**MEDICINES CONTROL AGENCY**

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| SECTION A ADMINISTRATIVE INFORMATION | | | | | |
| **Study Title:** | | | | | |
| **Responsible Person:** (*Please insert name and address),* | | | | | |
| Study identification, where applicable |  | | | | |
| Date of Start of the Study: |  | | | | |
| Date of End of the Study: |  | | | | |
| Was it an early termination | | Yes |  | No |  |
| **Date of this report:** | | | | | |

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| SECTION B General Information about the Clinical Trial | |
| **Purpose/ Rationale of the study:** | |
| Substantial Modifications: | |
| Statistical methods used: | |
| Objectives of Study: | |
| **Number of patients observed in the study:** |  |

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| SECTION D Products and Adverse Events |
| Description of products used: |
| Description of overall safety experience: |
| Summary and narratives of serious adverse reactions suspected to be related to the product (attach tables) |

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| SECTION E overall results of the clinical trial |
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**List the documents attached to this report**

Signature of Responsible Person:

Signature Date