

General Guidance for completing Adverse Event and Product Quality Complaint Form

* **Complete all sections** that apply
* **Dates** should be entered as DD-MMM-YYYY. If exact dates are unknown, provide the best estimate. Partial dates are acceptable.
* **Date Received:** Earliest date initial and/or follow up adverse event information is received by company employee or person/agent acting on the company's behalf. For Non-lnterventional Studies (NIS), where there is both an Investigator and Supplier, this field should be completed by the Supplier if the Supplier is managing AE/PQC reporting from the Investigator to MSD.
* **Patient/Reporter Details:** Name or initials
	+ Anonymized: Patient/reporter details need to be withheld for privacy
	+ Unknown: Patient/reporter details are not known
* **Age:** Enter patient's age at onset of event and age unit (days, weeks, months, years), e.g. 24 weeks
* **Age Group:** Enter patient's age group at time of event if Date of Birth or Age is not available
	+ Foetus (Prior to birth)
	+ Neonate (1 day - 28 days)
	+ Infant (>28 days - 24 months)
	+ Child (>2 year - <12 years)
	+ Adolescent (12 years – <18 years)
	+ Adult (18 years - <65 years)
	+ Elderly (>65 years)
* **Product:** Trade/brand name(preferred) Generic Name (acceptable)
* **Action Taken:** Dose (decreased, increased, interrupted, or not changed), Withdrawn, Unknown, NA
* **Lot/Batch/Serial#/ Model#/Catalog#/UDI#:** provide all numbers exactly as they appear on the device or device labeling (including spaces, hyphens, etc.) or pharmaceutical product (lot/batch), as applicable.
* **Seriousness:** Adverse event resulted in:
	+ **Hospitalization:** prolonged hospital stay, or an emergency room visit results in hospital admission
	+ **Life-threatening:** Substantial risk of dying or continued product use may have resulted in death
	+ **Death:** Death (include the date, cause of death, if known)
	+ **Disability:** significant, persistent or permanent impairment or diminished quality of life
	+ **Medically Significant:** could have jeopardized the patient or required medical or surgical intervention (treatment) to prevent serious outcome
	+ **Congenital Anomaly/Birth Defects:** Outcome in a child from exposure to a medical product prior to conception or during pregnancy
	+ **Required Intervention related to a device or device component:** Medical or surgical intervention was necessary to preclude permanent impairment of a body function or permanent damage to a body structure (provide details in the narrative)
* **Was the Adverse Event related to the product?** For multiple events, detail in narrative
* **Narrative:** Summary of all relevant medical information (clinical course, treatment) office visit notes, hospital discharge summary (if applicable)

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| **Adverse Event and Product Quality Complaint Form** |
| **Case Details** |
| Date Received | Country of Incidence | Program/Study ID# | Program/Study Name |
| **Sender Details (Business Partner (BP), Investigator, Vendor, Supplier)** |
| Name/Initials:Email Address: | BP/Vendor ID# |
| **Patient Details (complete in accordance with local privacy laws)** |
| Name/Initials:Address: | Patient/Subject ID# |
|  Anonymized □ Unknown □ Sex: Male□ Female□ Unknown□ | DOB: | Age: | Age Group: |
| Pregnant: Yes□ No□ NA□ If yes, date of last menstrual period? |
| **Reporter Details (complete** in **accordance with local privacy laws)** |
| Name/Initials: | Address: |
| Anonymized □ Unknown □ Phone: | Fax: | Email: |
| Physician□ Pharmacist□ Other Health Prof□ Consumer□ Lawyer□ Is the Reporter/HCP willing to be contacted? Yes□ No□ Unknown□ |
| **Product(s) Details** |
| **Product Name****Suspect (S) Concomitant (C)** | **Formulation Dose/Frequency** | **Indication** | **Start Date****DD/MMM/YYYY** | **Stop Date****DD/MMM/YYYY** | **Action Taken** | **Lot/Batch/Serial#/ Model#/Catalog#/UDI#** |
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| **Adverse Event/Product Quality Complaints** |
| **Event** |  | **Onset Date** | **Outcome** |
|  |  | Fatal□ Not recovered□ Recovered□ Recovering□ Sequelae □ Unknown□ |
|  |  | Fatal□ Not recovered□ Recovered□ Recovering□ Sequelae □ Unknown□ |
|  |  | Fatal□ Not recovered□ Recovered□ Recovering□ Sequelae □ Unknown□ |
|  |  | Fatal□ Not recovered□ Recovered□ Recovering□ Sequelae □ Unknown□ |
|  |  | Fatal□ Not recovered□ Recovered□ Recovering□ Sequelae □ Unknown□ |
| Was the event considered Serious? Yes□ No□ Unknown□**If yes,** select all that apply (see cover page for details): Hospitalization□ Life Threatening□ Death□ Disability□ Medically Significant□ Congenital Anomaly□ Required Intervention (Device/Device Component) (provide details in narrative)□Other (provide details in narrative) □ |
| Was the Adverse Event(s) related to the product? Yes□ No□ Unknown□ | This is a non-interventional study/program with no HCP assessment of seriousness or causality□(for internal use only) |
| Is this a Product Quality Complaint? Yes□ No□Is the product available for return, if requested?* Yes, provide contact details
* No, specify reason (if known)
 | Medical Devices Only: |
| Date Implanted | Date Explanted |
| Initial Use □ Repeated Use □ | Operator of Device: HCP □ Non-HCP □ Other□ |
| **Description of Adverse Event(s) and/or Product Quality Complaint:** *Information not captured in the fields (other products taken by the patient, current medical conditions, relevant medical history, laboratory tests etc.)* |
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| If applicable |
| Form Completed By: | Date Completed (DD-MMM-YYY): | QC check Completed By: QC Check Date (DD-MMM-YYY): |