Transcript for Podcast 1: How to get involved in research

Chapter 3: How to get started?

Tony Smith, podcast host

Hello, and welcome to our podcast series for rheumatology pharmacists. In this first episode, we've been talking about how to get involved in research. This last chapter gives you some tools on how to get started. I'm Tony Smith and I'm here today with Lewis Sutherland, a senior clinical pharmacist. So, the question is how to get started. So, Louis, how do trials get approved in the UK?

Lewis Sutherland, Senior Clinical Pharmacist

So clinical trials are, there's a lot of oversight from the medicines health and regulatory agencies.

So, I'll just say as an overall point, this is more of a general interest topic. It's not something we'd expect people who, unless they want to actually deliver or become a researcher themselves and come up with their own clinical trials, to need to be acutely aware of. It's good to have a rough understanding as a research deliverer, but not critical.

But for the purposes of this, yes, the Medicines Health and Regulatory Agency are usually involved, or they will be involved in giving the clinical trial authorisation.

And there's various committees that are involved overall in ensuring that trial is safe to use, because there will be the research ethics committee who will review it and say, is it ethical for this trial to be undertaken. And that is part of the local level of Trust as well. When they come to do a site initiation visits, part of the checklist that goes on will be the site themselves will decide, can we run this study from a logistical standpoint, such as do we have the correct storage requirements? Do we think we have the patient body that we need? Do we have access to the right aseptic facilities? And do they think it's ethical as well. They'll have their say, but obviously if it's been approved by the research ethics committee, it's very likely to go through and also be approval from the health research authority.

So again, I'm not wanting to, as part of this podcast go into a huge amount of detail about these organizations, but all this information is readily available on NIHR and, and gov.UK website.

2:07 Tony

So, you talked about ethical approval. Why is that so important?

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Lewis

Any study that involves patients has to go through ethical approval. This largely came in through various studies undertaken throughout the years where you look at them now and you would think they were completely barbaric, but this is the grounding for GCP declaration of Helsinki and research ethics.

Is what you're doing ethical and safe for the people that are involved. Now, ethics scares a lot of people because ethics are incredibly important, and as such they're incredibly stringent.

Now, as a pharmacist, it's very rare that you'll get involved in submitting ethics proposals, unless you happen to work for an education in educational institutions such as a university.

2:57 Tony

And who needs to authorise a trial?

Lewis

So, MHRA will authorize the clinical trial, as well as the Health Research Authority, as said before the NHS research committee. And it will be registered on an international database, which usually for UK trials will be the clinicaltrials.gov website.

3:18 Tony

So, with regards to authorizing a trial, you mentioned some agencies just there. Do participating hospitals have to authorize a trial as well?

Lewis

That's a fantastic point, of course.

It can be that the sponsor reaches out to certain clinicians that they know who will have run many clinical trials for them in the past and they have a good relationship with. Or, it can be that as a site or as an enthusiastic, up-and-coming PI, you approach certain people and bodies to ask to get involved and as part of any setup of any study there is a feasibility component where you assess: can we run this study with the facilities we have available.

4:09 Tony

You talked about the ethical considerations and also compliance.

So how do those two elements affect study design and protocol?

Lewis

It will determine, I guess, or it will largely be determined by what is actually involved.

So, if you've got a study looking at a medical device or a medication and the MHRA, the Medicines Health and Regulatory agency will guaranteed be involved.

If it's not a CTIMP (Clinical Trial of an Investigational Medicinal Product) study, a clinical trial, investigational medicinal product, it won't always be directly involved, and it will be more to the Health Research Authority, who take the lead.

So, the ethics largely come down to what are you actually measuring as well?

Is your study looking at 'This is a new medicine, I want to see how it benefits individuals', or if your study is looking at 'We've been told, or that we found from some of our earlier clinical trials this medicine has this side effect, so we're going to do a study to give patients this medicine, knowing it might cause this side effect and find out how often it actually happens', which is a different ethical consideration.

5:17 Tony

And Lewis for our listeners today, how can you reassure them that the ethical and compliance considerations that you've been talking about, are not too difficult to overcome?

Lewis

I think the thing with ethics is that it has to have a certain level of stringency to it, to do its job.

And what I would say about ethics is that as much as it is your concern, it will not be yourself alone who has to solve it. There will always be people on hand who are very au fait and very skilled in knowing ethics and can advise you quite early on what ethical approval you would need for different studies.

5:58 Tony

So, what areas of research can a pharmacist get involved in as a beginner and then as a PI?

Lewis

I think again, it really comes down to what type of research you want to do.

If you're looking at local level, or if you're looking at, I want to get involved in clinical trials and learning about the different medicines being used and supporting their use in practice in our patient population.

So that, obviously starts out with some small projects that you're leading yourself, such as audits, quality improvement projects, service evaluation.

But regards to clinical trials, there's not usually a specific clinical trial that will come along or specific research project that you should get involved in. It's making sure you find one, where one of the people involved in your team is someone that you know or someone you've discussed with and said they'd like to get involved and get some support. And just have a chat with your research and development team because they'll almost always be very happy to have you shadow site visits and learn what goes into the different stages of the clinical trial to get involved.

7:03 Tony

And would a pharmacist be involved as a beginner and then as a PI?

Lewis

Quite commonly, these days there are ways to do it. The associate principal investigator scheme is out there. There's the principal investigator essentials for principal investigators course, which I've been on myself. And I've gone from someone who was a delegation log pharmacist, for want of a better term and whose name was on with certain responsibilities but wasn't particularly hands on, to currently being a sub investigator in an academic study. And I plan in the next few years to take this forward and hopefully become a PI in certain studies going forward as part of my framework credentialing.

7:41 Tony

And Lewis, for you, where did you start your research career?

Lewis

So, my research career essentially started when I ended up working with the rheumatology team.

It's a clinical area that is heavily involved in research through new therapies and particularly clinical trials. And getting on the delegation log of trials was the first start and going through the GCP training via the NIHR and things like this was the first step of the ladder.

My research journey, and my interest really started through having someone who was very enthusiastic to tell me about it and make it sound really achievable. And I've learned through experience it is incredibly achievable. And I have also become very passionate myself as much as individually.

8:29 Tony

Yeah, and what roles would you recommend?

Lewis

I would definitely recommend setting aside time to evaluate different parts of the team you're working, where there can be improvements.

Research is the sort of thing where you can take half an hour out over lunch or try and spend half an hour here and there and go to your work's library or find a quiet space and just draft a proposal.

8:56 Tony

So, what should you do now if you want to get involved in research? What are the steps to take? Lewis, what would be your advice?

Lewis

The first thing really to get involved in research is to find out if you're not already aware who your links are for your local research and development department, because they are, as I say, almost universally an incredibly enthusiastic and helpful bunch of individuals who are very keen on research and improving patient care and taking things forward, and are very good at

bringing other people on. Because one of the underpinning qualities of research is: don't keep ideas to yourself, share it, expand it, learn from it.

9:39 Tony

And thinking about the advice that you'd give to a pharmacist who is looking to get involved in research.

What's the one thing you wish someone had told you?

Lewis

Right from the get-go is: research is easy and accessible. A lot of things sound scary. You get taught a lot of things are scary. But when you actually get involved in it, and when you actually get interested in it, it's not.

You don't have to touch the really complex stuff if you don't want to. There's various different levels of research involved.

10:07 Tony

And what's been the best advice that's been given to you over the years?

Lewis

So, the biggest bit of advice with research is, it never starts with a solution.

Always start with something that you know isn't working. And work up from there.

If you can develop the solution to something that you think is great, but when actually comes down to it, you thought this would be great if we did things this way. But the actual system works perfectly well and it does not require any change.

So, yes, pharmacists are very good at finding solutions to things.

But make sure that you always start with a problem.

10:47 Tony

Thank you for listening in. Before you go, I'd like to remind you about the infographic and My Plan template, both of which you can find from our Learning Rheum pages online. I hope they'll be useful resources for you. Until next time.

Abbreviations:

GCP, good clinical practice; MHRA, Medicines and Healthcare products Regulatory Agency; NIHR, National Institute for Health and Care Research; PI, principal investigator