

ABHI

2023 REVIEW

FOREWORD

In what was the 35th year of ABHI, which saw us welcome our 400th member, I am proud that our collective voice is louder and more impactful than it has ever been before.

Our long-term investment in talented, expert staff, has ensured that we have been able to effectively advocate for the challenges and opportunities of members. This strong team means that we are recognised as knowledgeable, credible and always candid, enabling deep relationships to be built across government, associated bodies, the NHS and globally. As a result, it is clear that no other Trade Association working across medical devices, diagnostics and digital health has this preeminent level of access, engagement and impact. News that ABHI was crowned UK Association of the Year was further evidence of our influence.

ABHI’s extensive stakeholder network allows us to deal with the many complex challenges that our industry faces. Regulation is the foremost example, where over the last 18 months we have led the discussion with MHRA and wider government on the need for enabling regulation in the UK, post-Brexit. We have made a compelling case for the recognition of product approvals from other, trusted jurisdictions, alongside streamlined local assurance arrangements. International recognition will mean that UK patients maintain access to safe and effective HealthTech, and using our seat at the Life Sciences Council, we have ensured Secretary of State level support for our position. We are pleased that the Roadmap has now been published. Whilst not entirely satisfactory, it does signal intent and provide the basis on which we can now challenge, to ensure the detail is now delivered in a timely manner ahead of June 2025.

Our partnership work across the NHS, the city regions and the devolved administrations of the UK allows us to address challenges at a sub-national level. This has facilitated opportunities for Member engagement, creating a platform for best practice to be scaled nationally. Formal collaboration with the Shelford Group, who represent 10 of the largest research and teaching hospitals in the UK, has further strengthened this work.

I have been engaged with Roland Sinker since the inception of the Innovation Landscape Review, and I have the privilege of leading one of the key workstreams, supported by a number of our team. Our goal is to cultivate a more effective environment for our industry,

from research to the adoption, diffusion and commercial processes for our technologies. This is not a one year review. Rather, it is supported by the Chief Executive of NHS England and work will continue over the next three years as part of a long-term, concerted effort to deliver meaningful change.

We have made strong progress in the new area of sustainability, yet despite well intended ambitions, some requirements are not suitable for our industry. We continue to provide NHS Supply Chain with examples of these asks, in order to make them more appropriate for HealthTech. Importantly, our knowledge is recognised here, and our relationships are strong, which has allowed us to improve the process of supplier engagement, ensuring better consideration is given to these metrics within tenders, particularly across the area of social value.

Our international agenda continues to be focussed on creating a positive environment for inward investment in the UK, whilst very actively supporting UK companies to build their export businesses. To that end, our work over the last year will lead to an exciting expansion of our UK Pavilion offer in 2024, and our US Accelerator, which continues to grow, will welcome a further 30 businesses into the programme.

It is important that our strategy, and subsequent member offer, is aligned to the structure of ABHI. Clarity of our responsibilities is necessary for helping to communicate the extent and scope of our work. As such, the roles of our team will soon be updated to explicitly represent the areas of medical devices, diagnostics and digital health, alongside our international work. Partnerships that underpin this activity are crucial to our impact, and Richard Phillips will lead this work.

As ever, I would like to thank you all for your continued support of ABHI, and the work you day every day on behalf of patients.

Peter Ellingworth, Chief Executive, ABHI



In my 25 years in our sector and in business the last 36 months have been some of the most complex and challenging. With separation from the EU, extraordinary inflationary rises, the covid pandemic, energy costs and medical device regulation, to name just a few, operating within our space has been exceptionally tough. As a leader, you have to make choices. Choices about where to compete and where to deploy your limited resources most effectively. As an SME, to survive and thrive, we are acutely aware that we need to maximise every opportunity to build our market knowledge, our technical expertise and have open dialogue with key industry stakeholders. Membership of the ABHI has been one of our core tools to achieve this. The breadth of groups, both technical and commercial, as well as the huge resource base available to us has been instrumental in allowing us to stay abreast of and relevant in this fast-changing environment. Without this, the challenge would have been so much greater.

Graeme Cameron,
Chief Executive Officer, Pennine Healthcare



Having made the transition from corporate life to running a start-up company back in 2001, a well-respected friend and colleague recommended that I join ABHI. Anyone who has made this change will recognise the challenges it brings and, for me, the Association was an enormous help in bridging the gap left by the absence of support from a mothership. The issues presented by procurement, international growth, regulatory matters etc. are of course common to all businesses in our sector and I do not doubt that the excellent team at ABHI will continue to drive and enable sustainable growth for HealthTech.

Simon Talbot,
Managing Director, P3 Medical

ACTIVITY SNAPSHOT: JAN - MARCH 2023



As part of an Innovate UK funded initiative, ABHI partnered with CPI to deliver the most comprehensive SME study to date. [The report](#), which was supported by a launch event in Westminster, is being used to assess how we can further enhance our own offer to SMEs.

ABHI responded to key consultations on behalf of industry, including the 2023/25 NHS Payment Scheme, the UK's research and development tax relief scheme, and the International Trade Committee Inquiry into export opportunities



Working with **KPMG**, we ran a Q&A session for members, looking at how businesses can navigate and make the most of innovation relief and incentives schemes in the UK.



Back at the Middle East's largest healthcare expo, **the ABHI UK Pavilion** welcomed over **150 organisations at Arab Health 2023**. With 130,000 attendees, this was ABHI's most impactful pavilion to date, as we provided exhibitors with a comprehensive support package, enabling them to enter and expand business within the region.



Discussing the shift from policy to practice, ABHI's [digital health report](#) set out the system changes needed to better enable digital technologies to address the NHS's most pressing challenges.

The Secretary of State led Life Sciences Council [established an advisory group](#), consisting of the heads of ABHI, the MHRA, Office for Life Sciences and the Department of Health and Social Care MedTech Directorate, to agree on aligned proposals to deliver the UKCA process effectively.

- ABHI ran a weekly series of communications and engagement webinars for members.
- After two months of intensive discussions, aligned proposals [were published](#).



ABHI's extensive sustainability support was also recognised at 2023's **Trade Association Forum Awards**, where we were delighted to have been shortlisted for the ESG Initiative of the Year.



Throughout 2023, ABHI members took the opportunity to use the ABHI's Innovation in HealthTech: Recognising Excellence campaign to meet with local Parliamentarians to discuss the innovative ways in which they are supporting the NHS to tackle the backlog, create a more sustainable NHS, support the workforce, and help deliver better patient outcomes. Amongst the 14 successful nominees, Zimmer Biomet met with their local MP, Sir Robert

Buckland, in Parliament where they met to discuss the organisation's achievement and priorities for the future.

"I am delighted to support the ABHI's Innovation in HealthTech: Recognising Excellence campaign. Innovation is vital for delivering positive outcomes for patients, and for the NHS."

Dame Caroline Dinenage DBE MP, MP for Gosport

ACTIVITY SNAPSHOT: APRIL - JUNE 2023



April saw ABHI host a series of **sustainability and social value webinars** for members.

This included:

- An Environmental Policy Update ([recording available here](#)),
- A session with NHS Services Scotland ([recording available here](#)) and
- A briefing on modern slavery in the NHS procurement process ([recording available here](#)).



In May, we were pleased to bring a delegation of member companies to University Hospitals Birmingham, which provided companies with a great opportunity to hear from Trust leaders on ongoing developments and challenges, as well as strategies for R&D, Data, the use of HealthTech and Procurement.



In representing the HealthTech industry, **Peter Ellingworth** joined 200 UK business leaders at the **Prime Minister's inaugural Business Connect event**, where our sector was called out as a key growth industry.



To support their delegation to the UK, ABHI partnered with the Miami-Dade Beacon Council, to co-host a networking event for SMEs interested in understanding the opportunities for doing business in Miami and the state of Florida.



Jane Lewis contributed to the [Flexible Apprenticeships Life Sciences Manual](#), alongside the Department for Education, the Office for Life Sciences, ABPI and BIA. The guide sets out how flexibilities in apprenticeships can be used and delivered in Life Sciences to meet the needs of employers and apprentices.



HealthTech was a strong feature of 2023's **NHS Confed Expo event**, and **Luella Trickett** joined the panel sessions to discuss the critical need for improved adoption practices.



Peter Ellingworth gave evidence to the **UK Trade and Business Commission**, where he discussed regulatory alignment and better support for exporters in the context of future trade deals.

ABHI submitted feedback to the **Department of Health and Social Care**, to inform the development of the government's major conditions strategy for England.

Since the establishment of **Coronavirus Test Device Approvals (CTDA)** regulatory regime, ABHI has advocated for its management structure to sit within the MHRA. In May, we were pleased to see this happen, with the transition to the MHRA from UKHSA.



As part of London Tech Week, **Andrew Davies** joined a **Founders Forum HealthTech panel** session to discuss digital health opportunities in the UK.



Luella Trickett joined the Institute for Government for a discussion on how the NHS can minimise waste and learn lessons from the pandemic about improving procurement processes. [A recording can be watched here.](#)



With HealthTech continuing to flourish in Northern Ireland, **Richard Phillips** spoke at **HIRANI's summer evening networking event**, providing perspectives on national life sciences policy.

ACTIVITY SNAPSHOT: JULY - SEPT 2023



Penned by **Luella Trickett**, we published our [Innovation Report](#), which sets out key solutions to the adoption challenge.



In July, ABHI's Parliamentary Reception game members, healthcare stakeholders and Parliamentarians a chance to connect with one another, and to celebrate **HealthTech's impact on the health and wealth of our country**.

We had the pleasure of hosting our latest **Women in Leadership networking event**. In what was an inspiring session, with some excellent, practical discussions, we discussed how we can work towards **greater gender parity in the workplace**, and also [published the results of our first Gender Equality in HealthTech survey](#).



We were pleased to host colleagues from **The Health Foundation** who presented their findings of a recent opinion survey on virtual wards. Access the [webinar recording here](#).

In September, we were pleased to partner with TOPRA colleagues for a webinar update on the trends they are witnessing within the sector and tips for attracting regulatory talent. [Access the recording here](#).



September saw us hold a **diagnostics round table** with clinical leaders, parliamentarians and colleagues from the ABHI membership, whilst also celebrating the successes of our 'Recognising Excellence' campaign.



Boosting our international support offer, we welcomed **Omar Jowhar** to the team in September, and we also have **Lucy Stevenson's** support for the next year, as she joins our external affairs team as part of her university placement.



We were delighted to host the Chairs and Vice Chairs of our various member groups in July, to share updates on key activity, as well as **best practice and tips to maximise impact**. This is now a regular feature of our calendar.

In a boost to UK HealthTech manufacturing, ABHI has signed an MoU with Make UK, the representative body for manufacturing in the UK. The partnership also entitles ABHI members to complimentary Affiliate Membership of Make UK which you can [claim here](#).



Peter Ellingworth had the enormous privilege of representing our industry at Westminster Abbey for a special service to celebrate the **75th anniversary of the NHS**.



Richard Phillips was pleased to join the panel of experts who [supported the launch](#) of Imperial College London's series of reports that detail recommendations on improving the UK's competitiveness in HealthTech.

September saw ABHI hosts its annual **Sustainability conference**, with an excellent range of speakers discussing the current state of play and what companies need to be doing to ensure that sustainability is built into all future business plans. [Access the recording here](#).

With the UK Government set to publish a 5-year National Action Plan to tackle **anti-microbial resistance**, ABHI members were invited to meet and discuss the Plan's draft commitments with Department for Health and Social Care colleagues who are leading this work.

Peter Ellingworth met with the **UK Mission to the European Union** - established to ensure the UK's interests are promoted to Member States and EU institutions. ABHI will be working closely with the Mission, providing briefings and addressing issues that companies may be experiencing when trading with the EU.

Exploring how partnership-working between a wide array of the life sciences industry, Government, the NHS, patient support groups and others can help grow the clinical application of advanced diagnostics, ABHI led a round table discussion with **Sir John Bell** in September.

ACTIVITY SNAPSHOT: OCT - DEC 2023



Members of the ABHI team joined the latest AdvaMed MedTech Conference in California, where there was standing room only for the session hosted by Peter Ellingworth on the future of UK HealthTech.



Held across two days, the ABHI UK HealthTech Conference returned in October, welcoming over 200 delegates each day for a packed agenda of networking and updates on all matters regulation and NHS access.

Focussing on the relationship between investment in women's health and economic growth, ABHI and a cohort of members kicked off a partnership with NHS Confederation to develop a landmark study on this important topic.



The ABHI UK Pavilion returned to MEDICA in November, where dozens of UK companies and national partners joined ABHI for a busy week of meetings with new and prospective international partners.



Collating responses from across the membership, ABHI submitted industry feedback on the proposals to update **Part IX of the Drug Tariff**.



Steve Lee became a full-time member of the ABHI team in 2023, and in September his industry leading regulatory expertise was recognised by TOPRA, where he was appointed to their **Board of Directors**.



The ABHI US Accelerator class of 2023 wrapped up proceedings for the year in style, with a week-long mission to Florida, taking in meetings with clinical leaders from across four of the State's largest cities.

With the theme of women's cardiovascular health in mind, ABHI convened a round table meeting with a cross section of members and stakeholders to discuss the role of HealthTech in bridging the health equity gap.

ABHI announced a new partnership with the **Shelford Group** to deliver a programme of joint work, ranging from events held at Trusts, to collaboration on national policy. Representing ten of the largest research and teaching hospitals in England, the Shelford Group accounts for almost two thirds of the country's clinical research infrastructure.



In another flagship study, **ABHI's Patient Safety Group** has commenced work with Patient Safety Learning (PSL), to author a report that advocates the new PSL Standards Framework, set to be launched in Spring 2024.

ACTIVITY SNAPSHOT: OCT - DEC 2023



ABHI Diabetes welcomed **NICE's announcement that hybrid closed-loop systems are to be recommended for people with type 1 diabetes** to improve management of their condition. We were also pleased to see enhanced recommendations that include children and young people, something we, and many others, called for during the consultation.

PACE

With several members inputting into its strategy, we were pleased to see the new £30m **Pathways to Clinical Efficacy (PACE)** programme launched in October, which is designed to support innovation that can address Antimicrobial Resistance's threat.



In November, we hosted a webinar for members with NHS England on the updated **Carbon Reduction Plan guidance**. You can view [the recording here](#).



With thanks to all the members who provided feedback, ABHI responded to the Government's consultation on the proposed **ban of the manufacture, supply and sale of wet wipes** containing plastic.



ABHI had the enormous honour of being recognised as the UK Association of the Year at the **Association Excellence Awards 2023**.



In December, ABHI partnered with **CPI** to launch the results of our latest business survey, highlighting the key challenges and opportunities for the sector.



We were pleased to see that **full expensing** was made a permanent feature of the UK tax system within the Autumn Statement, and is a response to the call that many members put their name to.



With innovation adoption the theme for the day, ABHI Scotland met in Edinburgh for a great discussion on how HealthTech can best support NHS Scotland. The following day saw the Scotsman Life Sciences Conference where **ABHI's Addie MacGregor** joined panellists to detail the work she is leading to support the ABHI membership's sustainability efforts.

THE LOOK AHEAD

As we enter the new year, ABHI remains focussed on two core priorities to support members, which are **growth** and **regulation**.

Growth refers to that of your companies and individuals within them, as well as the wider industry and its ability to increase the health and wealth of our country. Product regulation of devices, IVDs and digital health products remains central to what we do every day and is and of itself, a critical enabler of growth.

Underneath these overarching priorities sit 10 key work areas, each playing a vital role in achieving success for the industry.

UK Regulation



UK Regulation is at the forefront, and we are working closely with the MHRA regarding the new UK framework, including international recognition. These changes promise new market opportunities that could benefit UK research and patients. Our collaboration with international partners aims to align the UK with global best practices, whilst simultaneously assisting our members and stakeholders in adapting to these regulatory shifts.

Digital Health



In **Digital Health**, we are laying the groundwork for infrastructure and processes that facilitate efficient access and utilisation of data. This includes fostering policies and practices that enable the swift deployment of AI in clinical settings and securing funding mechanisms, assessment and procurement processes for the adoption and scaling of technologies.

Sustainability



Sustainability is no longer an option but a necessity. Our focus is to provide educational and practical support to members to meet NHS net zero targets and broader sustainability goals. Internationally, we are working to align ambitions and requirements for a sustainable HealthTech sector, and we are leading industry engagement to ensure that NHS's sustainability demands are both realistic and achievable.

UK Market Access



UK Market Access is multi-faceted. On procurement, we are working to implement value-based purchasing, to build on existing progress, and to navigate challenges with NHS England's Commercial Strategic Framework. We are ensuring NICE's changes to guidance programmes are fit for purpose, and shaping the outcomes of DHSC's MedTech Strategy.

Collaboration with the NHS



Our **collaboration with the NHS** is important in this regard and we are maintaining regular interactions with NHS England's senior leadership, driving industry input into the Innovation Ecosystem programme, enhancing our relationship with the Shelford Group, and expanding partnership activities with Health Innovation Networks and regional partners.

Innovation & Investment



Across **Innovation & Investment**, we are focussed on implementing HealthTech priorities within the Life Sciences Vision, garnering support for 'The Plan for HealthTech' across political parties, and influencing proposals that will bolster HealthTech investment in future spending reviews.

Health Equity, E,D & I



For **Health Equity, E,D & I**, our aim is to deliver events that promote diversity in leadership and health equity, and to work with members and stakeholders to achieve tangible outcomes for HealthTech. It is important to ensure our industry is representative of the people it serves.

UK Business Development



To enhance **UK Business Development**, we will collaborate with partners like MAKE UK, to influence national policies that are favourable to HealthTech growth. We will strengthen ties with the financial investment community, whilst working to realise the ambition of an exceptional HealthTech business environment as outlined in the Life Sciences Vision.

Diagnostics



In **Diagnostics**, we are on a mission to transform healthcare by placing diagnostic information at the core of early disease detection. The development of strategies to enhance diagnostic capabilities is key, and we are focussed on expanding genomic and precise diagnostics to enable personalised treatment plans. Work in 2024 will see us pave the way for the clinical deployment of AI and digital diagnostics, as we foster the growth of a vibrant diagnostics community.

International



In the **International** arena, we continue to offer prime engagement platforms at global trade shows, our US Accelerator programme continues to expand, and we are playing an ever increasing role in international trade policy to ensure seamless cross-border flow of goods and services.

These priorities collectively represent our roadmap for the year, each intertwined and essential in realising our dual mission of fostering growth and ensuring effective regulation for HealthTech.

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At some point in their lives, everyone will encounter a HealthTech product, ranging from wound dressings, clinical diagnostics tools that enable early detection, through to highly advanced robot-assisted surgery. That is why Thermo Fisher Scientific became full members of ABHI in 2020, conscious of the opportunities that we have as an organisation in the UK to support the HealthTech industry. The knowledge of the ABHI's staff, advisors, consultants, board and membership, along with the focus of its overarching priorities of growth and regulation, enables us all to better serve our customers and ultimately patients. I have the pleasure of working as part of the ABHI Board and look forward to advancing HealthTech in 2024 and beyond.

Suzanne Holden,
Vice President, Corporate Accounts,
Country Leader United Kingdom, Thermo Fisher Scientific



ABHI'S 2024 PRIORITIES

Key Work Areas



Strategic leadership provided by the ABHI Board, delivered through our network of member groups

- Single use
- Capital
- Surgical
- Digital
- Diagnostics (IVDs and Imaging)
- Robot-assisted surgery

WELCOME TO ABHI

In 2023, we were pleased to welcome the following new members to ABHI:



2Harris Consulting Limited



8fold Governance Ltd



Air Sentry Ltd



AKRA Team GmbH



Arena, a PTC Business



bioMérieux UK Ltd



Burgess Salmon LLP



Biotechnology and Biological Sciences Research Council



C2-Ai



CAPU Search Limited



Cepheid UK Ltd



Collocco Consultancy



Compliance Solutions (Lifesciences) Ltd



Costello Medical



Cutting Edge Surgical Instruments Ltd



Cytosorbents Medical UK Ltd



Dialogue Language Services



DQS Medizinprodukte UK LTD



eg technology Ltd



ETHOS Ltd



Ethypharm Digital Therapies SAS



GAMA Healthcare Ltd



Gowling WLG LLP



Halma plc



Highland Marketing Limited



Home Wound Care



IG-Technology Ltd



JensonR+ Ltd



JReg Consultancy Ltd



Kinsetsu Ltd

WELCOME TO ABHI

In 2023, we were pleased to welcome the following new members to ABHI:

Kennedys

Kennedys Law LLP

kiwa

Kiwa Ltd Medical

KPMG

KPMG LLP

LFH
Regulatory

LFH Regulatory Limited

MAS

MAS Innovation (Private) Limited

MERITMEDICAL

Merit Medical UK Ltd

mnhi.
maternal newborn
health innovations

MNHI Maternal Newborn Health Innovations

nuralogix

Nuralogix UK Limited

OrthoSolutions
Group

Ortho Solutions UK Ltd

OSLER

Osler Diagnostics Limited

Patient Guard
Medical Device Consultancy

Patient Guard Limited

pd
m

Pd-m International Limited

Presymptom
Health

Presymptom Health Ltd

ROBUST
CARE

Robust Care International Limited

seer

Seer Medical UK Pty Ltd

+sfm

Speciality Fibres and Materials Ltd (SFM)

STERIS

STERIS

SUSHVIN
Consultancy Services Limited

Sushvin Consultancy Services

TOPRA

TOPRA

VIRTUALSTOCK®

Virtualstock Ltd

VCLS
Voisin Consulting Life Sciences

Voisin Consulting Life Sciences, UK Ltd

xund

Xund Solutions GmbH

ZimVie

ZimVie

“

Organon have a heritage in pharmaceutical products and have recently joined ABHI to gain a more comprehensive understanding of the Medical Devices and HealthTech environment. The help and support provided by the ABHI has been outstanding, enabling us to create valuable networks and a platform to develop our market access and go-to-market plans.

ABHI have helped Organon navigate the regulatory and compliance differences between pharma and HealthTech and provided invaluable support around legislative changes on sustainability.

Every member of the ABHI team that we have interacted with has been approachable, friendly, and extremely knowledgeable.

Sarah Brown,
Access Lead – UK & Ireland, Organon



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ABHI