Swissmedic

Pharmacovigilance

Hallerstrasse 7

3012 Bern

Switzerland

dd.mm.yyyy

**Letter of intent to access the PV Gateway solution for reporting ICSR originated from Switzerland**

Dear Swissmedic-Team,

Company XY declares its intention to submit Individual Case Safety Reports (ICSR) electronically via Gateway to Swissmedic. Our preferred date for initiating the process of the implementation of the Gateway solution would be dd.mm.yyyy.

* We agree to pay the external activation costs of CHF 10’000 ahead of the initiation process.
* We will allocate the necessary resources to enable the integration of the gateway solution within 3 months.
* We are technically able to exchange ICSR electronically via AS2 protocols.

your Name will be the person responsible for coordination with the following contact details:

your Name, Safety Manager

Email:

Tel:

Kind regards,

your Name