ADVERSE EVENT AND SPECIAL SITUATION REPORTING
Pharmacovigilance (PV) training of Roche for contractors

WHAT IS AN ADVERSE EVENT (AE)?
Any untoward change to medical condition affecting a patient receiving a medicine, although it is not known whether a causal relationship to treatment with this medicine exists. Adverse event can therefore be:
- any adverse or unintended sign (for example, an abnormal laboratory finding)
- symptom
- disease temporarily associated with the use of a medicinal product, whether or not a causal relationship with the treatment

All AEs must be reported to Roche even if the event is described in the Patient Information Leaflet (PIL) or Summary of Product Characteristics (SPC) or the event has already been reported to Health Authority (SUKL)

SPECIAL SITUATIONS
- Pregnancy
- Lack of efficacy
- Overdose
- Misuse and abuse / overuse
- Medication and administration errors
- Occupational exposure
- Suspected transmission of infectious agents via a medicinal product (STIAMP)
- Counterfeits
- Reports from lawsuits
- Deaths
- Off-label use
- Disease progression related to the use of the product
- Drug interactions, drug addiction and withdrawal syndrome

REPORTING SPECIAL SITUATIONS
Pregnancy
All pregnancy notifications must be passed to Roche, including:
- Exposure of the mother before conception
- Exposure of the mother during pregnancy
- Exposure of the father
- Exposure during lactation

Lack of efficacy
All reports of lack of efficacy of the medicinal product must be submitted to Roche.

Overdose
Which means using an amount of medicine that exceeds the recommended maximum approved dose.
An overdose can occur accidentally or intentionally and can be administered in a single dose or cumulatively.
It also includes reports where the patient has taken the drug with intent to commit suicide.
Misuse
Which means the deliberate and improper drug administration in conflict with the registered use.

Abuse/overuse
Which means deliberate or repeated excessive use of the product which is accompanied by harmful physical or psychological effects.

Medication errors/incorrect drug administration
Which means any inadvertent errors in prescribing, issuing or administration of medicinal product by a doctor or patient.

Occupational exposure
Which means exposure to a medicinal product due to professional or non-professional employment.

Suspected transmission of infectious agents by means of a preparation (STIAMP)
Any organism, virus or infectious particle (e.g. prion proteins of spongiform encephalopathy), pathogenic and nonpathogenic, is considered to be an infectious agent. Transmission of infectious agents can be derived from clinical symptoms and laboratory findings.

Suspected or confirmed counterfeit product
Counterfeits of original medicinal products which look like the original may:
- Contain substances of lower quality or the wrong dose
- Be deliberately and fraudulently mislabelled with the intention to avoid identifying the source
- Have counterfeit packaging, wrong ingredients or a lower proportion of the active substance

Reports of litigation
All reports of litigation must be passed over to Roche.

Deaths
Reports on fatalities should be supplemented with missing data and an attempt should be made to obtain and report the cause of death.

Off-label use
This involves cases where the product contrary to the registration (SPC, PIL). The PV department of Roche shall receive a report of off-label use which is not associated with an adverse event if the off label use is clearly, unequivocally and voluntarily reported or notified by the reporter and the notification was unsolicited (not the result of a targeted query).

Progression of the Disease
1. All atypical or accelerated progression* of disease which indicates rather poor efficacy of the Roche product
   * E.g. faster progression than expected, or may include other unexpected elements of progression that may be attributed to treatment by the suspected product
and / or
2. The doctor suggests that the progression is causally related to treatment with a Roche product (rather points to the lack of effectiveness) or the causation was not commented on (then it has to be obtained within the supplementary information).

Drug interactions, drug addiction and withdrawal syndrome

ATTENTION: overdose, misuse, abuse / overuse, medication errors / incorrect administration of the drug, off-label use and drug exposure in employment - the event shall be reported even if not associated with AE!

DATE OF RECEIPT OF THE NOTIFICATION
All adverse events and specific circumstances notifications must be passed to Roche within 1 working day of learning 4 minimum criteria.
- Identifiable patient - (initials, gender, date of birth, age or age group – mandatory to report at least one of the categories)
- Identifiable reporter - name and available contact information of the reporter (phone, facsimile, address, e-mail).
- Adverse event or special situation
- Suspected medicinal product of Roche

All other medically relevant information on the report must also be provided in order to allow assessment of the case.

REQUEST FOR ADDITIONAL INFORMATION
Roche will exercise professional care in obtaining additional information on individual AE reporting and notification of specific circumstances. In the event that Roche requires additional information concerning the report, it will be the responsibility of Roche to directly contact the reporter and ask for such data.
Please provide the necessary support to Roche.

HOW TO REPORT ADVERSE EVENTS
1) By e-mail - if you do not receive an acknowledgment within 48 hours of receipt, please send the e-mail again
2) By phone: Please report the AE and the special situations by phone to the contact below

TRAINING
Training new employees
You must ensure that all employees will be trained before they begin working to finalize the activities specified in the Agreement.

DATA PROTECTION
Patient confidentiality must be respected throughout.
Roche does not wish to receive information on a patient in conflict with the law on personal data protection.
You do not have to provide personal data which the law does not allow. It is enough to provide patient identification such as: gender, initials, age category.
The aim is to ensure that data is collected and evaluated by Roche when it comes to all medical and safety-relevant data with the purpose to monitor on a continuous basis the benefit-risk of the Roche products.
ROCHE CONTACTS - WHERE TO REPORT
If you need to report AE, a specific circumstance or if you have additional questions about this training, please contact:

**Cell number:** +420-602-298-181  
**E-mail:** czech_republic.pa_susar@roche.com.