Pharmacy support for MCRN Clinical Trials

Claire Norton
WM MCRN Pharmacist Adviser
Lead Pharmacist for Clinical Trials and Psychiatry
Birmingham Children’s Hospital
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What is Pharmacy’s role?

- Pharmacy have to be involved with any CTIMP Clinical Trial with Investigational Medicinal Product
When should Pharmacy be involved?

- Successful CTIMPs involve Pharmacy from start to finish!
- Formulation and Regulatory issues can be sorted at Clinical Study Group stage
- MCRN adoption committee involves pharmacists
- Input at monthly WMMCRN teleconference
  BUT may not be enough info for us
What does Pharmacy do?

- Set up and manage pharmacy aspects of clinical trials
- Check study is feasible for site
- Produce/ customise trial paperwork: accountability, prescriptions, dispensing instructions
- Store, dispense and handle IMPs
When can the trial start?

- MHRA require that pharmacy authorises the final stage of approval
- All documentation in place
- All approvals- CTA/ REC/ R&D
- Delegation log signatures
- ‘Green light’ BEFORE 1ST DISPENSING
Pharmacies across the West Midlands MCRN

- 3 Lead centres
- Birmingham Children’s Hospital
- University Hospitals Coventry and Warwickshire
- University Hospital of North Staffordshire
- plus
- 17 hospitals with paediatric patients
Pharmacy Facilities and Staffing

- Will be different for each site
- Capacity issues
- General hospitals are experiencing increased demand from TSRNs
- CLRNs are trying to unblock pharmacy capacity, but challenges in attracting/training staff
MCRN researchers

- Need to get to know CT pharmacy staff (as well as paediatric pharmacists)
- Give early warning of studies
- Expected number of patients, duration of study and number of dispensings
- Funding details & is IMP provided free?
What does pharmacy need?

- Time to set up the trial
- Meet with Investigator, research team, CRA
- Documentation (Pharmacy file) and approvals
- An invitation to the Initiation Meeting
Help pharmacy to help you

- Prescriptions in advance or advance warning trial patient is due in
- Ensure prescriptions are completed correctly
- Give patients a realistic waiting time for prescriptions
Keep pharmacy informed

• If trial is amended we need copies of:
  Updated protocol & amendments
  Ethics approval for amendment

• If the trial is extended or suspended
Informed through to the end of the trial

- Tell us when the study has completed
- Archive pharmacy file with investigator file
- Let us know the outcome of the study
BCH Pharmacy CT team

- Is dedicated to supporting *paediatric* trials
- MCRN
- Wellcome Clinical Research Facility
- Haematology/Oncology
- Both commercial and non-commercial
MCRN pharmacy team

- Tracy Gazeley *WMMCRN Pharmacy Technician*
- Gemma McGuigan *Specialist Clinical Pharmacist (R&D)*
- Claire Norton *WMMCRN Pharmacist Adviser*
How can we help?

- Visit WM MCRN pharmacy sites
- Share documentation
- Offer advice and support
How to contact us

- Telephone – 0121 333 9308/9776
- Fax – 0121 333 9776
- tracy.gazeley@bch.nhs.uk
- gemma.mcguigan@bch.nhs.uk
- claire.norton@bch.nhs.uk
Take home messages

- Good communication essential
- Working together to sort out problems
- Exciting time ahead to improve the medicines we give to children