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| **Individual Case Safety Report** |
| **General Information** |
| **ICSR Number** |  | **ICSR Status** | Follow-Up VersionInitial Version |
| **First Receipt Date** |  | **LSR Receipt Date** |  |
| **Reporter Type** | RDS EmployeeConsumerHealthcare ProviderAuthority |
| **Reporter Initials** |  | **Can Reporter be contacted for follow-up?** NoYes |
| **Reporter Email** |  | **Reporter Phone No.:** |  |
| **Case Seriousness** | Life-ThreateningSeriousNon-Serious |
| **Other Case Numbers** (please specify, i.e. Complaint, Regulatory, Partner…etc.) |  |
| **Patient Information** |
| **Patient Initials** | **Age** | **Gender** | **Follow- Up Requested** **(Yes / No)** |
|  |  |  |  |
| **Reaction/ Event** |
| **Adverse Event** | **Duration** | **Outcome** | **Seriousness** |
|  |  |  |  |
| **Drug Information** (exclude those to treat adverse events) |
| **Drug Trade Name and Generic Name** | **Indication** | **Dose and Dosage Form** | **Route of Administration and Frequency** | **Action Taken** | **Start Date** | **Stop Date** | **Ongoing (Yes/ No)** |
|  |  |  |  |  |  |  |  |
| **Action taken regarding the suspect product** | UnknownWithdrawnDose ReducedDose IncreasedNo change |
| **Did reaction abate after stopping drug?** | NAYesNo | **Did reaction reappear after drug reintroduction?** | NANoYes |
| **Relevant Medical History/ Past Drug Therapy/ Procedures** |
| **Description of Condition** | **Start Date** | **Stop Date** | **Results/ Comments** | **Ongoing (Yes / No)** |
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| **Laboratory Tests including Vital Signs** |
| **Test Name** | **Result (with Units)** | **Reference Range (High/ Low)** | **Test Date** | **Comments** |
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