Stakeholder Engagement Meeting 16th November 2017

There are a number of areas in the new Clinical Trials Regulation that defer to national legislation. Included in those areas is who can be an investigator (Article 49), who can take consent (Article 29) and requirements for assembly of IMP in hospitals and health centres (Article 61).

These are areas that have not been reviewed for many years. Clinical practice has evolved since the implementation of the Clinical Trials Directive in 2004, therefore a review of how these areas are regulated is warranted.

Each of these areas will be discussed in the meeting in order to gather information and opinion from stakeholders that will shape the legislation in the UK.

Who can take Consent?

Whereas 30 - In view of the fact that in certain Member States the only person qualified under national law to perform an interview with a potential subject is a medical doctor while in other Member States this is done by other professionals, it is appropriate to provide that the prior interview with a potential subject should be performed by a member of the investigating team qualified for this task under the national law of the Member State where the recruitment takes place

Article 29 - Information given to the subject or, where the subject is not able to give informed consent, his or her legally designated representative for the purposes of obtaining his or her informed consent shall:
(c) be provided in a prior interview with a member of the investigating team who is appropriately qualified according to the law of the Member State concerned;

In the UK, a nurse, or other suitably trained member of the investigating team (e.g. this may be appropriate in ATIMP trials) obtaining consent may be both acceptable and appropriate. However, it is expected that a physician is readily available to answer any medically related questions, should such a question be raised by the subject during the consent process. In situations where the subject's ability to provide informed consent requires assessment e.g. for some psychiatric disorders, or vulnerable subjects, it would be expected that a physician is involved in the assessment and consent process. The process to be used for informed consent e.g. nurse or other member of the investigating team, should be clearly described in the Ethics application and approved.

To discuss:

- Does this still apply?
- Would a sponsor representative ever be suitable to take consent, for example in an ATIMP trial?
- Do we need to be clear about the definition of the 'investigating team' ? For example, would this include the pharmacist?

Who can act as an Investigator in a Clinical Trial ?

Article 49 states 'the investigator shall be a medical doctor as defined in national law, or a person following a profession which is recognised in the member state concerned as qualifying for investigator because of the necessary scientific knowledge and experience in patient care'.

Article 2 (15) Investigator means an individual responsible for the conduct of a clinical trial at a clinical trial site

Article 2, (16) Principal investigator means an investigator who is the responsible leader of a team of investigators who conduct a clinical trial at a clinical trial site.

Currently in the UK legislation (2004/1031) investigator means 'the authorised health professional responsible for the conduct of that trial at a trial site, and if the trial is conducted by a team of authorised health professionals at a trial site, the investigator is the leader responsible for that team'.

Authorised Health Professional means doctor, dentist, nurse, or pharmacist

Note: The extended list of healthcare professionals is used to determine the membership of the Ethics Committee in relation to a definition of a 'lay person' (as per Schedule 2, (3))

To discuss:

- Do we need to expand this to include other registered professionals – bearing in mind they need to have the necessary scientific knowledge and experience in patient care'.

For example, the following roles regulated by the Health and Care Professions Council that also have direct experience in patient care:

- Chiropodist – involved in diagnosis and treatment of patients
- Orthoptists/ophthalmic opticians - specialise in diagnosing and treating visual problems involving eye movement and alignment
- Paramedics - provide specialist care and treatment to patients who are either acutely ill or injured. They can administer a range of drugs and carry out certain surgical techniques
- Psychologist - the scientific study of people, the mind and behaviour. Psychologists attempt to understand the role of mental functions in individual and social behaviour
- Physiotherapists – dealing with human function and movement; physical approaches to promote, maintain and restore wellbeing.
- Registered Chiropractor (not regulated by HCPC)
- Any others?
- How will this be managed? Can it be left open to others who can demonstrate the necessary scientific knowledge and experience in patient care on a case by case basis to be reviewed in the Ethics/part II assessment?

Arrangements for Exemption of GMP for Hospital and Health Centres

Article 63 of Regulation 536/2014 states that IMPs shall be manufactured by applying good manufacturing practice. Article 63(2) states this GMP does not apply to those processes referred to in Article 61(5) - these processes are assembly activities in hospitals and health centres. Article 61 (6) states that these processes shall be subject to appropriate and proportionate requirements and member states shall subject the processes to regular inspections

To discuss:

The MHRA is considering how the provisions of Article 61(5) are to be transposed in practice; the issues relevant to 61(5) that are under consideration are:

- Whether exempt activities should be expected to follow 'the principles of' EU GMP, or a suitable equivalent (national guidance, PIC/S guidance for healthcare establishments etc).
- The application of GMP proportionate to the activities performed.
- The proportionate approach to GMP inspections of exempt activity
- Impact of implementing the Art 61(5) provisions, and whether this would require any substantial change for UK stakeholders, considering the similarity between Art 61(5) and the exemptions that already exist in the UK SI.