations between the institutes, university, hospital and companies both on and off the park.

Anglia Innovation Partnership launched the park's enterprise strategy in May 2022. The strategy was launched to ensure new innovative businesses are created from the excellent research at the 6 park partners listed above.

Since the launch there have been 12 explorer engagements, including 138 participants, that have connected academics and businesses with other businesses in areas such as additive manufacturing, clinical research, plant science and agri-tech. On top of this AIP have recently held two enterprise focused events on the park attended by a total of over 250 delegates.

Following promotion of the BBSRC ICURe programme, 13 early-stage companies from the park secured places and of those, eight companies went on to secure Pre-Seed Enterprise Funding.

AIP was also able to award small grants of up to £30,000 to fourteen early-stage companies and innovation projects as part of the Norwich Research Park Pre-Seed Enterprise Fund. The fund was set up to facilitate the early progression of business ideas. The total sum given in grants so far by AIP is over £270,000.

Visit our website

Word on the Street at the J.P. Morgan Healthcare Conference 2023

TaylorWessing **Our international team recently attended the J.P. Morgan Healthcare Conference (JPM) 2023 and share some of the scuttlebutt below.**

M&A

The expected boom in biotech acquisitions by pharma companies continues to stutter. Three mid-market deals were announced going into JPM (AZ/CinCor (up to $1.8 billion); Ipsen/Albireo (up to $952 million); and Chiesi/Amryt (up to $1.4bn)), but no banner deals. The message from pharma BD teams is that we are now in a buyers' market but many biotech C-suite and investors have still not adjusted to the new market reality.

IPOs

Macro factors are weighing heavily on the market. Recovery is dependent on a reduction in interest rates. High interest rates depress current valuations in biotech and prompt a move to less risky asset classes. The Federal Reserve is forecasting lower inflation and rate cuts towards end of 2023, so there is cautious optimism for a recovery in market conditions for public biotech in 2024.

Private Financings

VCs still have plenty of dry powder which they need to invest ($50bn raised for VC life sciences investment across 2021 and 2022). Seed stage and series A financings are largely unaffected. For later stage pre-clinical and clinical stage biotech, companies with recent readouts of strong data which de-risk their programmes are still finding it possible to raise capital. For others, it's a question of survival until sentiment improves.

Cost control and creative approaches to financings, including royalty financing and revenue financing, are back on the agenda.

Government Policy Changes

There was universal exasperation amongst the British contingent at JPM about the UK Government's changes to the R&D tax credit scheme. The announcement from the UK Chancellor of the Exchequer in the week before JPM of a possible change of heart, following a vigorous lobbying effort by the BioIndustry Association, was widely welcomed (and now confirmed in the Budget). Interestingly, the US Inflation Reduction Act is perceived to be impacting adversely on biotech valuations, and not just for late-stage assets.

Hot Indications

Oncology is being given a run for its money this year by CNS/neurodegeneration. Eisei secured its long-anticipated FDA approval for Leqembi™/lecanemab on the day before JPM started. Together with positive developments for Amylyx's ALS drug Relyvrio™, Biogen/Ionis's antisense therapy Tofersen™ also in ALS and Eli Lilly's donanemab in Alzheimer's disease, there is a sense of momentum building.

Recent developments in anti-obesity - in particular Novo's Wegovy™/semaglutide (a GLP-1 receptor agonist) and Eli Lilly's tirzepatide (a dual GIP/GLP-1 receptor co-agonist) - are also attracting attention. As for early-stage drug discovery efforts, anti-ageing is attracting significant investment and research effort.

Hot modalities

After a spate of approvals in 2022 (including Zynteglo™ (beta-thalassemia), Skysona™ (early cerebral adrenoleukodystrophy) and Hemgenix™ (Haemophilia B)), gene therapy is attracting a lot of attention. Gene therapy patent litigation is booming, as commercial products come to market. 2023 also should bring more data about the likely commercial potential of this modality. Gene editing was also attracted attention at JPM 2023, though concerns about off-target effects remain. Cancer vaccines in combination with immune checkpoint inhibitors are also in the spotlight.

In summary, we're facing a difficult financing environment, but with some grounds for cautious optimism for the healthcare sector as a whole, particularly as we move into Q3 and Q4.

By Adrian Toutoungi, Partner, Taylor Wessing

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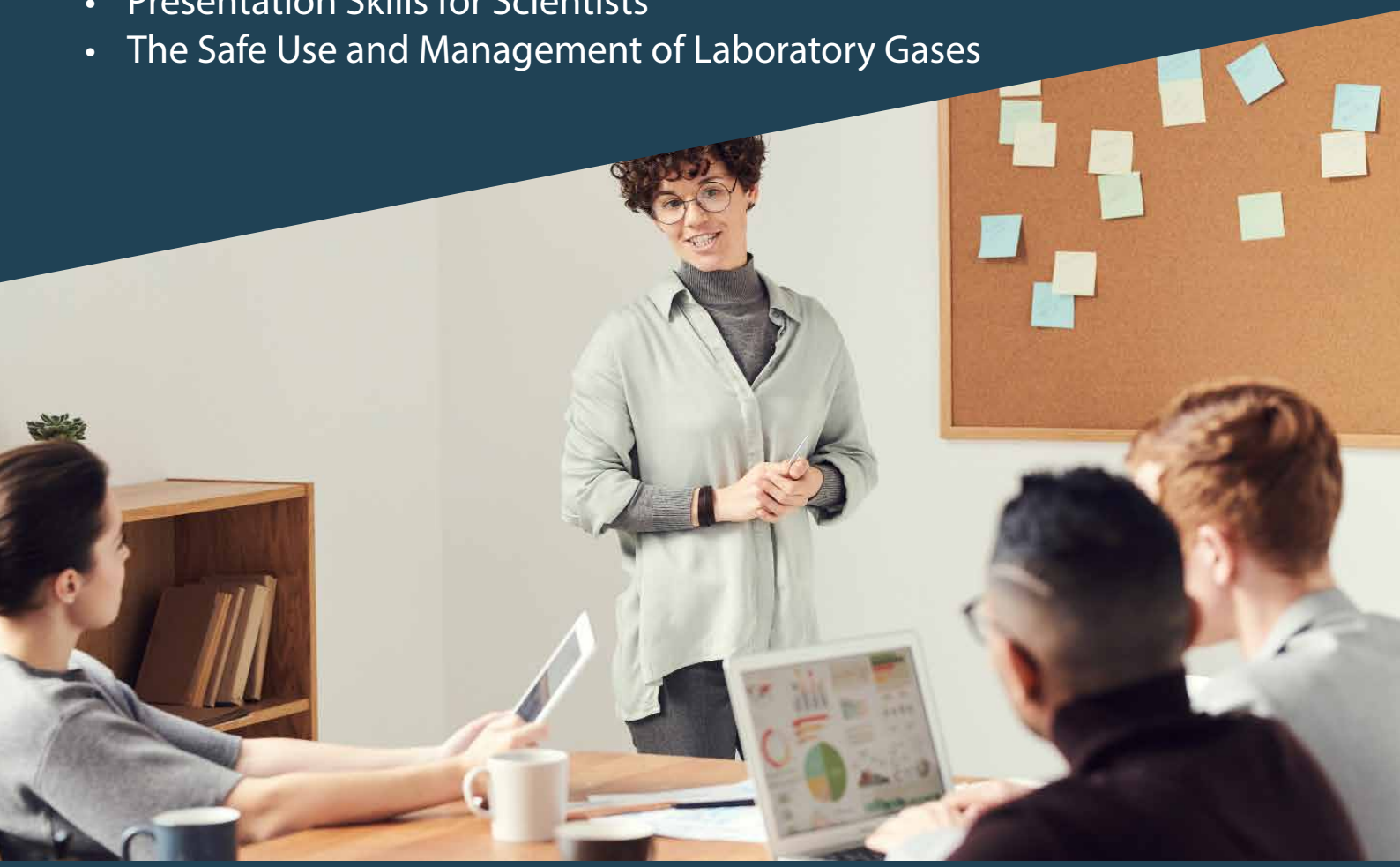

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