BIVDA Digital Working Party
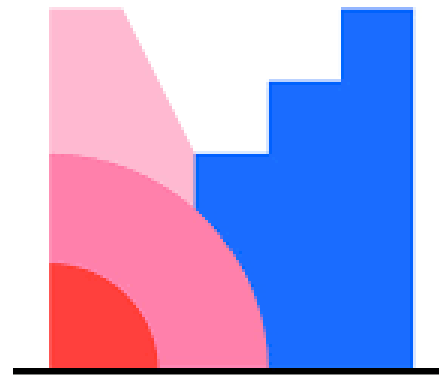# Tuesday 17th May 2022

British In Vitro Diagnostics Association

IVDs: Transforming Patient Pathways

Agenda

Time	Item	Presenter
09:30	**Welcome, introductions and apologies**	Phil Groom, Chair
09.35	**Competition Law**	Doris-Ann Williams, BIVDA
09.40	Discussion on Survey responses and the creation of 3 subgroups dependent upon member requirements • Data • Operational IT • Connected Tools	Helen Dent/ ALL
10.40	**Mentimeter Survey**	ALL
10.45	**AOB and Date for Next Meeting**	Phil Groom

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Competition Law Statement

Discussion on Survey Responses

Helen Dent

BIVDA

IVDs: Transforming Patient Pathways

- Ben called 67 registered members of the DWP.

- Spoke to 20 members.

- 44 have failed to reply to Ben's messages.

- 3 No longer work at the company.

- Survey covers 30% of DWP and 9% of all members.

- Have simplified responses for the purpose of this session.

* HD to follow up with main contacts of companies to expand results.

- 1. DWP propose that that Digital Governance becomes the overarching focus with 3 subgroups which members can focus on depending on their needs.

    - *Topics relating to Data e.g. who owns the data, what can we do with it, where should it be reported? GDPR, HIPAA, Cloud based systems, Big Data – what does this mean to the IVD industry?*

    - *Topics relating to day-to-day operational IT issues - Windows 10 and IVDR compliance. Laboratory data LIMS, NHS perspective and interoperability.*

    - *Topics relating to connected tools, Internet of Things (IoT) – test readers, portable PCR, Apps, mHealth, wearable diagnostics*

- Do you agree with this approach? Do you have any further comment?

- YES = 16

- NO = 2 (not interested in Digital/ Too Broad)

- Other = 2 (No time to answer, referred to a colleague.)

- Is there a priority topic among the 3 and why?

- Data (GDPR/ Patient Data) = 9

- Operations and Regulations (IVDR/UKCA) = 9

- Connected Tools = 2

- Other suggestions = AI/ CDS/Innovation to drive manufacturing.

- **What does 'digital' mean for you as a UK company? Same internationally?**

  - Same across the world - do things remotely, rely on data that can go straight into patient records.

  - Digital means products to sell and also the framework within which NHSE will operate, need more clarity about different requirements.

  - Enabler and facilitator of services primarily to the NHS and private labs - data, tests etc.

  - Covid home working IT systems, developing digital products, apps etc, digital security and safety of data, customer safety and operability.

  - Big data, using data effectively, digitisation, all for the benefit of labs. Operational processes/automation.

  - Digitisation of the NHS - labnostics. What requiremenrs are needed in future, info about hospital connectivity.

  - Means capturing data of non-connected analyser, gather data and centralise.

  - Same UK and internationally, safe methods of transferring (both data and equipment, communication) key to this.

  - GDPR etc/systems but also digital in terms of how tech will communicate with professionals/data.

  - Fulfilling NHS needs based on digital rules while driving best standards.

  - Data that is generated from tests and how that is handled.

  - Digitisation: paperless, automation etc, less on operational stuff. How can we improve society/patients through digital.

  - 5 different buckets could be 'digital'. SEO and Windows very different to say AI.

  - Specialist equipment supplier - see a huge opportunity to consolidate through digital connectivity between patient and hospital

  - UK and international requirements the same - how we use and comply by local rules in each territory.

  - New digitisation in products, massive changes ahead, how do we digitise equipment and support it? Seamless connectivity for customers.

Survey Questions

- Who in organisation is responsible for Digital and where are they based?

- DWP registered person

- All UK based.

- Observations – was intended to determine role and whether Digital strategy was determined in UK.

- All DWP registrants appear to be the only organisational interested party. This is unlikely.

- Need to discuss further.

- What would benefit your organisation most from attending this working party?

- Keeping compliant with all relevant legislation and standards.

- Keeping up to date with developments in "Digital" landscape.

- Information and knowledge sharing between companies.

- How to deal with the NHS requirements – issues and solutions.

- Promote standardisation across NHS as a group.

- UK and EU scope.

- Note on competition law = Discussing regulations, standards and different approaches **is** permissible. Discussing specific tenders and agreeing to any action that distorts the market **is not**. Policy advocacy and examining issues **is.**
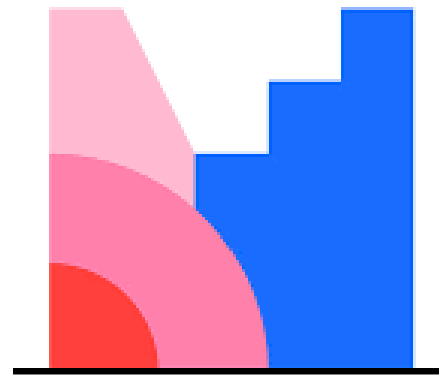
- Should the working party influence policy or just address day to day issues, or both?

- All but 1 member company says both, but all indicate that operational issues need to be addressed and understood before policy and BIVDA position can be determined.

- Day to day stuff can be boring.

- Policy to influence needs to be determined and a consensus agreed.

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- If both, how would you see this being undertaken?

- Ask companies for issues which can shape the agendas. (zero responses to survey's sent and no feedback from every meeting – this is why Ben called the group)

- Not engaging – people need to speak and contribute not just sit there.

- Cameras on and don't multi-task.

- Policy dependant on BIVDA staff

- Policy for the Exec Board

- Sub-groups depending on level of technical capability.

Mentimeter Polling

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