

THERAPEUTIC CAPABILITY CLUSTERS IN

1. INFLAMMATORY RESPIRATORY DISEASES AND
2. JOINT & RELATED INFLAMMATORY DISEASES

– QUESTIONS & ANSWERS –

Version 1, 8 March 2010

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SECTION 1: PURPOSE AND CONTEXT

Q1. What is a Capability Cluster?

A Capability Cluster will consist of several NHS and academic research centres of excellence with complementary capabilities in early and exploratory development of new medicines and interventions in specific areas of unmet clinical need. Collectively, the centres in the cluster will provide a single communication interface to potential industry partners who wish to collaborate with the Capability Cluster. The aim is for this tripartite collaboration to result in a mutually beneficial exchange of ideas and people, and better alignment of public/private research strategies, thus bringing potential new medicines and interventions to NHS patients. This may result in patient benefit in areas of high therapeutic need, as well as bring economic benefit to the nation.

Capability Clusters will focus on the early and exploratory clinical development phase in the development of healthcare technologies (e.g. medicines, devices, diagnostics) via first-in-man, phase 1 to phase IIa clinical trials.

Q2. Where did the idea of Capability Clusters come from?

The concept of Capability Clusters emerged from the notion of a UK Life Sciences Super Cluster in the Government's July 2009 *Life Sciences Blueprint*, which contained a number of measures to support economic growth and strong healthcare delivery. The Capability Clusters concept was developed jointly by industry and the public sector funders under the oversight of a cross-sector Capability Cluster Delivery & Oversight Group co-chaired by Professor Sir John Bell and Dr Richard Barker.

What sets Capability Clusters apart from other biomedical geographical clusters is their focus on early and exploratory development in specific therapeutic areas (hence they are also referred to as Therapeutic Capability Clusters).

SECTION 2: FOCUS AND GOVERNANCE

Q3. What therapeutic areas will Capability Clusters focus on?

Capability Clusters will focus on areas of unmet clinical need where:

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

For the Capability Clusters to have meaningful impact, it is unlikely that Capability Clusters will be formed unless all the above conditions are met.

The first pilot Capability Clusters will focus on the area of Inflammation and Immunology (see Q4).

Q4. What are the therapeutic areas for the pilot?

The pilot Capability Cluster will be in the area of Inflammation and Immunology (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).
- 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, Inflammatory Bowel Disease, and Psoriasis may also be included.

These areas have been chosen because there is:

- 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;
- Significant compounds attrition, especially in the early clinical phases of drug development.

Furthermore in these areas there is existing academic/NHS research excellence and the Capability Clusters can draw on existing capability.

This is complementary to - and builds on - an existing ABPI and MRC initiative in I&I which focuses on industry/academic collaborative opportunities in translational medicine, including pre-clinical I&I research.

Q5. Who chooses what Capability Clusters focus on?

The Capability Cluster concept is overseen by a cross-sector Capability Cluster Delivery & Oversight Group which is co-chaired by Professor Sir John Bell (Regius Professor for Medicine at Oxford University, President of the Academic of Medical Sciences, and Chair of

the Office for Strategic Coordination of Health Research, OSCHR), and Dr Richard Barker (Director General of the Association of British Pharmaceutical Industry, ABPI).

The Group has representation from all relevant industry sectors (drugs, devices, biotechnology, diagnostics and imaging), and the public sector funders (government and research charities). A separate stand-alone document with information about the Oversight & Delivery Group will be posted shortly.

The Group considers areas where all the key criteria are fulfilled (see Q3). The Group also agreed the first 2 pilot clusters' focus (see Q4).

Q6. Why is there going to be a pilot?

The concept of Capability Clusters is a new way of facilitating NHS, academia and industry collaboration in early and exploratory development. When (and if) the pilots are successful, it is intended that additional Capability Clusters will be rolled out. This may happen towards the end of 2010 at the earliest, following an evaluation of the pilot clusters.

Future therapeutic areas will be chosen by the Capability Cluster Delivery & Oversight Group according to the criteria in Q3. It has yet to be decided which areas future clusters will be asked to focus on. Possible areas may include for example: oncology, diabetes, neuroscience, infection, cardiovascular and metabolic diseases.

Q7. Will Capability Clusters cover the whole drug development pathway?

No. Capability Clusters will focus on the early and exploratory development phase of drug development pathway, i.e. first-in-man studies, and phase I to phase IIa clinical trials.

If the pilot Capability Clusters are successful, there may be potential to expand beyond this stage but this is yet to be determined.

Q8. What is early and exploratory development? Why has early and exploratory been chosen?

What is early and exploratory development? As far as the investigation of new medicines is concerned, early and exploratory development may be defined as the phase of drug development where the clinical pharmacokinetics and pharmacodynamics of experimental medicines are defined and early assessments are made of their safety, tolerability and efficacy profiles in humans. Principal objectives therefore include:

- The identification of the relationship between dose and plasma (or other) concentrations, and association with “on-target” biological activity;
- The definition of the shape of the dose/concentration/response curve and the location on it of both desired and undesired effects (i.e. a preliminary assessment of benefit/risk) and therefore
- the identification of a range of dose concentrations that produce maximum benefit with fewest adverse effects;
- The demonstration that new medicines impact the mechanism predicted in preclinical studies (proof of mechanism, PoM);
- Provision of evidence of efficacy in small numbers of patients to demonstrate that the hypothesis on which their discovery was based is valid and that they are likely to have the levels of efficacy necessary to become a drug (proof of concept, PoC);

- The evaluation of the new medicine in a range of different therapeutic indications quickly to establish where it might be best trialled in clinical studies.

The ultimate aim of early and exploratory clinical development is to select appropriate experimental medicines and interventions to take forward into full clinical development and to reject those that will not make useful medicines/interventions as quickly as possible. This will help to bring promising new medicines and interventions to patients more quickly.

These studies have been described as ‘20 patients/2 weeks’ reinforcing the idea that quick readouts of detailed information may be available in well characterised patient populations to understand the range of biological effects from a new medicine and allowing early decisions to be made about the compounds likely clinical role.

Why has this area been chosen? While the optimisation of “intervention”-based exploratory clinical development is a core aim of the Capability Cluster initiative, it is not the only one. The biopharmaceutical industry currently has a major unsolved problem with compound attrition and importantly the high proportion of compounds that fail in exploratory clinical development - most usually due to lack of efficacy. The resultant impact on industrial productivity is marked and is increasingly driving the industry to seek scientific solutions in partnership 1) with other companies and 2) with the best sources of science in the public sector.

Therefore, in addition to having a cluster infrastructure that is able to pursue early trials efficiently, it will be equally crucial for the Capability Cluster to be able to partner with industry on projects that aim to address the fundamental “grand challenges” in exploratory clinical development. These would logically be project partnerships that would be prosecuted on a non-competitive basis, e.g. to provide clinical data to support the validation of interventions, disease targets, biomarkers and endpoints or the development of new investigational methodologies. While these clinical studies would clearly still require patients and therefore all the infrastructural and operational capabilities described elsewhere, they would not be interventional studies in the manner of conventional, investigational compound-based exploratory development.

Q9. What is the main priority for the Capability Clusters: early phase clinical trial operational capacity or the intellectual and science contribution to the translational development of a novel medicine/intervention?

Key to success is the ability to bring exciting and novel clinical science to bear on exploratory development problems faced by industry. This means that scientific excellence and novelty will be rated extremely highly in the competition. Within any Capability Cluster, experience, competence and efficiency in running trials will be important to the ultimate success of the programme; the unique feature that would allow industry to access a Capability Cluster will be scientific ingenuity, in the context of clinical trial capabilities for example.

Q10. Will only potential drugs be tested? How about other interventions?

Capability Clusters will be asked to participate in early and exploratory clinical development of drugs and other interventions. This may involve the testing in human volunteers of promising chemical or biological compounds (potential new medicines), as well as new imaging technologies, novel diagnostics and/or devices.

The exact capabilities of the 2 pilot clusters will emerge during the process of selecting and forming the clusters. They will, to some degree, depend on the individual and collective capabilities of the participating centres. These centres will, however, have to demonstrate excellence and capabilities in the two pilot therapeutic areas (respiratory inflammatory

disease and joint & related inflammatory diseases) according to criteria specified in the Call for Initial Applications document, [Sections 1.2](#) and [1.5](#).

Q11. What is the advantage of collaborative working in this way for the NHS, academia and industry?

Successful Capability Clusters will provide benefits for all three constituents, and would also result in patient and economic benefits in the UK. For details, please see [Section 1.3](#) in the Call for Initial Applications document.

Q12. How will the Capability Clusters compare with other UK collaborations? Do these not have a similar role?

Capability Clusters are focusing specifically on early and exploratory development and have a UK-wide remit, linking up UK centres of excellence and asking them to work with industry in a new and innovative operational framework.

As such the Capability Clusters would be complementary to, and add value to, existing collaborations such as the English BRCs and BRUs, the AHSCs, and the Scottish Academic Health Sciences Collaboration (SAHSC).

Q13. What is the role of the Coordination Post(s) (Programme Director)?

The pilot 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 (i.e. provide a one-stop function as the interface between the Capability Cluster and potential industry partners), and might also facilitate a business development function.

The role is currently under development. The Programme Director will be recruited in the next few months according to a job description that is agreed by the cross-sector Capability Cluster Delivery & Oversight Group. It is likely that the Programme Director, or an interim Director, will be appointed before or at the time of the pilot Capability Cluster formation.

The Programme Director would be expected to work closely from the outset with all centres in the Clusters, and take a lead in the development of appropriate governance arrangements (Q14-16) and supporting operational functions (such as IP frameworks and contracts, see Section 4).

Q14. Who are Capability Clusters accountable to?

The individual centres in each Capability Cluster will work under a Programme Director (see Q13) who will report to the Capability Cluster Delivery & Oversight Group and to the OSCHR Board. The lead applicants/investigators for each centre are accountable to the Programme Director for the work that takes place in their centre for the Capability Cluster.

Governance and accountability arrangements of each centre within its host organisation are not affected and will apply as normal (subject to IP and contract frameworks, see Section 5).

Q15. Who decides the work plan/agenda of a Capability Cluster?

Each Capability Cluster will need to agree an internal governance structure and mechanism for handling incoming work, for instance in the form of a Scientific Steering Committee. It will be the responsibility of the Programme Director to set this up. Key will be the formation of a robust partnership between the Capability Cluster centre leads and their relevant counterparts in industry partners.

Q16. When I join a capability cluster, what proportion of my work will be to do with the Cluster? How will this be prioritised?

This will be determined through the Capability Clusters' governance structures referred to in Q15, ensuring that there is ongoing communication between all those involved (i.e. the centres' lead investigators, their host organisation, the Programme Director and industry partners), and it will depend on the level of successful collaborations with industry partners.

It may be that not all centres within a cluster are involved in a particular piece of joint research carried out by the Capability Cluster; it is also possible that several research activities may be run by the cluster in parallel.

The Programme Director may wish to seek the advice from the Delivery & Oversight Group on research priorities for each Cluster as appropriate.

SECTION 3: QUESTIONS ON THE CALL FOR INITIAL APPLICATIONS

Q17. Who can apply to become part of the pilot Capability Clusters?

The participating organisations (CSO, HSCNI, NIHR, NISCHR, MRC, TSB) launched the Call for Initial Applications on 8 February 2010 with a closing date of 12, noon, 29 March 2010. Any submissions received after this time/date will be returned without consideration.

NHS/academic centres wishing to make an application must be able to address the core requirements set out in Section 1.5 of the Call for Initial Applications document and 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).

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 are not eligible.

The lead applicant is usually the main applicant/investigator of the grouping/partnership (called "centre"). S/he will be accountable for the application and would act as the single accountable person for the centre if it was to participate in the cluster.

Q18. The application form must be signed by the applicant's host organisation. Why?

Each applicant must obtain the formal support from his/her Higher Education Institution and/or NHS organisation within which the centre is located (host organisation). This is usually at vice-chancellor and/or chief executive level, or the officer with authority to sign off applications for external research funding.

The host organisation must confirm that it is willing to enter into discussions with other centres in the Capability Cluster and with industry about agreeing workable operational functions applicable for all centres in the Cluster. This will involve a mutually agreeable suite of Intellectual Property (IP) frameworks and template model contracts between the Capability Cluster and its industry partners. Setting up suitable operational functions for the Capability Cluster is a key aspect of the concept (see also Section 4).

Q19. Can several groups/centres from the same host organisation apply?

Yes but only if this a coherent grouping as defined in Q17.

Because applicants need their host organisation's support, the host organisation may wish to coordinate the submission of more than one application from the same organisation (if appropriate). There is no guarantee however that all components of a coordinated submission would be successful at the short-listing stage as the components may be reviewed individually.

It is recommended that applicants cross-reference their application against those made by others (e.g. when considering a collaboration for the purposes of the cluster).

Q20. Can several groups/centres from different host organisations apply jointly?

Only if the criteria in Q17 are fulfilled, otherwise separate submissions have to be made.

Applicants may wish to cross-reference their application against others, for instance those with whom they may wish to collaborate for the purposes of the cluster. There is no guarantee however that such partnerships (pre-aggregation) would be successful at the short-listing stage as all applications will be reviewed individually as well as the context of all other applications made.

Q21. Why will applications from existing groupings of medical schools not be eligible?

Constituent elements of Capability Clusters will be chosen by excellence, regardless of their geographical location and/or pre-existing grouping/collaboration. Existing groupings of medical schools can therefore not apply as a whole but their individual units can apply individually (if they fulfil the eligibility criteria) and applicants may cross-reference applications to each other (see Q20).

A second reason for limiting the eligibility for joint applications is the requirement for each Capability Cluster centre to provide a single accountable person for governance purposes.

Q22. What must a centre have so that it can be considered for inclusion into a Capability Cluster?

The core requirement of centres becoming part of a Capability Cluster are listed in [Section 1.5](#) of the Call for Initial Applications document.

No single centre is likely to provide all the necessary aspects (e.g. access to patient cohorts, enabling technologies, expertise in disease biology) but collectively the final collection of centres will need to be capable of providing the full spectrum.

Participating centres would be required to commit both facilities and individual (clinical) investigators to the programme.

Q23. How many centres will be considered for a Capability Cluster?

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.

Q24. Can a centre apply for both pilot Capability Clusters?

Yes. Separate submissions may be made (by using the two application forms). Applications will be judged by excellence and what the centre would bring to one or both clusters. Applications for each of the Capability Clusters will be reviewed by separate Recommendation Panels.

Q25. Does a centre have to be a minimum size? Is there a maximum size?

Participating centres must comprise of a critical mass of researchers. There is no “minimum number” of researchers/investigators per centre, but the centre needs to satisfy the core requirements out in [Section 1.5](#) of the Call for Applications document. The expectation is that this would normally involve a lead investigator supported by a number of senior co-investigators or collaborators (up to five co-investigators can be named on the application form). The size of the centre is also determined by the eligibility criteria in Q17.

Q26. Does taking part in a Capability Cluster affect or limit my ability to collaborate with other centres and/or industry?

No. If a centre is included within a Capability Cluster there will still be flexibility for it to have other types of interactions. Being part of a 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 Capability Clusters should not attempt to deliver all aspects of industrial/academic interaction particularly in areas outside early and exploratory development.

Q27. How will applications be short-listed after 29 March?

A Recommendations Panel composed of industry and (international) academic experts in the 2 pilot therapeutic areas will assess the applications and produce a short-list (and long-list) for consideration and approval by the Delivery & Oversight Group (see stand alone document on governance). Applicants can expect to hear the outcome in May 2010.

While the overall objective is to ensure that - collectively - the short-listed centres would be able provide the various elements listed in Sections 1.2 and 1.5 in the Call for Initial Applications document (and potentially more), the precise “look” of the pilot Capability Clusters has not been determined in advance. It is likely that the two pilot clusters will to some degree “form themselves”, meaning that the cluster composition will emerge from the coalescing of complementary centres, which together bring the requisite constituents of a viable cluster.

The criteria for the short-listing will be based on the information requested in the Initial Application Form and so will be based on a combination of track record (excellence of the research team), potential and vision (what the team brings to a cluster) and ability to work collaboratively (willingness, ability and track record of collaborations with other centres).

The Recommendations Panel and Delivery & Oversight Group will look for evidence that there is an understanding of, and a willingness to participate constructively, in the proposed “new way of working” for the Capability Clusters (i.e. *within* the public sector, *within* the private sector and *between* the two). This will include that all centres (and their industry partners) are willing to work in an innovative and flexible environment.

Q28. What happens after the short-list has been confirmed by the Capability Cluster Delivery & Oversight Group?

Applicants will hear in May whether they have been successful in Phase 1 of the process. The short-listed centres will be invited to take part in Phase 2 of the process.

It is likely that Phase 2 will consist of an interactive workshop and the submission of full applications. Final applications will be reviewed by the Recommendations Panel and then considered by the Capability Cluster Delivery & Oversight Group. The details of Phase 2 are yet to be determined and will be announced later.

Q29. What happens if my application is not short-listed? Is the decision by the Delivery & Oversight Group final?

Applicants cannot challenge the decision by the Delivery & Oversight Group. If an applicant feels that the correct process was not followed, they have the right to appeal the decision on procedural grounds by writing to oschr@dh.gsi.gov.uk and clearly laying out the reasons for the appeal. Appeals have to be made within 5 working days of receipt of the rejection letter.

Q30. If my centre is not short-listed or awarded Capability Cluster status will it still be able to take part in the Capability Cluster?

Potentially yes. The Capability Cluster will need to be flexible and dynamic in order to respond to different projects and collaborations. It is likely that the clusters will consist of a “core” of several NHS/academic centres of excellence (see Q23) collaborating with industry partners on an ongoing basis; however, supplementary centres of excellence that have specific expertise may be invited to join the core cluster for specific projects.

Further, periodic review of cluster performance will be conducted which, dependent on its evolving research agenda, may identify technical or capacity gaps that will need filling by the addition of new centres to the Capability Cluster core centres.

Q31. Could paediatric investigations be part of a pilot Capability Clusters?

For the pilot clusters in the two areas (see Q4), early and exploratory development of new drugs and interventions is usually done in adults. Therefore it would seem unlikely (but not impossible) that centres specialising in paediatric interventions would form part of the “core” cluster (see Q30). Given the requirement to have a specific paediatric development plan for every new drug, and the potential importance of novel anti-inflammatory medicines to children, membership should however be encouraged on a case-by-case basis for specific projects.

Q32. How will Capability Cluster designation be awarded?

The Capability Cluster Delivery & Oversight Group will agree the pilot Capability Cluster compositions (see also Q27-28), following Phase 2 of the application process. The details of Phase 2 are yet to be determined.

SECTION 4: QUESTIONS ABOUT FUNDING

Q33. How will Capability Clusters be funded?

The Capability Cluster initiative is about harnessing and getting best value from existing public sector investment in the UK. For example, the clinical research infrastructure to support the Capability Clusters has been enabled by the £160 million per annum of NIHR support, which is channelled through the existing BRCs, BRUs, and CRFs. Specific infrastructure support has also been provided locally in Northern Ireland, Scotland and Wales.

Participating centres are expected to be ideally positioned to successfully secure funding from existing funding schemes aimed at academic/NHS and industry collaboration. Through industry participation in collaborative research and clinical trial activity, centres taking part in a successful Capability Cluster can expect to attract industry investment, expertise, access to facilities, technologies and materials, etc.

Funding for the strategic coordination and evaluation of the pilot Capability Clusters will be made available through the Strategic Investment fund (administered by the TSB) (to April 2011 in the first instance).

Activities are underway by the MRC and the TSB who are developing coordinated approaches to stratified medicine, and ABPI and the MRC are developing their I&I initiative. All of these activities and investment will complement the Capability Cluster pilot activities as well as increase capabilities in other relevant therapeutic areas, which will support the initiative in the longer term.

Q34. What are the existing MRC funding schemes aimed at industry collaboration?

Participating centres would be well placed to compete, in open competition, for MRC funding opportunities such as:

- MRC / ABPI Immunology and Inflammation initiative, which is of strong relevance to the foci of the clusters, having been developed in a co-ordinated manner.
- Research Leader Fellowship (senior researcher exchanges)

- Research grants utilising MRC Industry Collaboration Awards and CASE studentships

However, applicants should be aware that being part of a Capability Cluster does not give a guarantee for funding; funding decisions will be made based on the quality of the application.

Q35. Will there be future public sector funding for Capability Clusters?

The Capability Cluster initiative is about harnessing and getting best value from existing public sector investment. There are no plans at present by the public sector funders to channel funding to the Capability Cluster initiative.

The public sector funders are strongly committed to supporting exploratory and developmental research, recognising the potential of the Capability Clusters to be a high quality environment in which to deliver this strategic priority. As such, Capability Clusters should be well placed to compete effectively for funding.

Activities are underway by the MRC and the TSB to develop coordinated approaches to stratified medicine, and ABPI and the MRC are developing their I&I initiative. All of these activities and investment will complement the Capability Cluster pilot activities as well as increase capabilities in other relevant therapeutic areas, which will support the initiative in the longer term.

Q36. How will industry participate in the Capability Cluster initiative? Will there be industry funding for Capability Clusters?

Through industry participation in collaborative research, 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.

Industry contract studies, particularly in the competitive arena, conducted by the Capability Clusters would do so on a full cost recovery basis.

Q37. Will taking part in a Capability Cluster help us renew funding for our BRC or BRU?

While the Capability Clusters may build on the NIHR investment in BRCs and BRUs, the two initiatives are separate.

Q38. If I join a Capability Cluster will this affect my existing BRC and BRU funding or status?

No.

Q39. Will a centre in a Capability Cluster get preferential treatment in future funding rounds for capital equipment and infrastructure?

No. Competition for funding is strong with awards going to the best applications based on scientific excellence, strategic importance and timeliness. Participation in a successful Capability Cluster is likely to strengthen any centre's ability to put forward strong bids for funding.

Q40. How long will the Capability Cluster initiative last for?

The vision for the Capability Cluster is to establish a vibrant and permanent new way of working between the public and private sectors in exploratory clinical development. As such, if the pilot is deemed successful (consequent to a performance review), it will need to be sustained by attracting funding from a range of funding sources, possibly via a public-private partnership model. When (and if) the pilots are successful, it is intended that additional Capability Clusters will be rolled out. Each cluster would be envisaged to be an evolving and dynamic entity whose research agenda and constituent parts become largely self-determining through its own internal governance structures.

SECTION 5: IP FRAMEWORKS AND MODEL CONTRACTS FOR THE CAPABILITY CLUSTERS

Q41. Why do we need IP frameworks and model agreements for the Capability Clusters?

Setting up suitable operational functions, such as a mutually agreeable suite of IP frameworks and model contracts for the Capability Cluster is a key aspect of the concept. This is to ensure - for example - the rapid sign-off of projects, quick project start-up, and rapid recruitment of patients, potentially using several sites to speed up patient recruitment and study completion. Ideally, these operational functions should be applicable to all Clusters (pilot clusters and any future clusters).

Setting up operational functions for each Capability Cluster will help facilitate the important "Coordination, Collaboration and Communication" function that each Capability Cluster will need to provide. This will be done via the Programme Director and their communication with the participating centres and industry partners (a one-stop shop function).

Q42. What will the suite of IP frameworks entail and who develops these?

A suite of mutually agreeable IP frameworks will be developed in partnership between the participating centres and industry, and these will apply for all centres in the Capability Clusters. These will cover competitive and non-competitive aspects. The agreements will be based on the model research collaboration agreements devised by the Lambert Working Group:

<http://www.innovation.gov.uk/lambertagreements/index.asp?lvl1=2&lvl2=0&lvl3=0&lvl4=0>

A Capability Cluster Delivery & Oversight Group working group has been established to take this forward in the first instance. The Group will work closely with the Programme Director and the Capability Cluster centres and industry when developing model IP frameworks that are tailored towards the specific focus of the Capability Clusters on early and exploratory development.

Q43. What does this mean: competitive and non-competitive IP?

In a competitive setting (which in this instance will usually relate to the exploratory development of an investigational medicine), the IP arising from the use of that agent belongs to the sponsoring company which owns the underlying patents.

In a non-competitive setting (e.g. a public/private partnership to develop and validate a new clinical methodology), there is no compound-related IP. IP may however, arise as a consequence of the partnership. In this instance, IP will need to be shared equitably and as appropriate between all partners in the project. For example, industrial partners may not want to own the IP, but could request access to use it. This emphasises the critical importance of establishing cluster-specific IP frameworks very early once the cluster constructs are known.

Q44. What will model contracts entail and who develops them?

Model agreements will be developed to ensure - for example - the rapid sign-off of projects, and rapid recruitment of patients, potentially using several sites to speed up patient recruitment and study completion. These will be based on existing Model Clinical Trial Agreements.

A Capability Cluster Delivery & Oversight Group working group has been established to take this forward. The Group will work closely with the Programme Director and the Capability Cluster centres and industry when developing model agreements that are tailored towards the specific focus of the Capability Clusters on early and exploratory development.

This Group is also liaising with the NIHR/MRC Working Party on model collaborative clinical research agreements.

Q45. We have an IP policy / model contracts that our centre works to. Will we still be able to apply this policy/contract?

The Capability Clusters will have “tailor-made” IP frameworks which will have been developed and agreed by all parties (NHS/academic centres and industry). A condition of joining the Capability Cluster will be that the centres (and its industry partners) agree to work to the agreed IP frameworks for the Capability Cluster in which they take part – but only for the purposes of research under the aegis of the Cluster (this may or may not be identical to the one already used in each centre/host institution).

Given the multi-constituent nature of a Capability Cluster, for it to realise successfully the vision, it is hoped that the host institutions will, for work to be done under the aegis of a Capability Cluster, accept the Cluster’s own framework agreements/model contracts.

Q46. When will the IP frameworks and contracts be ready?

Preparatory work on developing appropriate IP frameworks and model contracts is on-going. The Programme Director and participating centres will participate in this work as soon as the pilot clusters are set up in summer 2010 with a view to having jointly agreed frameworks in place from late summer.

SECTION 6: WHAT WILL SUCCESS LOOK LIKE AND HOW WILL THIS BE MEASURED?

Q47. Will the pilot clusters be reviewed?

There is likely to be a real time evaluation of the pilot Capability Cluster until Autumn 2010, looking at (i) the pilot cluster set-up process and (ii) the evaluation of short-term metrics of success. The real time evaluation aims to assess the operational effectiveness and appropriateness of application of the first six months of the Capability Cluster pilot against the criteria for inclusion and initial benefits as outlined in the Call for Initial Applications document. This will help inform the formation of further Capability Clusters and to decide if any adjustments are required to the pilot clusters.

The evaluation will take place in partnership with all stakeholders (i.e. the cluster centres, the Programme Director and with the advice of the Delivery & Oversight Group).

Q48. How will we know if a Capability Cluster is successful? What are the criteria for Capability Cluster success?

The detail of the metrics of success have yet to be defined and it will be the responsibility of the Programme Director, in partnership with stakeholders to develop this. However, it is envisaged that metrics will need to be a mixture of short, medium and long-term measures.

Shorter-term metrics could be based on examples such as: (i) the number of new partnerships formed over a given time, (ii) degree of industry participation, (iii) number of new projects in a cluster, (iv) evidence of early and positive signs of change on the operational issues of time, cost and quality, and (v) qualitative “360 degree” feedback from stakeholders on the specific cluster successes.

Longer-term metrics would be based on evidence that the vision for the cluster and objective outcomes from its research agenda are being achieved (e.g. as specified in [Section 1.2](#) in Call for Initial Applications document).

Q49. What are the conditions/caveats to staying in a cluster?

As mentioned above, centres will need to agree to common operational functions, and they need to demonstrate the ability to collaborate with the other participant centres and with industry partners. Capability Clusters will need to be flexible and able to adjust to a variety of projects.

Participating academic/NHS centres are expected to commit both facilities and individual clinical investigators to the activities agreed to by the Capability Cluster. For instance, this would involve the expectation of recruitment of patients against timelines, advice on the development of protocols etc. Participating centres can expect to be judged against these criteria.

Q50. Can centres leave the Capability Cluster?

Yes. Leaving the Capability Cluster will have no effect on the centre’s existing funding (so long as this was not contingent on the Capability Cluster work).