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Pharmacogenetics Studies in Clinical Research

Regulatory Aspects - Perspective from Portugal

Roundtable

Isabel Vieira, PhD and **Helder Mota Filipe**, PhD

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Roma, 17-19 October, 2005

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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

Genotype

Efficacy ***Safety***

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Clinical Research: Pharmacogenetics Studies

Clinical phenotype-genotype studies in Clinical Trials

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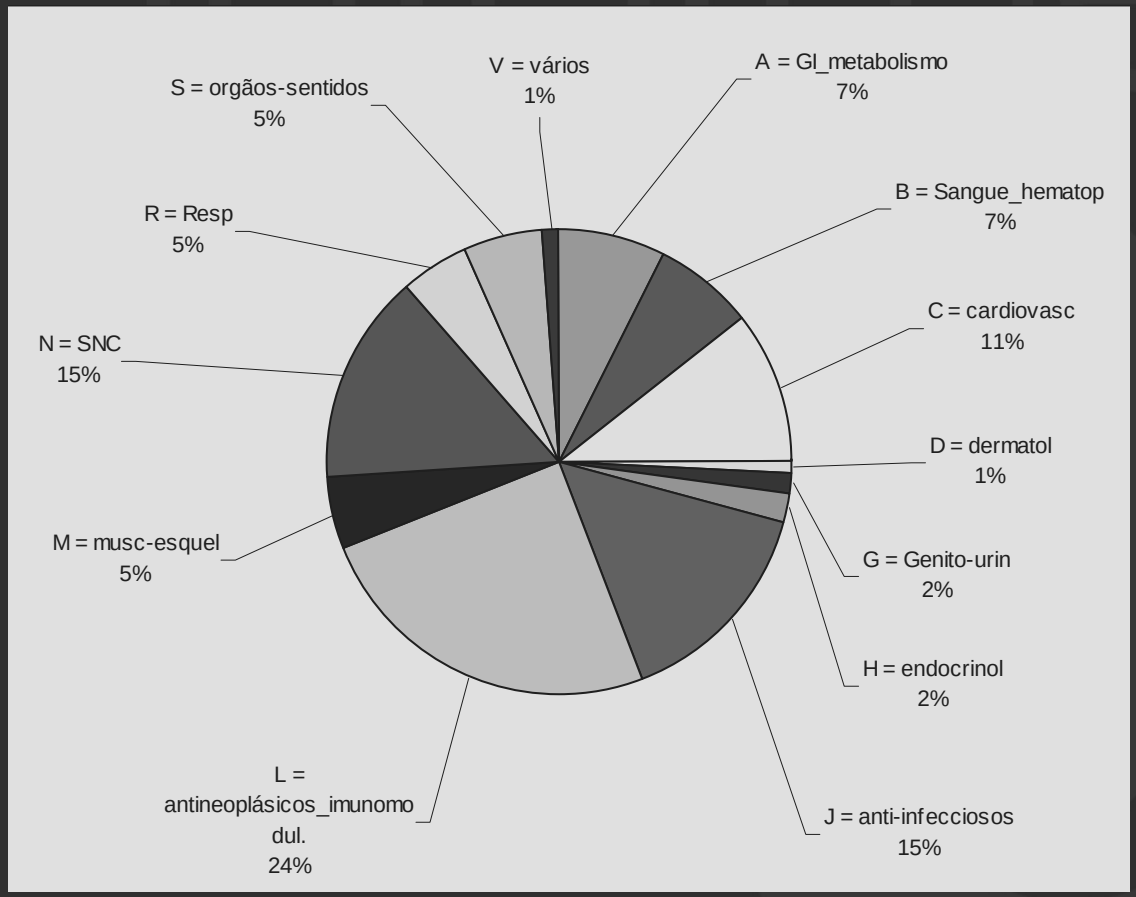
Clinical Research in Portugal (2003 - 2005)

(Investigational Medicinal Product ATC code)



Clinical Research in Portugal (2003 - 2005)

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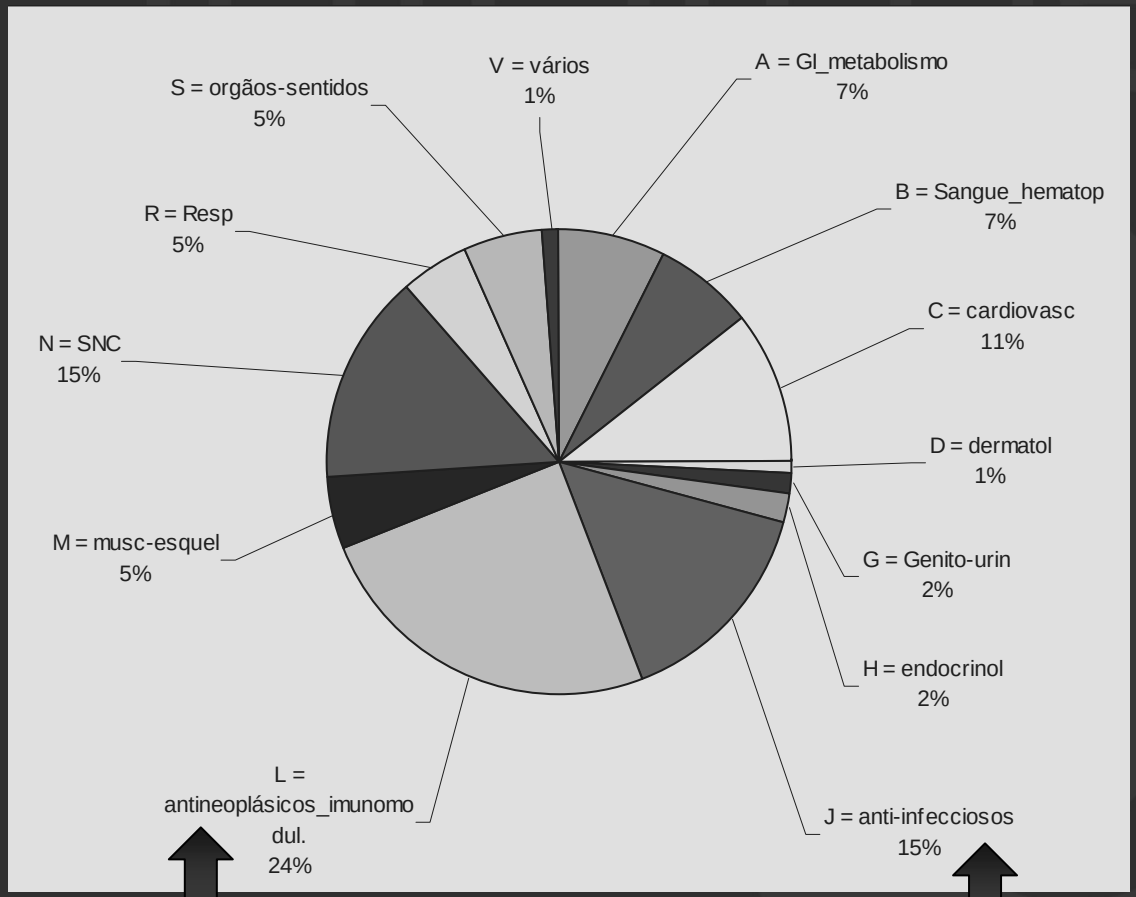

Pharmacogenetics studies in Clinical Trials

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Legal and Regulatory Framework in Portugal Transposing CT Directive

Directive 2001/20/EC - Implementation Guidelines

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

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Directive 2001/20/EC - Implementation Guidelines

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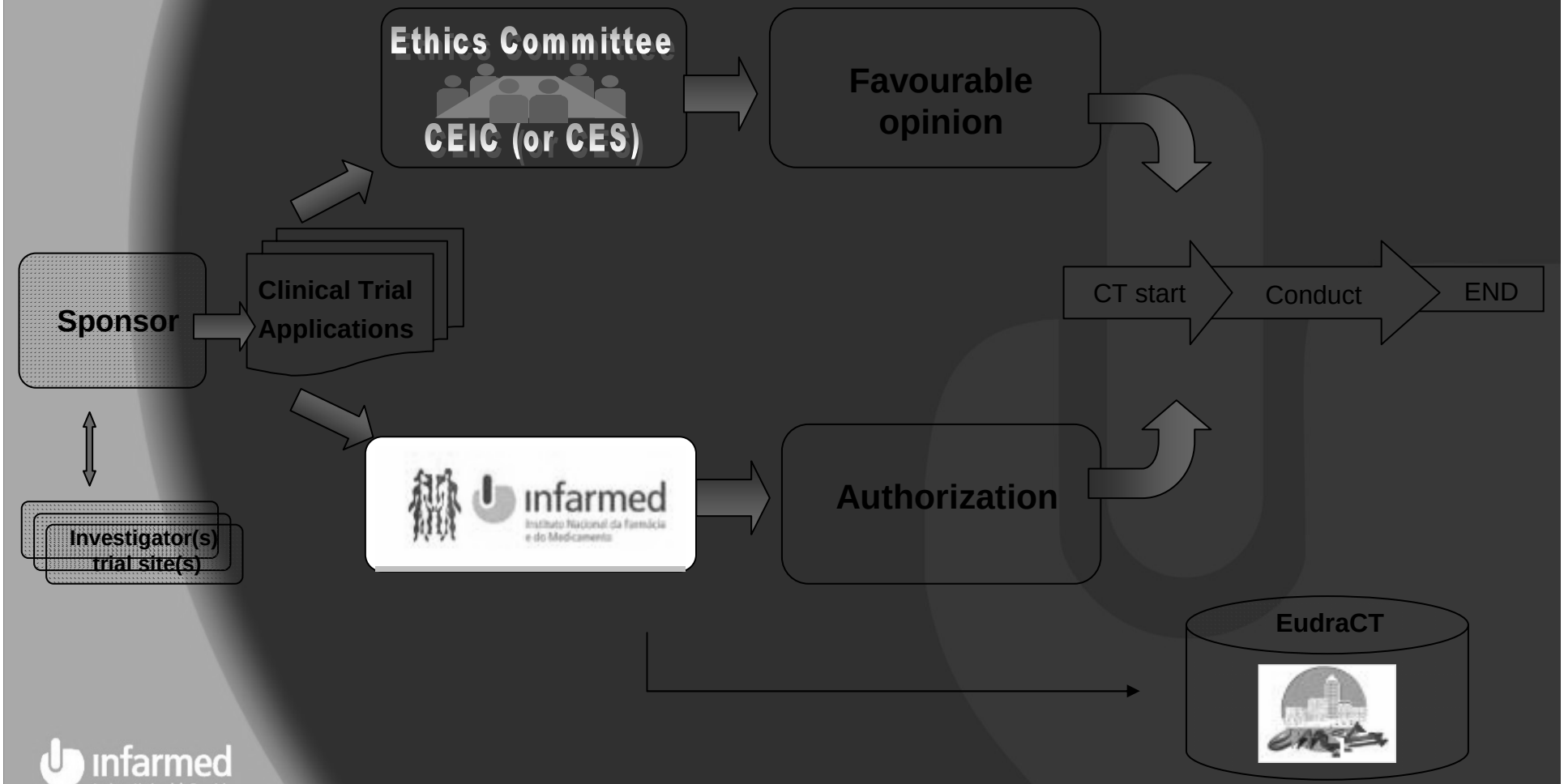

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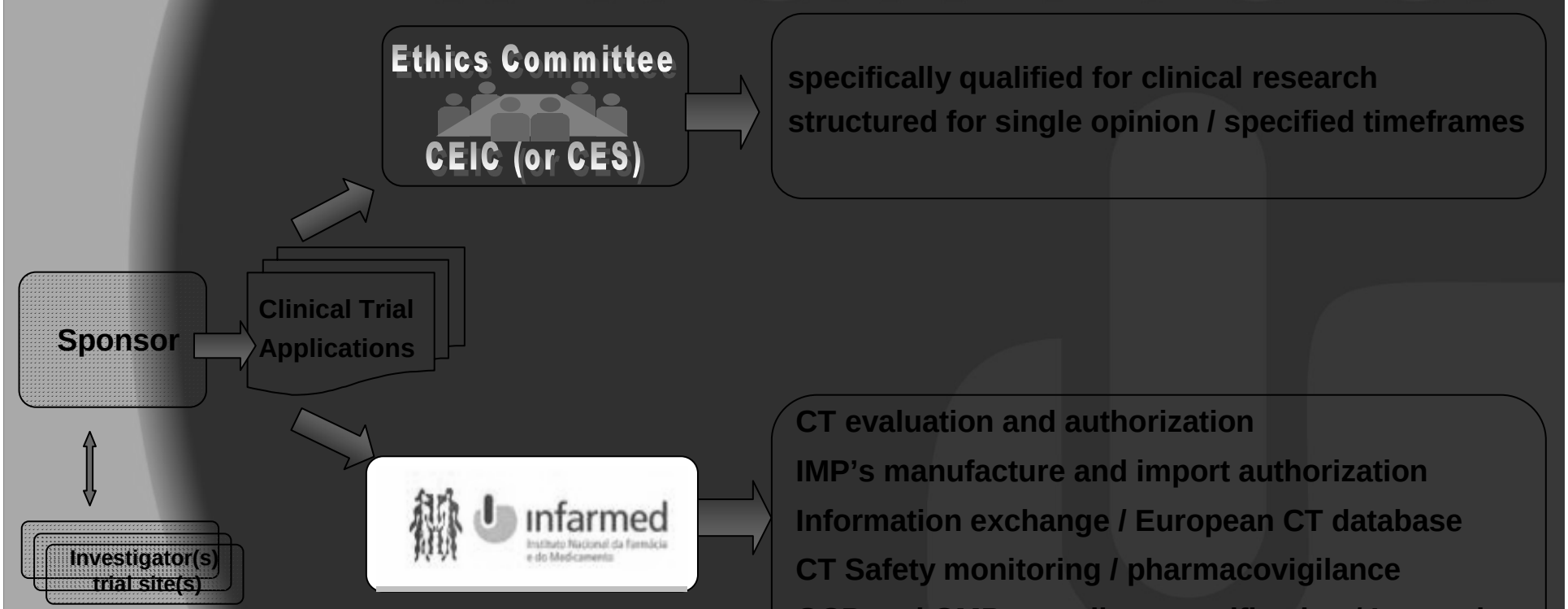
Directive 2001/20/EC - Implementation Guidelines

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



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Pharmacogenetics Studies: Clinical Practice

- Clinical implementation of TPMT testing - *Instituto Português de Oncologia*

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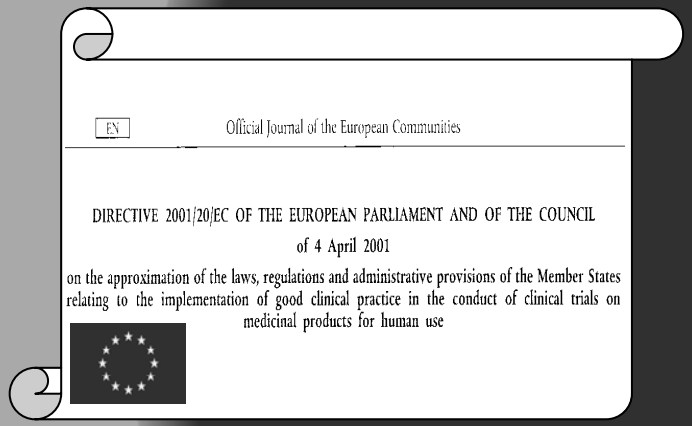
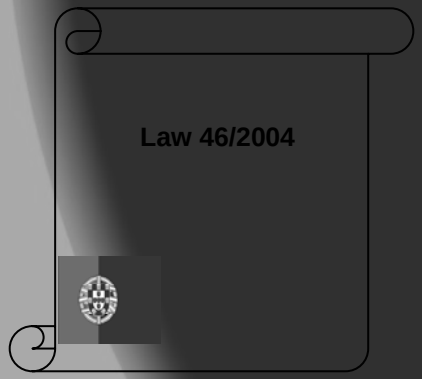
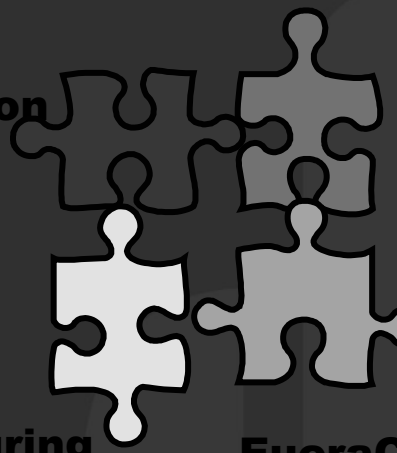
Regulatory framework post-transposition national legislation (2004 - ....)







CT authorization

GMP and GCP Inspections

IMP manufacturing or import authorization

EucraCT database
Eudravigilance CT Module

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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 ⇒ **New Directive**

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