



Medicines & Healthcare products  
Regulatory Agency



# Clinical Practice Research Datalink (CPRD): data access and application process

Dan Dedman, CPRD. 21 Jan 2019



*National Institute for  
Health Research*

# Clinical Practice Research Datalink



# What is CPRD?

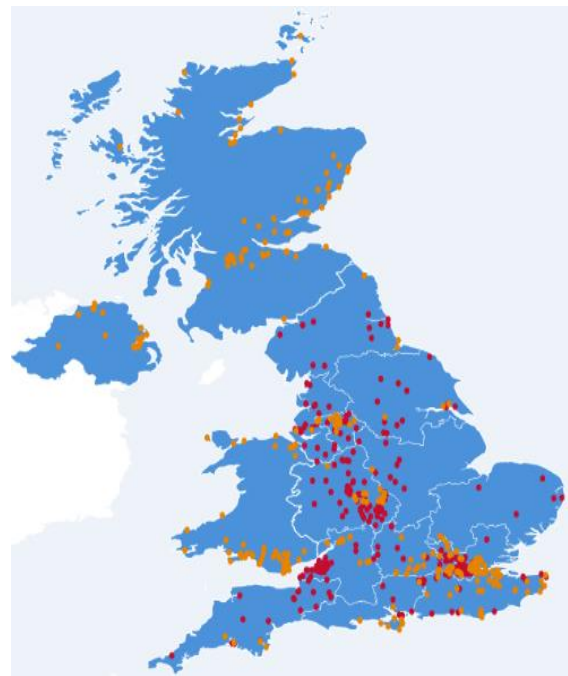


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National Institute for  
Health Research

- UK Government research service supporting **observational** and **interventional** research based on NHS patient records
- Patient records contributed network of **1150 GP practices** from GP practices across UK (>1 in 10 GP practices)
- **30 years** of **collecting** anonymised longitudinal NHS primary care **data**
- Support regulatory, academic & commercial public health research worldwide

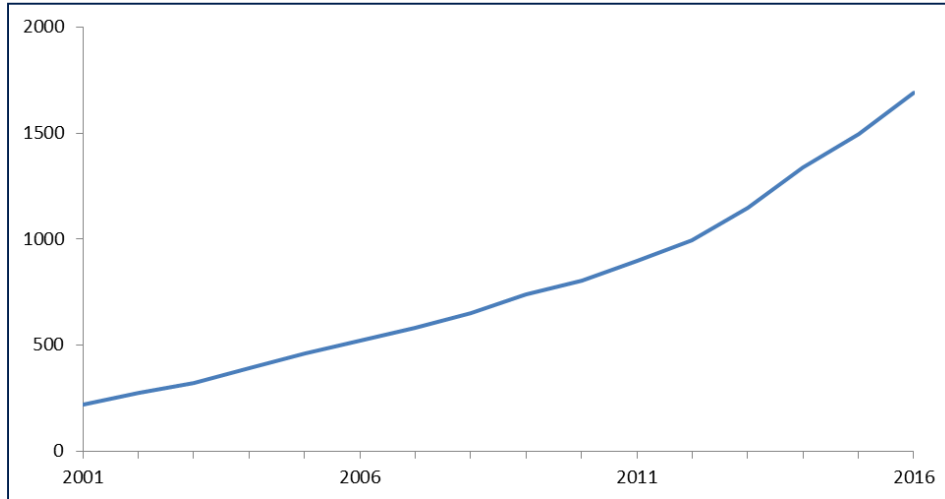


Royal College of  
General Practitioners



# Impact of CPRD data in observational research

>2000 peer-reviewed publications using CPRD data



Drug safety  
Drug use  
Disease epidemiology  
Incidence/prevalence  
Care delivery

PDS Pharmacoepidemiology  
& Drug Safety

Original Report

Use of selective serotonin reuptake inhibitors in pregnancy and cardiac malformations: a propensity-score matched cohort in CPRD<sup>†</sup>

PHARMACOEPIDEMIOLOGY AND DRUG SAFETY 2013; 22: 942-951

FDA



The NEW ENGLAND  
JOURNAL of MEDICINE

N Engl J Med 2016; 374:1145-1154 | March 24, 2016 | DOI: 10.1056/NEJMoa1506115

A Multicenter Observational Study  
of Incretin-based Drugs and Heart Failure

THE LANCET

Volume 364, Issue 9438, 11-17 September 2004, Pages 963-969

MMR vaccination and pervasive developmental disorders: a case-control study

Suspected Cancer Clinical Guidance

**NICE** National Institute for  
Health and Care Excellence

thebmj

Papers

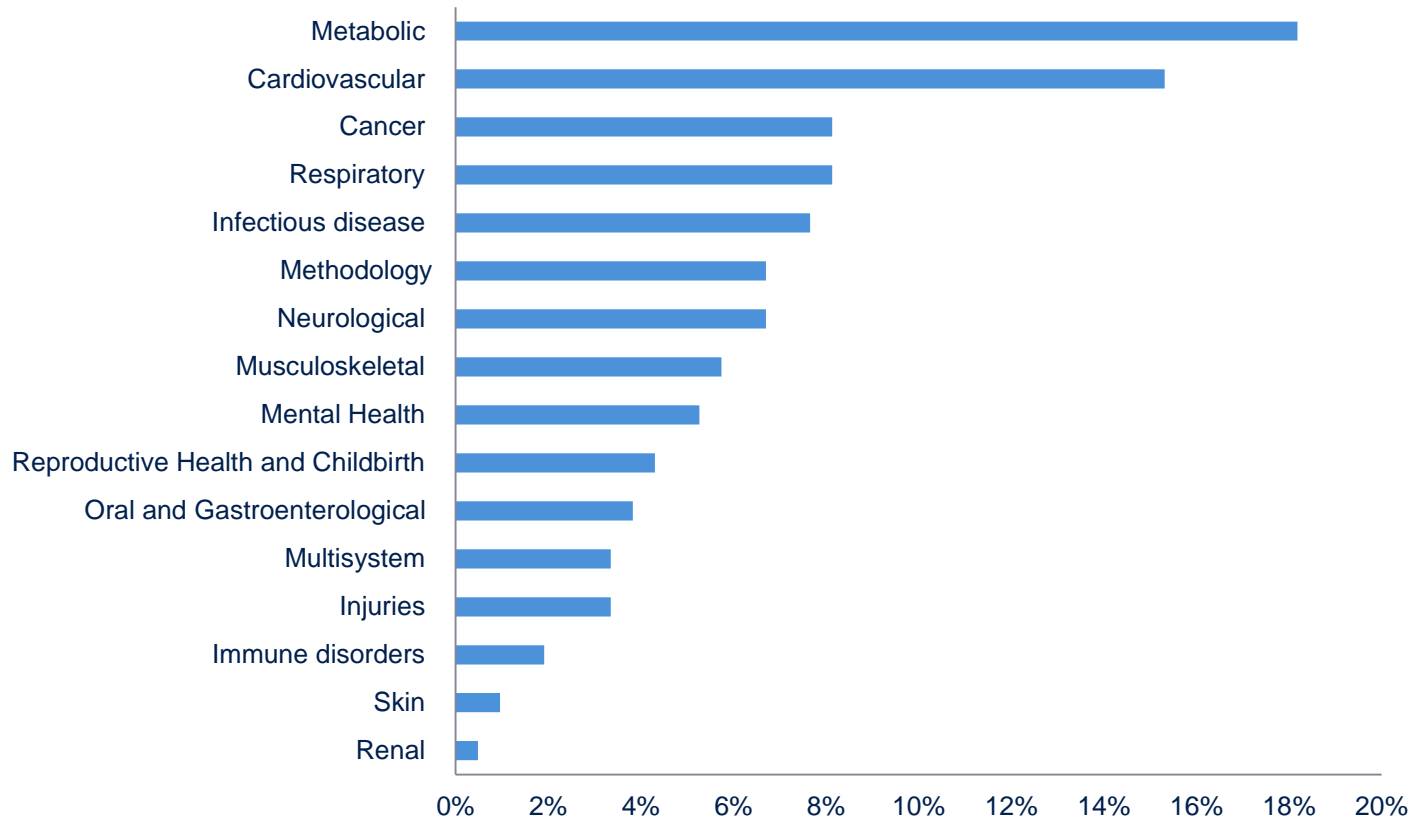
Antidepressant treatment and the risk of fatal and non-fatal self harm in first episode depression: nested case-control study

thebmj

RESEARCH





**Safety of pertussis vaccination in pregnant women in UK: observational study**

# CPRD research output by disease areas



**CPRD bibliography disease and conditions (2016)**

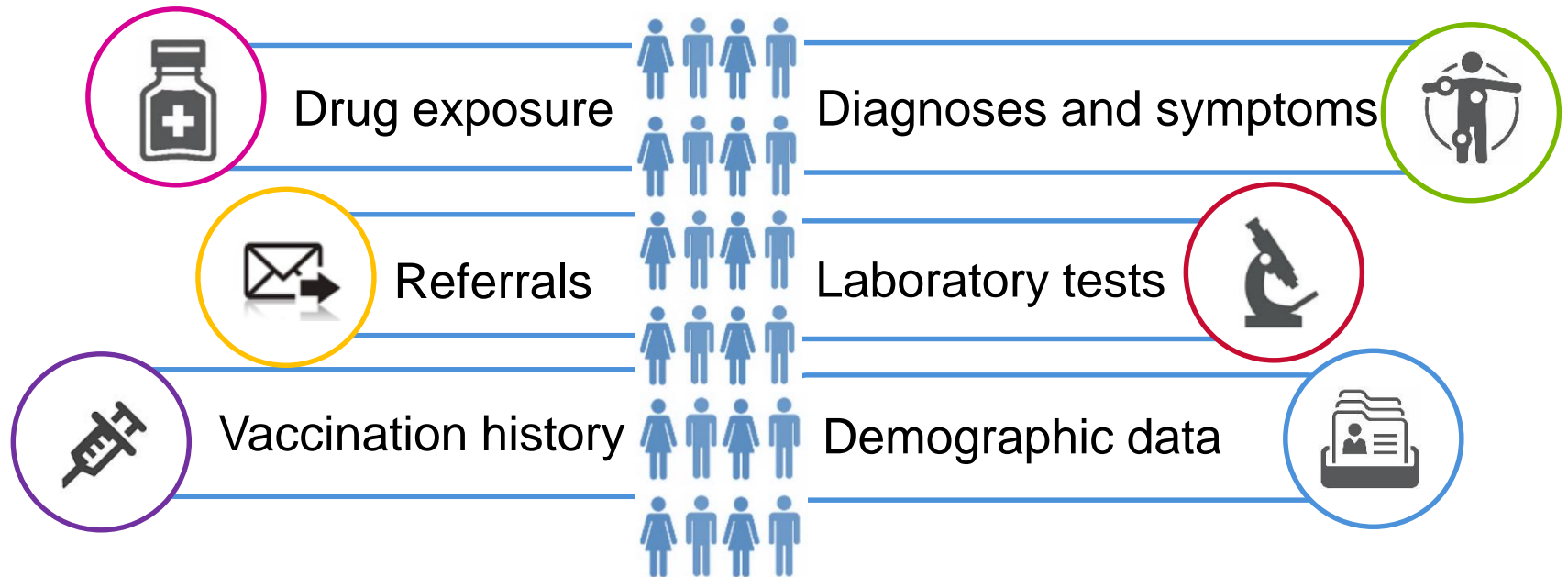
# CPRD UK Population Coverage

- Over 35 million total patient lives on CPRD database 
- 10 million currently registered patients – 15% of UK population
- Data representative of UK population 
- Near real-time data collection – daily updates
- Median follow up time of 10 years – some life long follow up 
- In-house quality checks to ensure a high quality research-ready data 



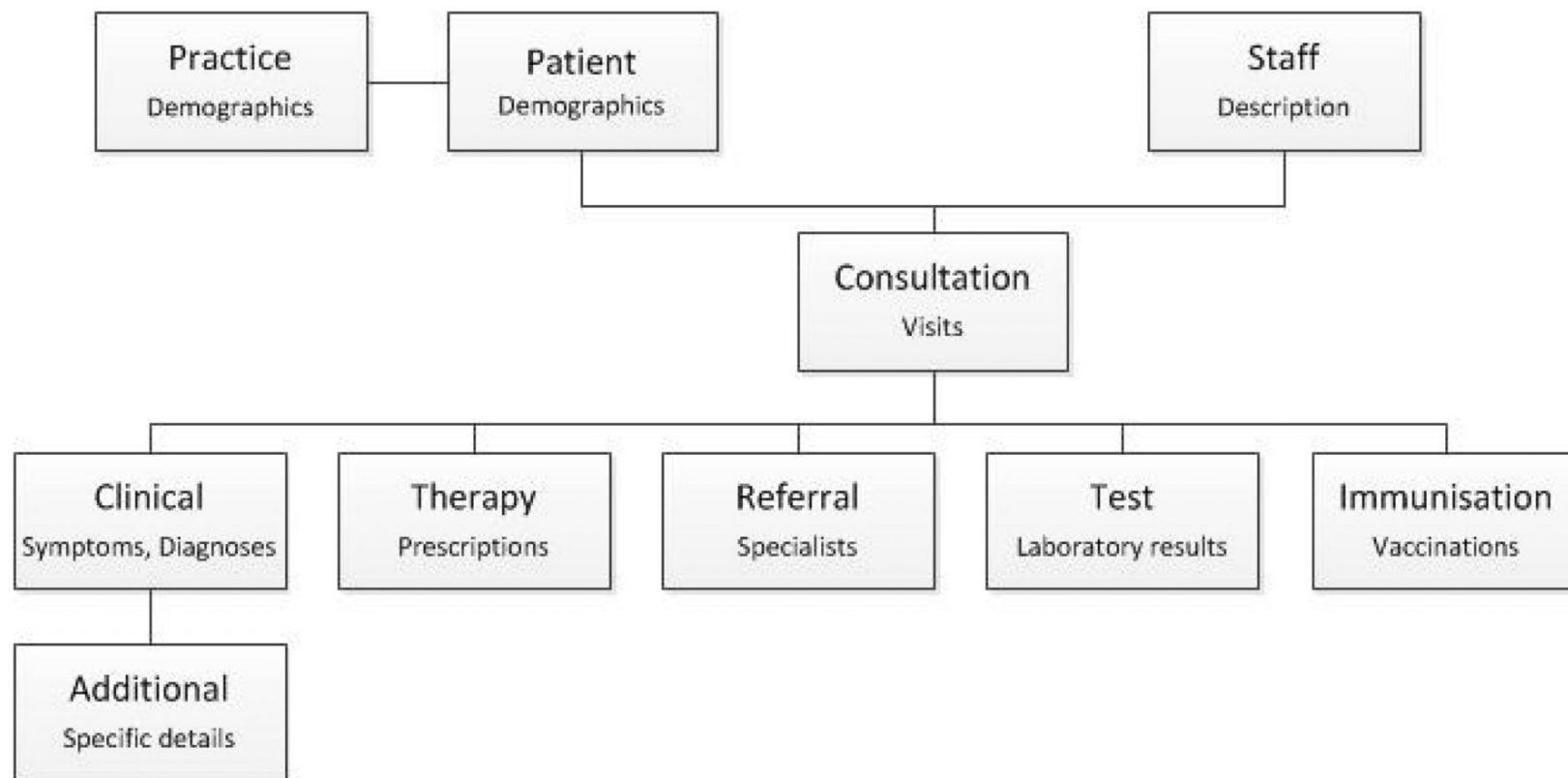
# Coded data from primary care records

Over 3.4 billion consultations including



**Linked to a range of other data sources**

# CPRD GOLD Dataset Structure



Emily Herrett et al. Int. J. Epidemiol. 2015;44:827-836



# Why use CPRD data linkage?

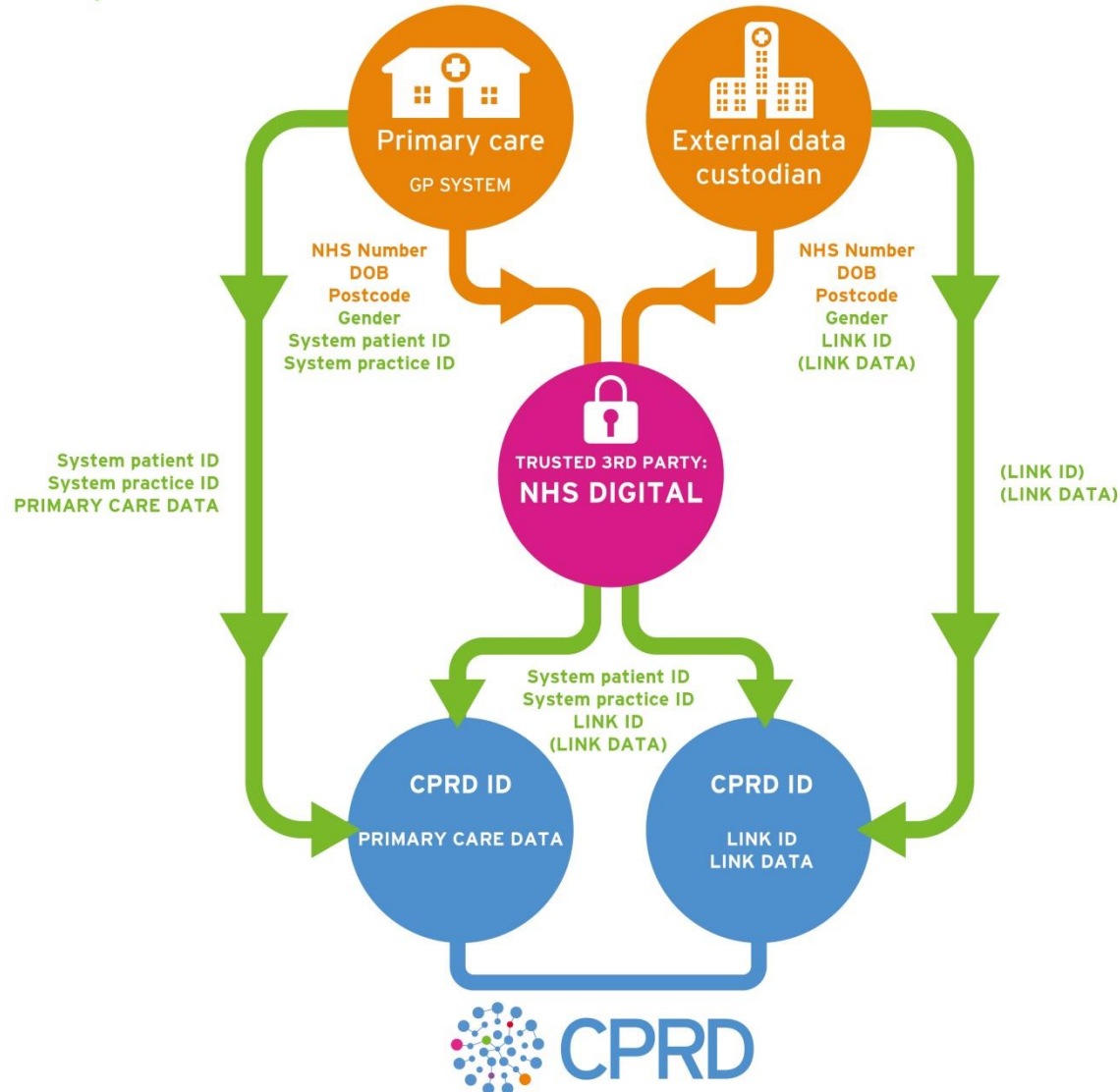


- There are gaps in the primary care data
- Other data sources may be able to help us get a clearer picture
- Questions linked data help us to answer:
  - What was the cause of death?
  - Were they hospitalised?
  - Did they have surgery?
  - Have they seen a specialist?
  - When were they diagnosed with cancer?
  - Is this result associated with socioeconomic status?

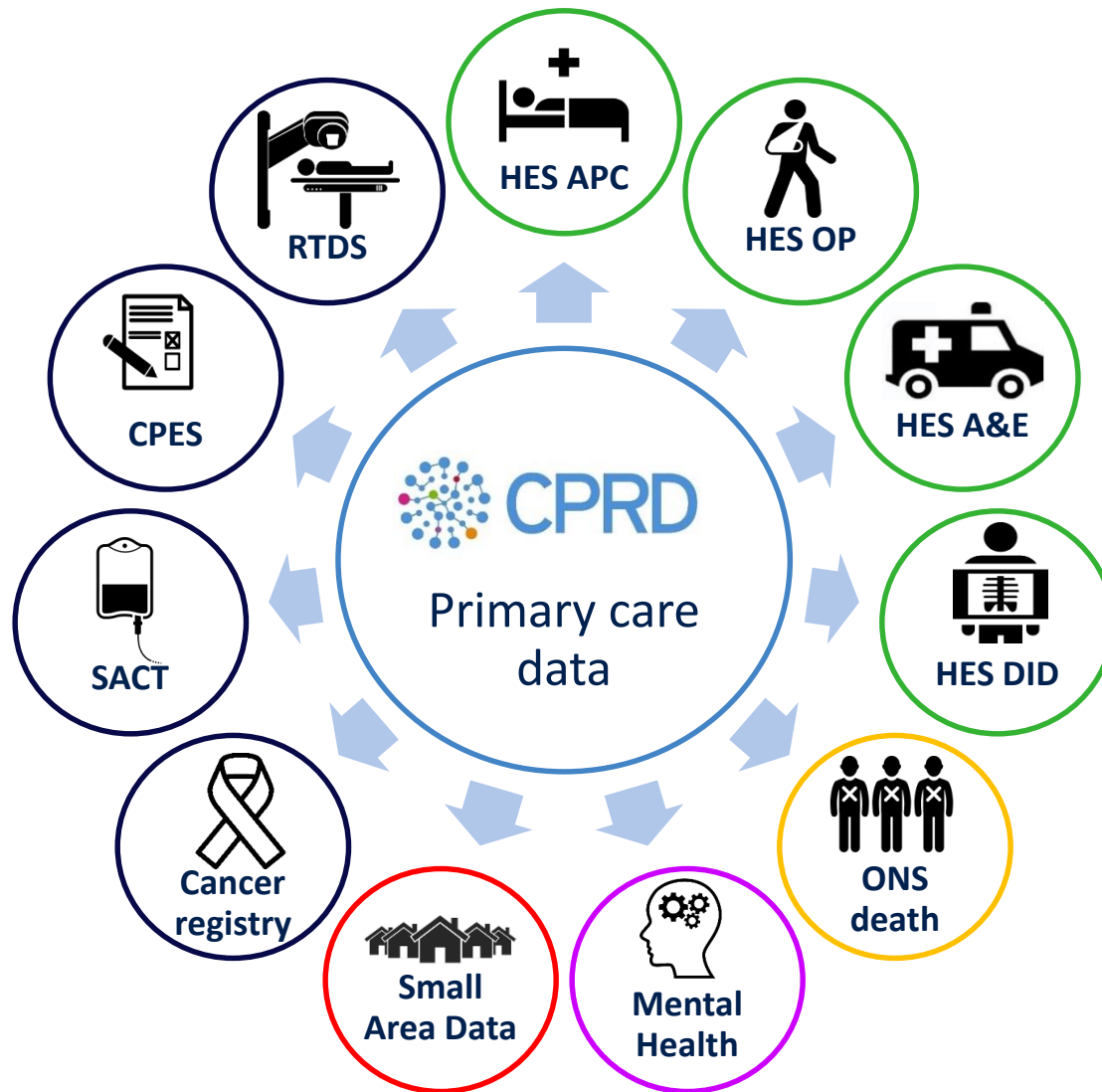
# Linkage Process Overview

Identifiable data

Anonymised data



# Extending scope of research through linkage



# ISAC (Independent Scientific Advisory Committee)

## What is ISAC?

- Expert advisory body for MHRA Database Research
- Consider scientific, ethical and confidentiality issues

## When is ISAC approval required?

- Patient level data for research intended for publication
- When linked data is requested

## The process

- New application form 2018 [cprd.com/research-applications](https://cprd.com/research-applications)
- Initial consideration (4 weeks) – resubmission if required
- Approval
- Amendment if required

# 10 General hints & tips on the forms & guidance

1. Make sure you have the current form & guidance
2. Read the guidance!
3. Look at what other people have done already
4. Answer all questions & complete all sections
5. Stick to 5-10 pages – if it doesn't fit, is it 2 protocols?
6. Include codelists as appendices
7. Number your pages
8. Speak to your collaborators!
9. Speak to a CPRD Researcher
10. Speak to the ISAC Secretariat if anything isn't clear

# Hints & tips on the application form

## General information

- Ensure your title is meaningful and descriptive

## Investigators & collaborators

- Carefully consider your CI and collaborators:
  - CI will take overall responsibility for the study
  - Corresponding applicant for ISAC comms.
  - Collaborators should include everyone who might end up as an author (hands on / off)

# Hints & tips on the application form

## Access to the data

- Ensure the study funding is made clear
- Ensure it's clear who'll be conducting the study
- Consider using EMIS data...and chat to CPRD

## Data linkages

- All linked data will be provided by CPRD
- Relatively new linked data must be discussed first
- Consider carefully which data you need
- If it's not on the list, chat to CPRD first



## 20 golden hints & tips on the protocol – part 1

- A. Ensure title is descriptive and easy to understand
- B. Get your (eldest / youngest / least epi – stats – med – tech - geek) friend to read your lay summary 😊
- C. Talk about your analysis methods in the tech summary
- D. Include an overarching objective as well as your aims
- E. Search the CPRD bibliography and reference papers
- F. Be honest if you are hypothesis testing!
- G. Justify your study design to an epi/stats colleague
- H. Use your fobholders! Include feasibility counts!
- I. Don't assume big = powerful – prove it
- J. Justify use of linked data and recognise limitations

## 20 golden hints & tips on the protocol – part 2

- K. Describe start and end of follow-up carefully – drawing pictures usually helps
- L. Describe matching procedure in detail (not just PS!)
- M. Include algorithms/codelists – don't have to be perfect!
- N. Describe methods in detail – esp. if “novel”
- O. Talk about handling confounding (repeat if necessary)
- P. Don't ignore missing data – where could it occur?
- Q. Consider involving patients and users – they help!
- R. Tell ISAC you're going to publish – and do!
- S. Be specific about the study limitations
- T. Include references

# Requesting Linkages

- After ISAC approval
- Linkage Request Form+ patient identifiers  
>>enquiries@cprd.com, copy in CI
- Dataset Agreement Signed
- Data delivered within 10 working days
- Cancer linkages by Public Health England (PHE) delivered ~3 months

# How to access linked cancer registry data

Before submitting an ISAC protocol:

- *If requesting a new cancer dataset discuss with CPRD first*

Complete a dataset agreement form

- *ask Eleanor Yelland (enquiries@cprd.com) to review your application*

When the agreement finalised, submit your ISAC protocol

CPRD extracts CPRD GOLD (and any other linked datasets) and generates new patient identifiers

- *The new ids cannot be linked back to the original cancer registry or to CPRD GOLD.*

Dataset is sent to PHE who link to the cancer registry data

- *PHE send the linked data back to CPRD*

For more information please contact CPRD at:  
**[enquiries@cprd.com](mailto:enquiries@cprd.com)**

