Pharmacovigilance Training

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Make your mark.
Improve lives.

Pharmacovigilance

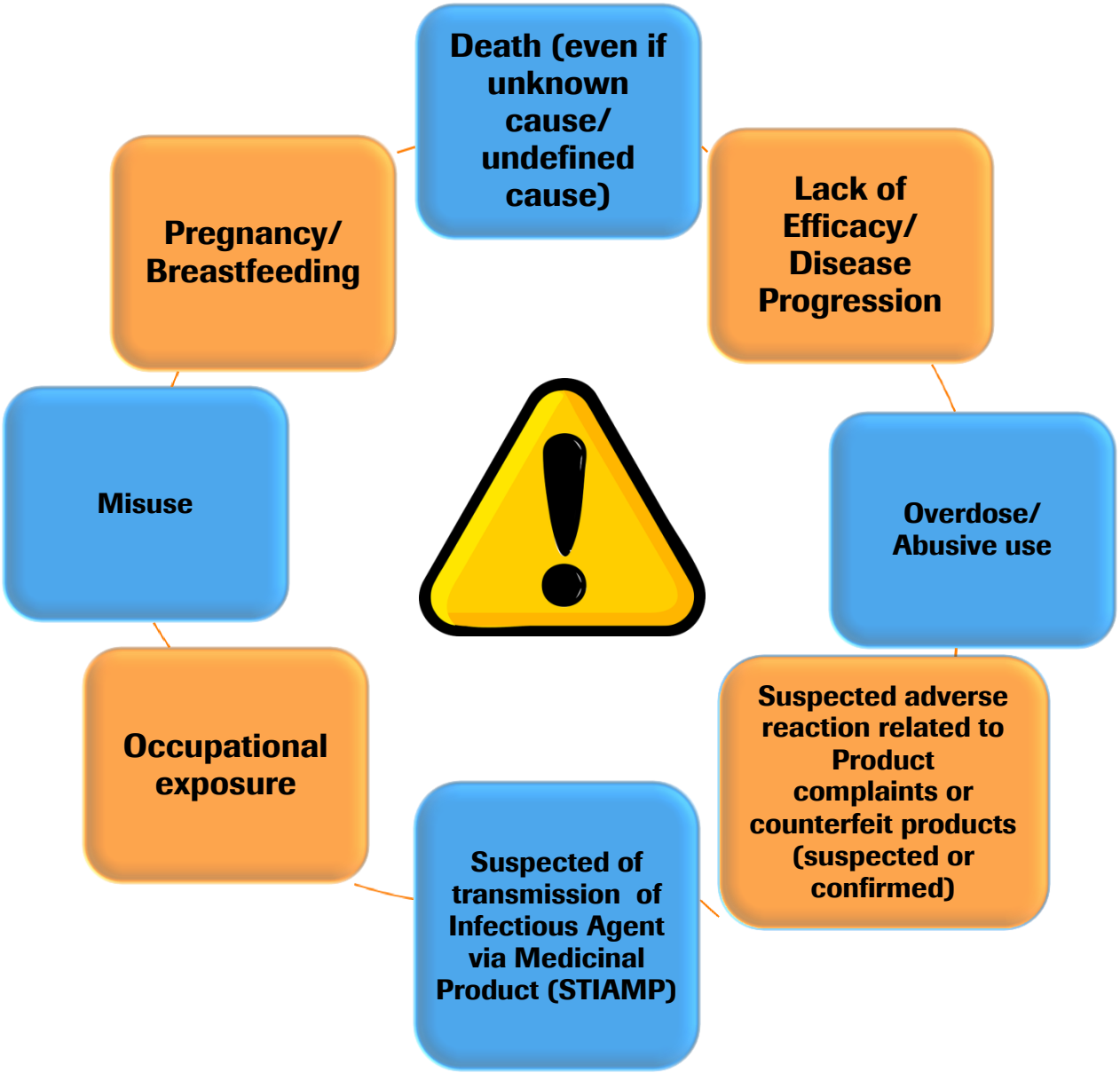
- Roche systematically monitors the benefit/risk of its products.
- As a part of this monitoring process, in case you/your company become aware of Adverse Events or Special Situations which have occured during or after the treatment with any Roche product, you must notify Roche Drug Safety Department.
- By reading this training, you will understand more about Pharmacovigilance and also learn about terms, deadlines and responsibilities with which Roche's partners should be committed to when having an agreement with us.

Adverse Event (AE)

Any **untoward medical occurrence** in a patient administered a pharmaceutical product, and which does not necessarily have a causal relationship with that treatment.

An adverse event
can thus be any abnormal laboratory finding, symptom or disease temporally associated with the use of a medicinal product,
whether or not caused by that product.

Special Situations must also be notified



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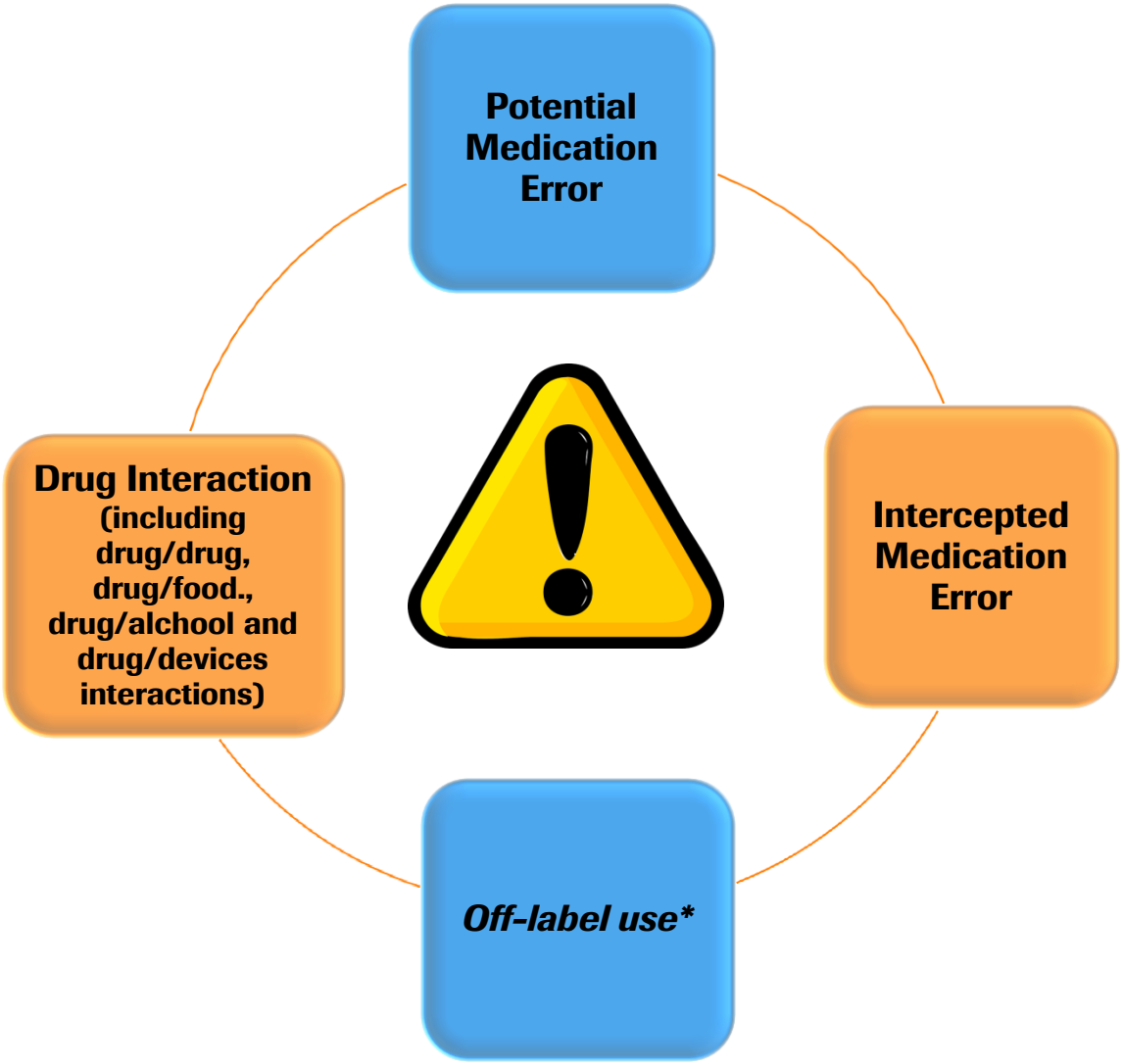

*Use not in accordance with the **authorized product information**

How to notify an Adverse Event/ Special Situation report?

The **Minimum data** needed to notify a report to Roche are:

- **Report received date** (date when the first employee acting on behalf of Roche, had acknowledgement of the report)
- **Patient** (except for reports involving potential medication error/intercepted medication error)
- **Reporter**
- **Adverse Event or Special Situation**
- **Product** **(When possible, provide Trade name and batch number*)**

Remember: The suspected product should be a product from Roche (trade name or International Nonproprietary Name).

Any additional information concerning the patient which is received by the contractor (e.g, clinically relevant medical history, concomitant medications and laboratorial tests results) should also be sent to Roche fulfilling the same deadlines for receipt of initial reports

**The batch number is especially important for the appropriate indentification of biologics products.*

Notifying Adverse Events/ Special Situation Reports

- The contracted partner must forward to Roche the complete reporter contact information (full name, telephone, e-mail address, etc) and must confirm if the reporter **authorizes**, if needed, future contact from Roche Drug Safety Department.

- In case the reporter is the patient, authorization for Roche to contact the HealthCare Professional who is responsible for patient's treatment must be obtained in order to obtain further clarification (HealthCare Professional name/contact must be sent to Roche).

- If reporter/patient refuses to provide further information regarding Adverse Events/ Special Situation or do not consent its personal data to be divulged, **this refusal must be clearly documented** in the e-mail sent to Roche. In this situation, the case still must be notify to Roche, following the same processes and deadlines mentioned before, however as an **anonimous report**.

Reporting flow

The **Contracted Partner** receives the Adverse Event/ Special Situation report and must forward it on the same day (or within **1 business day**), with all the available data, to Roche through e-mail:

brasil.farmacovigilancia@roche.com

Roche will send back an e-mail confirming the receipt of the report.

(in case this confirmation email is not received within 48h, the **Contracted Partner** should re-send the initial report until the receipt of the confirmation e-mail).

Deadline

The ***Contracted Partner*** has **1 (one) business day** to forward the reports involving Adverse Events/ Special Situation to Roche Drug Safety Department, **starting** from the report received date (RRD)

Responsibilities

- The Contractor must ensure that all its employees and subcontractors have undergone this pharmacovigilance training, which must be **finalized**, **documented** and **filed** prior to the beginning of activities that have implications for pharmacovigilance.

- Also, the Contractor must ensure that **any new employee** is trained before undertaking any activities covered by the agreement with Roche.

- All employees which are involved in activities covered by the agreement, in addition, must undergo an **annual** pharmacovigilance retraining.

Data Reconciliation

Ensures that all identified adverse events and special situations have been received and processed by Pharmacovigilance

- The Contractor shall forward to Roche a list of all adverse events / special situations that were received during the services rendered. This list must be provided to Roche in accordance with the frequency and deadlines established in the contract.
- When discrepancies are identified, each party agrees to inform the other part and take the necessary actions to resolve these discrepancies and prevent further recurrences.

How to notify Roche Drug Safety Department

E-mail: brasil.farmacovigilancia@roche.com

Telephone: CallCenter (SIR- Serviço de Informações Roche), requesting contact to Drug Safety Department

0800-77-20-289 (free phone number)

Questions?

For further information or any questions
please contact:

E-mail: brasil.farmacovigilancia@roche.com

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