**SIMPLIFIED Trial - Renal Data Collection [UKRR] Meeting**
**8th September 2015 Time: 16:00-17:00**

| Purpose of the meeting |
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| **To explore the available options and plan processes for the CCTU to obtain patient data from the UK Renal Data Collaboration (UKRDC) in order to meet the SIMPLIFIED trial protocol requirements.** |

**Attendees:**
***Cambridge Clinical Trials Unit (CCTU):*** *Thomas Hiemstra (Senior Trials Fellow), Amanda Collins (Clinical Research Coordinator), Paul Jones (Senior Database Programmer)*
***UK Renal Registry Representatives (UKRR):*** *Fergus Caskey (Medical Director), Keith Simpson (Medical Advisor), George Swinnerton* (*Senior Programming Lead)*

**Apologies:**
N/A

**MEETING MINUTES**

1. Trial overview:
    - *THiemstra* provided a brief overview of the trial and the anticipated interaction with the UKRR. Trial timelines are planned for First Patient First Visit 1st March 2016.

2. Patient data discussion :
    - **Patient data to UKRR:** Patient data is sourced via automatic download from the renal unit databases; it is envisaged that data for SIMPLIFIED will be obtained from the PatientView (PV) dataset. In order for the patient data to be obtainable for transfer, local units will need to insure that the PV box is ticked.
      Potential challenges include:
      <u>Utilising data from patients who are not currently or do not necessarily wish to use PV</u>
      Solution – local investigators obtaining consent will explain that consent to the use of the PV dataset does not mean patients need to use PV.
      <u>Quality of data</u>
      There may be incidences where data is incomplete depending on how the different renal units work. Solution- educating the trial sites / having an agreement around expectations for trial patient data would be beneficial. To this point *THiemstra* emphasised the trial needs to be pragmatic and the protocol not too restrictive to avoid non-compliance. It was agreed any detailed guidance around this would sit better outside of the trial protocol.
    - **UK renal data collaboration (UKRDC):** The UKRDC collects data on all dialysis patients nationally, and receives data feeds directly from renal units. The dataset currently sent to the UKRDC is being modified, and the more detailed set will only be fully implemented once the trial has already commenced. SIMPLIFIED will therefore harness the PV dataset (currently sent to the UKRDC) and this will be sufficient for the purposes of the trial.
    - **Data transfer to CCTU:** *GSwinnerton* explained that data can be pushed or pulled from the UKRDC as often as daily if required. *PJones* explained preference would be to pull the data in to the CCTU database. UKRR requested a list of variables CCTU wish to transfer; in addition what background information may be required such as laboratory ranges and methodology (metadata) on a per renal unit basis. **Action: ACollins / THiemstra** will compile the dataset required from the UKRDC for trial participants.
    - **Geographical implications:** England, Scotland, Wales and Northern Ireland all currently feed in to the UKRR data repository.

- **Data from questionnaires:** the use of EQ5D is planned for the trial quality of life assessment, it may be possible to utilise the Patient View interface to collect the required data directly from the patient; this is something that can be explored further. **Action: Agenda item for future meeting.**

**3.** Patient Information and Informed Consent discussion:

- **Data protection and confidentiality:** it was determined it is essential to ensure the relevant level of detail is present in patient information material and consent forms so that patients are fully informed around the transfer and use of their data. The CCTU would provide a draft of the patient information sheet / consent form to UKRR for review / input. **Action: ACollins / THiemstra.**
- **Per patient notification:** UKRR data management will require explicit notification on a per patient basis (via an XML file) that the relevant consent has been verified *prior* to release of any data for that individual. **Action: PJones / GSwinnerton** to liaise around this to test the file transfer process for notification.

**ACTIONS**

| # | Actions | Owner | Target Completion date |
|---|---|---|---|
| **1** | Provide the dataset and any background information required in terms of data to be transferred from UKRDC | ACollins / THiemstra | 30Sept2015 |
| **2** | Explore use of Patient View interface to collect EQ5D data | CCTU/UKRR | Agenda item for future meeting TBD |
| **3** | Provide draft patient information sheet and informed consent to UKRR for review and input | ACollins / THiemstra | 30Sept2015 |
| **4** | Test the file transfer process for per patient notification to UKRR data management | PJones / GSwinnerton | Ongoing |

**NEXT MEETING:**
**2nd October 2015 Time: 16:30**