FARSITE

Evaluation of an Automated Trial Feasibility Assessment and Recruitment Tool

Presented by Gary Leeming

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NWEH making sense of local healthcare | MANCHESTER 1824 The University of Manchester | Salford Royal NHS Foundation Trust University Teaching Hospital | NHS Salford | Northwest Regional Development Agency

Feasibility And Recruitment System for Improving Trial Efficiency

Software to assist in identification and recruitment of participants for clinical trials.

OBJECTIVES

Improve efficiency and accuracy of study recruitment

Preserve Consent-For-Consent for recruitment of GP patients

Protect patient privacy; researchers only access anonymised and aggregated data

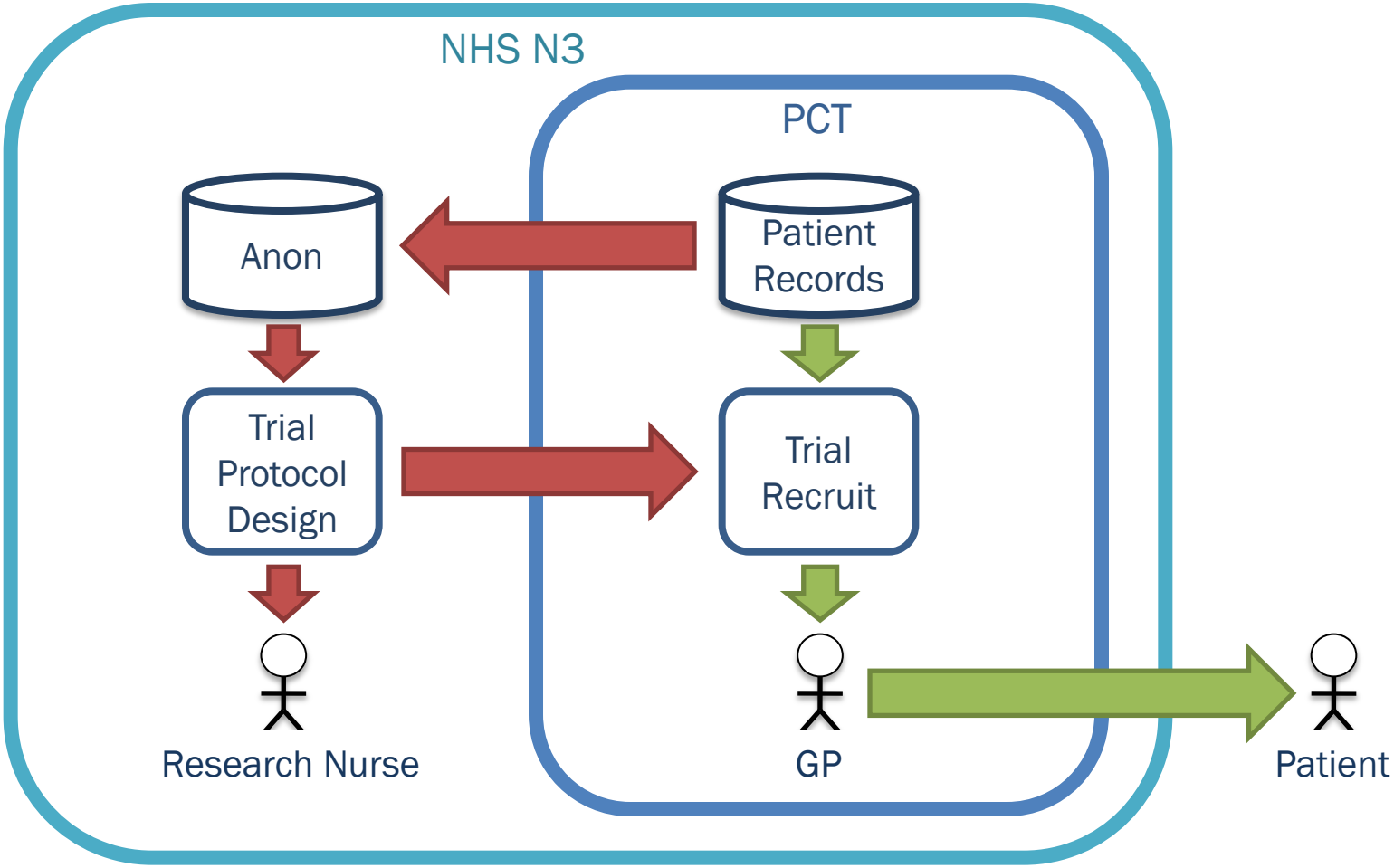
Share knowledge about the way medical data is recorded

Context

- Currently used for feasibility in Salford
- Developed with users in NW Diabetes Research Network and GM CLRN
- Datasets
  - Salford Integrated Record;
  - Secondary care and Primary care data;
  - Population of 242,000

Improving recruitment while preserving "consent for consent" and patient privacy

GP retains local control

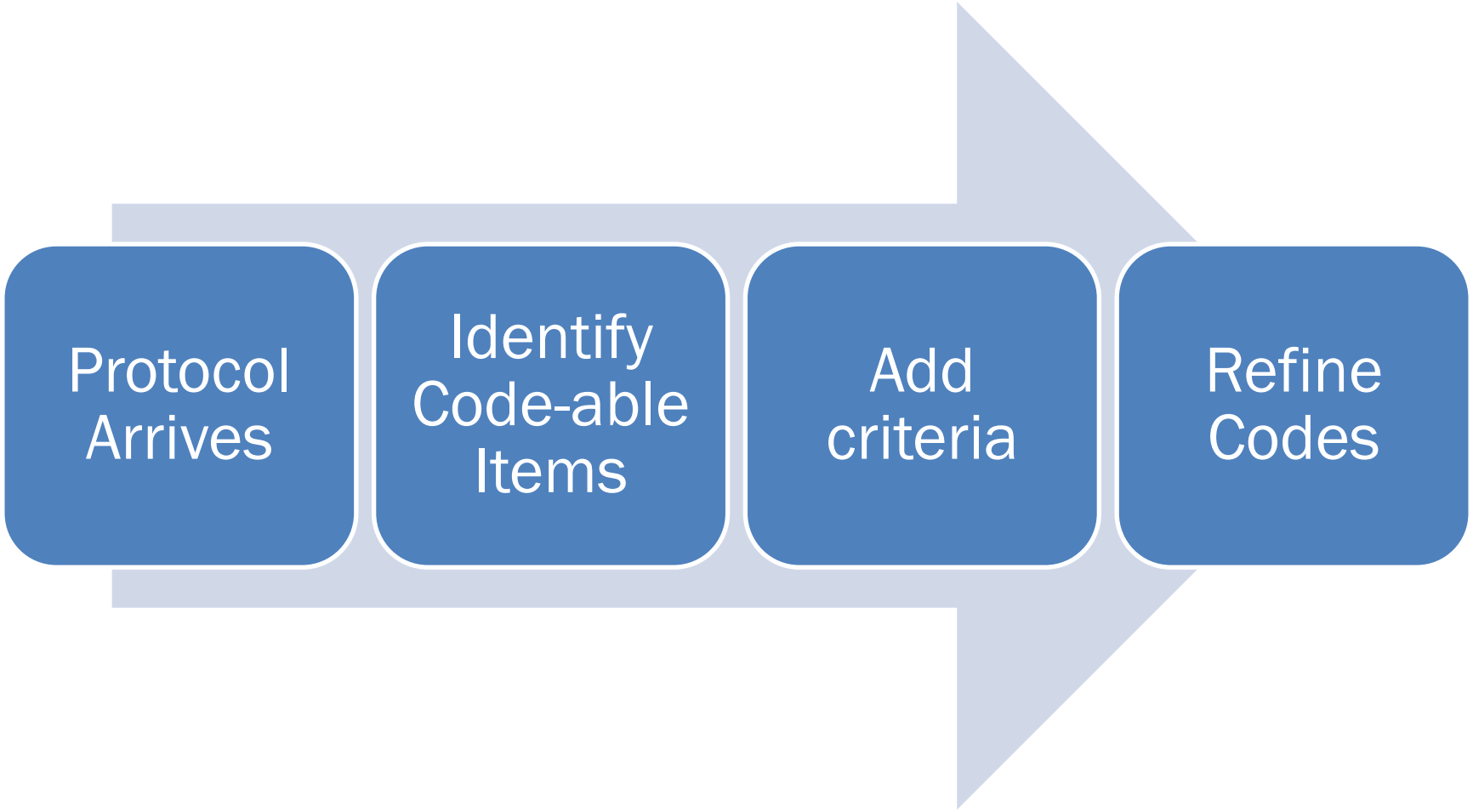


Consent for Consent

is the consent to search an individual's health record to determine whether or not they should be invited to take part in a clinical study

See MRC guidance: http://www.dt-toolkit.ac.uk/_db/_documents/Consent_for_Consent_DRAFT.pdf

Creating Feasibility Report



Instead of this…

- select distinct PatientID, GPPracticeCode from Patients where DeathDate is null and PatientID in (select distinct PatientID from Patients where Dob<=1991 and PatientID in (select distinct PatientID from Patients where Dob>=1931)) and PatientID in (select distinct PatientID from Patients where PatientID in (select distinct j.PatientID from Journal j where j.ReadCode in ('.C21.','.C2A.','.C2D.','.C2G2','C1021','C109.','C1094','C1095','C1097','C1099','C109D','C109F','C109G','C109H','C109J','C10F.','C10F4','C10F5','C10F7','C10F9','C10FD','C10FF','C10FG','C10FH','C10FJ','L1806','X40J5','X40J6','X40Jk','XaELQ','XaFn7','XaFn8','XaFn9','XaFWI','XSETp','XU70f','XU71F','XUKO0','XULXc','XUPHn','XUSbx') and j.EntryDate<@p4DateLimit1)) and PatientID not in (select distinct PatientID from Patients where PatientID in (select distinct j.PatientID from Journal j where j.ReadCode in ('.1226','.12C2','.12C3','.12C5','.12C8','.12CA','.12CB','.12CC','.12CD','.12CE','.12CF','.12CG','.12CH','.12CJ','.12CL','.12CM','.12CN','.12CP','.12CR','.12CS','.12CT','.12J3','.14A.','.14A3','.14A4','.14A5','.14A6','.14AD','.14AH','.14AJ','.14AL','.14AM','.14AN','.14AP','.14AQ','.14AR','.14H1','.187.','.1I10','.1I3.','.1I5.','.1I6.','.1J60','.1O1.','.2241','.679X','.68B2','.68B6','.6C0.','.7721','.7722','.865.','.8651','.8652','.8653','.8654','.865Z','.B1NZ','.G12.','.G121','.G122','.G123','.G12Z','.G131','.G2..','.G21.','.G211','.G212','.G213','.G21Z','.G22.','.G221','.G222','.G223','.G22Z','.G23.','.G231','.G232','.G233','.G234','.G235','.G236','.G23Z','.G2Z.','.G32.','.G34.','.G4..','.G41.','.G42.','.G420','.G43.','.G44.','.G440','.G441','.G442','.G443','.G444','.G445','.G446','.G45.','.G451','.G452','.G45Z','.G46.','.G47.','.G48.','.G49.','.G4Z.','.G5..','.G51.','.G511','.G52.','.G52Z','.G5Z.','.G6..','.G61.','.G612','.G613','.G614','.G62Z','.G63.','.G631','.G632','.G633','.G634','.G635','.G636','.G637','.G63Z','.G64.','.G641','.G642','.G643','.G644','.G645','.G646','.G64Z','.G65.','.G651','.G652','.G653','.G654','.G655','.G656','.G657','.G65Z','.G66.','.G67.','.G670','.G68.','.G681','.G682','.G68Z','.G69.','.G691','.G692','.G693','.G69Z','.G6A.','.G6A1','.G6A2','.G6AZ','.G6B.','.G6B2','.G6B3','.G6B5','.G6B6','.G6BZ','.G6C.','.G6E.','.G6Z.','.K2B5','.N2..','.N21.','.N211','.N212','.N213','.N214','.N21Z','.N22.','.N221','.N222','.N223','.N224','.N225','.N226','.N227','.N22Z','.P324','.P9H2','.P9N2','.P9OZ','.RJ10','1226.','12C..','12C2.','12C3.','12C5.','12C8.','12CA.','12CB.','12CC.','12CD.','12CE.','12CF.','12CG.','12CH.','12CJ.','12CL.','12CM.','12CN.','12CP.','12CR.','12CS.','12CT.','12J3.','14A..','14A3.','14A4.','14A5.','14A6.','14AD.','14AH.','14AJ.','14AL.','14AM.','14AN.','14AP.','14AQ.','14AR.','14H1.','1I10.','1I3..','1I5..','1I6..','1J60.','1O1..','2241.','679X.','68B2.','68B6.','6C0..','7902.','79020','79021','79022','79023','79024','79025','7902y','7902z','7930.','79300','79301','79302','79304','7930y','7930z','79340','79341','79342','79350','79351','79356','793E1','793M1','793M2','793M3','7L1H.','7L1H0','7L1H1','7L1H2','7L1H3','7L1H4','7L1H7','7L1H8','7P0G0','A17y0','A17y1','A2704','A32y1','A364.','A3640','A3642','A3643','A364z','A742.','A7420','A7422','A7423','A742z','A7A..','A860.','A8600','A932.','A9320','A9321','A9322','A9323','A9324','A932z','A93y1','A98y2','A98y3','AB2y0','AB404','AB414','AB4z4','AD03.','B241.','B2410','B2411','B2412','B2413','B241z','B25..','B727.','B728.','B93y1','Byu21','C1322','C34y1','C3733','F3918','F391B','G01..','G010.','G011.','G012.','G01y.','G01y0','G01yz','G01z.','G020.','G1...','G10..','G100.','G101.','G102.','G10z.','G11..','G110.','G111.','G112.','G113.','G114.','G11z.','G12..','G120.','G121.','G122.','G12z.','G13..','G130.','G131.','G132.','G133.','G13y.','G13z.','G14..','G140.','G1400','G1401','G1402','G1403','G1404','G1405','G140z','G141.','G1410','G1411','G1412','G141z','G14z.','G1y..','G1y0.','G1yz.','G1yz0','G1yz1','G1yzz','G1z..','G21..','G210.','G2100','G2101','G210z','G211.','G2110','G2111','G211z','G21z.','G21z0','G21z1','G21zz','G23..','G230.','G231.','G232.','G233.','G234.','G23z.','G3...','G30..','G300.','G301.','G3010','G3011','G301z','G302.','G303.','G304.','G305.','G306.','G307.','G3070','G3071','G308.','G309.','G30A.','G30B.','G30X.','G30X0','G30y.','G30y0','G30y1','G30y2','G30yz','G30z.','G31..','G310.','G311.','G3110','G3111','G3112','G3113','G3114','G3115','G311z','G312.','G31y.','G31y0','G31y1','G31y2','G31y3','G31yz','G32..','G33..','G330.','G3300','G330z','G331.','G332.','G33z.','G33z0','G33z1','G33z2','G33z3','G33z5','G33z6','G33z7','G33zz','G34..','G340.','G3400','G3401','G341.','G3410','G3411','G3412','G3413','G341z','G343.','G344.','G34y.','G34y0','G34y1','G34yz','G34z.','G34z0','G35..','G350.','G351

…intelligible…

Protocol Templates

- Load Template :

Study Overview

State

Approved

Study Members

- test (Creator)
- lucy (editor)

Inclusion Criteria (Match All Inclusion Groups)

- Include: Diabetes mellitus type 2
- Include: Coronary Heart Disease (QoF Register)
- Include: Measurements

Add Include Group

Exclusion Criteria

- Exclude: Palliative Care (QoF Register)
- Exclude: Heart Failure (QoF Register)
- Exclude: Cancer (QoF Register)

Add Exclude Group

Demographics

Age	Lower Age	50	Years
	Upper Age	- -	Years
Gender	Any		
Ethnicity	Any		

…and helpful…

Welcome **lucybridges!** [Log Off] | Profile | User Admin | Exception Log | Journal Config

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Help

Options
- Create new study
- Create copy of this study
- Cancel study
- Return to list of studies

Protocol Templates
- Load Template :

Study Overview

State
Feasibility
Study Members
- lucybridges (Creator)

Search | **Results** | Details

- Diagnoses (0)
- Procedures & Findings (0)
- Measurements & Tests (0)
- Medicines & Devices (12)
- Allergies & Adverse Reactions (2)

Hide Unused Terms

Medicines & Devices

Current

Salmeterol
(c19..) *Current* 99089 27

Deprecated

Salmeterol 25mcg inhaler - product
(c191.) *Retired* 30029

Salmeterol 25micrograms CFC-free inhaler
(c19z.) *Retired* 17325

Salmeterol 50micrograms breath-actuated dry powder inhaler - product
(c197.) *Retired* 9637

Salmeterol 50micrograms/blister disks refill - product
(c196.) *Retired* 2001

Salmeterol 50micrograms/blister disks+disk inhaler - product
(c195.) *Retired* 199

Salmeterol+fluticasone propionate 25micrograms/125micrograms CFC-free inhaler - product
(c1Dv.) *Retired* 9871

Salmeterol+fluticasone propionate 25micrograms/250micrograms CFC-free inhaler - product
(c1Dw.) *Retired* 8912

Close | Back

…query creation

Protocol Templates

- Load Template :

Study Overview

State

Approved

Study Members

- test (Creator)
- lucy (editor)

Inclusion Criteria (Match All Inclusion Groups)

Include: Diabetes mellitus type 2

Include: Coronary Heart Disease (QoF Register)

Add Include Group

Create new group

Choose from existing common criteria:

Asthma (QoF Register)
Atrial Fibrillation (QoF Register)
Blood Pressure - Hypertension
Blood Pressure - Normal
Cancer (QoF Register)
Chronic Kidney Disease (QoF Register)
COPD (QoF Register)
Coronary Heart Disease (QoF Register)
Diabetes (QoF Register)
Hayfever
Heart Failure (QoF Register)
Obesity (QoF Register)
Palliative Care (QoF Register)
Stroke And Transient Ischaemic Attacks (QoF Register)

Cancel Save

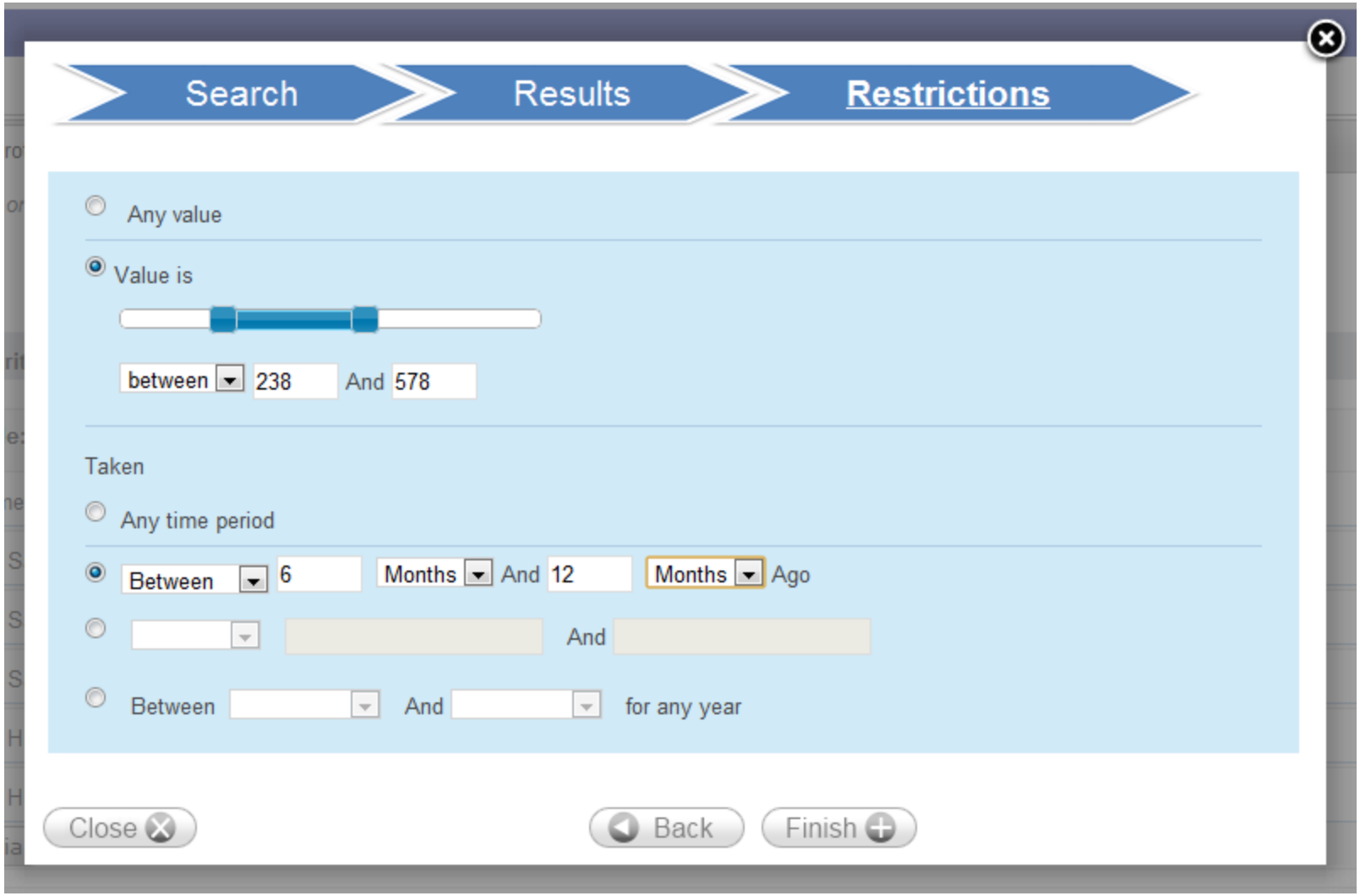
Years

Upper Age - - Years

Gender Any

Ethnicity Any

…with supported options



…and quick results

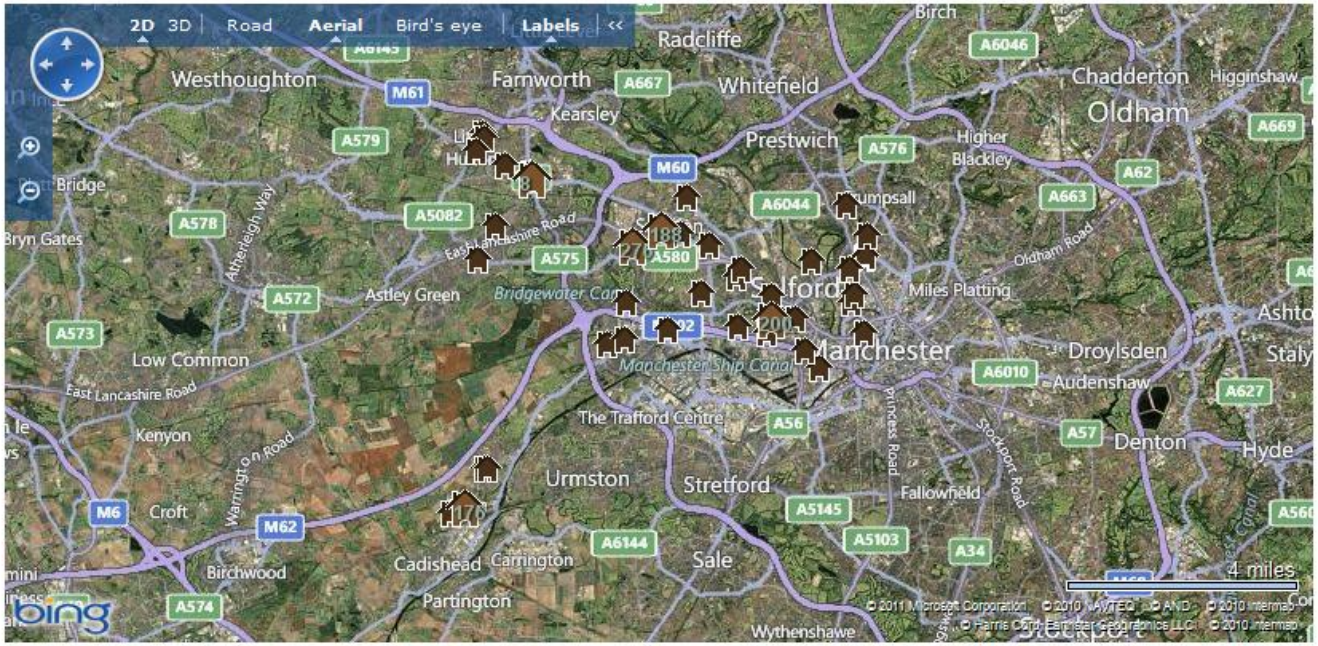
Population Total	242,055 people
Inclusion Criteria (Match All Include Groups)	
Include: Asthma Diagnosis	(Running Total) 31,247 people
Include: Short-acting beta2s	(Running Total) 14,425 people
Include: Recent exacerbation of asthma	(Running Total) 6,151 people
Running Total *(with duplicate matches removed)*	6,151 people
Exclusion Criteria	
Exclude: Salmeterol	(Running Total) 2,481 people
Exclude: Other respiratory disease	(Running Total) 1,645 people
Running Total *(with duplicate matches removed)*	1,645 people
Demographics	
Age is between 6 and 14	(Running Total) 451 people
Gender is Any	451 people
Ethnicity is Any	451 people
Smoker types: Any	451 people
Recruitment Estimate	451 people

Exploring the detail

Include: Asthma Diagnosis	*(Running Total)* **31,247 people**
Asthma (disorder) (with exceptions)	32,518 people
AND NOT Asthma resolved (finding)	31,247 people
Include: Short-acting beta2s	*(Running Total)* **14,425 people**
beta-2 agonists prescribed less than 1 Years ago	14,425 people
Include: Recent exacerbation of asthma	*(Running Total)* **6,151 people**
Corticosteroids used in the treatment of asthma prescribed less than 6 Months ago	4,507 people
AND/OR CLENIL MODULITE 100micrograms CFC-free inhaler prescribed less than 6 Months ago	5,040 people
AND/OR CLENIL MODULITE 200micrograms CFC-free inhaler prescribed less than 6 Months ago	5,125 people
AND/OR CLENIL MODULITE 250micrograms CFC-free inhaler prescribed less than 6 Months ago	5,145 people
AND/OR CLENIL MODULITE 50micrograms CFC-free inhaler prescribed less than 6 Months ago	5,618 people
AND/OR Asthma attack performed less than 6 Months ago	5,621 people
AND/OR Asthma Accident and Emergency attendance since last visit performed less than 6 Months ago	5,631 people
AND/OR Prednisolone 5mg e/c tablet - product prescribed less than 6 Months ago	5,844 people
AND/OR Prednisolone 5mg tablet - product prescribed less than 6 Months ago	6,151 people
Running Total *(with duplicate matches removed)*	**6,151 people**

Investigating site feasibility

You saved the study on 01/09/2011 13:42:10 (study approved)



GP Practices 848 people

Select all

E4	Example Practice 4	276 people
E2	Example Practice 2	200 people
E1	Example Practice 1	188 people
E3	Example Practice 3	176 people

Making recruitment easier

Add patient consent form — Choose File ExampleDocument.txt ★

and patient information sheet (if separate) — Choose File No file chosen

Add ethics approval letter — Choose File ExampleDocument.txt ★

Add protocol document — Choose File No file chosen ★

Click here to add another document

Patient invitation letter template

Header

Body

Dear [[PatientTitle]] [[PatientFirstName]] [[PatientLastName]]

-- Paste the invitation letter here --

Patient	Address Line 1	Address Line 2	Address Line 3	Address Line 4	Postcode
	Title	Firstname	Lastname		
GP	Practice Name	Address Line 1	Address Line 2	Address Line 3	Town
	County	Postcode	GP Name		
Consent	Date				

What the GP sees

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Farsite Recruitment

Home | GP Practices | News | Help

Options

- Return To List Of Studies

Options

Opt Out Of This Study

Opt Out

Opt out of the study if you don't wish to invite any patients to participate

Example Study

Details | Protocol | Documents | Identified Patients | Invitations

Patients identified from the study protocol.

	NHS Number	Title	First Name	Family Name	Birth Date	Address
☑	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
☑	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
☑	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
☑	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
☐	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
☐	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
☐	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
☐	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
☐	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
☐	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]

< 1 2 >

☐ Select All Patients

Select for Invitation

Back | Next

Data is pseudonymised

- No identifiable patient information is stored in FARSITE
- Medical data about patients is pseudonymised
  - Name removed
  - NHS number removed
  - Date of Birth translated to Year and Quarter
  - Postcode translated to Super Output Area
- Only aggregated results are displayed
  - Values <6 are not returned
- Identification service returns patient information only when needed and only for valid users (GPs)

Design: Picking the right codes is hard

Protocol Criteria

- Asthma (disorder)
  - Asthma (disorder) (H33..)
    - Exercise-induced asthma (disorder) (173A.)
    - Asthma without status asthmaticus (disorder) (XUGPV)
    - Chemical-induced asthma (disorder) (XUNpV)
    - Mixed asthma (disorder) (H332.)
    - Asthma unspecified (disorder) (H33z.)
      - Asthma NOS (disorder) (XE0YX)
    - Pneumopathy due to inhalation of other dust (disorder) (H44..)
    - Brittle asthma (disorder) (Ua1AX)
    - Childhood asthma (disorder) (X101t)
    - Late onset asthma (disorder) (X101u)
    - Hay fever with asthma (disorder) (X1020)
    - Non-allergic asthma (disorder) (XE0YT)
    - Asthma attack (disorder) (XE0YW)

Need to be able to define and share understanding

Asthma (QoF Register) (Common Criteria)

Name: Asthma (QoF Register)

Creator: lucy

Created: 04/11/2010

Protocol Criteria

- Asthma (disorder)
- AND NOT Asthma resolved (finding)

Sharing Options

Other users are allowed to see this common criteria

Feasibility Results

- Tested against studies currently in recruitment
- Results show poor recruitment where FARSITE shows low results
- Results also verified for individual practices by comparing local query results with FARSITE results
- GM CLRN working with a pharmaceutical company protocol to assist in designing where recruitment expectations can be shown to be realistic and quantifiable

Study 1

- Ongoing study recruited <10 patients in 12 months
- FARSITE identified max of 60 patients in area

Study 2

- Ongoing study with poor recruitment
- FARSITE identified ~1500 patients in area
- FARSITE confirmed local clinical practice not as required for study (as expected by local clinicians)
- Study redesigned…

Next Steps

- Test and prove recruitment with DRN and GM CLRN
- Develop use of system with national data by working with national DRN on Pathfinder project
- Work with other CLRNs to develop additional feasibility and recruitment databases
- Investigate other uses, e.g. re-use to provide GPs with same tools for own populations

Further details…

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NWCH making sense of local healthcare
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Northwest REGIONAL DEVELOPMENT AGENCY