Guidelines for the Completion of the Paediatric ECMC Network Review 2016

The Experimental Cancer Medicine Centre Initiative is jointly funded by Cancer Research UK, the National Institute for Health Research in England and the Health Departments for Scotland, Wales and Northern Ireland.

1 Contents

2 SUMMARY OF KEY DATES

11 Jan 2016	Announcement of call
18 Mar 2016	Expression of Interest (EoI) Deadline – *Only applicable to Adult ECMCs*
16 – 20 Apr 2016	Meeting of EoI panel – *Only applicable to Adult ECMCs*
30 Jun 2016	Draft paperwork submission deadline (optional)
15 Aug 2016	Full application deadline
17 – 20 Oct 2016	Meeting of review panel
Dec 2016	Decisions on full applications announced
1 Apr 2017	Commencement of funding

3 KEY CONTACTS

For enquiries on the application:

The Centres and ECMCs Teams CentresandECMCs@cancer.org.uk

4 INTRODUCTION

4.1 Background Information and Aim of the Review

Cancer Research UK (CRUK) currently supports a network of 15 Centres and co-funds (in collaboration with the National Institute for Health Research in England and the Departments of Health for Scotland, Wales and Northern Ireland) a network of 18 Experimental Cancer Medicine Centres (ECMCs) across the UK. These networks focus on the delivery of the highest quality translational research and accelerating the introduction of novel cancer treatments by providing the requisite infrastructure for early phase trials. CRUK and its funding partners are currently running a joint call for applications for CRUK Centre and ECMC funding, which will run from April 2017 to March 2022. Performing the review of CRUK Centres and ECMCs in parallel will enable applicants to formulate and submit a unified vision for cancer research at specific locations. The review will:

- Appraise the performance of existing Centres and ECMCs (Adult and Paediatric);
- Evaluate the future proposals for Centres and ECMCs;
- Assess the performance of the two networks, leading to an understanding of how they are delivering against CRUK and ECMC strategies;
- Determine Centre and ECMC financial support for the next funding period (April 2017 to March 2022);
- Enable applications for new Centres and new ECMCs;
- Consider applications for new CRUK Major Centres.

The UK Health Department component of ECMC funding is provided by the four Nations for their respective centres:

- National Institute for Health Research (NIHR), funding for ECMCs in England;
- Chief Scientist Office (CSO), funding for ECMCs in Scotland;
- Health and Social Care (HSC) Research & Development Division, Public Health Agency, funding for ECMCs in Northern Ireland;
- Health and Care Research Wales (HCRW), funding for ECMCs in Wales.

Unless otherwise stated, the term 'UK Health Departments' will be used to describe the appropriate administration (National Institute for Health Research in England and the Departments of Health for Scotland, Wales and Northern Ireland) for your application. The review process is managed by CRUK on behalf of all the ECMC funders. The purpose of this document is to provide guidance for the completion of the full application for the Paediatric ECMC Network.

4.2 The Paediatric Experimental Cancer Medicine Centre (ECMC) Network

The aim of the ECMC Initiative is to expedite the introduction of novel cancer medicines and other interventions to maximise patient benefit, through the support of local infrastructure. ECMCs are a partnership between the local university and NHS Trust/ Board, as appropriate and are expected to collaborate with the rest of the ECMC Network as means to maximise the local resources and impact.

The ECMC award does not aim to support all the experimental cancer medicine activity in the site bur rather, to enhance the existing bench-to-bedside pathway by supporting key infrastructure tailored to the needs of the site. Over the next five years, Paediatric ECMCs are expected to:

- Drive the design and delivery of translational studies and innovative early phase oncology trials to the highest international quality, on time and target and to consistently high standards;
- Enhance the delivery of early phase trials by increasing capacity, safety and speed, to maximise patient access to novel treatments and improve patient care;
- Maximise therapeutic opportunities for paediatric patients through the development and validation of novel molecular and/or imaging biomarker assays to regulatory standards;
- Support the geographical spread of trials across UK to facilitate recruitment and ensure effective collaboration with the Adult ECMC Network;
- Increase the attractiveness of the UK as the industry's destination of choice to lead on international paediatric early phase clinical trials;
- Promote patient and public involvement in experimental cancer medicine;
- Ensure that the UK remains at the forefront of international efforts to develop and test new treatments for cancer, built upon outstanding science and optimal trial design.

The purpose of the ECMC infrastructure funding for early phase trials for children with cancer is to meet infrastructure costs (including NHS Support Costs) associated with paediatric cancer research in early phase clinical trials as well as translational and/or biomarker studies associated with clinical trials.

5 ELIGIBILITY

Applications are invited for infrastructure funding to support Centres of Experimental Cancer Medicine from across the UK. Bids may be from individual or multiple locations and must be submitted as a joint application from a NHS Trust/Health Board organisation and a University partner.

Experimental Cancer Medicine Centres (ECMCs) should demonstrate the ability to develop innovative treatments, clinical biomarkers and/or devices through in-house translational research, as well as capacity to deliver early phase trials[1] to the highest quality with demonstrable impact in the field. In particular, infrastructure supported by an ECMC award should place the **emphasis** of their activity in the following fields:

- Translational activity of clinical relevance and aimed at informing treatment decisions;
- Biomarker activity directly relevant to prospective early phase clinical trials such as pharmacological (PK) and pharmacodynamic (PD) molecular biomarkers or prognostic/predictive/stratification where the endpoint clearly informs targeted therapies in pre-clinical or clinical studies;
- Early phase clinical trials (defined as from Phase 0 up to Phase IIa) with an interventional purpose and/or biomarker-associated activity;
- Funding may only be used to support late phase trials where there is a significant translational component;
- Biobanking is within remit of the ECMC award but should not be the core component of any individual site and when appropriate, the use of the NIHR National Biosample Centre is encouraged[2]

Areas of research **not** appropriate for this call include:

- Scientific research that has no clear and immediate translational pathway into clinical use
- Requests for sponsorship and/or funding of particular clinical trials or funding of research proposals;
- Biomarker discovery work, where this represents the core component of the research programme;
- Non-interventional studies and late Phase trials with no translational component or biomarker associated activity;
- Non-cancer research studies;
- Overheads on research awards;
- Capital equipment costing more than £5,000;
- Major capital investment, capital development, new buildings or refurbishments.

All Paediatric ECMCs should also be aware that compliance with the ECMC's branding requirements will form a strict precondition of acceptance into the Paediatric ECMC Network. Participating Paediatric ECMCs will be expected to fulfil all branding and research engagement requirements at the earliest opportunity after a successful funding decision (over a timeframe agreed in advance with the ECMC Secretariat).

Please ensure that you have read and agreed the ECMC Terms and Conditions which can be found here.

[1] We define early phase clinical development as Phase0, I and IIa, accepting that academic investigators and industry are increasingly adopting flexible early phase trial designs with the incorporating of Ph II endpoints into Ph I studies when signals of activity are detected.

[2] English Paediatric ECMCs will only be eligible to use ECMC funding for long-term (greater than 3 months) biosample storage at the NIHR National Biosample Centre. ECMC funding can be used for short-term biosample storage, and/or handling, processing, dispatch and storage where there is a strong case which precludes the use of the NIHR National BioSample Centre, for example, on the basis of cost-effectiveness.

6 REVIEW PROCESS

6.1 Review of the ECMC Paediatric Application

The review process is the key element of an open and competitive call for the next round of CRUK Centre and ECMC funding, which will run between April 2017 and March 2022. Paediatric Centres wishing to apply for ECMC funding are asked to submit a detailed single application (following the guidelines in Section 7 of this document) by the 15th of August 2016. Members of an expert review panel will assess this application before the review panel meeting which will take place between the 17th and the 20th of October 2016. At the meeting, the Paediatric Network lead applicant will be invited to CRUK's Angel Building in London to present a summary of their application before engaging in a discussion with the review panel. Further details about the interview process will be supplied to all applicants in due course.

After the conclusion of all presentations and interviews the review panel will recommend funding levels for the next quinquennium considered by all funding partners before final funding levels are decided. Decisions to fund the Paediatric Network will be independently from the results of the CRUK Centres and Adult ECMCs reviews.

The process is designed to be transparent and fair. The proceedings will be covered by confidentiality agreements to ensure that any disclosures of information and/or data are protected. Members of the review panel will be required to declare their interests and any conflicts of interest will be rigorously addressed both before the review and at any other stage of the process should they arise.

6.2. Format of Application

This form is for a joint application by Paediatric Oncology Centres for ECMC infrastructure funding. Centres are expected to work together in the development of the proposal and the completion of the paperwork.

This application should be completed by the 'Lead Applicant' (i.e. Principal Investigator), who is the person responsible for 1) submitting the application paperwork; 2) acting as the primary contact for the proposal; and if the application is successful 3) will be the award holder; 4) report on progress annually. He/she will also be the designated Lead for their centre.

A Co-applicant is a researcher who will act as ECMC Lead for their Paediatric centre's involvement in the proposed Network. They should provide significant intellectual input into the Network and will be responsible for the day to day running of the work at their ECMC.

The application should be submitted through the eGMS system. An overview of eGMS and guidance on completing successful applications can be found here. In addition to the compulsory information in the Executive Summary to be submitted directly into eGMS, applicants are asked to upload the main body of their submission (following the guidelines provided in Section 7 of this document, as well as the separate template document) as a PDF. Text should be single line spaced and use the black Calibri font, no smaller than font size 11. Submitted applications will generate an automatic request for approval to host institutions. University research services offices and NHS Trust/Board representatives must approve the final application

through eGMS prior to the submission deadline for successful completion of the application process. Applicants will receive an automated email upon submission of a completed application.

7 APPLICATION SECTION DETAILS

The following section provides guidance for each section of the full application. Please ensure the information provided in the application is accurate and complete before submitting it to CRUK.

The application consists of two main elements—the compulsory information to be included directly in eGMS and the main body of the application which should be prepared as a separate document and uploaded to eGMS. All sections of this document should be combined in a single PDF, and must be submitted to CRUK via eGMS by the **15th of August 2016**.

eGMS Process

To be completed by all applicants directly in eGMS.

This section of the application should be completed on CRUK's electronic Grant Management System. Access to the eGMS homepage can be found here. If you currently hold a grant from Cancer Research UK you will already have an account on eGMS and may access your account as instructed in Figure 1.

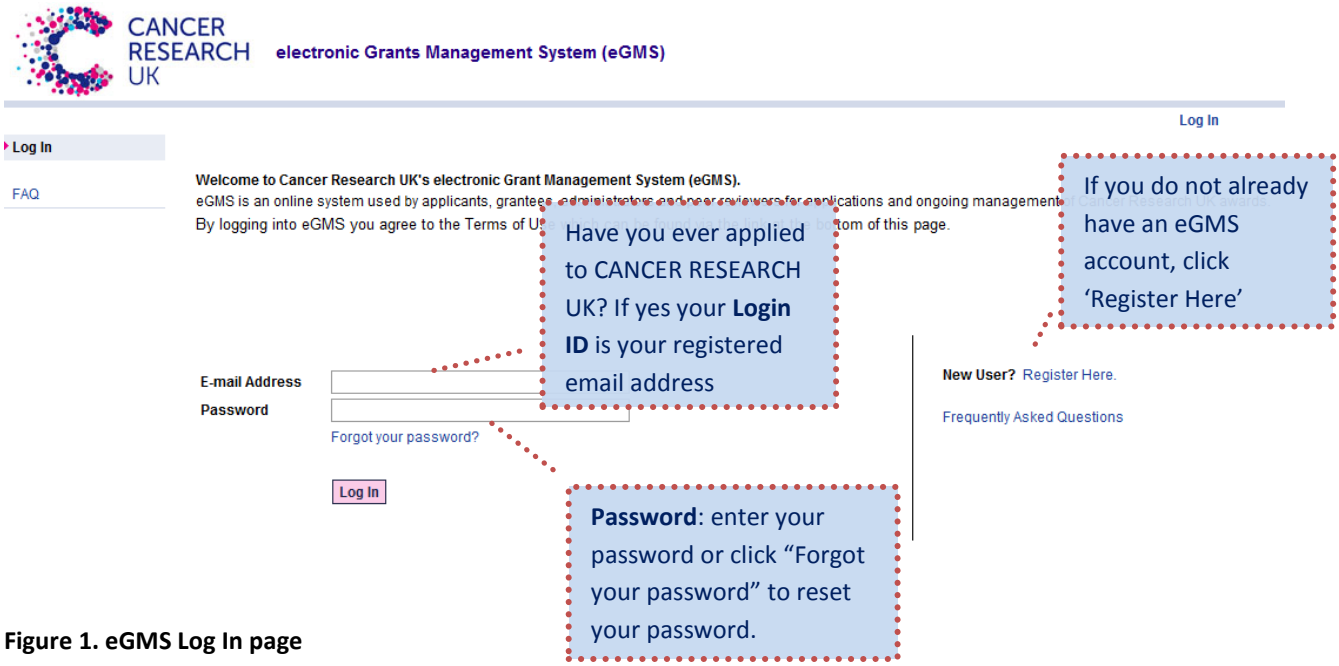

Figure 1. eGMS Log In page

eGMS is a task based system. The application procedure is completed through a series of individual or groups of tasks that are undertaken at each stage of the process. Tasks will have a series of dates that make them active and closed in the system automatically.

Figure 2 shows the symbols used in eGMS to designate functions, and to demonstrate whether a task is complete, incomplete or requires further attention.

			The Add Icon. Click this icon as instructed in the instructional text on the top of the page. It is used to add information to your application such as multiple positions held, supporting roles, costs etc.
			The Edit Pen Icon. Click to edit information already entered. For example to edit costs.
	**Complete**	Ready for submission to Cancer Research UK	Use the Review and Submit page of the *Complete Full Application* task to check the completeness of your application. These are the icons used to denote completeness of each application section on the Review and Submit page. Note that you will not be able to submit your application until all sections show as either 'Complete' or requiring 'Attention'.
	**Incomplete**	Not yet been completed and application cannot be submitted	
	**Attention**	Further information requested prior to submission	

Figure 2. Symbols used in eGMS to designate functions or the status of tasks.

Please inform the administrative authority of your host institution of your intention to submit a funding request. **Applications are only fully submitted to Cancer Research UK once approved by the administrative authority within eGMS.**

The required sections of the online eGMS form are:

i) Proposal outline

A brief summary of the key facts related to the submission:

Administrative Authority and Host Institution
Project title – Paediatric ECMC Network
Proposed start date – 1st of April 2017
Duration of proposed project – 60 months

The full application will need to provide confirmation from the Chief Executive of all the participating partner NHS Trusts that the NHS Trust agrees to support and participate in the programme of work as set out in the application should the application be funded

ii) Contact Information

Contact details of principal investigator for the CRUK Centre and/or ECMC and details of affiliated institutions.

iii) CV Posts and Qualifications

Up to six qualifications can be added for the lead applicant. Please list your qualifications in chronological order.

iv) CV Publications

Publications can be extracted from your Master CV, but will not automatically pull through to the application. If you have not yet created a Master CV, please input all publications that are relevant to your application in this section. Publications must:

- Contain a full list of authors;
- Be peer-reviewed;
- Be published within the last five years.

Listed publications should take the form: Andrews A, Brown B, & Charles C (2010) Paper Title. Nature 217, 199-201.

v) Equal Opportunity

Cancer Research UK operates a policy of equality and fair treatment and aims to ensure that unfair discrimination does not occur. To help CRUK monitor the effectiveness of this policy, please complete this confidential section as part of the application. All information entered will be removed from the application and used for statistical monitoring purposes only.

vi) Supporting Roles

One principal investigator must assume the responsibility of named Lead Applicant on the application for the purposes of the eGMS application process. Joint lead applicants must be added as supporting roles once the full application is opened on eGMS. Supporting roles are necessary where, for example, scientific and clinical leads are required or locations are applying for both CRUK Centre and ECMC funding. A maximum of 3 joint lead applicants may be added.

vii) Association of Medical Research Charities

As an Association of Medical Research Charities (AMRC) member charity CRUK monitors the full economic costs of the research it supports. All applicants are required to complete an AMRC Full Economic Costing information form as part of the application.

viii) Uploads

Please complete the main body of the application (following the guidelines outlined in Sections 7.2, 7.3 and 8 of this document and the structure given in the template document) and upload the required documents here. If any doubts exist, please consult with the ECMCs team to confirm what uploads are necessary for any individual application. All documents must be converted to PDF prior to upload.

ix) Terms and Conditions

Please read the relevant Terms and Conditions and Administrative Guidelines before accepting.

x) Review and Submit

This summarises the application and shows whether each section is completed, requires attention or is incomplete. Ensure that there is a green tick next to each required element. If not, choose the element for the left hand side to complete. Click *View PDF* to see the entire application. When you are satisfied with your application, click *Submit*.

Once the application has been submitted it will be sent to the administrative authority of the host institute for review and approval. Applicants will receive confirmation when this is complete.

Executive Summary

To be completed by all applicants in the template document and uploaded to eGMS as a single document.

Applicant Details
Please provide a brief summary of the key facts related to the submission. The following information is required:

- Host Institution;
- Project title – Paediatric ECMC Network
- Name and title of Lead Applicant and co-applicants for each of the participating sites;

Proposal Outline
Please provide a high level synopsis of the vision for the Paediatric ECMC Network, including a summary of the overarching research strategy and an outline of how this vision aligns with the ECMC strategy. This section is limited to **500 words**.

Costs
In the template document, please complete the two tables provided to give a top-line summary of the current award and future funding request, split by category. Applicants should use the ECMC Excel financial request appendix (for more details please refer to finance Section 8.1.1 of this guidelines document) to complete the rows and columns of the tables that are relevant to their bid.

Application Guidelines

Please ensure that the content in the different sections of this application (including the appendices in Section 8) complements and supports your site's vision for the next quinquennium as described in the ECMC research strategy proposal.

7.1 PAST WORK

7.1.1 1. Key Achievements

This section should summarise the activity and key achievements in experimental cancer medicine of the Paediatric ECMC Network since 1st April 2012. The activity must reflect good alignment with the progress to the established objectives/milestones stated in the previous application and achievements ought to have been facilitated by ECMC funding.

7.1.2 Impact

a) Impact to the Network

Explain the impact of secured funding in the expansion of the participating sites' activity and expertise in experimental cancer medicine. Examples might include any grant/commercial funding, any new treatment/clinical diagnostic developed or participation in activities/consortia amongst others, which were achieved as a consequence of ECMC-supported activity.

Please summarise the impact beyond a single site, in particular the implications of existing collaborations or how it has allowed the expansion of the Paediatric ECMC Network. If applicable, describe how being part of the Paediatric ECMC Network has added value to each participating ECMC, including your interaction with Adult ECMCs and the ECMC Secretariat.

b) Commercial partnerships

Summarise the Network interactions with industry since 1st April 2012.

7.2 FUTURE WORK

7.2.1 ECMC Summary and Focus Areas

a) Areas for infrastructure support

Please read carefully the eligibility requirements for an ECMC award stated in the guidelines (Section 5) and make sure they are aligned with the Network research strategy proposal.

b) Clinical and scientific focus

Work in the clinical and scientific focus areas listed in your application must be completed for each of the Paediatric ECMCs and should be justified in the Network research strategy proposal. The review panel will determine if the programme of work detailed in the proposal sufficiently supports these focus areas of the participating sites.

7.2.2 Pillar 1: Scientific Excellence

The maximum length for proposals is **6,000 words**, excluding the reference list, figures and figure legends.

The Network proposal for achieving your strategy should be detailed by describing the programme of work to be undertaken, its significance and how it will benefit patients. The information provided in this section should support the clinical and scientific focus areas listed in Section 2.2.1 of the application form. Please refer to the aims of the Initiative (Section 4.2) to ensure that your ECMC proposal is in line with the future direction of the Initiative. Paediatric ECMCs must address how they will support each other and work as part of the Network.

ECMC funding is provided to support infrastructure costs and therefore the proposal should explain clearly how the funding will provide capacity and capability to support the proposed work and should not include detailed scientific information. It should describe how the work builds on existing areas of expertise or research excellence. This may be related to the type of research conducted, disease site specific foci or research modalities (e.g. imaging).

A very brief summary of the different sites' current and other research relating to the proposed research strategy should be included as background. Reference should be made to the applicants' published work where relevant, or an indication of the availability of the appropriate expertise should be included. Any potential logistic or scientific problems should be identified and solutions or alternative plans proposed.

References
Listed publications should take the form: Andrews A, Brown B, & Charles C (2010) Paper Title. Nature 217, 199-201.

Non-peer reviewed papers should not be submitted with an application and any such papers sent will not be forwarded to reviewers. Research that has not been accepted for publication should not be cited in the reference list (e.g. 'manuscript in preparation', 'submitted for publication' etc).

Supporting documents
Only electronic copies of images should be submitted. Images should be inserted into a word document and a figure legend attached added. Any supporting documents submitted should contain the applicant's full name and the date in the header or footer. Only where absolutely necessary, should photographs or colour figures that cannot be photocopied successfully in black and white be submitted.

7.2.3 Pillar 2: Operational Delivery

a) Composition of the Network

Please explain why each of the participating sites was chosen to be part of the Paediatric ECMC Network. This section should justify why the request for funding has been divided between sites stating their track record in paediatric experimental cancer medicine and key strategic and performance criteria (patient accrual, current trial activity etc).

For Paediatric ECMCs that do not currently receive NIHR infrastructure funding for early phase trials for children with cancer, please explain why they have a sufficient track record (number of studies, patient accrual etc) in experimental cancer medicine to justify support as part of this proposal.

b) Selecting and prioritising trials

Please describe what governance processes each of the participating ECMCs NHS Trust/Board uses to decide which trials are sponsored or participate in, and the mechanisms they use to ensure that these trials are delivered on time and target.

c) Compliance to regulations

Please provide information about any significant audits and inspections related to Network supported trials of the participating site(s) since 1st April 2012 (e.g. by the MHRA, Host Institution or trial sponsor). Please summarise any critical or major findings and subsequent preventive actions.

d) Barriers to operations

Describe any barriers to operations that have impacted (or are likely to impact in the near future) trial delivery in the participating sites and/or across the Paediatric Network. Please summarise what measures were put in place (or you are planning to establish) to ensure that the impact on trial delivery minimised.

7.2.4 Pillar 3: Value to the Network

a) National collaborations

Please provide details of ongoing and planned new major national collaborations associated to the Paediatric ECMC Network (e.g. development of joint projects, sharing of expertise, participation in Network activities) as well as partnerships or initiatives with Adult ECMCs.

b) International collaborations

Please describe any ongoing and planned new major international trial activity, participation in international consortiums (e.g. ITCC) or programme grants relevant to experimental cancer medicine.

c) Commercial partnerships

Please describe how the Network would work in partnership with industry (e.g. pharmaceutical, biotech, and medtech companies, etc). Examples may include collaborative research projects, and delivery on industry-sponsored clinical trials.

8 SUPPORTING APPENDICES

8.1.1 Financial Request

The purpose of funding from Cancer Research UK and the UK Health Departments for ECMCs is to meet the research infrastructure costs incurred by the University and the partner NHS Trust/ Board organisation(s) in carrying out experimental cancer medicine. This includes the costs of NHS Trust/ Boards infrastructure for research including NHS Support Costs. It also includes both staff and running expenses associated with

laboratory research of clinical trials and translational or biomarker studies associated with late phase clinical trials.

Applicants are asked to complete the attached Excel file detailing ECMC spend for the current funding period and requested ECMC funding for the next funding period.

General exclusions from the ECMC award:
Funding is not intended to meet the:

- Direct research costs of individual studies i.e. each study should have its own separate research funding;
- Costs of research posts such as post doctoral and clinical fellows or fund senior salaries;
- NHS Treatment Costs of research.

As stated in the Eligibility criteria (section 5), funding cannot be used to:

- Undertake basic scientific research that has no clear and immediate translational pathway into clinical use, or support animal work.
- Support capital development, new buildings or refurbishments or to buy major capital equipment.
- Buy capital equipment costing more than £5,000.
- General office running costs or travel expenses.

If you are requesting significant funding to meet increases in costs, these should be explicitly justified within your ECMC proposal and referenced in the relevant space provided.

Financial requirements from the UK Health Departments:
Applicants are requested to take into account the financial details requested from their relevant Health Department when developing their financial form. Please note that the Departments of Health of the devolved Nations have not confirmed financial support to the ECMC Paediatric Network. Their support is dependent on the quality of the Paediatric ECMC application.

National Institutes of Health Research (NIHR)
NHS Support Costs are the additional patient care costs associated with the research, which would end once the R&D activity in question had stopped, even if the patient care involved continued to be provided.

Please note that no animal research will be supported by NIHR funding under the ECMC award.

Activities that are attributed to NHS Support Costs include:

- The processing of the patient record to identify NHS patients who may be suitable to approach to ask if they wish to participate in a research project.
- Obtaining informed consent from patients where the study is a health research study, taking place within the NHS.
- Additional investigations, assessments and tests where the results are required by the patient's care team to ensure patient safety and where arrangements are in place to feed the results back to the clinician.

Chief Scientist Office (CSO)
The purpose of CSO funding for ECMCs is to meet the NHS infrastructure costs for Experimental Cancer Medicine, including the NHS Support Costs of the research undertaken by the ECMC. NHS Service Support Costs are the additional patient care costs associated with the research, which would end once the R&D activity in question had stopped, even if the patient care involved continued to be provided (for detail see HSG (97)32: Responsibilities for meeting Patient Care Costs associated with Research and Development in the NHS1 and 'Attributing revenue costs of externally-funded non-commercial research in the NHS (ARCO)). CSO Funding for ECMCs is awarded to NHS organisations only.

Health and Care Research Wales (HCRW)
In Wales, access to NHS R&D funding is through the health and care research Wales support and delivery Infrastructure. Cost attribution for research studies is determined by the ACORD policy. In order to access R&D related NHS costs to support high quality research, researchers should discuss their requirements with relevant NHS R&D offices. NHS R&D offices will also be able to advise on appropriate mechanisms for accessing treatment and excess treatment costs.

Public Health Agency (HSC)
The purpose of funding from HSC should be agreed with the local R&D funding organisation.

8.1.2 Governance

a) Governance and local infrastructure

For the management of the Network supported trials, please provide details of network wide governance and processes for overseeing the delivery of trials. These include the trial steering committees, independent data monitoring committees and trial management groups. If applicable, add details of the local management of the CRF/trials office where experimental cancer medicine trials take place, as well as the processes for overseeing the delivery of individual trials.

In addition, provide an organogram outlining the proposed Paediatric ECMC Network management structure to facilitate communication across sites as well as among key departments in each site to support the flow of ideas towards the clinic to maximise patient benefit. Indicate clearly the strategy for aligning to, and maximising investment in, other large scale infrastructure for experimental cancer medicine research in each of the participating sites (e.g. English sites are requested to list NIHR infrastructure such as NIHR Biomedical Research Centres (BRC) and Clinical Research Facilities (CRF) must be included).

b) Anthena SWAN awards

In England, it is the Department of Health's policy that academic partners with NHS/university partnerships receiving NIHR funding for research infrastructure in the NHS hold at least silver-level Athena SWAN for Women in Science awards. The Department of Health in England is committed to extending this policy to NIHR funding for (English) ECMCs. Therefore, to introduce this in the next quinquennium, the Department of Health has stated that those English NHS/university partnerships where the university partner (i.e. Principal Investigator) who, at the time of the announcement of the new ECMC funding, has achieved at least silver Athena SWAN will be awarded NIHR funding for the full five years. However, if the university partner has not

achieved at least the silver Athena SWAN then NIHR funding will be awarded for two years in the first instance, with the last three years of funding being conditional upon them achieving this.

For applicants from the devolved nations it is not mandatory to reach silver Athena Swan award by April 2019. Nevertheless, applicants are still required to work towards achieving the Silver status. Please summarise your plans to achieve it providing some clear milestones and targets.

8.1.3 Scientific and Clinical Focus

a) Publications

Please list your top ten clinical trial and translational publications in peer reviewed journals supported by ECMC funding and highlight the ECMC-supported authors.

Clinical trial publication should present the activity of the Network rather than a single site. Comments (limited to 100 words) should briefly detail the importance of the work to this field of research in particular and to cancer research in general. For each publication please state which trial(s) the findings resulted from by providing the trial number and acronym (if not in the title) and briefly describe the relevance to the unit.

Comments for translational publications (limited to 100 words) should briefly detail the importance of the work to this field of research in particular and to cancer research in general. Please provide the name of the trial if not apparent in the title of the publication. Note that the lead author of this research need not necessarily have a direct relationship with any of the paediatric ECMCs.

e) Grants

Please provide a list of translational and clinical funding relevant to experimental cancer medicine, held by the Principal Investigator / ECMC Lead and co-investigators, during the last three years, including on-going funding. Grants should be listed in chronological order starting with the most recent and separate peer-review from other types of funding (e.g. commercial).

f) Biomarkers

This section should only be filled if your ECMC proposal has a component on biomarker development and clinical qualification.

Please fill in the table with all the biomarker activity that has taken place in your site since 1st April 2012. For each biomarker you should include:

- *Biomarker or assay name*
  The name used as it appears in the last publication/trial. If additional names apply, please include them in brackets.
- *Type of biomarker*
  Include one of the following classifications: discovery, pharmacodynamic, stratification/enrichment, prognostic, safety and early diagnostic. Use more than one if needed but explain all the stages in description box.
  Please note that in the last quinquennial period, the biomarker remit was broader than currently allowed (refer to Section 5 of this document for further details).

- *Centre reference*
  State which site has lead in each of the stages of the biomarker progression
- *Last stage and/or progression*
  Biomarker stages should be as follows a) in vitro/ex vivo stage, b) tested in both in-vivo and human tissue samples, c) tested in patients (trial or clinic) and d) clinical qualification.
  If more than one stage has been reached in the past five years, include them by chronological order but ensure that each stage is associated to a publication/trial/NHS approved assay in the relevant boxes.
- *Full trial title where it was tested*
  *A*dd the title of the trial(s) where it was tested and explain which cohort(s) it targeted.
- *Associated publication(s)*
  Include relevant publications for each of the stages that the biomarker has reached in the last five years.
- *Short description of its importance*
  100 words maximum. Briefly describe the importance of the biomarker to clinical practice and if more than one stage described, how it was prioritised to the next one.

8.1.4 Future Objectives

Objectives are meant to describe how you will reach the aims described in the application and as such must be highly focused and feasible. The information provided should be top line and should not include detailed scientific information.

The short, medium and long term objectives for should be summarised in this section along with the associated targets. All targets must have a specific measure that will determine their successful completion and to which will be measured against as part of the Paediatric ECMC Network's annual assessment (i.e. milestones).

Please ensure your objectives cover the following topics which should be stated in the "Field" section in the table:

- Science: Delivering all the aims of the proposal outlined in the application;
- Operational: Improvements in existing infrastructure and governance set up;
- Network: Engagement across the Paediatric ECMC Network and with relevant Adult ECMCs;
- Industry: Plans to grow the activity of the site including partnerships with industry;
- PPI: Patient and Public Involvement strategy;
- Athena Swan: If applicable, steps to reach the Athena Swan Silver status;
- Dissemination: ECMC branding and dissemination of results to key audiences.

8.1.5 Outreach

a) Research engagement and brand management

Paediatric ECMCs are expected to engage with relevant stakeholders to disseminate the relevance of their work and to promote the Paediatric ECMC Network as the destination of choice for early phase clinical trials that maximise patient benefit.

Even though it is only legally binding for Adult ECMCs, if the Paediatric ECMC Network proposal is successful, participating sites will be expected to follow the branding provisions as per the Collaboration Agreement in due course.

b) Patient and public involvement

To fill in this section, please refer to INVOLVE's definition of patient and public involvement in research.

Please provide examples of where you have successfully involved people affected by cancer in your work since 1st April 2012 and how you are planning to build from these successes in the next funding period. If some activities were not successful, please explain what you have learned from them and how you are planning to applied this learned knowledge in the future.

When developing the plan for patient involvement for the next five years, ensure that it is more than a list or programme of activities. It should include:

- Aims and objectives that align with, and support the delivery of the overall aims and objectives of the Paediatric ECMC Network
- Partners and collaborators with whom some aspects of the plan will be jointly delivered
- Where within your research activity you will be involving people affected by cancer and why you have made this decision (what value/difference do you think this involvement will have)
- A process for monitoring and reviewing delivery as well as measuring the impact of the plan and ensuring it is sustainable

Please just detail the patient and public (PPI) involvement activities relevant to the Paediatric ECMCs not general PPI activity occurring at the participating sites.

8.1.6 Case Studies

Case studies should summarise your site's most impactful research studies since 1st April 2012. These studies should reflect the diversity of the Paediatric ECMC Network's research portfolio and where ECMC support made a significant contribution to it. If a section does not apply, please mention why in the space provided.

Studies should have been completed or reached a significant research milestone(s) that enable firm conclusions to be made. They need not have produced positive data, if findings have made a significant contribution to the knowledge base and influenced the direction of future research and/or clinical practice.

a. Study title, name of Chief and Principal Investigator(s) and ECMCs involved

Please provide the full study title. If applicable, this should be identical to the one submitted on the ECMC trial spreadsheets.

Only the details of the principle investigator ought to be provided for multicentre studies but ensure all participating ECMCs are mentioned.

b. Background and primary purpose of the study

Maximum of 200 words. Please briefly explain the key scientific background and aim(s) and how it aligns to the Paediatric ECMC Network proposal

If applicable, explain how patients were involved in the activities related to this study.

c. Translational and/or pre-clinical work

Maximum 200 words. Please describe how the potential of the study was identified and how it became prioritised. Ensure you refer to the existing governance mechanisms described in the application.

If the activity took place across different units in a single site or multiple sites, make sure they are mentioned as well as how communication was supported across different teams.

d. Design and delivery of the trial

Maximum 200 words. This should be a basic summary of the trial protocol or methodology. Please state key study arms, controls, patient/sample numbers, treatment frequency/timescale, endpoints etc as appropriate. Briefly describe the involvement by other sites in trial delivery as either supporting a component of the trial or as a trial participating site.

e. How has ECMC funding supported this trial?

Please state which categories of ECMC-funded staff (research nurse, data manager etc) were involved and how they supported the study. If a study could not have been conducted without ECMC support, explain why.

f. Sponsorship and how was the study prioritised throughout the process

Describe how this study was supported throughout the path and how it was prioritised through the existing mechanisms outlined in the application.

g. Institution(s) involved

Please name the UK institutions within and outside your site that have participated in the study.

h. Short description of main findings

Maximum of 200 words. Please summarise the key findings and future direction based on the results obtained.

i. Potential impact of this study in the scientific/clinical field

Maximum 200 words. Use this section to explain how findings could be developed to improve clinical practice and patient outcomes if successful. This can be in terms of more effective therapy, reduced side effects, better diagnosis/prognosis, personalising treatment etc.

j. How were the findings presented (or will be presented) including conferences, peer-reviewed publications or local/national press

If presented, please provide publication references in full and/or dates and journals for any planned future submissions, dissemination to patients and/or outline any television or newspaper coverage that the study has received.