Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

Ariennir gan Lywodraeth Cymru
Funded by Welsh Government

Getting Feasibility Right

Lydia Vitolo, Senior Industry Manager

Susan Kearney, Research Manager

Abby Moore, Industry Research Coordinator

Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

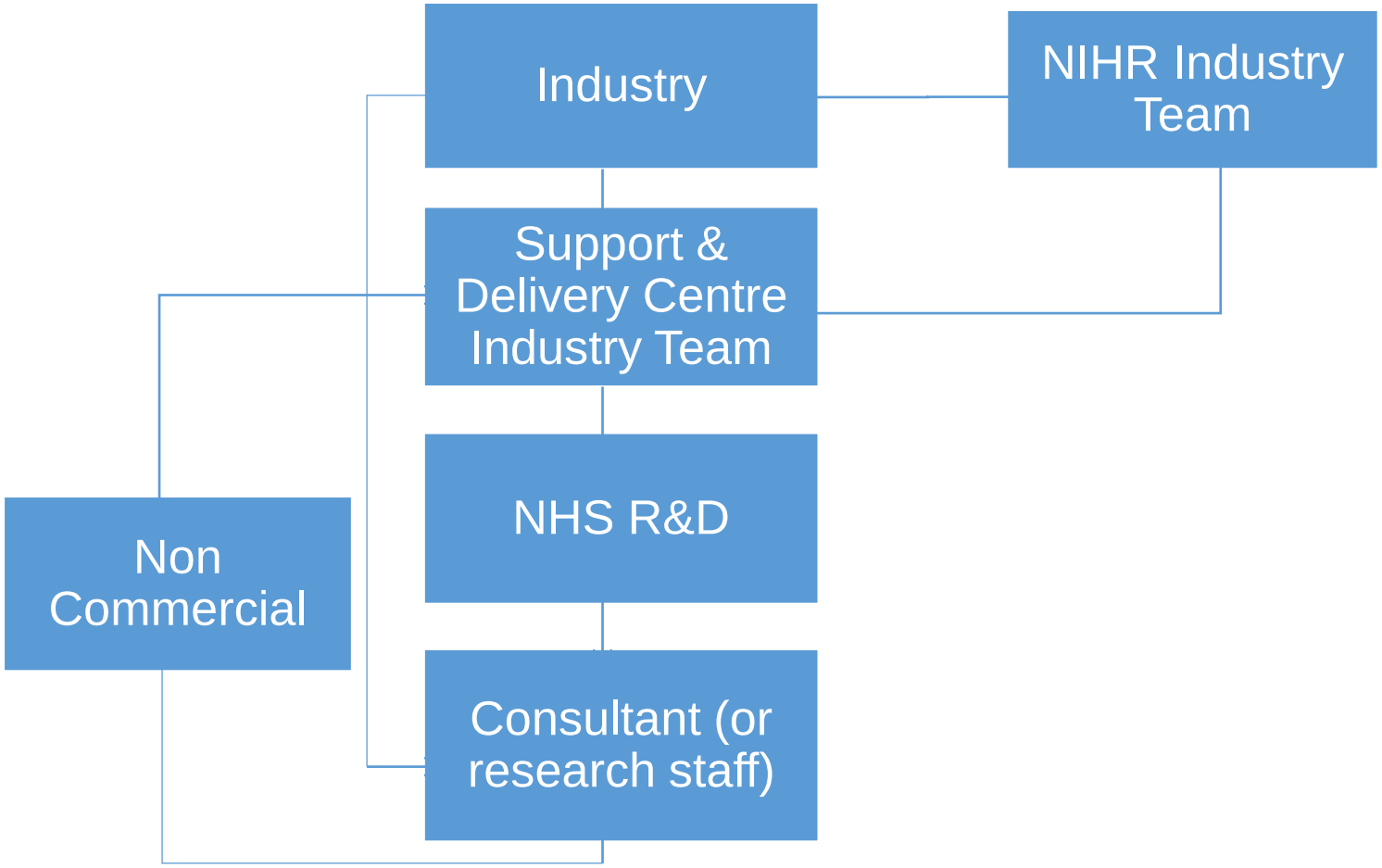
What is Feasibility?

- Feasibility assesses the suitability of a given site to participate in a proposed study. All factors at site level are taken into consideration in this feasibility assessment, such as qualification and experience of the investigator, presence of experienced study staff, good research infrastructure, availability of target patient population.

- Feasibility happens in the period between being approached to participate in a study…. and commencing study setup.
- 5 main stages to feasibility which will be covered during this presentation.

Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

Routes for Feasibility



Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

Stages of Feasibility

1 Early feedback (national level)

2 Expression of Interest (also referred to as site Identification)

3 Site list review (performed by sponsor)

4 Detailed feasibility

5 Site selection visit

Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

1 Early Feedback

- This service provides expert guidance for protocol development, set-up and helps guide decision to place a study in Wales or the UK.

  Examples of questions from Industry include:

❖ We have an early study synopsis and would like feedback on the design to advise our protocol development team of whether it would work in Health Boards in Wales.

- Providing early feedback is a really positive way of being involved in the earliest stages of feasibility. Opportunities to provide early feedback should be embraced as they may allow you to influence protocol development.

Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

2 Site Identification (expression of interest) – Central UK Process

- Managed by NIHR but involves all four nations.

- Intended to facilitate the rapid identification of interested sites for commercial sponsors. It is to help sponsors gather high level feasibility rapidly.

- Sponsor obtains the information needed to be able to identify sites they wish to perform more detailed feasibility with (these are normally sites that meet minimum requirements from the sponsors perspective).

- Site ID process is just an expression of interest and is not in any way a binding agreement. The sponsor is providing a limited set of information for the site to make an assessment on.

Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

2 Site Identification (expression of interest) Central UK Process - Paperwork

- Often a confidentiality agreement (CDA) has not been signed at this point and so there will be limited information available – but you should go ahead and complete the Expression of Interest anyway.

Documents you will receive are:

Section B form, schedule of events and a site identification questionnaire.

- The site identification form can be considered similar to a CV:

- Be concise. Keep the information provided to the point and avoid long text that does not add value.
- Be truthful and realistic – especially regarding recruitment rate and target.
- Make sure to use good English and use spell check before submitting.
- List your unique selling points. What makes your organisation different or better than others? Local geography? Patient Population? You or your teams experience? Specialist Equipment?

Sponsors see a lot of completed questionnaires, a well written EOI that demonstrates enthusiasm and stands out may well make all the difference.

Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

2a Site Identification (expressions of interest) direct from Industry

- EOIs don’t just come through the central UK system which is overseen by the NIHR
- We also receive EOIs directly from Industry. The same principles apply, but there isn't always an official document to complete.
- The CRO or Sponsor will usually send an email containing limited information and will then ask for sites to provide an EOI along with an estimate on patient numbers
- Sometimes the UK office of a sponsor or Contract Research Organisation (CRO) may use this process to help inform a bid to bring the study to the UK.

Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

3 Site list review

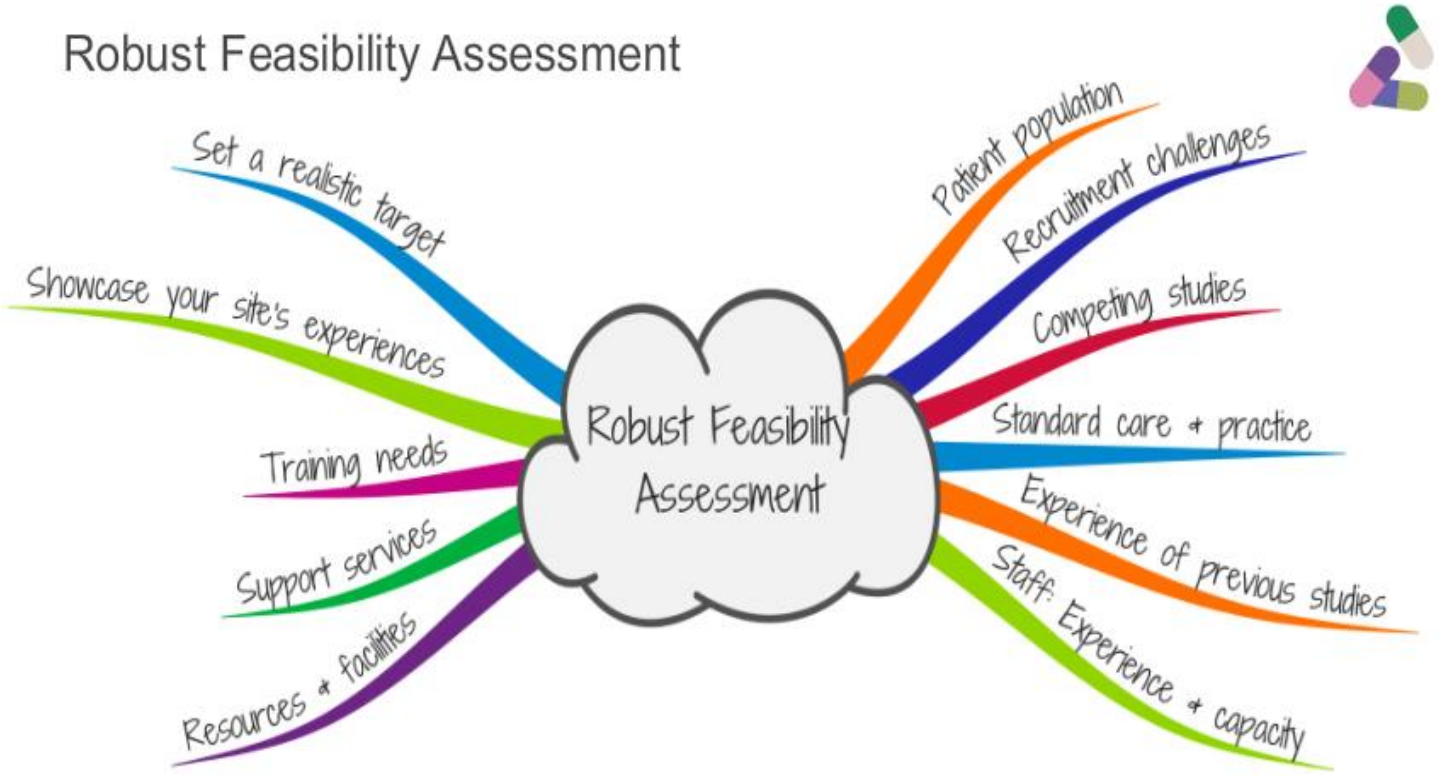
- This process is not handled by the Support and Delivery Centre
- The sponsor will review the list of sites that have expressed interest and will select those they wish to perform a more detailed feasibility with.
- They will focus on

- Patient numbers
- Specialist equipment
- Staffing levels
- PI experience
- Competing studies

Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

3 Detailed Feasibility

- CDA Signed and protocol released - now you should perform a more robust feasibility at your site.
- **National Institute of Health Research (NIHR)** advise you focus on the following areas when conducting in-depth feasibility at your site:



Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

Detailed Feasibility

Tips for completing questionnaires

- Industry Questionnaire can be a challenge
- They can use European or American terminology which can cause confusion.
- Questionnaires can be time consuming to complete.
- Can ask technical questions about support departments. This information may be difficult to obtain.
- Timelines can be a challenge.
- Keep in touch with the company – tell them if there will be a delay in returning the questionnaire and give details.
- If you are unsure on what the question is – go back to the company for clarification.
- Keep a capability folder or document which you can refer to, it might contain information about pharmacy, storage, fridge freezers, centrifuges etc.

Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

Site Selection Visit

- This is the final stage and last chance to showcase what you can do
- The visit is normally performed by a CRA (Clinical Research Associate)
- Involve a review of the protocol and discussion about any challenges the protocol might present and how the PI and team would handle the challenges
- Discussion about eCRF and ehealth records
- Discussion about patient numbers, availability of population and recruitment plan
- Any conflicts between Standard Care and recruitment criteria?
- Discussion about availability of PI and research staff.
- Availability of specialist equipment and support services.
- Also often asks about process for contracts and costings and how long negotiations take.
- Potential start date and FPFV (first patient first visit)
- Visit pharmacy, outpatient/ day care units and other clinical areas.

Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

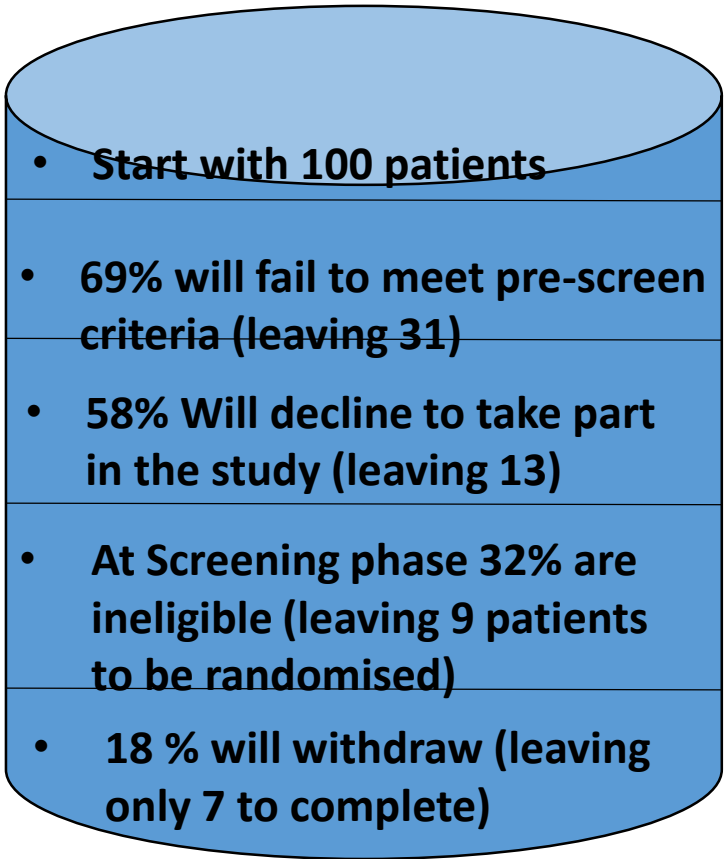
Tips for Site Selection

- Know your protocol.
- Have all your questions ready.
- Ensure all departments and staff have seen the protocol and raised any concerns or clarifications they require.
- Ensure all departments and staff are informed and are available on the day of visit.
- Ensure that meeting room is booked and that all IT required is setup. E.g. if a presentation is being given.
- Ensure PI turns up!

Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

Estimating patient numbers - The Leaky Pipe - by Beth Harper

- President of clinical performance partners, worked on supporting and rescuing over 200 studies as a specialist consultant.
- Performed a study that used information from studies conducted in the United States between 1998-2012 to produce typical funnel of patients from identification to randomisation.



Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

Remember…

- Not all patients you identify will be eligible. Ratio according to Harper's funnel is less that 10:1

- Those remaining may not pass the screening process.

- Of those who get through screening they may not agree to participate.

- Not all those randomised will complete the study (drop outs).

Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

Estimating Patients numbers

Speak to your PI – ensure the population are present in your Health Board.

How many patients did the PI see last year with particular condition?

Ask PI to consider how many of those he feels would be eligible to enter the study.

Consider limiting factors such as availability of PI and Research Nurse and whether they will always be available to approach and recruit. I.e. annual leave, sickness study leave and clinical commitments.

Take into consideration at what point in the year the study will open, do you have a full year to recruit, or just 6 months.

Over estimation of patient numbers by PI often leads to unrealistic targets.

Consider quoting a range e.g. 3-5

Quote the pace e.g. 2-3 per month

.

Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

Exercise

For the next 20 minutes please review the section B form and then in your groups go on to complete as much of the Site Identification form as you can. We will take 10 minutes at the end of the session to feedback.

Think about:

- Patient numbers
- Supporting information
- What would help you “stick out” as a site

e.g. won all studies applied for in this disease area, we’ve not been turned down for a study.

e.g. list specialist equipment or centres.

e.g. previously a Chief Investigator (CI) or considered a Key Opinion Leader (KOL) / Speciality Group Lead (SGL) in this area.