University of Nottingham
UK | CHINA | MALAYSIA

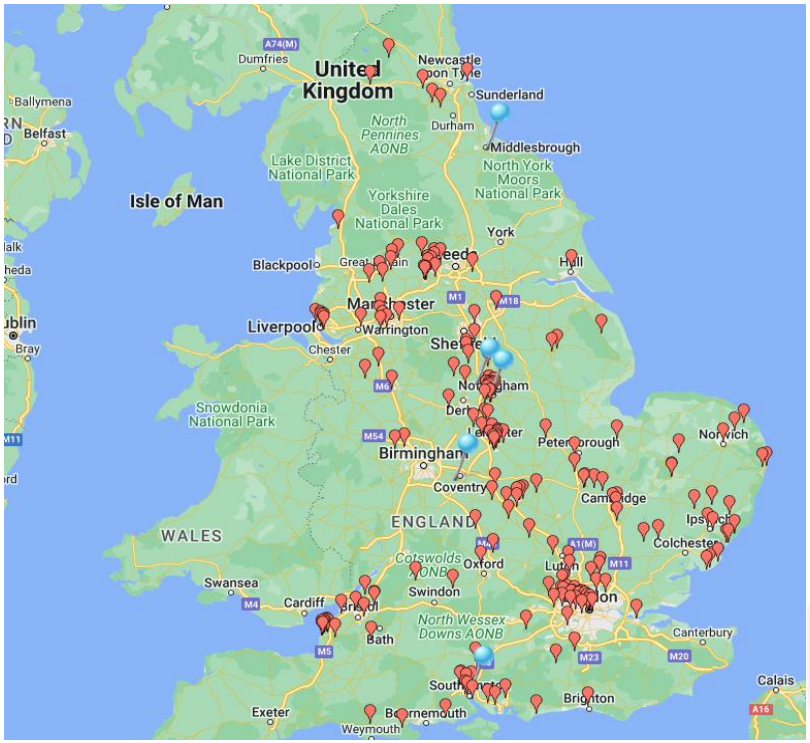
STopping Aminosalicylate Therapy in Inactive Crohn's Disease

A Randomized, Open-label, Non-inferiority Trial

Gordon W. Moran

STopping Aminosalicylate Therapy in Inactive Crohn's disease

People aged 18+ with Crohn's Disease in remission currently taking aminosalicylate therapy



n≈ 1000 patients from primary care
≥1500 GP practices

Eligible ✓

1:1 randomisation

Continue 5-ASA (n-790) 50% of the subjects will continue aminosalicylate therapy using the same dose

5-ASA withdrawal (n-790) 50% of the subjects will discontinue aminosalicylate

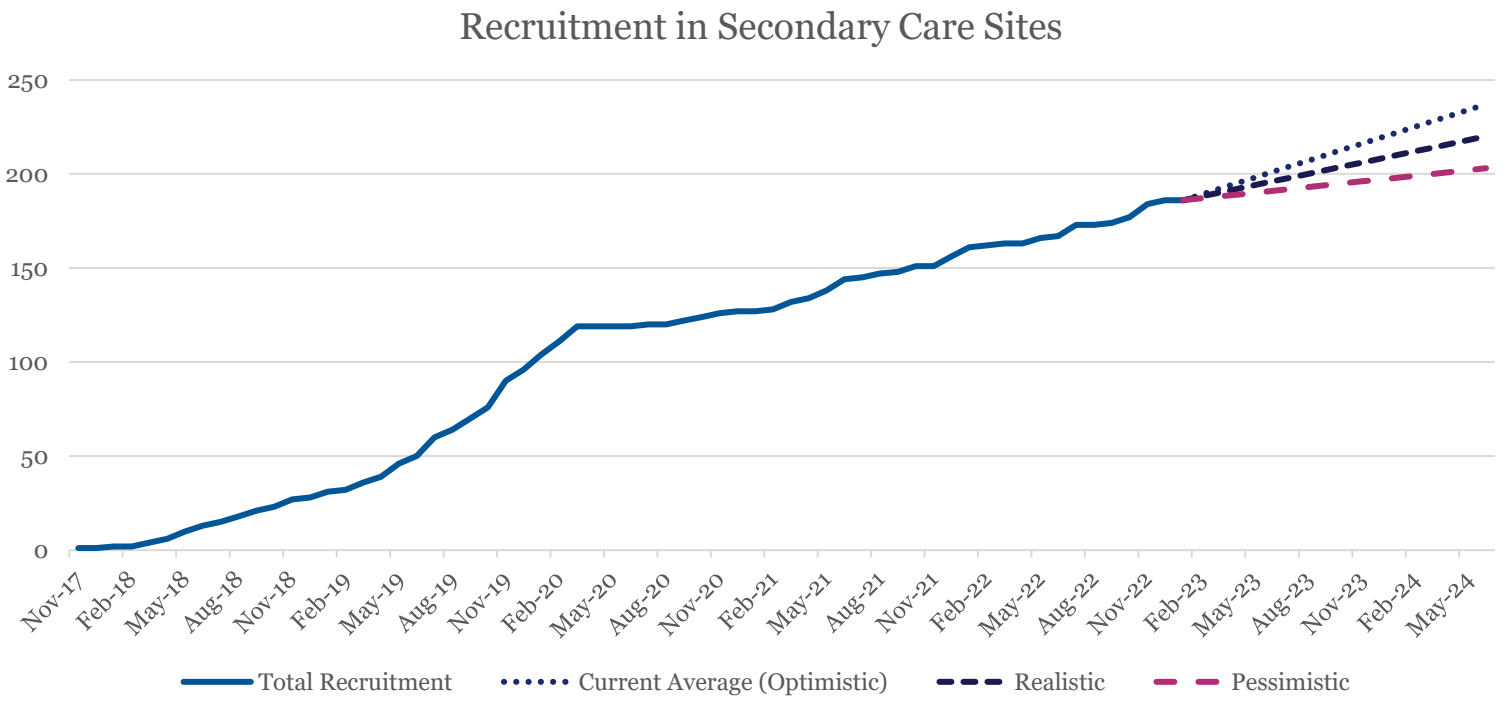
Ongoing usual care in both arms

Primary Objective of STATIC

Determine whether withdrawal of 5ASA is non-inferior to the continuation of 5ASA in subjects with CD in remission with regard to a primary endpoint of CD-related complication within 24 months after treatment allocation

Study Status Overview

Secondary Care - Recruitment



Data Driven Trial methodology

Screening and recruitment

Primary care data

Fragmented systems

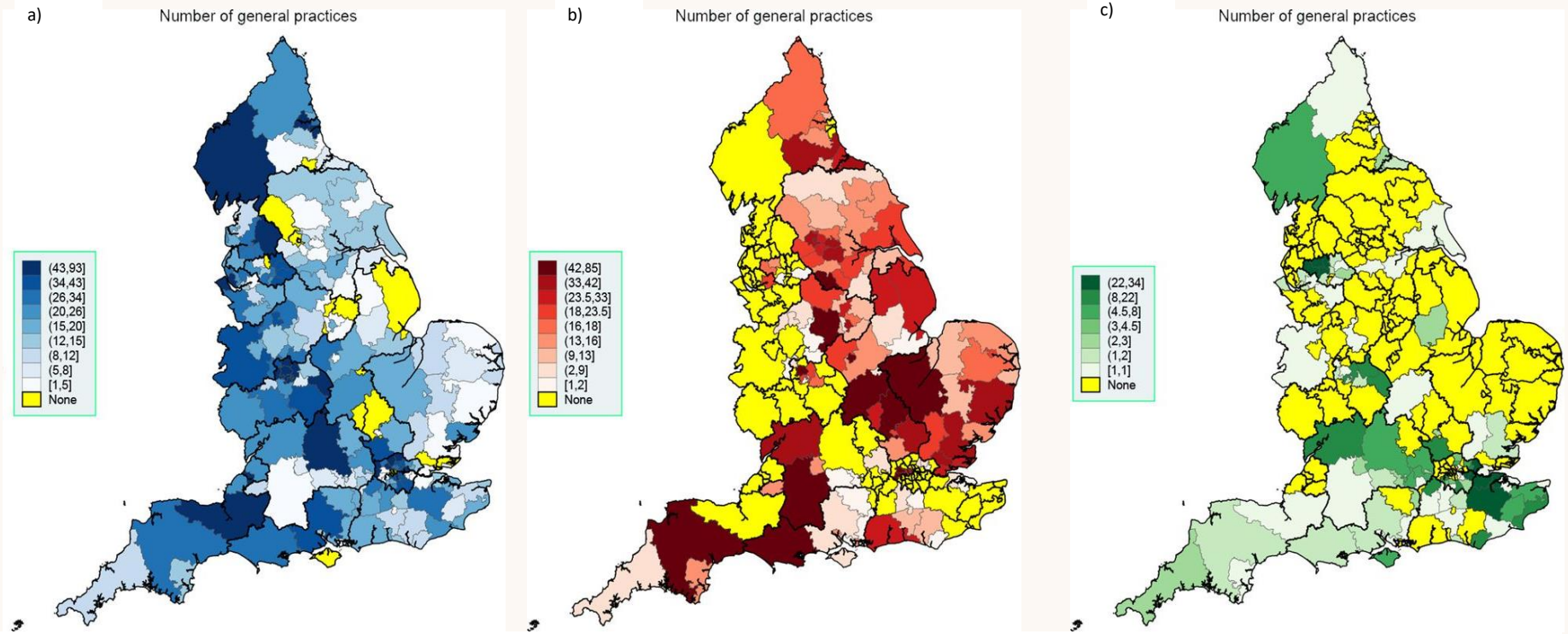
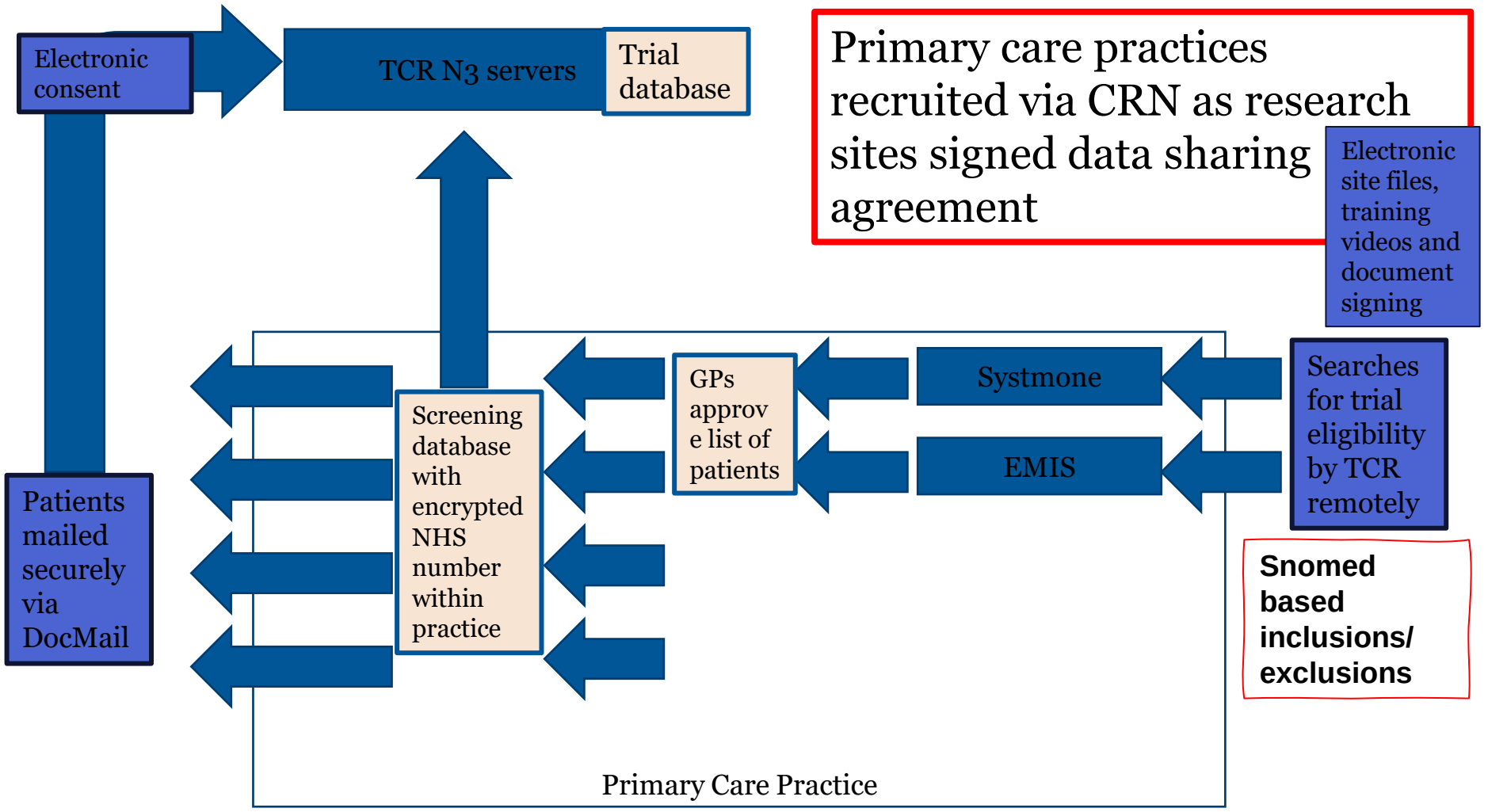


Figure 1 Spatial map at the CCG level, September 2016: a) EMIS b) SystmOne c) Vision. Thicker border lines correspond to the 14 NHS regions. Evangelos Kontopantelis et al. BMJ Open 2018;8:e020738 ©2018 by British Medical Journal Publishing Group


Electronic consent
TCR N3 servers
Trial database
Primary care practices recruited via CRN as research sites signed data sharing agreement
Electronic site files, training videos and document signing
Patients mailed securely via DocMail
Screening database with encrypted NHS number within practice
GPs approv e list of patients
Systmone
EMIS
Searches for trial eligibility by TCR remotely
Snomed based inclusions/ exclusions
Primary Care Practice

Follow up

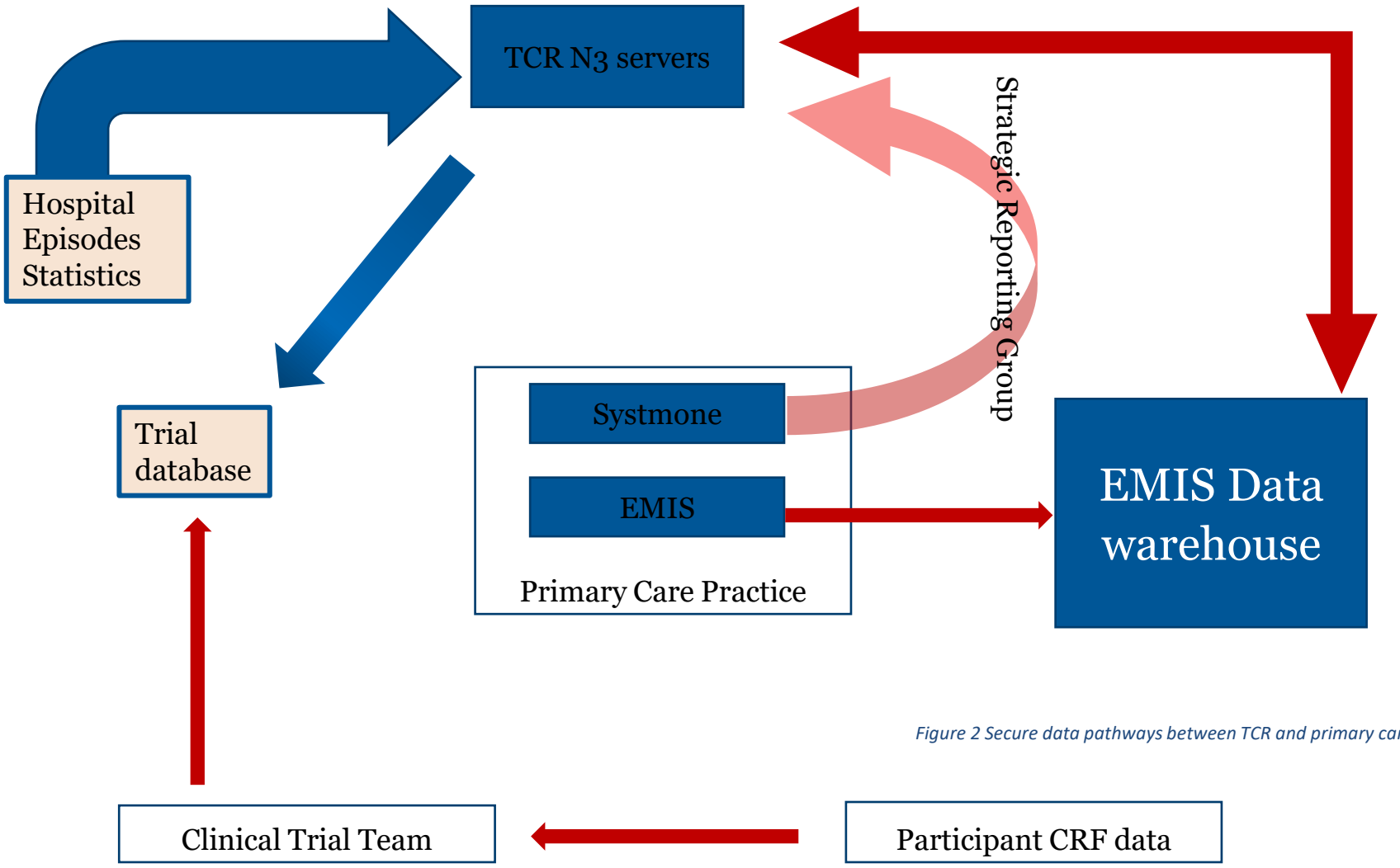


Figure 2 Secure data pathways between TCR and primary care practices

Date Of Report	**05/01/2024**
Total Packages Mailed To GP Practices	**392**
Activated GP Practices	**252**
GP Practices That Have Performed Patient Searches	**238**
GP Practices That Have Mailed Out Invitation Letters	**202**
Number Of Letters Sent	**977**
Number Of Non Responders Letters Sent	**536**
No	**187**
Maybe	**45**
Yes	**115**
Consented	**99**

Large Efficient Simple trials

Works best

- Eligibility is a prevalent condition
- Can be identified by routine coding
- Intervention does not require GP
- Outcome to be coded (e.g. HEAT, STATIC) though not necessarily (VESPER, Vascular Platform trials, other NIHR submissions in process)

Challenges

- Changes in coding systems
- NHS security and governance approvals
- Preparation is key for a smooth delivery
- Pressures in primary care / time for research
- Getting CRN on board, limiting factor by how many CRN practices are willing to participate ~ 500 practices (IBD prevalence of ~1%, with a standard practice size of 10,000 patients).

The University of Nottingham

NOTTINGHAM CLINICAL TRIALS UNIT

TCR Nottingham