

# Corporate Conflicts of Interest Policy and Procedure

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## Revision History

This table sets out the revision history for the last three versions.

Version No.	Effective date	Author's Title	Change
3.0	June 2016	Senior Policy Manager, Policy Division	To reflect changes suggested by CET, including regarding financial COIs.
4.0	January 2020	Head of Corporate Governance & Accountability, Policy Division	Document put in the standard format and revised to take account of current practice.
5.0	February 2021	Head of Corporate Governance & Accountability, Policy Division	Updated the CPRD annex to include all current types of potential COI. No changes to the main document.

## Consultation

Who	Date
NIBSC Business Development team	September 2019 (main document)
CPRD	January 2021

Corporate Conflicts of Interest Policy and Procedure v5.0

**Approval**

<b>Approval Path</b>	<b>Date</b>
COI CET Sub-Group	December 2019 approved main document and January 2021 approved CPRD annex
CET	January 2020 approved main document
Policy and Procedure Committee	January 2020 approved main document

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## **1 Introduction**

- 1.1 This document outlines the approach to handling potential conflicts of interest (COI) arising from the operation of the three centres of the Medicines and Healthcare products Regulatory Agency (the Agency): - the MHRA Regulator (the Regulator), the National Institute of Biological Standards and Control (NIBSC) and the Clinical Practice Research Datalink (CPRD).
- 1.2 NIBSC, CPRD or other parts of the Agency currently, or may in the future, undertake a variety of work that potentially falls within the remit of the Agency's regulatory responsibilities in relation to medicines and devices. This creates the risk of COI – that is, the Regulator being in a position where its regulatory decisions might be – or be seen to be - influenced by its other interests. While much of the work undertaken would be for third parties, and not via direct contact, this transparent policy for handling potential corporate COIs has been developed to manage this risk and ensure the Agency's regulatory integrity and impartiality is maintained whilst enabling the Agency to support innovation.

### **1.3 Aims and objectives**

- 1.3.1 The overall aim of the policy is to ensure that the Agency's regulatory integrity and impartiality is maintained.
- 1.3.2 The objective of this policy is to enable the Agency to continue its activities and develop new areas of work, in the interests of public health, whilst identifying, taking steps to mitigate and/or avoid potential, actual or perceived COI in a way that is transparent and maintains stakeholder confidence.

### **1.4 Background**

- 1.4.1 This policy and procedure came into operation in 2013 following the launch of CPRD as a function of the Agency and when NIBSC became a new centre within the Agency. Information about the Agency's role and responsibilities can be found on its website (see link in References, below).
- 1.4.2 In developing and reviewing this policy and procedure, 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 to support the UK Health Sciences Strategy, 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.

## 2 Scope

- 2.1 All staff must follow this policy and procedure.
- 2.2 This policy applies to activities that NIBSC, CPRD or other parts of the Agency may carry out, whether fee paying or not, that could pose a potential conflict of interest with the Agency's role as the Regulator and related responsibilities.

## 3 Policy

- 3.1 This policy has been developed in line with the principles laid down in the Statutory Code of Practice for Regulators. It sits alongside the Agency's staff COI policy and the Civil Service Code, which provides general guidance on the duties and obligations of all civil servants.
- 3.2 The Agency will operate in accordance with the following principles when managing potential conflicts of interest:
  - transparency
  - impartiality
  - robustness
  - efficiency
  - maximising the Agency's contribution to public health.
- 3.3 The Agency's mission is to protect and improve public health while supporting innovation. Staff are therefore encouraged to progress new work, identifying any potential COIs and ways of mitigating them in a transparent way.
- 3.4 NIBSC and CPRD operate within clearly defined parameters, set out in operational guidance to ensure COIs are identified and then either managed or avoided.
- 3.5 While operating in the interests of public health and innovation, the Agency will take steps to avoid having a stake in the success of a product, company or organisation which it also regulates.
- 3.6 Where the proposed mitigation for a potential or perceived COI is to ask another regulatory authority, individual or organisation to review a decision or finding, or to carry out some work on behalf of the Agency, this should be approved by the CET COI Sub-Group ('Sub-Group') in advance and all instances recorded on the COI Tracker by the Sub-Group Secretariat.

### **3.7 Intellectual Property**

- 3.7.1 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 Agency's regulatory role, the Agency will own and exploit the intellectual property. Intellectual property may be developed that may 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.
- 3.7.2 IP is often created during CPRD developmental projects. When IP for the benefit of CPRD is created, steps will be 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'. When CPRD 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.

## **4 Roles and responsibilities**

### **4.1 Operational level groups in both NIBSC and CPRD**

- 4.1.1 NIBSC's Opportunities Assessment Group (OAG), which includes Regulator representation, and CPRD's Senior Management Team considers all new areas of business from the perspective of potential COI.
- 4.1.2 These two groups are responsible for:
- Ensuring that their activities are carried out in accordance with the requirements laid down in their operational guidance.
  - Maintaining clear procedures, aligned with this policy and procedure, for handling any potential COIs that might arise, including when cases should be escalated to the Sub-Group.
  - Ensuring that all staff are fully aware of this policy and procedure, specifically the need to identify potential or perceived COIs in taking on new work or developments in current work and an understanding of the escalation routes within NIBSC/CPRD.
  - 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.

- 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.
- Managing a record of potential COIs identified with any mitigations agreed with the Sub-Group.
- Keeping minutes that record decisions and actions taken with regard to COIs and their mitigation, that can be shared with the Sub-Group.
- Escalating cases to the Sub-Group for discussion and decision, especially when the proposed mitigation is to approach another organisation or individual for independent review. See 'Escalation Arrangements' section below and Annex A for a suggested paper format.

## **4.2 COI CET Sub-Group**

4.2.1 A Sub-Group of the Corporate Executive Team (CET) will consider any cases where it is considered there may be justification for undertaking certain activities that fall outside the restrictions of operational guidance.

4.2.2 The Sub-Group's terms of reference are:

- consider escalated cases, coming to a decision on whether the proposed activity can be progressed and, if so, to agree any mitigations.
- monitor any emerging issues that might require the COI policy and/or its operation to be reviewed;
- review relevant activities carried out by NIBSC and CPRD to ensure compliance
- consider any complaints from stakeholders about the COI process; and
- sign off an annual compliance report to be approved by ARAC and published on the Agency's website.



4.3 The membership of the sub-group is:

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

4.4 The Sub-Group is quorate when the Chair or Deputy Chair, a Non-Executive Director and three Executive Directors are present.

## 5 Procedure

### 5.1 Identification of potential COI

5.1.1 Procedures are in place for Agency staff to raise awareness of potential COIs – see escalation arrangements below. Members of the public and staff in other organisations can also raise concerns through Customer Services ([MHRACustomerServices@mhra.gov.uk](mailto:MHRACustomerServices@mhra.gov.uk)) if they believe there may be a COI in activities undertaken by parts of the Agency.

### 5.2 Escalation Arrangements

5.2.1 The escalation arrangements that apply are as follows:

- Where possible, the majority of potential COIs will be managed within NIBSC, CPRD or the Regulator at an operational level in accordance with the principles set out above.
- 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, or
  - Part of the Regulator identifies something that may create a perceived or possible COI with another part of the Regulator or the rest of the Agency

they will escalate to the Sub-Group for decision.

- The Sub-Group has the option to call upon a person external to the Agency for independent input if required.
- In exceptional cases, where it is felt particular work should proceed (such as for public health or scientific reasons) but where despite agreed mitigations there remains a risk of reputational damage to the Agency, the Sub-Group may decide to seek a Ministerial steer.

### **5.3 Consideration by the CET COI Sub-Group**

5.3.1 Cases that are escalated to the Sub-Group may be considered by them at a formal meeting or in correspondence: - either as part of a virtual meeting or separately where a quicker response is required. Where papers are circulated in correspondence, the Secretariat manages the process, sending the paper to all members with a clear deadline and then collating and saving responses electronically. The Secretariat sends the Sub-Group's feedback to the case owner for consideration, response and/or action.

5.3.2 Where cases are considered in a formal meeting, the Secretariat writes formal minutes recording the decisions and updates the COI Tracker. The minutes and the tracker are stored electronically and a link circulated to the Sub-Group and other key members of staff across the Agency.

5.3.3 See Annex A for a suggested paper format. Cases being submitted to the Sub-Group should include:

- A short summary of the proposed work
- How this work could give rise to a perceived or potential COI
- How the potential COIs could be managed, for example:
  - seeking independent review or confirmation of an Agency regulatory decision (e.g.: asking another regulatory authority to review a licensing decision or to observe an inspection and review associated reports).
  - asking another regulatory authority to undertake specific regulatory activities on the Agency's behalf
  - seeking independent opinion on a particular matter from an independent committee or external body.
- Any public health justification for carrying out the proposed work, for example if part of the Agency the only body able to do this work?

### **5.4 Implementing the agreed actions**

5.5 Where the Sub-Group approves taking forward the proposed work, with appropriate mitigations, the work leads are responsible for implementing this

and updating the Secretariat who will keep the COI Tracker up to date.

- 5.6 If the agreed mitigation includes asking another regulatory authority or other body to review an Agency decision or finding (e.g.: a licensing decision), or undertake other regulatory activities on behalf of the Agency, the relevant leads will approach one of the regulatory authorities with whom the Agency has an agreement to undertake such activities and make these arrangements. The Secretariat will maintain the details of these regulatory authorities and each initial contact made.
- 5.7 Cases are marked closed on the COI Tracker when the COI mitigations have been implemented or the work is no longer being progressed. All closed cases will be reviewed by the Sub-Group before being moved to the closed tab on the spreadsheet.

## **6 Competence**

- 6.1 Staff require general Civil Service skills. No particular training is necessary.

## **7 Monitoring compliance**

- 7.1 An annual compliance report will be published, covering each calendar year and reviewing the Agency's adherence to this policy and procedure. This report will include a summary of cases considered by the Sub-Group and the mitigations agreed. The report will be approved by the Sub-Group itself before being sent to ARAC, in March, for approval to publish on the Agency's website. At that point, sensitive material (e.g.: commercially sensitive etc) may be redacted for publication but a full copy will be kept on SharePoint.
- 7.2 Compliance with this COI policy and procedure may be included in the Agency's internal audit programme.
- 7.3 Any complaints or comments about the application of this policy and procedure should be raised through the Agency's administrative complaints procedure or internal or external whistleblowing routes.
- 7.4 This policy and procedure will be reviewed at least every three years to take account of any new issues that emerge and any complaints or comments received.

## **8 References**

- 8.1 The following internal documents are associated with or linked to this document:

Internal Document	Document Location
Conflicts of Interest Policy	INsite/Policies and Procedures
Whistleblowing Policy and Procedure	INsite/Policies and Procedures
Administrative Complaints Policy and Procedure	INsite/Policies and Procedures

8.2 The following external documents are associated with or linked to this document:

External Document	Document Location
Seven Principles of Public Life	<a href="http://www.public-standards.gov.uk/about-us/what-we-do/the-seven-principles/">http://www.public-standards.gov.uk/about-us/what-we-do/the-seven-principles/</a>
Civil Service Code	<a href="https://www.gov.uk/government/publications/civil-service-code/the-civil-service-code">https://www.gov.uk/government/publications/civil-service-code/the-civil-service-code</a>
Statutory Code of Practice for Regulators	<a href="https://www.gov.uk/government/publications/regulators-code">https://www.gov.uk/government/publications/regulators-code</a>
Information about the Agency's role and responsibilities	<a href="https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency/about">https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency/about</a>
How to make a complaint to the Agency	<a href="https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency/about/complaints-procedure">https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency/about/complaints-procedure</a>

## 9 Glossary

9.1 The following key terms are used in this document:

Term	Definition of term
Conflict of interest (corporate COIs)	These may arise in situations where the work of different parts of the Agency overlaps and there could be the suggestion that decisions in one part are being influenced by another part. For example, the Regulator could be asked to make a regulatory decision on something on which another part of the Agency has been involved, which could be seen as a COI.

## **Annex A: Suggested COI CET Sub-Group Paper Format**

### **Paper for submission to Agency's CET COI Sub-group**

**[Title]**

#### **1. Issue**

1.1

#### **2. Background**

2.1

#### **3. Potential or Perceived Conflict of Interest**

3.1

#### **4. Justification**

4.1 (i.e. for doing the work, such as a public health justification)

#### **5. Proposed Mitigation of the Potential COI**

5.1

#### **6. Recommendation**

6.1

**[Author/s]**

**[Date]**

## **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 the Agency's regulatory role (the Regulator). 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
  - where the Regulator has a role in the regulation of the product
  - where NIBSC is the manufacturer of a product that is regulated by the Regulator.
3. Where a developer is making use of NIBSC products or services, conflicts of interest can usually be avoided. This is because:
  - the products and services NIBSC offer to developers are generally provided in such a way as to not give rise to any conflict of interest with the regulatory process. NIBSC has upfront terms which give clear guidance to prospective customers as to the work that we can and cannot do. NIBSC also has clear contractual clauses embedded in its agreements and contracts to further protect itself from direct conflicts of interest. These clauses also underpin the purpose and use of the products and services provided by NIBSC, so they are not used to provide decision critical data that has the purpose of being submitted or used for regulatory submission;
  - NIBSC has in place robust processes/audit systems to quality assure the goods and services; and
  - the developer is a third party and is subject to separate regulation by the Regulator.

### **Activities that should not give rise to a COI**

4. Some of NIBSC activities that do not have the potential to give rise to an actual or perceived conflict of interest; these activities include:

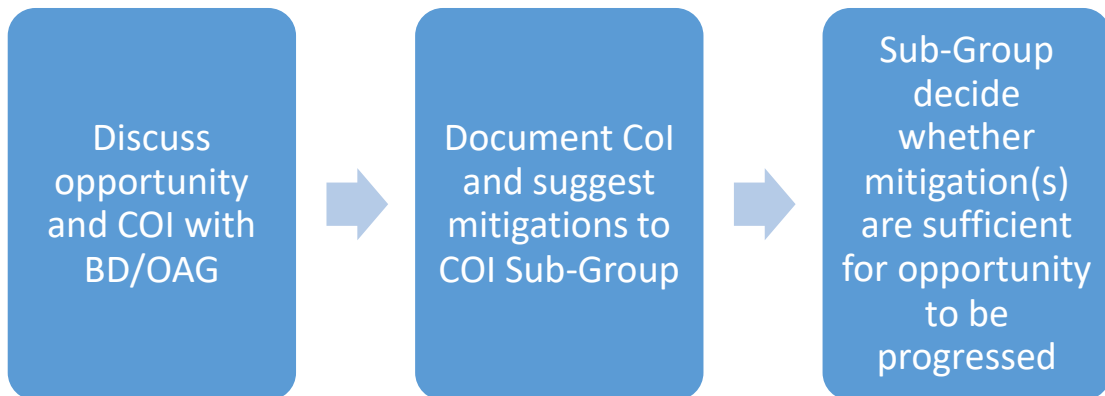
- Production and development of biological materials for general distribution. Materials may include reference materials, research reagents, stem cell lines and viruses;
- Production and development of biological materials customised for an individual user, providing that the material will not be used as a starting material or in the production of a medicine and that no decision-critical data will be included in a regulatory submission;
- Provision of informal and formal (via the Agency'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.

### **Activities where potential COIs may need managing**

5. There are a small number of activities carried out by NIBSC where potential COIs may occur and will need to be managed:
  - 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 Regulator
  - the involvement of NIBSC as a testing laboratory for a material that will be used in a clinical trial
  - the development of products or services that are intended for future clinical use in the UK market including providing seed stock material to make therapeutic products and the supply of starting material in vaccine production.
  - the provision of advice by the Regulator in relation to influenza vaccine potency assays.

### **How potential COIs may be managed**

6. As opportunities present, scientists engage with NIBSC's Business Division (BD) to triage, and uncover whether further scrutiny is required. The specific arrangements that apply are outlined in paragraphs below.
7. NIBSC are asked to suggest mitigations for indirect COIs, where possible, that the information, data generated or material to be provided is not part of the final decision-making step in a regulatory process. Therefore, NIBSC does not take overall responsibility for the regulatory submission and is at least one step removed from the process.



8. Evidence is required that appropriate mitigations be put in place to manage emerging COIs, where it is uncertain whether they are indirect or not. This is supported by colleagues from the Agency's Licensing, Devices and clinical trials teams with whom key NIBSC staff will work to communicate, explore and resolve conflicts of interest where possible to ensure NIBSC continues to explore new opportunities with potential customers.
9. NIBSC is responsible for alerting both the relevant regulatory division as soon as direct COIs are identified and via the Secretariat to the COI CET Sub-group ('the Sub-Group'). Where the following situations arise and NIBSC engages in activities which are a direct COI and not considered Business as Usual, sufficient justifications have to be presented to the Sub-Group so both NIBSC and the wider Agency are in agreement to mitigate the COIs as best as possible, to deliver its wider public health remit.
10. One or more of the following justifications would have to be met:
  - NIBSC is responding to a world-wide public health need
  - NIBSC is unique in its offering and no other organisation is able to respond
  - NIBSC is appropriately positioned within government to offer advice, services or products without bias.
  - NIBSC involvement with the Regulator is the reason for such an activity
  - The activity itself is part of NIBSCs core remit.
11. The Regulator will retain its regulatory role but refer to another suitable regulator and/or external body for an independent view of the specific documentation. This process is embedded within the main Corporate COI policy and procedure and its resource is subject to Sub-Group approval.



12. Other areas across NIBSC also have the capacity to provide seed stock material such as hybridomas, cell lines and flu reagents which could be further developed into clinical material. NIBSC already supplies human material for vaccine development. NIBSC recognises that it cannot participate i.e. develop and deliver in all therapeutic areas, but where there is a well-established or recognised need that NIBSC, in its basic remit and offerings, remains unique and well positioned to fulfil, it should continue to provide these offerings.
13. Should the opportunity involve the submission or review of regulatory data by the Regulator, and the Sub-Group recommends that the opportunity be progressed, the Regulator may seek to involve other appropriate regulators to carry out the review of the specific data.

## **Examples of COIs and how these are managed**

### **A. Provision of IVDs**

14. In the case of in vitro diagnostic reagents, there is the potential for a conflict of interest arising from the Agency'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. The Agency 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 for NIBSC's own in vitro diagnostic medical devices; or
  - should an adverse incident report be made to the Regulator about a NIBSC regulated in vitro diagnostic reagent or if a vigilance report is sent to the Regulator by NIBSC.
15. 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 the legal entity (MHRA since 1/4/2013) will need to appear on the accompanying documentation (the instructions for use.)

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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 COI policy will be reviewed to take account of any new legislative requirements

16. 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. Furthermore, as the UK is renegotiating its relationship with the EU it is possible that EU law will not be fully applicable.

## **B. Influenza Potency Reagents**

17. In the case of provision of advice by the Regulator 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.

18. The Regulator 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.

19. 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 should a therapeutic or prophylactic potential be established.

## **C. Advanced Therapies**

20. NIBSC recognises that the advanced therapies field is fast paced and the UK has a leading position in its current economic climate. Due to high ethical and quality standards, the UKSCB within NIBSC has a unique remit, as it offers seed stock provisions as starting materials in the form of clinical grade stem cell lines, for the development of advanced therapies (ATMPs). Careful considerations have been made when putting together the contractual arrangements to avoid COIs as best as possible. NIBSC ensures that customers are aware of their contractual duty to inform NIBSC if they are to use data generated from the human embryonic cell lines provided, for a regulatory submission. In turn, NIBSC can then inform the relevant division within the Regulator so appropriate mitigations can be put in place in a timely manner.

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

## Annex C: Clinical Practice Research Datalink (CPRD)

### CPRD Services

1. CPRD is a research service jointly supported by the Medicines and Healthcare products Regulatory Agency (the Agency) and the National Institute of Health Research (NIHR) 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 to support and facilitate clinical research through novel methods, including 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. These services are available for both academic and commercial clients.
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 Agency's regulatory role.
5. The clinical data received, processed and stored by CPRD are supported by separate IT systems from those serving the Regulator. Separation of CPRD's clinical source data from systems providing researcher access, including for CPRD researchers and the Regulator 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 specific COIs will need to be managed and mitigated. These include cases where CPRD is involved in clinical trials which are subject to clinical trial regulation. Typically this would involve low risk or type A trials classified as those where the risks to the

participants or to the robustness of the trial data are considered to be 'no higher than the risk of standard medical care'<sup>3</sup>.

### **Managing potential COIs**

7. At the outset of any involvement in a new post marketing study, CPRD will notify the Agency's 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 consider mitigation activities described below.
8. In situations where potential safety signals are associated with medicines involved in CPRD supported clinical trials, a review by the Agency's vigilance division will be conducted independently.
9. CPRD will also notify the Inspectorate, Enforcement and Standards division when a new trial may be supported by CPRD.

### **Potential mitigation activities**

10. To mitigate against any major COI, CPRD will never act as Sponsor of a clinical trial.
11. For cases where CPRD is providing a clinical trials service to a Sponsor, the following standard mitigations should be considered:
  - A full CTA submission completed by the Sponsor for MHRA assessment, (as opposed to the potential submission under the notification scheme).
  - For academic sponsored trials, the CHM Expert Advisory Group will be asked to verify the decision following CTA approval. For trials sponsored by commercial organisations, validation of MHRA's CTA may need to be sought from an external regulator.
  - For trials sponsored by academic organisations MHRA may undertake an inspection and have any findings reviewed by an expert committee such as the CHM Expert Advisory Group to review and assess any findings. For commercially sponsored trials, MHRA may request an inspection from an external regulatory body or for an external body to validate any findings following an MHRA led-inspection.

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<sup>3</sup> MRC/DH/MHRA Joint Project Risk-adapted Approaches to the Management of Clinical Trials of Investigational Medicinal Products 10 October 2011