

## Strengths of C&R PV team

### + *Competent Human Resources*

- Possessional staffs with experiences in PV tasks and clinical trial projects
- Retention of comprehensive knowledge in clinical, biomedical and scientific reports about medicinal products, medical devices, etc.

### + *Provide Efficient PV Service*

- Available 24 hours a day, 7 days a week
- Accumulated experience in using various Drug Safety DBs (Argus, ARISg, etc.)

### + *Timely and Effective Communication*

- Prompt and accurate response to the client
- Having good communication with client



# Pharmacovigilance

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Provide the Most Reliable and  
High Quality Pharmaceutical Safety  
Management Service

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# Pharmacovigilance Services (I)



## Pharmacovigilance Services

### + Overall PV Work Management

- Development and Maintenance of PV SOP
- Manage and Maintenance of Safety DB
- Safety DB reconciliation
- PV Training
- Individual Case Safety Report (ICSR) Management

### + PV Writing

- Risk Management Plan (RMP)
- Development Safety Update Report (DSUR)
- Periodic Benefit-Risk Evaluation Report (PBRER)

### + Clinical & Post-Approval Safety Data Management

- Receipt and validation of SAE Report and ICSR
- SUSAR Handling
- Preparation of CIOMS I report
- Medical Review
- KIDS Reporting

# Pharmacovigilance Services (II)

### + Full Service Solution

All works covered with Pharmacovigilance activities

### + Optimized Service Solution

The tasks that clients want to give delegation

- End-to-end Pharmacovigilance
- Regulatory maintenance
- Local affiliate support, etc.

## C&R PV System

- Allows reporting by healthcare providers, consumers, and health authority
- Well-structured to facilitate analysis
- Standardized procedures
- Allows analysis on product class level and on individual product level (by manufacturer or MAH)
- Procedures for analysis of aggregated information
- Good communication practices

