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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
Supporting Landscape for IVD Industry (pre-adoption)

- MRC Pathology Nodes x6
- Diagnostic Evidence Co-Operatives x4
- Innovate UK SMIP; KTN;
- AHSNs x15
- NICE
- Various ‘products’ & programmes

Supported by NIHR through NOCRI

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
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