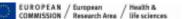


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			on Clinica	I I rials
L 121/34	EN	Official Journal o	f the European Communities	1.5.2001
	DIRECTIVE 20		OPEAN PARLIAMENT AND OF THE COUNC 4 April 2001	IL.
	on the approximati relating to the im	plementation of good of	ns and administrative provisions of the Member clinical practice in the conduct of clinical tri roducts for human use	States als on
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		COMMISSION	DIRECTIVE 2005/28/EC	
		of	8 April 2005	
		for human use, as v	es for good clinical practice as regards investig vell as the requirements for authorisation of mportation of such products	
		(Text w	ith EEA relevance)	
h	ttp://ec.euro	ba.eu/health/hi	uman-use/clinical-trials/inde	x_en.htm
				2



Clinical Trial topics

Total EC contribution to these projects: $\sim \in 100$ million 4 + 2 topics, with several projects to be funded in each topic

Purpose:

- to bring discoveries into clinical testing, to advance development of new approaches and to compare treatments
- Most topics are for investigator-driven clinical trials (IDCTs), complementing development of new drugs by industry

Scope:

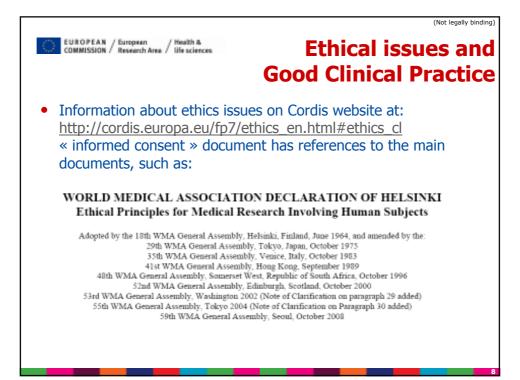
- Is specified in each topic
- Needs to consider available budget
- Expected to be mostly phase II, but also all other phases depending on the topic



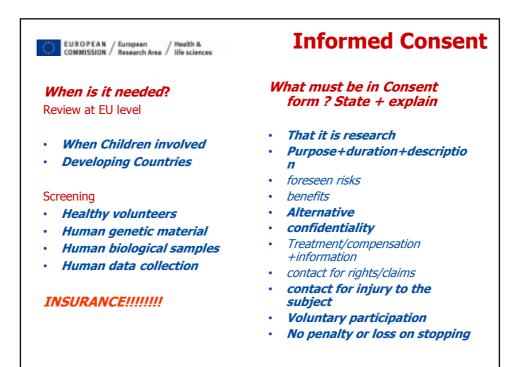












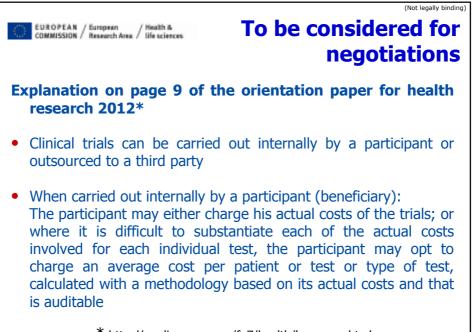


Privacy and Data Protection

How to Deal with Data Protection and Privacy?

- describe the procedures for informed consent + confidentiality
- inform consent for **duration** +
- code or **anonymised** banked biomaterial, security for storage and handling
- Fairly and lawfully processed
- Iimited purposes
- Adequate, relevant sufficient
- Accurate
- Timely storage
- Processed in due form subject's
 - rights
- Data privacy / share data while protecting identifiable information. • Secure • Not transferred abroad unprotected

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* http://cordis.europa.eu/fp7/health/home_en.html



To be considered for subcontracts

• best value for money, for example by providing the various offers requested, or, if a long term-cooperation with that third party to carry out such tests pre-exists (e.g university and university hospital)

EUROPEAN / European / Health & COMMISSION / Research Area / life sciences

- Participants that are public bodies are reminded that the selection of such a third party has to follow their internal rules and applicable legislation, in particular those related to public procurement
- According to the FP7 rules for participation, core tasks of a project can not be subcontracted

