1 Clinical trial/study synopsis

Trial/ Study title	
Sponsor	
Coordinating Investigator	
Deputy Investigator	
Trial/ Study Site(s)	
Trial/ Study Identification Code	
EudraCT Number (if applicable)	
Trial/ Study Phase	
Trial/ Study Design	
Rationale	
Indication/ Therapeutic Area	
Investigational medicinal product/ observed medicinal product	
Name of Investigational Product	
Active Ingredient	
Dose and mode of administration	

Reference Product / Placebo (if applicable)	
Name/ Descript. Of reference Product (if applicable)	
Active Ingredient (if applicable)	
Dose and mode of administration	
Duration of treatment	
Trial/ Study period (clinical part)	
Timing (Visits)	
Estimated Trial/ Study duration (begin of Trial/ Study set-up until delivery final Trial/ Study report)	
Trial/ Study Population	
Sample Size	
Sample size justification	
Inclusion Criteria	
Exclusion Criteria	
Trial/ Study Objectives	
Primary Objective	

Secondary Objective	
Evaluation Criteria (Endpoints)	
Primary Endpoint	
Secondary Endpoints	
Safety	
Statistical Methods	
Synopsis Version and Date	

2 Requested Support

Financial Support: ☐ Yes ☐ No *(if yes, insert details below)*

Personnel costs	☐ Yes ☐ No
Material costs	☐ Yes ☐ No
Analytical costs	☐ Yes ☐ No
Other costs	☐ Yes ☐ No
Other costs	☐ Yes ☐ No
Other costs	☐ Yes ☐ No

Summarized value for requested support

Support by Wörwag Pharma products: ☐ *Yes* ☐ *No (if yes, insert details below)*

Product Name

Dosage form[1]

Strength[2]

Required units[3]

[1] e.g. tablet, coated tablet, capsule, injection etc.

[2] Strength per unit, e.g. 300mg

[3] e.g. 200 packs a 100 tablets

Packaging Details	☐ *Market goods (original prim. & sec. packaging)* ☐ *Comparator required specify* ☐ *Placebo required* ☐ *Blinding Required (neutral prim. & sec. packaging)* ☐ *Blinding will be organized by requestor according to GMP* ☐ *Blinding is part of requested support*
Comments	

3 Suggested equivalent value

What is the equivalent value suggested for the support by Wörwag Pharma?

☐ Final study report according to ICH-E3

☐ Final study report according to another format *specify*

☐ Regular status reports/ newsletter about trial/ study progress

☐

☐

4 Regulatory requirements and experience of the Investigator

The clinical trial/ study corresponds to the current scientific standard in terms of study design and methodology and will be conducted in accordance to all applicable legal and regulatory principles, regulations and guidelines.

☐ Yes ☐ No

Applicable law & guidelines which will be followed	**Internationally valid:** ☐ Declaration of Helsinki ☐ ICH-GCP ☐ GPP[4] ☐ **Regional:** ☐ EU Clinical Trials Regulation 536/2014 ☐ ☐ ☐

It is planned to publish the findings of the trial/ study in an appropriate, transparent, and timely manner.

☐ Yes ☐ No

The investigator can present a valid GCP certificate that is not older than 3 years at trial/ study start.

☐ Yes ☐ No ☐ Not Applicable, NIS or preclinical research

[4] Good Pharmacoepidemiology Practice

There is recent evidence (within previous 3 years) of the investigators experience in undertaking clinical research.

☐ Yes ☐ No

Year	Title of studies	Study category
	1.	☐ Clinical Trial ☐ NIS
	2.	☐ Clinical Trial ☐ NIS
	3.	☐ Clinical Trial ☐ NIS
	4.	☐ Clinical Trial ☐ NIS
	5.	☐ Clinical Trial ☐ NIS
	6.	☐ Clinical Trial ☐ NIS

The investigator can present a valid license to practice medicine.

☐ Yes ☐ No

5 Comments

6 Data protection statement

I am interested in, and therefore give my voluntary consent, that WÖRWAG Pharma GmbH & Co.KG and its local legal entities (Flugfeld-Allee 24, 71034 Böblingen, Germany, email: info@woerwagpharma.com; Tel .: +49 (0) 7031 62 04- 0) saves my personal data (namely my name, address and information about the study for which I am requesting support), as part of processing my request, and forwards it within the company to employees of Wörwag Pharma involved in processing my request.

I am aware that I can revoke my declaration of consent (s) at any time without affecting the legality of the processing carried out based on the consent until the revocation.

☐ Yes ☐ No

Date, full name