BIVDA

Genomics Working Party – Minutes
Thursday 23 November 2021
Teams

Welcome, Introduction and Competition Law – Helen Dent, BIVDA

Helen Dent welcomed and thanked everyone for joining the Genomics Working Party meeting, HD continued to remind everyone that the meeting was covered under the competition law rules. The competition law had been sent out with the invitation.

	Action	Responsible	Action By	Status
AP1 (July 21)	Regulatory information to be sent to the GWP bi-weekly	**RM**	**Feb**	**Open**
AP1 (Nov 21)	Philip Beer to create a document requesting comments in relation to the current GWP workstream	**PB**	**Feb**	**Open**

1. Update on Ecosystem workstream and current priorities - Dr Philip Beer, Chair

- Aware of the problems around pathways to access the NHS, both in terms of regulatory approval and in terms of remuneration.
- Planning a roundtable discussion in January 2022 with the aim to engage with the NHS to discuss the current problems and to begin looking for solutions. PB will endeavour to create a document and circulate it around the group for comment. **AP1**
- Thank you to those members who have engaged so far.
- There is a lack of clarity around the pathway on how to bring new technology into the NHS.

2. A patient's perspective – Jo Gumb, OcuMel UK

(see slides)

- Jo Gumb leads OcuMel UK which is a registered charity run by eye cancer patients and family members providing support for anyone affected by eye cancer.
- Data that is collected by the NHS routinely is being used poorly as it is difficult to access for research with patients not receiving any benefits from what could be achieved by using the data.
- Funded for three years by HDR UK (national institute for data science) to work with industry to make better use of cancer data.
- OcuMel have created a discreet patient group who are advised and given the skills they need by OcuMel UK. There are two patients on the Board in addition to there being two patients on the regular operational management group who are involved in any interview or employment decisions.
- The patients view potential contracts that OcuMel sign with commercial partners. Patients are always directly involved with the work.

- 300 patients a year will learn that their cancer is aggressive and terminal. There are some treatments that have now started to finally come through, but not enough.
- Jo Gumb's father was diagnosed with an advanced stage of ocular melanoma and passed away shortly after being diagnosed.
- Patient experience (in Jo's case) has been somewhat slow and ineffective, this must change. Treatment pathways must be fast and as clear as possible for patients to access any new developments for the pathways to work as quickly as possible for people.
- 47% of all cancer diagnoses in England are from rare and less common cancers.
- 55% of all cancer deaths in England are from rare or less common cancers.
- Rare cancers – there are practical implications involved because people must travel to special centres to have treatment, and this will come with financial implications.
- It is thought that 40-50% of cancers could be preventable, early detection is critical.
- Cost of early detection can reduce treatment costs – liver resection v ipi/nivo costs £120k a year.
- The way the effectiveness of treatments is monitored now will hopefully enable some development to be seen in the area.
- Survivorship – finance, impact on family, life choices must be considered once a patient comes through treatment.

3. Update on the current regulatory environment with the replacement regulation for CE-IVDR and the suitability of ISO 15189 regulatory standard - Robyn Meurant, Vice Chair, Ashleigh Batchen, Regulatory Affairs Manager, BIVDA

(see slides)

- BIVDA's new Regulatory Affairs Manager, Ashleigh Batchen introduced herself to the group.
- A proposal has been developed by the European Commission to introduce some deferrals of certain aspects of the new European regulation, the IVDR.
- The requirement for high level of safety and performance of devices is recognised however it is known that there is only six notified bodies at present.
- The Commission proposed that there should be some delays in the implementation of certain aspects of the regulation.
- Manufacturers will need to be aware that there are important parts of the regulations that will be fully implemented by 26 May next year however they will not have an extension.
- The new regulation will bring in new requirements for in-house tests or laboratory developed tests, the requirements will not be around the tests so much themselves, but the health institution that makes them.
- Under the regulation if you are a health institution after the 26 May 2022 you cannot transfer to another legal entity, your in-house test must meet the general safety and performance requirements.
- Others have been delayed until 2024 (e.g QMS requirements, public declaration of IHT
- MHRA has published the consultation for the new UK Regulations for medical devices with the consultation closing on the 25 November.
- BIVDA have formulated a response based on the member feedback and utilising the existing UKCA Sub-group.
- ISO 15189 has been revised to align with ISO 17025.
- ISO 15189 mentions that any in-house testing must be verified or validated in the laboratory.

- A proposed new standard has been put forward that specifies requirements for ensuring quality, safety and performance of laboratory developed tests (LDT).

4. UKRI & MRC - Kate Aylett, Head of Strategic Engagement, Laura Dickens, Associate Director of Industry Partnerships, MRC

- Formed in 2018 and comprised of a variety of councils which are all responsible for supporting the research and innovation ecosystem in the UK.
- Most of the funding goes through research led grant mechanisms
- There is a five-year review based on how all funding will be split out. At present about a third of this is designated to translation applied and two thirds in the discovery science section.
- The Medical Research Council works with industry across the breadth of its activity, it is engaging with industry and wants to hear the industry perspective in order to build it into all funding decisions and strategies moving forward.
- MRC engage with industry around through direct partnerships, where the MRC is directly working with industry to progress a particular area, for instance by supporting the academic industry collaboration.
- 216 research projects awarded with industry, with there being a successful output in terms of the income generated from companies from the research that's been funded. There has been a blue-sky collaboration between MRC and AstraZeneca.
- MRC are currently working on pre-clinical research projects to improve the understanding of discovery and fundamental biology.
- It is at the early stage in terms of the types of projects that are being funded as opposed to some of the later stage translational activities that are looking at the development of drugs or therapeutics.
- Translational funding scheme was set up over ten years ago by MRC with its aim being to support studies across clinical and translational medicine.
- After a review it was shown that the translational funding schemes showed a positive impact that the development of these schemes had on the ecosystem.
- The £70m spent on Translation Schemes is not an EU budget but part of MRC's budget (see slide 10)
- Key element is that the MRC is supporting academic and industry collaborations through the scheme.
- Working with AstraZeneca to enable academics to work with industry in terms of small molecule drug discovery.
- Since 2008 they have supported 296 projects, with 47 of them having been diagnostic projects.

5. EUCOPE/ BIVDA – Roundtable Briefing - Helen Dent, BIVDA, Mathias Olsen, EUCOPE

- 19 January 2022 at 10:00am. Angela Douglas has agreed to join the roundtable briefing. In addition to Professor Michael Richards to discuss the report that he has written.
- Philip Beer has agreed to be a panellist.
- Professor Mike Messenger from the MHRA has been invited to attend.

Next meeting date: 25 January 2022, 10.30am – 13.00pm. Register here.

Meeting closed: 15.00pm