



eSource Symposium Seminar

26 April 2022, 1:00 PM – 2:00 PM U.S. EDT

Title: Scaling up Trustworthy RWD for Clinical Research: The Momentum in Europe

The contribution of Real World Data (RWD) to clinical research is accelerating across Europe. Building on results of public-private projects co-financed by the pharmaceutical industry and the European Commission (the IMI programs), hospital EHRs are being queried to help optimize clinical trial design, assist in recruitment and reduce duplication of data entry into EDC systems. RWD is also being used to generate regulatory-grade evidence for decision making. In parallel, Europe is investing in federated big health data infrastructures to scale up insight generation for the benefit of the whole health and research community. These trusting uses of RWD critically depend upon the eSource robustness of hospital EHR systems and the quality of the EHR data. The European Institute for Innovation through Health Data (i~HD) is working with industry and hospitals to develop assessment tools to verify this regulatory-grade quality, and to support hospitals with improving their readiness to support greater learning.

Presenter: Dr. Dipak Kalra, President of i~HD



Professor Dipak Kalra, PhD, FRCGP, FBCS, is the President of the European Institute for Innovation through Health Data (i~HD). Dr. Kalra plays a leading international role in research and development of Electronic Health Records, including the reuse of EHRs for research. Dipak was a former London general practitioner and until recently the Professor of Health Informatics at University College London. He is a Visiting Professor at the University of Gent. Dipak has over the past 25 years led the development of ISO standards on EHR

interoperability, personal health records, EHR requirements and data protection, and he leads multiple EU projects in these areas. His current projects include the generation of real-world evidence in pregnancy, the governance of patient-centric clinical trials, policies and frameworks for the design and governance of mobile health programs, scaling up the quality, interoperability and the reuse of health data for research including inputs to the European Health Data Space, the scaling up of the collection and use of health outcomes towards more value-based care, and initiatives to explain the value of research using health data to the public.

The European Institute for Innovation through Health Data (www.i-hd.eu), which Dr. Kalra co-founded in 2016, promotes the learning health ecosystem by developing strategies and enabling solutions that can improve healthcare and accelerate research through more trustworthy learning from health data. It is a multi-stakeholder not-for-profit body that supports healthcare and research organizations, and patients, to capture and reuse better quality health data. It promotes the adoption of interoperability standards, data quality assessment and improvement, good practices in privacy protection and focusing healthcare on outcomes and value.