ECMC Trial Harmonisation Programme (ETHP): Building the future of the network

ECMC/HRA Pharmacy Initiative

The Experimental Cancer Medicine Centre Initiative is jointly funded by Cancer Research UK, the National Institute for Health Research in England and the Health Departments for Scotland, Wales and Northern Ireland

Why we volunteered?

- CRUK to be at the forefront of innovative research and innovative processes

- Historically both Pharmacy and Medical Exposure reviews have been seen as barriers to research across the UK

- If the ECMC Network is to deliver a first class service we want to be the first to show that being collaborative and joined up really does make things quicker.

Listening to the problems that Pharmacists have

- Earlier work was undertaken to listen to pharmacists and understand what the problems really were:
  - Capacity is an issue but mainly because of the lack of accurate information from Sponsors to allow a review to take place and a sometimes inconsistent approach to the review of studies between pharmacists in different sites.

The answer….

- Work with the Health Research Authority on HRA Approval
- Be clear about what information Pharmacists need to review a study
- Be clear that no information means no review – put the responsibility back onto sponsors
- Produce a consistent standard approach to Pharmacy reviews created and agreed by Pharmacists

- Only do the technical review once to reduce duplication at site

- Provide the review information clearly so that sites can set up quickly

Why now?

- HRA will be rolling out the HRA Approval process this year in a phased approach.
- Technical reviews of both Pharmacy and Medical Exposures will be part of HRA Approval.
- ECMC Network creation underway

Structure of the review

- In earlier projects at UCL Partners a group of lead Pharmacists volunteered as “Pharmacy Guardians”
- Guardians have steered the single review, collaborated on refining the process, QC reviews, helped to trouble shoot issues, advised the project managers on issues that need to be resolved and linked to national groups – **They are invaluable.**
- This role of Guardian as advisor and trainer will continue into the HRA roll out of the process.
- Reviewers can be Pharmacists or Technicians
- This process has been created by Pharmacists for Pharmacists

The process

- Sponsor submits IRAS application
- Application validated for pharmacy involvement at the HRA
- HRA Technical Assessor collects information from sponsor if necessary
- Pharmacy Reviewer identified from taxi rank by HRA
- Technical Review completed once – local capacity assessed after MHRA approval

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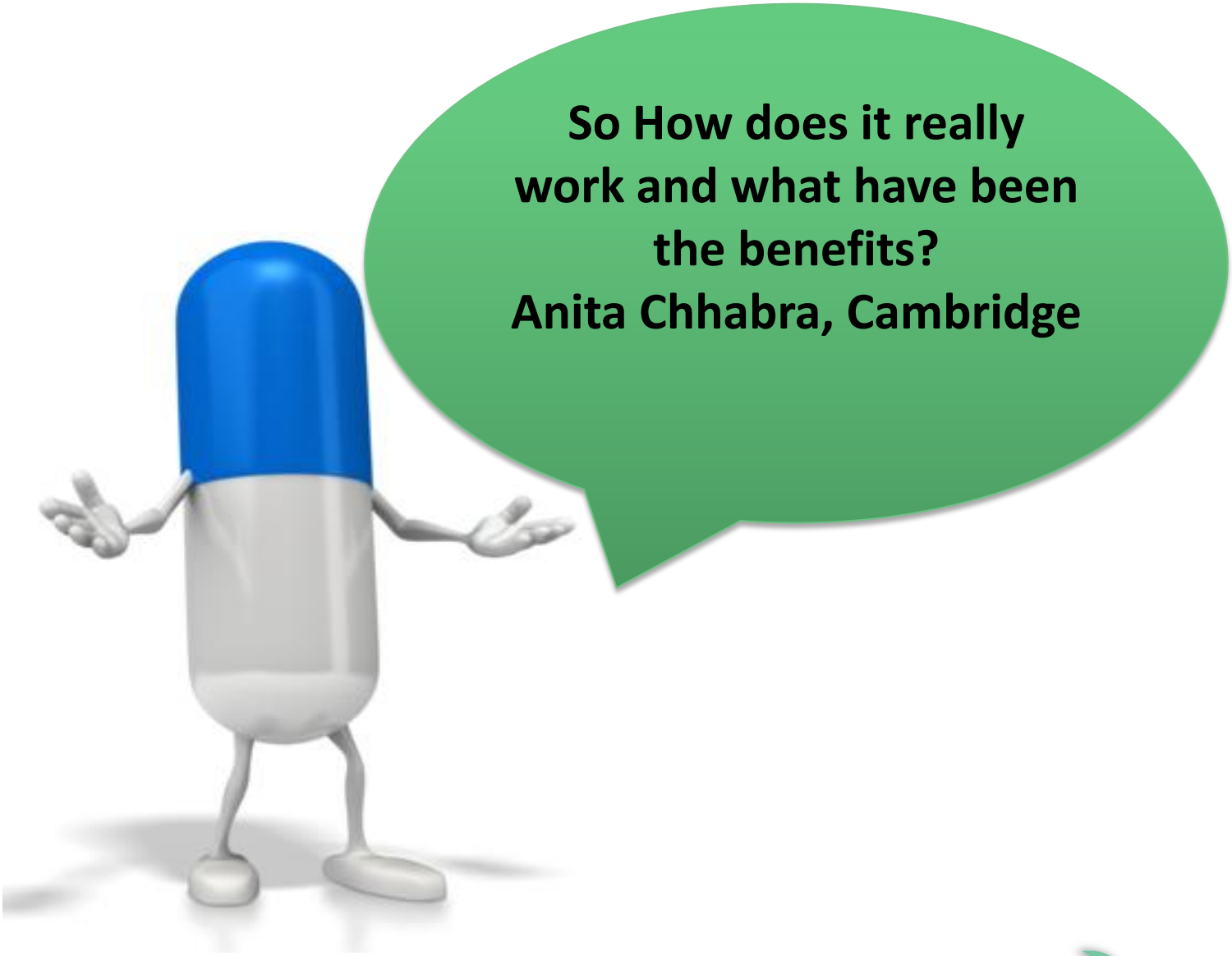
Outputs of the testing phase

- Further refinements to the summary form have been made – the summary form is a culmination of over two years work by over 40 pharmacists – it's fit for purpose.

- Time saving for pharmacists so far:
  - 38 studies in and reviewed once
  - Has saved 180 duplicated reviews
  - 14 day median turnaround time

Roll out

- The single Technical Pharmacy Review can stand alone and is not currently linked to the HRA Approval.
- This means it can be rolled out nationally ahead of the HRA taking on the assessment of CTIMPs.
- Devolved Nations have all been actively involved in the testing and will continue to use the process post testing phase.
- All ECMCs will continue to use this process with the HRA


So How does it really work and what have been the benefits?
Anita Chhabra, Cambridge

My Experience
How I got involved

When :June 2014

What: Single Technical Pharmacy Review

How: Wendy Fisher contact

Wendy had done a lot of work already

Sent the following

- Project Overview
- Pharmacy Guidance
- Clinical Trials Pharmacy Assessor Job Description
- Pharmacy Guardians Terms of Reference
- Pharmacy Costing Guide
- Pharmacy Costing Form
- Pharmacy Review Form
- Pharmacy Review Flowchart

When I first got it

- I had questions
  - Is it going to save me time?
  - How is this going to work in practice?
  - Hospitals have different environments, will it work here?
  - What is the Guardians' role in this?
  - What is included and what is outside the review?
  - At what stage does the review happen?
- More questions than answers
- Sceptical originally but went to the first meeting with an open mind

What happened?

- The Initial meeting:
  - People were enthusiastic
  - Supportive
  - Raised some good points
- Several Guardians' meetings:
  - The issue raised from the initial meeting were looked at.
  - Review form was modified to include relevant information and add clarity
  - Guidance on how to fill in the review form
  - Technical not clinical review
- Form was piloted in our hospital
- Relevant communication was all put on "sharepoint"

Benefits and Conclusions

- Benefits of review form
  - All the information needed was present
  - Quick, convenient, appropriate
  - No need to chase or wait for information
- Technical review: Clinical and SSI reviews still needs to be done at each site
- Encourage sponsors to provide all necessary information prior to application
- Speeds up the process and reduces wait time

Thank you

Any Questions?

Biography: Anita Chhabra

- Lead clinical trials pharmacist at Cambridge University NHS Foundation Trust
- Held this role since EU directive came into force
- Before this many years of experience as head of outpatient pharmacy
- Involved in setting up both commercially sponsored and Trust sponsored trials