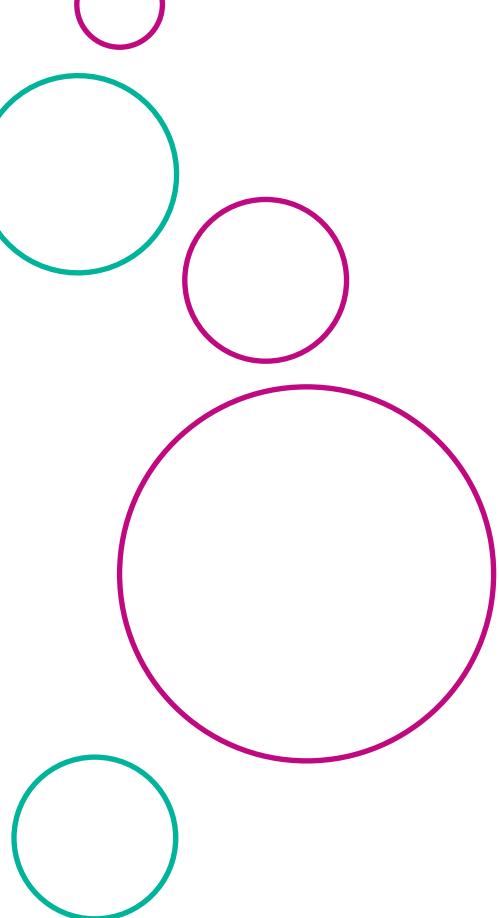




NorthWest EHealth



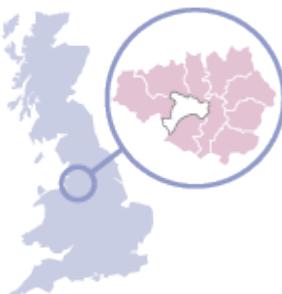


Generalizing and Scaling the Salford Lung Studies



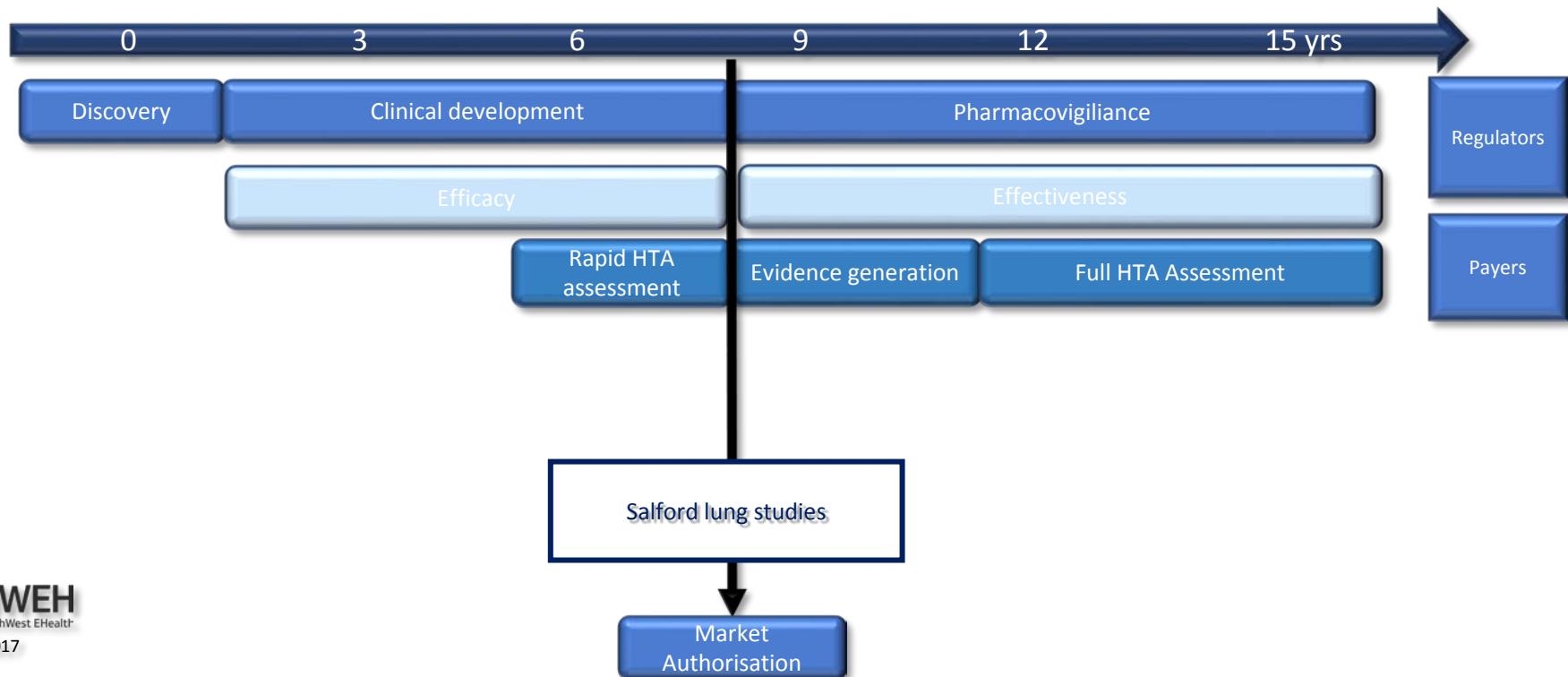
Salford Lung Studies

Where is Salford?



- Two late phase pRCT in Salford UK and surrounding areas sponsored by GSK.
- Over 7200 patients were monitored in near real-time for safety and outcomes using city-wide linked electronic health records.
- First study in the world to have evaluated the effectiveness of a pre-licence medication in a real world setting.
- The study demonstrated the success of Relvar Ellipta (FF/VI) when used in everyday clinical practice for the treatment of COPD and Asthma.
- Results of both the Asthma and COPD studies were positive.
- <http://www.nejm.org/doi/full/10.1056/NEJMoa1608033>
- [http://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(17\)32397-8/fulltext](http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(17)32397-8/fulltext)

Clinical evaluation lifecycle

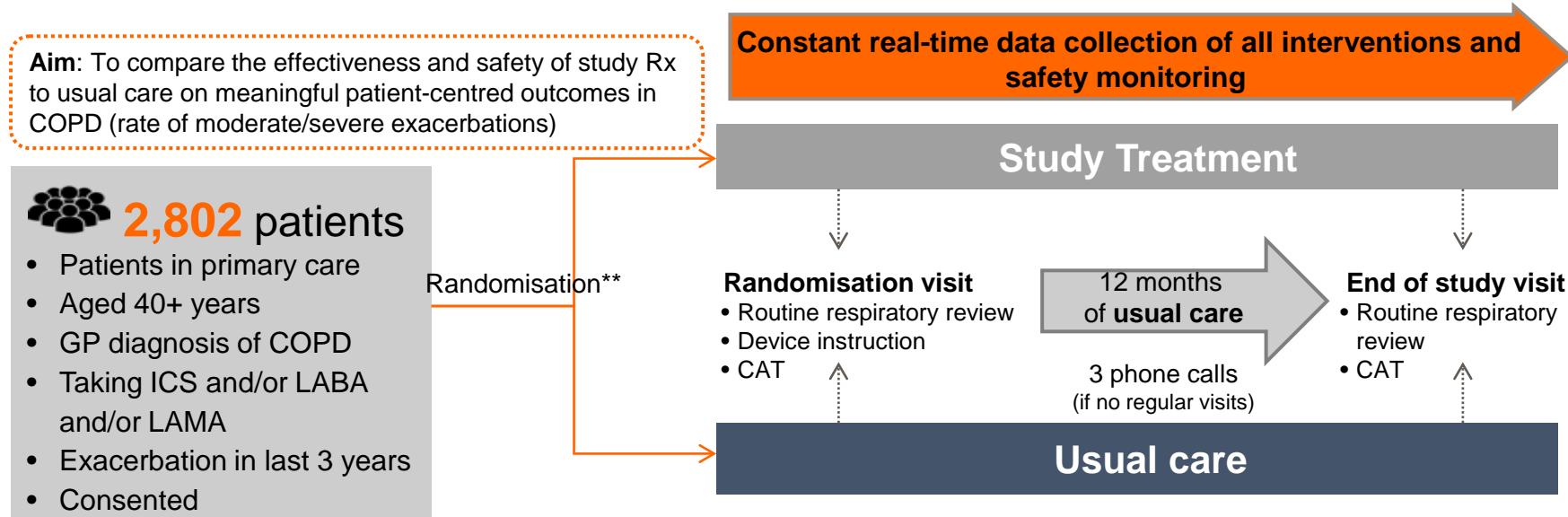




Why the UK and why Salford?

- The National Health Service (NHS)
- Single unique identifier (NHS number)
- Long-established use of electronic health records in primary care
- A national infrastructure to support research (NIHR)
- Stable Salford population (~240 000) serviced by a single large university hospital with an enterprise-wide EHR in place
- Salford integrated primary and secondary care electronic records from 2002
- A track record of close working between community and hospital care
- Manchester based NorthWest EHealth established 2008
- A 'Connected Community of Care'

Salford Lung Study design





What did we do first?

- Partnership with GSK – learning together as we progressed through the studies
- Study design – how could we best achieve internal and external validity?
- Feasibility –
- What data existed?
- How good were the data?
- How could we access, manage and validate the data?
- What were the needs of research authorities, regulators and payers?
- Did we have a large enough population to power such a study?



Operationalizing the studies

- How to recruit patients?
Broad inclusion criteria, pragmatic diagnostic criteria, few exclusions – recruit from primary care
- How to ensure “normal” care of patients during the study?
Minimal study procedures, collect study drug in same way as usual medications –
no additional review, access study drug through community pharmacy
- How to monitor patients without carrying out frequent reviews?
Minimize Hawthorne effect, ensure patient safety and endpoint data collection –
Use electronic health record system with real-time access for safety and outcomes



Operationalizing the studies

People

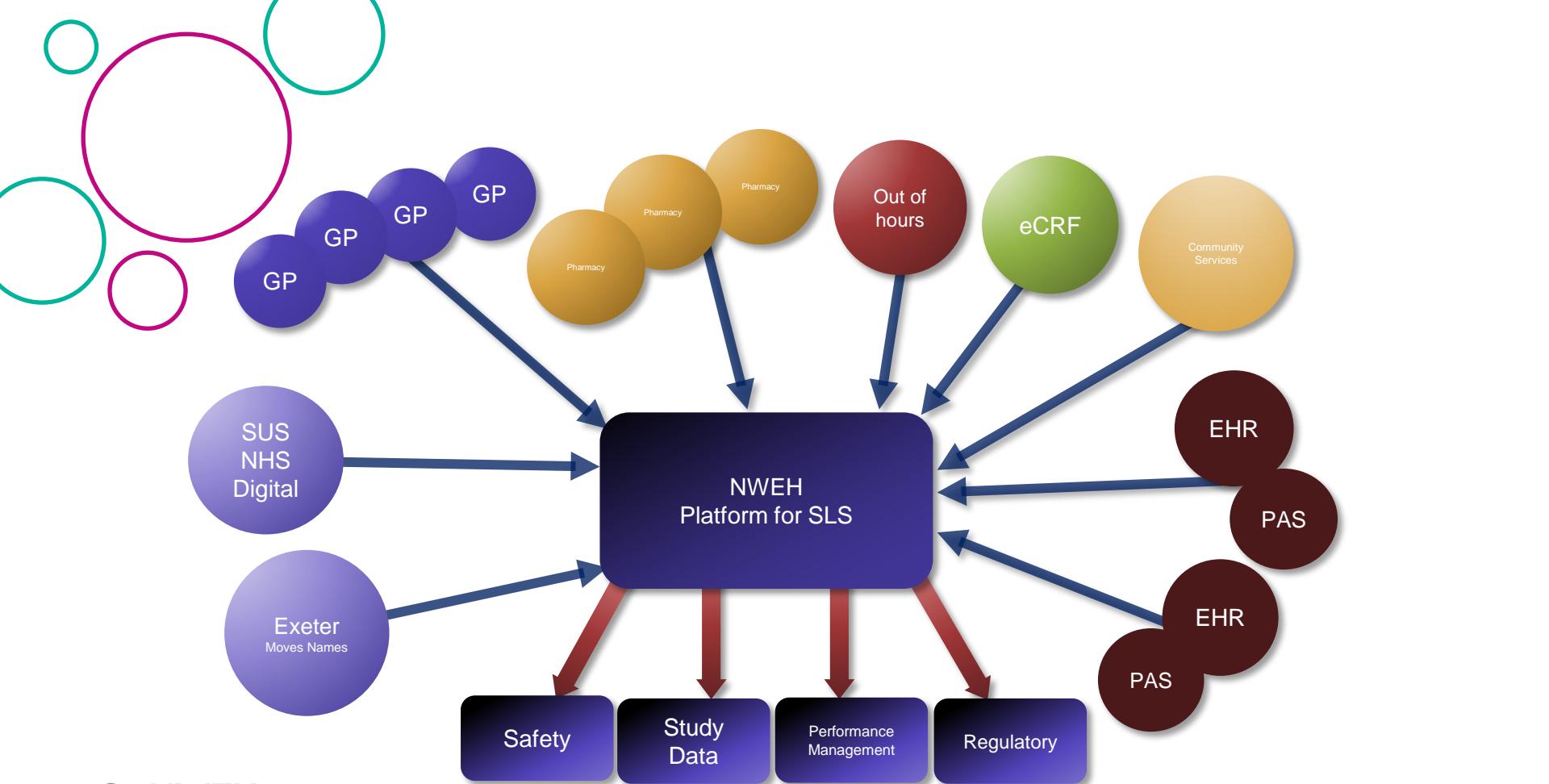
- Engage with practitioners – GPs, pharmacists, specialists
- Regulators and payers
- Hospital managers, CIOs, Pharmacy chains/providers
- Create research delivery team
- Train all staff to GCP standards

Data

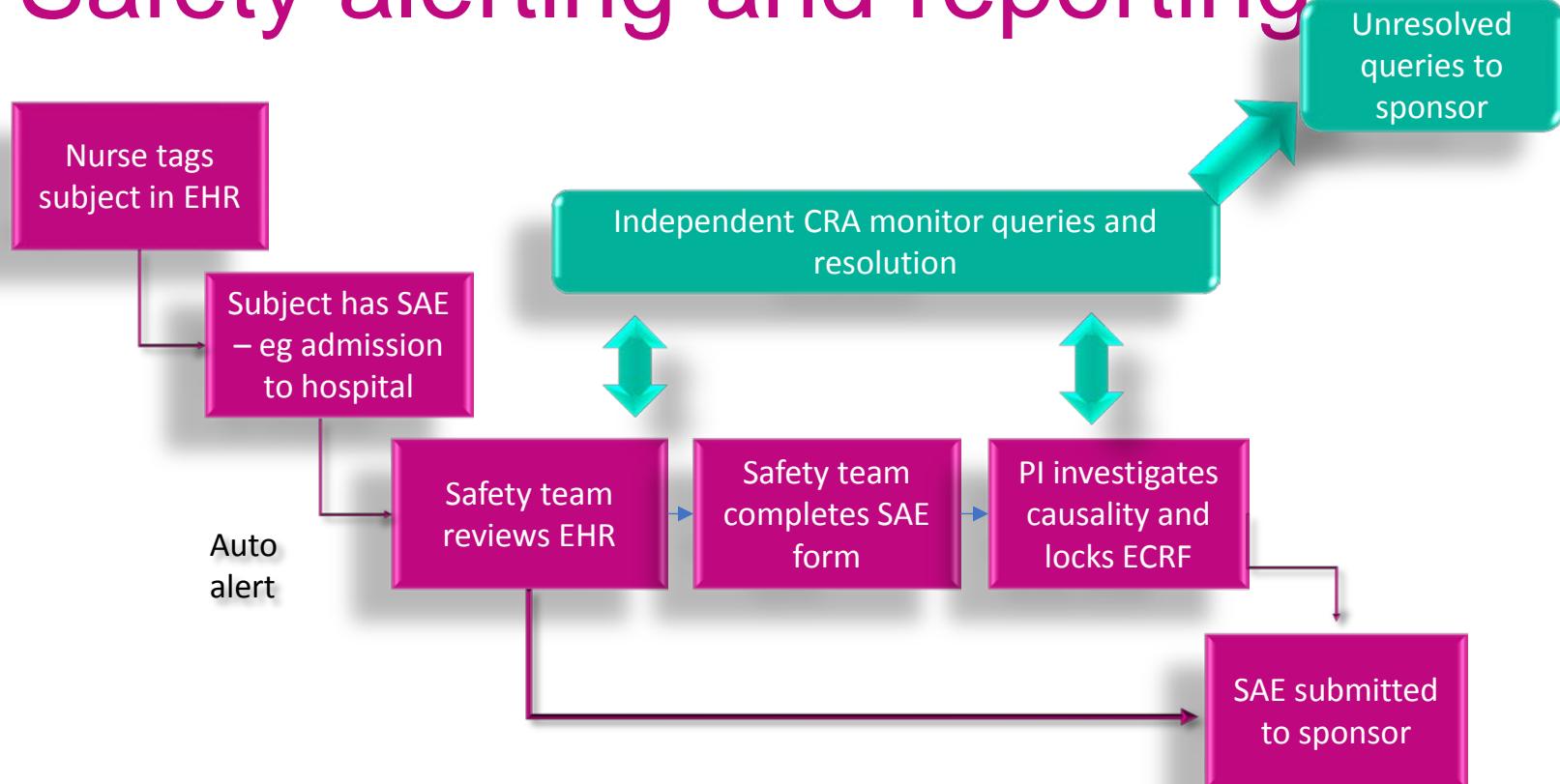
- Build a fully validated system and data set. Devise the processes for managing the data flows, build safety reporting application and processes, build community pharmacy data collection. Deliver data in sponsor determined format. Design and deliver data archival solution.

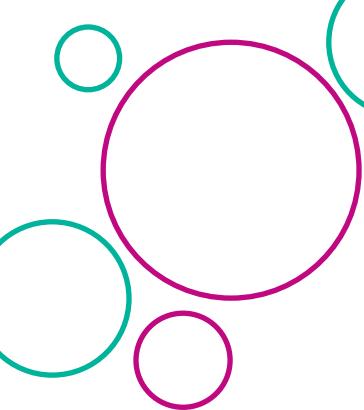
Delivery

- Recruit and manage patients and study milestones
- Data processing, error management, staffing, audits



Safety alerting and reporting





What were the barriers and how did we overcome them?

- Capturing all the patient interactions – Connected Community of Care
- Unknown unknowns in 2012
- Under estimating the scale and complexity of the task
- Relationship management
- Recruiting in primary care
- Recruiting the right staff to deliver the project



Lessons learned

- Disruptive innovation
- Engage sooner with all the study teams to manage expectations
- A learning experience for sponsor organisation as well – new ways of working
- We hadn't anticipated the impact on existing sponsor internal teams – eg stats
- More data is not always the answer. You need the right data. There is such a things as too much.
- Collect only what you need to collect from outside the EHR – potential transcription errors require SDV requirements which at this scale can severely impact efficiency



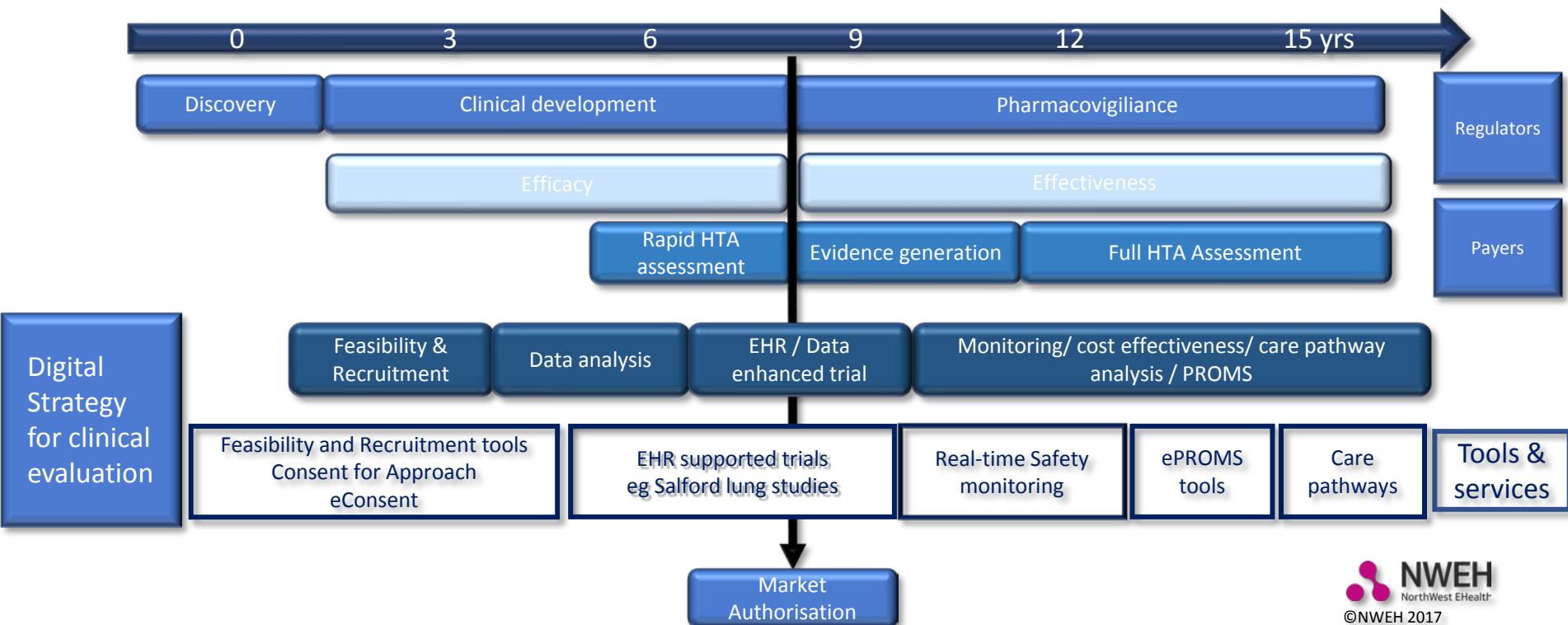
How are we scaling in the UK and beyond?

- Move to NHS cloud infrastructure
- Re-engineered fully validated platform – multiple trials in multiple indications
- New suite of validated applications
- Configurable data schema - SDTM
- Extending data footprint – more hospitals, more GPs, better pharmacy data
- New data sources – wearables, genomics, social care
- Create new Connected Communities of Care in UK and US.
- Standards, SDTM, FHIR
- Interoperability

NWEH Platform & applications



Clinical evaluation lifecycle



Feasibility and recruitment



FARSITE

Rapid results

GP view

CLASSIC

Patients identified from the study pro

Group 25 • entries

Selected for invitation

NHS Number	Title	First Name	Practice	Invitations Sent	Date Invited	Contact
TOJH4102PT	Mrs	Carole	(0161) Salford Care Ctrs Medical Pract	404	17/11/2014	Contact
SWUP0C055	Mrs	Kacey	11 Lower Broughton Medical Practice	0	17/11/2014	Contact
GEYBM35Q03	Mrs	Christie	11 Lower Broughton Medical Practice	0	17/11/2014	Contact
GFPS0Q0JMS	Dr	Andrea	11 Lower Broughton Medical Practice	0	17/11/2014	Contact
GWUP0Q0T03	Mrs	Kacey	11 Lower Broughton Medical Practice	0	17/11/2014	Contact
7NUQH0EV75	Mrs	Christel	11 Lower Broughton Medical Practice	0	17/11/2014	Contact
GEFS0Q0JMS	Dr	Andrea	11 Lower Broughton Medical Practice	0	17/11/2014	Contact
HYR8H05C0X	Mrs	Greta	11 Salford Medical Pract	310	17/11/2014	Contact
KD002QAXT2D	Dr	Nellie	11 Salford Medical Pract	145	17/11/2014	Contact
JDHRH0HTEWY	Mrs	Mari	11 Lower Broughton Medical Practice	479	17/11/2014	Contact
			41 Lower Broughton Medical Pract	0	17/11/2014	Contact
			55 St Andrews Medical Pract	362	17/11/2014	Contact
			55 St Andrews Medical Pract	491	17/11/2014	Contact
			55 St Andrews Medical Pract	0	17/11/2014	Contact

Showing 1 to 25 of 252 entries

Practices

Patients

Recruitment

Eligibility

Spouse

Residence

Recruitment via Consent for Approach



Register Now



ABOUT US OUR RESEARCH REGISTRATION EXPLAINED TYPES OF RESEARCH ARE YOU A RESEARCHER? CONTACT

Sign up today – together we can make a difference

Register Now

Registration Explained

Areas of Research



[Diabetes](#)

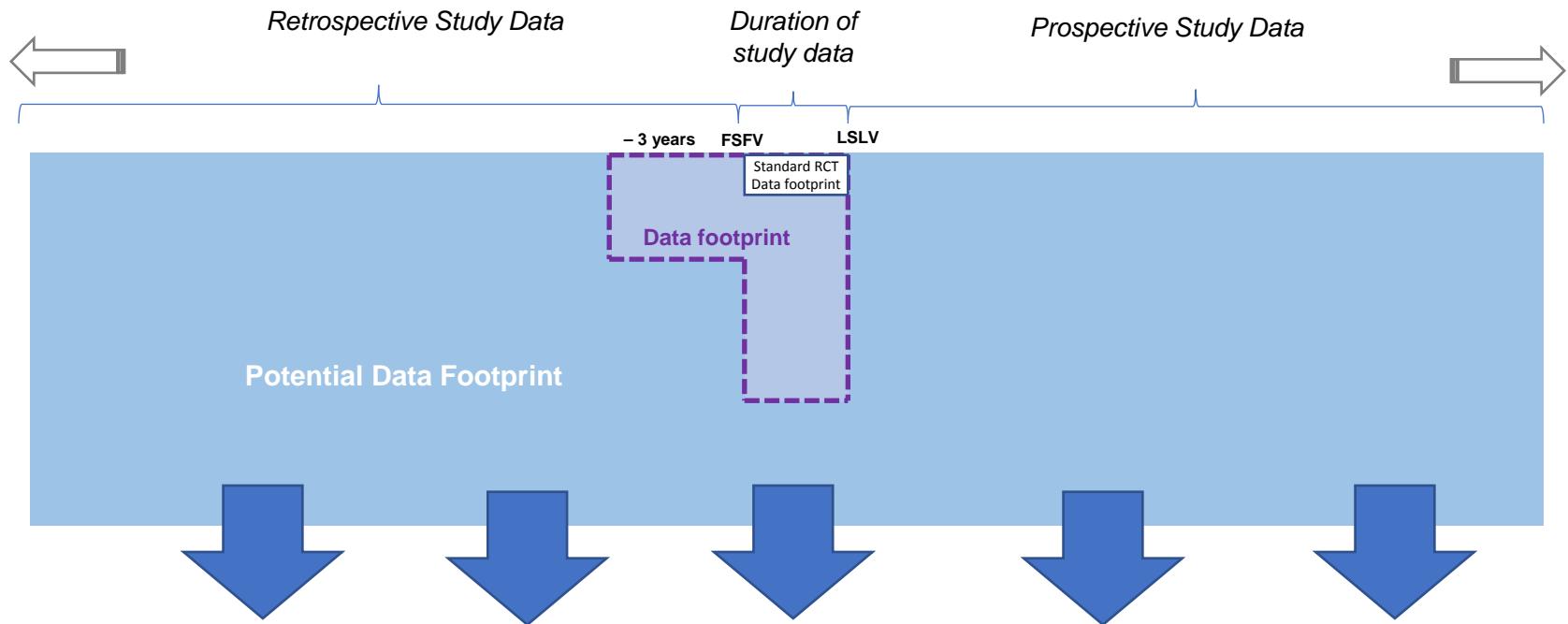


[Heart Disease](#)



[Respiratory Disease](#)

Data potential





Potential benefits

- **Design**
 - Reduce influence of research on patients' normal care pathway enabled through the use of data from EHRs
 - Maximise the use of existing EHR data to fulfil protocol and analysis requirements including total cost of care, care pathways and adherence
 - Design trials in collaboration with regulators, payers and consumers.
- **Delivery**
 - Minimise the amount of manually entered data
 - Ensure highest standards of data management and validation
 - Use EHRs to provide data to support improved patient safety
 - Challenge and revise existing standards and working practices where they are not appropriate
- **Deployment**
 - Utilise data from EHRs to understand patient pathway and disease before, during and following the trial program – providing the basis for richer analysis and deeper understanding of care pathways and disease progression.
 - Utilise safety monitoring systems for longer term follow up with alerts for recently introduced medications



What are the challenges for scaling success?

- Connected Communities of Care – people + technology.
- Data standards - input and output.
- Data availability / quality.
- Interoperability.
- Regulatory support for change.



Discussion topics

- Which problems can't RWE solve?
- What are the challenges?
- What are the opportunities?
- What are the characteristics of intervention, disease and population where this kind of study works?
- What are the different study models?



NWEH
NorthWest EHealth