CANCER RESEARCH UK

Induction and training information for new patient and public involvement representatives at our clinical trials units

December 2025

Together we are beating cancer

Contents

01. How to use this resource

CANCER RESEARCH UK

Support for patient and public involvement in clinical trials and studies

This resource is designed to support patient and public involvement representatives who want to learn more about being involved in the development of clinical trials and studies at our clinical trials units.

Whether you are new to it or already involved, there are a few different areas for you to explore.

1. Patient and public involvement in clinical trials and studies
2. Introduction to clinical trials, studies and clinical trials units
3. Patient and public involvement in each stage of clinical studies
4. Statistical information and definitions: the numbers behind clinical trials
5. Protocol development: the instructions and procedures involved in delivering a clinical trial

Key acronyms you may find useful

We've tried to avoid using acronyms throughout this resource. But as a patient and public involvement representative, you may come across some of these common ones related to clinical trials and studies.

AE	adverse event
CI	clinical investigator
CTU	clinical trials unit
FIH	first-in-human
GCP	Good Clinical Practice
HRA	Health Research Authority
IC	informed consent
PI	principal investigator
PIS	participant information sheets

PPI(E)	patient and public involvement (and engagement)
SAP	statistical analysis plan
PV	pharmacovigilance
QA	quality assurance
R&D	research and development
SOP	standard operating procedures
SAE	serious adverse event
TSC	trial steering committee
TMG	trial management group

02. Patient and public involvement in clinical trials and studies

CANCER RESEARCH UK

What is patient and public involvement?

Patient and public involvement is essential for all parts of designing, delivering and sharing findings of clinical trials and studies. Testing new cancer treatments and clinical interventions depends on people agreeing to take part in research.

Patient and public involvement in clinical studies doesn't mean taking part in a study. It means getting involved to help make sure that clinical studies are relevant to everyone's needs, are acceptable and designed in the best possible way for those who take part and benefit from the study in future.

This is essential for all parts of designing, delivering, and sharing findings of clinical trials and studies.

Participation, engagement and involvement

Participation, engagement and involvement of people affected by cancer and members of the public* can all add value to research in different ways. Here's how we define these terms.

Participation	Engagement	Involvement
Participation is where patients or healthy volunteers take part in a research study. They are the subject of the study and the research is being done **to** them, not **with** them. Participation is necessary to help researchers progress their research and gain data.	Engagement is where information and knowledge about research is **shared with the public.** Examples of this can include lab tours, research open days and blogs. By sharing their progress and passion, researchers can help inspire more people to get involved.	Involvement is when people affected by cancer or members of the public use their experiences of cancer to help shape research. This means research is carried out **with** or **by** patients rather than **to** or **for** them. Researchers can work with them to help define research questions, plan and design research, develop patient-facing documents or share progress.

**Referred to generally in this resource as patients and the public i.e. 'patient and public involvement'.*

Why is patient and public involvement important?

Patient and public involvement representatives can get involved to shape clinical studies in different ways. One example is through our clinical trials units, which is the focus of this resource.

People who have experienced health conditions such as cancer are important as their experiences can help make sure clinical trials and studies are relevant, meaningful and effective. Your insights help researchers design these trials in a way that truly meets the needs of the people who will participate and benefit from the results in the future.

Research and clinical trials may not reflect real-life scenarios and can overlook important nuances (such as family life or individual circumstances). This may result in researchers asking questions or designing trials that don't necessarily match what patients really want or need. This is why the input of people with experience as a patient, carer or family member of someone with cancer is important.

Getting involved in clinical trials

Here are some ways to patients, carers, family members, members of the public and representatives of community organisations or charities can get involved:

- ask questions
- make suggestions
- review materials
- add different perspectives

This will help health care staff and clinical trial professionals to design, manage and communicate clinical trials and studies for people invited to take part. It will also help those who will benefit from better treatments and health care in future.

Hear about patient and public involvement from our network

Watch this video to hear about why some of our patient and public involvement representatives decided to get involved.

Link

Watch this video to hear about some of our patient and public involvement representatives' most memorable experience in the role.

Link

Watch this video for advice and support for those who are new to patient and public involvement.

Link

Find out more:

Learn more about patient and public involvement at Cancer Research UK.

Link

Visit the National Institute for Health and Care Research website for patient involvement information.

Link

Visit the Medical Research Council Clinical Trials Unit website for patient involvement information.

Link

Watch this video to learn more about how patients, members of the public or people with lived experience are actively involved in research.

Link

Explore a non-exhaustive glossary of some terms you may also come across.

Link

03. Introduction to clinical trials, studies and clinical trials units

CANCER RESEARCH UK

What are clinical trials and studies?

Clinical research is the study of health and illness in people. Participation in clinical research helps researchers to develop new medications and other strategies to treat and prevent disease. There are two main types of clinical research, clinical trials and observational studies.

- **Clinical trials** are medical research studies involving people to thoroughly test interventions such as new drugs or devices. They may also compare different treatment options. Researchers test possible new interventions in the laboratory to begin with. If they look promising, they follow strict rules to carefully test them in people starting with a small group.
- In **observational studies**, researchers collect information from people in normal settings and compare changes over time. Observational studies do not test a medical intervention, such as a medication or device, but can help identify new treatments or prevention strategies to then test in clinical trials.

Both clinical trials and observational studies come under the broad term clinical studies.

What is a clinical trials unit?

Clinical trials units are specialised centres that design, coordinate and analyse clinical trials and studies. They can be generic or specialised in any or a mix of the following:

- Different types of trials and studies such as methodological studies including randomised controlled trials. This means comparing a new treatment to the current treatment assigning participants randomly to equal numbers with a computer programme. You can find out more in our statistical information section of this resource.
- Health conditions such as cancers.
- Specific phases and types of clinical trials such as early to later phase trials.

Hear about clinical trials units from our network

Learn more about his role and what a clinical trials unit is from Professor Allan Hackshaw, Director of our University College of London Clinical Trials Unit.

Link

Watch this video to hear about the roles of a statistician, trial manager and data manager at a clinical trials unit.

Link

Watch this video to learn how roles within clinical trials units interact with patient and public representatives and hear about the value they can bring to a clinical trial.

Link

Find out more:

Learn about clinical trials from Cancer Research UK.

Link

This video explains the different phases of clinical trials.

Link

Find out more about our Cancer Research UK funded clinical trials units.

Link

Watch this video to learn more about how patients and the public are actively involved in research.

Link

This video from University College London Hospital explains health research including clinical research and observational studies.

Link

Explore a non-exhaustive glossary of some terms you may also come across.

Link

04. Patient and public involvement in each stage of clinical studies

CANCER RESEARCH UK

Understanding the roles and stages of clinical studies

There are many opportunities for patient and public involvement representatives to help shape a clinical study and trial. This overview shows examples how these representatives can be involved at each stage of clinical studies at clinical trials units.

As you read through this information, you can also refer to the videos linked on slide 16. Or explore our one-page roadmap that outlines the stages of clinical studies and how patients and the public can get involved at each stage.

Access the roadmap

1 Idea

A chief investigator* comes to a clinical trials unit with an idea for new study or trial.

Patient and public involvement representatives do not need to be experts within this area, but they can help in the following ways at a clinical trials unit:

- Prioritising research areas and types of studies that are supported.
- Providing views on studies that may be managed

**Someone responsible for the trial design, conduct and reporting across all participating sites.*

EXAMPLE

Patient and public involvement representatives review and comment on a study proposal before the clinical trial unit decides if they can support and manage the study. This may be as part of workshop/focus group, or you may be invited to work with the research group.

2 Design

The trial design is developed, and the study team applies for funding. Patient and public involvement representatives can give input into design of a study or support the development of a funding application.

This means they can highlight practical issues from a patient and public perspective to prevent there being any potential barriers to people joining a trial.

EXAMPLE

Patient and public involvement representatives add their views on:

- Design of the study: Plans to recruit a representative patient population including targeted recruitment for underrepresented groups working with relevant communities, outcome measures that are important to patients, the acceptability of additional study visits and procedures commitments, the use of participant data, potential challenges to taking part and ideas how to address them.
- Funding application: Plain language summary, communication, reinforcing the relevance of the research in this area and on any patient and public involvement plans.

3 Set-up

Funding starts and the study is set up. Patient and public involvement representatives support by:

- Adding views on the study protocol development.
- Giving views on ethical questions for approval from ethics committees (review research proposals to ensure the rights, safety, and well-being of human participants are protected).
- Reviewing patient/participant information sheets* and other patient-facing communication materials.

**A document explaining all relevant study information to assist trial participants in understanding the expectations and requirements of participation in a clinical trial*

EXAMPLE:

Patient and public involvement representatives can advise on how to best communicate a study to potential participants and their carers. They can also advise on layout of study materials and help to make them easy-to-understand and identify potential barriers to people taking part in the study and how to overcome these challenges

4 Delivery

The study opens and starts to recruit patients to the study. A study/trial management group* is responsible for the study, and the study is closely monitored as it progresses.

Patient and public involvement representatives can add a patient and/or carer perspective on all aspects of the study as an active member of the study/trial management group. They can also monitor progress of studies and data collection as a member on a study/trial steering committee** or data monitoring committee***.

**Includes the people responsible for the day-to-day management of the trial.*
***Provides overall supervision of the trial, monitoring progress and conduct and advising on scientific credibility.*
****Looks at the safety and design of the trial and regularly checks progress.*

EXAMPLE:

Patient and public involvement representatives can plan and adjust recruitment strategies through community engagement and developing videos.

Or they can support on:

- In a study/trial management group advise how to communicate the study to patient networks or underrepresented groups or add ideas to improve plans if recruitment is lower than expected.
- In study/trial steering committees suggest potential solutions on challenges during the study delivery.
- In data monitoring committees contribute to data being used in the best interest of patients.

5 End of study

Study information (data) is analysed and interpreted. Study findings are written up and published. Patient and public involvement representatives can:

- Help to analyse and interpret study data.
- Review and contribute to the write up of the findings including plain language summaries.
- Advise on the communication of finding to stakeholders including study participants, health care professionals, researchers, policy makers and patient and public involvement representatives.

EXAMPLE:

Patient and public involvement representatives add their perspectives on data from the study, help to write up how patient and public involvement was included in the study in the publication, review a plain language summary for study participants and advice on way to communicate findings to a patient and public audience.

Find out more:

Explore a non-exhaustive glossary of some terms you may also come across.

Link

Read this article on Cancer Research UK's Cancer News platform on "Going public - the how and why of patient and public involvement"

Link

Learn about patient involvement at Cancer Research UK

Link

Find out how patient and public involvement representatives can be part of committees that decide which studies get funded.

Link

Patient and public involvement representatives can support the training of professionals. Read this blog post about a workshop to write better patient information sheets.

Link

Get involved as a patient and public involvement representative in clinical studies by contacting the Cancer Research UK public involvement team.

Link

05. Statistical information for clinical trials

CANCER RESEARCH UK

The numbers behind clinical trials

Here we'll provide definitions of different terms you may come across when talking with statisticians about clinical trials. Statisticians help ensure that experiments are designed, run and analysed in the best way to meet the study objectives.

The information is separated out into the three different key areas of a trial:

- idea and design
- delivery
- trial analysis

If you come across any other terms you think should be included here, please contact us at clinicalresearch@cancer.org.uk.

You may find this video useful to help you understand statistical information in clinical trials. Hear from Holly Tovey about the roles of a statistician, trial manager and data manager at a clinical trials unit.

Link

Trial idea and design

Sample size	How many participants are needed in the trial so that we can answer the question.
Statistical power	With the results from any trial there is an element of unknown because a small number of people take part (the sample) compared to all those people with the disease or condition (the population). We must decide before we start the trial how sure or confident we want our answer to be. The level of power chosen is a percentage. Ideally, we want to have a high level of power (for instance 90%) so that we are as sure as possible that the new intervention is better than the one that it is compared against.
Statistical significance	The results of a trial are statistically significant if the data collected in the trial has answered the trial question with enough certainty. The level of significance is used to show how confident we are that our findings are a new discovery and that the results could not have happened by chance.
Statistical hypothesis	A hypothesis is a statement that predicts the outcome of a trial. This will be proven or disproven based on the data collected during the trial.

Trial delivery

Expected recruitment	How fast or slow the trial plans to recruit participants. This will usually include how many people are joining from how many places over a defined period. For example, a trial may plan to recruit 500 participants from 10 sites over 5 years.
Recruitment rate	The speed at which participants are joining the trial. It might be given in terms of months, e.g. 10 patients a month or by site eg 5 patients per site per year.

Trial analysis

Statistical analysis plan	The statistical analysis plan is a document detailing how the trial statistician will use the data collected on trial participants to answer the trial research question.
Statistical assumptions	To apply statistical models, we must specify some conditions which may or may not be true. We call these assumptions.
Primary analysis	This is the main analysis which will take priority and aim to answer the research question.
Sensitivity analysis	This is an additional analysis to see if the answer to the research question changes when an assumption is changed. This is to check that the results from the primary analysis are valid.
Subgroup analysis	This is an additional analysis to see if the answer to the research question changes in different groups of participants. This is used to create new questions and could consider different ethnic groups, ages, or disease characteristics.

Find out more:

Learn about trial phases and how trials can use a small number of patients to check if an intervention is safe or a lot of patients to see if an intervention makes people live longer.

Link

Find out about the difference between an observational trial and an interventional trial, including information about different types of trial designs like a multi-arm multi-stage trial and a cohort trial.

Link

Learn what a primary and secondary endpoint is and how some of the more commonly used endpoints are defined. Sometimes endpoints are referred to as outcomes or outcome measures.

Link

Find out about randomisation, or how trial participants are fairly split between the different trial interventions or treatments.

Link

Explore a non-exhaustive glossary of some terms you may also come across.

Link

Read a blog post on statistics in clinical trials from a patient and public involvement representative.

Link

Read this dedicated blog on the numerical aspects of trials which was made to help make the numerical aspects of trials more accessible.

Link

Explore this glossary of some statistical terms you may hear when working with statisticians, created by some researchers working in statistics.

Link

06. Protocol development for clinical trials

CANCER RESEARCH UK

Protocol information for clinical trials

A clinical trial protocol is a roadmap or manual for exactly how a trial will be run.

Many different people are involved in delivering a clinical trial and often trials will recruit participants at lots of different locations across the country, or even internationally. So, it's vital that everyone follows the same set of instructions and procedures. The protocol sets out the expectations and duties of everyone involved.

As a public and patient involvement representative, you may come across clinical trial protocols in a variety of different roles. This section explains when you are likely to come across protocols if you are working with a clinical trials unit, as well as the different sections of a protocol and which ones may be most relevant for you to read as a patient and public involvement representative.

Not all patient and public involvement roles with clinical trials units will involve looking at the trial protocol. But there are some occasions when you may be required to read or review the protocol.

To help you understand where protocol development fits into the clinical trial process, explore our one-page roadmap. It outlines the stages of clinical studies and how patients and the public can get involved at each stage.

Access the roadmap

Patient and public involvement and protocols

Design

During the very earliest stages of the trial design, you may be asked to input into the development of the trial protocol.

This is most likely if you have been invited to be a co-applicant on the funding application for a trial, or if you are part of the trial management group during the very early stages of the trial design.

Set-up

Once the trial has been funded and is in set-up, the protocol will be finalised and approved by the ethics committee and if applicable, regulatory authority, ready to be used when trial begins.

At this stage, if you are a patient and public involvement representative on the trial management group you may be asked to review the protocol and give feedback, especially on the sections relating to patient safety, hospital visit schedules, and publication plans.

Patient and public involvement and protocols (continued)

Delivery

During trial delivery, if you are part of the trial management group or an oversight group such as the trial steering committee, you will be given the protocol to read. You may also be asked to help with amendments to the trial protocol.

Amendments may be needed if there are issues with trial recruitment or changes to trial design and your input as a patient and public involvement representative can help make sure these amendments will be acceptable to trial participants.

Write up and publication

At the end of a trial, the research team will analyse the results and publish the findings. The team will refer to the protocol and the publication plan to do this.

If you are a public and patient involvement representative on the trial management group or who has had lots of involvement in the trial, you may be asked to help with this and may need to refer to the protocol for guidance.

Sections of a protocol

A protocol is often an exceptionally long document with many sections covering the background, objectives, trial design, safety, and much more!

As a patient and public involvement representative, there are certain sections which will be relevant and helpful to you in your role, but others that are not so important for you. Here are a few of the sections which are most relevant, and you may want to prioritise if reading a protocol.

Note: before reading the trial protocol, ask the research team if there is a lay summary of the trial they can send you. This will give you a good, basic understanding of the trial before you get into the more complex protocol.

Sections of a protocol (continued)

List of abbreviations

This is usually near the start of the protocol and will give you a list of most of the common abbreviations used in the document. Many will be generic trial terms that will be in most protocol documents, and some may be more specific to the disease area or design of a certain trial.

Trial summary/ synopsis

This provides a short overview of what is involved in the trial, such as the number of participants, how long it will run for, the main outcomes being measured, etc. It can be useful if you want to quickly check basic information about the trial.

Background and rationale

These introductory sections of the protocol provide information on the disease or condition being researched, previous research and evidence about treatments, why the trial is important and what the research team hope to learn from it, as well as potential risks and benefits to participants. There may be quite a bit of scientific terminology and jargon, so it is helpful if you have read a lay summary of the trial before reading this.

Sections of a protocol (continued)

Objective and outcome measures (endpoints)

It's important that everyone understands what a clinical trial is hoping to achieve and how success or evidence will be measured. The protocol sets out exactly what clinical outcomes, or endpoints, will be used to indicate whether the trial is successful. Some endpoints will be 'primary,' such as the main indicator for whether the treatment or intervention has worked, others will be 'secondary' or 'tertiary,' such as looking at quality of life measures or whether a new treatment is cheaper than the current standard of care.

Trial design

There are many ways a clinical trial can be designed, depending on the treatment being studied, the patient population and what endpoints need to be measured. The protocol explains elements such as whether participants are 'randomised' (when trial participants are randomly assigned to the trial treatment or control groups), whether the trial is 'blinded' (when participants or researchers don't know who is randomised to the treatment or control), and which statistical methods are being used to analyse the data. As a patient and public involvement representative, it is helpful to understand the design of the trial.

Sections of a protocol (continued)

Participant eligibility criteria

Not all clinical trials will be suitable for all patients, even if they have the disease being studied. Things like other illnesses, previous treatment, or even a participants age may have a bearing on whether they should take part. This is to keep participants safe and make sure the data being collected in the trial is a true reflection of the whether the trial is successful.

Trial procedures and treatments

This section of the protocol outlines what procedures the trial participants will have as part of the trial and when these will happen. As a patient and public involvement representative, it's good to understand whether there is extra hospital visits involved, extra procedures such as scans, blood samples or biopsies, or things participants need to do in their own time, like filling in questionnaires or online assessments.

Sections of a protocol (continued)

Safety (pharmaco-vigilance)	The safety of trial participants is of the utmost importance. This section outlines any known or expected side effects from the trial treatment and how any unexpected side effects, called adverse events (AE) or adverse reactions (AR), should be recorded and dealt with.
Ethical considerations	All clinical trials are reviewed by an ethics board. A clinical trial protocol must include considerations of how taking part in the trial will affect participants and how their personal data will be collected, stored, and shared between members of the research team. The protocol must be formally approved by the ethics board before the trial can take place.
Dissemination/ publication policy	Reporting the findings of a clinical trial is vital to the research community, the health service, and patients. As a patient and public involvement representative you may be involved in helping to write a research publication that will be published in an academic journal, or in helping to find ways to publish the outcomes to patient groups and the wider public, so knowing what is in the trials publication policy may be helpful to you.

Find out more:

This template from the Health Research Authority is used by trial teams as a guide to writing protocols.

Link

Explore a non-exhaustive glossary of some terms you may also come across.

Link

Acknowledgements

CANCER RESEARCH UK

Developed by the Cancer Research UK clinical trials units' patient and public involvement working group

Including members from the following clinical trials units:

- Cancer Research UK and UCL Cancer Trials Centre
- Cardiff University Centre for Trials Research
- Glasgow Clinical Trials Unit
- Oxford Oncology Clinical Trials Office
- Queen Mary University of London Cancer Research UK Prevention Trials Unit
- Southampton Clinical Trials Unit
- The Institute of Cancer Research Clinical Trials and Statistics Unit
- University of Birmingham Cancer Research UK Clinical Trials Unit
- University of Leeds Clinical Trials Research Unit