UKIVAS - Committee meeting minutes:

Dec 8th 2015 (11.00-13.30 to be followed by Lockwood club meeting 14:00-18:00)
Graham Story Room, Trinity Hall, Cambridge
Attendees: Mark Little (ML), Richard Watts (RW), Jo Robson (JR), Raashid Luqmani (RL), Peter Lanyon (PL), Alan Salama (AS), Paul Brogan (PB), Ann Morgan (AM), Anthea Craven (AC), Mike Venning (MV), John Mills (JM)

Also in attendance: Maria King (MK), Angela Reynolds (AR), Pani Gopaluni (PG), Len Harty (LH), Kate Jones (KJ)

Apologies: Jackie Andrews, Neil Basu

RIVAS. Contract b/w Cambridge and Roche being signed this week after 2 years of development. RTX v non-RTX cohort. AC and MK will work on a sub-contract between Cambridge and UKIVAS to allow development of relevant "Rituximab Module" fields for EMA purposes, which will be accessible for use to all UKIVAS registry members. This will supply a software development funding stream for 5 years, which will also be usable for development of additional longitudinal fields. Roche will receive a 6-monthly aggregated data export. UKIVAS will own the dis-aggregated data.

UKIVAS end date: Mid 2019. RL raised the concept of developing a separate research database which will get around the issue of continuously renewing the registry ethics, which the Oxford ethics committee have raised concerns about. This would effectively mean that following completion of the UKIVAS registry, this would deliver a "son of UKIVAS" research database, with appropriate governance and data access committee, while the registry would continue to serve as an NHS main-streamed clinical tool.
The issue of loss of CLRN portfolio status will be a major issue as this develops. Of note, the BSR biologics register is on the portfolio.

Linkage to TARGET MRC project (AM). This infrastructure partnership aims to generate a GCA cohort study, with genomic analysis. AM keen to create a data sharing exercise with UKIVAS. One potential option is to use UKIVAS software infrastructure for TARGET (GCA data currently exist in paper format).

UKIVAS ethics re-boot (AC). Sponsor transfer complete. 2300 patients. 36 active sites, 6 under review. The primary goal is to allow **data linkage**, although it was noted that the ethics process is very cumbersome. There will be a system for consent management; the consensus was that we should limit the number of options that people can consent to, as this greatly increases the complexity, and was supported as an approach by JM. A new UKIVAS website is under development, which will mirror the DCVAS interface, which was shown by AC. The app will be retired.

RUDY is continuing to develop, but not yet linkable to UKIVAS; however, it does provide an excellent opportunity for self-referral and patient reported outcomes. This would require funding.

Working group for pulling together the expanded UKIVAS fields: AC, ML, JR, AM, MK, RL, PL, to convene as soon as possible. AC will manage this process.

Phase 1: RIVAS development

Phase 2: Wider UKIVAS data dictionary (which has already been developed: needs to be organised).

Action: Letter of support from Vasculitis UK stating that they are keen for data linkage to go ahead.

UKIVAS-lite: to support commissioning. This would sit separately from UKIVAS and would serve to allow purely audit data capture in the minority in whom we don't have formal UKIVAS consent. It was felt that this would need specific ethical approval or consent. Data won't be usable for research. Will look and feel the same as UKIVAS interface. No money currently available; if NHS England makes funding available, we will begin development of this. Until that point, collective decision to keep on ice.

Samples collected under UKIVAS. This has become a tricky issue. Some centres are looking to re-house their samples, but no resource exists for UKIVAS biobanking. Cambridge samples are stored in the local NIHR bioresource (which requires separate consent). This is not an easy option for most centres. It is possible to funnel samples through local BRCs; specific consent would need to be obtained locally, which would pose a logistic challenge.

European Reference Networks. Major EU commission initiative looking at developing formal networks for rare diseases. The first call will be April-May 2016. Vasculitis will fit under the Rare

Immunological / Autoimmune / Autoinflammatory umbrella. Any centres that wish to join this network must be signed off as centres of excellence by DOH. The designation process will derive directly from specialist commissioning: if a centre is commissioned for specialist rheumatology they will be eligible. This may be an issue for pure nephrology centres, such as RFH, who would have to link with their local rheumatology colleagues. There will not be lots of money for the network per se, although access to H2020 funds will likely be contingent upon membership of an ERN. A maximum of 4-5 centres will be allowable from the UK. It was felt that the most appropriate approach would be **for UKIVAS to function as the UK centre of excellence**; we (PL) would have to ask NHS England to endorse UKIVAS for this purpose. UKIVAS is most closely aligned with the Behcets network. ML will continue to feed back to the group as more information becomes available.

Action: PL investigate the concept of UKIVAS acting as a single centre of excellence

UKIVAS-NHS England interaction (PL). Rare disease commissioning and policy development outsourced to Deloitte; we must have mechanisms for capturing outcome and service data that will feed into policy. Audit will be key to this. Allows for RTX maintenance (a departure from NICE). Inequity with Behcet's commissioning? Under review next year. NCARDS is the entity of greatest relevance, which is operating under section 251 consent; this potentially could offer a route to NHS mainstreaming of UKIVAS. A standalone biologic audit platform has been set up in Derby (not a UKIVAS centre), which has a strong audit informatics setup.

RaDaR interaction (ML). 951 vasculitis patients have been recruited to RaDaR, which is currently not being curated; about 100 of these are also in UKIVAS, but there are 15 centres (Lister, Preston, Stoke the principal ones) that recruit solely to RaDaR. RaDaR recruits are linked to the data warehouse, which provides automatic population of blood results and meds, and to PatientView, which allows for patient data entry. There are 3300 recruits between UKIVAS and RaDaR. It was decided that UKIVAS would take control of the RaDaR recruits and to include them in the UKIVAS "inventory". We would work towards adding some of the core UKIVAS vasculitis fields to RaDaR and to linking the two databases using NHS number.

Next meeting: Leeds, hosted by AM and Jackie Andrews