South London
Cardiac and Stroke Network

JOINT WORKING WITH INDUSTRY

Collaborating for the benefit of patients

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Contents

SCOPE

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.

The South London Cardiac and Stroke Network (SLCSN) has developed the following policy for collaboration with industry, in alignment with the DH and ABPI toolkit, *Moving beyond sponsorship: Interactive toolkit for joint working between the NHS and the pharmaceutical industry*[1]. The SLCSN policy promotes closer, more mature working relationships between industry and the NHS and should be used in conjunction with the DH/ABPI document. Local sector working with industry policies should also be taken into consideration.

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.

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 centered projects and share a commitment to successful delivery".[2]

AIMS

The SLCSN aims to develop innovative and mutually beneficial partnerships, to enhance the health and well being of people living within the region. 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 Network will partner with industry. The policy is built upon the core values of SLCSN collaboration.

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[1] For the purpose of this document industry refers to both pharmaceutical and device companies providing cardiovascular drugs or services

[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).

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

GENERAL PRINCIPLES

Joint working relationships between the SLCSN and the pharmaceutical industry must promote and enhance equitable access to evidence-based, high quality healthcare for the people of South London. 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), European Society of Cardiology (ESC), Primary Care Cardiovascular Society (PCCS), Royal College of Physicians (RCP), Royal College of General Practitioners (RCGP), the American College of Cardiology (ACC) and British Cardiovascular Society (BCS) / Joint British Societies (JBS).

The SLCSN will pursue collaboration with all appropriate companies through its established South London Industry Working Group (IWG), 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. Multi-partner collaborations are desirable. Should a company approach the Network team to partner on a project, the SLCSN will inform the Industry Working Group to ensure that all companies which provide similar products are given the opportunity to contribute (in accordance with local and national policies).

The SLCSN team will preferentially support projects that aim to develop both the expertise and capabilities of NHS staff and projects that enhance the quality of care within regional NHS organisations. Projects should deliver long term, sustainable and measurable benefits.

The SLCSN is committed to confidentiality of discussions between members of the IWG members which may be commercially sensitive. It is understood that all

members will abide by their professional regulations and codes of conduct (*see Appendix A*).

Clinical Accountability

Clinical aspects of projects must always be under local control. Prescribing and clinical guidelines or protocols will be developed and endorsed through the relevant SLCSN clinical workstream or medicines management group.

The SLCSN management team may decide that advice or guidelines developed by the pharmaceutical industry are consistent with Network policies and suitable for discussion at the Pharmacy Working Group (PWG) and Prescribing Forum or constituent clinical workgroups.

The SLCSN management will keep the Industry Working Group informed of Network guidelines under development by sharing the annual Prescribing work plan.

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.

The SLCSN team will act in a transparent, objective manner, never endorsing any individual company or product through such agreements.

Corporate governance

All relationships must be open and transparent with a robust governance framework[3]. The production and review of this framework is the responsibility of the SLCSN, subject to approval by the Pan-London Cardiac and Stroke Network Board. This framework will be reviewed and ratified every two years.

All proposed collaborations must be submitted on the appropriate pro-forma for SLCSN approval. For large joint projects (*See Appendix B*) \\Slcsn-fsp\department\SLCSN\Industry Working Group\PROPOSALS REGISTER\SLCSN Industry Partnership Project Proforma - TEMPLATE.doc and – for individuals educational or meeting sponsorship (*See Appendix C*)

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Note local approval arrangements may also apply (Business support unit, industry etc.)

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[3] DH, (2000) *Commercial sponsorship, ethical standards for the NHS*, http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4005135 (2000).

Joint working arrangements should be explicitly documented within written agreements between the SLCSN and the relevant organisation(s). Formal contracts may be subject to legal review where necessary.

All proposals will be reviewed by the SLCSN Director and/or relevant Assistant Director for applicability, prioritisation and adherence to Network policies. The Network Director will provide final decisions on all proposals (approval or rejection).

The Network Director 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. \\Slcsn-fsp\department\SLCSN\Industry Working Group

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. *\\Slcsn-fsp\department\SLCSN\Prescribing South London (Workstream)\conflict of interest forms\SLCSN PRESCRIBING FORUM conflict of interest forms draft.doc*

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. Proposals with long-term staffing or service implications should have clear future arrangements at the outset to avoid any impact on patient care or site processes. These plans should have executive approval as required.

A nominated SLCSN 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 SLCSN workstream. Proposals based on recently published/yet to be published research must align with each Trust's research governance implementation plan as well as the government's research governance guidelines (Integrated Research Application System).

Industry Working Group

The SLCSN Industry Working Group (IWG) was created in 2006 and serves as a link between industry and NHS organisations to promote an open and proactive, positive

and synergistic way of working together which will ultimately benefit health services to local people.

Membership to the IWG is open to industry colleagues without bias, allowing a maximum of one representative from each organisation. The group is chaired jointly by the Network Consultant Pharmacist and a nominated industry lead and meets quarterly.

The remit of the group will be to share ideas and discuss projects that would benefit from joint working. These may include innovative pilot or service delivery projects, health professional training events, conferences or larger collaborative projects. Terms of reference take into account governance and accountability (*see Appendix D*).

COMMUNICATIONS

The relationship between industry and the SLCSN 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 the SLCSN.

Knowledge and resources (i.e. protocols, guidelines) acquired and developed through sponsored projects will be shared with other NHS organisations. The SLCSN 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 (including sales figures, Prescribing Analysis and Cost (PACT) data, strategic direction, product development or marketing information). 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.

The SLCSN 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

the SLCSN. 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[4] and individuals 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 the SLCSN. This should use a form of words such as "*This document has been printed with the support of xxx Ltd, who had no influence on its content".*

DISENGAGEMENT/EXIT CRITERIA

(from ABPI joint guidance[2])

Clearly defined, mutually agreed exit criteria must be written into joint working agreements at the outset. Clear end points in relation to timings, resources and budget commitments and outcomes will facilitate the disengagement/exit from a project.

During the course of the joint working project, if either party fails to deliver on its commitments, the other party can either exit or renegotiate and take reasonable steps to recoup its investment. In practice it may be difficult to establish whether a party is meeting its commitments, unless these are very tightly defined at the outset.

Either party should be free to exit an agreement if it is demonstrated that patients are not deriving benefit from the project and must do so forthwith if it is found that the project is detrimental to patients.

Joint working agreements should not be terminated by industry solely on the grounds of a negative return on investment for its product(s)).

[4] Department of Health NHS Constitution (2008)

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").

The SLCSN 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).

All SLCSN and clinical staff will comply with their own professional codes of conduct and the NHS Constitution[4]

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

APPENDIX B

Proforma for assessment of collaborations

Partnership Project Summary

1. **Names of the partners entering the partnership e.g**. SL Cardiac and Stroke Network, pharmaceutical pr device companies.	**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** (termination arrangements (The arrangements should be capable of early termination)	

Resources and costs

1. **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.**	

Governance arrangements

1. Who has been consulted prior to the partnership project and how was this done?	
2. How will patients be informed of the partnership?	
3. Decision making process of the project.	
4. Operational and management arrangements.	
5. How does the project relate to, and mesh with, existing systems of care in the primary and secondary care sectors?	
6. Has the project been piloted or are there plans to do this? How would this be done?	
7. Has the proposal been compared with other partnerships proposals currently on offer?	
8. Is sponsorship inline with National and local priorities and does it comply with SLCSN working with industry policy	

Monitoring and Evaluation

1. Management of the project Format 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. Audit arrangements	

1. What interests do the company and the NHS have in relation to the partnership proposal - where do those interests coincide?	
2. What are the potential conflicts of interests?	
3. Who "owns" the data generated by audit and monitoring of the partnership?	
4. Who has access to the data and in what form, i.e. aggregation and anonymisation criteria?	
5. 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.)	
6. How will the data be used?	

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Signature (SLCSN Director)	**Date**
Signature (SLCSN lead)	**Date**
Signature (Sponsor)	**Date**

APPENDIX C

Declaration of sponsorship, hospitality and gifts

Including education events

Name / contact details	
Name of company or organisations supplying hospitality/gift/education	
Dates of offer and receipt	
Is partnership in line with national and local healthcare priorities? Does sponsorship comply with SLCSN working with industry policy?	
Accepted Yes | No *If no, provide reason*	
Description of hospitality/gift/education session	
Actual or estimated value	
Additional details of education session or any other relevant details:	
Line manager approval *(signature)*	Date
Applicant signature:	
Return completed form to sara.nelson@slcsn.nhs.uk For filing in \\Slcsn-fsp\department\SLCSN\Industry Working Group\PROPOSALS REGISTER\PROPOSALS REGISTER template.xls	

APPENDIX D

Industry Working Group terms of reference

Aims

The South London Cardiac and Stroke Network's (SLCSN) Industry Working Group (IWG) was created in 2006 and serves as a link between industry and NHS organisations to promote an open and proactive, positive and synergistic way of working together which will ultimately benefit health services to local people.

The Department of Health (DH) supports this joint working, as the NHS and industry 'share a common agenda to improve patient care outcomes through high quality and cost effective treatment and management'[5]. To this end, the DH has published resources for best practice, including a comprehensive toolkit (co-authored by the Association of British Pharmaceutical Industries) and best practice guidance for working with industry.

Objectives

1. To bring together representatives from the industry and the SLCSN to explore joint working opportunities for the benefit of the South London population

2. For all parties to have the opportunity to share information about current priorities and relevant work streams in order to promote a more collaborative approach in tackling cardiovascular healthcare issues in South London

3. To share advice, skills, resources and knowledge in order to develop innovative partnerships and collaborative projects

4. To share best practice on successful joint working initiatives through round table discussion and publication where appropriate

Membership

- SLCSN
- Representatives from industry

The IWG will co-opt other members as appropriate to the agenda / workplan. Guests or observers may also be invited to attend meetings. All proposals for co-options or guest attendance will be made through the chair and agreed by the membership.

The IWG will also develop links with general medicine to facilitate joint working, particularly for those patients with co-morbidities such as diabetes, kidney and peripheral vascular disease.

Meetings

Meetings will take place quarterly (more frequently, as required) at a time and venue agreed by the members. Administrative support will be provided by the SLCSN.

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[5] Moving beyond sponsorship: Interactive toolkit for working between the NHS and pharmaceutical industry, Department of Health/Association of British Pharmaceutical Industries, August 2010

Accountability

The IWG will be co-chaired by the Network Lead Pharmacist for CVD and a nominated co-chair from the industry representatives.

The position of co-chair will rotate amongst industry representatives every 12 months.

Workplan

The workplan of the IWG will be aligned with the priorities of the SLCSN.

Links

The IWG will maintain links with:

- SLCSN Cardiac Prescribing Forum
- SLCSN Pharmacy Working Group
- Local formulary committees
- SLCSN workstreams
- Other cardiac and stroke networks
- Pan-London Stroke Pharmacists Group
- Pan-London Interventional Cardiology Pharmacists Group
- Others as appropriate

Outcomes

- Delivery of successful joint working projects that improve patient experience and health outcomes in line with national guidance (e.g. NICE)
- Increase the reputation of both the SLCSN as well as industry
- Deliver projects and collect lessons that might be replicated across other NHS organizations

Outputs

The IWG will:

- Agree terms of reference, membership and workplan
- Hold meetings on a regular basis bringing together a broad membership
- Seek issues in cardiovascular prescribing from relevant stakeholders
- Identify new opportunities for collaborative working between the industry and the SLCSN which benefit local patients
- Produce minutes of meetings to be circulated to members, key links and the SLCSN clinical reference groups
- Produce reports of any joint working initiative undertaken
- Produce recommendations to the SLCSN
- Produce information and support clinicians in implementing clinical and cost effective prescribing.
- Support the implementation of network guidelines through supporting educational programmes for healthcare professionals within the sector

Review

The IWG will annually review its terms of reference, membership and workplan.

Agreed at meeting: 11th May 2011 Review date: **April 2013**