***TEMPLATE***

**-TITLE OF THE PROTOCOL.**

**- PROTOCOL NUMBER:**

**- EUDRACT NUMBER :**

**- INVESTIGATIONAL MEDICINAL PRODUCT:**

**- DSUR NUMBER :**

1. **ANNUAL SAFETY REPORT**

**FIRST CLINICAL TRIAL AUTHORIZATION DATE :** *date on the CTA approval letter*

**DATE OF THIS REPORT***: Annually, within 60 days following the first authorization date of this trial in a European Union member state. Regardless of whether the trial has actually started.*

**NAME AND ADDRESS OF THE SPONSOR:**

**Dr/Prof ------------------**

**Cliniques universitaires Saint-Luc**

**Avenue Hippocrate, 10**

**B-1200 Bruxelles**

**INTRODUCTION:**

|  |  |
| --- | --- |
| **Full title of trial** |  |
| **Short title** |  |
| 1. **Date of the protocol** |  |
| **IMP(s) under investigation (generic name(s))** | *= INN (international non proprietary name)* |
| **Registered names(s) of the IMP(s) under investigation/ delivered by : “name of the company”** | ------------------ / DELIVERED BY -------------------- |
| **Date of the first approval of the IMP** | *International birth date of the IMP: see Summary of Product Characteristics* |
| **Dosage and route of administration** |  |
| **Trial Objectives** | *Objectives as per protocol* |
| * **Study population** | *As per protocol* |
| * **Trial design** | *A short description of the trial as per protocol synopsis* |
| **Trial start date** | *Consent given by the first subject* |
| **Trial end date** | *Last visit of the last subject or ongoing* |
| **Target number of subjects for whole trial** |  |
| **How many subjects have been enrolled since the trial started** |  |
| **Countries concerned by this trial** |  |
| **Reporting period** | **FROM** --------------- **TO**-----------------  *Period concerned by this DSUR* |

Contact details for person making this notification

|  |  |
| --- | --- |
| **Name** |  |
| **Address** | **Cliniques universitaires Saint-Luc**  **Avenue Hippocrate, 10**  **B-1200 Bruxelles** |
| **Telephone** |  |
| **Fax** |  |
| **Email** |  |

**PART 1: REPORT ON THE SAFETY OF SUBJECTS**

*The sponsor must provide a concise safety analysis and risk-benefit evaluation for the trial, describing all new findings related to the safety of the IMP and providing a critical analysis of them with respect to their impact for the subjects.*

**1.1 Overview of data:**

The trial is still ongoing and the database has not been locked.

*OR*

The trial has ended on ----------------------, and database is locked. *+ Give some details*

**1.2 Serious Adverse Events:**

|  |  |  |
| --- | --- | --- |
|  | ***Current Reporting Period*** | ***Cumulated since the beginning of the trial*** |
| * **Number of subjects enrolled** |  |  |
| **Number of SAEs observed** |  |  |
| **Number of SARs observed** |  |  |
| **Number of SUSARs observed** |  |  |

**1.3 Non-serious Adverse events:**

“ Since the data in this ongoing trial are not yet cleaned or unblinded, no information regarding non-serious adverse events will be presented in this report; however nothing of note has been identified to date.”

*OR*

*Summarise the following:*

* *how many non-serious adverse events have occurred in the period/trial:*
* *if they have been analysed yet*
* *if there are any points of note to be mentioned.*

|  |  |  |
| --- | --- | --- |
|  | ***Current Reporting Period*** | ***Cumulated since the beginning of the trial*** |
| 1. **NON SERIOUS ADVERSE EVENTS** | | |
| 1. ***n* non serious adverse events in *x* patients** | 1. **……. / ……………..** | 1. **……. / ……………..** |
| 1. **SEVERITY OF ADVERSE EVENTS** | | |
| 1. **n Mild** |  |  |
| 1. **n Moderate** |  |  |
| 1. **n Severe** |  |  |
| 1. **RELATIONSHIP TO THE TRIAL MEDICATION** | | |
| 1. **certain** |  |  |
| 1. **probable** |  |  |
| 1. **possible** |  |  |
| 1. **unlikely** |  |  |
| 1. **not related** |  |  |

**1.4 New findings related to the safety of the IMP**

*give details of any new data emerging on the safety of the IMP as a result of the trial.*

*“New” refers to findings (clinical or non clinical) not already present in the Investigator Brochure or in the Summary of Product Characteristics.*

***Give a detailed description of the SUSARs observed in the reporting period.***

*OR*

There have been no new findings related to the safety of the IMP in this trial.

**1.5 Impact of New findings for the Subjects of the Trial:**

*Describe what this new findings might mean to the trial subjects bearing in mind the following:*

* *Relationship with dose, duration, time course of the treatment*
* *Reversibility*
* *Evidence of previously unidentified toxicity in trial subjects*
* *Increased frequency of toxicity*
* *Overdose and its treatment*
* *Interactions or other associated risks*
* *Abuse of the IMP*
* *Risks which may be associated with the investigation or diagnostic procedures of the trial*

*OR*

There have been no new findings related to the safety of the IMP(s) in this trial.

**1.6 Implications for the Population of the Trial**

*Describe any safety findings that have implications for any specific populations such as children elderly, renally impaired, diabetic, pregnant women etc.*

* 1. **Analysis of the Safety Profile of the Tested IMP**

*This is a subjective analysis and is really a* ***risk benefit analysis on the pros and cons*** *of the treatment and its risks.*

* 1. **Measures Proposed to Minimise Risks Found**

*Where appropriate, give details of any measures previously taken or now proposed to minimise the risks identified.*

1. *Explain why you feel it is necessary, or not, to amend the protocol, investigator brochure or consent form or participant information leaflet as a result of the risks identified.*

*OR*

There have been no risks identified related to the safety of the IMP(s) in this trial.

**PART 2: LINE LISTING**

*The line listing should give details of all suspected* ***SARs (ONLY THE IMP RELATED SERIOUS ADVERSE REACTIONS)*** *reported* ***since the beginning*** *of the trial (****including SUSARs****).*

*Cases should be tabulated by body system (standard system organ classification scheme- MedDRA).*

*Usually there should be one listing per trial, but separate listings should be provided for active comparator or placebo or when appropriate and relevant for other reasons e.g. different formulations, indications or routes of administration studied in the same trial.*

*OR*

*There were no Suspected Serious Adverse Reactions in this trial; therefore no line listings have been completed.*

**DEVELOPMENT SAFETY UPDATE REPORT: SERIOUS CASES BY SYSTEM ORGAN CLASS**

**SPONSOR NAME: CLINIQUES UNIVERSITAIRES SAINT LUC**

**EUDRACT:**

**STUDY SHORT TITLE:**

**PRODUCT RECEIVED: Name of the IMP or Placebo**

**Route of administration as per protocol:**

**Daily dosage as per protocol:**

**SOC: see MedDRA list**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Subject ID/Case** | **Case**  **(SAR n°)** | **Country** | **Date of Birth** | **Sex** | **Daily Dose of IMP** | **Dates of Treatment** | **Date of Onset of AE** | **Adverse Reaction**  **MedDRA Lowest Level Term** | **Expected** | **Event serious code** | **Causality**  **Investigator/**  **Sponsor** | **Ongoing reaction with: Dechallenge/**  **Rechallenge** | **Unblinding Results** | **Outcome** | **Comments** |
| *QT001* | *QT001-001* | *BE* | *01.01.1950* | *M* | *150mg* | *01.01.2006-01.03.2006* | *27.02.2006* | *diarrhoea* | *YES/NO* | *Required intervention*  */caused or prolonged hospitalisation*  */results in death*  */life threatening/*  *persistent or significant disability/*  *congenital anomaly/*  *other*  */none* | *Certain;*  *probable*  *;possible;*  *unlikely; conditional; unassessable* | *YES; NO; NA /*  *YES; NO; NA* | *N/A* | *Resolved / Resolved with sequelae / Ongoing / Unknown / Fatal + date of death* |  |
| **\* = Previous ASR** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

**PART 3: SUMMARY TABULATIONS**

*Summary tabulations of SSAR terms for signs, symptoms and diagnoses across all subjects should be presented to provide an overview of the trial.*

*When the number of cases is very small a narrative description may be more suitable.*

*The summary tabulation should specify the number of reports:*

1. *for each body system*
2. *for each AR term*
3. *for each treatment arm (IMP, comparator or placebo, blinded treatment)*
4. *since the beginning of the trial*

*The SUSARS should be clearly identified.*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| SYSTEM ORGAN CLASS | LOWEST LEVEL TERM | IMP N°1 | | PLACEBO | |
| SAE | SUSAR | SAE | SUSAR |
| Gastrointestinal disorder | Jejunal perforation\*  (\* means SUSAR) | 0 | 1 | 0 | 0 |
|  | Abdominal pain | 3 | 0 | 0 | 0 |
| **Gastrointestinal disorder** | **SUBTOTAL** | **4** | | **0** | |
|  |  |  | |  | |
|  |  |  | |  | |

*There were no Suspected Serious Adverse Reactions in this trial; therefore no summary tabulation has been compiled.*

**CONCLUSIONS**

*The trial has not yet started to recruit subjects, so there are no safety data to report. There are therefore no line listings or summary tabulation to present.*

*(the ASR must be sent anyway)*

**OR**

-This Development Safety Update Report contains/ does not contain new data which modify the security profile of the IMP.

- The overall benefit/risk assessment is / is not modified.

- The following measures are taken for the safety of the patients:

**This document has been approved by:** *(the sponsor or the sponsor’s designed person)*

Signature ------------------------------------------------- Date:

Name

Title

Department

Address: Cliniques universitaires Saint-Luc

10, avenue Hippocrate

B-1200 Bruxelles