

Collaboration between the British In Vitro Diagnostics Association (BIVDA) and the *in vitro* diagnostics (IVD) industry has led to some significant improvements in the diagnosis, treatment and management of patients over the past 25 years.

Together, we have demonstrated the importance of IVDs at the point of care, in the diagnosis and management of diabetes patients, in tackling global health challenges such as antimicrobial resistance (AMR), in transforming digital pathology and in securing greater patient access to precision diagnostics to enable more personalised treatment.

While much has been achieved, the slow adoption of IVDs within the NHS continues to prevent the industry from achieving its full potential for the benefit of patients, the NHS and the UK economy. With Brexit on the horizon, it has never been more important for this issue to overcome so that the UK life sciences industry can continue to enhance its position as a global leader.

Looking to the future, I am excited to see the progress that will be achieved over the next 25 years. I am proud to be the Chief Executive of an association that represents such an innovative industry and I have no doubt that the sector will continue to develop during the years to come.

Doris-Ann Williams MBE
Chief Executive



BIVDA CHAIRS THROUGH THE AGES

1992-1994	George Zajicek (Shield Diagnostics)	2005-2007	Paul Weinberger (Roche Diagnostics)
1994-1996	Bill Cunningham (IDS)	2007-2009	Jag Grewal (Beckman Coulter)
1996-1998	Andy Bufton (Abbott Diagnostics)	2009-2011	Jeff Watson (Ortho-Clinical Diagnostics)
1998-1999	Malcolm Luker (Genzyme Diagnostics)	2011-2013	David Horne (Alere)
1999-2000	Bill Cunningham (CDx)	2013-2014	Carla Deakin (Abbott Diagnostics)
2000-2001	Andy Anderson (Metra BioSystems)	2014-2016	Ruth Powell (Siemens/ThermoFisher)
2001-2003	John Menzies (Ortho-Clinical Diagnostics)	Current	Simon Richards (Alere)

BIVDA KEY ACHIEVEMENTS AND MILESTONES: 1992 - 2017

- Began production of **vIVID**, a magazine to keep members updated on BIVDA's activities
- Introduced a **CEO Forum** as an initiative to engage the most senior members within BIVDA companies
- Secured a **Statutory Instrument** to protect the import of IVD products from unintended consequences as part of the Misuse of Drugs Act
- Established **Life Sciences UK** and the **Life Sciences All Party Parliamentary Group** with colleagues from across the life sciences industry
- BIVDA's Chief Executive **Doris-Ann Williams** was awarded an **MBE** for services to the healthcare industry
- Introduced **Technology Briefs** to highlight the costs and clinical benefits of IVDs to stakeholders
- Began production of **Diagnosics in Healthcare**, our newsletter on IVDs for external stakeholders
- Established social media campaigns **#TestingTuesday** and **#FiveFridayFacts**
- **Diagnostic Evidence Cooperatives (DECs)** created by NIHR from discussion with BIVDA
- Secured funding for **six molecular tests for cancer** following our call for a national commissioning framework in our 2016 vision

THE VALUE OF IVDs

In vitro diagnostics (IVDs) are an **essential part of the NHS**. They are used to both enable **diagnosis** and to **rule out** causes of ill health. They are also used to **monitor, screen and assess** people for any potential health problems they might have. Increasingly, they also allow people with chronic disease to **manage** their own conditions.

It is estimated that **70% of clinical decisions are** made using some form of IVD. As such, their contribution to healthcare systems around the world and to the health and wealth of our nation should not be underestimated.

Despite their benefits, IVDs continue to face a **glass ceiling** when it comes to the uptake and diffusion of new tests and technology across the health service. In fact, uptake of new IVDs within the NHS typically takes about **10 years**. This is typically due to:

- **Budget silos** – Currently, the budget for testing and general pathology in the NHS is separated from the rest of the budget for a medical pathway. This can often provide a disincentive to introduce cost-saving and potentially life-saving new tests because while the up-front and ongoing tests are borne by the innovators, the savings accrue further down the patient pathway.
- **Understanding** – When being commissioned, the use of diagnostics is either misunderstood, or worse, not considered at all.
- **Flexibility** – Currently, the NHS is too inflexible when it comes to adopting new IVD tests.

If we were able to **overcome the barriers to adoption**, IVDs would be in a better position to:

IMPROVE PATIENT OUTCOMES, DIAGNOSIS AND TREATMENT

Innovations in IVDs are resulting in faster, accurate testing and are allowing the NHS to target treatment more **precisely** and **effectively**, improving patient pathways and enabling **earlier intervention**.

IVDs can also have a **positive effect** on the treatment and quality of life of patients, particularly those with long-term conditions (LTCs) by:

- Allowing patients to manage their conditions themselves at home
- Regular self-management allows for early detection of changes in health status, reducing the likelihood of dangerous and costly complications
- Empowers the patient with greater understanding of their LTC, reducing anxiety

INCREASE EFFICIENCIES AND SAVINGS WITHIN THE NHS

When **utilised efficiently**, IVDs can be a key driver in delivering both **efficiencies** and **financial savings** for the NHS by:

- Reducing downstream treatment costs
- Lowering hospitalisation rates
- Reducing avoidable/inappropriate interventions
- Saving staff time

STRENGTHEN THE UK ECONOMY

IVDs have obvious benefits for the NHS and improving patient outcomes. However, the **IVD industry** also has a vital role to play in contributing to the **economic prosperity** of the UK.

- The IVD industry directly employs more than **8,000 people** in the UK
- The UK IVD sector was worth **£730 million** in 2014
- The UK is a **net exporter** of IVD products, with **£1.1 billion** exported in 2013
- The IVD industry reinvests between **12% - 15%** of its revenue into R&D, making it one of the most R&D intensive sectors on par with the pharmaceutical industry in Europe

BUILDING ON OUR SUCCESS – LOOKING AHEAD TO THE NEXT 25 YEARS

Over the past 25 years, **considerable progress has been made** in the IVD sector. However, there is still a **significant amount of change that needs to occur** if we are to ensure that the full benefits of IVDs are experienced by patients, the NHS and the UK economy.

Outlined in our vision for the future below, BIVDA has established **four key priority** areas where change could make the most difference. By continuing to work in partnership with the Government, NHS and industry colleagues, we can ensure that this vision becomes a reality and that the sector continues to thrive for the benefit of all.

Increasing Adoption of IVDs

NOW

The **adoption** of innovative IVD tests within the NHS is still **taking too long**. Typically, widespread adoption of new diagnostic tests takes approximately **10 years**.

THE FUTURE

We hope that the **Accelerated Access Review (AAR)** and the **Life Sciences Industrial Strategy** will provide a vital stepping-stone to **faster adoption**, so that patients of the future have access to the right IVDs, at the right time.

Playing a Leading Role in Overcoming Global Health Challenges

NOW

The need to tackle the **global challenge of antimicrobial resistance (AMR)** has been recognised and understanding of the role of IVDs has to play in this area is increasing.

THE FUTURE

The IVD sector wants to see **extensive use of IVD tests** to support the prescribing of antibiotics in both primary and secondary care to **reduce over-prescribing and unnecessary treatment**.

A New Mechanism for the Funding of IVDs

NOW

The budget for testing and general pathology in the NHS is separated from the rest of the budget for a medical pathway. This can often provide a **disincentive** to introduce cost-saving and potentially life-saving new tests because while the up-front and ongoing tests are borne by the innovators, the **savings accrue further down the patient pathway**.

THE FUTURE

For a funding mechanism to have been established which does not disincentive the uptake of IVDs, thereby encouraging the NHS to **increase the adoption of IVDs**, enabling better patient access to diagnostics.

Guaranteeing Patient Access to Molecular Diagnostics

NOW

NHS Improvement introduced a clear mechanism for funding an **initial six specific molecular tests for cancer** within the 2016/17 National Tariff Payment System (NTPS).

THE FUTURE

NHS England will have introduced a **national commissioning framework for molecular diagnostics in oncology**, ensuring widespread patient access to such tests and allowing more patients to benefit from personalised treatments.

Contact Us

If you would like to discuss any of the issues raised in the report or would like further information on IVDs, please do not hesitate to contact us using the details below:

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About BIVDA

The **British In Vitro Diagnostics Association (BIVDA)** is the national industry association for manufacturers and suppliers of *in vitro* diagnostics (IVD). It has been leading the industry for 25 years since its establishment in 1992 and represents over 150 members.

The IVD Industry in Numbers



70%

of clinical decisions are based on IVD tests

In vitro diagnostics is the largest category in the global medical technology market with annual sales of

£49.9 billion

in 2015

2 million

units of donated blood

are screened for infectious disease using diagnostic tests to enable safe transfusion into patients

The UK is the **fifth largest IVD market** in Europe



£10

 per capita on

IVD products, less than half of spend per capita in France, Germany and Italy



The UK IVD sector was worth

730 million

 in 2014

in demand for **blood and tissue tests** over the **next ten years** due to an **ageing population** and rising incidence of **chronic disease**



900 million

tests are carried out each year in the UK

The UK is a net exporter of IVD products, with

£1.1 billion

 exported in 2013