



NHS e-Lab for Efficient Trials

"...feasibility analysis and trials-management making best use of care records"

MRC Trials Methodology Hub, September 2010

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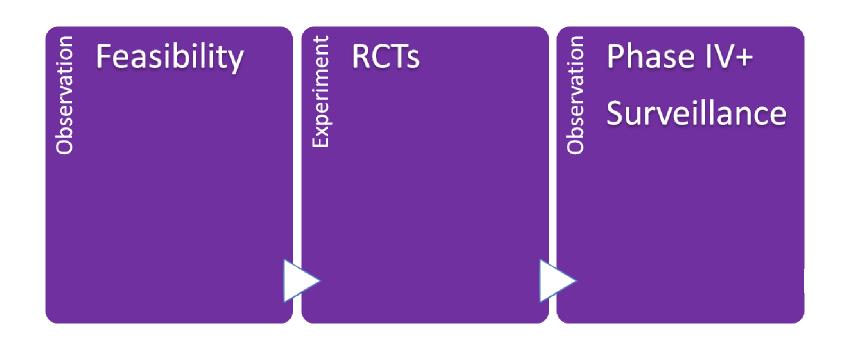
Key messages

Best use of care-records for research requires:

- Trust & transparency
- Local context & expertise
- Open innovation

...trials methodology can harness open software with inputs from other areas making decisions on analyses of care-records

The observational sandwich

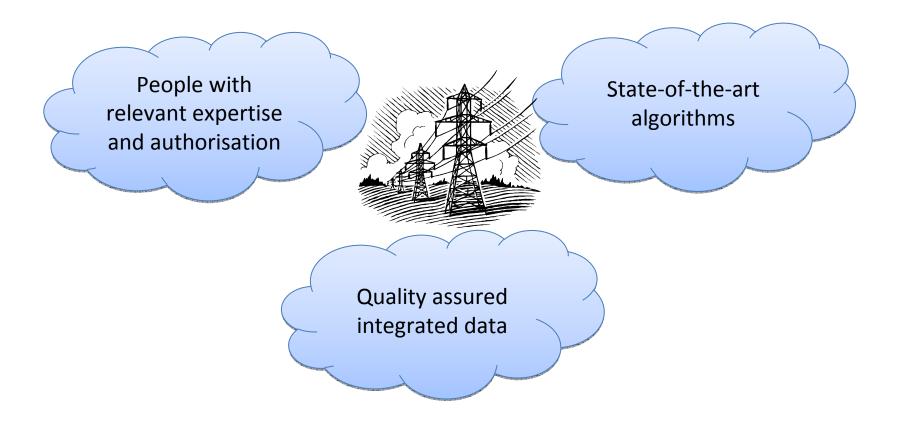




North West e-Health

What is an e-Lab?

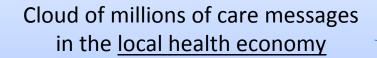
... a web-based software application bringing together **people**, **data** and **methods**

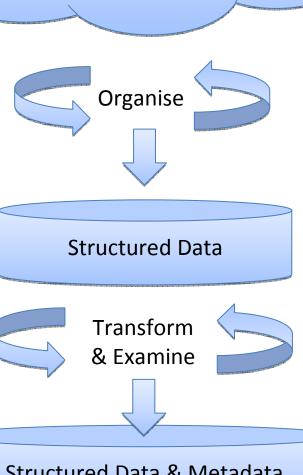


North-West e-Health

- NHS-University partnership
- Not-for-profit venture
- Developing open source software to make better use of electronic health records for
 - Research
 - Clinical Audit
 - Commissioning
 - Public health intelligence







Structured Data & Metadata

Problem: Lack of local ownership

Centralised intelligence systems do not empower local health professionals to build more locally useful information

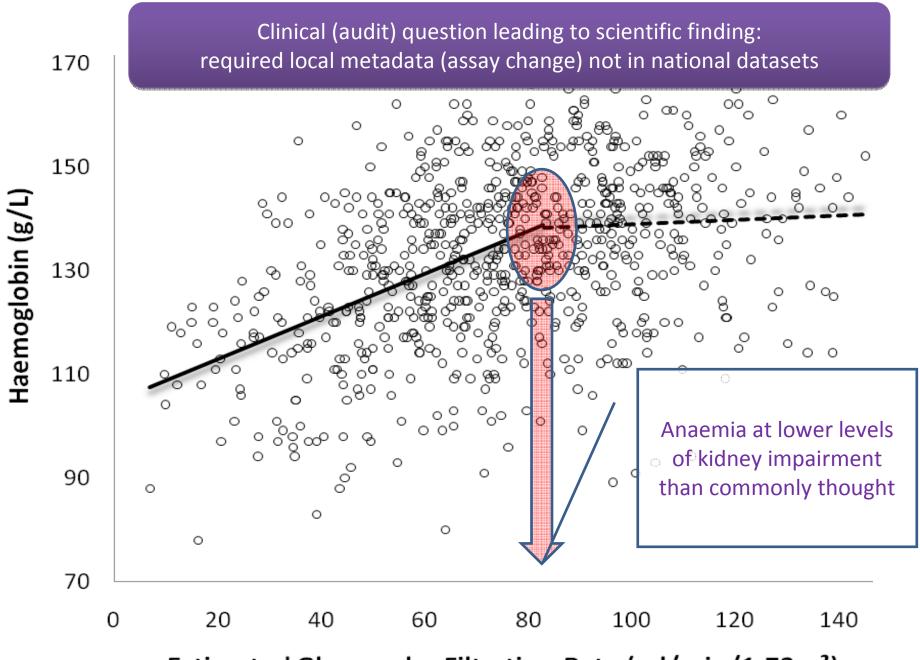
Due to:

- 1. Fixed reports rather than templates from centre
- 2. Costly to reproduce
- 3. Benchmarking imposed vs. community of trust
- 4. Additional local explanatory data left out
- 5. Lack of local ownership to act on the intelligence

e-Lab ownership: Local insights

- Additional sources of data
- Coding and other data quality issues
- Local context of questions
- Local context of explaining results
- Locally generated research and audit questions

...capture the local insight, attribute/credit the right people, share it, reuse it, enrich it...



Estimated Glomerular Filtration Rate (ml/min/1.73m²)

Problem: Unclear governance

Patients can't be assured of who has done what with their records or if the right calculations have been employed

Due to:

- 1. Closed/black-box health intelligence products
 - security measures hidden
 - formulae/algorithms hidden
- 2. Centralised security measures remove local control and impede work

Ethical Principles & e-Lab

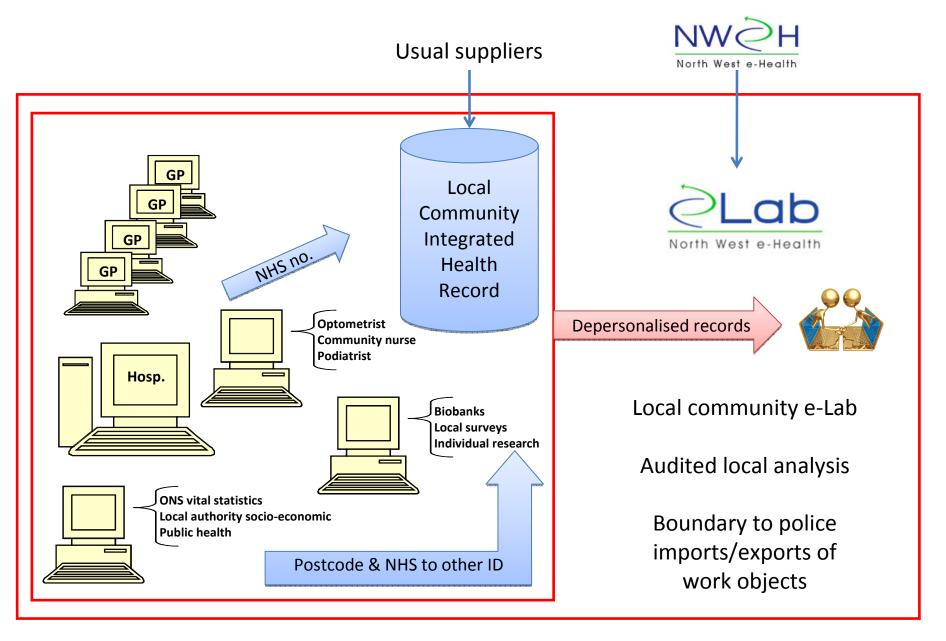
- Respect for <u>autonomy</u>
 - Patient consent: opt in/out?
 - Analyst-driven, not driving analysts
- Beneficence
 - Benefit: cost analysis of data sharing
 - Audit what was done with data
- Non-maleficence
 - Most governance is in place in the UK
 - Restricting data access has opportunity costs
- Justice
 - Fair access to data, models & tools
 - Credit for participation





Rousseau: "Social Contract"

e-Lab security: Double firewalling



e-Lab governance: Transparent

- Track record in security, e.g. openCDMS
- Open source software (external validation)
- ISO compliant procedures
- Local control over data and system access
- No shareholders: e-Lab system is owned by and accountable to the NWeH stakeholder community (all public service & NHS-led)



FARSITE

Feasibility Assessment

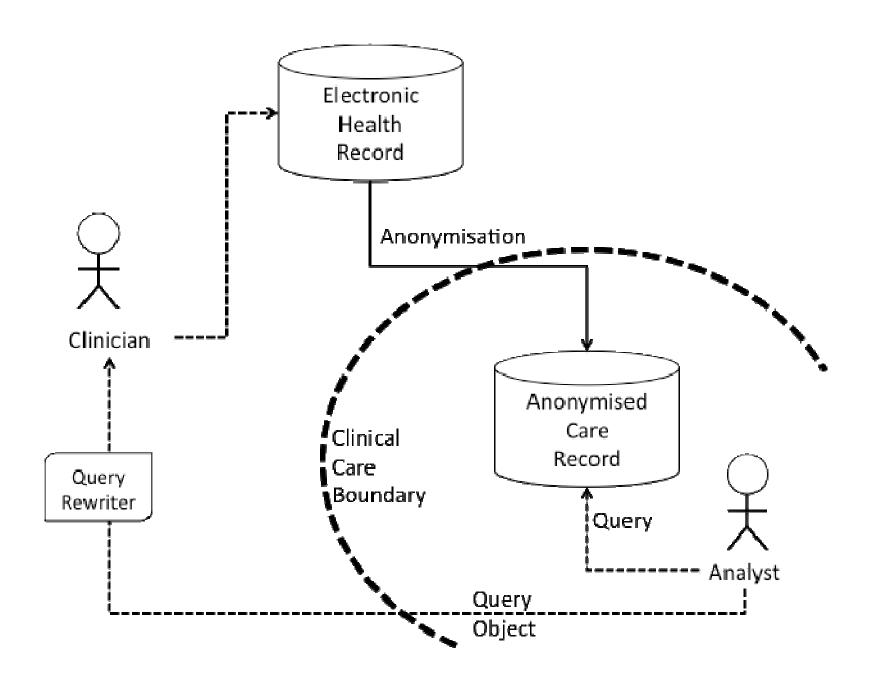
and Recruitment System

for Improving

Trial Efficiency

Major Issues with Clinical Studies

- Bias & generalisability
- >50% over-run
- >30% don't hit recruitment targets
- Unrealistic feasibility assessment
- Consent-management confusion



Consent-for-consent

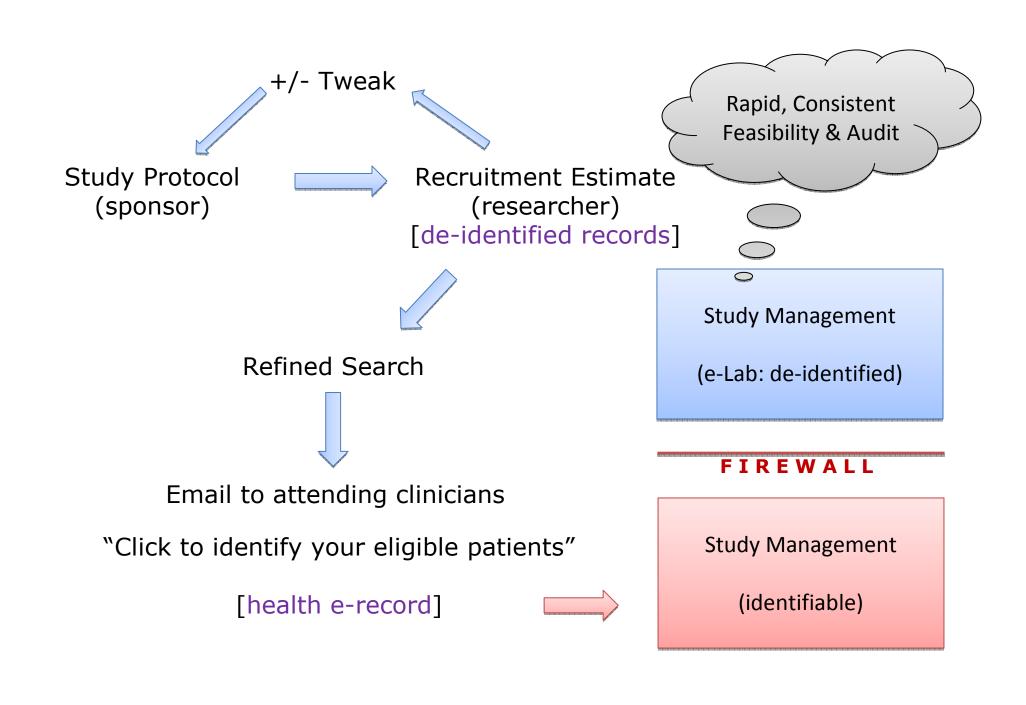
...is the consent to

search an individual's health record

to determine whether or not

they should be invited

to take part in a clinical study.



From 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','C10F1,'C10F4','C10F5','C10F7' ,'C10F9','C10FD','C10FF','C10FG','C10FH','C10FJ','L1806','X40J5','X40J6','X40Jk','XaELQ','XaFn7','XaFn8','XaFn9','XaFWI','XSETp','XU70f','XU71F','XUK O0', 'XULXc', 'XUPHn', 'XUSbx') and j.EntryDate<@p4DateLimit1) and PatientID not in (select distinct PatientID from Patients where PatientID in (select distinct i.PatientID from Journal i where i.ReadCode in ('.1226','.12C2','.12C3','.12C5','.12C8','.12CA','.12CB','.12CC','.12CD','.12CE','.12CF','.12CG','.12CH','.12CL','.12CL','.12CM','.12CN','.12CP','.12CR','.12C S','.12CT','.12J3','.14A.','.14A3','.14A4','.14A5','.14A6','.14AD','.14AH','.14AJ','.14AM','.14AM','.14AP','.14AQ','.14AR','.14AT','.187.','.1I10','.1I3 .','.1|5.','.1|6.','.1|60','.101.','.2241','.679X','.68B2','.68B6','.6C0.','.7721','.7722','.865.','.8651','.8652','.8653','.8654','.865Z','.B1NZ','.G12.','.G121','.G .122','.G123','.G127','.G131','.G2..','.G21.','.G211','.G212','.G213','.G212','.G221','.G222','.G223','.G227','.G231','.G231','.G232','.G233','.G234',' .G235','.G236','.G23Z','.G2Z.','.G32.','.G34.','.G41.','.G41.','.G42.','.G420','.G43.','.G440','.G441','.G442','.G443','.G444','.G445','.G446','.G45.','. G451','.G452','.G45Z','.G46.','.G47.','.G48.','.G49.','.G4Z.','.G5..','.G51.','.G511','.G52.','.G52Z','.G5Z.','.G61.','.G612','.G612','.G613','.G614','.G62Z','.G6 3.','.G631','.G632','.G633','.G634','.G635','.G636','.G637','.G632','.G641','.G642','.G643','.G644','.G645','.G645','.G642','.G652','.G651','.G652','.G631','. .G653','.G654','.G655','.G656','.G657','.G65Z','.G66.','.G67.','.G670','.G68.','.G681','.G682','.G68Z','.G691','.G691','.G692','.G693','.G69Z','.G6A.','.G6A 1','.G6A2','.G6AZ','.G6B.','.G6B2','.G6B3','.G6B5','.G6B6','.G6BZ','.G6C.','.G6E.','.G6Z.','.K2B5','.N2..','.N211','.N212','.N213','.N214','.N21Z','.N2 2.','.N221','.N222','.N223','.N224','.N225','.N226','.N227','.N22Z','.P324','.P9H2','.P9N2','.P9OZ','.RJ10','1226.','12C..','12C2.','12C3.','12C5.','12C8.','1 2CA.','12CB.','12CC.','12CD.','12CE.','12CF.','12CG.','12CH.','12CJ.','12CH.','12CM.','12CN.','12CP.','12CR.','12CS.','12CT.','12J3.','14A..','14A4.',' 14A5.','14A6.','14AD.','14AH.','14AJ.','14AL.','14AM.','14AN.','14AP.','14AQ.','14AR.','14H1.','110.','113..','115..','116..','1160.','101..','2241.','679X.','68 B2.','68B6.','6C0..','7902.','79020','79021','79022','79023','79024','79025','7902y','7902z','7930.','79300','79301','79302','79304','7930y','7930z','79 340','79341','79342','79350','79351','79356','793E1','793M1','793M2','793M3','7L1H.','7L1H0','7L1H1','7L1H2','7L1H3','7L1H4','7L1H7','7L1H8','7P0 G0','A17y0','A17y1','A2704','A32y1','A364.','A3640','A3642','A3643','A3642','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','B2 413','B241z','B25..','B727.','B728.','B93y1','Byu21','C1322','C34y1','C3733','F3918','F391B','G01..','G010.','G011.','G012.','G01y.','G01yz',' 1z.','G020.','G1...','G10..','G100.','G101.','G102.','G10z.','G11..','G110.','G111.','G112.','G113.','G114.','G11z.','G12..','G120.','G121.','G122.','G12z.','G122.',' G1412','G141z','G14z.','G1y..','G1y0.','G1yz.','G1yz0','G1yz1','G1yzz','G1z..','G210.','G2101','G2101','G210z','G211.','G2111','G2111','G211z',' G21z.','G21z0','G21z1','G21zz','G23..','G230.','G231.','G232.','G233.','G234.','G23z.','G3...','G300.','G301.','G3010','G3011','G301z','G302.','G301.','G3012' 03.','G304.','G305.','G306.','G307.','G3070','G3071','G308.','G309.','G30A.','G308.','G30X.','G30X0','G30y.','G30y0','G30y1','G30y2','G30yz','G30z.','G 31..','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.','G353.','G35X.','G36 ..'.'G360.'.'G361.'.'G362.'.'G363.'.'G364.'.'G365.'.'G366.'.'G38...'G380.'.'G381.'.'G382..''G383..'.'G382..'.'G38z..'.'G3v...'.'G40...'.'G400..'.'G40z..'.'G4

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..to this

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

Protocol Templates

Create Template

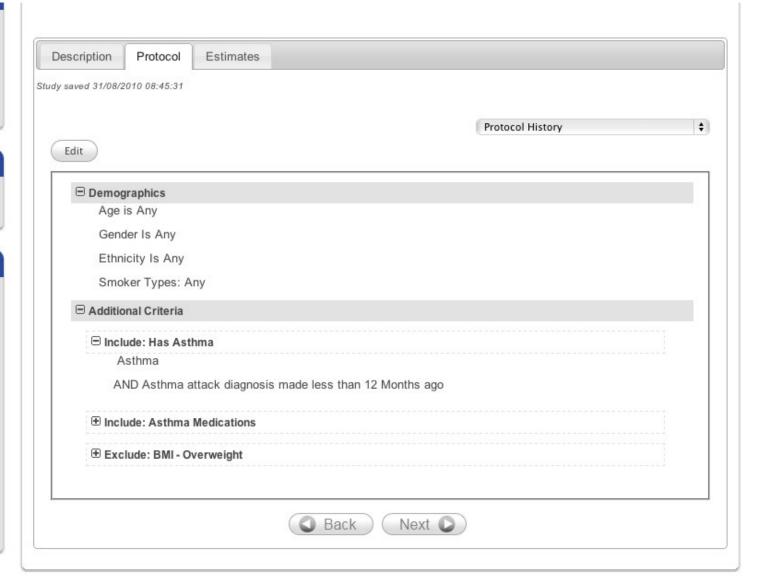
Study Overview

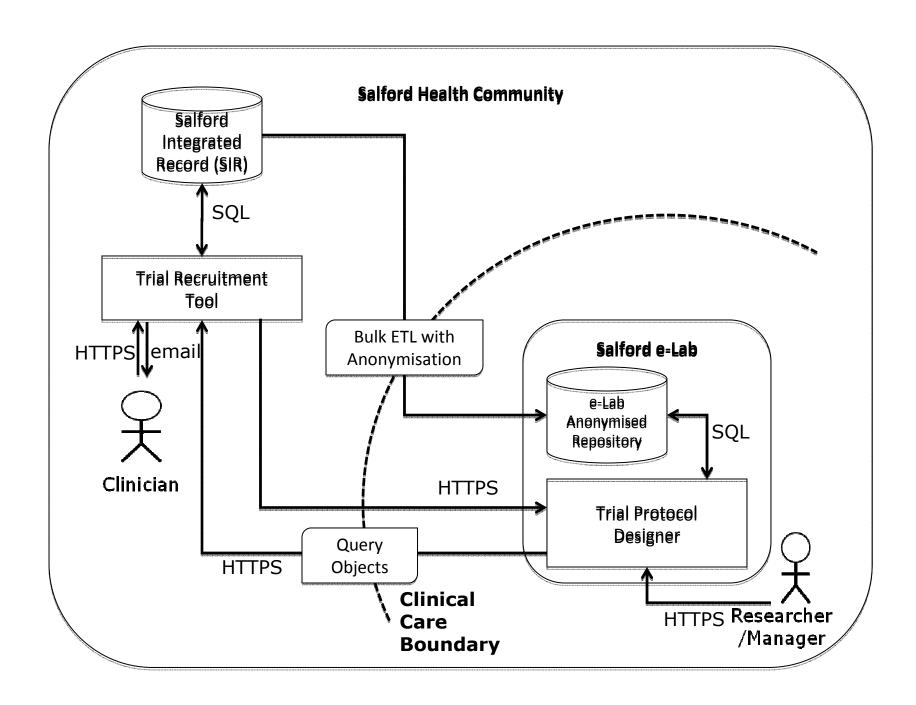
State

Feasibility

Study Members

- · lucy (Creator)
- bruce (Viewer)
- · gary (Editor)
- markdelderfield (Editor)
- normanstein (Editor)
- pat (Editor)
- · sarahthew (Editor)
- · steph (Viewer)





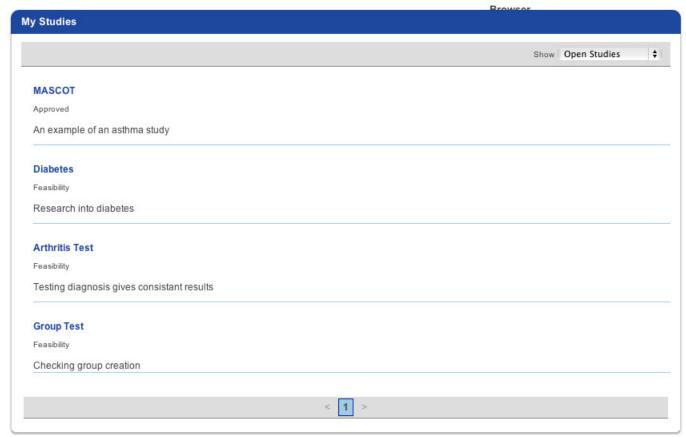
Study List

Welcome gary! [Log Off]



Farsite Home Protocol Templates Shared Criteria Research Networks Clinical Codes Help

Options Create new study



Feasibility Studies

Welcome gary! [Log Off]



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Options

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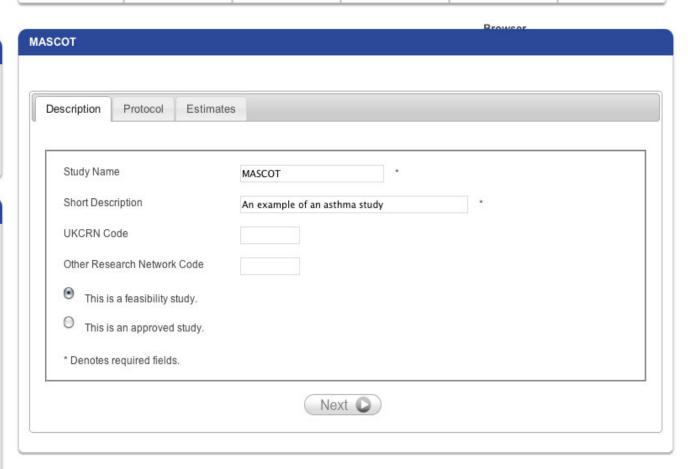
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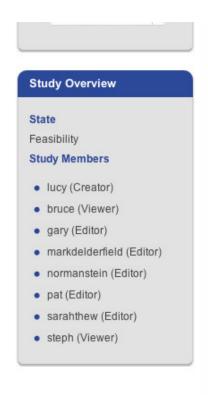
Feasibility

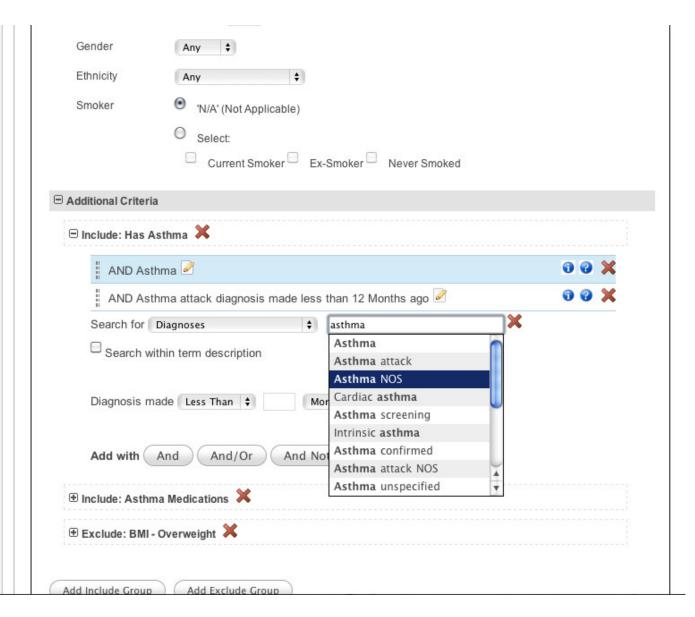
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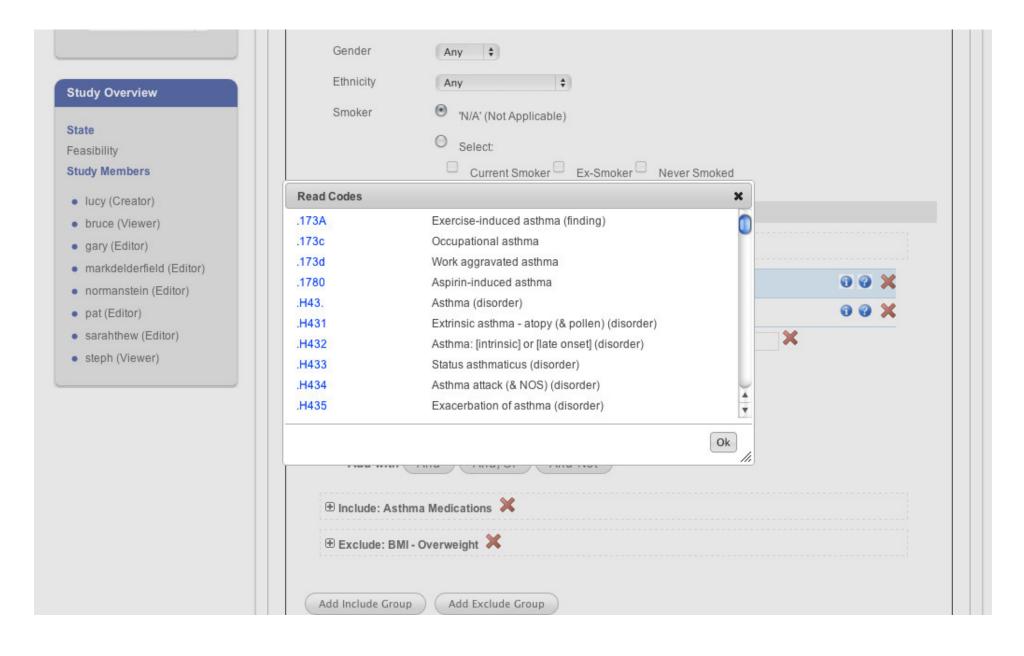


Creating a Protocol





Examining Coding



Shared Criteria

weiconie gary: [Log On]



Farsite Home	Protocol Templates	Shared Criteria	Research Networks	Clinical Codes	Help	
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Options

▶ Edit

Shared Criteria items

Diabetes Register Example (Shared Criteria)

Name: Diabetes Register Example

Creator: lucy

Created: 24/08/2010

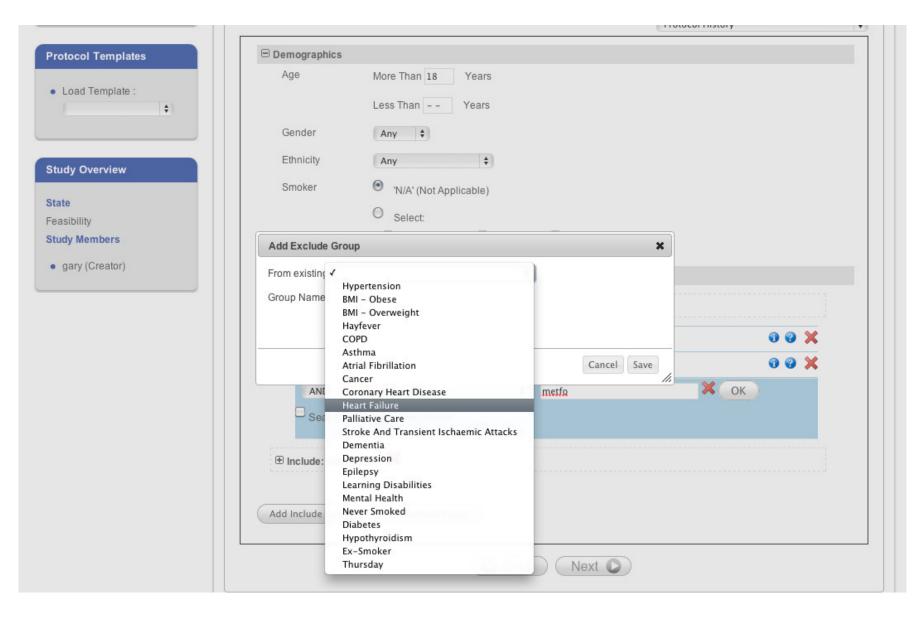
Additional Criteria

[Diabetes mellitus type 1

AND/OR Diabetes mellitus type 2]

AND NOT Diabetes resolved (finding)

Adding Shared Criteria



Query Results

making sense of local healthcare

Farsite Home

Protocol Templates

Shared Criteria

Research Networks

Clinical Codes

Help

Options

- Create new study
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- Cancel Study
- · Return to list of studies

Protocol Templates

Create Template

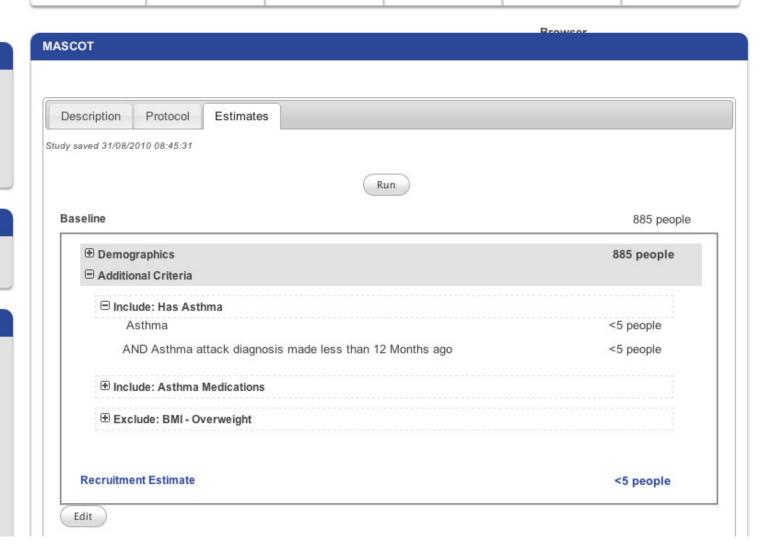
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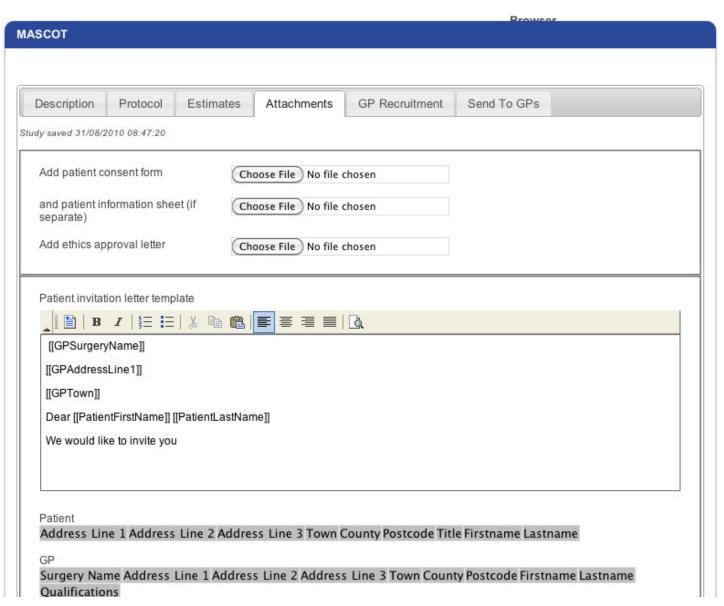


Recruitment

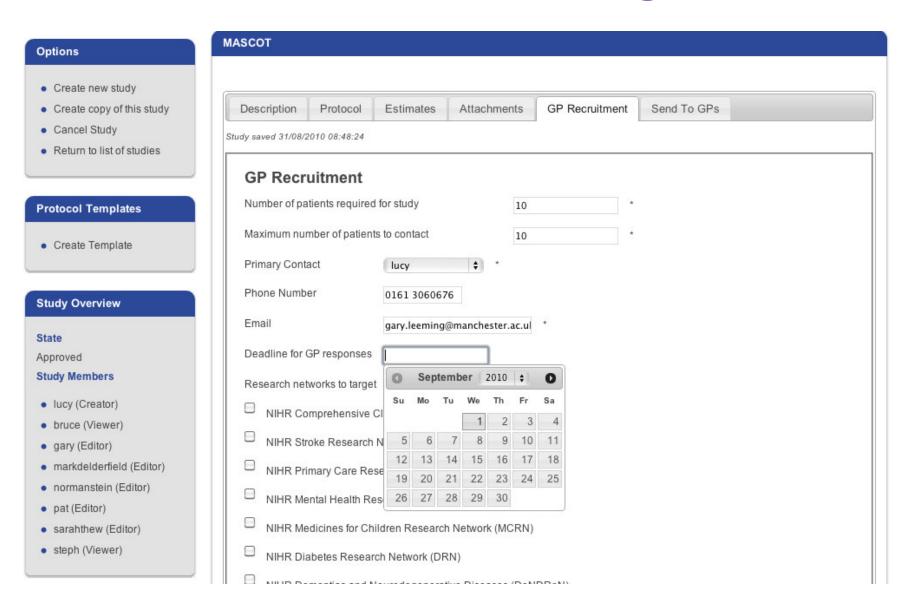
Options Create new study · Create copy of this study Cancel Study · Return to list of studies **Protocol Templates** Create Template **Study Overview** State Approved **Study Members** lucy (Creator) bruce (Viewer) gary (Editor) markdelderfield (Editor) normanstein (Editor) pat (Editor)

sarahthew (Editor)

· steph (Viewer)

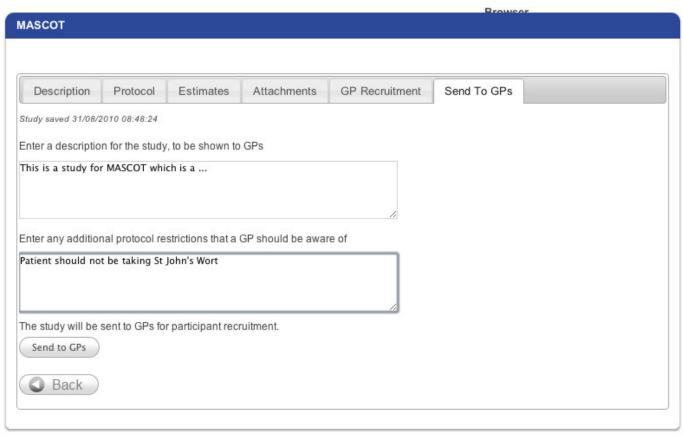


Recruitment Settings



Send to GPs





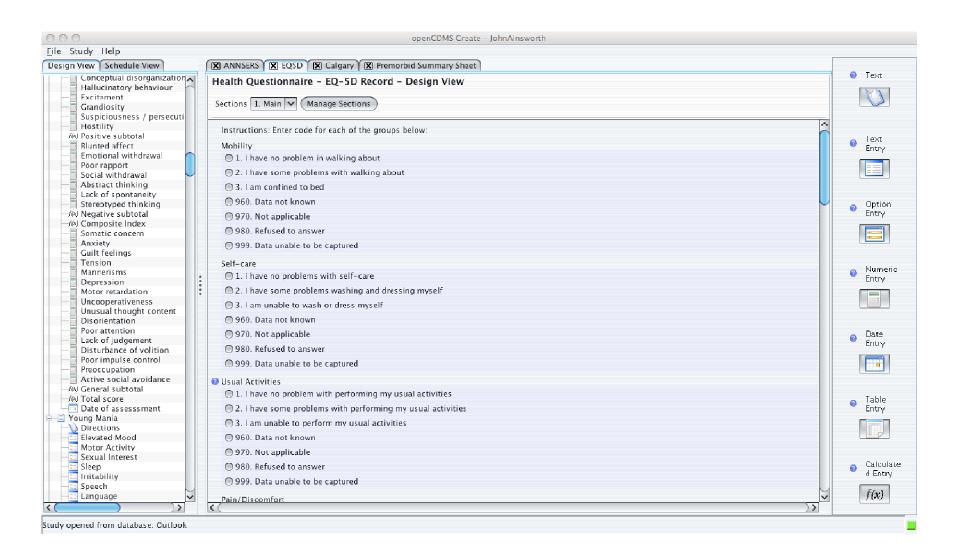




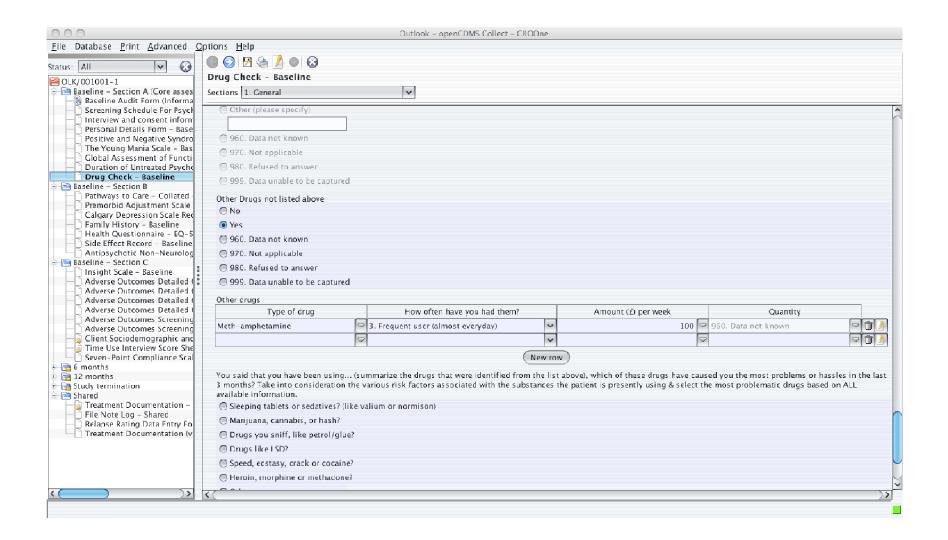
openCDMS in use

- PsyGrid study cohort of 900+ schizophrenics followed from first episode for 18 months
- Running numerous mental health trials
- ADDRESS Type I+II diabetes 10y cohort study
- DARE Diabetes cohort (phenotype and genotype)

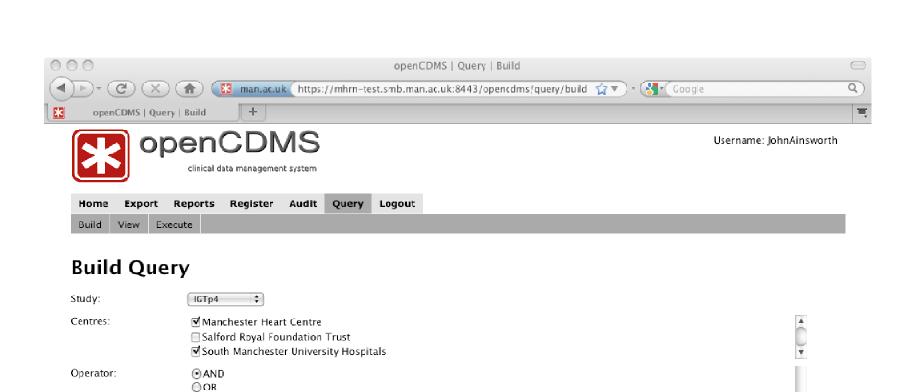












Statements:

Statement 1

Statement 2

Query Name: Description:

Submit

Help

(Remove)

(Remove)

Add Statement

Gender equal to Male

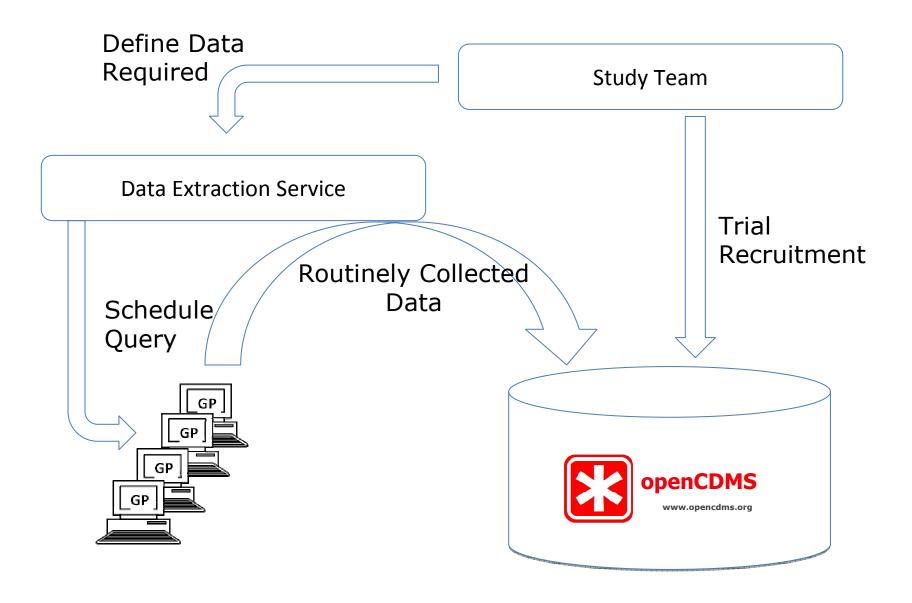
less than

Clinical Features - Baseline-Clinical Features

Clinical Features - Baseline-Clinical Features

Creatinine Clearnace (MDRD) 💠

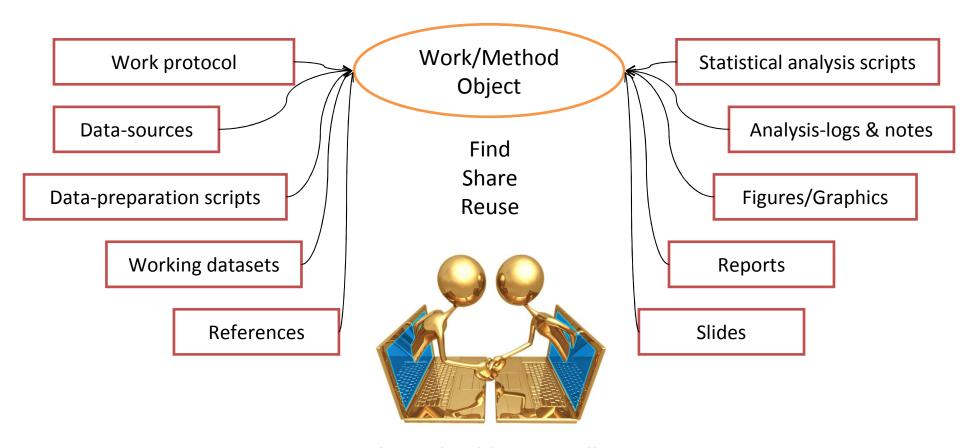
Automated Primary Care Data Import





More Observations

e-Lab ownership: Reproducible work



Stimulating healthcare intelligence

1) Find one your colleague made earlier; 2) take it apart and learn how it was done; 3) refill it with local data; 4) republish it (+/- enhanced); 5) get points for sharing and reusing

Professional Social Networking in e-Lab

- Builds on a track record of social computing and e-Science innovation at Manchester
- 'Facebook like' visibility → conversation → resource-sharing → shared understanding → collaboration +
 CPD points for participation = reward environment
- 'Amazon like' prompts: "others who selected those variables also selected these variables...".
 Borrowing strength from other NHS & trusted parties not on the local payroll.

Clear Public Good **Unclear Public Good** Audit; Research; **Work Objects** Intelligence De-identify e-Lab for a defined community **Local Ownership** Linked Health Linked Records Health Records **Asset Enrichment**



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Project Details

Prevalence of high HBA1C values for diabetics

Investigation into diabetes in Salford



Data

- ▶ High HBA1C Prevalence ۞
- ▶ Normalised HBA1C by Patient ③
- Repository



Documents

Diabetes ruleset 14.0 as PDF



Data Exploration

- ► HBA1C
- example Cube



Notes

- Info about data
- Prevalence of high HBA1C values for diabetics
- This is the QOF ruleset



Snapshots

- HBA1C by ward Mean HBA1C values by ward Map
- Normalised HBA1C by Patient High HBA1C Map



People

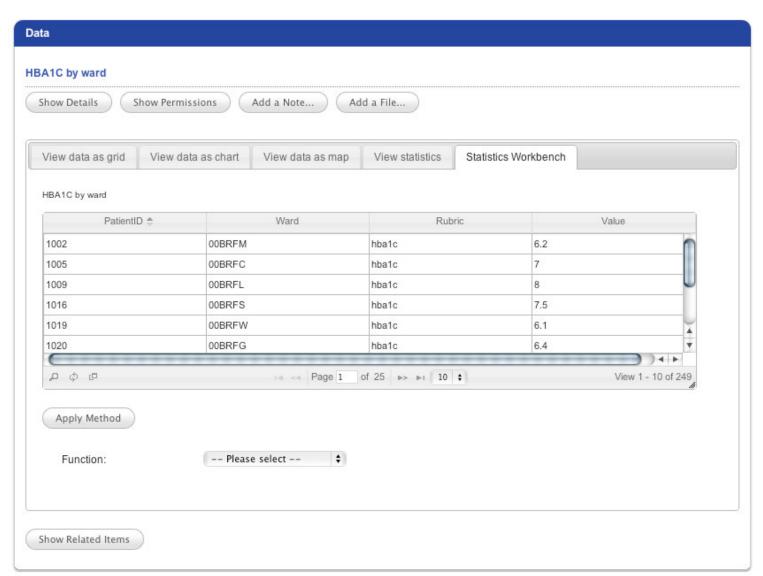
- gary
- dammers
- gmoulton

Show Project Details



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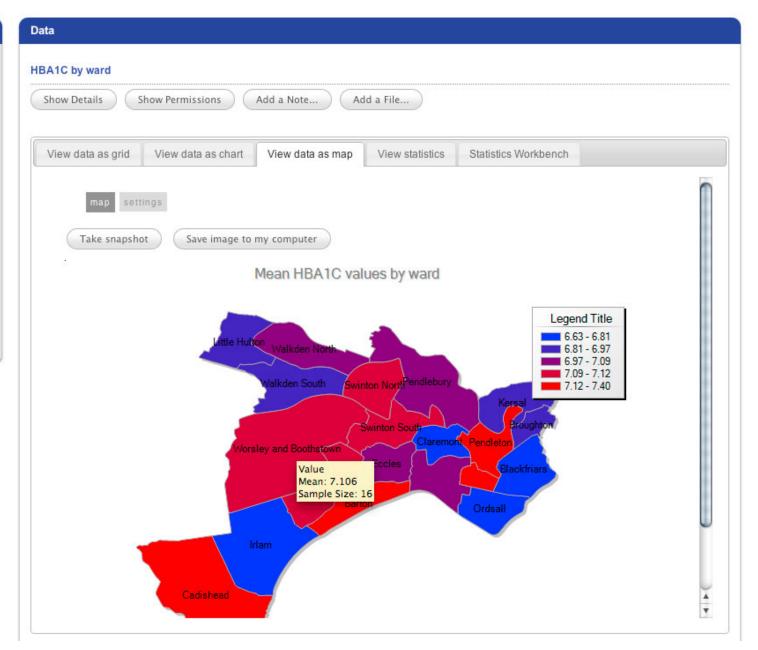
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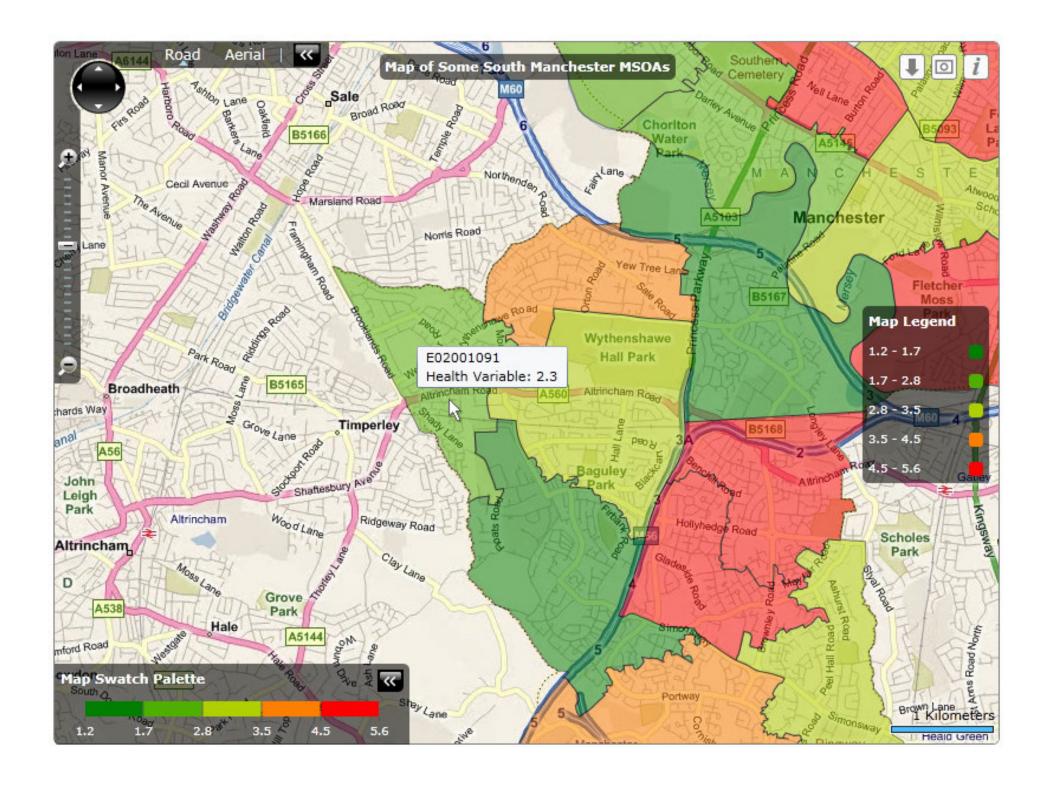


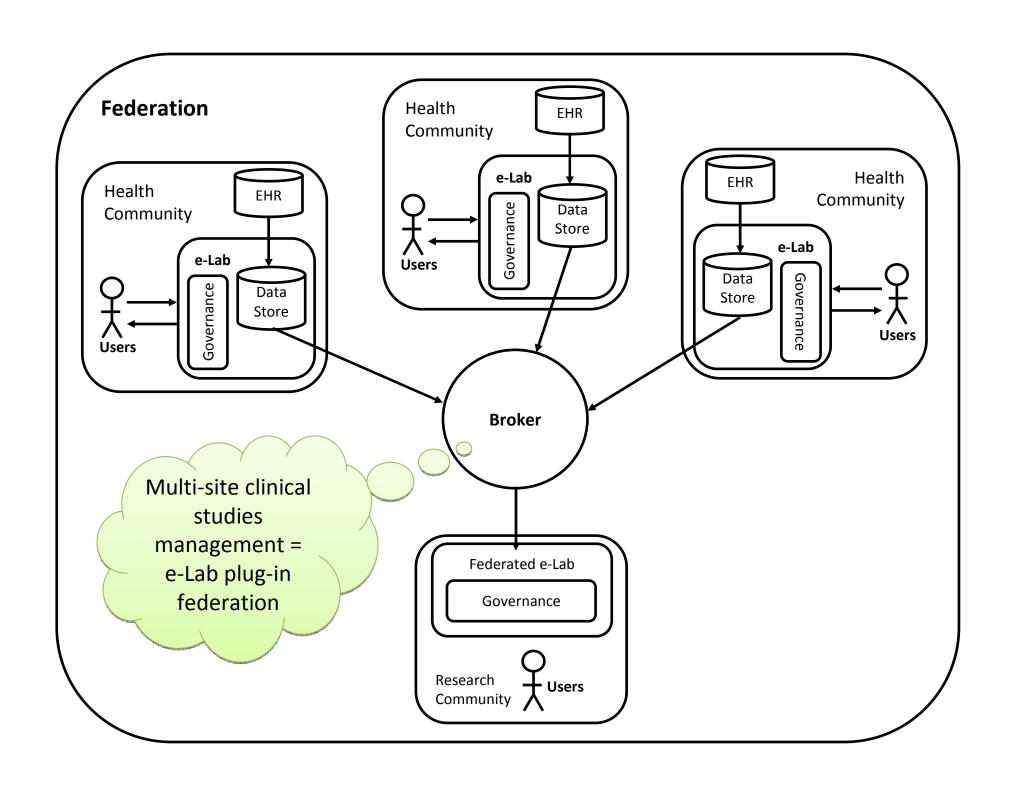


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Key messages

Best use of care-records for research requires:

- Trust & transparency
- Local context & expertise
- Open innovation

...trials methodology can harness open software with inputs from other areas making decisions on analyses of care-records