



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

Céline Dartois, Karl Brendel, Emmanuelle Comets, Céline M. Laffont, Christian Laveille, Brigitte Tranchand, France Mentré, Annabelle Lemenuel-Diot, Pascal Girard

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Data Abstraction Form for population PK/PD publications

GENERAL CHARACTERISTICS

**Brendel K.^{1*}, Dartois C.^{2*},
Comets E.¹, Lemenuel-Diot A.³, Laffont C.M.³, Laveille C.⁴,
Girard P.², Mentré F.¹**

¹INSERM U738, Paris, France

²EA3738, Lyon, France

³SERVIER, Courbevoie, France

⁴EXPRIMO NV, Lummen, Belgium

* the two first authors contributed equally to this Data Abstraction Form

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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

☐ Industry (R & D)

☐ Not reported

☐ Academic/Hospital

☐ Drug Agency

Drug(s) administered ¹

.....

.....

Therapeutic class(es) studied in this analysis ²

☐ Not reported

☐ Antidotes

☐ Antimicrobials

☐ Antiparasitics

☐ Cardiovascular-renal

☐ Central nervous system

☐ Contrast media / Radiopharmaceuticals

☐ Gastrointestinals

☐ Hematologics

☐ Hormones / Hormonal mechanisms

☐ Immunologics

☐ Metabolics / Nutrients

☐ Neurologics

☐ Oncolytics

☐ Ophtalmics

☐ Otics

☐ Pain relief

☐ Respiratory tract

☐ Skin / Mucous membranes

☐ 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

- | | |
|---|--|
| ☐ Combined studies | ☐ Not reported |
| ☐ Phase I | ☐ Phase III |
| ☐ Phase II | ☐ Observational studies |

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

- | | | |
|---------------------------------------|---|---------------------------------------|
| ☐ PK | ☐ PD | ☐ Not reported |
| ☐ Dose finding | ☐ Drug interaction | |
| ☐ Efficacy | ☐ TDM | |
| ☐ Toxicity | ☐ Other: | |

Target population of the clinical study(ies)

Total number of Subjects:

- | | | | |
|---|--------------------------------------|---|---------------------------------------|
| ☐ Adults | ☐ Paediatrics | ☐ Elderly | ☐ Not reported |
| ☐ Healthy volunteers | ☐ Patients | ☐ Special population | ☐ Not reported |

Administration route(s)

- | | | |
|---------------------------------------|--|---------------------------------------|
| ☐ PO | ☐ Nasal | ☐ Not reported |
| ☐ IV (bolus) | ☐ IV (Infusion) | ☐ SC |
| ☐ IM | ☐ Transdermal | ☐ Rectal |
| ☐ Other: | ☐ Intraperitoneal | ☐ 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 ☐
☐ Not reported

Randomization
 Yes ☐ No ☐
☐ Not reported

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 ☐