Harnessing Electronic Data Capture (EDC) Capabilities To Support World-leading High Impact Clinical Research

To ensure the continued efficiency and robustness of clinical research, a comprehensive EDC market evaluation and tendering activity were undertaken.


Imperial College London

LONDON, UNITED KINGDOM, July 14, 2021 /EINPresswire.com/ -- Based in the heart of London, Imperial College London focuses on four main disciplines of science, engineering, medicine, and business and is renowned for its application to both industry and enterprise.

Formed in 1907, Imperial College London is home to the greatest concentration of high-impact research of any major UK university and is fourth in the UK for world-leading research. Approximately 91% of their research activity has been judged as world-leading or internationally excellent; the highest proportion of all UK universities. Their mission is to achieve enduring excellence in Research, Education in Science, Engineering, Medicine, and Business for the benefit of society.

Clinical Data Systems, part of Imperial Clinical Trials Unit (ICTU), School of Public Health, manages and supports Imperial College London's academic researchers by providing Electronic Data Capture provision. To ensure the continued efficiency and robustness of any software provision for clinical research, a comprehensive market evaluation and tendering activity of electronic clinical trials software was undertaken in 2019/2020. The key objectives of this activity were to find a cloud-based Electronic Data Capture (EDC) software solution to achieve the following:

•A solution that meets forward-looking requirements from Chief Investigators (CIs)
•Provision of additional tools that would allow ICTU to increase the throughput of clinical trials

•Ensure the College continues to comply with all mandatory regulatory requirements that

support clinical trials-based research
•Provide appropriate services for small and large scale trials, a faster development timeline, and an ability to support trial needs, in a connected healthcare environment.

As a result, in September 2020 Imperial College London implemented OpenClinica; a GCP, 21 CFR Part 11, HIPAA, and GDPR compliant SaaS platform to support clinical research for academic researchers College-wide. After the implementation and necessary computer system validation activities, work started in earnest on several research studies sponsored by Imperial College London.

Below are brief overviews of these studies and how they are harnessing the technological capabilities of OpenClinica software to enhance and facilitate optimised data collection.

1. ePARCA-R Study CI: Professor Neena Modi

This prospective study involving all West London NHS neonatal units tests a new digital application developed by the ICTU team to enable parents to complete a validated questionnaire electronically when their child reaches their 2nd birthday. The ePARCA-R questionnaire provides standardised scores on language and cognitive development, information that is invaluable for both clinical care and research. The goal is to obtain this information systematically on all children at risk of learning problems so that they can receive timely intervention and support. Parents will be randomised to receive regular contact during the two-year study period either by Text and Email, or Email only. The study is designed to test all aspects of the process with a view to national scale-up.

OpenClinica has been used to develop prototype e-forms to facilitate a mobile phone/internet-based application, enabling the completed questionnaire to be externally linked back to data currently captured in the National Neonatal Research Database hosted by Professor Modi's team.

2. RIO CI: Professor Sarah Fidler

A randomised placebo-controlled Phase II trial of ART plus dual long-acting HIV-specific broadly neutralising antibodies (bNAbs) vs ART plus placebo in treated Primary HIV Infection on viral control off ART.

This is a blinded two-stage study utilising randomisation, triggered directly within an OpenClinica CRF. The software facilitates the integration of the complex design enabling the prospective unblinding of participants after the first stage of the study to determine treatment for the next stage. OpenClinica Insight allows the study team monitoring capabilities of visit windows in real-time and robustly supports timely safety data reporting.

3. CURESPONSE CI: Dr. Jon Krell

A Phase II, multi-centre prediction study of the cResponse Ex Vivo Organ Culture (EVOC) model in patients with suspected or confirmed advanced or metastatic malignancy. Primary objective to demonstrate the sensitivity and specificity of the cResponse EVOC model for predicting a patient's clinical response to a specific anti-cancer therapy.

For this non-IMP study, the OpenClinica provides a simple and slick design option, all the while integrating the powerful capabilities of the platform, allowing the study team to capture high-quality data.

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