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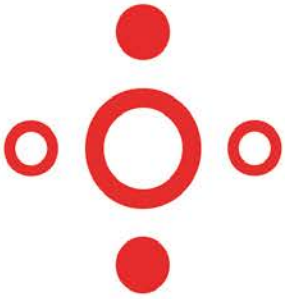

Guide to collaborative working between NHS organisations, primary care contractors and the pharmaceutical industry

December 2022

This document has been prepared by the All Wales Therapeutics and Toxicology Centre (AWTTC) in collaboration with the Association of the British Pharmaceutical Industry (ABPI), the Ethical Medicines Industry Group (EMIG), AWTTC's Industry Forum and the All Wales Prescribing Advisory Group (AWPAG), and has subsequently been endorsed by the All Wales Medicines Strategy Group (AWMSG).

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Contents

1.0 Background 2

2.0 Introducing collaborative working 3

3.0 Collaborative working: key considerations 4

4.0 NHS employers and primary care contractors 4

5.0 Monitoring arrangements 5

6.0 Research and development 6

Relevant documents 7

Appendix 1: Annual Declaration of Interests in the Pharmaceutical Industry and Allied Commercial Sector 9

Appendix 2: Partnership Working Initiative Assessment Checklist – A guideline 11

Appendix 3: Suggested service agreement template checklist (as published in the Welsh Health Circular 2005) 15

1.0 Background

Prudent healthcare is at the heart of A Healthier Wales, Welsh Government's long-term plan for health and care. *A Healthier Wales* highlights five core values that underpin the NHS in Wales; these include:

- putting quality and safety above all else;
- integrating improvement;
- focusing on prevention, health improvement and inequality;
- working in true partnerships; and
- investing in our staff.

NHS Wales wishes to develop prudent, innovative partnerships that benefit patients and achieve improved health outcomes for the people of Wales. NHS Wales organisations and primary care contractors are accountable for achieving the best possible health care within the resources available. This may be achieved through collaborative working on projects with short- and long-term arrangements, agreed between NHS Wales and the pharmaceutical industry.

The pharmaceutical industry welcomes the opportunity to work collaboratively with NHS Wales for the benefit of patients in Wales. The Association of the British Pharmaceutical Industry (ABPI) Cymru Wales and the Welsh NHS Confederation have developed a collaborative working and joint working toolkit for industry and NHS Wales which takes into consideration the five core values of NHS Wales. ABPI has also published guidance for the NHS, healthcare organisations and pharmaceutical companies which describes the benefits and challenges of working together. This explains joint working and collaborative working and how these can be successful.

Members of the ABPI should comply with the ABPI Code of Practice when undertaking collaborative arrangements; as should other pharmaceutical companies who abide by the ABPI Code of Practice. Reports of breaches of this Code are encouraged and should be reported to the Prescription Medicines Code of Practice Authority (PMCPA).

Welsh Government issued '*Guidance for partnership working between NHS organisations, primary care contractors, the pharmaceutical industry and the allied commercial sector in Wales*' in a Welsh Health Circular (WHC) in 2005. It gives a clear, ethical framework for partnership arrangements between NHS Wales and the pharmaceutical industry.

This document sets out the requirements for successful collaborative working and includes links to relevant resources. The document has been reviewed by AWTTC's Industry Forum, which includes representation from the ABPI Board Sponsored Group, ABPI Cymru Wales, and the Ethical Medicines Industry Group (EMIG). The document was considered by the All Wales Prescribing Advisory Group and then the All Wales Medicines Strategy Group (AWMSG).

2.0 Introducing collaborative working

NHS Wales encourages health boards, NHS trusts and educational providers to work together and in collaboration with other organisations to improve the health of the population they serve and the health services provided for that population. NHS Wales' e-Governance manual states that engaging with others should be seen as part of the core business. Partnerships should be kept under review and be prepared to change, adapt or come to an end where they no longer serve a useful purpose.

Collaborative working, in the context of this document, refers to pharmaceutical companies working with other NHS organisations, including Primary Care Clusters and Community Interest Companies, to deliver initiatives that enhance patient care or are for the benefit of patients or alternatively benefit the NHS and, as a minimum, maintain patient care. The joint development and implementation of patient and/or healthcare-centred projects must be able to demonstrate the pooling of skills, experience and/or resources from all parties involved.

The ABPI Code of Practice states that collaborative working must:

- enhance patient care or be for the benefit of patients or, alternatively, benefit the NHS and, as a minimum, maintain patient care;
- not constitute an inducement to health professionals or other relevant decision makers to prescribe, supply, recommend, buy or sell a medicine;
- be carried out in an open and transparent manner;
- be prospective in nature;
- be documented with a formal written agreement which is kept on record;
- have a summary of the collaborative working agreement publicly available before arrangements are implemented.

Successful collaborative working must ensure there is trust and reasonable contact between those working together, whether from NHS Wales or from the pharmaceutical industry. Such relationships, if properly managed, may provide mutual benefit to the organisations involved.

The ABPI collaborative working and joint working toolkit for industry and NHS Wales provides an excellent resource and outlines the key steps for ensuring successful collaborative and joint working. The tool kit provides a checklist for assessing whether a project meets the collaborative working criteria or joint working criteria.

Refer to the NHS–Industry Partnership Case Studies Repository.for examples of how collaboration and partnership can support the delivery of NHS priorities and enable improved patient outcomes, and more efficient use of NHS resources.

3.0 Collaborative working: key considerations

- Partners are expected to behave professionally and comply with their own professional and/or organisation's code of conduct.
- Where partnerships involve the pharmaceutical industry, then the proposed arrangements must comply with the Human Medicines Regulations 2012 (amended 2014).
- All collaborative partnerships which involve the pharmaceutical industry must comply fully with appropriate legislation. All patients' identification should be removed from data, in line with the Data Protection Act 2018, which brought the EU General Data Protection Regulation (GDPR) into law, and the Common Law Duty of Confidentiality (CLDC), to respect and preserve confidentiality. NHSX has now published The Records Management Code of Practice (2021). This is critical for anyone who is involved in decisions around keeping health and care records.
- Care must be taken if an individual physician or NHS employee could benefit personally from any joint working arrangement (Bribery Act 2010).
- Under the ABPI Code of Practice (Clause 1.24) companies are responsible for third parties working on their behalf or under their instruction, paid or otherwise.
- A partnership agreement should not be seen as an ongoing endorsement or promotion of a specific medicine or technology.
- If a collaborative or joint working project involves organising a meeting or conference then the pharmaceutical industry should not be expected to provide, or fund, rooms to be used for the meeting. When meetings are funded by the pharmaceutical industry, that fact must be disclosed in the papers relating to the meeting and in any published proceedings. Refer to Clause 10 in the ABPI Code of Practice for information on events/meetings and hospitality. The Human Medicines Regulations 2012 provide legislation relating to inducements and hospitality.
- The principles of collaborative working with the pharmaceutical industry are expected to apply to other organisations who embark on collaborative working arrangements.

4.0 NHS employers and primary care contractors

NHS employers and primary care contractors who are involved in a collaborative or joint working project should:

- Make all staff aware of NHS guidance, the relevant legislation and appropriate professional codes of conduct and guidance (General Medical Council (GMC), Nursing and Midwifery Council (NMC), General Pharmaceutical Council (GPhC), ABPI Code of Practice).
- Take responsibility for ensuring that they and their staff adhere to their professional codes and guidance. The code should contain clear guidance on collaborative working.
- Ensure all collaborative working agreements are documented through use of a register or simple ledger, held by the employer and which can be audited as appropriate. To demonstrate openness, it is essential that the register should be available on request to the public. In line with the ABPI Code of Practice, the pharmaceutical industry have to publish any joint-working or

collaborative-working projects on the ABPI website.

- Be aware that arrangements whereby the partnership is linked to the purchase of particular products, or to supply from particular sources, are not allowed, unless as a result of a transparent tender for a defined package of goods and services (see Section 6.0 on Research and Development).
- Ensure all staff record with their employer, in the interests of transparency, any material financial interest in organisations (e.g. company shares or research grants) which impact upon funding, whether through contracts, sales or other arrangements that they may make with non-NHS organisations. An official register should be established and maintained to demonstrate openness (see Appendix 1 for an annual declaration of interest form template).
- Refer to the checklists in the ABPI collaborative working and joint working toolkit for industry and NHS Wales for assessing whether a project meets the collaborative working criteria or joint working criteria. A guideline for a Partnership Working Initiative Assessment Checklist is in Appendix 2; and a S*uggested Service Agreement Template* is in Appendix 3.

5.0 Monitoring arrangements

NHS employers should ensure that monitoring arrangements are established to ensure that staff register any partnership working and are held accountable for it. This may be through scrutiny by an appropriate committee, e.g. local audit or ethics committees, as part of their usual activity, as well as through publication in the Annual Report, where this is practicable. An official Register of Interests should have been established under current policy and this should continue to be maintained as part of the monitoring arrangements. At corporate level, employers should ensure that contract negotiations are conducted according to high ethical standards.

Employers finding evidence of unrecorded partnership arrangements should act swiftly to deal with the situation and bring it within their local arrangements. Records of partnership arrangements should be kept in accordance with WHC (2000) 71, *Managing records in NHS Trusts and Health Authorities*.

The ABPI Code of Practice states that pharmaceutical companies should document and publicly disclose transfers of value made directly or indirectly to healthcare professionals and healthcare organisations. The European Federation of Pharmaceutical Industries and Associations Code stipulates that the pharmaceutical industry have to disclose payments made to healthcare professionals. To ensure the process is open and transparent, the pharmaceutical industry is taking the lead on disclosing details of transfers of value – payments and other benefits in kind – made by industry to healthcare professionals and healthcare organisations through Disclosure UK.

6.0 Research and development

Collaboration between the NHS and commercial organisations on clinical trials is essential to the development of new medicines. The ABPI worked with the National Institute for Health and Care Research (NIHR) and other stakeholders to produce a standardised approach to the contracting process for clinical trials and studies. Unmodified use of the appropriate UK Template Model Agreement helps to speed up the contracting process for studies carried out in the NHS, by removing site-by-site review and negotiation.

A decision-tree, including guidance and template, is available through the NIHR web page. A further suite of model agreements is available on the Integrated Research Application System (IRAS) website. Non-commercial research and development (R&D) originated or hosted by NHS providers should be in accordance with the WHC (2001) 025, Non-commercial externally funded R&D in the NHS: Meeting associated NHS costs. Where there is industry collaboration in such studies, companies may contribute towards the study's costs, rather than supply of product.

Any funding for research purposes should be transparent and have been approved by the local research ethics committee and multicentre research ethics committee where appropriate. There should be no incentive to prescribe more of any particular treatment or product other than in accordance with the peer reviewed and mutually agreed protocol for the specific research intended. When considering a research proposal, whether funded in whole or part by industry, NHS bodies and the industry involved must consider how the continuing costs of any pharmaceutical or other treatment initiated during the research will be managed once the study has ended.

Where R&D is primarily for commercial purposes, NHS providers are expected to recover the full cost from the pharmaceutical industry on whose behalf it is carried out.

Details of collaborative and joint working projects, as well as grants and donations to healthcare organisations, will be published on the database – Disclosure UK. For examples of potential conflict, refer to Commercial Sponsorship – Ethical Standards for the NHS, (2000*; archived Jan 2013)*.

Relevant documents

Legislation

- The Human Medicines Regulations 2012 No. 1916
- The Human Medicines (Amendment) (No.2) Regulations 2014 No. 1878
- The Consumer Protection from Unfair Trading Regulations 2008 No. 1277
- Directive 2001/83/EC on the Community code relating to medicinal products for human use, as amended by Directive 2012/26/EU
- Bribery Act 2010

United Kingdom

- ABPI (2022) Working together: A guide for the NHS, healthcare organisations and pharmaceutical companies.
- ABPI (2021) Collaborative Working and Joint Working: A toolkit for industry and NHS Wales.
- Prescription Medicines Code of Practice Authority (PMCPA) (2021) The ABPI Code of Practice for the Pharmaceutical Industry
- Committee of Advertising Practice (2014) The UK Code of Non-broadcast Advertising and Direct and Promotional Marketing
- Proprietary Association of Great Britain (PAGB) (2016) Medicines Advertising Codes – Professional Code
- British Medical Association (BMA) (2021) Medical Ethics Today
- General Medical Council (GMC) (updated 2019) Good Medical Practice
- General Pharmaceutical Council (GPhC) (2020) New ethical decision-making framework to support pharmacists and pharmacy teams
- Nursing and Midwifery Council (NMC) (2015) The Code: Professional standards of practice and behaviour for nurses and midwives
- General Dental Council (GDC) (2013) Standards for the Dental Team
- Department of Health (2000) Commercial sponsorship – Ethical standards for the NHS (Archived Jan 2013)
- Department of Health (updated 2022) Standards of Business Conduct for NHS Staff

Guidelines

- Medicines and Healthcare products Regulatory Agency (MHRA) (third revision -2020) Blue Guide: Advertising and Promotion of Medicines in the UK – includes Disease Awareness Campaigns Guidelines and Medicines which are promoted for use during pregnancy.
- NHS England Standards of Business Conduct Policy, 2019
- Department of Health (2008) Best practice guidance on joint working between the NHS and pharmaceutical industry and other relevant commercial organisations

- Department of Health/Association of the British Pharmaceutical Industry (ABPI) (2010) Moving beyond sponsorship: Interactive toolkit for joint working between the NHS and the pharmaceutical industry (Archived Jan 2013).
- IFPMA, EFPIA, Japan Pharmaceutical Manufacturers Association (JPMA), Pharmaceutical Research and Manufacturers of America (PhRMA) (updated 2018) Joint Position on the Disclosure of Clinical Trial Information via Clinical Trial Registries and Databases.
- IFPMA, EFPIA, JPMA, PhRMA (2010) Joint Position on the Publication of Clinical Trial Results in the Scientific Literature
- Pharmaceutical Information and Pharmacovigilance Association (PIPA) (2018) Guidelines on Standards in Medical Information
- British Healthcare Business Intelligence Association (BHBIA) (2022) Legal and Ethical Guidelines for Healthcare Market Research

International

- International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) (2019) Code of Practice
- European Federation of Pharmaceutical Industries and Associations (EFPIA) (2019) EFPIA Code of Practice
- World Health Organization (WHO) (1988) Ethical Criteria for Medicinal Drug Promotion
- International Pharmaceutical Congress Advisory Association (IPCAA) (2017) Healthcare Congress Guidelines

Appendix 1: Annual Declaration of Interests in the Pharmaceutical Industry and Allied Commercial Sector

NHS organisation name……

Name:.....

Position within organisation: .....

Position within any other NHS organisation or primary care contractors organisation: (e.g. primary care team or practice)

Under the guidance of the Code of Practice on Declarations of Interests, I wish to declare to the ***(insert name of organisation)*** that my only interests in the pharmaceutical industry and allied commercial sector are as follows:

1. Current personal interests

Name of company	**Nature of interest** (e.g. shares, fees, consultancy, salary, grants, retainers, etc.)	**Duration of interest**

A 'personal interest' involves payment to the member personally. The main examples are:

- **Consultancies**: any consultancy, directorship, position in or work for the pharmaceutical industry and allied commercial sector that attracts regular or occasional payments in cash or kind.
- **Fee-paid work**: any work commissioned by the pharmaceutical industry and allied commercial sector for which the member is paid in cash or kind.
- **Shareholdings**: any material shareholding in, or other beneficial interest in, shares of the pharmaceutical industry and allied commercial sector. This does not include shareholdings through Unit Trusts or similar arrangements where the member has no influence on financial management.

2. Current non-personal interests

Name of company	Nature of interest (e.g. shares, fees, consultancy, salary, grants, retainers, etc.)	Duration of interest

A “non-personal interest” involves payments that benefit an employer but are not received by the member personally. The main examples are:

- **Fellowships**: the holding of a fellowship endowed by the pharmaceutical industry and allied commercial sector.
- **Support by the pharmaceutical industry and allied commercial sector**: any payment, other support or sponsorship in cash or kind which does not convey any pecuniary or material benefit to a member personally but which does benefit his/her position or parent organisation. For example:
  - A grant from a company for the running of a unit or department for which a member is responsible.
  - A grant or fellowship to sponsor a post or member of staff or student in the unit.
  - The commissioning of research or other work by, or advice from, staff who work in a unit for which the member is responsible.
  - Income generating schemes.

Members are under no obligation to seek out knowledge of work done for, or on behalf of, the pharmaceutical industry and allied commercial sector, within units for which they are responsible if they would not normally expect to be informed.

3. Any additional relevant information

- Please state if your interest is limited to a particular product or group of products.
- “Current” interests refer to involvement within the last 12 months.
- “Non-current” interests refer to involvement prior to the last 12 months.
- “Nil” returns are required.

Appendix 2: Partnership Working Initiative Assessment Checklist – A guideline

1. General

A checklist (as published in the Welsh Health Circular 2005) is available to help NHS organisations and primary care contractors in Wales assess whether proposals/requests for support from the pharmaceutical industry and allied commercial sector offer appropriate opportunities for partnership.

Partnership with the pharmaceutical industry and allied commercial sector should aim to support the overall objectives and requirements of the organisation and be in keeping with the objectives and priorities of the NHS.

These arrangements should demonstrate tangible benefits to individual patient management and to the organisation and support or, at a minimum, not be in conflict with the activities and decisions of the NHS. Agreements to participate in these programmes should:

- consider their overall purpose;
- have reference to any issues of probity and transparency in respect of their objectives and compliance with relevant legislation.

Agreements should consider the proposed initiatives' clinical effectiveness, value for money and equity, and take account of the requirements of patient confidentiality.

Any such agreement must be documented in the Register of Interests.

Questions in the checklist should be able to be answered positively. Before proceeding with any agreement, organisations should discuss with their employer proposed partnership working with pharmaceutical industry partners and allied commercial sector partners.

2. Data and confidentiality issues

A clinician should give written consent for his or her patients to be involved or for their patients' data to be used in any way. If patient data are used, such use must be in compliance with the Data Protection Act 1998. This normally requires advance permission being sought from the patient and informing the patient in general terms about the proposed use of their data, including:

- How the data may be used.
- Who will have access to the data.
- Who the organisation's data may be disclosed to.
- Who is responsible for the data.
- Their right to impose restrictions (where the patient is offered a choice about how information about them is to be used).

If practice/clinic or patient data are to be used, there must be a clear statement included in the Service Agreement regarding:

- Who will have access to those data and in what form (i.e. aggregation and anonymisation criteria).
- How, where and by whom those data will be manipulated.
- What purpose the data will be put to.

In maintaining confidentiality, if direct contact with patients is required:

- It is the responsibility of the practice/clinic to identify patients who may be eligible.
- It is the responsibility of the practice/clinic to inform and invite patients to participate.
- Any invitation should indicate that the patient is under no obligation to take part.
- Prior to patient involvement in the programme, informed consent must be obtained.

If data are stored electronically then:

- Any patient-identifiable information must be retained for use solely within the practice/clinic except with prior express written agreement of the patient.
- Data must be password protected.
- There must be a clearly defined protocol for satisfactory data encryption.
- This should be at practice/clinic level with patient codes held within the practice/clinic (similar to a clinical trial). Encryption must not rely on identifiers such as patient name, NHS number, practice/clinic computer ID codes, addresses or postcode.

If data are to be aggregated, then:

- The practice/clinic must have a clear understanding of how the data are to be used.
- There must be a clearly defined protocol for data management, which includes information on the nature and “ownership” of the aggregated data and protocols to govern requests for access to that data.
- No practice/clinic level data should be identifiable from the aggregated data set.
- The practice/clinic should have the option not to share their data as part of the aggregated data set if they wish.

Before any service is implemented, the following external issues will also need to be addressed:

All practice/clinic staff must be aware of, and have agreed to participate as appropriate with, the proposed service. They should:

- Agree clearly who is responsible for supervising, reporting and seeking approval for the partnership from the employer (e.g. trust, health board, independent contractor) and any other relevant healthcare person or organisation as appropriate, e.g. hospital consultants, practice managers.
- Be satisfied that any information or materials to support the proposed service is valid, evidence-based, balanced, contemporaneous, and non-promotional.
- Ensure that appropriate professional indemnity and liability arrangements are in place.

Organisations should make arrangements to involve or make patients aware of the service as early as practically possible.

Organisations should agree a process for reviewing the service at appropriate intervals and assessing the success of the service in achieving its stated objectives. Organisations may wish to involve patients in this process.

Checklist

		Yes	No
1	Is the organisation satisfied with its knowledge of the sponsoring organisation(s), i.e. is there evidence of audited accounts? Is the organisation and its ownership known? Is it capable of being independently audited?		
2	Does the support on offer align with current views on evidence-based clinical practice?		
3	Is the service on offer consistent with organisation and NHS priorities?		
4	Has the organisation documented the service in any local register of interests?		
5	Is the organisation satisfied that the offer is independent of purchasing or prescribing decisions?		
6	Is this or a similar service available from another local source e.g. health board, practice or NHS Trust? Can it be compared favourably with any other?		
7	Can participants confirm that there is no current or potential conflict of interest for the organisation or any others in relation to the service offered?		
8	Have all participants discussed the proposed service? Are the participants prepared for their registered patients to be involved and are they willing to sign any service agreement?		
9	Will the organisation be provided with a fully documented service agreement that covers:		

		Yes	No
	• the aims and objectives of the service; • an outline of the accountability framework within which the service will operate; • the protocols to be used on the programme including a full description of the service(s) to be provided and the names and details of personnel to be involved; • the procedure to be followed in the event of any adverse incidents; • for clinical services, the professional indemnity and liability arrangements that the service provider has in place; • the option to modify or suspend the service in the light of any assessments, evaluations or adverse events; • the option for either party to withdraw, with agreed and clearly defined notice periods on both sides.		
10	Are the skills, competencies, professional status and qualifications of the named individuals who will be providing the service of a sufficient level to provide the service effectively, efficiently and reliably?		
11	Are the lines of accountability of that individual – clinical, professional and managerial – clearly documented and appropriate?		
12	If the service requires direct access to patients or to patients' information, is the organisation satisfied that both it and the service provider can meet the requirements outlined in the section on "Data and Confidentiality Issues"?		
13	Research Ethics Committee approval is not required for the service?		

If all of the answers to the questions in the checklist are "Yes" the partnership may go ahead. If any of the answers are "No" participants should seek further advice from their employer.

The organisation and the service provider should hold copies of all Service Agreements. It would be best practice for the employer to hold copies of all Service Agreements.

Appendix 3: Suggested service agreement template checklist (as published in the Welsh Health Circular 2005)

NHS Organisation:

Service agreement with:

Title of project:	Title by which the project will be known.
Aim of project:	Clearly define the aim(s) of the project.
Project objectives:	List of clearly defined objectives describing exactly what the project has been established to achieve.
Service to be provided:	Clear description of exactly what the pharmaceutical industry and allied commercial sector will do. This will identify all services to be provided by the company. It will also identify any areas or activities in which the company must not be involved or where approval by the employer must be obtained. Details of how the project will be taken forward, personnel to be involved and how the project will be managed must be stated.
Period of agreement:	The period or duration of agreement is to be specified.
Financial implications	The amount and duration of any funding must be agreed in advance and mechanisms must be in place to amend or adjust the funding arrangements during the course of the project. There must be clear and unambiguous arrangements regarding the longer term funding for projects which may have a duration beyond that envisaged by the initial project. Funding must not be contingent upon any arrangement to use a specific product other than in circumstances where this is the basis of the project itself (for example, a clinical trial) or provide positive references about a company sponsoring, supporting or working in partnership with the NHS organisation. Financial arrangements should not be entered into with a single individual from the company but should be entered into with the company and approved by a senior member of the company, as appropriate. Funding must be kept in separate accounts and must comply with current accounting conventions adhered to by the NHS and be available for audit by both external

	and internal auditors and the organisation's Audit Committee. Income and expenditure should be in balance at the end of the project and the initial agreement should ensure the NHS organisation is not left with any deficit as a result of project, unless as a result of its failure to perform appropriately.
Methods of payment	Payment terms must be agreed in advance. The organisation should not commit to any start up costs for which no funding has been agreed and received in advance. The method for making payments or receiving funding must be identified and comply with Standing Orders and Standing Financial Instructions.
Period of notice:	The period of notice by which the agreement may be terminated by either party must be stated.
Performance:	The performance monitoring methodology and arrangements must be clearly stated.
Variation:	Arrangements for any mutual variation of the contract must be specified.
Unsatisfactory performance:	The methods for dealing with unsatisfactory performance must be stated.
Arbitration:	Arrangements for arbitration or other dispute resolution mechanisms must be stated.
Confidentiality:	A comprehensive Confidentiality Clause must be included
Legality:	The agreement must state that appropriate consideration has been given to the legal implications of the partnership work (Note: pharmaceutical companies and the allied commercial sector will usually be required to have appropriate sanction from their Legal Departments).
Agreement:	The agreement must be signed by appropriate representatives from each organisation.