The**AHSN**Network

abpi
Bringing medicines to *life*

Simplifying cross-sector working between NHS Integrated Care Systems, Sustainability and Transformation Partnerships and industry
Guidance on governance and process

May 2019

Contents

Document purpose

This document has been developed by the AHSN Network and the Association of the British Pharmaceutical Industry (ABPI).

It sets out a series of governance and process recommendations to enable NHS Sustainability and Transformation Partnerships (STPs) and Integrated Care Systems (ICSs) rapidly and confidently to develop collaborations with industry partners to address local health needs.

These recommendations are intended as supportive guidance and are not mandatory for the development of cross-sector collaborations.

Background and context

The 2017 Life Sciences Industrial Strategy report to government recognised the NHS as a unique asset for life sciences and, consequently, for the economic growth of the UK. The government's subsequent Life Sciences Sector Deals in 2017 and 2018 and the formation of the Accelerated Access Collaborative built upon the vision that rapid patient access to biomedical innovation can improve both the economic prosperity of the UK and the health of its people – a theme further amplified in the NHS Long-Term Plan.

Realising the opportunity presented by biomedical innovation will depend on NHS, life sciences and industry stakeholders collaborating more effectively than in the past to tackle health needs, prepare for major new developments such as Advanced Therapy Medicinal Products (ATMPs) and develop integrated health data assets that allow outcome-based planning. Success will be derived from demonstrating the ability of innovative medicines and technologies to improve people's health in real-world settings and by scaling these improvements nationally. The prize will be a virtuous circle that delivers health and economic benefits to the UK from a thriving life sciences ecosystem.

The formation of STPs and ICSs represents a positive shift in the ability of local NHS and public sector organisations to work together to improve health outcomes for the populations they serve – and, crucially, to measure those improvements. The new structures also create an opportunity for more ambitious strategic partnerships with industry to address health needs at local population level.

However, the complexity of developing such cross-sector partnerships is increased by the fact that many NHS, local government and other organisations are still at a formative stage in working together, let alone engaging with industry partners. While there is widespread interest in and goodwill towards cross-sector collaboration, industry and NHS stakeholders have frequently been frustrated by the time taken to agree collaborations, concerns about governance and the challenge of aligning system needs with industry offers.

The guidance set out in this document aims to address these challenges and make it easier for STPs, ICSs and industry to develop and implement local collaborative initiatives that improve patient outcomes, make more efficient use of NHS resources and generate evidence of impact for industry – a 'triple win'. Adherence to this guidance is not mandatory but we suggest that it is helpful in avoiding some of the issues which have frequently hindered the type of collaboration described in this document.

Roles and responsibilities

Role of the AHSN Network

The AHSN Network is a collaborative of the 15 Academic Health Science Networks (AHSNs) across England which were set up with the objective of supporting the adoption and spread of innovations in healthcare for the benefit of patients and the wider NHS. Through the support of innovations deriving from UK life sciences expertise, AHSNs also have the role of facilitating economic growth through the creation of the jobs required to develop and supply the innovations. The AHSNs were re-licensed by NHS England in May 2018 for a further five years. As a condition of their relicensing, AHSNs are required to deliver a series of national programmes involving technology and service redesign.

AHSNs also have a wider role in promoting and facilitating innovation in the NHS. To this end, the national AHSN Network and the ABPI signed a Memorandum of Understanding (MoU)[1] in September 2018. The MoU creates a commitment between the ABPI and the AHSN Network to work together to increase the ability of the NHS to embrace innovation to improve patient care.

As described in this document, each AHSN can help its local STPs and ICSs to articulate local health challenges in the form of a call to industry and by providing a robust process for selecting the best industry partner / partners to address the challenges identified.

Role of the ABPI

The Association of the British Pharmaceutical Industry (ABPI)[2] represents innovative research-based biopharmaceutical companies, large, medium and small, leading an exciting new era of biosciences in the UK. We represent companies which supply more than 80 per cent of the value of all branded medicines used by the NHS and which are researching and developing the majority of the current medicines pipeline, ensuring that the UK remains at the forefront of helping patients prevent and overcome diseases.

The ABPI fully supports the goal of the NHS Long-term Plan to 'create a service fit for the future', able to embrace innovation, improve the health, wellbeing and longevity of the population and provide world-class standards of care. We are working closely with NHS England and with NHS organisations across the country to maximise the broad contribution that our industry can make towards achieving this goal through developing ambitious cross-sector collaborations, helping to develop an innovation-ready NHS and helping to build UK health data assets.

The ABPI is a co-signatory to the 2018 MoU with the AHSN Network and works alongside the AHSNs to create the conditions where cross-sector collaboration can flourish. The ABPI's Code of Practice[3] governs pharmaceutical industry interactions with stakeholders and we also provide detailed guidance[4] on practical considerations regarding cross-sector working. We represented industry in developing the NHS England Conflicts of Interest[5] guidance, which enables NHS personnel to continue to work innovatively with partners whilst also providing transparency to the taxpayer. On behalf of industry, we also manage the Disclosure UK[6] database, which sets out payments and other benefits in kind made by industry to healthcare professionals and NHS organisations. We do not, however, play any part in advance assessment of individual cross-sector collaborations or in overseeing individual projects while they are active. Decisions to work together rest entirely with individual ICSs / STPs and the company or companies involved.

Role of NHS organisations and industry partners

While it is essential for NHS organisations and industry partners to comply with legal and regulatory guidance in working together, compliance alone does not guarantee a successful outcome in collaborative working. Collaborative initiatives may originate from NHS organisations or from individual companies. However, to create the conditions for success, they should address an identified local health need integral to ICS / STP delivery plans. Experience has shown that initiatives that do not meet these criteria are much less likely to succeed. Successful examples of cross-sector working where a local health priority has been addressed with an industry partner are shown in **Appendix 1.**

NHS organisations can enter cross-sector collaborations with either a single industry partner or a collective of industry partners working together, provided there is a robust and transparent selection process. Working with a single industry partner can reduce complexity and allow the project to deliver outcomes more rapidly.

For complex and lengthy initiatives where multiple industry partners are required, it is helpful that each company has a clearly defined role and that the initiative is divided into phases.

The AHSNs can provide governance and process support for NHS organisations in selecting the most appropriate industry partner or partners, as described overleaf.

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1 - https://www.abpi.org.uk/media-centre/news/2018/september/new-partnership-to-accelerate-uptake-of-biomedical-innovations-into-the-nhs

2 - https://www.abpi.org.uk

3 - http://www.pmcpa.org.uk/thecode/Documents/Code%20of%20Practice%202016%20.pdf

4 - http://www.abpi.org.uk/publications/joint-working-with-the-pharma-industry-guide

5 - https://www.england.nhs.uk/ourwork/coi/

6 - https://www.abpi.org.uk/ethics/ethical-responsibility/disclosure-uk

Governance and process framework

Step 1: Formation of Collaboration Oversight Group

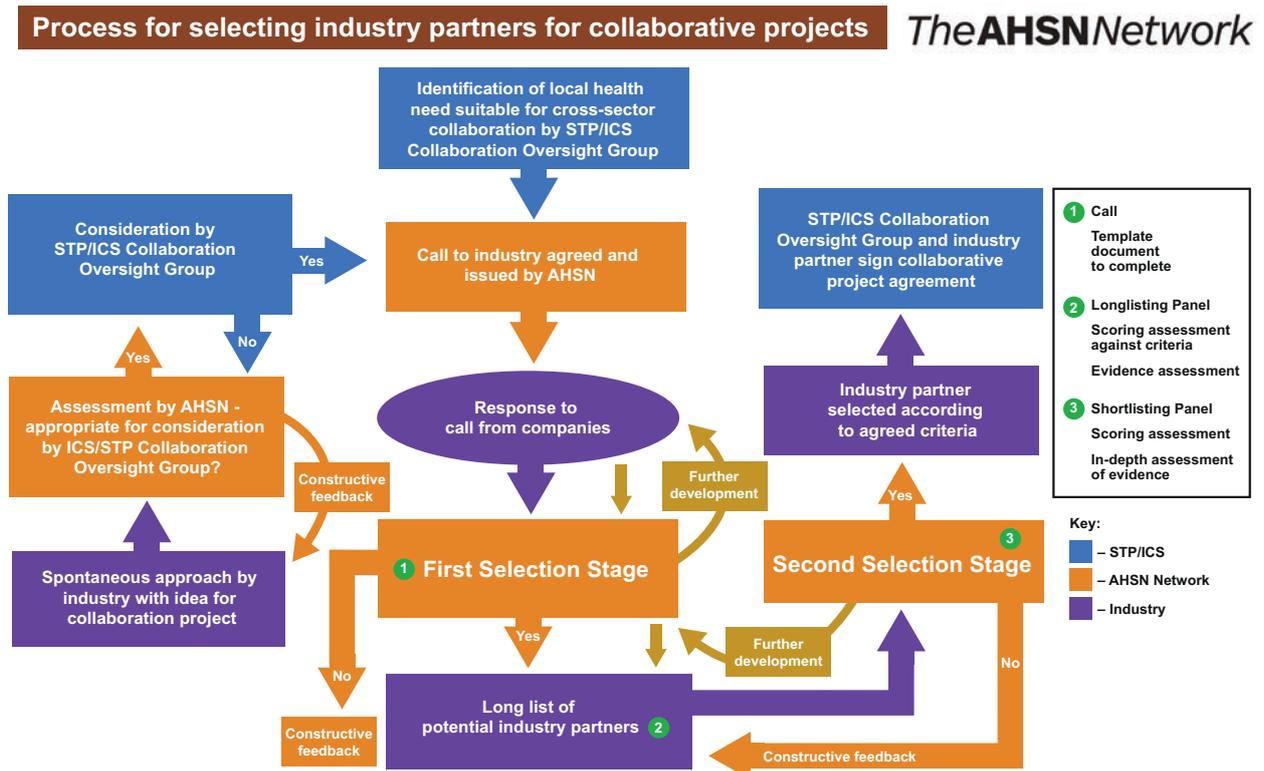Each STP/ICS should establish a Collaboration Oversight Group (or similar title) with responsibility for:

- identifying local health need challenges that could be addressed through cross-sector collaboration and articulating these through the local AHSN as calls to industry
- considering spontaneous industry proposals deemed of merit by the local AHSN and issuing calls on these via the AHSN to ensure the widest choice of industry partner
- governing all resulting collaborations

Model terms of reference for a Collaboration Oversight Group are set out in **Appendix 2.**

Step 2: Involving the AHSN Network

The AHSN can help its local NHS organisations by:

- articulating local health challenges in the form of a call to industry and managing responses
- evaluating spontaneous approaches from industry and bringing those with merit to the attention of the Collaboration Oversight Group so that a call to industry can be generated if appropriate
- providing a robust process for selecting the best industry partner/partners
- An example of how this process might work is illustrated below. Depending on the complexity of the challenge and level of interest from industry, it may be possible to combine the first and second stage selection processes:

Process for selecting industry partners for collaborative projects **The AHSN Network**

Identification of local health need suitable for cross-sector collaboration by STP/ICS Collaboration Oversight Group

Consideration by STP/ICS Collaboration Oversight Group — **Yes** → Call to industry agreed and issued by AHSN

No

Yes

Assessment by AHSN - appropriate for consideration by ICS/STP Collaboration Oversight Group?

Response to call from companies

Constructive feedback

Spontaneous approach by industry with idea for collaboration project

Further development

1 First Selection Stage

Further development

Yes

No

Constructive feedback

Yes

Long list of potential industry partners **2**

Constructive feedback

STP/ICS Collaboration Oversight Group and industry partner sign collaborative project agreement

Industry partner selected according to agreed criteria

Yes

3 Second Selection Stage

No

Constructive feedback

1 Call
Template document to complete

2 Longlisting Panel
Scoring assessment against criteria
Evidence assessment

3 Shortlisting Panel
Scoring assessment
In-depth assessment of evidence

Key:
■ – STP/ICS
■ – AHSN Network
■ – Industry

Step 3: Project Governance

Once the industry partner(s) have been selected by the ICP/STP, all parties should complete to the satisfaction of their organisations a project agreement which sets out, at minimum:

- the patient, population or user groups intended to benefit
- the parties to the agreement – clinicians, NHS/local authority and industry or third sector partners
- project goals and methodology and the nature of the interventions required
- the measures to be used to assess the patient outcomes or benefits achieved and over what time period
- any legacy improvements for the NHS partners, such as improved systems, better data quality, more skilled workforce
- the nature of the partnership between the NHS/public sector and the industry or third sector partner including any commercial benefits or other incentives to be received by the latter and the assumption or otherwise of any costs or financial liabilties
- the information governance and data security measures to be adopted
- any arrangements thought necessary to avoid the disclosure of commercially confidential information
- any training needs arising for the participating NHS personnel
- any other factors that would need to be addressed prior to wider adoption

All projects should adhere to local NHS/Local Authority organisational policies as well as the relevant industry guidelines and Disclosure UK[7] requirements. A model collaborative project agreement is set out in **Appendix 3.**

Step 4: Evaluation

- Exit strategy, sustainability and evaluation of impact should be planned from the outset of the project
- Outcomes should be documented and published by all parties within three months of the project's completion, so that other NHS organisations can learn from and potentially replicate the initiative

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7 - https://www.abpi.org.uk/ethics/ethical-responsibility/disclosure-uk/

Appendix 1:

Successful examples of collaborative projects addressing local health needs

ABPI / Greater Manchester Partnership formed in 2017, which has already delivered member collaborations tackling hepatitis C, COPD, atrial fibrillation and psoriasis with four further priorities under development
http://www.gmhsc.org.uk/new-partnership-set-to-help-transform-access-to-medicines-for-patients-in-greater-manchester/

AstraZeneca and Leeds Teaching Hospitals NHS Trust collaborated on the 'Re-engineering the Post-Myocardial Infarction Medicines Optimisation Pathway' Joint Working project, providing a comprehensive medicines review for patients with cardiovascular disease who have recently suffered a myocardial infarction (MI) to assess if this intervention improved patient outcomes. The project adopted a patient-centred approach and shared-decision making strategies to enable the establishment of true medicines partnership and has been NICE Quality Assured as an example of Shared Learning.
https://www.nice.org.uk/sharedlearning/re-engineering-the-post-myocardial-infarction-medicines-optimisation-pathway

Bayer's 'Don't Wait to Anticoagulate' collaboration with West of England AHSN delivered a project aimed at helping prevent strokes amongst patients with AF by optimising medicines management in primary care. 13 strokes have been avoided through joint working reducing the overall burden of care to the NHS and saving significant sums of money.
http://www.dontwaittoanticoagulate.com/

Janssen UK, Welsh Government, NHS Wales and Myeloma UK have partnered to co-create and implement an All Wales Haematological Malignancy Data Solution, which will capture Real World Evidence for improving patient outcomes and facilitating a value-based healthcare environment.
https://www.janssen.com/uk/collaboration/joint-working-declarations

MSD worked with Aylesbury Vale and Chiltern CCGs to improve the quality of their diabetes service, by looking at innovative ways to address population health challenges and to standardise the approach across all the practices involved. The programme aimed to better support patients to manage their diabetes by having a greater understanding of their condition and the treatment options available to them, thus supporting self-care leading to improved management and quality of life.
https://www.msd-uk.com/partnerships/joint-working.xhtml

Novartis and Chelsea and Westminster Hospital NHS Foundation Trust collaboration in heart failure (HF) aims to improve detection and treatment of HF in primary and secondary care as well as educate patients on how to manage their condition at home. The expected outcome of the project is optimisation of care for HF patients irrespective of setting of care.
https://www.novartis.co.uk/partnerships/partnering-with-the-nhs/joint-working

Pfizer Vaccines are working with Pharmacy London and NHS England to increase public awareness and boost adolescent uptake of meningococcal ACWY commissioned services.
http://www.nellpc.org.uk/wp-content/uploads/2017/08/Briefing-Pfizer-Details4-Prom-materials-andOrderingNimenrix-.pdf

Appendix 2:

Collaboration Oversight Group Model Terms of Reference

Set out below are the type of governance matters that would normally be included in a Terms of Reference document when a new group is established. Any newly formed Group may wish to include governance matters which are not set out below, in accordance with the relevant local context in which the Group is being established.

1. **The Purpose or Role of the Group** - *Details to be included here:*
   - A general description of the role/purpose of the group
   - The aims and responsibilities of the group
   - Accountability of the group

2. **Membership of the Group** – *Details to be included here:*
   - The current members of the group
   - The type of role/function that will be able to join the group and the process for joining the group
   - Length of membership period, process for extension and termination of membership
   - Chair and deputy chair

3. **Responsibilities** - *Details to be included here:*
   - The responsibilities of the different members of the Group, extending to their organisational interest within the Group
   - Whether there will be an annual review (or another period) of the work of the Group and if so, how will this be carried out and by whom
   - Set out who will chair the Group, how the Chairperson will be elected and length of tenure
   - Who will lead on establishing and maintaining Terms of Reference

4. **Ways of Working** – *Details to be included here:*
   - When and how often Group meetings will take place
   - The process for organizing meetings
   - The values and principles of the group
   - Whether Group members can join meetings by phone, or only on a face to face basis
   - Who will be responsible for the agenda of the meeting, the circulation of meeting papers (if any) and arranging the dates for submission of meeting papers prior to circulation
   - The minimum number of attendees that must be present before a meeting is a valid meeting
   - Who will take minutes of the meeting and the process for approving minutes
   - Where documents produced by the Group will be stored (both hard copy and soft copy)
   - Whether decisions will be taken by a vote and a simple majority of those attending the meeting, or in another way. Does the chairperson have the final vote on any matter?
   - When these terms of reference will be updated.

5. **Confidentiality**
Set out the need to protect confidential information and the practical methods to be taken to protect confidential information generated by the work of the Group.

6. **Remuneration**
Set out whether members of the group will receive any additional remuneration and if so, how this will be calculated and who has responsibility for this decision. Also set out whether members of the Group will be paid expenses (such as travel expenses) incurred in the course of serving the Group.

7. **Transparency and Conflicts of Interest**
Set out whether the minutes of meetings will be published, and where publication will take place. Include the process by which any conflicts of interests by members should be documented and where this register will be kept.

Appendix 3:

Model collaborative project agreement

Collaborative project agreement between

[NHS organisation] and

[Industry Partner]

Date

Summary	Summary of project
1. Goals	To include legacy benefits and potential for scalability
2. Duration	To include milestones and detail on phases (if appropriate)
3. Intended benefits	Specify intended benefits to 1. patients 2. NHS and 3. industry partner
4. Methodology	To include measurement of progress and results
5. Cost	Include liability and value of contribution in kind (if appropriate) Include training needs for NHS personnel (if required)
6. Governance process	Append Terms of Reference of governing body (eg collaboration advisory and oversight group) Include information governance measures, data security measures and measures to avoid disclosure of commercially sensitive information
7. Success criteria	Identify factors critical to the success of the initiative
8. Evaluation plan	Identify how the project will be measured and the resources that will be allocated to evaluation and publication of outcomes

Contact:

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If you have a question specifically relating to the one of the 15 AHSNs, please contact them directly using the details below:

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