

A global data and Secured Data Environment technology framework to support healthcare decision-making with Real-World Data

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OBJECTIVES The growing demand for robust Real-World Evidence (RWE) in healthcare decision-making, has prompted the development of Secure Data Environments (SDE). The SDE developed by BC Platforms hosts deidentified Real-World Data (RWD) from hospitals, biobanks, and research centers, and aims to facilitate health technology assessments and post-launch evidence generation. This work elucidates the functionalities of the SDE and how it fosters the generation of Real-World Evidence pertaining to standard of care and patients' outcomes.

METHODS: The SDE provides remote, web-access to data adhering to the Five Safes model for privacy (Safe People, Projects, Settings, Data, and Outputs). It offers multiple deployment options: on-premises setups at hospital/biobank sites, utilization of national high-performance computer clusters, and integration with major cloud providers. The deployment options are designed to comply with local, regional, and national data governance regulations such as GDPR, HIPAA and EHDS. Structured RWD encompasses demographics, healthcare encounters, prescribed medications, hospital admissions, International Classification of Diseases diagnoses, genomics, proteomics, diagnostic methods, and imaging data.

RESULTS: As of May 2024, BC Platforms encompasses a network of over 90 data partners across six continents. The Data Network covers a catchment of 80 million subjects with clinical data and 500,000 subjects with linked clinical-genomic data. The covered therapeutic areas include oncology, haematology, neurology, metabolic disorders, cardiovascular diseases, autoimmune conditions, and rare diseases.

CONCLUSION: This expansive Data and SDE technology framework enable the creation of representative cohorts for drug development and is currently tested for applying machine learning models to explore drug repurposing opportunities. It allows to aggregate multimodal RWD, gathered during patient care with the potential to uncover biological signals, and to assess test pathways that reflect standard of care. This structure is instrumental in developing comparator groups for clinical utility and cost consequence analyses, particularly relevant for precision medicine and rare diseases.