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Collaborative Working and Joint Working: A toolkit for industry and NHS Wales

December 2021

Jointly published by
ABPI Cymru Wales and the
Welsh NHS Confederation

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. We represent companies of all sizes who invest in discovering the medicines of the future.

Our members supply cutting edge treatments that improve and save the lives of millions of people. We work in partnership with Government and the NHS so patients can get new treatments faster and the NHS can plan how much it spends on medicines. Every day, we partner with organisations in the life sciences community and beyond to transform lives across the UK.

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The Welsh NHS Confederation is the only national membership body representing all the organisations making up the NHS in Wales: seven Local Health Boards, three NHS Trusts, Digital Health and Care Wales, and Health Education and Improvement Wales (HEIW). We are also part of the NHS Confederation.

Our mission is to be the authentic voice of the NHS leadership in Wales. We aim to support our members in improving the health of the population and the planning and delivery of high-quality health care.

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Introduction

We are both agreed that a lot has happened since we published our toolkit to support joint working between NHS Wales and the pharmaceutical industry nearly two-years ago. When we stood together in February 2020 to launch the first iteration of this publication, COVID-19 was still thought to be a problem the other side of the world. We now know that this changed quickly and with devastating consequences for so many of us.

However, we have seen some positives emerge from the last year; we've talked more about innovation in, and transformation of, our health and care services in Wales than at any other time. We've seen the way we deliver services in Wales change, sometimes beyond all recognition and everyone is agreed that it sets us on the right path to deliver patient care, which is safe and sustainable across the whole of our country for the years ahead.

We have also recognised that the effective delivery of those services will benefit from greater collaboration across all sectors. This must be fundamental to the road to our recovery and the introduction of services for the future.

That's why we're delighted to be able to update the work we published in early 2020 to take account of the lessons learnt from the pandemic and the publication of the latest ABPI Code of Practice for the pharmaceutical industry. The updated ABPI Code sets out new requirements for the pharmaceutical industry and supports an ongoing commitment to self-regulation and to working in a professional, ethical, and transparent manner.

In recognition of the increasing importance of collaborative working - and acknowledging that there might be some projects which are not carried out with the NHS or cannot show a direct benefit to patients - a new section of advice has been included in this latest ABPI Code. This updated toolkit reflects this substantial change.

We hope that this toolkit helps all our colleagues' aspirations to support patients, and health and care organisations; to deliver the very best services, wherever they are in Wales. We have committed to its continued development as we learn more, together, and can provide greater evidence of the benefits that can be derived for everyone of transparent and equitable collaboration.

Dr Richard Greville
Director, ABPI Cymru Wales
& Distribution Supply Chain

Darren Hughes
Director, Welsh NHS Confederation

Overview

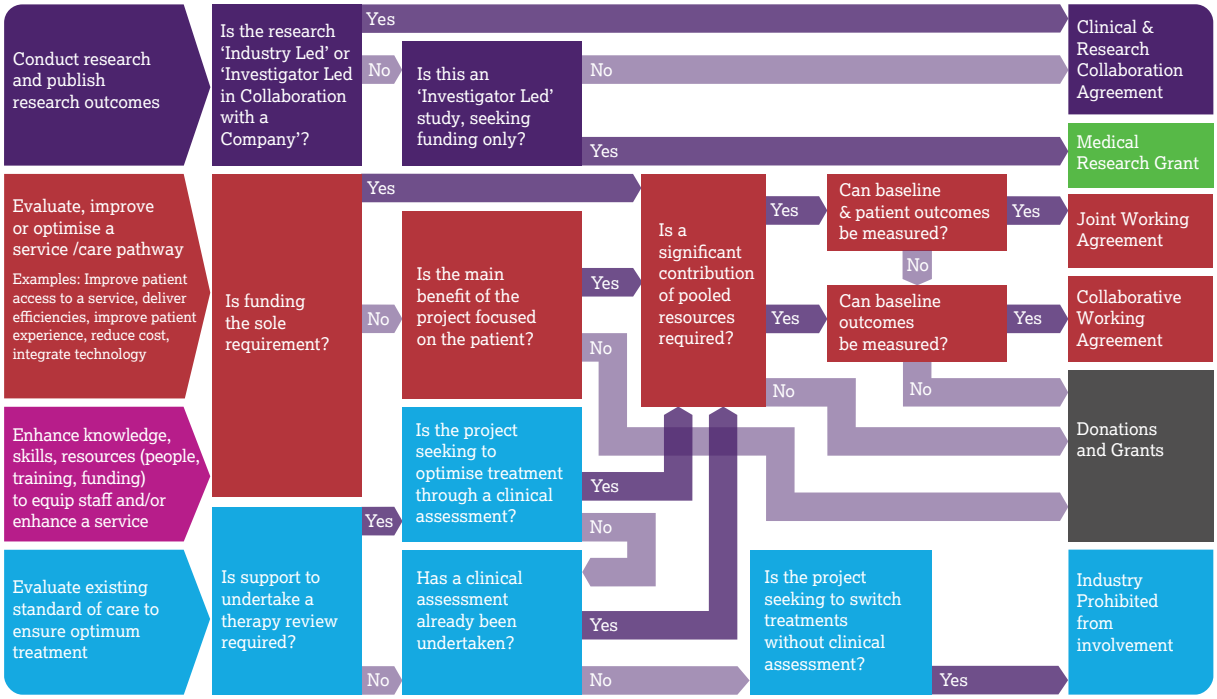
In July, The ABPI Code of Practice 2021[1] (hereafter referred to as the ABPI Code) was published. This version introduces an overarching structure, as well as sections relating to specific stakeholders and recent changes to UK legislation. These changes, particularly in structure, aim to improve understanding, usability, and navigation of the ABPI Code.

Importantly for this toolkit, the ABPI Code has introduced new clauses in its documentation to recognise that there may be some projects which are either not carried out directly with the NHS or which cannot show a direct benefit to patients and thus could not be "joint working" as defined by the Department of Health and set out in the 2019 Code.

To allow for this, there are now three sections of the ABPI Code, which will be of particular interest to anyone looking to work across the health and pharmaceutical sectors in Wales:

- **Collaborative working** with organisations must enhance patient care or be for the benefit of patients, or alternatively benefit the NHS and, as a minimum, maintain patient care
- As part of this, **joint working** must continue to be patient centred and always benefit patients and is thus now an example of collaborative working
- Some of the previous language that has been used for **Medical and Educational Grants and Services (MEGS)** (2019 Code, Clause 19) has also been adapted

Routes to Cross-Sector Working
Choosing the most appropriate model



Further governance Support and guidance Is available from:

Organisations Conflicts of Interest Guidance

Disclosure UK

ABPI Code of Practice

Further information on clinical trials collaboration, Medical Education Goods and Services (MEGS) projects and working with patient organisations can be found in the appendices and on the ABPI website www.abpi.org.uk

[1] https://www.abpi.org.uk/publications/code-of-practice-for-the-pharmaceutical-industry-2021/

What is Collaborative Working and when is it appropriate?

Collaborative working, which either enhances patient care or is for the benefit of patients or alternatively benefits the NHS and, as a minimum maintains patient care, is acceptable to the regulator of the branded pharmaceutical industry, the Prescription Medicines Code of Practice Authority (PMCPA)[2], providing it is carried out in a manner compatible with the latest edition of the ABPI Code[3].

Collaborative working is generally between one or more pharmaceutical companies, healthcare organisations and possibly other organisations, which may include the third sector or social enterprises. It must have, and be able to demonstrate, the pooling of skills, experience and / or resources from **all the parties** involved. There must be a shared commitment to successful delivery from everyone involved and each organisation must make a significant contribution.

Collaborative working must:

- enhance patient care or be for the benefit of patients, or alternatively benefit the NHS and, as a minimum, maintain patient care
- not constitute an inducement to health professionals or other relevant decision makers to prescribe, supply, recommend, buy or sell a medicine
- be carried out in an open and transparent manner
- be prospective in nature
- be documented with a formal written agreement which is kept on record
- have a summary of the collaborative working agreement publicly available before arrangements are implemented.

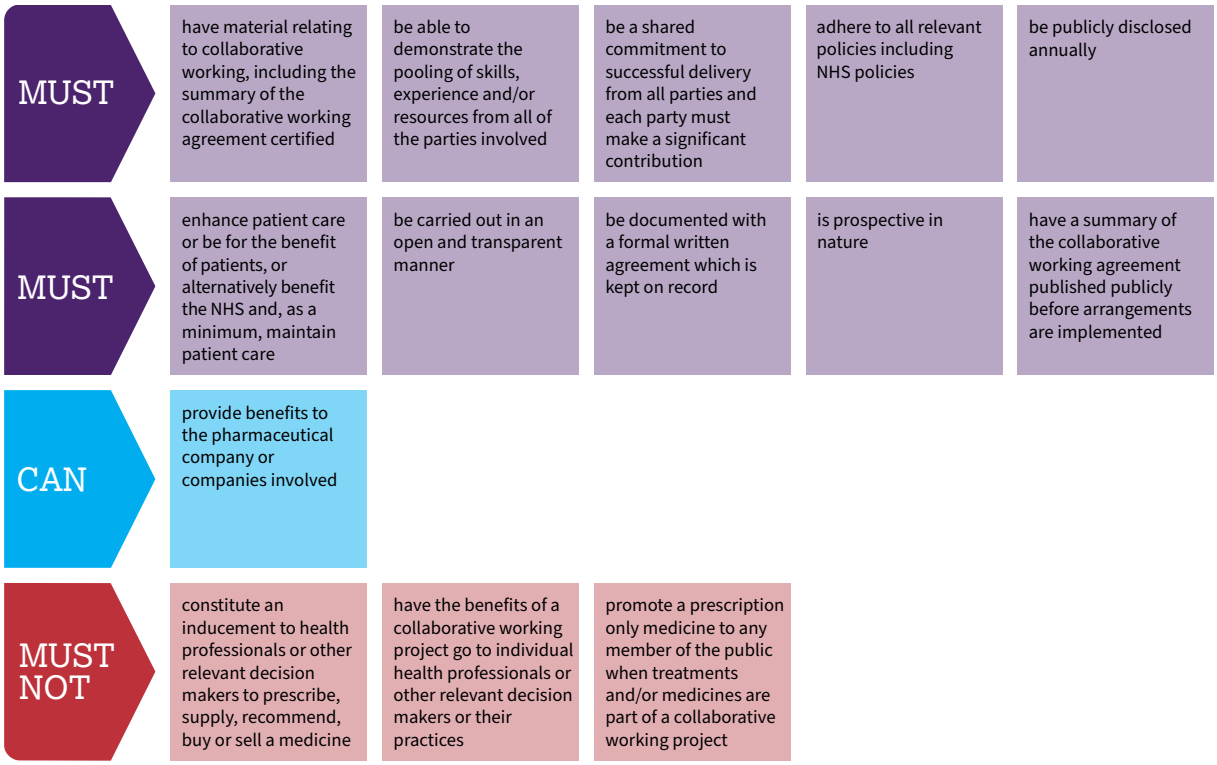
Collaborative Working
Collaborative Working Criteria

Red Questions		Yes	No
1	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?		
2	Do all parties acknowledge that the arrangement may benefit the NHS and company partner(s) involved?		
3	Are any subsequent benefits at an organisational level and not specific to any individual?		
4	Is there a significant contribution of pooled resources from all parties, which may include people, finance and equipment wholly or partly dedicated to the project?		
5	Is there a shared commitment to joint development, implementation, and successful delivery?		
6	Will anonymised, aggregated, outcome data be measured and documented?		
7	Are all partners committed to publishing an executive summary of the Collaborative Working Agreement?		
8	Are all proposed treatments involved in line with national guidance, where it exists?		
9	Will all activities be conducted in an open and transparent manner?		
10	Has an exit strategy and any contingency arrangements been agreed?		
Amber Questions		Yes	No
11	Will the project be managed by a team including representatives of industry, NHS with industry, NHS and any appropriate third-party representation?		
12	Do all parties and their respective organisations have appropriate skills and capabilities in place to manage the project?		
13	Have all partner organisations got clear procedures in place for reviewing and approving collaborative working projects?		
14	Are all parties aware of and committed to Working Together – a Ten Step Process?		
15	Are all partners clear on who within their organisation is the signatory to ensure Collaborative Working Agreements can be certified?		

[2] https://www.pmcpa.org.uk/

[3] "This ABPI Code of Practice applies to the promotion of medicines to members of the United Kingdom (UK) health professions and to other relevant decision makers… The Code also applies to a number of areas which are non-promotional, including information made available to the public about prescription only medicines…" More details are available here: https://www.pmcpa.org.uk/the-code/2021-interactive-abpi-code-of-practice/clause-1-scope-of-the-code-and-definition-of-certain-terms/

Collaborative Working including its implementation



Reference – PMCPA - https://www.pmcpa.org.uk/media/3294/pmcpa-guide-to-the-code-technical-release.pdf

For the pharmaceutical industry partners, some material relating to collaborative working **will** need to be certified, including the summary of the collaborative working agreement. For further information, partners are encouraged to refer to the ABPI Code, Clause 20.3[4]. Similarly, all collaborative working should adhere to all relevant policies, including those of NHS Wales, Health Boards / Trusts and / or Welsh Government and, where appropriate, those of other regulating bodies.

Please note that all transfers of value made by pharmaceutical company partners as part of a collaboration must be disclosed annually. Further details are available from Disclosure UK[5].

What is Joint Working and when is it appropriate?

Joint working is a specific type of NHS / pharmaceutical industry collaborative working, rather than a generic term for all cross-sector collaboration. It must be patient centred and always benefit patients directly, which gives it a narrower focus than collaborative working.

The 2021 ABPI Code has a specific clause (20.4) which refers to joint working. This clause states:

> *"Joint working between one or more pharmaceutical companies and the NHS and others 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 Code.*
>
> *It must be clear in the documentation that the project is a joint working project and account must be taken of relevant best practice guidance on joint working between the NHS, the pharmaceutical industry and other relevant commercial organisations."*

[4] Material relating to collaborative working must be certified, including the summary of the collaborative working agreement. The collaborative working agreement does not need to be certified. Only the final documents etc. for any collaborative working project need be certified. All documents etc. used during the development of the project should be of the same standard as certified material but there is no requirement to certify such material. Material used in the delivery of the collaborative working project must also meet the requirements of Clause 8.3, for example educational material for the public or patients which relates to diseases or medicines used during the delivery of collaborative working must be certified.

[5] https://www.abpi.org.uk/our-ethics/disclosure-uk/

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 companies 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 two-fold:

(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 or companies 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 6 months or more. Ideas for Joint Working projects can arise from either party, hence pharmaceutical companies (as well as NHS organisations) can pro-actively 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

Reference – PMCPA - https://www.pmcpa.org.uk/media/3294/pmcpa-guide-to-the-code-technical-release.pdf

Joint Working
Joint Working Criteria

Red Questions		Yes	No
1	Is the main benefit of the project focussed on the patient?		
2	Do all parties acknowledge that the arrangement may benefit the NHS and company partner(s) involved?		
3	Are any subsequent benefits at an organisational level and not specific to any individual?		
4	Is there a significant contribution of pooled resources from all parties, which may include people, finance and equipment wholly or partly dedicated to the project?		
5	Is there a shared commitment to joint development, implementation and successful delivery of a patient-centred project by all parties involved?		
6	Will anonymised, aggregated, patient outcome data be measured and documented?		
7	Are all partners committed to publishing an executive summary of the Joint Working Agreement?		
8	Are all proposed treatments involved in line with national guidance, where it exists?		
9	Will all activities be conducted in an open and transparent manner?		
10	Has an exit strategy and any contingency arrangements been agreed?		
Amber Questions		**Yes**	**No**
11	Will the project be managed by a Joint Working Team with industry, NHS and any appropriate third-party representation?		
12	Do all parties and their respective organisations have appropriate skills and capabilities in place to manage the project, thus enabling delivery of patient outcomes?		
13	Have all partner organisations got clear procedures in place for reviewing and approving Joint Working projects?		
14	Are all parties aware of and committed to using the Joint Working Agreement template (or similar)?		
15	Are all partners clear on who within their organisation is the signatory to ensure Joint Working Agreements can be certified?		

Included below are some examples of joint working, to show the range of different opportunities open to this subset of collaborative working. They include, but are not limited to,

- facilitation of pathway redesign
- economic analysis
- funding of project staff requirements (e.g., provision of administrative, clinical, analytical health, economic and / or management resources by either party)
- proportionate contribution to nurse services which lead to measurable interventions and outcomes
- identification of undiagnosed patients
- reviewing uncontrolled patients
- improving patient adherence to medicines
- generating patient experience data Increasing system capacity to treat patients

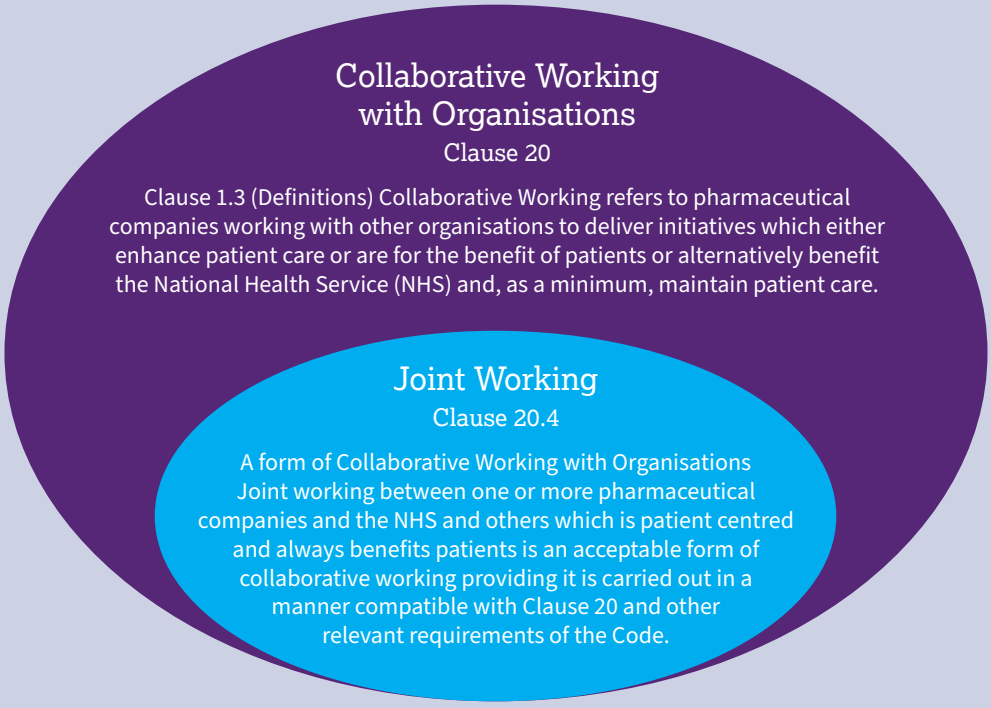
You can further explore further joint working case studies in Appendix 1 of this document, through the ABPI NHS-Industry Partnership Case Study Repository and on ABPI members' own websites.

What is the difference between Collaborative and / or Joint Working?

Collaborative working between healthcare organisations (and others) and the pharmaceutical industry is new to the ABPI Code (2021) and has been introduced as a means of recognising that there might be some projects which are not carried out with the NHS or cannot show a direct benefit to patients and therefore could not be considered joint working as defined by the Department of Health and set out in the 2019 Code, Clause 20.

Collaborative working with all organisations must enhance patient care or be for the benefit of patients, or alternatively benefit the NHS and, as a minimum, maintain patient care.

Joint working must continue to be patient centred and always benefit patients and should be considered as an example of collaborative working.



Reference – PMCPA - https://www.pmcpa.org.uk/media/3294/pmcpa-guide-to-the-code-technical-release.pdf

Why Undertake Collaborative and / or Joint Working Projects?

Both Collaborative and Joint working projects should aim to deliver 'triple wins' in the form of benefits to patients, the NHS and the pharmaceutical company (or companies) involved. However joint-working projects MUST be patient-centred and always benefit patients. These new ways of working provide a platform for a key part of the Welsh Government's long-term plan for health and social care, A Healthier Wales[6] . As the introduction to the plan outlines,

> *"We will need broader and deeper partnerships, new skills and ways of working and we will need people to take more responsibility for their own health and wellbeing."*

Both the NHS organisation and the company (or companies) involved must clearly set out the anticipated benefits in advance of embarking on a project and may consider quantifying these as projected returns on investment (ROI). Potential benefits of collaborative and joint working include:

For patients:

- Care closer to home
- Fewer hospital admissions
- Better information about conditions and treatment options
- Better experience of the healthcare system

For NHS Wales:

- Higher quality care
- Services configured around patient needs
- Better health outcomes
- Better use of resources in line with Value Based Healthcare / Prudent Healthcare agenda
- Lower hospital admissions

For the industry partner:

- Potential expansion of the relevant and eligible patient population as a result of the activity
- Increase in the appropriate use of medicines aligned to local or national guidance
- Better understanding of the challenges faced by the NHS in delivering high-quality patient services and care
- Faster implementation of NHS policy which may be relevant to an organisations business

All forms of collaborative and joint working must be underpinned by a formal written agreement[7], an executive summary of which must be made publicly available before the project begins. Agreements must:

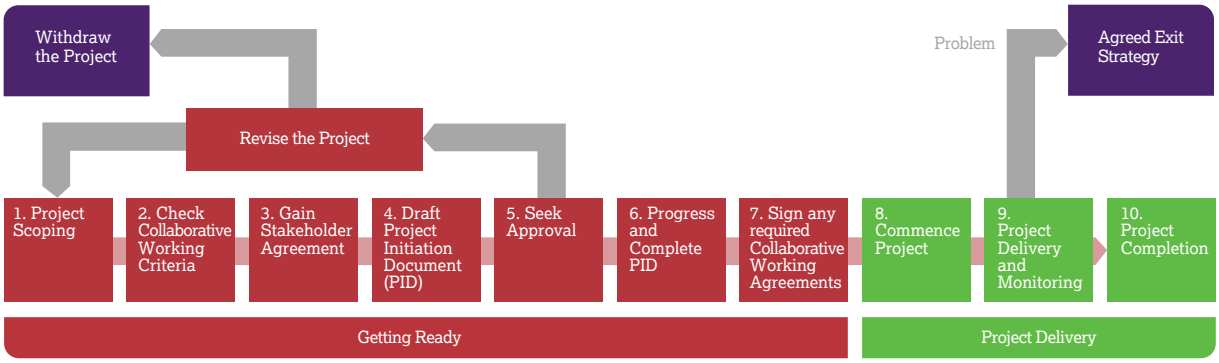
- take place at a corporate / organisational level
- not take place with individual healthcare professionals out with their organisational structure
- include an exit strategy, contingency arrangements, clear milestones, and a commitment to measure, sustain, and document outcomes to facilitate replication and scaling across the NHS

Each party must make a significant and defined contribution to the project, and transfers of value[8] made by companies must be publicly disclosed. Contribution of resources may come in various forms, including people, expertise, equipment, communication channels, information technology, and finance. Further governance guidance is also contained in the ABPI Code and can be explored in interactive form on the Prescription Medicines Code of Practice Authority (PMCPA) website[9].

[6] https://gov.wales/healthier-wales-long-term-plan-health-and-social-care
[7] https://www.pmcpa.org.uk/media/3406/2021-abpi-code-of-practice.pdf (Clause 20.3)
[8] For a definition of Transfer of Value (ToV) please refer to: https://www.abpi.org.uk/reputation/disclosure-uk/about-disclosure-uk/definitions/
[9] http://www.pmcpa.org.uk

Collaborative Working

A summary guide to the ten steps involved in collaborative working



1. Scoping

Partners involved, often Healthcare Professionals and Industry Representatives, scope the concepts that will help improve patient care and outcomes.

2. Check Collaborative Working Criteria

Each party reviews the proposed project against the Collaborative Working Criteria to ensure that these will be met.

3. Gain Stakeholder Alignment

Each party involved reviews the project idea to check it aligns with their respective objectives and compliance processes.

4. Draft Project Initiation Document (PID)

A more detailed plan or 'Project Initiation Document' (PID) can be developed.

5. Seek Approval

Representatives from each organisation submit the PID for review through their own internal governance structure.

6. Progress and Complete PID

The Project team convenes to finalise the PID, taking into account any feedback. This may involve resubmission for final approval.

7. Sign Collaborative Working Agreement

Once the PID is approved, each party signs any necessary Collaborative Working Agreements to ensure compliance with relevant organisation rules and requirements. An Executive Summary is published on (at least) the company website.

8. Commence Project

The Project should only start once all partners have complied with their organisational rules / regulations.

9. Project Delivery & Monitoring

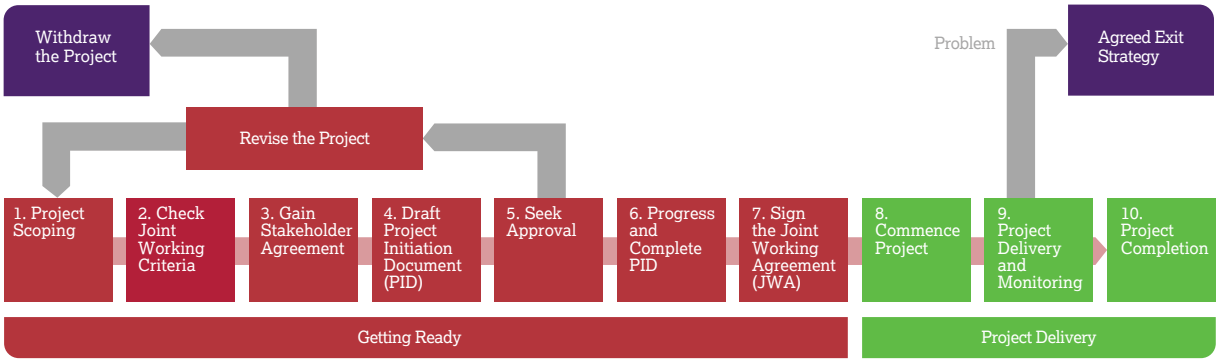
The Project Team deliver the agreed activities and monitor progress in accordance with the Collaborative Working Agreement.

10. Project Completion

Defined outcomes are documented and consideration is given to producing a case study to share learning.

Joint Working

A summary guide to the ten steps involved in joint working



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Once the PID is approved, each party signs the Joint Working Agreement and an Executive Summary is published on (at least) the company website.

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The Project can only start after the Joint Working Agreement has been signed and the Executive Summary has been published.

9. Project Delivery & Monitoring

The Project Team deliver the agreed activities and monitor progress in accordance with the Joint Working Agreement.

10. Project Completion

Defined outcomes are documented and consideration is given to producing a case study to share learning.

Working Together - A Ten-Step Process

Step 1: Project Scoping

Potential partner organisations from NHS Wales, the pharmaceutical industry – and potentially other organisation(s) - identify projects and initiatives that will enhance patient care or are for the benefit of patients or alternatively benefits the NHS and, as a minimum, maintains patient care.

These projects are often drawn from data analysis or patient feedback, which highlight an area of proven patient or clinical need. If the collaboration is defined as joint working, it must be patient centred and always benefit patients directly, which gives it a narrower focus than collaborative working.

Potential partners must 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. Amongst other resources, the ABPI publishes an NHS-Industry Partnership Case Studies Repository, where projects are available to search[10].

Once the initial project idea has been generated, the foundation project team is encouraged to review it against the collaborative or joint working criteria checklist set out in Step 2.

Step 2: Check Against Collaborative and Joint Working Criteria

Potential partner organisations should review the checklists for collaborative and joint working earlier in this toolkit and satisfy themselves that each criterion will be met under the project; whether it is collaborative or joint working (the criteria shown on pages 6 and 8 may be helpful in this).

If the answer to any RED questions in the images is "NO", the project is NOT a collaborative or joint working arrangement as defined by the ABPI Code and appropriate action will be required to address these areas before proceeding further as a either a collaborative or joint working project

If adequate changes to the project cannot be made, then partners should consider an alternative approach. Previously, this may have been through a Medical and Educational Goods and Services (MEGS). However, MEGS have been incorporated into the wider donations and grants section in the latest update to the ABPI Code. MEGS, as previously understood, are no longer a permissible activity from December 2021. For further information on Donations and Grants, see Appendix 3.

A negative response to any AMBER questions signals potential issues that should be addressed to encourage successful and timely project delivery.

Some of those previously involved in the foundation project team, and potentially others, reconvene as the final collaborative working or joint working project team.

Step 3: Gain Stakeholder Alignment

Potential partner organisations check that the project aligns with their organisations' objectives and compliance / legal processes. The Internal Review Process for a pharmaceutical company (or companies) involved in collaborative or joint working usually consists of legal, medical, compliance[11], joint working and / or partnership leads, who have the authority as a panel to sign-off each stage of the project.

They will be set up as a governance committee or Internal Review Committee (IRC) and this group will remain engaged to ensure that the project remains compliant against the criteria set out by the ABPI Code and any other relevant guidance. They will,

[10] https://www.abpi.org.uk/partnerships/working-with-the-nhs/nhs-repository-key-aims/
[11] Industry only

- Review the principles of the project against collaborative or joint-working criteria, and
- Ensure that the initial idea has been reviewed by each participating organisations management and experts[12]

At this stage, it is vital that good communication between partners is maintained to align and manage expectations, refine the outcomes and objectives of the project, and confirm the inputs into the project from each organisation. It is important to set realistic timescales and deadlines, and to complete a stakeholder map, communication plan and data collection plan, which will help align all stakeholders within the project.

Step 4: Draft Project Initiation Document (PID)

When the project concept has been approved in principle by partner organisations, a more detailed plan, or Project Initiation Document (PID) can be developed. The PID captures all relevant details of the project and is appended to the collaborative working agreement or joint working agreement. It includes, but may not be limited to,

- Aims and objectives
- Benefits to patients / NHS / pharmaceutical company partner(s)
- Principal activities and accountabilities
- Composition of the steering group and project group
- Timelines and project milestones
- Description of pooled resources
- Plans for monitoring and evaluation
- Communications plan
- Process for project amendment, should this be required
- Defined exit strategy (for all parties)

Step 5: Seeking Approval

Timelines for this stage can vary depending on the complexity of both the project and the organisations concerned. It is important to maintain communication between partners at this stage and to manage expectations. 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.

Step 6: Complete PID

The collaborative or joint working project team reconvenes to discuss and implement actions from the IRC's review. In some instances, the collaborative or joint working project team may have to return to their governance committee or IRCs to gain further comment before completing the Project Initiation Document (PID).

Step 7: Sign the Joint Working Agreement / Collaborative Working Agreement where required:

Once all IRC signatories have approved the PID, all organisations sign the necessary collaborative working agreement or joint working agreements. The project team produces an executive summary using content from the PID. The executive summary is published on the respective company(ies) website(s) for the duration of the project at a minimum, with other stakeholders encouraged to do the same. The project should not commence until the executive summary has been published by the industry partner.

[12] NB – As this is a non-promotional draft document, it can be emailed to all parties without needing further approval

Step 8: Project Commences

The project begins AFTER the collaborative working agreement or joint working agreement has been signed by all parties and the executive summary has been published on (at least) the industry partner(s) website(s).

Step 9: Project Monitoring and Delivery

It is critical that baseline measurements and the method and frequency of monitoring progress and outcomes are determined at the outset of the project. Monitoring of agreed messages begins and may 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, 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

Regular review meetings are set up at for the duration of the project to monitor progress against objectives and milestones and to ensure that people / resource allocation is fit for purpose. Timelines are also monitored, and plans put in place if an overrun or delay looks likely. This can be in the form of a letter of amendment or extension.

Step 10: Project Completion

Once completed, the defined outcomes are measured and documented. All parties consider completing a case study write-up of the project to enable others to replicate. It may also be the case that all partners undertake a review of lessons learned during the project.

Within six months of completion, the organisations involved in the collaborative or joint working project should publish a short summary of outcomes and lessons learned to their websites.

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 will involve NHS patients, it would be preferable to make clear in the CWA / JWA (and / or secondment / NHS honorary contract) that the NHS 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 or NHS employee could benefit personally from any Joint 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.

Although the NHS as an 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. This is why it is preferable to agree primary care collaborative or joint working projects at Health Board / Trust level or above.

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 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

Legal Considerations Regarding Collaborative and Joint Working

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

Do not disclose or discuss confidential or commercially sensitive information. In particular do not discuss or disclose confidential 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 1 - NHS – Industry Partnership Working

The ABPI and its member companies share a common belief in the power of collaboration as the best way to improve outcomes for patients, address healthcare challenges and support the delivery of sustainable NHS health and care across the UK. Collaboration has taken place for many years, and hundreds of projects are happening right now. All are aimed at helping to achieve NHS priorities throughout England, Scotland, Wales and Northern Ireland.

ABPI launched its NHS-Industry Partnership Working Repository in 2021. The site is intended for NHS organisations, and it enables access through a single portal to many tangible examples of projects set up, delivered and resourced by specific NHS and pharmaceutical industry partners across the UK. The aim is to demonstrate how collaboration and partnership can support delivery of NHS priorities and enable the 'triple win' - of improved patient outcomes, more efficient use of NHS resources and evidence of impact for industry – as well as replication and scaling across the NHS.

The Repository is updated regularly and the team welcome feedback from users to inform ongoing improvement to the structure, content and functionality of this site. Please share your feedback by emailing ABPICollaborationsRepository@abpi.org.uk

Appendix 2 - Clinical Trials Collaboration

Collaboration between the NHS and commercial organisations on clinical trials is essential to the development of new medicines. The ABPI has produced a guidance series to support this critical process. All parts of the guidance are under regular review to ensure they are consistent with the latest regulations.

Model Clinical Trial Agreement (mCTA)

The ABPI has worked with the four nations of the United Kingdom to develop a model Clinical Trial Agreement for commercial clinical research. We continue to work together to keep this single template agreement up to date. This collaboration also develops guidance to assist understanding of the template agreement[13,14].

Clinical Trial Compensation

The ABPI also produces guidelines on clinical trial compensation for use in clinical trials in the UK[15,16].

Appendix 3 - Donations and Grants

Provision to healthcare organisations, patient organisations or other organisations

Clause 1.5 (Definitions) **'Donations and grants'** collectively, mean providing 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, institution and the like to provide goods or services to the benefit of the pharmaceutical company in return. Donations and grants to individuals are prohibited.

In general donations are physical items, services or benefits in-kind. Grants are the provision of funds. Donations and grants may be offered or requested.

Note: offer with respect to grants can, for example, be the call for grant applications.

Donations
Clause 23

Service Provision, Physical Items or In-Kind Support

Service Provision	Physical Items	In-kind Benefit
A company can work with healthcare organisations, patient organisations and other organisations to provide a Service	A company may provide Goods eg. equipment or text books or in-kind benefits such as a member of staffs time, experience or expertise	

Grants
Clause 23

Funding

Grant Funding
Note: the key difference between the provision of a grant and sponsorship is that for grants there is no obligation on the recipient to provide goods or services to the benefit of the donor company in return

MUST:	support healthcare/ scientific research or education	be certified in advance	be prospective in nature	have a written agreement (for each donation or grant)	be documented and held on record	be publicly disclosed annually as a donation or grant	have the company involvement made clear to the extent possible
CAN:	be offered or requested Note: offer with respect to grants can, for example, be the call for grant applications			bear the name of the company providing them			
MUST NOT:	offset any normal operating expense	bear the name of any medicine	be provided to an individual	be provided with any obligation or expectation that the recipient will provide goods or services to the benefit of the company in return		constitute an inducement to recommend and/or prescribe, purchase, supply, sell or administer specific medicines	

Clause 23 Medical and Educational Goods and Services which comply with Clause 19 of the 2019 ABPI Code including their transition under the 2021 ABPI Code.

Medical and educational goods and services (MEGS) provided under Clause 19 of the 2019 Code are likely to fall under donations in Clause 23 or collaborative working in Clause 20 of 2021 ABPI Code. Companies wishing to continue with ongoing MEGS from 1 July 2021 can do so until 31 December 2021 under the 2021 ABPI Code without the need for them to be reclassified as either a donation or as collaborative working and comply with any new requirements as a result of this change. Thus there is a six month transition period for MEGS.

Reference – PMCPA - https://www.pmcpa.org.uk/media/3294/pmcpa-guide-to-the-code-technical-release.pdf

[13] https://www.nihr.ac.uk/documents/model-site-agreements-model-contracts-standard-research-agreements/11612
[14] https://www.myresearchproject.org.uk/help/hlptemplatesfor.aspx#mCTA-CROmCTA
[15] https://www.abpi.org.uk/partnerships/working-with-the-nhs/joint-working-a-toolkit-for-industry-and-the-nhs/appendix-2-clinical-trials-collaboration/
[16] https://www.abpi.org.uk/partnerships/working-with-the-nhs/joint-working-a-toolkit-for-industry-and-the-nhs/appendix-2-clinical-trials-collaboration/

The research-based pharmaceutical industry is committed to supporting healthcare and research organisations to drive improvements in patient care and help achieve the best results for patients and the NHS.

One of the ways to do this is by providing donations and grants to support healthcare and / or scientific research or education. A donation or grant must be certified in advance and be prospective in nature. It must also have a written agreement, be documented and those files held on record. Any support must be publicly disclosed as part of an annual declaration, with the company involvement made clear.

A donation or grant can be offered or requested and can also bear the name of the company providing it.

However, a donation or grant must not offset any normal operating response or bear the name of a medicine. It must not be provided with any obligation or expectation that the recipient will provide goods or services to the benefit of the company in return, nor must it constitute an inducement to recommend and / or prescribe, purchase, supply sell or administer specific medicines. It must not be provided to an individual.

Donations may include service provision, physical items, or in-kind support. A company can work with healthcare organisations, patient organisations or others to provide a service. It may also provide goods (i.e., equipment, textbooks, etc.) or in-kind benefits, such as a staff member's time, experience or expertise.

Grants are different to sponsorship insomuch as there is no expectation on the recipient to provide goods or services to the benefit of the donor company in return.

Appendix 4 - Working with Patient Organisations

The ABPI has produced guidance entitled Working with Patients and Patient Organisations: A Sourcebook for Industry to support pharmaceutical companies in working successfully and collaboratively with patients and patient organisations. We want to support relationships that are in the interests of patients and within the law and the ABPI Code. We also hope that the sourcebook will be helpful to patient organisations as they build partnerships with industry.

Many people have asked for a simple declaration that the ABPI, and its Code of Practice, support industry and patient organisations working together. The Introduction to the ABPI Code has always referred to this and in the introduction to the 2021 edition it states that:

> *"Working with patients and patient organisations can bring significant public health benefits."*

While the ABPI Sourcebook provides informal guidance, following it does not guarantee compliance. Pharmaceutical companies need to ensure they comply with the ABPI Code whenever undertaking projects and work with other organisations.

The Sourcebook has been produced in response to suggestions from the pharmaceutical industry and patient organisations. There is a great deal of useful and thoughtful guidance available already from national and international organisations, in addition to the ABPI Code, and we are not seeking to replicate or replace that which already exists. Rather, our aim has been to collate practical tools and tips and to provide pointers to sources of information.

The ideas you will find in the Sourcebook constitute a framework for thinking and deciding on how best to engage. **One size does not fit all**, so inevitably there is not one template that can be applied to every situation. But we hope that you will find enough advice to help guide your way.

You can download a copy of the Sourcebook from the ABPI website[17].

[17] https://www.abpi.org.uk/publications/working-with-patients-and-patient-organisations-a-sourcebook-for-industry/

In 2021, ABPI launched a 'patient organisation gateway'[18]. Pharmaceutical companies have been required to disclose information about relationships with patient organisations on their websites since 2006.

The new gateway is a collection of hyperlinks which enable visitors to find and review patient organisation disclosures on individual company websites. This additional resource is part of industry's ongoing commitment to promote transparency and has been built into the existing Disclosure UK database (more information in Appendix 5 – Disclosure UK).

To view the gateway, visit www.disclosureuk.org.uk, click the green button and then search for 'Patient Organisations'. For more information about the gateway, please see the ABPI's factsheet – Patient Organisation gateway FAQs[19].

Appendix 5 - Disclosure UK

The relationship between the pharmaceutical industry and healthcare professionals (HCPs) and healthcare organisations (HCOs) 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. We want to ensure that patients have confidence that this relationship is open and transparent, and this is why the pharmaceutical industry is taking the lead on disclosing details of transfers of value (ToVs) - payments and benefits in kind - made by industry to HCPs and HCOs through Disclosure UK - the disclosure database. 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 the key areas of partnership between industry and HCPs / HCOs, 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 (only HCOs)
- Sponsorship of events for the provision of medical education to HCPs (only HCOs)

Details of collaborative and joint working projects, as well as grants and donations to healthcare organisations, will be disclosed, alongside research and development transfers of value, which are being disclosed in aggregate.

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

[18] https://www.abpi.org.uk/our-ethics/disclosure-uk/resources/patient-organisation-gateway-faqs/
[19] https://www.abpi.org.uk/our-ethics/disclosure-uk/resources/patient-organisation-gateway-faqs/

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We consider requests on an individual basis.