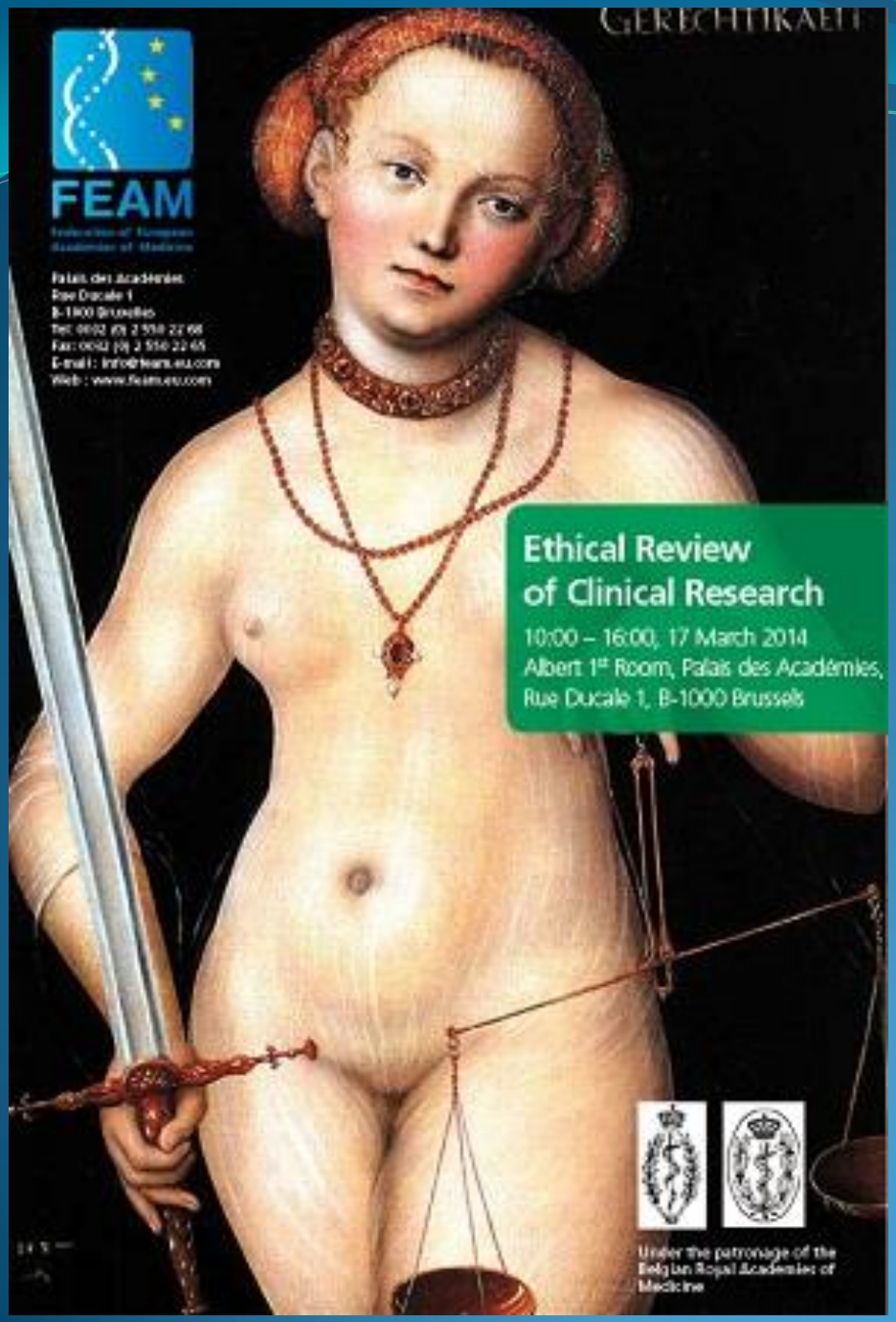

Outcomes from the FEAM Ethical Review discussion

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Background to FEAM workshop on ethical review of clinical research (Brussels March 2014)

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- FEAM 2010 Statement on reforming EU Clinical Trials Directive – recommendations for streamlining and standardising ethical review procedures
- FEAM 2013 Dublin conference – discussion of responsibilities of Ethics Committees and implications of proposed Clinical Trial Regulation
- April 2014 – Clinical Trial Regulation now proceeding to implementation; what issues for ethical review of clinical research still need to be explored?

Functions of Ethics Committees (ECs)

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- To review applications for research and give an opinion on proposed participant involvement:
  - To safeguard rights, safety, dignity and well-being of human subjects; also helping to protect rights of researchers to carry out legitimate research and protect sponsor's reputation.
  - To advise researchers on concerns for subjects or broader community.
  - To increase knowledge and awareness of ethical issues and research regulations (in particular, Declaration of Helsinki, EU requirements, national frameworks).
  - To support research quality by ensuring that the requirement for assessment of scientific soundness is satisfied.

FEAM workshop designed to help academies clarify some key issues for effectiveness of ECs

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- What is controversial?
- Where is consensus most likely to be obtained?
- Where should further evidence be gathered or initiatives piloted to resolve disrepancies?
- 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?

Questions posed at the start of the FEAM workshop

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- Should ethics review of multi-national trials remain the responsibility of Member States or should there be more progress towards EU harmonisation?
- Even if remaining a national responsibility, should functions of ECs be more closely specified at EU level?
- What are the options for improving national governance of ECs?
- Should there be expansion of EC functions?
- What good practice can be shared to ensure appropriate EC composition and effective performance?
- Where else is more consistency possible, e.g. in management of vulnerable subjects?
- What will be the impact of other policy developments, e.g. Data Protection Regulation and Medical Devices Regulations?

A range of evidence-based perspectives were contributed in the workshop

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- European Commission – DG Sanco, DG Research, European Group on Ethics
- Not-for-profit organisations (e.g. EORTC) and specialist areas (e.g. paediatric oncology)
- Pharmaceutical industry (EFPIA)
- Academic experts (with links to Science Europe and other international research organisations)
- Individual FEAM member academies – Romania, Spain, Hungary, Belgium, Portugal, Germany

Areas discussed in the workshop (FEAM Report in preparation)

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- What is specified in the Clinical Trial Regulation
- ECs and the wider inter-institutional landscape relating to clinical ethics issues
- Suggestions for revising remit, composition, effectiveness and integration of ECs across the EU
- Views from international research organisations on how to address issues for scope and standards so as to foster cross-border clinical research studies
- Options for improving EC operation at the national level

Recommendation 1: Is there scope for the harmonisation of ECs?

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- ECs should be part of the ongoing EU strategic discussion in response to the changing nature of health care and research, and need for improved, consistent quality control in evaluation.
- There is scope for harmonising advice on how ECs might function to assess benefit-risk, to raise quality throughout EU, and how best to align ethical and scientific assessment.
- A case can be made for centralising assessment in specialised areas e.g. new technologies.
- The desired eventual balance between national and EU-level responsibilities in clinical research ethical assessment requires further thought.

Recommendation 2: Should ECs acquire other functions?

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- ECs should not be restricted to assessment of protocols relating to medicinal products – it is important to share good practice for the broader remit currently operating in some Member States – assessing all medical research.
- With regard to publication of research outputs – ECs should ensure in protocol evaluation that the sponsor/researcher commits to publication in due course.
- Current reforms by the European Commission with the Eurovigilance database are helpful in sparing ECs the burden of assessing Serious Adverse Events.
- An extension of the EC role to cover medical audit would be contoversial.

Recommendation 3: How should patients be more involved in research and ECs?

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- More needs to be done to inform patients about research, rather than regarding them only as the end users of the products of research.
- ECs should increase their efforts to assist patients in understanding their roles in clinical research.
- Lay members are a vital part of ECs. However, there is a concern that including patients in ECs may sometimes introduce conflict of interest in provision of independent advice. Patients should be involved earlier in research design and protocol preparation.

Recommendation 4: What are the training needs of ECs?

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- EC members, including lay members, benefit from training – various options can be conceived and it may be possible to draw on clinical investigator training material.
- Training of EC secretariats is also important to ensure continuity in EC performance.
- In view of the large variation in current practice, it is desirable to share good practice as part of harmonising core principles in training. Academies could have an important role to play in supporting these efforts.
- It would be useful to develop an EU accreditation system for ECs.

In conclusion – continuing need for FEAM attention

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- From the perspective of Member State authorities, a Member State-oriented EC system works well. But from the perspective of international research-based organisations, the current system is not optimal for EU researchers, patients in research, or EU competitiveness.
- It is necessary to continue exploring what can be better coordinated, learning about respective strengths and weaknesses, spreading good practice, scanning the horizon for new science, technology and policy developments, and monitoring the impact of changes already made.
- These tasks should be tackled now rather than waiting for the interim review of the Clinical Trials Regulation.

What should be the next steps for FEAM?

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- All participants in the workshop agreed that there is a continuing role for FEAM to catalyse fundamental debate and action across the EU and assess the implications of EU decisions for global research.
- The ethical review issues are highly relevant for other FEAM current priorities, e.g. Data Protection Regulation, Personalised Medicine, Genetic Testing.
- The workshop was a useful first step – what next?
- Suggestions for next steps, in using the FEAM report, in organising additional events and in focusing on particular priorities, are welcome.