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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

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

**TITLE**.....

.....

.....

**FIRST AUTHOR**.....

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### 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: .....

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## I. CONTEXT OF THE ANALYSIS

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### 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 <sup>1</sup>

.....

.....

### Therapeutic class(es) studied in this analysis <sup>2</sup>

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 .....                    |  |

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<sup>1</sup> International Nonproprietary Names (=DCI) (if not published, company identification number)

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

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## 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      |

<b>Dose</b>		
<input type="checkbox"/> Single dose	<input type="checkbox"/> Multiple doses	<input type="checkbox"/> Not reported
<input type="checkbox"/> Multiple cycles		

<b>Number of center(s) involved</b>	
<input type="checkbox"/> Monocentric	<input type="checkbox"/> Not reported
<input type="checkbox"/> Multicentric	

<b>Duration of the clinical study(ies)</b>		
..... days	<input type="checkbox"/> Unclear	<input type="checkbox"/> Not reported

<b>Duration of the treatment(s)</b>		
..... days	<input type="checkbox"/> Unclear	<input type="checkbox"/> Not reported

<b>Experimental design</b>			
Number of Arms: .....			<input type="checkbox"/> Not reported
<input type="checkbox"/> Cohort study			
<i>if number of arms &gt;1:</i>			
<input type="checkbox"/> Parallel group			<input type="checkbox"/> Not reported
<input type="checkbox"/> Cross-over study			
Dose escalation (titration)	<b>Yes</b> <input type="checkbox"/>	<b>No</b> <input type="checkbox"/>	<input type="checkbox"/> Not reported
Randomization	<b>Yes</b> <input type="checkbox"/>	<b>No</b> <input type="checkbox"/>	<input type="checkbox"/> Not reported
<b>Is there a comparator?</b>			
<input type="checkbox"/> None			<input type="checkbox"/> Not reported
<input type="checkbox"/> Placebo			
<input type="checkbox"/> Reference treatment(s)			
<input type="checkbox"/> Other, define:.....			
<b>Are the design optimised with respect to the sampling times</b>			
		<b>Yes</b> <input type="checkbox"/>	<b>No</b> <input type="checkbox"/>