



BIVDA MEMBERS' UPDATE

**July - September
2024**

Diagnostics for all



BIVDA congratulate Labour on election victory

BIVDA congratulated the new Government on their election victory. We wrote to relevant secretaries of state and ministers to welcome them to their posts and offer our sector expertise to address the significant challenges facing the new Government. Labour's aim of improving economic growth and public health, and linking the two, make our sector integral to their plans.

Professor Mike Messenger participates in ABPI expert regulatory roundtable

The event focused on how regulation can help to unlock preventative medicines. BIVDA's Head of Regulatory Strategy, Professor Mike Messenger, emphasised that the regulatory framework must consider the critical role of diagnostics and the interplay between the two regulatory frameworks, reflecting the partnership working that is needed to improve outcomes in this space.

Helen presents at North West London Pathology Symposium

Helen spoke about fostering collaboration between industry and laboratories in an open and transparent manner. She addressed common misconceptions about engaging with suppliers to achieve mutual goals and explored how unintended consequences from large-scale managed service contracts can still be effectively managed.



BIVDA to host Parliamentary Reception in October

In early July, we announced that we would be holding a Diagnostics State of the Nation in the Churchill Room of the House of Commons in October. Former Health Minister and Chair of the Fleming Initiative, Lord Darzi, will host and provide a keynote speech at the event. Other speakers include Director of the OLS, Roz Campion and Managing Director of North West London Pathology, Saghar Missaghian-Cully.



BIVDA President Angela Douglas chairs BD's Infection Diagnostics symposium

Angela provided the opening address, 'Infection Diagnostics: Why are we here?'. The event covered topics including AMR and near-patient testing through lectures and workshops. Kaye Walton helmed BIVDA's stand where she spoke with members and stakeholders about BIVDA's current activity.



Paul attends IDAP Expo in Whitehall

The event brought together the first cohort of the IDAP programme, which includes BIVDA member Upfront Diagnostics. Health Minister Baroness Merron provided the keynote address, which was followed by speeches from influential stakeholders including David Lawson (DHSC), Laura Squire (MHRA), Jeanette Kusel (NICE), and Tony Young (NHSE). Paul welcomed the minister's speech which called out the role of trade associations, the importance of faster regulatory approval, and better market access, particularly for SMEs.



Cancer Research UK release Early Detection and Diagnosis of Cancer Roadmap in consultation with BIVDA

We were pleased to be involved in developing Cancer Research UK's roadmap, endorsed by Professor Sir Chris Whitty, which aims to establish a path towards a future where early detection and diagnosis of cancer is the norm. You can find the roadmap [here](#).

BIVDA attend inaugural IBMS Awards

We were pleased to attend the first ever IBMS awards over the summer. The awards celebrated those who have contributed exceptionally to biomedical science over the past twelve months, including many BIVDA members. We look forward to continuing our close collaboration with IBMS leading up to next year's awards.





Stuart attends MDSAP Forum in Germany

BIVDA's Regulatory Affairs Working Party Chair, Stuart Angell, headed to the annual 5-day forum in Germany which was opened up to industry for the first time this year. Attendees generally agreed that MDSAP implementation had been successful, however, operational inefficiencies remain a challenge.

New Regulatory Affairs Manager for BIVDA

We were delighted to welcome Neil Plumridge to his new role on 1st September. Neil has over 25 years' experience in the IVD sector, both as an end user of IVDs, supporting Clinical Chemistry and POCT systems in the UK and Ireland, as well as working in and supporting IVD manufacturers in the UK, Germany and the US for global distribution. He was formerly Global Regulatory Manager at EKF Diagnostics.



BIVDA join launch of NIHR HealthTech Research Centre in Emergency and Acute Care

BIVDA's Head of Membership Engagement, Kaye Walton, attended the launch event of the new NIHR HealthTech Research Centre (HRC) in Emergency and Acute Care in Manchester. The event was particularly useful for discovering how HRCs could support members with co-developing pioneering devices, diagnostics and digital solutions for the NHS.



BIVDA facilitating ministerial visits for members

The Department of Health and Social Care have contacted us to see which members would be interested in a ministerial visit. Please contact ben.kemp@bivda.org.uk if this is of interest.



BIVDA Submission to Lord Darzi Review

BIVDA were one of only 75 organisations chosen to form Lord Darzi's Expert Reference Group to assist the peer with his review. BIVDA's own submission examined how diagnostics could be better utilised by the NHS and detailed industry's frustrations, including slow adoption of products into the NHS and issues pertaining to siloes and lack of operational coordination. The topics outlined focused on BIVDA's key priority areas: AMR, genomics and point-of-care testing, as well as others including virtual wards.

Kaye and Lucy attend Barclays Eagle Labs Health Elevate event

BIVDA's Kaye and Lucy hosted a members area at the event and were joined by members including GeneDrive, Veritie, Native Design, Marldell and Forte Medical. The day included several keynote presentations from industry experts, innovators and health professionals, while Lucy took part in a panel.



Health Secretary commends BIVDA's work to tackle NHS challenges

Health and Social Care Secretary Wes Streeting responded to BIVDA's letter welcoming him to his role by recognising BIVDA's ongoing work. He called out our engagement with the MedTech and Innovation Directorate to tackle NHS challenges and welcomes BIVDA's ability to support his department's continued engagement with industry. He stressed the key role industry plays in solving issues affecting the NHS.

BIVDA Market Audit shows recovery of UK IVD market

The BIVDA Market Audit Report for Q1 and Q2 2024 showed growth in the UK IVD market, after accounting for the reduction in COVID-19 testing. Significant recovery was found in the core laboratory testing market with the exception of infectious diseases. The total IVD market was assessed at £1.2bn, of which over 10% is glucose blood testing as recorded in published prescription data.





BIVDA respond to integrated, rules-based medtech pathway consultation

We broadly welcomed the pathway's potential to assist with the adoption of innovation in the NHS. However, we had concerns regarding delivery and potentially onerous demands placed on developers. We have asked for greater clarity in the innovation pathway across assessment, funding and procurement and clear demand signalling.

Paul supports an Innovate UK India-UK Trade Mission workshop

The event focused on AMR, diagnostics and therapeutics and was part of Innovate UK's Global Business Innovation programme, run throughout 2024. The programme aims to help businesses maximise the opportunities identified in India and provide international partnership opportunities to help develop innovation and bring ideas to commercialisation.

Beth Loudon officially joins BIVDA as Head of Market Access

We were delighted to welcome Beth Loudon to the BIVDA team in mid-September. Beth will be using her vast expertise, gained over 25 years in NHS procurement, to help members to better understand and access emerging markets. Prior to joining BIVDA, Beth was Medical and Surgical Consumables Director for NHS Supply Chain, leading the clinical and commercial team responsible for assurance of value and resilience for the supply of clinical goods to the NHS.



Helen speaks at Curia event on advancing healthcare leadership to drive innovation

Helen emphasised the need for UK patients to have access to the latest innovations and technology to improve patient outcomes. She insisted the UK must be more proactive in adopting novel innovations; enshrining continual improvement in the NHS which integrates into day-to-day operational decision-making.



BIVDA response to MHRA Fees Consultation

We have raised our concerns with the MHRA that suggestions to charge per GMDN code and duplicate charging will see fees rise dramatically for companies, imperilling businesses financially and discouraging innovation. Thank you to those companies who provided their responses which allowed for such a comprehensive submission,

BIVDA step up NHS Net Zero advocacy

We have raised serious concerns with NHSE regarding their Scope 3 requirement outlined in their Net Zero Roadmap, following member feedback. The consequences would result in higher costs and less patient choice. Recently, Alexandra Hammond confirmed to us that these plans are not final and will be subject to industry engagement.



Helen attends Labour Party Conference

Helen noted that while the conference was light on policy, the atmosphere was charged with energy and positivity following Labour's election win. In the evening of the final night, Helen was invited to events on diversity and growth. She discussed growth opportunities for BIVDA members with the Deputy Mayor of London for Business and Growth, Howard Dawber, and spoke with MPs on improving NHS supply chains to drive growth.



Helen presents at Westminster Health Forum event, 'Next steps for digital health and medical technology'

The event was chaired by Baroness Dido Harding. Helen delivered a presentation which looked at how industry develops and delivers innovative diagnostics in line with clinical demand. Helen used the recently published Darzi Review to highlight the need for digital solutions as the NHS is modernised and reformed and underscored how diagnostics, including AI, will play a significant role.

2024 Memcom Awards

Ben and Kaye represented BIVDA at this year's awards where BIVDA were shortlisted for the Best Trade Association award and the Sustainability Award.





HR Working Party
Formed to discuss and disseminate the latest thinking on HR and specifically how this understanding relates to the day-to-day challenges of our membership.

Message from the new BIVDA Regulatory Affairs Manager, Neil Plumridge

I am delighted to join BIVDA and continue providing leading regulatory expertise for our members alongside Professor Mike Messenger. I have worked closely with BIVDA in my professional career and look forward to using this understanding to provide the best experience possible for members.

What have I been working on?

Since joining in September, I've been involved in the MHRA Trusted Advisor discussions with Mike Messenger and Stuart Angell on the revision of the UK MDR.

It has been announced that the Post Market Surveillance SI is due to be laid before parliament, before the end of the year. We don't currently have sight of the final draft, but we'll review it and share it with members when released.

As mentioned, we have been concerned by the proposals to change the MHRA fees structure. Therefore, I have been gathering feedback from members to build a case for an alternative proposal to the MHRA.

I have attended a number of events already on behalf of BIVDA, including the ReMed conference in Loughborough and speaking in a panel session at the 2024 TOPRA Symposium in Rotterdam.

On the Environmental front, I've spoken with representatives of DEFRA regarding the changes to POPs (Persistent Organic Pollutants), RoHS, and WEEE legislation, and Helen and I responded on behalf of members to the Scottish NHS Consultation on Plastic Packaging.

BIVDA Regulatory Affairs Seminar 2025

I have begun organising the rescheduled Regulatory Affairs Seminar, taking place on 11th and 12th February 2025.

Tickets are priced at £895 for one night's accommodation, an evening reception, and two days filled with guest speakers, workshops, and specialist sessions.

Please register your interest by emailing regulatory@bivda.org.uk.



External Affairs

BIVDA's core route for developing and communicating the sector's public affairs agenda, raising member profiles across Parliament, government and the NHS.



Genomics

BIVDA's Genomics working group examines and advocates for better patient access to genomic diagnosis and medicine in cancer and rare diseases.



Infectious Diseases

Focusing on promoting the role for IVDs to rapidly identify the cause of infection allowing targeted therapy as well as to support drug development.



Market Intelligence

BIVDA's Market Audit provides the most detailed and accurate metrics available on the whole industry. Data is accessible to members.



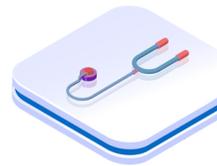
Procurement

Ensuring members are fully up to date with the changing procurement landscape and related topics, covering market access and fair competition across the sector.



Regulatory Affairs

This working party develops and communicates policy on regulations and standards including UKAS, ISO, UKCA marking and EU IVDR.



Near Patient Testing

A topical meeting incorporating information and policy updates for point of care, near patient testing, community testing and digital solutions.



Environmental

Providing advocacy and education for members addressing the issues that impact use from fundamental changes to Environmental and Chemical legislation.



Export & Manufacturing

Ensuring BIVDA's manufacturing and exporting companies receive the latest updates in business and trade developments from across the globe.

BIVDA



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