

The NEW normal COVID-19 IVDs in the spotlight  
**Equality and diversity** 97% of IVD companies are members UKCA IVDR  
Voice of the industry **IVDR** Membership increasing **New members**  
**Sustainability** COVID-19 Procurement Report **Networking**  
Access to markets for all members **Diagnostics**  
Maximising NHS resources **APPG for Life Sciences**  
Helping health outcomes Maximising NHS resources **Best Trade Association**  
Amplifying your voice **BIVDA Salary Survey** **Weekly SMEs** Amplifying your voice  
Free meeting rooms **AMR** **30** years old **Members updates** **Newsletter** Procurement  
**IVD Regulation** **Best Trade Association** **Stem 4 Britain** **Regulation** **SMEs** **Procurement** **Domestic Assurance Paper** **What's in a colour?**  
**Regulation** **SMEs** **Procurement** **Sustainability** **Regulatory Affairs Seminar**  
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**Weekly Newsletter** **Point of Care testing** **AMR** **report**  
**BIVDA Salary Survey** **IVDR** **Springboard programme** **Promote values and effectiveness of IVDs** **AMR**  
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**What's in a colour?** 30th year celebration **Team members** **Membership increasing**  
**Regulatory Affairs Seminar** **New Board members** **Team members** **What's in a colour?** **COVID-19**  
**New members** **Stem 4 Britain** **UKCA** **a colour?** **Prevention** **UKCA**  
**Sustainability Seminar** **Diagnostics** **Prevention** **UKCA** **Working party updates**  
**IVD Regulation** **Helping young businesses** **APPG for Life Sciences** **AMR** **The go-to association**  
**Free meeting rooms** **Infection Management Coalition** **Prevention** **SMEs** **30** years old **Working party updates**  
**Domestic Assurance Paper** **UKCA** **Life Sciences** **BIVDA Salary Survey** **Best Trade Association**  
**Working party updates** **The Sustainability Award** **AMR** **Weekly** **UKCA** **Springboard programme**  
**Access to markets for all members** **SMEs** **Newsletter** **Best Trade Association**

## Welcome from Chief Operating Officer, Helen Dent

Looking back to the last issue of **vivid**, we were anticipating living in “the new normal” as the UK emerged from the pandemic. I’m not sure I can really remember what “the old normal” was, so I suppose this is what is to be commonly known as we are where we are!

When I joined BIVDA in June 2020, the UK diagnostics industry was moving quickly to respond to the testing strategies proposed by the government to meet the COVID-19 needs, whilst also maintaining the provision of tests for wider services - this was an extremely challenging time for us all in the sector.

The pandemic brought IVDs into the spotlight and the centre of the government policy agenda and increased the public awareness that diagnostic tests could be available to be able to test, diagnose and potentially guide treatment for a disease or condition themselves. The pandemic has provided a chance to consider more closely the potential applications across a wider range of health conditions from acute care conditions like respiratory health, urinary tract infections to longer term monitoring in conditions like diabetes monitoring and heart failure. There is quite rightly a focus on Point of Care testing, in order for us to ensure engagement in this policy area, but BIVDA is committed to ensuring that our members receive the best possible support for their own strategic objectives and UK operations across the entire IVD space. Members can rely on us to promote and support the whole industry and to create an environment that helps our members to develop and improve products to shape the future of diagnostics.

Over the past 3 years, the core of the BIVDA strategy was to be the go-to association for external stakeholders, to strengthen our position as THE voice of the industry and be bolder and louder with our interactions across the sector.

BIVDA has longevity and in-depth expertise and is specific to IVDs. We are not a general buzzword organisation or a shallow pond; therefore stakeholders come to us in order to access our membership and organisational expertise. We won't cut and run when it comes to the detail.

We are proud of our long history and proven track record in supporting members. Last October we celebrated our 30th anniversary. However, through a difficult time for the industry in terms of the cost-of-living crisis and inflation over the past 3 years, we have recognised that members consistently seek better value for money, more activity and ever stronger representation. I'm pleased to be able to say that we have seen a notable change in our position and look forward to the next steps to be more commercial, more visible and for BIVDA's relevance and influence to continue to grow.

Our membership base has increased by 35% and that we really are the most representative trade association for IVD companies, with an estimated 97% of companies as part of our membership.



The depth of our membership is a strong factor in the influence we have as a sector with policy and decision makers.

Unfortunately for some, the times were too difficult and the issues around cost to serve, adoption of technology, regulation and inflation were too much to bear and there have been a few of our young businesses who haven't made it. We hope that we can work on behalf of this membership group to increase their chances of success, and as such, we launched our invitation-only Springboard programme for young businesses and start-ups to give them tailored and specific support for these early years.

Working with the Executive Board to ensure that we continue to grow and increase our influence and your voice, we have undertaken several exciting projects to make sure that we stay top of our game. During the autumn, you will be asked to give your views and perception and we will use your feedback to develop our next strategy.

We have already refined our organisational purpose and priorities to better reflect our positioning, and these are:

- To promote the value and effectiveness of IVDs in clinical pathway optimisation to improve health outcomes and maximise NHS resources.
- To ensure fair and equitable access to markets for all member companies through policy and process influence.
- To provide members with the necessary information, tools and guidelines for IVD Regulation, Equality, Diversity, and Social Value.

I'm delighted to say that the initial success of this is reflected by us being shortlisted for two awards for membership organisations: The Sustainability Award and the Best Trade Association!

Our team grew with the addition of Ashleigh as Head of Regulatory Affairs, Tehelj joined us as Regulatory Support Officer and Dawn came into post as our Office Manager, making sure everything runs smoothly for us and members. Natalie continues to manage all our operations and membership activity and Ben provides our policy and external affairs support. We also have Sarah-Joy Newton and Stuart Angell as our Sustainability and Regulatory Programme Managers, which demonstrates our commitment to resource key policy areas.

I'm very much looking forward to the next set of activities for BIVDA and making sure that we capture and take full advantage of the investment, policy and advocacy for Diagnostics and IVDs.

Please feel free to contact any of us as you need to, we are here to make sure you have all the support you need.

# Hear from BIVDA Chair, *Helen Tucker*



There have been some key changes from the centre this year, which we looked at our AGM in March. This includes the creation of the Department for Science, Innovation and Technology, several MHRA updates concerning the new regulatory framework and the adoption of the recommendations for digital technologies from Sir Patrick Vallance, new procurement regulations are expected and the announcements for Life Sciences investments are exciting. There are many opportunities for IVDs and BIVDA is ideally placed to ensure that the industry and our members are at the forefront of improving access to technology for patients and clinicians and to support the policy objectives of the UK across HealthTech and the wider UK PLC agenda.

BIVDA's focus for 2023 moving into 2024 centres on maintaining alignment with government strategy and membership requirements and the secretariat are undertaking various projects to ensure this can be delivered. There will be a stakeholder survey for members and external stakeholders which will be completed by the end of the year.

Increasing BIVDA's voice and influence will also be critical to ensure that the obvious increase in visibility of diagnostics and testing is taken advantage of to deliver BIVDA's and members' objectives so we can continue to raise the profile of IVDs across the sector within the Diagnostic Industry Advisory Group (DIAG), Health Technology Partnership (HTP) and the OLS and with our partners at the MHRA and across the NHS.

Working parties will actively be generating more thought leadership and evidence papers as part of their agendas. We published the Genomics and Covid Test Procurement white papers which you can read about within this issue of **vivid**.

Our secretariat is obviously passionate about IVDs and is dedicated to members. There is a wide range of skills and talents which members can utilise. BIVDA is currently resourcing key policy areas which shows BIVDA's commitment to support the membership's policy priorities. Their expertise in regulation, procurement, sustainability and equality and diversity is industry leading.

BIVDA has seen rapid growth in membership numbers and Twitter and LinkedIn followers are increasing every month. BIVDA is truly representative of the sector.

Looking ahead, the team will apply an agile task based resourcing policy which is an efficient use of funds for specific expertise. This will ensure that we can support members through the changing regulatory and procurement landscape and increase government engagement following this year's announcements. There is strong Executive Board participation and accountability and each of them are all fantastic and working on your priorities to keep IVDs front and centre.

As Chair, I offer my thanks to you, our members, for your continued support of BIVDA, to the great BIVDA board, who are a brilliant bunch of people giving something back and bring a broad bank of expert knowledge, and to the secretariat for the great work they do on behalf of you, our members.

I look forward to participating in the continued work at BIVDA!

## A message from BIVDA's Operations Manager, *Natalie Creaney*



I'd like to remind members about a few things related to the daily operations of BIVDA and the membership, but first as this is my first article for **VIVID**, I would like to take the opportunity to thank you for the communications and engagement that I have with you all. If you need anything at all relating to your membership, you can contact me at [natalie@bivda.org.uk](mailto:natalie@bivda.org.uk) or [dawn@bivda.org.uk](mailto:dawn@bivda.org.uk) or anything related to the facilities or meetings.

We have almost reached the levels of attendance at working parties that we enjoyed before the pandemic. We decided to continue with a mix of in person and on-line meetings for working parties, as hybrid is a headache for everyone involved. We are finding that Chairs of the working parties and attendees are moving slowly but surely to in-person meetings over on-line. We tend to give information and training on-line, and welcome speakers and hold discussions in person. We have introduced a new registration system in the office in place of the old visitor book where you electronically sign in and get a printed badge – it's very hi-tech. Registration is via our Eventbrite page.

We still have challenges with non-attendance when places are booked, we use our meeting room for expected numbers under 40 and external meeting venues which we pay when numbers exceed this. When people don't attend, it wastes valuable funds, so we would appreciate members keeping us up to date and letting us know if you can no longer attend. We also cater for every meeting, and we want to reduce the amount of food waste generated by non-attendance.

It is critically important that you make sure that your company contacts are up to date, all our correspondence is electronic and if we cannot get information to you, then you will not receive important business information from us. We send working party specific information to members who are registered to the working party lists and this includes booking details, agendas, surveys and invitations to working party meetings and stakeholder meetings. Please make sure BIVDA is whitelisted as we find a lot of our correspondence is bounced, even though our Outlook emails reach the intended individual.

You also will be restricted in taking full advantage of the benefits that your membership provides.

We encourage all our members to make the most of the benefits we offer, including access to our facilities, publications, good practice guidance, training resources and exclusive member-only publications including:

- A free subscription to **VIVID**
- Dialogue
- Members only weekly Newsletter. You can access this at [www.bivdanewsletter.com](http://www.bivdanewsletter.com) and this contains all our activity, events, news and training

- 3 x per annum members update which details the activities and progress that has been made in that 4-month period
- Market Audit, which is free to participate in, please contact [enquiries@bivda.org.uk](mailto:enquiries@bivda.org.uk) to join
- BIVDA Salary Survey
- Free Working party meetings and networking events throughout the year
- Daily/Weekly/Monthly topical updates

Members can maintain their continuing professional development through Sustainability training, diversity and inclusion training and certificate, and the BIVDA Code of Conduct certificate. 2 x Free Sustainability Seminars, 2 x Regulatory Affairs Seminars (1 and 2 day), 12 months free licenced access to Life Sciences Academy (LSAA) for BIVDA members, and 2 free LSAA event links exclusively for members per month, as well as several ad-hoc events that are arranged throughout each year.

We have two meeting rooms available to book **FREE OF CHARGE** in central London at 299 Oxford Street, with complimentary WiFi and hot and cold soft drinks and the latest AV equipment. Members often don't realise this is available!

We have a new BIVDA APP coming soon which will also include much of the information you need to participate as a BIVDA member. We had the first version of this at our working party seminar and regulatory affairs seminar last year at our 30th Anniversary event in October. Please look out for the launch soon! It's very exciting with lots of functionality added!

We also are updating and refreshing our website, we know it's not that user friendly and whilst it contains everything you need (and probably more) if you can't find it, it's not helpful. We anticipate this will be refreshed by the end of the year too.

A final note from Operations, is that renewals will be issued in early December. We need to ensure that these are sent to the correct person at your company. They are also electronic and suffer the same challenges as the general correspondence. Membership will auto-renew if the forms are not completed by the end of January and the membership cost will be at the banding above the previous year and 6 months written notice has not been provided as per the BIVDA Terms and Conditions. We are also looking to be more flexible with payment options with monthly and annual direct debit options, but we are not there yet!

## Scott McKenzie *on the importance of near patient diagnostics*



*It's a pleasure for us to invite Scott McKenzie to provide an article for this issue of **vivid** as we look to move into 2024, insights from people like Scott will be paramount to BIVDA leading the promotion of IVDs and our member interests across the Sector.*

I'm delighted to be asked to write for **vivid** and to be working with the team at BIVDA as the work they do and members that they represent are, in my view, critical in helping the NHS to work through its challenges and help patients have a better healthcare experience. I strongly advocate that key system stakeholders maintain dialogue and engagement with them so they can collaboratively achieve their aims.

### Why near patient diagnostics are so important – especially now

The issue of people stuck in hospital queues, creating long backlogs is a well-beaten path that I've written about often<sup>1</sup>. At the moment, my own work with the NHS tells me this problem is worse than it has ever been.

We know that these people don't just sit at home and wait. They don't feel well so they're back to their GP – often numerous times – taking up unnecessary appointments because they've already been referred for tests. But the problem is, they're waiting months for them.

With waiting lists growing every day, is there anything that can be done to improve the situation? Or is it just going to keep getting worse until the health system as we know it collapses?

### BIVDA's work could be a lifesaver for the NHS

With these questions ringing in our ears, there's perhaps never been a better time to talk about near-patient diagnostic tests.

When diagnostics are mentioned to me, BIVDA's work is at the forefront of my mind. I'm doing a lot of work around the use of blood tests and tissue samples to diagnose conditions at the moment, particularly around allergies.

Historically, I've done a lot of work with near patient testing for things like HbA1c<sup>2</sup> in diabetics and cholesterol – they were part of the NHS Health Check.<sup>3</sup>

And I can remember all the way back to 2010 in Greater Manchester where they looked to put in near patient testing equipment so practices could actually do the tests there and then. Near patient tests mean potentially rapid access to diagnosis and treatment.

### Fancy a blood test while you're out shopping?

Rolling forward to 2020, Professor Sir Mike Richards<sup>4</sup> was commissioned to undertake a review of diagnostic capacity and that came off the back of the NHS Long Term Plan.

He produced the independent report Diagnostics: Recovery and Renewal<sup>5</sup> which included recommendations for the need to have a new diagnostic model. It lobbied for a greater number of diagnostic facilities away from hospitals in, for example, shops.

That was all about providing quicker and easier access to a range of tests where results were available on the same day. A near patient test done in general practice could be a great fit because early access to a correct diagnosis leads to early access to treatment.

That gives the patient a better outcome so they need fewer appointments and fewer referrals to hospital. It would cut the numbers of strokes, heart attacks and exacerbations of long-term conditions, keeping people out of A&E and, more importantly, cutting numbers of admitted inpatients.

### Subcontracting is a great way to trim the backlog

So there is a lot in favour of both in vitro and standard diagnostics – ambulatory blood pressure monitoring, Holter ECGs, event monitors, scans – all of these can be done in primary care outside the hospital.



## Scott McKenzie *on the importance of near patient diagnostics* continued...

For hospitals with big backlogs, now might be a good time to subcontract some of that work away. In my work, I've got places up and down England where primary care – through the networks or GP federations – hold subcontracts from the hospital to deliver near patient tests and diagnostics.

It works well because there's no need for additional capacity – those unnecessary GP appointments can be used for near patient tests and getting that early diagnosis.

It's also worth mentioning that on August 4 the Government announced it will expand the use of the private sector to try and tackle NHS backlogs.<sup>6</sup> That's all part of this, unlocking spare capacity to get more people a diagnosis, however it can be done.

### A quick route to the right treatment is the only goal

To sum up, I'd reiterate that there has never been a better time to look at the whole range of in vitro and standard diagnostic tests, with wearable technology and equipment being deployed into primary care and away from the hospital so we avoid the backlog.

Let's get the patient rapid access to an early, correct diagnosis and then rapid access to early and correct treatment, avoiding the need for GP and hospital appointments, referrals, and admissions.

*Scott McKenzie<sup>7</sup> helps GPs, PCNs and GP federations build sustainable and resilient practices and organisations that thrive. If you want to know how to double your revenue and reduce the overwhelm, Scott can share these processes with you too. Contact Scott McKenzie Consultancy<sup>8</sup> today.*

<sup>1</sup> <https://scottmckenzieconsultancy.com/latest-news-and-blogs/>

<sup>2</sup> [https://www.diabetes.org.uk/guide-to-diabetes/managing-your-diabetes/hba1c#:~:text=The%20hemoglobin%20A1c%20\(HbA1c\)%20test,your%20diabetes%20is%20being%20controlled.](https://www.diabetes.org.uk/guide-to-diabetes/managing-your-diabetes/hba1c#:~:text=The%20hemoglobin%20A1c%20(HbA1c)%20test,your%20diabetes%20is%20being%20controlled.)

<sup>3</sup> <https://www.nhs.uk/conditions/nhs-health-check/>

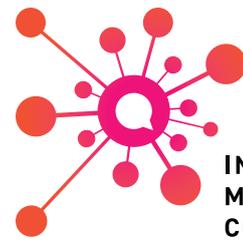
<sup>4</sup> [https://en.wikipedia.org/wiki/Michael\\_Adrian\\_Richards](https://en.wikipedia.org/wiki/Michael_Adrian_Richards)

<sup>5</sup> <https://www.england.nhs.uk/publication/diagnostics-recovery-and-renewal-report-of-the-independent-review-of-diagnostic-services-for-nhs-england/>

<sup>6</sup> <https://www.bbc.co.uk/news/health-66319064>

<sup>7</sup> <https://uk.linkedin.com/in/scott-mckenzie-83a6986>

<sup>8</sup> <https://scottmckenzieconsultancy.activehosted.com/f/11>



**INFECTION  
MANAGEMENT  
COALITION**

BIVDA is a member of the Infection Management Coalition and have been heavily involved in their activities over the last year in order to advance their stated aim: to drive change in support of infection management and pandemic preparedness in response to the COVID-19 pandemic.

Firstly, we are pleased to share that our work with the rest of the membership of the IMC has been 'highly commended' by the Communiqué Awards 2023 in the award category: "Excellence in Communications – Payers/Polymakers".

Special recognition was reserved for the IMC's push for a more holistic approach to infection management. The judges stated that "the Infection Management Coalition really had a good handle on the situation. It had remarkable feedback from top figures and coverage was impressive. The entry was ambitious and pragmatic and achieved a huge amount for the budget. To get that level of endorsement in a crisis, they were clearly doing something right."

Earlier this year, the IMC launched a White Paper which called for the creation of a healthcare system which is resilient and mature regarding: outbreak and pandemic preparedness; infection prevention; rapid treatment of time-critical viral and bacterial infection; to deliver effective antimicrobial stewardship (AMS).

BIVDA attended Parliament with the group to launch the White Paper, promoting its recommendations to the assembled MPs and peers, including now-Chancellor Jeremy Hunt. Doris-Ann and Ben led one of four stands which emphasised the importance of diagnostics in the fight against future pandemics and the growing battle against antimicrobial resistance. The extensive application of targeted diagnostics throughout the pandemic was held up as a reliable template for future pandemics and the responsible use of antibiotics going forward.

A meeting was held recently to reflect on the IMC's key milestones and their progress to date and, importantly, to agree on the strategic imperatives for the next steps.

Discussions included whether to broaden the reach globally as the previous focus was UK and England specifically. There were many considerations to contemplate including other governmental priorities and local pressures, and while engagement and lobbying fits well internationally, country level implementation needs tangible actions and examples of best practice.

With an election looming next year, it was agreed that practical solutions are needed. Issues common to the HealthTech sector were raised, such as the failure of systems to integrate infection management into pathways and difficulty in disseminating best practice. Lack of data and variation across ICBs was also identified as a challenge.

Whilst AMR is a huge priority, it is still important to ensure that it doesn't affect the wider remit of infection management overall. Finally, financial savings – versus societal benefits, quality of life and health disparity – were covered, posing the question of what the policy asks should be.

If any member would like to find out more about the Infection Management Coalition or the work it undertakes, please contact Helen.

# What's in a colour?

Cleve Wright is a director of HORIBA UK Limited, a leading manufacturer in the fields of energy and environment, materials, and semiconductor, as well as bio and healthcare. He comes from an engineering background and has a great deal of experience in healthcare diagnostics.

Cleve has been working in the IVD space for many years and most of us know him and have worked with him throughout our careers, his point of view and experiences in relation to equity and inclusion are introduced in this article and we look forward to developing our work with Cleve's help.

*What do you see when you look around your organisation?  
When you look around your team?*

My increasing observation is that I don't see many people that look like me in senior positions within an industry that I have devoted over 40 years of my life to. This observation is not restricted purely to our industry; however, this is the industry that I work in and love.

*This is not a new situation neither is it a new observation. What is new is my desire to bring this observation to the fore and to initiate a debate. If not me, who? If not now, when?*

Born in Nottingham in 1958, during the 60s I went from pre-school through to Junior school, in a predominately Windrush-generation Black and Asian inner-city neighbourhood. People from all over the commonwealth had willingly answered the call to come and help rebuild the motherland. I often overheard snippets of the day-to-day hostilities my parents had to endure and navigate through simply to survive. I also recall from that time, the fear generated by teddy boys back then. That all said, as a child growing up, I felt safe and comfortably black.

Passing my 11-plus, I found myself transported into an alien "old skool" Grammar school, far removed from the relative comfort of my neighbourhood and into an environment where less than 2% of fellow pupils looked like me. For the first time in my life, I felt uncomfortably black.

From that time, I began a compartmentalised existence. Despite encountering almost daily racism from some pupils, and constant name calling whenever I encountered one particular teacher, I became an "honorary white" some may say, version of me at school, and a regular black teenager version of me outside of school or with local friends and family. School and neighbourhood friends were separate entities.



After navigating and surviving school life I left my hometown black and white friends behind and ventured further afield to Hatfield Polytechnic. This was against the backdrop of the rise of a more organised National Front, and their skinhead followers, and the racial and social unrest of the 70s and 80s. What was increasingly obvious was that a significant section of society reacted negatively to me and people of colour, not on our abilities, our demeanour, our education or based on anything we did wrong or could do anything about. Negative judgements were made purely on seeing someone with melanated skin.

I have never once wished that I were born a different colour, but I have often pondered on what is it about the colour of my skin that generates fear, hatred or both.

Many organisations have implemented policies and produced statements, based around EDI, without any understanding of the day-to-day experiences of their black or Asian employees. Without meaningful, open, and honest debate, a policy can suggest that all is well within an organisation and thereby nullify any ongoing discussion.

*From ongoing discussions there is a clear appetite within BIVDA to be more directly involved in leading the fight within our industry however BIVDA can only act on what the membership mandates it to act on or what the membership will actively engage with. Is there an appetite for this within the membership I wonder?*

I don't come with the answers, that is not my objective here, but I do know that to change things we absolutely need white allies. Allies willing to stand up and fight the ongoing injustices, to speak up whenever and wherever they encounter racist attitudes, behaviours, and any form of discrimination. We need white allies to challenge the very status quo, which through "privilege," remains to their advantage.

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*If you change the way you look at things  
the things you look at change!*

Wayne Dyer

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# BIVDA reports 2023

It has been an incredibly productive six months for the team and our members with the release of two new White Papers: a genomics report and a report examining the UK Government's procurement of COVID-19 tests. Thank you to everyone who contributed, and we look forward to working together with all working parties to produce more impactful reports in future.

## Genomics White Paper

The genomics whitepaper titled, 'Leveraging advanced diagnostics to realise the UK's potential in genomics: A new whitepaper', examined the UK genomics landscape, with a focus on patient access to genomic testing.

The independent report, undertaken by Charles River Associates under commission for BIVDA, identified a series of reasons for limited access to genomic testing for UK patients, while also recognising opportunities to improve the current situation.

Regulatory issues, a lack of centralised guidance on the applicability of different funding pathways and underdeveloped infrastructure to increase testing capacity are all persistent issues which currently hamper the UK genomics climate.

Establishing critical partnerships across both the public and private sector, alongside the enactment of policy change, can begin to erode these barriers and improve the adoption of, and access to, genomic testing for UK patients.



## COVID-19 Procurement White Paper

BIVDA commissioned the University of Nottingham to produce this White Paper examining the UK Government's procurement of Covid-19 tests during the pandemic to ensure an independent account of the Government's strategy was captured for future learnings.

This Paper is a comprehensive examination of their strategy and has discovered several compelling findings. The research revealed a high number of direct awards to select companies, limiting market access of established suppliers who have provided diagnostics to the NHS over many years, leading to questions concerning transparency and best use of taxpayer money.

The Paper, produced by Dr Luke Butler, Associate Professor in Law at the University of Nottingham, investigated how test kit contracts were awarded, technically validated for use, and approved for placement on the market as part of the Government's Test and Trace strategy.

There are several lessons and recommendations which emerge from the Paper, which we hope will improve pandemic preparedness, ensure closer engagement with UK diagnostics operators in future and highlight to government the effect their procurement decisions have on industry.

Direct awards and higher regulatory burden for the sector is something BIVDA strongly opposed on behalf of its members throughout the UK's response to the pandemic and the Paper has provided a roadmap for closer collaboration between our industry and government to ensure failings are not repeated.



# BIVDA Event Highlights

## MGM and 30th anniversary

BIVDA celebrated our 30th anniversary last year with a spectacular MGM and evening celebration at The Belfry, Birmingham. Moreover, all our working parties were held in-person, allowing BIVDA members to attend different sessions and hear from a variety of speakers.

New BIVDA Chair Helen Tucker kicked off the MGM with a run-down of BIVDA activities, followed by Professor Luke Butler's overview of his BIVDA-commissioned report which examined government procurement of COVID-19 tests during the pandemic.

Members were then treated to presentations delivered by senior figures from NHS England and DHSC, including Sandra Barrow and David Lawson.

The evening's 30th anniversary celebratory dinner was enjoyed by all, and we were delighted to welcome many special guests including Matt Whitty, Maggie Throup MP and Dame June Raine. Matt gave a presentation on access to innovation in the NHS before the BBC's Dr Michael Mosley provided an amusing and informative after-dinner speech covering the many diagnostic tests he has undertaken for his television shows (and other gruesome tales!)



## Regulatory Affairs Conference

The Regulatory Affairs Working Party carried on the fun by hosting a two-day conference at the same venue.

Ashleigh Batchen and Stuart Angell helmed the conference, with Penny Wilson of the MHRA providing the opening address. We welcomed attendees and speakers from across the UK and Europe and digested a number of topics including UKCA regulations, IVDR and sustainability legislation.

There were plenty of opportunities for networking during the first night's dinner and attendees were also treated to a now BIVDA regulatory conference tradition: a quiz!

## AGM

This year's AGM was spearheaded by our keynote speaker, Chief Commercial Officer at NHS England, Jacqui Rock.

Jacqui outlined ambition plans for a complete overhaul of the NHS's procurement operation. Heather Hobson, Deputy Director at the Office for Life Science, then spoke about how the MedTech Strategy will help achieve the ambitions for the Life Science Vision.

Sarah-Joy Newton reported on progress for sustainability, while Helen gave an overview of activities from the working parties. John Bagshaw spoke about the newly created Market Intelligence group.

Finally, we were delighted to announce our new board, including three new members – Dominique Huxham, Stuart Angell and David Budd.

## STEM 4 Britain Awards in Parliament

Doris-Ann, BIVDA Chair Helen Tucker and Ben spent the day in Parliament with young scientists and researchers who exhibited their latest research to compete for STEM 4 Britain's prestigious awards.

BIVDA had the honour of sponsoring the gold award in the Biological & Biomedical Sciences category, which was won by Devon J Crouch of the University of Liverpool and demonstrated the use of biomaterials to combat glaucoma.

Many MPs from all parties attended, including David Jones, Tulip Siddiq and Joanna Cherry, which demonstrates the enthusiasm for STEM innovations across the whole political spectrum.

## March Regulatory Affairs Seminar

The Spring Regulatory Affairs Seminar took place in Reading and was again led by Ashleigh Batchen and Stuart Angell.

The well attended event included many fantastic speakers from MHRA, BSI and industry whose presentations provoked lively dialogue. There was an excellent panel discussion on the MHRA IVD Roadmap, UKCA, and the Life Science Review with Ashleigh Batchen (BIVDA), Tom Beale (Agilent Technologies) and Camilla Fleetcroft.

The day concluded with a presentation from Stuart discussing how to navigate the US regulatory system and providing an overview of requirements.



# Regulatory Changes

## EU IVDR

The EU IVDR came into force on 26 May 2022, with amended timelines for certain products due to the Covid-19 pandemic. These dates extend to 2028, with the first major milestone approaching in 2025 for products being up-classified to class D. It appears that Notified Body capacity is now increasing with 10 Notified Bodies designated, and most are actively encouraging submission of class D documentation before the end of 2023 to meet the IVDR transition timelines.

Many new guidance documents have been published to support understanding of the EU IVDR, and BIVDA have been involved in discussions to ensure member companies are prepared for the requirements on their products.

There are still some outstanding aspects of the IVDR such as functionality of Eudamed and designation of EU Reference Laboratories, but the IVD industry has been robust enough to power through with implementation despite these gaps. BIVDA work closely with MedTech Europe who are at the forefront of these remaining aspects. As and when new information is made available, this will be shared with the BIVDA membership.

Updates and information around the IVDR are disseminated to the BIVDA membership through our Regulatory Affairs Working Party.

## UK MDR

Work also continues within MHRA and the Department of Health and Social Care in developing a new regulatory structure for medical devices and IVDs within Great Britain. We have now had the first statutory instrument passed through parliament for the future regime, implementing transitional arrangements for existing CE-marked products. The second statutory instrument, detailing requirements for post-market surveillance, is currently out for comment as a draft. It appears that many of the expectations from the EU IVDR will be utilised within a British regulatory regime, with some amendments to make it better suited to the needs of Great Britain.

BIVDA have been heavily involved in discussions cross-Government and with key stakeholders to continue to support in the development of these new regulations. The main topic of conversation of late has been an international recognition model to ensure the continued supply of products onto the British market. To allow Government to understand the needs of the IVD industry, BIVDA have produced a position paper on the possible domestic assurance routes and what the membership would like to see in the future regime. This is the second in a planned series, after our first paper on Labelling was published in June.

It is currently a very pressing time in the regulatory sphere, with multiple changes ongoing simultaneously.

BIVDA have focussed primarily on two of these landscapes: EU and Great Britain. Both are resulting in vast changes to systems in the IVD sector and require cost and energy to be put in by those in the IVD supply chain.

We hope to continue pushing the needs of the membership to enable a realistic and pragmatic regulatory structure to be generated.

Updates and information around the UK MDR are disseminated to the BIVDA membership through our UKCA Sub-Group, a spin off group from the Regulatory Affairs Working Party.

## BIVDA activities

Alongside contributing to the development and implementation of these regulatory changes, we are also passionate about educating the sector where possible.

In August, an article written by Ashleigh on in-house testing requirements was published in the Official Journal of Medical Device Regulations. Additionally, BIVDA have contributed articles to Pathology in Practice and have close working ties to the team at MedTech Insight, TOPRA and RAPs. BIVDA routinely joins conferences to speak on regulatory matters including the future UK regulations and IVDR specifics.

Given the complexity of the current situation, it's imperative that the sector has as much information as possible to ensure compliance.

There are many more projects in the pipeline for the remainder of 2023 and beyond to ensure we have as much reach as possible. We are very open to hear suggestions and needs from the membership directly; it's crucial that we are aware of your opinions to ensure you get the most of your membership. Please continue to feed into discussions, consultations and meetings to allow BIVDA to represent the IVD industry fully. BIVDA are here to support with your needs as your Trade Association, so engagement is hugely welcomed to allow us to continue to do so.

Ashleigh left her role as Head of Regulatory Affairs in August, and we are actively recruiting for her replacement. To support while recruitment is ongoing, Stuart has joined the BIVDA team as Regulatory Affairs Programme lead on an interim basis. Stuart has been involved with BIVDA for many years and is well versed to lead on regulatory support in the coming months.

The full schedule of BIVDA meetings can be found on our Eventbrite page. In October, BIVDA will be hosting our annual Regulatory Affairs Seminar, taking place in Edinburgh. This is a fantastic opportunity for the IVD sector to come together to discuss the hot topics. Our expert speakers will be on hand to provide key insights and answer any burning questions you may have. We hope to see you there!



# appg for Life Sciences

## 2022 - 2023

It has been a busy year of events for the APPG for Life Sciences – of which BIVDA is part of the secretariat alongside ABPI and BIA – and it has been very encouraging to see so many MPs and peers engage with the challenges and opportunities associated with our industry in the meetings.

Last summer, the APPG considered the 'Data Saves Lives' Strategy first published in June 2022. This was an opportunity to engage parliamentarians and facilitate sector discussions on the use of digital technology and health data for the benefit of patients, industry and the NHS. The roundtable event was hosted by the ever-present APPG Chair and life sciences champion, Daniel Zeichner MP.

The agenda covered discussions on the NHS app, access to clinical trial data, the UK biobank, interoperability within NHS trusts, approaches to improving system, and learning from international comparisons regarding health data legislation and effective action. From the BIVDA perspective, data within diagnostic provision was examined, including how results are communicated to patients and the benefits of a 'joined up' system for delivering efficient patient care and boosting public trust in providing their data for healthcare service improvements.

The next event occurred in September 2022, where we welcomed Roz Campion, Head of the OLS, to aid our discussion on "Implementing the Life Sciences Vision: one year on".

Over a working breakfast, Roz candidly discussed where the Life Sciences Vision was succeeding and areas where improvement was required. From a BIVDA perspective, it was pleasing to hear Roz praise the progression of genomics over the past year and reiterate the importance of early diagnosis for health outcomes.



The Shadow Minister for Science, Research & Digital Chi Onwurah MP stressed the importance of access to finance for the UK life science industry, which can often be a laboured process. Moreover, she emphasised how the life science sector was key to UK economic growth and has the potential to significantly boost areas all across the country, not just the South-East.



The APPG held its AGM in May 2023, where the seven MPs were present, including Father of the House, Sir Peter Bottomley MP and Maggie Throup MP. The event examined access to innovation in the NHS.

There was criticism of the Government's commitment to the life sciences industry, with claims that their words did not match their actions. This came amidst warnings that business was turning its back on the UK and would continue unless the Government made the UK a more attractive place to conduct business.



There were also calls for the Government to provide funding over a longer period to provide business with greater security and assurance. It was universally acknowledged that the UK possesses a world class life sciences industry which is not invulnerable, therefore work must be done to ensure it is not lost.

We look forward to holding further meetings on apprenticeships and AMR later on in the year and, as ever, we will endeavour to elucidate parliamentarians on the pressing issues which affect our industry.

# Working Party Updates



## Regulatory Affairs

Chair: Stuart Angell

The Regulatory Affairs Working Party (RAWP) has always been seen as a positive and proactive network where BIVDA members can engage and discuss the challenges the industry faces with regards to the regulation of IVDs. We continue to monitor, and discuss the implications of implementing the European IVD Regulation (IVDR) and utilise our connections with MedTech Europe. This year, we have seen special focus on the changing regulatory landscape within the UK and how devices may be regulated within Great Britain. The RAWPs include key stakeholders from the MHRA and Approved Bodies, and our newly created UKCA sub group allows a broad view for the implementation of UKCA marking under the UK Medical Device Regulation and how our members can engage specifically with government, providing an IVD specific industry view on the impact of these changes. The RAWP group look forward to the annual 2-day seminar held in Edinburgh in October, this is always a full and well attended event to learn and share industry knowledge on the challenges and opportunities of the regulation changes.



## Genomics

Chair: Philip Beer

It has been a hugely successful year for the Genomics Working Party as we have held three meetings and released a report, 'Leveraging advanced diagnostics to realise the UK's potential in genomics: A new whitepaper'.

Unsurprisingly, our early meetings in 2023 were dominated by the report's release. We were fortunate to welcome Angela Douglas, Deputy Chief Scientific Officer for NHS England and Chris Wigley, CEO of Genomics England to our January meeting in which we presented the final draft and held a productive discussion.

Our May meeting allowed us to digest the report post-release and analyse the impact it made. Our last meeting in July contained a packed agenda with many speakers. We were treated to a presentation on the 'Next Generation Genomics Centre – The need for sector translational support' from Rahul Kapoor, Director of Health Tech, UK-CPI and Lewis Oakley of Innovate UK.

Following this, the newly installed Head of Diagnostics at MHRA, Joseph Burt, updated the group on the MHRA's Genetics Test Guidance Document. This also included a piece on how the MHRA and Approved Bodies can play a role in realising the potential in genomics.



## Procurement

Chair: Richard Hames

As ever, it has been a busy and productive six months for the Procurement Working Party. Our two meetings this year provided an array of expert speakers, who gave updates and informed members of any key changes that they needed to be aware of.

At our March meeting, we were given an update on the Category Towers by Akeso & Co in addition to a presentation on Equality and Diversity leadership from Cleve Wright, Horiba. The event was sold-out and we were delighted to see so many attendees present.

Our next meeting came shortly after the release of BIVDA's report on the Government's COVID-19 test procurement strategy, which proved an informative read for all members of the group. To supplement this, the author, Professor Luke Butler presented his work at the meeting, which allowed attendees to ask any burning questions.

There was also an update from BIVDA's Sustainability Lead, Sarah Joy Newton, on Social Value in tenders as well as a general update from NHS Supply Chain. We look forward to an equally compelling set of meetings later this year.



## Infectious Diseases

Chair: Katy Turner

2023 has got off to a great start for the IDWP, holding 2 online meetings and 1 in person. Thank you to all the members for active contributions and enthusiasm. Online meetings have provided options for international and more distant members to take part and learn from what we do with BIVDA which is exciting and our in-person events offer the opportunity for more personal connections and informal discussions. Much of our focus this year has been on how industry can work with NHS to address key health challenges such as winter pressures, driven by respiratory diseases (COVID/Flu especially) and how diagnostics can help. We were delighted to welcome several speakers at our August in person meeting representing NHS, AHSN and Academia demonstrating the continued challenge of AMR and progress towards the National Action Plan (2025 plan in preparation as I type and eagerly awaited) led by speakers Dr Jane Freeman and Robert Annan of NHSE, how industry and NHS can partner to integrate new testing pathways for COVID/Flu in community settings by Mandy Townsend of the Innovation Agency, and novel approaches to evaluating diagnostics with "platform trials" delivered by Dr Phillip Pallman of Cardiff University. These 3 talks also highlighted the key role that industry has to play in innovation within the NHS and some of the challenges of scale-up of novel technologies.



## Environmental

Chair: Neil Plumridge

So far in 2023 we have seen the increasing activity in the UK, EU and globally on a number of fronts both related to chemicals and environmental legislation. As well as the weekly updates in the newsletter which includes regular updates from ECHA and HSE on CLP/ GB MCL, REACH, POP, PIC and Biocides, we also seen an increase in public consultations and proposals to update regulations. A reminder, that if you're impacted by the chemicals updates or consultations then please do let BIVDA know. Unless we receive feedback from members, we don't know which of the many updates are important and need to be further monitored or require advocacy on your behalf.

Update highlights include: increase in the Plastic Packaging tax; the application date under the Extended Producer Responsibility for reporting on packaging is in force, but there has been a delay in introducing the fees being introduced; imposition of fees for UK RoHS Exemption pack renewals - BIVDA are working with the Joint Trade Association (JTA) on how joint submissions might be managed for exemption packs that have wider interest to the electronics and electricals sector; proposals to update UK RoHS were delayed; increased activity to restrict PFAS substances in the EU, potentially in the UK and globally; BIVDA joins and is working with the JTA (Joint Trade Association), JTA work on RoHS, WEEE and Extended Producer Responsibility – Packaging; UK Proposal for mandatory assessment and labeling of packaging regarding recyclability under EPR; UK Government introduces new Sustainability Disclosure Standards aligned to ISSB; and EU – Progress with the EU Green Deal agenda, Introduction of the Batteries Regulation, Microplastics, review of CLP, REACH, RoHS, ECO Design etc.



## Near Patient Testing

Chair: David Wilson

This year the Near Patient Testing (NPT) Working Party was relaunched following a lull during the COVID-19 pandemic, with the appointment of two Vice Chairs, Lucy Lehane (Lehane Consulting), and Wendy Thompson (PremaLabs Diagnostics).

The aim of the NPT Working Party is to help members understand the rapidly changing market landscape for NPT in the UK, changes driven by the role NPT can play in helping the NHS address overwhelming service delivery challenges post-pandemic.

The group will meet 3 times during 2023, initially online followed by two in person meetings. Topics are member led and have covered a discussion with Karen Stalbow, Head of Diagnostics Policy & Performance NHS England, on Acute Respiratory Infection (ARI) Hubs and how industry can engage and influence the development of the ARI Hub programme; the changing regulatory environment for near patient tests; and a discussion with the NHS-formed Sustainability Healthcare Coalition on the growing importance of

*Near Patient Testing continued...*

sustainability considerations in NHS procurement. The final meeting will be a panel discussion on "The Future of Point of Care Diagnostics in Community Pharmacy" with key opinion leaders on the topic.

The market for Near Patient Testing is growing, yet still complex and changing, and the NPT Working Party aims to help BIVDA members understand the drivers and barriers of adoption of testing outside the hospital laboratory, to identify new market opportunities.



## Market Dynamics

Chair: John Bagshaw

The BIVDA Market Intelligence Group (MIG) held a launch meeting using Teams® on 13th March with the following objectives:-

1. Find out what market intelligence BIVDA members (you) really want and need.
2. Find out how much (if any) of that is already available to you, and how much you are aware of it
3. IF DESIRED - establish a group to help you to access this information, and mechanisms to share it

Previously the Market Dynamics Working Party (MDWP), chaired by John Bagshaw, had been meeting twice per year to review the report generated by the BIVDA Market Audit, to comment on trends and developments in the UK IVD market and on comparisons with other European countries, and to discuss and have input into any modifications of the GIVD classification used to generate the reports. Attendance at these meetings had been low, and the MDWP had been changed from WP status to that of a service function for member companies, however it was thought that there could be an unsatisfied need for help with market data gathering and analysis, and perhaps a change of emphasis would attract more interest and participation.

The launch meeting was well attended, and it was agreed that there could be some value to members in a follow up face to face meeting where specific queries on aspects of market sizes and trends could be discussed. This follow up was held in the BIVDA offices on 17th April and minutes are available on the website.

Currently the last submissions for the Market Audit to June 2023 are being collated, and the report should be released by the end of the month to the 28 participating companies. A MIG meeting will be called subsequently, and all BIVDA members are welcome. Participation in the Market Audit is free for BIVDA members – non-members may also participate for a fee. The reports are estimated to cover more than 90% of the UK IVD market by revenue, and detail to test level for all disciplines of pathology. If your company does not currently participate (or if, as is often the case, you don't know!) and you are interested in finding out more, contact us.

## Meet new members of the BIVDA team!



### Ben Kemp Policy Officer

Before joining BIVDA, Ben was a Parliamentary Researcher for Adam Holloway MP. Experience of producing research, creating reports and briefings, and interacting with stakeholders has proved invaluable to his current policy role at BIVDA, as well as providing a better understanding of the inner workings of British politics. He also holds a BA in History from Royal Holloway, University of London, and has worked for a time in the NHS, primarily in administration and communication.

1. Currently listening to: Animal Collective
2. Currently Reading:  
Entangled Life by Melvin Sheldrake
3. Favourite album:  
Low by David Bowie
4. Favourite city:  
Bologna
5. Favourite football team:  
Chelsea
6. Favourite TV programme:  
Twin Peaks
7. What makes you laugh?:  
The Mighty Boosh
8. Last film watched at the cinema + a five word review:  
Indiana Jones and the Dial of Destiny - good, but old ones better



### Tehelj Regulatory Affairs Officer

Tehelj joined us from Omega Diagnostics where she worked closely with partners, suppliers and distributors in support of creating labelling policy, product labels and translations. Her experience includes authoring high quality technical files and clinical evaluations of medical and IVD devices, in support of gaining market authorisation. Additionally, she has R&D background in nanoscience and molecular biology. Tehelj has been providing regulatory support to member companies in all areas of regulation, including environmental, chemicals and standards.

1. Currently listening to:  
Take Me Home, Country Roads  
by John Denver
2. Favourite book:  
The Alchemist
3. Favourite hobby:  
Hiking
4. Favourite holiday destination:  
Lauterbrunnen, Switzerland
5. Favourite TV programme:  
Atypical
6. If not (in current job) I would like to be...  
A pilot
7. Would most like to visit:  
Iceland
8. You wouldn't know it, but I'm very good at...  
Field Hockey



### Dawn Farquharson Office Manager

Dawn has previously held roles with the NHS as a Personal Assistant to General Managers within the CXH Acute & Specialist Medicine and Stroke & Neurosciences at Charing Cross Hospital supporting consultants in the management of the administrative areas of the department.

Dawn holds a foundation degree in FdSC Supporting Innovation in Health and Social Care.

Dawn is in the office daily so please do say hello if you pay a visit to our Oxford Street premises!

1. Favourite album:  
Joe – My Name Is Joe
2. Favourite film:  
Welcome Home Roscoe Jenkins
3. Favourite food:  
Tapas
4. Favourite football team:  
Arsenal
5. If not (in current job) I would like to be...  
Relationship Counsellor
6. Star sign:  
Scorpio
7. Would most like to...  
Spend a year traveling through South America
8. Would most like to meet:  
Bruce Willis

## Meet new Board members!



### Dominique Huxham

Dominique Huxham is a Senior Manager for Contracts and Commercial Partners at QIAGEN and has worked in the Diagnostics industry for over 25 years, from her beginnings in Microarray Technology through to Syndromic and the latest infectious disease testing. Dominique began working in a start-up/SME environment and has developed her career through senior roles in Affymetrix, ThermoFisher and QIAGEN. She has the unique perspective on the challenges faced by our industry from also having worked closely on Regulation and Legal projects on EU and UK policy. Her insights in the market support our members across the board.

1. Currently reading?  
Grit: The Power of Passion and Perseverance by Angela Duckworth, recommended by a friend and haven't been able to put it down!
2. Favourite film?  
The Money Pit (1986), with Tom Hanks, an old classic comedy but can certainly relate to this with a house project!
3. Favourite food?  
A Sunday roast and a good glass of wine, certainly hits the mark every time
4. Favourite holiday destination?  
St Agata in Southern Italy, tucked behind Sorrento, the views of Naples and Capri are breathe taking
5. Dream dinner party guest (dead or alive)  
Michael Palin, fascinating stories on his travels and a great sense of humour!



### David Budd

David Budd is an experienced diagnostic leader that has held leadership positions in a variety of SME and global Diagnostics companies, including Genedrive, Leica Biosystems, Siemens, and Bayer Diagnostics. He has worked on an international basis developing, accessing, and commercialising new products in the UK, EU, India, North America, and Africa.

David has been involved in leading and navigating many of the more infrequently trodden regulatory and approval process in our industry, including WHO pre-qualification and NICE approval for new innovations.

1. Favourite city?  
Venice - but in November
2. Favourite film?  
Bladerunner - the sequel is good too.
3. First job?  
Delivered newspapers door to door.  
My first career job was as a sales rep for Beckman Instruments
4. What would your dream job be?  
(can't be your current role!)  
Something to do with vintage watches and clocks - they're fascinating given their size, accuracy, age, and often being fully handmade
5. Dream dinner party guest (dead or alive)  
Robin Williams



### Stuart Angell

Stuart is the Managing Director and Co-founder of IVDeology, a UKRP, training and consultancy provider to the IVD industry. Stuart brings over 20 years' experience within the IVD industry and is an experienced, friendly and well-respected regulatory affairs professional working throughout the IVD industry. In his current roles at BIVDA as Regulatory Affairs Programme Manager and Chair of the BIVDA Regulatory Affairs Working Party,

Stuart is passionate about helping the wider healthcare industry to understand and navigate the IVD regulations in the UK, EU and rest of the world, and how recent changes impact the wider healthcare system. Stuart is based in Kent and is a strong advocate and champion of mental health awareness and fair flexible working for all.

1. Currently reading?  
The EU IVD Regulation of course!
2. Favourite city?  
Edinburgh or Tokyo
3. Favourite film?  
The Peanuts Movie (2015)
4. Favourite food?  
Cheese with anything
5. Dream dinner party guest (dead or alive)  
My dad, there's so much I'd like to ask him as an adult
6. Strangest experience?  
I have this problem on rainy summer days, frogs love to climb up the inside of my trouser leg, surely that can't just happen to me

# New BIVDA Members 2023

## Full members:



**Microbiosensor Ltd** [www.microbiosensor.co.uk](http://www.microbiosensor.co.uk)  
Manchester, M13 9XX

Microbiosensor develops and manufactures point-of-care devices that function as early warning systems for infection, and are designed to be compatible with and complementary to existing (lab-based) infection control processes and techniques.



**Novacyt** [www.novacyt.com](http://www.novacyt.com)  
Eastleigh, SO53 4DG

Novacyt delivers customer-centric solutions that advance the science behind diagnostics, fueling their drive to deliver products that save lives and help in the fight against infectious disease. They offer an increasing portfolio of in-vitro diagnostic tests, utilising molecular and protein detection technologies – supporting healthcare and disease prevention across the globe in the clinical and life science sectors.



**Dynamic Diagnostics** [www.dynamic-diagnostics.org.uk](http://www.dynamic-diagnostics.org.uk)  
Yeovil, BA22 9QX

Dynamic Diagnostics manufactures a range of in vitro diagnostic products – supplying to companies globally. They also offer contract manufacturing. They are happy to discuss any way they can work with you or point you in the right direction.



**PBD Biotech** [www.pbdbio.com](http://www.pbdbio.com)  
Birmingham, B3 1RB

PBD Biotech's mission is to support the scale-up of latent tuberculosis test-and-treat campaigns with Actiphage to achieve the goals of the WHO End TB strategy. Leveraging Actiphage's unique role in detecting active TB, PBD aims to drive innovation in the novel uses for TB screening and drug management.



**ReadyGo Diagnostics Limited** [www.readygotest.com](http://www.readygotest.com)  
Bath, BA2 3DQ

ReadyGo is providing tools that enable consumer testing. Snapshot™ is a universal tool that provides self-collection and processing of sample. It is designed with the user in mind to allow testing at home providing convenience, ease of use and confidence in the test result.



**Llusern Scientific** [www.llusern.co.uk](http://www.llusern.co.uk)  
Pontypridd, CF37 1DL

Llusern Scientific specialises in rapid and affordable point-of-care molecular diagnostics developed specifically to detect bacterial and viral infections. Llusern aims to revolutionise the molecular testing market by providing an affordable and rapid point of care (POC) diagnostic testing platform, capable of providing highly accurate results in 40 minutes.



**Selamedical UK Ltd** [www.selamedical.co.uk](http://www.selamedical.co.uk)

London, N11 1GN

Sela Medical UK is committed to improve the quality of life for patients by providing premier quality health care products to professional doctors and patients. They are dedicated to absolute customer satisfaction and building long-term, service-centred relationships with their clients. Founded in 2010 they have become a well-established distributor within the UK and the Irish Market.



**ProAxis Ltd** [www.proaxis.com](http://www.proaxis.com)

Belfast, BT3 9DT

ProAxis develops and supplies diagnostic assays focusing on respiratory biomarkers that aid clinical intervention which leads to improved patient outcomes. Their inhouse expertise offers clinical services that supports the identification of active biomarkers.



**Digistain** [www.digistain.co.uk](http://www.digistain.co.uk)

Newport Pagnell MK16 9PY

Digistain® is a cancer diagnostics company combining advanced and validated techniques with machine learning methods to deliver radically faster breast cancer treatment decision-making data for physicians and patients, reducing informed actionable treatment decision times (time to treatment) from months and weeks to days and hours – all at a dramatically lower cost.



**PhenUtest Diagnostics** [www.phenutest.com](http://www.phenutest.com)

Liverpool, L69 7BE

PhenUtest Diagnostics is a diagnostic company revolutionising the diagnosis and treatment of urinary tract infections (UTI). It is developing an innovative point-of-care test to give results in under an hour including a full antimicrobial susceptibility test.



**Tagomics** [www.tagomics.com](http://www.tagomics.com)

Birmingham, B15 2SQ

Tagomics are developers of epigenetic-based chemicals designed for high throughput and cost-effective epigenetic biomarker discovery. They specialise in epigenetic chemical modifications which provide DNA a second layer of information, enabling patients with biomarkers for early detection of colorectal and other common cancers.



**Accurex UK** [www accurx.com](http://www accurx.com)

London, EC2A 3LT

Accurx is the easy-to-use platform where patients and healthcare professionals communicate. Their software connects people across the system to make NHS professionals happier and patients healthier.

## Associate members:



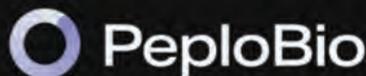
**EDX Medical Ltd** [www.edxmedical.co.uk](http://www.edxmedical.co.uk)  
Cambridgeshire, CB4 0WA

EDX Medical improves the detection and personalised management of diseases and disorders by translating clinical insights into trusted diagnostic solutions – developing and validating outstanding biological and digital technologies in the process.



**Ultrapolymers Ltd** [www.ultrapolymers.com/en](http://www.ultrapolymers.com/en)  
Warrington, WA4 2TG

As a leading polymer distributor, Ultrapolymers' aim is to provide a high-quality service and expert technical consultation to develop long term relationships with its customers. Established in Belgium in October 2002, Ultrapolymers has rapidly become a respected leader in polymer distribution.



**PeploBio** [www.peplobio.co.uk](http://www.peplobio.co.uk)  
Guildford, GU2 7YG

PeploBio is a leading biotech company dedicated to transforming the future of healthcare via precision medicine. With a passion for innovation and a relentless pursuit of scientific excellence, they combine cutting-edge research, advanced technologies, and multidisciplinary expertise to develop groundbreaking solutions that improve lives worldwide.



**Akeso** [www.akeso.co.uk](http://www.akeso.co.uk)  
London, EC4A 1LL

Akeso is an independent and dynamic management consultancy with proven top-tier experience focusing on Procurement and Supply Chain operations across the Healthcare and Life Sciences sectors. They bring top quality consulting resources to deliver real and lasting cost benefits, particularly in the most challenging and important areas of organisational spend.



**Enbiosis Biotechnology Ltd** [www.enbiosis.com](http://www.enbiosis.com)  
London, E1 2EF

Enbiosis produces scientific inventions, products, and services by using microbiome organisms to improve the quality of human health. Their artificial intelligence-powered technologies analyse the human gut microbiome in order to provide personalised health solutions that cover a special microbiome diet program and prebiotics.



Collocco Consultancy

**Collocco Consultancy** [www.colloccoconsultancy.com](http://www.colloccoconsultancy.com)  
Port Talbot, SA12 7AX

Based in South Wales, Collocco Consultancy have been offering Quality, Compliance and Regulatory expertise since 2018. With over 40 years' experience between them, their work plays an important role in the Medical Device and Life Sciences sector. They help companies bring safe devices to market and ensure they remain so.



**Patient Guard** [www.patientguard.com](http://www.patientguard.com)

Blackpool, FY4 2RP

Patient Guard provides a wide range of high-quality services, such as regulatory consultancy for medical devices and IVDs, and consulting and advice around medical device and IVD compliance. They provide full document generation services such as compliant Technical files, as well as UK Responsible Person Services and EU Authorised Representative Services.

native

**Native Design** [www.native.com](http://www.native.com)

London, EC2A 3EQ

Native Design is an independent design company, with world class capabilities across multiple design disciplines from insight to launch. They add billions to the value of their clients' businesses, through unique growth strategies that develop valuable IP and contribute to exceptional financial performance.



**BICI London** [www.bici.net](http://www.bici.net)

London, WC1A 2TH

BICI is an international, non-governmental, non-profit innovation platform established in 2014 focusing on the six key areas of medical devices, intelligent manufacturing, optoelectronics, materials, biomedicine, and environmental engineering. BICI is committed to building a global collaborative innovation system, transferring university fundamental scientific and technological achievements into real productive forces, and serving the sustainable development of mankind.



**J R Biomedical Ltd** [www.jrbiomed.com](http://www.jrbiomed.com)

Saint Asaph, LL17 0JD

J R Biomedical Ltd develops new medical devices and in vitro diagnostics, as well as offering an innovation service to companies and institutions based in Europe, Asia and the USA. The aim of the innovation service is to help organisations to fully commercialise their health care products and services as quickly as possible for entry into the UK and European markets.

JEMMDx

**JEMMDx** [www.jemmdx.com](http://www.jemmdx.com)

Bedford, MK40 2QW

JEMMDx is a Clinical, Regulatory and Medical Affairs consultancy uniquely focused on enabling commercialisation of patient-centric diagnostics: Point of care tests, Consumer Diagnostics and FemTech.

# Meeting Room use at BIVDA

Our two meeting rooms are available for members to book free of charge as part of your member benefits. Members are requested to book in advance so we can ensure a BIVDA team member can be at the office to greet you.

There is AV available in our Madden room which sits 16 in Boardroom style and 34 in theatre style. Our Fishwick room can accommodate 6-8 people.



Catering can be arranged through our external providers and invoiced as part of your booking. There are hot and cold drinks facilities also available.

You can book the meeting rooms via our website, or directly through dawn@bivda.org.uk or natalie@bivda.org.uk



## Getting to 299 Oxford Street - travel & local amenities

Our office at 299 Oxford Street is just 200 metres from Oxford Circus tube station, and about 350 metres from Bond Street station along one of the most famous shopping streets in the world.

The newly opened Elizabeth Line Bond Street station is located just behind us about 5 minutes from our front door in Hanover Square.

Mainline Stations, Paddington, Marylebone, Victoria, Waterloo, Euston and Kings Cross are all less than 10 minutes away on the Tube, and Liverpool Street is just a little further on the central line to Oxford Circus. There are also frequent buses from right outside the office, including the 73 every 7-10 minutes which goes to Victoria Station.

For those using the office and wanting a break and some fresh air, Cavendish Square Garden and Hanover Square are both round the corner and Hyde Park is only a 15 min walk away.



**VIVID** is a membership magazine produced by BIVDA - The British In Vitro Diagnostics Association.

**If you want to advertise in the next issue of *VIVID*, please contact BIVDA on 0333 3208 823**

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