Harnessing routinely-collected data for efficient and low-cost clinical trials

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University of Oxford
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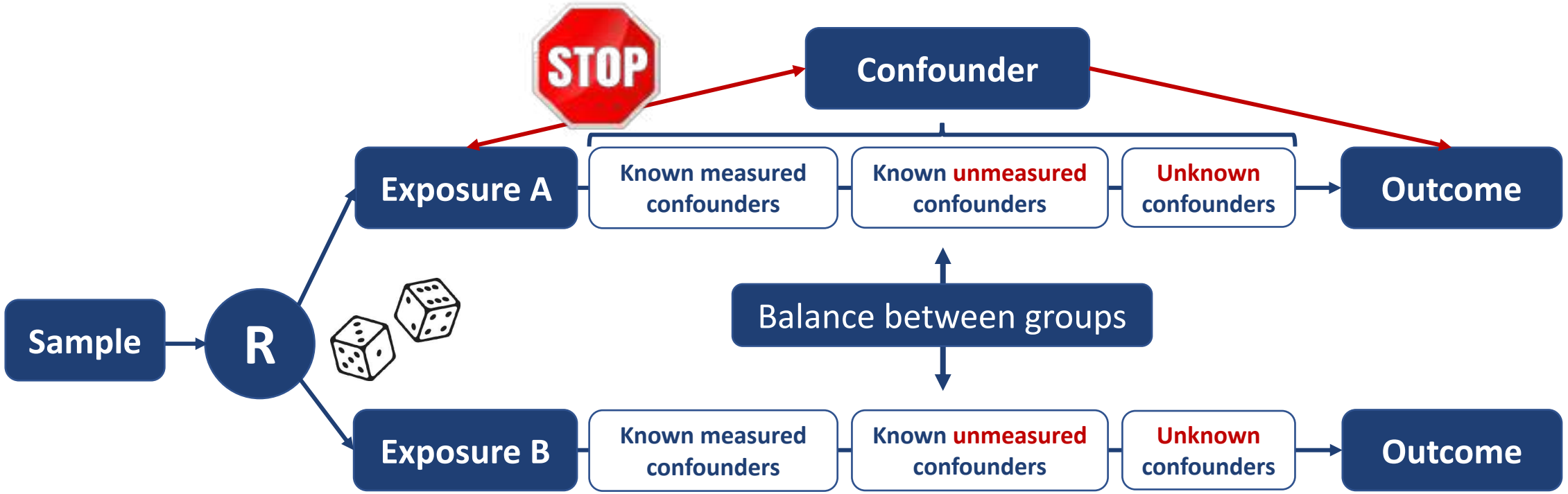
Medical Sciences Division
MRC Population Health Research Unit
NIHR | National Institute for Health Research

WHY DO WE CARE ABOUT TRIALS?

Randomized controlled trials (RCTs)

Yetley et al, American Journal of Clinical Nutrition 105 2016 10.3945/ajcn.116.139097.

WHY DO WE CARE ABOUT TRIALS?



RCTs are the best way to reliably establish and quantify a causal relation between an exposure and an outcome

WHY DO WE CARE ABOUT TRIALS?

Observational data can provide unreliable estimates:

Different effect **size**

(beta-blocker use and mortality after myocardial infarction)

	Deaths/patients		Risk ratio† (95% CI)
	β-blocker*	No β-blocker*	
Observational study‡	~123/785 (16%)	~886/2952 (30%)	0·57 (0·47–0·69)
Randomised trials	827/10 452 (8%)	986/9860 (10%)	0·77 (0·70–0·85)

Different **direction** of apparent effect

(antihypertensive therapy and coronary artery disease)

	CHD events/patients		Risk ratio† (95% CI)
	Antihypertensive therapy*	No antihypertensive therapy*	
Observational study	50/839 (6%)	420/20 475 (2%)	1·8 (1·3–2·6)
Randomised trials	934/23 847 (4%)	1104/23 806 (5%)	0·84 (0·77–0·92)

Discordance regarding **presence** of effect

(higher-dose vs lower-dose aspirin and stroke after carotid endarterectomy)

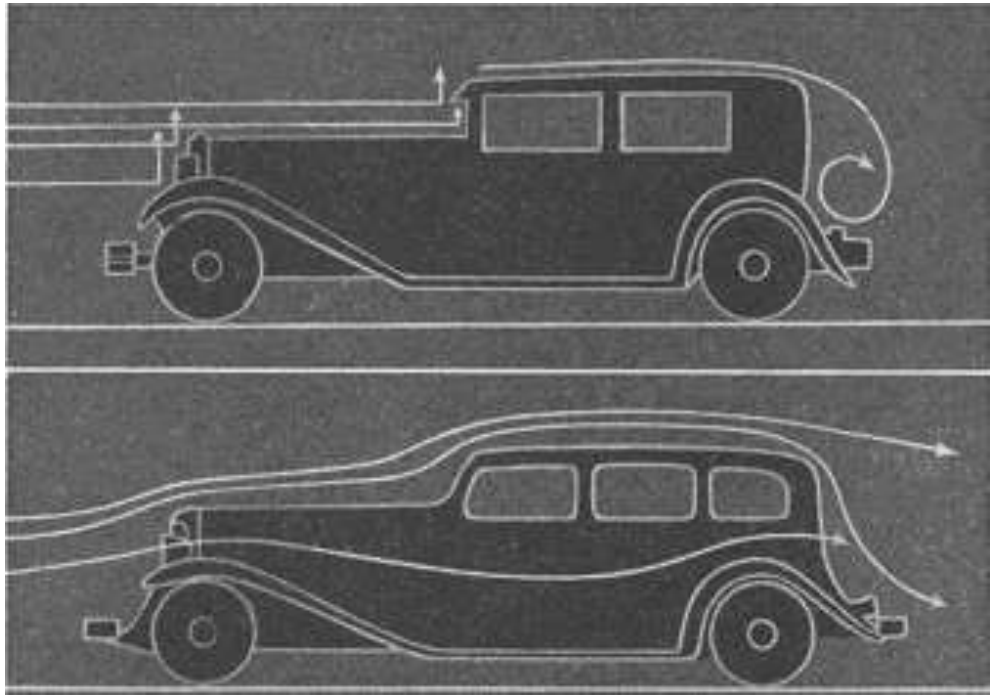
	Stroke/patients		Risk ratio† (95%CI)
	Lower-dose aspirin (<650 mg daily)*	Higher-dose aspirin (650–1300 mg daily)*	
Observational study	96/1391 (7%)	15/835 (2%)	2·3 (1·3–3·9)
Randomised trial	64/1417 (5%)	86/1432 (6%)	0·74 (0·53–1·03)

DON'T DITCH RANDOMIZATION!

NON-RANDOMIZED METHODS

VS

STREAMLINING RCTS



STREAMLINED RANDOMIZED TRIALS

- Focusing on the things needed to
  - Answer the research question
  - Keep the participants safe
- CTTi ‘Quality by Design’ principles
- Data enabled clinical trials
  - Health Data Research UK
  - Collaboration with NHS Digital - NHS DigiTrial

CLINICAL TRIALS VS ROUTINE HEALTH CARE

Trial data
collection systems

Study visits

Participant questionnaires

Trial laboratory tests

Routine health care data
collection systems

Hospital Admission Data

Primary Care Systems

Prescribing

Mental Health

Registries

Screening programs

WHAT'S SIMILAR ABOUT TRIALS?

Trial records

- Answer the research question **reliably**
- Keep **participants safe**
- Keep participants' **data safe**

Routine health care records

- Record patient care **reliably**
- Keep **patients safe**
- Keep patients' **data safe**

WHAT'S SIMILAR ABOUT TRIALS?

Participant ID	460001451	NHS (or CHI number in Scotland)	
National Identifier		Participant Initials	AB
Participant Name	Anna Bullivant	Date of Birth	01-Jan-1950
Sex	Female		
LCC	New site DEMO UK (41598)		

Participant ID	460001451
Date of birth	01-Jan-1950
Sex	Female
Race	Mixed
Title	Ms
First name	Anna
Family name	Bullivant
Initials	AB
Address	98 The Lane
Postcode/Zipcode	JH8 8YY
GP practice	PARADISE MEDICAL CENTRE BROAD STREET COVENTRY CV6 5BG Tel. 02476689343

WHAT'S SIMILAR ABOUT TRIALS?

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Participant ID	460001451
Date of birth	01-Jan-1950
Sex	Female
Race	Mixed

Screening visit: Medical history
Inclusion criteria and relevant medical history

Myocardial infarction	No
Coronary artery bypass graft	No
Coronary artery angioplasty or stent (PCI)	No
Stroke	No
Lower limb arterial revascularisation (i.e. angioplasty or stent or bypass procedure)	No
Aortic aneurysm repair (surgery or stent)	Yes
Has the participant been diagnosed with diabetes?	No

Screening visit: Medical history
Exclusion criteria Part 1

Has had an acute coronary syndrome in the last 4 weeks	No
Is due to undergo a coronary revascularisation procedure (angioplasty, stent or bypass graft) within the next 6 months	No
Is known to have chronic liver disease	No
Has previously had, or is planned to have, a kidney transplant	No
Is on, or is planned to start, dialysis	No
Has severe respiratory disease	No
Has cancer been diagnosed or spread within approximately the last 5 years (other than non-melanoma skin cancer)	No
Has a history of any other medical condition that might limit their ability to take trial treatments for the duration of the study	No

Randomization visit:
Adverse Events

Myocardial infarction	No
Stroke or transient ischaemic attack	No
Percutaneous coronary intervention (PCI), e.g. coronary stent or angioplasty	No
Coronary artery bypass surgery	No
Non-coronary arterial surgery or stent insertion, e.g. bypass graft, endarterectomy, aneurysm repair, angioplasty, or stent insertion	No
Non-traumatic amputation	No
New diagnosis of diabetes mellitus	No
Diagnosis of, or treatment for, cancer (except non-melanoma skin cancer)	No
Has the participant had any other SERIOUS adverse events since their last visit?	No

ORION-4 study, simulated patient and data – reproduced with permission

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Sex	Female
Race	Mixed

Laboratory Results Table

Date	Source	Kit ID	ALT (ULN)	AST (ULN)	Bilirubin (ULN)	Alkaline phosphatase (ULN)	Creatinine	eGFR	
13-Sep-2019	Local Laboratory		100.00 (50.00) IU/L	60.00 (50.00) IU/L	20.0 (22.0) µmol/L	300 (150) IU/L	120.00 µmol/L	39.69 mL/min/1.73m2	Mark as invalid

Myocardial	
Coronary a	
Coronary a	
Stroke	
Lower limb [illegible] stent or bypass procedure)	
Aortic aneurysm repair (surgery or stent)	Yes
Has the participant been diagnosed with diabetes?	No

Has severe respiratory disease	No
Has cancer been diagnosed or spread within approximately the last 5 years (other than non-melanoma skin cancer)	No
Has a history of any other medical condition that might limit their ability to take trial treatments for the duration of the study	No

Non-traumatic amputation	No
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ORION-4 study, simulated patient and data – reproduced with permission

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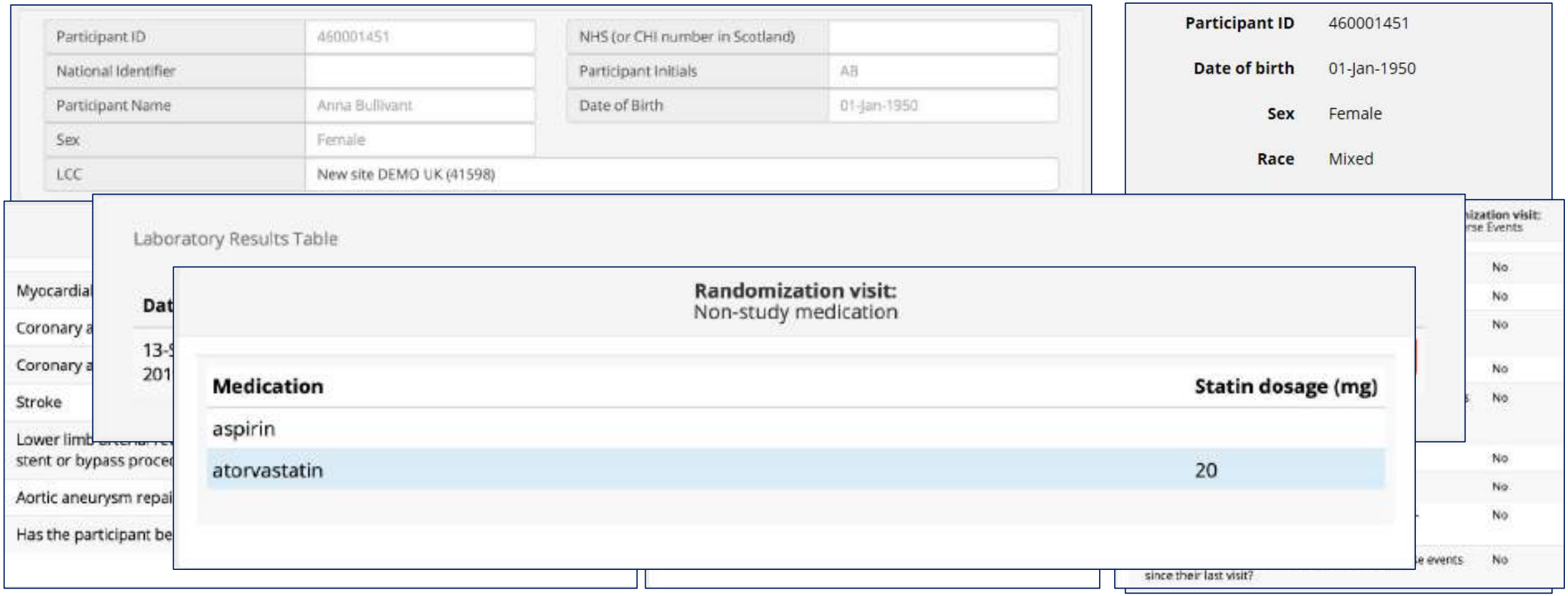
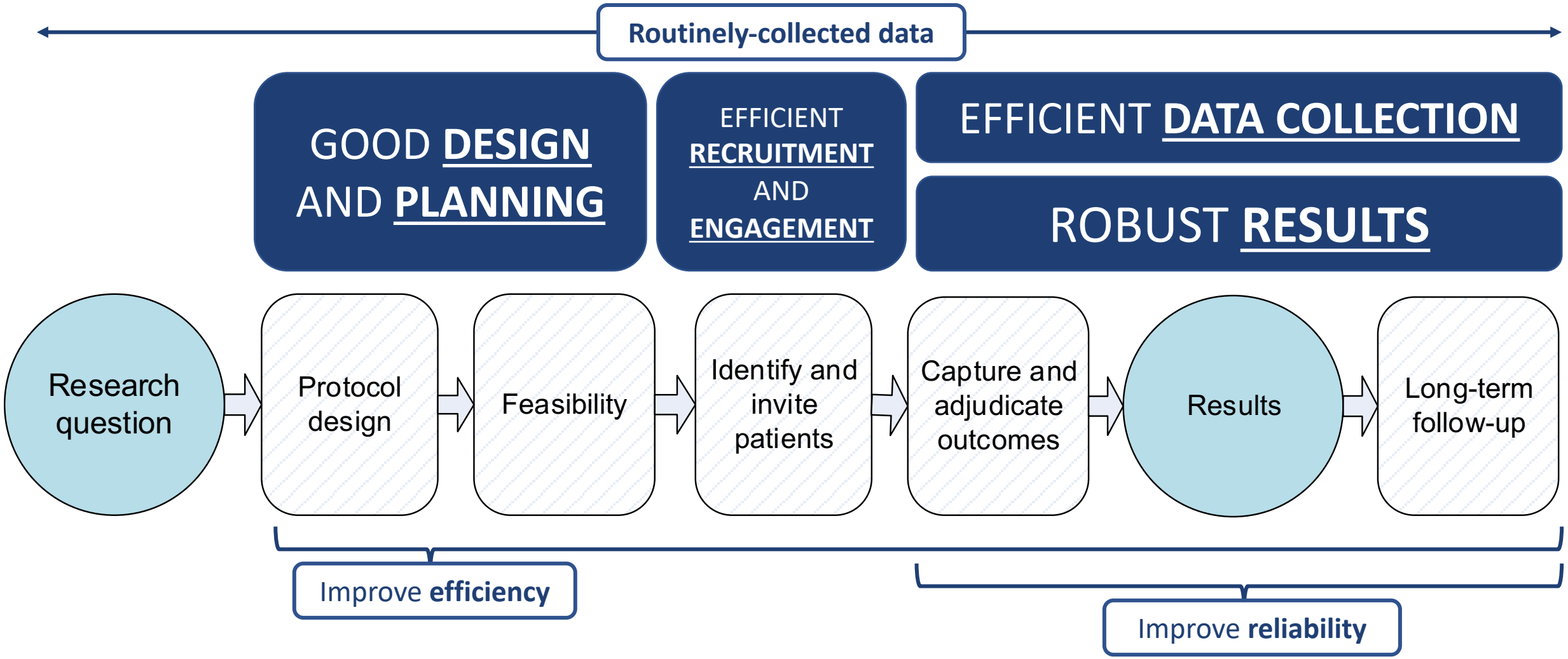
WHAT'S SIMILAR ABOUT TRIALS?



ORION-4 study, simulated patient and data – reproduced with permission

USING ROUTINELY-COLLECTED DATA IN DIFFERENT STAGES OF CLINICAL TRIALS



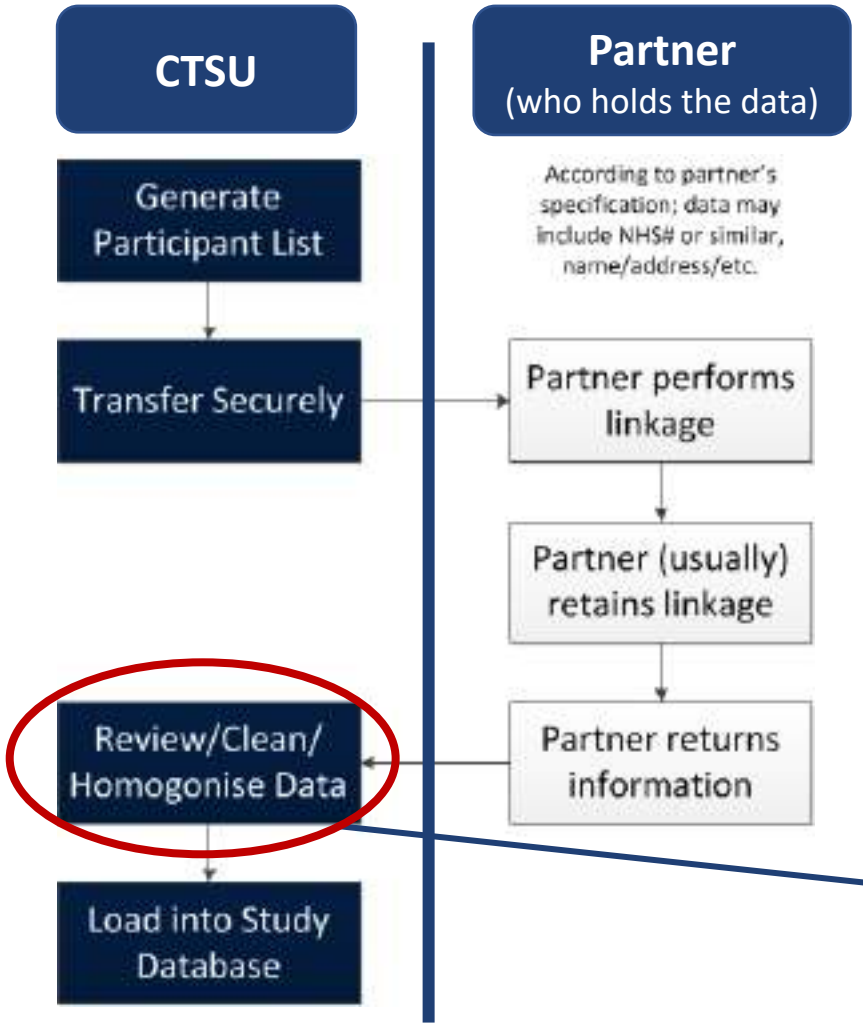
SOURCES OF ROUTINELY-COLLECTED DATA IN CLINICAL RESEARCH

- **Hospital Episode Statistics** (HES) Admitted Patient Care
- **Other HES** data sets (Accident and Emergency)
- **Death certifications** (Office for National Statistics)
- Disease specific **registries** (Cancer, UK Renal Registry)
- **National Audit Programmes** (Diabetes)
- Other (General Practice data, Prescribing data)

CHALLENGES OF ROUTINELY-COLLECTED DATA IN CLINICAL RESEARCH

- **Completeness of linkage**
- Data **format** issues
  - **Multiple sources and formats**
- **Coding** practice and data quality
- **Timeliness** of receiving data
  - may clash with regulatory requirements

IMPORTING ROUTINELY-COLLECTED DATA IN CLINICAL RESEARCH



- Check **completeness** of linkage
- Create a dataset-specific **mask**
  - Defines the data format and potential checks
- **Review, clean and homogenise** data
  - "Sanity checks" include the correct number of columns and whether the participant ID returned "belongs" to that registry
  - Some checks are automatic (if a column is marked as "date", ICD10, OPCS or similar)
  - Other checks and lists can be specified (using regular expressions)

USING ROUTINELY-COLLECTED DATA IN CLINICAL RESEARCH

- Transform and import data automatically
- Use a bespoke data viewer:

A TALE OF THREE TRIALS

HPS-4
TIMI 65
ORION-4

British Heart Foundation
ASCEND
A Study of Cardiovascular Events iN Diabetes

Active Monitoring for AtriaL Fibrillation

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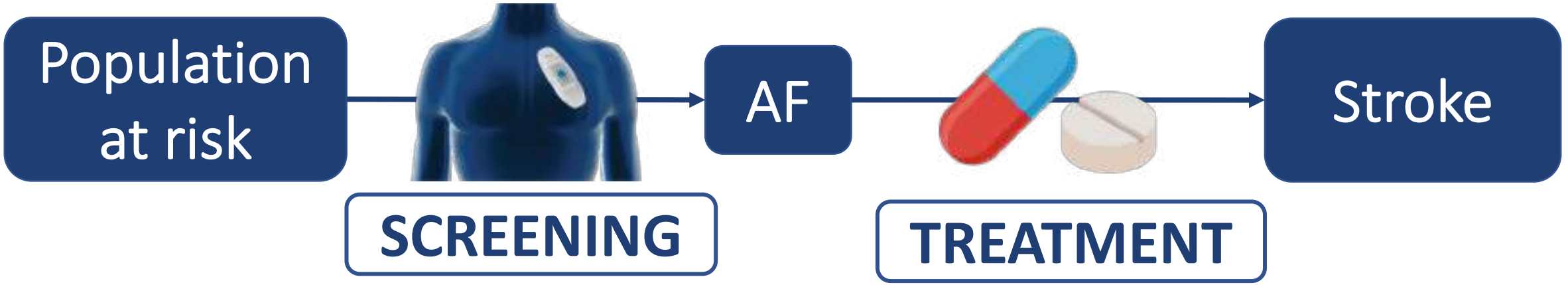
AMALFI

(Active Monitoring for AtriaL FIbrillation)



AMALFI

http://www.isrctn.com/ISRCTN15544176

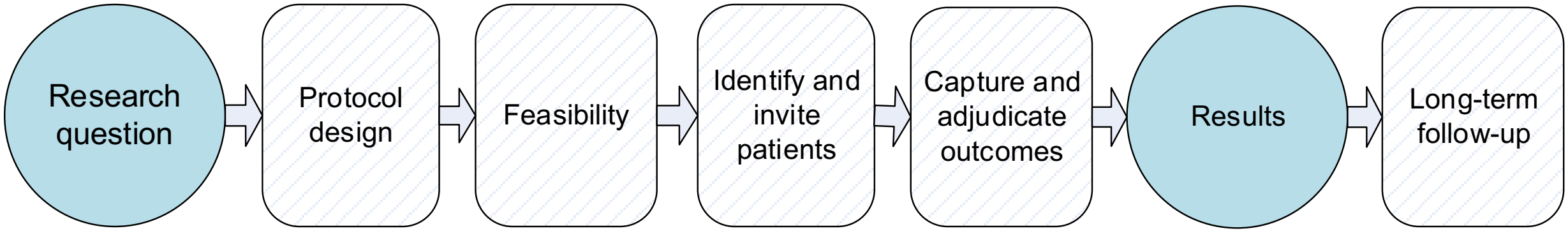
USING PRIMARY CARE DATA FOR TRIALS

GOOD **DESIGN** AND **PLANNING**

EFFICIENT **RECRUITMENT** AND **ENGAGEMENT**

EFFICIENT **DATA COLLECTION**

ROBUST **RESULTS**



Simple eligibility criteria aligned with primary care records

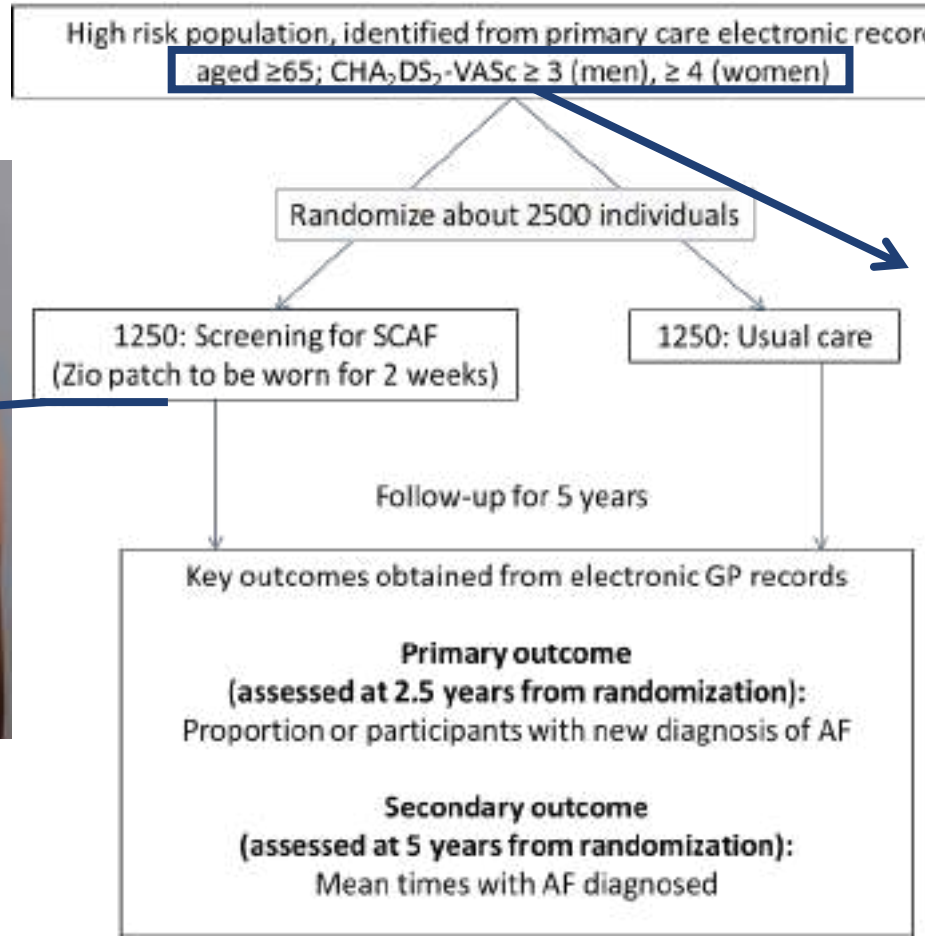
Study site planning

Eligibility search

Large-scale **mail-based** invitation methods

Data extracts from primary care records and central records

PROTOCOL DESIGN



Risk factor	Score
Congestive heart failure/LV dysfunction	1
Hypertension	1
Age > 75	2
Diabetes mellitus	1
Stroke/TIA/thromboembolism	2
Vascular disease*	1
Age 65–74	1
Sex category (ie, female sex)	1
Maximum score	9

Note: *Prior myocardial infarction; peripheral artery disease; aortic plaque.
Abbreviations: LV, left ventricular; TIA, transient ischemic attack.

CHA_2DS_2VASC SCORE

PROTOCOL DESIGN

High risk population, identified from primary care electronic records:
aged ≥65; CHA_2DS_2-VASc ≥ 3 (men), ≥ 4 (women)

AGE (>64/>74)
GENDER
HEART FAILURE
HYPERTENSION
DIABETES
STROKE/TIA/THROMBOEMBOLISM
VASCULAR DISEASE (HEART ATTACK, PAD)
ATRIAL FIBRILLATION
LATEX ALLERGY
(DEMENTIA, PALLIATIVE CARE)

Risk factor	Score
Congestive heart failure/LV dysfunction	1
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Note: *Prior myocardial infarction; peripheral artery disease; aortic plaque.
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CHA_2DS_2VASC SCORE

TRIAL SETUP

AMALFI
Active Monitoring for Atrial Fibrillation

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Nuffield Department of POPULATION HEALTH
Medical Sciences Division

Radcliffe Department of Medicine
Medical Sciences Division

NUFFIELD DEPARTMENT OF PRIMARY CARE HEALTH SCIENCES

+

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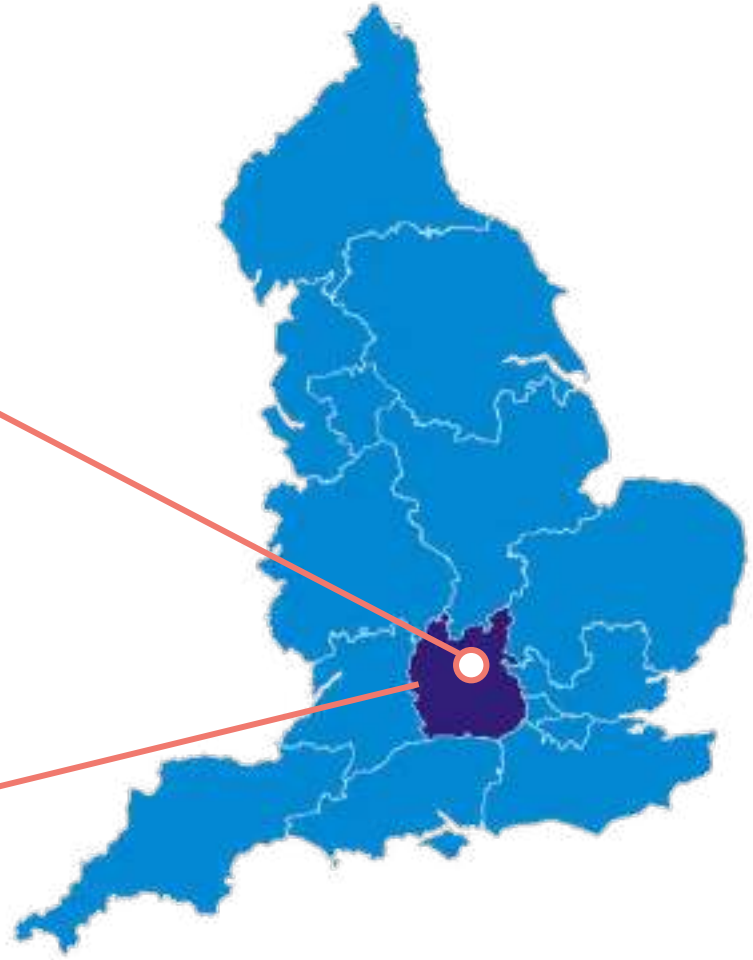
CRN Thames Valley and South Midlands

5 CLINICAL COMMISIONING GROUPS (GP PRACTICES)
6 ACUTE NHS TRUSTS



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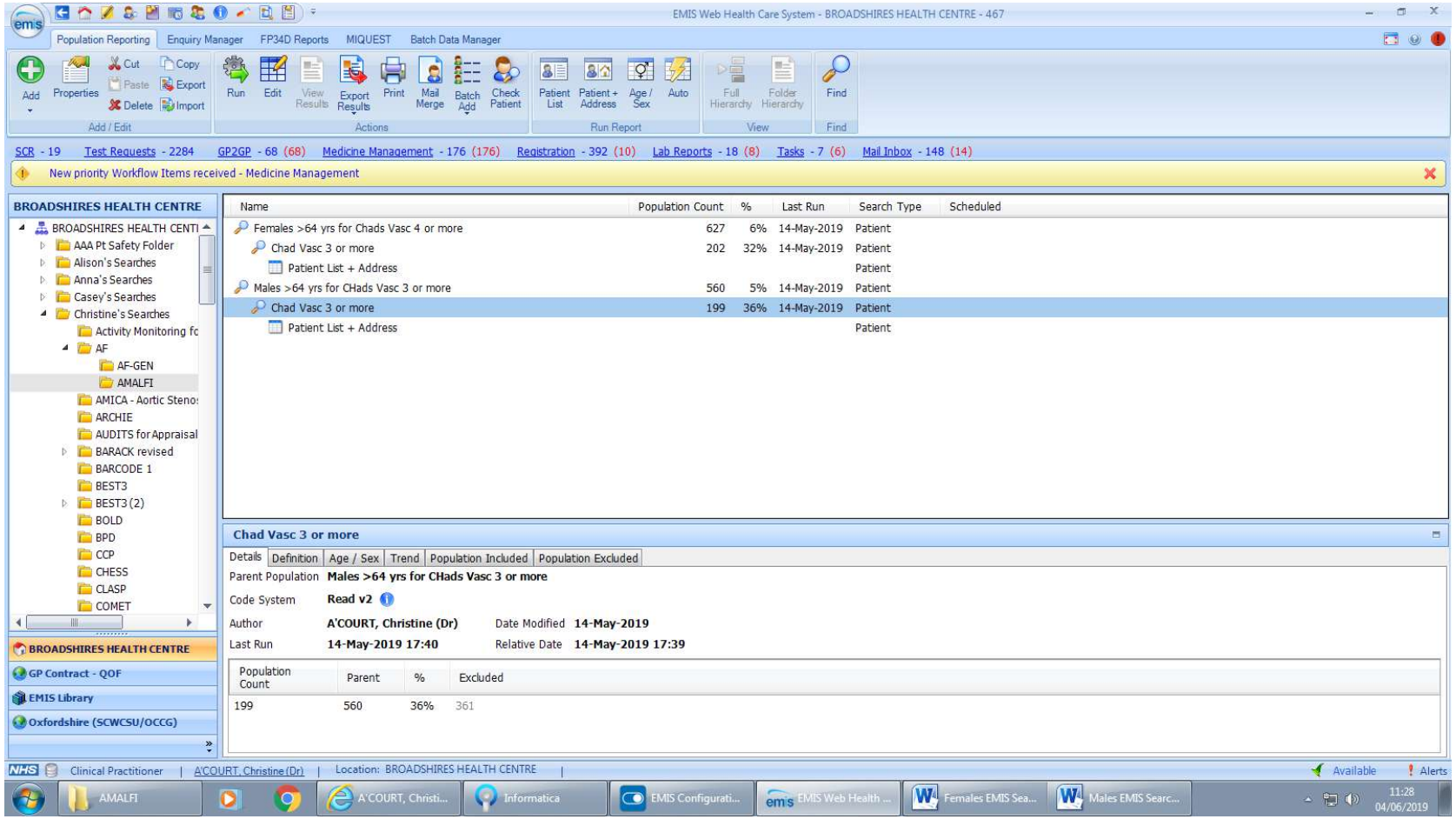
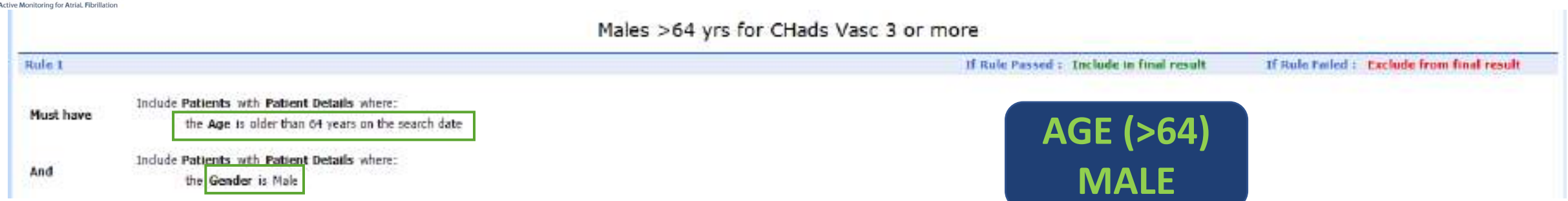
USING PRIMARY CARE RECORDS

(or other systems)



USING PRIMARY CARE RECORDS



AGE (>64)
MALE

LATEX ALLERGY
ATRIAL FIBRILLATION/FLUTTER
DEMENTIA
PALLIATIVE CARE

USING PRIMARY CARE RECORDS

USING PRIMARY CARE RECORDS

AGE (>64/>74)

GENDER

HEART FAILURE

HYPERTENSION

DIABETES

STROKE/TIA/THROMBOEMBOLISM

VASCULAR DISEASE (HEART ATTACK, PAD)

ATRIAL FIBRILLATION

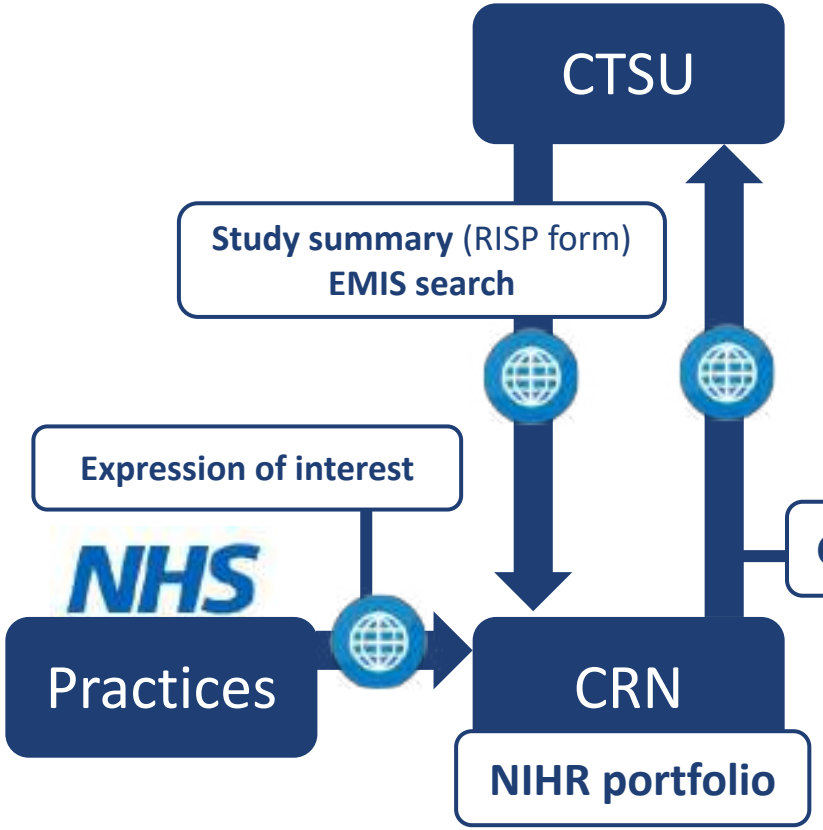
LATEX ALLERGY

(DEMENTIA, PALLIATIVE CARE)

NHS emis

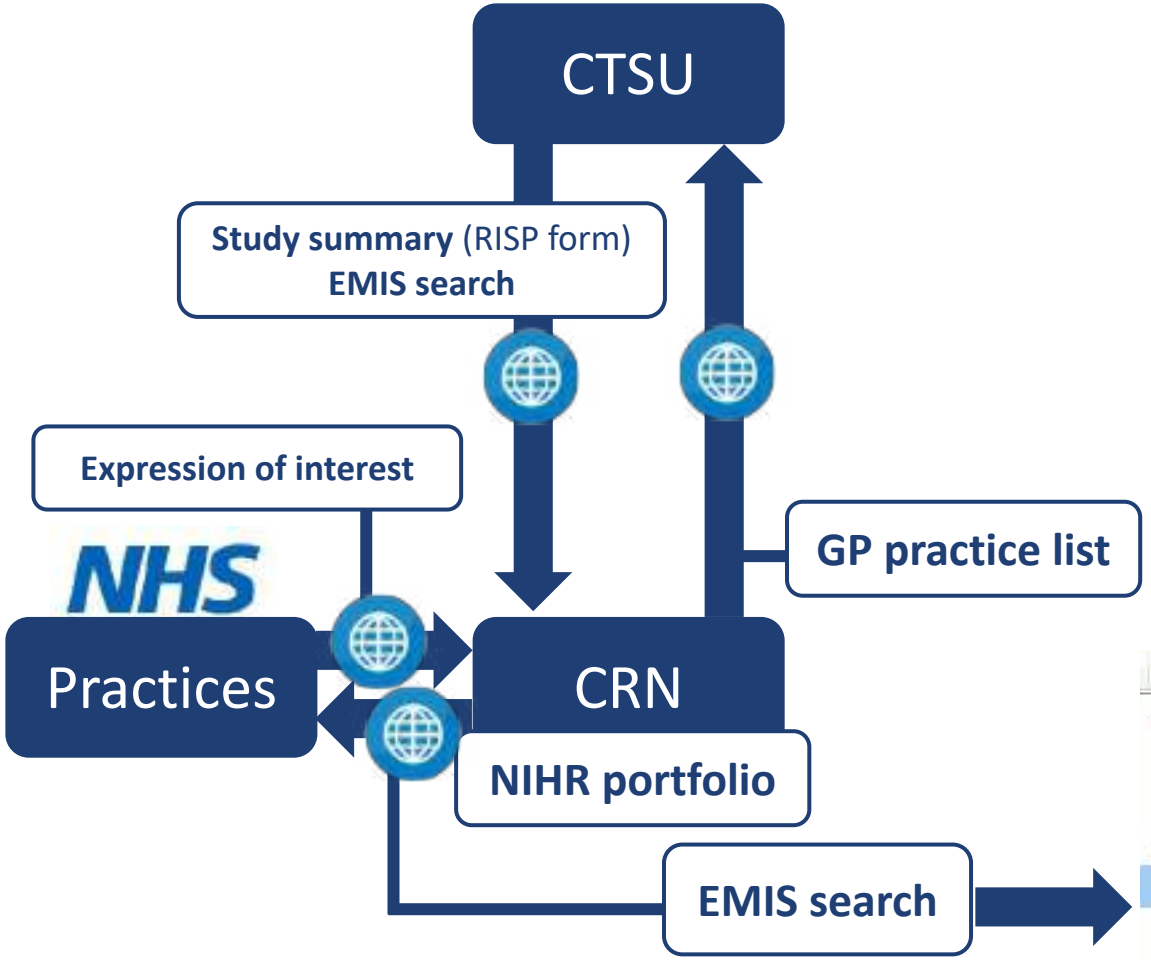
Coded search (XML)

FEASIBILITY & PLANNING



CCG	NACS code	Practice Name	List size	System	EOI date	SIV date	Reconfirmed EOI
Oxfordshire CCG	K84617	SOUTH OXFORD HEALTH CENTRE	4172	EMIS	18/10/2018	younger pop - families	12/12/2019
Oxfordshire CCG	K84052	BICESTER HEALTH CENTRE	13652	EMIS	24/01/2019	mid age, families	12/12/2019
Oxfordshire CCG	K84006	EYNSHAM MEDICAL GROUP	13922	EMIS	24/01/2019	older population	24/12/2019
Berkshire West CCG	K81040	MILMAN ROAD HEALTH CENTRE	14561	EMIS	24/01/2019		18/12/2019
Berkshire West CCG	K81012	THE BOATHOUSE SURGERY/Pangbourne	11451	EMIS	24/01/2019		18/12/2019
Oxfordshire CCG	K84011	SUMMERTOWN HEALTH CENTRE	16273	EMIS	24/01/2019	younger, studnets	18/12/2019
Oxfordshire CCG	K84017	WINDRUSH MEDICAL PRACTICE	16700	EMIS	24/01/2019	avegage, slight older	19/12/2019
Oxfordshire CCG	K84016	19 BEAUMONT STREET SURGERY	14575	EMIS	06/06/2019	students	06/01/2020
Oxfordshire CCG	K84021	BANBURY ROAD MEDICAL CENTRE	8018	EMIS	07/01/2020	families, just under national a	07/01/2020
Oxfordshire CCG	K84045	GOSFORD HILL MEDICAL CENTRE	7165	EMIS	23/01/2019	older population	10/01/2020
Oxfordshire CCG	K84008	THE CHILTERN SURGERY/CHALGROVE & V	7441	EMIS	24/01/2019	older population	21/01/2020
[illegible]	K81022	WOKINGHAM MEDICAL CENTRE	23407	EMIS	24/01/2019		07/01/2020
[illegible]	K82026	WHADDON MEDICAL CENTRE	12820	System-1	26/06/2018	average population	waiting
[illegible]	K84013	ST. BARTHOLOMEW'S MEDICAL CENTRE	19211	EMIS	19/12/2018	young pop, students	waiting
[illegible]	K82049	HUGHENDEN VALLEY SURGERY	12664	EMIS	24/01/2019		waiting
Buckinghamshire CCG	K82006	IVERS PRACTICE	9490	EMIS	24/01/2019		waiting
Oxfordshire CCG	K84007	TEMPLE COWLEY HEALTH CENTRE	7959	EMIS	24/01/2019	young families	waiting
Buckinghamshire CCG	K82007	THE SWAN PRACTICE	30482	EMIS	24/01/2019		waiting
Oxfordshire CCG	K84037	WALLINGFORD MEDICAL PRACTICE	16757	EMIS	24/01/2019	families and older population	waiting
Oxfordshire CCG	K84028	WEST BAR SURGERY	16978	EMIS	24/01/2019	average population	waiting
Oxfordshire CCG	K84063	COWLEY ROAD MEDICAL PRACTICE	8465	EMIS	11/04/2019	younger families	waiting
Oxfordshire CCG	K84041	MARCHAM RD FAMILY HEALTH CENTRE	12245	EMIS	16/05/2019	older population	waiting
Oxfordshire CCG	K84075	BROADSHIRES HEALTH CENTRE	10202	EMIS	24/01/2019		in follow up
Oxfordshire CCG	K84051	WHITE HORSE MEDICAL PRACTICE	15272	EMIS	24/01/2019		in follow up
Oxfordshire CCG	K84001	THE HART SURGERY	10375	EMIS	26/06/2018	older population	WITHDRAWN

FEASIBILITY & PLANNING



Name	Population Count	%
Females >64 yrs for Chads Vasc 4 or more	627	6%
Chad Vasc 3 or more	202	32%
Patient List + Address		
Males >64 yrs for CHads Vasc 3 or more	560	5%
Chad Vasc 3 or more	199	36%
Patient List + Address		

IDENTIFICATION, INVITATION & ENGAGEMENT

AMALFI
Active Monitoring for Atrial Fibrillation

CTSU

Contact details

Royal Mail

Invitation letter
PIL
Consent form
Questionnaire

docmail

Royal Mail

Study summary (RISP form)
EMIS search

Expression of interest

NHS
Practices

GP practice list

CRN

NIHR portfolio

Contact details

EMIS search

Name	Population Count	%
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Patient List + Address		
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Patient List + Address		

List extract
Review and
approval by GP

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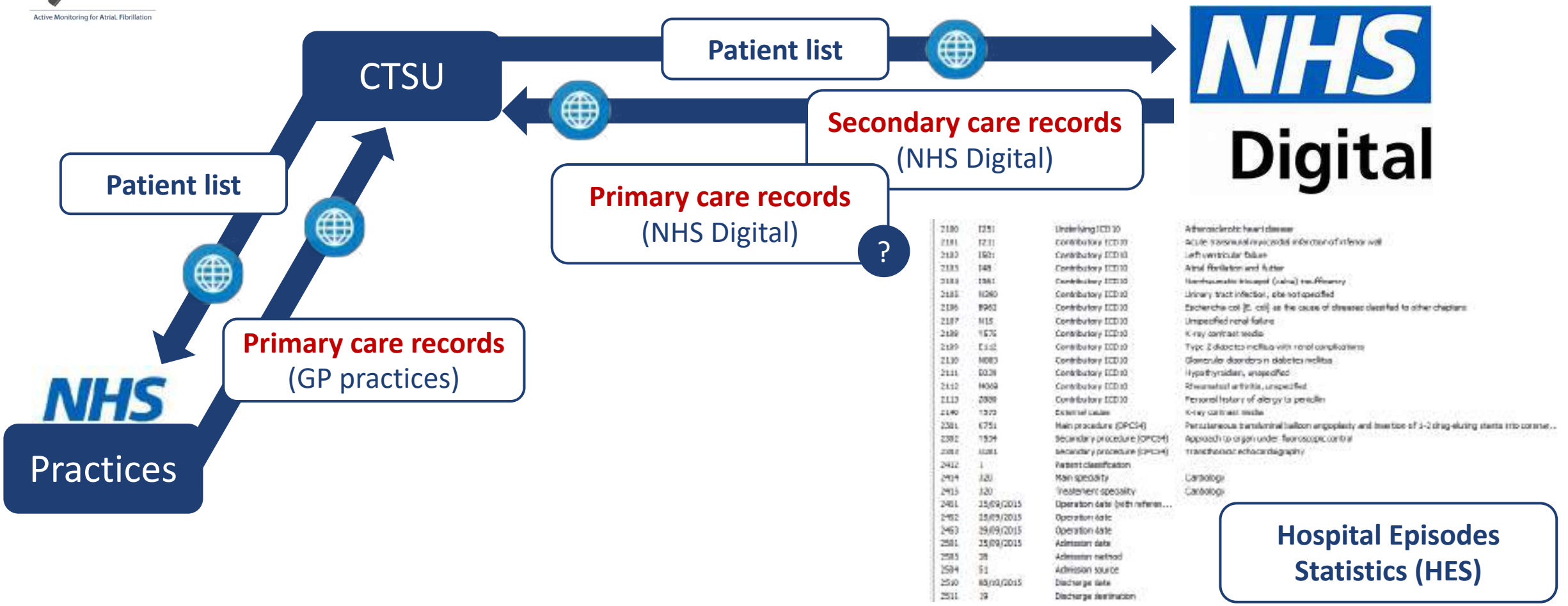
OUTCOME COLLECTION



2180	I251	Underlying ICD10	Atherosclerotic heart disease
2181	I211	Contributory ICD10	Acute transmural myocardial infarction of inferior wall
2183	I501	Contributory ICD10	Left ventricular failure
2185	I48	Contributory ICD10	Atrial fibrillation and flutter
2186	I061	Contributory ICD10	Rheumatic tricuspid (valve) insufficiency
2188	N390	Contributory ICD10	Urinary tract infection, site not specified
2196	B962	Contributory ICD10	Escherichia coli [E. coli] as the cause of diseases classified to other chapters
2197	N18	Contributory ICD10	Unspecified renal failure
2198	Y676	Contributory ICD10	X-ray contrast media
2199	E112	Contributory ICD10	Type 2 diabetes mellitus with renal complications
2200	N083	Contributory ICD10	Glomerular disorders in diabetes mellitus
2201	E039	Contributory ICD10	Hypothyroidism, unspecified
2202	M069	Contributory ICD10	Rheumatoid arthritis, unspecified
2203	Z889	Contributory ICD10	Personal history of allergy to penicillin
2249	Y579	External cause	X-ray contrast media
2381	K751	Main procedure (OPCS4)	Percutaneous transluminal balloon angioplasty and insertion of 1-2 drug-eluting stents into coronar...
2382	Y974	Secondary procedure (OPCS4)	Approach to organ under fluoroscopic control
2383	U281	Secondary procedure (OPCS4)	Transthoracic echocardiography
2402	1	Patient classification	
2404	320	Main specialty	Cardiology
2405	320	Treatment specialty	Cardiology
2481	15/09/2015	Operation date (with referen...	
2482	15/09/2015	Operation date	
2483	15/09/2015	Operation date	
2581	15/09/2015	Admission date	
2583	28	Admission method	
2584	51	Admission source	
2590	15/10/2015	Discharge date	
2591	19	Discharge destination	

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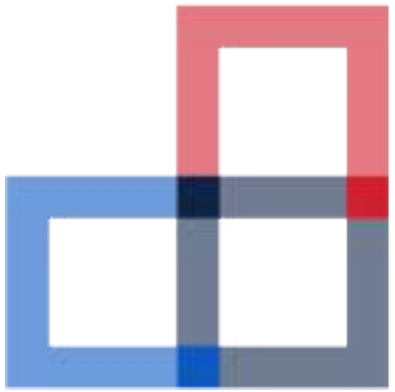
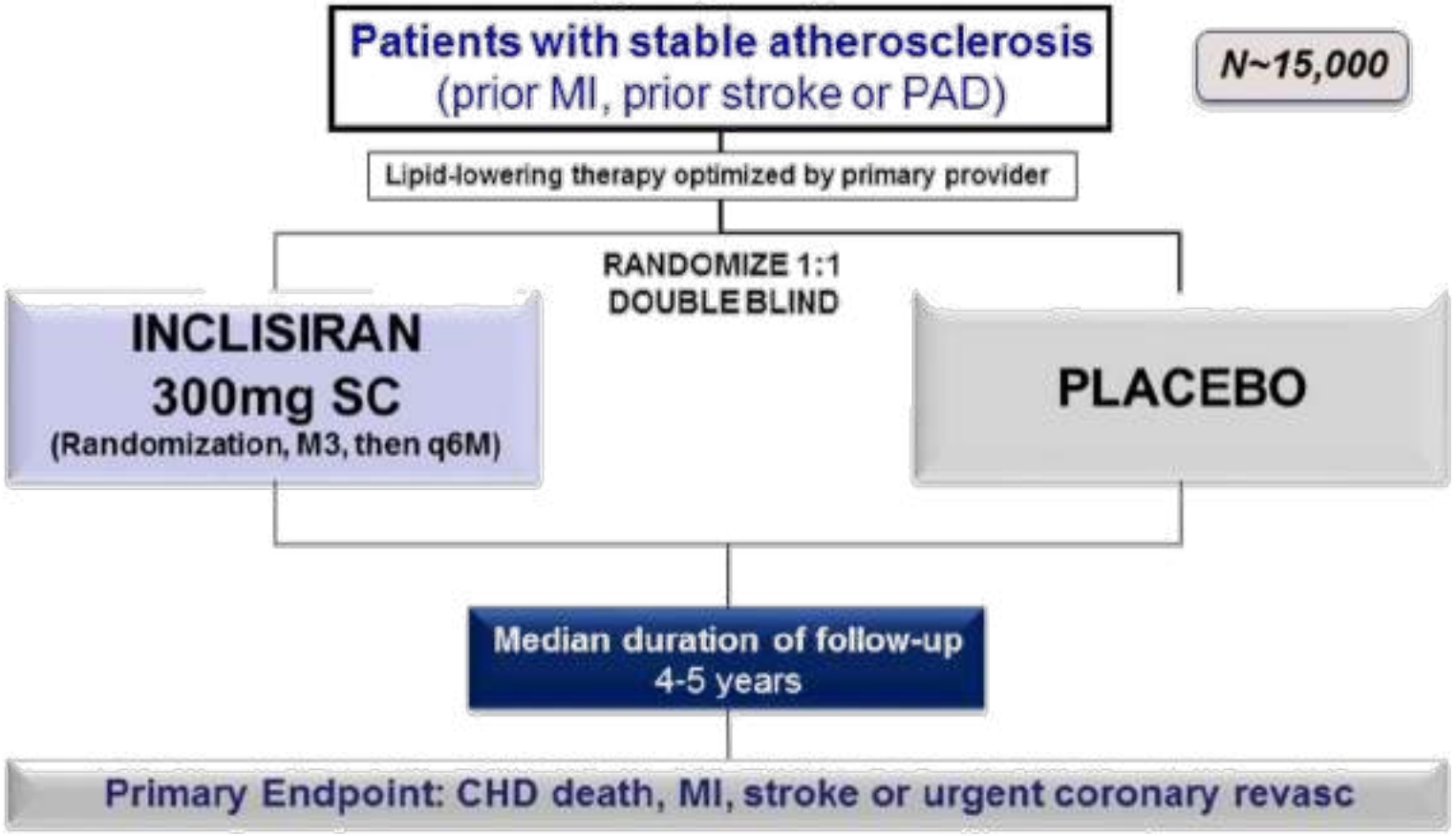


HPS-4
TIMI 65
ORION-4

HPS-4
TIMI 65
ORION-4

TRIAL DESIGN



https://clinicaltrials.gov/ct2/show/NCT03705234

Image source: www.timi.org

HPS-4
TIMI 65
ORION-4

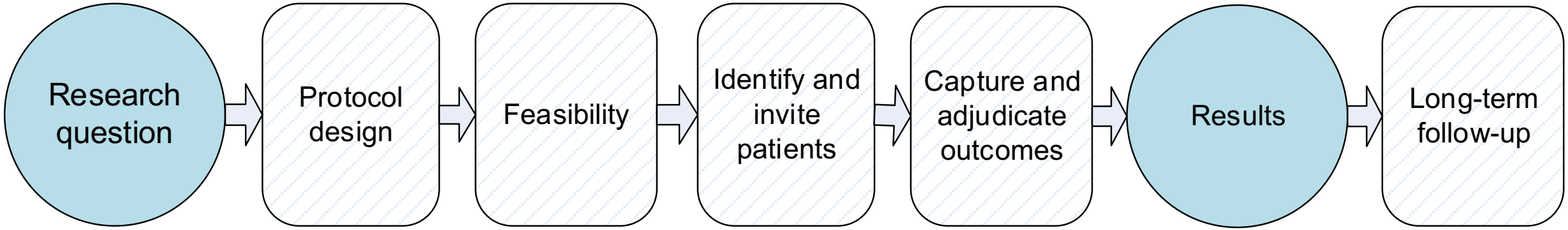
USING SECONDARY CARE DATA FOR TRIALS

GOOD **DESIGN** AND **PLANNING**

EFFICIENT **RECRUITMENT** AND **ENGAGEMENT**

EFFICIENT **DATA COLLECTION**

ROBUST **RESULTS**



Refining the research question

Simple eligibility criteria aligned with central records data

Study site **planning**

Patient identification

Pre-screening

Data extracts from central records

Large-scale **mail-based** invitation methods

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HPS-4
TIMI 65
ORION-4

PROTOCOL DESIGN

Simple inclusion criteria:

Age ≥**55y** and:

1- Prior **myocardial infarction**; or

2- Prior **ischaemic stroke**; or

3- **Peripheral vascular disease**

(prior lower extremity artery revascularization or aortic aneurism repair)

vs

"Standard" inclusion criteria:

Proven coronary artery disease

- Prior MI defined by chest pain, ST elevation on ECG and rise in cardiac troponin
- Angiographically proven coronary disease with critical stenosis on at least 1 coronary artery or moderate (>50%) stenosis in at least 2

Proven cerebrovascular disease

- Prior ischaemic stroke with evidence of cerebral infarction on CT or MRI
- Transient ischaemic attack with moderate (>50%) stenosis in appropriate carotid artery on duplex ultrasound

Proven peripheral arterial disease

- Symptoms of intermittent claudication assessed by vascular surgeon with proven moderate stenosis on duplex ultrasound or angiogram
- Previous revascularisation surgery for documented arterial stenosis

HPS-4
TIMI 65
ORION-4

PROTOCOL DESIGN

Simple inclusion criteria:

Age ≥**55y** and:

1- Prior **myocardial infarction**; or

2- Prior **ischaemic stroke**; or

3- **Peripheral vascular disease**

(prior lower extremity artery revascularization or aortic aneurism repair)

Simple **electronic search** criteria:

1- Diagnosis of **MYOCARDIAL INFARCTION**:
ICD9 codes: 410*, 412* and/or
ICD10 codes: I21*, I22*, I23*, I252 and/or
READ codes: G30*

2- Diagnosis of **STROKE**:
ICD9 codes: 433*, 434* and/or
ICD10 codes: I63*, I64* and/or
READ codes: G63*, G64*, G66 and/or

3- Surgery/procedure for **PERIPHERAL VASCULAR DISEASE**:
OPCS-4 procedure codes: L16*-L28* inclusive,
L48*-65* inclusive, L71*

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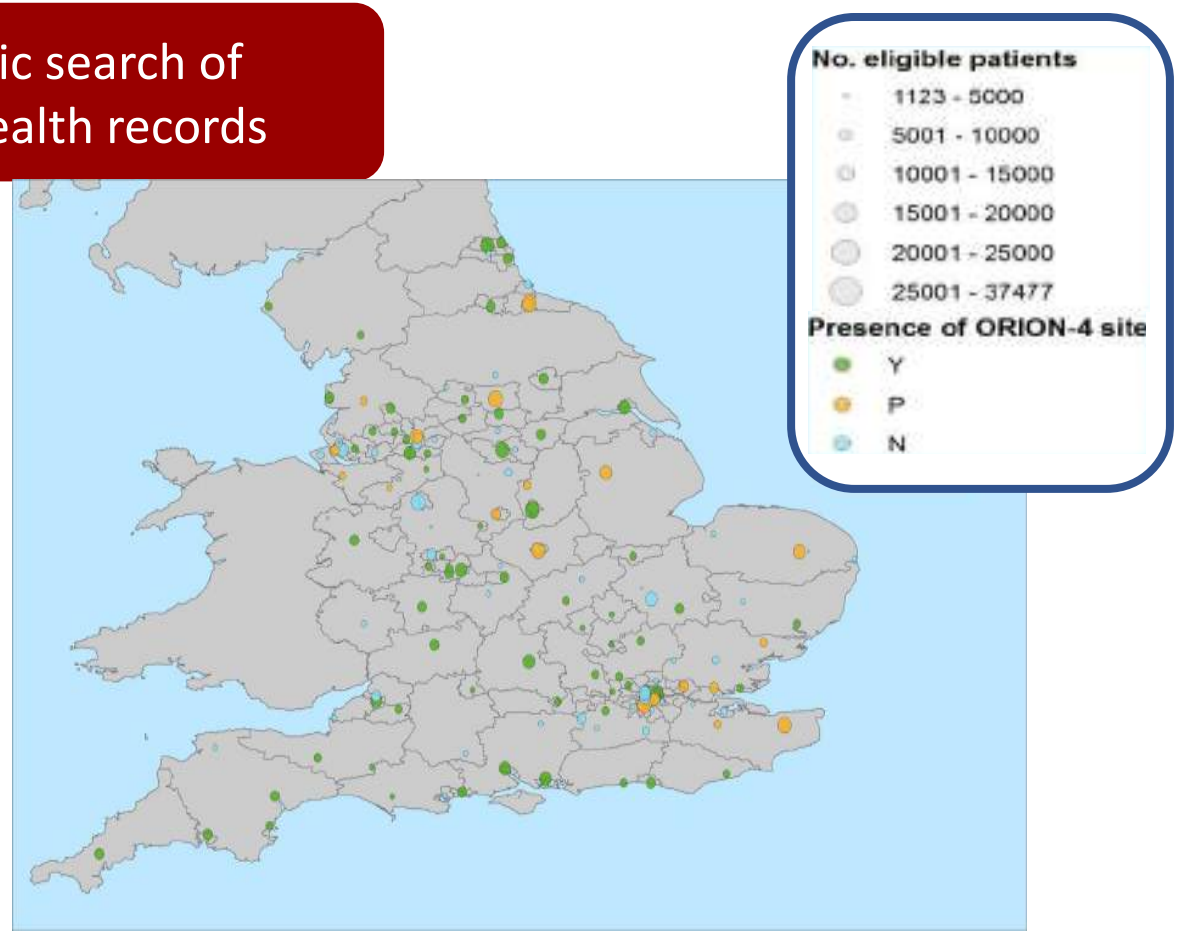
TIMI 65
ORION-4

FEASIBILITY & PLANNING

NHS Digital

Electronic search of central health records



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TIMI 65
ORION-4

IDENTIFICATION & INVITATION

University Hospitals Bristol
NHS Foundation Trust

Name/address

Coded data

NHS Digital

Name/address

Coded data

UNIVERSITY OF OXFORD

Invitation letter

Royal Mail

Pre-screening

UNIVERSITY OF OXFORD

Appointment

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TIMI 65
ORION-4

IDENTIFICATION & INVITATION

NHS Digital

UNIVERSITY OF OXFORD

Electronic search of central health records

Details of potentially-eligible patients sent to CTSU

>90 datasets
>1M patient records

Data checking (vital status, location, duplicates)

Invitation

Regulatory requirements

Confidentiality Advisory Group (England and Wales)
Ethics committee approval
Independent review by **iGARD** (NHS Digital)
Data sharing agreement with NHS Digital

Section 251 (NHS Care Act)

Technical requirements

9 **computer applications**
4 **programmers**
Spec writers / testing team
20 years of **experience**

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HPS-4
TIMI 65
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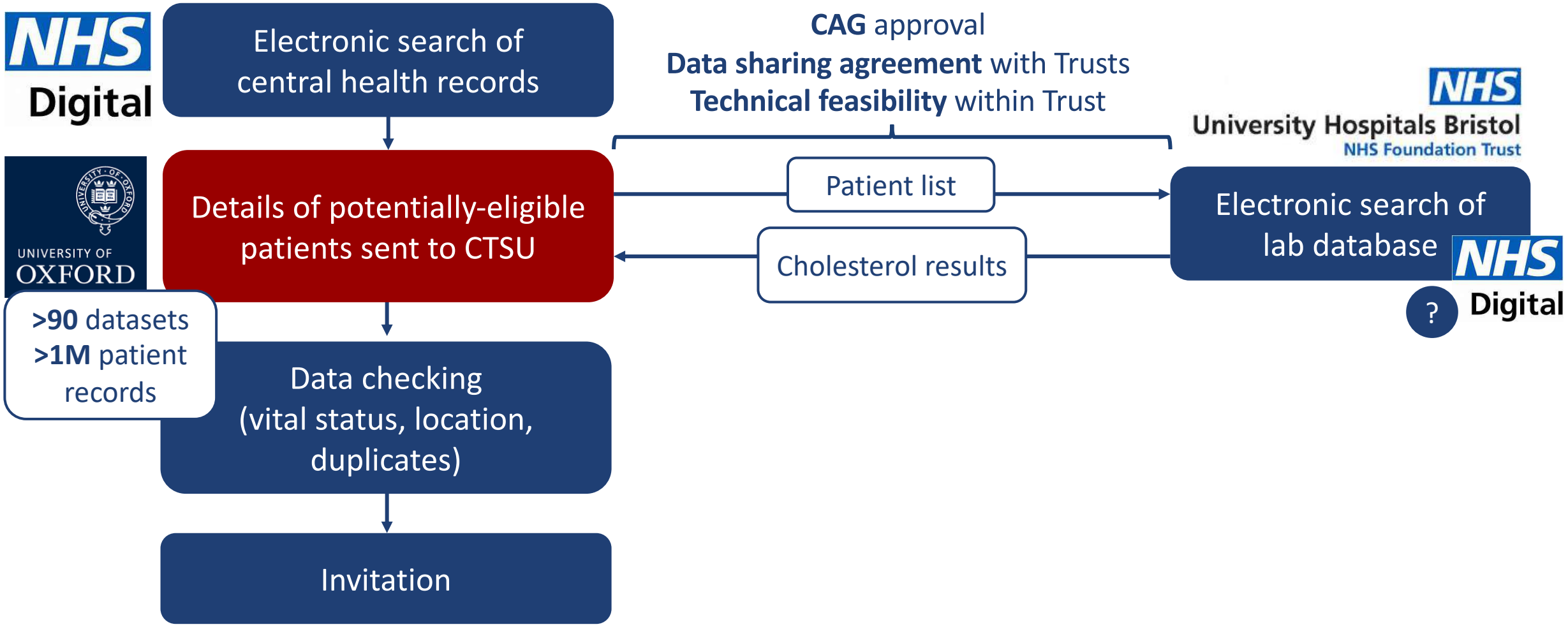
IDENTIFICATION & INVITATION



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TIMI 65
ORION-4

IDENTIFICATION & INVITATION

NHS Digital

Electronic search of central health records

Details of potentially-eligible patients sent to CTSU

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>90 datasets
>1M patient records

Data checking (vital status, location, duplicates)

Invitation

Enhancing addresses
- Apply uniform formatting
- Get Royal Mail approved version
- Get location (OS grid information)

Study centre allocation

Apply centre catchment radius

Check age

Check if GP practice not excluded (NWEH)

Check cholesterol results

Check date and status of the last list cleaning

Adjustable according to study requirements

Send list for cleaning

NHS Digital

Ready to invite

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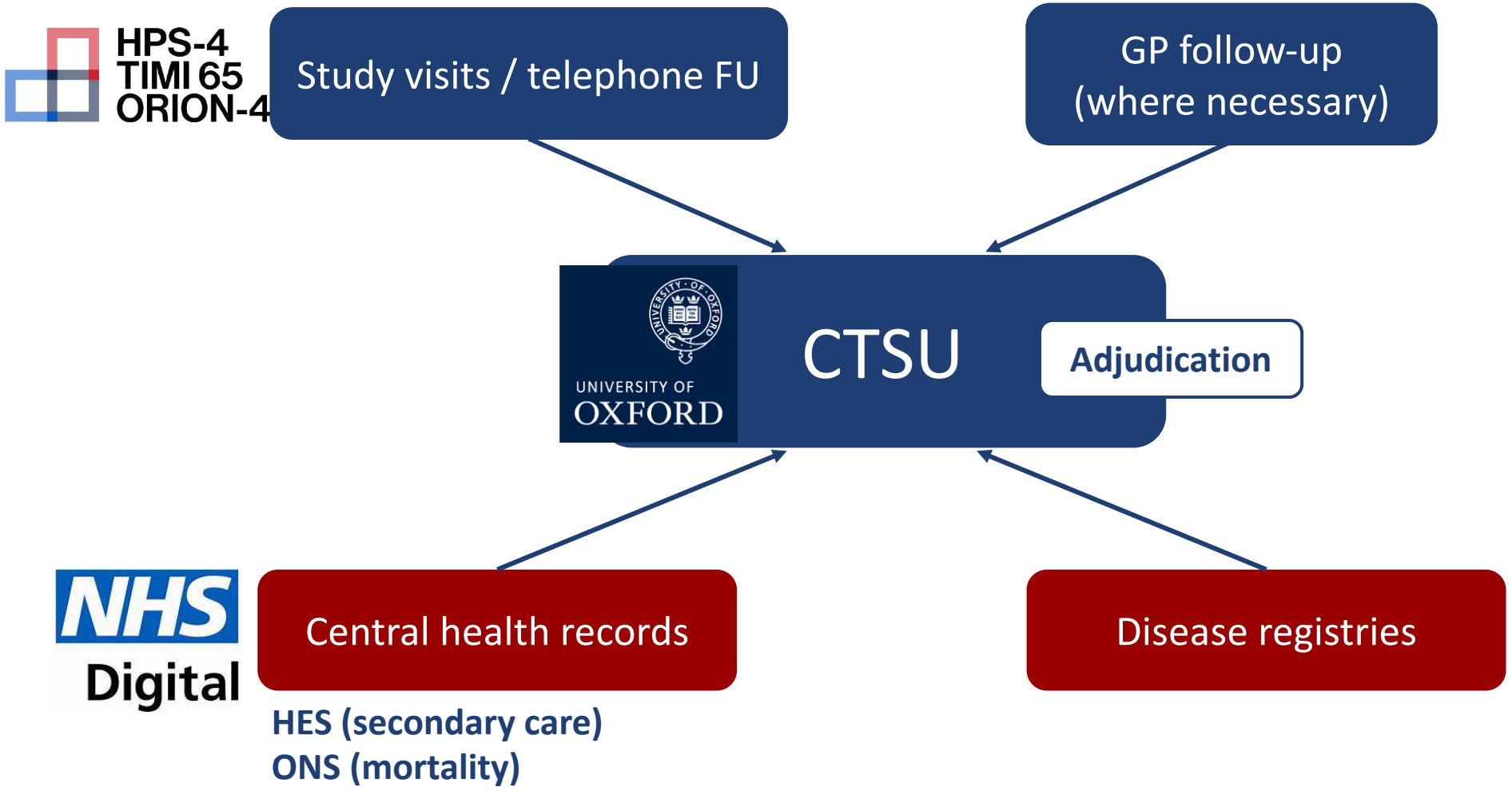
ORION-4

CTSU CV trials – invitation numbers

	SEARCH	THRIVE	REVEAL
	Early 2000s	*Late 2000s*	*Early 2010s*
Invite			
Screen			
Run-in			
Randomise			
Conversion			

HPS-4
TIMI 65
ORION-4

OUTCOME COLLECTION



ASCEND

A Study of Cardiovascular Events iN Diabetes

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A Study of Cardiovascular Events iN Diabetes

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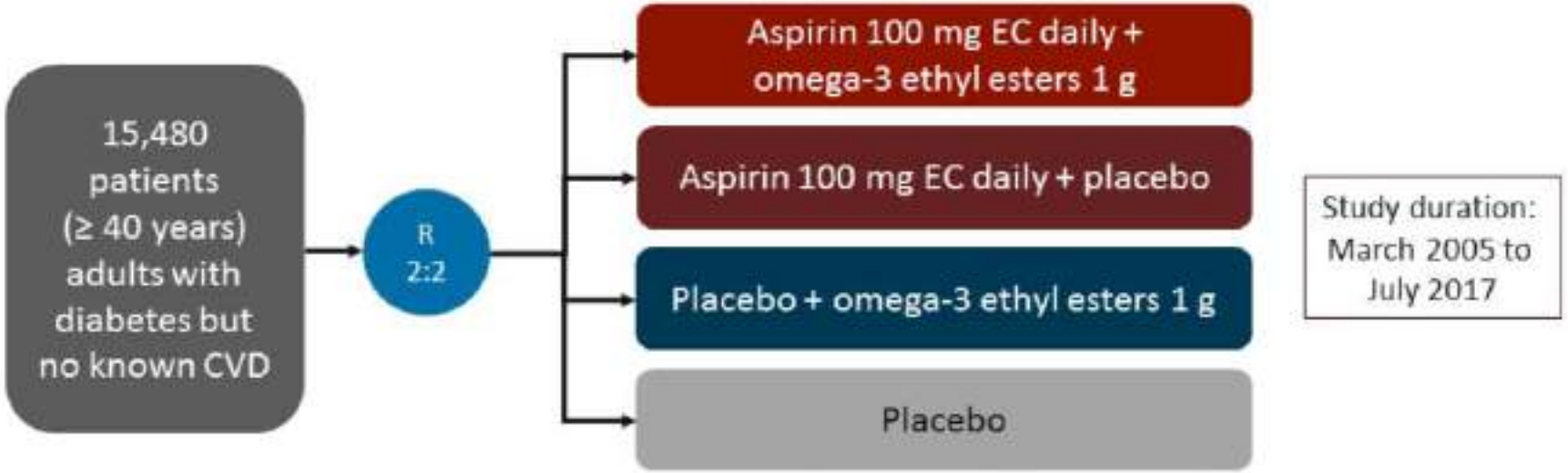
Phase 4, double-blind, randomized, 2 × 2 factorial primary prevention study in patients with diabetes but no overt CVD



- Primary efficacy outcome: first serious vascular event (MI, stroke, TIA) or death from any vascular cause (excluding ICH)
- Primary safety outcome: first major bleeding event (ie, ICH, sight-threatening bleeding, GI bleeding, or other serious bleeding)
- Secondary outcomes: included GI tract cancer

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ASCEND study collaborative group. NEJM 2018;379:1529-1539
ClinicalTrials.gov: NCT00135226
Figure source: www.medscape.com

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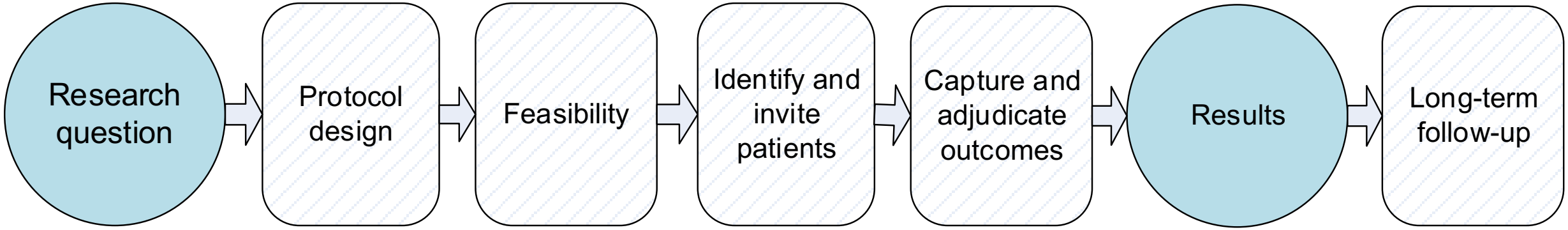
USING ROUTINE DATA DATA FOR TRIALS

GOOD **DESIGN** AND **PLANNING**

EFFICIENT **RECRUITMENT** AND **ENGAGEMENT**

EFFICIENT **DATA COLLECTION**

ROBUST **RESULTS**



Identification and invitation

Large-scale **mail-based** invitation methods

Data extracts from central records

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INVITATION

Recruitment and follow-up entirely by mail (no sites)

	Diabetes registries	General practices	Traditional sources	Overall
Invited	300,000	120,000	2,300	422,300
Responded	100,000 (33%)	20,000 (17%)	1,200 (~50%)	121,200 (~29%)
Randomized	9,000 (3%)	6,000 (5%)	400 (17%)	15,400 (~3.6%)

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OUTCOME COLLECTION

- Postal questionnaires/GP review
- Targeted **HES search** and clinician review if lost to FU
  - Enabled **99% completeness of follow-up** (vs ~94% without HES)
- Automated 'event' creation (e.g. death notification)
  - Usually followed by manual review by trial clinician

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OUTCOME COLLECTION

(bespoke HES data viewer)

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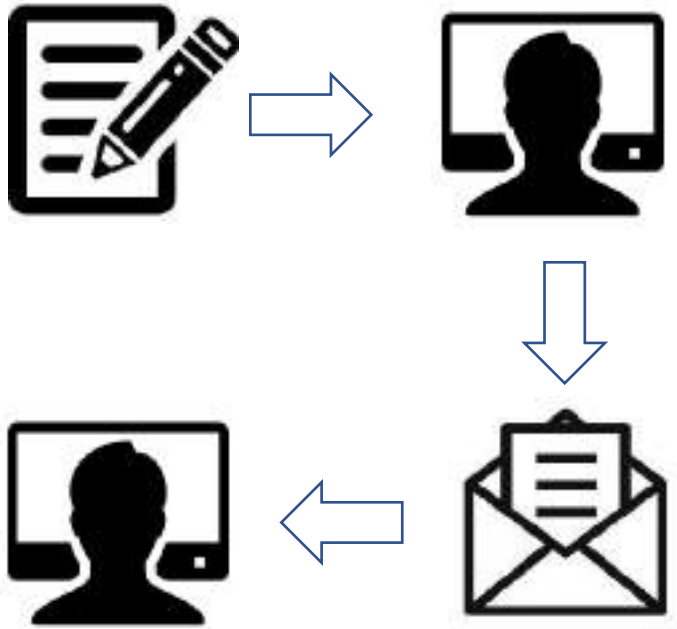
OUTCOME COLLECTION

How does routinely-collected data compare against clinician adjudication?

Hospital Episode Statistics (England and Wales)

Clinician adjudication "Gold Standard"



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OUTCOME COLLECTION (excluding Scotland)

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OUTCOME COLLECTION (excluding Scotland)

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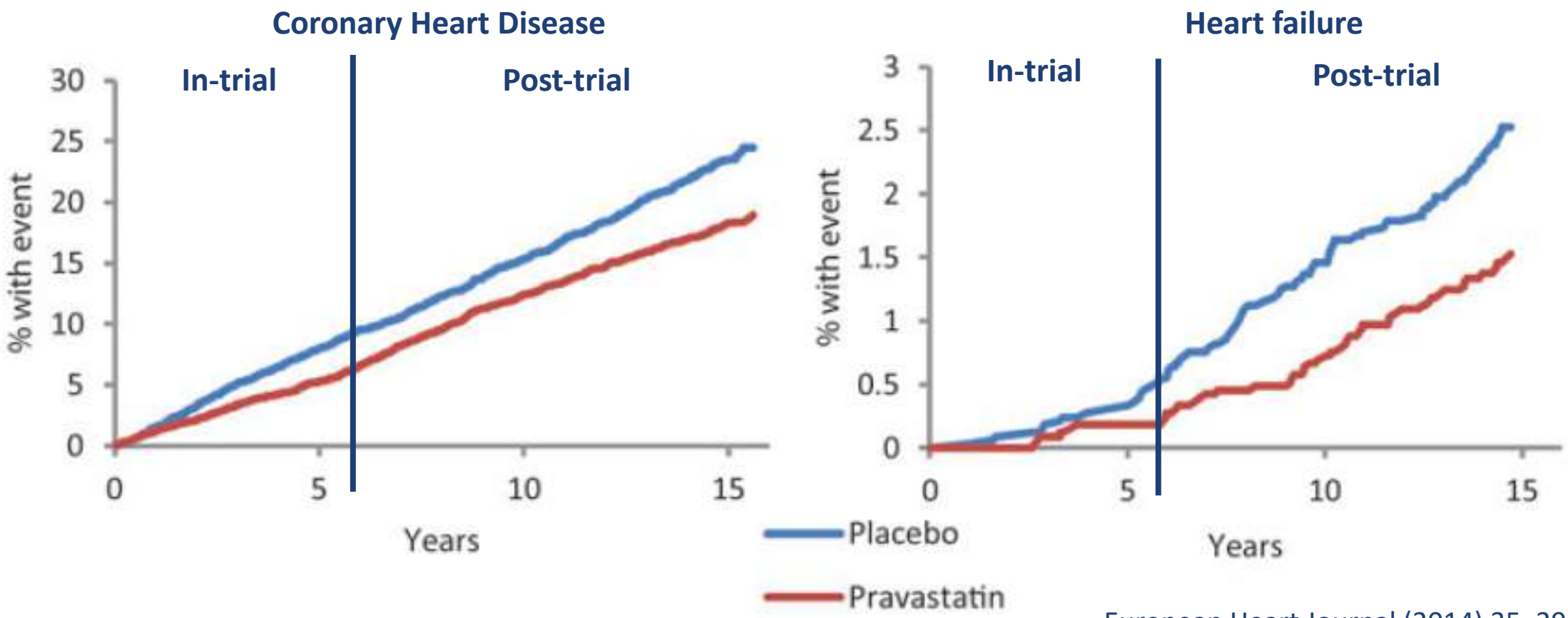
OUTCOME COLLECTION (excluding Scotland)

OPPORTUNITIES: POST-TRIAL FOLLOW-UP (WOSCOPS study)

Routinely-collected records in Scotland (Scottish Morbidity Record)



European Heart Journal (2014) 35, 290–298

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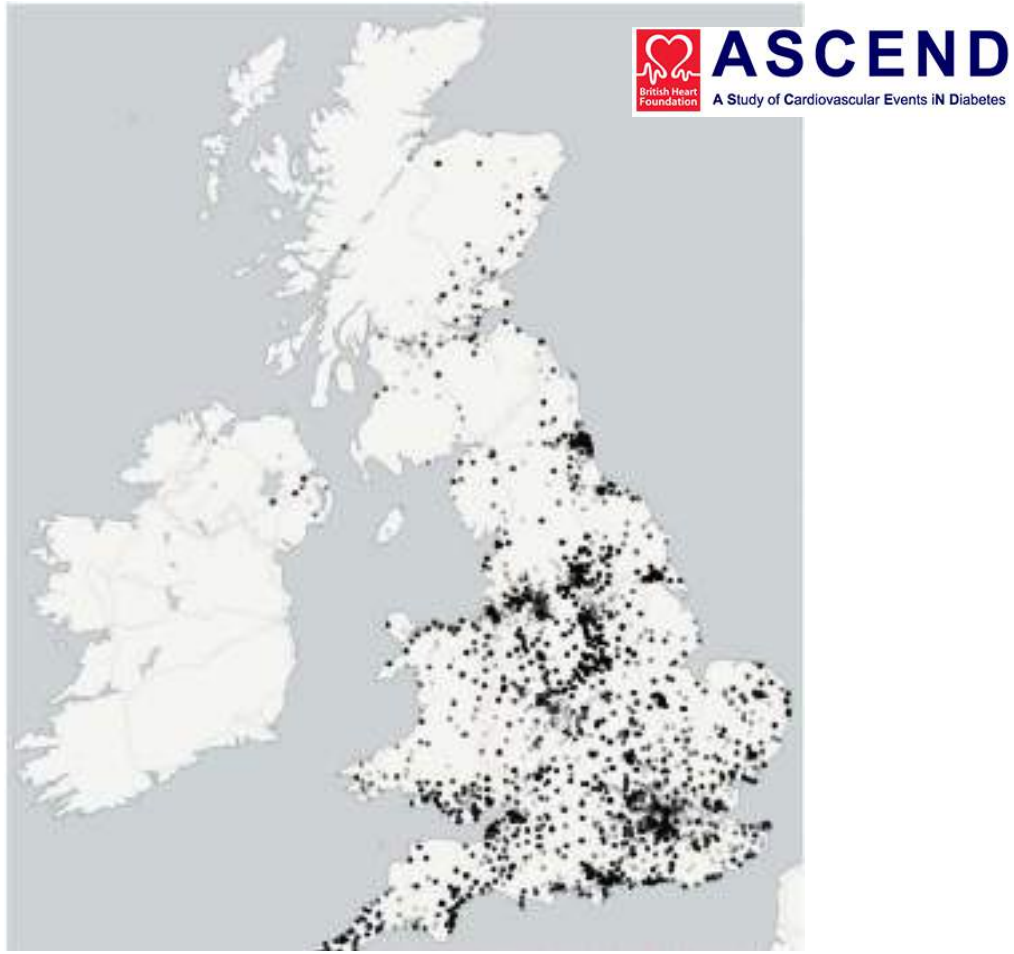
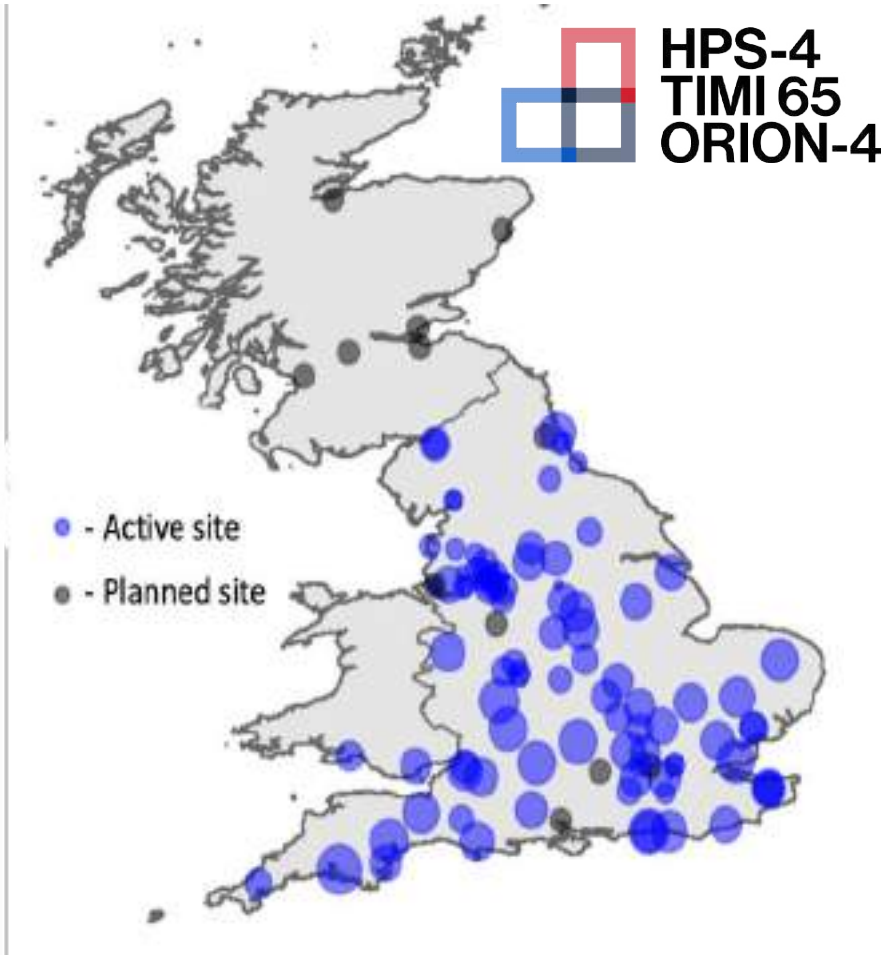
OPPORTUNITIES FOR ROUTINELY-COLLECTED DATA: INCLUSIVE TRIALS



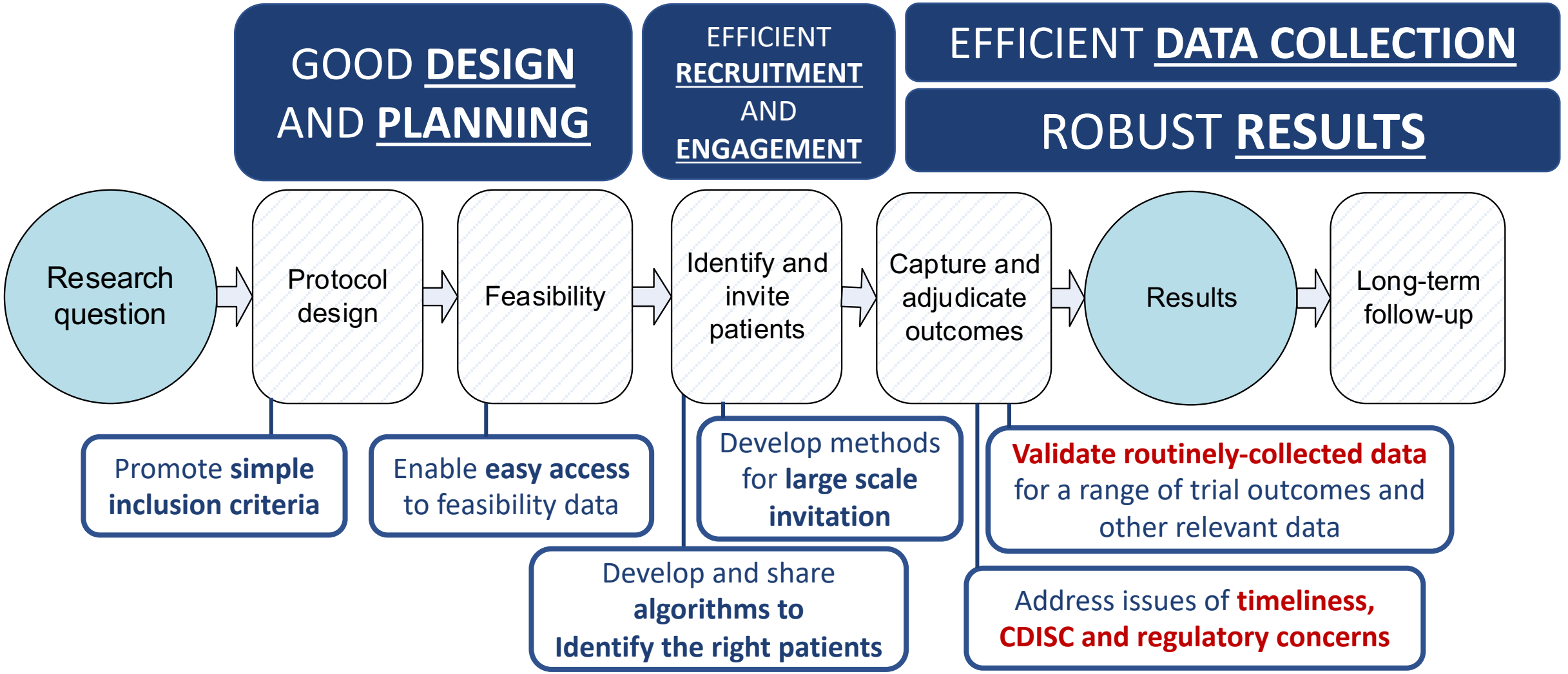
Randomized patients (ASCEND)



NHS Trusts involved (ORION-4)

OPPORTUNITIES AND CHALLENGES FOR ROUTINELY-COLLECTED DATA:

DATA-ENABLED CLINICAL TRIALS



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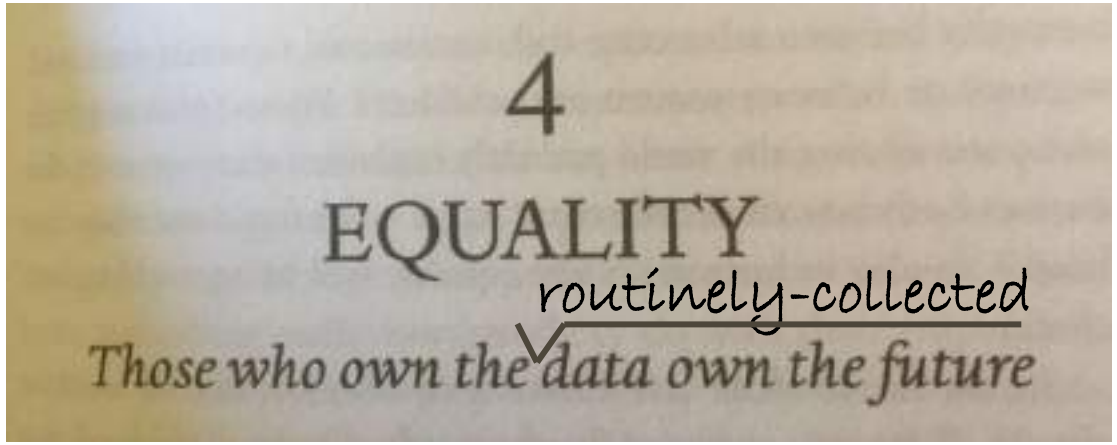
4
EQUALITY
routinely-collected
Those who own the data own the future

Harnessing routinely-collected data for efficient and low-cost clinical trials

Guilherme Pessoa-Amorim

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University of Oxford
Radcliffe Department of Medicine
Nuffield Department of Population Health
Medical Sciences Division
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