Bury Clinical Commissioning Group

Joint working with Industry - Collaborating for the benefit of patients

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Joint working with Industry - Collaborating for the benefit of patients

Contents

1. Introduction

The Department of Health (DH) and the Association for British Pharmaceutical Industry (ABPI) seek to encourage collaborative working for the benefit of the local healthcare economy and ultimately the patient.

This policy aims to promote closer working relationships between industry and the NHS and should be used in conjunction with the DH/ABPI document "*Moving beyond sponsorship: Interactive toolkit for joint working between the NHS and the pharmaceutical industry*"[1]

This framework also applies to projects undertaken in partnership with non-NHS organisations in the independent or private sector, as well as sponsorship by non- profit making or charitable organisations.

1.1 Definition

Joint working is defined 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". [2]

2. Aims

NHS Bury Clinical Commission Group (CCG) aims to develop innovative and mutually beneficial partnerships, to enhance the health and well being of people living within Bury. This work aims to lead the way in testing new opportunities for the NHS and industry to interact in a more open, proactive, positive and synergistic way. The goal is to assess potential collaborative projects and build long-term relationships based upon mutual recognition and regard. The policy provides defined criterion and guidelines within which the CCG will partner with industry. The policy is built upon the core values of NHS Bury CCG collaboration.

2.1 Core values of collaboration

- Patient needs comes first
- Openness and transparency
- Mutual trust, honesty and respect
- Patient / clinician confidentiality
- Responsibility and accountability
- A balanced, whole systems approach to healthcare

[1] Department of Health (DH) and the Association of the British Pharmaceutical Industry (ABPI), 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 (2010).

[2] APBI Guidance notes on joint working, http://www.abpi.org.uk/our-work/library/guidelines/Pages/code-guidance.aspx (2009).

- A consensus based, collaborative approach to decision making
- Value for money
- Evidence-based practice
- Alignment with local and national priorities

3. General Principals

Joint working relationships between NHS Bury CCG and the pharmaceutical industry must promote and enhance equitable access to evidence-based, high quality healthcare for the people of Bury. This collaboration will support projects that address local and national priorities, and will maintain the freedom of clinicians to prescribe the most clinically appropriate and effective treatment for individual patients.

Clinical and prescribing policies or guidelines will always be based upon principles of evidence-based medicine and cost effectiveness. These will be consistent with national recommendations and expert bodies, including the National Institute for Health and Clinical Excellence (NICE) and Royal College of General Practitioners (RCGP).

NHS Bury CCG will pursue collaboration with all appropriate companies irrespective of size or resources. It will ensure approval only for arrangements which benefit all collaborators. Approval will not be granted to any project that: increases direct costs; reduces quality of care; shifts the balance of investment in service; does not align with local and/or national priorities.

Collaboration is key to these relationships. Thus, projects which focus on broader health improvement areas are preferred to those which focus on specific drugs or products. Projects should deliver long term, sustainable and measurable benefits.

NHS Bury CCG is committed to confidentiality of discussions between itself and potential collaborators which may be commercially sensitive. It is understood that all NHS Bury CCG members will abide by their professional regulations and codes of conduct (see Appendix A).

4. Inducement to treatment

Any partnerships working must ensure that all arrangements are neutral, free from preference regarding the use of the sponsor's product over other more clinically appropriate or cost effective products or services. In addition, arrangements must be in keeping with local guidelines and formularies.

NHS Bury CCG will act in a transparent, objective manner, never endorsing any individual company or product through such agreements.

5. Corporate Governance

All relationships must be open and transparent with a robust governance framework.

The production and review of this framework is the responsibility of NHS Bury CCG, this framework will be reviewed and ratified every two years.

All proposed collaborations must be submitted on the appropriate pro-forma to the Quality and Risk Committee for NHS Bury CCG approval (see Appendix B – Pro forma for assessment of collaborations).

Joint working arrangements should be explicitly documented within written agreements between NHS Bury CCG and the relevant organisation(s) (see Appendix C, Formal contracts may be subject to legal review where necessary).

All proposals will be reviewed by NHS Bury CCG's Quality and Risk Committee for applicability, prioritisation and adherence to the policy or associate guidelines. The Quality and Risk Committee will provide final decisions on all proposals (approval or rejection).

There may be occasions when the Quality and Risk Committee need not formally meet to consider a proposal (absentia arrangements) i.e. for time sensitive conditions. In these instances it is at the discretion of the Chair of the Committee whether the proposal can be circulated amongst all members for their consideration. The conditions for approval or rejection shall be as if the Committee had met in person to approve or reject the proposal.

The Board Secretary will maintain a register of sponsorship and collaborative agreements. This register will record submitted and approved proposals, as well as proposals not approved and the applicable reason(s). The register will be open to inspection by the public.

All meetings connected to the development or delivery of a collaborative project will be formally minuted. Individuals involved in the development or consideration of proposals must declare any potential conflicts of interest they or their family may have at the outset of the process and at the beginning of all meetings (See website for the Conflicts of Interest Policy and Hospitality Policy).

Examples include:

- Shareholding or directorships in companies
- Research or educational grants
- Consultancy work
- Speaking at industry sponsored events

Proposals should specify sufficient reporting arrangements to enable progress to be monitored. A nominated NHS Bury CCG representative should manage each project in conjunction with a nominated lead from industry. Progress should be subject to regular and frequent review to ensure adherence to defined timescales and outcomes.

Clinical/prescribing proposals should have the expert feedback of the relevant NHS Bury CCG workstream.

6. Clinical accountability

Once approved by the Quality and Risk Committee (see section 5 Corporate Governance) the clinical aspects of projects will be controlled and monitored by the Clinical Cabinet.

Prescribing and clinical guidelines or protocols will be developed and endorsed through the relevant NHS Bury CCG clinical workstream or medicines management group.

7. Communications

The relationship between industry and NHS Bury CCG will be conducted in an open and transparent manner as befits a publicly funded body.

Communication with stakeholders (trusts, commissioning, medication management groups, etc.) should begin at the outset of the project and/or proposal. Information with appropriate representatives should flow with appropriate frequency for the duration of the project. Publications or events developed with the support of industry should contain a statement delineating the level and type of sponsorship. This disclosure must explicitly state that sponsorship and/or funding in no way constitutes endorsement of the organisation's products or services by NHS Bury CCG.

Knowledge and resources (i.e. protocols, guidelines) acquired and developed through sponsored projects will be shared with other NHS organisations. NHS Bury CCG retains the right to reproduce and/or modify all project outcomes. Certain projects may benefit from the analysis of sensitive data, both qualitative and quantitative but any such exchange of information should be underpinned by a discrete, defined confidentiality agreement, subject to relevant policies and regulations (including the Prescription Pricing Authority, information governance policies, Caldicott principles, Freedom of Information and Data Protection Acts). Information should be exchanged only after express consent of all owners has been documented and the benefit/purpose for information exchange has been made clear.

At no time will industry representatives be given access to confidential patient information or other NHS data.

NHS Bury CCG recognises the need for ethical companies to promote their products to the NHS and will continue to engage in positive collaboration. Similarly, it is the expectation that collaborative partners will not seek to gain advantages outside the scope of each individual project. This includes, but is not limited to, access to NHS staff for the marketing purposes under the pretext of the project. Any efforts outside of the scope of the original project specifications require advance written consent by NHS Bury CCG. Individuals employed in post as part of a collaborative project should be made explicitly aware that the post is supported by industry and they are obliged to act in a manner consistent with the NHS constitution and individual's professional code of conduct, independent of influence by the industry organisation.

Any publication produced with the support of industry should contain a statement to the effect that sponsorship of the publication does not imply the endorsement of the company's products or services by NHS Bury CCG.

Appendix A

Regulations and codes of conduct

This guidance complies with the following guidance:

- Department of Health, November 2000 Commercial Sponsorship: Ethical Standards for the NHS
- HSG (93) 5 Standards of Business Conduct for NHS Staff
- EL (94) Commercial Approaches to the NHS Regarding Disease Management Packages
- Good Medical Practice, General Medical Council 2006, updated 2009.
- Best practice guidance for joint working between the NHS and the pharmaceutical industry, Department of Health (February 2008) ("DH Joint Working Guidance").
- Moving beyond sponsorship: Interactive toolkit for joint working between the NHS and the pharmaceutical industry, Department of Health/ABPI (March 2008) ("Joint Working Toolkit")

NHS Bury CCG requires companies to conduct themselves within the legal framework for the promotion of pharmaceutical products, the ethical code of the ABPI and their internal regulations (irrespective of whether the company is a member of the ABPI).

The NHS Bury CCG and clinical staff will comply with their own professional codes of conduct and the NHS Constitution[3]

Commercial organisations must not be in breach of article 85 (1) of the EC treaty which prohibits agreements preventing, restricting or distorting competition or section 21 (1) of the Competition Act 1980 which makes it unlawful to engage in practice preventing, restricting or distorting competition in the supply and acquisition of goods.

Where a project involves access to, or processing of, patient sensitive data, all staff will comply with the provisions of the Data Protection Act 1998, the APBI code for the Secondary Use of Data for Medical Research Purposes and the recommendations of the Caldicott Report. In such circumstances the advice of the organisations Caldicott guardian must be sought.

Parties to a joint working project should consider the following principles and rules and seek guidance where necessary:

- Caldicott Principles (England) within the Caldicott Guardian Manual
- ABPI Code of Practice for the Pharmaceutical Industry (2012)
- ABPI Guidelines for the Secondary Use of Data for Medical Research Purposes (2007)
- Joint working and the ABPI Code of Practice for the Pharmaceutical Industry http://www.pmcpa.org.uk/?q=node/700/print

[3] NHS Constitution, 26 March 2013

Appendix B

Pro forma for assessment of collaborations

[Copy to be held with project documentation]

Section 1: Pre collaboration considerations

Negative responses to the following questions may stop the collaboration	Yes	No
1. Are you satisfied with your knowledge of the collaborating organisation(s) i.e. is there evidence of audited accounts, is the organisation and its ownership known?		
2. Does the proposal on offer align with current views on evidence-based clinical practice?		
3. Is the proposal on offer consistent with CCG priorities?		
4. Are you satisfied that the arrangement will be independent of purchasing or prescribing decisions?		
5. Can you confirm that there is no current or potential conflict of interest for the CCG in relation to the proposed collaboration project?		

Section 2: Partnership Project Summary

1. Names of the partners entering the Partnership. Names of the lead representative of each partner	
2. Project details: Exact nature of the partnership proposal Summary of intended aims/objectives	
3. Summary of expected outcomes / benefits to the NHS e.g. improvement in services defined by strategies in the NSF, NICE	
4. Start date	
5. Finish date	
6. Exit strategy – What are the termination arrangements? The arrangements should be capable of early termination.	

Section 3: Resources and costs

1. What is the overall cost of the partnership project	
2. What are the direct and indirect resource/cost commitments by each partner?	
3. How will the resources/costs be monitored and recorded?	
4. List valid and relevant information on cost effectiveness.	
5. Has value for money been shown – if so please indicate.	

Section 4: Governance arrangements

1. Who has been consulted prior to the partnership project and how was this done?	
2. Has an Equality Analysis been carried out on the proposal? Equality Analysis Forms can be accessed from the CCG website.	Yes/No Please delete as appropriate. An analysis form will need to be completed before the project can be signed off.
3. How will patients be informed of the partnership?	
4. What is the decision making process of the project?	
5. What are the Operational and management arrangements?	
6. How does the project relate to, and mesh with, existing systems of care in the primary and secondary care sectors?	
7. Has the project been piloted or are there plans to do this? How would this be	

done?	
8. Has the proposal been compared with other partnerships proposals currently on offer?	
9. Is sponsorship inline with National and local priorities and does it comply with NHS Bury CCG working with industry policy?	
10. Who provides indemnity for negligent harm?	
11. Who has entitlement to intellectual property rights and how will they be managed?	

Section 5: Monitoring and Evaluation

1. Management of the project What is the Formal Process?	
2. Who has designated responsibility at each stage of the proposal? [please list]	
3. On completion for the project how will it be evaluated in terms of patient benefits?	
4. What have been the learning outcomes / opportunities?	
5. What are the audit arrangements?	

Section 6: Interests and Data Governance

1. What interests do the company and the NHS have in relation to the partnership proposal - where do those interests coincide?	
2. Who “owns” the data generated by audit and monitoring of the partnership?	

3. Who has access to the data and in what form, i.e. aggregation and anonymisation criteria?	
4. What arrangements have been put in place to ensure patient confidentiality? (Bearing in mind the Data Protection Act and the requirements for patient confidentiality of healthcare records.)	
5. How will the data be used?	

Signature (NHS Bury CCG Governing Body member) Date

Signature (NHS Bury CCG Clinical lead) Date

Signature (Sponsor) Date

Agreement for Collaborative Working

Funding of: (eg, name of project) **From** *(Non-NHS organisation)*

Application for funding of £……

Basis for the Work: Justification for the work, brief background, purpose and objectives of the work to be funded. To include the contribution from NHS Bury CCG, if any, defining the work to be held.

Description of the Work and Personnel involved: Overall and detailed objectives, personnel / organisations involved, expected benefits and outcomes.

Project Action Plan: Detailed description of the project to show how funding will be used and timescales including start and end dates if known.

Exit Strategy: What are the termination arrangements?

It is agreed that:

1) (Non-NHS organisation) agrees to abide by the NHS Bury CCG's Joint working with Industry – Collaborating for the benefit of patients policy for working with Non-NHS organisations.
2) (Non-NHS organisation) may only be involved to the extent defined in this agreement, consistent with NHS Bury CCG's Joint working with Industry – Collaborating for the benefit of patients policy for working with Non-NHS organisations.
3) Any reports resulting from the work may acknowledge (Non-NHS organisation's) contribution.
4) Such reports will be used for the purposes described above. (Non-NHS organisation) cannot use any reports or information from this work without explicit permission from the CCG.

(*Non-NHS organisation)* know of no potential embarrassment that would accrue to NHS Bury CCG as a result of this agreement. (Non-NHS organisation) shall not use the name of NHS Bury CCG including logos or its employees or services to infer endorsements of products or activities of (Non-NHS organisation) without explicit agreement.

Name of clinical lead or CCG representative	Signature Designation	Date
Name of Non-NHS organisation representative	Signature, Designation and Non-NHS organisation name	Date

Name of Chair or nominated representative	Signature and date	Approved? y/n