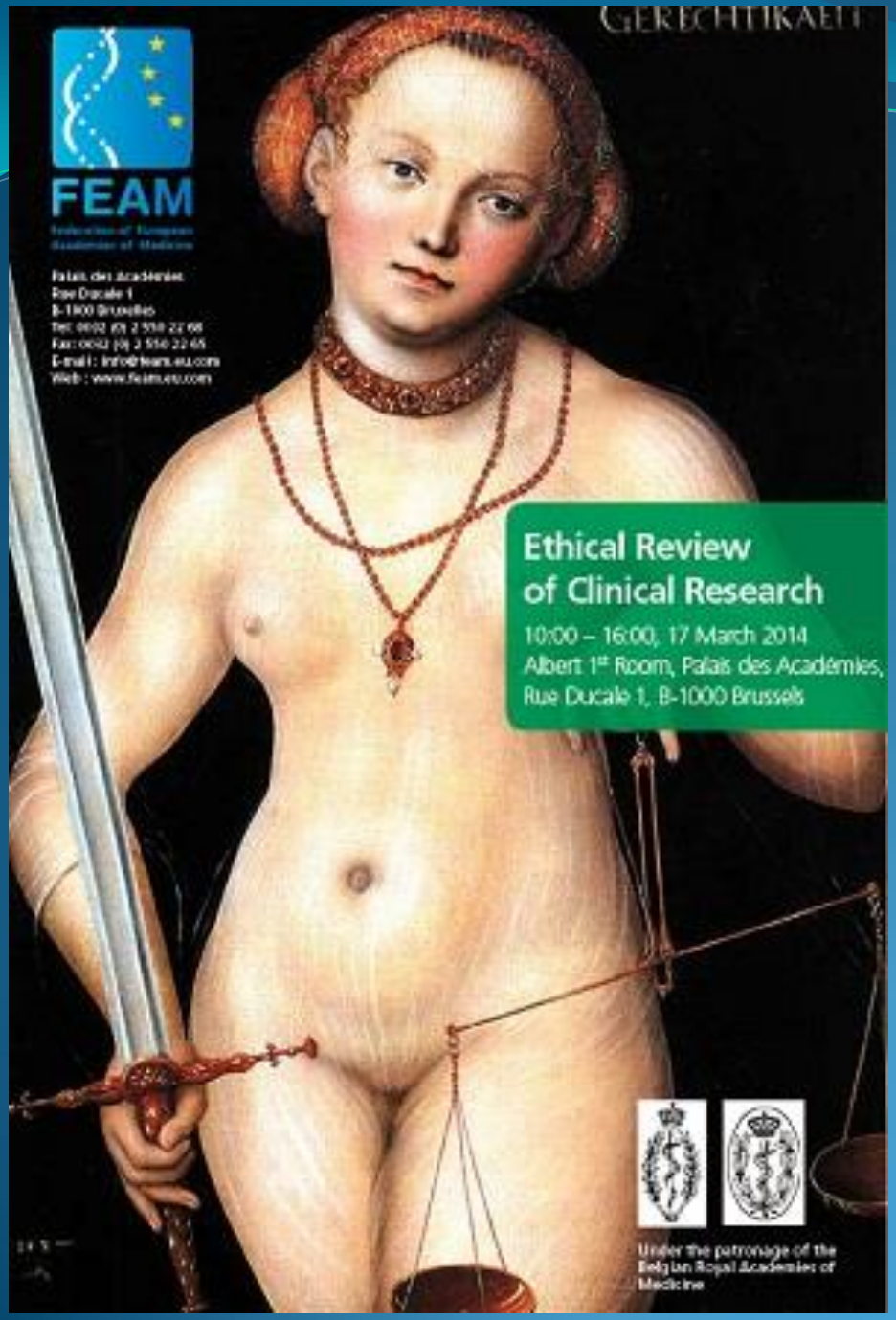

Wellcome

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FEAM workshop on ethical review of clinical research (17 March 2014, Brussels)

FEAM
Federation of European Academies of Medicine

A few words about FEAM:

- A 20-year old independent network of 16 national Academies with over 5000 elected members, among the best biomedical scientists in Europe and across the whole spectrum of disciplines
- FEAM Academies are independent from all vested interests (commercial, ideological, political)
- Policy recommendations are based on scientific evidence
- Established in 1995 at the Palais des Académies as a not-for-profit international association with a scientific objective

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The FEAM network

- **16 national Academies** in the following Member States: Austria, Belgium, Czech Republic, France, Germany, Greece, Hungary, Ireland, Italy, Lithuania, Portugal, Netherlands, Romania, Spain and UK (Candidate members: Croatia, Latvia and Switzerland)

- **Two sister academic networks as observers**: European Academies Science Advisory Council (EASAC) and the global InterAcademy Medical Panel (IAMP)

- **Wider science policy cooperation**: Science Europe, Wellcome Trust, EFPIA, EuropaBio, EFGCP, patients' organisations…

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Mission of FEAM:

- to promote cooperation between national Academies of Medicine and Medical Sections of Academies of Sciences in Europe
- to provide them with a platform to formulate and express their common position on European matters concerning human and animal medicine, biomedical research, education, and health
- to extend to the European authorities the advisory role that they exercise in their own countries on those matters.

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Vision of FEAM:

- To underpin European biomedical policy with the best scientific advice drawn from across Europe, through the FEAM network of Academies
- To improve the health, safety and wealth of European citizens through research by promoting a nurturing, creative and sustainable environment for medical research and training in Europe.

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Governance of FEAM:

- An appointed Council made up of 16 members of the Academies
- An elected Board led by the FEAM President: Prof. Dermot Kelleher, UK and Irish Academies of Medicine, Vice-President (Health) and Dean of Medicine at Imperial College
- + four Vice Presidents, the Past President and a Treasurer
- An appointed Science Policy Committee to advise Council on the FEAM policy programme

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Current policy priorities:

- Informing EU regulations/directives (clinical trials, data protection…)
- The future of health research
- Personalised medicine: direct-to-consumer genetic testing, public health genomics
- One Health: human, animal and environmental health
- The culture of prevention in health
- Education and training in Europe

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Reasoning for organising a workshop on ethical review of clinical research:

- FEAM 2010 statement on the Clinical Trials Directive:
  - Harmonising ethical assessment of multi-national trials may be difficult
  - But made several recommendations for streamlining and standardising ethical review procedures
  - Ethical committees as a national responsibility, not harmonised at EU level (also in EC regulation proposal)
- Discussion at the 2013 Dublin Spring Conference (Prof. David Smith)
- 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 (FEAM, Quarterly Journal of Medicine, September 2013)

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Reasoning for organising a workshop (ctnd.)

- Yet this allocation of responsibility remains controversial

'Ethical review must remain the responsibility of MSs because of the different legal frameworks and ethical review between MSs. [] We are concerned by amendments 5 and 22 [proposed by EP ENVI Committee] that seek to bring ethical opinions within the scope of part I assessment (covering aspects of CT that can be jointly assessed by MSs). Including these would mean that a dispute between MSs over an ethical issue could prevent a trial from being approved in all other MSs involved.

Currently, there is no co-ordination or harmonisation of ethical committees in Europe therefore meaning a joint decision would be difficult to achieve. []ethical consideration should remain at MS level, as there may be specific contexts for trials in differing environments that individual MSs are best place to judge. However, developing guidance for shared, best practice, training and accreditation in EU countries should be considered.'

Academic, hospital and charity sectors' comments on amendments adopted by the EP's ENVI committee on the Clinical Trials Regulation, August 2013

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A workshop to share perspectives and to initiate discussion on the place of ethical review in the longer-term EU framework for CT assessment and management

Issues for consideration:

- What is controversial and key issues for consideration?
- Where is consensus likely to be obtained?
- Where should further evidence be gathered or initiatives piloted to resolve discrepencies?
- What advice to offer to the EC, national decision-makers and others to inform the discussion of options for ethical review after inception of CTR?

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Key issues for consideration after inception of the CTR:

- Ethics review of multi-national trials to remain a national responsibility or progress towards more joint decision-making/EU harmonisation?
- Functions of research ethics committees more closely specified by EU – even if remaining a national responsibility?
- Options for improving current national governance of research ethics committees? (ie centralising single ethical opinion at MS level?)
- Considering expansion of research ethic committee's role?

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Key issues for consideration after inception of the CTR:

- Good practice to be shared between MSs to ensure high performance of ethics committees and increased consistency across Europe?
- Is more consistency across EU in management of research on vulnerable subject achievable? (ie. subject unable to provide informed consent in research in ermergency medicine)
- Ensuring consistency in covering all CR, not just clinical trials – having greater role in deciding risk-dependent proportionality of review - monitoring research, not just reviewing research proposals – broader involvement in upholding research integrity?

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Key issues for consideration after inception of the CTR (ctnd.):

- 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 by defining to whom ethics committees report and using common criteria for review of research proposals?
- A role for research ethics committees in the publication of trial results?
- Involvement of ethics committees in handling reports about serious adverse events?

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Workshop programme:

- Setting the scene and views from the different stakeholders (academia, research groups, national decision-makers, European Commission, industry, patients' groups)
- View points of the Academies
- General discussion
- Subsequent elaboration of written output to stimulate further discussion at 2014 FEAM Spring Conference (12-13 May, Bucharest)

Thank you!