Guidelines for the Completion of the CRUK Centres and Adult ECMCs 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 deadline (new Centres and new ECMCs only)
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 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/or new ECMCs;
- Consider applications for new CRUK Major Centres.

All locations that submit full applications will be invited to present their vision for cancer research to an international review panel, which will then make distinct recommendations for Centre and ECMC awards for the next funding period. The purpose of this document is to provide guidance for the completion of the full application for CRUK Centres and Adult ECMCs.

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.

4.2 Cancer Research UK Centres

The CRUK Centres initiative is one of the Charity's highest priority strategic initiatives and aims to support locations in delivering high quality translational research. The Centres are partnerships working on a local level with Universities, NHS Hospital Trusts/Health Boards, cancer networks and other charities, and on a national level with Government and industry. Over the next five years, the Centres initiative is expected to play a key role in delivering against CRUK's objectives in translational research. The aims of the initiative are to:

- Facilitate the delivery of translational research of the highest international quality;
- Facilitate multidisciplinary collaboration, removing barriers between scientific disciplines and between discovery and clinical research;
- Build long lasting and effective partnerships, leveraging activities and funding of all partners;
- Accelerate progress in CRUK's strategic priorities through networks of excellence;
- Raise the profile of UK cancer research globally and attract international leaders, and ensure our national network of excellence is visible on an international stage;
- Train the clinical and non-clinical work force of the future.

CRUK Centres also provide a powerful opportunity to demonstrate our impact to scientific, public, and commercial audiences. Branding and Research Engagement are crucial in bringing our role in funding cancer research to life, and this is key to the success of CRUK and our ability to fund world-class research in the future.

4.3 The Experimental Cancer Medicine Centre (ECMC) Network

The aim of the ECMC Initiative is to expedite the development 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/Health 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 at a specific site but 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, Adult ECMCs are expected to:

- Drive the design and delivery of translational studies and scientifically-driven, rationally designed early phase[1] 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 improve the success rates in developing new therapeutic modalities for patient benefit.
- Maximise therapeutic opportunities for patients through the development and validation of novel molecular and/or imaging biomarker assays to regulatory standards;
- Ensure effective joint working across the Network and between Universities and Trusts.
- Increase the attractiveness of the UK as the industry's destination of choice for the development of high impact, innovative treatments, and thereby contribute to economic growth;
- 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.

5 ELIGIBILITY

5.1 New CRUK Centres and/or new ECMCs

Applications from locations that are not already part of the CRUK Centres and/or Adult ECMC Network, but that wish to apply to become a Centre and/or Adult ECMC, should first submit an Expression of Interest (EoI). The EoI panel will assess each EoI and recommend whether the applicant should be invited to submit a full application (as per 5.2 and/or 5.3). In both cases, approval must be obtained before a full application can be submitted. More information on how to submit an EoI can be found on the CRUK Centre and/or Adult ECMC webpages. Locations that are not currently CRUK Centres or ECMCs should discuss their potential eligibility with the CRUK office before submitting an EoI.

[1] We define early phase clinical development as Phase 0, 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.

5.2 CRUK Centres

CRUK Centres are expected to have a substantial programme of cancer research with significant CRUK funding (typically in excess of £2M per year), as well as funding from other charities and funding agencies.

All existing CRUK Centres are eligible to apply for renewal and should follow the guidelines in Section 7 of this document to submit a full application.

Applicants should be aware that new Brand and Research Engagement terms and conditions for CRUK Centres will be introduced prior to the award of grants for the next funding period. New Centres will be expected to fulfil all brand management and research engagement requirements at the earliest opportunity after a successful funding decision (over a timeframe agreed in advance with CRUK). Existing Centres will also be expected to execute any recommendations given as a result of the review (over a timeframe agreed in advance with CRUK). General Terms and Conditions for the award of a CRUK grant can be found in the Grant Conditions document.

5.3 Experimental Cancer Medicine Centres

Applications are invited for infrastructure funding to support experimental cancer medicine activity in sites 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 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].

[2] English 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.

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;
- Capital equipment costing more than £5,000;
- Overheads on research awards;
- Major capital investment, capital development, new buildings or refurbishments.

Applicants should also be aware that compliance with the ECMC's branding and research engagement requirements will form a strict precondition of acceptance into the ECMC Network. Successful 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 to the ECMC Terms and Conditions which can be found here. In addition, ECMCs will also be requested to comply under the ECMC Collaboration Agreement once finalised.

6 REVIEW PROCESS

Locations wishing to re-apply for CRUK Centre and/or ECMC funding are asked to submit a detailed application (following the guidelines in Section 7 of this document) by the 15th of August 2016. Applicants wishing to apply for both a CRUK Centre and an ECMC are asked to submit a single, aligned bid for funding across the entirety of the location. However, funding decisions for CRUK Centres and Adult ECMCs will be made independently of one another. Locations that are not already part of the CRUK Centres and/or Adult ECMC Network, but that wish to apply to become a Centre and/or Adult ECMC, must first submit a successful (EoI) as per Section 5.1. above.

Members of an expert review panel will assess all applications before the review panel meeting which will take place between the 17th and the 20th of October 2016. At the meeting, representatives from each location will be invited to CRUK's Angel Building in London for an interview with the review panel. Further details about the interview process will be supplied to all applicants in due course.

The review panel will recommend funding levels for the next quinquennium. For CRUK Centre funding, these recommendations will pass directly to the December 2016 meeting of the CRUK

Scientific Executive Board for approval. In the case of ECMCs, these recommendations will be considered by all funding partners before final funding levels are decided.

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.

6.1 Format of Application

The full application form will be split into several distinct sections:

- Executive Summary
- Section 1 – CRUK Centre
- Section 2 – Training
- Section 3 – ECMC
- Section 4 – Supporting Appendices

Depending on the nature of the application only certain sections should be completed. All applications should include an Executive Summary - a high level overview of the location's vision for cancer research over the duration of the next funding period. Locations applying to join or rejoin the Centres network should complete Sections 1 and 2 of the application. Locations applying to join or rejoin the ECMC network should complete Section 3 of the application. Locations applying to join or rejoin both the Centres and the ECMCs network should complete Sections 1, 2 and 3 of the application.

All applications 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 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. Universities must approve the final application through eGMS prior to the submission deadline for successful completion of the application process. In addition, for Adult ECMC applications, the NHS Trust/Board representatives must also approve the final application. Applicants will receive an automated email upon submission of a completed application.

7 APPLICATION 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 (including Executive Summary, CRUK Centre, Training, ECMC and appendices) 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: https://egms.cancerresearchuk.org/. 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.

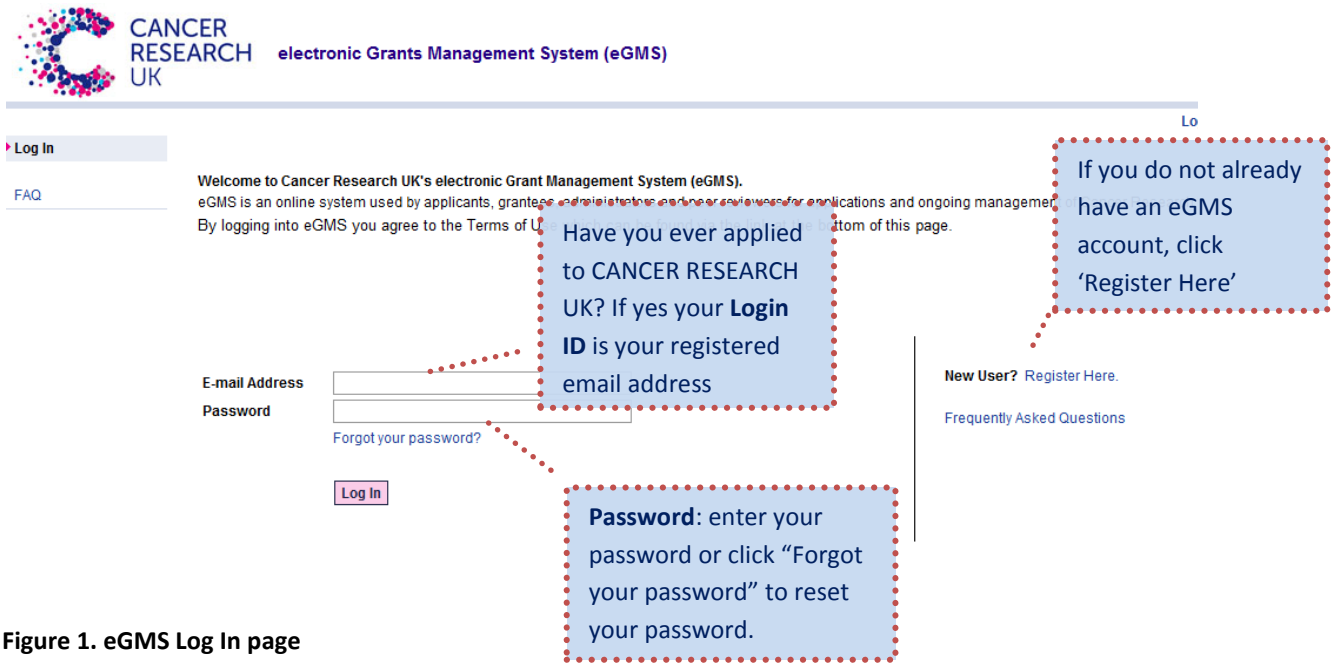

Figure 1. eGMS Log In page

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 (e.g. Cancer Research UK [location] Centre and/or [location] ECMC)
Proposed start date – 1st of April 2017
Duration of proposed project – 60 months

For Adult ECMCs, all full applications will need to provide confirmation from the Chief Executive of the partner NHS Trust 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.

For ECMC applications, it is possible to have joint principal investigators but only one of these individuals can be the ECMC grant holder. Only details of the principal investigator who is also the grant holder should be provided in this section. Details of the other joint principal investigator should be included in section vi).

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 Section 7 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 CRUK Centres and ECMCs teams 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 (e.g. Cancer Research UK [location] Centre and/or [location] ECMC);
- Name and title of Centre Directors for the CRUK Centre and/or ECMC;
- Name and title of any joint lead applicants.

Proposal Outline
Please provide a high level synopsis of the vision for the CRUK Centre and/or the Adult ECMC across the location, including a summary of the overarching research strategy (including planned thematic priorities or focus areas), and an outline of how this vision aligns with CRUK and ECMC strategies. This section is limited to **1000 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 CRUK Centres and ECMC Excel financial request appendices (for more details please refer to Section 11.1.1 and 11.2.1 of this guidelines document) to complete the rows and columns of the tables that are relevant to their bid.

8 Section 1: CRUK Centres

To be completed by all renewing Centres, existing Major Centres, and newly applying Centres that have been invited to submit a full application.

8.1 Centre Vision and Strategy

This section should provide an overview of the overall cancer research strategy across the entirety of the location (including all elements of the Centre/proposed Centre). Responses are limited to **3,000 words for existing Major Centres and 2,000 words for all other applicants**. Points for discussion could include:

- A top-level strategic vision for cancer research at the location, including a summary of key developments over the last funding period and a summary of how the strategy will evolve during the next funding period;
- A description of how the cancer programme integrates with the location's overall research strategy;
- A description of how the strategy aligns with CRUK's Research Strategy;
- A brief introduction to the key research themes in the cancer programme and the infrastructure components that support them;
- A description of how discovery, translational, and clinical research are integrated;
- A description of how the location currently collaborates across the network, and an outline of proposed thematic collaborations with other locations;
- A description of the research facilities, and details of any proposed developments;
- An introduction to the governance and leadership structure of the Centre (to complement the diagram to be supplied in the Governance and Leadership Appendix discussed in Section 11.1.2 of this guidelines document).

8.2 Scientific Performance – Research Themes and Focus Areas

CRUK Centres are expected to deliver high quality translational research and facilitate multidisciplinary collaboration. Applicants are asked to demonstrate how the activities that they currently engage in meet these expectations, structuring their applications around individual research themes that they have identified as being strategic priorities.

Existing **Major Centres are limited to a total of 10,000 words** for this section. **All other applicants are limited to a total of 6,000** words. The number of priority research themes should be appropriate for the scale of research being conducted at that location. Applicants can consult with CRUK regarding the number and suitability of the research themes chosen, and should present their themes according to the headings outlined on the following page. To support each theme, applicants are asked to append a list of up to ten publications, published from January 2011 onwards, that best represent the research within this theme (see the Publications Appendix discussed in Section 11.1.3a of this guidelines document). Applicants can also add up to 1 page of information that focuses on any major (>£500k) awards supporting research into individual research themes in the Supporting Information Appendix (more details are provided in Section 11.1.3b of this guidelines document).

Research theme: A priority research theme or focus area for the Centre.

Key achievements: This section should summarise the key research achievements within this theme over the past 3 years, demonstrating, where appropriate, the impact (or potential impact) of these achievements on patients. Examples of points for discussion could include:

- Any significant scientific/translational/commercial breakthroughs that contribute to progress in this theme at an international level;
- A summary of the key researchers contributing to the theme at the location;
- A summary of research collaborations at a local, national, or international level that contribute to progress in this theme.

Future objectives: This section should outline plans for how the Centre intends to progress the research within this theme during the next funding period, and should include specific short-, medium-, and long-term objectives within this theme and, where applicable, appropriate milestones. All objectives across all research themes should be compiled in the Objectives Appendix. Further details regarding this appendix are provided in Section 11.1.4a and Section 11.1.4b of this guidelines document. Other points for discussion could include:

- Planned major research directions and programmes;
- Recruitment plans (all senior recruitment and departures from the last triennium should be compiled in the Recruitment and Departures Appendix discussed in more detail in 11.1.6 of this guidelines document);
- New or continuing collaborations and plans to engage with other Centres across the network.

8.3 Additional Appendices

All CRUK Centre applicants should also complete the Outreach Appendix (encompassing Research Engagement, Brand Management, and Patient Involvement) discussed in further detail in Section 11.1.5 of this guidelines document.

9 Section 2: Training

To be completed by all renewing Centres, existing Major Centres, and newly applying Centres that have been invited to submit a full application.

The training of the next generation of researchers is of paramount importance to CRUK. In this section applicants are asked to demonstrate how their training programme supports the research themes and scientific strategy of the Centre. Newly applying Centres should take this opportunity to describe any training programme that they currently have in place and how they intend to extend this for their proposed CRUK Centre. Applicants are encouraged to read and, where applicable, refer to the recent MRC Cross-Funder Review of Early-Career Clinical Academics when preparing responses.

The length of this section should be appropriate for the size of the training programme at the location, and is limited to **2,000 words.** Where applicable, this section should cover the points highlighted below:

- Key features of the clinical/non-clinical training programmes and student recruitment processes as well as any differences between current and proposed future training programmes;
- How the training programme has supported the research themes at the Centre as well as an assessment of the role that training accounts will play in the future;
- Supervision, mentoring, and support mechanisms or systems in place;
- Any programmes in place to expose students to multidisciplinary research;
- How the Centre encourages and enables career pathway progression in cancer research;
- How the training programme supports Centre strategy and CRUK's Research Strategy;
- Any plans to significantly change the training programme currently in place.

Applicants should also complete the Training Metrics Appendix discussed in further detail in Section 11.1.7 of this guidelines document.

10 Section 3: Experimental Cancer Medicine Centres

To be completed by all renewing ECMCs and any newly applying ECMCs that have been invited to submit a full application.
Please ensure that the content in the different sections of this application (including the appendices in Section 11.2) complements and supports your site's vision for the next quinquennium as described in the ECMC research strategy proposal.

10.1 PAST WORK

10.1.1 Key achievements

This section should summarise in **700 words** the activity and key achievements in experimental cancer medicine at your site since 1st April 2012.

If the applicant is currently an ECMC, the activity must align with the progress to the established objectives/milestones stated in the previous application and achievements ought to have been facilitated by ECMC funding.

10.1.2 Impact

a) Impact on your site

Explain the impact of secured funding in the expansion of your site's 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. If you are currently an ECMC, please focus on growth as a consequence of ECMC-supported activity.

b) Impact beyond your site

Please summarise the impact beyond your site, in particular the implications of existing collaborations or how it has allowed you to expand your network. If the site is currently an ECMC, emphasis must be placed on the impact of contribution to the success of the ECMC Network.

Both sections should not exceed **700 word** limit.

10.2 FUTURE WORK

10.2.1 ECMC Summary and Focus Areas

a) Areas for infrastructure support

Please indicate which areas will ECMC funding support and make sure they are aligned with the ECMC research strategy proposal (guidance in Section 10.2.2). When filling this section, please take into account the eligibility requirements for an ECMC award stated in the guidelines (Section 5.3)

b) Clinical and scientific focus

Work in the clinical and scientific focus areas listed in your application should be justified in your ECMC research strategy proposal. The review panel will determine if the programme of work

detailed in your ECMC research strategy proposal sufficiently supports these focus areas for your centre.

10.2.2. Pillar 1: Scientific Excellence

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

The proposal for achieving your strategy should describe the programme of work to be undertaken, its significance and how it will benefit patients. The information provided in this section should support the listed clinical and scientific focus areas listed in the proposal. Please refer to the aims of the Initiative (Section 4.3) to ensure that your ECMC proposal is in line with the future direction of the Initiative.

Joint applications must be able to demonstrate real value beyond broadening patient catchment area to boost recruitment to justify their combined application. The research strategy and operational delivery of both sites must be aligned and complementary and a track record of working together would be advisable (i.e. well-established governance processes between sites).

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

A very brief summary of your current and other research relating to the proposed ECMC should be included as background. Reference should be made to the applicant's own 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
The listed references should follow the format: 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.

10.2.3. Pillar 2: Operational Delivery

a) Selecting and prioritising trials

Please describe (maximum **300 words**) the governance processes your NHS Trust/Board uses to decide which trials it will sponsor or participate in, and the mechanisms it uses to ensure that these trials are delivered on time and target.

b) Compliance to regulations

Please provide information about any significant audits of your centre and inspections 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. Word limit: **300 words**

c) Barriers to operations

Describe any barriers to operations that have impacted (or are likely to impact in the near future) trial delivery in your centre (maximum **300 words**). Please summarise what measures were put in place (or you are planning to establish) to ensure that the impact on trial delivery minimised.

10.2.4. Pillar 3: Value to the Network

a) National collaborations

Please describe how your ECMC's proposed programme of work will contribute to the local site and also the wider ECMC Network (maximum **300 words**). Ensure that your proposed network activity is aligned to the ECMC research strategy proposal. Do not limit your activity to the set up and delivery of multi-site trials but rather, focus on activity that would not occur without the support of the ECMC Initiative and emphasise the collaborative nature of your site.

b) International collaborations

Please describe the type of ongoing and planned international activities (e.g. multi-site trials, international grants, etc.) and how these will benefit the ECMC Network (maximum **300 words**).

c) Commercial partnerships

Please describe how your ECMC will work in partnerships with industry (e.g. pharmaceutical, biotech, and medtech companies etc.). Examples may include collaborative research programmes or projects, and participating on industry-sponsored clinical trials. Word limit: **600 words**

11 Section 4: Supporting Appendices

11.1. CRUK CENTRES

To be completed by all renewing Centres, existing Major Centres, and newly applying Centres that have been invited to submit a full application.

11.1.1. Financial Request

a) Excel sheet

Infrastructure awards in the previous funding cycle ranged from £0.25M to £2M per annum. Awards are designed to enable high quality translational research across the CRUK Centre and may be used to fund a wide range of supporting infrastructure, including:

- A Centre development fund;
- A Centre Manager post;
- Infrastructure posts (such as laboratory technicians, research nurses, bioinformaticians);
- Training accounts;
- Programmed activities for clinicians (eg. pathologists);
- Equipment and equipment maintenance;
- Limited clerical support;
- Strategic senior recruitment (in exceptional circumstances and after discussions with CRUK).

Applicants are asked to complete the attached Excel file detailing CRUK Centre spend for the current funding period (for existing Centres only), requested Centre funding for the next funding period, partner and non-CRUK commitment funding, and development fund information. Applicants should engage in discussions with CRUK staff regarding appropriate funding requests and levels of training account support.

b) Financial justification

In the context of the funding request outlined in the Excel file, applicants should also provide a narrative justification of how a Centre award would be used to drive the overall strategy of the Centre throughout the duration of the next funding period. Responses are limited to **2000 words** and should offer a scientific and operational rationale for the funding request, as well as discussing the impact that this (and any investment from other partners) would have on progress within the Centre's priority research themes.

11.1.2. Governance and Leadership

This appendix should provide an overview of the leadership and governance model of the proposed Centre. A description of the position of Centre Governance Board within existing university governance structures and any overlap between Centre and ECMC governance should also be included (a diagram may be useful to illustrate the structure). Responses are limited to **700 words**.

11.1.3. Research Themes

a) Publications

Please list up to 10 publications from the last 5 years that best represent the research carried out at the location into each research theme discussed. Comments (limited to 100 words per publication) should briefly detail the importance of the work to the theme.

b) Supporting information

The inclusion of a one page appendix that supports the information provided in the main body of the example is permitted. This appendix should include a list of major (over £500k) awards that will specifically support research into the theme.

11.1.4. Objectives

a) *Past Objectives*

To be completed by existing Centres only.

Clarification of terms:

- Objective: A top-line summary of past objectives of the Centre. Existing Centres should derive their past objectives from their last Annual Report.
- Research theme: These may be derived from Section 1 of this application or adapted from the Strategic Themes of last Annual Report. If the objective spans several Research Themes, this column should be left blank.
- Progress and challenges: A summary of progress made and challenges faced in meeting the objective.
- Lead: PI or project lead.
- Status: Estimated percentage completion of objective.
- Ref: Past objectives should be numbered in the form a1, a2, a3…

b) Future Objectives

Clarification of terms:

- Objective: A top-line summary of future objectives for the Centre. This can include common objectives with ECMCs or other CRUK infrastructure investment at the Centre location.
- Research Theme(s): These should link to Research Themes identified in Section 1 of this application.
- Actions to be taken: A list of specific and measurable actions to be taken to achieve each objective. Please include key milestone dates for the completion of each action.
- Lead: PI or project lead.
- Ref: Applicants should use the reference numbers from the Past Objectives Appendix to refer to continued or modified past objectives (i.e. a1, a2, a3…). New objectives, which have not been described in the Past Objectives, should be numbered in the form b1, b2, b3…

11.1.5. Outreach

a) Research Engagement and Brand Management

CRUK's ability to fund world-class research relies on its world-class fundraising efforts and global research brand. The research and scientists funded by CRUK are crucial in inspiring the public to provide further support.

CRUK expects Centres to support its Research Engagement agenda, working with the Research Engagement Managers to enable our fundraising and policy teams to bring our science to life through a range of events and local communications, as well as delivering public engagement and media activities to raise CRUK brand awareness locally and nationally.

CRUK also expects that Centres recognise the investment in their Centre appropriately. A consistent approach to branding across all CRUK Centres helps our national network of excellence to be visible on an international stage to scientific, philanthropic and commercial audiences. Building a strong brand in this way strengthens CRUK's ability to sustain its long-term investment in Centres, helping to maximise their scientific potential.

Each applicant should use the table in the template document to demonstrate:

- How it engages with CRUK supporters and the public to raise awareness of CRUK's role in funding world class research;
- How it manages the Centre's brand and utilises it fully as a platform to drive local, national and international visibility of cancer research in their location.

Applicants should be aware that new Brand and Research Engagement terms and conditions for CRUK Centres will be introduced prior to the award of grants for the next funding period.

With these new expectations in mind, applicants should show how they plan to proactively manage their Centre brand throughout the next funding period, ensuring branding is used consistently across all touchpoints and channels, and is adopted by all Centre staff. To monitor branding, Centres will be expected to carry out a brand audit which will be reported on annually through the governance board. In recognition of their influential role in raising the profile of the Centre's brand, CRUK also expects the Centre leadership (Centre Director and senior researchers) to act as ambassadors for the Centre and the Centres Network as a whole.

Senior level contribution and support is also expected for Research Engagement activities and is vital to reach our ambitious fundraising targets. This includes, but is not limited to, hosting bespoke lab tours for donors, attending or speaking at fundraising events, or acting as a CRUK ambassador in the media.

b) Patient involvement

By drawing on the first-hand experiences and knowledge of those affected by cancer, CRUK will be more effective and efficient as an organisation. These perspectives hold huge potential to influence and shape the cancer research and policy landscape, ensuring that all CRUK-funded research is relevant, purposeful and sensitive to cancer patients. Involving patients in CRUK's work can help to add legitimacy and credibility to CRUK's position within the field of cancer research.

Applicants are asked to discuss any current, or planned, efforts to involve patients in the direction and implementation of research activities across the entirety of the location (with the exception of the ECMC which will be considered separately in the ECMC section). This section is limited to **500 words** and should be prepared using the headings below:

Patient involvement strategy and achievements:

This section should, where applicable, discuss patient involvement in the Centre's research and could comment on:

- Any patient involvement in the Centre's research activities;
- Any engagement with CRUK's Patient Involvement & Communications Team.

Future plans to develop patient involvement activities:

This section should, where applicable, summarise any plans for patient involvement in research activities over the next funding period. Where no concrete plans exist, a discussion of potential future opportunities that could lead to increased patient involvement should be included.

11.1.6. Recruitment and Departures

Applicants should list all senior (PI level and above) recruitment and departures within the last triennium, including additional rows in the tables as necessary.

11.1.7. Training Metrics

Please complete the metrics for PhD students that commenced their studies (in the field of cancer research) between the 1st of May 2011 and the 1st of May 2016. Applicants that are not currently in the Centres network should only complete the column referring to other CRUK awards and awards from other funders.

11.2. EXPERIMENTAL CANCER MEDICINE CENTRES

11.2.1. 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.

Infrastructure awards in the previous funding cycle ranged from £200k to £500k per annum. Applicants are asked to complete the attached Excel file detailing ECMC spend for the current funding period (for existing ECMCs only) 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 postdoctoral and clinical fellows or fund senior salaries;
- NHS Treatment Costs of research.

As stated in the Eligibility criteria (Section 5.3), 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.

National Institute 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.

11.2.2 Governance

a) Governance and local infrastructure

For the management of the site, please describe the internal management at the CRF/trials office where experimental cancer medicine trials take place, as well as the processes for overseeing the delivery of individual trials. These include the trial steering committees, independent data monitoring committees and trial management groups.

In addition, provide an organogram outlining the proposed ECMC management structure to facilitate communication across key departments in your 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 your site (e.g. for English sites your NIHR infrastructure funding such as NIHR Biomedical Research Centres (BRC) and Clinical Research Facilities (CRF) facilities must be included).

Word limit: **700 words**

b) Athena 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.

Word limit: **500 words**

11.2.3 Scientific and Clinical Focus

a) Publications

Please list your top ten clinical trial and translational publications in peer reviewed journals in the tables provided.

Clinical trial publications should present the activity of the site rather than the lead applicant. 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.

If you currently hold an ECMC award, please include only publications supported by ECMC funding and highlight the ECMC-supported authors. Note that for translational publications, the lead author of this research need not necessarily have a direct relationship with the ECMC.

b) Grants

Please provide a list of translational and clinical funding relevant to experimental cancer medicine, held by the Principal Investigator / Centre 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).

c) Biomarkers

This section should only be completed if your ECMC proposal has a component on biomarker development and clinical qualification. For existing ECMCs, you must fill in this form if biomarkers were a component of your previous application even if not relevant for the current proposal.

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 5.3 of the guidelines 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*
  Add 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*
  200 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.

11.2.4 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 your ECMC'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 ECMC research strategy proposal outlined;
- Operational: Improvements in existing infrastructure and governance set up;
- Network: Engagement with the ECMC Network;
- 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.

11.2.5 Outreach

a) Research engagement and brand management

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

Successful ECMCs will be expected to follow the branding provisions as per the Collaboration Agreement in due course.

b) Patient and public involvement (PPI)

To fill in this section, please refer to INVOLVE's definition of '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 (maximum **500 words**). If some activities were not successful, please explain what you have learned from them and how you are planning to apply this knowledge in the future.

When developing the plan for patient and public 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 ECMC
- 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 involvement activities relating to the ECMC. Involvement activities across the entirety of the location will be considered separately in the CRUK Centre PPI section (as per Section 11.1.5 of this document).

11.2.6 Case Studies

Case studies should summarise your site's most impactful research studies in the last five years. If currently an ECMC, these studies should reflect the diversity of your ECMC'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.

Applicants are encouraged to provide examples of collaboration across sites, particularly if they currently hold an ECMC award. 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 and name of Chief and Principal Investigator(s)*
   Please provide the full study title. If applicable, this should be identical to the one submitted on the ECMC trial spreadsheets. Only the principle investigators at your site need to be provided for multicentre studies.

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 ECMC research strategy 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 outlined in the application.
   If the activity took place across different units in your site or different 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.

   If applicable, 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. *If applicable, how has ECMC funding supported this trial?*
   Please state which categories of ECMC-funded staff (research nurse, laboratory staff, trial coordinator, 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. *How was the study prioritised throughout the process and type of sponsorship*
   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 **150 words**. Please summarise the key findings and future direction based on the results obtained. If applicable, include how it will be done through ECMC Network.

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

Maximum **150 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.