

Roche Product Vigilance Training 2025

November 2025

RoVig

Roche Product Vigilance Training



Roche Product Vigilance Training



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Navigation

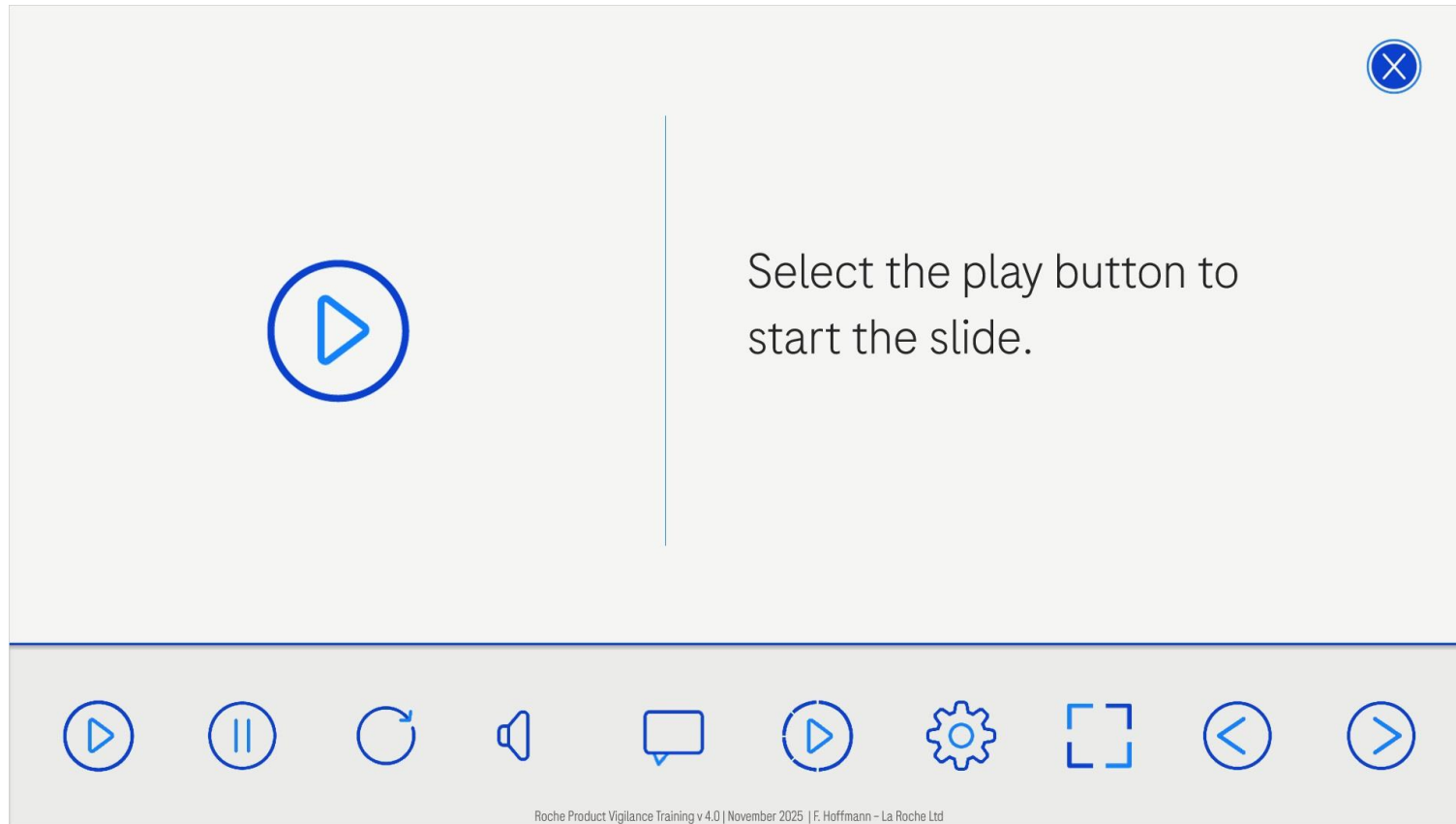


Navigation: Click on each icon to learn more




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Play





✕





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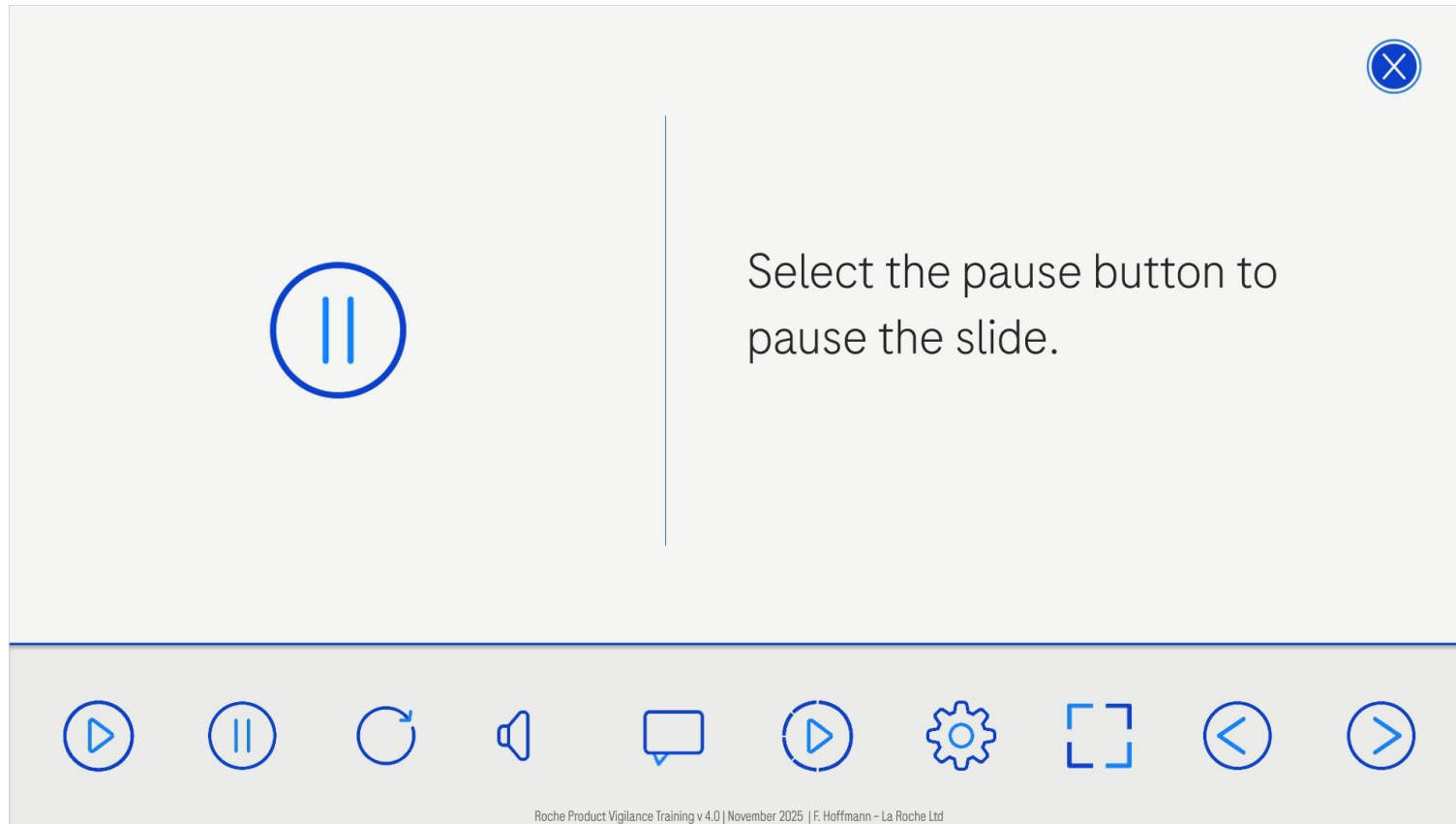






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Pause





Select the pause button to pause the slide.

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Replay




Select the replay button to restart the slide.





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Sound

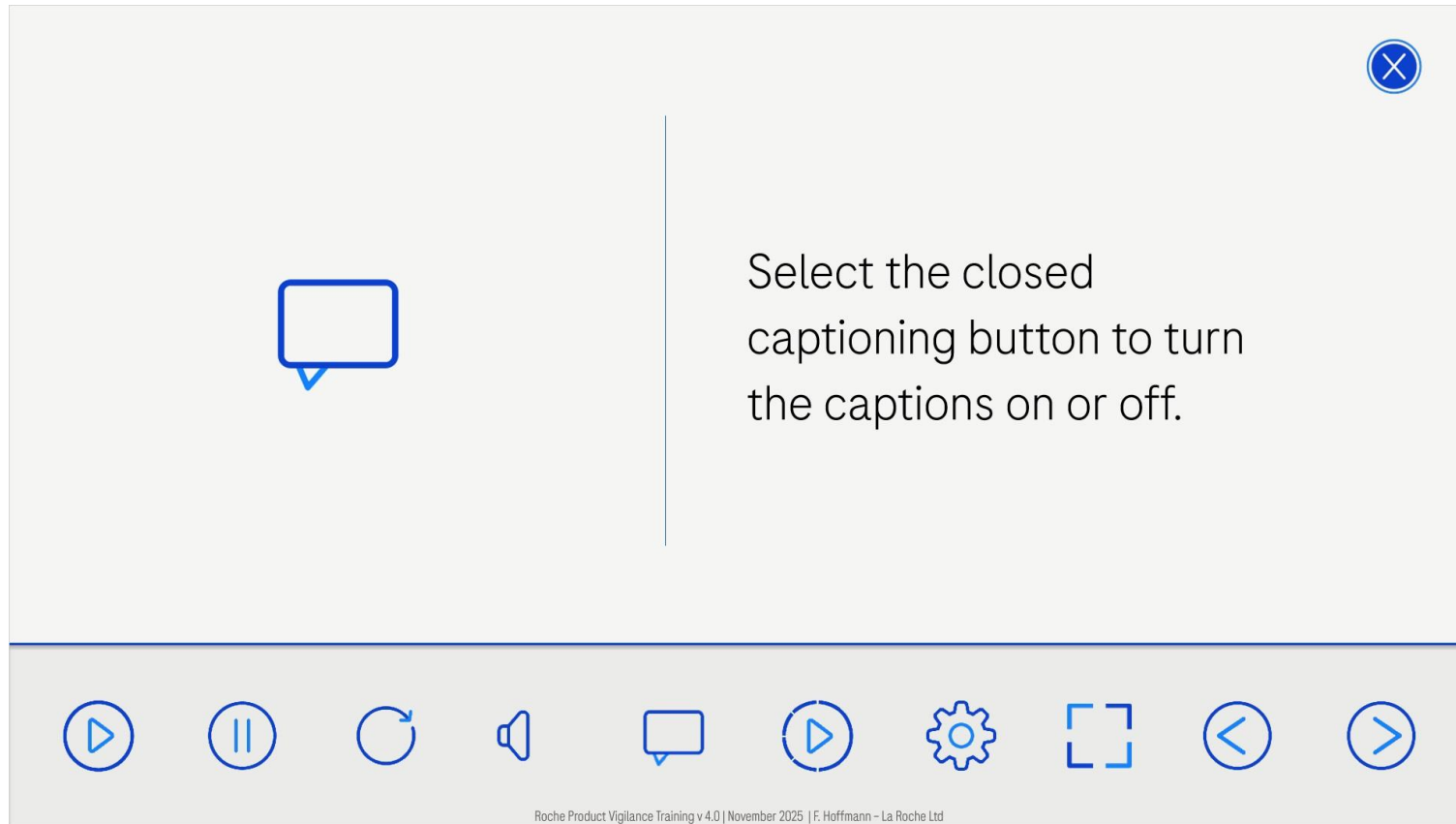


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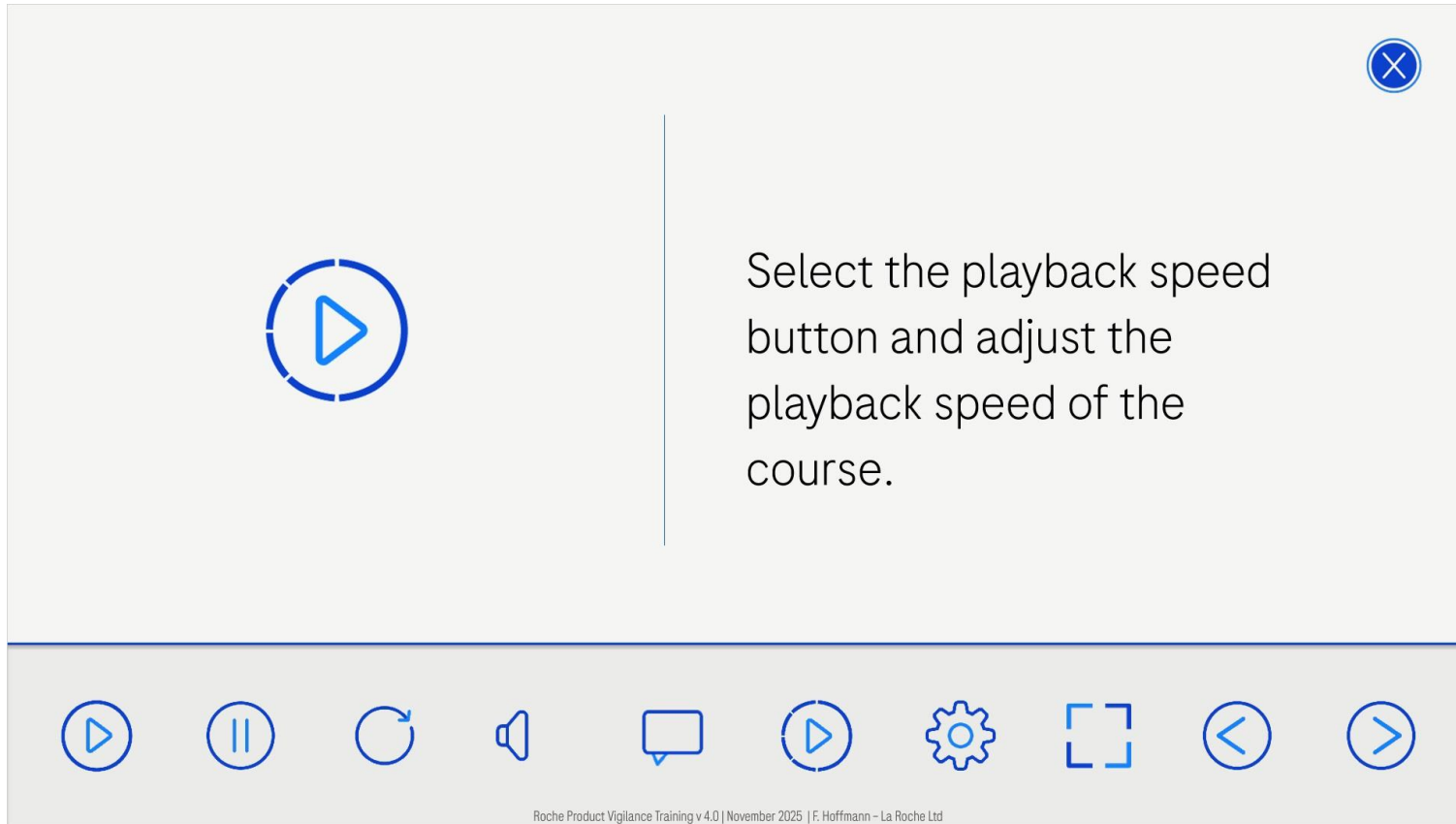


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ClosedCaptions



Playback



Select the playback speed button and adjust the playback speed of the course.

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Settings

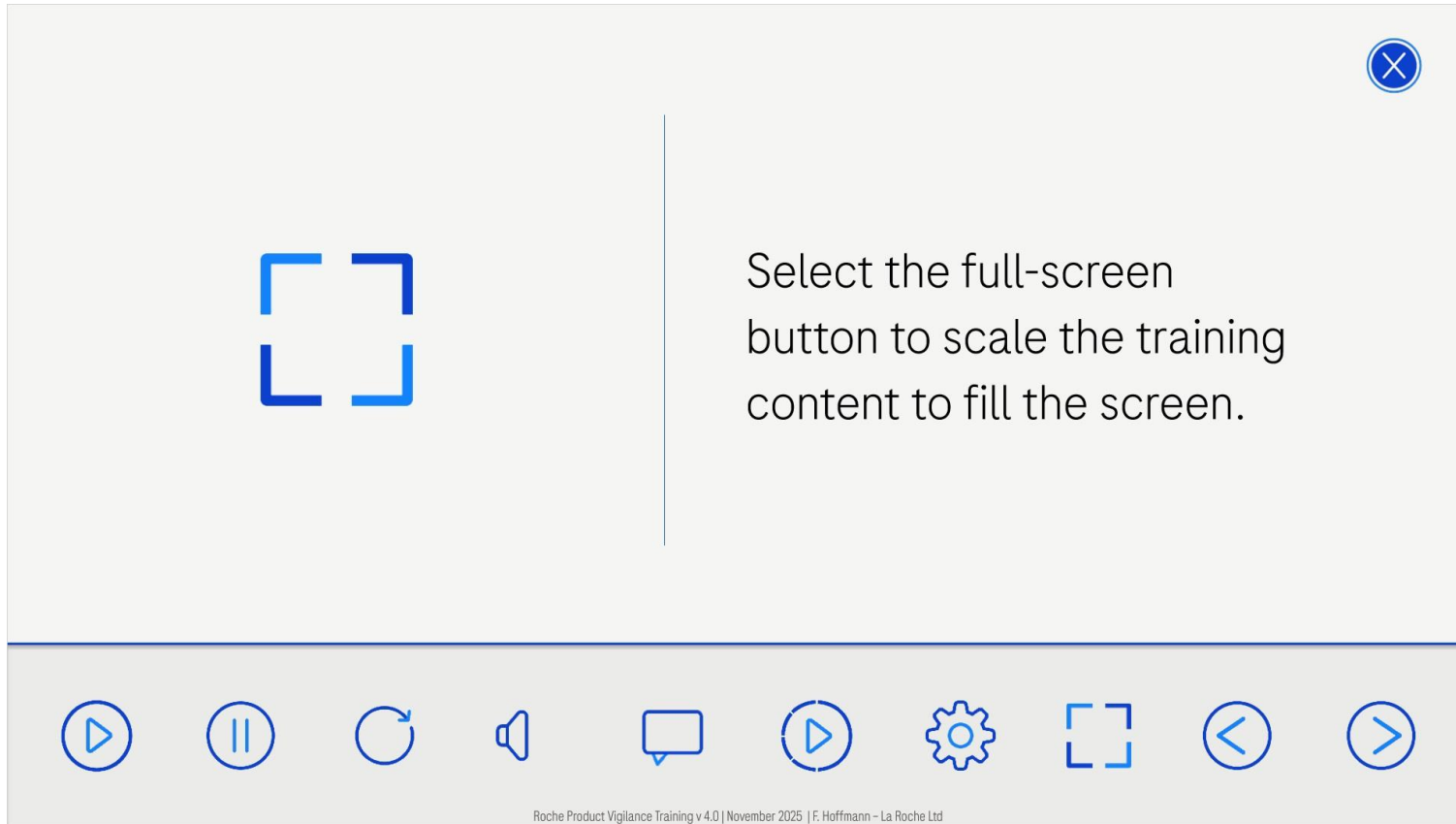


Select the settings button
to access the accessibility
controls.



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Enter Fullscreen




The screenshot shows a video player interface. On the left, there is a large blue icon representing the fullscreen button, which consists of four corner brackets. To the right of this icon, a vertical line separates it from a text box. The text box contains the instruction: "Select the full-screen button to scale the training content to fill the screen." In the top right corner of the video player, there is a small blue circular button with a white 'X' inside, likely a close button. Below the video player, there is a control bar with several icons: a play button, a pause button, a refresh button, a speaker icon for volume, a speech bubble icon for subtitles, a play button, a gear icon for settings, a blue fullscreen icon (four corner brackets), a left arrow, and a right arrow. At the bottom of the control bar, there is small text: "Roche Product Vigilance Training v 4.0 | November 2025 | F. Hoffmann – La Roche Ltd".



Select the full-screen button to scale the training content to fill the screen.

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Previous




Select the previous button to move backward through the course.





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Next



Select the next button to move forward through the course.



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Objectives



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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?

Welcome from the CEO



Welcome from the CEO

After watching the video, click Next to continue.



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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.

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Roche Divisions




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Roche Divisions

- There are two divisions within Roche: Pharmaceuticals and Diagnostics.
- 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 plus icon by the division names below to find out more.

Pharmaceutical Division 

Roche Diagnostics Division 

Pharmaceutical Division



Pharmaceutical Division



Our products include medicinal products, devices and combination products manufactured by the Pharmaceuticals Division. Other terms you may see/hear that mean the same thing as medicinal products include 'medicine' or 'drug'. For example: Evryski.

[Click the minus icon to return.](#)



Roche Diagnostics Division



Roche Diagnostics Division



Our products are manufactured by the Diagnostics Division 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.

Click on the next button to continue.



Your Responsibility



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Your Responsibility

If you see or 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.

Recognising Potential Adverse Events and Product Complaints



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Recognising Potential Adverse Events and Product Complaints

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



Adverse Event



Product Complaint

Before you proceed, please click to view a list of special situations that must be reported, even in the absence of a potential adverse event.



Special Situations

[View the list](#)

Special Situations



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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 Effects
- Suspected Transmission of Infectious Agent via a Medicinal Product (STIAMP)



Drug Adverse Events



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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, you may be familiar with the term Adverse Event, also known as Potential Safety Impact (PSI) and Potentially Reportable Incident (PRI).

Click the plus icons below to view the examples and the scenario.

Examples



Scenario



Examples



Examples



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 the minus icon to return.

Scenario



Scenario




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 on the next button to continue.

In-Vitro Diagnostics - Medical Device Adverse Events



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In-Vitro Diagnostics/Medical Device Adverse Events

- An In-Vitro Diagnostics/Medical Device adverse event (AE) is when a Roche product (e.g., implant, instrument, reagent, hardware, or software) may have caused or contributed to a death or any other injury of a patient or user of a device.
- Adverse events may be caused by a device malfunction or it failing to perform as intended, or can be a side-effect of normal device use which are not a result of malfunctions.
- Additionally, the injuries may be direct such as cuts or burns, or indirect such as ones caused by the device failing to deliver therapy or diagnose a disease.

Click the plus icons below to view the examples and the scenario.

Examples 

Scenario 

Examples



Examples



Examples of potential in-vitro diagnostics/medical device adverse events include:

- Death
- Infection following device implantation
- Swelling at the location of device use
- Unintended cuts to the patient during device use
- Erroneous results (causing health deterioration)
- Patient injury during device misuse or off-label use

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 the minus icon to return.

Scenario



Scenario



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

A neighbour of yours heard that you work at Roche. She is very happy that you work at such a great company since she was able to receive treatment with a very innovative medical device. She had some swelling following use.

You must report this potential adverse event because the new information may impact the safety profile of the device and may be used to better inform the device's design and use instructions.

Click on the next button to continue.

Product Complaints



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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
 - Devices
 - Software
 - Reagents
 - Combination Products

Click the plus icons below to view the definition, examples, and scenarios.

Definition



Examples



Scenarios



Definition



Definition 

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 the minus icon to return.](#)

Examples



Examples



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 the minus icon to return.

Scenario1: Product Complaint



Scenarios



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 colour 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 on the next button to go to the next scenario.

Scenario 2: Product Complaint



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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 on the next button to go to the next scenario.

Scenario 3: Product Complaint



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Scenario 3: Product Complaint

Simon visits his brother, Calvin. Calvin mentions to Simon that he was rather frustrated 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 on the next button to go to the next scenario.

Scenario 4: Product Complaint



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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 on the next button to go to the next scenario.

Scenario 5: Product Complaint



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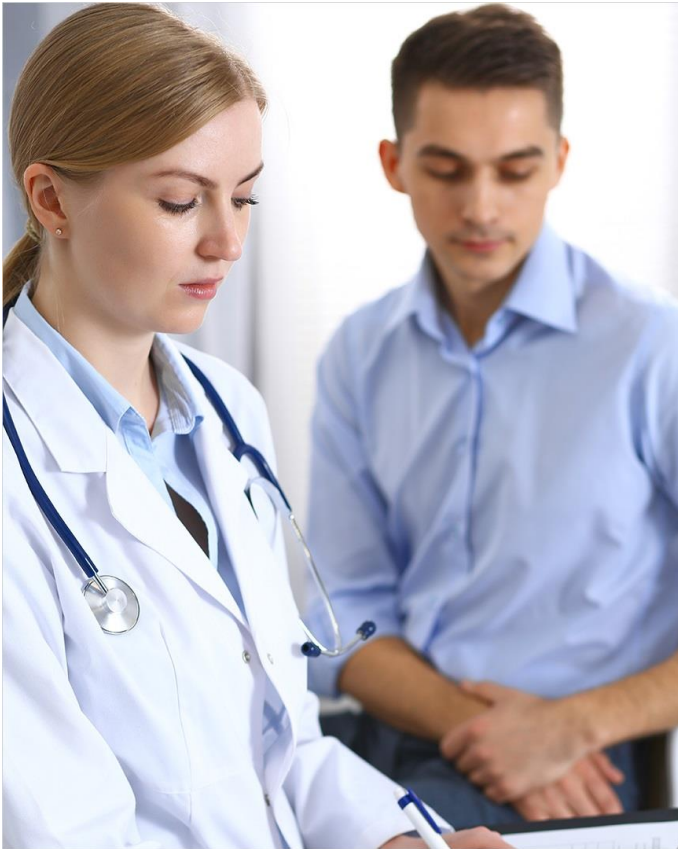
Scenario 5: Product Complaint (Software)

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 on the next button to go to the next scenario.

Scenario 6: Product Complaint



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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 product 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 on the next button to continue.](#)

Choose a Division to Continue

Choose a Division to Continue



If you work for Roche Pharmaceuticals

CLICK HERE




If you work for Roche Diagnostics

CLICK HERE


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2. Roche Pharmaceuticals Division

Special Situations



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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.](#)
 - **Note:** You are not required to determine whether the information you are reporting qualifies as a special situation, potential adverse event, or both. However, you are responsible to identify that it is reportable, and report it.

Click the plus icons below to view the list and the scenario.


List of Special Situations 

Scenario 

List Of Special Situations

Pregnancy	<div>List of Special Situations</div> <p>The following events are considered Special Situations for safety reporting even in the absence of a potential adverse event.</p> <p><i>Click each special situation to learn more.</i></p>
Breastfeeding	
Lack of Efficacy	
Overdose	
Misuse	
Abuse	
Off-label Use	
Medication Error	
Drug Interactions	
Occupational Exposure	
Unexpected Beneficial Effects	
STIAMP	

Pregnancy

Pregnancy	Back to Special Situations 
Breastfeeding	
Lack of Efficacy	
Overdose	
Misuse	
Abuse	
Off-label Use	
Medication Error	
Drug Interactions	
Occupational Exposure	
Unexpected Beneficial Effects	
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.

Breastfeeding

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

[Back to Special Situations](#)



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.

Lack of Efficacy

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

[Back to Special Situations](#)



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 reported.

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

Overdose

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

[Back to Special Situations](#)



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 report this.

Misuse

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


[Back to Special Situations](#)



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 report this.

Abuse

Pregnancy	<div>Back to Special Situations </div> <p>This refers to the persistent or sporadic, intentional excessive use of a Roche drug, which is accompanied by harmful physical or psychological effects.</p> <p>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 report this.</p>
Breastfeeding	
Lack of Efficacy	
Overdose	
Misuse	
Abuse	
Off-label Use	
Medication Error	
Drug Interactions	
Occupational Exposure	
Unexpected Beneficial Effects	
STIAMP	

Off-Label Use

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

[Back to Special Situations](#)



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.

Note: Off-label Use can be difficult to identify. You are not expected to actively identify it if it is not specifically mentioned, but it is your responsibility to report it when you do identify it.

Medication Error

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

[Back to Special Situations](#)



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 realized 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.

Drug Interactions

Pregnancy	<div>Back to Special Situations </div> <p>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:</p> <ul style="list-style-type: none">• 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 <p>Example: A patient states she had a headache after taking a Roche drug and her asthma medication.</p>
Breastfeeding	
Lack of Efficacy	
Overdose	
Misuse	
Abuse	
Off-label Use	
Medication Error	
Drug Interactions	
Occupational Exposure	
Unexpected Beneficial Effects	
STIAMP	

Occupational Exposure

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


[Back to Special Situations](#)




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.

Unexpected Beneficial Events

Pregnancy	<div>Back to Special Situations </div> <p>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.</p> <p>Unexpected Beneficial Effects are not usually considered as Adverse Events but a Special Situation.</p> <p>Example: Patient took Drug X for symptomatic anaemia and was pleased that his hair grew faster than normal.</p>
Breastfeeding	
Lack of Efficacy	
Overdose	
Misuse	
Abuse	
Off-label Use	
Medication Error	
Drug Interactions	
Occupational Exposure	
Unexpected Beneficial Effects	
STIAMP	

STIAMP

Pregnancy	Back to Special Situations 
Breastfeeding	
Lack of Efficacy	
Overdose	
Misuse	
Abuse	
Off-label Use	
Medication Error	
Drug Interactions	
Occupational Exposure	
Unexpected Beneficial Effects	
STIAMP	<h3>Suspected Transmission of Infectious Agent via Medicinal Product (STIAMP)</h3> <p>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).</p> <p>Any organism, virus or infectious particle (e.g. prion protein transmitting Transmissible Spongiform Encephalopathy), pathogenic or non-pathogenic, is considered an infectious agent.</p> <p>Example: A patient developed a blood infection within 24 hours after receiving their last intravenous dosage of a Roche drug.</p>

Scenario



Scenario



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.

Tell Someone

Tell Someone



The most important thing to remember is that if you **HEAR** of, or **SEE**, something about any potential adverse event or complaint in relation to 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.


**IF YOU  OR 
SOMETHING
 SOMEONE**

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




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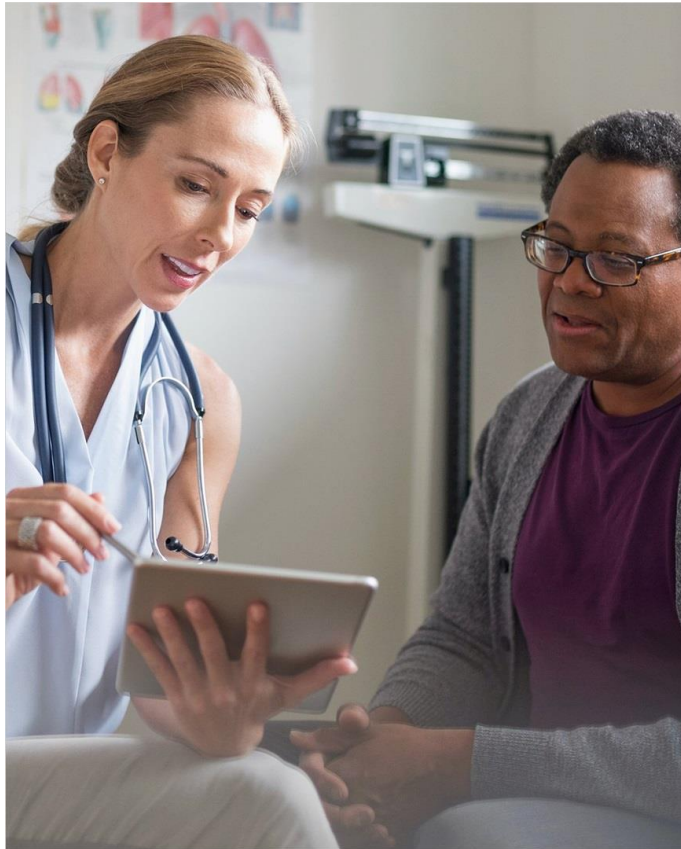
Roche Group Code of Conduct



 **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.

Why do I need to report?




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? 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.

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





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

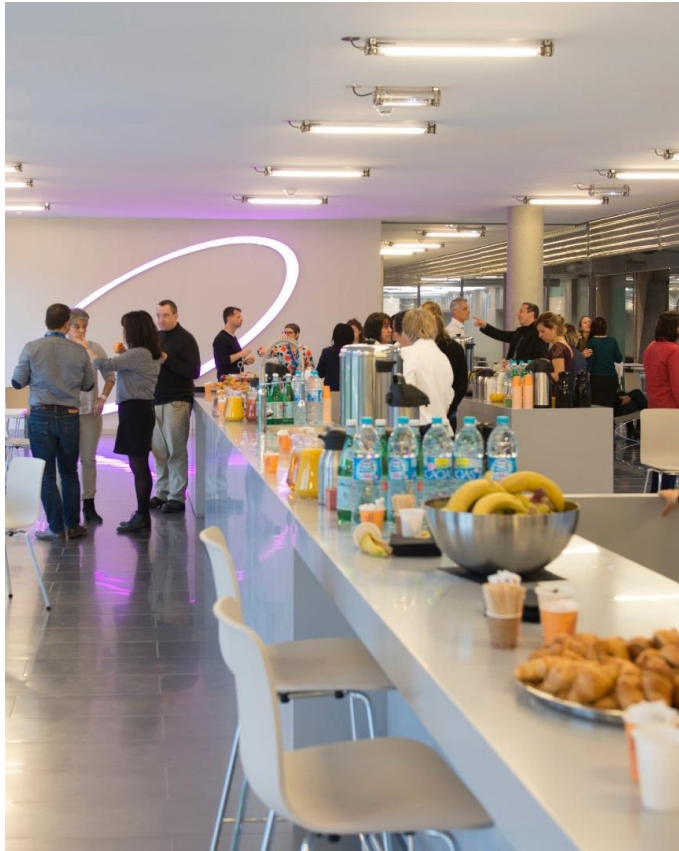
Click each option to learn more about where you might see or hear about a potential adverse event or product complaint.

At work, or outside of work 

Using digital media 

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

Where: At Work, or Outside Work



At work, or outside of work

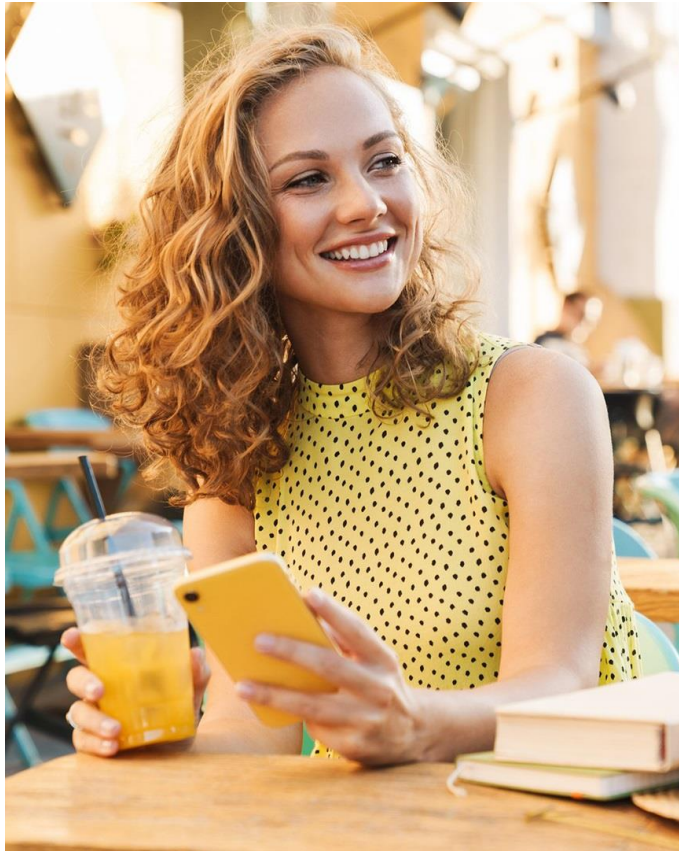


In the scenarios earlier in this course, you learned you may see or hear about them at work or outside of work. For example:

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

Click the minus icon to return.

Where: Using Digital Media



Using digital media



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

Click the minus icon to return.



Where: Working on a program or activity



Working on a program or activity

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



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:

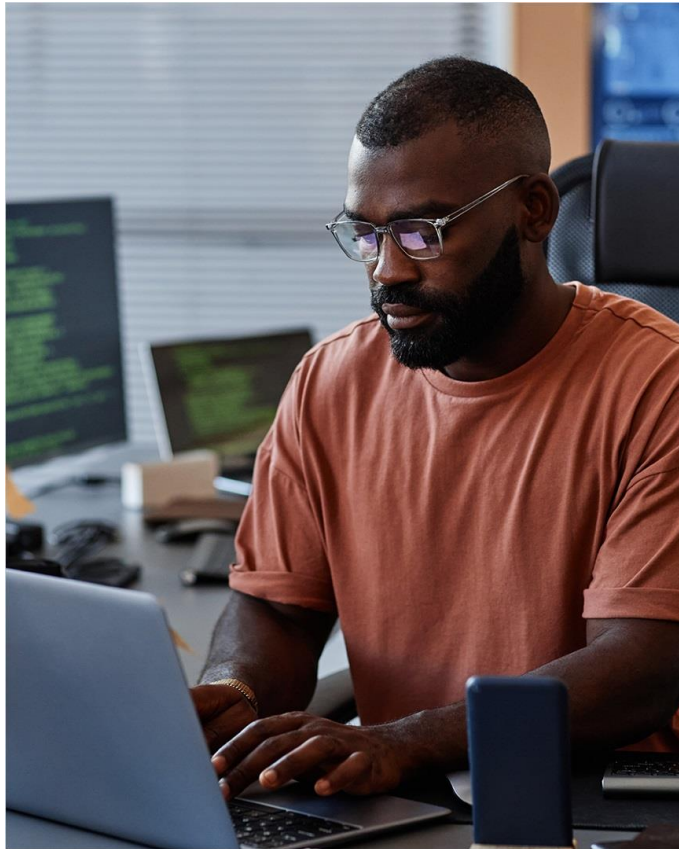
- Market research activities
- Interactions (including digital) with patients, healthcare professionals (e.g., Customer Relationship Management [CRM] systems), and other customers
- Review of literature (e.g., scientific journal, news articles)
- Digital Customer Engagement and Listening Activities

If you are planning to use an external-facing digital communication channel (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 communication channels 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.

[Click on the next button to view the scenario.](#)

Scenario: Working on a program or activity



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Scenario: Working on a program or activity


Johnny decides to create a website 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 communication channels 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.

Click on the next button to continue.

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

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



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

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

Click each option to learn more.

Who Do I Tell?

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



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 potential 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 Division:


- Contact your [Diagnostic 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.

How Do I Tell Them?

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



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 Division who are responsible for receiving and managing reports of potential adverse events and product complaints. They have processes in place to ensure that you will receive an acknowledgement for any safety information you share, and they will ensure that the right group is subsequently notified.

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

What if I am an External Business Partner?

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



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.

Reporting a Product Complaint



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



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 Diagnostics product, she can contact the Local Regulatory and Safety function via Roche Diagnostics 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 Diagnostics Division) to report this, knowing that they will ensure her information gets to the right expert function.

Reporting a Potential Adverse Event



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



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 Diagnostics 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 Diagnostics* 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.

*Roger could also report the potential adverse event directly to the local Affiliate Patient Safety, Pharma.

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)



If you identify a potential adverse event or product complaint online, take a screenshot capturing the details and include this when you report it.

If you know that the information that you are reporting is part of a structured digital activity, please include identifiers (e.g., an activity ID).

Conclusion



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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:

**IF YOU  OR  SOMETHING
SOMEONE**

Knowledge Assessment


Next Steps



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Next Steps

- Bookmark this link for reporting adverse events and product complaints:
go.roche.com/RocheVigilance
- Complete the knowledge check that appears after you click the NEXT arrow.
- The passing score is 80%, so you must answer at least 9 questions correctly.




Course Start

Go Back



Pharmaceutical Division

Go Back



Diagnostics Division

Go Back

Click the next button to continue to the knowledge check.

Knowledge Check



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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**.*

1. Knowledge Check

Q1.1

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

Question 1 of 11

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Q1.2

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.



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

Question 2 of 11

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Q1.3

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 Human Resources department
- ☐ Your manager
- ☐ Your local Legal department

Question 3 of 11

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Q1.4

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.



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

Question 4 of 11

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Q1.5

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



☐ No

☐ Yes

Question 5 of 11

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Q1.6

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?



☐ No

☐ Yes

Question 6 of 11

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Q1.7

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

Question 7 of 11

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Q1.8

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



☐ No

☐ Yes

Question 8 of 11

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Q1.9

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

Question 9 of 11

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Q1.10

Joe has been made aware that an implant (Roche product) has been dislocated in a patient's eye. Should this be reported?



☐ Yes

☐ No

Question 10 of 11

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Q1.11

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?




☐ No

☐ Yes


Question 11 of 11


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Completion



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**You have completed the Roche Product Vigilance Training.**

Congratulations on successfully completing this training.

Select the button below to exit the course.

Exit