Data Abstraction Form for population PK/PD publications

GENERAL CHARACTERISTICS

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**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)  
- [ ] Academic/Hospital  
- [ ] Drug Agency  

### Drug(s) administered

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

### Therapeutic class(es) studied in this analysis

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### II. CLINICAL STUDY(ies)

#### Phase(s) of clinical development

- [ ] Combined studies
- [ ] Phase I
- [ ] Phase II
- [ ] Not reported
- [ ] Phase III
- [ ] 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
- [ ] Intraperitoneal
- [ ] IM
- [ ] Transdermal
- [ ] Rectal
- [ ] Ophtalmic
- [ ] Other: ..........................................................

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### 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