Research Awareness for Pharmacy (Secondary)
Welcome

- The importance of clinical research
- Ways that pharmacy can support clinical research
- Ways that pharmacy can contribute to clinical research
- Further information and support
The importance of clinical research
Why is clinical research important?

“Research is central to the NHS...

We need the evidence from research to deliver better care. Much of the care that we deliver at the moment is based on uncertainties or experience, but not on evidence.

We can only correct that with research.”

– excerpt from NIHR video
Enhancing Patient Care Through Research

Professor Dame Sally Davies, Chief Medical Officer for England, Director General of Research and Development and Chief Scientific Adviser for the Department of Health and NHS.
Research is a frontline service

The NHS is committed to “continuous improvement in the quality of services [patients] receive, identifying and sharing best practice in quality of care and treatments”.

An example of the importance of pharmacy in clinical research

The development of Herceptin®, the brand name of a medicine called trastuzumab

Research Idea

Research discovered that HER2 was amplified in some cancers and was associated with poorer outcome.

HER2 became a good target for drug development.
An example of the importance of pharmacy in clinical research

The development of Herceptin®, the brand name of a medicine called trastuzumab

<table>
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<tr>
<th>Research Idea</th>
<th>Clinical Trials</th>
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<tr>
<td>Research discovered that HER2 was amplified in some cancers and was associated with poorer outcome.</td>
<td>A monoclonal antibody drug was developed to block the receptor activity of HER2.</td>
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<td>HER2 became a good target for drug development.</td>
<td>The monoclonal antibody drug eventually became known as trastuzumab (brand name Herceptin®), and was tested in clinical trials.</td>
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The development of Herceptin®, the brand name of a medicine called trastuzumab.
Research is important to patients

How important is it to you that the NHS carries out clinical research?

- Very/fairly important: 93%
- Not important: 2.4%
- Don’t know: 5%
- Don’t know: 4.7%

How important is it to you to be offered new treatments by your healthcare professional?

- Very/fairly important: 94%

Results are taken from a Censuswide consumer poll of 3,000 people in England, commissioned by NIHR CRN in September 2014.
Inspirational experiences from patients, their families and carers

We've gathered some fantastic stories from people across England, whose lives have been transformed by clinical research. All you need to do is click on the links below to access experiences relating to a wide range of conditions. You'll find short-films and videodiariews to explore, plus audio and written accounts too.

Our vision is for Wales to be internationally recognised for its excellent health and social care research that has a positive impact on the health, wellbeing and prosperity of the people in Wales.

Strategic Aims (part 1)

To achieve our vision we will:

• ensure public involvement and engagement is central to what we do and visible in all elements of it;

• ensure our work is aligned to Welsh Government policy and has real impact;
Health and Care Research Wales

Strategic Aims (part 2)

To achieve our vision we will:

- fully integrate our infrastructure and programmes across health and social care;

- invest in areas in which Wales excels and is unique;

- increase capacity in health and social care research in Wales;

- develop systems that ensure excellent delivery and maximise the use of our resources.
Summary

- High quality research stops us making assumptions and ensures we have the evidence we need to deliver better care.

- Research is a frontline service, making a vital contribution to the improvement of the NHS and the treatments and services it delivers.

- Pharmacy staff actively contribute to the research process, and are essential in ensuring the delivery of high quality clinical research.

- Health and Care Research Wales ensures that the delivery and support for research and development in the NHS and social care in Wales enables studies to happen as quickly and efficiently as possible.
Pharmacy can *support* clinical research in a variety of ways.
Being aware of and promoting clinical research

You can support research by being positive about research and directing people to useful information

The UK Clinical Trials Gateway provides easy to understand information about clinical research trials running in the UK. It is designed to enable patients and their clinicians to locate and contact trials. [http://www.ukctg.nihr.ac.uk](http://www.ukctg.nihr.ac.uk)


HealthWise Wales is an opportunity for everyone in Wales aged 16 or over to take part in research for better health, care and wellbeing. [https://www.healthwisewales.gov.wales](https://www.healthwisewales.gov.wales)
Encountering clinical trials medicines in normal practice

You may come into contact with clinical trials medicines in your everyday work:

- Medicines returns
- Medicines use reviews or reconciliation.
Medicines returns

• Clinical trials medicines could be returned to you along with other medicines

• Look for the study team’s details on the label

• Contact them to let them know the medicine has been returned to you and why (eg. the patient has died)

• They will tell you whether they need you to return or destroy it

• If they ask you to destroy it, check for any special instructions.
Medicines use reviews or reconciliation

- During a MUR you might identify that a patient is participating in a clinical trial.

- You may identify concerning issues such as:
  - their adherence to the trial instructions provided is poor
  - they express concerns about remaining on the study

- Establish as much information as practical

- Advise the patient to contact the study team and, if necessary, their GP

- If you feel it is appropriate to raise the issue with the study team yourself, ask for the patient’s permission to do so

- Record your actions in the Patient Medication Record (PMR).
Adverse events

• A patient might also tell you about an adverse event, such as a potential side effect or a minor injury they have suffered

• An **Adverse Event (AE)** is any untoward medical occurrence which happens during a study

• Adverse events **do not** have to appear to be related to the study medication or procedures

• Sometimes it is only when data from a very large number of people is collated together that patterns emerge showing the medicine is resulting in unexpected reactions

• If the patient is participating in a study your Health Board/Trust is involved in, **follow your local SOPs** for notifying the study team about adverse events.
**Adverse events**

- If the patient is involved in a study being conducted by another organisation, contact the study team to let them know about the side effect reported.

- They should not need any patient identifiable information, but they are likely to need the patient identification number, batch number and other information on the label.

- Advise the patient to tell the study team about the side effect themselves as well. They will have been provided with contact details for the Health Board/Trust that recruited them into the study.

- You might also suggest they let their GP know, depending on the specific circumstances and side effects.

- If you cannot contact the study team, report the side effects using the MHRA Yellow Card scheme.
Pharmacy can *contribute to* clinical research in a variety of ways.
Identifying potential research participants

- Identifying the right people to participate in research is an important part of conducting effective studies

- Pharmacy may be asked to
  - display a poster about a specific study
  - give leaflets about a study to patients who meet certain criteria
  - search patient databases to identify and contact patients who meet certain criteria

- All study activities, including those to identify potential participants must be approved by a Research Ethics Committee, which the researcher will arrange

- It is important your Health Board/Trust clinical research lead agrees the activity is appropriate before agreeing to anything.
Identifying potential research participants

• You must carry out any activities in line with the instructions provided by the researchers. Do not change any language or images in the letters, leaflets or posters provided.

• The researchers will notify you when the study has begun and you can carry out the activities required, it is important not to begin the study before all the checks and approvals are complete.

• The documents can be changed several times before they are approved by the Research Ethics Committee. New versions can also be provided once the study has begun. Ensure you are always using the correct version.
Pharmacy can also *contribute to clinical research* by...

- Providing a **study intervention** such as weight loss or smoking cessation support

- Ensuring study medicines are **stored** appropriately and the right participant receives the **right medicine** at the **right dose**

- ** Recruiting participants** into studies and **gathering data** to answer the research question
Find out more

- If you’re thinking about engaging in research activity, talk to your organisation/company/Health Board/Trust clinical research lead or research and development department.

- Health and Care Research Wales provides an innovative infrastructure to support and increase capacity in research and development. [https://www.healthandcarereresearch.gov.wales/research-infrastructure/](https://www.healthandcarereresearch.gov.wales/research-infrastructure/)

- Health and Care Research Wales also provides training to help you deliver research activities effectively. [https://www.healthandcarereresearch.gov.wales/training-and-development/](https://www.healthandcarereresearch.gov.wales/training-and-development/)
Session complete!

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