BADGEM Informatics Meeting Minutes
14:00, 5th July 2017

In attendance – Neil Rajan (Chair), Irene Leigh, Edel O'Toole, Celia Moss, Simon Tso, Zoe Venables & Alexander Lyons

Apologies – Mozheh Zamiri

AGENDA ITEMS

1. Update on the register in Scotland (MZ). Mozheh Zamiri was unable to attend this meeting to provide an update on the registry in Scotland.

2. Update on the progression of register across the UK; Survey for regional BADGEM representatives (NR). Extending the registry to England was discussed in the BADGEM Steering Committee meeting at 08:00 this morning. The Regional Representative Survey showed promise with 19 of 38 responses expressing an interest in volunteering to be regional representatives.

Neil Rajan agreed to contact potential candidates from the Regional Representative Survey to ask them if they would be willing to consent and register patients and to provide their Curriculum Vitae for shortlisting, given the various experiences between the potential candidates.

It was proposed that regional representatives will constitute a liaison between the BADGEM Steering Committee and other consultants, and not necessarily be experts with laboratories. The rationale is to relieve pressure on experts such as professors. Perhaps the regional representatives can also involve their trainees or team to consent and register patients locally as the project expands. The possibility of involving people that recruit participants for the 100,000-genome project was discussed but concluded as unfeasible because this is mostly done by geneticists and not dermatologists.

It was agreed to expand the registry to England under the existing ethical approval from Scotland, if possible, instead of submitting an ethics application to an English REC for approval to enter data into the existing HICK Registry. It was brought to attention that Dundee has yet to receive site-specific approval for the Registry according to a prior conversation between Sarah and Edel O'Toole.

Neil Rajan, Edel O'Toole and Zoe Venables agreed to have a conversation with Mozheh Zamiri to acquire site-specific approval for other sites including Dundee and England.

It will be practical to open the first three sites in England where Neil Rajan, Edel O'Toole and Zoe Venables (Leicester) work to oversee the initial process. This may involve the HRA. Following this, consent forms and local documentation will need to

be printed and then, in theory, recruitment can commence. Recruiting patients to the registry should be an ongoing process as they are seen by clinicians in the first instance. It was noted that the number of patients seen per site, per day will vary and this will affect recruitment to the registry and therefore appointing a high number of regional representatives should accelerate recruitment.

Sourcing anonymised information from existing groups/databases such as the GOSgene, EB and Open App databases was discussed and it was brought to attention that ER and Skin have a lot of working groups including an informatics group. The GOS commented on their registry being more extensive than a minimal dataset, given that deep phenotyping is done on a range of conditions, and it will not be feasible to re-consent patients for use of their diagnostic data for BADGEM but they are happy to respond to our calls. It was suggested that a mechanism is needed in the BADGEM registry to allow collaboration with other groups.

ERN projects are generating guidelines for minimum dataset registers for Europe, which are like the BADGEM registry, and developing functional platforms. Their meeting in May focused on data management surrounding the EB database and the next meeting is on the 20th November, which Fiona is going to attend as she is unclear about the status of Open App.

Neil Rajan agreed to contact Allen and Dmitry for an update on Open App, since they were both involved with this previously, and ask them for a list of their patients, if possible.

There may be other repositories that will request data from the BADGEM registry and we will therefore seek advice from our data management panel about consenting patients to share information with other sites.

3. Changes to BADGEM leadership and Committees. There is the issue of changing the memberships of the committees. Reducing the size of the Steering Committee was discussed and agreed in the BADGEM Steering Committee meeting at 08:00 this morning

4. Fellowship post – update from ZV. No changes to the PHE disease register since the previous meeting. Data continues to be added to the congenital anomalies register but this is not relevant to dermatology at this stage. Section 2.5.1 restriction prevents such data from being shared at patient level. Zoe Venables shared the non-melanoma skin cancer data with the UK TREND team.

5. A.O.B. Best contact Mozheh Zamiri by telephone to discuss site-specific approvals as opposed to a series of emails between Neil Rajan, Edel O'Toole and Zoe Venables. Edel is available to have this conversation either on a Monday or Wednesday afternoon (after 14:30) and Neil will approach Mozheh with dates based on that.

6. Next Meeting March/April 2018 TBC. To be organised in January 2018 with the BADGEM Steering Committee meeting. Invitations extend to elected Regional Representatives.

ACTIONS POINTS

- Neil Rajan agreed to contact selected candidates from the Regional Representative Survey to ask them if they would be willing to consent and register patients and to provide their Curriculum Vitae for shortlisting.
- Neil Rajan, Edel O'Toole and Zoe Venables agreed to have a conversation with Mozheh Zamiri to acquire site-specific approval for other sites including Dundee and England.
- Neil Rajan agreed to contact Allen and Dmitry for an update on Open App since they were both involved with this previously.

POST-MEETING ADDITIONAL INFORMATION

Mozheh Zamiri - Site specific approvals from all Health Boards in Scotland have been received following national ethical approval for Scotland from the East of Scotland Research Ethics Committee. All of these approvals have been sent to me directly including for Tayside.

Sara Brown is the listed local collaborator for Tayside but had expressed some private concerns to me about the premise of the database despite full ethical approvals and a full Caldicott Guardian submission to eDRIS, Edinburgh, and in terms of her current workload. In respect of this, Irwin McLean recommended that the other 10 Health Boards are supported to get up and running as a priority, as their local collaborators have been very enthusiastic about being involved and we have tried to capture this energy. Each Health Board is coming on board in terms of patient recruitment according to an appropriate timescale, which is working well and we are meeting our targets to date. Tayside is currently listed to be the final local team to come on board although it is incorrect that site specific approvals have not been received for Tayside.

Tayside R&D (the Scottish Database sponsor) were informed that England and Wales would seek their own ethical approvals and would not be piggy backing onto the Scottish ethics following the Informatics meeting in January, as Neil and Simon wished to submit ethics as a "research project" and not a "database" and intended to seek their own sponsor in England. HIC were similarly informed at this time that England and Wales would have a stand alone database to Scotland. I hope this helps clarify matters.

Finally, I have asked previously for Irwin McLean to be included in the group email regarding minutes and Informatics Group meetings as he is currently the funder for the database and closely involved in the Scottish work. I hope he can be included in the future. Thank you.