opcrd

An introduction to the Optimum Patient Care Research Database

About this brochure

The purpose of this brochure is to describe the contents of the Optimum Patient Care Research Database (OPCRD), to help prospective users assess the suitability of its data for their needs. The technical workbook can be found online and technical data specifications can be provided to authorised users of OPCRD upon request.

A profile of OPCRD developed in collaboration with Momentum Data can be found here.

Further details are available on our website:
https://opcrd.optimumpatientcare.org/

Data accurate as of 25th October 2024.

A unique database

The Optimum Patient Care Research Database (OPCRD) is one of the largest enhanced healthcare databases. It provides de-identified data from almost 1,200 general practices and more than 24 million patients in the UK. It is established and maintained by Optimum Patient Care Ltd (OPC UK), a UK based not-for-profit social enterprise.

The de-identified electronic medical records, patient questionnaires and clinical review data provided by OPCRD offer an essential source of real-world data to promote evidence-based research and quality improvement.

Over the two decades since its establishment, the OPC Collaborative Network (OPC) has grown to become a global leader in the provision of technologically enhanced healthcare data and clinical research services. OPCRD is proud to have supported more than 100 research publications in disease management, therapy, and population health. These publications have covered a range of research questions, such as the first database assessment of 'Blood eosinophil count and prospective annual asthma disease burden: a UK cohort study'.

A complete list of the publications is accessible from our website.

OPC Research Database provides de-identified data from almost 1,200 general practices across the UK and over 24 million de-identified patients.

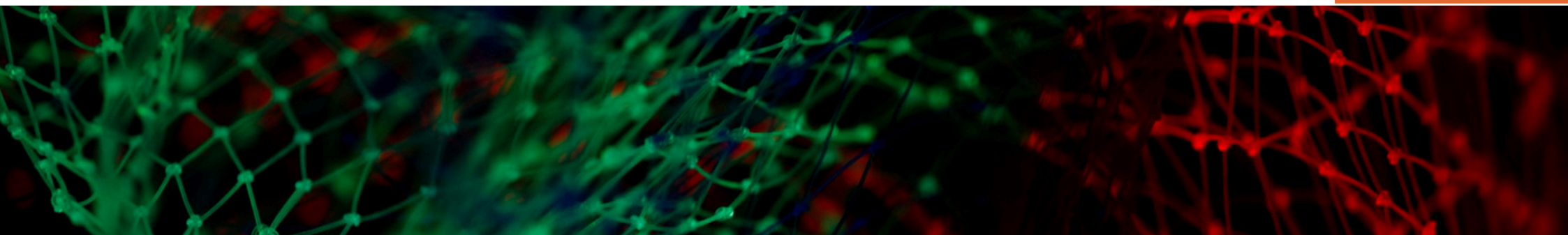
Database disease summary :
(numbers of patients)

8.8m **Lower respiratory tract infections**	**6.0m** **Anxiety / depression**	**5.0.m** **Eczema**
3.0 m **Asthma**	**2.9 m** **Rhinitis**	**2.7 m** **General Cardiovascular Disease**
1.9m **Diabetes**	**1.9m** **GERD**	**1.9m** **Ischaemic Heart Disease**
1.2m **Chronic Kidney Disease**	**888k** **Liver disease**	**710k** **COPD**

GERD = Gastroesophageal reflux disease
COPD = Chronic obstructive pulmonary disease

OPCRD has been purposefully designed to facilitate real-world data collection and address the growing demand for observational and pragmatic medical research, both in the UK and internationally. OPCRD is known to have several unique qualities which set it apart from other scientific research data resources:

- De-identified electronic medical records of more than 24 million patients, of which 8 million are active patients.
- OPCRD covers all major UK GP clinical systems (EMIS, TPP SystmOne, Vision).
- OPCRD covers approximately 12% of the active UK GP population, including England, Scotland, Wales and Northern Ireland.
- Long-standing relationships with almost 1,200 GP practices, facilitating enhanced data collection, trial feasibility and site identification.
- Linked patient-reported outcomes for more than 74,000 patients (asthma, COPD and COVID-19).
- Clinical reviews for more than 4,000 patients.
- Ethical approval for linkage to secondary care data sources.
- Complimentary clinical and research expertise on all data requests, including 12 professors and 8 PhDs.
- Numerous peer-reviewed publications featured in world-renowned scientific journals.
- All data is Read/SNOMED coded and OMOP mapped.
- Data made available within 2 weeks of ethical approval.



Suitable projects

OPCRD facilitates a broad range of projects including:

- Epidemiological study designs (i.e., cohort, case-control, case-series).
- Post-authorisation safety studies (PASS).
- Research of innovative diagnostic and therapeutic methodologies.
- Pragmatic randomised clinical trials (RCTs).
- Power calculation assumptions informed by real-world data.
- Government and academic funded randomised cluster-controlled trials.
- Quality improvement programmes delivered directly in primary care.

A range of analytical and research opportunities which are accessible through the use of high-quality real-world data and can be extended further by:

- Accessing expert-level clinical advice from OPC and its collaborators.
- Making applications to link the data with other data sources, including secondary care datasets, such as Hospital Episode Statistics (HES).

OPC – the collaborative network

Founded by Professor David Price in 2005 and guided by an international team of leading clinical and academic experts, our collaborative network continues to grow. We have become a global leader in the provision of technologically enhanced primary care data and clinical research services.

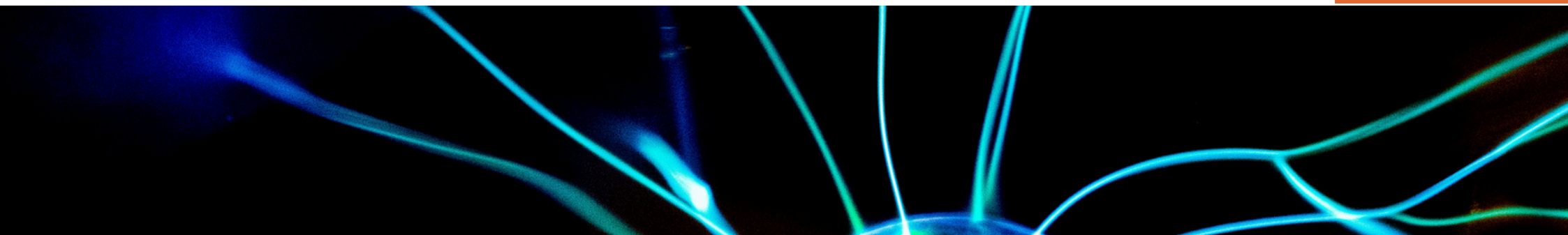
The OPC collaborative network offers a unique opportunity to deliver clinical research and services that make a difference to patient care and clinical practice.

The collaborative network includes:

- Optimum Patient Care Ltd (OPC UK).
- Optimum Patient Care Australia Pty Ltd (OPC AU).
- Optimum Patient Care Global Ltd (OPC Global).
- Observational and Pragmatic Research Institute Pte Ltd (OPRI).
- Observational and Pragmatic Research International Ltd (OPRI UK).

OPC is affiliated with OPRI and OPRI UK, which have scientific expertise from senior epidemiologists, clinical experts, data analysts, statisticians, and medical writers (with over 15 years of experience using OPCRD). This provides a one stop shop for all your research requirements.

By conducting research using OPCRD, we can provide a unique opportunity to disseminate research back to healthcare practitioners via our social enterprise organisations (OPC UK and OPC AU) and their educational services.



Data Sources

Electronic Medical Records

Within the UK, the NHS records the medical care of patients through the use of Electronic Medical Records. OPCRD provides a comprehensive picture of over 24 million de-identified Electronic Medical Records including:

- Demographic Information
- Treatments and prescription issued
- Test results and measurements taken in the practice
- Diagnoses
- Symptoms
- Referrals

Clinical Review Data Collection

OPC UK's clinical services allow bespoke opportunities to conduct data collection as part of standard clinical practice. OPC UK has been delivering clinical reviews to over 4,000 respiratory patients, enabling OPCRD to hold unique and enhanced data in respiratory:

- Fractional Exhaled Nitric Oxide (FeNO)
- Basic spirometry
- Inhaler technique assessment and training
- Patient symptoms
- Therapy concordance
- Side effects
- Disease impact
- Lung function
- COVID

Secondary Care

OPC UK has ethical approval to link OPCRD primary care data to secondary care and other datasets. This linkage enables OPCRD to provide a fuller picture of the patient care record to support vital public health research, informing advances in patient safety and delivery of care.

Hospital Episode Statistics

In England, Hospital Episode Static (HES) data linkageis carried out by NHS Digital. Provision of HES linked data is only possible under appropriate governance conditions and subject to CAG Section 251 approval.

Information services division ISD EDRIS Scotland

In Scotland, secondary care data linkage can be carried out by the by the Public Health Scotland (PHS) electronic Data Research and Innovation Service (eDRIS). Provision of linkage data is only possible under appropriate governance conditions and subject to a successful NHS Scotland Public Benefit and Privacy Panel for Health and Social Care (HSC-PBPP) application.

National Registries

Linking routine electronic medical record (EMR) data with clinical registry data provides a more complete picture of the patient journey through episodes of care. OPCRD EMR data can be linked to existing and new registries, some active examples include:

- International Severe Asthma Registry (ISAR)
- International Helping Asthma in Real-life Patients (iHARP)
- Death Registration data from the Office for National Statistics (ONS)
- Deprivation data: Townsend Scores/Index of Multiple Deprivation (IMD)

NHS Wales Information Service (NWIS)

In Wales, secondary care data linkage can be carried out by the NHS Wales Information Service (NWIS).Provision of linkage data is only possible under appropriate governance conditions and subject to a successful application.

Questionnaire Data

OPC UK's questionnaires are a compilation of validated clinically relevant questions covering symptoms, disease control, triggers, side effects, quality of life, and adherence measures. The questionnaires can be distributed to patients from their GP practice as part of OPC clinical review services. OPCRD currently holds de-identified questionnaire data in respiratory (adult asthma, child asthma, COPD and COVID) covering more than 74,300 patients:

- Symptoms
- Smoking status
- Allergy
- Adherence
- Patient preferences/beliefs/concerns
- Side effects
- Quality of life

Clinical trials and intervention programmes:

Following a new strategy or intervention being introduced into GP practices, OPC UK can use prospectively collected EMR data as captured within routine clinical practice to assess outcomes. This provides reduced operational demands, patient burden and costs as compared to classical randomised controlled trials (RCTs). Furthermore, by keeping data collection protocols to routine care, the trials are more reflective of the real world.

Data format

The data collected from general practices are held within a relational SQL database (with multiple rows of data allowable per patient) in 6 raw files:

- Patient Data – patient demographics
- Clinical Data – medical history pertaining to a selection of clinical records defined by a compiled list of Read codes
- Therapy Data – details of prescriptions for drugs issued by GPs. Drug codes are based on British National Formulary (BNF) codes
- Referral Data – referrals to external care centres e.g., secondary care locations/hospitals and reasons for referral information
- Practice Data – contains practice administration information
- Questionnaire Data – contain de-identified patient questionnaire records for child asthma, adult asthma, COPD and COVID

Presently, all data in the database are coded using Read coding system and SNOMED CT system for clinical terminology.

Our data is also mapped to OMOP. More information on the structure and content of the data is accessible from the OPCRD Technical Workbook.

Anonymised data

Data provided from OPCRD for the use in research studies is considered anonymised in accordance with the Data Protection Act 2018 and the Information Commissioner's Office guidance.

Patient level data is de-identified at source, so that the patients' personal identifiers such as name, date of birth and post code are not extracted.

Data collection

OPCRD receives data from the Clinical Review Services conducted by OPC UK, including the delivery of quality improvement programmes, patient and physician questionnaires and clinical trials.

OPC UK receives de-identified data from practices via an initial bulk extract followed by incremental monthly extractions. Thus, ensuring an up-to-date database for current research is provided to clients.

Due to the regular OPCRD refresh, the data is as recent as the most recent month.

Patient consent

OPC UK respects patients' requests to opt-out of data sharing. Options available in the GP EHR system allow for selection of an individual patient and for that patient to be flagged as opting out of the data sharing and OPCRD extraction. If this option is selected, the patient's data will not be extracted by OPC UK for research or for data linkage. OPC UK also reviews and respects clinical codes that flag patient objections to their data being used for various purposes by not collecting this data.

Data access and governance

OPC UK implements a strict data governance framework, licensing and fees. The NHS Health Research Authority (NHS HRA) has approved OPCRD for clinical research purposes (REC reference: 20/EM/0148).

The Anonymous Data Ethics Protocols Transparency (ADEPT) committee, an independent body of experts and regulators, has been commissioned by the Respiratory Effectiveness Group (REG) to govern the standards of the research conducted on internationally recognised databases, including OPCRD. The committee comprises scientists with statistical and epidemiological experience, members with specific OPCRD related expertise and independent clinical experts adhering to UK standards.

Any research project conducted on OPCRD data needs to be reviewed and ethically approved by the ADEPT committee prior to any data being accessed. The ADEPT committee will be responsible for reviewing applicant study protocols for scientific quality.

All research using OPCRD is expected to be registered on established study databases such as the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP).

The ADEPT approval process is fast, taking less than 15 working days.

Adept data access application

Administration of applications for access and/or use of anonymised data from OPCRD will be provided by the ADEPT Secretariat. All applications to use OPCRD data should be submitted online via ADEPT. See the below requirements:

- Application form
- Study protocol
- Ethics/Regulatory approvals (if applicable)
- ADEPT Application fees

OPCRD's unique vantage point is the speed at which we can deliver data. The ADEPT approval process is fast and normally requires 15 working days but may be completed faster (currently averaging just 8 working days – August 2024).

As per common practice for large research databases and registries, applications can have one of the following outcomes:

- Full Approval
- Conditional Approval
- Re-submission with Amendment
- Rejections

From ethics to data in just 10 days

Following the approval of your request by the ADEPT committee, we can provide access to the licensed data within 10 working days, frequently accommodating your needs faster.

Data provision

For those wishing to perform their own analyses, anonymised datasets can be provided for ADEPT approved projects. The OPC UK data team will work with approved applicants to define the data specification/ requirements.

All submissions for data should be made via the Data Request Form.

You will need to include the following in all data submissions:

- Company/Organisation
- Study Name
- Researcher/Point of Contact
- Data Delivery Date
- Funding Source
- ADEPT Approval number (if available)
- ENCEPP registration (if available)
- REC Reference (if applicable)
- Uploading supporting documents: Study Protocol, Data Specification (Cohort Criteria & Read Codes & SNOMED codes: Download specifications template) and Regulatory Approvals (ADEPT. REC etc).

Supporting documents

Studies requiring use of OPCRD will also be required to be registered on recognised study databases such as the European Network of Centres for Pharmacoepidemiology and Pharma-covigilance (ENCePP), unless OPC and the client agree otherwise.

Before sharing the data, the customer will be asked to enter into a Data Sharing & Use Agreement and the payment of Licence Fees.

The OPC UK data team will then process your request and, once it is done, provide you with detailed guidance regarding the process of accessing the licensed data. If, as a part of your licensing arrangements, you require access to a specific dataset, our data team will create it for you. Datasets can be provided within 15 working days of request.

For holders of an unlimited licence, a secure remote access shall be provided to an anonymised client version of OPCRD. The dataset is updated at least monthly.
More information on the technical aspects of data provision is available upon request.

Research support

Our affiliated companies offer a truly bespoke arrangement with customers, which cannot be found with any other medical database provider.

Scientific expertise

For those less familiar with data analysis, through our partner research organisation, OPRI and OPRI UK, we can deliver as much or as little of the project as required, from simple feasibility assessment to final publication. Our experienced team of senior epidemiologists, data analysts, statisticians, and medical writers provide research support services for a wide range of studies.

Research support from OPRI and OPRI UK can be provided at reduced rates to the holders of an unlimited licence for OPCRD. More information on research support is available upon request.
Services include:

- Proposal generation
- Scientific research review
- Feasibility assessment
- Study design
- Protocol generation
- Data specifications
- Ethics approval and study registrations
- Dataset creation
- Statistical analysis
- Final report generation
- Abstracts and posters
- Manuscript writing.

Clinical trial delivery

OPC UK can provide support in the delivery of clinical trials in primarycare, from site identification to completion of patient recruitment. Our network of almost 1,200 GP practices and experienced team of clinical experts, research clinicians and project managers provide a wide range of services to successfully deliver your study. These include:

- feasibility assessment
- site identification
- site recruitment
- eligible patient identification
- secure NHS approved study mailing
- identifying eligible patients
- dedicated coordinators to facilitate patient recruitment
- provision of a research clinicians to conduct study clinics on behalf of a GP practice.

Clinical Trial Delivery from OPC UK can be provided at reduced rates to the holders of an unlimited license for OPCRD.

More information is available upon request.

Support examples

The following are some historic examples of the data request management and research support services provided by OPC to our customers.

Carachteristics of patients preferring once-daily controller therapy for asthma and COPD: a retrospective cohort study

Research question to OPC: Can you identify the characteristics of patients with asthma or COPD who prefer a once-daily controller medication regimen?

Our approach: Questionnaires were included as part of standard clinical assessments and were completed by patients to evaluate a number of relevant factors: patient preference for once-daily therapy, disease severity, asthma or COPD control, health status, exacerbation history, attitudes and beliefs towards medication and medication adherence.

More information on the study is accessible from here

The CRITIKAL Study

Research question to OPC: Can you investigate the association between specific inhaler errors and asthma outcomes?

Our approach: Delivery of best practice asthma Clinical Reviews by OPC nurses working on behalf of GP practices. This process included collection of data from more than 5,000 patients covering demographic characteristics, asthma symptoms, and inhaler errors observed by purposefully trained health care professionals.

More information on this study is accessible from here

The REACH Study

Research question to OPC: Can you investigate clinical and cost effectiveness of switching typical asthma patients from FP-SAL to efBDP-FOR?

Our approach: Targeted Extractions to identify early adopters following the product launch and offering our Clinical Review services to enable fast delivery of available data for analysis.

More information on this study is accessible from here

Licensing

At OPC we offer different pricing structures for accessing datasets from OPCRD. The licence types, detailed below, depend on the use of the data and the outputs. We also offer the Unlimited License, in which we provide TRE access to a client version of OPCRD which allows for an unlimited number of datasets to be produced by the client during the one-year licence period.

<table>
<tr><th></th><th>Research
Ethically approved, protocolised research studies</th><th>Platform
Pre-agreed use cases (1)</th><th>Patient finder
Identification of patients for QI or research</th></tr>
<tr><td rowspan="2">Limited license</td><td rowspan="2">N/A</td><td>Non-published, internal use only</td><td>No data released to client</td></tr>
<tr><td>Project dependent (2)</td><td>£ 33,000 commercial
£ 15,000 academic</td></tr>
<tr><td rowspan="2">Publication extension</td><td rowspan="2">N/A</td><td>To publish platform derived analysis</td><td>To provide data cut to client for project evaluation</td></tr>
<tr><td colspan="2">£ 33,000 commercial
£ 15,000 academic</td></tr>
<tr><td rowspan="2">Single project license
(up to 600k individuals, 12 months license)</td><td>Single, ethically approved, protocolised research study</td><td rowspan="2">N/A</td><td>Combination of limited and publication extension.</td></tr>
<tr><td>£ 66,000 commercial
£ 30,000 academic</td><td>£ 66,000 commercial
£ 30,000 academic</td></tr>
<tr><td rowspan="2">Unlimited project license
(12 months license) (3), (4)</td><td>Unlimited number of protocols during period</td><td>Access to full database with quarterly updates</td><td>Unlimited number of concurrent projects in period</td></tr>
<tr><td colspan="3">£ 220,000 commercial
£ 75,000 academic</td></tr>
</table>

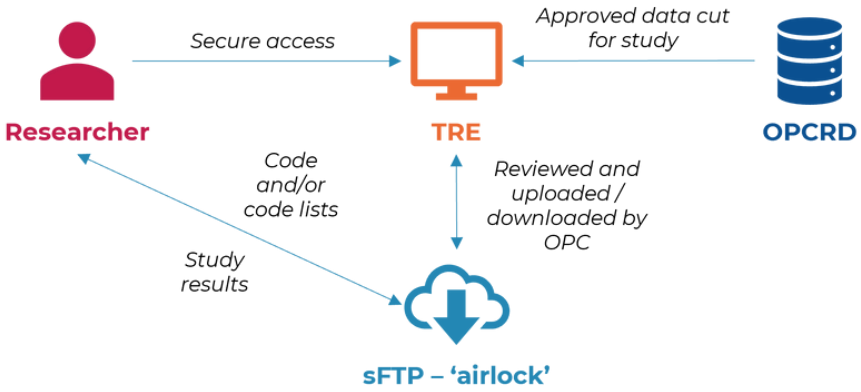
1. In line with OPCRD REC approval, including supporting strategic decision making, feasibility assessments and other non-published use of the data that is considered in the public good,
2. limited platform license, 20-30% of project fees (minimum fees of £7,500),
3. Unlimited license does not cover linked datasets (additional license required),
4. Unlimited license in one pilar, does not automatically provide access to others.

TRE - Trusted Research Environment

In line with the evolving healthcare data landscape in the UK, OPC is moving towards a model of access OPCRD via a Trusted Research Environment (TRE).

A Trusted Research Environment (TRE) is a secure and controlled platform designed to facilitate secure access, analysis, and sharing of sensitive data for research purposes. TREs are implemented to ensure the highest standards of data privacy, security, and compliance with legal and ethical guidelines.

Illustrative TRE costs, 12 months:
£ 10,903 commercial
£ 7,759 academic



Illustrative TRE specification

Access to TRE for 12 months (in line with data license length)

Hosting:

- Cloud (Azure) or local options available.
    - Typical local technical specification:
        - 8gb of RAM
        - 2 CPUs
        - 500gb disk
        - Up to 2 registered users.

Software provided:

- MS SQL Server Management Studio, Python, R & R Studio.
- Additional software can be provided on request.

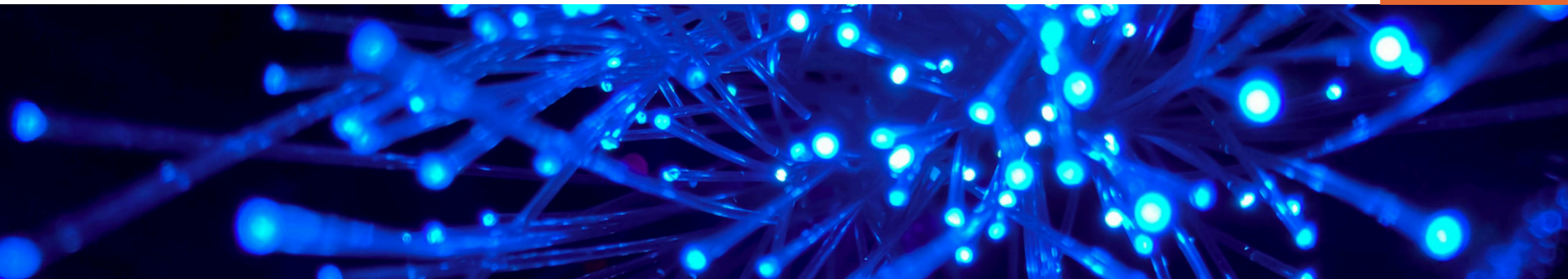
Support provided as standard:

- Technical support accessing and using the environment, including:
    - User and access management
    - Ingress of code lists, code and other tools, etc.
    - Egress of results and other information from the environment at the end of the study

Research support

- Understanding the data and its structure
- Effective query design for partitioned databases
- Support around study design, ethics and related topics.

Bespoke TRE specifications available on a per customer basis.



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