



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 |

