NHS Confederation

In partnership with abpi

# Accelerating transformation: How to develop effective NHS-industry partnerships

## Guidance

June 2024

Version 1.0

# About us

## NHS Confederation

The NHS Confederation is the membership organisation that brings together, supports and speaks for the whole healthcare system in England, Wales and Northern Ireland.

The members we represent employ 1.5 million staff, care for more than 1 million patients a day and control £150 billion of public expenditure. We promote collaboration and partnership working as the key to improving population health, delivering high-quality care and reducing health inequalities.

To find out more, visit www.nhsconfed.org

## abpi

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

# Contents

# Foreword

Cross-sector collaborations between NHS organisations and the research-based pharmaceutical industry have a strong track record of delivering benefits for patients, the NHS and industry – the so-called 'triple win'.

You can explore the wealth of health system efficiencies and patient benefits gained from these collaborations in the ABPI' s library of cross-sector initiatives.

Despite these successes, we believe the potential of cross-sector partnerships to accelerate health system transformation is still to be realised. Now that England has formally integrated health and care across primary, secondary and social care, it should be possible to make a step change in the scale and ambition of cross-sector collaboration and demonstrate measurable correlations between project interventions and patient outcomes.

The NHS Confederation and ABPI have now been working together with industry and system leaders for seven years to understand and unblock the barriers to making the potential of partnership a reality – exploring issues such as culture, trust and the sheer challenge of stepping outside health system operational norms.

In doing so, we have heard directly what NHS leaders and industry need to work more easily together:

- practical resources and sources of assurance to enable scoping, implementation and reporting across the lifecycle of partnership programmes
- greater understanding by NHS leaders of the regulations governing industry collaboration.

This new guidance aims to meet those needs as the next step in our work together – providing a practical, step-by-step guide to help NHS and industry develop, contract, implement, measure partnerships more easily, and deliver the benefits more rapidly.

Key to this new guidance is the introduction of recommended frameworks, endorsed by both our organisations, that can be used by NHS organisations at all levels – trusts, practices, networks and integrated care systems – to make each stage of partnering straightforward, both for the initial project and for scaling to other locations.

We are indebted to the multiple NHS and industry leaders who gave their time to help us design this guidance and hope that it ushers in an uplift in the scale and ambition of collaboration between our sectors to transform the NHS and improve patient care.

Matthew Taylor
Chief Executive
NHS Confederation

Dr Richard Torbett
Chief Executive
ABPI

# About this guidance

This guide provides a practical, step-by-step resource to help the NHS and industry develop, contract, implement, measure and deliver benefits more rapidly.

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

Access downloadable, editable documents wherever you see the icon.

Download templates

## Who this guidance is for

This document is aimed at local NHS organisations in England, 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 for NHS-industry partnership working

**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.

# What are NHS-industry partnerships?

## NHS-industry partnerships allow local NHS organisations and the pharmaceutical industry to collaborate for patients' benefit.

Since joint working was established in 2008, the Department of Health and Social Care (DHSC) has acknowledged the value of external expertise in helping NHS organisations overcome challenges. This includes providing additional skills and resources to achieve patient benefits beyond what NHS organisations could do alone. These partnerships not only offer innovative treatments to enhance patients' outcomes, but also bring industry skills and expertise to support project management and 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, such as provider collaboratives in England, and the added complexity of gaining agreement across multiple organisations.

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

# The benefits of working together

## Working across sectors can accelerate improvements in patient care at an organisation, population or system level.

Often cross-sector projects will pilot innovative models of care that can be replicated and scaled up. Pharmaceutical companies can bring much-needed expertise, skills and resources to complement the expertise of healthcare organisations and patient organisations, such as:

- data evaluation, health, economic and project management expertise
- medical writing, business management, marketing and communications skills
- process redesign
- educational resources.

This triple win – benefiting patients, healthcare organisations including the NHS, and pharmaceutical companies – is more important than ever in the context of the challenges facing healthcare organisations.

The online ABPI-NHS case study library brings together over 180 examples of projects set up, delivered and resourced by NHS and pharmaceutical industry partners. Unlike the provision of grants and sponsorships by pharmaceutical companies, or simple provision of services such as homecare, or patient-support programs, NHS-industry partnerships represent a true pooling of skills, experience, and resources from all parties involved.

Collaborative working and joint working NHS-industry partnerships, which are the focus of this guidance, and described in more detail below, are a specific type of activity which is defined and described in the ABPI Code of Practice. These requirements including those pertaining to set-up and approval of the collaborative or joint working partnership, as well as specific transparency stipulations form key guardrails around such partnerships. These are described in more detail, below.

## Types of NHS-industry partnership

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.

# 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 professional 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.

<table>
<tr><th>Collaborative-working projects</th><th>Joint-working projects</th></tr>
<tr><td>Are for the benefit of patients and/or the healthcare organisation, including the NHS.</td><td rowspan="2">Must always be for the benefit of patients directly and must include the NHS as a party.</td></tr>
<tr><td>Enhance patient care or be for the benefit of patients, or alternatively benefit the NHS and, as a minimum, maintain patient care.</td></tr>
<tr><td colspan="2">May not constitute a grant/donation (see Clause 23 of ABPI Code of Practice for further information on Donations and Grants).</td></tr>
<tr><td colspan="2">May provide benefits to the company or companies involved.</td></tr>
<tr><td colspan="2">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:<ul><li>the progress towards the objective/outcomes</li><li>their roles and responsibilities and the actions they must take to ensure the outcomes are achieved in accordance with the agreement</li><li>the outcomes achieved can be demonstrated following the completion of the project.</li></ul></td></tr>
<tr><td colspan="2">Must be carried out in an open and transparent way, with a certified summary of the project agreement publicly available before it begins.</td></tr>
<tr><td colspan="2">Must respect clinical independence.</td></tr>
<tr><td colspan="2">Must be prospective – not relating to a project that has already begun.</td></tr>
<tr><td colspan="2">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.</td></tr>
<tr><td colspan="2">Must not constitute an inducement to health professionals or other relevant decision-makers to prescribe, supply, recommend, buy or sell a medicine.</td></tr>
<tr><td colspan="2">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.</td></tr>
<tr><td colspan="2">Must not promote a prescription-only medicine to any member of the public.</td></tr>
</table>

## The ABPI Code of Practice

The 2021 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 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 ABPI Code of Practice.**

"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."

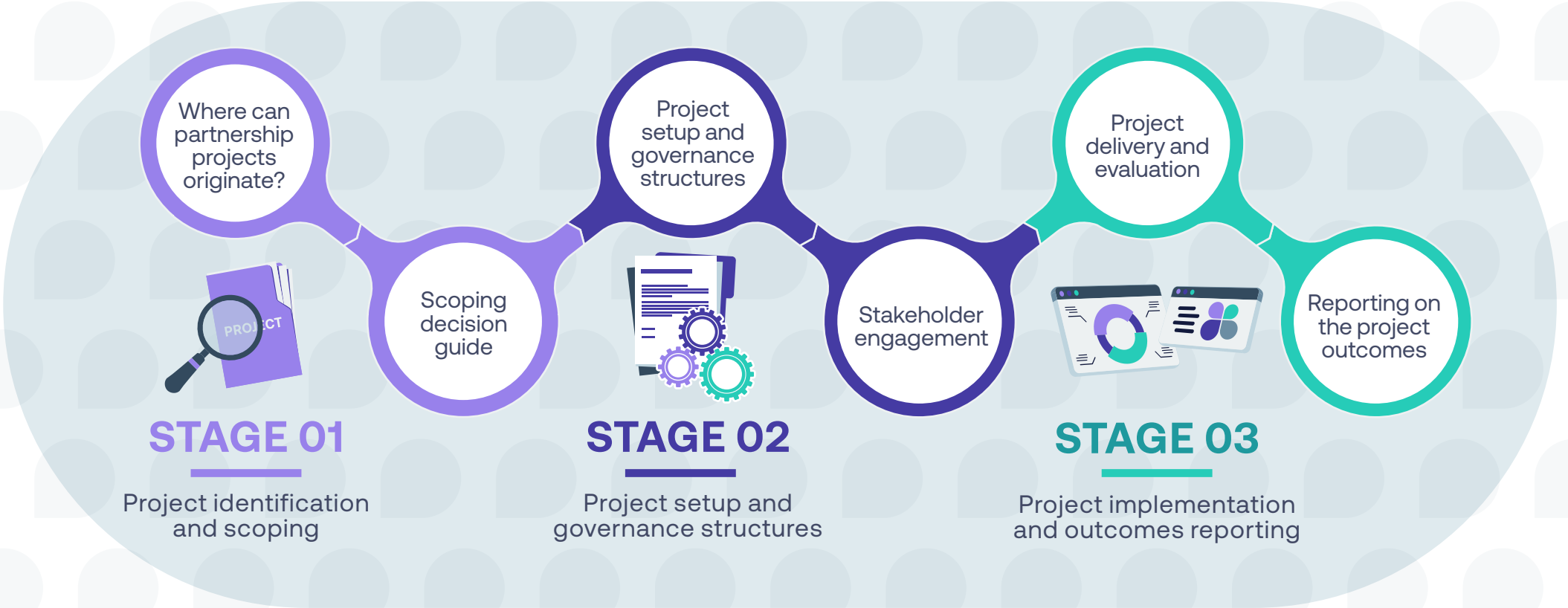
Dr Amit Aggarwal, Executive Director,
Medical Affairs and Strategic Partnerships, ABPI

## Achieving impact with partners


**Supported by NHS-industry Partnership Guidance and ABPI Code of Practice**

# 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

"NHS leaders are working hard to find ways to deliver high-quality services, while also helping people to stay healthier longer and seeking to reduce inequalities. Opportunities presented by effective NHS-industry partnership working have a valuable contribution to make to these efforts. This joint NHS Confederation and ABPI guidance is designed to enable teams to collaborate with confidence in the interest of the local communities that they serve."

Sarah Walter, Director, NHS Confederation's ICS Network

# Where can partnership projects originate?

| Primary care | Secondary care | Integrated care system/ place level |
|---|---|---|
| Primary care or primary care network (PCN) partnerships often arise from existing relationships with industry providers.<br><br>At other times, this will take place through proactive work by PCNs, federations and individual practices interested in finding partners to support specific projects.<br><br>Industry partners will also often research and directly scope out primary care providers where projects can directly support their existing clinical priorities. | Across secondary care settings, partnership working is well established and, as such, clearer routes exist when identifying projects.<br><br>Often agreed avenues for exploring partnerships are in place, such as via relationships between industry and trusts, as well dedicated commercial services teams which will issue expressions of interest regarding partnership objectives and opportunities.<br><br>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. | Partnership working with integrated care boards (ICBs) in England 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 national obligations and local objectives.<br><br>Early-stage discussions about entering a collaborative or joint-working arrangement with board staff should include relevant clinical leads and executive leads, including the chief pharmacist as appropriate.<br><br>If proposals are deemed suitable to explore further, it is advised that the designated NHS and industry leads should provide initial details on the scope and aims to relevant board-level working groups, such as the ICB Integrated Medicines Optimisation Committee (IMOC) or equivalent medicines committee, for their consideration.<br><br>The 15 health innovation networks (HINs) in England that operate across ICBs can also serve as an important conduit by which to streamline processes of setting up 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 patient care and/or system improvement? |
| What is the scale of the problem? | |
| What is the evidence to back this up? | Which companies have expertise in this area? |
| What is the priority improvement area, and can this realistically be addressed within the resources and duration of the project? | |
| What are the patient or system benefits of addressing this need? | Are there other organisations that would be relevant to engage in the project? For example, at an ICS level, can HINs play a convening and facilitation role for the partnership? |
| What would be the impact on patient care or the system if this need is not addressed? | |
| Are other internal stakeholders supportive of addressing the need and the feasibility of doing so? | |
| Which NHS plan and/or local improvement plan goal is the challenge aligned to? | |

Table continues on page 15.

| 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? | How are partners considering the impact of health inequalities and equality of healthcare access? |
| 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? | |
| 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? | |
| 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 Clause 23 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.

| Collaborative working | | |
|---|---|---|
| 1A. 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 collaborative-working project – go to question 2 (page 17) | **NO** Please go to question 1B |
| **Joint working** | | |
| 1B. Is the main benefit of the project focused on the patient? | **YES** This is a joint-working project – go to question 2 (page 17) | **NO** Consider another form of support |

Checklist continues on page 17.

| Red questions | | | |
|---|---|---|---|
| 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 an 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 the signatory to ensure Joint Working Agreements and collaborative-working documents can be certified? | YES | NO |

**Stage 1**
Project identification and scoping

**Stage 2**
Project setup and governance structures

**Stage 3**
Project implementation and outcomes reporting

# 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-working agreement. |
| 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 Q4 2024. |
| Length of project | Overall length of the project in months. |
| Decision | Include detail if the decision to go ahead with the project was positively made. |

Stage 1
Project identification and scoping

Stage 2
Project setup and governance structures

Stage 3
Project implementation and outcomes reporting

# Stage 2

## Project setup and governance structures

# 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. Examples of stakeholders who might be required to participate in this team can be found on page 21. 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. As such, they should follow NHS England's Conflicts of Interest Guidance, which was co-developed with the ABPI. 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. PRINCE2 (Projects In Controlled Environments) is perhaps the best known and most widely used by the NHS, but the methodology may vary depending on the complexity of the project. It 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 NHS resources is challenging, so contributions should be comparable and proportionate. If the collaboration aims to address healthcare organisation constraints, precautions must be taken when using pharmaceutical funding to retain staff. Any staff paid through industry funding should operate under NHS control, with clear employment law compliance. Exit strategies for industry-funded posts should be outlined in project documents.

# 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**<br>• PCN Clinical Directors / relevant deputies<br>• GP federation Chief Executives/Managing Directors<br>• Community Pharmacy Leads<br>• HIN Innovation and Commercial Leads | **Industry**<br>• Programme Manager<br>• Medical Affairs Lead<br>• Partnership Lead |
| **Secondary care**<br>• Associate Medical Directors / Chief Pharmacists<br>• Relevant Secondary Care clinical lead<br>• HIN Innovation and Commercial Leads | **Industry**<br>• Programme Manager<br>• Medical Affairs Lead<br>• Partnership Lead |
| **System-level care**<br>• Directors of Strategy and Innovation<br>• Heads of Medicines Management<br>• ICB Pharmacists<br>• HIN Innovation and Commercial Leads | **Industry**<br>• Programme Manager<br>• Medical Affairs Lead<br>• Partnership Lead |

# Key resource: Steps to build trust

Trust 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

## 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

## Continuity

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

## Outcomes

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

**Stage 1**
Project identification and scoping

**Stage 2**
Project setup and governance structures

**Stage 3**
Project implementation and outcomes reporting

# 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.

The PID must be approved by not only the project team, but also the relevant governance committee(s) – see page 27 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 should be provided here, including their full addresses. |
| 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 Q4 2024. |
| 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. |

PID continues on pages 25 and 26.

| 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 examples of any NHS or National Institute for Health and Care Excellence (NICE) policies that are relevant to the project. |

PID continues on page 26.

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

# Establishing a robust governance framework

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

This involves establishing 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 NHS organisations, governance will usually be provided by existing governance committee or Internal Review Committee (IRC). For collaborative projects, one must find stakeholders with the authority to approve the project.

Examples of key individuals who can form part of a governance committee are presented in the key resource:

**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

# Stakeholder 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.

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.

### Key resource: Examples of stakeholder groups to engage across care settings (non-exhaustive)

| | |
|---|---|
| Primary care | GPs, pharmacists, patients and residents, local Healthwatch and voluntary and community sector organisations |
| Secondary care | Chair of Trust Quality Committee, Chair of Medicines Optimisation Group, patients and residents, local Healthwatch and VCSE organisations |
| System-level care | Chair of ICB Quality Committee, patients and residents, local Healthwatch and VCSE organisations |
| Industry | Company decision makers, local representatives, market access teams, project managers |
| Others | NHS England, Department of Health and Social Care, patient groups |

# Patient engagement

NHS and 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' 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.

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
- 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 Disclosure UK by the industry partner.

**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 issued in the PID.

As outlined in the ABPI Code of Practice, an executive summary of the project rationale, period and objectives must be published on the industry partners' website once the project has commenced. 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 period | Include anticipated dates for the project's initiation and completion. |
| Project objectives | Include expected benefits for patients, the NHS, and the relevant industry partner. |
| Contact details | Include details of the relevant name, title and email address of both the industry and NHS project lead. |

# Stage 3

## Project implementation and outcomes reporting

"Building and managing successful partnerships is difficult, and healthcare teams often face complex challenges when attempting to innovate or work in new ways. The guidance set out by NHS Confederation and ABPI helps to show the clear steps that can support effective collaboration."

Clair Huckerby, Chief Pharmacist,
Consultant Pharmacist Primary Care, Our Health Partnership

# 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.<br>• The partnerships between parties are operating effectively.<br>• Issues are identified as early as possible so that they can be addressed.<br>• All parties and participants have a clear view of the status of the project.<br>• Stakeholders are fully informed about the project.<br>• Opportunities to publicise success are identified and communicated.<br>• Confidence is built throughout the entire lifecycle of the partnership. |
| Effective monitoring should also comprise: | • Clearly pre-defined success criteria.<br>• Clear milestones and timelines.<br>• Clear arrangements to monitor and review how successfully the success criteria are being met.<br>• Clear arrangements to monitor how effectively the collaborative/joint working between the parties is operating.<br>• Mechanism to identify and communicate issues and successes.<br>• 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.

Stage 1
Project identification and scoping

Stage 2
Project setup and governance structures

Stage 3
Project implementation and outcomes reporting

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 | Included details of what has deviated and been changed from the PID which has been 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 Disclosure UK, 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. |
| Project partners | Outline the partnering organisations that took part in the collaboration. |
| Duration | Detail the project initiation and completion dates to the nearest month, e.g. November 2022 – May 2023. |
| 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:<br>• Has the shared vision agreed at the beginning been sustained?<br>• 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?<br>• Have all parties made their contributions according to the original agreement?<br>• If not, has variance been addressed to mutual satisfaction?<br>• Has each party benefited from the collaborative/joint-working arrangement? How?<br>• Have good relationships been maintained?<br>• Has trust been generated and maintained?<br>• Have differences been managed effectively?<br>• Did the project enable them to build a business case to commission services differently?<br>• Did the pilot meet the threshold criteria for scaling? |
| Conclusions and learnings | Include the conclusions and learnings drawn from the project, with the aim of supporting learnings for other projects. |
| References | Include examples of any NHS or National Institute for Health and Care Excellence (NICE) policies that are relevant to the project. |

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

**Stage 1**
Project identification and scoping

**Stage 2**
Project setup and governance structures

**Stage 3**
**Project implementation and outcomes reporting**

# 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)




* Disclaimer: Please be aware that this publication replaces the previous guidance highlighted above. Any publications not already archived will be so once this report is published.

# Acknowledgments

On 5 March, 12 March and 27 March 2024, roundtables were held with industry and local NHS organisation leaders from across primary, secondary and system care settings.

We express our gratitude to all colleagues who dedicated their time and insights during the three roundtables, integral in shaping the development of this guidance.

Please be aware that the guidance in this paper, developed by NHS Confederation or ABPI, may not reflect the opinions of the mentioned organisations and individuals.

| Name | Role | Organisation |
|---|---|---|
| Amit Patel | Chief Executive Officer | Community Pharmacy South West London |
| Anna Carratt | Deputy Director of Strategic Development | North East London ICS |
| Brian Duggan | Strategic Partnership Policy Director | ABPI |
| Charlotte Moss | Industry Engagement and Policy Manager | NHS Confederation |
| Clair Huckerby | Chief Pharmacist, Consultant Pharmacist Primary Care | Our Health Partnership |
| Donal Sutton | Assistant Director, Industry Engagement and Policy | NHS Confederation |
| Dr Jeanine Smirl | GP and Clinical Director | Norwich PCN |
| Dr Paul Stevens | Consultant Nephrologist and Medical Examiner | East Kent Hospitals University NHS Foundation Trust |
| Dula Alicehajic-Becic | Consultant Pharmacist | Wigan Infirmary |
| Farrah Ahmad | NHS Collaboration Partner | Daiichi Sankyo |
| Helen Hoyland | Head of Commercial Innovation and Growth | Health Innovation Network Yorkshire |
| James Thomas | Medical Director | West Yorkshire Integrated Care Board |

# Acknowledgments


| Name | Role | Organisation |
|---|---|---|
| Jennifer Gilroy-Cheetham | Senior NHS Engagement Manager | Chiesi |
| John Byrne | Chief Medical Officer | South West London ICB |
| Kelly McCormick | NHS Engagement and Access Manager | Sanofi |
| Louise Organista | Advanced Clinical Pharmacist | University Hospitals of Derby and Burton NHS Foundation Trust |
| Michael Smith | Chief Executive | Bolton GP Federation |
| Mike Stansfield | Market Access Project Support Manager | Sanofi |
| Nabil Rastani | Strategic Partnership Policy Manager | ABPI |
| Rakesh Marwaha | Managing Partner and Chief Executive | Erewash PCN |
| Rebecca Gale | Assistant Director, Primary Care Network | NHS Confederation |
| Roisin McCann | Senior Industry Engagement and Policy Officer | NHS Confederation |
| Rory Deighton | Director, Acute Network | NHS Confederation |
| Ross Rotherham | Health System Engagement Lead | Boehringer Ingelheim |
| Sarah Ferry | Senior Policy Advisor, Innovation and Life Sciences | NHS Confederation |
| Sarah Walter | Director, ICS Network | NHS Confederation |
| Sarika Passi | National Oncology Projects Manager UK | MSD |
| Su Jones | Collaborative Working Owner | AstraZeneca |
| Sue Consterdine | Associate Director, NHS Partnership and Strategy Lead | Bristol Myers Squibb |
| Tracey Palmer | Oncology Business Manager | Lancashire Teaching Hospitals NHS Foundation Trust |


Stage 1
Project identification and scoping

Stage 2
Project setup and governance structures

Stage 3
**Project implementation and outcomes reporting**

# Appendices

## 1 and 2

# Appendix 1: The ABPI Code of Practice

The 2021 ABPI Code of Practice 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 Traders 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 Disclosure UK 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 certain members of the public). The ABPI Code requires that this information is published on the individual pharmaceutical companies' websites. To increase access to this information, Disclosure UK includes two 'gateways' comprising a list of links to the individual company websites publishing this information. While not fully integrated in the same way as healthcare professional, other relevant decision maker, and healthcare organisation disclosure data, the gateways enable visitors to Disclosure UK to find patient organisation information more easily from the same place.

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

NHS Confederation

18 Smith Square
Westminster
London SW1P 3HZ

020 7799 6666
www.nhsconfed.org
@NHSConfed

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**



Registered charity no. 1090329