

Pharmacovigilance at LSK Global PS

STRATEGIC SAFETY SERVICES

Your drug safety representative

The LSK Pharmacovigilance Department's team of Medical Directors and Pharmacists are committed to providing Regulatory Authority and ICH compliant solutions in drug safety guaranteed to integrate smoothly with your team.

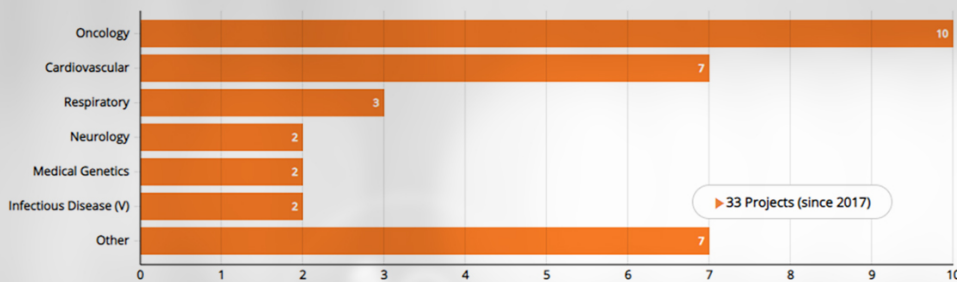
LSK Global PS
LSK Global Pharma Services Co., Ltd.

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PHARMACOVIGILANCE

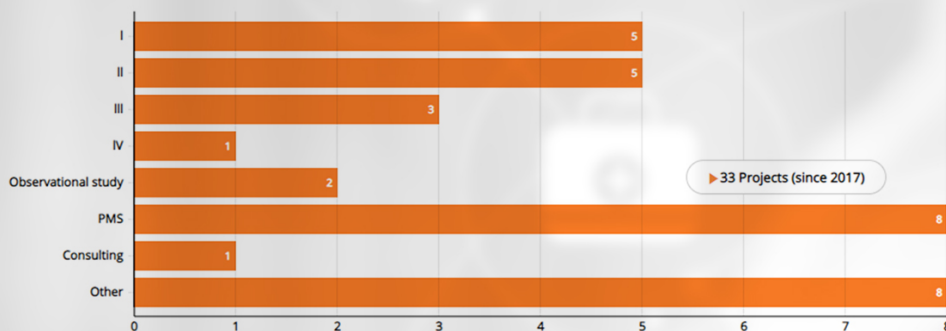
Consisting of the Medical Director and the pharmacists, our Pharmacovigilance Team supports our clients in tasks related to the safety information of drugs, medical devices, etc. pre- and post-marketing.

Therapeutic Area



[updated on June 2018]

Study Types



[updated on June 2018]

Clinical Trial Safety

- ICSR Management
- Expedited Reporting of SUSARs
- Safety Narratives for Study Reports
- AOSE (Analysis Of Similar Events)
- Periodic Reports (DSURs)

Post-Marketing Safety

- Case Processing (ICSRs)
- Expedited Reports
- Periodic Safety Update Reports (PBRERs)
- Risk Management Plan (RMP)
- Literature screening
- Safety Signals

PV System Development

- PV SOP writing
- PSMF (PV system Master File)
- Safety Database / System Hosting
- Annual Staff Training
- Company registration in Eudravigilance Database
- Registration of a pharmaceuticals in XEVMPD Database

PV Audit

Medical Consultancy



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