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]

[1]INSERM U738, Paris, France
[2]EA3738, Lyon, France
[3]SERVIER, Courbevoie, France
[4]EXPRIMO NV, Lumnen, Belgium
* the two first authors contributed equally to this Data Abstraction Form

Table of contents

ARTICLE IDENTIFICATION……...3

Date of publication (year) 3
Title 3
First author 3
Journal 3

I. CONTEXT OF THE ANALYSIS……...4

Team performing the analysis 4
Drug(s) administered 4

II. CLINICAL STUDY(ies)…….....5

Phase(s) of clinical development 5
Main objective(s) of the clinical study(ies) 5
Target population of the clinical study(ies) 5
Administration route(s) 5
Dose 6
Number of center(s) involved 6
Duration of the clinical study(ies) 6
Duration of the treatment(s) 6
Experimental design 6

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/tbldclas.txt)

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: ……..

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** ☐