



Medicines & Healthcare products  
Regulatory Agency

# Policy for handling conflicts of interest



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# **POLICY FOR HANDLING CONFLICTS OF INTEREST**

## **INTRODUCTION**

1. This policy outlines the approach to handling potential conflicts of interest (COI) arising out of the merger with the Medicines and Healthcare Products Regulatory Agency (MHRA) of the National Institute of Biological Standards and Control (NIBSC), and the separate launch within the MHRA of the Clinical Practice Research Datalink (CPRD). The policy came into operation in 2013 and sits alongside the MHRA staff COI policy.
2. On 1 April 2013, NIBSC, formerly part of the Health Protection Agency (HPA), became a new centre of the MHRA. The CPRD, formerly the General Practice Research Database, was launched as a function of the MHRA in April 2012. These two developments resulted in a significant expansion of the MHRA's responsibilities. The 'Regulatory Centre' (i.e. the MHRA's regulatory Divisions relating to medicines and devices), NIBSC Centre and CPRD Centre constitute the three operational 'pillars' of the Agency since 1 April 2013 – together with the supporting corporate divisions already in existence in the MHRA.
3. NIBSC and CPRD currently, or may in the future, undertake a variety of work that potentially falls within the remit of the MHRA regulatory responsibilities in relation to medicines and devices. This creates the risk of COI – that is, the MHRA being in a position where its regulatory decisions might be influenced by its other interests. While much of the work undertaken would be for third parties, and not via direct contact, nevertheless, in order to manage this risk and ensure the MHRA's regulatory integrity and impartiality is maintained, a transparent policy for handling potential COI has been developed. This policy was developed taking account of all of the activities carried out by NIBSC and CPRD and is reviewed on a regular basis.
4. The MHRA is an Executive Agency of the Department of Health and a government trading fund. Its mission is to protect and improve the health of millions of people every day through the effective regulation of medicines and medical devices, underpinned by science and research.

5. The MHRA is responsible for the regulation of medicines and medical devices including in vitro diagnostic medical devices (IVDs). It has a range of regulatory responsibilities under both medicines and devices legislation, which are delivered through the following regulatory Divisions:
- Licensing Division is responsible for assessing and approving applications for marketing authorisations. These may be for new medicines, new routes of administration or new formulations of existing medicines. The Licensing Division is also responsible for assessing and granting clinical trial authorisations.
  - Inspection, Enforcement and Standards Division is responsible for ensuring compliance with the standards that apply to the manufacture and supply of medicines on the UK market. This is achieved by licensing and inspecting all UK manufacturers, wholesale dealers and importers of medicines and by inspecting all aspects of clinical trials, marketing authorisation holders and toxicology laboratories.
  - Vigilance and Risk Management of Medicines Division is responsible for pharmacovigilance including responsibility for adverse drug reactions (ADRs) / the Yellow Card Scheme.
  - Devices Division investigates reports of adverse incidents involving medical devices (vigilance / post-market surveillance), and works with healthcare professionals and manufacturers to improve device safety. Its remit also includes enforcement of the European Medical Devices Directives and investigation of cases of non compliance with UK regulations. The Division also reviews proposals from manufacturers for clinical investigations with medical devices, keeps a registry of class 1 medical devices and in vitro diagnostic devices as well as having responsibility for audit of notified bodies.
6. NIBSC is responsible for developing and producing many of the international standards in use around the world to assure the quality of biological medicines. NIBSC is also the UK's Official Medicines Control Laboratory (OMCL) responsible for independent batch release testing of biological medicines within the European regulatory framework. It also provides research into and advice on the characterisation, standardisation and control of biological medicines and

provides a rapid UK response to investigate issues and incidents involving biological medicines.

7. CPRD is a research service jointly funded by MHRA and the National Institute of Health Research (NIHR) since 2012 that provides anonymised healthcare data to support observational and interventional research. CPRD services are designed to maximise the use of NHS clinical data in research studies aimed at improving and safeguarding public health.
8. In developing and reviewing this conflict of interest policy, the Agency has sought to reconcile its aim of safeguarding public health, and the opportunities for growth, enterprise and innovation offered both by NIBSC and CPRD, with the need to maintain propriety and transparency. In many cases, the activities conducted by both NIBSC and CPRD are provided to a third party and it is the third party who would go on to have a relationship with the regulator. However, the policy is designed to ensure that where potential conflicts may arise or be perceived to arise; these are dealt with in an appropriate and open manner. This is the second review of the policy.

## **SCOPE**

9. This policy applies to potential COI that may arise from the enlargement in the MHRA's role to incorporate NIBSC and CPRD. The activities it encompasses are those of the NIBSC and CPRD centres that could pose a potential conflict of interest with MHRA's regulatory role and related responsibilities. The policy also applies to activities carried out by both NIBSC and CPRD where there is a fee charged for provision of a service and where there may be a perceived or possible financial COI with the agency's regulatory role and responsibilities.
10. This policy sits alongside the requirements that are laid down in the Agency's staff COI policy and the Civil Service Code, which provides general guidance on the duties and obligations of all civil servants and the seven principles of public life. These are:

**Selflessness**

Holders of public office should act solely in terms of the public interest. They should not do so in order to gain financial or other benefits for themselves, their family or their friends.

**Integrity**

Holders of public office should not place themselves under any financial or other obligation to outside individuals or organisations that might seek to influence them in the performance of their official duties.

**Objectivity**

In carrying out public business, including making public appointments, awarding contracts, or recommending individuals for rewards and benefits, holders of public office should make choices on merit.

**Accountability**

Holders of public office are accountable for their decisions and actions to the public and must submit themselves to whatever scrutiny is appropriate to their office.

**Openness**

Holders of public office should be as open as possible about all the decisions and actions that they take. They should give reasons for their decisions and restrict information only when the wider public interest clearly demands.

**Honesty**

Holders of public office have a duty to declare any private interests relating to their public duties and to take steps to resolve any conflicts arising in a way that protects the public interest.

**Leadership**

Holders of public office should promote and support these principles by leadership and example.

## **COMPLAINTS AND APPEALS**

11. The policy is also consistent with the Agency's whistle blowing and complaints policies. Staff, members of the public and stakeholders should use these procedures as appropriate to address any concerns or complaints about the application of the COI policy, or general COI issues (<http://www.mhra.gov.uk/contactus/howtomakeacomplaint/index.htm>).

## **OBJECTIVES**

12. The objectives of this policy are to:
  - ensure that the MHRA, in a way that is effective and maintains stakeholder confidence, avoids COI in the delivery of CPRD and NIBSC activities; and
  - enable the MHRA to avoid COI in such a way that it can carry out activities that are in the interests of public health and in line with its remit.

## **PRINCIPLES AND CRITERIA**

13. The MHRA will operate in accordance with the following principles and criteria when managing potential conflict of interest. The principles are:
  - transparency
  - impartiality
  - robustness
  - efficiency
14. The MHRA will aim to avoid having a stake in the success of a product, company or organisation which it also regulates, while operating in the interests of public health and innovation.

15. The overall aim of the policy is to ensure that the Agency's regulatory integrity and impartiality is maintained. The policy has been developed in line with the principles laid down in the Statutory Code of Practice for Regulators.

## **GOVERNANCE ARRANGEMENTS**

### *Operation of COI policy*

16. At an operational level (in both NIBSC and CPRD), mechanisms have been developed to set out the practical arrangements that are applicable for avoiding or, where necessary, handling any potential COI that may arise. There are specific escalation arrangements that apply in NIBSC and CPRD. Those operational mechanisms have been brought to the attention of all staff in the appropriate MHRA centres.

### *Identification of potential COI*

17. Potential COI may be identified by a number of means, including (but not limited to): operational activity, internal or external groups or individuals, whistle blowing, and changes to business. The processes below are designed to maximise the opportunities for capturing and dealing with potential COI. In addition, staff have been briefed on recognising potential COI, and there is a public email address for reporting potential COI and other supporting material on the MHRA website alongside this policy.
18. The escalation arrangements that apply are as follows, and terms of references for the relevant groups are at **Annex A**:
  - (i) Where possible, potential COIs will be managed within NIBSC and CPRD at an operational level in accordance with the criteria and principles set out above. This is anticipated to address the majority of potential COI cases and this has been the case since the policy came into operation.
  - (ii) NIBSC and CPRD are responsible for ensuring that their activities are carried out in accordance with the requirements laid down in operational guidance.



- (iii) NIBSC and CPRD are responsible for considering any activities they carry out which may create a perceived or possible financial COI. For example, this includes cases where the Agency provides a service and receives a fee for provision of the service.
- (iv) NIBSC and CPRD are responsible for considering cases where there might be a public health justification for undertaking activities that fall outside the restrictions of operational guidance.
- (v) In those cases where NIBSC and CPRD consider there may be merit in undertaking activities that fall outside the restrictions of operational guidance including activities that may create a perceived or possible financial COI, they will escalate to a group comprising representatives from the CET (Directors of the regulatory divisions, NIBSC, CPRD, Operations & Finance, a representative from Legal Services along with a non-executive representative from the Agency Board and chaired by the Director of Policy Division) for decision.
- (vi) in those cases where there is a significant risk of reputational damage to the Agency, or where there is a risk of perceived or possible financial COI, the group will provide advice to the Chief Executive, who will take account of that advice in deciding an appropriate course of action. Such cases might include services provided by either NIBSC or CPRD where there is a significant financial fee charged for provision of a service and where there is a possibility that MHRA may be required to undertake a regulatory function in the future .
- (vii) The Chief Executive, taking into account the advice of the CET group, may decide to escalate the issue to the Chairman or another member of the Agency Board for decision. To preserve separation and clarity of roles, there will not be overlap between NEDs on the subgroup and those on the Agency's Audit, Risk and Assurance Committee (ARAC).
- (viii) The group will also have the option to call upon a person external to the Agency for independent input.

19. **NIBSC and CPRD** operate within clearly defined parameters to ensure COI is avoided. Those parameters are set out in

operational guidance. Two groups have been established to ensure compliance with this guidance – NIBSC’s Operational Assessment Group (OAG), enlarged to include representation from the regulatory divisions of MHRA and a comparable group within CPRD. The groups have responsibility for:

- considering all new areas of NIBSC and CPRD business from the perspective of potential COI (including COI related to MHRA’s regulatory activities and financial COI where a service is provided and fees received for provision of the service);
- ensuring that in taking on new business, appropriate strategies are in place to avoid any COI in line with agreed operational guidance;
- identifying cases that fall outside the agreed operational parameters but where there may be justification on public health grounds for NIBSC and CPRD to undertake those activities; and
- making recommendations to the CET subgroup on how such opportunities could be pursued with appropriate arrangements in place for mitigating the potential for conflict of interest. This may include calling on another EU regulatory authority to undertake specific regulatory activities on MHRA’s behalf or seeking review from an independent committee and/or external body. **Such arrangements would be subject to prior agreement between the parties involved and with the approval of the CET subgroup.**

20. Decisions/recommendations will be considered on a case by case basis.

#### *Oversight and review of this policy*

21. In addition to considering specific COI cases as outlined above, the CET subgroup will oversee the operation and effectiveness of the COI policy. Specifically, it will:

- keep the policy under active review, including monitoring actively any emerging issues;

- undertake a six monthly review of the activities that are carried out by NIBSC and CPRD to ensure compliance with the policy;
  - oversee handling of any issues arising from the regular publication of information about operation of the COI;
  - consider any complaints from stakeholders about the COI process (the Agency's usual procedures for handling complaints will apply to COI complaints including the appeals process);
  - undertake regular case reviews with the NIBSC and CPRD internal groups to ensure good practice and support them in their decision-making; and
  - sign off an annual compliance report to be produced by NIBSC and CPRD and that will be considered by the MHRA's Audit, Risk and Assurance Committee.
22. Any substantive changes to the COI policy will need to be agreed by the CET and Agency Board respectively. Approval of any substantive changes will be sought from Department of Health (DH) officials and Ministers where appropriate.
23. Compliance with COI policies will be included in the Agency's regular programme of internal audit. An annual summary of COI cases will be published on the MHRA website, along with any other relevant material.

## **TYPES OF OPERATIONAL CONFLICTS OF INTEREST**

24. The business areas where a potential COI may arise are outlined in the annexes that accompany this document. **Annex B** covers activities carried out by NIBSC. Under this policy, NIBSC will not undertake any activities for which the Agency has regulatory responsibility unless there is considered to be public health justification for doing so. For example, if there is an urgent public health need and NIBSC is the only available organisation with the necessary competence to meet this need. In those cases, the escalation procedures that are described earlier in this document apply. **Annex C** covers activities carried out by CPRD and the same policy applies to CPRD's activities.

## **INTELLECTUAL PROPERTY**

25. In keeping with the Agency's mission to protect and improve public health while supporting innovation, MHRA will encourage staff to continue to generate new intellectual property (IP). In the case of NIBSC, the Agency will file patent applications for inventions where the intellectual property has the potential to provide benefit to public health, and to be novel. Where there is no COI with the MHRA's regulatory role, MHRA will own and exploit the intellectual property. In the case of NIBSC, intellectual property may be developed that may potentially lead to a new medicinal product. In such cases, the intellectual property will be divested to another organisation within eighteen months of the filing of a patent application, or promptly thereafter should a therapeutic potential be established.
  
26. IP is often created during CPRD developmental projects. When IP for the benefit of CPRD is created, steps are taken to ensure its ownership is secured for the Agency and any necessary rights are established. IP is held in the name of the MHRA as MHRA is the relevant legal entity. When CRPD develops IP for the benefit of a client in the course of a commissioned research study, the arising IP is generally owned by the commissioning organisation, in accordance with normal research practice. In such cases, the IP becomes the property of the client, while background IP (the source CPRD data) remains the property of the Agency. This is clearly set out in CPRD research study contracts.

## **REVIEW**

27. The operation of this policy was reviewed quarterly during its first year and has been reviewed since then. This is the second review of the policy. The policy will be kept under active review to ensure it continues to fulfil its purpose, including taking account of any new issues that emerge in the future and any complaints from stakeholders about the Agency's COI processes.

## **FURTHER INFORMATION**

28. Further information including the MHRA's standard operating procedures (SOPs) is available on the MHRA website at [www.mhra.gov.uk](http://www.mhra.gov.uk).

## **ANNEX A**

### **GROUPS WITHIN MHRA FOR CONSIDERING COI AND TERMS OF REFERENCE**

1. In addition to the arrangements that apply at an operational level and which are outlined earlier in this document, a subgroup of the CET has been established to consider/handle those exceptional potential COI cases that may arise within MHRA.

#### **Subgroup of the corporate executive team (CET)**

2. Potential COIs will be managed within the relevant Divisions (NIBSC and CPRD) of the MHRA in accordance with the COI policy outlined in this document. It is anticipated that this policy will address the majority of cases. In those exceptional cases where Divisions consider a corporate view is required, the case will be escalated to a group comprising representatives of the CET. The group may also escalate an issue to the Chief Executive for decision where necessary.
3. The suggested terms of reference for this group are to:
  - consider cases escalated from Divisions where it is considered there may be justification for undertaking certain activities that fall outside the restrictions of operational guidance;
  - where necessary provide timely advice to the Chief Executive on those cases;
  - monitor actively any emerging issues that might require the COI policy and/or its operation to be reviewed including any financial COI;
  - undertake a six monthly review of the activities that are carried out by NIBSC and CPRD to ensure compliance with the operational guidance;
  - oversee handling of any issues arising from the regular publication of information about operation of the COI policy;
  - consider any complaints from stakeholders about the COI process (the Agency's usual complaints procedures will apply to COI complaints including the appeals process); and

- sign off an annual compliance report that will be considered by the MHRA's ARAC and published on the MHRA website.

**Membership of this group to include:**

Director of Policy (Chair)  
Director of Inspection, Enforcement & Standards  
Director of Licensing  
Director of Vigilance and Risk Management of Medicines  
Director of Devices  
Director of Operations & Finance  
Representative from Legal Services  
NIBSC Director  
CPRD Director  
A representative of the Agency Board

**Subgroup of non-executive directors (NEDs)**

The Chief Executive, taking account of the advice provided by the Subgroup of the CET, may decide that certain exceptional cases should also be considered by a subgroup of NEDs for advice before a final decision is reached. In such circumstances, the Chairman or one or more non-executive members of the Agency Board who are not members of the ARAC will be called upon. The terms of reference for this group are to:

- be called upon in exceptional cases to provide timely advice to the Chief Executive on any particularly difficult COI cases; and
- be called upon to provide advice to the Agency on those COI cases where a review of decisions/actions taken by the Agency is required.

Membership of this group will be drawn from the Agency Board as appropriate.

## **ANNEX B**

### **NATIONAL INSTITUTE FOR BIOLOGICAL STANDARDS AND CONTROL (NIBSC)**

1. The National Institute for Biological Standards and Control (NIBSC) aims to improve public health through ensuring the quality of biological medicines used in the treatment and prevention of disease. NIBSC operates at the interface between scientific research, product development, regulation and policy. Many biological medicines - such as vaccines, blood products and novel biopharmaceuticals may require the use of bioassays to assess their potency and safety for which NIBSC has the required unique expertise in biological medicine characterisation.
2. Most of the activities/functions carried out by NIBSC are carried out in a way that is not considered to present any potential conflict of interest with MHRA's regulatory role. In relation to regulation, NIBSC's activities can be regarded as falling within two categories:
  - where a product developer makes use of NIBSC products or services when seeking to get a product to market in the EU and where MHRA has a role in the regulation of the product; and
  - where NIBSC is the manufacturer of a product that is regulated by MHRA.
3. Where a developer is making use of NIBSC products or services, conflicts of interest can usually be avoided. This is because:
  - (a) the products and services NIBSC provides to developers are generally provided in such a way as to not give rise to any conflict of interest with the regulatory process;
  - (b) NIBSC has in place robust processes/audit systems to quality assure the goods and services; and
  - (c) the developer is a third party and is subject to separate regulation by the MHRA.
4. Internal controls within NIBSC were updated to take account of the merger with MHRA, as detailed in the policy



document, and those updated arrangements provided assurance that NIBSC's activities are being managed in the appropriate manner.

5. Operational guidance has been developed that details those NIBSC activities that do not have the potential to give rise to an actual or perceived conflict of interest. Activities include:

- Production and development of biological materials for general distribution. Materials may include reference materials, research reagents, stem cell lines and viruses;
- Production and development of biological materials customised for an individual user, providing that the material will not be used as a starting material or in the production of a medicine and that no decision-critical data will be included in a European regulatory submission;
- Provision of informal and formal (via the MHRA's process) advice;
- Participation in early stage collaborative research, and development of biological assays for the general benefit of public health;
- Testing of biological medicines as part of the Official Control Authority Batch Release programme or for a manufacturer's own use only.

6. There are a small number of activities carried out by NIBSC where it is considered that specific conflict of interest protocols are required.

6.1 Those activities are:

- activities relating to NIBSC's production and distribution of reference materials for quality assurance of in vitro diagnostic tests for the diagnosis of clinical conditions in patients. These reference materials are classed as in vitro diagnostic reagents, and thus subject to regulation. This is the one case where NIBSC is the manufacturer of a product that is regulated by the MHRA; and

- the provision of advice by the MHRA in relation to influenza vaccine potency assays.

6.2. In those cases, the conflict of interest policy that will apply is that the MHRA will retain its regulatory role, but put in place a system of oversight from other European regulators or expert external bodies. In those cases, NIBSC is responsible for alerting the relevant regulatory division as soon as a potential or perceived COI is identified along with the Secretariat to the Subgroup of the CET. The specific arrangements that apply are outlined in paragraphs 6.3 to 6.6 below.

### **PROVISION OF IVDs**

6.3. In the case of in vitro diagnostic reagents, there is the potential for a conflict of interest arising from the MHRA's role as a regulator of medical devices/IVDs and NIBSC's role as producer and distributor of in vitro diagnostic reagents. However, under current European legislation<sup>1</sup> there is joint oversight and monitoring with other European regulators of the notified bodies who carry out assessment prior to higher risk products being placed on the market. MHRA will seek the involvement of an external body should any of the following events have occurred in the previous year:

- should NIBSC formally request regulatory advice related to NIBSC in vitro diagnostic medical devices; or
- should an adverse incident report be made to MHRA about a NIBSC regulated in vitro diagnostic reagent or if a vigilance report is sent to MHRA by NIBSC.

6.4 In vitro diagnostic reagents must by law include the trade name or the name of the legal entity of the manufacturer on the label and documentation accompanying them. To counter any concern about the regulator's (MHRA's) name appearing on product labels, NIBSC brand name and address only will be used on the reagent label and description. Under the current regulations, the name of

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<sup>1</sup> The current European legislation is due to be reviewed and it is possible that this may result in further strengthening of regulatory oversight in the EU. This Col policy will be reviewed to take account of any new legislative requirements

the legal entity (MHRA since 1/4/2013) will need to appear on the accompanying documentation (the instructions for use.) The European legislative requirements are currently being reviewed and under the proposals<sup>2</sup> it is possible that it may be permissible for NIBSC's brand name rather than MHRA to be used on the product documentation. However, it is expected that any changes to the legislation would not be applicable before 2014.

## **INFLUENZA POTENCY REAGENTS**

- 6.5. In the case of provision of advice by the MHRA in relation to influenza vaccine potency assays, NIBSC is a leading supplier of influenza vaccine potency reagents for the current 'gold standard' potency assay, the Single Radial Diffusion (SRD) assay. Should an influenza vaccine manufacturer seek advice on use of an alternative assay to the SRD potency assay, this could give rise to a perceived conflict of interest.
- 6.6. The MHRA will continue to provide advice but ensure that it is aligned to published EU/WHO guidance. In addition, any advice provided will be accompanied by a clear declaration of NIBSC's financial interest in provision of potency reagents as one of the WHO Essential Regulatory Laboratories within the Global Influenza Surveillance and Response System (GISRS) network, and guidance on alternative sources of advice.
7. In accordance with the principles outlined in the policy document, NIBSC will not:
  - Exploit intellectual property arising from research carried out at NIBSC that leads to a potential new therapeutic or prophylactic. Intellectual property relating to a potential therapeutic or prophylactic will be divested to another organisation within eighteen months of the filing of a patent application, or promptly

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<sup>2</sup> European Commission's proposal for a regulation on IVDs – essential requirement 17.2 paragraph (iii)

should a therapeutic or prophylactic potential be established.

- Provide materials for direct clinical use.

## **ANNEX C**

### **CLINICAL PRACTICE RESEARCH DATALINK (CPRD)**

1. CPRD is a research service jointly funded by MHRA and the National Institute of Health Research (NIHR) since 2012 to provide anonymised healthcare data to academic, charity, government and commercial researchers in the UK and internationally. CPRD services are designed to maximise the use of NHS clinical data in research studies aimed at improving and safeguarding public health.
2. Data provided by CPRD have been used for many years in a range of drug safety and epidemiological studies that have benefited patient care and impacted on the health of the public. The UK is in a unique global position to use clinical records in novel ways for patient recruitment, clinical trials management and follow up. In addition to supporting high quality observational research, CPRD is developing world leading services based on using real world data to support clinical trials and intervention studies.
3. Services provided by CPRD include:
  - Observational research services and provision of data for studies such as pharmacoepidemiology, epidemiology, drug safety, incidence and prevalence.
  - Interventional research services encompassing patient feasibility estimates, location of patients for potential recruitment into clinical studies and supporting clinical trials by capturing and managing clinical data in the patient record into research ready dataset for analysis by the Trial Sponsor.
4. The use of anonymised NHS records to support CPRD's observational research services are subject to ethical, scientific and regulatory approval processes. These functions are not considered to present any potential conflict of interest for the MHRA's regulatory role.

5. The clinical data received, processed and stored by CPRD are supported by separate IT systems from those serving the MHRA regulator. Separation of CPRD's clinical source data from systems providing researcher access, including for CPRD researchers and the MHRA as a CPRD customer, is necessary to further protect patient confidentiality and the identity of contributing GP practices.
6. There are a number of activities carried out by CPRD where it is considered that specific COI protocols are required. Those include cases where CPRD may be involved in clinical trials or may provide data and services to companies where MHRA may be required to carry out a regulatory function.
7. To mitigate against any major COI, CPRD will never act as Sponsor of a clinical trial nor carry out analyses of clinical trial data. In cases where CPRD is providing a clinical trials service to a Sponsor, CPRD will notify all the relevant divisions within the regulator.
8. At the outset of a new post marketing study, CPRD will notify the MHRA licensing division because it is possible that a licence variation may be required as a result of a CPRD supported study. In such a case it will be necessary to call on another EU regulatory authority to undertake an independent review on MHRA's behalf or seek review from an independent committee and/or external body.
9. In situations where potential safety signals are associated with medicines involved in CPRD supported clinical trials, the MHRA vigilance division will not take on specific rapporteurships.
10. CPRD will also notify the Inspectorate, Enforcement and Standards division when a new study is supported by CPRD. This action will ensure that sites involved with a CPRD supported study are not be inspected by the MHRA, and can be inspected by another EU Agency if required.