



Drug Safety Governance Framework: Process and Responsibilities for safety assessment and benefit/risk

We have global systems in place throughout Roche to monitor and collect adverse events associated with our products, follow-up with the reporter where necessary, transmit the adverse event data to the central safety departments, forward relevant reports to the regulatory authorities and evaluate any new and emerging safety information. We also have a policy and set of standard operating procedures requiring all Roche staff to immediately report any issues relating to the safety or quality of our medicines.

The responsibility for recording, investigating and evaluating adverse events and reporting these to the relevant regulatory authorities (e.g. EMEA, EU National Authorities or US Food and Drug Administration) include:

- The global pharmacovigilance group located in Welwyn, UK
- The US operations group located in Nutley, NJ, USA
- Global affiliates located throughout the world.

Each country manager is responsible for ensuring the collection of safety information from all sources, and reporting this to the relevant safety department and to the local regulatory authority.

Drug Safety decision-making within Roche is centralised within the Drug Safety Committee (DSC). The DSC is responsible for ensuring patients safety proactively by driving the medical opinion on safety both within Roche as well as outside the Roche organisation. This applies to all development compounds and products throughout their lifecycle. The DSC is comprised of Drug Safety experts and very senior leadership from the Roche pharmaceutical research development and global medical organisation.

The role of the DSC is to:

- Minimise the safety risks to all volunteers during drug development and to all patients taking Roche marketed drugs
- Foster a proactive safety profile assessment for each drug thereby providing a single medical opinion within Roche on safety issues
- Educate the organisation on the need for sensitivity in decision making on safety issues and levels of appropriate risk
- Provide a single medical opinion on safety which can be used for external partners e.g. co-development partners and regulatory authorities.

The global safety systems are overseen by appropriate bodies which carry out various training and audit activities to ensure compliance.