

UKIVAS steering committee meeting minutes

April 22nd, 2015 (12:00 to 13:30)

Business Design Centre, London

Attendees: Richard Watts, Mark Little, Richard Watts, Alan Salama, Mike Venning, Neil Basu, John Mills, Nina Brown, Paul Brogan, Mike Robson

In attendance: Cristina Ponte, Jan Sznajd

12:00 Linking RareRenal and UKIVAS databases (Detlef Bockenbauer, Chairman RareRenal)

- Detlef got the day wrong, so **held over until next meeting**

12:30 Ethics amendment, sponsorship and governance (Anthea Craven, Richard Watts)

- 2-stage process, rather than closing the study.
 - Transfer of sponsorship to Oxford major amendment; agreed. Documentation need to be changed. No change to active participants. New recruits will use revised documents
 - Main amendment to include storage of NHS number once first amendment completed.
 - Protocol will need to be revised (developed de novo) to fit within Oxford template. As simple as possible.
 - Revised information and leaflets revised, to include industry collaboration in the future. Link to other approved projects.
 - PIL and consent form to be shared with Nina Brown to ensure aligns with VasCOT
 - Ability to contact people by email / phone, which may facilitate re-consent. Broad dynamic consent. Neil Basu noted that only 20% of people opt for online consent.
 - Keep options to mix and match consent elements as simple as possible.
 - Richard Watts: Rituximab patients whom NHS England mandate registration, who refuse consent. Nina Brown suggested that such individuals be stored locally only, without central transfer of data, as part of NHS care.
 - Re-consenting process will be defined within the amendment: must be very carefully managed within database (version control etc). Must be a mandatory field.

Occurs at routine visit and by telephone/post if possible.
Draft letter to be included in amendment. Involve nurses in designing this.

- CLRN funding for re-consent process? Not clear whether nurses will be supported to do this (or indeed enter longitudinal data).
- Separate SOPs to cover sample collection.

13:00 Database development (Anthea Craven)

- Issue with how people allocated IDs (Imperial), leading to mismatch. We cant see what they have got. As it stands, not robust enough to ensure data quality. This may be addressed once NHS number stored locally.
- Database development is stalled due to issues with Joe Rosa availability. He is solely supported by CLRN funds currently and therefore most of his time is going to orthopaedics.
- Ongoing issue of philosophical approach comparing DCVAS approach v current UKIVAS approach. UKIVAS has pursued the modular database design championed by Joe Rosa for the last 18 months.
- **General thrust of group was towards starting again with a DCVAS type approach;** employ new programmer under the direction of Joe Barrett using existing Vasculitis UK funds.
- The interface may be web based rather than app-based.
- Need an estimate of how much programming time required to push this forward to guide an estimate of the funds required. **This should be addressed in a teleconference within 6 weeks.**
- Richard Watts noted that to simply add the NHS number does not need a full re-programming; could be added by Joe Rosa in a couple of hours.

AOB:

1. Funding issues.

Now critical. 6 months left from Vasculitis UK for programming. Much emphasis placed on potential NHS funding stream linked to biologic prescribing, pursued by Peter Lanyon.

Meeting occurring later this week that should clarify this.

Vasculitis UK: Needs to be self-contained and defined end point, but John Mills willing to bring this to the charity. Needs to be made more tangible in addressing a question.

Industry interaction: preliminary link between Cambridge and Roche. Issue of different companies being sensitive to involvement of other companies raised by Richard Watts; eg using the data to compare 2 agents from 2 companies. Faced by BSR as well, contractual problems. BSR acted as “middle man”; this concept may be useful for UKIVAS, perhaps using EUVAS as the middle man as negotiator between UKIVAS and industry. There may be issues with UKIVAS being both the developed and maintainer of the database, as well as the contractual link with industry.

Grant funding: Alan Salama proposed a big data project that links to electronic health records in collaboration with Harry Hemingway and the Farr institute. He suggested that **he would start drafting a fellowship proposal**. Neil Basu offered to share a similar Scottish proposal as a basis for a draft.

2. Now **45** sites active or pursuing activation
3. ukivas@ndorms.ac.uk now active as sole means of communication with sites
4. Turkey, Poland, Adelaide, Switzerland additional sites. How to handle these, given that most would like to simply clone the software for use locally?
 - a. Should the data be returned to Oxford or retained in each country? They should be responsible locally for data quality.
 - b. Raashid suggested that current V1 database be made available for free to international users (“UKIVAS-lite”), with charges for the longitudinal version.

Next meeting:

TC in 6 weeks to discuss programming strategy

TBC: around October