



# SBRI Healthcare Programme: NHS England and NHS Improvement competition for development contracts

## APPLICANT AND PORTAL GUIDANCE

These Guidance Notes complement the Invitation to Tender document, the Challenge Brief and the Template Application form, and are designed to help you complete your application to the SBRI Healthcare Programme. You can find the documents on the dedicated webpage for Mental Health Inequalities for Children and Young People, and NHS Reset and Recovery and New Ways.

# **Funding prerequisites**

The following funding prerequisites apply to all applications and will be considered by the funding Panel:

- 1. A commitment to involving members of the public and patients in the design and management of the research, evaluation or study.
- 2. A commitment to actively engage in tackling healthcare inequalities, and in supporting diversity and inclusion, by including communities where the proposed innovation will make the biggest impact.
- 3. Steps towards contributing to the overall carbon neutral strategy for the NHS.

# Guidance for completing your application on the PMO Portal

These notes should be read alongside your application as they are designed to help you provide the information required.

Please keep the use of acronyms to a minimum. Only use acronyms where a term is mentioned frequently throughout the proposal. If you do choose to use an acronym, do not assume that the reader knows what it means, and be sure to define it, bearing in mind that individual sections of the application may be read separately during the selection process.

In order for your application to be accepted, you must submit the minimum required information. This information includes all mandatory fields from the application form (as indicated with a red asterisk next to questions). If you do not complete this information, you will not be able to submit your application.

We ask that all participants in the application (Team Members, Sub-Contractors, and Clinical Partners) have approved accounts on the Research Management System so that they can be added to the application form. Please ensure you leave enough time for this.

If you do not have all the answers you need to fully complete the application, you may save your progress using the 'Save and Close' button and return to the application process at a later date.

Guidance on the individual sections of the application form is provided in the following sections.

## **Section 1: Application Summary**

Information entered into this section provides a summary of your application.

#### **Application title**

Please provide the title for the project. This should be descriptive, concise and contain keywords relevant to the project. Any abbreviations should be spelled out in full.

## **Challenge selection**

There are 2 categories within this call. Please state clearly which category your innovation falls into using the dropdown list. Please select the option that best describes the main outcome of the innovation. You may only select one of the two challenges.

#### **Sub-category selection**

Please select the appropriate sub-category addressed by your innovation.

#### **Host organisation**

Please give details of the organisation who will be responsible if the project is funded.

#### **Contract duration**

Projects can be up to a maximum of 9 months in duration.

#### **Project Start date**

Please enter the start date for your project, which are expected to start approximately six weeks after the Interview Panel. The start date is provisional and will be confirmed by the PMO.

#### Total contract cost

This will be auto-populated based on the information provided in Section 6. The upper funding limit of this SBRI Healthcare Phase 3 competition is £500,000 inclusive of VAT.

Costs to support basic research, development of research hypotheses, and experimental designs that have no practical commercial application are not eligible.

## Type of innovation

Please choose the most appropriate description of the innovation using the dropdown list provided.

## **Health category**

Please choose the most appropriate health category related to your application.

#### Market size

Please provide the expected market size for your proposed technology (max 150 words). Please consider including details from reputable sources on patient population size, cost of the problem, percentage share of the market that the solution could realistically capture, etc.

#### AHSN involved in the project

Please select all that apply from the list provided.

#### **AHSN role**

Please describe the role of AHSN in the project (max 50 words).

## Section 2: Company Details

Complete details relevant to your organisation. Please choose from the dropdown list where provided.

- Company website
- Company registration number (for those in the UK)
- VAT registration number. If this is not applicable, please use N/A
- Region (where the company is registered)
- Type of organization
- Company size

- Company status
- Main business activity (max 10 words)
- Annual turnover (max 10 words)

## Section 3: Plain English Summary (max 300 words)

A plain English summary is a clear explanation of your project. The plain English summary may be used to inform reviewers, including experts who might not have specialist knowledge of your field as well as members of the public of your funding application. If your application for funding is successful, the summary may be used on the SBRI Healthcare website.

Please make sure your summary is free of technical jargon, easy to read, and provides an overview of your proposal.

It is helpful to involve patients / carers / members of the public in developing a plain English summary.

When writing your summary consider including the following information where appropriate:

- 1. aim(s) of the project
- 2. background to the project
- 3. design and methods used
- 4. patient and public involvement
- 5. dissemination

The plain English summary is not the same as a scientific abstract, please do not cut and paste this or other sections of your application form to create the plain English summary.

## Section 4: Project Plan

## 4a) Description of unmet need and how the proposed technology addresses it (max 700 words)

Please provide a narrative description for what the innovation is and how it addresses the challenge AND sub-category selected.

The following should be provided:

- The problem being addressed and how it meets the challenge brief.
- A description of the people and/or systems affected by the problem.
- A brief description of the proposed solution and how it addresses the problem, providing examples and figures where appropriate to describe the expected outcomes of the project.
- The entry point and expected outcomes of the project.

## 4b) Description of the technology's evidence accumulated to date (max 700 words)

The applicants should address the following questions in detail, using the descriptions provided in the application form:

- What stage of development is your innovation? In particular the following evidence should be provided:
  - o **CE marking or UKCA certification** for the innovation in the proposed pathway.
  - o If not yet CE marked/UKCA certified, evidence must be provided that this is in process and whether approval will be obtained within the duration of the project.
  - o If CE mark or UKCA are not relevant, please specify if **other regulatory approval** is needed and whether this has been obtained.
  - Demonstration of clinical efficacy through the appropriate studies, e.g. clinical trials.
- Where does your innovation fit within the care pathway?
  - o Applicants may attach a schematic to illustrate this.
- What is the evidence?

- This may include a description on the size of sample of evidence, which may include the number of patients and sites involved in the generation of evidence.
- Whether PPI played a role in the development of the innovation and how PPI contributed to the studies to gather evidence. For Mental Health Inequalities in Children and Young People, it is important that the product was developed with children and young people, and/or their families/carers' input.
- How will the technology affect services described in the challenges?

#### 4c) Project description and breakdown (max 1500 words)

The applicants are expected to provide the following information:

- The proposed work packages, including what will be conducted within each of the work packages, key measurable deliverables, and how these will be delivered.
- A detailed description of the implementation process and how it will be measured.
- A project Gantt chart to support the project breakdown.
- Key risks to the project and state how these will be mitigated against.
- A description of how patients and service users have been involved in the development of your solution to date and how you plan to involve and engage with them during this project. If you are not planning to engage with patients you MUST explain why.
- A description of evaluation plans for project outputs and outcomes.
- Sample size of the study and how it was calculated.

## 4d) Milestones

Please list up to <u>10 key milestones</u> for the project along with timings for completion. The number of milestones should be appropriate for the project, you do not need to use the maximum number.

The milestones should be comprehensive and the success criteria able to be assessed objectively (e.g. 'all tests delivered to 99% accuracy' or 'for statistical significance, 2000 samples must be processed') with an emphasis throughout on practicality as this initiative is seeking evidence that the technology is viable in the proposed setting and can be effectively deployed to and adopted by NHS trusts. Appropriate record keeping and reporting are essential, but reports are not in themselves the main goal of the project.

#### 4e) Patient and public involvement and engagement (PPIE) (max 500 words)

Patient and Public Involvement and Engagement (PPIE) is an accepted and recommended working practice within healthcare research ensuring that solutions are co-produced with patients, meet patient needs, and to ensure there is an acceptability among end-users. Applicants are expected to develop a thorough PPIE strategy as part of their project. Please consider including the following information in this section:

- What are your plans for PPIE? Please provide specific details such as the way you will be engaging
  with the patients and the public, the frequency at which you will plan this engagement and the
  specific outputs.
- How will the relevant patient groups be involved in the development of innovation roll out and NHS adoption strategy?
- How will you ensure that the innovation will be acceptable to patients, their families, carers, the wider support network, and healthcare professionals?

For further information regarding PPIE, we strongly recommend applicants to refer to <u>Involve guidance</u>.

#### 4f) Equality, diversity, inclusion, and net zero policy (max 300 words)

The SBRI Healthcare programme is committed to promote equality, diversity and inclusion, reduce health inequalities through the development of technologies and solutions it is funding and finally, to ensure that proposed technologies/solutions are considering steps towards the carbon neutral strategy and objectives for the NHS.

Please provide a description on how the technology will:

- Minimise health inequalities, promote equality of access to underserved ethnic and economic groups, and whether steps will be taken to alleviate the potential negative impacts introduced by the technology.
- Contribute to net-zero emission by 2040.

For Mental Health Inequalities in Children and Young People, it is particularly important that the proposed innovation does not exacerbate existing inequalities. It is expected that the applicants have considered all possible ways to mitigate inequalities and how the application would address the problems.

More information on what constitutes a health inequality can be found on The King's Fund website.

The "Delivering a 'Net Zero' National Health Service" report can be found here for further guidance.

## 4g) Intellectual property (IP) (max 300 words)

The definition of Intellectual Property (IP) includes patents, trademarks, designs, copyright (such as new software, checklists, scales, protocols, questionnaires, toolkits, guidelines or similar), research tools (such as data analysis techniques, assays, cell lines, biomarkers, materials or equipment and devices) and (clinical) data.

Please provide details on the following:

- Any relevant existing background IP that will be utilised during the project and the current ownership arrangements, including patents or patent applications.
- Any foreground IP which will be produced or improved during the project and how this IP will be captured and managed. Also provide details regarding expected ownership of foreground IP.
- Any Freedom to Operate (FTO) search that has been conducted to date. If no search has been conducted, please explain your rationale.

## 4h) Key competitors and unique selling point (max 400 words)

Please provide details of any competitor technologies or market alternatives, which should include the following:

- The advantages of the proposed solution compared to the current standard of care.
- Details of any competing technologies or alternatives in the wider market (either on the market or in development), and describe the advantages and innovativeness of your proposed solution over these (i.e. what is your unique selling point).
- Define the market you plan to address; including size, barriers to entry, and cost of the problem.

#### 4i) NHS/Social care implementation strategy and commercialisation plans (max 1400 words)

Please give an overview of your commercialisation and business plan for the product or service you are developing, including market launch and long-term adoption. Please include:

- An overview of your commercialisation and business plans, with consideration to whom will use the solution, how it will be purchased and the likely cost of the solution.
- Your business model for adoption, including implementation costs/implications, workforce requirements, etc.
- Stakeholder engagement plan to support end user/operational/clinical uptake/buy-in/roll out of the innovation
- The expected timescales for regional/national spread and the steps needed for adoption after the project.
- Plans for long term sustainability of the technology.
- How you will ensure that the innovation is affordable to the end users, NHS, and the wider system such as Integrated Care Systems (ICSs) both immediately and throughout the life of the product.
- The evidence, both health economics and delivery of true impact, the NHS and wider system will require before the technology can be adopted.

#### Section 5 - Team

Please note that all project partners should be invited to the application. All participants (Team Members, Subcontractors and Clinical Partners) will need to have approved accounts on the Research Management System so that they can be added to the application form. Accounts are approved by our systems team during office hours. We have included some wording at the end of the document for you to send to your team to help them register. Please ensure you leave enough time for this.

The forecast cost of team members, advisors and subcontractors should be included.

#### 5a) Project team members

Please provide a job title, detailed description of the role performed in the project, time allocated to the project and relevant experience and skills. This section is auto-populated using information provided in the "manage my details" section of the Research Management System account. This should be updated prior to form submission. Please do not include subcontractors in this section.

Team members are those with responsibility for the day-to-day management and delivery of the project. Team members are considered part of the project team and are expected to share responsibility for its successful delivery.

Time allocated to the project should ideally be expressed as a Full Time Equivalent (FTE) percentage (the time allocated during the period of the project indicated as a proportion of the working hours for a FTE position).

Relevant commercial and management expertise of team members should be included.

#### 5b) Clinical partner(s)

Please provide organisation name, clinician's job title, relevant expertise/skills, a detailed description of the role performed in the project, and time allocated to the project.

The use of a clinical/social care partner is not mandatory but it is strongly recommended.

#### 5c) Subcontractor(s) and advisor(s)

Please provide the details of any subcontractors or advisors involved in your application. Please provide a job title, detailed description of the role performed in the project, time allocated to the project and relevant experience and skills of the subcontractor(s) or advisor(s).

The use of subcontractors is optional, however where your proposal involves subcontracted individuals or companies, or benefits from the input of named expert advisors, details should be provided.

While quotes for activities can be in the form of forecasts in this application, you will be asked to provide formal quotes as part of the due diligence process if you are successful.

If an advisor provides services at no cost or at a level of expenses incurred only, this detail should be indicated.

## 5d) Other Posts (max 300 words)

Please provide a detailed description of any other posts that are yet to be confirmed or appointed for the project. Please note, these team members will be expected to start work in around 6 weeks post application acceptance.

Please also provide the job title, a detailed description of the role performed in the project, time allocated to the project and relevant experience and skills that are required for the role.

## Section 6 - Budget

## 6a) Application Finances

Please note that SBRI Healthcare is a pre-commercial procurement programme and as such it is not a grant and not VAT exempt. If you are successful, you will be awarded a Development Contract, which is subject to VAT. All indicated costs should be inclusive of VAT.

On the application portal, please provide the **NET** cost of labour, materials, capital equipment, subcontract, trave & subsistence, indirect, costs, and other in the table supplemented. The cost should exclude VAT. 20% VAT will be applied automatically to calculate the total gross costs.

Applicants will also need to complete and upload the detailed Finance sheet provided before submitting the application.

On the finance spreadsheet, please provide details of all project costs. All costs should **INCLUDE VAT**. The costs quoted must reflect actual costs at a "fair market value" and profit should not be included. Please also provide a breakdown of the following:

- Labour costs for all those contributing to the project
- Material costs (including consumables specific to the project)
- Capital equipment costs
- Subcontract costs
- Travel and subsistence costs
- Indirect costs
- Other costs

Project activities and associated costs that applicants are encouraged to consider (as appropriate) are:

- Cost to supply the innovation.
- Training costs.
- Clinical staff time to administer the innovation.
- Management costs for hospital trusts to implement the innovation.
- Other implementation costs.
- Independent evaluation costs including data collection and analysis, impact on care pathway, clinician and patient acceptability, health economics
- Human factors.
- Minor technology development work (e.g. minor adaptations for user acceptability, system integration, etc.).

Further guidance on how to complete the Finance sheet:

For the staff costs, please provide details of posts and salaries: Staff Member, Employing Organisation, Role on this funding proposal, Grade (put N/A if not relevant), Salary and On-costs (cost incurred by the organisation to employ someone).

The annual costs of posts section is completed using the information from the above section. Please include additional information such as %FTE dedicated to the project & total months on the project (1-9). Use Year 1 for the current Financial Year and Year 2 for the next Financial Year (2022/23). Please also

include details about staff that are to be recruited.

For the travel, subsistence and conference section, please include project-related travel costs using the most economic means possible. Please note that meals & accommodation are acceptable. Remember to add details to justify the costs (number of visits, travel required, subsistence associated to a specific meeting, etc.) and provide details of conferences and the number of people attending (if applicable).

In the equipment section, capital expenditure should be clearly justified in relation to the project and the cost should take into account the duration of the project. Leasing equipment from a provider or borrowing from existing facilities is an option to consider. Any equipment over the value of £250 should be itemised. Anything under can be grouped. All equipment should be clearly justified at the bottom of the spreadsheet.

In the consumables section, please provide details of the consumables required for the project and justify the costs wherever possible, particularly for larger consumables items.

In the PPIE section, we expect to see payment for PPIE time (rates should be provided to justify the costs), PPIE travel fees, accommodation and subsistence where applicable, support costs if required and training.

In the dissemination section, please provide any dissemination costs related to publication or dissemination of findings.

Finally, you will have to complete the other direct costs and indirect costs categories. The other direct costs usually refer to all other cost items which do not fit elsewhere. Hourly/daily rate should be included for each provider e.g. consultancy, subcontractors, IP and legal. Please note that services outside England are acceptable but should be clearly justified in the justification section. Indirect costs may include estate costs (for example building and premises costs, services/utilities, rent or lease, insurance, etc.). Other indirect costs may include other departmental costs (for example Finance & HR).

#### 6b) Justification (max 500 words)

Please provide a justification of the costs, (ALL COSTS SHOULD INCLUDE VAT), including indirect and other costs, daily rates for staff involved, and quotes from subcontractors where applicable.

If there is significant use of subcontractors, please explain how these will be used and the costs of each. Please note the Assessors are required to judge the application finances in terms of value for money, evaluating whether the proposed cost for effort and deliverables in a proposal reflect a fair market price.

## Section 7 – Supporting Information

Please submit the following supporting document with your application form:

- Regulatory approval document/clinical evidence to support innovation
- Healthcare pathway diagram (requested in section 4b not mandatory)
- Project Gantt chart (requested in section 4c)
- Finance Sheet (requested in section 6a)

In addition to the supporting documents above, applicants may submit **1 A4 page**, (e.g. a flow diagram illustrating the study design and the flow of participants, diagrams, pictures etc.). If submitting a flow diagram, applicants should also describe complex interventions and controls as accurately and fully as possible within their diagram.

Please note that uploads must be provided as a Word or PDF document.

Please note that excessive attachments may lead to your application being excluded from the assessment process.

#### Section 8 - Administrative Contact Details

Please provide the details of an administrative lead as a secondary point of contact for any queries relating to this application.

## Section 9 - Validation Summary

Please follow the steps on the screen in order to validate and submit your application.

All mandatory fields should be completed and project partners invited should have validated and approved their participation.

Once submitted, the completed application can be viewed or downloaded from the PMO RMS Portal. However, you will no longer have the ability to edit the application.

Please visit the <u>SBRI Healthcare competition pages</u> for details on the application deadlines. Only those applications received before the competition deadline will be accepted. **PLEASE <u>DO NOT</u> SEND COMPLETED APPLICATIONS BY POST OR BY ANY OTHER MEANS OTHER THAN THROUGH THE PORTAL.** 

For more information please see <a href="www.sbrihealthcare.co.uk">www.sbrihealthcare.co.uk</a>. Questions on the challenges and scope of this SBRI Healthcare competition should be addressed to the Programme Management Office via email to <a href="mailto:sbri@lgcgroup.com">sbri@lgcgroup.com</a>.

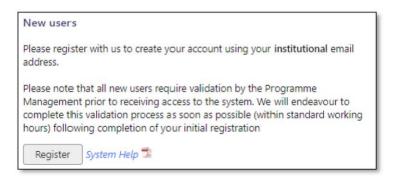
# Further guidance on using the Research Management System (RMS)

Applications must be made through the RMS <u>online application portal</u>. A template application form may be downloaded from the SBRI Healthcare website. However, please note that this is for demonstration purposes only and may not be used to submit an application.

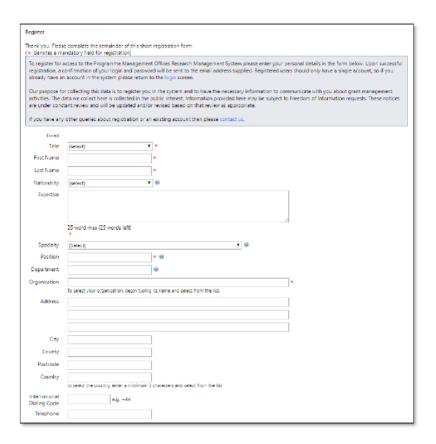
## Register as a new user

Only registered users of the RMS application portal can apply. Applicants new to using the application portal should register as a new user. Once logged into your account the application portal home page is the starting point to create applications, access co-applications and to update contact information and professional details.

1. As a new user, on the right-hand side of the homepage, select "Register"



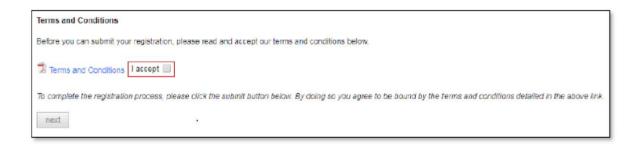
- 2. Enter your organisation email address and confirm. Your email address will become your sign-in username. Please use your organisational (NOT personal) email address for this. Select "Next"
- 3. Enter your details in all fields and select 'Next'. Note: denotes a mandatory field which must be completed.



4. Ensure the Consent question entitled "Communication Preferences" at the bottom of the page is answered.



5. Select the "Terms and Conditions" and, once read, tick the confirmation box.



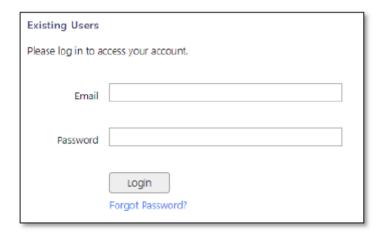
- 6. Click "Submit"
- 7. An email containing a link to create your password to subsequently gain access to the system will be

- sent to the previously entered email address once your registration details have been approved by a grant administrator. Please allow two working days for the registration to be completed.
- 8. Please add <a href="mailto:pmo@ccggranttracker.com">mailto:pmo@ccggranttracker.com</a> to your trusted senders as these emails are prone to Spam or Junk folders.

In order to register successfully, please comply with the following:

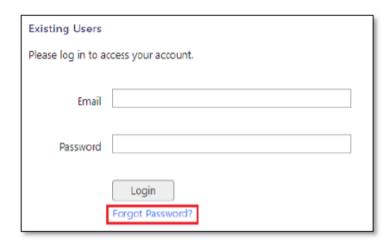
- We insist on institutional emails if available This is a double check that the contact is who they say they are and represent the organisation registered with (anyone can create a Gmail/Hotmail account and claim to be someone).
- We do not accept generic / group emails The RMS is used for conflict checks and will flag
  these. If numerous people are using one email conflicts aren't picked up and we will not know who
  is using the system.
- We do not accept multiple accounts Again to ensure conflict checking is effective.
- Registered Organisations The UK associated organisation must be registered / available on Companies house, Charity Commissions, UK Register of Learning Providers or Organisations Data Service. Funding will only be given to organisations which are suitably credit checked using these.
- Sole Traders The PMO does not fund sole traders as they will not pass financial checks.

#### Access the RMS



- 1. Enter your email address and password and click "log in". If you are accessing the system for the first time, the Basic Information page will display. Once the relevant fields have been completed, press Save button
- 2. The account home page will now display indicating access to the system.

#### Forgotten password



- 1. From the PMO home page click the "Forgotten Password?" hyperlink.
- 2. Enter the email address with which you registered and click submit
- 3. An email containing instructions for resetting your password will be sent to the registered email address.

Please note, persistent use (>3 attempts) of an incorrect password will lock your account; this is to protect you from attempts to access your data by a third party. If this happens, you can request a new password via the forgotten password function.

#### The RMS Home Page



#### Managing my details

Select "Manage My Details" from the left-hand menu



Lead applicants and project partners (team members, clinical partners or subcontractors) can manage their basic contact information and curriculum vitae (CV) through the 'Manage my Details' link on their application portal home page. Lead applicant and project partners' contact information is integrated by the application portal into the relevant fields during the application process.

The lead applicant must initially create the new application.

1. Select "My Applications" from the left-hand menu and click the "New Application" button

New Grant Application

To apply for funding from one of our grant streams click here.

- 2. A list of open funding rounds will display along with further information about the competition.
- 3. Selecting "Apply" will open an application form for completion Denotes a mandatory field

From the application summary page, the application can be edited by clicking on the 'Edit' button. The different sections of the application form can then be accessed via the list of hyperlinked buttons on the left-hand side of the application portal webpage. You can move from page to page either by using the 'Previous' and 'Next' buttons, or using the list on the left-hand side of the web page.

Most questions are associated with contextual help buttons and clicking on them will open up pop-up windows containing brief guidance notes that supplement the published guidance for applicants. It is strongly advised that applicants refer to the published guidance first and then use contextual help as they complete and review each question, as contextual help is not designed to replace it. Mandatory questions are flagged with a red dot.

The research team can collaborate with the lead applicant to edit the content in the application by being invited to be a team member or a clinical partner through the Team section (section 5) of the application form.

The lead applicant can use the search tool to find project partners and then to invite them to join the application. The application portal will automatically dispatch an email inviting the project partners to confirm their participation in the application. The invited project partners can then decide whether to accept the invitation and consent to the application being submitted jointly in their name. They will need to log into the application portal and follow the links to 'Confirm' their involvement on the co-application summary page. Once confirmed, the project partner will be granted access to edit the online application form.

All project partners must not only 'Confirm' but also 'Approve' their invitation to participate in the application electronically on the co-application summary page in advance of the submission deadline.

The system will prevent your project partners accessing your application at the same time as you. This stops applicants and co-applicants inadvertently making changes to the same part of the application at the same time and overwriting each other's work.

#### Remember to save your work

You will be prompted to save your work if you leave the browser in application editing mode. We recommend you save your work regularly to minimise the risk posed by any local computer or internet problems. You can save and return to the application form as often as you like prior to submission.

## Exiting and returning to work on your form

Should you wish to exit your form, you can return at any time; simply log in using your username and password and select 'My Applications' from the menu. You will then be presented with a list of all the applications you are currently involved with as well as providing details as to their stage in the submission process.

#### Validation and submission of the form

The lead applicant can review the progress of their application at any time by selecting the 'View/Print' option on the application summary page to generate the application as a PDF File.

When the application form is complete, it must be validated prior to submission. The validation step is a check run by the application portal to assess whether all the mandatory questions contain information. It will provide a list of links to any parts of the form where corrections or additional content are needed.

Once the application has been validated successfully and no further corrections are needed, the lead applicant can submit the application by clicking on the 'Submit' button on the lower right-hand side of the application summary page.

## Following submission

A programme specific reference number will be assigned to the application once it has been submitted. After the relevant competition round closes, the application will automatically enter the process of being considered for funding.

If you have any questions regarding your application, please email <a href="mailto:sbri@lgcgroup.com">sbri@lgcgroup.com</a>