



**Call for Letters of Support from Chief Executives of CROs for  
High Throughput Clinical Research Centres in the NHS**

**Revised Deadline : 24 July 2018**

Dear Sir or Madam,

Currently there is a unique opportunity for CROs to utilise the disruption caused by Brexit and raise their profile in the eyes of the UK Government. This summer the UK Department of Health and Social Care will consider an application for the funding of High Throughput Clinical Research Centres in the NHS – your letter of support for this funding request is vital.

High Throughput Centres will be enormously beneficial to patients, the NHS and CROs such as yours. Your letter will also raise the profile of your company and CROs in general. This is important because at UK Parliamentary level, the vital role of CROs and the funding you bring to NHS through clinical trials is largely unrecognised. *Most Government ministers and civil servants wrongly believe that UK commercial clinical research is conducted by pharmaceutical companies, despite CROs funding in excess of 60% of commercial trials within the NHS.* In order for CROs to have a voice at the table and to maximise the value they can bring to patients and the NHS that perception needs to change!

**Your Letter of Support**

Details of what to include in your letter of support can be found in Attachment 1 to this letter.

**About High Throughput Centres and the Life Sciences Industrial Strategy 2017**

IAOCR and Dr Sheffield OBE, CEO of the NIHR (National Institute for Health Research) have co-authored a white paper in response to the Life Sciences Industrial Strategy (LSIS) 2017 on “High Throughput Clinical Research Centres in the NHS”. One of the LSIS goals is to increase the number of clinical trials conducted in the UK over the next 5 years by 50%. We believe that High Throughput Centres will provide a major contribution, facilitating the NHS and industry working together, collaboratively for the benefit of patients and all stakeholders.



Details of features and benefits of High Throughput Centres are included in Attachment 2 to this letter. The full paper will be released for review within the next few days. In the interim, if you have any questions or comments Dr Sheffield would be pleased to speak directly to you and answer any questions you may have (please let me know if you require an introduction).

Save the Date

IAOCR and NIHR will be jointly hosting a round table meeting on High Throughput Clinical Research Centres in the NHS for clinical research and NHS CEOs on 18 October 2018 in London (location to be confirmed).

IAOCR will collate the “pack” for the Department of Health and Social Care and will also deliver letters of support to the Prime Minister, Theresa May. To meet the deadline for the review of the funding application please email me a copy of your letter by Tuesday 24 July 2018.

I look forward to hearing from you. Please don't hesitate to contact me if you have any questions or comments.

Yours faithfully,

*JJNorth*

Jacqueline Johnson North  
Co-Founder and CEO, IAOCR

## What to include in your letter of support

Please provide your letter on company letter head with your logo (scanned, emailed copied will be sufficient – hard copies will not be necessary).

- A brief overview of the size and importance of your company within the clinical research industry (UK/globally).
- A line or two about your belief that there is an opportunity for the NHS to attract more clinical trials.
- A clear statement that changes and investment are needed to take advantage of the post-Brexit opportunity.
- A clear statement of your support for High Throughput Clinical Research Centres in the NHS.
- The letter should come from the CEO of your organisation.
- Please email your letter to [jjnorth@iaocr.com](mailto:jjnorth@iaocr.com)

Thank you for your support!

## Features and Benefits of High Throughput Clinical Research Centres in the NHS

*Excerpt from High Throughput Centres in the NHS, a report to the UK Government from the clinical research sector - aiding delivery of the Life Sciences Industrial Strategy 2017 by Sir John Bell*

High Throughput Clinical Research Centres can provide a major contribution to the way in which clinical trials are conducted in the UK. They will facilitate the NHS and industry working together, collaboratively for the benefit of patients and all stakeholders.

A 2014 paper published in the BMJ (4) highlighted that the challenge of working with busy healthcare professionals who have competing priorities is one of the key reasons for delays in the setup and conduct of clinical trials.

**The creation of High Throughput Centres, staffed with clinical professionals that are competent in conducting clinical trials and whose work is dedicated entirely to the conduct of clinical trials, would provide a number of benefits:**

- Rapid setup times:
  - The need for the assessment of the feasibility of research would be largely redundant. The centres would be fit-for-purpose and there would be no need for repetitive surveys to be done.
  - All processes, people and technology would be in place ready for a fast and effective study startup.
  - Centres would be pre-approved by the HRA.
  - Centres would have pre-determined capabilities and would declare these capabilities for conducting studies in the therapeutic areas in which they had the relevant expertise and specialisms.
  - R & D function based in the High Throughput Centre so that any review would be prioritised and expedited.
- Higher rate of trial completion within timelines:
  - The exclusive commitment to the conduct of clinical trials would enable the relevant expertise and efficiencies to be developed.
  - The centres could provide advice on protocols to Sponsors pre-trial to help facilitate good trial design and to avoid unnecessary protocol amendments downstream.
  - Improved patient recruitment and engagement through:
    - Community outreach initiatives can be focused around the centres to raise the general awareness of clinical trials within the local communities.
    - Robust and systematic patient recruitment and engagement processes.
    - Increased awareness of High Throughput Centres would enable increased patient referral rates.

4. Opening research sites in multicentre clinical trials within the UK: a detailed analysis of delays, Anna Kearney et al., BMJ Open, vol. 4, Issue 9

- Further professionalising the investigator site model:
  - Providing consistent standards and processes across the High Throughput Clinical Research Centres system, giving confidence to Sponsors and patients alike.
  - Providing best practice advice to other NHS Investigator Sites – demonstrating a “Centre of Excellence” approach.
  - Lack of competing priorities for site staff, enabling them to remain focused and engaged with the research and participating patients.
- Reduction in the amount of site oversight and monitoring needed.

**Features of the centres would include:**

- For ease of access to large numbers of patients, the centres could be located within large conurbations.
- Access to patient data nationally so that potentially eligible patients could be identified while complying with data protection laws and respecting patient confidentiality. This could enable more accurate predictions of patient recruitment rates. Regional data hubs can help with access to potential clinical trial subjects from the patient population.
- The centres would need:
  - Adequate resources of expert staff, perhaps with a full time core team and access to bank staff as necessary.
    - Competence in GCP and UK regulations thereby avoiding unnecessary delays in study set up (by having all the relevant documents etc. on file).
    - Competence in ethical patient recruitment and retention methods.
    - Competence in collaborating with Sponsors, and CROs acting on behalf of Sponsors.
    - Specialism in relevant therapeutic areas.
  - Appropriate equipment.
  - Use of a central laboratory.
  - Making best use of any UK trial infrastructure already set up.
- The centres could provide a very positive experience for patients by:
  - Providing transport if required.
  - Providing advice to Sponsors on protocols to ensure they are both practical to conduct and patient-friendly.
  - Providing options for visiting patients at home if necessary.
  - Making the general experience of patient’s visit to the site a positive one by ensuring the patients are adequately engaged and informed during and after the trial e.g. the outcomes of the trial, etc.
  - Actively seeking feedback from patients about their experience during the clinical trial.
- The centres would be rigorously tracked regarding progress to help ensure that they are on target and if not what solutions there might be to correct any significant variance on progress.