#### Our offer of support

The National Institute for Health Research (NIHR) works in partnership with the UK's National Health Service (NHS) to help the life sciences industry plan, set-up and deliver high quality clinical research to time and target.

Our Study Support Service is free and is available to all life science industries, and Contract Research Organisations, regardless of location, study type, study size, or therapy area. Through this service we will provide you with unparalleled access to, and understanding of, the NHS research environment.

Our service includes a range of practical support and tools to assist with study feasibility, set-up, costing and contract negotiations, and performance monitoring. The service is designed to be flexible and can be shaped to meet your needs - we can support the development of your study from the outset, or enhance work you've already begun. The earlier you get in touch, the more we can help.

All our NHS sites are connected through our national network which is managed through 15 regions covering England. Our dedicated, research-ready workforce is embedded in the NHS within these 15 regions. This research infrastructure is globally unique and enables a 'do once and share' approach to study delivery which means you benefit from country-wide expertise and experience. It also enables national oversight of all the studies we support and the ability to target local support where, and when, it is needed.

So whether you are a pharmaceutical giant, a medium-sized medical technology firm, or a small CRO... we can help.

#### **Further information**

This free offer of support is provided by the NIHR Clinical Research Network. Further information is available on the NIHR website:

www.nihr.ac.uk/industry-study-support-service



#### Contact us

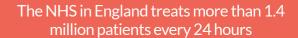
We have a dedicated Study Support Service Helpdesk to answer your questions:

Phone: 00 44 (0) 113 343 4555 Email: supportmystudy@nihr.ac.uk



# Our offer to the life sciences industry

Free support, advice and expertise to help the life sciences industry to plan, set up and deliver high quality clinical research in the UK's National Health Service.



The NIHR spends more than £500 million per year on clinical research infrastructure

In 2018/19 we supported delivery of 1,523 commercial contract studies

In 2018/19 we recruited 870,250 participants into clinical research studies

Over 46,000 of those participants were recruited into commercial contract studies

In 2018/19 we worked in partnership with 533 companies and 113 Contract Research Organisations

"This was our first UK trial and working with the NIHR enabled us to hit the ground running in the UK. From quick adoption of the trial into its research portfolio and identifying interested investigators and sites within NHS, to ongoing monitoring of enrolment against performance objectives. We felt like we had a partner who was genuinely interested in a successful outcome."

Novian Health Inc, US-based medical device manufacturer



## Providing free support throughout the study life cycle, across England



# 1. Early contact and engagement

Get a head start in delivering your clinical trial. We offer personalised one-to-one advice about all the different areas of support available to you.

By working with us early on, you can access our full range of support and create a bespoke service that meets your needs and provides benefits throughout the full life-cycle of your study.

Our support at this stage may involve advice on regulatory submissions, completion of costing templates, standardised Clinical Trial Agreements, exploration of recruitment pathways, access to Good Clinical Practice (GCP) training and local intelligence to optimise delivery of your study.



# 2. Early feedback (national feasibility)

One single online submission provides you with access to rapid feedback from communities of NHS clinical experts and key opinion leaders across all therapeutic specialties. This helps you determine if your study is compatible with UK practice and can be delivered in the NHS. It increases your chances of delivering your study on time and meeting your recruitment target.

Our nation-wide network structure enables us to deliver comprehensive and efficient early feedback within 10 working days. Clinical experts embedded in the NHS look at study complexity, patient population, competing studies, timelines and recruitment strategy and offer valuable feedback that can improve study delivery and success.

Our national database collates and provides data from all commercial and non-commercial studies that have registered for our support. This intelligence gives a unique and invaluable insight into the capacity and capability of the Network.



### 3. Site identification

Our site identification service enables you to rapidly receive expressions of interest from investigators from over 240 NHS organisations and 10,000+ General Practices in England. All you need to do is complete a simple online submission form with basic details of the study. After receiving expressions of interest, you can engage directly with interested investigators and teams for more in-depth site selection discussions.

Our national approach to site identification is a globally unique mechanism through which all NHS organisations and General Practices can be notified of the latest commercial contract research opportunities and express an interest in participating. It gives you an up-to-date insight into the most suitable sites to deliver your study, while minimising the resource you need to rapidly identify interested sites for detailed feasibility discussions.



## 4. Optimising delivery (site level feasibility)

If you have not benefitted from our early contact and engagement service we undertake an assessment to inform and enable the type of support you'll need.

Our site intelligence service utilises local site and study data and expertise on previous recruitment performance to sense check local recruitment targets, identify competing studies and identify any potential resource issues. This intelligence is designed to supplement your own feasibility, site qualification and selection activities, giving you greater confidence in setting site targets and set-up timelines. This improves the predictability of site set-up and recruitment.



## 5. Effective study set-up

We create a study-wide action plan which serves as a central resource to help all sites set-up effectively. It helps to maximise study delivery, enables sites to develop proactive solutions and encourages collaborative working.

The study-wide action plan also works alongside our good practice principles for local site assessment, arrangement and confirmation of capacity and capability to provide consistency in set-up across all sites. Our national approach ensures your study is set up as quickly and efficiently as possible.



### 6. Performance monitoring

Once your study is open to recruitment, we work with you to ensure it is making steady progress. Our dedicated Industry Operations Managers in each of our 15 regions are embedded at site level to support study management and delivery. Our data systems collate site level information to provide study-wide oversight, which enables proactive performance monitoring. Our Red-Amber-Green (RAG) reporting system enables a nationwide understanding of recruitment status and helps us to pinpoint areas where additional clinical trial support may be needed.