The Clinical Research Facility – Cork

Quality and Regulatory Department

The CRF-C Quality and Regulatory Department helps to ensure that patient focused research undertaken under the supervision of the CRF-C is conducted to the highest standards. The Quality and Regulatory Department currently consists of the Quality and Regulatory Affairs Manager, a Pharmacovigilance Officer, a Monitor and a Quality Executive Assistant.

Our staff are available to assist Investigators and study staff by:

Quality

- Monitoring: A dedicated, trained Monitor is available to carry out a full range of monitoring activities including site initiation, ongoing clinical activity monitoring, drug accountability and site close out for Health Products Regulatory Authority (HPRA) regulated and non-regulated trials.
- GCP Training: ICH-Good Clinical Practice (GCP) training is provided for Investigators and study site personnel
- Other Training: Other training services are available to both the Principal Investigators and study site personnel as requested: e.g. Pharmacovigilance, Study Documentation etc.
- Audits / Quality Reviews: Sponsors and Investigators can request quality reviews and audits of studies to ensure compliance with national and international legislation and guidelines.
- Pre Study Audit: Review of study documentation (Investigator Site file) before site initiation.

Regulatory Affairs

- Study Planning: Providing advice on prospective studies /trials to PI and study site personnel at study set up.
- Regulatory Planning: Interacting with HPRA to seek advice on behalf of PI re prospective study/ trial.
- HPRA Approval: Submitting Clinical Trial Applications to HPRA on behalf of PI.
- Ethics Committee Approval: Submitting Application to Research Ethics Committees (REC) on behalf of PI for Clinical Trials and studies.
- Amendments: Submitting study/ trial amendments to HPRA and REC.

Pharmacovigilance services

- 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

    - Medra coding
- Querying sites for additional/missing information.
- Receipt and processing of updates to initial SAE reports until close out of case.
- Determination of expectedness of SAE using Reference Safety Information (RSI) agreed with Sponsor.
- Management of Reference Safety information (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 to 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, as required.