DEVELOPMENT SAFETY UPDATE REPORT

**${products}**

**Period Covered:** ${dateRangeStartAbsolute}

**–** ${dateRangeEndAbsolute}

**Document Date:** ${CurrentDate}

**DSUR Number:** ${Number}

${CompanyName}

|  |  |  |
| --- | --- | --- |
| **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Chief Investigator** | **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Signature** | **\_\_\_ \_\_\_ / \_\_\_ \_\_\_ \_\_ / \_\_ \_\_**  **Date** |

*This Development Safety Update Report contains confidential information and should not be distributed without consent from the Chief Investigator.*

**EXECUTIVE SUMMARY**

* This is the Development Safety Update Report # ${Number} for ${products} summarizing safety data received by ${CompanyName} from ${dateRangeStartAbsolute} - ${dateRangeEndAbsolute}.
* ${products} is being developed for the treatment of ${Indication} given <insert Dose Details>.
* Overall, approximately <insert Patient Count> patients and healthy volunteers have been enrolled into the ${products} clinical development program; approximately <insert Subject Count> subjects have received ${products}.

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1. **Introduction**

This is the Development Safety Update Report # ${Number} for ${products}. This DSUR summarizes safety data received by ${CompanyName} between ${dateRangeStartAbsolute} and ${dateRangeEndAbsolute}. It is compiled in accordance with the ICH E2F (DSUR) guideline.

We have provided a copy of this report to the manufacturer(s) and supplier(s) of ${products}.

1. **Worldwide Marketing Approval Status**

${products} is supplied by ${CompanyName} who manufactures the IMP in accordance with their Marketing Authorization Number, <insert Marketing Authorization Number>.

1. **Actions Taken in the Reporting Period for Safety Reasons**

The following amendments have been made:

|  |  |  |  |
| --- | --- | --- | --- |
| **Amendment Number** | **Amendment Date** | **Summary of Amendment** | **Reason for amendment** |
|  |  |  |  |

1. **Changes to Reference Safety Information**

The Investigator’s Brochure (IB) provides a summary of clinical and non-clinical data for the product relevant to its study in human subjects. Section 7 of the ${products} IB (Summary of Data and Guidance for the Investigator) provides investigators with a clear understanding of the possible risks, adverse reactions, specific tests, observations and precautions relevant to ${products}, and acts as the reference safety information for the purposes of this report.

1. **Inventory of Clinical Trials Ongoing and Completed during the Reporting Period**

This DSUR covers the following studies: ${StudyNum}.

The primary objective of this study is to assess <insert Patient Count> patients treated with ${products} (<insert Dose Details>) in the treatment of ${Indication}.

This study is conducted at <insert Study Center Count> sites, as listed: <insert Study Center list>.

Further details for each clinical trial completed and ongoing during the reporting period are provided in Appendix 1.

1. **Estimated Cumulative Exposure**
   1. Cumulative Subject Exposure in the Development Program

<insert Subject Count> subjects have been exposed to ${products}. Demographic data is provided in Appendix 2.

* 1. Patient Exposure from Marketing Experience

Not applicable.

1. **Data in Line Listings and Summary Tabulations**
   1. Reference Information

Medical Dictionary for Regulatory Activities (MedDRA) has been used for the coding of adverse events. The line listings and the summary tabulations are arranged alphabetically by primary System Organ Class (SOC) and Preferred Term (PT) level.

The Investigator’s Brochure / SmPC served as the reference point for determination for ‘expectedness’ of all adverse events.

* 1. Line Listing of Serious Adverse Reactions during Reporting Period

During the reporting period, ${EventCount} serious adverse reactions (SARs) were considered as being possibly related to the study drug.

The details of the Serious Adverse Reactions that occurred during this reporting period are provided in Appendix 3.

Each case report appears only once within the line listing and is presented in the primary SOC determined by the most serious adverse reaction for the case.

The drug identity is provided for all case reports that include unblinded data. For case reports where the code break has yet to be completed, the drug is identified as ‘Blinded’.

* 1. Cumulative Summary Tabulations of Serious Adverse Events

The table in Appendix 4 summarizes Serious Adverse Events (SAEs) by System Organ Class (SOC) for the duration of the trial to date.

1. **Significant Findings from Clinical Trials During the Reporting Period**
   1. Completed Clinical Trials

Not applicable.

* 1. Ongoing Clinical Trials

There are no significant findings to date.

* 1. Long Term Follow-up

At present, patients completing ${products} studies are not subject to long-term follow up.

* 1. Other Therapeutic Use of Investigational Drug

No pre-approval patient access programs have been initiated for ${products}.

* 1. New Safety Data Related to Combination Therapies

Not applicable.

1. **Safety Findings from Noninterventional Studies**

Not applicable.

1. **Other Clinical Trial/Study Safety Information**

No other studies have been conducted with ${products}.

1. **Safety Findings from Marketing Experience**

Not applicable.

1. **Nonclinical Data**

Not applicable.

1. **Literature**

<Insert literature section>

1. **Other DSURs**

${CompanyName} is not aware of any clinical trials being conducted on ${products} by any other organizations.

1. **Lack of Efficacy**

Not applicable.

1. **Region-Specific Information**

Appendices 5 and 6 provide information meeting local requirements, as follows:

* Appendix 5: Cumulative summary tabulation of serious adverse reactions
* Appendix 6: List of subjects who died during the reporting period

1. **Late-Breaking Information**

No relevant information was received subsequently to the data-lock for this DSUR.

1. **Overall Safety Assessment**
   1. Evaluation of the Risks

CI to provide statement (or a statement that there benefit-risk considerations have not changed)

* 1. Benefit-Risk Considerations

CI to provide statement (or a statement that there benefit-risk considerations have not changed)

1. **Summary of important risks**

CI to provide statement per risk identified in IB, by manufacturers, at trial design stage etc, an example is given below:

***Renal Toxicity:*** *E.g. Dovitinib has been associated with renal toxicities in subjects with ........... To date no renal toxicity has been observed in our population. Subjects are monitored with GGT blood tests fortnightly.*

1. **Conclusions**

The risks remain consistent with the experience described in our previous DSUR, and we conclude that the information obtained in this reporting period justifies continuation of the study, with the modifications noted in this DSUR.

**APPENDIX 1**

**Document Fetching Test**

|  |  |  |
| --- | --- | --- |
| **Description** | **Parameter** | **Expected Behavior** |
| Plain parameter | ${Plain\_parameter} | System should display this. |
| Parameter in upper case | ${UPPER\_CASE\_PARAMETER} | System should display this in upper case. |
| Duplicate parameter | ${Plain\_parameter} | System should not display this. |
| Duplicate parameter in upper case | ${PLAIN\_PARAMETER} | System should not display this. |
| Parameter in inappropriate format | ${Inappropriate parameter} | System should not display this. |
| Parameter in inappropriate format | ${Inappropriate-parameter} | System should not display this. |
| Parameter in inappropriate format | ${@Inappropriate\_parameter} | System should not display this. |
| Parameter in inappropriate format | ${!Inappropriateparameter} | System should not display this. |
| Parameter in inappropriate format | ${Inappropriate${parameter}} | System should not display this. |
| Parameter in inappropriate format | ${Inappropriate${parameter} | System should not display this. |
| Parameter in inappropriate format | ${Inappropriate\_parameter } | System should not display this. |
| Parameter in inappropriate format | ${Inappropriate/number\_parameter} | System should not display this. |
| Parameter name size more than 255 characters | ${TheInvestigatorsBrochureIBprovidesasummaryofclinicalandnonclinicaldatafortheproductrelevanttoitsstudyinhumansubjectsSection7oftheIBSummaryofDataandGuidancefortheInvestigatorprovidesinvestigatorswithaclearunderstandingofthepossiblerisksaDversereactionsspecifictestsobservationsandprecautionsrelevanttoandactsasthereferencesafetyinformationforthepurposesofthisreport} | System should not display this. |
| Parameter in Bold upper case | **${BOLD\_UPPER\_CASE\_PARAMETER}** | System should display this in upper case and return in bold font. |
| Parameter in Italics lower case | *${bold\_upper\_case\_parameter}* | System should display this in lower case and return in italics font. |
| Parameter in date format | ${DD}/${MMM}/${YYYY} | System should identify and display 3 separate parameters. |
| Parameter in numeric format | ${12345678} | System should display this. |
| Parameter to view space validation | relevant${products}is | System should display this. |
| Parameter to view character limit | ${TheInvestigatorsBrochureIBprovidesasummaryofclinicalandnonclinicaldatafortheproductrelevanttoitsstudyinhumansubjectsSection7oftheIBSummaryofDataandGuidancefortheInvestigatorprovidesinvestigatorswithaclearunderstandingofthepossiblerisksadversereactionssp} | System should display this. |

${#IF conditionVariable2}

condition2

In text ${#IF conditionVariable3} condition3${#ENDIF conditionVariable3}

In text ${#IF conditionVariable4} condition4${#ENDIF conditionVariable4}

${#ENDIF conditionVariable2}

${#IF conditionVariable1.size()>0 && conditionVariable1.size()<7}

condition1

${#ENDIF conditionVariable1.size()>0 && conditionVariable1.size()<7}

${#EACH loopData}

Some item${#ITEM[0]} some text item${#ITEM[1]} some text

${#IF conditionVariable7} condition7 itemcond${#ITEM[0]} ${#ENDIF conditionVariable7}

${#IF conditionVariable8} condition8 itemcond${#ITEM[1]} ${#ENDIF conditionVariable8}

${#ENDEACH}

${#IF wasUpdated} condition5 ${#ENDIF wasUpdated}

${#IF wasNotUpdated} condition6 ${#ENDIF wasNotUpdated}

joinresult

#DEFINITIONSTART

#VAR BOOLEAN wasUpdated = ctx.changesData.size()>0

#VAR BOOLEAN wasNotUpdated = !ctx.wasUpdated

#VAR TEXT changeList = ctx.changesData.collect{it[1]}.join(“,“)

#DEFINITIONEND