FEAM Workshop on Ethical Review of Clinical Research

10:00 – 16:00, 17 March 2014

Albert 1st Room, Palais des Académies, Rue Ducale 1, B-1000 Brussels

BACKGROUND PAPER

Introduction

The FEAM 2010 Statement on reforming the EU Clinical Trials Directive noted the difficulties in harmonising ethical assessment of multi-national trials but made several recommendations for streamlining and standardising ethical review procedures. The European Commission's proposal for a new Clinical Trial Regulation (CTR) is broadly consistent with the FEAM position in seeing ethical committees as a national responsibility rather than harmonised at the EU level. However, this allocation of responsibility remains controversial. For example, one of the recent EP ENVI Committee proposed amendments to the CTR would require joint decision making in ethical review (by bringing ethical opinions within the scope of part 1 assessment) – in FEAM's view this might be difficult to achieve.

Basis for a FEAM workshop

Because of the current differences of opinion between academies and within the broader scientific and policy communities regarding the handling of ethical review of clinical research, it is considered useful to organise a workshop to share perspectives and initiate further discussion on the place of ethical review in the longer-term EU framework for clinical trial assessment and management. The scoping workshop would be designed to maintain the momentum of FEAM attention and help academies understand:

- What is controversial and what are the most important issues to consider?
- Where is consensus most likely to be obtained?

- Where should further evidence be gathered or initiatives piloted to resolve discrepancies?
- What further advice might be offered, in due course, to the European Commission, national decision-makers and other stakeholders to inform the continuing discussion of options for ethical review after the inception of the CTR?

Background material

- FEAM 2010 Statement Opportunities and Challenges for Reforming the EU Clinical Trials Directive: an Academic Perspective – section on reforming ethics committees' roles (page 11).
- EFGCP 2011-2012 update of their earlier report "The procedure for the ethical review of protocols for clinical research projects in Europe and beyond".
- August 2013 – Academic, hospital and charity sectors' comments on amendments adopted by the European Parliament's ENVI committee on the Clinical Trials Regulation.
- September 2013 – Quarterly Journal of Medicine article mentioning FEAM's current position, "FEAM does not support EU-wide legislation for regulating national ethics committees. However, guidance for shared best practice, training and accreditation in EU countries would be helpful."
- October 2013 - Report of FEAM annual scientific meeting in Dublin.

Some current issues

The starting point for a workshop would be – what issues still need to be tackled following the CTR? Among questions that might be addressed are:

1. Should ethics review of multi-national trials remain the responsibility of individual Member States or should there be progress towards more joint decision-making or EU harmonisation?

2. Even if remaining a national responsibility, should the functions of research ethics committees be more closely specified by the EU?

3. What are the options for improving current national governance of research ethics committees e.g. to centralise single ethical opinion at the Member State level?

4. Should there be an expansion of research ethics committees' roles? For example:
- To ensure consistency in covering all clinical research, not just clinical trials.
- To have greater role in deciding risk-dependent proportionality of review.
- To monitor research, not just review research proposals.
- To be involved more broadly in upholding research integrity.

- To cover medical audit studies as well as research.

5. What good practice can be shared between Member States to ensure appropriate, composition and effective performance of ethics committees and increase consistency across EU? For example:

- Inclusion of appropriate expertise (such as on data protection).
- Recruiting of lay members.
- Designation of specialist research ethics committees.
- Provision of training to members of ethics committees.
- Increasing consistency between national systems in other ways – such as defining to whom ethics committees report and using common evaluation criteria for review of research proposals.

6. Is it possible to achieve more consistency across EU in management of research on vulnerable subjects? For example, where the subject is unable to provide informed consent in research in emergency medicine?

7. Should research ethics committees have a role in the publication of trial results?

8. How closely involved should ethics committees be in handling reports about serious adverse events?

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