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## Leveraging the power of real-world data across the R&D value chain

Pharma companies and regulatory agencies recognize how real-world data can enhance drug development from target identification to clinical trials. BC Platforms provides broad and secure access to this valuable resource in addition to critical tools, interoperable infrastructure, and expertise.

For over 25 years, BC Platforms has been a world leader in life science and healthcare data-management and analysis. Through its unrivalled network of data partners, and a powerful discovery and research platform, BC Platforms brings together and harmonizes complex biological and patient data in a secure trusted collaboration environment (TCE), enabling end users to safely access and utilize data without moving them, to help fuel data-driven decisions across the entire pharmaceutical value chain.

Through BC Platforms' global data-partner network, users can access and analyze not only vast amounts of curated, annotated, and harmonized multi-omic data, but also real-world data (RWD) on patients observed in real-world settings collated from a diverse range of sources including electronic health records, insurance claims, and patient surveys.

#### **Providing real-world evidence**

RWD are increasingly recognized by drug developers and regulatory agencies as a powerful means to generate real-world evidence (RWE) to inform therapeutic development, outcomes research, patient care, and safety surveillance. The datapartner network draws on more than 17 partners around the world to bring together secure and harmonized RWD on more than 55 million demographically diverse patients from a wide range of geographic regions-the European Union (EU), Americas, Asia-Pacific and Africa (Fig. 1)—with genomic data available for more than half a million.

Randomized clinical trials (RCTs) comprising a treatment arm and a control or placebo arm have long been the gold standard for providing evidence of drug efficacy and safety, and the experimental data they produce are often contrasted with RWD. Yet there is growing appreciation that experimental data and RWD are often complementary, and that RWD offer a way round the challenges inherent in running RCTs for rare diseases or in situations where it would be unethical to give patients a placebo.

For rare diseases, it can be challenging to recruit a sufficient number of patients in a standard RCT to create a control arm that has the required statistical power. With BC Platforms' global data-partner network, trial sponsors investigating a rare disease can create an external control arm (ECA) that brings together historical and contemporaneous information about patients with the disease who have not received the experimental therapeutic. Using RWD to create ECAs not only can make clinical trials feasible, but also can reduce costs and shorten development timelines.



encompasses over 55 million patient lives globally.

In other contexts, running a control arm in a standard RCT may be deemed unethical, such as when investigating an experimental drug for a cancer that has no available treatment options. In this situation, RWD on patients who have the disease and have never had the option of receiving the experimental therapy can be used to create an ECA that can be compared with a single-arm trial in which every patient received the experimental drug.

Creating valid ECAs to complement single-arm trials requires matching patients based on various characteristics, which has historically been challenging due to a lack of interoperability and harmonization between various RWD sources. BC Platforms' global data-partner network overcomes these limitations, allowing users to leverage the full power of RWD in designing and running clinical trials that may otherwise have been unfeasible.

Beyond acting as an ECA in a clinical trial, RWD can also be used at earlier and later timepoints in the developmental pathway. BC Platforms has, for example, worked with companies to enhance early target discovery using phenotypic data from 500,000 individuals in the UK Biobank; this required the curation and harmonization of the data through BC Platforms' proprietary software systems, and led to more-focused target identification and reduced timelines for data access and analysis.

### Partnerships and beyond

At the other end of the pipeline, BC Platforms worked with a leading biotech to use RWD to support an application for label expansion for an approved drug-a process that required clinical

and genomic data on more than 100,000 patients. Creating this database was unfeasible for the company; but BC Platforms, through its global network of partners, provided key sources of data—which the sponsoring company would not ordinarily have been able to access or analyze-to identify patients at greatest risk and most eligible for targeted treatment to support label-expansion discussions with health authorities. In addition, genomic analyses allowed for the creation of a polygenic risk score to facilitate a personalized treatment path for the drug.

Access to the right data-from multi-omics to RWD and clinical trial data—and the means to interrogate and analyze them are widely recognized as key drivers of success and cost-effectiveness in the drug development space. BC Platforms provides access to these crucial data from its global partners through its platform technology and federated architecture. Being International Organization for Standardization (ISO) certified as well as both Insurance Portability and Accountability Act (HIPAA) and General Data Protection Regulation (GDPR) compliant, this technology allows users to curate, annotate, harmonize, and query datasets within a TCE that meets the highest global security, privacy, and safety standards, making BC Platforms a trusted advisor and the data partner of choice for your needs.

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