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, Lumnen, Belgium

* the two first authors contributed equally to this Data Abstraction Form
# Data Abstraction Form for population PK, PD publications

## GENERAL CHARACTERISTICS

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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:  

Other:  

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## I. CONTEXT OF THE ANALYSIS

### Team performing the analysis

- [ ] Industry (R & D)
- [ ] Not reported
- [ ] Academic/Hospital
- [ ] Drug Agency

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### Drug(s) administered

[ ] Antidotes
[ ] Antimicrobials
[ ] Antiparasitics
[ ] Cardiovascular-renal
[ ] Central nervous system
[ ] Contrast media / Radiopharmaceuticals
[ ] Gastrointestinalss
[ ] Hematologics
[ ] Hormones / Hormonal mechanisms
[ ] Immunologics
[ ] Metabolics / Nutrients
[ ] Neurologics
[ ] Oncolytics
[ ] Ophtalmics
[ ] Otics
[ ] Pain relief
[ ] Respiratory tract
[ ] Skin / Mucous membranes
[ ] Other

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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/tbldclas.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)

- [ ] Adults
- [ ] Paediatrics
- [ ] Elderly
- [ ] Not reported
- [ ] Healthy volunteers
- [ ] Patients
- [ ] Special population
- [ ] Not reported

### Administration route(s)

- [ ] PO
- [ ] Nasal
- [ ] Not reported
- [ ] IV (bolus)
- [ ] IV (Infusion)
- [ ] SC
- [ ] Intraperitoneal
- [ ] IM
- [ ] Transdermal
- [ ] Rectal
- [ ] Ophtalmic
- [ ] Other: .................................................................
### Dose
- Single dose
- Multiple doses
- Not reported
- Multiple cycles

### Number of center(s) involved
- Monocentric
- Not reported
- Multicentric

### Duration of the clinical study(ies)
 PyErr
- Unclear
- Not reported

### Duration of the treatment(s)
- 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]
- Randomization [Yes] [No]
- Is there a comparator?
  - None
  - Placebo
  - Reference treatment(s)
  - Other, define:…………………………………

- Are the design optimised with respect to the sampling times [Yes] [No]