electronic Primary Care Research Network (ePCRN)

The University of Minnesota, USA.

The University of Birmingham, UK.

The University of California San Francisco, USA.

Funded by the National Institutes of Health (NIH), USA.

Outline

- Who is ePCRN?

- Why ePCRN is needed?

- What is ePCRN?

- What ePCRN needs?
  - obstacles, challenges and requirements

Project team

Minnesota:
- Family Medicine
  - Kevin Peterson
  - Joe Stone
  - Pat Fontaine
  - Carol Lange
  - Adam Wolff
  - Mark Janowiec
- Computer Science
  - Stuart Speedie
  - Jon Weissman
  - Seonho Kim
  - Mike Coonrod

San Francisco
- Internal medicine
  - Ida Sim

Birmingham:
- Primary Care
  - Brendan Delaney
  - Richard Hobbs
  - Darren Douglas
  - Hardeep Sandhar
- Electrical Engineering
  - Theo Arvanitis
- Computer Science
  - Marta Kwiatkowska
- Joint appointments
  - Adel Taweel
  - Lei Zhao

Problems and Challenges

Subjects Identification

Communication

Intervention Management

Complexity of Managing (Primary Care) clinical trials

Monitoring

Paper Work

Data Collection

A big issue with capacity and methodology

- Even common clinical problems need far bigger numbers in RCTs than a single practice can provide.

- Primary Care RCTs need Research networks.

- Research Networks need infrastructure.

The NIH Roadmap for Medical Research

- Position NIH to address evolving public health challenges

- Accelerate the pace of discoveries

- Develop more rapid two way translation: from Laboratories to patients and vice versa

ePCRN clinical Perspective

Research
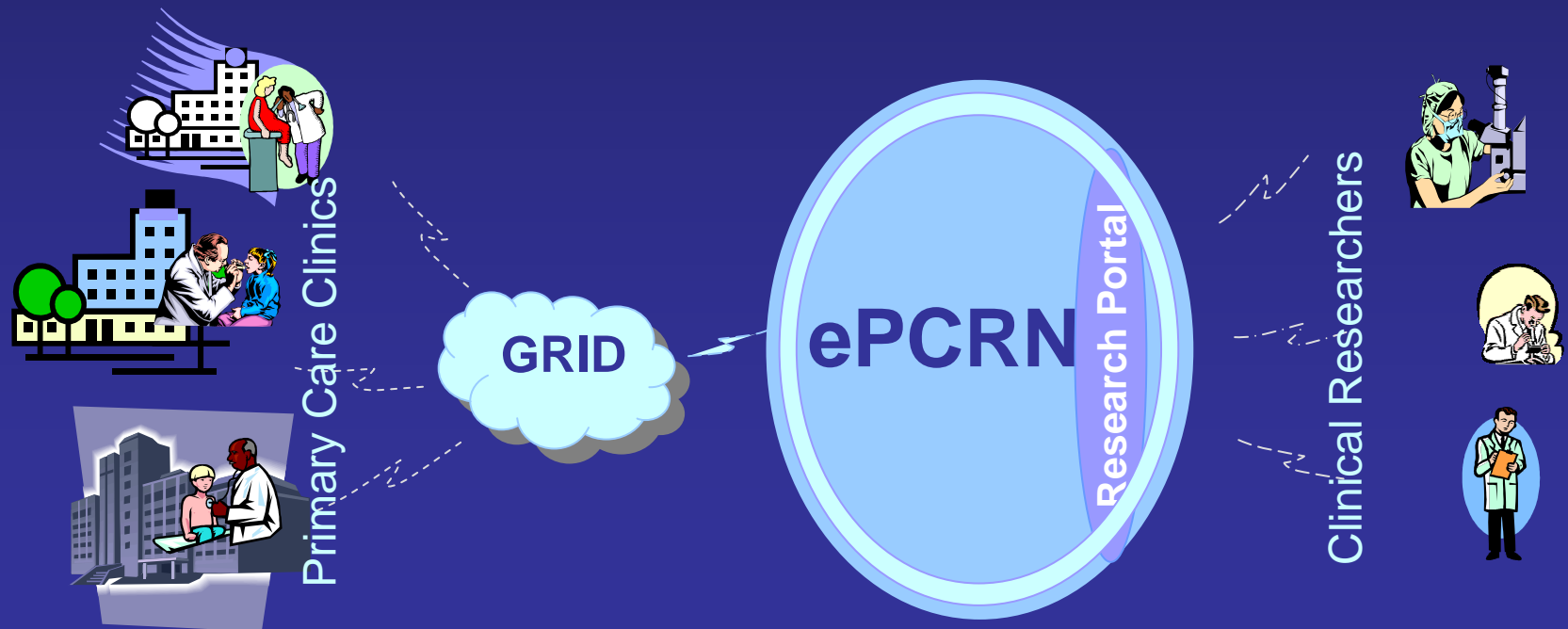
Research

ePCRN

Translation

Primary care clinic

Quality Improvement

Researcher

Main Goals

- To establish an RCT management system for US Primary Care
- To establish a secure distributed query process for US EHRs
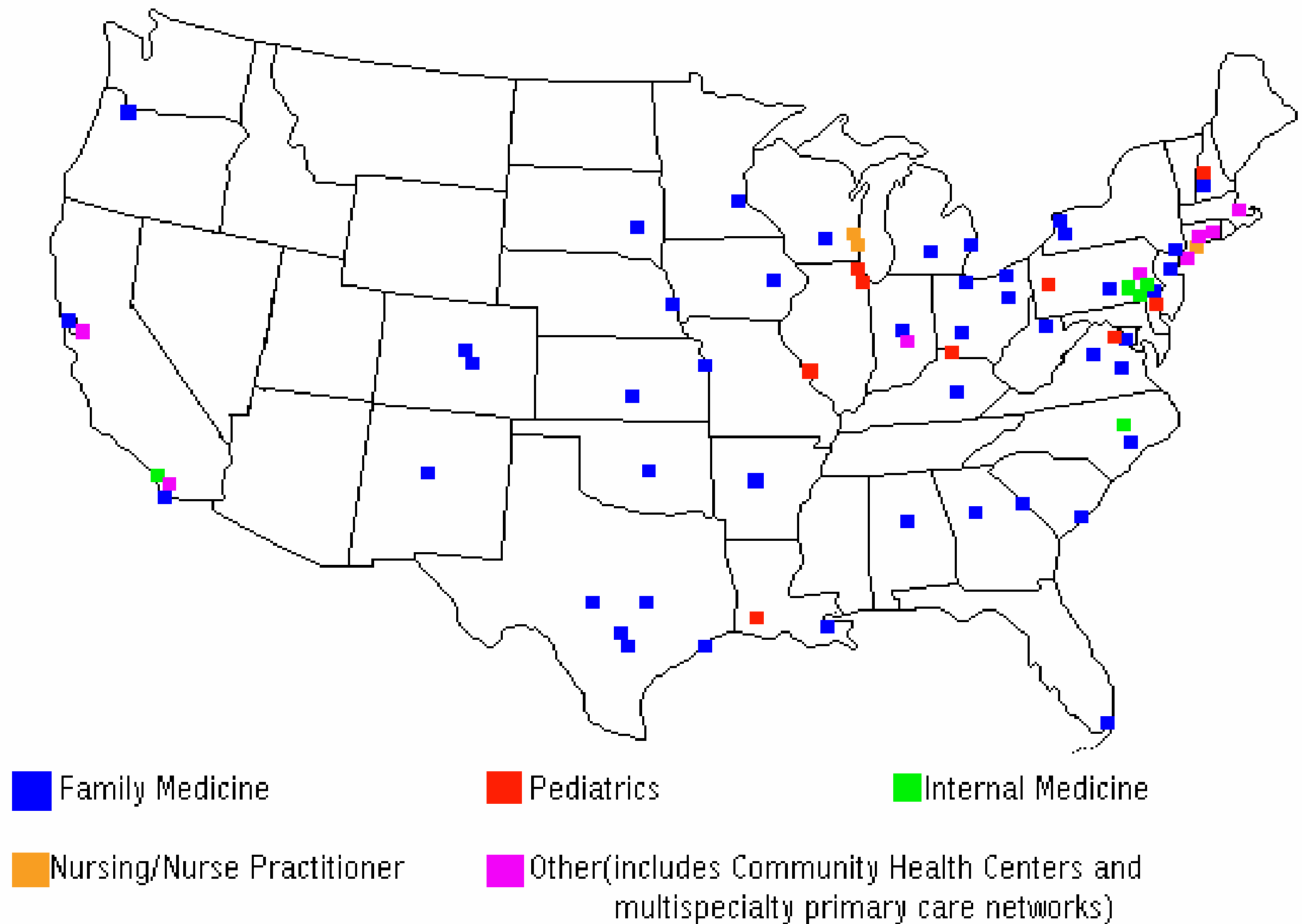- To establish a secure research portal for the US FPBRN

eScience and Primary Care RCTs and epidemiology

- The Internet is about accessing information

- The eScience/Grid/Internet 2 is about sharing information, enabling:
  - Large amounts of data widely distributed
  - Robust security, provenance preservation
  - Virtual community and communication

ePCRN Research Collaboration Centers

Birmingham, UK

Minneapolis, MN

San Francisco, CA

Geographic Location of Headquarters for Primary Care PBRNs in the US

- ■ Family Medicine
- ■ Pediatrics
- ■ Internal Medicine
- ■ Nursing/Nurse Practitioner
- ■ Other(includes Community Health Centers and multispecialty primary care networks)

Relationships

- With the 'Roadmap' projects
  - Represent roadmap with CaBIG
  - BRIDG model
  - CDISC/RIM

- With WHO GlobalTrialBank

- With UK MRC e-Science projects
  - NHS CfH

CaBIG

- https://cabig.nci.nih.gov/

- Cancer Biomedical Informatics Grid

- Funded by National Cancer Institute
  - ePCRN part of two groups
    - CTMS - Clinical Trial Management Systems
    - EVS - Vocabularies and common data elements

RCT Design

◈ Modelling
  - Specification
  - Comparators

◈ Piloting
  - Accrual
  - Consent
  - Outcomes

"Operationalising" an RCT

- Ethics and research Governance
- Ascertainment
- Eligibility
- Baseline data collection
- Randomisation
- Prompt for intervention
- Follow up
- Analysis and archiving

ePCRN: Trials workpackage-1

- Develop use cases based on existing RCTs
- Develop generic use cases
- UMLS modelling of these use cases mapping to BRIDG and WHO
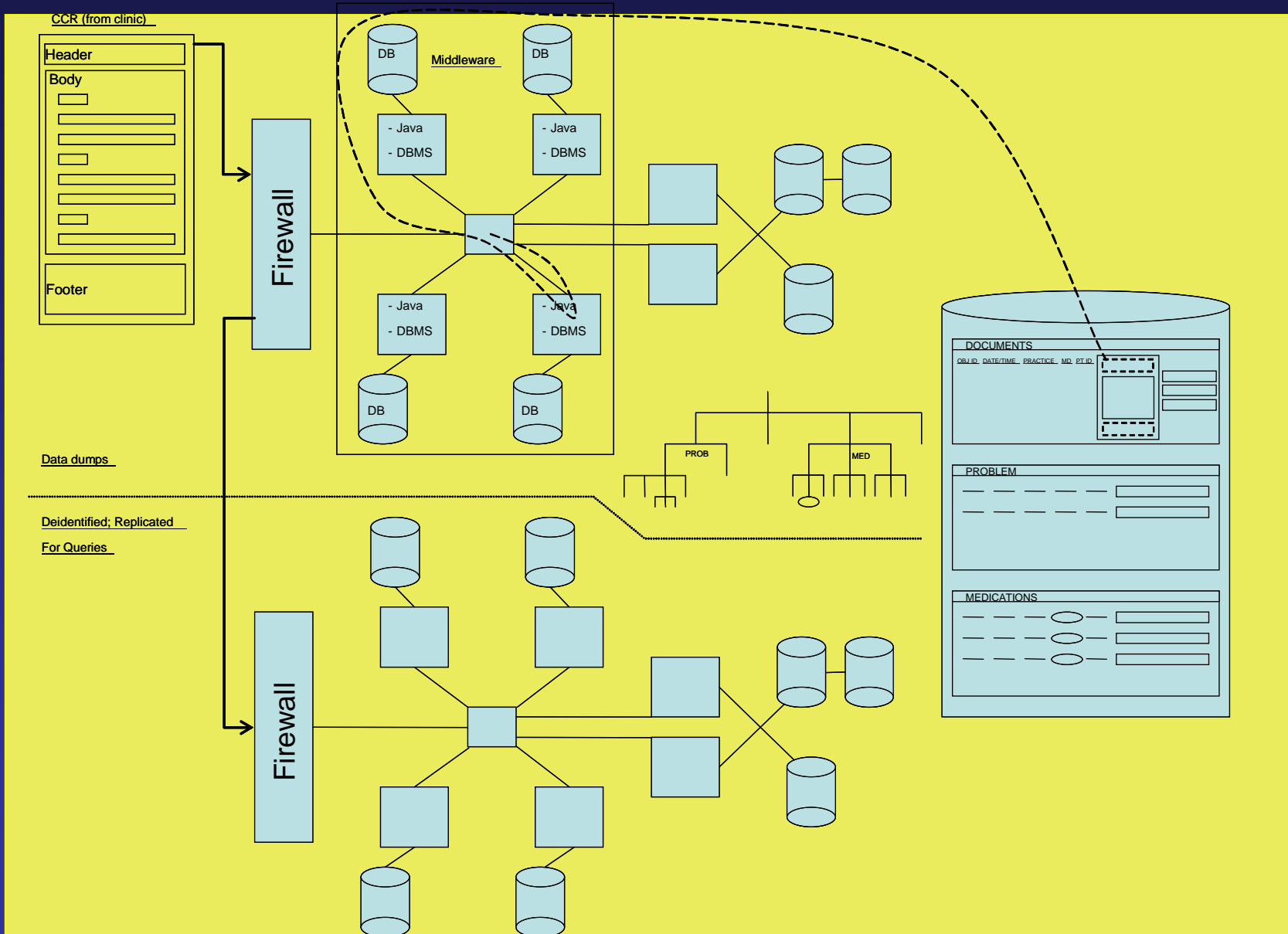- Develop a generic Data model, mapping CDISC/RIM

ePCRN: Trials workpackage-2

- Trial design tools and virtual pilots
- Trial protocol capture and registration
- Trial management
  - Site management
  - Subject management
    - Identification of trial subjects
  - Intervention management
  - Data collection
    - Subject present
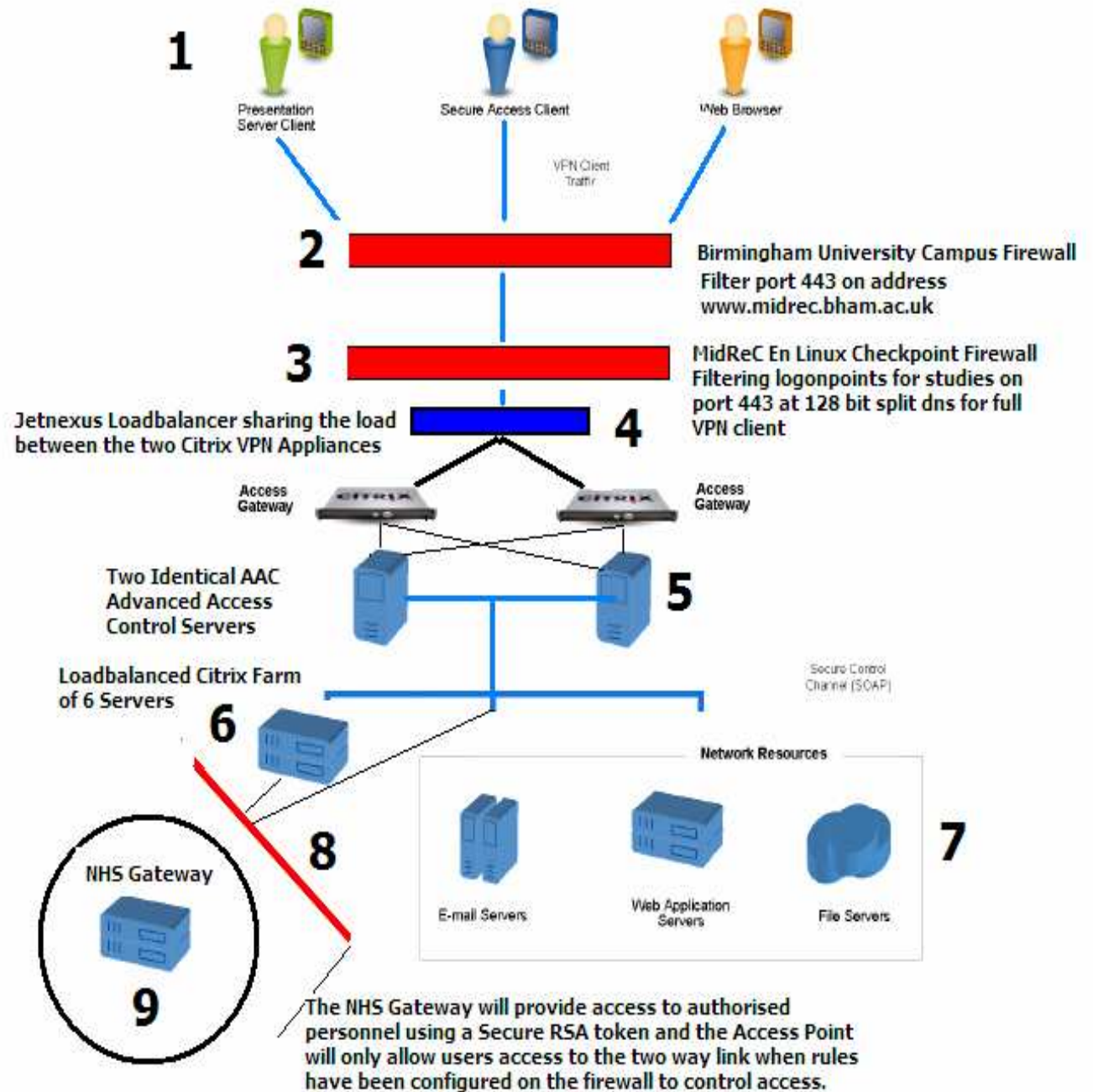   - From EPR

ePCRN: Distributed querying and data collection

- USA EHRs have agreed to a common XML export standard using the AAFP 'Continuity of Care Record' (CCR)

- Clinic-level (mySQL) databases hold the CCR exports

- Use OGSA-DAI-based tools to extract data from the clinic-level databases.

- The CCR standard also allows data to be uploaded to the EHR.
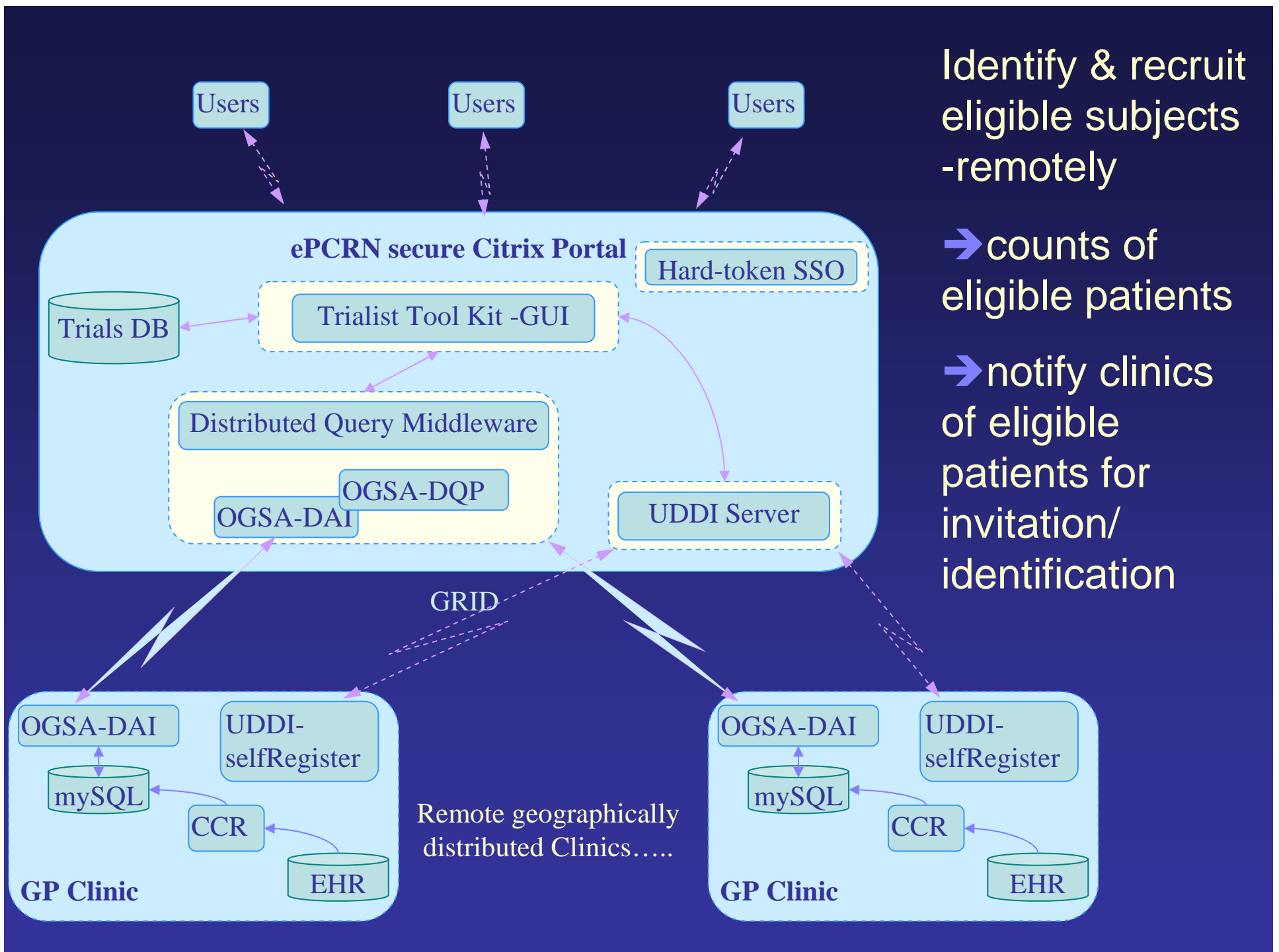
ePCRN: Translational workpackage

Portal and Security

(based on citrix)

1 Presentation Server Client — Secure Access Client — Web Browser

VPN Client Traffic

2 Birmingham University Campus Firewall Filter port 443 on address www.midrec.bham.ac.uk

3 MidReC En Linux Checkpoint Firewall Filtering logonpoints for studies on port 443 at 128 bit split dns for full VPN client

4 Jetnexus Loadbalancer sharing the load between the two Citrix VPN Appliances

Access Gateway — Access Gateway

5 Two Identical AAC Advanced Access Control Servers

Secure Control Channel (SOAP)

6 Loadbalanced Citrix Farm of 6 Servers

7 Network Resources — E-mail Servers — Web Application Servers — File Servers

8

9 NHS Gateway

The NHS Gateway will provide access to authorised personnel using a Secure RSA token and the Access Point will only allow users access to the two way link when rules have been configured on the firewall to control access.

IECRN demonstration

- June 1st 2006

- Major meeting of 'Roadmap' networks in Washington

- Demonstration of 'find an eligible patient' functionality

Identify & recruit eligible subjects -remotely

→counts of eligible patients

→notify clinics of eligible patients for invitation/ identification
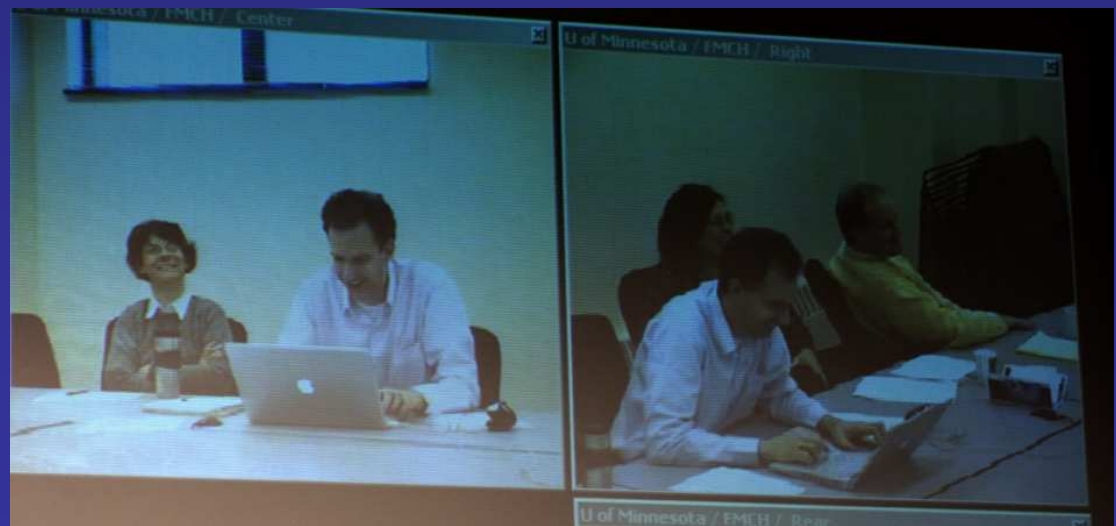
UK projects

- Phase 1
  - Citrix site allows secure access to centralised RCT database via VPN tunnel
  - Maratech and AGN for IP video conferencing
  - Website for open access data collection and surveys

Access Grid

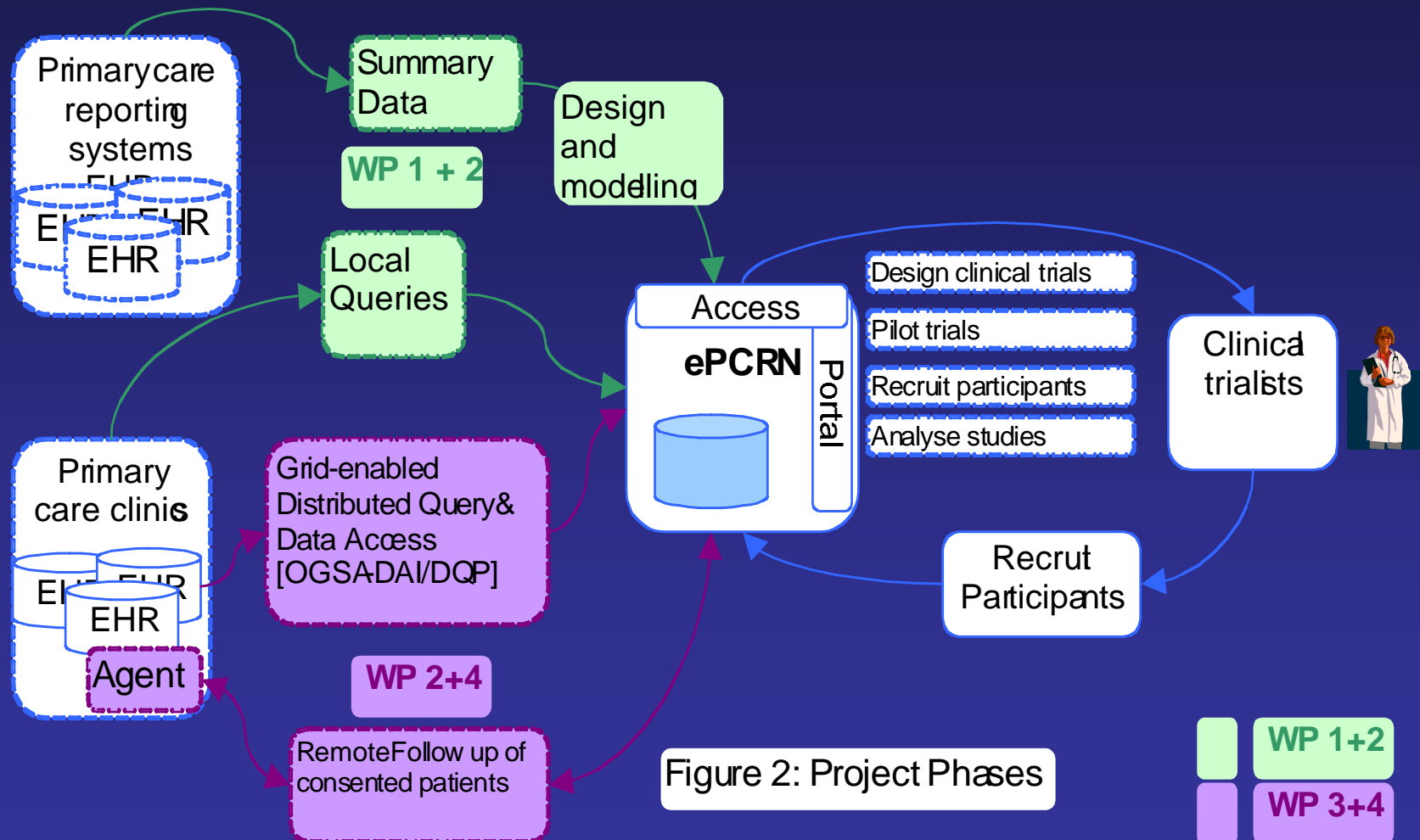- Communication

- Collaboration
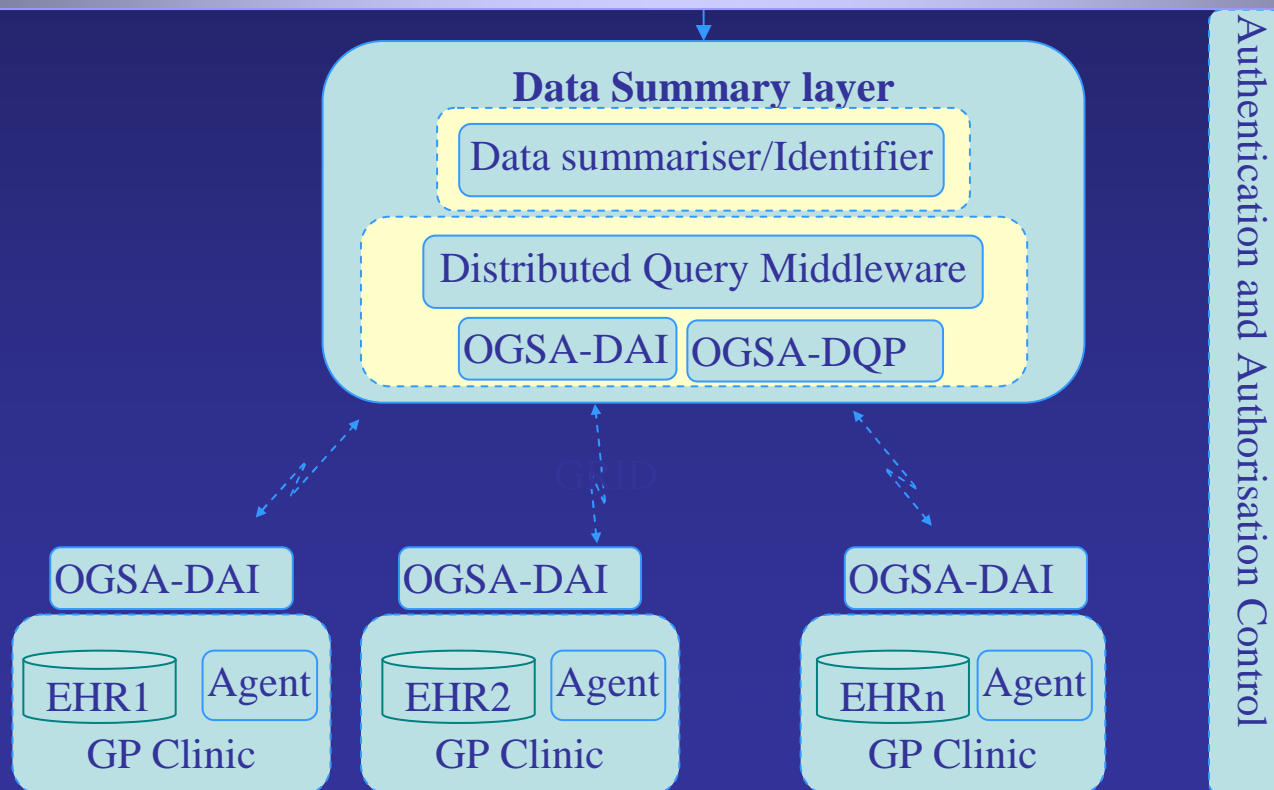
NHS links and future plans

- Phase 2
  - Develop OGSA-DAI based DQP system for UK EHRs
    - For anonymised identification of potential RCT subjects
    - For data collection where subject has consented
    - → Application under consideration-S MRC

Clinical trial system

Figure 2: Project Phases

System architecture

Funded by the NIH

Authentication and Authorisation Control

Data Summary layer

Data summariser/Identifier

Distributed Query Middleware

OGSA-DAI OGSA-DQP

OGSA-DAI

EHR1 Agent

GP Clinic

OGSA-DAI

EHR2 Agent

GP Clinic

OGSA-DAI

EHRn Agent

GP Clinic

Thank you for your attention

QUESTIONS?