GIG CYMRU NHS WALES
Bwrdd Iechyd Prifysgol Caerdydd a'r Fro
Cardiff and Vale University Health Board

Where Would You be Without Admin?

The life-cycle of a clinical trial from an administrative perspective

Cardiff and Vale Research Delivery Team
Tîm Cyflawni Ymchwil Caerdydd a'r Fro

Study Set-Up

- Creating profiles for studies on the CRF Manager online system and department shared drives
- Localising and storing study documents
- Ensuring trials have received required approvals, from Ethics, R&D, HRA and MHRA
- Arranging Site Initiation Visits
- Ensuring all forms are signed by relevant staff and all relevant training has been completed
- Sending copies of staff's Research CVs and Good Clinical Practice (GCP) certificates to sponsor

Archiving

- Ensuring CTIMPs are archived for 15 years, non-CTIMPs for 5
- Completing and sending the relevant documents to R&D, including archiving records and document lists
- Removing patient-identifiable information and materials likely to decay or rust
- Ensuring adequate space and funding is available
- Packing and sealing documents into boxes

Recruitment

- Maintaining investigator site files (ISF) with current localised documents
- Providing recruitment packs (information sheets, consent forms, case report forms, etc.) to nurses
- Managing trial supplies and kits
- Inputting recruitment data onto the Wales Local Portfolio Management System (ReDA 3)
- Collating recruitment statistics
- Ensuring correct documents go into patients' notes
- Maintaining expenses database and monitoring department budget
- Producing recruitment posters, leaflets and flyers

Data Management

- Transcribing data from study visits onto Case Report Forms (electronic or paper)
- Reporting data back to sponsor
- Resolving data queries
- Completing training to access databases and handle medical data in accordance with GCP guidelines
- Completing data entry within strict time constraints

Laboratory Support

- Receiving and checking lab kits and manuals
- Preparing kits for study visits
- Ensuring samples are processed and stored correctly, including temperature, centrifuge settings, timings, amounts, and labelling
- Preparing and completing logs and accountability forms
- Arranging dry ice packaging and courier services
- Packing samples correctly for shipment

Clinic Co-Ordination

- Booking appointments on CRF Manager
- Allocating rooms, beds and staff
- Sourcing patient notes
- Co-ordinating travel arrangements
- Reimbursing patients' expenses
- Making patients feel as comfortable as possible

Monitoring

- Acting as primary contact for sponsor's Clinical Research Associate
- Ensuring investigational medicinal products are correctly stored, handled and documented
- Documenting protocol deviations and violations appropriately and within the accepted timeframe
- Receiving and disseminating feedback from the trial sponsor
- Ensuring site's activities are being carried out to the sponsor's satisfaction

Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

Michaela Cox, Adele Farrugia, Martin Grigg, Liz Harmer-Griebel, Cathy Harrison, Marc Jones, Charlotte Randell, Olivia Tiley, & Katherine Williams