Second World Conference on Research Integrity

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A Way Forward?

A report from the European Forum for Good Clinical Practice

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What is the European Forum for Good Clinical Practice (EFGCP)?

A non-profit organisation established by and for individuals with a professional involvement in the conduct of biomedical research.

Membership of the EFGCP Research Integrity Sub-Group ('The Group')

Dr Michael Bone, Consultant Physician, Gateshead, United Kingdom

Dr Erick Gaussens, Consultant Statistician, Paris, France

Professor Jean-Marc Husson, Co-Director, Eudipharm, Lyon, France

Professor JanHasker Jonkman , Professor of Pharmaceutical Sciences, Groningen, the Netherlands.

Professor Ana Marusic, Editor in Chief, Croatian Medical Journal, Split, Croatia

Dr Detlef Niese, Head, Development External Affairs, Novartis, Basel, Switzerland

Dr Yannick Pletan, Medical and Scientific Director, Pfizer, Paris, France

Professor Povl Riis, Chairman, Age Forum, Copenhagen, Denmark

Mr Fergus Sweeney, Principal Scientific Administrator, European Medicines Agency, London, UK

Dr Richard Tiner, President, Faculty of Pharmaceutical Medicine, London, UK

Dr Frank Wells (Chairman), Ethics Officer, EFGCP, Ipswich, UK

Professor Nicholas Steneck, Office of Research Integrity, Rockville, MD, USA (Advisor to The Group)

Topics we have covered

1. Definitions of ‘fraud’ and ‘misconduct’
2. The case for establishing a national body on research integrity
3. The importance of training in research integrity
4. Support is needed for research into research misconduct
5. ***A whistleblower’s charter***

Topics we have covered

6. A standard operating procedure for the handling of suspected research misconduct
7. The role of the auditor in cases of suspected research misconduct
8. The role of the statistician in cases of suspected research misconduct
9. ***A case for the establishment of dedicated 'rapid response' forensic units***
10. The role of the national competent authority

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A Charter for Whistleblowers

Internationally agreed guidelines for whistleblowers are urgently needed, given that the fate of whistleblowers is generally not an easy one to accept. The EFGCP Group has drafted a version of such guidelines:

- What is whistleblowing?
- Raising concerns: the principles
- Types of concern
- Concerns about research
- What are the contractual entitlements?
- What are the professional obligations?
- Who do I approach in order to raise a concern?
- Raising a concern
- Will there be personal consequences if concerns are raised?
- Where else can guidance be found?

A case for the establishment of dedicated ‘rapid response’ forensic units

Experience in the UK and elsewhere in Europe has shown that the involvement of a dedicated team of trained professionals can bring about an early decision on whether or not there is a case to be answered. Successful (forensic) investigation leads to successful prosecution or exoneration.

The MLI Approach

- To check and double check the integrity of information which suggests that misconduct may well have occurred
- To assess the whistleblowers motivation and credibility
- Gather and evaluate evidence

The MLI Approach

- Liaison with the relevant authority to obtain cooperation in contacting patients if appropriate
- Visit patients, interview and obtain written evidence
- Present case to relevant authority

In an ideal world, fraud and misconduct in biomedical research wouldn't happen.

The next best thing is to have all these elements to achieve maximum integrity in place.

It is in the ultimate interests of all involved, and especially patients, that this is done.

The complete (but interim) report on which this presentation was based can be accessed at www.efgcp.eu