EUCROF
European CRO Federation

New Clincial Trials Regulation: Driving Transparency and Stimulating Innovation in Europe
EUCROF releases its Position Paper on Transparency in Early Phase Clinical Research

(31 October 2014): Patients, healthcare professionals and the public have the right to access clinical research information that may affect patients' and public health, new and existing treatments of health conditions and access to innovative clinical research.

EUCROF released proposals on the early publication of clinical trial information, balancing the public's need for transparency and innovators' intellectual property and confidentiality rights.

Early phase clinical trials study basic mechanisms and actions of potential new medicines rather than their therapeutic efficacy. Patients and healthy volunteers who participate in these studies are usually not expected to gain any health benefit. In order to provide a transparent approach of public access to early clinical research information, it is proposed to release the information as and when it becomes relevant for patients, health care professionals and the public and thereby ceases to be commercially confidential:

1. Relevant registration information is made publicly accessible via the EU database following clinical trial authorisation and prior to study commencement.
2. All further publication milestones, such as access to further registration information, summary results and lay summary and general rules for publication (e.g. if a study has been terminated on safety grounds), are clearly defined and justified in each clinical study protocol and approved via the clinical trial authorisation.
3. In case of any changes to the authorised publication process and timelines, a Substantial Modification is submitted and, if justified, authorised prior to implementation.

EUCROF believes that the proposed approach has a number of advantages:

- It meets patients' and public need for disclosure of all information when it becomes relevant for the recipients.
- There is a firm commitment by innovators to be transparent and to publish at specified time points.
- The process has regulatory approval.
- It can be modified via Substantial Modification, if necessary.
- It is the responsibility of the sponsor and investigator to comply with the commitments made, in the same way as complying with all other parts of the clinical trial and its authorisation. Competent Authorities are able to assess compliance with the commitments made.
- It follows a tried and tested process of study design, regulatory approval and change management; it would therefore require little (if any) additional administrative effort.
- It is an efficient and pragmatic process which operates in compliance with the Clinical Trial Regulation and its objectives.
- Commercially Confidential Information is respected.

EUCROF is committed to continue working with regulatory bodies and all stakeholders and help implement the EU Clinical Trials Regulation to meet its objectives of stimulating transparent, innovative clinical research in Europe. We are seeking to find a balanced approach which is useful to patients and yet not harmful to European early drug development and innovation, so that the Clinical Trials Regulation can achieve what it was intended for: to boost clinical research in Europe, to give patients access to the most innovative clinical research and treatments and to improve existing treatments.

Read the full Position Paper

EUCROF Position Paper Public Access

About EUCROF

The European Contract Research Organisation Federation (EUCROF) represents members from 11 EU countries: Czech Republic (ACRO-CZ), the Netherlands (ACRON), Spain (AECIC), France (AFCROS), Italy (AICRO), Sweden (ASCRO), Belgium (BeCRO), Germany (BVMA), UK (CCRA), Greece (HACRO) and Turkey (SAKDER) as well as six associate members in Denmark, Ireland, Poland, Portugal, Switzerland and Ukraine. It speaks for 300 member Contract Research Organisations and their over 15,000 employees.

EUCROF's aims and objectives are - amongst others - to promote clinical research of high quality in Europe/the European Union, and to represent its members in interactions with regulatory bodies, the pharmaceutical-biotechnology industry and the medical research community.

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