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Overview of model-building strategies in population PK/PD analyses: 2002-2004 literature survey.

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Data Abstraction Form for population PK/PD publications

GENERAL CHARACTERISTICS

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ARTICLE IDENTIFICATION

DATE OF PUBLICATION (YEAR)..... | | | | |

TITLE.....

.....

.....

FIRST AUTHOR.....

Journal

- Anesthesiology
- Antimicrobial Agents and Chemotherapy
- British Journal of Clinical Pharmacology
- Cancer Chemotherapy and Pharmacology
- Clinical Pharmacokinetics
- Clinical Pharmacology and Therapeutics
- Clinical Therapeutics
- European Journal of Cancer
- European Journal of Clinical Pharmacology
- European Journal of Drug Metabolism and Pharmacokinetics
- European Journal of Pharmaceutical sciences
- Journal of Acquired Immune Deficiency Syndromes
- Journal of Clinical Oncology
- Journal of Pharmaceutical Sciences
- Journal of Pharmacokinetics and Pharmacodynamics
- Journal of Pharmacy and Pharmacology
- Therapeutic Drug Monitoring
- Pharmacotherapy
- Other:

I. CONTEXT OF THE ANALYSIS

Team performing the analysis

- | | |
|--|---------------------------------------|
| <input type="checkbox"/> Industry (R & D) | <input type="checkbox"/> Not reported |
| <input type="checkbox"/> Academic/Hospital | |
| <input type="checkbox"/> Drug Agency | |

Drug(s) administered ¹

.....

.....

Therapeutic class(es) studied in this analysis ²

Not reported

- | | |
|---|--|
| <input type="checkbox"/> Antidotes | <input type="checkbox"/> Antimicrobials |
| <input type="checkbox"/> Antiparasitics | <input type="checkbox"/> Cardiovascular-renal |
| <input type="checkbox"/> Central nervous system | <input type="checkbox"/> Contrast media / Radiopharmaceuticals |
| <input type="checkbox"/> Gastrointestinals | <input type="checkbox"/> Hematologics |
| <input type="checkbox"/> Hormones / Hormonal mechanisms | <input type="checkbox"/> Immunologics |
| <input type="checkbox"/> Metabolics / Nutrients | <input type="checkbox"/> Neurologics |
| <input type="checkbox"/> Oncolytics | <input type="checkbox"/> Ophthalmics |
| <input type="checkbox"/> Otics | <input type="checkbox"/> Pain relief |
| <input type="checkbox"/> Respiratory tract | <input type="checkbox"/> Skin / Mucous membranes |
| <input type="checkbox"/> Other | |

¹ International Nonproprietary Names (=DCI) (if not published, company identification number)

² Major classes of FDA National Drug Code Directory (<http://www.fda.gov/cder/ndc/tblclas.txt>)

II. CLINICAL STUDY(ies)

Phase(s) of clinical development

- | | |
|---|--|
| <input type="checkbox"/> Combined studies | <input type="checkbox"/> Not reported |
| <input type="checkbox"/> Phase I | <input type="checkbox"/> Phase III |
| <input type="checkbox"/> Phase II | <input type="checkbox"/> Observational studies |

Main objective(s) of the clinical study(ies)

- | | | |
|---------------------------------------|---|---------------------------------------|
| <input type="checkbox"/> PK | <input type="checkbox"/> PD | <input type="checkbox"/> Not reported |
| <input type="checkbox"/> Dose finding | <input type="checkbox"/> Drug interaction | |
| <input type="checkbox"/> Efficacy | <input type="checkbox"/> TDM | |
| <input type="checkbox"/> Toxicity | <input type="checkbox"/> Other: | |

Target population of the clinical study(ies)

Total number of Subjects:

- | | | | |
|---|--------------------------------------|---|---------------------------------------|
| <input type="checkbox"/> Adults | <input type="checkbox"/> Paediatrics | <input type="checkbox"/> Elderly | <input type="checkbox"/> Not reported |
| <input type="checkbox"/> Healthy volunteers | <input type="checkbox"/> Patients | <input type="checkbox"/> Special population | <input type="checkbox"/> Not reported |

Administration route(s)

- | | | |
|---------------------------------------|--|--|
| <input type="checkbox"/> PO | <input type="checkbox"/> Nasal | <input type="checkbox"/> Not reported |
| <input type="checkbox"/> IV (bolus) | <input type="checkbox"/> IV (Infusion) | <input type="checkbox"/> SC |
| <input type="checkbox"/> IM | <input type="checkbox"/> Transdermal | <input type="checkbox"/> Rectal |
| <input type="checkbox"/> Other: | | <input type="checkbox"/> Intraperitoneal |
| | | <input type="checkbox"/> Ophthalmic |

Dose

Single dose Multiple doses Not reported

Multiple cycles

Number of center(s) involved

Monocentric Not reported

Multicentric

Duration of the clinical study(ies)

..... days Unclear Not reported

Duration of the treatment(s)

..... days Unclear Not reported

Experimental design

Number of Arms: Not reported

Cohort study

if number of arms >1:

Parallel group Not reported

Cross-over study

Dose escalation (titration)	Yes	No	<input type="checkbox"/> Not reported
	<input type="checkbox"/>	<input type="checkbox"/>	
Randomization	Yes	No	<input type="checkbox"/> Not reported
	<input type="checkbox"/>	<input type="checkbox"/>	

Is there a comparator?

None Not reported

Placebo

Reference treatment(s)

Other, define:.....

Are the design optimised with respect to the sampling times

Yes **No**