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RECOMMENDATIONS TO THE EUROPEAN COMMISSION ON THE CLINICAL TRIALS DIRECTIVE.

The Federation of European Academies of Medicine welcomes the potential benefits for multinational collaboration in clinical research that could result from the Clinical Trials Directive (2001/20/EC). However the Federation continues to have some reservations on the application of this directive to academic, non-commercial, clinical trials which it would like to bring to the attention of the European Commission.

High quality clinical research which aims at developing state of the art treatment - and not at registering new compounds - is vital for improving the quality of patient care and these "academic trials" need to be conducted on a multi-disciplinary basis and at the European level.
"Academic trials" should be defined as studies not aiming at the registration or commercialisation of a new agent ***and whose results may not be used for these purposes***. The ownership of the database of these trials should belong to the academic sponsor; and the study design, the final analysis of the results and the appropriate peer review process should all be under the control of the academic sponsor.

Support from industry by providing free drug for an academic trial and/or by the making an educational grant should not be taken to imply that industry is "involved" in the trial for the purpose of an EU directive and should not disqualify the trial from being regarded as an academic, non-commercial venture.

For such academic trials the Federation further recommends to the Commission:

1. That access to marketed drugs should be on the same basis as when these drugs are used for routine treatment.

2. Re-labelling of marketed drugs should not be required; although the batch of the drug used should always be traceable.

3. The academic sponsor should have free cross referral to the IMPD dossier.

4. No fee should be paid to the competent authority or the ethics committee for review of academic clinical trials.

The Federation further encourages the Commission, with regard to all clinical trials, to:

1. Minimise duplication of regulatory procedures for multinational trials.

2. Establish an environment for clinical research that is proportionate to the risks to participants.

3. Provide for appropriate flexibilities for researchers by using binding legislation only for the principles of good clinical practice and non-binding guidance for the details of good clinical practice.

4. To allow for alternative procedures for assuring the interests, rights, safety and well-being of participants in clinical trials that take account of the likelihood of risks.

5. To establish a forum to resolve difficulties in commencing and conducting clinical trials that result from member states transposing or implementing the directives in different ways. Such a forum should involve all the relevant stakeholders – academic institutions and international networks, national academies, competent authorities, ethics committees, patients' advocacy groups, charities, funding bodies, the European Commission and the European Parliament.

The Federation supports the view put forward by the Committee of Medical Journal Editors that all clinical trials should be registered in a database that provides the information that the editors recommend:

- A unique identifying number,
- A statement of the interventions and comparisons studied,
- A statement of the study hypothesis,
- Definitions of the primary and secondary outcome measures,
- Eligibility criteria,
- Key trial dates,
- Anticipation of actual date of last follow-up,
- Planned or actual date of closure to data entry and date the trial data is considered complete,
- The target number of subjects,
- The funding source and contact information for the principle investigator.

All large trials need to have a data monitoring committee independent of the principal investigator.

The Federation is aware that the European Medicines Evaluation Authority does maintain a clinical trial database which could be upgraded to provide all the information above and they would urge that this should be done and, further, that this database should be freely available to all stakeholders.

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