

UK PV/PE Scene



John Parkinson PhD
Director, GPRD
Seconded Expert- Research Capability Programme

UK Health Care

- | NHS- 99.9% of people
- | Registered with one GP practice
 - | Transfer to another with longitudinal record GP2GP
- | All but 2 practices (9000+) have e- records
- | Essentially only 4 GP IT systems
 - | Problem based
 - | And or Record based
- | Many are paperless or paper light
- | GP is gatekeeper
 - | Apart from emergency care, no access anywhere else
 - | Key secondary and other care data flows back to GP who enters into EHR
- | Except when in hospital/day care- all drugs via GP
- | Unique NHS ID- NHS# 10 numeric
- | BUT
- | 4 Health Services
 - | England 80%, Scotland 10%, Wales, 4%, NI 3%
- | Research Capability Programme- England -
 - | Connecting for Health (CfH)- English NHS IT project (£12 Billion)
 - | UK Clinical Research Collaboration (UKCRC)
 - | Office of Central Coordination of Health Research (OSCHR)
 - | National Institute for Health Research (NIHR)

Drug Exposure

- 95% of all drugs Rxed by GP
 - Primary care
 - Secondary care recommendation
 - Post hospitalisation
- 5% administered in hospital setting
 - In Hospital
 - Cancer Day care
 - Some highly specialist drugs
 - 2010 person level data
- Dispensed data starting 2010

Events

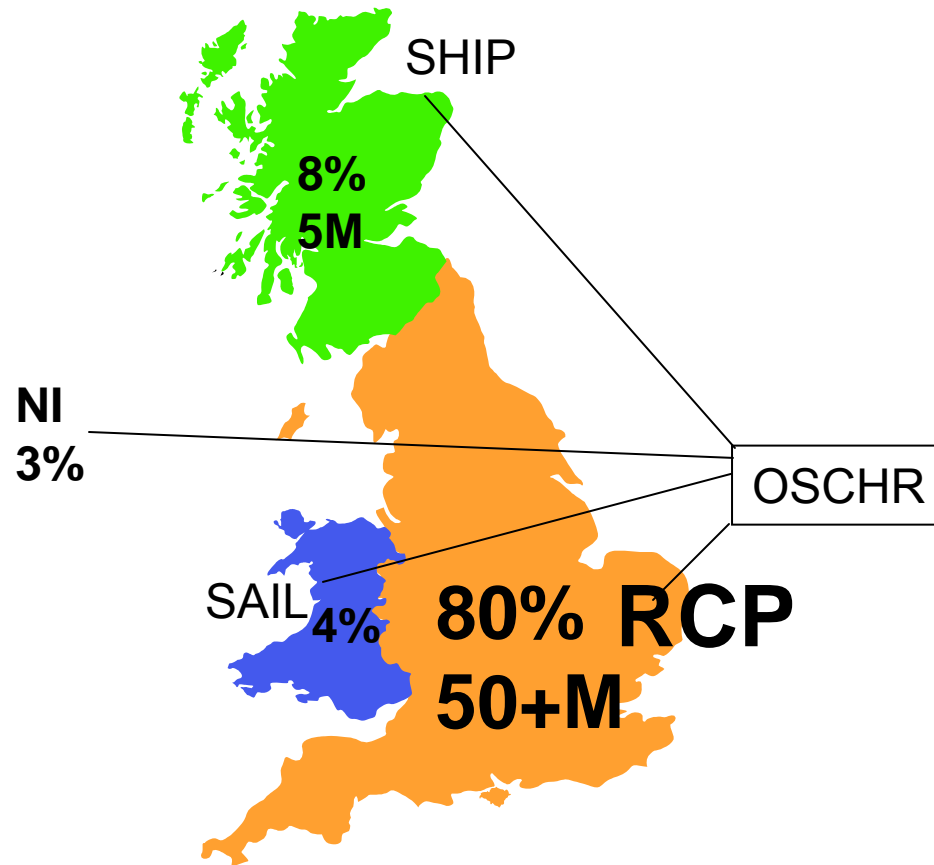
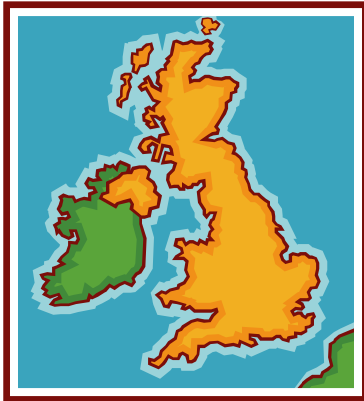
- | GP records
 - | All Events- (READ)
 - | Consultations
 - | By email, letter, phone
 - | Primary hospital discharge summary (TEXT to READ)
 - | GPRD (5% sample UK) 60 billion events over 23 years
- | Hospital Episode Statistics
 - | All events (ICD10)
 - | 99.9% cover
- | Death data
 - | 90-95% in GP record
 - | Fully in central linkable record

UK Health Research....Data today

| GPRD

- | 5% UK sample
- | High quality longitudinal data
- | 2.8 billion events (41M BMI), 12 million n ever, 3.5 M active
- | Linked to
 - | Full admin Hospital data (HES) ICD9, OPCS4, dates by ward
 - | Full detailed CVD record (MINAP)
 - | Full Cancer registry data
 - | Central Death data
 - | 2010 Hospital and day care Rx (admin)

United Kingdom



ENGLAND RCP

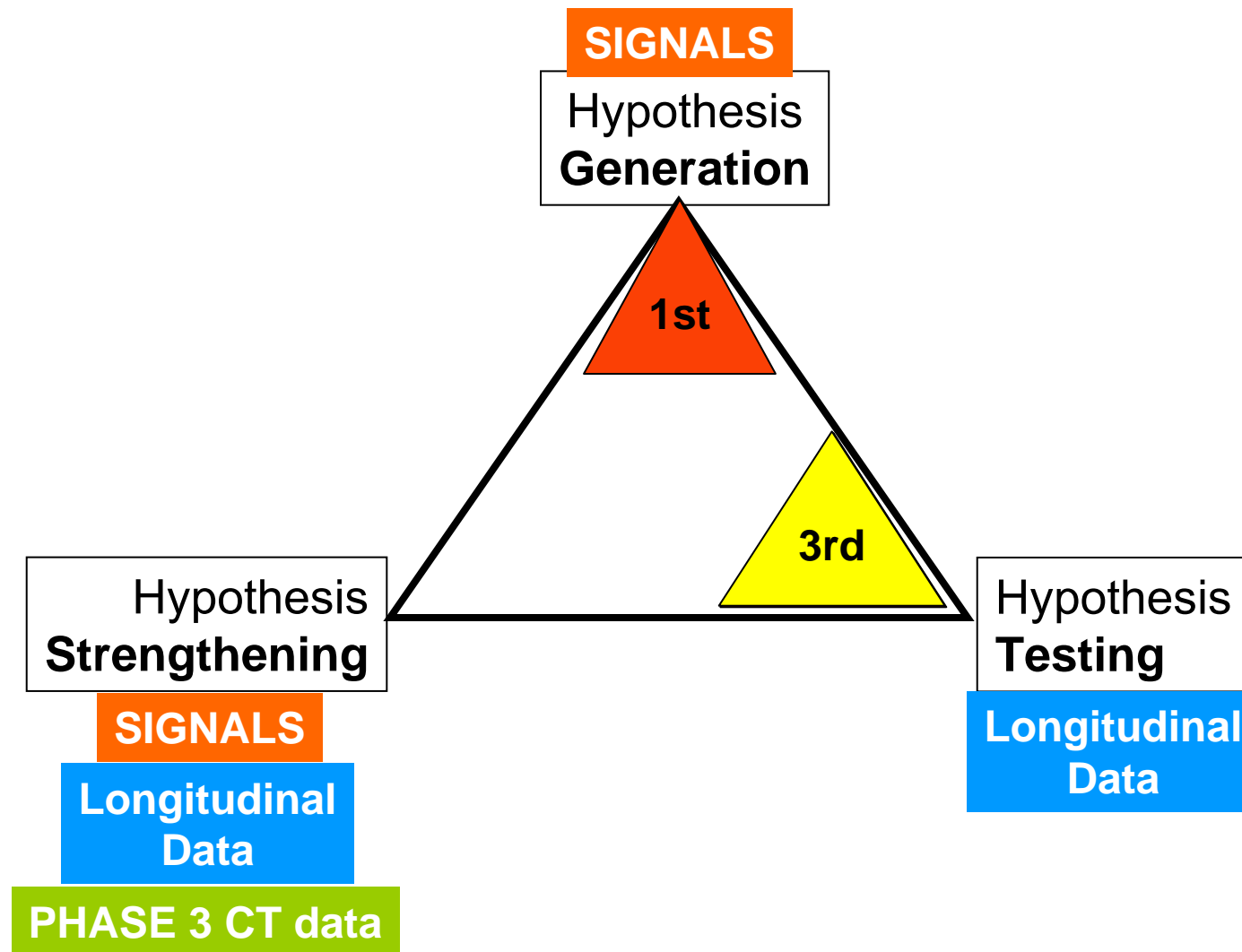


Research Capability Programme

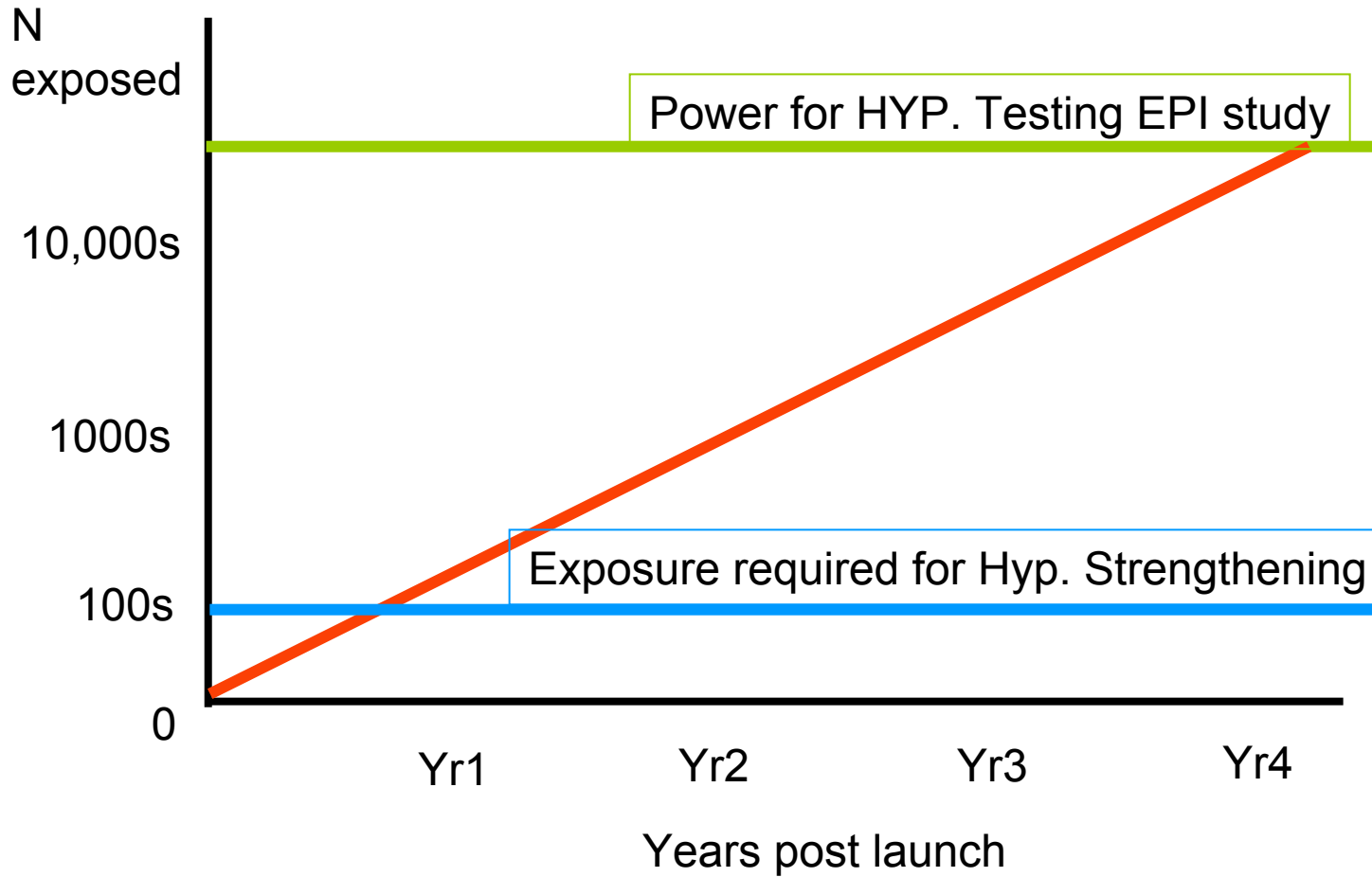
Health Research Support Service

- **Max collection of Primary Care data**
 - **Some in near real time**
 - **Essentially FULL all person EHR**
 - **All Lab tests**
 - **All life style**
 - **All events**
- **Linked with**
 - **Central Death data (99.9%)**
 - **Central Hospitalisation (99.9%)**
 - **Key disease registers (40)**
 - **MINAP Cancer Implants**
 - **BIOBANK (500,000)**
- **Central single point Clinical Trial system**

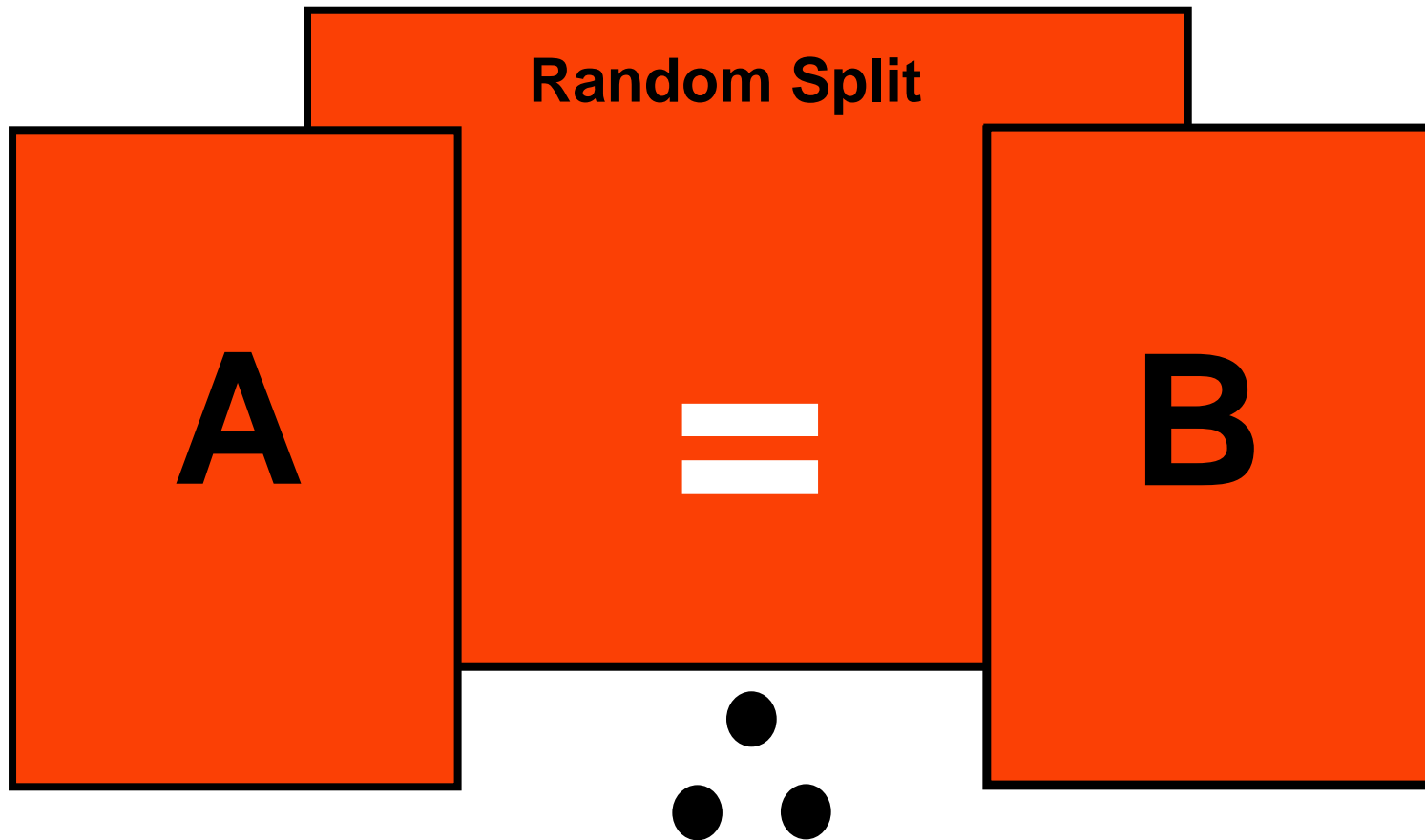
**Underlying
Principles
of
PV/PE**



United Kingdom



Data Mining and Hypothesis Testing in One dataset



UK Hypothesis generation **SIGNALS**

- Yellow Card system- paper based
 - Doctors
 - Health Care Professionals
 - Patients
- eYellow Cards
 - Fully embedded within EHR systems
 - Expert system
 - Auto-filled in with key details
 - Comments added
 - Sent in over NHSnet
 - “Conversation” possible

UK Hypothesis Strengthening

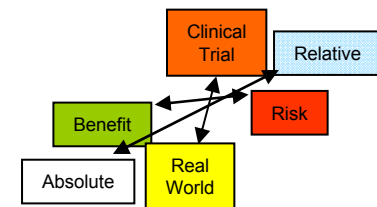
SIGNALS Longitudinal Data PHASE 3 CT data

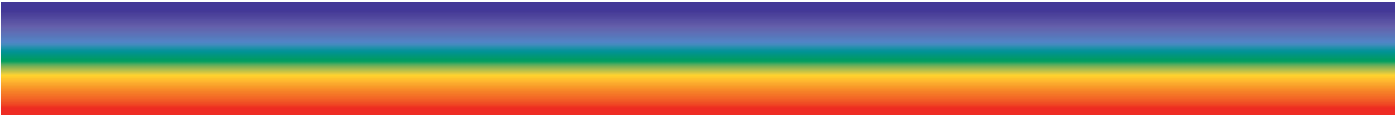
- | On day 1 of a new product
 - | RR from Phase 3 studies modelled with real world data
 - | Uses ExEtrac methodology
- | Better contextualisation of signal data

Outline methodology ExEtrac

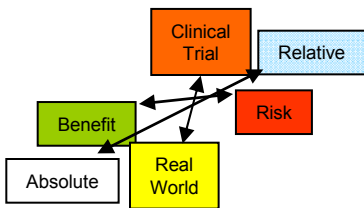
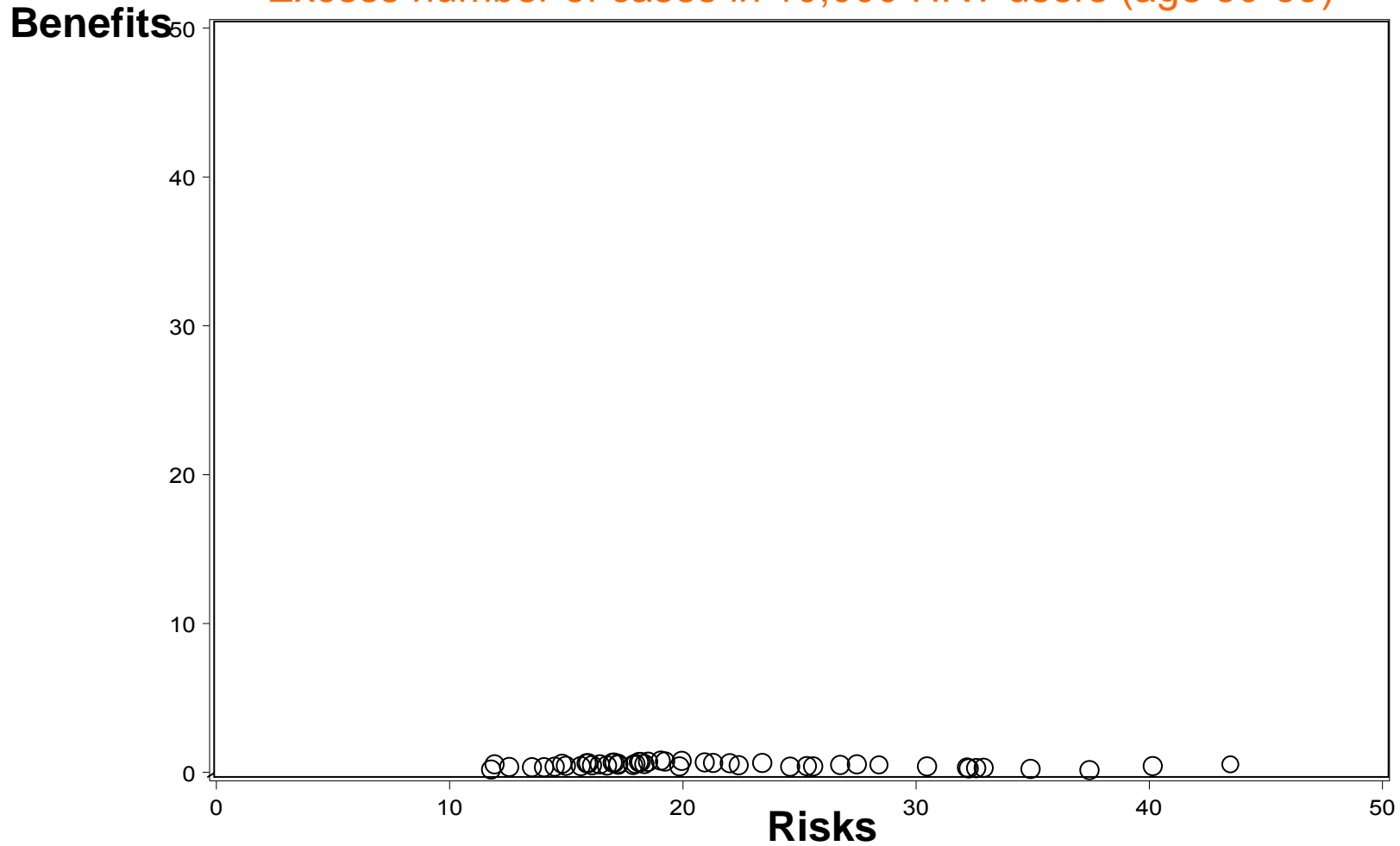
- | Relevant RRs from Phase 3 trials
- | Real/observed incidence rates –on treatment
- | Derived real world “non Treatment” rates
- | Attributable (absolute rate)= treatment R- non T R

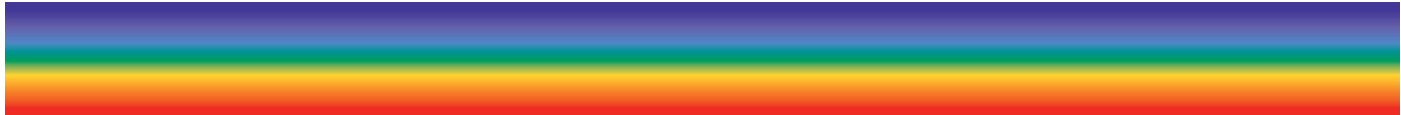
- | (Causal)
- | What if true
- | Model uncertainty
- | Weighted Risk to Benefit
- | QOL can also be involved





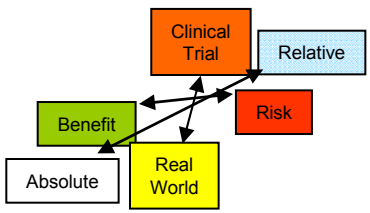
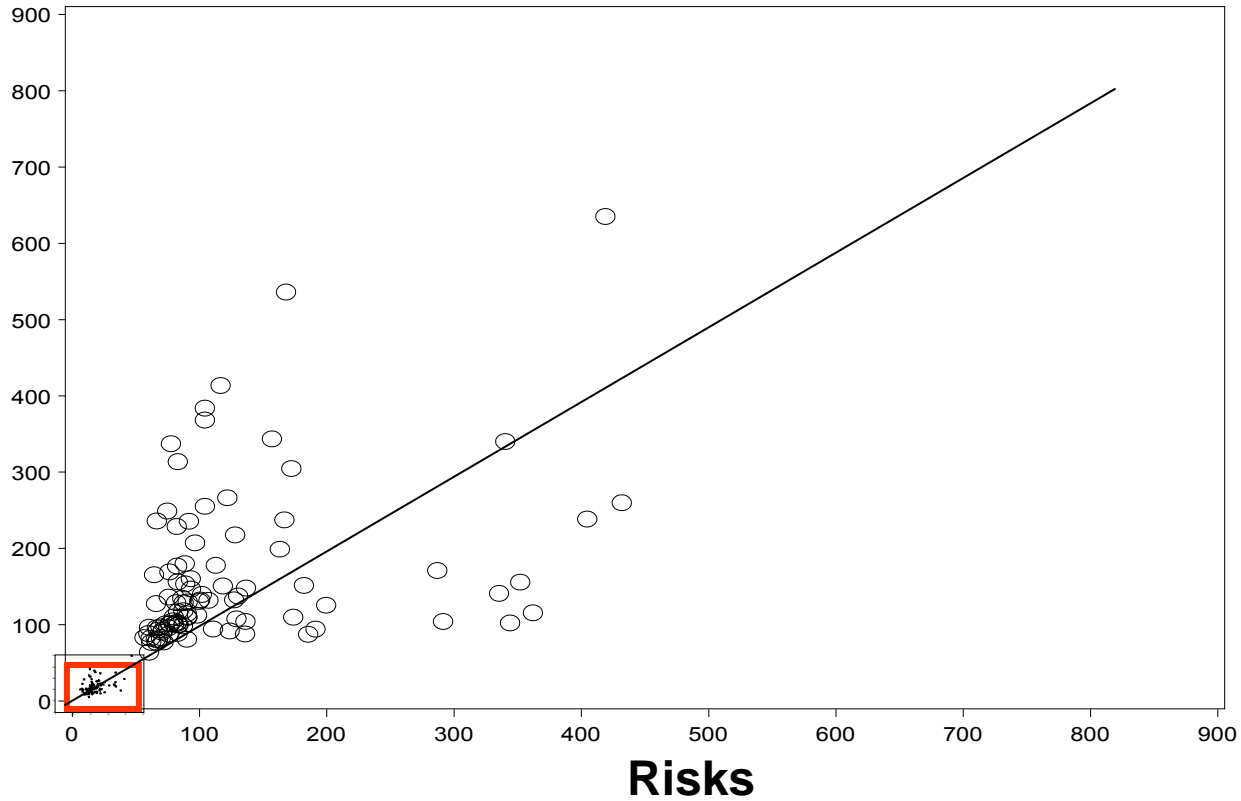
Excess number of cases in 10,000 HRT users (age 50-59)





Excess number of cases in 10,000 HRT users (age 70+)

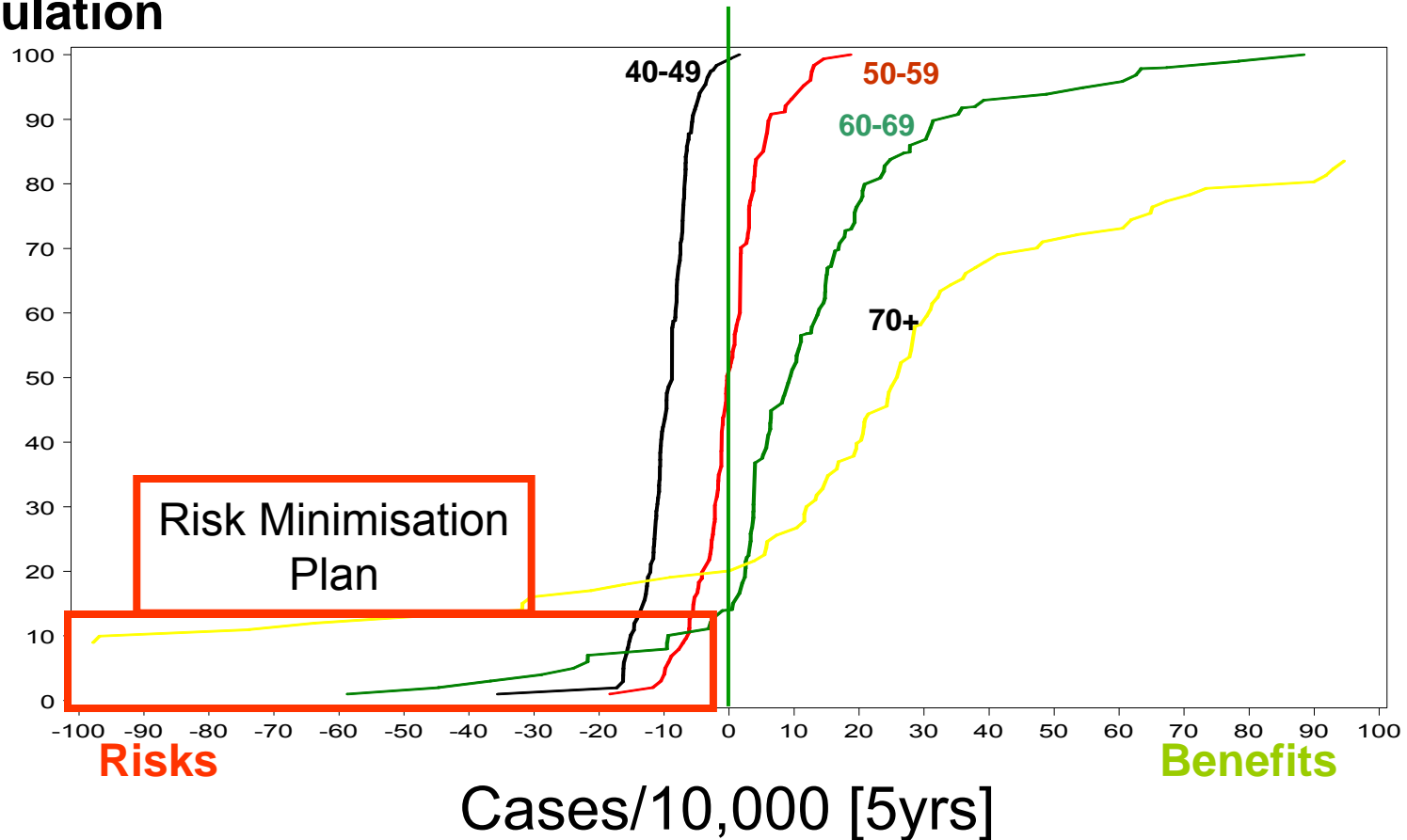
Benefits



United Kingdom

Risk-benefit acceptability curves by age (5 year HRT use)

% population



Randomisation in everyday clinical care

- Confounding/ channelling
- Possible because of eHR
- Modified IT system for auto-prompt
- Randomisation across web
- Data collection in EHR
- Wait for events
- Low cost- big Ns possible
- 3 studies in GPRD network, funded and in final planning

Summary

- Encourage more GP, HC professionals to report ADRs- Yellow Cards
- Auto- e Yellow cards
- Full EHR/ linkable data
- Better contextualisation of YC data
- Risk Management – new products
 - ExEtrac methodology
 - Earlier licensing- full n follow up
- Rando. In every day care
- Full exposure record including Phase 3 CTs.

