

Working together: Guidance to support transformative pharmaceutical industry partnerships with the NHS in Wales



About us



The Welsh NHS Confederation is the only national membership body representing the leaders of the organisations making up the NHS in Wales: the seven local health boards, three NHS trusts and two special health authorities.

We host NHS Wales Employers and are part of the NHS Confederation.

We support our members by acting as a driving force for positive change through strong representation, facilitating system leadership and our proactive policy, influencing, communications, events and engagement work.

To find out more, visit www.nhsconfed.org/wales



The Association of the British Pharmaceutical Industry (ABPI) exists to make the UK the best place in the world to research, develop and access medicines and vaccines to improve patient care.

We represent companies of all sizes that invest in making and discovering medicines and vaccines to enhance and save the lives of millions of people around the world. In England, Scotland, Wales and Northern Ireland, we work in partnership with governments and the NHS so that patients can get new treatments faster and the NHS can plan how much it spends on medicines.

Every day, our members partner with healthcare professionals, academics and patient organisations to find new solutions to unmet health needs.

To find out more, visit www.abpi.org.uk



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Foreword

Across Wales, the potential of NHS and industry partnerships to transform health services and improve outcomes for patients has never been greater. A growing body of research confirms that where partnerships take place, they are associated with better health outcomes for patients, improve access to innovation, and create system-wide benefits. The evidence from Wales and beyond is clear: collaboration between the NHS and industry is not just transformational, it is essential.

We have seen this first-hand through the wealth of examples captured in the Association of the British Pharmaceutical Industry's (ABPI's) NHS-Industry Partnership Case Studies Library, which features projects from across all four nations of the UK, including many from Wales. These projects demonstrate the 'triple win' in action, delivering better outcomes for patients, strengthening NHS capacity and capability, and making responsible use of industry expertise and resources.

This new Welsh guidance is the product of a truly collaborative effort between the Welsh NHS Confederation and the ABPI. It draws together the experiences, insights and lessons from NHS leaders and industry partners into a single, practical resource designed to make partnership working easier, more transparent and more impactful.

Central to the guidance are new, jointly endorsed frameworks and sources of assurance that support every stage of the partnership lifecycle, from identifying opportunities and scoping a project, through governance and delivery, to reporting outcomes. Building on the strong foundation laid by the 2024 English guidance Accelerating Transformation: How to Develop Effective NHS-Industry Partnerships, these resources are designed to help teams navigate the practicalities of partnership working with confidence, ensuring ethical robustness, local relevance, and measurable benefits for all involved.

Our shared aim is to equip NHS organisations in Wales and industry partners with the tools, clarity, and confidence to deliver high-quality, patient-centred projects that address real needs, respond to local priorities, and can be scaled when successful. By setting out clear steps, templates, and checklists, this guidance helps to remove barriers, reduce complexity, and create the space for innovation to flourish.

Above all, it is an invitation to think ambitiously about what partnership can achieve in Wales and to act on that ambition. We encourage those working to improve health in Wales to use this guidance as a springboard for action, building collaborations that turn potential into progress and progress into lasting, measurable impact for patients, communities and the health system.



Darren Hughes
Director
Welsh NHS
Confederation



Dr Richard Torbett Chief Executive ABPI





At a glance: How to develop effective NHS-industry partnerships



This summary provides an overview of guidance to support partnership working. It has been developed in collaboration with NHS and industry leaders. The full guidance pack can be accessed on the NHS Confederation website.

Who this guidance is for

Healthcare organisations in Wales, industry leaders and those leading on the partnership and transformation agenda within their organisation or system.

Use it to:

bring stakeholders and partners together to assess priorities

design and implement
partnership projects aligned
to strategic objectives and
informed by the guidance
resources

strengthen assurance and nurture the culture of effective partnership working

scale existing partnerships across care settings.



Project identification and scoping

Key activities

- Identify unmet need: Healthcare organisations and industry partners identify unmet needs to support improved clinical outcomes and explore how collaborative working and joint working projects can assist. This process includes community engagement and patient feedback to identify opportunities for improvement.
- Assess scope: Undertake assessment of the project scope and aims to help identify whether a project is a collaborative or joint working project.
- Agree objectives and timescale:
 Outline the project's purpose,
 objectives, resource impact and
 timelines to be approved by parties
 to enable progression to Stage 2, the
 project setup stage.



Project setup and governance structures

Key activities

- Form project team: Project team or steering committee is formed.
- Build trust: Work undertaken to engender trust and ethos of effective partnership working.
- Develop project initiation document (PID): Develop and approve a project initiation document (PID) that details the aims and objectives of the project, expected outcomes, project completion date, exit strategy, project organisational structure, resources as well as data and patient protection.
- Governance frameworks: Establish project governance arrangements.
- Engage with stakeholders: Undertake stakeholder engagement relevant to the project setup.
- Certify PID: PID developed and agreed with the healthcare organisation, project team, governance committee and industry partner respectively. It must then be certified by the industry partner.
- Publish executive summary: An executive summary of the project rationale, period, objectives, roles and responsibilities of the parties, and financial arrangements must be published on the industry partners website before arrangements are implemented. It should be certified by the industry partner.



Project implementation and outcomes reporting

Key activities

- Deliver project: Project delivery and evaluation.
- Monitor progress: Project monitoring and regular reporting against outcomes outlined in the PID and within the written agreement. If significant changes to the project occur during implementation, an amendment framework should be completed and agreed by the project team and the governance committee.
- Publish project outcomes: All parties should publish outcomes of the project within six months of completion.
- Disclosure UK: Transfers of value related to projects must also be disclosed via the Disclosure UK database.

The 2024 ABPI Code of Practice exists to regulate the promotion of prescription medicines to UK health professionals, industry interactions with health professionals, and the www.abpi.org.uk provision of information about prescription-only medicines to the public.



About this guidance

This guide provides a practical, step-bystep resource to help the NHS in Wales and pharmaceutical industry develop, deliver and evaluate partnerships that will drive improvements to the health and wellbeing of patients in Wales. It contains templates, recommended frameworks, and handy checklists and prompts to support you.

It contains template forms, recommended frameworks, and handy checklists and prompts to support you.

Access downloadable, editable documents wherever you see the 👌 icon.

Who this guidance is for

This document is aimed at NHS organisations in Wales, pharmaceutical industry leaders, and those leading on the partnership and transformation agenda within their organisation or system.

We want you to use it to:



bring stakeholders and partners together

to assess priorities for NHS-industry partnership working



design and implement partnership projects aligned to strategic objectives and informed by the guidance resources



and nurture the
culture of effective
partnership working



scale existing partnerships across care settings.



What are NHS-industry partnerships?

NHS-industry partnerships allow NHS organisations and the pharmaceutical industry to collaborate for patients' benefit. Joint working was recognised by the Welsh Government when it issued a Welsh Health Circular (WHC) in 2005 'Guidance for partnership working between NHS organisations, primary care contractors, the pharmaceutical industry and the allied commercial sector in Wales'

Since then, multiple publications have acknowledged the value of external expertise in helping NHS organisations overcome challenges. This includes providing additional skills and resources to achieve patient benefits beyond that which NHS organisations could deliver alone. These partnerships bring industry skills and expertise to improve appropriate patient access to innovative treatments, support project management and enhance the efficient delivery of healthcare services.

Partnerships can be formed between a single NHS organisation and a single pharmaceutical company, or multiples of either. In general, there is a trade-off between the advantages of greater scale in working with multiple partners, as seen through regional working in Wales, and the added complexity of gaining agreement across multiple organisations.

While patient organisations cannot directly be included in collaborative working arrangements, they may be contracted to deliver a service to support an element of such collaborative working.

There are two types of NHS-industry partnership: collaborative working and joint working projects. These partnerships involve cooperation between industry and local NHS organisations across primary, secondary and system-level healthcare settings.

Collaborative working is generally between one or more pharmaceutical companies, healthcare organisations and possibly other organisations. It must have, and be able to demonstrate, the pooling of skills, experience and/or resources from all parties involved. There must be a shared commitment to successful delivery from everyone involved and each organisation must make a significant contribution. In the case of NHS organisations, this contribution does not have to be financial. It can involve the sharing of support in the form of skills and experience to deliver projects successfully.

Joint working projects are a specific type of NHS-industry collaborative working, rather than a generic term for all cross-sector collaboration. They must be patient-centred and always benefit patients directly, which gives them a narrower focus than collaborative working.



^{1.} Guide to collaborative working between NHS organisations, primary care contractors and the pharmaceutical industry

The benefits of working together

Partnerships offer a proven 'triple win' — improving outcomes for patients, strengthening the health system, and supporting responsible industry innovation. In Wales, where health inequalities, service variation, and workforce pressures remain major challenges, these partnerships offer a strategic opportunity to accelerate transformation:

Equitable and evidence-based prescribing

Evidence indicates that NHS organisations engaged in industry partnerships are up to 2.5 times more likely to follow NICE-recommended prescribing for clinically and cost-effective medicines, especially in areas like cardiovascular care. This is particularly pertinent in Wales, where prescribing practices can vary across health boards. Partnership working helps standardise treatment approaches and improve consistency in care.

Improving Outcomes and Reducing Inequalities

Partnerships across the UK have helped align clinical practice with national guidance and guidelines, improved access to diagnostics and treatments, and reduced unwarranted variation – benefits that are especially meaningful in Wales, where health outcomes often correlate with levels of deprivation.

Capacity and Capability for Transformation

As demonstrated by The King's Fund,
partnerships deliver more than just resources
– they create space for innovation by funding
project management, analytics, and digital tools,
enabling frontline clinicians to lead sustainable
service redesign. This external support is
particularly valuable in the Welsh context, where
health boards and trusts often operate with
limited headroom for service improvement while
balancing day-to-day operational pressures.



Collaborative and joint-working approaches: a comparison

As noted in the comparison table, one of the key benefits of collaborative working is the 'triple-win' - benefiting patients, healthcare organisations including the NHS, and pharmaceutical companies. Benefits for pharmaceutical companies in embarking upon collaborative working can be myriad, from gaining experience in partnering with an NHS organisation, to an increase in patient identification and prescribing in accordance with national and local guidelines. Most importantly however, and in accordance with Clause 20 of the ABPI Code of Practice, such benefits must not constitute an inducement to health professionals or other relevant decision makers to prescribe, supply, recommend, buy or sell a medicine. A key safeguard here is the requirement in the ABPI Code of Practice to have a have a summary of the collaborative working agreement publicly available before arrangements are implemented.

It is also worth noting that in embarking upon collaborative working with NHS organisations, companies will have no direct contact with patients, or with identifiable patient level data.

	Collaborative-working projects	Joint-working projects	
	Are for the benefit of patients and/or the healthcare organisation, including the NHS.	Must always be for the benefit of patients directly and mus include the NHS as a party.	
	Enhance patient care or be for the benefit of patients, or alternatively benefit the NHS and, as a minimum, maintain patient care.		

May not constitute a grant/donation (see Clause 23 of ABPI Code of Practice for further information on Donations and Grants).

May provide benefits to the company or companies involved.

Outcomes must be defined in such a way that they can be measured or tracked, so that at any time during the collaboration all parties are aware of:

- the progress towards the objective/outcomes
- their roles and responsibilities and the actions they must take to ensure the outcomes are achieved in accordance with the agreement

• the outcomes achieved can be demonstrated following the completion of the project.

Must be carried out in an open and transparent way, with a certified summary of the project agreement publicly available before it begins.

Must respect clinical independence.

Must be prospective – not relating to a project that has already begun.

Must have the value to the healthcare organisation publicly disclosed annually on the Disclosure UK database and, if relevant, the contracted service value to the patient organisation published on the industry partner's website.

Must not constitute an inducement to health professionals or other relevant decision-makers to prescribe, supply, recommend, buy or sell a medicine.

Must ensure that the rights and legitimate interests of all parties are continuously observed throughout, including considerations related to data security, the protection of confidentiality and privacy, and anti-bribery compliance.

Must not promote a prescription-only medicine to any member of the public.



The ABPI Code of Practice

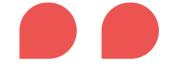
The 2024 ABPI Code of Practice (see Appendix 1 for further details) exists to regulate the promotion of prescription medicines to UK health professionals, industry interactions with health professionals, and the provision of information about prescription-only medicines to the public.

It is administered by the <u>Prescription</u>

<u>Medicines Code of Practice Authority</u>

(PMCPA) and is the cornerstone of the UK system of industry self-regulation.

All NHS-industry partnerships are bound by the ABPI Code of Practice.



"Partnerships have to operate within the safeguards of the ABPI Code of Practice, which reflects and goes beyond the law. This means partnerships take place in an ethical and transparent manner, which puts patients at the heart of everything we do."

> Dr Amit Aggarwal, Executive Director, Medical Affairs and Strategic Partnerships, ABPI

Achieving impact with partners





Multi-partner considerations

Collaborative working projects between a single healthcare organisation and a single pharmaceutical company are common.

Less common but still possible are cross-sector projects involving more than one healthcare organisation and/or more than one pharmaceutical company.

Cross-sector projects between one or more healthcare organisation and one or more pharmaceutical company are often more complex. This is because each individual organisation has its own governance and approvals processes, which can lengthen the timelines for project set-up and implementation. In addition, ABPI members are actual or potential competitors in certain therapy areas and are therefore subject to stringent competition law safeguards that must also be reflected in any agreement on working together. A shared desire to improve patient outcomes through a collaboration will not justify anticompetitive conduct, such as the illegal exchange of sensitive information between competitors or other types of collusive practices.

There should be a lead contracting party, identified by job role, in each sector in a cross-sector project where there are multiple healthcare organisations or to have an individual contract with each organisation involved.

Where there is more than one contracting party on each side of the cross-sector project, steps should be taken to understand the differing legislative competence, governance processes and timelines involved.

Given that the legal risk and opportunities for error are higher when multiple organisations are involved in the same collaboration, it is best to agree rules of engagement upfront, which can be recorded in the agreement. Such rules should set out clear governance principles, such as:

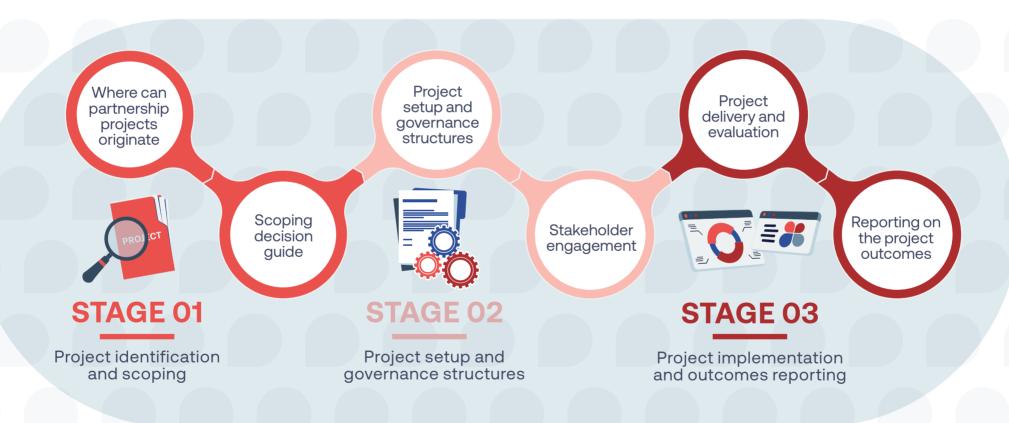
- All project meetings will only take place if at least one representative of each party can attend
- Minutes of all meetings will be taken, approved by all participants, and kept on record for an agreed period after the completion of the project
- All project participants will receive a briefing on competition law rules and will be asked to sign a competition compliance and non-disclosure statement.

If the nature of the project would require specific discussion on topics of the utmost sensitivity such as costs, patient information, potential tendering opportunities, R&D activities etc., the parties should consider having a specialist competition lawyer attend the meetings.



Key stages of the project lifecycle

The figure below outlines the stages of a partnership, from planning to delivery and monitoring:





Stage 1

Project identification and scoping



"Across Wales, NHS leaders are working hard to improve care and health outcomes for patients, while seeking to reduce inequalities. When industry and NHS organisations develop effective partnerships, there are significant benefits for all concerned – higher quality care, lower hospital admissions and more appropriate use of medicines.

We want to help more people in Wales benefit from this triple win. The joint Welsh NHS Confederation and ABPI guidance will support teams to confidently collaborate in the interest of their local communities."

Jonathan Morgan, Chair, Welsh NHS Confederation



Where can partnership projects originate?

In Wales, partnerships can originate from across the NHS in Wales, as well as from the pharmaceutical industry. The table below sets out some suggestions. Both parties can discuss initial project ideas with the Life Sciences Hub Wales.²

Primary care Primary care or cluster partnerships often arise from existing relationships with industry providers. At other times, they will emerge from proactive work by the clusters or individual practices who are interested in finding partners to support specific projects. Industry partners will also often research and directly scope out

Industry partners will also often research and directly scope out primary care providers where projects can directly support their existing clinical priorities.

Secondary care

Across secondary care settings, partnership working is well established, and as such clearer routes exist for projects to be developed.

In many cases, agreed avenues for exploring partnerships are in place, such as via relationships between industry and trusts, as well as dedicated commercial services teams who will issue expressions of interest regarding partnership objectives and opportunities.

This is further enhanced by the wealth of existing secondary care networks, which enable a greater spread of successful projects from one locality to another.

Integrated care system/ place level

Partnership working with Health Boards (HBs) can be more challenging to establish. It is important therefore that any prospective partnership is underpinned by mission-oriented priorities that directly support the system's regional obligations and local objectives.

Early-stage discussions about entering a collaborative or joint working arrangement with LHB staff should include relevant clinical leads and executive leads, including the Chief Pharmacist as appropriate.

If proposals are deemed suitable for further exploration, it is advised that the designated NHS and industry leads should provide initial details on the scope and aims for consideration by the relevant Board level working groups.

The NHS Wales Performance and Improvement (previously NHS Wales Executive) and Life Sciences Hub Wales, who operate separately from the LHBs in Wales, can also serve as an important conduit for streamlining the setup of system-level partnerships aligned to system priorities.









Key resource: Scoping decision guide

At the start of a partnership, NHS and industry organisations need to identify unmet needs to support clinical outcomes. Industry partners often align their capabilities with NHS goals or issues identified through health data analysis.

This process includes community engagement and patient feedback to identify opportunities for improvement. Colleagues should use these questions to explore and develop the scope of a project, to ensure the aims are clear and the entire lifecycle of the project has been considered.

Questions to consider during the scoping of a project	Questions to consider if the project has a therapy/medicine focus
What is the unmet need the project is seeking to address?	Which clinical pathway(s) require service redesign to improve
What is the scale of the problem?	patient care and/or system improvement?
What is the evidence to back this up?	
What is the priority improvement area, and can this realistically be addressed within the resources and duration of the project?	Which companies have expertise in this area?
What are the patient or system benefits of addressing this need?	Are there other organisations that would be relevant to
What would be the impact on patient care or the system if this need is not addressed?	engage in the project? For example, at a HB or system level,
Are other internal stakeholders supportive of addressing the need and the feasibility of doing so? can the Life Sciences Hub Wales or NHS Wales and Improvement play a convening and facilitat partnership?	
Which NHS plan and/or local improvement plan goal is the challenge aligned to?	









Questions to consider during the scoping of a project	Questions to consider if the project has a therapy/medicine focus
What interventions are required and in what timescale?	
What is the likely impact on the clinical and non-clinical workforce? For example, will this project involve complex pathway redesign?	
Are prospective partners clear on existing operational pressures, and their potential impact on the project?	How are partners considering the impact of health inequalities and equality of healthcare access?
What related challenges need to be addressed in other parts of the system for the project to succeed?	
What does success look like? How will it be measured? When and by whom?	Has the Well-being of Future Generations (Wales) Act 2015 and Socio-economic Duty been considered?
Is the project intended to demonstrate a sustainable solution? If so, what outcomes will be necessary to ensure a successful business case?	
Is there capacity to release the necessary internal team members to participate in the project?	









Key resource: Checklist for determining if a project is collaborative working, joint working or neither

To help identify if a project is a collaborative or joint-working project, an assessment of the project scope and aims should be undertaken, which can be supported by completing the checklist below.

If the answer to any **red** questions on the checklist is 'No', the project is not a collaborative or joint – working arrangement, and will need to be modified before proceeding. If changes cannot be made, prospective partners should consider an alternative approach, such as a research collaboration or a donation/grant, as described in <u>Clause 23</u> of the 2021 ABPI Code of Practice.

If the answer to any **amber** questions is 'No', this signals an issue or risk that should be addressed to encourage successful and timely project delivery.

Joint working			
1A. Is the main benefit of the project focused on the patient?	YES This is a collaborative-working project – go to question 2 (page 14)	NO Please go to question 1B	
Collaborative working			
1B. Does the project aim to enhance patient care or be for the benefit of patients, or alternatively benefit the NHS and, as a minimum, maintain patient care?	YES This is a joint-working project – go to question 2 (page 14)	NO Consider another form of support	

Checklist continues on page 18.









Red au	uestions			
2	Do all parties acknowledge that the arrangement may benefit the NHS and company partner(s) involved?	YES	NO	
3	Are any subsequent benefits at an organisational level and not specific to any individual?	YES	NO	
4	Is there a significant contribution of pooled resources from all parties, which include people, finance and equipment wholly or partly dedicated to the project?	YES	NO	
5	Is there a shared commitment to joint development, implementation and successful delivery?	YES	NO	
6	Will anonymised, aggregated, outcome data be measured and documented?	YES	NO	
7	Are all partners committed to publishing a measured and documented executive summary of the Collaborative Working Agreement?	YES	NO	
8	Are all proposed treatments involved in line with national guidance, where it exists?	YES	NO	
9	Will all activities be conducted in an open and transparent manner, with appropriate governance arrangements in place to manage any conflicts of interest?	YES	NO	
10	Has an exit strategy and any contingency arrangements been agreed?	YES	NO	
Amber questions				
11	Will the project be managed by a team including representatives of industry, NHS with industry, NHS and appropriate third-party representation?	YES	NO	
12	Do all parties and their respective organisations have appropriate skills capabilities and capacity to manage the project?	YES	NO	
13	Have all partner organisations got clear procedures in place for reviewing and approving collaborative-working projects?	YES	NO	
14	Are all parties committed to working together across the entire lifecycle of the partnership?	YES	NO	
15	Are all partners clear on who within their organisation is responsible for ensuring that relevant joint working/collaborative working documents should be certified or approved?	YES	NO	









Key resource: Project Concept Framework

The key recommended documentation for stage 1 is a **Project Concept** Framework, outlining the project's purpose, objectives, resource impact and timelines. It must be approved by all relevant parties to support progression to the project setup stage.

View a case study demonstrating the step-by-step implementation of a project in a primary care setting.

Project Concept Framework		
Partner organisation and key stakeholders Include a full list of organisations involved in the signing of the collaborative		
Purpose of the project	Briefly contextualise the background, including why it is taking place. This can be outlined in bullet point form.	
Objectives	Include the intended benefits for patients, the NHS and the industry partner.	
Budgetary/resource impact on industry/ NHS partner organisation	Discuss the financial contributions shared by partnering organisations. This may not always be in the form of financial costs if the partnership only focuses on project management time, but a significant contribution is required from all parties.	
Anticipated start date	Include here the anticipated start date to the nearest quarter, such as Q1 2026.	
Length of project	Overall length of the project in months. Include detail if the decision to go ahead with the project was positively made.	
Decision		











Project setup and governance structures



"It is often difficult building and managing successful partnerships, with those involved facing time constraints and complex challenges when seeking to innovate or work in new ways. The guidance set out by the Welsh NHS Confederation and ABPI helps to show the clear steps that can support effective collaboration."

Joe Castle, Head of External Affairs & Operations (Wales), ABPI



Project setup and governance structures

At this stage, a **project team** or **steering committee** is formed, including all involved parties and active participants. This team will guide and manage the project, being responsible for its success and operating within the agreed limits.

The members of this project team may differ depending on the care setting. The team should be 'right sized' to be both effective and inclusive.

All project team or steering committee members must declare any conflicts of interest.³ Those with a conflict should not vote on related matters. These declarations should be recorded in the meeting minutes. Either party can object to someone's involvement due to a conflict of interest.

The project team should agree on a project methodology. <u>PRINCE2</u> (Projects In Controlled Environments) is perhaps the best known and most widely used, but the methodology may vary depending on

the complexity of the project. The team should also agree on a regular meeting schedule to make initial decisions, keep the project on track, and manage any issues. Meetings should be action-oriented, with clear agendas, decision points, and minutes recorded.

When considering project resourcing, all parties must commit to detailing the resources they will contribute to the project, which could include finances, skills, or experience. These contributions should go beyond normal day-to-day roles, like funding additional staff or clinics. Assigning a monetary value to healthcare resources is challenging, but it should be clear that contributions from partners should be

comparable and proportionate. If the collaboration aims to address organisational constraints within the NHS in Wales, precautions must be taken when using pharmaceutical funding to retain staff. Any staff paid through industry funding should operate under the control of an organisation within the NHS in Wales, be time limited and outlined in collaborative working documentation, with clear employment law compliance. Exit strategies for industryfunded posts should be outlined in project documents.

3. In the NHS in Wales, conflicts of interest are addressed through a combination of policies, guidance, and procedures. Staff are expected to declare any interests that could potentially influence their decision-making or create a conflict with their NHS duties. This includes outside employment, financial interests, and personal relationships that could create a conflict.



Stage 2
Project setup
and governance
structures





Key resource: Project team / steering committee members (non-exhaustive)

Who should be in a project team/project steering committee? (non-exhaustive)

Care setting (options depending on local context)	Key stakeholders	
 Primary care Health Board Clinical Directors / relevant Deputies GP Cluster Leads Community Pharmacy Leads Health Board Innovation and Commercial Leads 	IndustryProgramme ManagerMedical Affairs LeadPartnership Lead	
 Secondary care Associate Medical Directors / Chief Pharmacists Relevant Secondary Care Clinical Lead Hospital Innovation and Commercial Leads 	Industry • Programme Manager • Medical Affairs Lead • Partnership Lead	
 Health board Directors of Strategy and Innovation Heads of Medicines Management Health Board Chief Pharmacist Health Board Innovation and Commercial Leads 	Industry • Programme Manager • Medical Affairs Lead • Partnership Lead	

• Health Board Innovation and Commercial Leads

Due to the non-promotional nature of collaborative working projects, careful consideration should be given to the industry stakeholder job roles within their company, particularly with regards to sales or promotional roles.







Key resource: Steps to build trust

Trust and transparency is fundamental to any partnership, especially during the early scoping phase. All parties should ensure that they work towards engendering trust, which can be supported through the following steps:

Process and organisation

- Developing a shared vision together, aligned to priorities to improve capacity, capability and outcomes
- · Transparent decision-making
- Joint ownership of decisions and collective responsibility for direction, activities and outcomes
- Identify and mitigate potential risks, eg data privacy, intellectual property

Continuity

- Not moving goalposts (such as pulling budgets, changing priorities)
- Minimal personnel changes or at least good practice in transition

Behaviour

- Recognition of the value of each party's contribution
- · Maintaining deadlines and actions
- Sharing knowledge
- · Demonstrating the ability to be flexible and adaptable
- Ability to compromise
- · Acknowledgement of cultural differences

Outcomes

- · Clear recording and reporting of outcomes
- · Agreed plans for upskilling and knowledge transfer
- After Action Review or similar feedback and learning processes



Stage 2
Project setup
and governance
structures





Key resource: Project Initiation Document (PID)



Once the necessary criteria have been fulfilled, the project team should develop and approve a project initiation document (PID) to ensure a shared understanding of the project's outcomes, its governance framework and to provide a clear exit strategy that details the overall responsibility of each party if the project needs to be terminated.

The PID is a key document that sets out requirements ahead of project implementation and the agreed copy should be kept on record for both parties' reference.

Confidentiality of patient information must be maintained in all partnerships, as outlined in the PID. This includes respecting the confidentiality of project-related information and not sharing it beyond the project's scope. The PID should be collaboratively created by relevant individuals from all partnering organisations.

It is important to note that PIDs will, at times. need to be updated following the initiation of the project. This can be addressed via a project amendment form (see implementation section).

The PID must be certified by the industry partner and be approved by both the project team also the relevant governance committee(s) - see page 28 for further details.









Project Initiation Document		
Project title	Name of the project.	
Background	Briefly contextualise the background to the project, including why it is required.	
Intended aims and objectives of the project	Include a set of bullet points outlining the aims of the project, using easy-to-understand language.	
Expected outcomes of the project	Set out outcomes in accessible, ideally bullet point form. Divide into predicted benefits for patients, the NHS, and the relevant industry partner.	
Name of partner organisations	Provide a short description of the partner organisations involved in the project, including their full address.	
Name of representatives for each organisation	List the accountable leads from each of the respective organisations, including their email addresses, job titles and full names.	
Project start date	Provide anticipated dates for the project's initiation. It is advisable to use quarter dates to allow for a degree of flexibility when establishing a timeline for the project, such as Q1 2026.	
Project completion date	Please follow as above.	
Exit strategy	Set out a clear exit strategy to ensure that patient care is maintained to the highest level throughout and after the project. This section should also include an agreed process and timelines should it be necessary to terminate the project early.	

Stage 1
Project
identification
and scoping





PID continues on pages 26 and 27.



1. Project organisational structure – included here should be the organisational structure of the project as outlined below	
Stakeholders	Include an explanation of who all the relevant stakeholders are in the project. This should include individuals who are required to sign off projects, sign the contract and make decisions overall. This should also include individuals required as points of contact in case of termination or amendment to the collaborative-working agreement.
Risk management plan	Include a short explanation of the plans in place to mitigate any risks associated with the project, such as capacity and any budgetary issues.
Project governance	List the core members of the governance committee who will be responsible for delivery and oversight of the project, setting out clearly their responsibilities
Project managers	List the lead project manager involved in the project, with one name per organisation.
Project team	List all members of the project team who will be involved in the day-to-day delivery and co-ordination of the project. Outline how the project reporting mechanisms will be developed and adhered to.
Project plan	Set out the project plan, including how outcomes will be monitored, how data will be collected, activities, resources (including funding), and clear milestones.
References	Included here should be examples of any NHS or National Institute for Health and Care Excellence (NICE) or All Wales Medicines Strategy Group (AWMSG) policies relevant to the project.

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PID continues on page 28.



2. Resources and costs Include a simple headline figure, which should also consider VAT. This should include the projection of costs Overall cost of the according to employee time and resource across NHS and industry partners. collaborative-working project Direct and indirect resources Provide details here of the resource commitment proposed by all partnering organisations. This should include any monetary funding as well as transfer of value.* Arrangements for longer term Describe the implications for sustainable support if the project continues longer term. funding implications of project 3. Data and patient protection In completing this section, note that data generated by the project will normally be held within the NHS partner Ownership of data generated by the organisation. Access to new data arising from the project and shared by the NHS partner will be managed in a project manner that retains full patient confidentiality.

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*Clause 20 of the ABPI Code states that collaborative working, including its implementation, must have and be able to demonstrate the pooling of skills, experience and/or resources from all of the parties involved for the joint development and implementation of patient and/or healthcare centred projects. There must be a shared commitment to successful delivery from all parties, and each party must make a significant contribution.



Establishing a robust governance framework

When entering into a partnership initiative, industry and organisations need to ensure they are working within a robust governance framework to ensure the project aligns with their organisations' goals and legal processes.

Projects should include the establishment of a governance committee to oversee the project. The governance committee will also review the principles of the project against the collaborative and joint-working checklist criteria and ensure that the project has been reviewed by each participating organisation's management and experts.

Within pharmaceutical companies, governance expertise will be provided by legal, medical, compliance and healthcare engagement functions. Within healthcare organisations, governance will usually be provided by existing governance committee, or other appropriate committee, such as an Internal Review

Committee (IRC). For collaborative projects, stakeholders must have the authority to approve the project.

Examples of key individuals who can form part of a governance committee are presented alongside:

Key resource:

Potential governance committee members across care settings (non-exhaustive)

- Named executive senior responsible officer from each party to the partnership
- · Relevant clinical lead
- Programme management and support
- Insight and intelligence teams
- Pharmaceutical legal director
- Pharmaceutical medical / compliance director



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Engagement

Building confidence in the project with stakeholders, both internal and external, is vital to avoid misunderstandings and ensure transparency.

This includes clarifying aligned interests and disclosing benefits to industry transparently. Clear communication between partners is essential to refine project objectives, manage expectations and confirm inputs from each organisation. At this stage, the project team should develop a stakeholder map, communications plan and data collection plan if not already done in the PID. Realistic timescales should be set, with the first three steps taking four to six months, including scoping, development and approval of governance arrangements and legal framework.

Key resource: Examples of stakeholder groups to engage across care settings (nonexhaustive) It is a helpful exercise to divide stakeholders between internal and external stakeholders who:

- should be involved in the project
- are not directly involved in the project, but whose views could influence the outcome and who should be kept informed throughout the entire project lifecycle
- will ultimately be impacted by the outcome
- whose opinions could facilitate or prevent success.

Primary care	GPs, pharmacists, patients and communities, patient organisations
Secondary care	Chair of Quality Committee, Chair of Medicines Optimisation Group, patients and residents, patient organisations
System-level care	Chair of Quality Committee, patients and residents, patient organisations
Industry	Company decision makers, local representatives, market access teams, project managers
Others	NHS Wales Performance and Improvement, Welsh Government









Patient engagement

NHS organisations and pharmaceutical industry partners should give due consideration to the impact on patients, and if appropriate, gain feedback from patients or patient groups.

Ways to incorporate patients' views and experiences can include:

- Patient stories of their experiences
- Mapping the key pathways of service with patients and staff working in coordination
- Considering community representation so that plans being developed represent diversity and the needs of different groups impacted, and ensuring inequalities are considered
- Recording a patient's experience of a service and asking for their views following the completion of the project for inclusion in the project outcomes.

Key resource: Recommended Collaborative/ Joint Working Agreement Framework

Once the project has been approved in principle by all relevant parties, the project team must work with its organisational legal experts to draft and sign a Collaborative/ Joint Working Agreement. The agreement is a legal contract that will include key information about the project and plans, drawn directly from the PID. It must be entered into with legal, corporate entities and not with any individual in primary, secondary and system-level settings.

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The agreement must ensure that any confidential, competitive or personal data are protected by strong contractual provisions. It should include the following:

- The name of the collaborative-working project, the parties to the agreement, the date and the term of the agreement
- Aims and objectives
- Considering community representation so that plans being develop represent diversity and the needs of different groups impacted and ensuring inequalities are considered
- The expected benefits for patients, the population or user groups, the NHS or other healthcare organisation, the pharmaceutical company and other organisation(s) as applicable
- · Principal activities and accountabilities
- Composition of the steering group /project group
- Timelines and project milestones
- Description of pooled resources
- Financial arrangements
- Roles and responsibilities of the healthcare organisation, the pharmaceutical company and other organisations
- · How the success of the project will be measured, when and by whom
- Relationship, if any, to the company's or companies' medicine(s)

- An executive summary of the project which will at minimum be published on the industry partner's corporate website before the project begins; healthcare organisations are encouraged to do the same
- · Process for project amendment
- Dispute resolution clause
- Defined exit strategy (for all parties)
- Contingency arrangements to cover possible unforeseen circumstances, such as changes to summaries of product characteristics or updated clinical guidance
- Agreement as to intellectual property rights to the project after its completion: will these be joint or handed over to the healthcare organisation?
- Data management/ sharing plans
- Pharmacovigilance plans (if required)
- A plan to fulfil the required commitment to publish outcomes by all parties as soon as possible and usually within six months of the project's completion, so that other healthcare organisations and others can learn from and potentially replicate the initiative.
- A commitment to disclosing the transfers of value to healthcare organisations via <u>Disclosure UK</u> by the industry partner.

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Please note: Any collaborative or joint-working agreements must be entered into with legal, corporate entities and not with any individual member of staff across primary, secondary and system-level settings.



The executive summary

The last stage in the project setup is the publication of an executive summary, which will largely draw from the content in the collaborative working agreement.

As outlined in the ABPI Code of Practice, a summary of the collaborative working agreement (executive summary) must be published on the pharmaceutical company's or companies' website before arrangements are implemented. It is also advisable that relevant NHS partners do the same. The project should not commence until the executive summary has been published on the relevant industry partner(s)' website. A recommended executive summary framework is shown in the key resource.

View a case study demonstrating the step-by-step implementation of a project in a secondary care setting. Key resource: Recommended Collaborative / Joint Working Project Executive Summary Framework



Collaborative / joint working executive summary		
Project title	Include a short sentence that outlines the project title.	
Project rationale	Briefly contextualise the background including why it is taking place. This can be outlined in bullet point form.	
Project objectives	Include expected benefits for patients, the NHS, and the relevant industry partner.	
Project period	Include anticipated dates for the project's initiation and completion.	
Financial arrangements	Include an outline of the financial arrangements that will be in place as part of the project.	
Plans for publication	Include the plans for publication of the project's data and outcomes.	
Contact details	Include details of the relevant name, title and email address of both the industry and NHS project lead.	
Summary of the roles and responsiblities of each party	Include in here details on the roles and responsibilities of the parties undertaking the project.	



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Stage 3

Project implementation and outcomes reporting



"I have seen first-hand the benefits of NHS-industry collaboration for patients, staff, the NHS and the local economy. In the face of the myriad challenges facing health and care services and our patients, we must find new ways to drive improvement and transformation for our local communities.

The NHS alone does not have all the answers, so responsibly using industry partners with expertise and additional resource is key to 'doing things differently' if we want to see real change. Tackling the barriers we know leaders on both sides face will ensure we are best placed to seize these opportunities."

Professor Phil Kloer, Chief Executive, Hywel Dda University Health Board



Project delivery and evaluation

Once the collaborative agreement is signed and published on the industry partners' website, the project officially starts.

To monitor project progress effectively, partners should refer to the outcomes outlined in the PID and executive summary.

Collaborative and joint-working projects are not set up as clinical trials or real-world evidence generating trials, and as such the project metrics need to be realistic and based upon the objectives of the project and intended purpose thereafter, ie business case or scalable solution. Examples of relevant metrics include clinical impact, delivery, service effects and economic impact. After project completion, outcomes will be measured and documented, with stakeholders and the project team evaluating learnings from the project.

Key resource: Project monitoring guidance

Regular monitoring is essential to ensure that:

- The collaborative/joint working arrangement is meeting pre-defined aims and objectives.
- The partnerships between parties are operating effectively.
- Issues are identified as early as possible so that they can be addressed.
- All parties are contributing resources as agreed in the written agreement
- All parties and participants have a clear view of the status of the project.
- · Stakeholders are fully informed about the project.
- · Opportunities to publicise success are identified and communicated.
- Confidence is built throughout the entire lifecycle of the partnership.

Effective monitoring should also comprise:

- · Clearly pre-defined success criteria.
- · Clear milestones and timelines.
- Clear arrangements to monitor and review how successfully the success criteria are being met.
- Clear arrangements to monitor how effectively the collaborative/joint working between the parties is operating.
- · Mechanism to identify and communicate issues and successes.
- Clear arrangements to ensure that all parties have access to the monitoring information.

If an overrun or delay looks likely, the project team should agree on mitigating actions and amend plans as necessary. This can be recorded in a letter of amendment or extension, known as a variation agreement, which the pharmaceutical company's legal team can draft on behalf of the project team.









If significant changes to the project occur during implementation, the following form should be completed and agreed by the project team and the governance committee in order to keep a record of the project aims as part of good governance:

Key resource: Recommended project amendment framework (for use only if necessary)



Project amendment framework		
Name of project	Outline the name of the project here.	
Project owner	Include the project leads from across all parties.	
Amendment to project initiation document requested		
Impact of this amendment	Include a brief explanation of the impact that this will have on the project timelines, logistics as well as financial impact.	
Submitted date	Include the date that this form was completed and shared with a member of the project steering committee/group.	









Reporting on the project outcomes

It is important to recognise that successful organisations will learn from their experiences of partnerships.

Learning is more beneficial when it is preserved beyond the end of the project in the outcome report. As well as evaluating the outcome of the project, it is useful to assess how successful or unsuccessful the operation of the project has been so that lessons can be learned and can be usefully applied in the design and running of other projects.

As stated in the ABPI Code of Practice, **all parties** should publish outcomes promptly, **within six months**. Local NHS organisations are encouraged to do the same. To promote and expand successful collaborations in healthcare, these outcome reports should be shared with ABPI for their NHS-Industry Partnership Case Studies Library to support more partnerships.

To ensure that partnerships are transparent, transfers of value related to **collaborative projects must also be disclosed via the Disclosure UK database** (see **Appendix 2** for further details on <u>Disclosure UK</u>, including how any contracted service values to patient organisations are disclosed).









Key resource: Recommended Summary of Project Outcomes Framework



Summary of project outcomes - template Project name Include a short sentence that outlines the project title. Outline the partnering organisations that took part in the collaboration. Project partners Duration Detail the project initiation and completion dates to the nearest month, e.g. December 2025 – July 2026. Project overview Provide an overview of the project, including its objectives and how the project set out to achieve them. Project outcomes Outline the results from the project, including benefits to patients, the NHS, and industry. This section should address the following: • Has the shared vision agreed at the beginning been sustained? If not, has variance been addressed to mutual satisfaction? Has the project achieved more through collaborative/joint working than it would have done if parties had worked individually? Why? · Have all parties made their contributions according to the original agreement? If not, has variance been addressed to mutual satisfaction? Has each party benefited from the collaborative/joint-working arrangement? How? Have good relationships been maintained? Has trust been generated and maintained? • Have differences been managed effectively? • Did the project enable them to build a business case to commission services differently? Did the pilot meet the threshold criteria for scaling? Include the conclusions and learnings drawn from the project, with the aim of supporting learnings for Conclusions and learnings other projects. References Include here examples of any NHS or National Institute for Health and Care Excellence (NICE) or All Wales

Medicines Strategy Group (AWMSG) policies that are relevant to the project.

identification and scoping

View a case study demonstrating the step-by-step implementation of a project that involved system level partners.







Further reading

Previous ABPI/ NHS Confederation publications

- Collaborate to innovate: learning from NHS, charity and life sciences industry experience to build a culture of research and innovation in the UK (April 2024)
- Partnering with purpose: how integrated care systems and industry can work better together (November 2023)
- Transforming lives, improving health outcomes: tackling the true cost of variation in uptake of innovative medicines (January 2023)

Historic partnership guidance

- Working Together A guide for the NHS, Healthcare Organisations and Pharmaceutical Companies (April 2022)
- Joint Working A Toolkit for Industry and the NHS (September 2019)
- Simplifying cross-sector working between NHS
 Integrated Care Systems, Sustainability and
 Transformation Partnerships and industry: Guidance on governance and process (May 2019)
- Joint Working A Quick Start Reference Guide for NHS and Pharmaceutical Industry Partners (2012)
- Moving Beyond Sponsorship Joint Working Between the NHS and Pharmaceutical Industry (August 2010)
- Best Practice Guidance on Joint Working Between the NHS and Pharmaceutical Industry and Other Relevant Commercial Organisations (February 2008)
- Collaborative Working and Joint Working: A toolkit for industry and NHS Wales

Additional reading

Guide to collaborative working between NHS, primary care contractors and the pharmaceutical industry

A Common Understanding 2025
Working Together for the People of
Scotland

The King's Fund: NHS and life sciences industry partnerships: collaborating to improve care

Partnering for progress: a datadriven analysis of NHS-industry partnerships













Appendix 1: The ABPI Code of Practice

The <u>ABPI Code of Practice</u> exists to regulate the promotion of prescription medicines to UK health professionals, industry interactions with health professionals, and the provision of information about prescription-only medicines to the public, including patients and patient organisations.

It is administered by the Prescription Medicines Code of Practice Authority (PMCPA) and is the cornerstone of the UK system of industry self-regulation.

All NHS-industry partnerships are bound by the code, which serves as a guardrail by which industry is regulated to ensure that throughout all collaborations, patient safety is maintained, in a professional, ethical and transparent manner to ensure the appropriate provision of high-quality care. At its heart, the code gives confidence to local NHS organisations that partnerships operate in a clear and robust framework.

Strong support is given to the code by the industry with all companies devoting considerable resources to ensure that their activities comply with it. Any complaint made against a company under the code is regarded as a serious matter both by that company and by the industry as a whole. Sanctions are applied against a company ruled in breach of the code.

Underpinning this are the ABPI
Principles, which sit alongside the code. These set out the behaviours that embody the spirit of the code, and the ABPI expects that companies build these into their culture and approach.

The four key principles are as follows:

- Commitment to benefiting patients and ensuring patient safety by operating in a professional, ethical and transparent manner to ensure the appropriate and rational use of medicines and to support the provision of high-quality healthcare.
- Acting with integrity and commit to engaging in relationships which are responsible, professional, ethical and transparent.
- Commitment to ensuring that transparency is respected.
- Interact with all stakeholders with respect.

The ABPI Code reflects and extends beyond relevant UK legislation and ensures that the ABPI meets its commitments to implement other codes, such as the International Federation of Pharmaceutical Manufacturers and Associations and European Federation of Pharmaceutical Industries and Associations Codes.

The code is also supplemented by Disclosure UK, a Europe-wide initiative to increase transparency between pharmaceutical companies and the organisations they work with. Further information on <u>Disclosure UK</u> can be found in **Appendix 2**.



Appendix 2: Disclosure UK

The relationship between the pharmaceutical industry, healthcare professionals, and healthcare organisations plays a vital role in the development of life-enhancing and life-saving medicines.

At the core of the relationship is sharing knowledge to improve patient outcomes. To ensure this relationship is open and transparent, the pharmaceutical industry has taken the lead on disclosing 'transfers of value' – payments and benefits-in-kind – made by industry to healthcare professionals and healthcare organisations through Disclosure UK, a publicly searchable database, hosted by the ABPI. Disclosure UK is part of a Europe-wide initiative to increase transparency between pharmaceutical companies and healthcare professionals and organisations.

Data shown on Disclosure UK covers certain key areas of cross-sector working between industry, healthcare professionals, other relevant decision makers, and healthcare organisations, including:

- participation in advisory boards
- speaking at or chairing meetings
- working with and advising doctors and scientists in pharmaceutical companies
- speaking at conferences and symposia
- attending and contributing to national and international conferences
- participating in medical education and training funded by pharmaceutical companies
- provision of grants and donations to healthcare organisations
- sponsorship of healthcare organisation events for the provision of medical education to healthcare professionals.

Details of collaborative and joint working projects with healthcare organisations,

among other things, are disclosed individually on the database. Certain research and development transfers of value to healthcare professionals, other relevant decision makers, and healthcare organisations are also disclosed in aggregate.

Separately, pharmaceutical companies are also required to disclose transfers of value made to patient organisations (and fees for certain contracted services paid to members of the public, including patients and journalists). The ABPI Code requires that this information is published on the pharmaceutical companies' websites and that there are gateway links to this information from Disclosure UK.

For more resources and to search the database, please visit: www.disclosureuk.org.uk

It should be noted that these disclosure requirements are in addition to those already described previously in this document:

- An executive summary of the project which will at minimum be published on the industry partner's corporate website before the project begins.
- All parties should publish outcomes as soon as possible and within six months of completion.



Welsh NHS Confederation

Tŷ Glan-yr-Afon 21 Cowbridge Road East

Cardiff CF11 9AD

029 20 349 850

www.nhsconfed.org/wales Welsh NHS Confederation

ABPI

2nd Floor Goldings House Hay's Galleria, 2 Hay's Lane London SE1 2HB 020 7930 3477 www.abpi.org.uk @ABPI_UK

If you require this publication in an alternative format, please email **enquiries@nhsconfed.org**

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