Phase I Advisory Group
Minutes
27 July 2016
11:00 - 14:00

Present

Richard Tiner (RT)	Chair
Ashleigh Wilson (AW)	Bio-kinetic
Ben Grey (BG)	Quintiles
Carl Phillips (CP)	Wales REC 2
Catherine Blewett (CB)	HRA
Charlotte Allen (CA)	HRA
Ceri Edwards (CE)	Simbec
Claire Walker (CW)	ACRO
Clive Collett (CC)	HRA
Daryl Rees (DR)	Generic Document Review Group
Deidre McCollom (DM)	Bio-kinetic
Jagit Sidhu (JS)	Wales REC 1
Jennifer Martin (JM)	MHRA
Joan Kirkbride (JK)	HRA
Joanne Slee (JSl)	Quotient Clinical
Jo Brady (JB)	Quotient Clinical
John Poland (JP)	ACRO
John Sheridan (JS)	Berkshire B
Keith Berelowitz (KB)	Richmond Pharmacology
Liz Allen (LA)	Quintiles
Malcolm Boyce (MB)	HMR
Margaret Jones (MJ)	Riverside REC
Michael Hammond (MH)	AHPPI
Neil Fawkes (NF)	Bio-kinetic
Peter Dewland (PD)	MAC Clinical Research
Robert Goldstein (RG)	Vice Chair Westminster REC
Stephanie Ellis (SE)	Hampstead REC
Kereen McDairmant (KD)	PPD
Graham Scott (GS)	ABPI/Takeda

Present by telephone:

Adrian Baillie (AB)	Surrey Borders REC
Raj Bains (RB)	Oxford A REC
Matthew Mills (MM)	HSC REC Manager

Item	Item details	Action
1.	**Apologies** Alan Ruben (Westminster REC) Christiane Abouzeid (BIA) Kath Osborne REC Manager (GM Central) David Carpenter (Berkshire) Roger Rawbone (GM Central) Sarah Walsh (GSK) Odile Dewit (ABPI) Ulrike Lorch (Richmond Pharmacology) Ian Skidmore (Cambridgeshire and Hertfordshire REC) Jan Downer (Harrow REC) Stefan Stringer (AHPPI) Janet Wisely (HRA)	
2.	**Minutes of previous meeting on:** 9 February 2016 The minutes were agreed as an accurate record. **Matters Arising** RT informed the group that he had taken the decision to step down as chair of the group after this meeting. He had intended to stay until after the EU CT Regulations had been implemented but in light of referendum outcome, he had decided he will step down at this time as there would be issues which come up which will affect Phase 1 and clinical trials for which RT said he did not feel he had the current insight and contacts to chair the group through this transitional time. The announcement regarding RTs resignation went to the HRA Board and they had nominated a Non Executive Director to be the replacement Chair unless there are other nominations from the group. Phase 1 is important and having a NED from the HRA Board would send a clear message about how dedicated the HRA is to this area and to ensuring the UK is, and is known to be, a great place to undertake phase 1 clinical trials. The name of the NED nominated by the HRA would be confirmed soon. The group were invited to put forward any alternative nominations for a replacement Chair and these should be sent to Catherine Blewett no later than 31 August 2016. It was suggested that the process should be a quick as possible and that there should not be a contest if avoidable. **Pre review advice:** JK informed the group that this had not been rolled out fully yet but the expectation was that this function would be undertaken by all Phase 1 RECs soon.	**All**
3.	**French study BIA-10-2474** JM informed the group that the MHRA had a task group looking at the trial review. The group had looked at a translation of the summary article and was waiting for the	

	full article to be translated. The MHRA was involved in the update to mitigation guidelines and there had been an extensive review of that. There was a summary paper out for consultation http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2016/07/WC500210825.pdf and guidelines following that would subsequently be out for consultation. The closing date for the consultation is 30 September 2016. The MHRA would also look at in the context of the phase 1 accreditation scheme and assess the impact. RT introduced the BMJ editorial and invited comments from the group. It was suggested that some language in the editorial was quite damning and that there was no clear target or aim with this particular trial. The group discussed the issue of knowing how much preclinical pharmacology supporting information is required before undertaking clinical trials of this nature. Additionally, it was noted that it was not unusual to undertake trials such as this without a specific indication. The group discussed the lessons which could be learned from this incident and whether there were any particular points which needed to be picked up. JM suggested that she had noted that it was not done as sentinel dosing which would not happen in the UK as this is something that would be picked up by the MHRA as part of the Phase 1 accreditation scheme. It was also suggested that the assessment of preclinical data should be final data and not preliminary data which has the potential to change. It was also suggested that monitoring emerging data was important as reactions in humans can be different to animal studies. It was asked whether the IB was publicly available for this trial and confirmed that the IB was not yet publicly available. JM confirmed that the IB and protocol had been seen by the MHRA task group. The group discussed how it is necessary to demonstrate safety margins in phase 1 trials but this should not be taken to the extreme when finding the maximum tolerated dose as this then becomes human toxicology. The group discussed what approach the UK should be taking to give public confidence, particularly to global sponsors, as it was felt that this type of incident would not happen in the UK. The UK has a regulatory structure which is robust and well informed which would mean that trials such as this would not get through the regulatory process. It is important to be able to demonstrate that clinical trials in the UK are ethical and as safe as possible. It was noted that the BMJ article appeared to have been written by an academic and not by someone who really understood the detail of drug development. JK said that there was nothing to stop someone from the group submitting an article to a journal setting out the UK position.	
4.	**Update on the Clinical Trials Regulations** Bill Davidson provided the group with a general update. The HRA objectives to protect and promote the interests of patients and the public in health and social care research still stood, as did the latest function regarding streamlining and co-ordinating research functions. The HRA had continued to attend meetings in Brussels and still had a remit to promote the UK as a great place to undertake research. The HRA continued to work closely with stakeholders and Government to continue to move forward and influence	

	the relevant sectors. The HRA had been working with the MHRA and colleagues from the Devolved Administrations to undertake process mapping and gap analysis work in relation to the information systems and operational processes. This is to ensure there is understanding of what the EU IT systems will do and what will be expected in terms of workload and workflow management. This work is progressing. Work was also being undertaken to look at the interactions between the REC system and the MHRA. Under the EU Regulation, the assessment is split into two parts. Part two is mainly for the REC to undertake, with site suitability requiring input from others in the NHS, but the part one includes elements which will require input from both the MHRA and also the REC side. It will be important to understand how these interactions can work and ensure consistency regarding which organisation will review which sections of the part one assessment. The 4 Nations (UK Ethics Committee Authority) group have been exploring the site suitability element of the Regulation. It will be important to ensure that it is managed in a proportionate way so that the full site sign off doesn't come under the Regulation when only a small element of the site review needs to be undertaken by the REC. George Freemen, previously the Minister for Life Sciences, has now moved on to Chair the PM's Policy Committee. The Life Sciences portfolio has now gone back to the Department of Health under Nicola Blackwood, who had previously been the Chair of the Science and Technology Select Committee. She is the Minister for Public Health and Innovation and has R&D and Life Sciences within her remit, amongst other things. Her counterpart in the House of Lords is Lord Prior. There has been no indication that there will be a step back from the life sciences focus and no reason to think that it will not continue. There has been a recent workshop and the expectation is that the outcomes will be known in September (2016). There are a number of guidelines in development which relate to the EU CT Regulation: • Ethical Considerations for Clinical Trials on Medicinal products conducted with Minors • Definition of Investigational Medicinal Products (IMPs) and use of Auxiliary Medicinal Products (AMPs) • Summary of Clinical Trial Results for Laypersons • Risk proportionate approaches in clinical trials http://ec.europa.eu/health/human-use/clinical-trials/developments/index_en.htm Comments should be sent directly of for RECs to Clive Collett who was co-ordinating the HRA response. There was also a document about the medical devices Regulations which was coming out in the next few days. RT noted that Article 50 had not yet been invoked and that there would be a further 2 years after the article is invoked before the UK formally leaves the EU. This timeframe would likely be similar to the timeframe for the implementation of the EU CT Regulations. It was queried whether work would still be undertaken in the UK towards meeting the requirement of the EU legislation, knowing that the UK would	

	not continue to be a member state. JM informed the group that the MHRA was under purdah again so were unable to say too much. However, they did have a task force looking into this matter. Work was continuing as before the referendum and the MHRA was continuing to work with the EMA. How this goes forward was for the task force to decide. In terms of the 4 guideline documents under consultation (see above), they were on the EU Commission website as the Commission is taking responses directly, not via the MHRA. BD confirmed that the HRA was also continuing as it had pre referendum and continued to work with the EMA with no changes happening at this time. The HRA will be feeding into the Life Sciences strategy group and will support the development of strategies going forward. It was queried whether the work being undertaken by the MHRA task group and the Life Sciences Steering Group would be aligned to ensure a co-ordinated approach. It was suggested that this is likely to be happening at a high level at this stage. RT suggested that Phase 1 clinical trials are different to other types of research and do need a different approach as they are often single site, single nation trials. There is a good history in the UK of working within a system for phase 1 clinical trials and it is hoped that this will be developed even further to develop phase 1 trials in the UK. It was noted that GSK among others are on the life sciences group so there was a link between the Phase 1 Advisory Group and the Life Sciences Steering Group through , Odile de Wit . There is a positive way to address the needs of the phase 1 community and demonstrate that there is a phase 1 industry in the UK which wants to undertake phase 1 clinical trials in the UK. Additionally, there would no doubt be various trade organisation wanting to get their messages across. BS added that the HRA does not have a seat on the LS steering group but does have links which can be used to ensure that we do get our message heard. BD added that the decision to leave the EU affected various legislations, not just the Clinical Trials Regulation. It also affected data protection and medical devices. The group discussed whether there was knowledge or understanding of the perception from global industry and other EU Member States. This was unknown at this time but the UK was considered to be a key Member State and had been pivotal, not least because of the very close working relationship between the MHRA and the EMA, often taking the lead on developing and implementing initiatives. It was suggested that it may be in the interest of Europe to maintain these links with the UK, even if this is outside of the European Union. RT asked whether there had been a noticeable difference in Phase I business since the referendum. The general opinion was that there had not been a difference as such but there had been questions asked. There was no evidence that global sponsors were put off coming to the UK and in fact, the lower value of the pound made coming to the UK more cost effective at this time. The group agreed that a joint statement would be helpful, something that was in the public domain to give public confidence. A recommendation will be put to the HRA Board to develop a statement to say that clinical research in the UK is continuing as normal. RT noted that he is attending the HRA Board meeting in October to present the work of the Phase 1 Advisory Group and the position of Phase 1 research in the UK.	RT / CB / JK

5. Transparency

Tom Smith updated the group on the outcome of the Transparency Forum which had been held the previous week, acknowledging that the scope of the Forum is all research so wider than clinical trials. There had been representation from groups such as EMIG, ABPI and AHHPI.

There had been a presentation from ISRCTN who have been looking at facilitating the linking of information. Pilot work had been undertaken encouraging researchers to put links to research and trial outputs into ISRCTN once that stage had been reached and ensuring that there is no impact on subsequent publication. There had been an update for Researchregistry.com. There had been 1,200 studies registered on the site since January 2015.

The HRA had been working with INVOLVE to produce a joint statement regarding public involvement. This was now available on the HRA website. http://www.hra.nhs.uk/news/2016/05/23/new-hra-and-involve-briefing-and-guidance-on-public-involvement-and-ethical-review/

The HRA had presented the outcomes of a piece of work undertaken to look at rates of compliance with the expectation that clinical trials are registered as a condition of the favourable ethical opinion.

	August 2015		**January 2016**	
Total number of Phase 1 trials with a FO during the reporting period	331		331	
Total number of Phase 1 trial registered on a publicly accessible database at the time of reporting	208	63%	254	77%
Of the total number registered, those found on ISRCTN or other	(6)	(3%)	(15)	(6%)
Of the total number registered, those found on clinicaltrials.gov	(202)	(97%)	(239)	(94%)
The number of Phase 1 trials where a deferral was allowed	49	15%	50*	15%
The number of Phase 1 trials that could not be found at the time of reporting (breakdown of response to these below)	74	22%	27	8%
Of the Phase 1 clinical trials not found or not known to have registered: **Reply received**			17	(63%)
Of the replies received, those which stated that registration not yet required (e.g trial not yet recruited / trial not yet started / trial terminated before recruitment commenced)			5	(29%) Of those where reply received
Of the Phase 1 clinical trials not found or not known to have registered: **Reply not received**			10	(37%)

*Due to a recording error, one trial did have a deferral in place but was not identified at the start of the monitoring

The full paper will be in the public domain once it has been presented to the HRA Board.

	The HRA has been working with EQUATOR with the intention of producing recommendations around the sharing of research outcomes and access to study data. The wording of the questions on IRAS will be reviewed to see whether they could be improved so that the information provided is more useful and meaningful. A further piece of work will be undertaken in relation to understanding what other information, such as protocols, should be publicly available or available on request, or whether a plain English summary should be provided. There had been a lot of feedback from the forum on these issues. RT noted that the registration compliance rate was high at 97% (either registered or a deferral agreed) which was good. RT asked the group whether the condition to register was an issue for sponsors or whether sponsors were accepting this. The group fedback that there were no real issues. When having discussions with sponsors it was made clear that the trial would need to be registered or a deferral could be requested which was being accepted. JK informed the group that an issue with the deferral of some research summaries on the HRA website had been identified and wanted to highlight this in the interests of being open and honest. One research summary which had a deferral agreed had been found on the website by the sponsor. This was reported to the HRA and in response to this, all deferred research summaries were checked. A further 5 research summaries were found to have been published in error. The research summaries were all immediately removed from the website and the CROs were informed. The issue had been due to the way the database had originally been set up. This had been rectified in September 2015 but unfortunately the errors were not picked up at that time. The HRA is confident that the change to the database and centralised management will mean that research summaries will not be published in error going forward. RT asked the group whether transparency needed to remain on the agenda as a standing item. The group agreed that it should remain, especially moving towards the ET CT Regulations.	
6.	**REC Consistency** 6.1 & 6.2 DM fed back that they had encountered some discrepancies when attending various RECs. Advice had been given by one REC which when they implemented the same thing for another study, a different REC said something different. With the PIS, they use the template provided by the HRA but then some RECs will say it is too long and some will say not enough information. It was difficult to get the balance right and know what the REC wants. CC commented that the guidance available on the HRA website is intended to be guidance and it is acknowledged that this is not a one size fits all. The HRA had moved away from using templates and now had suggested sections to include. However, it was possible that some organisations continued to use the previously published template as they think that RECs are familiar with that. The PIS should be adapted using the HRA guidance and based on the nature of the study or trial. It is also helpful if some explanation can be provided to the REC as part of the application regarding why the PIS includes what it does. This shows that this has been thought through and is well considered. Additionally, being able to demonstrate that work has been undertaken with patient or public groups when developing the PIS is also reassuring to the REC.	

The HRA was also publishing some guidance on proportionate consent which would be available in due course.

It was noted that whilst RECs do suggest that information sheets should be reviewed by patients groups before being used, it was not clear what the actual requirements were. Studies had been held up while patient groups were convened to review information sheets and it would be helpful to know what is expected in advance. Additionally, patient groups have been critical of REC approved information sheets because they don't understand why they contain all of the information which the REC has expected to see. It was noted that this problem largely related to patient trials rather than healthy volunteer trials but some of the issues were the same.

It was suggested that one way to better understand the information requirement of healthy volunteers is to collect data on why volunteers choose not to participate after reading the information sheets and additionally, why volunteers withdraw, in terms of the difference between the expectation when reading the information sheet and their actual experience of participating. It was acknowledged that it was not possible to insist on this feedback from volunteers but it could be requested to improve the experience for future volunteers. It was also an option to ask volunteers who have completed a trial to give their opinion on the information sheets and comment on whether the information sheet adequately provided the information which they wanted and whether the actual experience mirrored their expectation based on the information sheet which they were provided with at the start of the study.

It was suggested that there were two elements to an information sheet and they could be separated into two distinct sections. The information which a person needs to decide whether to participate and the information which they will need to refer to throughout the duration of the trial. Another suggestion was to provide a summary information sheet as well as the main information sheet, particularly when sponsors require lengthy information sheets. RECs will generally like this approach.

It was noted that one area of confusion is with umbrella studies and the complexity of the information sheets for these types of studies.

In relation to the involvement of patients and the public, it was highlighted that for studies funded by the NIHR, funding would not be released for studies which did not have PPI involvement.

6.3
Inconsistency between RECs regarding HIV testing in healthy volunteer early phase studies involving blood sampling.

JK explained that it had previously been agreed that for Phase 1 clinical trials involving healthy volunteers, such screening was considered acceptable. Additionally, the National Research Ethics Advisory Panel (NREAP) had issued a statement (which had been distributed to the group in advance of the meeting for information). The question had initially been prompted due to claims that the FDA required this type of screening. The statement from the NREAP was initially aimed at later phase clinical trials but contains principles which apply to all clinical trials.

The NREAP statement was that:
"It is not ethically problematic for screening tests to be required as part of a study

	provided that these: 1. Are justified test by test. (If the tests cannot be justified on methodological and/or ethical grounds then they should not be allowed.) 2. Are not indirectly discriminatory in relation to race, gender etc., and 3. Are properly explained to prospective participants, including the consequences if the test(s) is positive." The above was in response to issues raised in a Phase III trial. ACTION: CB to ensure this statement has been sent out to all Phase 1 RECs. DM said that she had attended a REC which was different to the REC which they usually attend and it appeared as though that REC was not familiar with Phase 1 in Healthy Volunteers and was more familiar with later phase trials in the NHS. This REC was not in agreement with the proposed screening which had been included in previous trials. JK noted that the group had previously had a discussion about the number of RECs which review Phase 1 clinical trials as it is accepted that to have a larger number of RECs reviewing this type of research means that some RECs will review fewer in number over the year. The group had previously agreed to retain the same number of RECs reviewing phase 1 clinical trials. Post meeting note: It was confirmed that the issues raised were a first in human study but not a CTIMP study and the REC was not flagged for Phase 1 research. JK requested that when issues such as this arise to contact the HRA to discuss as it may be possible to resolve the matter and additionally, it is helpful to know that such issues are occurring so that action can be taken more broadly. JK added that she wanted to give thanks to Quotient who had provided a 'dummy' phase 1 application. The HRA was undertaking a Shared Ethical Debate with this application which means that all Phase 1 RECs are reviewing the same application so that it is possible to ascertain any differences between the REC reviews. The report of the ethical review would be submitted to the Group for consideration.	**CB**
7.	**Generic Screening Documentation** 7.1 CB gave a general update on the Generic Document Review Group (GDRG). This group had initially been set up to review generic, non study specific adverts but the scope had been expanded to review all generic documentation, such as generic screening information sheets. A policy and procedure had been developed to set out the scope of the group and also the process which is followed by the HRA to review these documents. The policy and procedure is on the HRA website for information http://www.hra.nhs.uk/documents/2016/03/generic-review-committee-policy-procedure.pdf 7.2 CB explained that the P1AG had previously discussed the most efficient way of managing generic documents which have been reviewed by the GDRG when submitting trial applications to the REC. Previously there had been mixed views as some REC Chairs did not want to see them at all, others did want to have them but for	

	information only and others were of the view that if they received them they would review them as they do with all the document submitted. It was important to come to an agreed and consistent way forward. JK informed the group that the database used by the REC staff and members was now being used more commonly by REC members to view documents and it may be possible to develop the database so that documents which are submitted to the GDRG are uploaded to the database and can then be made viewable to REC members. Members could then view the documents via the database if they wanted to see them. It was agreed that the HRA look into developing the database to undertake this function and then REC members would be informed that they could view the documents on the database and that it is not expected that any changes to these documents are requested unless there is a particular reason why the document in its current format would not be suitable for that study. ACTION: CA - complete a SCR form to develop the database The group asked for a summary of the type of documents which are submitted to the GDRG. DR informed the group that they receive a wide range of documents including standard phase 1 adverts and screening documents and non-phase 1 documents such as information for signing up to GP databases to be contacted to be involved in future research studies and social media adverts. MB expressed his thanks to the GDRG, explaining that it is very useful and efficient service. KB noted that Richmond Pharmacology were using generic documents which had been approved several years ago and asked whether there should be a regular re-review after a certain period of time. The group agreed that it would be good practice to review such documents internally on a regular basis and update them when required. The revised version should then also be sent to the group for review. 7.3 Generic adverts with study specific payment information: How can they be managed most efficiently? CB explained that CROs had produced a stock of generic advertising, such as radio and TV scripts, magazine and newspaper adverts which were submitted to the GDRG. The generic template would remain the same but for some trials, this template would be used but with the addition of the overall payment for that study. This therefore made the advert study specific as it included the individual study payment. It was acknowledged that an efficient way was required so that such adverts weren't being reviewed by individual RECs when the only difference was the addition of the payment. The group discussed whether there would be an issue with organisations leaving adverts in the public domain after the individual trial had been recruited to, thus acting as a generic advert which could incentivise individuals to contact the organisation due to the full payment amount being included. The group agreed that there needed to be some trust of the integrity of organisations to remove the advert once it was no longer required for a specific trial. Additionally, with the high cost of advertising it would be unlikely to be cost effective to do this. The group agreed that a code of conduct should be developed which gave assurance that such adverts would	**CA**

	only be public after the REC had approved the payment amount and would be removed when no longer required for that trial. JM added that this could also be something that was picked up through monitoring. RT asked whether this would be something that ACRO would be interested in. JP agreed that he would take this back to ACRO to discuss. JK also advised that if advertisements were misleading then this would fall within the remit of the Advertising Standards Authority (ASA). HRA had referred healthy volunteer advertisements from job agencies to ASA previously. ACTION: JP to discuss a code of conduct regarding advertising with ACRO 7.4 Payment reduced when volunteer withdraws for medical reasons JS summarised the issue for the group. The GDRG had been asked to review a document which stated that if a volunteer had to withdraw from the study for medical reasons, they would receive a reduced payment. There were concerns that this would not be fair for volunteers who are withdrawn due to medical reasons which are due to their participation in the trial. It was noted that in practice, a volunteer would not be withdrawn from a trial due to medical reasons caused by the trial. If there was a reaction which meant that a volunteer does not continue to be dosed then they would still continue to be followed up, possibly more often than would have been standard. The volunteer would therefore continue to receive payment as the payment is for their time and inconvenience and not for how often they are dosed. The group agreed that for volunteers who withdraw from a trial due to medical reasons which are not related to the trial, it would be fair to give a reduced payment. It would be considered unfair for a person who volunteered for 2 days to receive the same as a person who volunteered for 21 days. It was noted that in practice this is rarely a problem as agreement is usually reached with the volunteer regarding payment. There have been very few incidents when the volunteer has not been in agreement and in these cases, the volunteers sometimes approached the HRA for assistance but this had not happened now for a few years. The group also discussed the importance of ensuring that it was explicit in the information sheets that a reduced payment would be given when a volunteer withdraws early due to medical reasons. It was queried whether it was acceptable to use data previously collected when a volunteer withdraws. It was agreed that this would be acceptable but should be explicit in the information sheet that this would happen. Additionally, not keeping data isn't sensible as long term consequences aren't always understood until a later time, so it is safer to retain data collected. 7.6 (there was no 7.5) Using interactive social media and blogs to advertise and promote clinical trials. CC summarised the issue to the group. He had become aware of posts on facebook which were organisations informing people about trials and then interacting when responses were received. The language being used to describe the trials was not in keeping with what would usually be expected when advertising trials. For example, claims were being made about how successful the trials were and how much they had	**JP**

	improved peoples quality of life. DR said that the GDRG had also received submissions relating to social media, notably a web chat. The GDRG had requested copies of the information which would be conveyed during the webinar and also copies of the answers which would be given to any anticipated questions. These had subsequently been provided for review. The group agreed that it would be difficult to control this but submissions of materials to be used should be encouraged to be submitted to the GDRG. Where adverts were considered to be making claims which were untrue, this could be reported to the advertising standards agency. JK added that training was available to REC members regarding social media and the ethical issues which may come up relating to the research projects which they are reviewing.	
8.	**Management information** The data was available to the group via the HRA website for information. CB informed the group that the format had been updated since the last P1AG meeting to include graphs as it was thought that sponsors would prefer this more visual representation of the data. There was a need for some data cleansing for the "time to book to submission" as a high number of days indicated that the first available slot must have been refused. It was queried why the CRO specific data was no longer presented to the group. CB explained that the CRO specific data had been presented as a one off request. The database does not pull that information as part of the MI report and it therefore involves going into each individual study record in the database to get the information. If the group wanted this information then it could be produced but would not be routinely produced.	
9.	**Any other business** JK expressed thanks on behalf of the HRA and the Phase 1 Advisory Group to Richard for his time and dedication to the group over the years he has been the Chair. Richard thanked the group and expressed that it had been a pleasure to be part of the group, adding that he hoped that there would be a positive way forward to demonstrate that the UK is a great place to do clinical trials and in particular Phase I.	
10.	**Date of Next meeting** February 2017 TBC (Will confirm when there is a new Chair in place)	