



## CALL FOR INITIAL APPLICATIONS:

### THERAPEUTIC CAPABILITY CLUSTERS IN

- 1) INFLAMMATORY RESPIRATORY DISEASES
- 2) JOINT & RELATED INFLAMMATORY DISEASES

## INTRODUCTION

The UK is a world leader in Life Sciences, with vibrant and innovative academic/clinical, pharmaceutical and medical (bio)technology sectors. A thriving and integrated UK Life Sciences industry, working in close collaboration with academia and the NHS, plays a vital role in driving economic growth and prosperity, and supports world-class healthcare delivery.

In July 2009, the Government published the *Life Sciences Blueprint*, a comprehensive package of high-impact measures to support economic growth and strong healthcare delivery. One measure is to support the formation of a UK Life Sciences Super Cluster. The public funders and industry have been working together to develop a concept for this with the aim to capture and promote the UK's world leading capability in translational research, to deepen academic-NHS-industry collaboration, enabling the UK to function - as a global leader - on the international stage and to encourage global industry collaboration with UK health research centres.

The vehicle for achieving this will be a series of **Therapeutic Capability Clusters** in areas of substantial health burden and unmet medical need. The Capability Clusters will focus on areas of translational medicine, particularly early clinical studies, where industry has a strong interest in working with academia and where both the public (NHS and academic) and private (life sciences industry) sectors will gain by working closely together.

The first of these Therapeutic Capability Clusters will be in the area of Inflammation & Immunity with two pilot clusters in **inflammatory respiratory diseases** and **joint & related inflammatory diseases** where there is existing academic excellence and the cluster can draw on existing capability.

This "call for initial applications" document sets out the process for initial applications and invites relevant academic and/or NHS centres of excellence in inflammatory respiratory diseases and joint & related inflammatory diseases to submit short applications to take part in one or both of these pilot clusters.

## PURPOSE OF THIS DOCUMENT

This call is structured as follows:

Section 1	Sets out the purpose, core requirements and scope of the Therapeutic Capability Clusters (page 2-8).
Section 2	Sets out the application process, the deadlines and eligibility criteria to become part of the pilot Therapeutic Capability Clusters in <u>inflammatory respiratory diseases</u> and <u>joint &amp; related inflammatory diseases</u> . (page 8-11).

This document sits alongside two short “Initial Application Forms” for the two pilot clusters (and guidance therein). **These three documents form the application pack.**

## 1 BACKGROUND

### 1.1 What is a Therapeutic Capability Cluster and why?

The *Life Sciences Blueprint* called for a new approach to collaboration in life sciences: an approach that would provide opportunities for engagement of academic and NHS communities with the commercial life sciences sector to develop new drugs and interventions for patient and economic benefit.

From this, the concept of Therapeutic Capability Clusters was born, in which academic and NHS centres with expertise in specific therapeutic areas come together to work more closely with industry on early clinical development of new drugs and interventions. This would bring patient and economic benefits, and further scientific pursuit and endeavour in areas of high therapeutic need. Therapeutic Capability Clusters will therefore focus in areas where

- (i) there is expertise in the UK NHS/academic community and
- (ii) where industry has significant research interests and pipeline activity and
- (iii) where there is significant infrastructure and enabling technologies in place, for example to provide appropriate patient cohorts.

In the first instance, the Capability Cluster initiative is focusing on early and exploratory development (phase 1 and 2a human clinical trials and the technologies to inform and support these). In the longer term, successful Capability Clusters may evolve to expand more broadly into the translational medicine space.

The Therapeutic Capability Cluster concept is a unique opportunity for the UK. No existing cluster has a focus on early clinical development and experimental medicine. Were it to be achieved, this would provide a unique selling point for UK biomedical research activity, enabling the UK to retain and attract inward investment and reinforce opportunities for future collaborations in clinical science between the NHS, academia and industry.

## **Structure**

Each Therapeutic Capability Cluster will comprise of:

- **Several academic/NHS research centres of excellence** that have relevant and complementary capabilities, and collective critical mass, in developing and implementing several exploratory development programmes at any one time. The number of centres that will comprise a Therapeutic Capability Cluster has not been determined in advance. It will be influenced by the number, scale and quality of the applications. However an initial assessment suggests that it is likely that each Therapeutic Capability Cluster will comprise of 4-6 centres.
- A **single point of contact** to coordinate the collective activities of the academic/NHS centres forming the cluster and its interface with industry. This coordination post needs strong programme management expertise, experience within the funding and research landscape, and experience of working with the life sciences industry.

### **1.2 Scope of the pilot Therapeutic Capability Clusters**

The joint industry/public sector Capability Cluster Delivery & Oversight Group<sup>1</sup>, which oversees the development of Therapeutic Capability Clusters, decided that the first capability cluster would be in the area of Inflammation and Immunity (I&I). This therapeutic area is to be taken forward by 2 pilot clusters in:

- **Inflammatory respiratory diseases** (e.g. Asthma, Chronic Obstructive Pulmonary Disease (COPD)).
- **Joint & related inflammatory diseases.** This involves inflammatory joint diseases and those that relate to and inform on them (e.g. Rheumatoid Arthritis, Osteoarthritis, Ankylosing Spondylitis. Related condition such as Systemic Lupus Erythematosus (SLE), Inflammatory Bowel Disease (IBD), and Psoriasis may also be included.

These are areas with:

- High medical need, variable treatment responses, sub-optimal range of therapies; and high attrition in early development of new treatments.
- Need for greater understanding of therapeutic pathways and their application to human disease;
- Poor understanding of disease progression and their markers that may be used earlier;
- Crippling attrition, especially in the early clinical phases of drug development.

Industry researchers will work with publicly funded experts in the Capability Clusters to tackle key developmental challenges:

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<sup>1</sup> For further information, see the supplementary document on governance which can be found as a stand alone document (to be posted on the web shortly).

- The clinical validation of Proof of Mechanism, disease related biomarkers;
- The clinical validation of efficacy endpoints;
- The clinical validation of experimental medicine disease model endpoints e.g. allergen and viral challenge;
- The clinical validation of disease targets,
- The stratification of patient groups by disease or biomarker phenotype;
- Novel clinical study design (e.g. non-frequentist methodologies, modelling and simulation);
- Exploration of novel approaches to disease modification including validation of new surrogate markers for assessing potential for new interventions;
- New and/or improved methods of drug delivery.

### **1.3 Benefits of taking part in a therapeutic capability cluster**

The benefits from the Capability Cluster concept are shared between the constituents; for example, a mutual recognition that industry, academia and the NHS are credible, equal scientific and clinical partners. Increased collaboration should result in a mutually beneficial exchange of ideas and people; it would improve the training for academic, NHS and industry researchers and provide links with future employers, thus resulting in health and economic benefit for all.

Specific benefits to the main constituents may include the following:

#### ***Benefits to academia / NHS researchers***

- Access by academic researchers to industry lead compounds to conduct first-in-man studies with novel therapeutic agents, leading to the validation of new compounds and development and validation of new biomarkers.
- Sharing of expertise in methodology: joint development with industry of specialised protocols to address challenges (in inflammatory respiratory diseases and joint & related inflammatory diseases).
- Potential to undertake research to jointly (academically and commercially driven) investigate the utility of agents to treat inflammatory respiratory and joint & related inflammatory diseases in humans. This includes:
  - Better access to collaborative funding for translational research,
  - discovery of compound mechanisms of action and demonstration of efficacy in humans,
  - discovery of drug metabolism and effects on metabolic pathways,
  - study of molecules directed at novel targets and pathways,
  - patient/disease stratification (comparison across disease entities or patient subgroups),
  - identification of appropriate clinical indications,
  - defining potential responder and non-responder patient populations,

- The research is likely to result in new discoveries and so lead to publications in high-profile journals targeting translational medicine.
- Collaboration with industry will count towards the significant REF coefficient attributable to “impact”. This may prove to be a key determinant in renewal, or acquisition, of status that provides translational infrastructure support.
- Potential to create a fully translational operating environment for industry/academic/NHS collaboration as a major joint platform for engagement with other important stakeholders, including regulators and health care providers.
- Jointly develop and consider with industry new endpoints that meet the requirements by regulators.
- Opportunities to establish inter-institutional collaborations to achieve global competitiveness in research quality and capacity.

### ***Commitments from industry***

- To create shared appointments and greater access to industry labs for training (including GCP-related if requested) at all stages of a clinician scientist's career.
- To seek publication of all results – positive and negative.
- To explore actively the creation of unique joint public/private research biorepositories.
- To explore actively new models of shared risk and reward.
- To give access to tool compounds, e.g. pharmacologically active molecules that have been deprioritised from current research portfolios (on consideration of IP and legal liability issues).
- To establish a cross-sector stakeholder “cluster forum” to review progress, develop and implement solutions to new and emerging challenges; e.g. moving to a more open R&D paradigm (via better industry-industry working and public-private partnerships), regulatory acceptance of new research methodologies).

### ***Benefits to industry***

- Faster development of drugs/interventions for companies with novel lead compounds.
- Improvement in the protocols used to evaluate new classes of medicines by refining approaches for measuring pathway function, identifying surrogates of disease and selecting appropriate patient populations with the leading therapeutic area scientists in the UK.
- Understanding of Proof of Concept, and Proof of Mechanism through studies with academic partners.
- An effective communication interface between therapeutic capability cluster and industry partners/collaborators through an ongoing programme of dialogue between capability cluster, industry and research funders.

- Improved opportunities to access public funding schemes aimed at collaborations in translational science and exploratory development.

#### 1.4 Eligibility criteria to join a Capability Cluster

To become part of a pilot Therapeutic Capability Cluster the following groupings are invited to come forward with applications (called “centres” throughout this document):

- Centres must be one or more of the following:
  - any coherent grouping within a Higher Education Institution (School, University Department, Unit, Research Centre etc);
  - any coherent grouping within an NHS organisation (Department, Specialty Grouping etc);
  - any coherent partnership grouping between a Higher Education Institution and an NHS organisation (Biomedical Research Centre, Biomedical Research Units, Academic Health Sciences Centre etc).
- Centres must be able to address the core requirements set out in Section 1.5.

In all cases, explicit and formal support is required from the Higher Education Institution and/or NHS organisation within which the centre is located. Applications from groupings of medical schools will **not** be eligible.

#### 1.5 Core requirements of centres becoming part of a Capability Cluster

Alongside the above eligibility requirements, there are some core requirements that all Therapeutic Capability Clusters must provide.

##### Essential capabilities for eligible centres

- Participating academic/NHS centres must have recognised expertise and suitable complementary capabilities to address the needs outlined in Section 1.2. This may include, but is not limited to, one or more of the following:
  - Recognised experience in current exploratory development protocols, expertise in pathophysiology and disease mechanisms, expertise in modelling, etc;
  - Enabling technologies/infrastructure; e.g. Clinical Research Facilities (including clinical research beds) available for commercial collaborations, including invasive or non-invasive monitoring (in a clinical research environment where VAT has already been paid), core imaging infrastructure and clinical pharmacology, GMP manufacture capabilities, accredited laboratory support (e.g. for biomarker detection, genomics or cellular assays), IT capability, Biobanks, etc;
  - cohorts of well-characterised patients available for clinical development studies.
- Participating academic/NHS centres must comprise a critical mass of researchers. This would normally involve a lead investigator supported by a

number of senior co-investigators or collaborators. The lead investigator will make the application and act as a point of contact for the purpose of this call. Centres must show a willingness to collaborate with other centres to provide the full spectrum of capabilities required of each cluster.

- Participating academic/NHS centres must commit both facilities and individual clinical investigators to the activities agreed to by the Therapeutic Capability Cluster.
- Applicants will need to provide evidence that the applicant's host organisation supports the application and is willing to enter into discussions about agreeing a suite of common IP frameworks and template model contracts with industry partners.

### **Essential deliverables for the cluster**

- Collectively, the participating academic/NHS centres must work through a single point of contact that will act as the centralised "Collaboration, Coordination and Communication" function for interactions with industry. Funding for this is available (see Section 1.6).
- Collectively, the participating academic/NHS centres must be able to coordinate their activities and deliver fast, high-quality clinical studies. This will require the single point of contact having the full support of the centres to collaborate effectively with each other, and with industry.
- Collectively, the participating academic/NHS centres must be capable of bringing their key clinical scientists together with a potential commercial partner to discuss and agree protocols for Proof of Mechanism (PoM) and Proof of Concept (PoC) studies. This would allow both classical approaches to be delivered efficiently, and novel protocols to be developed.
- Collectively, the participating academic/NHS centres must have clear, transparent governance arrangements from the outset that outlines the ways of working between centres and industry. This means that participating centres and industry partners will be required to enter into discussions about a mutually agreeable suite of IP frameworks and to draw up template model contracts with industry partners. These discussions will focus on pre-competitive (as well as competitive) aspects. Workable operational functions are a cornerstone of the Capability Cluster initiative and will need to be developed in partnership.
- Collectively (but not necessarily individually) participating centres will be expected to add value by covering the whole spectrum of aspects required from a Therapeutic Capability Cluster by working together to meet the agreed criteria that will generate benefit, demonstrate the capability, flexibility, adaptability to enable collaboration with other organisations/centres, and so maximise the value for money from public and private investment in people and infrastructure.

Being part of a Therapeutic Capability Cluster should not prevent other types of interaction between NHS/academic centres and industry to continue occurring as they do at present, and the Therapeutic Capability Clusters should not attempt to deliver all aspects of industrial/academic interaction particularly in areas outside exploratory development.

## 1.6 Coordination post(s)

The Capability Clusters will be supported by a Programme Director. It is likely that the Programme Director will oversee both pilot clusters although the need for more than one post has not been ruled out at this stage. The Programme Director(s) will act as the single point of contact between industry and the cluster, and might also facilitate a business development function. They may not necessarily be directly associated with any of the participating centres nor any of the industry partners involved with the pilot. The pilot Programme Director(s) post will initially be funded through the Strategic Investment Fund which will be administered by TSB (until April 2011 in the first instance).

## 1.7 Opportunities for funding

Participating centres would be expected to be ideally positioned to successfully secure funding from existing funding schemes aimed at academic/NHS and industry collaboration.

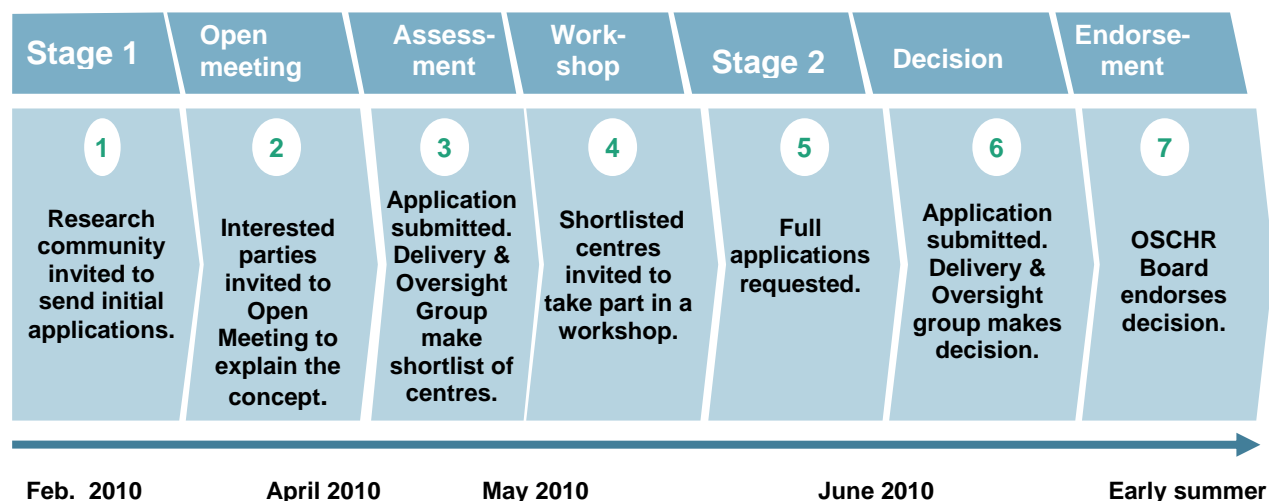
Centres taking part in a successful Capability Cluster could expect to attract significant industry participation in collaborative research and clinical trial activity, with in kind contributions in the form of expertise, access to facilities, technologies or materials, etc.

## 2 PROCESS AND DEADLINES

The application process will be run in two phases.

- **Phase 1** (this phase): initial applications invited to enable shortlisting.
- **Phase 2** (late spring/early summer): assessment of shortlisted applicants.

An outline of the process is set out in the diagram below.



## Phase 1 – initial application (this phase)

1. Applicants from the academic/NHS research community are invited to send in a completed short initial application form for inclusion into one or both of the two pilot clusters (inflammatory respiratory diseases and joint & related inflammatory diseases).
2. Interested parties are invited to attend an **Open Meeting** on **Wednesday, 3 March 2010** (9.30-14.00, Central Hall Westminster, Storey's Gate, London SW1H 9NH) when the concept of Therapeutic Capability Clusters will be explained in more detail. Since **allocation of spaces will be subject to availability**, interested organisations and research groups will need to register an interest in advance of their wish to attend the Open Meeting. **Please register your interest here: [www.eventsforce.net/tcc2010](http://www.eventsforce.net/tcc2010).**

The deadline for submitting the initial application form is **12 noon** on **Monday, 29 March 2010**. These must be sent in electronic form to [OSCHR@dh.gsi.gov.uk](mailto:OSCHR@dh.gsi.gov.uk). A signed paper copy must also be submitted to the same deadline (as per post mark). Please send these to: OSCHR Office, HMT Room G-41, 1 Horse Guards Road, London, SW1A 2HQ. Applications will be acknowledged and a unique reference number will be allocated which should be used in all subsequent communications. Short CVs of named individuals will be needed.

3. A Recommendations Panel<sup>2</sup>, comprising of senior industry and clinical/academic researchers, will consider the initial applications received and produce a shortlist (and longlist) for consideration by the joint industry/public sector Capability Cluster Delivery & Oversight Group. The Group will produce the final shortlist and applicants will be notified whether or not they have been shortlisted in May 2010.

Queries about Phase 1 of the process should be directed to the Secretariat at the OSCHR office: [OSCHR@dh.gsi.gov.uk](mailto:OSCHR@dh.gsi.gov.uk), Tel. 020 7270 5251.

## Phase 2 – full application (late spring/early summer)

4. Shortlisted applicants will be invited to attend an interactive workshop in **late spring 2010**.
5. Shortlisted applicants will then be invited to submit full applications. The specification for the final application form will develop as the work progresses and the requirements/strengths for each Capability Cluster are refined at the workshop.
6. It is anticipated that pilot Capability Cluster designations may be made in the **early summer**. A Programme Director, recruited through open competition according to a person specification approved by the Capability Cluster Delivery & Oversight Group, is likely to be in post at this stage.

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<sup>2</sup> For further information, see the supplementary document on governance which can be found as a stand alone document (to be posted on the web shortly).

Details of Phase 2 of the process will be finalised when the shortlist is approved by the Capability Cluster Delivery & Oversight Group.

Phases 1 and 2 of the application require formal sign-off by the lead applicant's host organisation. This is to ensure that the applicant's host organisation supports the application and is willing to enter into discussions about agreeing common operational functions across all participating centres.

## **ACCOMPANYING FORMS**

- Initial application form and guidance on how to fill in the application form for the **inflammatory respiratory diseases** pilot cluster (separate document).
- Initial application form and guidance on how to fill in the application form for the **joint & related inflammatory diseases** pilot cluster (separate document).

Applicants are welcome to apply for one or both clusters using the appropriate form(s).

**NOTE: Supplementary information** such as a Questions & Answers document and information about governance (Recommendations Panel and Delivery & Oversight Group) are available as stand alone documents from the participating organisations' websites (to be posted shortly).