FONDAZIONE
PER LA RICERCA FARMACOLOGICA
GIANNI BENZI onlus

RICERCA, INNOVAZIONE E COMPETITIVITÀ:

QUALI VANTAGGI PER IL PAESE?

LA SPERIMENTAZIONE CLINICA: UN'OCCASIONE PER L'ITALIA E PER L'EUROPA ?

Mercoledì 24 ottobre 2012 ore 08.30 – 13.30

CAMERA DEI DEPUTATI

SPERIMENTAZIONE CLINICA E AUTORIZZAZIONE ALL'USO IN EUROPA: ASPETTI GENERALI E NUOVI STRUMENTI

Prof. Adriana Ceci

Presidente Fondazione Ricerca Farmacologica GIANNI BENZI

PDCO Member - representing HP

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Iscritta in data 19/11/08 al n 47/P del Registro delle Persone Giuridiche della Prefettura di Bari

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Agenzia Italiana del Farmaco

La **sperimentazione clinica** è uno straordinario mezzo per valutare l'efficacia e i rischi di un farmaco e, in definitiva, per decidere della opportunità della sua **commercializzazione**

EFFETTO ECONOMICO

Tuttavia l'importanza della ricerca non può mai giustificare la violazione dei diritti delle persone che partecipano alla sperimentazione.

Le norme che regolano la **Sperimentazione Clinica** hanno il principale scopo di **mettere in equilibrio** queste due componenti

VALORE ETICO

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Valore economico e Interesse Pubblico

Spesa lorda a carico del Servizio Sanitario Nazionale per classificazi

Classificazione terapeutica – ATC 1° livello		Spesa totale (milioni di euro)
C	Sistema cardiovascolare	4.407
A	Apparato gastrointestinale e metabolismo	1.905
N	Sistema nervoso	1.448
R	Sistema respiratorio	1.095
J	Antimicrobici generali per uso sistemico	1.034
B	Sangue e organi emopoietici	574
M	Sistema muscolo-scheletrico	558
G	Sistema genito-urinario e ormoni sessuali	404
L	Antineoplastici e immunomodulatori	336
H	Preparati ormonali sistemici, escl. ormoni sessuali	225
S	Organi di senso	211
V	Vari	120
D	Dermatologici	59
P	Antiparassitari, insetticidi e repellenti	12
	Totale	**12.388**

Fatturato farmaceutico totale (valory ex factory) – 2011

Paesi	Fatturato complessivo (farmacia e ospedali, milioni di euro)	%
USA	233.326	*37,6*
Giappone	72.289	*11,6*
Paesi Ue	**137.700**	***22,2***
Paesi Big UE 5	**112.563**	***18,1***
Germania	30.545	*4,9*
Francia	30.193	*4,9*
Italia	**20.272**	***3,3***
Spagna	16.071	*2,5*
Regno Unito	15.482	*2,6*
Belgio	4.538	*0,7*
Grecia	3.573	*0,6*
Svezia	3.248	*0,5*
Austria	3.096	*0,5*
Paesi Bassi	2.933	*0,5*
Portogallo	2.156	*0,3*
Danimarca	1.957	*0,3*
Finlandia	1.897	*0,3*
Irlanda	1.739	*0,3*
Svizzera *	4.944	*0,8*
Norvegia *	1.456	*0,2*
Altri	171.611	*27,6*
Totale	**621.326**	***100,0***

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Normativa di rilievo

I principi di riferimento Etico e Legale identificati nelle fonti Internazionali sono:

- *Ogni studio sull'uomo deve essere giustificato*
- *I diritti del soggetto devono essere rispettati*
- *La persona deve essere adeguatamente informata*
- *La Privacy va salvaguardata e i dati raccolti devono essere tutelati.*



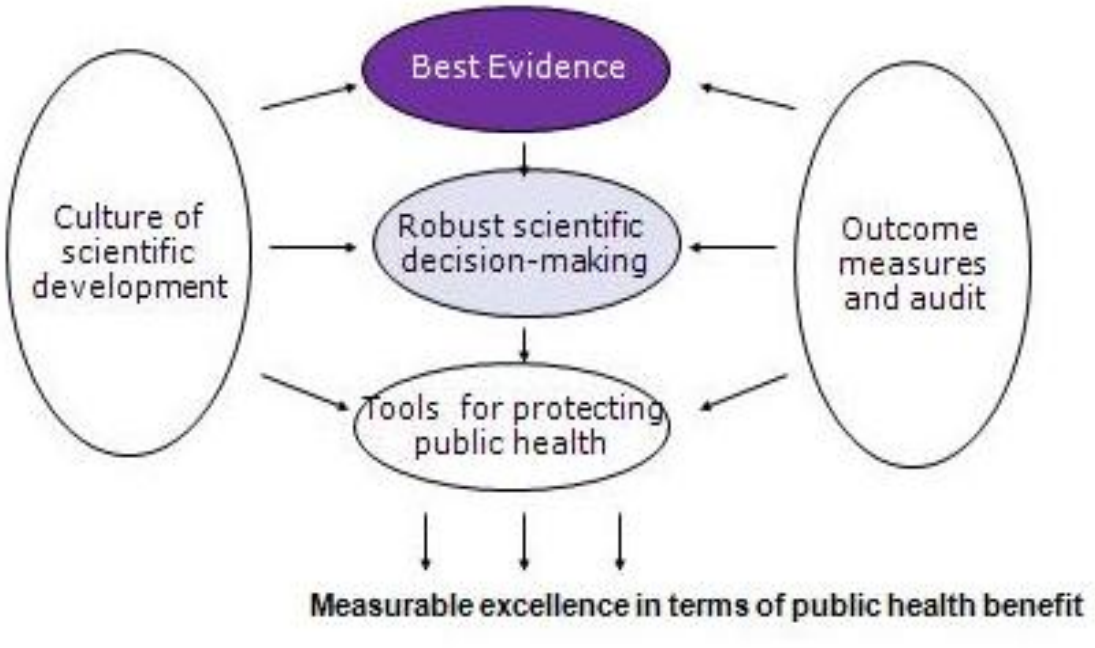
Main Sources: Helsinki Declaration – WMA (2008); Convention on human rights and biomedicine (Oviedo, 1997) and **Additional Protocol (2005)**; Inter. Ethical Guidelines for Biomedical Research – CIOMS/WHO (2002), Dir. 20/2001, ICH-GCP, etc

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Dir. 20/2001, ICH-GCP, Dec. Leg. 211, 2003

Applicazione delle Good Clinical Practices (GCP) in Europa - aspetti scientifici

- Standard Metodologici
- Evidenza statistica
- Reports intermedi e finali
- Qualificazione dei ricercatori e dei centri, etc



Esistono Lineeguida specifiche per tipo di patologia, tipo di studio, età, sede degli studi, etc. Un insieme continuamente aggiornato e disponibile all'indirizzo:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000085.jsp&mid=WC0b01ac0580027549

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APPLICAZIONE DELLE GCP - DIRITTI FNDAMENTALI

Il Comitato Etico deve garantire :

- Che i principi etici sono rispettati (rispetto della persona, a prinicipi di 'benevolenza' 'non maleficienza' e 'giustizia'
- Che I diritti fondamentalòi siano rispettati (DIGNITY, RIGHT TO LIFE, PHYSICAL AND MENTAL INTEGRITY, SELF-DETERMINATION)
- Che la ricerca non mette a rischio il paziente o il suo gruppo di riferimento

'Nessuno studio può essere iniziato se non ha ricevuto un parere positivo da parte di un Comitato Etico'



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IL SOGGETTO DEVE ESSERE ADEQUATAMENTE INFORMATO

"Informed Consent is the decision, which must be written, dated and signed, to take part ***in a clinical trial****, taken freely* ***after being duly informed*** *of its nature, significance, implications and risks and appropriately documented,*

by any person capable of giving consent or, where the person is not capable of giving consent

by his or her legal representative

(Ref. ICH-GCP and Dir. 20/2001)

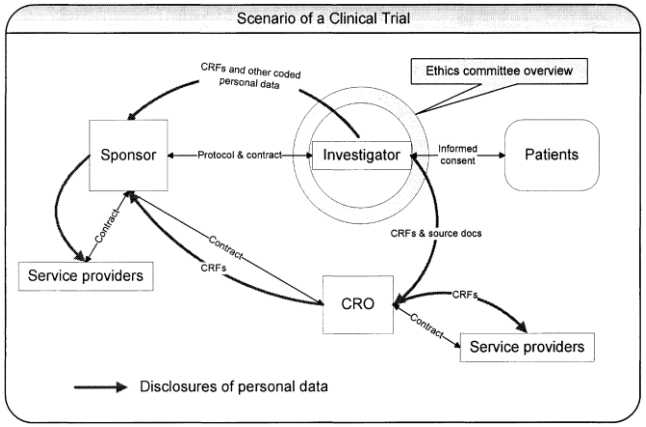


La Dir. 20/2001 ha introdotto con l'art. 4 il 'diritto' dei bambini ad essere destinatari di sperimentazioni disegnate sulle loro esigenze e le Racc. EMA del 2008 hanno previsto il CONSENSO o l'ASSENSO del minore!

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TUTELA DELLA PRIVACY

Tutti coloro che entrano in contatto con informazioni personali del paziente sono tenuti al rispetto della Direttiva sulla Privacy (Dir. 95/46/EC)



Diritti del soggetto/paziente:

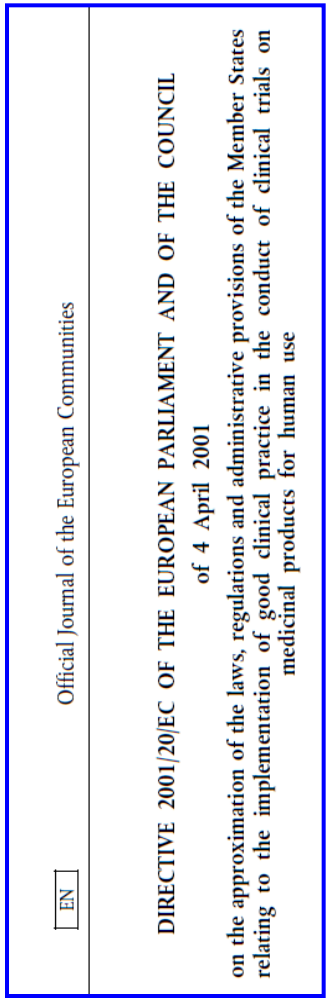
- ***Dare il proprio CONSENSO all'uso dei dati***
- ***Avere la sicurezza che i propri dati sono protetti e non verranno trasmessi ad altri***
- ***Diritto alla tutela della Privacy***

- E' assicurata la confidentialità
- I dati devono essere resi anonimi

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Directive 2001/20/EC
Obiettivi generali ed economici

Obiettivo:
armonizzazione e garanzie



Official Journal of the European Communities

EN

DIRECTIVE 2001/20/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 4 April 2001
on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use

La Dir. 20/2001 ha dato valore legislativo alle GCP.

TEMPI certi per le autorizzazioni

REGOLE COMUNI in tutti gli Stati Membri

PARERE UNICO NAZIONALE :

- studi multicentrici nazionali
- Studi multicentrici multinazionali

RISPETTO delle Autonomie Nazionali (e Regionali)

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Dir. 20/2001: riavvicinamento delle norme? Armonizzazione?

Una norma di successo?

Problemi non risolti in tutti i Paesi

L'intero sistema Europeo in difficoltà



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Dir. 20/2001: perché cambiare??

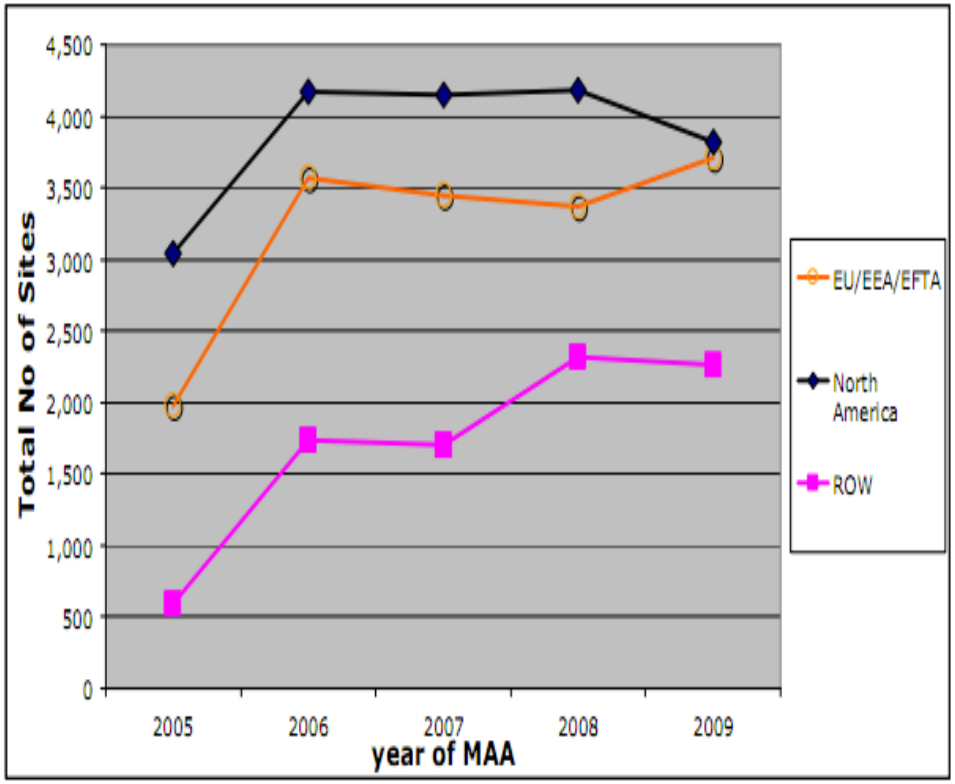


Figure 7: The number of investigator sites involved in pivotal clinical trials submitted in MAAs to th EMA per region and year. The data are shown as three "global regions" – EU/EEA/EFTA, North America and ROW (Rest of the World).

- Clinical trials directive only partially successful in harmonising requirements
- Issues remain across a number of areas
- Need for changes to ensure EU remains an attractive place for clinical research

Concept Paper EU-SANCO, 2011

Clinical research is moving away from Europe, esp. academic CTs: from 2007 to 2010: 17% less approved protocols and 26% less enroled patients [source EudraCT])

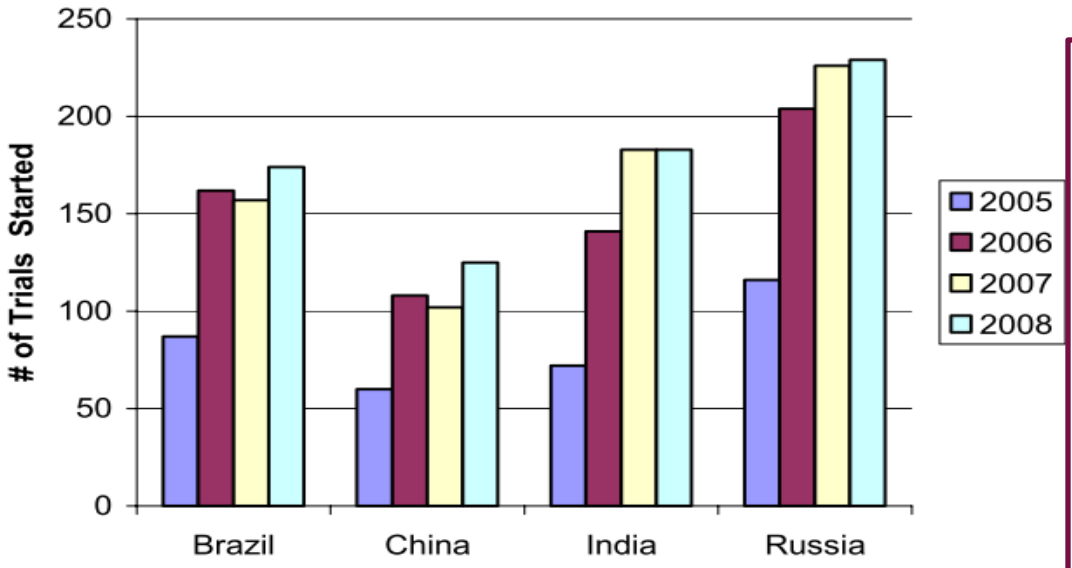
FONDAZIONE PER LA RICERCA FARMACOLOGICA GIANNI BENZI ONLUS

Dir. 20/2001: perché cambiare??

Il (parziale) fallimento degli obiettivi di semplificazione/armonizzazione della Dir. 20/2001 ha stimolato l'Europa a procedere alla sua modifica

CT in BRIC countries

Doc. EMA/INS/GCP/154352/2010

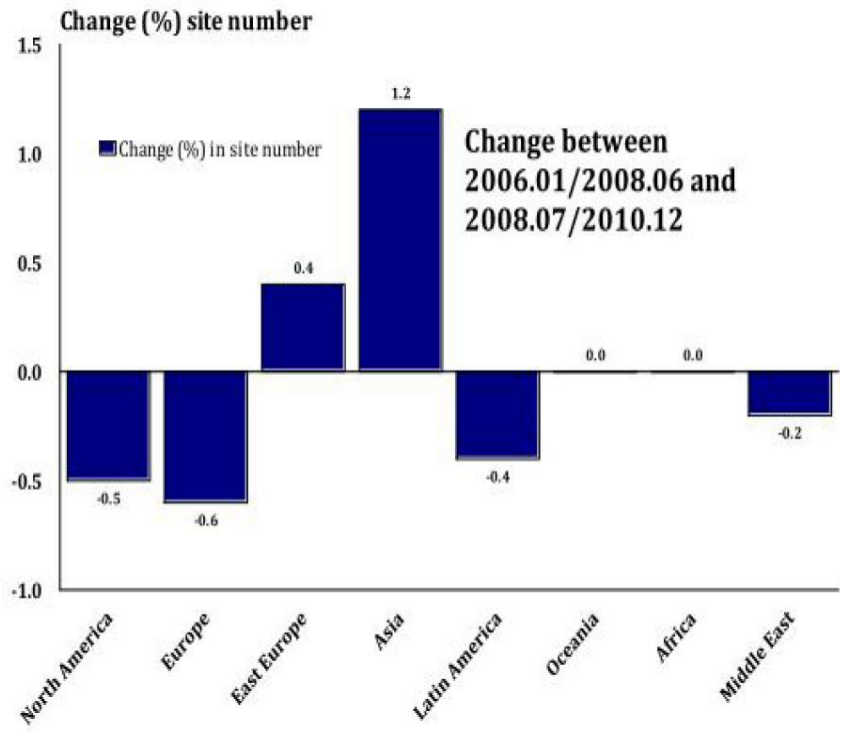


61% of the patients in pivotal trials submitted in MAA to the EMA during the observation period from January 2005 to December 2009 were from third countries, comprising 25.9% from the ROW region

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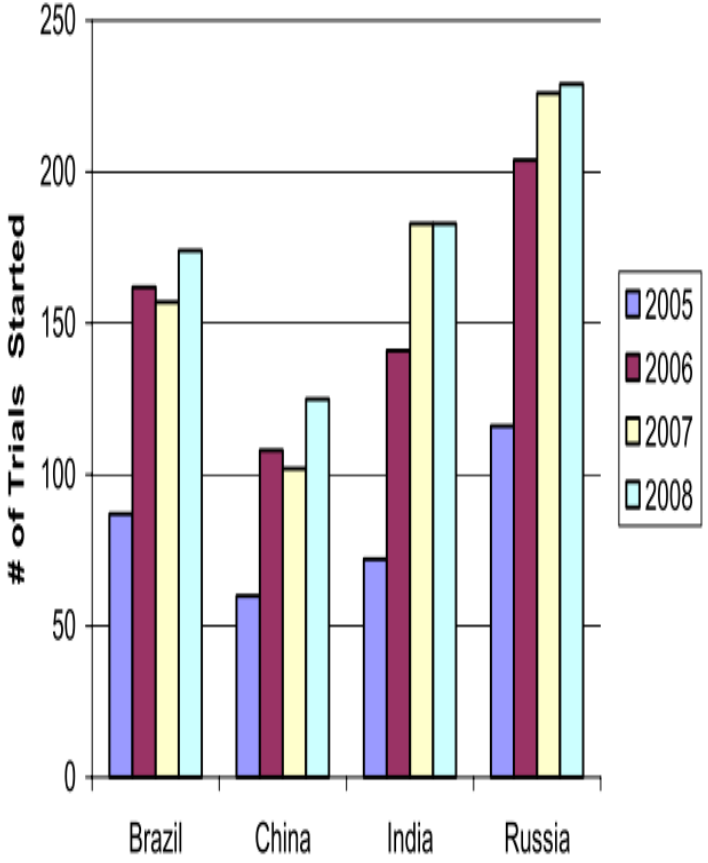
Globalization of clinical trials: the establishment of emerging regions

Change in % of phase II-III CT sites



Source: Clinical Trial Magnifier Vol. 4, Feb 2011

CT in BRIC countries



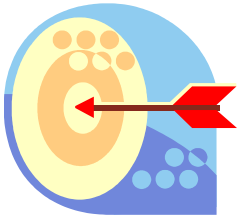
Source: Translational Medicine India, 2009

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The Proposal for a regulation on CTs COM (2012) 369

CONTEXT

- **Reduced number of applications for CT -25% (2007-2011)**
- **Incresead cost (administrative +98%, insurance fees +800%)**
- **Increased average delay for launching a clinical trial**



OBJECTIVES

- reducing administrative burdens and operational costs,
- reducing delays for the launch of the clinical trial,

<u>without</u>

➢ compromising the safety, well-being and rights of participants in clinical trials and

➢ compromising data robustness.

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The revision of Directive 2001/20/EC: Concept Paper

Main Topics

1. Assessing and following up **applications** for clinical trials

2. Adaptation to practical requirements and a more **harmonised**, **risk adapted** approach

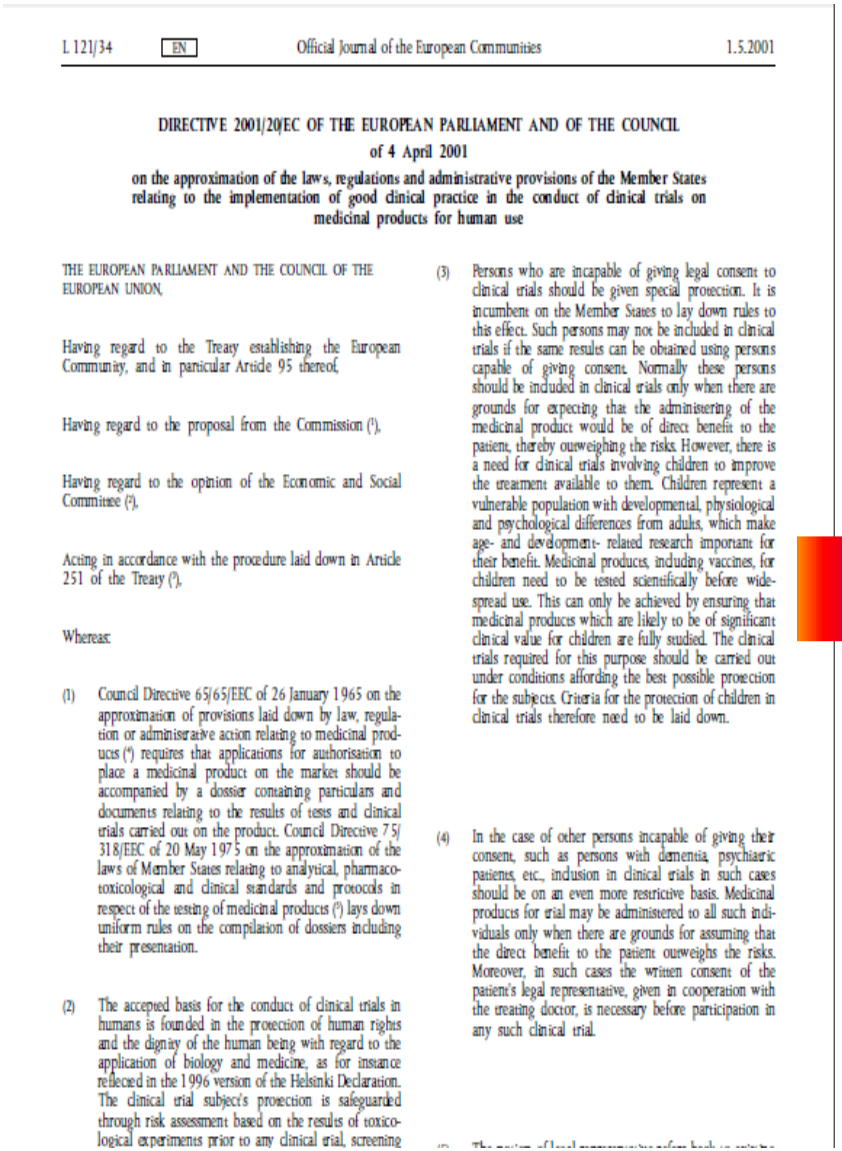
3. **Procedural Aspects**
   - non interventional trials
   - academic/non commercial sponsored trial
   - definition of IMP and rules for auxiliary medicinal products
   - **insurance**
   - single/multiple sponsor
   - emergency clinical trials

4. Ensuring compliance with Good Clinical Practice in clinical trials performed in **third countries**



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From the revision of Directive 2001/20/EC to a proposal for a regulation



L 121/34 EN Official Journal of the European Communities 1.5.2001

DIRECTIVE 2001/20/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 4 April 2001
on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission (1),

Having regard to the opinion of the Economic and Social Committee (2),

Acting in accordance with the procedure laid down in Article 251 of the Treaty (3),

Whereas:

(1) Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products (4) requires that applications for authorisation to place a medicinal product on the market should be accompanied by a dossier containing particulars and documents relating to the results of tests and clinical trials carried out on the product. Council Directive 75/318/EEC of 20 May 1975 on the approximation of the laws of Member States relating to analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of medicinal products (5) lays down uniform rules on the compilation of dossiers including their presentation.

(2) The accepted basis for the conduct of clinical trials in humans is founded in the protection of human rights and the dignity of the human being with regard to the application of biology and medicine, as for instance reflected in the 1996 version of the Helsinki Declaration. The clinical trial subject's protection is safeguarded through risk assessment based on the results of toxicological experiments prior to any clinical trial, screening

(3) Persons who are incapable of giving legal consent to clinical trials should be given special protection. It is incumbent on the Member States to lay down rules to this effect. Such persons may not be included in clinical trials if the same results can be obtained using persons capable of giving consent. Normally these persons should be included in clinical trials only when there are grounds for expecting that the administering of the medicinal product would be of direct benefit to the patient, thereby outweighing the risks. However, there is a need for clinical trials involving children to improve the treatment available to them. Children represent a vulnerable population with developmental, physiological and psychological differences from adults, which make age- and development- related research important for their benefit. Medicinal products, including vaccines, for children need to be tested scientifically before widespread use. This can only be achieved by ensuring that medicinal products which are likely to be of significant clinical value for children are fully studied. The clinical trials required for this purpose should be carried out under conditions affording the best possible protection for the subjects. Criteria for the protection of children in clinical trials therefore need to be laid down.

(4) In the case of other persons incapable of giving their consent, such as persons with dementia, psychiatric patients, etc., inclusion in clinical trials in such cases should be on an even more restrictive basis. Medicinal products for trial may be administered to all such individuals only when there are grounds for assuming that the direct benefit to the patient outweighs the risks. Moreover, in such cases the written consent of the patient's legal representative, given in cooperation with the treating doctor, is necessary before participation in any such clinical trial.



EUROPEAN COMMISSION

Brussels, 17.7.2012
COM(2012) 369 final

2012/0192 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC

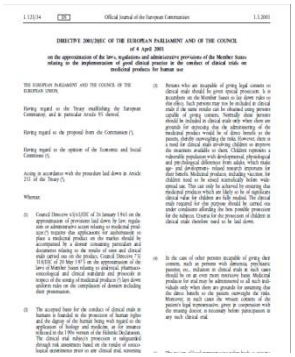
(Text with EEA relevance)

{SWD(2012) 200 final}
{SWD(2012) 201 final}

Glenis Willmott (UK) appointed by the European Parliament's Rapporteur on proposed clinical trial regulation

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PER LA RICERCA FARMACOLOGICA
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From the revision of Directive 2001/20/EC to a proposal for a regulation



DIRECTIVE 2001/20/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
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(Text with EEA relevance)

{SWD(2012) 200 final}
{SWD(2012) 201 final}

1. AUTHORISATION / ETHICAL REVIEW OF PROTOCOLS
2. RISK/BENEFIT RATIO
3. INSURANCE/INDEMNISATION
4. PAEDIATRIC RESEARCH
5. RESEARCH IN NON-EU COUNTRIES

From the revision of Directive 2001/20/EC to a proposal for a regulation

1. AUTHORISATION / ETHICAL REVIEW OF PROTOCOLS

PROPOSAL FOR REGULATION

To start a clinical trial sponsor must:

- submit application to an **EU PORTAL**
- **propose one of the Member States concerned as** "reporting Member State" (principal assessment)

Su richiesta dello Sponsor il trial può essere definito poco interventistico « low intervention »





FASTER PROCEDURE

FONDAZIONE PER LA RICERCA FARMACOLOGICA GIANNI BENZI ONLUS

The Proposal for a Regulation on CTs COM (2012) 369

DEFINITIONS

Clinical study

'Clinical study': any investigation in relation to humans intended

(a) to discover or verify the clinical, pharmacological or other pharmacodynamic effects of one or more medicinal products;

(b) to identify any adverse reactions to one or more medicinal products; or

(c) to study the absorption, distribution, metabolism and excretion of one or more medicinal products;

with the objective of ascertaining their safety or efficacy.

Clinical trials

'Clinical trial': a clinical study which fulfils any of the following conditions:

(a) the investigational medicinal products are not authorised;

(b) according to the protocol of the clinical study, the investigational medicinal products are not used in accordance with the terms of the marketing authorisation of the Member State concerned;

(c) the assignment of the subject to a particular therapeutic strategy is decided in advance and does not fall within normal clinical practice of the Member State concerned;

(d) the decision to prescribe the investigational medicinal products is taken together with the decision to include the subject in the clinical study;

(e) diagnostic or monitoring procedures in addition to normal clinical practice are applied to the subjects.

Low-intervention clinical trials

'Low-intervention clinical trial': a clinical trial which fulfils all of the following conditions:

(a) the investigational medicinal products are authorised;

(b) according to the protocol of the clinical trial, the investigational medicinal products are used in accordance with the terms of the marketing authorisation or their use is a standard treatment in any of the Member States concerned;

(c) the additional diagnostic or monitoring procedures do not pose more than minimal additional risk or burden to the safety of the subjects compared to normal clinical practice in any Member State concerned.

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From the revision of Directive 2001/20/EC to a proposal for a regulation

1. AUTHORISATION / ETHICAL REVIEW OF PROTOCOLS

PROPOSAL FOR REGULATION

Included reference to many guidelines /legal textes
(e.g. ICH, Declaration of Helsinki, ...)

Not included reference to key documents

Oviedo Convention
ratified by
16 european countries
compulsory for them

Additional Protocol on biomedical research
ratified by
5 european countries
compulsory for them

No mention to Ethics Committees



LEAVES UP TO MEMBER STATES TO ORGANISE INTERNALLY THE ATTRIBUTION OF TASKS TO DIFFERENT BODIES

Article 9
Persons assessing the application

1. Member States shall ensure that the persons validating and assessing the application do not have conflicts of interest, are independent of the sponsor, the institution of the trial site and the investigators involved, as well as free of any other undue influence.
2. Member States shall ensure that the assessment is done jointly by a reasonable number of persons who collectively have the necessary qualifications and experience.
3. In the assessment, the view of at least one person whose primary area of interest is non-scientific shall be taken into account. The view of at least one patient shall be taken into account.

REPORTING MEMBER STATE

(i) The anticipated therapeutic and public health benefits taking account of all of the following:

- the characteristics of and knowledge about the investigational medicinal products;
- the relevance of the clinical trial, taking account of the current state of scientific knowledge, and of whether the clinical trial has been recommended or imposed by regulatory authorities in charge of the assessment and authorisation of the placing on the market of medicinal products;
- the reliability and robustness of the data generated in the clinical trial, taking account of statistical approaches, design of the trial and methodology (including sample size and randomisation, comparator and endpoints);

(ii) The risks and inconveniences for the subject, taking account of all of the following:

- the characteristics of and knowledge about the investigational medicinal products and the auxiliary medicinal products;
- the characteristics of the intervention compared to normal clinical practice;
- the safety measures, including provisions for risk minimisation measures, monitoring, safety reporting, and the safety plan;
- the risk to subject health posed by the medical condition for which the investigational medicinal product is being investigated;

FONDAZIONE PER LA RICERCA FARMACOLOGICA GIANNI BENZI ONLUS

From the revision of Directive 2001/20/EC to a proposal for a regulation

1. AUTHORISATION / ETHICAL REVIEW OF PROTOCOLS

PROPOSAL FOR REGULATION

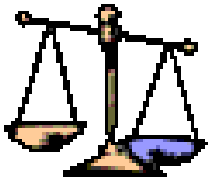
Ogni Stato Membro decide nel suo territorio le regole per:

a) compliance with the requirements for **informed consent** (Chapter V);
b) compliance of the arrangements for rewarding or **compensating investigators and subjects** (Chapter V);
c) compliance of the arrangements for **recruitment of subjects** (Chapter V);
d) compliance with Directive 95/46/EC (**data protection**);
e) compliance with Article 46 (**suitability of investigators**);
f) compliance with Art. 47 (**suitability of sites**);
g) compliance with Art. 72 (**regime of insurance**);
h) compliance with the applicable rules for the collection, storage and future use of biological samples of the subject

may communicate any relevant considerations that will be taken into accont by the reporting Member State
(e.g. legislation prohibiting or restricting the use of human/animal cells)

From the revision of Directive 2001/20/EC to a proposal for a regulation

2. RISK/BENEFIT RATIO



Dir. 2001/20/EC

RISK/BENEFIT RATIO

Stabilito dai CEs sia con riferimento ai soggetti nel trial che ai futuri pazienti

PROPOSAL FOR REGULATION

C'è un'importanza crescente della valutazione rischio/beneficio (varia il tipo di autorizzazione!) ma manca una base comune

MINIMAL RISK/MINIMAL BURDEN/MINIMAL HARM

DIRECT BENEFIT/MINOR INCREASE OVER MINIMAL RISK

Su questi concetti esiste grande incertezza. Il Regolamento non specifica e lascia allo Stato Rapporteur il compito di decidere.

3. Assicurazioni/Indennità

Dir. 2001/20/EC

Uno trial clinico può essere condotto solo se :

Sono previste strumenti assicurativi e indennità che coprano le responsabilità e i rischi provenienti dalle procedure sperimentali. Tali strumenti devono essere vautati idonei dal Comitato Etico.

EU Directive does not set forth the specific contours of the requirement

FONDAZIONE PER LA RICERCA FARMACOLOGICA GIANNI BENZI ONLUS

INSURANCE POLICY in National legislations

Costo aumentato dell'800%!!

	USA	Belgium	France	Germany	Italy	Holland	UK	Spain
Compulsory insurance	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Indemnifiable injuries: death, serious harm, pain, suffering, economic losses	Variable	No	No	Death or permanent disability	Death, serious harm, pain, suffering, economic losses	Death and other harms	"any injury" in phase 1 trials; "serious harm" in phase 2 and 3 trials	Physical injuries and their economic consequences
Limits to compensation (e.i.: exclusion of the harms which are inevitable in particular kind of trials; exclusion of the health problems which can depend on the natural progression of the subject's disease)	Yes	No	No	No	No	Yes	Yes	Yes
Indication for the informed consent document	Yes	No	No	No	Yes	Yes	No	No
Differences in compensation plans according to the type of trial (phase 1, 2, 3 or 4) or to the level of risk of the trial	Not stated	No	Yes	Yes	No	Yes (exemption for studies with minimal risks)	Yes (different kind of compensation available)	Yes (exemption for studies with minimal risks)
No fault compensation available	Variable	Yes	Yes	Yes	Not clear	Not clear	Yes, for phase 1 trials, without "legal commitment" for phase 2 and 3 trials	Yes
Exemption from insurance or special terms for public clinical trials	Not stated	Not stated	Yes, exemption	Not stated	Yes, special terms	Yes, exemption	Yes, possible exemption	Yes, possible exemption
Responsibility for compensation (public/private)	Private and public	Private	Private and public	Private	Private	Private and public	Private and public	Private and public
Temporal indications	Not stated	No	No	No	Yes, 24-36 months after the trial completion 10 years for pediatric studies and studies with biological materials	Yes, 5 years after subject's participation	No	No

Table 1: Comparison of USA and European Countries regulations on the issue of insurance and compensation of injured research participants.

FONDAZIONE PER LA RICERCA FARMACOLOGICA GIANNI BENZI ONLUS

From the revision of Directive 2001/20/EC to a proposal for a regulation

3. INSURANCE/INDEMNISATION

PROPOSAL FOR REGULATION

Introducing "an obligatory insurance/indemnity" Directive 2001/20 substantially increased the costs and administrative burden of clinical trials

LOW-INTERVENTION CLINICAL TRIAL
(no/minimal additional risk compared to treatment in normal clinical practice)
NO NECESSARY TO PROVIDE INSURANCE/INDEMNIFICATION

OTHER THAN **LOW-INTERVENTION CLINICAL TRIAL**, SPONSOR SHALL ENSURE COMPENSATION **in accordance with the applicable law on liability of the sponsor/investigator**

FREE OF CHARGE
Per I Clinical Trials che, al momento della sottomissione, non sono destinati a procedure di MA

Con FEES o su base NO-PROFIT secondo decisioni nazionali
(risk, potential damage or likelihood of the damage)

Gli Stati Membri dovranno stabilire un Sistema Nazionale di INDENNITA'

From the revision of Directive 2001/20/EC to a proposal for a regulation



4. PAEDIATRIC RESEARCH

Dir. 2001/20/EC	Regulation
ART. 4 and European Ethical Recommendations 2008	No mention of the existing requirements in EU Ethical Reccomendations,

Integrated

by Paediatric Regulation 2006/1901/EC

5. RESEARCH IN NON-EU COUNTRIES

PROPOSAL FOR REGULATION

Se lo Sponsor non è stabilito in Europa esso deve comunque assicurare una 'contact person' che sia stabilita in Europa

Se il clinical trial deve essere condotto al di fuori dell'UE, si deve dimostrare che verranno seguiti principi almeno equivalenti a quelli della proposta Regulation con riferimento ai

'diritti dei pazienti'

'sicurezza'

'validità e robustezza'

dei dati prodotti dal trial.

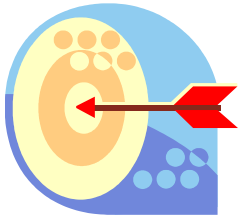


INSPECTIONS

FONDAZIONE
PER LA RICERCA FARMACOLOGICA
GIANNI BENZI
ONLUS

Nuovo Sistema per le Sperimentazioni Cliniche: Quali effetti sul contesto Italiano?

Reduce costs, approval delays and administrative burden of clinical trials



BUT

Può una nuova regolamentazione rappresentare un'opportunità per migliorare la qualità e la competitività del nostro sistema di Ricerca????

FONDAZIONE PER LA RICERCA FARMACOLOGICA GIANNI BENZI ONLUS

Nuovo Sistema per le Sperimentazioni Cliniche: Quali effetti sul contesto Italiano?

Comitato Nazionale per la Biosicurezza, le Biotecnologie e le Scienze della Vita, Presidenza del Consiglio
GRUPPO DI LAVORO SULLE SPERIMENTAZIONI CLINICHE , Roma 2010

Criticità emergenti in Italia nel settore della sperimentazione clinica

Sistema autorizzativo lento e nel complesso non efficiente	Può migliorare. Richiede revisione normativa nazionale
Eccessivo Numero di Comitati Etici	Nessun effetto. La materia resta di competenza nazionale
Scarsa aderenza alle GCP e insoddisfacente qualità percepita delle sperimentazioni	Nessuna influenza. Servono interventi nazionali
Italia realtà periferica rispetto all'intensa attività di ricerca clinica in Europa	Rischia di peggiorare. Il regolamento tende a privilegiare i paesi con sistemi più efficienti

FONDAZIONE PER LA RICERCA FARMACOLOGICA GIANNI BENZI ONLUS

Nuovo Sistema per le Sperimentazioni Cliniche: Quali effetti sul contesto Italiano?

STATI GENERALI DELLE MALATTIE RARE

LA LEGGE 648/96:
MODELLO EUROPEO DI SANITÀ PUBBLICA DA PERFEZIONARE

Criticità emergenti con riferimento alle Malattie Rare

I FARMACI ORFANI SONO ANCORA POCHI (60 per migliaia di malattie!)
LE IMPRESE E I RICERCATORI HANNO DIFFICOLTA' A SVILUPPARLI

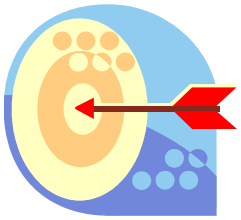
- Sostegno economico alla Ricerca e potenziamento pubblico/privato
- Metodologie Innovative per la sperimentazione clinica
- Strumenti per favorire **studi non-profit ed osservazionali**
- Metodologie Innovative per la Registrazione (adaptive, progressive, ecc)

Nessun effetto atteso. La norma non fa riferimento alla ricerca 'spontanea' e non-profit. Nessun riferimento metodologico o registrativo!

BUT

FONDAZIONE
PER LA RICERCA FARMACOLOGICA
GIANNI BENZI
ONLUS

Nuovo Sistema per le Sperimentazioni Cliniche: Quali effetti sul contesto Italiano?



La nuova regolamentazione può rappresentare un'opportunità per migliorare la qualità e la competitività del nostro sistema di Ricerca



Continuare il processo di Innovazione del Sistema Nazionale

Darsi una vocazione finalmente e francamente Europea

Svolgere un ruolo attivo nel cambiamento e renderlo combatibile con le priorità nazionali