Pharmacogenetics Studies in Clinical Research
Regulatory Aspects - Perspective from Portugal

Roundtable

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Pharmacogenetics Studies and Clinical Research
- R&D of new drugs
- Identifying genes influencing polygenic drug responses
- Clinical phenotype-genotype studies
Clinical Research: Pharmacogenetics Studies
Clinical phenotype-genotype studies in Clinical Trials
Clinical Research in Portugal (2003 - 2005)
(Investigational Medicinal Product ATC code)

Pharmacogenetics studies in Clinical Trials
Legal and Regulatory Framework in Portugal Transposing CT Directive

Directive 2001/20/EC - Implementation Guidelines

Law 46/2004 - National legal, regulatory and administrative provisions
Directive 2001/20/EC - Implementation Guidelines

Law 46/2004 - National legal, regulatory and administrative provisions

Ethics Committee
CEIC (or CES)

Favourable opinion

Authorization

Sponsor
Clinical Trial Applications

Investigator(s)
trial site(s)

CT start
End

Conduct

EudraCT
Specifically qualified for clinical research
Structured for single opinion / specified timeframes

CT evaluation and authorization
IMP’s manufacture and import authorization
Information exchange / European CT database
CT Safety monitoring / pharmacovigilance
GCP and GMP compliance verification / Inspections
Pharmacogenetics Studies: Clinical Practice

• Clinical implementation of TPMT testing - Instituto Português de Oncologia
Regulatory framework post-transposition national legislation (2004 - ....)

CT authorization

IMP manufacturing or import authorization

GMP and GCP Inspections

EucraCT database Eudravigilance CT Module
Directive 2001/20/EC
Implementation Guidelines

Detailed Guidance for the request for authorisation of a clinical trial on a medicinal product for human use to the competent authorities, notification of substantial amendments and declaration of the end of the trial

Detailed Guidance on the application format and documentation to be submitted in an application for the Ethics Committee opinion on the clinical trial on medicinal products for human use.

Detailed guidance on the European clinical trials database

Detailed guidance on the European database of Suspected Unexpected Serious Adverse Reactions

The principles of good clinical practice
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Sponsor
- Clinical Trial Application

CEIC - Ethics Committee for Clinical Research

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Written authorisation

Time limit 90 days in CT investigating
- medicinal products for gene therapy
- somatic cell therapy or
- medicinal products containing genetically modified organisms

Time limit 180 days if experts are consulted

No time limit to authorisation period: CT with xenogenic cell therapy