

The Role of the Research Nurse

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Disclosures

- None

Question:

Do you currently have a research nurse at your Trust who specialises in IBD studies?

1 Yes

2 Yes, but I don't know who they are....

3 No

4 Not sure...?

10

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A bit of history...



James Lind

Surgeon on board HMS Salisbury

His 1747 experiment for the prevention of scurvy on board was one of the first reported, controlled, clinical experiments using control groups.

International Clinical Trials Day 20th May

Question: Is this research?

You want to do a questionnaire with your patients, to find out how they are experiencing the telephone service you provide? Is this research?

1 yes

2 no

10

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2 no



10

Research is.....

Aiming to create generalisable new knowledge about treatments, services or conditions.

Can involve a change/intervention to care or treatment, and randomisation to a treatment arm.

Often involves collecting additional data or samples

qualitative research has a clearly defined question, aim or objective.

HRA Decision Making Tool

http://www.hra-decisiontools.org.uk/research/docs/DefiningResearchTable_Oct2017-1.pdf

My Role: What is a Clinical Research Nurse?

- Not a nurse researcher
- Role is often funded by the NIHR/CRN, and employed by the Trust.
- usually working within a speciality team, within a wider research team.
- Identify/recruit patients who meet inclusion criteria
- Collect, input, and clarify data as requested by the researchers
- Administer interventions
- Collect samples
- Manage study paperwork
- Caseload of patients (often overlaps with CNS team)
- Identify and assess feasibility for new studies

Inflammatory Bowel Disease

- Approx IBD 3000 pts HHFT
- Approx 30 studies across the two sites
- Mixture of interventional and observational studies
- Most of our consultants are involved
- 6 IBD nurses working across 2 sites + 1 gastro pharmacist

Typical Daily activities

- Screen the inpatients, IBD Advice line logs, check emails for urgent items
- Link in with IBD nurses about patients
- Rush! Surprise prescription to get dispensed.
- Print some emails and site file documents that need filing.
- Complete a CRF and enter into online database.
- Collect data on screening and approaches for a study for return to data manager
- Discussion with a PI re a patient's eligibility
- Liaised with IBD CNS, assisted with venepuncture for urgent bloods
- Arrange for trial equipment to be PAT tested.
- Reviewed feasibility of a study with research facilitator, and checked costings.
- Review trial supplies with lab tech, and find somewhere to store them(!)
- Track down notes in the medical records library
- Learn to spin and aliquot samples
- Create a spreadsheet with automatic highlighting and dates

Research infrastructure in The UK

- NIHR (England)
(<http://www.nihr.ac.uk>)

NIHR | National Institute
for Health Research

Clinical Research Facilities (23 funded by NIHR)

Biomedical Research Centres (11)

- Health and Care Research Wales
(<https://www.healthandcareresearch.gov.wales>)
- NHS Research Scotland <https://www.nhsresearchscotland.org.uk/>
- Health and Social Care Research and Development (HSC R&D) Division
(Northern Ireland) (<https://research.hscni.net/>)

Regulation

- **EU Clinical Trials Directive** (as transposed into UK law by UK Medicines for Human Use (Clinical Trials) Regulations 2004).
- **HRA** (a single UK wide approval includes ethics) since 2016
- **MRHA** – need a clinical trials authorisation for a CTIMP
- **UK Policy Framework for Health and Social Care Research (2017)**
- **Good Clinical Practice**

Why be involved in research?

- Every patient has the right to be involved in research (NHS Constitution)
- It can offer our patients more options, or quicker access to new/varied treatments
- Patients cared for in research active institutions have better outcomes
- It can produce income for the trust to fund internal projects
- Research is a core activity for improving care



Andover War Memorial Hospital

Basingstoke and North Hampshire Hospital

Royal Hampshire County Hospital

CQC

Clinical research now to be included in the well-led domain

- Research equity
- Research facilitation
- Research awareness

What sort of research?

Commercial

Non-commercial

Portfolio

CTIMPs (Clinical Trial of an Investigational Medicinal Product)

Interventional - device studies

Observational studies / registries

Investigator initiated

How do we get involved in a project?



- NIHR Portfolio
- CRN meetings of specialities
- Personal approach
- Capacity
- Capability
- Patient group
- Competition
- Contracts or agreements
- Target setting

In detail – some examples

IBD BioResource: Can recruit across **both sites**

Wide inclusion criteria – enables patient participation

- Biobank for current research
- Identification of patients by genotype for future projects
- 25,000 patients across the UK.



PROFILE (RHCH, Basingstoke)

- Aim is to demonstrate a **biomarker** can be used to **personalise Crohn's treatment** in newly diagnosed patients
- Open across both sites, so a pool of resources and experience.
- 2 x PI's

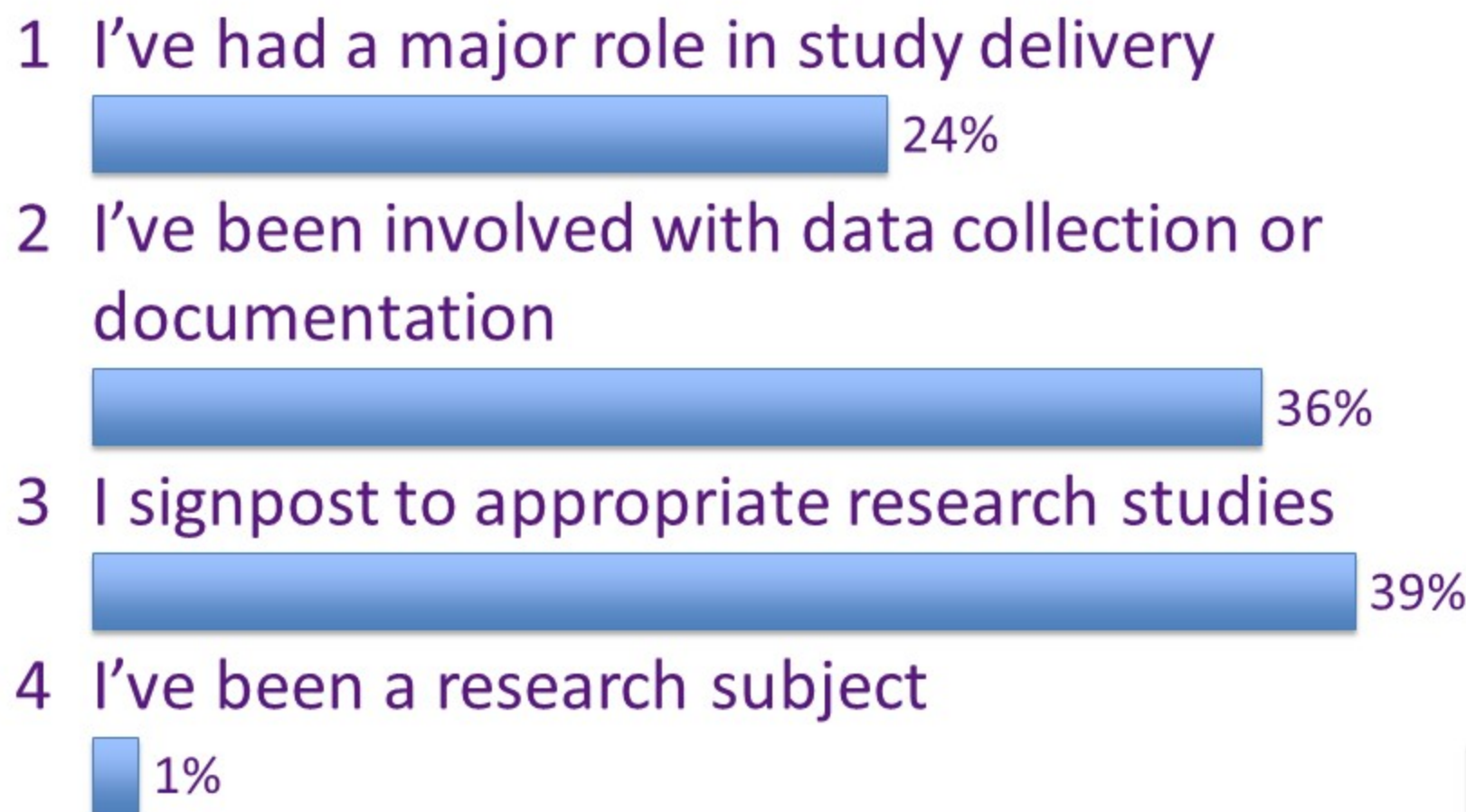
What is a commercial study like?

- Intense workload
- A lot of support from the sponsor and CROs
- Supplies and equipment provided
- Contracts and targets
- Frequent patient visits
- Involvement of many departments e.g. imaging, endoscopy, infusion unit, pharmacy and labs.

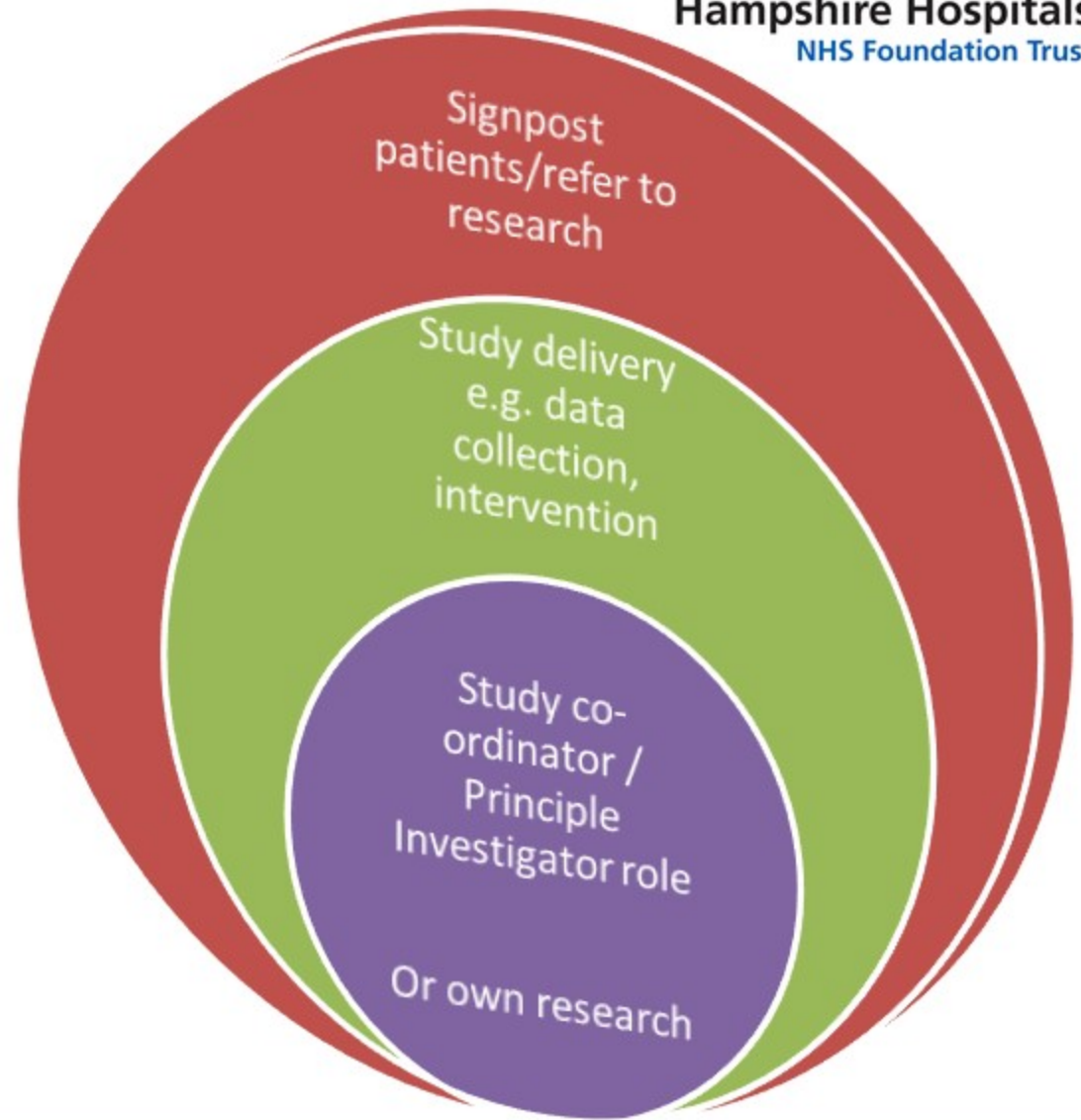
Question: What's your involvement in research?

- 1 I've had a major role in study delivery
- 2 I've been involved with data collection or documentation
- 3 I signpost to appropriate research studies
- 4 I've been a research subject

Question: What's your involvement in research?

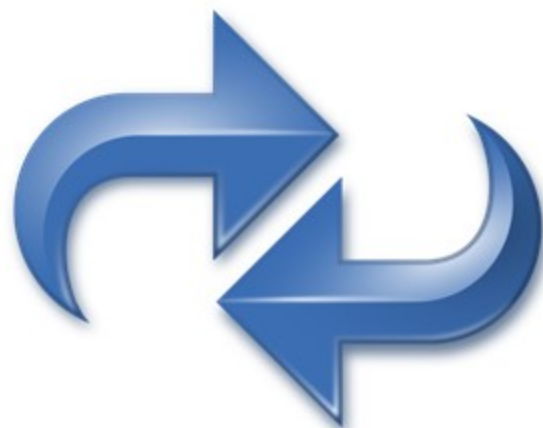


Levels of involvement



Engaging with the Wider Team

- Integrate – attend MDT, nurse meetings etc.
- Align common clinical processes
- Communicate about trials open for recruitment
- Advise about current care/protocols
- Support with identifying patients



Top Tips from my IBD Team

- Do a face-to-face GCP course
- Keep in contact and work together
- Ask for information

My top tips

- Involve your research nurse
- Documentation – be precise
- Safety reporting
- Changing treatment – check first!
- Align your procedures if possible
- Be patient with questions!
- Review your capabilities and capacity to support research activity as part of your clinical role

IMPACT – translating results into practice

Downloaded from <http://ig.bmj.com/> on February 20, 2018 - Published by group.bmj.com

COLORECTAL

RESEARCH

Disease status, patient quality of life and healthcare resource use for ulcerative colitis in the UK: an observational study



Infliximab versus ciclosporin for steroid-resistant acute severe ulcerative colitis (CONSTRUCT): a mixed methods, open-label, pragmatic randomised trial

John G Williams, M Fasih Alam, Laith Alrubayy, Ian Arnett, Clare Clement, David Cohen, John N Gordon, A Barney Hawthorne, Mike Hilton, Hayley A Hutchings, Aida U Jawahar, Mirella Longo, John Mansfield, Jayne M Morgan, Frances Rapoport, Anne C Seagrave, Shaji Sebastian, Ian Shaw, Simon P L Travis, Alan Watkins, for the CONSTRUCT investigators

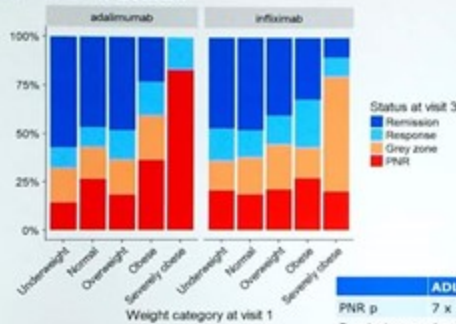
Summary

Background Infliximab and ciclosporin are of similar efficacy in treating acute severe ulcerative colitis, but there has been no comparative evaluation of their relative clinical effectiveness and cost-effectiveness.

Methods In this mixed methods, open-label, pragmatic randomised trial, we recruited...



Factors associated with week 14 PNR: baseline BMI status



Oral presentations (2018)

OP031 Clinical effectiveness, safety and immunogenicity of anti-TNF therapy in Crohn's disease: 12-month data from the PANTS study

N.A. Kennedy^{1*}, G. Heap^{1,2}, B. Hamilton¹, G.J. Walker¹, C. Bewshea¹, S. Bouri³, J. Goodhand¹, PANTS Investigator Consortium, T. Ahmad¹

¹University of Exeter, IBD Pharmacogenetics, Exeter, UK, ²Abbvie, Chicago, USA, ³St Mark's Hospital, IBD