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ICON Contributes to Major European Research Study That Aims to Improve Treatment for Traumatic Brain Injury

Recommendations from the longitudinal observational research study will be presented today at the European Parliament

DUBLIN--(BUSINESS WIRE)-- **ICON plc, (NASDAQ: ICLR)** a global provider of drug development solutions and services to the pharmaceutical, biotechnology and medical device industries, today announced that it has contributed to a complex pan-European traumatic brain injury (TBI) research study involving over 4,500 patients in 65 sites in 20 European countries. ICON provided site management and source data verification (SDV) services to the study, which was supported by the European Union and led by Professor Andrew Maas from the University Hospital Antwerp (Belgium) and Professor David Menon from the University of Cambridge (UK). ICON's Dr. Valérie Legrand, VP Project Management and a recognised expert in CNS, also provided clinical expertise as a member of the project's [Management Committee](#). The [Lancet Neurology Commission on TBI](#) is being launched at the European Parliament today and will set out clinical and research priorities and recommendations to address the varied challenges in TBI.

In the European Union, 2.5 million people suffer a TBI each year of which 57,000 patients die. TBI is also the leading cause of death and disability in young adults and the incidence in elderly patients is also increasing. Treatment for TBI is challenging and large variations exist between countries which led to a global TBI initiative involving research projects in the Europe, the US, Canada, Australia, China and India. [CENTER-TBI](#) is the European longitudinal observational research study that combines the expertise of over 150 international clinicians and researchers.

From December 2014 to October 2017, almost 4,500 patients enrolled in the study at 65 sites in 20 European countries. ICON deployed both remote and onsite monitoring services and performed SDV on a pre-defined sub-set of key patient data points, which in the course of the study amounted to verification of over 13,000 data points.

The [Commission on TBI](#), published today in [The Lancet Neurology](#), identifies 12 key recommendations and policies to improve the prevention, quality of care and clinical research in TBI. It seeks to identify strategies to better characterise TBI, increase prognostic accuracy, and adopt a more precision-medicine approach to treatments. The Commission also promotes the use of new tools for clinical evidence generation and implementation, so that research outputs can be more rapidly integrated into clinical care. Moreover, it highlights the importance of international collaboration of funding agencies and researchers to provide a global response to reduce the individual and societal burden of TBI.

"The need to improve prevention and clinical care in TBI is huge," commented Professor Andrew Maas, Project Coordinator, CENTER-TBI. "The international collaborations between funding agencies and researchers combined in the [InTBIR initiative](#) is unparalleled and offer a great opportunity to pioneer new approaches to research, including the creation of a "living evidence base". The involvement of ICON in the European CENTER-TBI study has been fundamental in managing this large study across so many different countries and in ensuring quality control of CENTER-TBI. All partners are, however, equally important: CENTER is a team effort, characterized by collaboration, data sharing and group authorships. The recruitment to CENTER-TBI is nearly complete, and we are proceeding to the analysis phase with results expected in 2018."

"ICON is proud to have contributed to such an important research project to advance the diagnosis, treatment and care of patients with TBI," commented Dr. Valérie Legrand. "TBI is a highly complex and heterogeneous condition which has hindered the development of new treatments. The CENTER-TBI research project, together with the other large global research international programmes, will help healthcare professionals, patient organisations, policy makers and funding agencies to better understand TBI which will result in more targeted treatments and better overall patient care."

About CENTER-TBI

CENTER-TBI is a large European project that aims to improve the care for patients with Traumatic Brain Injury (TBI). Led by Professor Andrew Maas (Antwerp University Hospital and University of Antwerp, Belgium) and Professor David Menon (University of Cambridge, UK), it combines the expertise of over 150 international clinicians and researchers, many of whom are part of the International [Initiative for Traumatic Brain Injury Research](#) (InTBIR) More information on CENTER-TBI is available at <https://www.center-tbi.eu/>

About ICON plc

ICON plc is a global provider of drug development solutions and services to the pharmaceutical, biotechnology and medical device industries. The company specialises in the strategic development, management and analysis of programs that support clinical development - from compound selection to Phase I-IV clinical studies. With headquarters in Dublin, Ireland, ICON currently, operates from 97 locations in 38 countries and has approximately 13,100 employees.

Further information is available at www.iconplc.com/cns

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