**Phase I Advisory Group**

**Minutes**

**6 February 2014**

**11:00 - 14:00**

**Present**

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| Richard Tiner | Chair | RT |
| Catherine Blewett | Health Research Authority | CBl |
| Joan Kirkbride | Health Research Authority | JK |
| Clive Collett | Health Research Authority | CC |
| Tom Smith (items 1-5) | Health Research Authority | TS |
| Gary Johnstone | BioKinetic | GJ |
| Malcolm Boyce | HMR | MB |
| C Brearly | ABPI Experimental Medicines Group | CB |
| Simon Lee | Quotient Clinicals | SL |
| Sarah Dobbin | Quotient Clinicals | SD |
| Ulrike Lorch | Richmond Pharmacology | UK |
| Keith Berelowitz | Richmond Pharmacology | KB |
| John Keen | Brent REC | JK |
| Daryl Rees | Cambridge East REC | DR |
| Ian Skidmore | Hatfield REC | IS |
| Siobhan McGrath | HSC Northern Ireland | SM |
| Stephanie Ellis | Hampstead REC | SE |
| Poonam Chowdhary | Quintiles | PC |

**Via teleconference**

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| John Sheriden | Berkshire B REC | JS |
| Peter Dewland | AHPPI | PD |
| Jennifer Martin | MHRA | JM |
| Raj Bains | Oxford A REC |  |

**Apologies**

Art Tucker - London City & East REC

David Carpenter - Berkshire REC

Kath Osborne - REC Manager: GM Central REC

Peter Heasman - York REC

Deidre McCollam - Biokinetic

Roger Rawbone - GM Central REC

Christiane Abouzeid - BIA

Chris Vallin - Surrey REC

Joe Brierley - Bloomsbury REC

Ashley Totenhofer - Bloomsbury REC

Jan Downer - Harrow REC

Noel Landsman - Quintiles

Susan Tonks - Berkshire REC

Anita Chhabra - Cambridge Central

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| **Item** | **Item details** | **Action** |
|  | RT thanked those present and joining the meeting by teleconference for attending, especially due to the travel disruption.  RT requested that item 5 (Update on the Clinical Trials Regulations) be brought forward on the agenda to before item 4 (Registration of all Phase 1 clinical trials as a condition of the favourable ethical opinion). This was due to the context of the EUCTR being relevant for the discussion regarding clinical trial registration. |  |
|  | **Minutes of previous meeting on:** 25 July 2013  The minutes were agreed as an accurate record.  RT noted that in the last meeting (25.7.13) the group agreed for the minutes of the meeting to be published. There had not been any required redactions identified but RT asked the members of the group to inform CBl of any required prior to publication on the HRA website. | **All** |
|  | **Matters Arising**  4.2 - Patient volunteers with active disease where there is no therapeutic benefit - Confirmation had been requested regarding which type of REC such studies should be reviewed by. JK confirmed that they fall under the remit of Phase 1 as they fall under Phase 1 insurance requirements. This will be clarified as part of the ongoing work to revise SOPs. Clarification would also be included in a NRES staff Operational Management Email Alert to ensure that staff are aware to manage such studies in line with Phase 1 studies in healthy volunteer timelines.  3.3 - RT stated that the Terms of Reference for this group needed revising. It was agreed that a tracked changes version of the document tabled at the meeting would be sent out to members. All comments should be sent to CBl. This document will then be revised and shared before the next meeting.  4.1 - CC informed the group that the National Research Ethics Advisory Panel had reviewed a document regarding payments which included offering luxury items, particularly in regard to comparing the cost of the item with monetary value. This issue had not been picked up by the panel however and no further guidance had been offered on the matter.  JK suggested that if the offer related to a specific study then this would be reviewed by the REC and be considered as part of the ethical opinion. If generic however, this could go through the generic review committee. The generic review committee members confirmed that this issue had not arisen to date. It was queried whether CROs or industry had requested such guidance and JM noted that this had come up through a complaint received by the MHRA. A member of the public had complained that luxury items such as i-pads might be seen as coercion. JM suggested that from a MHRA perspective, if the stance was clear in the SOPs that if the advertising is part of the study it is approved by the REC, if it was generic then this would be the responsibility of the site, this would be acceptable.  4.3 - This point refers to the potential need to declare payment for tax purposes. This should also include reference to declaration for benefit purposes too. This is an area where currently a more unsympathetic stance might be taken by the officials in the field. The group noted that the issue was whether the HMRC accept expenses and not in excess of £8,000. | **CBl**  **CBl** |
|  | **Update on the Clinical Trials Regulations**  CC explained that the paper which had been distributed to the group had been written by Sue Bourne and set out the text which had now been agreed. The text will now go through language and legal checks prior to being formally adopted by the European Parliament before being officially published.  The expectation is that the Regulation will come into force two years after being published which will be mid 2016. However, there is a caveat which states that the Regulation will not come into force until the EU portal is up and running. It has been agreed that the EMA portal will be responsible for the EU portal. It was queried whether they would be true ECDT submissions. CC suggested that this was not clear at this stage but Sue Bourne may be able to answer this. There may be implications if published in this format.  RT suggested that Sue Bourne be invited to attend the next meeting to update the group regarding this matter as it will be an important factor. JK stated that the HRA and MHRA had been heavily involved in the negotiations which is reassuring.  CC explained that The new Regulation will introduce:  • A simplified application process - one application will be submitted regardless of how many Member States will be taking part in the trial. This will replace the current situation of individual submissions to each competent authority and ethics committee(s) in each Member State. Additionally, the requirements for the application package, which will be submitted electronically via an “EU portal”, will be harmonised  • A streamlined process for review and authorisation – there will be one authorisation (decision) for the trial in each Member State, replacing the current separate approvals of competent authority and ethics committee(s). Where multiple Member States are involved in a trial the Member States will jointly assess the application, except in respect of defined aspects, such as ethical review. The processes and timelines are defined (up to 60days for decision on an initial application (where no questions), rising to maximum 91 days where questions asked at each stage); tacit approval is assumed where timelines are missed.  • A category of “Low-intervention trials” – where trials fall into this category they are afforded less stringent requirements for monitoring and documentation.  • Rules on the protection of subjects and informed consent – these are intended to harmonise requirements but still allow for national rules in some aspects, such as who may act as a legal representative of a subject or legal age of consent. Additionally provisions have been added for some particular areas of interest to the UK, such as trials in emergency situations and cluster trials.  • Transparency requirements - all clinical trials in the EU will need to be registered and summary of results must be published within one year of the trial ending. Additionally where a clinical study report (CSR) has been submitted in support of a marketing authorisation (MA), it must be made available by the applicant within 30 days of the regulatory decision on the MA application. Note, the Regulation requires Member States to have penalties for infringement of Regulation and particular attention is drawn to non-compliance with requirements for information to be made publicly available.  CC noted that tacit approval where a response is not received within the set timeframe had been controversial but was included in the final text. The HRA & MHRA are confident that the set timeframes are not only achievable but the UK should be able to work to lesser timeframes than proposed.  IS queried what the actual impact for Phase 1 studies would be as they are usually single country and single site? JK explained that there would not be a significant impact on Phase 1 studies. The MHRA will remain the competent authority and the NRES will undertake the ethical review. The timelines agreed (60 days) are the same as current timelines rather than 90 days which had been the case during early discussions. The MHRA and HRA are committed to doing whatever is required to meet the proposed timelines. This may require a tweak to current processes or it may require a more radical change.  CC fedback that the final text did make explicit reference to Ethics Committees, which has not been included in earlier versions. The text also included a definition of an Ethics Committee: *“an independent body in a Member State established in accordance with national law and empowered to give opinions for the purposes of this Regulation, taking into account the views of lay-persons, in particular patients or patients organisations.”*  The text regarding patient inclusion as part of the review process has been revised and it was noted that the updated wording was preferable.  SL asked whether there was any reference to ARSAC approval in the Regulations. CC replied that he was not aware that this was referenced.  CC explained that the EU Portal will be a database which includes all information uploaded to the portal and this will be publicly accessible. There is also reference to penalties, including for non compliance with the requirements for registration and publication. CC further noted that any studies which are referenced in the application for a new study will need to be registered and published. RT -suggested that not all studies are registered and therefore some would need to be registered retrospectively. CC said that this would be something that would need to be worked through.  Cluster randomised trials are now included, with a reduced consent process. There was deemed to be informed consent if information had been provided and no objection had been offered. CC suggested that further consideration would need to be given to what would constitute ‘having been given information’ i.e would a poster on the wall in a GP waiting room meet this criteria? Members of the group suggested that this was not ‘informed’ consent.  DR suggested that tacit approval is concerning for both the sponsor and the EC. It was confirmed that this would be from receipt of a valid application so there would be evidence that the application was in the system. Approval could be assumed if there is no formal approval or non approval given by the member state.  RT suggested that there is an element of tacit approval in place already with the current system. JK noted that there have been issues with modified amendment which can go ahead if there is no objection given by the EC after 14 days. However, most sponsors don’t go ahead without checking with the EC in the first instance.  UL asked whether the EU Portal would be a single submission or whether the relevant parts of the submission would go to the relevant organisations. CC explained that it would still be necessary to work through the details. It was unclear what the submission process will look like for applicants. JK suggested that the process would probably be similar for Phase 1 studies but for other studies would be more complex e.g involvement of section 251.  UL asked for confirmation whether there would be an option to submit to EC & Competent Authority (CA) separately, as this has logistic advantages and saves time. SD reiterated this concern. It was clarified that it was not possible to submit to EC and CA separately.  RT suggested that once the text is officially approved, CROs should go through the Regulation in detail and highlight areas of concern which should be forwarded to CBl, particularly where there were concerns regarding the EU becoming less competitive (It was noted that the US turnaround is currently 30 days).  It was suggested that there would be an advantage in that the applicant won’t be asked for changes by both EC and MHRA as there will be just one review. It was confirmed that substantial amendments, referred to as substantial modifications in the Regulations, would go through the EU portal.  PD suggested that if the EMA validation phase before the application goes to the relevant member state for review, particularly for phase 1, could increase the overall time. Currently there is a 14 day turnaround with the MHRA and ECs are doing their best to keep times down. Concern had been expressed by AHPPI members that it is difficult to see how the new process is as efficient as the current service. It was suggested that anything that makes the process any worse will take work away from the UK. JK reiterated that the HRA and MHRA were determined that the review and approval process will be as quick as possible, even if this requires radical changes to process. PD suggested that it would be good to have input in regard to the construction etc. of the EU Portal. JK said that she was not aware that there was an additional EMA validation. The expectation is that the application goes into the EU portal, then ends up with the member state area and they validate at this point, particularly with a e single nation trial. It is therefore not expected that the new process will make a significant difference for Phase 1 studies. Even with a multi state study, the chosen member state would undertake one validation for the whole study.  RT suggested that it was only once the EU Clinical Trials Directive was written that the work started to ensure that the service was excellent and it will probably be the same with the Regulation. There would be continued discussions over the forthcoming two years. The UK will need to try to keep timelines less than they are legally required to be, as we currently do. CC reiterated that the timelines set are always a maximum and there is nothing to stop member states being quicker.  PD suggested that CROs would need the support of UK agencies to guarantee quicker timelines than stated in the Regulation. It was noted that it would be beneficial for CROs to have something to show to sponsors to provide these reassurances. RT suggested that Janet Wisely should be informed regarding the concerns of CROs in regard to the EUCTD and asked to take this message forward. JK said that she found it difficult to understand the concerns as the HRA and MHRA were confident that the current timelines would be maintained and probably improved. RT explained that there will be companies who look at final documents out of context and who will consider going to US rather than the EU because of this.  RT confirmed that the request to escalate this matter was for a statement from a senior source confirming that it will be business as usual. This would need to be within the next few months to prevent too many problems.  JK reiterated that nothing has changed in terms of timeframes, they remain the same in the Regulations as they were in the Directive, 60 days.  It was agreed that metrics should be published to demonstrate that the UK review in significantly less than 60 days.  UL stated that the UK’s share of global Phase 1 studies continues to decline and that it is therefore important to show to sponsors the advantages of conducting studies in the UK. She suggested that there should be a public commitment to fast REC review times, similar to that given by the MHRA on the MHRA website. She stated that the MHRA publishes performance measures on their website which is credible evidence for fast turnaround times to sponsors.  It is important that sponsors, in particular international sponsors who may not be familiar with UK practices, are informed about the translation of regulation into practice. Sponsors who read the updated legislation may assume that approvals will take 60 days and this will put them off. It is important to ensure that the perception of fast review times in the UK is maintained. We need to be able to attract business to the UK. It was agreed that a statement of intent regarding timeframes would be beneficial.  JK suggested that the HRA should start work with the communications team to get the message out. KB stated that there are sponsors who would be willing to say that they are happy with the service being provided in the UK.  It was queried whether validation be in accordance with UK standards? For example, in Germany the CRF has to be submitted to the EC. CC confirmed that validation should be standard across the EU. UL asked for confirmation on what the documentation would be and whether this would include CRF as this is very impractical. CC referred the group to the relevant annex in the provided document.  It was agreed that all feedback would be sent to CB who will keep a log and forward on to the relevant person to take forward.  RT noted that the Regulations empowered RECs to be involved in the assessment of SUSARS, commenting that he is not sure whether RECs would like to take this on. CC confirmed that this was not mandatory but allows the provision.  RT noted that the Regulations state that the Principal Investigator is responsible for compliance with the Regulation. It was confirmed that the “Principal Investigator” is responsible for compliance with the Regulation of the clinical trial at site. | **CBl** |
|  | **Registration of all Phase 1 clinical trials as a condition of the favourable ethical opinion**  RT outlined the situation. The HRA requires registration of clinical trials within 6 weeks of recruitment of the first participants as a condition of the favourable ethical opinion. In phase 1 this may actually be after the trial has finished. The HRA also introduced a process of registration deferral as it recognises that there are occasions where this would be appropriate. RT said that the message for companies who have stated that they will not register phase 1 clinical trials, is that they will have to as if they want to undertake clinical trials in Europe in 2 years time, it will be a requirement. Therefore, there is not much to discuss in terms of whether the decision is right or wrong as it is known that it will be a requirement. Clinical trial registration had initially been a HRA initiative but the issue was now wider than this.  RT stated that his personal view is that this is the right way to go but appreciated that others disagree with this opinion. The question should be what can people do between now and when there is a requirement to publish to manage difficulties with sponsors and whether the deferment process helps. RT explained that he had been sent details, in confidence, of one sponsor who has categorically said that they will send their work to the US. It was noted that the company are not members of the ABPI. The assumption is that the ABPI will be encouraging members to move in this direction. CB noted that at a recent ABPI meeting, this issue was discussed and it was agreed that this is the way to go.  JK asked whether there is a likelihood that the US will move in the same direction in this regard. It was noted that the FDA insist on registration for Phase II but this is for the purpose of the Government and not transparency. It was suggested that it would become clear whether the US follow suit in due course.  SL noted that it has been important to be able to defer registration, quoting reasons having been given by sponsors as commercial sensitivity and having their own transparency policy. It was suggested that it would be interesting to see how companies will amend their transparency policy to meet the upcoming requirement determined by the Regulation.  UL noted that until implementation of the updated clinical trials regulation there are still two years of business during which the UK should be able to compete on a level playing field with other European countries. The benefit of registering early phase trials is not clear, unless a study is terminated for safety reasons, has therapeutic benefit for patients or is publicly funded, in which cases registration is clearly beneficial. It was suggested that one way forward would be for the deferral process to be made simpler, such as a tick box on the IRAS form, as the current process is time consuming and perceived as difficult.  MB noted that when a patent application is submitted they have one year to gather information. MB added that he is aware of one company saying that they would request deferral, one saying that they would take their business elsewhere and one which said if they can have deferral during the patent year this would be acceptable, otherwise they will go outside the EU.  TS introduced himself to the group as the person in the HRA who is taking the lead on the transparency work. TS clarified that registration exemption is not something that would be considered but deferral was accepted to be appropriate under certain circumstances. Of all requests to defer registration received to date (14), no requests have been refused. In terms of process, the HRA consider this to be an easy process so welcome feedback regarding this. In regard to the two year intervening period, the HRA are looking at the barriers to registration so that solutions can be identified where possible. The HRA are seeking examples of practical issues which arise with registration and would welcome comments regarding this.  It was noted that in regard to the suggestion to include a tick box on the IRAS form, this would not be possible as updates could not be made to the form. It was also stated that blanket deferral was not acceptable and the requirement would be for each request to be given consideration on a case by case basis. MB said that he finds the process for requesting deferral acceptable and is grateful that the HRA have this position, adding that it was unfortunate that this would change with the implementation of the EUCTR.  JK confirmed that some Phase 1 studies are being registered. It was suggested that the issues would be less for larger companies. Small companies are usually a spin off company from universities and are the ones who are apprehensive about doing their work in the UK as they don’t want other companies to know what they are doing until they have got a head start.  SM suggested that as every REC is obliged to publish an annual report, which includes the full title of all studies reviewed and could be only one month after approval, information which could be deemed sensitive is already in the public domain. It was noted that it is possible to disguise certain information when devising a study title. SE added that there have been occasions when the REC have asked for the study title to be changed as it does not reflect the study, as well as requesting rewording of the research summary.  SE suggested that industry would say that ‘if you don’t know what your competitors are doing then you’re not doing your job properly’. It is naive to think that rivals don’t know what companies are doing, regardless of registration.  JK stated that Janet Wisely has made it clear that HRA will not ‘back track’ on the decision and will not make this a tick box exercise. RT noted that there had been an editorial in the BMJ shortly after the announcement had initially been made by the HRA. It is in the public domain that the HRA have done this and there is a lot of support for the initiative. It is important to be transparent but also maintain and increase the amount of Phase 1 in the UK. The issue is getting sponsors on board and getting them to recognise that this is the way forward. There are opportunities for sponsors to get praise for this, a good example is GSK. They are a big company but after negative press in the past, they are now perceived to be ethical in terms of transparency. It would be a sad state of affairs if companies took their work away from what is a very good service in the UK due to concerns regarding transparency.  RT asked for clarification regarding what happens if a safety issue arises. TS confirmed that the expectation is that the study would be registered immediately if the study was terminated early due to safety concerns.  UL asked whether the request to defer registration could be included in the cover letter sent to the REC so that the sponsor only needs to review and approve one letter. CB agreed that this would be acceptable and is already being done by some companies. As long as the information which is required is included then this is acceptable. TS added that it is important to be clear that such requests should be when required and not just an automatic and standard request.  JK suggested that when companies do have policies, the HRA can encourage them to give consideration to policy revision now in preparation for EUCTR implementation. JK added that the HRA will be actively monitoring registration of clinical trials where a request to defer registration has not been received.  TS said that he would be grateful to receive feedback regarding barriers to publication, before the end of May if possible, and can be e-mailed via the following [tom.smith2@nhs.net](mailto:tom.smith2@nhs.net)  RT asked whether metrics could be provided which set out the number of studies being registered and the number of deferral requests received and allowed.  SD queried whether the clinical trial dossier would be publicly available under the EUCTR. CC confirmed that personal and commercially sensitive information will not be accessible on the EU database. | CBl |
|  | **"How does NRES plan to implement the changes that will be brought about by the impending single central EU Clinical Trial Application process” Will Ethics review be swift enough to meet the planned timelines?"**  It was agreed that this had been covered under item 5. |  |
|  | **Advertising for Healthy Volunteers for Phase 1 clinical trials on job websites.**  This issue arose due to a complaint received about a CRO recruitment advert which had been noted on a job advertising website. The issue was referred to the generic advert review panel who suggested discussion at this group. JK suggested that it would not be appropriate to advertise on a job website. DR added that one of the issues was that sites are using a ‘scraping’ technique to get the data from other sites, it is not necessarily placed there in the first instance.  JKe noted that newspapers often advertise for clinical trial volunteers in close proximity to job adverts and suggested if there was a blanket rule that job sites should not be used, this should also be given consideration. The group discussed whether this would be considered unethical and whether volunteering in clinical trials could be considered to be ‘work’ as there is a payment associated with taking part. JK added that this issue had previously arisen in regard to people coming into the country and stating that they were taking part in a clinical trial would be refused entry. CC was asked to look into this matter further and feedback to the group.  KB they said that in his experience, any referrals through this route would not be accepted.  The review committee confirmed that this was how they had managed the enquiry which was reassuring and thanked the group for their input. | CC |
|  | **Electronic submission of generic advertising and REC submissions**  GJ fedback that they found the generic advertisement process easy and quick which was appreciated. GJ asked that the principle of generic/virtual committee review could be applied to new applications so that they also benefited from such a quick service. GJ also suggested that industry would gain from the availability of such committees rather than adhering to set meeting dates.  JK explained in accordance with the Clinical Trial Regulation that there must be at least 7 members with no more than 2 co-opted members to review a CTIMP. There have however been early discussions in regard to how the UK will structure the ethics service to meet the requirements of the EU Clinical Trials Regulation from 2016. This may involve a radical change to the process.  Discussion took place regarding whether the issue of maintaining experience of reviewing Phase 1 studies could be managed via the Shared Ethical Debate process. It was agreed that this would be beneficial and JK asked those present who submit Phase 1 applications to consider allowing an application to be used for this purpose. IS suggested that would need a virtual committee to review the ShED, otherwise it would be no different. It was suggested that reviewing a Phase 1 application as a ShED would not address the issue raised.  JK reiterated that it was not possible to revise the process at this time but there may be scope in the future. |  |
|  | **TOPS**  CB provided an update regarding The Over-volunteering Prevention System. TOPS transferred to the HRA in April 2013. It was agreed that improvements would be made to the system and a questionnaire was sent out to TOPS users to request suggestions for possible improvements. The feedback which was received was very positive about the system and there were only a few suggested improvements. There were also a number of improvements to the administrator functionality which would not affect the users of the system but would assist with the management of the system.   1. Include the IRAS project ID. 2. Online form for enquiries of request for data changes. This is a preferable process to e-mail as it filters out spam. 3. The site will be branded in line with the HRA. 4. It was identified that each site has only two log on usernames but up to10 people per site were using the system. Sharing of passwords is always discouraged and therefore it was agreed that all users of the system would have their own username and password. This would ensure that there is an accurate audit trail of use and also prevent possible problems when staff leave the organisation. 5. Add a search functionality. Records are currently listed in chronological order with no search functionality. This can make identifying the required record difficult and time consuming. 6. Alter functionality - It was noted that there are a large number of incomplete records where a prospective participant has been added but there is no information regarding dosing. An alert will therefore be added which reminds users after a set period of time that there are records which need to be updated. There will also be a category ‘not dosed as participant already in trial’. This will ensure that we capture how often the system prevents over volunteering. 7. Archiving of records over 2 years. The system currently holds all records since it commenced, which is approximately 10 years. It was noted that there is no requirement to keep all of these records and it was suggested that keeping the last two years of records active would be preferable and the remaining records archived. 8. Management Information reporting functionality - this would allow for the collection of key metrics such as the number of potential participants registered and the number of participants dosed etc.   KB stated that he strongly disagreed with the management information reporting functionality and the development of the TOPS system beyond what it is intended for. Further stating that this is supposed to be a tool to help asses a volunteers eligibility to participate in a clinical trial based on their “current clinical trial history” and the tool should be used for that only.  JK raised concern in regard to the information being held on the system and the length of time for which it was being held, particularly where potential participants are never dosed. She advised that the records should be destroyed and not archived. If a FOI request was made, it would be a requirement to disclose this information by CRO. It was therefore suggested that only the minimal information should be retained for the shortest period of time appropriate. KB agreed with this and advised that he had recent experience of volunteers refusing to participate in studies because they became aware that historical personal data was stored.  It was also noted that by including the IRAS ID, this was extra data than previously collected. KB questioned the necessity of this and what value it would add to assess a volunteers suitability for a clinical trial.  MB explained that when the system had initially been set up, it was confirmed that the data which is being collected, i.e passport number / NI number, was not considered to be identifiable information and therefore there were no issues with data protection. JK advised that she had consulted the HRA Confidentiality Advisory Team and they had confirmed the referenced data would be classified as personal identifiable and there was a common law duty of confidentiality. The main issue with the system was encouraging its use. JK added that it was important to note that using the system means completing all of the required fields and not just registering potential participants with no further information being added. It had been disappointing to see that the condition of the favourable ethical opinion to register participants on TOPS had in some instances been seen as just registering and not completing all required information. JK confirmed that the condition of the favourable ethical opinion does require all relevant fields to be completed.  JK said that the hope was that the information which could be extrapolated from the system would be a good news story for UK phase 1 research. JK suggested that if CROs were concerned regarding linking their organisation with other information, i.e in case an FOI request was made, this could be un-linked on a regular basis.  MB explained that the intention has always been to only keep 2 years worth of data but unfortunately this hadn’t happened. The intention had however been to keep all records archived in case there was ever a requirement to trace a participant after a long period of time, such as with a biological agent or vaccine. It was agreed that consideration needed to be given to data protection and ensuring that TOPS was managed in accordance with the Data Protection Act at all times. CB added that it would be possible to set up automatic deletion or archiving rules into the system but this would only be possible where there was confidence that the information being put into the system was complete which is not currently the case. If such rules could be set up then the records could be removed after the most appropriate period of time dependant on the study instead of defaulting to 2 years which is the current proposal.  KB suggested that if a subject had not been dosed then the TOPS check by one unit should not be visible to anther unit.  KB offered to help with the redesign of the system to ensure that only relevant data is displayed for the shortest time possible and to promote the system to be used by all units including those outside of the UK as there are a number of volunteers crossing borders to participate in clinical trials both in the UK and mainland Europe. | **CBl** |
|  | **Phase I Management Information Data**  The group noted the management information. It was requested that in future, tables only are included as they are preferable to charts. CB agreed that this would be possible. | **CBl** |
| 1. **C** | **CRO data**  CB explained that this data had come about due to a request for information by CRO on ethical opinion at first review, length of time to respond to provisional opinions by the CRO and length of time it takes the REC to respond to the further information provided.  All CROs who are part of the Phase 1 Advisory group were asked whether they could be identified. All responded that they accept identification but unfortunately the paper had been finalised prior to receiving confirmation from Richmond Pharmacology. Richmond Pharmacology are CRO12.  CROs who are not part of the group were not identified by name but allocated a code.  The group agreed that this was interesting information. CB asked that if there were any specific requests for data reports at future meetings to let her know. |  |
|  | **Any other business**   * 1. Request from Celerion to discuss SOPs for complaints handling in regard to informing the REC   It was agreed that if the complaint is resolved satisfactorily, then the REC don’t need to know about it. The REC don’t have a role in this process and may give false hope to the complainant that they can reach a resolution. RT suggested that any further discussion regarding this should be outside of this meeting.  JK fedback that the HRA are currently developing a new Research Ethics Database which is known as HARP. Following on from this, there will be a centralised booking process from April 2014 onwards. Phase 1 studies can continue to be booked directly with the REC Manager for the required REC. The new process will require electronic submission of the IRAS form and all supporting documentation so electronic authorisation via IRAS will be compulsory. Wet ink signatures and posted applications will not be accepted after this time.    JK fedback that after the success of the ‘Ethics Officer’ pilot which indicated that pre REC review advice improved the quality of the application when reviewed at the meeting, this is now moving to a live implementation on a pilot basis in the London office.  The HRA are currently awaiting for DH to confirm whether funding will be available to support the proposed HRA assessment. A role of ‘application manager’ will be set up in the London REC Centre to manage complex applications with a view to rolling out the function.  JK informed the group that there is currently a consultation process ongoing with the London REC staff as it has been decided to reduce the number of REC being administered from the Centre by half, from 12 to 6. The RECs which do not continue to be administered from this Centre will be transferred to the Nottingham Centre. This will result in staff redundancies. JK asked those present to be mindful of this over the next two months as it will be a difficult time for all staff affected. |  |
|  | **Date of Next meeting**  17 July 2014 - 11:00-14:00 - Lunch will be available after the meeting |  |