EUCROF

Welcome to EUCROF, the European CROs Federation

EMEA
FIM Guideline

12th June 2007

- Thank you to invite

EUCROF

The European Federation of CROs

We want to stress 5 points

- Protection of the subjects
- Scope of the guideline
- Quality
- Clinical requirements
- Regulatory aspects

Protection of the subjects

- The guideline specifies that “the safety of subjects participating in first in man studies is the paramount consideration”.

- To reinforce the protection of subjects (healthy volunteers or patients), we propose to include in the guideline:
- A process of accreditation of the centres (private or public) which perform non therapeutic clinical studies or wich perform FIM studies, as it’s already done in France and as it’s considered by the MHRA,
- A process of national or European database for the registration of the healthy volunteers and the patients included in the these non therapeutic clinical studies,
- A restriction of the fees that an healthy volunteer can receive per study or per year (non professional volunteers).

The scope of the guideline

The scope of the guideline has to cover:

- all first in man administrations,
- acute or repeated administrations,
- with high risk or with no high risk medicinal products,
- with healthy volunteers and with patients.

- The guideline has to give a clear definition of what is a no high risk product and of what is a high risk product.

Quality

- The requirements for quality should be the same for all products and studies.

Clinical requirements

- The guideline is not clear about the sequential design for acute and repeated administrations
- The guideline can proposed rules or methods or example: 1 + 2 + 3 subjects… methods for calculation of the period of times between 2 sub-groups of subjects in the same dose, between 2 doses, which rules for an acute administration, for a repeated administration,
- Same situation for “the stopping rules for the individual subjects”: how to define what is unexpected?
- and the guideline is really blurred about the definition of appropriate clinical facilities (“facilities for the treatment of medical emergency” = in hospital phase 1 unit?)

Regulatory aspects

We have 2 questions :

- Will the FIM studies performed outside of Europe be accepted by the EMEA?
- Is the guideline to be accepted by the FDA or the PMDA or to be harmonised by ICH (to prevent possible differences between European and the other phase 1 centres)?