

# **Joint Working**

A Quick Start Reference Guide for NHS and Pharmaceutical Industry Partners

Supported by





#### **NHS Confederation and Industry Foreword**



"Joint Working has already benefited thousands of patients across the UK with projects assisting in the reduction of COPD admissions, improvements in vascular checkups and improved outcomes for diabetes patients. Initiating a Joint Working project can be

challenging, despite the clear benefits to patients of combining pharmaceutical industry and NHS expertise. I believe this guide can help you overcome those challenges whether you are an NHS or industry professional and I hope you will share this guide with your colleagues and partners. Ultimately I invite you to use this as an opportunity to begin initiating that great idea you have, utilising the expertise of the industry and NHS, to deliver better patient outcomes."

#### Stephen Whitehead, Chief Executive, ABPI, 2012



"I believe this is important work for the NHS. We need to innovate because it will be better for patients. We also need to be more innovative because it will lead to more efficient care. Supporting and developing new ideas has never really been a problem in that there have always

been plenty of innovative ideas out there. The real problem has always been that the NHS has found it difficult to spread these ideas throughout the system. This guide will be a useful tool in helping build the foundations between the NHS and industry partners so, together, we can help create innovative new services to benefit patients."

Mike Farrar, Chief Executive, NHS Confederation, 2012



Joint Working provides the foundation for creating, developing and implementing innovative healthcare solutions which can lead to better health outcomes for the patient and the NHS. This guide has been developed to help both the NHS and their industry partners seek out opportunities to work together, as well as a streamlined process for Joint Working so projects are moved forward quickly and effectively.

Deepak Khanna, President, ABPI, 2012

#### Introduction

Joint Working describes situations where, for the benefit of patients, NHS and industry organisations pool skills, experience and/or resources for the joint development and implementation of patient-centred projects and share a commitment to successful delivery. Many such projects have been successfully implemented, benefiting patients across the UK.

However, feedback from some partners found that Joint Working can be difficult to initiate due to the number of parties involved and the lack of clear shared objectives.

#### The Purpose

The purpose of this Quick Start Guide is to support the NHS/Pharmaceutical Partners' commitment to Joint Working with the aim of simplifying the initiation of Joint Working projects in order to ultimately improve the health and wellbeing of more patients across the NHS.

#### For Whom

The guide is designed for those who are beginning their first Joint Working project or those who are looking to improve their project management capabilities in the context of Joint Working initiation. It will assist you during the start-up phase of a Joint Working project through 7 steps, from Idea Generation to developing the Joint Working Agreement.

The steps outlined in the guide are not compulsory, but will provide useful practical tips for how to go about setting up a Joint Working project.

#### **ABPI Code and DH Guidance**

The guide is not a substitute for suitable regulatory and/or legal advice. Pharmaceutical companies are reminded that Joint Working must comply with the ABPI Code of Practice and it is recommended that all parties refer to the DH Best Practice Guidance on Joint Working. Following the Guide should not be taken as a guarantee of compliance with the ABPI Code of Practice, but it will ensure that any project is well thought through and able to address appropriate issues.



#### **Recommended reading**

Moving Beyond Sponsorship: Interactive toolkit for Joint Working between the NHS and the pharmaceutical industry http://www.dh.gov.uk/en/Publicationsandstatistics/ Publications/PublicationsPolicyAndGuidance/DH\_082840

Clause 1.1 and 18.5: ABPI Code of Practice for the Pharmaceutical Industry http://www.pmcpa.org.uk

DH Best Practice Guidance on Joint Working between the NHS and the pharmaceutical industry and other relevant commercial organisations http://www.dh.gov.uk/prod\_consum\_dh/ groups/dh\_digitalassets/@dh/@en/ documents/digitalasset/dh\_082569.pdf

A Common Understanding: Guidance on Joint Working between NHS Scotland and the pharmaceutical industry 2003 http://www.scotland.gov.uk/Publications/ 2003/12/18625/29956 Guidance for Partnership Working between NHS Organisations, Primary Care Contractors, the Pharmaceutical Industry and the Allied Commercial Sector in Wales 2004 http://www.wales.nhs.uk/sites3/Documents/814/WHC%282 005%29016-PartnershipWorkingPharmIndustry.pdf

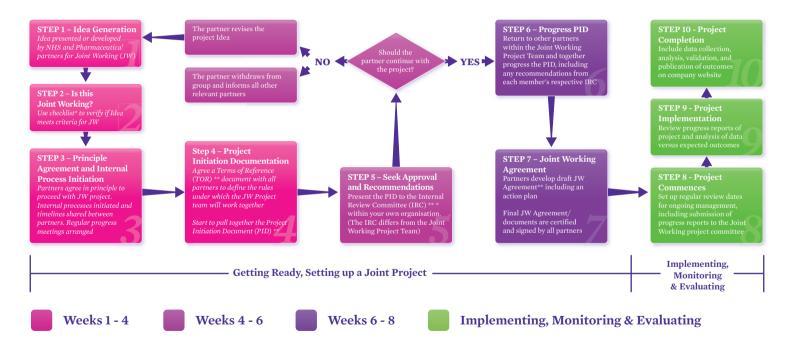
A number of the documents/templates referred to in this guide can be found in the 'Quick start – tools & resources' section of the Joint Working toolkit.



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The flowchart describes the standard steps suggested to start a Joint Working project, and is applicable to both single and multi-company projects.

Any obligatory internal processes should be completed in tandem.



\* refer to the JW checklist in this guide

\*\* the template can be found in the JW Toolkit (refer to recommended reading)

\*\*\* a description of the IRC can be found in this guide at Step 3

#### **Important note**

The flowchart in the fold-out section opposite describes 7 steps to consider when embarking on a Joint Working project. The following pages describe in more detail the considerations to delivering a successful Joint Working project and should be read in conjunction with the flowchart.

### Step 1 - Idea Generation

At this stage the partners involved, often healthcare professionals and industry representatives, brainstorm ideas that will help improve patient care. These projects are often identified by data analysis or patient feedback which highlights an area of proven patient need.

Popular areas for Joint Working you may wish to consider include:

- Identification of undiagnosed patients
- Reviewing uncontrolled patients
- Improving patient adherence to medicines
- The generation of real life patient experience data
- Treatment pathway redesign

In many cases an NHS employee will identify the need and approach the relevant pharmaceutical partner who has the required knowledge and expertise to assist.

Once the initial idea has been generated the representatives from NHS and industry, who usually form the foundation of the Joint Working Project Team, are encouraged to review it against the Joint Working Criteria Checklist at Step 2.

## Step 2 – Joint Working Criteria Checklist

All potential parties should review this checklist and satisfy themselves that each criterion would be met under the project. The parties should also establish that their respective organisations have the required structures in place to enable successful delivery in line with Clause 18.5 of the ABPI Code of Practice for the Pharmaceutical Industry. If the answer to any of Red Questions is **No**, the project is not a true Joint Working (JW) arrangement and should not be viewed as such. Appropriate steps to address the outstanding areas should be taken before proceeding further under the heading of JW.

Red Questions		Yes	No
1	The main benefit of the project is focused on the patient		
2	All parties acknowledge the arrangements may also benefit the NHS and pharmaceutical partners involved		
3	Any subsequent benefits are at an organisational level and not specific to any individual		
4	There is a significant contribution of pooled resources (taking into account people, finance, equipment & time) from each of the parties involved		
5	There is a shared commitment to joint development, implementation and successful delivery of a patient- centred project by all parties involved		
6	Patient outcomes of the project will be measured and documented		
7	All partners are committed to publishing an executive summary of the Joint Working Agreement		
8	All proposed treatments involved are in line with national guidance where such exists		
9	All activities are to be conducted in an open and transparent manner		
10	Exit strategy and any contingency arrangements have been agreed		

A negative response to the Amber Questions signals potential issues that may arise. These should be addressed as soon as possible to ensure successful and timely project delivery.

Amber Questions		Yes	No
11	Will the project be managed by a joint project team with pharmaceutical 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 equivalent) developed by the DH and ABPI?		
15	Are all partners clear on who within their organisations is the signatory to ensure Joint Working agreements can be certified?		

If all the answers are '**yes**' you should proceed with internal compliance discussions. Pharmaceutical partners must verify that the project complies with the ABPI Code of Practice.

## Step 3 - Principle Agreement and Internal Process Initiation

At this stage each member of the Joint Working Project Team, having generated the idea and reviewed the Joint Working Criteria Checklist, returns to their own organisation. The purpose of this is to check with NHS or company managers / experts that the project idea aligns with the organisations' own objectives and compliance processes. Although not officially formed at this stage, these internal managers will often form part of the Internal Review Committee (IRC). Please note that the IRC may be called something different within your organisation but will share the purpose of reviewing and signing off Joint Working projects. Stakeholders you may wish to contact for review include line managers, legal experts and those aligned to partnership working. These internal reviews of JW project proposals should aim to support and provide constructive feedback on where a JW party has concerns or requires further clarity on project proposals.

Contact should be maintained between all parties on the Joint Working Project Team during this step. The group may wish to set deadlines for reviews by managers and compliance experts, in order to sustain momentum. If access to the relevant internal personnel is difficult or time consuming within an organisation, the Joint Working Project Team should be alerted to altered timescales.

## Step 4 – Project Initiation Documentation

Now that the project idea has had the initial green light from the managers and experts at each of the Joint Working Project Team's organisations, a more detailed plan can be developed. Project Initiation Documentation is an umbrella term used for project management documents such as a Terms of Reference (TOR) document and a Project Initiation Document (PID).



#### **Terms of Reference (TOR)**

The TOR is an agreement to the principles and terms under which discussions and actions will be conducted. Key areas to include are:

- The vision, objectives and outcomes of the project
- Deliverables and key success factors
- Timelines and milestones
- Accountabilities, roles and responsibilities
- Governance arrangements
- Arrangements for monitoring and evaluation
- An exit strategy.

The TOR should ideally be signed by the individual/s who will be the main representation for their organisation during the project. It is this individual's responsibility to ensure any additional members of their organisation who may attend project group meetings are fully aware of the TOR. Taking time on the TOR document can save time in the latter stages of a Joint Working Project.

A template Terms of Reference document is available on the DH Toolkit > Quick Start Option > Tools and Resources.



#### **Project Initiation Document (PID)**

A Project Initiation Document outlines the planned approach to achieving the project objectives in the Idea Generation stage. The PID allows the JW Project Team members to understand whether the project is viable and provides benefit to patients. The PID can be used with NHS or Industry Internal Review Committees as a business case to justify the project.

The Joint Working Project Team should write this up as a team utilising different members' expertise and contacts. Completing the PID can reduce the risks of poorly conceived projects from being initiated.

If each organisation's IRC approves the PID it can be used to form the basis of a more detailed project plan or Joint Working Agreement. The Joint Working Agreement should be approved separately and requires a higher level of detail.

A PID template can be found via the DH Toolkit > Quick Start Option > Tools and Resources.



## Step 5 – Seek Approval and Recommendations

JW projects require review at various stages by individual organisations' authorised personnel or Internal Review Committee, to ensure the project remains compliant and meets the criteria set out by the DH Guidance and ABPI Code of Practice for the Pharmaceutical Industry. Partners are encouraged before progressing with this stage to have:

- Reviewed the principles of the project with the Joint Working Criteria Checklist
- Had the initial idea reviewed by each participating organisation's Management and Experts
- Developed a Terms of Reference Document approved by managers and experts

The IRC for an organisation involved in JW usually consists of legal, medical, compliance, Joint Working and/or partnership leads, who have the authority as a panel to sanction each stage of JW projects.

The IRC will usually review a JW proposal at the very early stages (Step 3), to decide if the project is viable, and if the partner should continue to be involved.

The IRC usually meets on a regular basis, depending on the volume of projects being reviewed, and should provide guidance and decisions for JW project leads, to enable them to move the project forward.

If any organisation does not have an IRC set up, it should flag this with the JW party, and if possible, attempt to gather this committee together for the purpose of speeding any review of documentation required for the project.

## Step 6 – Progress and Complete PID

The Joint Working Project Team then reconvenes to discuss and implement actions from the IRC's review. In some instances the JW Project Team may have to return to partners' IRCs to gain further comment before progressing and completing the PID. If all IRCs' signatories have approved the PID, the project can commence.

### Step 7 – Joint Working Agreements

If you have followed the steps outlined in the flow chart, by the time you start completing a JW agreement you should:

- have discussed the project and gained feedback from your Internal Review Committee (IRC)
- know who your organisation's signatory for JW agreements is
- be clear on any internal processes your organisation has/requires in order to complete the agreement
- have ensured all relevant personnel/departments within your organisation are aware of the project and the requirements for signing the agreement.



## JW Agreement Top Tips

Use the JW Agreement template on the ABPI/DH toolkit and not an adapted version, unless necessary. This agreement has been developed by representatives across the NHS and pharmaceutical industry. Commitment to its use will help to ensure a consistent and recognised approach for all parties, thereby reducing additional complexities and/or time delays in putting together and gaining agreement to alternatives.

All parties should go through the agreement, and as a project team complete as much detail as possible. Much of this information should already be within your Project Initiation Document.

As a group, agree a timeline by which all parties must have taken the agreement back to their respective organisations for review and feedback. It is essential that all parties understand and are clear on the potential consequences if the deadline is not met. Delay in completing agreements due to internal organisation procedures is a key barrier to successful JW. Hence early involvement of the IRC before reaching the agreement signing stage is key.



Each partner representative should be responsible for taking the completed agreement to the IRC and JW signatory within their organisation for review and feedback. The JW Project Team should meet to collate feedback and make amendments as required. Agree a date by which all signed agreements must be returned.

6

Consider how you would physically get the agreements signed, especially if there are multiple partners involved in the project. Where possible, you may want to invite your signatories to a 'signing meeting' so they can all discuss any relevant issues and sign the agreements should it be appropriate.

Remember, project implementation cannot commence until the JW Agreement has been signed and certified by all parties and an executive summary published online, hence this step should be closely managed for success.

Now that you have followed the crucial initial steps (1-7) in this guide please now refer the DH Toolkit and the documents outlined in the Recommended Reading section to assist you through the remainder of your project (Steps 7-10).

## Bringing medicines to *life*

#### Acknowledgements

The development of this handbook has utilised the broad range of Joint Working experience across the industry and NHS to assist others in initiating successful projects. The ABPI would like to thank all those who have contributed to this work, particularly the immediate project team: Scott Jardine (ABPI/GSK), Alan Hamilton (MSD), Funmi Oluwa (Lundbeck), Chris Beckley (Almirall) and Jack Wood (Astra Zeneca).

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