

Global Perspectives in Establishing Secure Environments

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First Principles for a Trusted Research Environment (TRE) - 2020



The Five Safes

- First Presented in a UK Health Data Alliance Green Paper July 2020
- Represents the essential requirements of a Trusted Environment
- These essential requirements are likely to be used in future to certify any Trusted Environment
- “Safe Return” as an extension of the Trusted Environment (mapping a valuable result in a research environment back to the clinical record)

 <p>Safe People - Individuals given access to TREs must be appropriate and approved</p>	 <p>Safe Data - Proportionate to the approved project and GDPR compliant</p>
 <p>Safe Projects - The use of data is appropriate and has public benefit</p>	 <p>Safe Setting - Secure, transparent and engineered to be easy for researchers to use</p>
 <p>Safe Outputs - A barrier or “air lock” to prevent unauthorised export/import</p>	

Broadening the “TRE” to become a Secure Data Environment - 2022+



NHS Data Saves Lives initiative

- First Published in June 2022
- Public facing documentation for a Secure Data Environment building on the 5 Safes first principles
- Simply stated “Secure Data Environments give approved users access to health data for analysis, without them needing to receive a copy. The organisation providing the environment can control many factors, including;
 - Who can be a user;
 - The data that users can access;
 - What users can do in the environment;
 - The findings of analysis that users can remove.”

The screenshot shows the NHS England website. At the top is the NHS 75 England logo. Below it is a navigation bar with links for 'About us', 'Key tools and info', 'COVID-19 response', and 'News archive'. The main content area has a header 'NHS England - Transformation Directorate' and a large blue section titled 'Secure Data Environments (SDEs)'. Below this title is a sub-header: 'A summary of what Secure Data Environments are and why we're making this change'. The main text reads: 'We know from the Covid-19 pandemic that data saves lives. Data helps our doctors and nurses to make better decisions in delivering care and helps our researchers to discover life-changing new treatments. Our recent [strategy](#) set out how we use data more effectively and save even more lives by making the NHS more data driven.'

The Secure Data Environment in the broader European Context - 2023+



European Health Data Space (EHDS) and the proposed Data Governance Act

- Data Intermediaries must register by 2025
- Outlines the need for “Secure Environments”
- CNIL and other European countries also refer to “Data Processing Environments”
- EHDS FAQ:
https://ec.europa.eu/commission/presscorner/detail/en/qanda_22_2712
- Proposal for a Data Governance Act:
<https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52020PC0767>

European Commission | English EN

Home > Press corner > EU Health: European Health Data Space

Available languages: English

Questions and answers | 3 May 2022 | Brussels

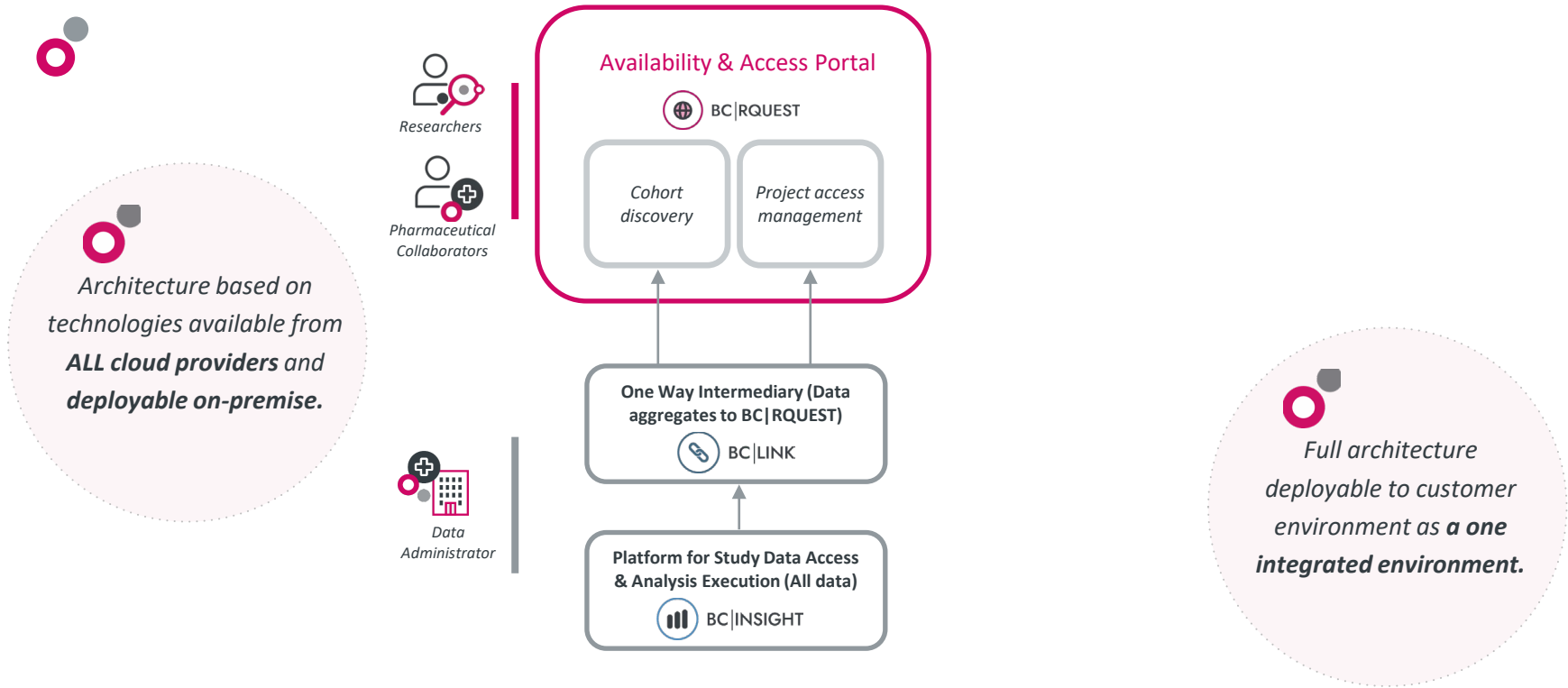
Questions and answers - EU Health: European Health Data Space (EHDS)

Moreover, **your security and privacy will be ensured:**

- researchers, industry or public institutions will have **access** to your health data only for specific purposes that benefit individuals and society
- but they can only access data that do not **reveal your identity**
- the data can only be accessed and processed in **closed, secure environments** and only anonymised data can be downloaded.

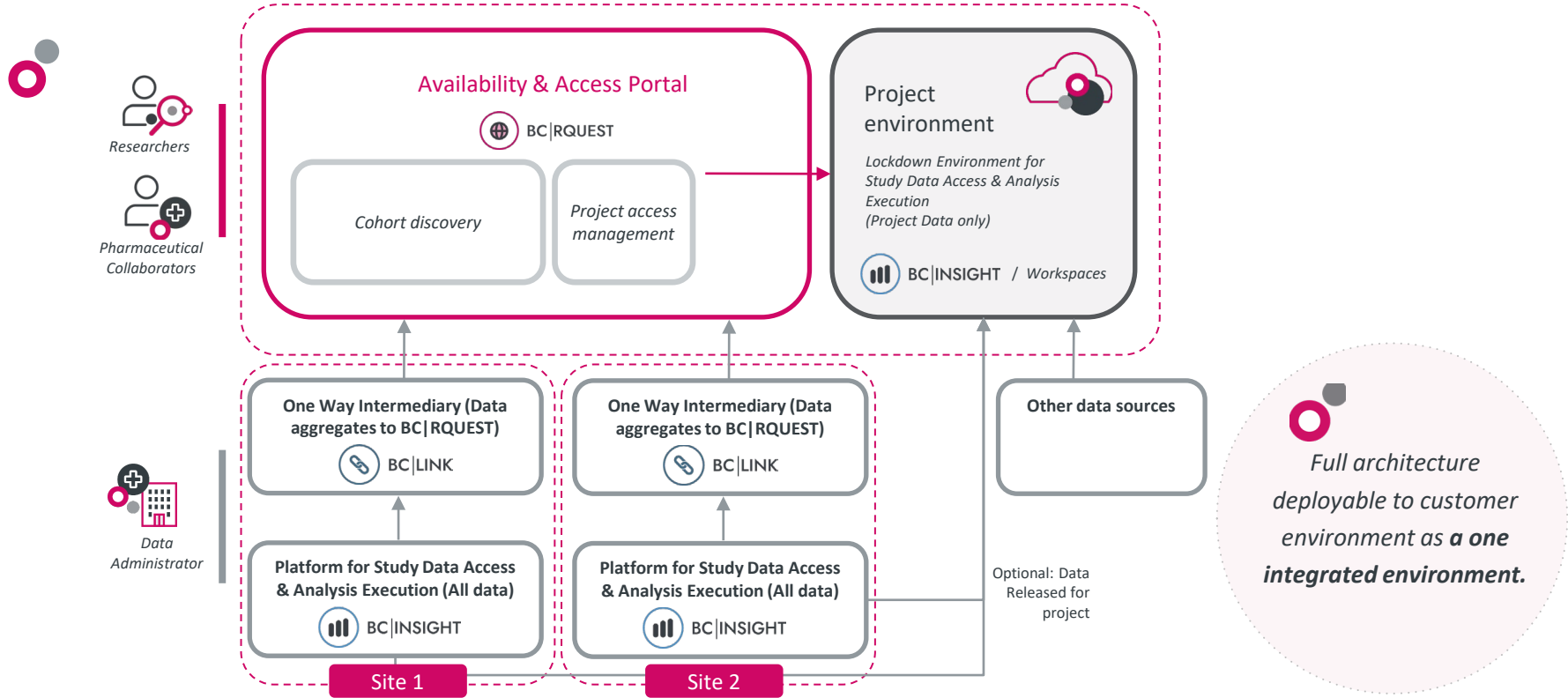
The Secure Data Environment for a single organization/site

Cloud-agnostic or on-premise deployment or hybrid

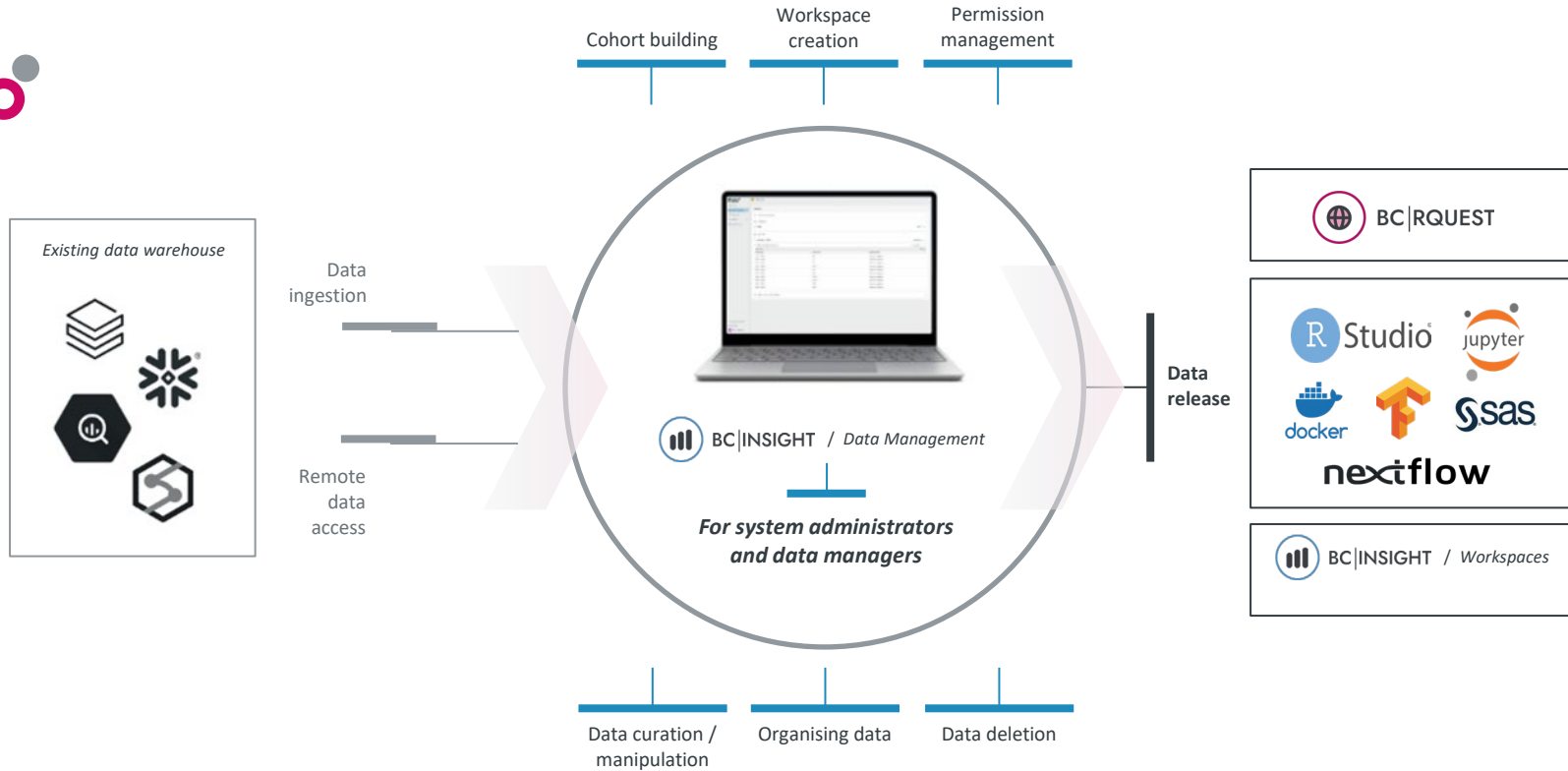


The Secure Data Environment for a network of multiple organizations/sites

Cloud-agnostic or on-premise deployment or hybrid



The BC|INSIGHT features supporting our Secure Data Environment Solution



Case Study 1 - NHS Pilot for Wessex SNSDE

- A pilot for Wessex sub-national SDE was run from January to April 2023.
- NHS SDEs are designed to support researchers across six broad R&D use cases:



Case Study 1 - NHS Pilot for Wessex SNSDE



The Team



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BC Platforms



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BC Platforms



Dr Mark Hufferan
BC Platforms





Cohort Discovery: meeting specific data needs

The Innovation Gateway's Cohort Discovery search tool allows researchers to search, assess and request access to potential datasets that precisely match information on particular populations of interest – for example data across multiple datasets relating to non-smoking patients aged 18 to 30 that have asthma and diabetes.

The tool enables multiple dataset searches to be done in a fast, secure, de-identified and ethical way. At no point is there any individual level data transferred from the custodian.



How can Cohort Discovery help you?



Gateway users, including researchers, can carry out more specific searches and assessments on datasets listed in the Gateway, so that potential datasets which match the requirements of a research project are easier to find.



For data custodians, Cohort Discovery means requests to access data are more likely to result in success, whilst still retaining control over who has access to the data.



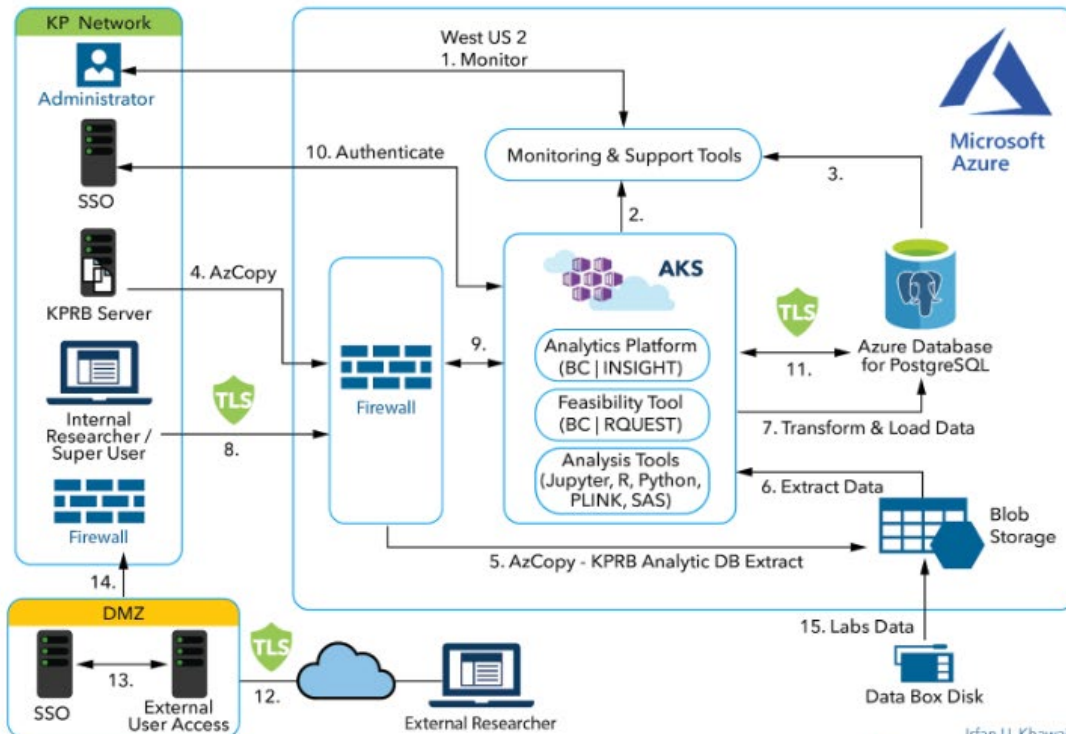
HDR UK has extensively tested the cybersecurity of the Cohort Discovery tool, and had this independently verified, providing confidence in its privacy and security.



Case Study 3 - meeting the 5 safes for Kaiser Permanente Research Biobank



High-level Architecture



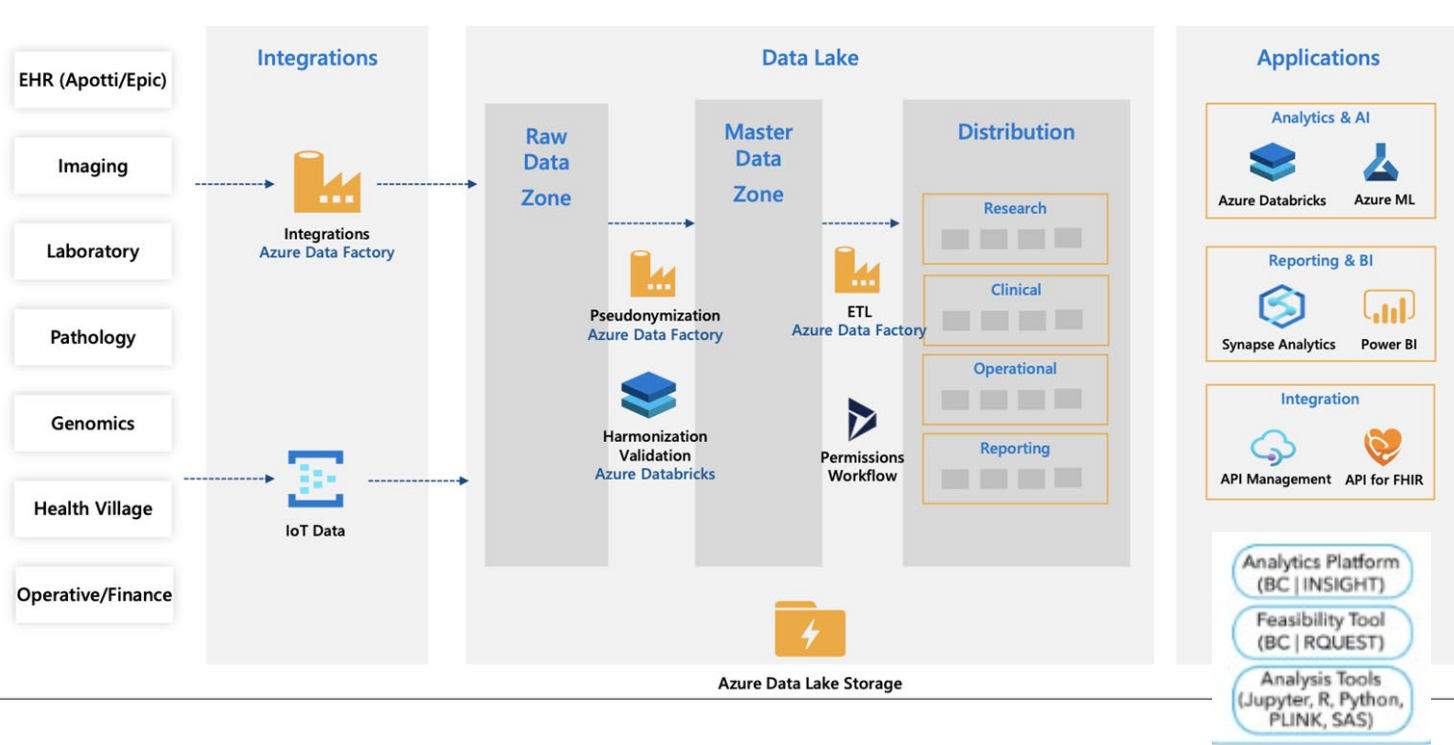
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Proprietary & Confidential for KP Internal Use Only

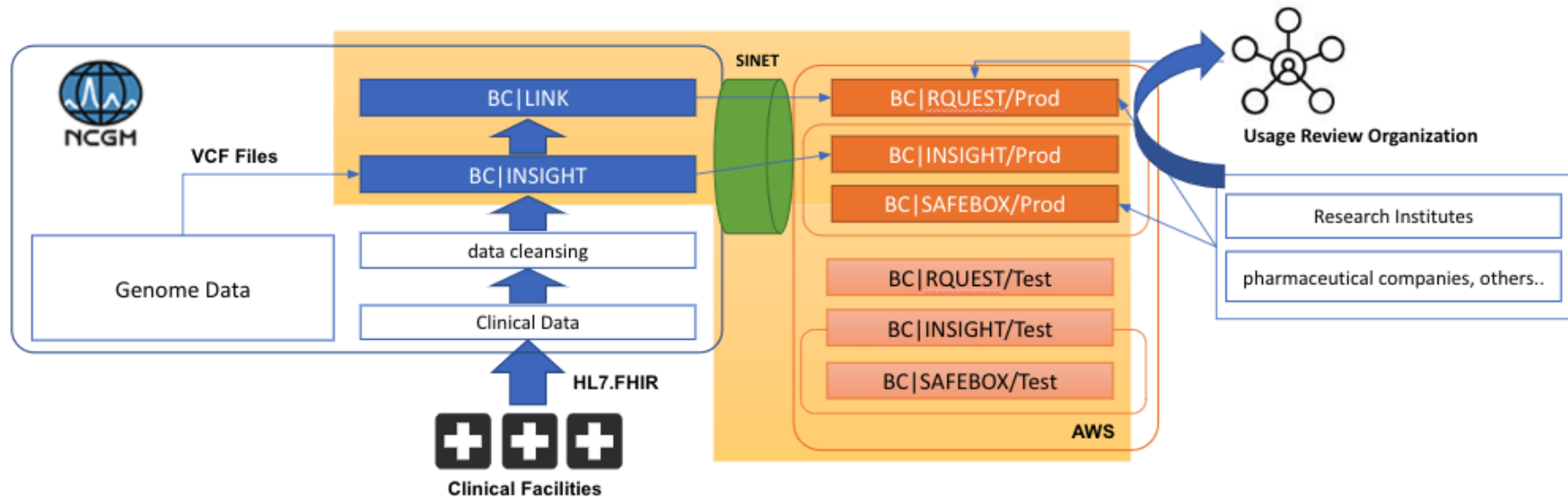
Irfan U. Khawaja



Case Study 4 - Helsinki University Hospital SDE with Azure Data Lake



Case Study 5 - Japan NCGM for Rare Diseases. SDE running on AWS.



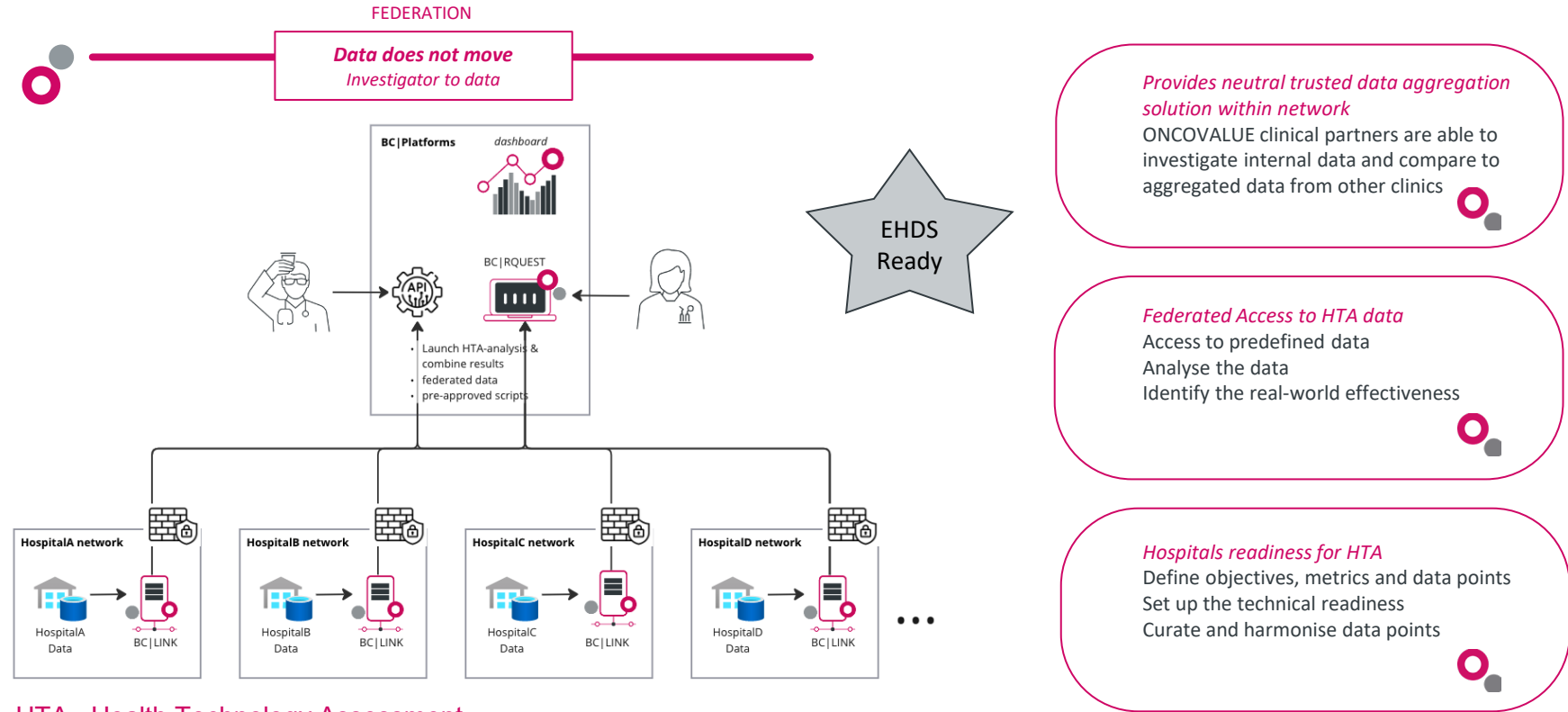
国立国際医療研究センター

ゲノム医科学プロジェクト-戸山

National Center for Global Health and Medicine
Genome Medical Science Project - Toyama

Case Study 6 - ONCOVALUE. Federated HTA Analysis of RWD across multiple European countries

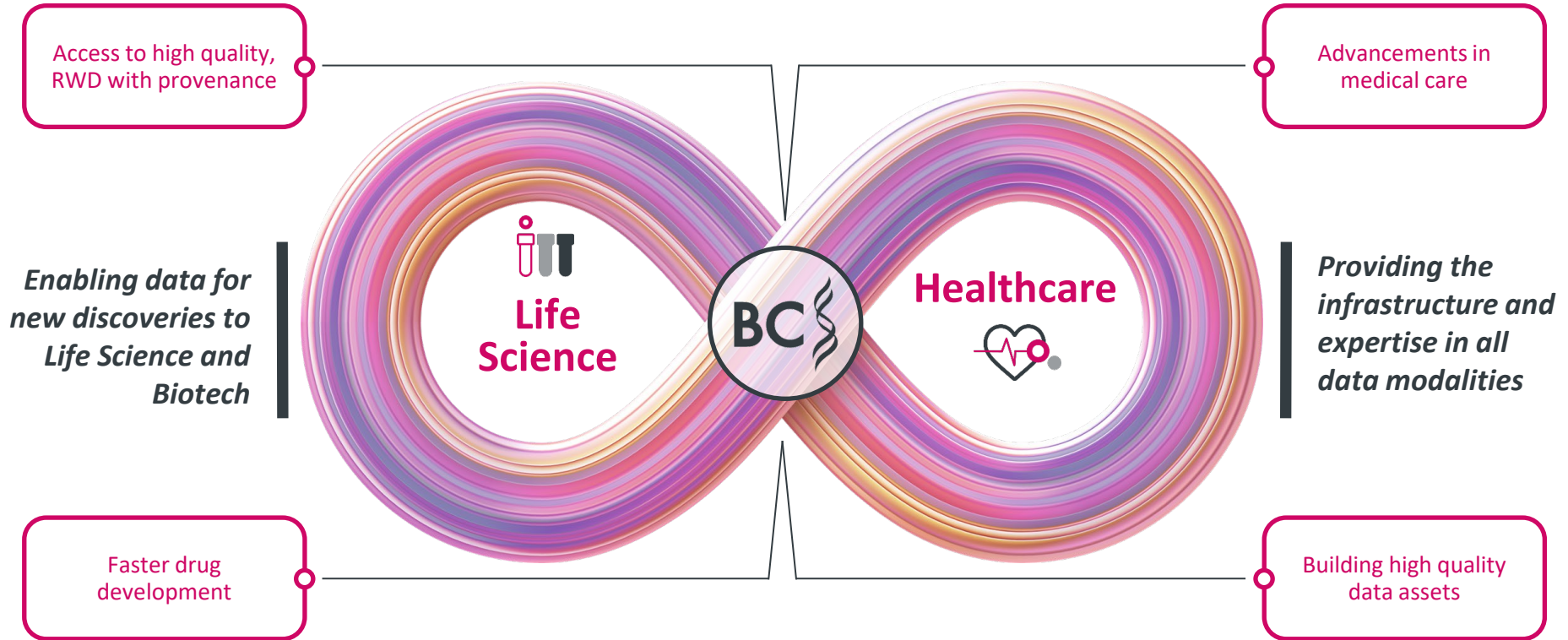
To measure the effectiveness of medical treatment: identify subgroups for whom the treatment is optimal and for whom it is not



HTA= Health Technology Assessment

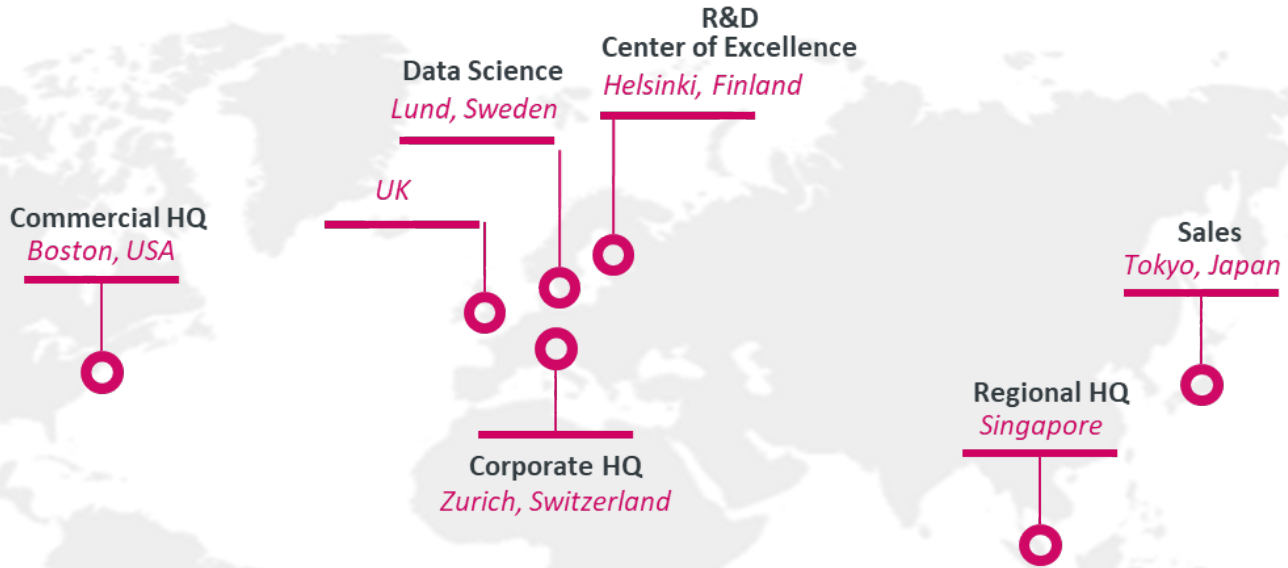
Our Mission: Accelerating Drug Development and Personalizing Care

Leveraging 26 years of experience in RWD analytics and secure research collaborations



BC Platforms service centers assist you globally

Key locations ensuring proximity to key users and optimal data sourcing



*Presence in Europe, North America
and Asia-Pacific*

FOCUS

- Top data driven Pharma & Biotech companies
- Top Global hospitals and healthcare systems