Dedicated pharmacy trials staff

- Lead Pharmacist, Service Co-ordinator
- Pharmacists: Band 7 and 8a
- Technicians: Band 4 and 5
- Assistant technical officers: Band 2 and 3
- 70% of posts fully or partially supported by CRN -EM
Active studies June 14: 136

Specialise in:
Digestive diseases, especially liver disease
Neurology, especially multiple sclerosis
Emergency medicine
Ophthalmology
Diabetes
Dermatology
Anaesthesia / pain management
Rheumatology
Obstetrics and gynaecology
Paediatric medicine, including cancer
Pharmacy Contacts for CRN/R and I Staff QMC Campus

Paediatric Cancer
Adam Henderson
Bev Harwood

Non cancer
Sheila Hodgson
Active studies June 2014: 175
Specialise in:
Adult cancer (79% of total)
Stroke medicine
Respiratory medicine
Cardiology/Cardiac Surgery
Renal medicine and transplant
Urology
Obstetrics and Gynaecology
Palliative Care
Pharmacy Contacts for CRN/R and I Staff
City Campus

Commercially sponsored oncology and haematology

Maria Scott
Non commercially sponsored oncology

Tin Tsang
Non commercially sponsored haematology

Pauline Brookes
Non cancer

Sheila Hodgson
What do pharmacy clinical trials do?

- Protocol review/editing (IMP section)
- Support the regulatory approval of the Protocol
- Study documentation design
- Provision of IMP
- IMP management in NUH pharmacy for NUH subjects
- IMP management in remote sites for studies sponsored by NUH and U of N
Protocol review/editing

Description of IMP:
Choice of agents, active comparators and placebos
- Source, manufacturing methods, storage, handling and testing of raw materials and final products
- Choice of dosage form
- Presentation and packaging

Management of storage, distribution, dispensing, accountability and disposal of unused and expired material

Code breaking arrangements

Co-ordination of IMP management at recruiting sites
1. Advise on the completion of the IMP section of the MHRA application
2. Develop and prepare IMP dossiers to include with MHRA application
3. Design and approve sample IMP labels submitted with MHRA application
4. Appraise and review for SSI, including assessment of pharmacy costs.
Document design

1. Prescription forms
2. Dispensing and accountability records
3. Destruction records
4. Shipping records
5. Study specific SOP
On behalf of the sponsor:

- Purchase licensed and unlicensed products or raw materials for manufacture of final IMP
- Develop technical agreements between NUH and suppliers for NUH sponsored studies.
- Develop and maintain Product Specification files for each IMP which is QP released by NUH pharmacy
- Test raw materials or products prior to assembly or manufacture by NUH pharmacy
- Prepare controlled documents, including MHRA approved labels
- Assemble or manufacture IMP batches in accordance with approved documents, including validated randomisation schedules.
- Test final products
- QP release of final products

Liaise with external suppliers as required if NUH pharmacy cannot provide final QP released IMP
IMP Management for NUH subjects

- IMP storage in dedicated, secure, temperature controlled and monitored facility
- **Approve facilities and environmental monitoring in wards and departments used for IMP storage**
- Receive IMP from Sponsor
- IMP and NIMP dispensing and accountability
- Receive returned, unused IMP from subject for accountability and storage until authorised by Sponsor for destruction
- IMP destruction with record
- Provide emergency code breaking facility, including out of hours
- Expiry date monitoring and management of controlled relabelling to extend expiry
IMP management for non NUH subjects

- IMP dispatch to remote recruiting sites
- Pharmacy file preparation for use at remote sites
- Co-ordinate IMP recall, if required
- Co-ordinate relabelling to extend IMP expiry date
- Advise on IMP monitoring in remote pharmacies
Focus today on

- Protocol appraisal
- SSI authorisation
- Study set up/pharmacy green light
- IMP management of active studies
New protocol received from Sponsor following site selection

Assess feasibility:

- Review protocol and pharmacy specific aspects and procedures
- Confirm subject numbers to assess impact
- Liaise with colleagues in manufacturing/aseptic dispensing departments if necessary
- Liaise with Sponsor to clarify points and resolve issues

Calculate pharmacy costs

Give pharmacy authorisation via SSI
Some are easier than others!

Eg: Cancer protocols

- Complex treatment regimes using combinations of injectable and oral medicines

- Combination of IMPs and NIMPs, have different labelling and accountability requirements

- Response guided therapy makes it difficult to predict the number of treatment visits and/or number and type of medicines a trial subject may receive

- Appraiser may need to review proposed treatment regimes or processes to assess compliance with NUH policy and procedure

- Early receipt of protocol and liaison with research team and Sponsor ensures most of the work needed to provide authorisation is completed before R and I submit the SSI to pharmacy which supports an efficient approval process.
Costings

Can only be calculated when appraisal is complete

Commercially sponsored studies now largely costed in accordance with the National Costing Template

Non commercially sponsored studies costed in accordance with AcorD
Misunderstood by 99% of the research community!
Summary information on the pharmacy page of the template is good!
Costings: Prescription Charges 2

- Legislation dates from 1975, but is still the only guidance available and confirmed as relevant
- Tax which pharmacies are legally obliged to collect, considered as fraud if not managed correctly
- **Not related to the cost of the IMP, including FOC supply from Sponsor**
- Applies only in protocols where all subjects are receiving an active treatment, **ie placebo controlled studies are exempt**
- Applies only to those subjects who would normally pay a prescription charge, usual exemptions based on age, certain diseases (including cancer) prepaid certificates and receipt of valid benefits apply
- **Applies only to outpatient treatments**
- Charge **per IMP** only applied once for the whole course of treatment (no charge for placebo supplied only for blinding purposes)
In practice:

• Sponsor is responsible for any potential prescription charges
• For costing purposes, assume all subjects will need to pay
• Most Sponsors pay the total possible charge as stipulated in the contract without question, some will ask for a record of subjects who are subject to the charge before authorising payment.
Pharmacy will resist requests to do this!

On the occasions where it is considered appropriate a handling charge is applied for each order to cover the costs of purchasing support.
Adequately identify the Protocol in correspondence
Ensure Sponsor/Investigator are aware of appropriate pharmacy contact
Consider if protocol amendments need pharmacy input eg

- changes to treatment regimes
- change in IMP provider
- increased number of trial subjects
- increased recruitment period.

Relay Sponsor queries to the pharmacy contact to ensure prompt resolution of queries
Ensure pharmacy costs are translated accurately into the final contract or costing proforma and send a copy to the pharmacy contact.

Apportion research costs to pharmacy as appropriate for non commercial protocols.

Regular reporting to pharmacy on invoice requests to commercial Sponsors to avoid duplication and omission.
Process

- Write protocol summary (validated by investigator)
- Draft dispensing procedure and IMP management guidelines
- Draft prescriptions, accountability logs, aseptic preparation worksheets, fluid sheets, if applicable
- Start set up on Chemocare, if applicable
- Confirm outstanding details at initiation visit
- Complete set up on Chemocare, if applicable (validated by Investigator)
- Ensure all regulatory documents received
- Receive study IMP, check labelling,
- Complete final version of all pharmacy SOP documents
- Complete final sign off, (Pharmacy Green light)
• Ensure prompt review of pharmacy protocol summary document by the PI
• Provide a copy of the study delegation log as the pharmacy reference document for authorised prescribers
• Coordinate the completion of study delegation log by pharmacy staff
• Coordinate the completion of study training log by pharmacy staff, if required by the Sponsor
• Provide / highlight copies of approval letters including those issued for amendments
• Provide a copy of the Study Contract
IMP management of active studies

Process
• Receive study prescription with confirmation fax/email if applicable
• Clinical screen by a pharmacist, if applicable
• Dispense in accordance with study specific SOP
• Complete accountability logs in accordance with study specific SOP
• Final accuracy check.

CHN trials pharmacy processes on average 318 items per month, 40% need assembly for aseptic manufacture.
QMC trials pharmacy processes on average 369 items 12% need assembly for aseptic manufacture.
IMP management of active studies
Support from the R and I and research team

- Provide the trials dispensaries with clinic lists, appointment calendars, or use QMC outlook calendar to facilitate planning.
- Provide prescriptions in advance whenever possible
- Communicate any changes in planned treatment visits
- Reinforce instructions to subjects to return IMP at each visit to allow timely accountability
- Direct Sponsor representatives to liaise directly with pharmacy
- Ensure information re amendments is communicated promptly and approval letters are provided/highlighted
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