WHERE WOULD YOU BE WITHOUT ADMIN?

THE LIFE CYCLE OF A CLINICAL TRIAL FROM AN ADMINISTRATIVE PERSPECTIVE

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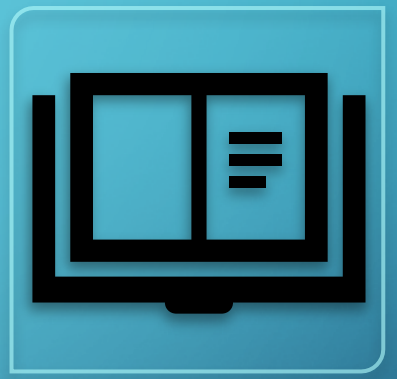
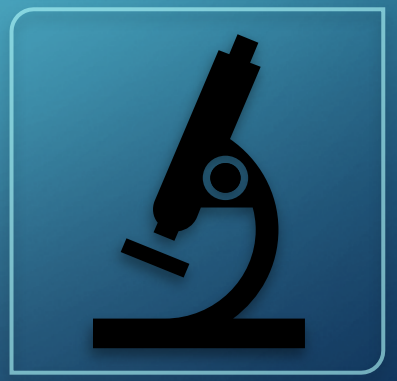
CONTENTS

- Introduction – Aims of the presentation
- Meet the Team
- Study Set up
- Recruitment
- Data
- Monitoring
- Lab work
- CRF Coordination
- Archiving
- Conclusion – Where would you be without Admin?





INTRODUCTION:
AIMS OF THE PRESENTATION

MEET THE TEAM

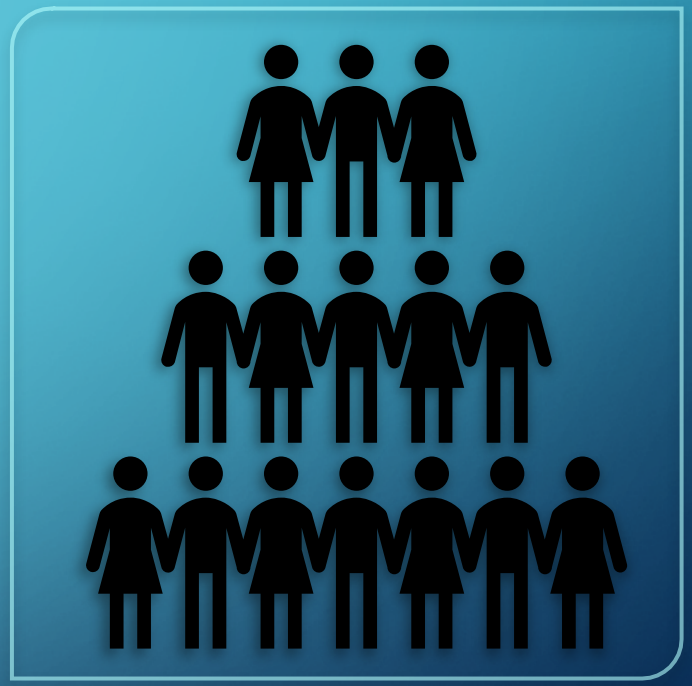
Michaela, Olivia, Martin, Charlotte, Adele, Cathy, Liz, Kat, Marc, & Lisa

STUDY SET UP

- Working alongside the Research and Development team when receiving an expression of interest for a new study
- Facilitating and arranging pre site visits
- Ensuring capacity is available to take on the study throughout all departments involved
- Ensuring all approvals are in place for the study to start
- Arranging the Site initiation visit
- Ensuring necessary materials have arrived to conduct the study including; site files, lab kits, any digital tablets etc.
- Ensuring all training has taken place on any relevant databases and all those involved have the required access
- Getting all financial disclosures, site capacity and any other legal documents signed and sent off to the sponsors.
- Rolling out the activation of a study trial for recruitment.

RECRUITMENT

- Producing and disseminating study outreach documentation to the wider community to promote the study
- Maintaining study site files both electronically and hard copy
- Creating recruitment packs for recruitment visits
- Locating and collecting patient notes for the study visits
- Inputting recruitment data on the Wales Local Portfolio system (ReDA 3)
- Collating recruitment statistics



DATA MANAGEMENT

- The process of transcribing source documentation from a study visit onto a paper case report or electronic case report form
- Facilitating data entry and query resolution
- Performing required training to access a wide variety of databases
- Being able to multi-task and work within tight deadlines

MONITORING

- Liaising with Clinical Research Associate's (CRA'S) to book and facilitate monitoring visits
- Providing all study documentation
- Working with the CRA to ensure all collected data is accurate and accounted for and can easily be Source Data Verified (SDV'd) during a monitoring visit
- Able to assist with documenting any protocol deviations
- Receiving and disseminating feedback from the trial sponsor and being able to work through action points noted during the monitoring visit.

LAB WORK

- Receiving, managing and stocking lab kits and essentials for the running of a study
- Processing and storing samples
- Documenting the process and samples
- Completing lab requisition forms for samples
- Ordering the required dry ice and arrange couriers as needed

CRF CO-ORDINATION

- Booking appointments with patients
- Sourcing and collecting patient notes
- Welcoming patients
- Making travel arrangements
- Organising financial reimbursement for patients
- Maintaining GCP and CV records and ensuring all are up to date for all staff
- Collaborating with nurses and wider team to support and enhance research delivery

ARCHIVING

- Archiving is started once a study has been completed and approved to be archived.
- The study sponsor will issue a list of items that require archiving
- The administrative team will go through the process of archiving all study materials
- Confirmation is then sent to the sponsor to confirm all study information has been archived and the details of the location where the archived boxes will be stored as per our site SOP.

CONCLUSION

QUESTIONS?