Tackling cancer through research

Collaborating and delivering for patients in Wales

Purpose

The Welsh Government and wider research community is committed to delivering an ambitious, collaborative approach to improving cancer outcomes for the people of Wales.

Some of the most current, innovative and 'state of the art' cancer treatments, diagnostics and prognostics are available only through clinical trials that help find the most effective means to prevent, diagnose and treat cancer. Some trials help answer questions about interventions already in use, other trials may test whether combining treatments is more effective or they might focus on different ways to give a treatment, so it is more effective or causes fewer side effects.

Clinical trials help make new options available, from enhancing earlier diagnosis, optimising patient benefits form current therapies or when all other known treatments have been exhausted. As part of industry development programmes, whether in pharmaceuticals, radiotherapies, surgical, diagnostics or prognostics, having our clinical trial delivery environment in a state of readiness is important, as the faster the trials deliver, the faster the proven treatment could become a standard of care.

216 patients were recruited to commercial cancer clinical studies in Wales in 2023/24 and whilst this is an increase since the pandemic, it remains far too low. As a result cancer patients are missing out on opportunities to access new and novel cancer treatments.

In addition, it is estimated that industry funding of clinical trials helps generate £1.2 billion of NHS savings in the UK and supports 13,000 NHS jobs[1]. Delivering on our ambition will ensure that Wales generates more significant savings and supports more NHS jobs.

More research drives better patient outcomes and better services[2,3] and we must increase cancer research activity to realise these benefits for the people of Wales.

This plan sets out the challenge, ambition and actions we will take in Wales to:

- **deliver better cancer outcomes and survival for Welsh patients**
- **reduce healthcare inequalities**
- **attract greater commercial cancer clinical trial activity into Wales**
- **increase patient access to new and novel treatments via these trials**
- **attract investment in Welsh healthcare, employment and wider economy**

The aims of this plan are:

- ❖ to increase cancer patient recruitment to commercial clinical studies by 400% to over 1000 patients, by Q4 2027.
- ❖ to increase access to commercial clinical studies to patients with a diverse range of cancers, and from a diverse range of backgrounds and geographies
- ❖ *to increase the percentage of Phase 3 trials in Wales's commercial cancer trial portfolio to >50% by 2027.

Background

Research is part of core NHS business. Participation in trusted clinical research is one of the best measures of the quality of care being delivered by clinicians, organisations and cancer services in Wales. A strong research base offers a platform for innovation, results in better patient and population outcomes and social well-being, positively impacts on recruitment and retention, and contributes to economic productivity.

It is also known that patients admitted to more research active hospitals have more confidence in staff and are better informed about their condition and medication. [2-9]

The contributions of research to economic productivity is also widely documented[10-11] with numerous analyses supporting the case[12-14], with the **total impact of biomedical and health research in the UK on the UK economy** calculated to provide an annual rate of return between 17% and 25%.[15-18]

This includes additional health gain that UK research provides in the range of 7% to 10% per annum.[19] In other words, a £1 investment from public spending benefits the economy to an extent equivalent to receiving between 17p and 25p per year in interest each and every year after.[20-21]

It is also important to note that whilst clinical research is essential for the advancement of medicine; trials often enrol homogeneous populations that do not accurately represent the patient populations served. Representative and diverse research participation is necessary to establish fair standards of care, minimise outcome disparities between populations, and achieve and uphold social equity. This aligns with the Welsh Government's Duty of Quality Statutory Guidance 2023 and Health and Care Quality Standards 2023.

There is increasing interest within the industry community of the unique characteristics of clinical trial participants as it is hoped that this will lead to a better understanding of the variability in treatment responses in individuals and certain patient populations, including those currently under-studied and unable to access potentially beneficial research. Overall, this imbalance leads to substantial differences in their lifelong care, leading to additional health inequities.

The activities in this plan are starting from an already evolving space where there have been, and are, many developments and enablers in train to boost clinical research in Wales:

a) The **Wales Cancer Industry Forum (WCIF)** has wide industry membership, which meets alongside partners from charities, NHS, and HEIs. Over the last year, members have participated in various forums and workshops discussing the

challenges in delivering commercial cancer research, as well as potential resolutions to inform this plan

b) A united Welsh vision is in place via **Moving Forward: A Cancer Research Strategy for Wales ((CReSt)** overseen by the Wales Research Cancer Centre (WCRC)) which not only sets out our strengths and the importance of industry collaborations, but also importantly highlights the need to address the lower patient participation in trials compared to England and inequities in access for patients to research across Wales.

c) A strong **track record of excellence** (radiotherapy, immuno-oncology, precision oncology) with internationally renowned Welsh researchers leading and contributing to the global understanding of cancer at a UK and international level, and supporting infrastructure in place e.g. diagnostics, data linkage (SAIL) and genomics.

d) An existing dynamic research delivery improvement programme within Health and Care Research Wales' (HCRW) activities including **One Wales approaches** to research delivery, which includes nationally coordinated site identification, rapid feedback from clinical specialty leads and delivery experts, enhanced study set-up, a single price for Wales, a single review of contracts and a single study-specific point of contact for sponsors. Where appropriate to the trial, we can also deliver a 'One site' model enabling all recruitment from individual studies from the whole of Wales, or a referral pathway for research that crosses organisational boundaries (the equivalent process to the Cancer Vaccine Launchpad in England).

e) Active Welsh Government commitment to the response to the **Lord O'Shaughnessy review** now embedded in the UK-wide implementation programme of the UK Vision for Clinical Research Delivery, enables Wales to play its part in a wider UK ecosystem.

f) Wales' engagement in the **UK Lifesciences cancer mission** which aims to make the UK a leading testbed for oncology innovation by accelerating the development and commercialisation of a new generation of cancer diagnostics and therapeutics.

g) Recently signed **partnership agreements** between Health and Care Research Wales and two pharmaceutical companies - Moderna and BioNTech, as part of ambitions to accelerate research into mRNA vaccines including cancer vaccines. Following the success of Covid vaccines using the same messenger-ribonucleic-acid technology, scientists now want to conduct more trials in cancer patients. Some of the patients in the trials will have cancer that has already been treated and the vaccine will hopefully prevent it returning. Others will have advanced cancers that the vaccine might help shrink and control. A more programmatic approach to the delivery of a pipeline of trials is developing with a number of other companies – with the aim for Wales being a preferred partner.

h) The investment of approximately £22m over 5 years in Wales for commercial clinical trials as part the UK Government and Association of Pharmaceutical Industries (ABPI) 2024 voluntary scheme for branded medicines pricing, access and growth scheme, will enable us to strengthen our Welsh NHS research delivery infrastructure to deliver more commercial research, including cancer trials.

Implementation

In summary, and based on the outputs of several stakeholder events and workshops during 24/25, the key issues identified in the system that are perceived as critical barriers that need to be overcome are:

a. The need to put in place efficient referral pathways between NHS organisations across Wales and into UK sites so that patients can access suitable clinical trials
b. The need to balance population reach (geographical and economic equity of access to treatment options) versus local NHS organisation's autonomy and capability to prioritise support for different trials
c. The need to increase speed of set-up and delivering to the recruitment targets agreed, but also the need to open studies across multiple sites at pace to facilitate speedy recruitment to compete globally
d. The need to support staff to lead and participate in clinical research (and for some to develop their research and academic careers), and to ensure healthcare systems and organisations support the staff in their endeavours but also to build capacity and accountability to deliver research studies
e. The need to increase patient awareness that trials are open that might be relevant to specific patients (digitally and through clinical interactions)
f. The need to increase clinician awareness that trials open might be relevant to their patients
g. The need to increase awareness of the importance and relevance of research more generally to the NHS

Most of these barriers, and their solutions, are not specific to cancer – however as part of the 'Tackling Cancer through Research' plan the intention is to identify the key points of challenge in the system and put in place tangible and systematic improvements to overcome them.

Commercial clinical trials is a very competitive area – Wales must have in place "order qualifiers" i.e. same access, simplified processes, speed to set up, as other international competitors and build on our unique strengths. Industry's needs are simple – they need to see fast set-up and the NHS must meet the targets agreed with industry from the outset. If Wales can deliver as promised to industry, then the business will come.

The next section of the plan outlines the actions to ensure that the delivery of commercial cancer research is efficient and is embedded in the health care systems, organisations and professionals in Wales, and that the public and patients are enabled and empowered to participate in research wherever they live and whatever their backgrounds.
The work will be guided by a number of principles:

- It will be collaborative across Wales, with a lead partner/(s) for each action in partnership with R&D teams integrated within the wider health care services
- Innovations developed in R&D will take a person-centred and inclusive approach to tackle health inequalities
- There will be continued and ongoing engagement with industry colleagues to refine approaches, whilst working alongside clinicians

- Whilst developing specific individual company strategic partnerships is part of ongoing activity, Wales is interested in approaches from **all** industry partners to maximise the opportunities for patients
- We will value, nurture, grow and develop our research workforce and support them in the vital work they are doing, whilst ensuring the healthcare system in Wales values their important work
- There will be strong national oversight and coordination of commercial cancer research to strengthen delivery, accountability and performance.

Action plan and lead organisations

Tackling strategic constraints

Action	Owner
A nationally coordinated and locally delivered research infrastructure is established. This includes developing mechanisms and organisational systems (national coordinated delivery network) for greater collective oversight across Wales of commercial cancer research, prioritisation of studies undertaken in NHS Wales and study placement. All cancer trials coming to Wales will be routed via a One Wales process that is already established – this will enable active discussions about study placement, optimal delivery models, facilitated set-up, and reduced bureaucracy via a single contracting service. **Phase III trials offered to Wales will be prioritised for delivery to increase the proportion of the portfolio in later trial phases. (see annex 2 for more detail)** **Impact:** This will enable faster and more effective set-up and delivery of cancer research and increase the access to trials for patients.	Health and Care Research Wales in partnership with R&D Directors and WSCN
Appoint strong clinical leadership for the 'Tackling Cancer Through Research' programme, empowered to represent Wales in strategic partnership discussions with commercial companies, NHS Wales clinical service leads, and the welsh research community, and enabled by political support. **Impact:** This will provide a senior clinical leadership figure, with credibility and influence, to support driving forward the actions in this paper.	Health and Care Research Wales /NHS Performance and Improvement
NHS organisations should set cancer R&D metrics as part of cancer services quality metrics, and report income received from industry for commercial cancer research. These should be reported as part of IMTPs process, at JET meetings, and be available as a live dashboard to CEOs.	Welsh Government in partnership with NHS Performance and Improvement

Impact: This will tackle the low profile and priority given to cancer R&D and improve NHS accountability on reporting on research as part of overall cancer metrics**.**	

Tackling system and environmental constraints

Action	Owner
A project is initiated that will work with NHS organisations to remove cancer service barriers relating to delivering standard of care for patients outside the NHS organisation's boundary or standard care pathway that impact on research. This will involve increasing the profile of research to Cancer Site, Service Groups and Operational Managers who will support the development of and operationalise an all-Wales framework. **Impact:** This will enable the referral of patients to appropriate research studies at different NHS organisations, make best use of resource and clinician expertise. It will accelerate set up times – as research participant referral pathways will not have to be negotiated for each trial - as is currently the case adding unnecessary bureaucracy and delay.	NHS Performance and Improvement /WSCN in partnership with NHS Wales
Support the development of National, Cancer Site, Service and organisational systems to enable clinical leadership and ownership of clinical trial activity by service Multi-Disciplinary Teams and have appropriate discussions at service and business meetings. **Impact:** This will embed cancer trials in discussions on treatment/interventions and care, and trials becoming routinely considered as a care option, resulting in improved access for public and patients. This will also embed research as key component of a continuously improving healthcare system.	NHS Performance and Improvement/WSCN in partnership with NHS Wales
A programme of work is initiated to **a) support and educate managers by including research in job descriptions and owning a shared mission with clinicians in meeting cancer trials metrics (alongside other service metrics).** **b) support clinicians by including R&D in job descriptions, appraisals and job planning and is actively monitored by the R&D office.** **Impact:** This will strengthen the leadership role of managers and ensure research is part of improving safety, quality, efficiency, access, recruitment, and financial performance. This will also support clinicians have adequate time and recognition for leading and supporting cancer research and embedding it into service activities.	Health and Care Research Wales/ NHS Performance and Improvement/WSCN in partnership with NHS R&D Directors.

Tackling capacity and resource constraints

Action	Owner
Invest in cancer research-enabling NHS infrastructure as part of the VPAG programme. **Impact:** This will initially plug resource gaps that often result in NHS organisations not undertaking commercial cancer research or completing it in a time attractive to industry. Investment will cover clinical session time, resource for diagnostics (pathology, genomics, radiology and endoscopy) delivery (nursing and pharmacy), trial coordinators, outreach teams and equipment. Over time, NHS organisations will be expected to become sustainable from increased commercial income.	Health and Care Research Wales
Investment to be made in diagnostic infrastructure including genomic profiling to support participant identification processes. **Impact:** Enables patients with a specific genetic marker to be matched to available trials. An established genomics-enabled trial delivery capability is becoming an increased ask from industry and without this service, a growing number of commercial trials will not be offered to Wales.	All Wales Genomics Medical Service (AWMGS) in partnership with Health and Care Research Wales
Create a dedicated project to increase capacity of clinicians to deliver research through targeted growth of new Principal Investigators (PIs), by providing sessional funding on a fixed term basis to lead champion research locally, regionally and nationally, and work with industry and academic institutions to become Chief Investigators of UK and international studies. **Impact**: This will support research portfolio growth and develop the next generation of leading researchers (Principal and Chief Investigators). This will create the cohort of future leaders in cancer research.	Health and Care Research Wales in partnership with WCRC

Tackling communication and engagement constraints

Action	Owner
Develop a behavioural science-informed patient communication/engagement plan in partnership with the public that provides a range of push and pull actions, supported by digital technologies, to ensure patients are aware of trials that may be relevant to them. For example, this may include writing research into all new patient letters informing patients that research can be discussed at appointments.	Health and Care Research Wales in partnership with NHS Performance and Improvement/WSCN and NHS Wales

Impact: Increased awareness of research to patients and will drive clinicians to be research aware.	
Develop a strategic communications and marketing plan to 'sell Wales' to individual Sponsors/CROs. **Impact:** Increased industry awareness of Wales' strengths, capability and assets that will lead to attracting business.	Health and Care Research Wales in partnership with LSHW
Develop an engagement plan to target industry, develop more strategic partnerships and forge closer relationships with industry partners **Impact**: Wales becomes a default country for feasibility for all cancer trials	Health and Care Research Wales in partnership with WCIF and ABPI
Develop guidance to ensure that clinicians have information on trials open across Wales and the UK and understand referral processes. **Impact**: Increased awareness of clinical staff of cancer trials that are open across the UK and increased offer of trial options to patients.	Health and Care Research Wales in partnership with NHS Performance and Improvement/WSCN

Oversight and monitoring

- A new cancer research oversight group will be established within the NHS Performance and Improvement/Wales Strategic Cancer Network. This group will direct and monitor delivery of the actions described above.
- The *Making it Happen* group will receive progress updates at meetings and unresolved issues will be escalated for attention and support/advice in developing solutions. There are also further governance structures evolving within NHS Performance and Improvement (such as the Cancer Steering Group) and this will also be considered as a mechanism to leverage action as required.

What does success look like?

Measures of progress for commercial cancer research will include:

a) Increased cancer research (no. of studies) in Wales
b) Improved speed of set up and recruitment to time and target
c) Increased commercial income from cancer studies
d) Alignment of trials underway (where they exist) with cancer diagnosis data

Benchmarking will be undertaken against other regions across the UK to determine what is realistic and in context of resources available.

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22. Duty of Quality Statutory Guidance

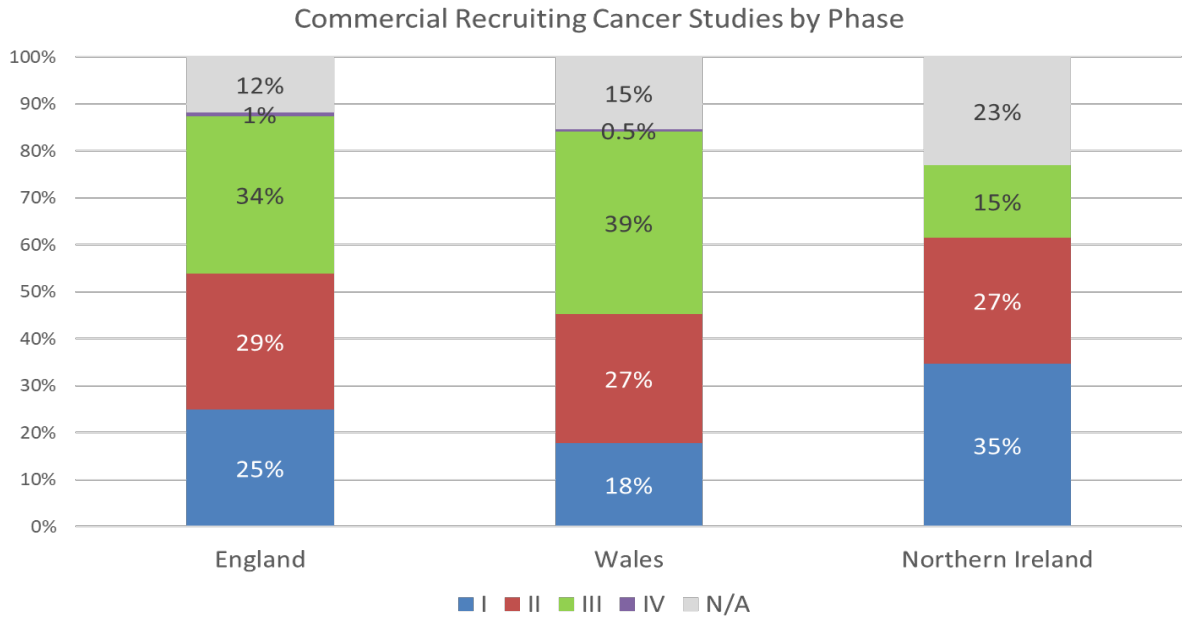
Annex 1 - Profile of current commercial cancer trial delivery in Wales (to 2023/4)

1. This annex includes some additional background information on current/past activity in cancer commercial trials – trial phases, tumour sites and recruitment across NHS organisations. More detailed information is available within the CReST strategy and will be updated in a separate short report in due course. It is useful to consider the data below in the context of the wider cancer research portfolio (non-commercial studies), strengths in Wales in leading cancer research, and analysis of the available trials that come to the UK to identify where there are opportunities to strengthen Wales's delivery of commercial cancer trials within a UK and global market.

2. Commercial cancer trials are open in Wales in all phases of trial (fig 1), albeit, like other nations, most trials recruiting in the NHS are later phase (II/II). Wales also has well-established early phase capability in Cardiff (ECMC) and ambition to increase capability in North Wales (CRF in Wrexham).

3. The distribution of activity across phases is similar to England, albeit Wales delivers proportionally fewer early phase trials. That might be expected as many early phase trials will be open in only a few centres across the UK and patients are supported to travel to access trials elsewhere.

Figure 1: Phases of commercial cancer trials



4. A breakdown of trials delivered in the last few years, by cancer site, is provided below. Figure 2 shows three tumour sites (haematology (35), breast (19), lung (17), prostate (14)) account for over 70% of commercial trials delivered in Wales, albeit recruitment figures (figure 3) give a broader picture across tumour sites – colorectal, gynaecological, skin and upper GI cancer patients are recruited in equivalent numbers to those above, indicating small numbers of later phase trials give patients access to trials also.

5. Also included in the tables below is a breakdown across NHS organisations – which in some areas will mirror clinical care pathways, which may be different to where they live. Although postcode data will be collected as part of a study, it is currently not possible to analyse this across studies. UK work is underway to determine the most efficient method of collecting recruitment data by postcode (rather than NHS location that participant was recruited).

Figure 2

Recruiting Cancer Studies in Wales by Cancer Sub-Specialty: 2019/20 – 2023/24
[Commercial studies]

Cancer Sub-specialty	AB UHB	BC UHB	CTM UHB	CV UHB	HD UHB	PHW	PTHB	SB UHB	VUNHST	Grand Total
Bladder Cancer	0	0	0	1	0	0	0	1	2	**4**
Brain Cancer	0	0	0	0	0	0	0	0	0	**0**
Breast Cancer	0	0	0	1	1	0	0	3	14	**19**
Children's Cancer and Leukaemia	0	0	0	1	0	0	0	0	1	**2**
Colorectal Cancer	0	0	0	0	0	0	0	0	7	**7**
Gynaecological Cancers	0	1	0	0	0	0	0	2	3	**6**
Haematological Oncology	3	1	0	27	0	0	0	6	0	**35**
Head and Neck Cancer	0	0	0	1	0	0	0	0	3	**4**
Lung Cancer	0	1	0	1	1	0	0	2	13	**17**
Lymphoma	1	1	0	3	0	0	0	4	2	**10**
Primary Care	0	0	0	0	0	0	0	0	0	**0**
Prostate Cancer	0	0	0	3	2	0	0	2	8	**14**
Psychosocial Oncology and Survivorship	0	0	0	0	0	0	0	0	0	**0**
Radiotherapy	0	0	0	0	0	0	0	0	1	**1**
Renal Cancer	0	0	0	0	0	0	0	4	2	**6**
Sarcoma	0	0	0	0	0	0	0	0	0	**0**
Skin Cancer	0	0	0	0	1	0	0	2	4	**6**
Supportive and Palliative Care	0	0	0	0	0	0	0	0	0	**0**
Teenage and Young Adult's Cancer	0	0	0	0	0	0	0	0	0	**0**
Testicular Cancer	0	0	0	0	0	0	0	0	0	**0**
Upper GI	0	0	0	2	0	0	0	0	4	**6**
Total	4	4	0	34	4	0	0	24	55	**120**

Figure 3

Cancer Recruitment in Wales by Cancer Sub-Specialty: 2019/20 – 2023/24
[Commercial studies]

Cancer Sub-specialty	AB UHB	BC UHB	CTM UHB	CV UHB	HD UHB	PHW	PTHB	SB UHB	VUNHST	Grand Total
Bladder Cancer	0	0	0	3	0	0	0	1	11	**15**
Brain Cancer	0	0	0	0	0	0	0	0	0	**0**
Breast Cancer	0	0	0	2	5	0	0	11	68	**86**
Children's Cancer and Leukaemia	0	0	0	2	0	0	0	0	1	**3**
Colorectal Cancer	0	0	0	0	0	0	0	0	63	**63**
Gynaecological Cancers	0	129	0	0	0	0	0	12	10	**151**
Haematological Oncology	9	1	0	99	0	0	0	26	0	**135**
Head and Neck Cancer	0	0	0	2	0	0	0	0	10	**12**
Lung Cancer	0	4	0	2	11	0	0	21	36	**74**
Lymphoma	2	1	0	13	0	0	0	10	5	**31**
Primary Care	0	0	0	0	0	0	0	0	0	**0**
Prostate Cancer	0	0	0	6	4	0	0	9	57	**76**
Psychosocial Oncology and Survivorship	0	0	0	0	0	0	0	0	0	**0**
Radiotherapy	0	0	0	0	0	0	0	0	10	**10**
Renal Cancer	0	0	0	0	0	0	0	20	10	**30**
Sarcoma	0	0	0	0	0	0	0	0	0	**0**
Skin Cancer	0	0	0	0	11	0	0	22	13	**46**
Supportive and Palliative Care	0	0	0	0	0	0	0	0	0	**0**
Teenage and Young Adult's Cancer	0	0	0	0	0	0	0	0	0	**0**
Testicular Cancer	0	0	0	0	0	0	0	0	0	**0**
Upper GI	0	0	0	19	0	0	0	0	15	**34**
Total	**11**	**135**	**0**	**135**	**20**	**0**	**0**	**107**	**273**	**681**

Annex 2 - Phases of clinical trials

A clinical trial portfolio typically includes a mix of early (Phase I and II) and late (Phase III) trials. Early phase trials are primarily focussed on establishing the safety of a new drug/treatment, whilst late phase trials are primarily focussed on demonstrating benefit/efficacy in a larger group of patients before a treatment becomes a new standard of care.

Phase 1 trials:

- A small number of people, who may be healthy volunteers, are given the medicine.
- The drug is being trialled in human volunteers for the first time.
- Researchers test for side effects and calculate what the right dose might be to use in treatment.
- Researchers start with small doses and only increase the dose if the volunteers do not experience any side effects, or if they only experience minor side effects.

Phase 2 trials:

- The new medicine is tested on a larger group of people who are ill. This is to get a better idea of its effects in the short term.

Phase 3 trials:

- Carried out on medicines that have passed phases 1 and 2.
- The medicine is tested in larger groups of people who are ill, and compared against an existing treatment or a placebo to see if it's better in practice and if it has important side effects.
- Trials often last a year or more and involve several thousand patients.

Phase 4 trials:

- The safety, side effects and effectiveness of the medicine continue to be studied while it's being used in practice.
- Not required for every medicine.
- Only carried out on medicines that have passed all the previous stages and have been given marketing licences – a licence means the medicine is available on prescription.

Wales' commercial cancer trial portfolio 2023/24 was as follows: Phase 1: 18%, Phase 2: 27%, Phase 3: 39%, Other: 15%. This needs to change.

It is important to recognise that phase III trials can be complex to deliver and may need access to specialist services, that are not always available close to a patients' home. Phase I trials tend to recruit smaller numbers of patients but are important as they tend to offer access to newer/more novel treatments to patients and mean that staff/the NHS get experience of setting-up new pathways and systems to deliver the treatments (e.g. cell therapies, cancer vaccine treatments).