opcrd

AN INTRODUCTION

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. Technical data specifications can be provided to authorised users of OPCRD upon request.

Further details are available on our website: https://opcrd.co.uk/

OPTIMUM PATIENT CARE RESEARCH DATABASE PROVIDES DE-IDENTIFIED DATA FROM OVER 800 GENERAL PRACTICES ACROSS THE UK AND OVER 12 MILLION DE-IDENTIFIED PATIENTS

A UNIQUE DATABASE

The Optimum Patient Care Research Database (OPCRD) is one of the largest enhanced healthcare databases providing de-identified data from over 800 general practices and approximately 12 million patients in the UK. It is established and maintained by Optimum Patient Care Ltd (OPC UK), a UK based social enterprise.

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

In less than a decade since its establishment, the OPC Collaborative Network (OPC) has grown to become a global leader in the provision of technologically enhanced health care data and clinical research services. OPCRD is proud to have supported more than 80 research publications in disease management, therapy and science. 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
https://opcrd.co.uk/publications/

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 a number of unique qualities which set it apart from other scientific research data resources:

- De-identified electronic medical records of more than 12 million patients
- OPCRD covers all major UK GP clinical systems (EMIS, TPP SystmOne, Vision)
- OPCRD covers approximately 18% of the UK population, including England, Scotland, Wales and Northern Ireland
- Long standing relationships with over 800 GP practices facilitating enhanced data collection
- Linked patient reported outcomes for more than 70,000 patients (asthma, COPD and COVID-19)
- Ethical approval for linkage to secondary care data sources
- Provides complimentary clinical and research expertise on all data requests
- Numerous peer-reviewed publications featured in world-renowned scientific journals

Our database 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

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 a team of leading clinical and academic experts including Dr Dermot Ryan, Dr Iain Small, Dr Mukesh Singh and Dr Katherine Hickman our collaborative network has grown to 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 through which scientific expertise from senior epidemiologists, clinical experts, data analysts, statisticians, and medical writers (with over 12 years of experience using OPCRD) provide 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.

Further information on any of the services we offer is available upon request.

As part of our commitment to social responsibility, OPCRD offers support for publicly important research initiatives on a pro bono basis. Our academic and charitable contributions include exclusive data access agreements with academic research groups.

Leveraging on the wealth of clinical data provided by OPCRD, our partners and others, conduct research and provide recommendations helping to improve the quality of healthcare, cure diseases and save lives. Our partners include:

- Asthma UK Centre for Applied Research (AUKCAR, www.aukcar.ac.uk),
- Respiratory Effectiveness Group (REG, www.effectivenessevaluation.org)

DATA SOURCES

OPC UK has ethical approval to link OPCRD primary care data to secondary care data and other datasets. This linkage includes:

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 12 million de-identified Electronic Medical Records including:

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

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 70,000 patients:

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

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 70,000 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 data linkage is carried out by NHS Digital, which is the only statutory entity authorised to link and provide HES data in England. Provision of linkage data is only possible under appropriate governance conditions and subject to a successful application.

INFORMATION SERVICES DIVISION (ISD) EDRIS: SCOTLAND

In Scotland, secondary care data linkage can be carried out by the Electronic Data Research and Innovation Service (eDRIS). Provision of linkage data is only possible under appropriate governance conditions and subject to a successful application.

NHS WALES INFORMATION SERVICE (NWIS): WALES

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.

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)

CLINICAL TRIALS AND INTERVENTION PROGRAMS

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 (RCT's). 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. We are also mapping against the OMOP CDM and will have this completed in 2022. More information on the structure and content of the data is accessible from the OPCRD Technical Workbook.

DE-IDENTIFIED DATA

Data provided from OPCRD is de-identified and does not contain any patient identifiable information.

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 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.

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 research conducted on internationally recognised databases, including OPCRD. The committee comprises scientists with statistical and epidemiological experience, members with specific OPCRD related expertise, independent clinical experts and lay members 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 and normally requires 3 weeks.

ADEPT DATA ACCESS APPLICATION

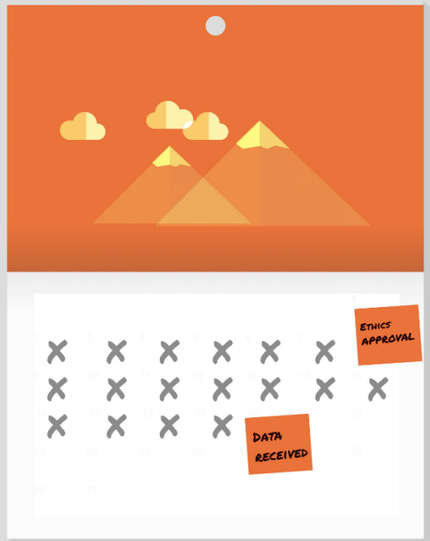
Administration of applications for access and/or use of de-identified data from OPCRD will be provided by the ADEPT Secretariat. All applications to use OPCRD data should be submitted online via ADEPT. See the below requirements:

- 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 3 weeks but may be completed faster.

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 20 DAYS

Following an approval of your request by the ADEPT committee, we can provide access to the licensed data within 20 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: https://opcrd.co.uk/opcrd-data-request/

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: 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 Pharmacovigilance (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 3 weeks of request.

For holders of an unlimited licence, a secure remote access shall be provided to a de-identified full data cut of OPCRD. The de-identified data cut 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 primary care, from site identification to completion of patient recruitment. Our network of 800+ 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 and
- 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 licence 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.

CHARACTERISTICS OF PATIENTS PREFERRING ONCE-DAILY CONTROLLER THERAPY FOR ASTHMA AND COPD: A RETROSPECTIVE COHORT STUDY

Research question to OPC: Identify characteristics of patients with asthma or COPD who prefer a once-daily controller medication regimen.

Our response: 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: https://rdcu.be/cqTGD

THE CRITIKAL STUDY

Research question to OPC: Investigate the association between specific inhaler errors and asthma outcomes.

Our response: 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 5000 patients covering demographic characteristics, asthma symptoms, and inhaler errors observed by purposefully trained health care professionals.
More information on this study is accessible from: https://opri.sg/research-and-development-programs/uncontrolled-severe-asthma/critikal/

THE REACH STUDY

Research question to OPC: Investigate clinical and cost effectiveness of switching typical asthma patients from FP-SAL to efBDP-FOR.

Our response: 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: https://opri.sg/case-studies/

LICENSING OPTIONS

At OPC we offer two different models and pricing structures for accessing datasets from OPCRD. We offer a Standard Licence, which is a one-off analytical dataset which is provided to answer an approved study question. We also offer the Unlimited Licence, in which we provide VPN 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.

- Standard Licence (one-off dataset request)
- Unlimited Licence (for those requiring multiple datasets within a year)

THE STANDARD LICENCE

Our standard option is for those who require a one-off dataset to be produced using OPCRD data. A Dataset will be produced by our highly skilled and experienced team in line with the requested specification. All the primary care data associated with each patient in a study specific dataset is provided as a series of text files.

The Dataset will be transferred to the customer by a secured-encrypted file transfer, from which it can then be held on the customer's server during the licence period, which is 1 year from the date of delivery.

A range of additional services will be offered to the holders of this licence at the following rates:

- Bespoke data to be collected in accordance with protocol requirements – cost to be determined on a project-by-project basis.
- Bespoke data to be collected via questionnaires to answer unique study questions – cost to be determined on a project-by-project basis.
- We can provide a feasibility report at a one-off cost of £6,000 (£3,000 for academic institutions) – these costs are charged at 50% for those holding an unlimited licence.
- Cost List Generation – cost to be determined on a project-by-project basis.
- Validation of SQL - cost to be determined on a project-by-project basis.

	Number of Data Subjects	Commercial Fees	Academic Fees
Standard Licence	Up to 600,000	Up to £60,000	£15,000
	Over 600,000	Bespoke pricing	Bespoke pricing

THE UNLIMITED LICENCE

This licence is optimal for those organisations which have the capability of producing datasets 'in-house' or are seeking multiple datasets using data from OPCRD in a year.

Unlimited licence holders will be able to securely access the whole of the OPCRD database by way of a secure VPN for a one-year period. These customers will be able to produce as many datasets as they wish (having first received ADEPT approval for the dataset) and may host such datasets on their own servers during the licence period.

OPC can also produce datasets for unlimited licence holders. Holders of an unlimited licence will be offered a 50% discount of the standard licence rate.

A range of additional services will be offered to the holders of this licence at the following rates:

- Bespoke data to be collected in accordance with protocol requirements – cost to be determined on a project-by-project basis.
- Bespoke data to be collected via questionnaires to answer unique study questions – cost to be determined on a project-by-project basis.
- We can provide a feasibility report at a one-off cost of £6,000 (£3,000 for academic institutions) – these costs are charged at 50% for those holding an unlimited licence.
- Cost List Generation – cost to be determined on a project-by-project basis.
- Validation of SQL - cost to be determined on a project-by-project basis.

	Commercial Fees	Academic Fees
Unlimited Licence	£190,000	£75,000

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