## Applicability (max. displayed 12)

| | | |
|---|---|---|
| clinical gred | clinical pred | clinical dev gma |
| clinical dev operations | clinical dev pv | clinical dev science |
| clinical global_product_strategy | clinical local operations | clinical local pv |

## Site(s) where applicable (max. displayed 6)

Global

## Author(s) (max. displayed 3)

Beatriz Bustillo

## Electronic Signatures (max. displayed 10)

| Signed by | Meaning of Signature | Date (dd-MMM-yyyy HH:mm:ss Basel Server Time) |
|---|---|---|
| Tomita Kristen | Quality Approval | 26-Jan-2018 15:53:12 CET |
| Diedrick Maria | Document Approval | 29-Jan-2018 18:41:21 CET |

## Change Control Number

N/A

## Reference Numbers(s) of Governing Documents (max. displayed 10)

## Reference Numbers(s) of Attached Documents (max. displayed 35)



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# Global: Adverse Event and Special Situation Reporting Form

**Instructions:**

This form is to be used for reporting Adverse Events (AEs) and Special Situations originating from a spontaneous source, a Non-Interventional Study (NIS), a Market Research and Patient Support Program (MAP), a Pre-Approval Access (PAA) / Compassionate Use (CU) Program and a Post-Trial Access Program (PTAP).

AEs and Special Situations will be collectively referred to as "adverse events" hereafter.
For AEs and Special Situations originating from:

- Spontaneous sources: Omit section A, B,C and D and start to complete the form with Section 1 – Reporter Details.
- NIS: Complete section A first in addition to the other sections.
- MAP: Complete section B first in addition to the other sections.
- PAA/CU Program: Complete section C first in addition to the other sections.
- PTAP: Complete section D first in addition to the other sections.

The four essential elements for AE/Special Situations reporting are marked with * .

Once completed, forward the form to your Roche Local Safety Unit (LSU) or to Roche Safety Operations as applicable.

For dates, spell out the first three letters of the month, DD/MMM/YYYY, e.g., 07/APR/2015.

*Note: The format/wording of this form may be modified by the Roche LSU as needed as long as the requirements on essential data that needs to be collected is not omitted.*



**A. Non-Interventional Study (NIS) REPORTS ONLY**

| | |
|---|---|
| NIS Protocol Number: | |
| Site Number: | |
| Patient Number: | |

Did the patient receive a studied medicinal product as per the NIS protocol? ☐ Yes ☐ No

Are any of the adverse events reported on this form exempted from collection as per the NIS protocol? ☐ Yes ☐ No

**B. Market Research and Patient Support Program (MAP) REPORTS ONLY**

*Note: Even if there is no identifiable patient, complete as many details as possible.*

| | | | |
|---|---|---|---|
| MAP Identifier: | | Project Title: | |
| MAP Service Provider: | | Respondent ID: | |
| Address: | | E-mail Address: | |
| | | Telephone Number: | |
| Country: | | Fax Number: | |

**C. Pre-Approval Access (PAA)/Compassionate Use (CU) Program REPORTS ONLY**

| | |
|---|---|
| Program Number: | |
| Patient Identifier: | |

**D. Post-Trial Access Program (PTAP) REPORTS ONLY**

| | |
|---|---|
| Program Number: | |
| Patient Identifier: | |

**1. REPORTER DETAILS *** *Note: If available please provide reporter's occupation. If data privacy allows please provide name, address and/or phone number.*

| | | |
|---|---|---|
| Reporter First Name: | | Occupation: |
| Reporter Surname: | | ☐ Physician (specify speciality): |
| Address: | | ☐ Pharmacist |
| Postal/Zip Code: | | ☐ Nurse |
| Country: | | ☐ Consumer/Patient |
| E-mail Address: | | ☐ Legal |
| Telephone Number: | | ☐ Company Representative |

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# Global: Adverse Event and Special Situation Reporting Form

| | | |
|---|---|---|
| Fax Number: | | ☐ Other (specify): |

Has the Regulatory Authority been notified of this report? ☐ Yes ☐ No ☐ Unknown

## 2. PERMISSION TO CONTACT HEALTHCARE PROFESSIONAL (HCP)

| | |
|---|---|
| If the reporter is a consumer/patient, permission to contact HCP regarding adverse event(s)? ☐ Yes ☐ No | HCP Contact Details: |

## 3. PATIENT DETAILS *

*Note: If data privacy allows please provide at least one descriptor. Please ensure the patient's age or age group is captured wherever possible.*

| | | | |
|---|---|---|---|
| Name/Initials: | | Weight: | ☐kg ☐lb |
| Gender: | ☐ Male<br>☐ Female<br>☐ Unknown | Height: | ☐cm ☐inch |
| Date of Birth:<br>or age at time of event: | ☐ Year(s) ☐ Month(s) ☐ Day(s) | Ethnic Origin: | ☐ Asian ☐ Black ☐ Caucasian ☐ Hispanic<br>☐ Other (specify): |

## 4. SUSPECT PRODUCT * - *If more than 4, continue in Additional Relevant Information, Section 8.*

| Product Name (report brand name if available) | Indication/ condition for which the product has been prescribed | Dose and Unit | Route | Frequency | Start Date | Stop Date (or ongoing) | Batch/ Lot Number |
|---|---|---|---|---|---|---|---|
| **A** | | | | | | | |
| Was the suspect product discontinued due to the adverse event? ☐ Yes ☐ No<br>If so, did the patient's condition resolve/improve? ☐ Yes ☐ No ☐ Unknown | | | | Was the suspect product reintroduced? ☐ Yes ☐ No<br>If so, did the event recur? ☐ Yes ☐ No ☐ Unknown | | | |
| **B** | | | | | | | |
| Was the suspect product discontinued due to the adverse event? ☐ Yes ☐ No<br>If so, did the patient's condition resolve/improve? ☐ Yes ☐ No ☐ Unknown | | | | Was the suspect product reintroduced? ☐ Yes ☐ No<br>If so, did the event recur? ☐ Yes ☐ No ☐ Unknown | | | |
| **C** | | | | | | | |
| Was the suspect product discontinued due to the adverse event? ☐ Yes ☐ No<br>If so, did the patient's condition resolve/improve? ☐ Yes ☐ No ☐ Unknown | | | | Was the suspect product reintroduced? ☐ Yes ☐ No<br>If so, did the event recur? ☐ Yes ☐ No ☐ Unknown | | | |
| **D** | | | | | | | |
| Was the suspect product discontinued due to the adverse event? ☐ Yes ☐ No<br>If so, did the patient's condition resolve/improve? ☐ Yes ☐ No ☐ Unknown | | | | Was the suspect product reintroduced? ☐ Yes ☐ No<br>If so, did the event recur? ☐ Yes ☐ No ☐ Unknown | | | |

## 5. ADVERSE EVENT(S)/SPECIAL SITUATION(S) * - *If required, continue in Additional Relevant Information, Section 8.*

| Adverse Event (AE) (list primary first) | Onset Date | Outcome (enter number as per the key below) If outcome is unknown, use key 6 and add further details in Section 8 | Resolved/ Improved Date | Seriousness (enter one or more numbers as per the key below) | Causality Y=Yes, N=No, U=Unknown, NP=Not Provided (specify all suspect products that may have caused the adverse event). If causality is unknown, specify "unknown" and add further details in Section 8 | | | |
|---|---|---|---|---|---|---|---|---|
| | | | | | Suspect Product | | | |
| | | | | | A | B | C | D |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
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# Global: Adverse Event and Special Situation Reporting Form

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |

**Key for outcomes:**

**1. Fatal, 2. Not Recovered/Not Resolved, 3. Recovered/Resolved, 4. Recovered/Resolved with sequelae, 5. Recovering/Resolving, 6. Unknown**

**Key for seriousness:**

**1. Death** (if yes, provide date): **2. Life-Threatening** (use only if patient was at immediate risk of death due to adverse event) **3. Initial/Prolonged Hospital Admission** **4.Congenital Anomaly/Birth Defect** **5. Persistent or Significant Disability** **6. Medically Significant** (important medical event that may jeopardize the patient and may require medical/surgical intervention to prevent the other outcomes) **7. Non-serious Adverse Events of Special Interest (AESI**) as per NIS protocol **8. Non-serious**

## 6. CONCOMITANT MEDICATIONS

*Also include herbal, homeopathic medications and supplements as well as OTC products. If more than 6, continue in Additional Relevant Information, Section 8.*

| Product Name (report brand name if available) | Indication | Dose and Unit | Route | Frequency | Start Date | Stop Date (or ongoing) |
|---|---|---|---|---|---|---|
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |

## 7. TEST(S) PERFORMED TO EVALUATE ADVERSE EVENT(S)

*E.g., baseline results prior to product. If required, continue in Additional Relevant Information, Section 8.*

| Test | Date of Test | Test Result (include units if applicable) | Reference Range | Result Pending? |
|---|---|---|---|---|
| | | | | ☐ |
| | | | | ☐ |
| | | | | ☐ |
| | | | | ☐ |
| | | | | ☐ |
| | | | | ☐ |

## 8. ADDITIONAL RELEVANT INFORMATION

*Provide a description of the adverse event(s), severity, concurrent conditions and relevant medical history (including start and end date if applicable), clinical course, causality (if unknown), treatment for adverse event(s) and outcome.*

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# Global: Adverse Event and Special Situation Reporting Form

## 9. MEDICATION ERROR INFORMATION

*Please complete for all reports of intercepted or confirmed medication error. If any other information is considered of relevance, please provide it in section 8.*

A. Brief description of the medication error:

B. Stage where the error first occurred:

- ☐ Storage
- ☐ Prescribing
- ☐ Dispensing
- ☐ Preparation for administration
- ☐ Administration
- ☐ Drug monitoring

C. Was the patient exposed to the error?
☐ Yes ☐ No

*If the answer is Yes, continue to section C1. If the answer is No, continue to sections C2 and C3.*

C1. Did the error have any clinical consequences?
☐ Yes ☐ No

*If the answer is yes, please provide the numbers of the associated adverse events (as per section 5) below:*

C2. Stage where the error was intercepted:

- ☐ Storage
- ☐ Prescribing
- ☐ Dispensing
- ☐ Preparation for administration
- ☐ Administration
- ☐ Drug monitoring

C3. Please describe the potential for harm that might have occurred if the error had reached the patient:

D. Setting(s) where the error occurred (list more than one if applicable, e.g. pharmacy, hospital, private home…):

E. Contributing factors and root causes:

F. Mitigating factors that prevented or moderated the progression of the error towards harming the patient:

G. Corrective and/or preventative actions taken in response to the error:

**ROCHE USE ONLY OR VENDORS ACTING ON BEHALF OF ROCHE**

LRN: AER: Local Received Date: Company Received Date:

**Report Type** ☐ Initial ☐ Follow-Up
☐ Spontaneous ☐ Literature ☐ Other (specify):
NIS Protocol Number: MAP ID: PAA/CU Program Number:
PTAP Program Number:

**Ancillary Documentation?** ☐ Yes ☐ No
**Supplementary Form attached?** ☐ Yes ☐ No

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