

UKPID Registry Committee Telephone Conference,
Monday 20th June 2016 2pm

Present: , Matthew Buckland, David Guzman, Andrew Gennery, Ben Shillitoe, Sarita Workman, Cathy Bangs,

1. **Apologies:** Austen Worth
2. **Minutes of the last meeting:** (25th January 2016 telephone conference) : accepted
3. **Change of members:** The new membership is Matthew, David, Austen, Andrew, Ben, Sary and Cathy
4. **Validation of level 1 data progress/recruitment progress:** Cathy circulated a progress report before the conference showing recruitment per centre and Level 1 data complete. The current total is 4165 entries, with 3888 active (i.e. neither deceased nor lost to follow up). 2734 have been validated and have Level 1 complete. David said transfer of data should be fairly straight forward in the new design. He is waiting to be given dates for transfer of our data . Only data with Level 1 complete will be accepted. Matthew will contact Nizar to try to move things forward and set a date. In the new system we should be able to transfer data more frequently.

Matthew has looked into funding for the registry from various bodies but hasn't been offered any money so far, so for the foreseeable future UKPIN will be unable to employ another study coordinator. Pharma companies fund UKPIN and are unwilling to provide separate funding for the registry. Current funding covers Cathy 4 days a week (0.8 WTE).and David one day a week(0.2 WTE). Andrew asked what the cost would be of a second part time coordinator and Matthew said around £30,000 per annum plus travel expenses. NIHR funding is not available for established studies, although it may be possible to get NIHR funding for a new multi centre level 3 funded study. Andrew suggested approaching the companies who make monoclonal antibodies as they have a niche market. See point 11 re MDSAS funding.

5. **Transfer of Level 2 Code:** Matthew has spoken to Nizar about making Level 2 available. He said the datasets have been agreed but the code hasn't been completed yet and we don't have a date when it will be ready.

- 6. Secondary HGG study :** This study has been approved, however it involves level 2 data which is currently not available. Matthew suggested using the historic data (up to October 2015) and will check with Hilary if she wants to go ahead with that. David is unable to add any new fields (needed for Level 2 Secondary HGG and HAE) without receiving the source code from Freiberg. He will request this.
- 7. UKPID Registry comparison with IOS:** This research proposal from Hilary has been sent to committee members for approval. Shire collect data on HAE patients in the Icatibant Outcome Survey, but only from a few centres. The data overlaps with registry data. The registry collects far less data but many more HAE patients. Depending on the results , it may be possible for the registry and Shire to work together with Shire willing to fund this. Cathy will send out a survey monkey for response – please complete asap.
- 8. Level 2 data for HAE:** Since ESID no longer include HAE data we are free to add in whatever fields we want for the Level 2 HAE dataset. As stated in point 6, David cannot add these without first obtaining the source code from Freiberg.
- 9. APDS Study:** This is a level 3 funded project from ESID. 24 patients to date have been identified as eligible , 10 have been registered and a further 3 are in the process of registration. The CRFs are very detailed and have recently been made available online. Of the 10 registered, so far 2 have completed CRFs.
- 10. Thymoma and XLA studies:** these are going ahead as planned.
- 11. MDSAS project:** MDSAS run the National Immunoglobulin Database. David Edgar has been working with them to compare their database with the registry to produce a combined report of triangulated data. The National Immunoglobulin Database is funded by the Department of Health , so Matthew has discussed with MDSAS the possibility of merging the 2 registries with overarching Dept of Health funding. MDSAS are taking this to their steering committee .
- 12. Substantial Amendment:** A substantial amendment is need to clarify the eligibility criteria for the registry and to add adults who cannot consent for themselves. The HRA have recently taken over the amendment process and were swamped with applications so have asked no further amendments be submitted for the time being. Cathy will take this forward as soon as possible.

Cathy will check if a minor amendment is needed for transfer of the main site when Matthew moves at the end of July from Barts to his new post between the Royal Free and GOSH.

- 13. AOB Diagnosis validation:** Cathy brought up the problem of diagnosis validation for CVID patients diagnosed pre 2000, for whom she cannot find documented evidence of pre treatment IgG levels or vaccine response. According to the ESID diagnostic criteria these entries should no longer be included as CVID, but moved to

Unclassified Antibody Deficiency (if one of the above is available) or Unclassified Immune deficiency (if neither available). This will result in large numbers of patients in the unclassified groups and may not be what we would want for the UK registry. Cathy will report the numbers involved and Matthew will discuss at the ESID steering group and check if other countries have problems with this.

14. *Next Meeting* – Cathy to arrange in 3 months.