



## ETHICAL REVIEW OF CLINICAL RESEARCH

Report of a workshop organised by FEAM

17 March 2014, Brussels

### 1. INTRODUCTION

The FEAM 2010 Statement on reforming the EU Clinical Trials Directive<sup>1</sup> 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 was broadly consistent with the FEAM position in seeing ethical committees as a national responsibility rather than harmonised to provide a single ethical opinion at the EU level. However, this allocation of responsibility remains controversial.

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 was 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 workshop was 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 Regulation?

### 2. SOME CURRENT ISSUES

The 2013 FEAM scientific conference in Dublin, Ireland<sup>2</sup> discussed a range of issues for the reform of clinical trials research assessment and the responsibilities of Ethics Committees.

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<sup>1</sup> FEAM, Opportunities and challenges for reforming the EU Clinical Trials Directive: an academic perspective, August 2010.

<sup>2</sup> [Report of FEAM's Spring Conference 2013](#).

The output from the Dublin meeting helped to scope the design of the present workshop in terms of critical priorities and the starting point - What issues still need to be tackled following the legislative agreement on the form of the Regulation? Among questions that the workshop was asked to address addressed were:

1. Should ethics review of multi-national trials remain the responsibility of individual Member States<sup>3</sup> 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 ensuring the publication of trial results?
8. How closely involved should ethics committees be in handling reports about serious adverse events?

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<sup>3</sup> The situation in individual Member States was reviewed in 2011-2012 by EFGCP: [The procedures for the ethical review of protocols for clinical research projects in Europe and beyond](#)

### 3. SUMMARY OF THE MEETING

#### Overview on the agreed Regulation on clinical trials

Following very supportive debate in the European Parliament and extensive discussions in Council, [the text of the Regulation](#) has now been agreed. Publication of the approved text is underway but there will be a transitional period of at least two years before implementation.

**Fabio D'Atri** (Deputy Head of Unit “Medicinal Products – quality, safety and efficacy”, DG Health and Consumers, European Commission) reviewed the key provisions of the Regulation, noting the explicit more recent introduction to the text clarifying the place of Ethics Committees (ECs), whose role follows national rules with national responsibility. The ECs will work within the general Framework of the Regulation relating to protocol assessment procedures and timelines, and standard criteria for independence from sponsors, investigators and trial site. ECs are expected to include appropriately qualified members, with specialised expertise, where needed, and with participation by lay persons (and particularly patients). ECs are encouraged but not mandated to exchange good practice.

Some of the issues for ethical review have been contentious. For example, the protection of subjects in emergency research has previously varied between Member States but should now satisfy the criterion of producing potential direct clinical benefit for the subject, with minimal risk and minimal burden (in comparison to standard treatment). In discussion, it was clarified that if it is not possible to seek consent in the emergency situation (for example, if the subject is unconscious and no family are present) then an EC-approved protocol can commence but consent must be sought as soon as possible afterwards.

One other innovation in the Clinical Trials Regulation is the introduction of an EU centralised portal and database to be developed and managed by the European Medicines Agency, discussed in more detail later in this meeting.

#### The EGE and the clinical trials regulatory framework

**Jim Dratwa** (European Group of Ethics in Science and New Technologies, Bureau of European Policy Advisers, European Commission) described the broad inter-institutional landscape in which clinical research ethics review is embedded in the EU. The [Interservice Group on Ethics and Policies](#) includes several DGs (Sanco, Research and Justice are particularly relevant for research ethics review) as well as EGE, the advisory body to the European Commission on ethics in science; ECs are organised at the national level, and at the global level there are relevant discussions in the G20 and with the African Union, for example.

Sometimes, ethical review has been misconstrued – as a bureaucratic obstacle rather than as a vital step in protecting the subject and supporting innovation. Broadly, the initial concerns raised by the EGE on earlier drafts of the Clinical Trials Regulation have now been

addressed during the legislative process. Mostly, these concerns related to the concept of ethical subsidiarity, that is dealing with issues at the appropriate level and identifying where there is need for coordination and where there may be EU-added value. For example, concern had been raised at the prospect of “ethics shopping” – the research sponsor approaching the less experienced Member States in expectation of an easier review. Although this concern has been allayed, there remains the need to build capacity in the less experienced countries to ensure that EU activity is not dominated by the more experienced countries.

Continuing dialogue is important to fill the gaps that legislation has not reached and the Academies through FEAM have a crucial role to catalyse both the sharing of good practice between Member State systems and to ensure that ECs can develop the expertise to take account of rapid advances in science (for example, biobanking) and the implications of other policy developments (for example, in data protection and privacy). These critical responsibilities were explored further throughout the meeting.

### [Re-engineering and integrating research ethics committees](#)

Although the development of the Clinical Trials Regulation has been highly useful in drawing attention to what can be integrated in clinical research assessment, [Adam Cohen](#) (Science Europe’s Medical Sciences Committee and Director of the Centre for Human Drug Research, The Netherlands) considered that attitudes embodied in the Regulation were outdated in several respects<sup>4</sup>:

- The Regulation covers medicinal products but there should be a wider view taken of what must be assessed in interventional medical research to include, for example, surgery and medical devices. While some Member States do cover medical research more widely in their national assessment systems, it would be better to harmonise an agreed scope at the EU level.
- The Regulation artificially separates science and ethics in the dual approval procedures yet ethics is part of good science and integrated evaluation would be preferable.
- Member States are at different stages in their development of scientific expertise so their assessment of clinical research protocols will necessarily be different, resulting in uneven quality of evaluation by both regulatory authorities and ECs across the EU.

What is the solution? These concerns should be taken into account in the work that will lead up to the interim revision of the Regulation in order to improve matters in the longer-term – regulating all medical research, not just that using medicinal products, avoiding the dual approach and committing to EU-wide quality control – while, at the same time, building on the EU advantages already gained such as fast approval mechanisms, committed ECs and thorough record-keeping.

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<sup>4</sup> Further information about this analysis and recommendations is in the publication: Kenter MJH & Cohen AF “Re-engineering the European Union Clinical Trials Directive” *Lancet* 2012 379, 1765-1766.

In discussion, a national Health Research Authority was proposed as one option to begin the desired reforms and to encourage research within the health services. Creation of this body in Member States would facilitate desired EU-wide objectives for shared responsibility, managed actions, mutual learning.<sup>5</sup> With regard to the ambitious and controversial goal of EU harmonisation in ECs, because many Member State governments would be sceptical about the value of increased EU powers, it is the responsibility of EU organisations such as FEAM to help lead the debate to explore issues for better EU coordination and integration.

### [Issues for remit, composition and effectiveness of research ethics committees](#)

[David Smith](#) ([Irish Academy of Medical Sciences](#) and Associate Professor of Health Care Ethics, Department of General Practice, Royal College of Surgeons in Ireland) provided an update and extension of his presentation to the Dublin meeting in 2013. Among the key questions for ECs are:

- Should there be specialist ECs to deal with particular research complexities? For example, the use of datasets and provision of data protection, currently interpreted in different ways by Member States.
- What should be the remit of ECs? For example, should the role be extended to include assessment of medical audit practices, as the dividing line between audit and research in the health services is sometimes blurred? And as discussed by other presenters, should all Member State ECs cover more than the study of medicinal products? If so, how should this remit be harmonised? A case can be made for harmonisation of guidelines for EC performance rather than legislative prescription.
- How should Member State variation in composition of ECs be tackled? Some countries struggle to recruit specialist members and lay members – how could recruitment be incentivised or standardised? And should there be formal training in principles and procedures for all EC members (as well as for clinical investigators)? The [recent revision of the Declaration of Helsinki](#), in characterising the responsibilities and functions of ECs, emphasises the importance of incorporating appropriate scientific education and training for EC members.
- In view of the general responsibility of ECs to help uphold research integrity, might they take on an additional role in monitoring research? In discussion, it was proposed that ECs might be particularly helpful in supporting and monitoring patient understanding of the ongoing research rather than monitoring data (where the responsibility lies elsewhere).

Member State ECs also vary in other respects, for example in who they are responsible to and whether there is an appeal mechanism following a negative EC decision. Therefore, there is continuing need for fundamental debate on what further changes would be desirable or practical to develop common standards in ethics review, reducing the present big differences in EC working procedures and workload and, thereby, facilitate multi-national research. Academies have an important role to drive this fundamental debate not

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<sup>5</sup> For discussion in the UK, see Transforming the regulation and governance of health research in the UK, [May 2012](#), and discussion at the Dublin meeting (footnote 2).

just with respect to reform in the EU but also in ensuring that the impact of those EU precepts and principles on research in the rest of the world is positive.

### [Ethical review in paediatric oncological research](#)

**Laurence Dedeken** (Deputy Head of Clinic, Department of Hemato-oncology, Queen Fabiola Children's Hospital, Brussels, Belgium) provided a practical perspective drawing on case studies in a challenging therapeutic area. Oncology trials remain essential because although survival has improved markedly (since 1960), there are still many new cases. Paediatric trials are essential because children cannot be regarded as small adults, their malignancies may differ and there are specific goals relating to identification of subpopulations at high risk of relapse and the need to decrease long-term toxicities in those with good prognosis. Many paediatric malignancies are rare, necessitating recruitment, by consortia from academia and in partnership with industry, from a wide geographical area.

Ethical considerations recognise that children are a vulnerable group but that to omit them from research prejudices them as a group. Respecting the child's view in research raises questions of assent and how to assess that the degree of maturity is sufficient to support assent. This maturity cannot be assumed at a particular age and must be assessed on a case-by-case basis. In discussion, the question was raised as to whether a more prescriptive Clinical Trials Regulation will now reduce Member State flexibility to define procedures for assessing maturity and the age of assent (although it must also be acknowledged that current Member State practices are not always applied consistently).

Considerations of what criteria should be used to allow Phase I studies in children and how to define quality of life endpoints stimulated more general discussion about the balance to be set between protecting subjects and progressing science. One perspective assumes that the only inducement to a healthy subject to participate in Phase I is monetary, but subjects may participate because of their altruism and commitment to the value of health research. In all cases, it is essential for ECs to assess and communicate benefit-risk balance for the participant and to disallow inappropriate inducements.

### [The perspective from not-for-profit organisations on clinical research ethics review](#)

**Anastasia Negrouk** (Head of International Regulatory and Intergroup Office, Chair of EORTC IRB, European Organisation for Research and Treatment of Cancer) based her perspective on the experience of EORTC, with 180,000 patients in their database, 50,000 patients in follow-up, 2,000 collaborators – clinicians, pathologists and researchers – from 300 institutions in the network from 32 different countries and with 15 new trials opened in 2012-2013.

International research organisations such as EORTC are facing a changing clinical research environment, characterised by disease fragmentation (and personalised medicine); an increasing number of cancer survivors whose longer term health and insurance problems are not satisfied; a need for new models of cooperation between academia and industry to optimise clinical and translational research; new forms of evaluation (outcome monitoring, Health Technology Assessment) with implications for the regulatory framework; and

increasingly unaffordable drug development coupled with the inception of “pay for performance”, where payors do not reimburse inefficacy.

Currently there are various hurdles to surmount in conducting international research, in particular bureaucratic and cumbersome processes, lack of harmonisation with consequences for Member State variability, inappropriate (lengthy) timelines for approval, together with increasingly long and demanding Patient Information Sheets that do not aid patient understanding of the research. These obstacles risk being amplified by the changing clinical environment, advent of new methodologies and particular issues generated by tissue collection for future research (whether broad consent is applicable, how long storage is permissible) and data privacy<sup>6</sup> (again accompanied by issues for storage and long-term follow-up as well as for combining data from different sources and transparency of procedures).

The Clinical Trials Regulation can be expected to deliver a more coordinated and streamlined process, harmonisation in requirements for submission documents, consistent and (in most cases) timely approvals, and sufficient flexibility to manage some of the new challenges. It will still be necessary at the national level to devise ways to involve patients in research design and EC review, a point developed in subsequent discussion. Where there is room for significant improvement is in the harmonisation of patient information, the interaction between the Clinical Trials Regulation and other policy development, particularly the Data Protection Regulation, the Medical Devices Regulations and Cross-Border Directive, and in extending the scope of the standardised evaluation procedures to provide an integrated legal and ethical framework to other relevant clinical research and thereby foster international research. In this context, an EU Forum for ECs is desirable.

### [The perspective from the pharmaceutical industry on clinical research ethics review](#)

Many of the points from the EORTC perspective were endorsed by [Nick Sykes](#) (Pfizer and Co-chair, Clinical Trials Regulation Working Group, European Federation of Pharmaceutical Industries and Associations). EFPIA welcomed the agreement on the Clinical Trials Regulation and its rapid adoption, in expectation that it will attain the desired goals of fostering clinical research and EU competitiveness<sup>7</sup>. Success depends on how it is implemented in practice and this depends on commitment by all the stakeholders. The Regulation does not itself change much in the operation of ethical review and it is important for ECs now to be pro-active in seeking quality improvement by sharing best practice and learning collectively. ECs need to be supported in doing this (and this support is missing from the final text of the Regulation). To reiterate a previous point, there is a role for FEAM and other international organisations to inform the European Commission and Member State authorities about the importance of quality improvement and better coordination.

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<sup>6</sup> The Data Protection Regulation is being introduced in an attempt to harmonise the current very variable applicable laws in Member States. However, European Parliament amendments to the European Commission’s draft legislation, to remove exemptions to the use of personal data for health research, brings big implications for the health research community. The current work of FEAM on this topic is available [here](#).

<sup>7</sup> The EFPIA perspective is described in further detail in the publication: “EFPIA position on Clinical Trials Regulation trialogue” [November 2013](#).

Industry also supports the responsible sharing of clinical data<sup>8</sup>, while maintaining the necessary incentive to invest in medical research. As the EU portal and database represents a key pillar in the implementation of the Regulation, it is crucial that all stakeholders work with the European Medicines Agency to ensure its functionality, and this includes clarifying access by ECs. The inclusion of a review clause in the legislation (at five years) is also welcome and important in enabling eventual incorporation of new thinking on what will be the appropriate evaluation of all clinical research.

### [The ethics appraisal in Horizon 2020](#)

[Isidoros Karatzas](#) (Head of the Ethics Sector, DG Research and Innovation, European Commission) observed that the biomedical sciences are ahead of other research areas in their commitment to ethics assessment. For example, social sciences research using protocols involving MRI or other functional assessments are not routinely submitted to ECs for approval. The success of Horizon 2020 depends to a significant degree on the training and education of researchers and ECs to help them navigate the complex legislative framework and to share good practice.

In supporting points made by previous speakers, it was also seen to be essential to ensure the voice of the EC community in other relevant legislative developments, for example the Data Protection Regulation: FEAM on behalf of the biomedical community has to continue communicating about the issues to policy makers and the public. Moreover, various ethical issues need to be taken into account in appraising scientific integrity, and the Academies have a continuing role more broadly to analyse and promote responsible science<sup>9</sup>.

### [Slides](#)

### [Perspectives from member academies of FEAM](#)

#### ROMANIA

[Maria Dorobantu](#) (Member, [Romanian Academy of Medical Sciences](#); Head of the Cardiology Section, Emergency Hospital, Bucharest) welcomed the Clinical Trials Regulation as helping to remedy current problems and delays in obtaining ethical and scientific approval for protocols. When surveyed, her Academy colleagues were in favour of ECs remaining a national responsibility (because of the variability between Member States in the social, legislative and cultural environment) but there was room for EC functions to be more closely informed by EU-level activity - to deliver greater consistency in covering all clinical research and to become more involved in monitoring research (from the patient's perspective) and upholding research integrity. There was also some enthusiasm for extending EC activities to assess ethical issues for medical audit as well as research and to have a greater role to ensure publication of trial results – recognising that these additional functions might be found controversial. ECs might also adopt a greater advisory role in

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<sup>8</sup> See [“A roadmap for sharing clinical trial data”](#) 2013.

<sup>9</sup> See, for example, the IAC-IAP publication, [Responsible conduct in the global research enterprise](#), September 2012.

biostatistics to determine if research studies are appropriately powered and do not waste the contribution made by patients to research.

#### SPAIN

**Diego Gracia** (Member, [Spanish Royal National Academy of Medicine](#); Emeritus Professor of history of Medicine and Bioethics, Complutense University, Madrid) observed that there is insufficient clarity on what is presently meant by clinical research ethics and, hence, on why ethical and regulatory assessment functions are demarcated. What is certain is that ethics responsibilities of ECs should not be confined to the tasks of evaluating and revising Patient Information Sheets but must take a more comprehensive perspective based on patients' rights. In reinforcing the point made by previous speakers, it was also clear that biomedical research will change markedly, perhaps particularly in consequence of routine use of data from patient records and that ECs must prepare to help manage this flow of information to assure the quality of data generation and use in the clinical context. FEAM must look forward to assess the implications appearing on this new horizon.

#### HUNGARY

**Sandor Kerpel-Fronius** (Representative of the [Hungarian Academy of Sciences](#); Department of Pharmacology and Pharmacotherapy, Semmelweis University, Budapest) agreed that it is critically important to take into account new sources of data. The professional knowledge needed by ECs to do this is now so diverse that a single, centralised EC is probably unrealistic for many Member States. There are important implications for the training of EC members in the core competences relating to clinical investigation – initiatives by ECRIN and others in training clinical investigators may also yield material useful for training ECs.

In returning to the practical challenges of obtaining consent for use of patient data, it was proposed that a new form of the social contract should be advanced: in return for using publicly-funded health care services and innovation that has drawn on publicly-funded research, citizens should give broad consent for anonymised use of their data for the future benefit of society.

#### BELGIUM

**Jean-Marie Maloteaux** (Member, [Royal Belgian Academy of Medicine \(ARMB\)](#); Head of the Department of Clinical Neurology and Chair of the Ethics Committee, Brussels Saint Luc Hospital, University of Louvain) also highlighted the difficulty in ECs recruiting lay members and finding specialists in some areas (for example, emerging technologies). These difficulties are likely to contribute to the variability in approvals in multicentre trials and there would be benefit in sharing specialist expertise across borders.

#### PORTUGAL

**Daniel Moura** (Vice-President, [Portuguese National Academy of Medicine](#); Institute of Pharmacology and therapeutics, Faculty of Medicine, University of Porto), substantiating points made by previous speakers, noted that while the present EC system in Portugal

functioned efficiently in many respects, there is lack of transparency and lack of lay representation, and there is need for EC education.

## GERMANY

[Hans-Peter Zenner](#) (Member of the Presidium, [German National Academy of Sciences 'Leopoldina'](#); Professor and Chairman, Department of Otolaryngology, Head and Neck Surgery, University of Tübingen) agreed that the Clinical Trials Regulation represents significant progress in harmonisation, with the prospect of simplified and faster approvals. However, major concerns had been articulated in inter-academy discussions in Germany<sup>10</sup>. For example:

- The protection of minors and incapacitated persons might unfortunately be reduced compared to existing legislation, since more extensive national protective regulations, such as the German Medical Products Act, could become ineffective.
- ECs should be independent rather than being a product of the authority that approves the protocol.
- Emergency research protocols should only be allowed if they cannot be achieved by non-emergency research.
- For cross-border studies, there is risk that sponsors could choose to seek approval in a Member State requiring a lesser standard.
- The possibility of tacit approval (if the permitted time for approval is exceeded) is worrying.

The German academies' report makes a series of recommendations to ensure the protection of vulnerable clinical trial subjects, to involve an autonomous, independent, certified, legally regulated EC in every Member State participating in a trial, and to promote harmonisation of a high level of protection.

## 4. CONCLUSIONS AND RECOMMENDATIONS

Many of the questions posed in the presentations were addressed in greater detail during group discussion.

### [Is there scope for further harmonisation of ECs?](#)

It was agreed that ECs need to be part of the EU discussions on future strategy development in response to the changing nature of international research (for example, availability of large data sets, advent of personalised medicine) and the need for improved and more consistent quality control in evaluation. Member States vary greatly in their current organisation of ECs and the more immediate need in many countries is to create coherent and efficient national provision before moving to considerations of EU-level harmonisation.

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<sup>10</sup> Comprehensive details are in the publication: Leopoldina Nationale Akademie der Wissenschaften, acatech, Deutsche Akademie der Technikwissenschaften, Union der Deutschen Akademien der Wissenschaften, Clinical Trials with medicinal products on humans, January 2014

There is scope for EU harmonisation of advice on how ECs might function in integrating information to assess benefit-risk. Any subsequent progress towards centralisation depends on building trust among stakeholders, and there may always be local accountability issues that require a distributed network of ECs, near to major health services and research centres. A case can be made for centralising EC assessment in Member States for specialised areas, for new technologies or where there are new quality control issues.

### Should there be an increasing role of ECs in other clinical research?

It was agreed that there is scope for extending EC activities to cover more than studies on medicinal products, consistently in all Member States.

### How should patients be more involved in research and ECs?

It was agreed that more needs to be done to inform patients about medical research rather than perceiving them as the “end user”. ECs can be part of this better communication. However, there is a concern that including patients in ECs might introduce a conflict of interest to their provision of independent advice. In that eventuality, it would be preferable to involve patients earlier in protocol elaboration and research design to measure benefit-risk rather than in EC protocol review.

### Should ECs acquire other additional functions?

As discussed previously, ECs may exert a useful function in helping patients understand their roles in clinical research.

With regard to the publication of research outputs, the prime function of an EC is to ensure in protocol evaluation that the sponsor/researcher commits to publication in due course.

### Should ECs handle SAEs?

It was agreed that ECs should focus on evaluating benefit-risk balance and that emergence of SAEs during a trial may change that balance. Nonetheless, the situation where individual SAE reports flow to ECs has not been productive because many ECs lack expertise and resource to assess the implications of SAEs. The reformed procedures put into place by the European Commission, where the Eurovigilance database is responsible for cumulative experience of SAEs, for evaluation by Competent Authorities and, where appropriate, a trial-specific safety monitoring board, is considered helpful in sparing ECs from the SAE burden.

### What are the training needs of ECs?

It was agreed that EC members (including lay members) benefit from training. Various options were proposed – to use training material developed for clinical investigators, to require an induction period before new EC members can decide on protocols, to encourage EC members to train together, and to support the training of EC secretariats, who have a critical role in continuity of EC performance.

There is, again, large variation in current practices for EC training between Member States and it is desirable to share and spread good practice preparatory to harmonising core principles in training. Training programmes could be associated with accreditation

standards. There is no EC accreditation system in the EU, so sponsors often use the US standards; further discussion is warranted on whether the EU should develop EC accreditation in support of quality assurance across borders.

In conclusion, 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 citizens or EU competitiveness. How, collectively, do we engender a better system? It is vital, in order to avoid (further) marginalisation of ECs, to share good practice, learn about respective strengths and weaknesses, scan the horizon for impending technology and policy developments, and monitor the impact of change already made. These tasks must be tackled now rather than waiting for Clinical Trial Regulation interim revision. The FEAM meeting has been a useful first step and FEAM will now consider options for catalysing further dialogue and action.

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*FEAM warmly thanks Professor Bernard Charpentier (FEAM Vice-President; Member of the [French National Academy of Medicine](#)) for chairing this workshop and activity.*

[Programme](#)

[List of participants](#)

[Background paper](#)



**FEAM is the European umbrella group of national Academies of Medicine and Medical Sections of Academies of Sciences.**

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### Mission

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

### Membership

- FEAM's strength lies in its member Academies that give it the authority to provide an EU-wide scientific opinion on the European medical science base and evidence to underpin European biomedical policy.
- Its growing [membership](#) currently includes **18 national Academies that represent over 5000 among the best scientists across the biomedical spectrum** in Austria, Belgium, Croatia, Czech Republic, France, Germany, Greece, Hungary, Ireland, Italy, Lithuania, Netherlands, Portugal, Romania, Spain, Switzerland, United Kingdom.
- Active collaboration with two sister networks and observers: the European Science Advisory Council ([EASAC](#)), representing the national Academies of Sciences in Europe, and the InterAcademy Medical Panel ([IAMP](#)), representing the national Academies of Medicine worldwide.

### Policy priorities

- EU regulations and directives
- Ethical review of clinical research
- Personalised medicine
- One Health: human, animal and environmental health
- The culture of prevention in health
- Medical education and training in Europe