abpi
Bringing medicines to *life*

Working together

A guide for the NHS, healthcare organisations and pharmaceutical companies

April 2022

Contents

1. Introduction

The Association of the British Pharmaceutical Industry (ABPI) exists to make the UK the best place in the world to research, develop and use new medicines and vaccines. We represent companies of all sizes that invest in discovering and bringing to patients the medicines and vaccines of the future.

Our members believe that working with healthcare organisations, including the NHS, to develop and deliver treatment and care is the best way to improve outcomes for patients, address healthcare challenges and support sustainable health and care across the UK.

Many healthcare organisation colleagues also know from experience that working with industry can be highly effective in all these areas. Collaboration has taken place for many years, with many cross-sector projects happening right now. You can read more about these in the ABPI repository of cross-sector collaborations.

Healthcare organisations, industry and other appropriate partners often face challenges in working together, particularly when several organisations are involved. Our aim in developing this guidance is to support the process by providing practical information for partners from sectors who are thinking about, or are already, working together.

It provides information about different mechanisms for collaboration and offers practical guidance to encourage cross-sector working that delivers for all parties – and most of all, for the benefit of patients.

ABPI member companies are regulated by the Prescription Medicines Code of Practice Authority (PMCPA), which is responsible for the administration of the ABPI Code of Practice. Many pharmaceutical companies that are not members of the ABPI have also agreed to comply with the ABPI Code and accept the jurisdiction of the PMCPA. This guidance is based on, and consistent with, all aspects of the latest version of the Code, published in 2021.

It provides information on:

- the main mechanisms for working together, along with the characteristics of each, to help with decisions about which is most appropriate for a specific idea or project
- the standards and regulatory frameworks used when working together across sectors

The guidance then focuses in on two specific activities – **collaborative working** and **joint working**. It sets out a practical and detailed ten-step approach to planning and making successful these ways of working together, including processes, governance, possible pitfalls and ways to manage them.

Four appendices to the guidance provide more detail on working with multiple partners, legal considerations, and data and disclosure issues.

We hope this guidance is useful: feedback is always welcome so that we can learn and adapt for future users.

2. Why work together?

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

The triple win – examples of potential benefits that cross-sector working may bring

Potential Patient benefits	Potential Healthcare organisation benefits	Potential Industry benefits
More patients receive evidence-based care	Improved quality of care delivery	Expansion of an eligible patient population
Care closer to home	Services configured around patient needs	Increase in the appropriate use of medicines aligned to local or national guidance
Fewer hospital admissions	Improved health outcomes	Better understanding of the challenges faced by healthcare organisations including the NHS
More information about conditions and treatment options	Better clinical quality outcomes	Improved implementation of national treatment guidance
Better experience of the healthcare system	Better use of resources	Real-world evidence and data generated to enhance research
Health inequalities reduced	Lower hospital admissions	
Improved outcomes	New approaches to preventative care and treatment developed	
Improved quality of life	Efficiency and system challenges addressed	

This triple win – benefiting patients, healthcare organisations including the NHS, and pharmaceutical companies – is more important than ever in the context of the UK's recovery from the COVID-19 pandemic and the challenges facing healthcare organisations. The online ABPI-NHS collaboration case study repository brings together over 50 examples of projects set up, delivered and resourced by NHS and pharmaceutical industry partners during the last seven years.

Overcoming challenges

Although there are many examples of successful projects involving healthcare organisations and pharmaceutical companies, we know there are also examples that have been unsuccessful.

This can be due to many factors including differences in understanding of the proposed outcomes or the principles set out for the project, a lack of planning and deploying governance and/or project management processes, as well as issues relating to contracting and aligning the different requirements and approval mechanisms of multiple partner projects.

If obstacles cannot be overcome, potentially valuable collaborations fail despite the best intentions of all parties. When that happens, everyone loses – healthcare organisations, pharmaceutical companies and, potentially, patients and their families.

To improve success and reduce obstacles, prospective collaborators should work on ensuring objectives and outcomes are clear and understood from the outset. This requires good planning, open communication, clear and appropriate governance and a relationship built on trust, shared outcomes and knowledge of, and adherence to, agreed rules.

3. Routes to cross-sector working

There are three main types of cross-sector working between healthcare organisations and pharmaceutical companies:

- research collaborations
- joint working
- collaborative working

Research Collaborations are essential to the development and evaluation of new medicines and vaccines. The ABPI has worked with the four nations of the United Kingdom to develop Phase 1 trial guidance; a model Clinical Trial Agreement; and guidelines on clinical trials compensation to support this critical process. Findings of cross-sector research collaborations are expected to be reported on the ISRCTN Registry and the value of certain research collaborations is disclosed in aggregate on the Disclosure UK database.

Helpful to know:

Sometimes a donation or grant may be more appropriate to the needs of a healthcare or patient organisation than true cross-sector working. Donations and grants are funds, benefits-in-kind or services freely given for the purpose of supporting healthcare, scientific research or education, with no consequent obligation on the recipient organisation to provide goods and services to the benefit of the pharmaceutical company in return.

In general, donations are physical items, services or benefits-in-kind which may be offered or requested. Grants are the provision of funds. A company can work with healthcare organisations, patient organisations or other organisations to provide a service. It may also provide goods (e.g. equipment, textbooks, etc.) or in-kind benefits, such as a staff member's time, experience or expertise. Donations and grants to individuals are prohibited.

More information on donations and grants from pharmaceutical companies can be found in Clause 23 and its supplementary information of the ABPI Code of Practice.

If a healthcare or patient organisation's need is for support, the best place to start is the corporate website of companies with an interest in the relevant disease area. Many company websites signpost healthcare organisations, healthcare professionals, and patient organisations to '**Requests for funding**' routes. Funding options, including grants at national or regional level, may also be open for application.

Joint Working is the best-known mechanism for cross-sector working between pharmaceutical companies, healthcare organisations and others, and has been referenced in the ABPI Code of Practice since 2008. Joint Working is a specific type of cross-sector project focused on direct benefit to patients. You can find examples of joint working case studies in the ABPI NHS-Industry Case Study Repository and on ABPI members' own websites. However, some requirements for Joint Working have made it challenging to progress projects where direct patient benefit was not the primary goal. A definition of Joint Working is set out opposite, and is further defined in Clause 20.4 of the ABPI Code of Practice.

Joint Working is defined in the DH Joint Working Guidance and Joint Working Toolkit as: Situations where, for the benefit of patients, one or more pharmaceutical company and the NHS pool skills, experience and/or resources for the joint development and implementation of patient-centred projects, and share a commitment to successful delivery.

ABPI Guidance notes states: The key requirements from this definition are twofold:

(i) the Joint Working project must be focused on benefits to patients; and

(ii) there must be a 'pooling' of resources between the pharmaceutical company and the NHS organisation(s) involved. Each party must, therefore, make a significant contribution to the joint working project to avoid the arrangement being construed as merely a gift, benefit-in-kind, donation or some other non-promotional/commercial practice. Resources may come in various forms, including people, expertise, equipment, communication channels, information technology and finance.

In addition, given the significant governance and administrative requirements involved in setting up proper joint working arrangements, it is likely that most joint working projects will be of a significant size and duration – as a guideline, generally involving resources (manpower, materials, funding etc.) in the region of £15,000 – £20,000 and lasting six months or more. Ideas for Joint Working projects can arise from either party, hence pharmaceutical companies (as well as NHS organisations) can proactively propose ideas for joint working.

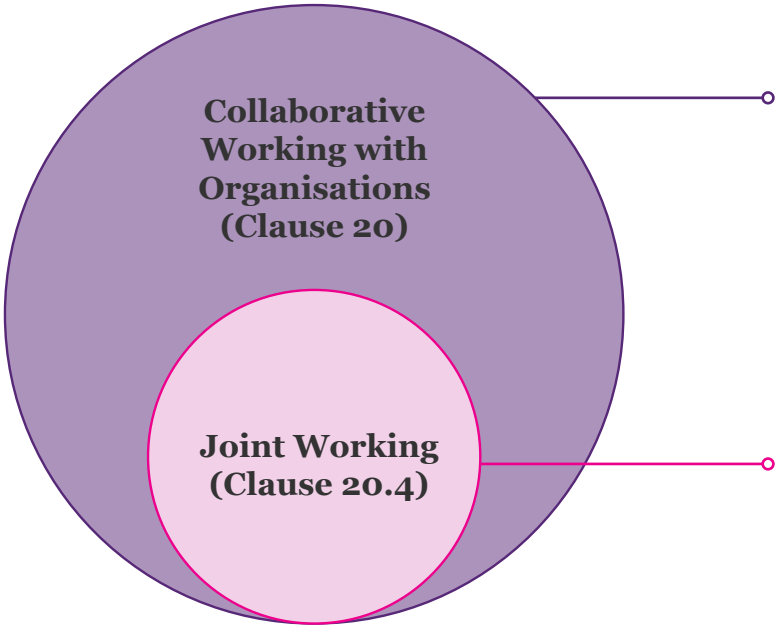
Reference – ABPI Guidance notes on Joint Working between pharmaceutical companies and the NHS and others for the benefit of patients. March 2009.

Collaborative Working is a new, broader category of cross-sector working introduced into the 2021 ABPI Code of Practice. Collaborative Working is broader than Joint Working, in that project outcomes can be for patient- and/or healthcare-centred projects. Amongst other things, this allows process improvement as a potential outcome and for healthcare organisations that are not part of the NHS to work with pharmaceutical companies.

Examples of projects which might be defined as collaborative working projects include:

- increasing system capacity to treat patients
- supporting pathway redesign
- identification of undiagnosed patients
- reviewing uncontrolled patients
- improving patient adherence to medicines
- generating patient experience data

The relationship between Joint Working and Collaborative Working is shown below. More information can be found in Clause 20 of the 2021 ABPI Code of Practice.



Clause 1.3 (Definitions) 'Collaborative Working' refers to pharmaceutical companies working with other organisations to deliver initiatives which either enhance patient care or are for the benefit of patients or alternatively benefit the NHS and, as a minimum, maintain patient care.

Joint working between one or more pharmaceutical company and healthcare organisation(s) which is patient-centred and always benefits patients is an acceptable form of collaborative working, providing it is carried out in a manner compatible with Clause 20 and other relevant requirements of the ABPI Code of Practice.

Collaborative and Joint Working approaches: a comparison

Collaborative Working Projects	Joint Working Projects
Must have desired outcomes clearly articulated from the beginning and recorded in a written agreement	Must have desired outcomes clearly articulated from the beginning and recorded in a written, certified agreement
Are for the benefit of patients or the healthcare organisation, including the NHS	Must include the NHS as a party to the project Are designed for the benefit of patients
May enhance patient care and where they benefit the healthcare organisation, they must as a minimum maintain standards of patient care	Must have enhanced patient care as primary goal
The contributions of parties involved must demonstrate pooling of skills experience and/or resources and each party must make a significant contribution	The contributions of parties involved must demonstrate pooling of skills experience and/or resources and each party must make a significant contribution
May not include a grant/donation	
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 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 their value publicly disclosed annually on the Disclosure UK database	
Must not constitute an inducement to health professionals or other relevant decision-makers to prescribe, supply, recommend, buy or sell a medicine	
Must not generate benefits directly for an individual healthcare professional	
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	
Must not interfere in doctor/prescriber-patient shared decision-making	

While Joint Working remains an entirely legitimate model for conducting cross-sector projects that meet the necessary criteria, it is likely that most new cross-sector projects will be set up under the more flexible Collaborative Working agreements.

4. Standards to follow in working together

Whichever route for working together is chosen, healthcare organisation colleagues can be confident that ABPI members, and other pharmaceutical companies that have agreed to comply with the ABPI Code, are required to meet the highest standards of ethics and compliance in their collaborative activities.

These standards are set out in the ABPI Code of Practice, which supports pharmaceutical companies' commitment to operating in a professional, ethical and transparent manner in the UK and internationally. The Code is overseen by the Prescription Medicines' Code of Practice Authority (PMCPA), which is independent from the ABPI.

The ABPI Code of Practice is supplemented by legal frameworks such as US and UK anti-bribery and anti-corruption legislation, as well as various corporate global and local compliance policies and procedures. It 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 3**.

The following **common standards** (**Legislative**, **ABPI Code**, and **governance** as agreed by the parties) will also always apply:

Common Standards	Purpose
GDPR (General Data Protection Regulation) legislation	Ensures no access to identifiable patient-level data
Anti-bribery, anti-corruption and modern slavery	Legislative requirement, reflected in organisational values and due diligence arrangements
Transparency Reporting	Transfers of Value declarations as required by EFPIA Code (European Federation of Pharmaceutical Industries and Associations) are also an ABPI Code requirement for disclosing direct and indirect payments and benefits-in-kind to healthcare organisations
Outputs, monitoring and evaluation	Outlined in the Project Initiation Document. Publication of outcomes within six months of project closure on UK Company corporate website
Governance/Steering Committee	Ensures clear oversight, governance, project decision-making, financial and risk management for the project, underpinned by agreed Terms of Reference
Data and Intellectual Property ownership	Should be defined and agreed within a formal Working Agreement
Declarations of interest	Clear arrangements to ensure conflicts of interest are declared and managed at project outset in line with NHS guidance on Conflicts of Interest
Dispute Resolution procedure	Executive sponsor oversight from each party

These requirements are in place to ensure that cross-sector working happens in an ethical, transparent, regulated, and well-governed way, with pharmaceutical industry partners clear on what they can and cannot do to support the NHS and other healthcare organisations. In turn, healthcare organisations can be clear about what they can and cannot expect from working together.

5. Collaborative Working and Joint Working: Ten steps to success

This section provides a practical ten-step approach to making cross-sector working successful, whether using the Joint Working or Collaborative Working mechanism.

The ten steps are:

1. Scope the project, all parties agreeing the objectives/outcomes
2. Check the project meets Collaborative Working or Joint Working criteria
3. Develop the Collaborative/Joint Working project plan
4. Gain Stakeholder Alignment
5. Draft the Collaborative/Joint Working Agreement
6. Gain formal approval from all organisations working together
7. Sign the Collaborative Working Agreement/ Joint Working Agreement and publish the Executive Summary
8. Start the project
9. Monitor delivery of the project
10. After completion

For each step, we briefly describe the process areas to consider. To support this, we pose questions to stimulate thinking and to assist active risk management. Pink boxes contain additional information relevant and helpful to know at this step in the project, based on the experience and expertise of ABPI member company compliance experts.

Some of the steps can be undertaken in parallel: the guidance makes clear where a step must be completed before proceeding further.

Bringing together a cross-sector team early on is important: it will form the basis of the project team in part or whole, and its make-up is likely to change over time. The key point is for it to include people from all organisations engaged in working together.

Cross-sector 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. These ten steps can be used in all examples, but there are more issues to consider when planning a project with multiple partners. **Appendix 1** provides more guidance on working together with multiple partners.

Step 1: Scope the project, with all parties agreeing the objectives/outcomes

Potential partner organisations identify projects and initiatives that will enhance patient care or are for the benefit of patients or the healthcare organisation, and at minimum maintain patient care (Collaborative Working) or are of direct benefit to patients (Joint Working).

These projects are often drawn from data analysis or patient feedback which highlight an area of proven patient or clinical need.

Potential partners consider the project's desired benefits and outcomes, in addition to its sustainability and how it could be replicated or scaled-up if successful.

At this point, it is also worth investigating if other healthcare organisations have successfully tackled a similar challenge and, if so, whether it may be more appropriate to learn from/replicate/modify their work than to initiate a completely new project. A useful source for similar projects is the searchable ABPI-NHS collaboration case study repository.

Questions to consider during project scoping:

- What is the unmet need the project is seeking to address?
- What is the evidence to back this up?
- What are the patient or system benefits of addressing this need?
- What would be the impact on patient care or the system if this need is not addressed?
- What is the scale of the problem?
- What challenge(s) need to be addressed at a place, population/system level?
- Which NHS plan and/or local improvement plans goal is the challenge aligned to?
- What interventions are required and in what timescale?
- Are internal stakeholders supportive of addressing the need and the feasibility of doing so?
- What does success look like? How will it be measured? When and by whom?
- What is the priority improvement area and can this realistically be addressed within the resources and duration of the project?
- Is the project intended to demonstrate a sustainable solution? If so, what outcomes will be necessary to ensure a successful business case?

If the project is disease/medicine focused:

- Which clinical pathway(s) require service redesign to improve patient care and/or system improvement?
- Which companies have expertise in this area?
- Are there other organisations which would be relevant to engage in the project, e.g. AHSNs, third-party digital or quality improvement tool providers, local government, academia?

Step 2: Check the project meets Collaborative Working or Joint Working criteria

Identify representatives from potential partner organisations to form an early-stage project team.

They should use the set of questions on page 18 which cover collaborative and joint working to test the proposed scope and to confirm that the proposed project meets the necessary criteria for **collaborative** or **joint working**.

If the answer to any **RED** questions on the checklist is '**NO**', the project is NOT a collaborative or joint working arrangement. Action will be needed to address these points 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 Q2	**No** Please go to Q1b
	Joint Working		
1b	Is the main benefit of the project focused on the patient?	**Yes** This is a joint working project - go to Q2	**No** Consider another form of support

	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?	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 my appropriate third-party representation?	Yes	No
12	Do all parties and their respective organisations have appropriate skills and capabilities in place 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 – a Ten Step Process?	Yes	No
15	Are all partners clear on who within their organisation is the signatory to ensure Joint Working Agreements and final Collaborative Working documents can be certified?	Yes	No

Step 3: Develop the Collaborative/ Joint Working project plan

When all the necessary criteria are met, the project team develops a detailed project plan, known as a Project Initiation Document (PID). There are many PID templates available to download and most organisations will have their own formats. A good PID should contain:

- Expected benefits for the patient, the healthcare organisation and the pharmaceutical company, all of which must be clearly stated
- The overall timeframe for the project, noting that timelines for individual stages can be amended or extended where previous steps are not completed fully. For example, stakeholder consultation and leadership buy-in can be done in tandem with planning and PID writing
- The resources (money, people, skills, technology) required to be able to deliver the project; how these will be obtained and managed; and which party has responsibility for providing each
- When financial resource is required, how this will be obtained and managed
- If a business case for funding/wider adoption is required, with whom responsibility for writing this sits and who should be consulted to ensure the project delivers the evidence required for the business case
- An assessment of how the outputs from the project can be sustained longer term

Key documents required in the planning phase:

- Project Initiation Document (PID)
- Collaborative or Joint Working Agreement (CWA)
- Executive Summary

These documents should be co-created by people in all the organisations involved. Additional guidance and support for developing the PID should be available from pharmaceutical companies.

Helpful to know during planning:

Industry partners cannot get involved in activities such as administrative/clerical tasks, internal reporting or other healthcare organisations' policy/process requirements. Additionally, companies cannot participate in initiatives that would involve direct engagement with patients, for example the provision of medical advice, the interpretation of test results, or the adoption of treatment decisions.

There must be a clear commitment from all parties to detail the resource they intend to put into the project. Resource can be financial, skills and/or experience based. Any resource put into the project must be over and above the normal day-to-day role, e.g. resourcing for additional roles, setting up of additional clinics, which the healthcare organisation would not otherwise be able to implement.

ABPI members recognise that it is often difficult to place a monetary value on healthcare organisational resources dedicated to a collaboration. The parties should therefore consider whether their individual contributions represent comparable or proportionate input, considering the resources each of them contributes compared to the overall volume of resource at their disposal.

If the healthcare organisation partner is unable to make a meaningful contribution to the collaboration, the project should not be progressed and an alternative route such as a grant and/or donation should be considered.

Where the collaboration aims to address the healthcare organisation's capacity constraints or resource shortages, special precautions need to be taken when using funding provided by a pharmaceutical company to retain staff to be involved in the collaboration and the delivery of the agreed outcomes. Paying staff wages from funding provided by a pharmaceutical company should not be the exclusive purpose of a collaboration, but where it is reasonable or necessary, the contractual documentation must be with the healthcare organisation and specify that any staff hired by the healthcare organisation in relation to the collaboration will operate under the sole direction and control of the healthcare organisation, and the organisation will be responsible for complying with all applicable employment law requirements.

Step 4: Gain Stakeholder Alignment

Members of the project team check that the project aligns with their organisations' objectives and compliance/legal processes and establish a governance committee or Internal Review Committee (IRC) which has the authority as a panel to sign off each stage of the cross-sector project.

The Internal Review process for pharmaceutical companies involved in collaborative or joint working projects usually consists of legal, medical, compliance and healthcare organisation engagement leads. This group will remain engaged throughout the project to ensure it remains compliant with the 2021 ABPI Code of Practice and any other relevant guidance.

The IRC will also:

- Review the principles of the project against the collaborative and joint working checklist criteria
- Ensure that the project has been reviewed by each participating organisation's management and experts

Good communication between partners is vital at this formative stage to refine the objectives and desired outcomes of the project, manage and ensure complete alignment of expectations, and confirm the inputs from each organisation.

The project team should develop a stakeholder map, communication plan and data collection plan at this stage, if it has not already done so as part of completing the PID. The team should set realistic timescales and deadlines, and be aware that it can take **four to six months** to complete the first three steps of the project, i.e. scope, develop and approve the governance arrangements of the project, including the legal framework.

Helpful to consider when gaining stakeholder alignment:

Ensuring leadership buy-in

- Does the healthcare/patient organisation have a policy for collaborating with industry and/or a history of similar initiatives that can inform development of the project?
- Who in the healthcare/patient organisation will act as the Executive Sponsor?
- Have all potential stakeholders/project interface groups been identified? Are they aware of the project and/or included in the communication plan?
- For NHS and other healthcare organisations, is there buy-in from both the clinical and administrative sides of the organisation?
- For pharmaceutical companies, have medical affairs colleagues had the opportunity to fully explore the project and input expertise?

Early engagement between partners' legal teams

- Who from the legal team will be able to support the contractual development and sign-off?
- Are both legal teams aware of the project and/or included as part of the communication plan?
- What is the organisational process for a project to be signed off?
- Are there specific Senior Management Board meetings/committees where the project proposal will need to be presented for approval? When and how often do these take place?

Publication

Is there a desire to jointly publicise the project and potential to consider an award submission? (Note that the industry partner is obliged under the ABPI Code to publish an Executive Summary of the project on its website on commencement, and to publish outcomes within six months of completion.)

Step 5: Draft the Collaborative/ Joint Working Agreement

When the project has been approved in principle by all the organisations involved, the project team should use its legal experts to draft a Collaborative/ Joint Working Agreement.

The Agreement is a legal contract and will include information about the project objectives and plans taken from the PID, as well as setting out agreed processes for various contingencies such as project amendment, dispute resolution, unforeseen external changes and an exit strategy. Its contents will include (but may not be limited to):

- The name of the collaborative working project, the parties to the agreement, the date and the term of the agreement
- Aims and objectives
- 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 and 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?
- 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. Pharmaceutical companies are required to publish the outcomes on their websites.

Healthcare organisations should also be aware that ABPI members may require that standard contractual commitments are provided to ensure compliance with US and UK anti-bribery legislation. Further legal guidance on can be found in **Appendix 2**.

Step 6: Gain formal approval from all organisations working together

If an organisation seeking to enter a collaborative or joint working project does not have an established governance committee, Internal Review Committee (IRC) or similar, it must identify relevant stakeholders with appropriate authority to approve the project. Approval can be an iterative process, and in some instances, the project team may have to return to their organisation's governance committee or IRC to gain further comment before finalising the agreement.

Timelines for this stage will vary depending on the complexity of both the project and the organisations concerned. It is important to maintain open communication between partners at this stage and to be clear about any issues that arise, as this will help to manage expectations.

Step 7: Sign the Collaborative Working Agreement/Joint Working Agreement and publish the Executive Summary

Once IRC signatories from all parties have approved the PID, all organisations sign the necessary collaborative working or joint working agreement.

The project team produces an executive summary using content from the PID, which must be certified by the industry partner(s) involved.

All participating pharmaceutical companies involved in working together must publish the project summary on their website(s) prior to the project starting; this should be available on the website(s) for at least the duration of the project. The project team should encourage healthcare organisation participants and stakeholders to do the same. The project should not commence until the executive summary has been published by the pharmaceutical company or companies involved.

Step 8: Start the project

The project formally begins once the collaborative working agreement or joint working agreement has been signed by all parties and after the executive summary has been published on the partner(s') website(s).

Step 9: Monitor delivery of the project

As the project progresses, it is critical that the partners monitor progress towards the outcomes agreed at the outset and documented in the PID and executive summary.

Outcome-focused data gathered as part of monitoring the project's progress could include:

- Increased numbers of appropriately diagnosed or treated patients
- Changes to patient satisfaction/experience levels
- Patient-reported outcomes
- Improved patient concordance and adherence to therapy
- Reduced wastage
- System efficiency measures e.g. waiting times and touchpoints, which may also link to patient experience indicators
- Market expansion with consequent proportionate increase in the appropriate use of specific medicines, aligned to local or national guidance
- Proxy patient outcomes

Project delivery monitoring of progress against objectives and milestones should take place on a regular basis, to ensure that people and resource allocation is fit for purpose, and that timelines remain appropriate. Set up the project review meetings at the beginning of working together. If an overrun or delay looks likely, the review meetings should agree 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 legal team can draft on behalf of the project team. Any changes to project documentation resulting from a variation of the agreement may also need to be recertified by the relevant company signatory, and an update made to the publicly available summary.

Helpful to know during project delivery

Continuous compliance: The parties must ensure at all times that any confidential, competitively sensitive, or personal data are made subject to robust contractual provisions related to the safeguarding of confidentiality and privacy. Any policies regarding the use of data must also be continuously adhered to.

Exchanges of sensitive or confidential information between competitors are highly problematic, including where they occur indirectly via a third party passing on information from one competitor to another. Organisations should consider internal protocols that ensure data ringfencing, especially where the same staff are involved in multiple collaborations with different ABPI members.

If the project is not on schedule, any agreed gated payments will shift accordingly to align with project deliverables.

Metrics: Project metrics need to be carefully considered given the scope, timescale and resources associated with the project. Clearly, collaborative 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, i.e. business case or scalable solution.

Examples of relevant metrics to consider could be: clinical, delivery, intervention, experience and economic.

Step 10: After completion

Once completed, the defined outcomes are measured and documented. The project team and their stakeholders should also consider undertaking a review of lessons learned during the project, again for others to benefit from.

Within six months of completion, the pharmaceutical companies involved in the collaborative or joint working project are required by the ABPI Code of Practice to publish a summary of project outcomes and lessons learned on their websites. Healthcare organisation and industry partners are encouraged to do this together, creating case studies to enable others to learn from and replicate outcomes.

Appendix 1: Working with single and multiple partners

Cross-sector 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.

It is worth considering whether it would be appropriate to have a lead contracting party 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 collaborative or joint working 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 of time 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.

Appendix 2: Legal considerations regarding Collaborative and Joint Working

Data Protection

All parties to a collaborative working arrangement (CWA) or joint working arrangement (JWA) will need to comply with Data Protection legislation including, but not limited to, the Data Protection Act 2018 (in each case as such law(s) may be replaced, supplemented, substituted or amended from time to time).

Under the ABPI Code, neither a pharmaceutical company nor its medical/generic representatives may be given access to data/records that could identify or could be linked to particular patients. This does not preclude individual employees from accessing patient-identifiable information provided they are an appropriately qualified person (e.g. a healthcare professional, statistician) and not employed in a promotional role.

Given that collaborative or joint working may involve patients, it would be preferable to make clear in the CWA/JWA (and/or secondment/NHS honorary contract) that the healthcare organisation is the 'data controller', i.e. the person or entity that determines the purpose and the means of any data processing. The data controller is ultimately responsible for ensuring that patient confidentiality and/or privacy are adequately protected.

Anti-Bribery and Corruption

Care must be taken if an individual physician, NHS or other healthcare organisation employee could benefit personally from any Joint Working or Collaborative Working arrangements. This is because UK corruption laws (including, but not limited to, the Bribery Act 2010) and comparable legislation in the United States (the Foreign Corrupt Practices Act), prohibit the offering, promising or giving of a financial or other advantage to public officials for the purpose of obtaining any improper business advantage. Particular attention needs to be paid to this aspect when working with small healthcare organisations such as GP practices.

Although the NHS as an organisation or other healthcare organisation may benefit from a collaborative or joint working project, this is unlikely to breach Anti-Bribery and Anti-Corruption laws unless one or more public body officials (e.g. an individual NHS healthcare professional or NHS employee) is offered, promised, or given a direct or indirect personal benefit from a particular collaborative or joint working project.

It is also critical to ensure that any payment is not being requested for a service offering which an NHS organisation should be providing under the terms of the NHS Constitution.

Competition and Commercial in Confidence Issues

Collaborative or Joint working projects may involve more than one pharmaceutical company, so Competition and Commercial in Confidence issues may arise. Anticompetitive agreements, decisions or concerted practices between companies (e.g. agreeing prices or discount schemes with competitors) are illegal. Each company should seek its own advice to ensure that it complies with competition law in force at the relevant time and enters into appropriate confidentiality agreements and other safeguards to keep its commercially sensitive information confidential.

Where competing companies need to discuss setting up a collaborative or joint working project, they should consider taking the following additional steps:

- Establish a written understanding of the purpose and scope of the discussions to ensure that they remain consistent with the parties' objectives and do not stray into areas that could raise competition law issues (e.g. pricing, market practices)
- Create a written agenda for meetings which can be approved in advance
- Limit participation to appropriate personnel who are briefed about the potential competition concerns and the importance of keeping to the approved agenda
- Consider whether legal counsel from at least one of the companies should be present at the meetings
- Take detailed minutes of all meetings which are then reviewed by legal counsel and retained

Companies should ensure that during the collaboration, they do not disclose or discuss confidential or commercially sensitive information or enter into agreements in the following areas:

- The pricing of products or commercial strategies of any of the companies
- Individual company cost components or structures, or the relationship between cost and price in the industry generally
- Allocation of markets or market practices, either in relation to particular customers or geographical regions
- Actual or potential company-specific customer relationships
- Actual or potential bidding opportunities, and each other's responses to such opportunities
- Individual company or industry production levels, capacities or inventories, or individual company market shares, or research and development activities or results

Appendix 3: Disclosure UK

The relationship between the pharmaceutical industry and healthcare professionals and healthcare organisations plays a vital role in the development of life-enhancing and life-saving medicines. It is a relationship we are proud of.

At the core of the relationship is sharing knowledge to improve patient outcomes. To ensure that 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 the Disclosure UK 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 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, amongst other things, are disclosed individually on the database. Certain research and development transfers of value are also disclosed in aggregate. For more resources and to search the database, please follow this link.

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