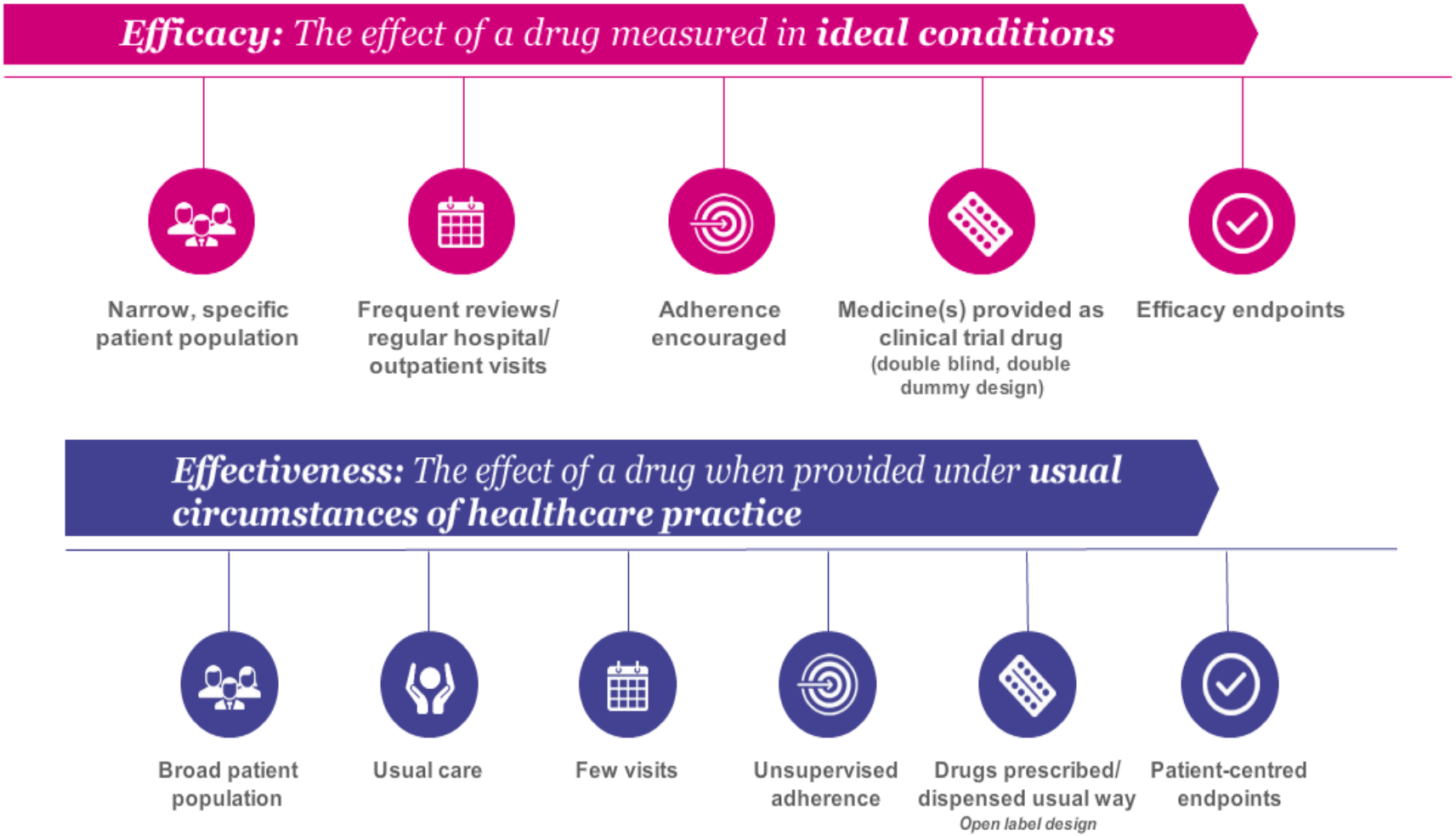
The Salford Lung Studies: Demonstrating effectiveness in everyday clinical practice

Andrew Roddam

19th October 2016

Evidence needed for medicines in today's world

From efficacy to effectiveness



What is the Salford Lung Study?

The Salford Lung Study is the world's first effectivess RCT, initiated on what was, at the time, a pre-licence medicine. The study aims to:

- Compare, in everyday practice, the **safety and effectiveness** of BREO/Relvar Ellipta, with existing maintenance therapy for COPD and asthma in a general practice setting in the UK
- Provide relevant and important information for clinicians, healthcare providers, payers and patients

Salford Lung Study

Evidence representing medicines in everyday practice

Real-time integrated data

Effectiveness

Broad population – age, comorbidities, disease definition

Close monitoring

Open label

Drugs prescribed and collected in usual way

No extra review

Set in normal care

Health Outcome and Utilisation Endpoints i.e. Real life

Unique collaboration

Minimal intrusion

One geographical location

RCTs

Efficacy

Double dummy

Science to answer specific questions

Double blind

Traditional Efficacy Endpoints

Strict inclusion criteria

Frequent reviews

Exclusions

Adherence encouraged

Study design

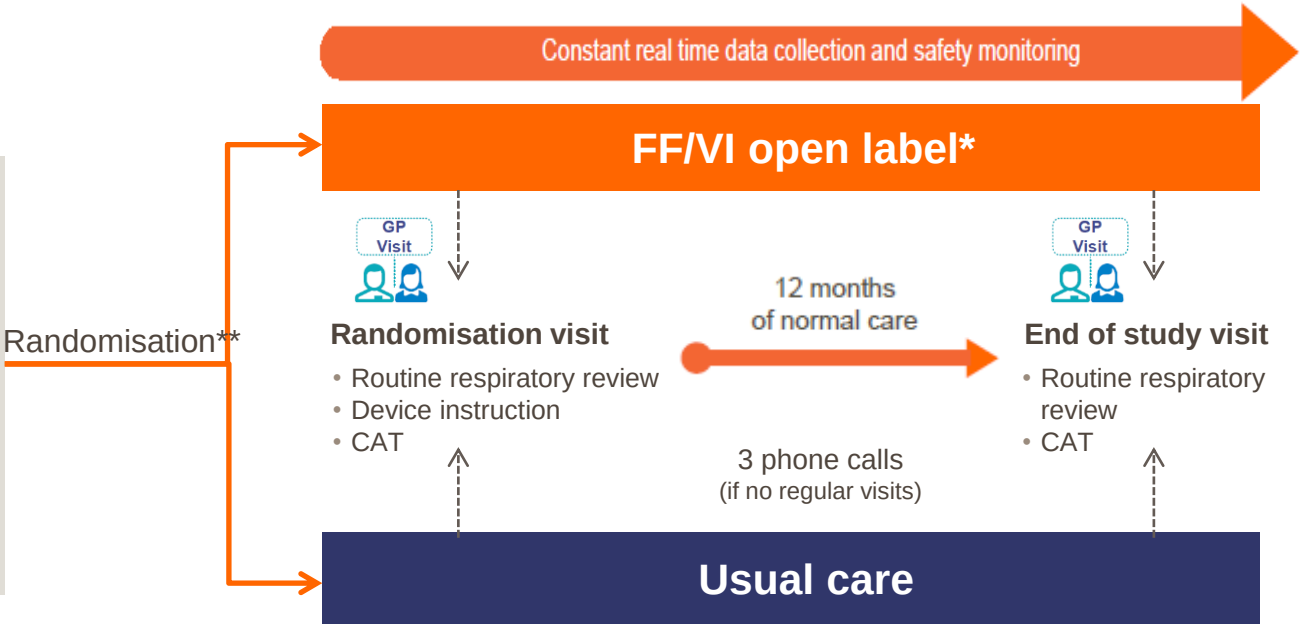
A 12 month open-label prospective RCT: COPD

The question :
How effective is initiating treatment with FF/VI compared to continuing treatment with usual care

Safety Reporting :
Reporting as randomised and by actual treatment

2,802 patients

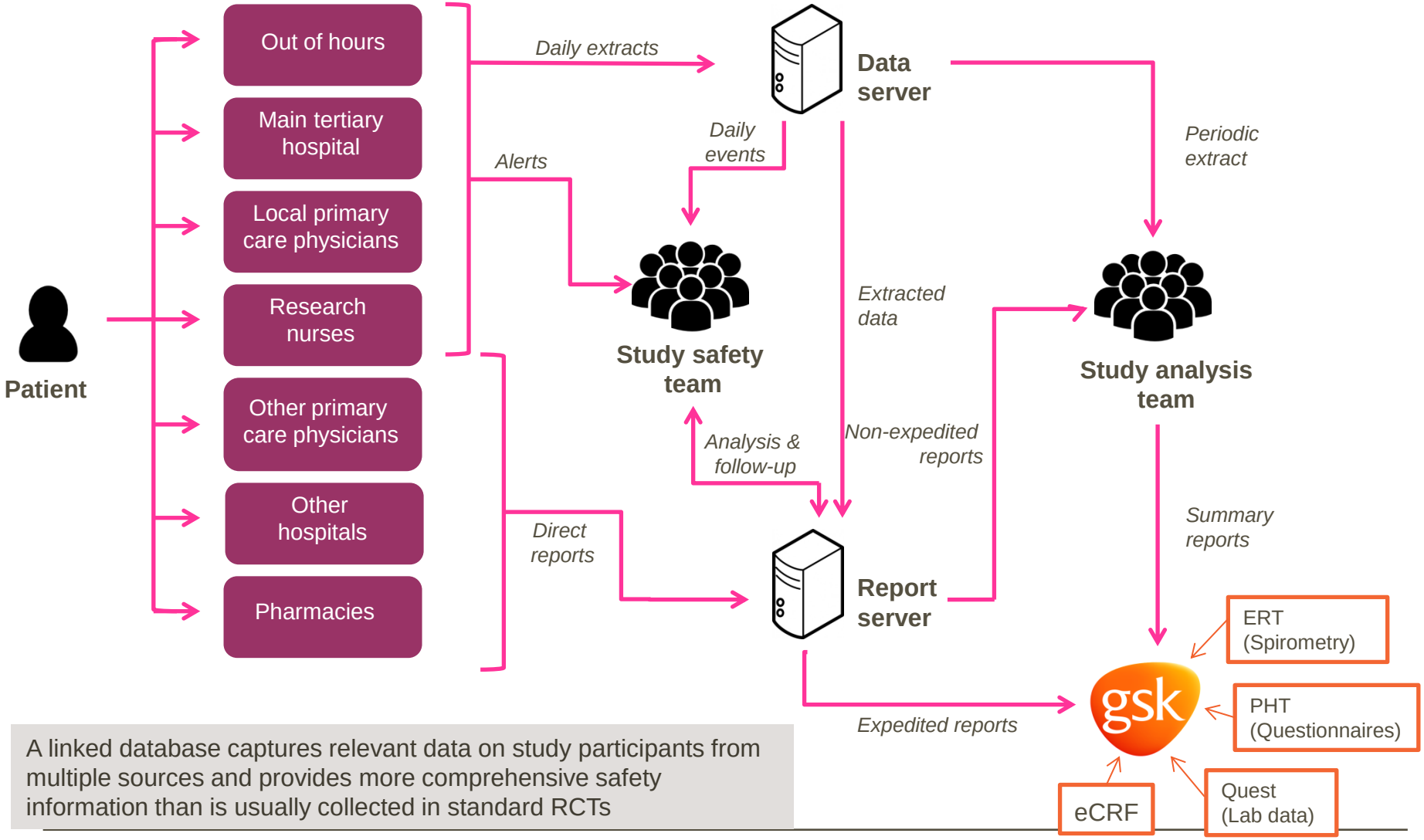
- Patients in primary care
- Aged 40+ years
- GP diagnosis of COPD
- Taking ICS and/or LABA and/or LAMA
- Exacerbation in last 3 years
- Consented



* Patient allowed to remain on LAMA in addition to FF/VI if already receiving LAMA therapy at randomisation
** Randomisation stratified by recent exacerbation status and existing COPD maintenance therapy at baseline

Bakerly N et al. *Respir Res* 2015;16:101[4]

Collecting the data

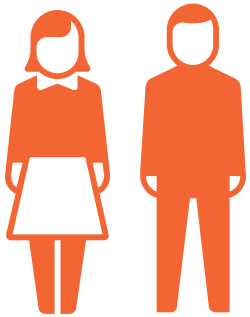


A linked database captures relevant data on study participants from multiple sources and provides more comprehensive safety information than is usually collected in standard RCTs

[1]New JP, et al. *Thorax* 2014;69:1152–4; [2]Bakerly N et al. *Respir Res* 2015;16:101

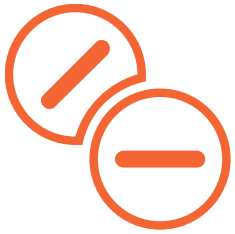
Salford Lung studies in numbers

The BREO/Relvar Salford Lung Studies are RCTs conducted in everyday clinical practice

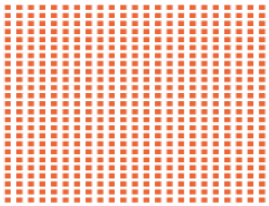


2,802
COPD &

4,237
asthma patients



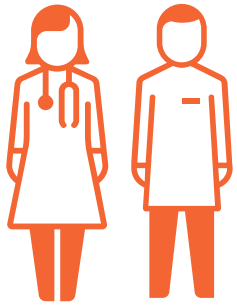
~130
pharmacies involved



>235 million
rows of data

~80
GP practices

1
electronic health medical record system



>3,000
people trained as part of study

Relvar/Breo Salford Lung study in COPD

Headline Results

- The Relvar/Breo SLS met its primary end point and demonstrated superior reduction of 8.41% (CI 1.12, 15.17) in the rate of moderate /severe exacerbations compared to usual care (p=0.025). 86% of the patients were on an ICS-containing regimen as part of their usual care
- Incidence of SAEs were similar between groups (29% FF/VI, 27% usual care) and non-inferiority was confirmed for FF/VI vs usual care on SAEs of pneumonia (7% vs 6%)
- These attributes of FF/VI deliver meaningful patient benefits in everyday clinical practice when compared to other COPD treatments, including BD ICS/LABAs

Vesbo et al., N Engl J Med 2016; 375:1253-1260

Summary

- The Salford Lung Study is the first of its type in the world
- It has generated important information for clinicians, healthcare decision makers and patients
- Partnership and team working has been critical to success
- EHRs provide significant opportunity for efficiency but significant challenges remain
- These type of studies provide a way to address questions about effectiveness in the real world