

RWD basert på register- och journaldata

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Agenda outline - 4 questions covered

WHY

Why is the interest for RWD data increasing?

WHAT

What is driving the need for RWD? What kind of RWD can be generated from register and EMR?

HOW

How is RWD used across the product life cycle by payers, regulators, and industry?

WHEN

When is RWD important?

Patient data reflects a seismic shift in evidence evaluation

THE PAST

RCT

Controlled trials,
manufacturer led

Few

Few evaluators at launch, mostly
regulators and large payers



Efficacy and Safety

Initial view of
benefit-risk

THE PRESENT

RCT and RWE

Shift to secondary patient-level
data across sources

Many

Many groups over time
including clinical and
small payers



Almost everything

Insights on environment,
outcomes, costs,
comparative effectiveness

Drivers of change



Increasing patient-level data and analytic technologies

- Explosion in volume of electronic patient data
- Ability to bring data across silos
- New technologies and methodologies
- New stakeholders conducting analysis

More scrutiny by more stakeholders

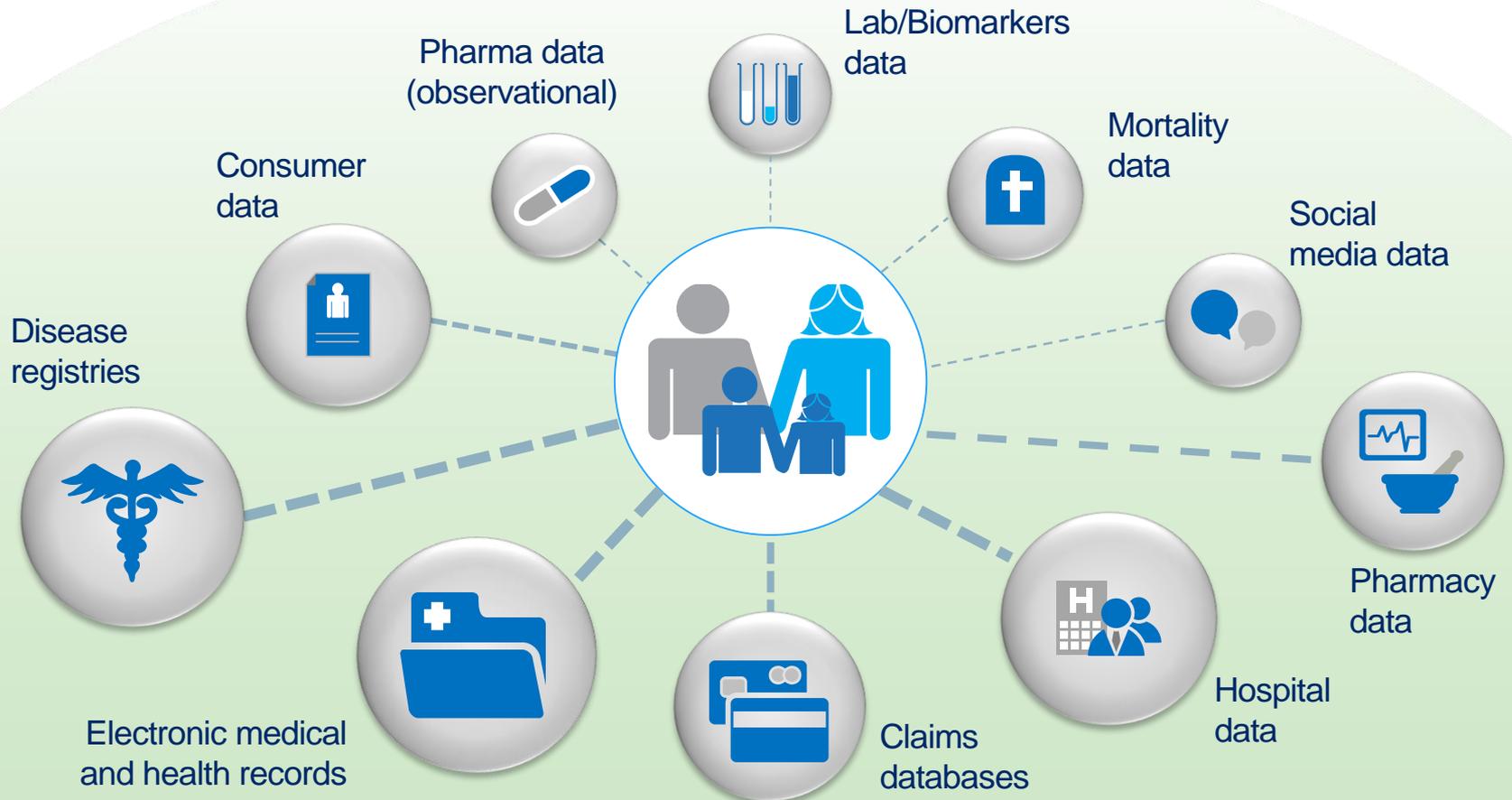
- Increasing cost pressures
- New treatments to fund
- Providers evaluated on quality
- Increase in post-authorization regulatory requirements
- Adaptive licencing
- Need for differential value proposition
- Need for R&D, clinical trial efficiency

Supply: Growth in Real-World Data (RWD)

“90% of the world's data has been produced in just the last two years”

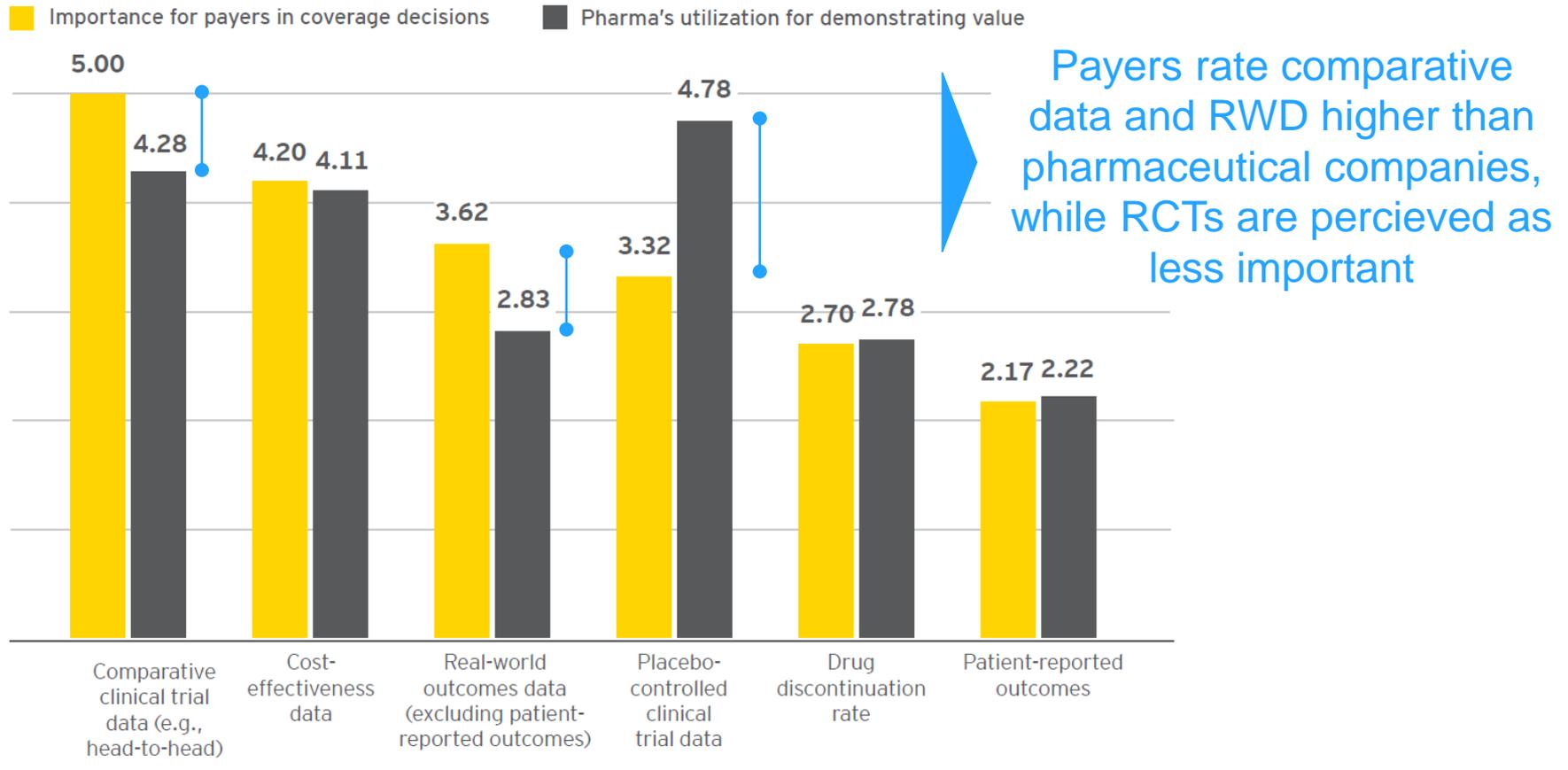
- U.S. Chamber of Commerce Foundation

RWD is PATIENT data



Importance of different data types

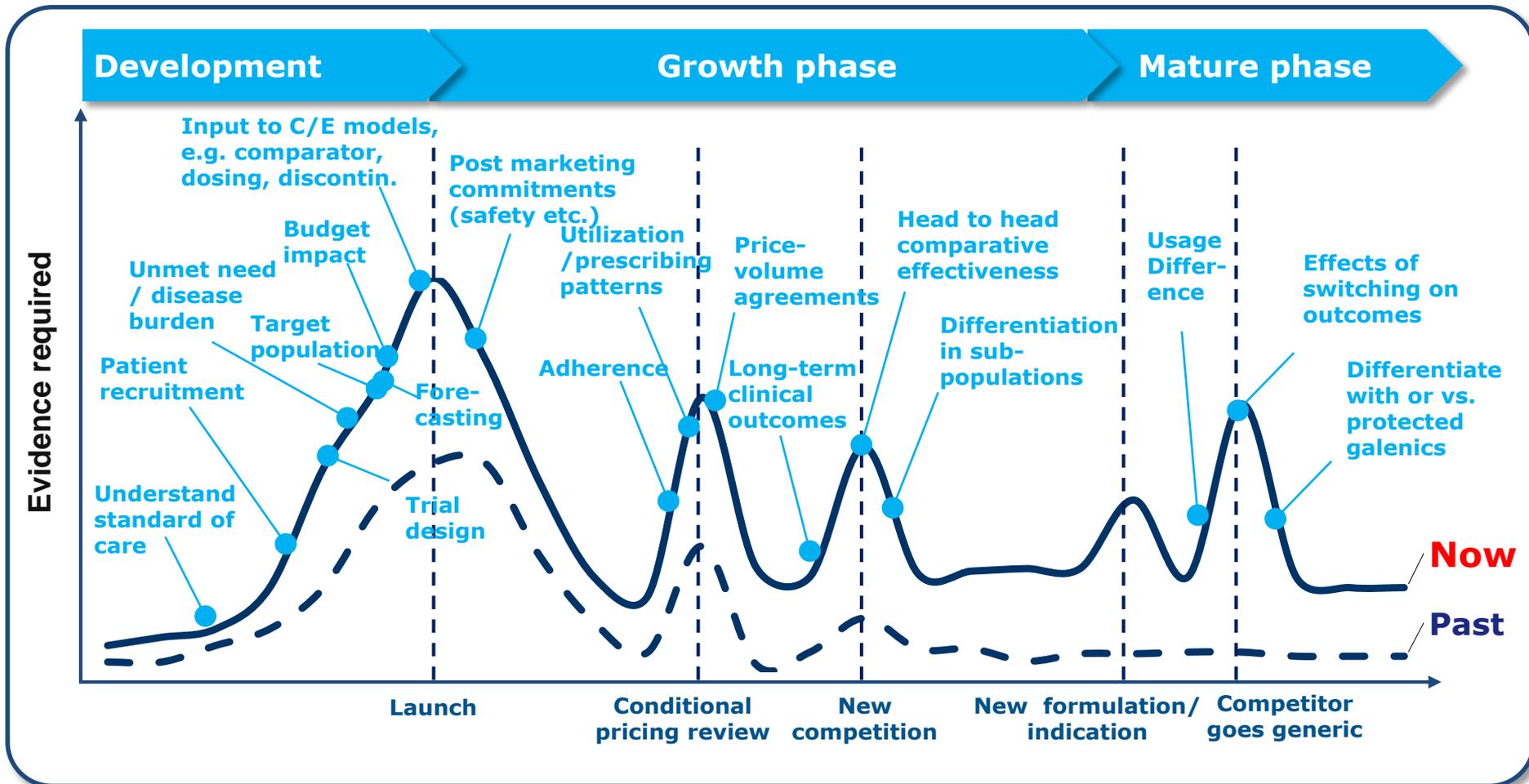
Different perspectives among payers and pharma industry



Source: EY Progressions 2014 Payer Survey. Payers' higher scores indicate data types that are more important for payers in coverage decisions. For pharma companies, higher scores indicate data types they use more frequently in demonstrating value to payers.

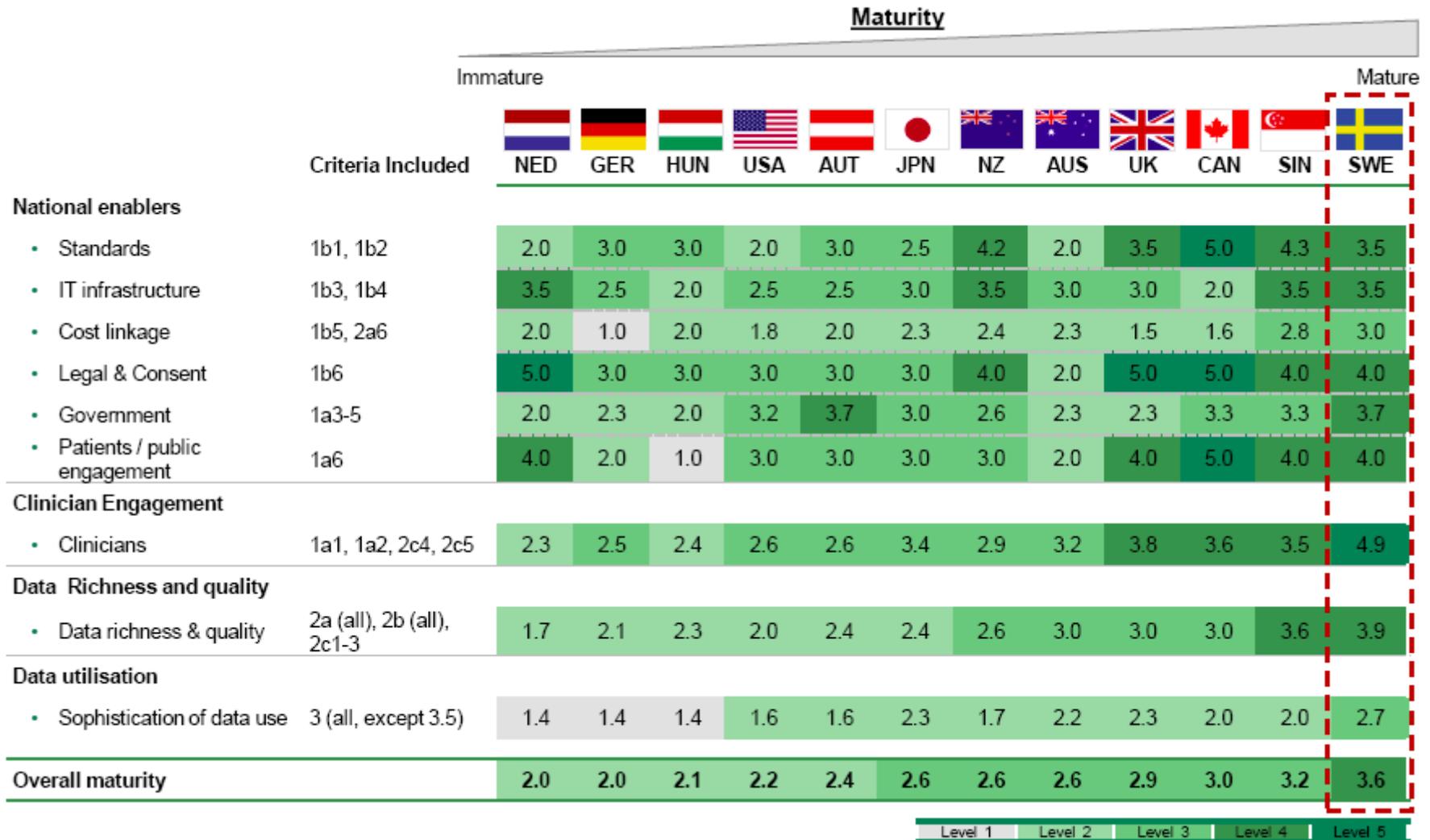
RWE intensifying across the product lifecycle, particularly around launch

Example below is RWE curve for a key oral anti-diabetic launch



Maturity for RWE and Value Based Health Care

Source: BCG report; Progress toward value-based health care, 2012



Nordics have outstanding opportunities in Real World Evidence

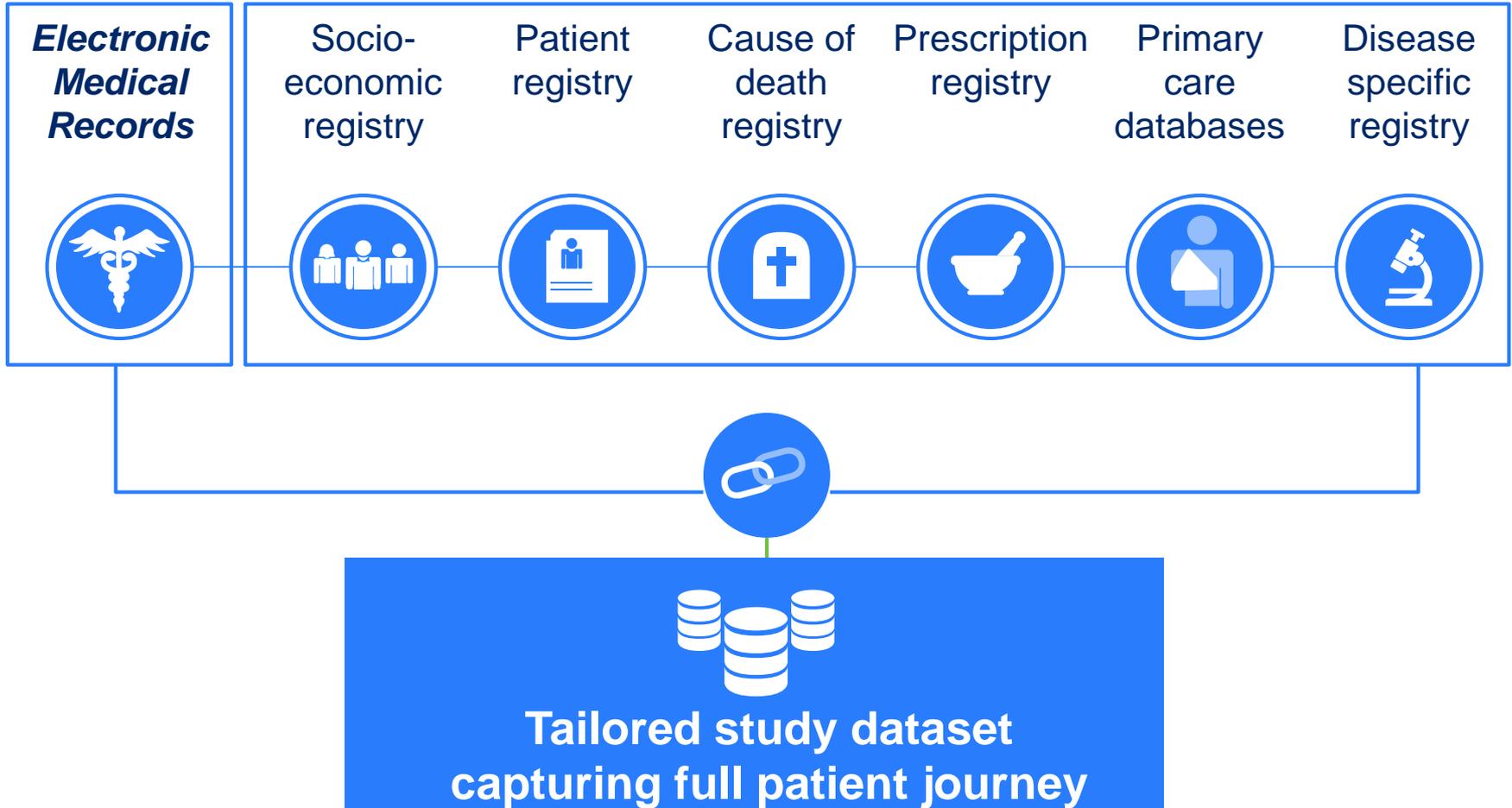


- Well structured public **health care system**
- Universal implementation of **EMRs** since 1990's
- National and population-based health **registers** in the region since 1950's
- **Common** set-up of health care, health information and classification systems
- Strong **academic** hubs to collaborate with in the region

RWD from Nordic registries



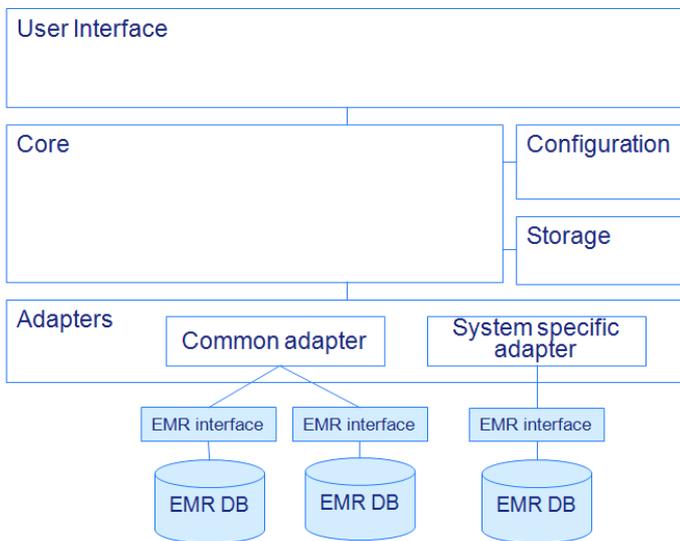
Via CXP



Pygargus CXP 3.0

- ✓ Application for extracting relevant data from EMRs
- ✓ Modern extraction tool that delivers anonymized patient data for clinical studies
- ✓ Supports extraction from different health care (EMR) systems at hospitals, GPs, psychiatric care, geriatrics, spirometry, E-archive systems, etc
- ✓ Makes the complex task of collecting data from different sources into a single, standardized and quick task
- ✓ International development focus

CXP 3.0 – Architecture



CXP 3.0 – Supported information objects

- Demographics
- Diagnoses
- Encounter Diagnoses
- Measurements
- Case Notes
- Medications
- Prescriptions
- Vaccinations
- Laboratory results
- Radiology results
- Pathology results
- Encounters
- Procedures
- Consultation referrals
- Sickleaves
- Chemotherapy

What data can we extract from EMRs?

Basically all patient data added into the EMR

Demographic data
(age, gender etc.)

Prescriptions
(ATC code, brand
name, dose, pack
size, strength etc)

Drugs
administrated in
hospitals

Diagnoses/co-
morbidity (ICD 9
or 10)

All lab tests
performed (date,
test value)

Type of HCP
contacts (doctor,
nurse, other HCP
etc)

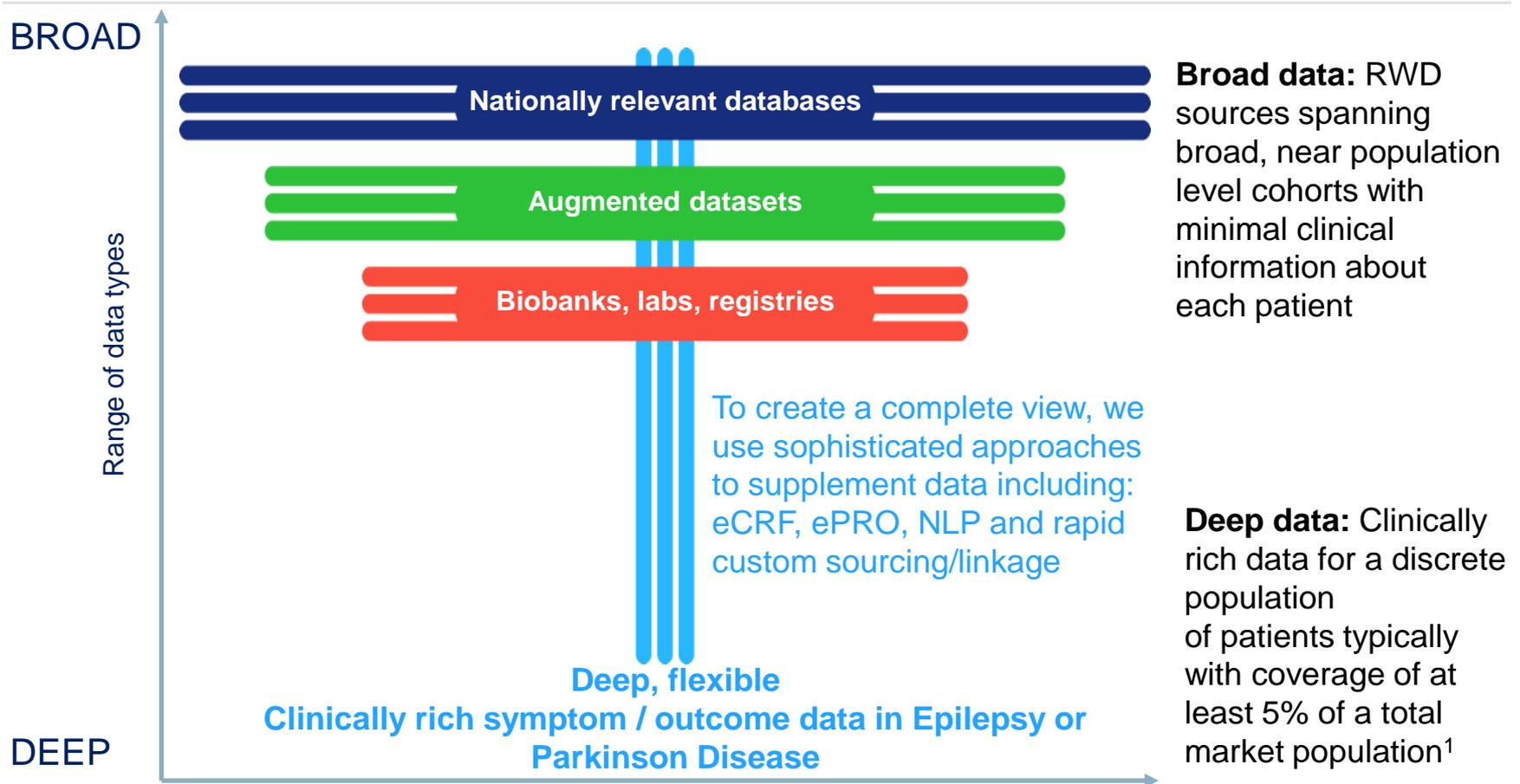
Patient data
(weight, length,
BMI etc.)

Pathology
Surgical reports

Measures (Blood
pressure, BMI, ...)

Free text, search
by stick words

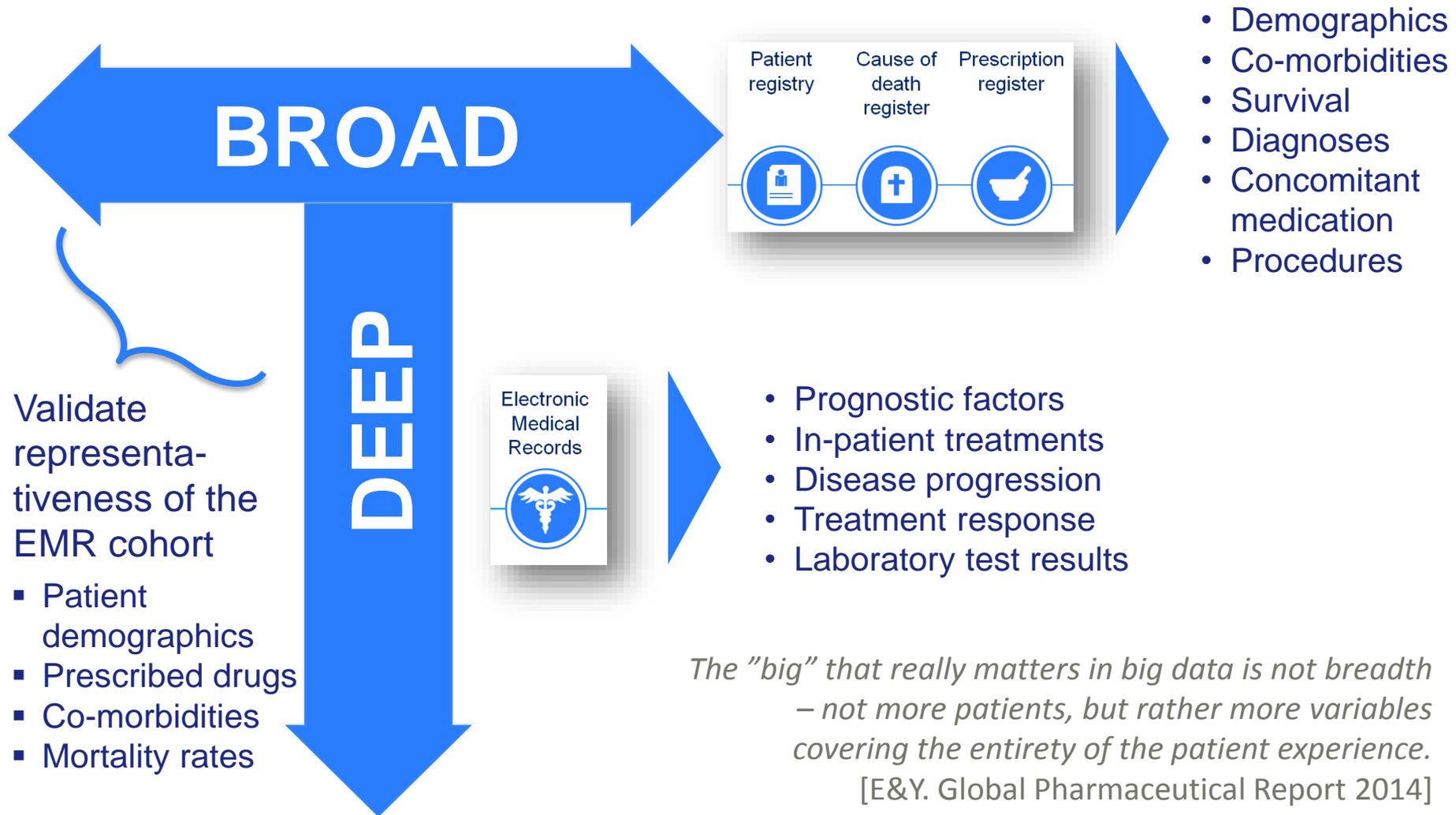
Emerging trend: focus on creating T-Shape Evidence Networks that balance data source breadth and depth



T-Shaped Evidence Network: A set of relationships, spanning different organisations, which provides access when required to high quality, clinically rich data

¹ Estimation based on incidence rates

T-shaped data strategy to increase study power, external validity, and clinical depth



Validate representativeness of the EMR cohort

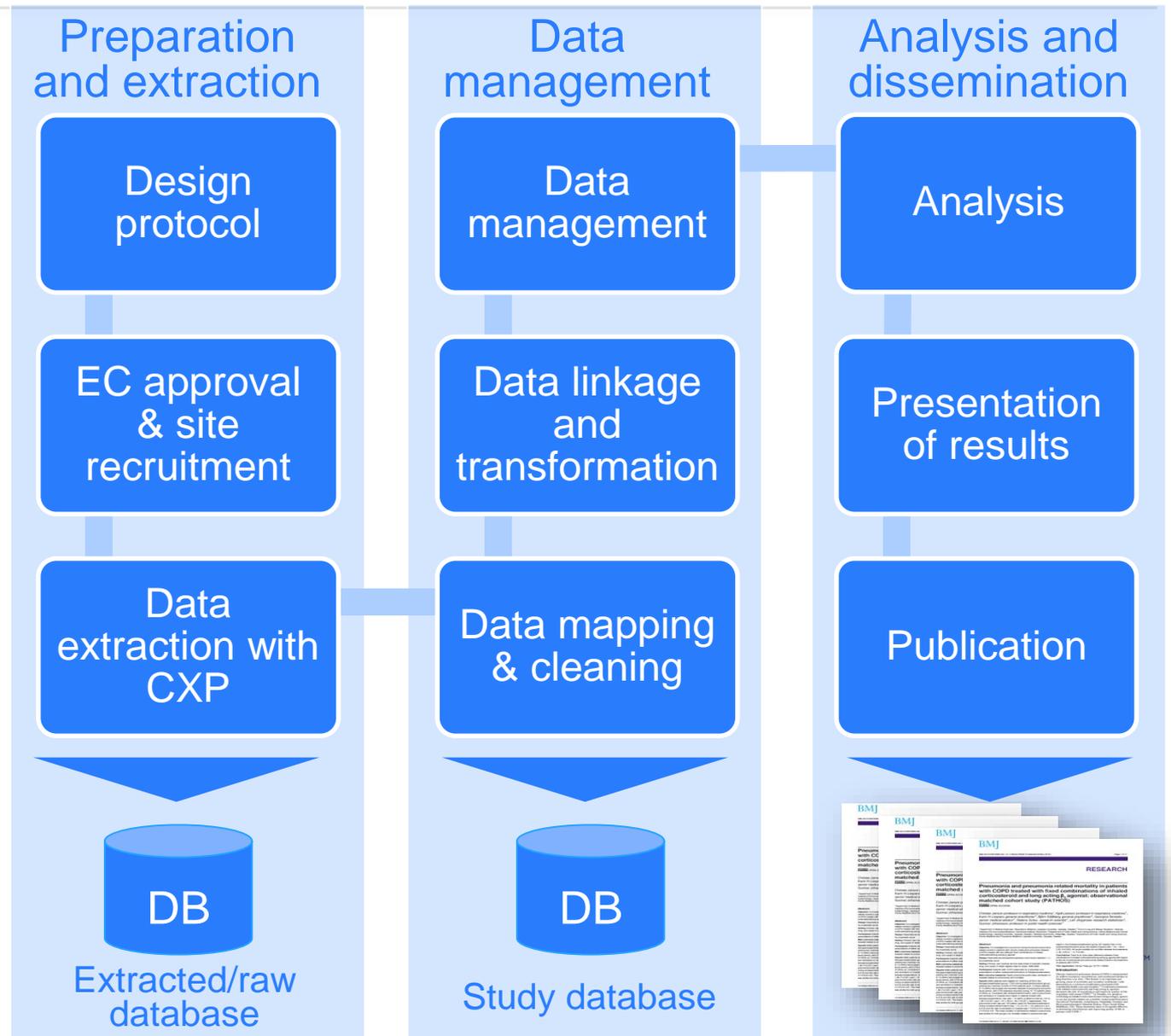
- Patient demographics
- Prescribed drugs
- Co-morbidities
- Mortality rates

The process from protocol to dissemination

... based on > 40 projects



 Timelines vary according to complexity



Example of RWD

Overall rationale



To better **understand the epidemiology** of COPD including treatment practice, co-morbidity and mortality during the last decade

Study Objectives



Describe the long-term **epidemiology** of COPD and the health care **structure** in primary care



Assess the **comparative effectiveness** between fixed ICS/LABA combination treatment in COPD



To investigate occurrence of **pneumonia** in a COPD population treated with fixed combination



Estimate the **cost-effectiveness** amongst fixed combination treatments in COPD

COPD Case study



Background

- COPD associated with considerable morbidity, mortality; pneumonia is a frequent complication
- To prevent exacerbations, patients are frequently prescribed fixed-dose ICS/LABA combinations
- Pharma client wanted to develop credible insights about the best treatment course for COPD patients to work with stakeholders to improve guidelines, COPD management

The Study

Retrospective, observational, population-based study of 21,361 COPD patients in Sweden over 11 years to focus on

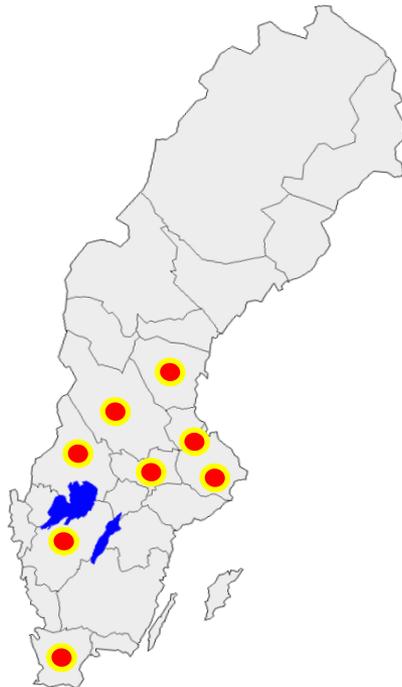
- Prevalence and incidence
- Co-morbidities
- Disease management
- Complete clinical data on each patient
- Mortality and life expectancy

The results

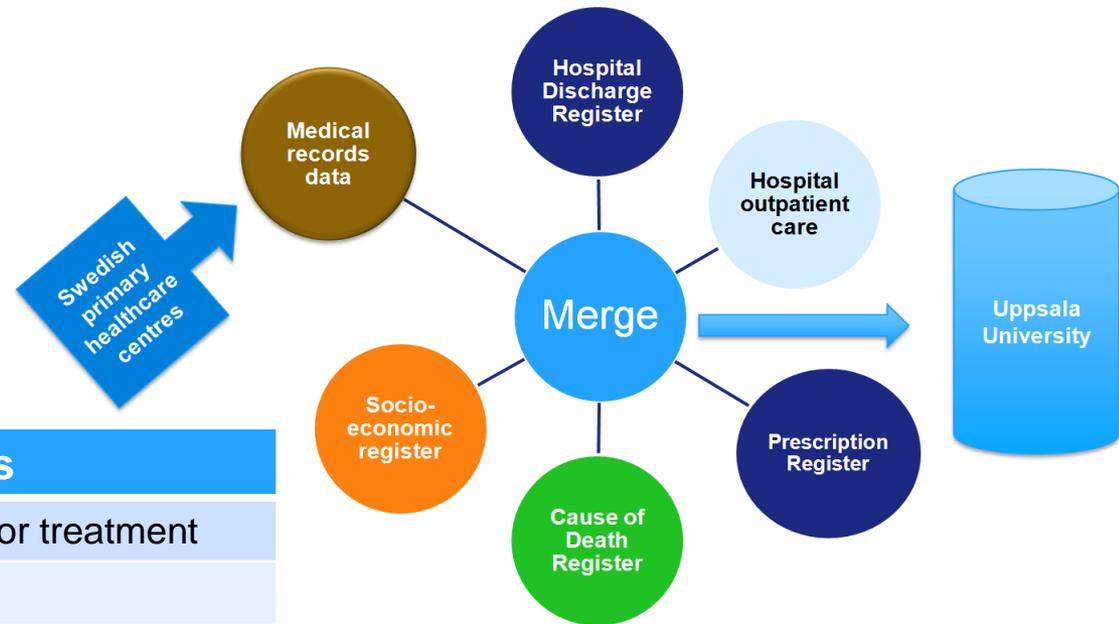
- Improved outcomes
 - Earlier diagnosis
 - Primary care focus
 - Changed treatment options
 - Decreased exacerbations
- TA-specific impact on exacerbations, pneumonia-related mortality
- 4 publications in BMJ and J Int Medicine, Prim Care Resp Journal
- 5 scientific abstracts presented

The study design

Retrospective, observational, population-based, propensity score matched study



- EMR data from 76 primary health care centres linked with data from Swedish registries (8% of the Swedish pop)
- Patients followed from January 1999 to December 2009, or end of treatment, emigration or death



The PATHOS study in numbers

27 934	Patients with COPD or treatment
21 361	COPD patients
190 000	Visits at hospital
3 500 000	Contacts with primary care
1 300 000	Prescriptions

Propensity score matching of populations at index to limit potential for bias

Propensity score matching was performed to account for individuals disease severity*

Number of eligible patients by treatment

2738	Patients using Seretide
7155	Patients using Pulmicort
9893	Total number of COPD patients

- Data 2 years before index date used for matching

Variables included in propensity score

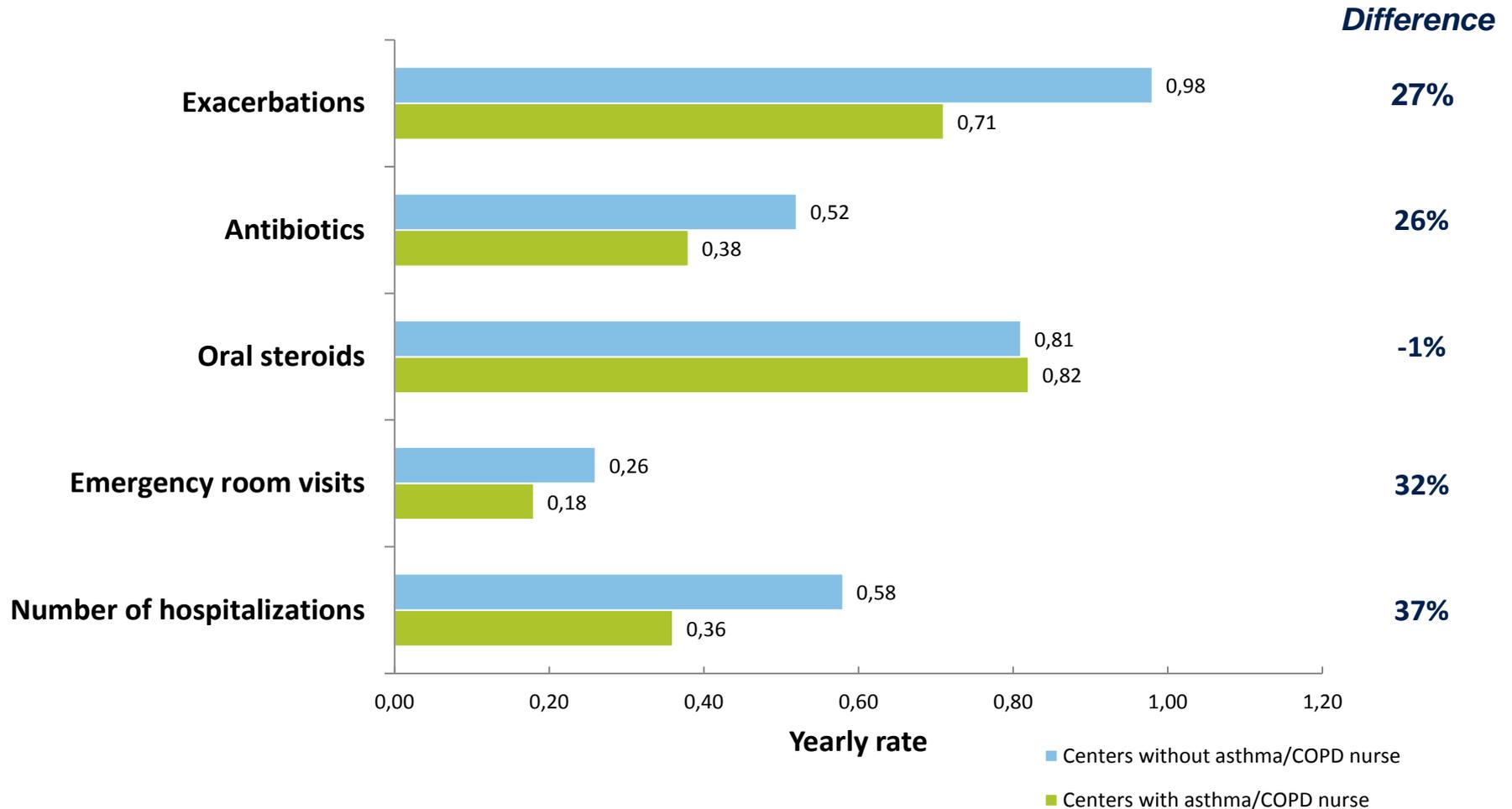
Demographics	Age, gender, time from COPD diagnosis
Medication	Antibiotics, SABA, oral/inhaled steroids, LABA, anticholinergics, CV medications
Hospitalisation	For exacerbations, any cardiovascular reason, pneumonia and asthma
Co-morbidities	Diabetes, asthma, cancer, heart failure, hypertension, stroke, FEV1 % pn

- Pairwise matching with 2734 patients per treatment group including 19,170 PY's follow-up with either ICS/LABA combination
- Only 4 patient from the smaller treatment group could not be matched to a corresponding patient within the database

* It was not possible to match for patient weight, height, BMI and smoking, as these measurements were available for just a minority sub-sample.

Stratification by primary care centers with and without asthma/COPD nurse

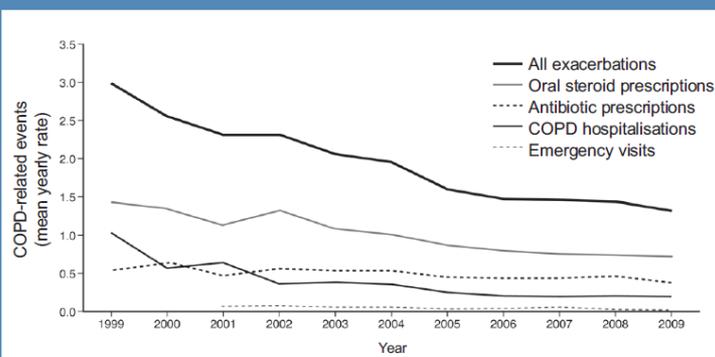
Rate of exacerbations and hospitalizations lower in PCC with COPD nurse



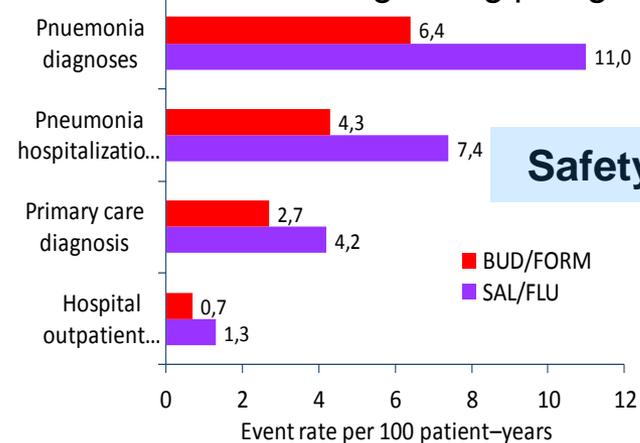
The study demonstrated better disease management, safety, and comparative effectiveness

Disease management
evolution over 11 years showed dramatic decrease in number of exacerbations

Figure 3. Chronic obstructive pulmonary disease (COPD)-related events (mean yearly rate) during the 11-year study period (1999–2009)



Pneumonia and related mortality in COPD treated with fixed combinations of inhaled corticosteroid and long acting β 2 agonist

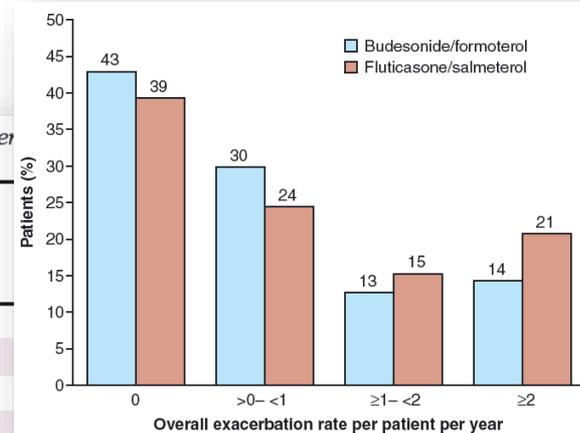


Safety

Comparative effectiveness between two treatments in preventing exacerbations in COPD

Table 2 Yearly occurrence of events among pairwise (1 : 1) propensity score-matched populations of COPD patients with budesonide/formoterol versus fluticasone/salmeterol

Variable	Fluticasone/salmeterol (n = 2734)	Budesonide/formoterol (n = 2734)	Treatment contrast ^a
Events, per patient-year	Mean (95% CI)	Mean (95% CI)	Rate ratio (95% CI)
All exacerbations	1.09 (1.05–1.14)	0.80 (0.77–0.84)	0.74 (0.69–0.79)
COPD hospitalizations	0.21 (0.20–0.23)	0.15 (0.142–0.163)	0.71 (0.65–0.78)
COPD-related hospital stay, days	0.95 (0.88–1.02)	0.63 (0.58–0.67)	0.66 (0.62–0.71)
Emergency visits	0.034 (0.031–0.037)	0.027 (0.025–0.030)	0.79 (0.71–0.89)
Oral steroid use	0.85 (0.81–0.90)	0.63 (0.60–0.67)	0.74 (0.68–0.81)
Antibiotic use	0.54 (0.52–0.57)	0.38 (0.37–0.40)	0.70 (0.66–0.75)



Publications from the study

BMJ

BMJ 2013;346:f3306 doi: 10.1136/bmj.f3306 (Published 29 May 2013)

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RESEARCH

Pneumonia and pneumonia related mortality in patients with COPD treated with fixed combinations of inhaled corticosteroid and long acting β_2 agonist: observational matched cohort study (PATHOS)

OPEN ACCESS

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Original Article

Journal of INTERNAL MEDICINE

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Combination of budesonide/formoterol more effective than fluticasone/salmeterol in preventing exacerbations in chronic obstructive pulmonary disease: the PATHOS study

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Improvement in COPD management by access to asthma/COPD clinics in primary care: Data from the observational PATHOS study



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RESEARCH PAPER

Management, morbidity and mortality of COPD during an 11-year period: an observational retrospective epidemiological register study in Sweden (PATHOS)

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