



Roche Product Vigilance Training 2023

September 2023



Roche Product Vigilance Training

Version 3.0



Roche Product Vigilance Training v 3.0 | September 2023 | F. Hoffmann-La Roche Ltd

Introduction to Roche Product Vigilance

Welcome from the CEO

Welcome from the CEO



Roche Product Vigilance Training v 3.0 | September 2023 | F. Hoffmann-La Roche Ltd

Ensuring our medicines, in-vitro diagnostics and medical devices are safe for our patients is at the core of our responsibilities. So it is essential that we know about any problems experienced with one of our products -- whether it is a medicine, a diagnostic test, or a device.

You could hear about an adverse event or product complaint anywhere -- while talking to a friend who is using a Roche product, during a conversation with a healthcare professional, or on your social media channels.

This course will show you how to deal with these kinds of issues, and describe how to promptly report them. This is a key element of Roche's Code of Conduct. And I'm counting on your support in this very important matter. If you hear something, tell someone.

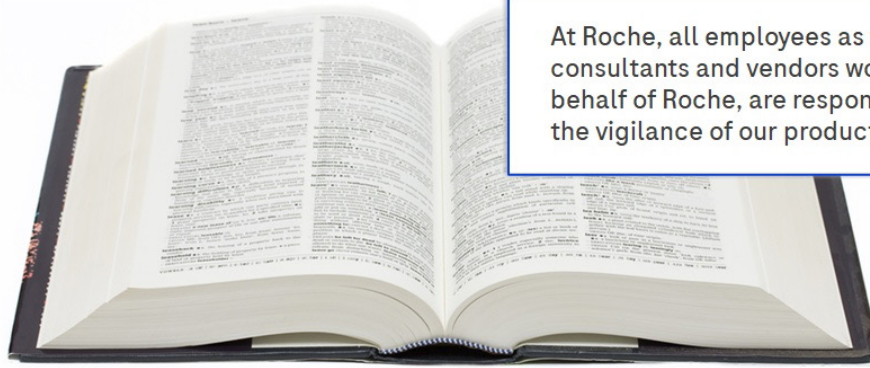
Our patients and customers trust us to listen to their feedback and to take appropriate actions when required.

Thank you.

Introduction

Introduction

vig·i·lance \ vi-jə-lən(t)s \ noun: the action or state of keeping careful watch for possible danger or difficulty.



At Roche, all employees as well as consultants and vendors working on behalf of Roche, are responsible for the vigilance of our products.

2

Roche Product Vigilance Training v 3.0 | September 2023 | F. Hoffmann-La Roche Ltd

Roche Divisions

Roche Divisions

There are three divisions within Roche: Pharmaceuticals, Diagnostics and Diabetes Care.

You are responsible for reporting any potential adverse event or complaint related to a Roche product, according to regulations and Roche company standards.

It can sometimes be difficult to know if a product is a Roche product or which division is responsible for taking care of that product. Click the ⊕ by the division names below to find out more...

Pharmaceuticals
Division



Roche Diagnostics and
Diabetes Care Divisions



3

Roche Product Vigilance Training v 3.0 | September 2023 | F. Hoffmann-La Roche Ltd

Pharmaceuticals Division

Roche Divisions

Pharmaceuticals Division

Our products include medicinal products, devices and combination products manufactured by the Pharmaceuticals Division. Other terms you may hear that mean the same thing as medicinal products include 'medicine' or 'drug'. Examples include: Evrysdi and Pegasys.



Roche Diagnostics and Diabetes Care Divisions

3

Roche Product Vigilance Training v 3.0 | September 2023 | F. Hoffmann-La Roche Ltd

Diagnostics and Diabetes Care Divisions

Roche Divisions

Roche Diagnostics and Diabetes Care Divisions

Our products are manufactured by the Diagnostics and Diabetes Care divisions at Roche. The products are instruments and tests used for disease screening and diagnosis in laboratories, at the point of care, and for patient self-management. They also include instruments, reagents and test kits that are used in the research market.



3

Roche Product Vigilance Training v 3.0 | September 2023 | F. Hoffmann-La Roche Ltd

Your Responsibility

Your Responsibility

If you hear of a problem with our products, you must report it to the appropriate contact.

This course will provide you with the necessary information to recognize and report potential adverse events and product complaints that you learn about inside and outside your daily work.

A complete list of Roche products can be found in the Resources tab located in the top-right corner of the screen.

Further information about how to report will be provided later in the course.



4

Roche Product Vigilance Training v 3.0 | September 2023 | F. Hoffmann-La Roche Ltd

Objectives

Objectives

After completing this course, you will be able to answer the following questions:

- What is a potential adverse event or product complaint and how do I recognize it?
- Why do I need to report potential adverse events and product complaints as an employee or while working on behalf of Roche?
- How do I report a potential adverse event or product complaint within Roche?



5

Roche Product Vigilance Training v 3.0 | September 2023 | F. Hoffmann-La Roche Ltd

Recognizing Potential Adverse Events and Product Complaints

Recognizing Potential Adverse Events and Product Complaints

The first step in being able to **report** potential adverse events and product complaints is being able to **recognize** them. The following pages will help you learn how to identify these issues.

**Adverse
Event**

**Product
Complaint**

**Special
Situations**
[View the List](#)

Before you proceed, please click to view a list of special situations that must be reported, even when a potential adverse event is not suspected.

6

Roche Product Vigilance Training v 3.0 | September 2023 | F. Hoffmann-La Roche Ltd

Special Situations

Recognizing Potential Adverse Events and Product Complaints

The
is be
thes

Special Situations

The following events are considered Special Situations for safety reporting even in the absence of a potential adverse event. Special situations should be reported for both Roche drugs and falsified Roche drugs.

- Pregnancy
- Breastfeeding
- Lack of Efficacy
- Overdose
- Misuse
- Abuse
- Off-label Use
- Medication Error
- Drug Interactions
- Occupational Exposure
- Unexpected Beneficial Events
- Suspected Transmission of Infectious Agent via a Medicinal Product (STIAMP)

Before
even when a potential adverse event is not suspected.

6

Roche Product Vigilance Training v 3.0 | September 2023 | F. Hoffmann-La Roche Ltd

Drug Adverse Events

Drug Adverse Events

When a patient experiences something harmful or negative while taking a Roche product, this is called an adverse event.

A drug adverse event (AE) is any untoward medical occurrence in a patient or clinical trial subject administered a medicinal product and which does not necessarily have a causal relationship with this treatment. A drug adverse event (AE) can therefore be any unfavorable and unintended sign (including abnormal laboratory finding), symptom or disease temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product.

Example: A patient developed a blood infection within 24 hours after receiving their last intravenous dosage of a Roche drug.

Note: If you work in Diagnostics or Diabetes Care, you may be familiar with the term Adverse Event also known as Potential Safety Issue (PSI) and Potentially Reportable Incident (PRI).

Click each icon for more information about drug adverse events



7

Roche Product Vigilance Training v 3.0 | September 2023 | F. Hoffmann-La Roche Ltd

Drug Adverse Events: Examples

Drug Adverse Events

Examples of potential Roche drug **adverse events** include:

- Headaches
- Rashes
- Sudden Death
- Suspected Transmission of Infectious Agent by Medicinal Product (STIAMP)
- Any adverse events reported with a Falsified Product

Even if you don't know what caused the potential adverse event or if you suspect that it was not caused by the Roche drug, the potential adverse event still needs to be reported.

Click each icon for more information about drug adverse events



7

Roche Product Vigilance Training v 3.0 | September 2023 | F. Hoffmann-La Roche Ltd

Drug Adverse Events: Scenario


Drug Adverse Events

W
th
A
or
no
ad
(in
as
re
E:
re



Scenario: Potential Drug Adverse Event

Miguel is attending a regional medical conference. One of the speakers at the conference is a patient who is receiving a Roche drug for her condition. During the presentation, the patient tells the audience that when she first started taking the drug she experienced frequent headaches. Because of this, her doctor reduced her dosage and after that, her headaches went away.

Miguel must report this potential adverse event because the new information may impact the safety profile of the drug.



Click each icon for more information about drug adverse events

 Examples  Scenario

7

Roche Product Vigilance Training v 3.0 | September 2023 | F. Hoffmann-La Roche Ltd

In-Vitro Diagnostics/Medical Device Adverse Events

In-Vitro Diagnostics/Medical Device Adverse Events



An In-Vitro Diagnostics/Medical Device adverse event (AE) is when a Roche product (reagent, hardware, or software) may have caused or contributed to a death or serious injury of a patient or the user of a device.

A serious injury means an injury or illness that:

- Is life threatening
- Results in permanent impairment of a body function or permanent damage to a body structure
- Requires medical or surgical intervention to prevent permanent impairment of a body function or permanent damage to a body structure

Permanent means irreversible impairment or damage to a body structure or function.

Click each icon for more information about In-Vitro Diagnostics/Medical Device adverse events

 Examples  Scenario

8

Roche Product Vigilance Training v 3.0 | September 2023 | F. Hoffmann-La Roche Ltd

In-Vitro Diagnostics/Medical Device Adverse Events: Examples

In-Vitro Diagnostics/Medical Device Adverse Events

Examples of potential Roche product **adverse events** include:

- Death
- Public Health Threat
- Serious Injury
- Erroneous Result
- Malfunction likely to cause/contribute to death or serious injury if it were to recur
- Cyber Security or Data Breach
- Notification of Competent Authority has been initiated by customer or 3rd party

Even if you don't know what caused the potential adverse event or if you suspect that it was not caused by the Roche product, the potential adverse event still needs to be reported.

Click each icon for more information about In-Vitro Diagnostics/Medical Device adverse events

Examples Scenario

8

Roche Product Vigilance Training v 3.0 | September 2023 | F. Hoffmann-La Roche Ltd

In-Vitro Diagnostics/Medical Device Adverse Events: Scenario

In-Vitro Diagnostics/Medical Device Adverse Events

Scenario: Potential In-Vitro Diagnostics/Medical Device Adverse Event

A technician working in a hospital realized that the results provided by a Roche instrument are erroneous. After repeating the test, the same result is shown. The technician knows that the results are wrong because that does not match the clinical picture of the patient.

Even if you don't know what caused the potential adverse event or if you suspect that it was not caused by the Roche product, the potential adverse event still needs to be reported.



Click each icon for more information about In-Vitro Diagnostics/Medical Device adverse events

Examples Scenario

8

Roche Product Vigilance Training v 3.0 | September 2023 | F. Hoffmann-La Roche Ltd

Product Complaints

Product Complaints

A product complaint is when a person claims something is wrong with a Roche product.

The complaint can be about any Roche product, including:

- Drugs
- Reagents
- Devices
- Combination Products
- Software

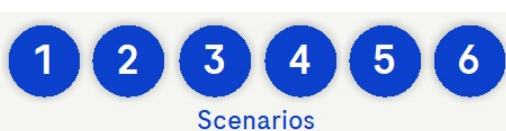
Click each icon for more information about product complaints



Definition



Examples



Scenarios

9

Roche Product Vigilance Training v 3.0 | September 2023 | F. Hoffmann-La Roche Ltd

Product Complaints: Definition

Product Complaints

A product complaint is when a person claims something is wrong with a Roche product.

The



A product complaint is any written, electronic, or oral communication from a customer/end-user that alleges a deficiency related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a product after it is distributed to the commercial market or a clinical trial.

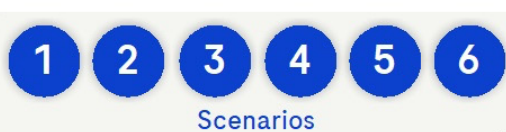
Click each icon for more information about product complaints



Definition



Examples



Scenarios

9

Roche Product Vigilance Training v 3.0 | September 2023 | F. Hoffmann-La Roche Ltd


Product Complaints: Examples


Product Complaints

Examples of product complaints include:

- a missing label
- a broken bottle cap
- an unusual appearance to the product
- a water leak in an instrument
- a person is injured while using a device
- an insulin pump has a leak
- a device generates an inaccurate result
- a needle manufactured by Roche did not work when administering a Roche drug, therefore the product was not given
- a cracked syringe
- a product that shows evidence of tampering
- product contamination
- a counterfeit/falsified/illicit/fake Roche Product

Click each icon for more information about product complaints

Definition

Examples

123456

Scenarios

9

Roche Product Vigilance Training v 3.0 | September 2023 | F. Hoffmann-La Roche Ltd


Product Complaints: Scenario 1

Product Complaints


Scenario 1: Product Complaint


Peter's Aunt Ivy is currently taking a Roche drug for her arthritis. Ivy called Peter to tell him that the last time she gave herself an injection of the Roche drug at home, it appeared to have a different color than what she usually sees.

Peter must report this product complaint because it may mean there is a problem with the quality of the Roche drug. This may ultimately impact patient safety, since the drug has effectively been administered.



Click each icon for more information about product complaints

Definition

Examples

123456

Scenarios

9

Roche Product Vigilance Training v 3.0 | September 2023 | F. Hoffmann-La Roche Ltd


Product Complaints: Scenario 2

Product Complaints


Scenario 2: Product Complaint


Angela is at her local laboratory to have some routine blood tests. Angela mentions to the lab technician drawing her blood that she works for Roche. The lab technician tells Angela that they use Roche's Cobas analyzer in the lab and last week he noticed that some of the reports from Cobas were reporting out in milliliters instead of microliters.

Angela must report this complaint because the diagnostic tool is reporting the wrong units of measurement which may lead to inaccurate test results.



Click each icon for more information about product complaints

Definition

Examples

123456

Scenarios

9

Roche Product Vigilance Training v 3.0 | September 2023 | F. Hoffmann-La Roche Ltd


Product Complaints: Scenario 3

Product Complaints


Scenario 3: Product Complaint


Simon visits his brother, Calvin. Calvin mentions to Simon that he was in hospital for a few days last month because of a reaction on his leg after he injected his Roche medication. Calvin said that the needles for the Roche product were not as sharp as expected.

Simon must report this as a potential adverse event with a product complaint. Roche investigated the report and determined that the Roche product had malfunctioned and that this malfunction needs to be reported to Health Authorities and investigated further by Roche to understand why this happened.



Click each icon for more information about product complaints

Definition

Examples

123456

Scenarios

9

Roche Product Vigilance Training v 3.0 | September 2023 | F. Hoffmann-La Roche Ltd


Product Complaints: Scenario 4

Product Complaints


Scenario 4: Product Complaint (Hardware)


Jill is a laboratory technologist and her lab uses Roche equipment. Jill mentions to her friend Mark, a Roche employee, that recently she cut her hand when operating the equipment and required some medical care. She didn't bother to report it to Roche because it was her fault.

Mark must report this product complaint because Jill was potentially injured while using a Roche device.



Click each icon for more information about product complaints

Definition

Examples

123456

Scenarios

9

Roche Product Vigilance Training v 3.0 | September 2023 | F. Hoffmann-La Roche Ltd

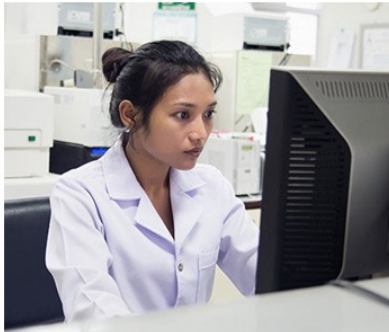
Product Complaints: Scenario 5

Product Complaints


Scenario 5: Product Complaint (Software)


During an on site visit, an account manager learned that one of his customers was not happy with the Roche software because the software was not transmitting information correctly to the hospital information system. They had a few complaints from physicians that results did not make sense for their patients.

The account manager must report this product complaint as the Roche software may not be transmitting correct information.



Click each icon for more information about product complaints

Definition

Examples

123456

Scenarios

9

Roche Product Vigilance Training v 3.0 | September 2023 | F. Hoffmann-La Roche Ltd

Product Complaints: Scenario 6

Product Complaints

Scenario 6: Product Complaint (Medical Device)

John visited a health care clinic. John mentioned to his health care provider that he is working for Roche. The health care provider told John that they are using Roche's ocular implant for patients with macular degeneration. The health care provider noticed that the implant pack was missing a blue cap for the needle usually included in the pack.

John must report this implant complaint because it may mean there is a problem with the packaging of the medical device and it might affect administration of the product using this implant.



Click each icon for more information about product complaints



Definition



Examples

123456


Scenarios

9

Roche Product Vigilance Training v 3.0 | September 2023 | F. Hoffmann-La Roche Ltd


Choose a Division to Continue

Choose a Division to Continue



If you work for Roche Pharmaceuticals

CLICK HERE



If you work for Roche Diagnostics or Diabetes Care

CLICK HERE

Note: If you belong to an Affiliate be aware that service level agreements are in place to ensure that information is shared among Roche divisions as required.

10

Roche Product Vigilance Training v 3.0 | September 2023 | F. Hoffmann-La Roche Ltd

Special Situations

Special Situations

Special Situations are additional reportable events about a Roche drug that Roche is required to monitor.

Special situations are not considered potential adverse events but are reportable as they provide important information about the drug.

It may be when a Roche drug is used during a specific condition such as pregnancy or when a Roche drug is used outside its recommended use.

Details on Special Situations are not required for employees of Roche Diagnostics and Diabetes Care.

Click each icon for more information about special situations



11

Roche Product Vigilance Training v 3.0 | September 2023 | F. Hoffmann-La Roche Ltd

Special Situations: Scenario

Special Situations

Scenario: Special Situations

Anita is excited to meet her friend, Margaret, for coffee. During their conversation, Margaret tells Anita that her cousin, Anthony, has been taking a Roche drug for almost six months. She said he is responding well to the treatment, and he just found out that his wife is 6 weeks pregnant.

Anita must report this special situation. The baby that Anthony's wife is carrying may have been exposed to the Roche drug, so Roche needs to understand more about any potential effects the Roche drug may have on the pregnancy.



Click each icon for more information about special situations



11

Roche Product Vigilance Training v 3.0 | September 2023 | F. Hoffmann-La Roche Ltd

Special Situations

Special Situations

The following events are considered Special Situations for safety reporting even in the absence of a potential adverse event.

- Pregnancy
- Breastfeeding
- Lack of Efficacy
- Overdose
- Misuse
- Abuse
- Off-label Use
- Medication Error
- Drug Interactions
- Occupational Exposure
- Unexpected Beneficial Events
- STIAMP

Click each special situation to learn more

11

Roche Product Vigilance Training v 3.0 | September 2023 | F. Hoffmann-La Roche Ltd

Special Situations: Pregnancy

Special Situations

The following events are considered Special Situations for safety reporting even in the absence of a potential adverse event.

- Pregnancy**
- Breastfeeding
- Lack of Efficacy
- Overdose
- Misuse
- Abuse
- Off-label Use
- Medication Error
- Drug Interactions
- Occupational Exposure
- Unexpected Beneficial Events
- STIAMP

This refers to when an embryo or fetus may be exposed to a Roche drug through the mother or father.

Example #1: A woman taking a Roche drug for 6 months, discovers she is 2 months pregnant.

Example #2: A woman who is 4 months pregnant begins taking a Roche drug.

Example #3: A woman, who is not taking any Roche drug, discovers she is 2 months pregnant, and the father of the baby has been taking a Roche drug for the last 4 months.

11

Roche Product Vigilance Training v 3.0 | September 2023 | F. Hoffmann-La Roche Ltd

Special Situations: Breastfeeding

Special Situations

- Pregnancy
- Breastfeeding**
- Lack of Efficacy
- Overdose
- Misuse
- Abuse
- Off-label Use
- Medication Error
- Drug Interactions
- Occupational Exposure
- Unexpected Beneficial Events
- STIAMP

The following events are considered Special Situations for safety reporting even in the absence of a potential adverse event.

This refers to a situation where an infant is exposed to a Roche drug through breast milk.

Example: A woman who is taking a Roche drug, feeds her child with her breast milk either by breastfeeding or through a baby bottle.

11

Roche Product Vigilance Training v 3.0 | September 2023 | F. Hoffmann-La Roche Ltd

Special Situations: Lack of Efficacy

Special Situations

- Pregnancy
- Breastfeeding
- Lack of Efficacy**
- Overdose
- Misuse
- Abuse
- Off-label Use
- Medication Error
- Drug Interactions
- Occupational Exposure
- Unexpected Beneficial Events
- STIAMP

The following events are considered Special Situations for safety reporting even in the absence of a potential adverse event.

This refers to a situation of lack of therapeutic effect of a Roche drug which should be reported.

Any reports of disease progression could potentially represent **Lack of Efficacy** of a Roche drug and should be forwarded to Affiliate Patient Safety.

Example: A patient had a rash and took a Roche drug for 5 days, which did not reduce the symptoms as expected.

11

Roche Product Vigilance Training v 3.0 | September 2023 | F. Hoffmann-La Roche Ltd

Special Situations: Overdose

Special Situations

- Pregnancy
- Breastfeeding
- Lack of Efficacy
- Overdose**
- Misuse
- Abuse
- Off-label Use
- Medication Error
- Drug Interactions
- Occupational Exposure
- Unexpected Beneficial Events
- STIAMP

The following events are considered Special Situations for safety reporting even in the absence of a potential adverse event.

This refers to the administration of a quantity of a Roche drug given per administration or cumulatively, which is above the maximum recommended dose according to the authorized product information.

It doesn't matter if an overdose is intentional, accidental or unknown, it still needs to be reported. Here are a few examples to help you understand:

Accidental Overdose example: A patient accidentally took three tablets of a Roche drug, instead of one originally prescribed for him, and experiences arrhythmia. The prescribing doctor considers the dose to be unsafe to the patient.

Intentional Overdose example: A patient took three tablets of a Roche drug as prescribed to him by his doctor off-label, and experiences arrhythmia. Affiliate Patient Safety assesses the prescribed dose puts the patient's health at risk.

Unknown Type of Overdose example: A patient took three tablets of a Roche drug, instead of the one tablet originally prescribed for him. It is unknown whether the patient took 3 tablets intentionally or accidentally. The patient didn't experience any adverse event however you still need to inform your Affiliate Patient Safety.

11

Special Situations: Misuse

Special Situations

Pregnancy
Breastfeeding
Lack of Efficacy
Overdose
Misuse
Abuse
Off-label Use
Medication Error
Drug Interactions
Occupational Exposure
Unexpected Beneficial Events
STIAMP

The following events are considered Special Situations for safety reporting even in the absence of a potential adverse event.

This refers to situations where the Roche drug is intentionally and inappropriately used not in accordance with the terms of the marketing authorization.

Example: A patient deliberately took their medication twice daily instead of once daily as guided. He has not informed his doctor yet. The patient didn't experience any adverse event however you still need to inform your Affiliate Patient Safety.

11

Roche Product Vigilance Training v 3.0 | September 2023 | F. Hoffmann-La Roche Ltd

Special Situations: Abuse

Special Situations

Pregnancy
Breastfeeding
Lack of Efficacy
Overdose
Misuse
Abuse
Off-label Use
Medication Error
Drug Interactions
Occupational Exposure
Unexpected Beneficial Events
STIAMP

The following events are considered Special Situations for safety reporting even in the absence of a potential adverse event.

This refers to the persistent or sporadic, intentional excessive use of a Roche drug, which is accompanied by harmful physical or psychological effects.

Example: A patient decides to take a Roche drug in a larger dose in order to experience a heightened effect than the current dose offers. The patient doesn't experience any adverse event; however, you still need to inform Affiliate Patient Safety.

11

Roche Product Vigilance Training v 3.0 | September 2023 | F. Hoffmann-La Roche Ltd

Special Situations: Off-Label Use

Special Situations

- Pregnancy
- Breastfeeding
- Lack of Efficacy
- Overdose
- Misuse
- Abuse
- Off-label Use**
- Medication Error
- Drug Interactions
- Occupational Exposure
- Unexpected Beneficial Events
- STIAMP

The following events are considered Special Situations for safety reporting even in the absence of a potential adverse event.

This relates to situations where the Roche drug is **intentionally** used for a medical purpose not in accordance with the terms of the marketing authorization

- This includes use outside, for example, the approved indication, age group, dosage, route of administration

Example 1: A Roche drug indicated for use in adults was prescribed and used off label to treat a 6 year old child.

Example 2: A physician intentionally decided to prescribe 10 mg daily of a Roche drug, instead of 2.5 mg as was recommended on the label. The patient took the product and then had airway irritation.

11

Roche Product Vigilance Training v 3.0 | September 2023 | F. Hoffmann-La Roche Ltd

Special Situations: Medication Error

Special Situations

- Pregnancy
- Breastfeeding
- Lack of Efficacy
- Overdose
- Misuse
- Abuse
- Off-label Use
- Medication Error**
- Drug Interactions
- Occupational Exposure
- Unexpected Beneficial Events
- STIAMP

The following events are considered Special Situations for safety reporting even in the absence of a potential adverse event.

A medication error is an adverse failure in the drug treatment process that leads to, or has the potential to lead to, harm to the patient. This includes:

Intercepted medication error: This refers to situations where a medication error occurred, and an intervention caused a break in the chain of events in the treatment process before reaching the patient. The intervention has prevented actual harm being caused to the patient.

Potential medication error: This refers to the recognition of circumstances that could lead to a medication error and may or may not involve a patient. It refers to all possible mistakes by all persons who are involved in the medication process.

Example 1: A nurse dispensed a Roche drug to the patient. The patient took the product; however, he realised his symptoms were not under control. When he checked the package, he noticed that the wrong Roche drug had been dispensed to him.

Example 2: A pharmacist stored a Roche drug on the shelf instead of the fridge. The pharmacist noticed the error prior to supplying this Roche drug to the patient.

11

Roche Product Vigilance Training v 3.0 | September 2023 | F. Hoffmann-La Roche Ltd

Special Situations: Drug Interactions

Special Situations

- Pregnancy
- Breastfeeding
- Lack of Efficacy
- Overdose
- Misuse
- Abuse
- Off-label Use
- Medication Error
- Drug Interactions**
- Occupational Exposure
- Unexpected Beneficial Events
- STIAMP

The following events are considered Special Situations for safety reporting even in the absence of a potential adverse event.

Drug interaction is when a Roche drug is taken at the same time as another substance which may impact its efficacy or toxicity. This includes:

- A Roche drug with another drug (including biological products)
- A Roche drug with food or beverage
- A Roche drug with a device
- A Roche drug with alcohol

Example: A patient states she had a headache after taking a Roche drug and her asthma medication.

11

Roche Product Vigilance Training v 3.0 | September 2023 | F. Hoffmann-La Roche Ltd

Special Situations: Occupational Exposure

Special Situations

- Pregnancy
- Breastfeeding
- Lack of Efficacy
- Overdose
- Misuse
- Abuse
- Off-label Use
- Medication Error
- Drug Interactions
- Occupational Exposure**
- Unexpected Beneficial Events
- STIAMP

The following events are considered Special Situations for safety reporting even in the absence of a potential adverse event.

Occupational exposure is when a person is exposed to a Roche drug as a result of one's professional or non-professional occupation. It does not include exposure to one of the ingredients during the manufacturing process before the release as a finished product.

Example: A nurse was moving bottles of Roche drug in the ward, and one broke in her hand.

11

Roche Product Vigilance Training v 3.0 | September 2023 | F. Hoffmann-La Roche Ltd

Special Situations: Unexpected Beneficial Events

Special Situations

Pregnancy
Breastfeeding
Lack of Efficacy
Overdose
Misuse
Abuse
Off-label Use
Medication Error
Drug Interactions
Occupational Exposure
Unexpected Beneficial Events
STIAMP

The following events are considered Special Situations for safety reporting even in the absence of a potential adverse event.

Unexpected Beneficial Effect applies to a scenario where the product has caused an unforeseen useful or favorable result of a condition different from the one the product was prescribed for.

Unexpected Beneficial Effects are not usually considered as Adverse Events but a Special Situation.

Example: Patient took Drug X for symptomatic anaemia and was pleased that his hair grew faster than normal.

11

Roche Product Vigilance Training v 3.0 | September 2023 | F. Hoffmann-La Roche Ltd

Special Situations: STIAMP

Special Situations

Pregnancy
Breastfeeding
Lack of Efficacy
Overdose
Misuse
Abuse
Off-label Use
Medication Error
Drug Interactions
Occupational Exposure
Unexpected Beneficial Events
STIAMP

The following events are considered Special Situations for safety reporting even in the absence of a potential adverse event.

Suspected Transmission of Infectious Agent via Medicinal Product (STIAMP)

Any suspected transmission of an infectious agent via a medicinal product, whether identified via a clinical event (adverse event of infection) or via a quality defect for the product (without an identified report of infection).

Any organism, virus or infectious particle (e.g. prion protein transmitting Transmissible Spongiform Encephalopathy), pathogenic or non-pathogenic, is considered an infectious agent.

Example: A patient developed a blood infection within 24 hours after receiving their last intravenous dosage of a Roche drug.

11

Roche Product Vigilance Training v 3.0 | September 2023 | F. Hoffmann-La Roche Ltd

Reporting Potential Adverse Events and Product Complaints

Tell Someone

Tell Someone

The most important thing to remember is that if you **HEAR** about any potential adverse event or complaint that has the potential to impact a Roche product (even if you are not sure), you should **TELL** someone. You will learn how to tell someone later in the course.



Your reports are an important source of information for the departments that collect potential adverse events and product complaints. The information you provide helps improve the quality and safety of Roche's products and protect the health of people using our products.

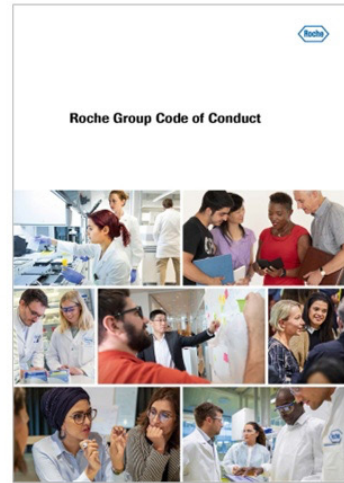
Why do I need to report potential adverse events and product complaints?

Why do I need to report potential adverse events and product complaints?

It is our collective responsibility to report adverse events and product complaints to protect the safety of our patients.

The Roche Group Code of Conduct requires all staff to report any potential adverse event or complaint relating to a Roche product to the relevant function within **1 business day** of hearing about it.

You will learn more about how to report later in the course.



13

Roche Product Vigilance Training v 3.0 | September 2023 | F. Hoffmann-La Roche Ltd

Why do I need to report?

Why do I need to report?

Monitoring the safety and quality of our products enables Roche to:



Protect the health and safety of the people who use our products.



Provide healthcare professionals with important, up-to-date safety and quality information.



Meet our patient safety and quality regulatory requirements.

As an employee of Roche or someone working on behalf of Roche, you play a critical role in this process.


14

Roche Product Vigilance Training v 3.0 | September 2023 | F. Hoffmann-La Roche Ltd

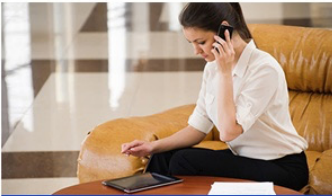
Where might I hear about a potential adverse event or product complaint?

Where might I hear about a potential adverse event or product complaint?



Click each option to learn more about where you might hear about a potential adverse event or product complaint.



At work, or outside work +



Using digital media +



Using an external-facing digital platform in your program or activity (for example a website, app or social media platform)

Working on a program or activity +

15

Roche Product Vigilance Training v 3.0 | September 2023 | F. Hoffmann-La Roche Ltd



Where: At Work, or Outside Work

Where might I hear about a potential adverse event or product complaint?

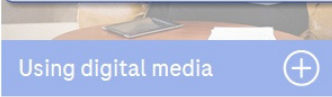
At work, or outside of work

In the scenarios earlier in this course, you learned you may hear about them at work or outside of work. For example:

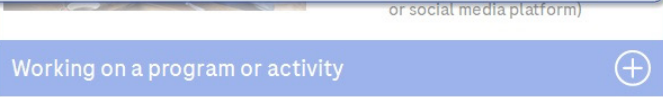
- Talking to a relative on the phone
- Having coffee with a friend
- Attending a medical conference
- Getting routine lab work done



or social media platform)



Using digital media +



Working on a program or activity +

15


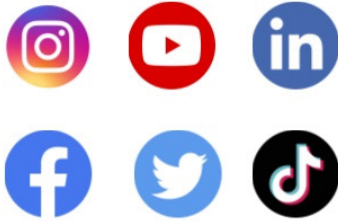
Roche Product Vigilance Training v 3.0 | September 2023 | F. Hoffmann-La Roche Ltd

Where: Using Digital Media


Where might I hear about a potential adverse event or product complaint?

Using digital media

You may come across potential adverse events or product complaints using digital media. For example, browsing social media sites like Facebook or Instagram whether you are at work or not at work.



Using digital media



Working on a program or activity

Using an external-facing digital platform in your program or activity (for example a website, app or social media platform)

15

Roche Product Vigilance Training v 3.0 | September 2023 | F. Hoffmann-La Roche Ltd

Where: Working on a Program or Activity

Where might I hear about a potential adverse event or product complaint?

Working on a program or activity



You may work on a program or activity where potential adverse events or product complaints may be collected. If you find yourself involved in any of these activities, you need to contact the relevant function in your country before beginning the activity.

Examples include:

- Market research activities
- Interactions with patients, healthcare providers, and other customers
- Review of literature (e.g., scientific journal, news articles)
- Digital Customer Engagement Listening Activities

If you are planning to use an external-facing digital platform (for example a website, app or social media platform) for your program or activity you must monitor it on a daily basis. Even if you don't intend to collect potential adverse events or product complaints, if the public has access to it and has the ability to communicate through it, there is a potential for people to report safety information.

It's important to remember that our digital activities often involve Service Providers that perform work on behalf of Roche in accordance with a written agreement, in this case the agreement must include appropriate safety language and the Roche employee (contract owner) retains responsibility to oversee adherence to the contract's safety language.



15

Roche Product Vigilance Training v 3.0 | September 2023 | F. Hoffmann-La Roche Ltd

Where: Working on a Program or Activity: Scenario

Where might I hear about a potential adverse event or product complaint?

Scenario: Working on a program or activity

Johnny decides to create a website as a digital media platform to share information with customers on disease awareness. He wants to allow customers visiting the website to leave feedback on its design, so he decides to include a free text comment box and an email address, allowing customers to email Roche directly.



Because a comment box and the email address allow customers to communicate freely with Roche, Johnny should consider the possibility that a customer can report a potential adverse event or product complaint. Therefore, Johnny must review and follow the relevant process on digital activities and ensure that the comments and emails that are received are monitored so if a potential adverse event or product complaint is reported, it can be submitted to the appropriate expert vigilance function within one business day.

15

Roche Product Vigilance Training v 3.0 | September 2023 | F. Hoffmann-La Roche Ltd

How do I report a potential adverse event or product complaint?

How do I report a potential adverse event or product complaint?

You are required to report a potential adverse event or a product complaint within **one business day** of becoming aware of it.

Who Do I Tell?

How Do I Tell Them?

What if I am an External Business Partner?

Reporting a Product Complaint

Reporting a Potential Adverse Event

Click each option to learn more.

16

Roche Product Vigilance Training v 3.0 | September 2023 | F. Hoffmann-La Roche Ltd

How: Reporting a Potential Adverse Event

How do I report a potential adverse event or product complaint?

You are required to report a potential adverse event or a product complaint within **one business day** of becoming aware of it.

Who Do I Tell?

How Do I Tell Them?

What if I am an External Business Partner?

Reporting a Product Complaint

Reporting a Potential Adverse Event

For resources on how to report adverse events and product complaints visit go.roche.com/RocheVigilance and add it to your bookmarks

For Pharmaceuticals Division, you have two options:

- Use the [online reporting tool](#)
- Contact your [Affiliate Patient Safety](#)
A Product Complaint without a potential adverse event must be reported to your Affiliate Complaints Management Team

For Diagnostics/ Diabetes Care divisions

- Contact your [Diagnostic and Diabetes Care Local Safety Officers](#)

Keep your Affiliate Patient Safety/Local Safety Officer details handy. [Download and print out the RoVig contact card](#) and add relevant information.

16

Roche Product Vigilance Training v 3.0 | September 2023 | F. Hoffmann-La Roche Ltd

How: How Do I Tell Them?

How do I report a potential adverse event or product complaint?

You are required to report a potential adverse event or a product complaint within **one business day** of becoming aware of it.

Who Do I Tell?

How Do I Tell Them?

What if I am an External Business Partner?

Reporting a Product Complaint

Reporting a Potential Adverse Event

The simplest approach to report the information is to **contact the expert vigilance function* in your country and/or in your part of the business**. There are expert vigilance functions in the Pharmaceuticals and Diagnostics/Diabetes Care business divisions who are responsible for receiving and managing reports of potential adverse events and product complaints. They have processes in place to ensure that the information you share will get to the right group.

*Affiliate Patient Safety for Pharmaceuticals and Local Safety Officer for Diagnostics and Diabetes Care.

16

Roche Product Vigilance Training v 3.0 | September 2023 | F. Hoffmann-La Roche Ltd

How: What if I am an External Business Partner?

How do I report a potential adverse event or product complaint?

You are required to report a potential adverse event or a product complaint within **one business day** of becoming aware of it.

Who Do I Tell?

How Do I Tell Them?

What if I am an External Business Partner?

Reporting a Product Complaint

Reporting a Potential Adverse Event

If you work as an external business partner (e.g., consultant, vendor, distributor) on behalf of Roche please **follow the instructions in your work contract** about where to report potential adverse events and product complaints.

Even if you don't know what caused the potential adverse event or if you suspect that it was not caused by the Roche product, the potential adverse event still needs to be reported.

16

Roche Product Vigilance Training v 3.0 | September 2023 | F. Hoffmann-La Roche Ltd

How: Reporting a Product Complaint Example

How do I report a potential adverse event or product complaint?

You are required to report a potential adverse event or a product complaint within **one business day** of becoming aware of it.

Who Do I Tell?

How Do I Tell Them?

What if I am an External Business Partner?

Reporting a Product Complaint

Reporting a Potential Adverse Event

Jenny is an Information Technology Analyst working in the Group Finance and Informatics function in Poland. While at an external conference on the use of digital media in healthcare, she speaks to an exhibitor. On hearing that she works for Roche, he tells her that his sister has been having problems with her Roche glucose meter, and the display screen keeps cutting out.

If Jenny knows that the glucose meter is a Diabetes Care product, she can contact the Local Regulatory and Safety function via Roche Diabetes Care Poland.

If she is not sure which part of Roche is responsible for this product, she could contact either of the Roche affiliates in Poland (Pharmaceuticals Division or Diabetes Care division) to report this, knowing that they will ensure her information gets to the right expert function.



16

Roche Product Vigilance Training v 3.0 | September 2023 | F. Hoffmann-La Roche Ltd

How: Reporting a Potential Adverse Event Example

How do I report a potential adverse event or product complaint?

You are required to report a potential adverse event or a product complaint within **one business day** of becoming aware of it.

Who Do I Tell?

How Do I Tell Them?

What if I am an External Business Partner?

Reporting a Product Complaint

Reporting a Potential Adverse Event

Roger works as a sales representative in Roche Diabetes Care in Canada. While playing basketball, his friend John mentions that his wife has been receiving a Roche drug and she has been experiencing dizziness.

Roger should contact his Local Safety Officer (LSO) in Roche Canada Diabetes Care to report this potential adverse event.

The LSO will forward the report to their counterpart in Roche Pharmaceuticals Canada Local Safety Unit, who will record the report and follow-up as necessary.



16

Roche Product Vigilance Training v 3.0 | September 2023 | F. Hoffmann-La Roche Ltd

What information do I need to report?

What information do I need to report?

When you contact the expert vigilance function, provide them with as much information as you know. At a minimum, tell them:

- The **potential adverse event or product complaint (Event)**
- The **Roche Product** involved

The following information should also be reported, **if available**:

- The **Reporter** (the person who initially reported the potential adverse event or product complaint) and the **Day** it was reported to you
- The **Patient** (the person who experienced the potential adverse event or product complaint)

Patient + **R**eporter + **E**vent + **P**roduct = **PREP**

17

Roche Product Vigilance Training v 3.0 | September 2023 | F. Hoffmann-La Roche Ltd

Conclusion

Conclusion

At Roche all employees as well as external business partners working on behalf of Roche are responsible for the vigilance of our products and each employee is responsible for immediately reporting any potential adverse event or complaint relating to a Roche product.

You should now understand:

- What is a potential adverse event or product complaint and how to recognize it
- Why you need to report potential adverse events and product complaints as an employee or while working on behalf of Roche
- How you report a potential adverse event or product complaint

Remember:



18

Roche Product Vigilance Training v 3.0 | September 2023 | F. Hoffmann-La Roche Ltd

Next Steps

Next Steps

- 1 To review a topic, click its title in the navigation menu located in the top-right corner of the screen.



- 2 Complete the knowledge check that appears after you click the NEXT arrow.

The passing score is 80%, so you must answer at least 8 questions correctly.



19

Roche Product Vigilance Training v 3.0 | September 2023 | F. Hoffmann-La Roche Ltd

Knowledge Check

Knowledge Check

You are about to begin the knowledge check to confirm your understanding. To complete this course, you must complete the knowledge check with a minimum score of 80%.

*To begin the knowledge check, click **NEXT**.*

Roche Product Vigilance Training v 3.0 | September 2023 | F. Hoffmann-La Roche Ltd

Knowledge Check: Question 1

Why do we monitor the safety and quality of our products and devices?
Select the best answer.

- ☐ To protect the health and safety of the people who use our products and devices
- ☐ To provide healthcare professionals with important, up-to-date safety and quality information
- ☐ To meet our patient safety and quality regulatory requirements
- ☐ All of the above

Roche Product Vigilance Training v 3.0 | September 2023 | F. Hoffmann-La Roche Ltd

Knowledge Check: Question 2

You hear about an adverse event related to a Roche product on Friday afternoon. The office will be closed on Saturday and Sunday. At the latest, when do you need to report the event to the relevant business unit? Select the best answer.

- ☐ Saturday
- ☐ Sunday
- ☐ Monday
- ☐ Tuesday

Roche Product Vigilance Training v 3.0 | September 2023 | F. Hoffmann-La Roche Ltd

Knowledge Check: Question 3

To whom should you report potential adverse events or complaints about a Roche product? Select the best answer.

- ☐ The expert vigilance function in your country or part of the business
- ☐ Your manager
- ☐ Your Human Resources department
- ☐ Your local Legal department

Roche Product Vigilance Training v 3.0 | September 2023 | F. Hoffmann-La Roche Ltd

Knowledge Check: Question 4

At a minimum, what information should you include when you report a potential adverse event or complaint about a Roche drug? Select all that apply.

- ☐ A description of the potential adverse event or product complaint
- ☐ The name of the Roche drug
- ☐ The medicine dosage
- ☐ The time of day you heard about it
- ☐ The location where you heard about it

Roche Product Vigilance Training v 3.0 | September 2023 | F. Hoffmann-La Roche Ltd

Knowledge Check: Question 5

You are on a social media site and see that a patient experienced dizziness and blurred vision with a Roche product. Is this reportable?

- ☐ Yes
- ☐ No

Roche Product Vigilance Training v 3.0 | September 2023 | F. Hoffmann-La Roche Ltd

Knowledge Check: Question 6

Your friend tells you that his mother is taking a Roche drug and for the last 3 months she has had problems opening the bottle because the cap design changed. Is this reportable?

- ☐ Yes
- ☐ No

Roche Product Vigilance Training v 3.0 | September 2023 | F. Hoffmann-La Roche Ltd

Knowledge Check: Question 7

Your friend's son just started treatment with a Roche product. His son was hospitalized with a respiratory infection and he is concerned that his son is not responding well to his treatment. Is this a reportable event?

- ☐ Yes
- ☐ No

Roche Product Vigilance Training v 3.0 | September 2023 | F. Hoffmann-La Roche Ltd

Knowledge Check: Question 8

You discover that a Roche reagent is incorrectly labeled.
Is this reportable?

- ☐ Yes
- ☐ No

Roche Product Vigilance Training v 3.0 | September 2023 | F. Hoffmann-La Roche Ltd

Knowledge Check: Question 9

In the central laboratory, Alex spilled the reagent cassette solution on their uncovered left arm. This contact triggered an allergic reaction that led to anaphylactic shock subsequently causing death. Is this reportable?

- ☐ Yes
- ☐ No

Roche Product Vigilance Training v 3.0 | September 2023 | F. Hoffmann-La Roche Ltd

Knowledge Check: Question 10

Joe has been made aware that a Pharma implant has been dislocated in a patient's eye. Should this be reported?

- ☐ Yes
- ☐ No

Roche Product Vigilance Training v 3.0 | September 2023 | F. Hoffmann-La Roche Ltd

Knowledge Check: Question 11

A lancet has broken in the patient's finger and had to be removed by a healthcare professional. Two stitches were also needed. Should this be reported?

- ☐ Yes
- ☐ No

Roche Product Vigilance Training v 3.0 | September 2023 | F. Hoffmann-La Roche Ltd