

UKPID Registry Committee Telephone Conference,
Monday 25th January 2016 2pm

Present: , Matthew Buckland, David Guzman, Austen Worth, Andrew Gennery, Ben Shillitoe, Hilary Longhurst, , Sarita Workman, Cathy Bangs, Stephanie Farrell

1. ***Apologies:*** None
2. ***Welcome to new members:*** Matthew welcomed the new members of the UKPID Registry Committee: Austen Worth for GOSH, Andrew Gennery and Ben Shillitoe for Newcastle paediatrics and Sarita Workman from the Royal Free as nurse representative.
3. ***Minutes of the last meeting:*** (28th September 2015 telephone conference) : accepted
4. ***Validation of level 1 data progress/Transfer of level 2 and 3 data:*** To date, 929 entries have been validated and have a complete dataset on the new design UKPID Registry, which is good progress. The ESID Registry is no longer including 2nd HGG and HAE, but Matthew has set the diagnostic criteria so we can continue to include these in the UK Registry. Diagnostic criteria for Acquired Angiodema still need to be written. David said very few users had applied for a password for the new system. Matthew suggested sending out a newsletter reminding users to request a password from David and for the PIs at each centre to validate the diagnoses of their entries if they haven't already done so. Cathy said it would be useful if the level 2 and 3 data could be transferred to the new registry as soon as possible, as this will be needed for research studies and also means the data can be entered altogether in one visit, rather than requiring further visits to add the level 2 data. Matthew said that not all the datasets had been signed off yet, but he will email Gerhard Kindle to see if the transfer is possible.
5. ***Minor Amendments 4 and 5:*** Minor Amendment 4 was to remove the reference to the Plasma Protein Therapeutic Association (PPTA), previous funders of the ESID Registry, from the Young Persons consent form (ages 11 to 15). The children's and adult forms weren't affected as they didn't contain the reference. The change was prompted by a request from Gerhard Kindle in order for the consent forms to be accepted for the APDS study (Activated P13 Kinase Delta Syndrome). Minor

Amendment 5 implemented a change in PI at Newcastle adults to Dr Helen Bourne as Dr Gavin Spickett has now retired.

6. ***GOSH and Newcastle amendment approval/data transfer:*** GOSH and Newcastle paediatrics have a different system for entering data. The data was previously downloaded from their own database into files and sent directly to Benjamin Gathmann at ESID, then transferred back from the EISD to the UK registry. More recently the data files have been sent to David Guzman to enter onto the UK Registry and these would then be included in the annual transfer of UK data to ESID. At most sites Cathy or Steph visit to enter the baseline and follow up data – at a few, local staff enter data. As the GOSH and Newcastle system is different, it runs under a separate REC number. When Cathy was liaising with R&D offices about the recent minor amendments, it came to light that the information sheets/consent forms at Newcastle and GOSH include the REC number used by other sites rather than their own REC number. Cathy asked about the ethics approval as she doesn't have the documents for the paediatric approval. Austen said he will speak to his R&D department about this and liaise with Cathy. Regarding the data transfer, Cathy said that not many of the fields were completed in the automatic data transfer, which could be due to these fields not being present in the local database, the data not being completed in the local database or a problem with the mapping of data between the local data base and the registry. In particular, the latest visit date is not transferred. Cathy will provide Newcastle and GOSH with a list of the required fields and those that aren't being successfully transferred.
7. ***Research proposals: Peter Arkwright Thymoma and XLA/ Hilary 2nd HGG:*** Peter Arkwright's proposals have been approved. Hilary said she hasn't received any feedback regarding her proposals – Cathy to re-send the information to the committee. There was some discussion on the potential level 3 study from Biotest. This type of study provides much needed funds for the registry. We are waiting to hear if Biotest want to go ahead with this. We would need to have the Level 2 datasets in place in order to implement such a study.
8. ***Activated P13 Kinase Delta Syndrome (APDS) study:*** This study is running on ESID and has been adopted by the UK with central funding directly to UKPIN. 6 UK patients have been registered to date, 3 from Newcastle and 3 from Belfast. There are thought to be around 20 in the UK in total. At a few sites we are waiting for patients to be consented (or re-consented where the existing consent form is pre 2009 or has been incorrectly completed). We need the level 3 dataset for this study in order to be able to contribute our data- David is working with Gerhard to transfer this to the UK Registry over the next few weeks.
9. ***Centre status:*** Preston has recently gained R&D approval bringing the total number of sites to 36. The R&D office at Bristol adults (Southmead) required a data processing contract to be in place between UCL and UKPIN. This has now been

completed and sent to R&D, but we are still waiting to hear if they are happy with it so we can continue the approval process.

Adults without capacity: Cathy suggested a substantial amendment to include adults without capacity as they were excluded in the original ethics application. Austen brought up the issue of consenting children that are currently under the care of social services without a specific guardian. Cathy will request advice on this from ethics before submitting any amendment. The current priority is to get all the entries validated and Level 1 dataset complete, so there will be a delay in raising the amendment.

10. AOB: Cathy asked if there was any progress in adding the live stats pages to the UKPIN registry webpage. These show the recruitment (“alive” patients only i.e. not deceased, discharged or lost to follow up) by centre and by diagnosis. Matthew will email Tomaz regarding this.

11. Next Meeting – Cathy to arrange in 3 months.