



Medicines & Healthcare products
Regulatory Agency



Clinical Practice Research Datalink (CPRD)

Use of CPRD data in clinical research

Dr Puja Myles, Head of Observational Research, CPRD
Joint BIA and MHRA Conference, 5 July 2018



Overview of CPRD

- UK Government research service supporting **observational** and **interventional** research based on NHS patient records
- A Centre of the MHRA that is jointly funded by the NHS National Institute for Health Research (NIHR) and the MHRA
- Patient records contributed from network of GP practices across UK
- Database contains 30 years of anonymised NHS primary care data
- Linked data
- Other services include: Bespoke linkage, Supplementary data collection (for e.g. GP validation questionnaires and patient reported outcomes) and electronic healthcare record (EHR)-enabled pragmatic trials
- Support regulatory, academic & commercial public health research worldwide



CPRD

UK data driving real-world evidence



years of electronic health record data collection



of UK healthcare consultations are in primary care



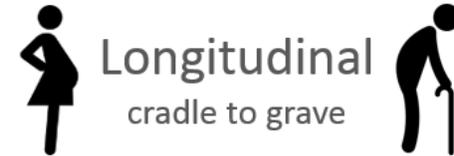
Over

30M

patient lives

10M

currently registered patients



Longitudinal
cradle to grave

Representative
age, sex and ethnicity



Data linkage

Over

20

countries worldwide use CPRD data producing more than

2000

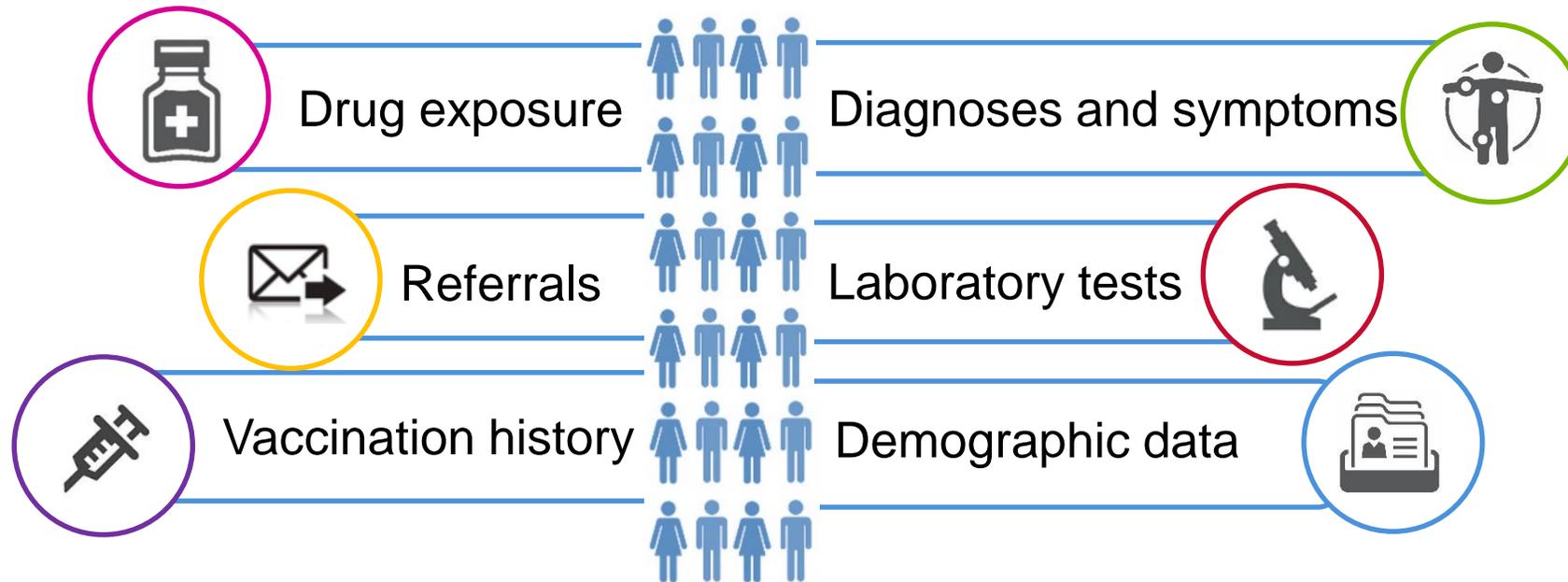
peer-reviewed publications



CPRD

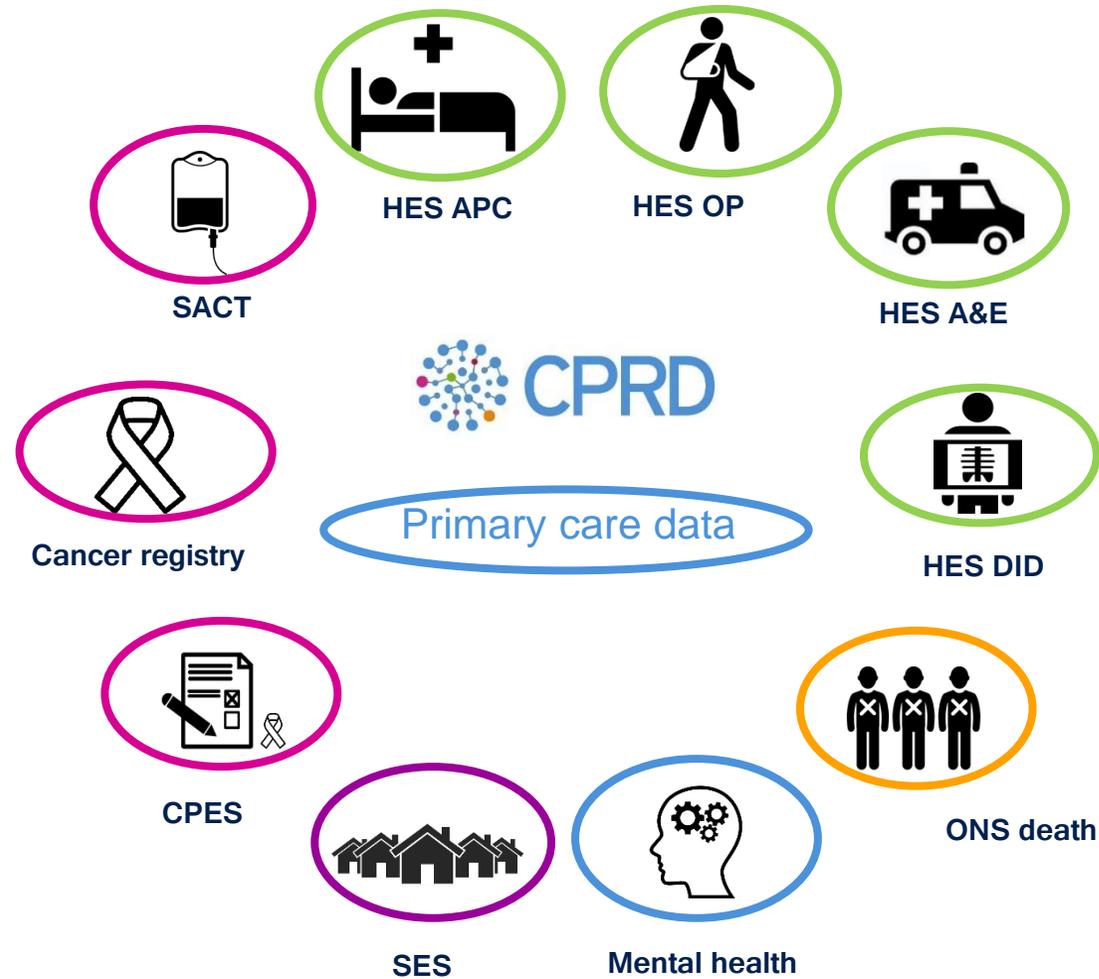
CPRD data: Coded data from primary care records

Over 3 billion consultations including



Linked to a range of other data sources

Extending scope of research through linkage



How is CPRD data used?

Epidemiology and public health



Prevalence and incidence estimates

Temporal Trends in Incidence, Prevalence, and Mortality of Atrial Fibrillation in Primary Care (Lane, 2017)



Nature of and risk factors for disease

Clinical relevance of thrombocytosis in primary care: a prospective cohort study of cancer incidence using English electronic medical records and cancer registry data (Bailey, 2017)



Healthcare resource utilisation

The frequency of asthma exacerbations and healthcare utilization in patients with asthma from the UK and USA (Suruki, 2017)



Public health burden and costs

Cost-Effectiveness of Orthogeriatric and Fracture Liaison Service Models of Care for Hip Fracture Patients (Leal, 2017)

How is CPRD data used?

Pharmacovigilance and comparative effectiveness



Drug safety

Cardiovascular safety of vildagliptin in patients with type 2 diabetes: a European multi-database, non-interventional post-authorization safety study (Williams, 2017)



Vaccine safety and real-time monitoring

Implementing near real-time vaccine safety surveillance using the Clinical Practice Research Datalink (Leite, 2017)



Treatment evaluation

Dapagliflozin therapy for type 2 diabetes in primary care: Changes in HbA1c, weight and blood pressure over 2 years follow-up (Wilding, 2017)



Comparative effectiveness

Comparative effectiveness of novel oral anticoagulants in UK patients with non-valvular atrial fibrillation and chronic kidney disease: a matched cohort study (Loo, 2018)

Additional EHR-enabled CPRD services



Supplementation of EHR data collection

Supplementing electronic health records through sample collection and patient diaries: a study set within a primary care research database (Joseph, 2017)



Patient recruitment

Linking e-health records, patient-reported symptoms and environmental exposure data to characterise and model COPD exacerbations: protocol for the COPE study (Moore, 2016)



Cluster randomised interventions

Electronically delivered, multicomponent intervention to reduce unnecessary antibiotic prescribing for respiratory infections in primary care: a cluster randomised trial using electronic health records - REDUCE Trial study original protocol (Juszczak, 2017)



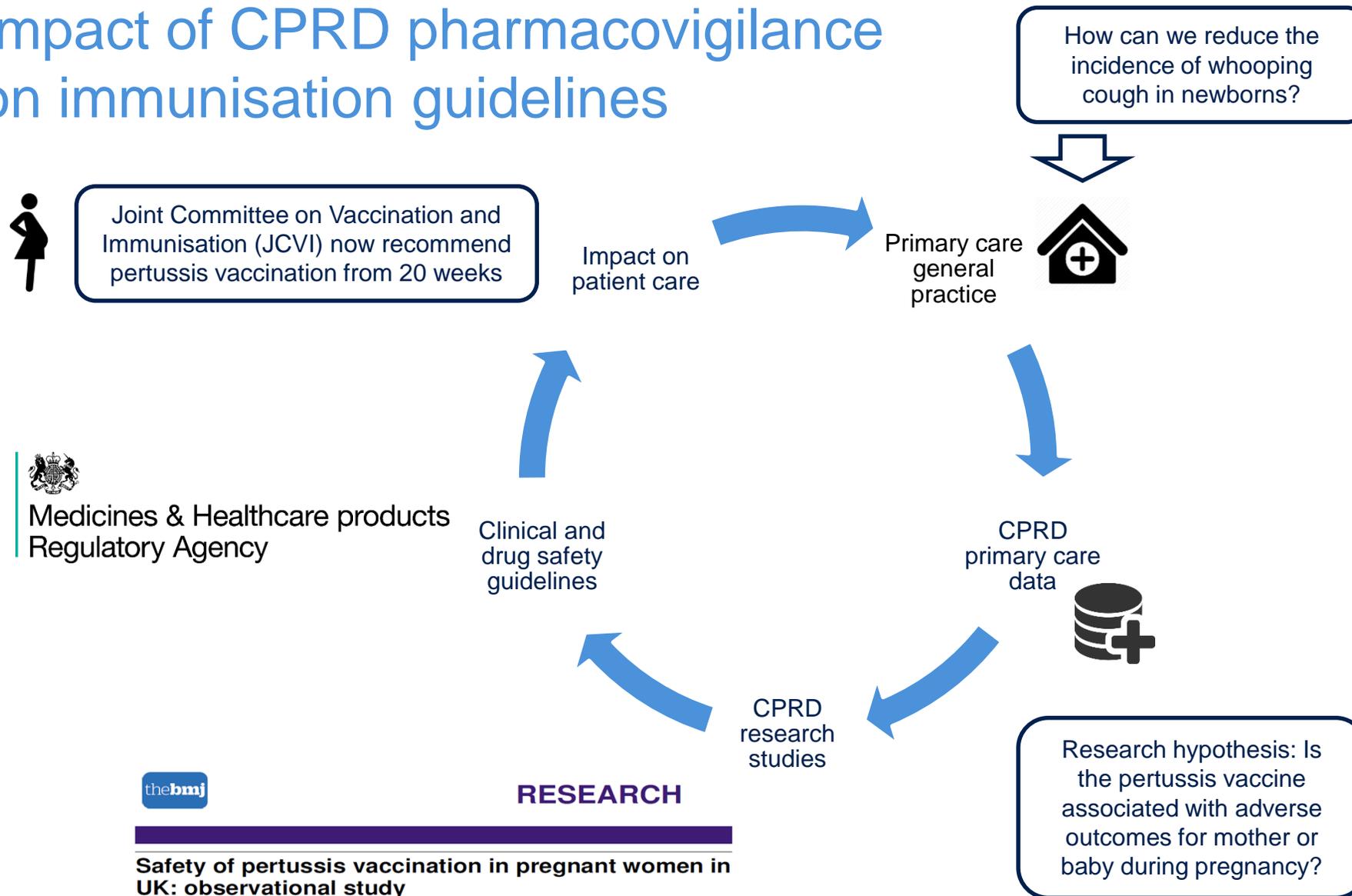
Pragmatic randomised trials

A Pragmatic Trial to Evaluate the Comparative Effectiveness between Dapagliflozin and Standard of Care in Type 2 Diabetes Patients

Case studies



Impact of CPRD pharmacovigilance on immunisation guidelines



Safety of whooping cough vaccine during pregnancy

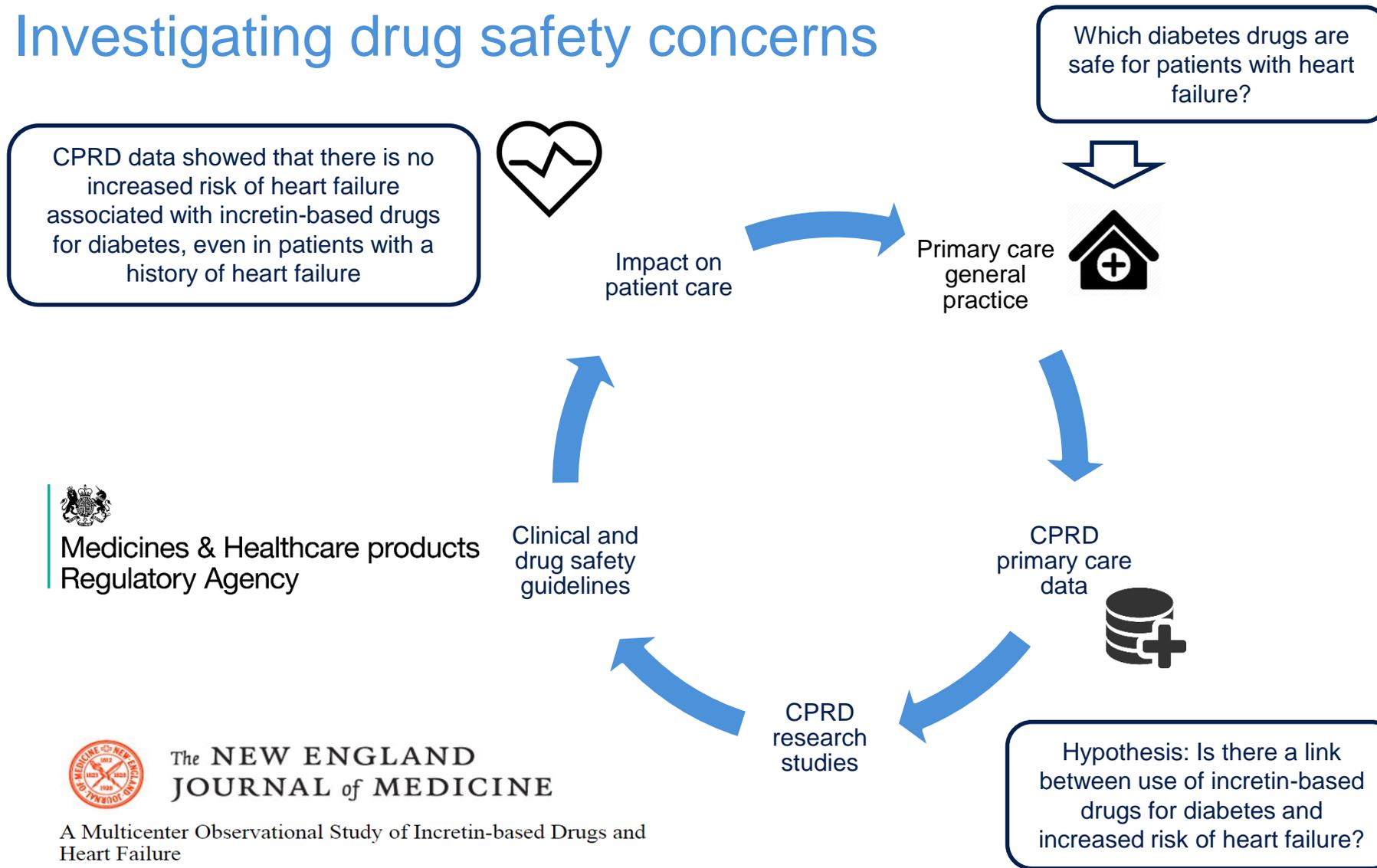
- National pertussis immunisation programme introduced in 2012 for pregnant mothers in response to an outbreak in newborns
- MHRA statutory responsibility for vaccine safety - as close to real time pharmacovigilance as possible
- Used **CPRD primary care data + CPRD mother baby link** for 20 074 pregnant women who received the pertussis vaccine and a matched historical unvaccinated control group
- No increased risk of stillbirth immediately after vaccination or across pregnancy
- As of April 2016 all GP and maternity services offer the vaccine from 20 weeks of pregnancy



Donegan K et al. BMJ. 2014 Jul 11;349:g4219

<https://www.bmj.com/content/349/bmj.g4219.long>

Investigating drug safety concerns



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The NEW ENGLAND JOURNAL of MEDICINE

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

Kristian B. Filion, Ph.D., Laurent Azoulay, Ph.D., Robert W. Platt, Ph.D., Matthew Dahl, B.Sc., Colin R. Dormuth, Sc.D., Kristin K. Clemens, M.D., Nianping Hu, M.D., Ph.D., J. Michael Paterson, M.Sc., Laura Targownik, M.D., M.S.H.S., Tanvir C. Turin, M.D., Ph.D., Jacob A. Udell, M.D., M.P.H., and Pierre Ernst, M.D., for the CNODES Investigators*
N Engl J Med 2016; 374:1145-1154 | March 24, 2016 | DOI: 10.1056/NEJMoa1506115

Safety of incretin-based drugs for diabetes care

- Concerns over the use of incretin-based drugs for diabetes and increased risk of heart failure
- **CPRD primary care data + HES APC**
- Results **pooled with data with Canadian and US health** data (1.5M patients total)
- Rate of hospitalisation for heart failure did not increase with the use of incretin-based drugs compared with other antidiabetic agents, even in patients with a history of heart failure
- Large, multicentre case-control study essential for high quality pharmacovigilance



Filion KB et al. N Engl J Med. 2016 Mar 24;374(12):1145-54.

Selective serotonin reuptake inhibitor use and breast cancer survival

- Investigated the association between SSRI use and cancer-specific mortality.
- **PHE cancer registry data + CPRD + ONS death registration + IMD** at the practice level
- 24,000 breast cancer patients, of which 2672 used SSRIs and 3053 died due to their breast cancer during follow-up
- There was some evidence of increased breast cancer mortality among SSRI users, even when restricting to patients with prior depression
- Possible confounding by indication as SSRI users had a higher underlying risk of mortality than the non-users



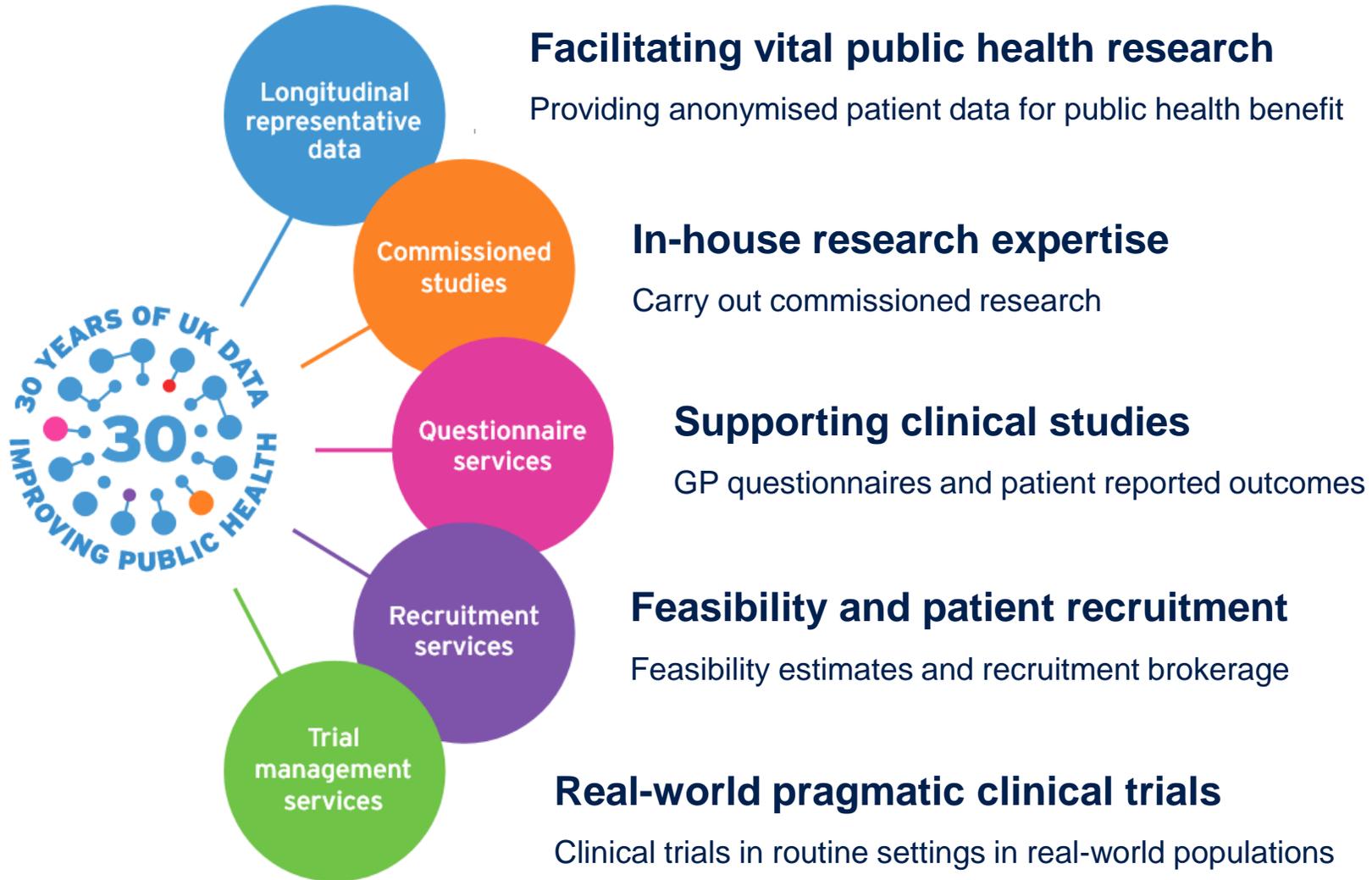
Busby et al *Breast Cancer Research* 2018 **20**:4

<https://breast-cancer-research.biomedcentral.com/articles/10.1186/s13058-017-0928-0>

Caveats when using EHR data

- Prescribed medication vs. dispensed vs. used
- Over the counter use
- In-hospital drug exposure
 - Ward trolley
 - Emergency use
- Specialist prescribing
- Some patient groups and therapeutic areas are absent (prisoners, the homeless, private treatment, biologics)
- Confirmation/validation
 - Use linked data sources
 - Consider questionnaires to patients/GPs

CPRD primary care real-world data research services



Questions?

For more information please contact CPRD at:

enquiries@cprd.com

We look forward to continuing to work with you.

