GLOBAL REGULATORY PARTNERS

Case Study 65:
Pharmacovigilance Services: Clinical Safety in Japan

Client
A multinational pharmaceutical company conducting a clinical study in Japan was looking for a local PV service provider partner who can handle the PV activities related to the new drug in the clinical investigation.

Products
1 investigational drug for oncology

Products Category
Oncology drug

Countries of Interest
Japan

Solution Offered

- ✓ Pharmacovigilance outsourcing
- ✓ Pharmacovigilance during clinical study
- ✓ SUSAR collection and reporting to PMDA
- ✓ SUSAR translation in English,
- ✓ Literature screening in JAPIC and other databases.
- ✓ DSUR

Key Highlights:

- ✓ Client benefited from GRP strong PV local expertise in Japan and was able to outsource all the PV activities related to the clinical study to GRP Japan.
- ✓ Standardized checklists and templates for Literature screening and Reporting in Japan, allowed efficiency in screening process of local literature and databases and SUSAR on time reporting to PMDA.
- ✓ **100% compliance** maintained during clinical study in Japan
- ✓ GRP continues to be **Strategic PV Partner in Japan** for the Client

Keywords:
Japan , Pharmacovigilance outsourcing ,PMDA Literature screening, Literature Screening reports, Adverse Event Assessment and reporting, DSUR,SUSAR , SESAR, clinical study PV

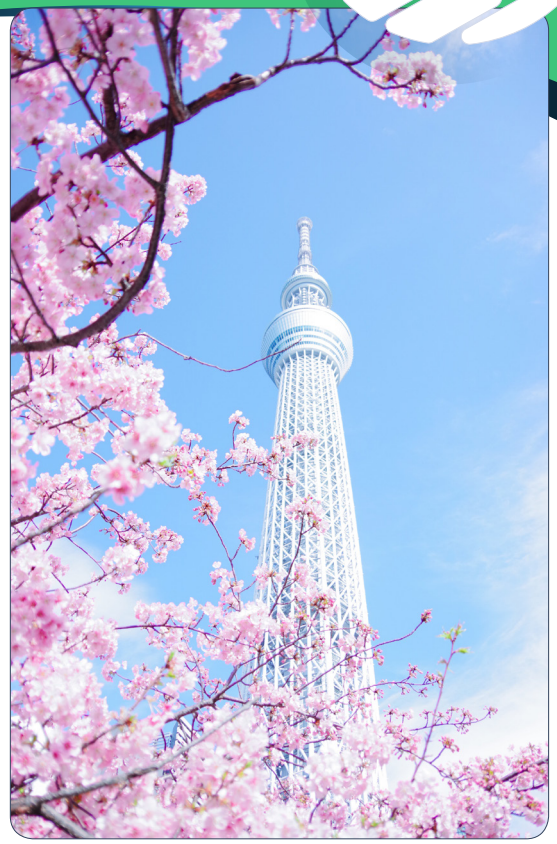
Client Situation

The Client is a multinational pharmaceutical company conducting a clinical study in Japan for an oncology product was looking for a local PV service provider who has the experience in handling all Pharmacovigilance activities related to a clinical study in Japan, in compliance with PMDA GVP regulations and ICH E2A and E2B and GVP guidelines.

GRP Solution

GRP PV team in Japan has more than decade of experience in providing pharmacovigilance services in Japan, and was able to provide the following services during the clinical study in Japan:

1. **Preparation/support for preparation of specific working practice**
2. **Set-up and Maintenance of reporting system**
3. **Translation of ICSR**
4. **ICSR report preparation and submission to PMDA**
5. **Preparation and submission of safety information line listing to authority, as required**
6. **Literature report translation, preparation and distribution/ submission: Preparation of a monthly global literature search report for the Japanese regulatory authority, according to the literature material for the report is provided by client**
7. **DSUR preparation and submission to PMDA**
8. **Providing initial PV intelligence**



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