

## **[Study Name]**

### **Sponsor**

[Name]

[Address]

Phone: [xxx xxx xx xx], Fax: [xxx xxx xx xx]

Email: [email address]

### **Principal Investigator**

[Name]

[Address]

Phone: [xxx xxx xx xx], Fax: [xxx xxx xx xx]

Email: [email address]

### **Investigators**

[Name]

[Address]

[Name]

[Address]

[Name]

[Address]

[Name]

[Address]

### **Study Product**

[Name (dosage, ATC number)]

*[ICH 6.1]*





## Table of contents

<b>SYNOPSIS</b> .....	<b>6</b>
<b>STUDY FLOWCHART (EXAMPLE)</b> .....	<b>7</b>
<b>STUDY SCHEME (EXAMPLE)</b> .....	<b>7</b>
<b>ABBREVIATIONS</b> .....	<b>8</b>
<b>1. BACKGROUND [ICH 6.2]</b> .....	<b>9</b>
1.1. Fundamentals .....	9
1.2. Study treatment and target pathology .....	9
1.3. Study Rationale .....	9
<b>2. OBJECTIVES [ICH 6.3]</b> .....	<b>9</b>
<b>3. STUDY DESIGN [ICH 6.4]</b> .....	<b>9</b>
3.1. Overall description .....	9
3.2. Primary and secondary endpoints .....	9
3.3. Randomisation and blinding .....	9
3.4. Study duration for subjects, stopping rules and procedures for breaking codes....	9
3.5. Data collected in the CRF .....	9
<b>4. STUDY POPULATION [ICH 6.5]</b> .....	<b>10</b>
4.1. Inclusion criteria .....	10
4.2. Exclusion criteria .....	10
4.3. Withdrawal criteria.....	10
4.4. Selection and recruitment procedures.....	10
<b>5. STUDY TREATMENTS (INCLUDING PLACEBO) [ICH 6.6]</b> .....	<b>10</b>
<b>6. EVALUATION CRITERIA [ICH 6.7]</b> .....	<b>10</b>
<b>7. DATA COLLECTION AND MANAGEMENT [ICH 6.10 &amp; 6.13]</b> .....	<b>10</b>
7.1. Source data.....	10
7.2. CRF.....	10
7.3. Documents storage and keeping.....	10
<b>8. ADVERSE EVENTS MANAGEMENT [ICH 6.8]</b> .....	<b>10</b>
8.1. Definitions (AE, SAE, ADR, SUSAR, Imputability) .....	10
8.2. Adverse events collection and grading .....	10
8.3. AE reporting .....	10

<b>8.4.</b>	<b>Follow-up of AE</b> .....	<b>10</b>
<b>8.5.</b>	<b>Data Safety Monitoring Board</b> .....	<b>10</b>
<b>9.</b>	<b>QUALITY CONTROL AND ASSURANCE [ICH 6.11]</b> .....	<b>11</b>
<b>9.1.</b>	<b>Monitoring</b> .....	<b>11</b>
<b>9.2.</b>	<b>Audit and inspection</b> .....	<b>11</b>
<b>10.</b>	<b>STATISTICS [ICH 6.9]</b> .....	<b>11</b>
<b>10.1.</b>	<b>Number of subjects</b> .....	<b>11</b>
<b>10.2.</b>	<b>Data analysis</b> .....	<b>11</b>
<b>10.3.</b>	<b>Dropouts and missing data management</b> .....	<b>11</b>
<b>10.4.</b>	<b>Criteria for the termination of the trial</b> .....	<b>11</b>
<b>11.</b>	<b>ETHICS [ICH 6.12]</b> .....	<b>11</b>
<b>11.1.</b>	<b>Good clinical practices</b> .....	<b>11</b>
<b>11.2.</b>	<b>Ethical committee</b> .....	<b>11</b>
<b>11.3.</b>	<b>Information and consent</b> .....	<b>11</b>
<b>11.4.</b>	<b>Confidentiality</b> .....	<b>11</b>
<b>12.</b>	<b>PUBLICATION POLICY [ICH 6.15]</b> .....	<b>11</b>
<b>12.1.</b>	<b>International registry of clinical trials</b> .....	<b>11</b>
<b>12.2.</b>	<b>Publication</b> .....	<b>11</b>
<b>12.3.</b>	<b>Clinical study report</b> .....	<b>11</b>
<b>13.</b>	<b>FINANCING AND INSURANCE [ICH 6.14]</b> .....	<b>11</b>
<b>13.1.</b>	<b>Funds</b> .....	<b>11</b>
<b>13.2.</b>	<b>Insurance</b> .....	<b>11</b>
<b>14.</b>	<b>REFERENCES</b> .....	<b>11</b>
<b>15.</b>	<b>APPENDICES [ICH 6.16]</b> .....	<b>11</b>

## Synopsis

Sponsor	
Name of the finished product	
Name of the active substance	
Study title	
Investigators	<u>Principal Investigator:</u>  <u>Investigators :</u>
Study centre	
Study period	
Objectives	
Methodology	Type d'étude
Number of patients	
Selection criteria	<u>Inclusion criteria :</u>  <u>Non-inclusion criteria :</u>
Test product Dose Route of administration	
Duration of treatment	
Reference therapy	
Efficacy evaluation	
Statistical Methods	

**NB : Lorsque le protocole est rédigé en anglais, une page de résumé en français doit être jointe à la feuille de soumission à la Commission d'Éthique.**

### Study Flowchart (example)

	Visit 1	Visit 2	Visit 3
Informed consent	x		
Clinical evaluation, physical evaluation	x		
xx	x		
xx	x		
	x		
Randomisation		x	
		x	x
		x	x
		x	x
		x	x
		x	x
		x	x
		x	x
		x	x

### Study scheme (example)

Time	J-15	J1	J5	J10	J30	J40
Visit	Visit 1 (Inclusion)	Visit 2	Visit 3	Phone Call	Visit 3 (Evaluation)	Visit 4 (termination)
Treatment		Dose1	Dose 2	Dose 3	Dose 3	



## Abbreviations

ICH	International Conference on Harmonisation
AE	Adverse Event
SAE	Serious Adverse Event
ADR	Adverse Drug Reaction
SUSAR	Suspected Unexpected Serious Adverse Reaction

## **1. Background [ICH 6.2]**

### **1.1. Fundamentals**

- Summary of knowledge and findings on the topic
- References to literature and data relevant to the trial and providing the scientific basis of the study

### **1.2. Study treatment and target pathology**

- Name and characteristics of the investigational product
- Summary of preclinical studies, their potential clinical significance, and relevant clinical studies
- Pharmaceutical and clinical data, drug interactions
- Summary of known and potential risks and benefits for the study population
- Pregnancy and contraception

### **1.3. Study Rationale**

Population studied, methodology, placebo vs reference treatment,...

## **2. Objectives [ICH 6.3]**

Primary objective

Secondary objective(s)

## **3. Study Design [ICH 6.4]**

### **3.1. Overall description**

Type of trial : retrospective, epidemiological, longitudinal study, cross-sectional study, pilot, phase I, II, III or IV...

Open-labelled, single or double blind, parallel groups, cross-over study ...

Study course : description of the trial design and stages

### **3.2. Primary and secondary endpoints**

### **3.3. Randomisation and blinding**

Block design, stratification etc.

### **3.4. Study duration for subjects, stopping rules and procedures for breaking codes**

### **3.5. Data collected in the CRF**

Especially any data recorded directly on the CRF and to be considered to be source data.

#### **4. Study population [ICH 6.5]**

##### **4.1. Inclusion criteria**

##### **4.2. Exclusion criteria**

##### **4.3. Withdrawal criteria**

Withdrawal procedures.

Replacement procedures.

##### **4.4. Selection and recruitment procedures**

#### **5. Study treatments (including placebo) [ICH 6.6]**

(Treatment, placebo)

- Description and rationale of the dose, the route of administration, the treatment periods
- Labelling, packaging, drug accountability
- Authorized and prohibited concomitant treatments
- Pregnancy and breastfeeding

#### **6. Evaluation criteria [ICH 6.7]**

- Description, acquisition, analysis, methods of measurement (including of biological samples, timing)
- Primary endpoint
- Secondary endpoints

#### **7. Data collection and management [ICH 6.10 & 6.13]**

##### **7.1. Source data**

##### **7.2. CRF**

##### **7.3. Documents storage and keeping**

#### **8. Adverse events management [ICH 6.8]**

##### **8.1. Definitions (AE, SAE, ADR, SUSAR, Imputability)**

##### **8.2. Adverse events collection and grading**

##### **8.3. AE reporting**

##### **8.4. Follow-up of AE**

##### **8.5. Data Safety Monitoring Board**

## **9. Quality control and assurance [ICH 6.11]**

### **9.1. Monitoring**

### **9.2. Audit and inspection**

## **10. Statistics [ICH 6.9]**

### **10.1. Number of subjects**

### **10.2. Data analysis**

Type of analysis, interim analysis, statistical tests, level of significance, etc.

### **10.3. Dropouts and missing data management**

### **10.4. Criteria for the termination of the trial**

## **11. Ethics [ICH 6.12]**

### **11.1. Good clinical practices**

### **11.2. Ethical committee**

### **11.3. Information and consent**

### **11.4. Confidentiality**

## **12. Publication policy [ICH 6.15]**

### **12.1. International registry of clinical trials**

### **12.2. Publication**

### **12.3. Clinical study report**

## **13. Financing and insurance [ICH 6.14]**

### **13.1. Funds**

### **13.2. Insurance**

## **14. References**

## **15. Appendices [ICH 6.16]**