

# University of Cambridge

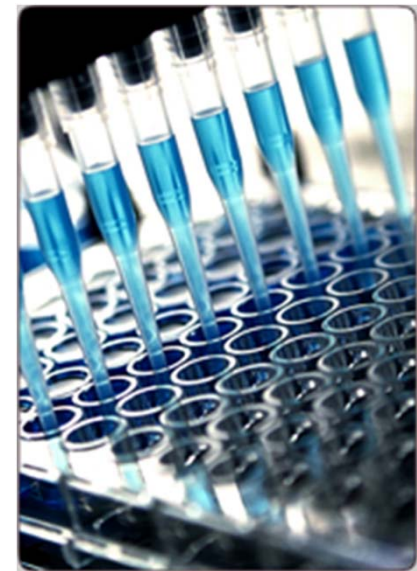
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Chief Executive



# What is an In Vitro Diagnostic Medical Device?

- An **IVD** Medical Device is **defined** as a device which, whether used alone or in combination, is intended by the manufacturer for the in-vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes.



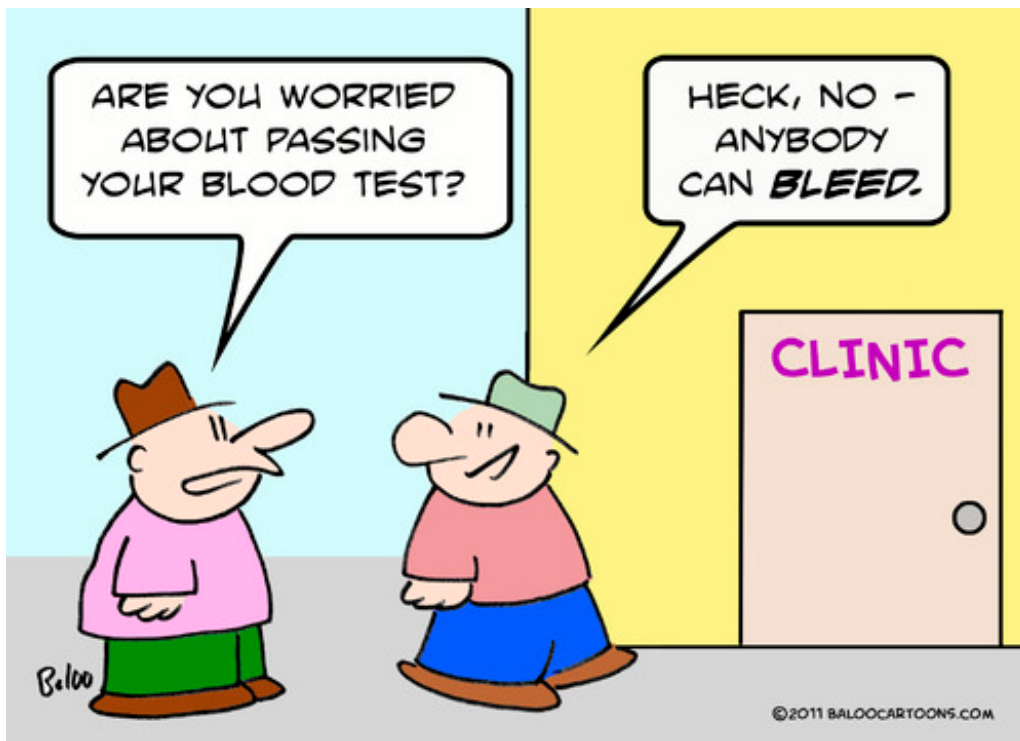
# IVD Market

- Global issue – gain recognition for value as opposed to cost of products
- Global value about \$60 billion
- UK sales to NHS in 2015 £900million (less than cost of statins alone) versus amount of information provided to allow safe diagnosis, monitoring, screening



# What is BIVDA?

- British In Vitro Diagnostics Association
- Based in central London
- Established February 1992
- Acts as voice for the IVD industry with Government and other stakeholders
- Supports & informs activity of member companies



# What does BIVDA do - External Communications



Office for Life Sciences





# Supporting Landscape for IVD Industry (pre-adoption)

MRC Pathology Nodes x6

Diagnostic Evidence Co-Operatives x4

Innovate UK SMIP; KTN;



Supported by NIHR through NOCRI

AHSNs x15

NICE

Various 'products' & programmes

Adoption & Diffusion by NHS





# Regulatory landscape



- For industry – more rigorous and expensive both globally and in the EU (increasing number of regulations in different markets)
- ISO 13485
- Other EU regulation – WEEE, RoHS, REACH etc
- New EU IVD Regulation – expected to be published end 2016 with 5 year transition period
- For Clinical Labs – assessment to ISO 15189,
- Different approach, similarity to application of EU regulation

# Procurement landscape



- Managed Equipment Service
- Polarising large versus SME
- Driven out many mid-size companies
- Some successful niche players
- Some more 'traditional' companies struggling with new way to 'do business'
- Shouldn't impact adoption of innovation (but doesn't help either)



# Development of IVDs

- Industry is looking for unmet clinical needs
- Miniaturisation of instruments and simplification of procedures allow Point of Care Testing
- Opportunities for diagnostics to be used in combination with drug therapy – Diagnostic Dependent Drugs
- Funding streams within hospital “don’t work easily” for novel diagnostics
- Need access to patient samples – both normal and with disease



# Frustrations

- Amazing time for people in the UK to be working in the IVD industry or in pathology
- Laboratory medicine (broadly to include point of care testing) has ability to significantly alter outcomes and allow better utilisation of resource
- Never been more initiatives to allow this but barriers to adoption remain



# Contact info

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