Serious adverse event report form

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Serious adverse event report form** | | | | | |
| Health centre name: | | | | Study number: | |
| Locality: | | | | Patient study number: | |
| District: | | | | Date of visit: dd/mmm/yyyy | |
| Province: | | | | Follow-up day: | |
| **Demographic data** | | | | | |
| Date of birth: dd/mmm/yyyy | | | or estimated age:       in:  months or  years | | |
| Height (cm): | Weight (kg): | | Height (cm): | | |
| If female, is the patient pregnant?  Yes  No  Not sure | | | | | |
| Provide the date of the last menstrual period: dd/mmm/yyyy | | | | | |
| **Serious adverse event** | | | | | |
| Type of event: | | Severity | | | Relationship to the study drug |
| Death | | Mild | | | None |
| Life-threatening | | Moderate | | | Possible |
| Hospitalization or prolongation of hospitalization | | Severe | | | Probable |
| Permanent disability | | Life-threatening | | | Definite |
| Congenital anomaly or birth defect | |  | | |  |
| Date of occurrence: dd/mmm/yyyy | | | | | |
| Describe the serious adverse event (include all relevant laboratory results): | | | | | |
| Describe how the reaction was treated: | | | | | |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Serious adverse event report form (page 2)** | | | | | | | |
| Comments (e.g. relevant medical history, drug allergies, previous exposure to similar drugs, other laboratory data, whether reaction abated after stopping the drug, whether reaction reappeared after reintroduction): | | | | | | | |
| **Outcome** | | | | | | | |
| Recovered completely | | | | | | | |
| Not yet recovered | | | | | | | |
| Recovered with long-term consequences  If patient recovered, provide date of recovery: dd/mmm/yyyy | | | | | | | |
| **Medicines** (list the **medicine suspected of causing** the serious adverse event as well as all **concomitant medicines**) | | | | | | | |
| Brand name, batch number, manufacturer name  (list suspected medicine first) | Daily dose | Route | | | Start date | End date | Indications for use |
|  |  |  | | | dd/mmm/yyyy | dd/mmm/yyyy |  |
|  |  |  | | | dd/mmm/yyyy | dd/mmm/yyyy |  |
|  |  |  | | | dd/mmm/yyyy | dd/mmm/yyyy |  |
|  |  |  | | | dd/mmm/yyyy | dd/mmm/yyyy |  |
|  |  |  | | | dd/mmm/yyyy | dd/mmm/yyyy |  |
| **Reporting officer** | | | | | | | |
| Name: | | | | | | | |
| Qualification: | | | | | | | |
| Address: | | | | | | | |
| Phone: | | |  | | | | |
| Fax: | | |  | | | | |
| Email: | | | | | | | |
| Signature: | | | | Date: dd/mmm/yyyy | | | |