Pharmacovigilance Services

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The HRB-Clinical Research Facility – University College Cork is equipped to support study sponsors and Clinical Investigators by providing the infrastructure, facilities and experienced research and specialist support staff to successfully conduct high-quality, patient-focused research to international standards.

In addition to its existing services the CRF-C can now provide pharmacovigilance services as follows:

Pharmacovigilance services for Clinical Trials of Investigational Medicinal Products (CTIMP)

- Provision of a dedicated pharmacovigilance email, phone and fax for submission of Serious Adverse Events (SAEs) for single and multicentre / multinational trials.
- Provision of a validated safety database and dedicated pharmacovigilance staff.
- Individual Case Safety Report (ICSR) receipt and processing, including:
  - Data Entry
  - Quality Control
  - MedDRA coding
- Querying sites for additional/missing information.

- Receipt and processing of updates to initial SAE reports until close out of case.
- Determining the expectedness of SAE using Reference Safety Information (RSI) agreed with Sponsor.
- Management of RSI.
- Narrative writing for Serious Adverse Reactions/Suspected Unexpected Serious Adverse Reactions (SARs/SUSARs).
- Submission of SUSARs via EudraVigilance to Health Products Regulatory Authority (HPRA) in Ireland and other applicable competent authorities within specified timelines.
- Designing course material and delivery of pharmacovigilance training to investigators and site personnel.
- Providing summary tables and listings for annual Development Safety Update Report (DSUR).
- Writing and implementing study specific pharmacovigilance SOPs, pharmacovigilance plans as required.

Dedicated pharmacovigilance email is monitored by CRF-C PV staff Monday to Friday, 52 weeks of the year to ensure timely reporting of SUSARs.

CRF-C can also assist with safety reporting for clinical investigations of Medical Devices.

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