

ABPI Guidance: Working together.
A guide for the NHS, healthcare organisations and pharmaceutical companies

Potential Patient benefits from collaboration between pharmaceutical companies and healthcare organisations are:

- More patients receive evidence-based care
- Care closer to home
- Fewer hospital admissions
- More information about conditions and treatment options
- Better experience of the healthcare system
- Health inequalities reduced
- Improved outcomes Improved quality of life

Potential healthcare organisation benefits from collaboration between pharmaceutical companies and healthcare organisations are:

- Improved quality of care delivery
- Services configured around patient needs
- Improved health outcomes
- Better clinical quality outcomes
- Better use of resources
- Lower hospital admissions
- New approaches to preventative care and treatment developed
- Efficiency and system challenges addressed

Potential pharmaceutical company benefits from collaboration between pharmaceutical companies and healthcare organisations are:

- Expansion of an eligible patient population
- Increase in the appropriate use of medicines aligned to local or national guidance
- Better understanding of the challenges faced by healthcare organisations including the NHS
- Improved implementation of national treatment guidance
- Real-world evidence and data generated to enhance research

When comparing Collaborative and Joint Working approaches the following differences are noted:

- Collaborative Working projects must have desired outcomes clearly articulated from the beginning and recorded in a written agreement whereas Joint Working projects must have desired outcomes clearly articulated from the beginning and recorded in a written, certified agreement.
- Collaborative Working projects are for the benefit of patients or the healthcare organisation, including the NHS whereas Joint Working projects must include the NHS as a party to the project and are designed for the benefit of patients.
- Collaborative Working projects may enhance patient care and where they benefit the healthcare organisation, they must as a minimum maintain standards of patient care whereas Joint Working projects must have enhanced patient care as primary goal

- Collaborative Working projects

If the project aims to enhance patient care or be for the benefit of patients, or alternatively benefit the NHS and, as a minimum, maintain patient care then it is a collaborative working project. If the main benefit of the project focused on the patient, then this is a joint working project.

With either Collaborative and Joint Working projects the contributions of parties involved must demonstrate pooling of skills experience and/or resources and each party must make a significant contribution

Regarding both collaborative working and joint working the following apply

- 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 and 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.

Regarding both collaborative working and joint working the following common standards are required 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:

- GDPR (General Data Protection Regulation) legislation because this ensures no access to identifiable patient-level data.
- Anti-bribery, anti-corruption, and modern slavery because this is a Legislative requirement, reflected in organisational values and due diligence arrangements.
- Transparency Reporting because 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.

- Project Outputs, monitoring and evaluation as outlined in the Project Initiation Document. Publication of outcomes within six months of project closure on UK Company corporate website
- Governance/Steering Committee who will ensure clear oversight, governance, project decision-making, financial and risk management for the project, underpinned by agreed Terms of Reference
- Data and Intellectual Property ownership and this should be defined and agreed within a formal Working Agreement.
- Declarations of interest with 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 with executive sponsor oversight from each party

Regarding both collaborative working and joint working, all of following points must be true:

- All parties acknowledge that the arrangement may benefit the NHS and company partner(s) involved.
- any subsequent benefits are at an organisational level and not specific to any individual.
- There is a significant contribution of pooled resources from all parties, which include people, finance and equipment wholly or partly dedicated to the project.
- There is a shared commitment to joint development, implementation, and successful delivery.
- All outcome data will be anonymised, aggregated, measured and documented.
- All partners are committed to publishing an executive summary of the Collaborative Working Agreement.
- All proposed treatments involved are in line with national guidance, where it exists.
- All activities will be conducted in an open and transparent manner.
- An exit strategy and any contingency arrangements have been agreed?

The following points would signal an issue or risk that should be addressed to encourage successful and timely project delivery:

- The project be managed by a team including representatives of industry or NHS with industry or NHS and my appropriate third-party representation.
- All parties and their respective organisations have appropriate skills and capabilities in place to manage the project.
- All partner organisations have got clear procedures in place for reviewing and approving collaborative working projects.
- All parties committed to Working Together – a Ten Step Process.
- All partners are clear on who within their organisation is the signatory to ensure Joint Working Agreements and final Collaborative Working documents can be certified.

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.

