Workshop 1:
A Risk-based Approach to Patient Information?

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Risk-based Approach in Clinical Trials

European Commission's proposal for a draft Regulation for Clinical Trials: July 2012

2 different risk categories for clinical trials:

1) IMPs without and with marketing authorisation
2) "Low-intervention clinical trial" with IMPs with marketing authorisation, within their labelled use, with minimal additional risk and burden

Shorter approval timelines, simpler IMPD, risk-adapted monitoring, national indemnification mechanisms for low-intervention CTs **BUT**

"Ethical aspects relate, in particular, to the need to obtain Informed Consent from the subject. Irrespective of the risk that a clinical trial may pose to a patient, the mere fact that the treatment is part of an experiment renders it necessary – from an ethical viewpoint – to obtain the informed consent of the subject".

Risk-based Approach to Patient Information

HOWEVER:

There is general complaint that our current approach to Patient Information Sheets (PIS) is not suitable: too long, incomprehensible, too much technical and legal detail.

Would it not make sense to adapt the Patient Information Sheet to the risk category of the clinical trial?

There are three sources of risk to subjects

1) Investigational Medicinal Product (IMP)
2) Research interventions to test the IMP's safety and efficacy (e.g., blood drawals, imaging procedures, biopsies, etc.)
3) Interventions that would be provided as part of routine care

The degree of risk and potential clinical benefit of all interventions varies

Risk-based Approach to Patient Information

Key questions:

1) **Which information does the subject need to decide on his/her participation in the trial?**
2) **Which information do sponsor and investigator consider necessary to be provided to the subject?**
3) **How could structure and lay-out of the PIS support the efficient delivery of the information?**
4) **Can this be handled differently for clinical trial categories 1 and 2?**