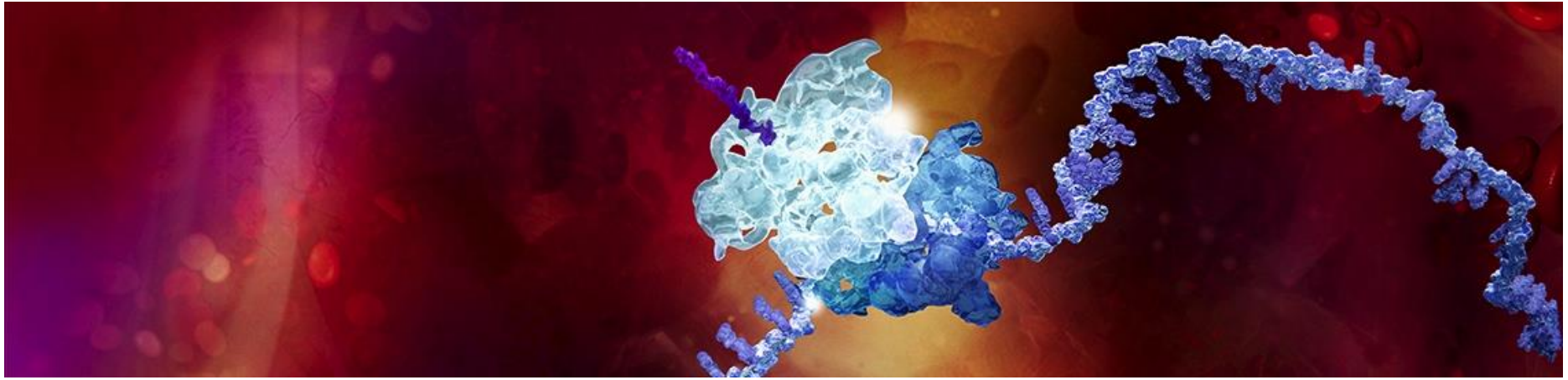
The collaboration of pharma with health systems: Co-creating better outcomes

i-HD Hospital Network Workshop, Brussels

Tomas Andersson, Vice President Cardiovascular/CKD, Global Medicines Development, AstraZeneca

09 February 2017



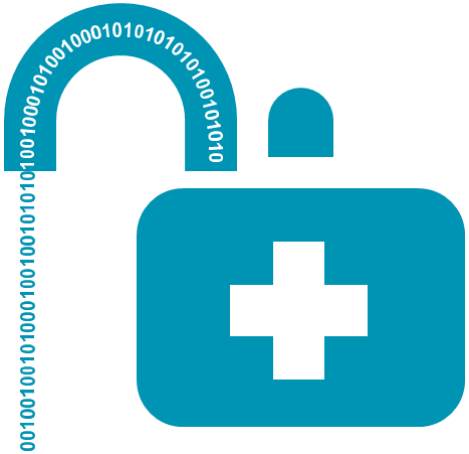
Setting the scene

“Few people yet realize the capabilities of the new data-collection technologies and how they can impact not only clinical research but also discovery research. They can transform the entire biomedical research enterprise, making innovation faster, more powerful and radically cheaper”

Bernard Munos, Senior Fellow at Faster Cures 2017

EHRs is one key enabler for clinical research

- Rapid expansion over past 5-10 years
- EHR is now routinely used in clinical care
  - In some countries nearly 90% of all healthcare records are digital
- Integration of large data platforms needed
- EHRs are generally not optimized to support research
- Lack of scalable collaboration models that can bridge between health care and industry



Pharma perspective

Clinical research is costly, long, complex

- Challenges with clinical trials

- Incomplete and delayed clinical trials are a sore spot of drug development

The percentage of studies that complete enrolment on time:
18% in Europe,
7% in the US[1]

50%
of today's clinical trials fail to achieve the target recruitment[4]

Almost
50% of all trial delays caused by patient recruitment problems[2]

1/3 of protocol amendments are avoidable, at a cost of **$0.5m**

Each day a drug is delayed from market, sponsors lose[3] up to
$8m

1. State of the Clinical Trials Industry: A Sourcebook of Charts and Statistics, Center Watch, 2008.
2. Study Participant Recruitment and Retention in Clinical Trials: Emerging strategies in Europe, the US and Asia, Business Insights, June 2007.
3. Beasley, "Recruiting" 2008
4. Tufts -http://clinicalperformancepartners.com/wp-content/uploads/2012/07/Fixing-Feasibility-Final-Jan-2012.pdf

Redundant data entry

- Clinical trial data are manually entered into dedicated electronic clinical trial systems (EDC) and the same information is often also entered into EHR systems
  - Cumbersome and slow processes
  - Transcription inconsistencies
  - Accounts for approximate for 20% of total study cost

Investigational sites estimate that over

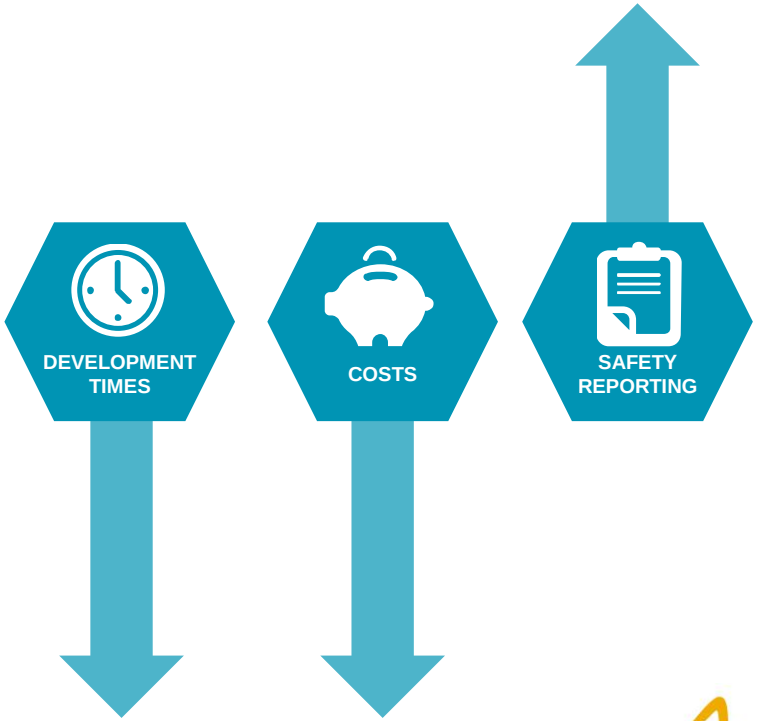
70%

of data are duplicated between EHR and clinical trial systems[2]

1. Integrating Electronic Health Records and Clinical Trials: An Examination of Pragmatic Issues, Michael Kahn, University of Colorado.
2. EDC Site Survey: Investigational Site Perspectives on Clinical Trial Information Systems, eClinical Forum 2009. Available at: www.eclinicalforum.org (accessed December 1, 2011).

Trustworthy use of EHR data can resolve bottlenecks in clinical research

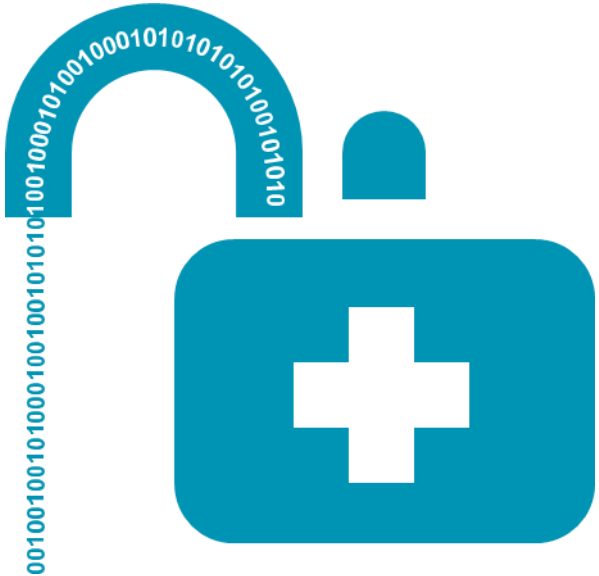
- Optimise clinical protocol design (reduce amendments)
- Accelerate and improve accuracy of patient identification and recruitment (identify patients missed today, achieve recruitment targets)
- Eliminate non-value added tasks (reduce redundant data entry)
- Improve quality of data (fewer transcription errors)
- Improve Adverse Event reporting (real-time safety monitoring and reporting)



1. Beasley, “Recruiting” 2008

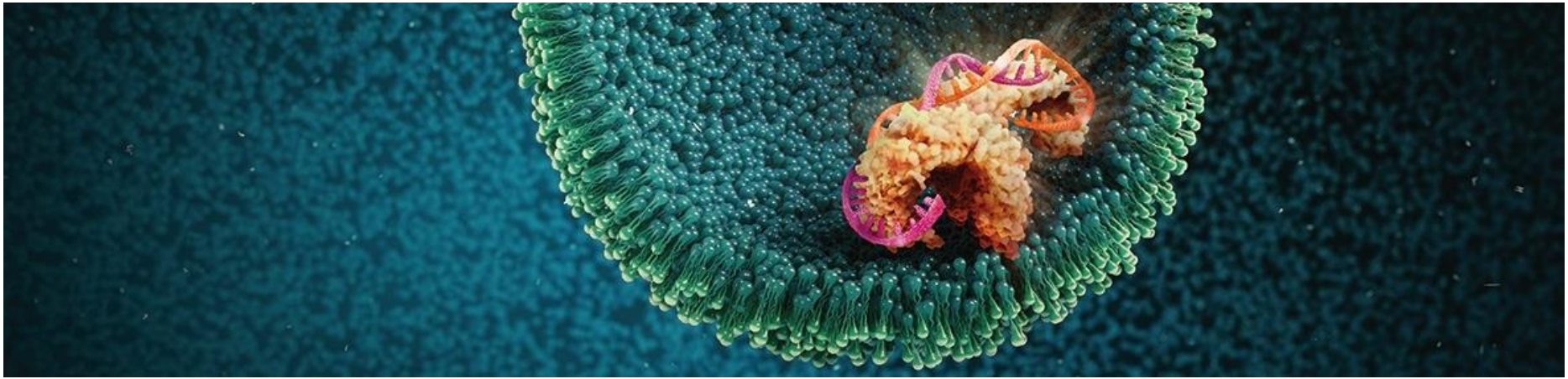
Challenges for making the most of RWE data

- Trust
- Use cases & applications
- Access
- Quality of data
- Interoperability and harmonization
- Collaboration models, processes, governance, and finances



Trends in Real-World Evidence, eye-for pharma, 2017

Some use cases from AstraZeneca



Observational registry study in collaboration with Swedish hospitals

Rationale

RCTs are the gold standard for demonstrating efficacy & safety of novel therapies but have **inherent limitations, including selected and highly controlled patient populations**

Post-approval studies in real-world patients may therefore provide valuable data to further *complement* RCT findings

Objective

To study clinical outcomes in a large real-world population post- in acute coronary syndrome (ACS)
Ticagrelor reduces ischaemic events and mortality in acute coronary syndrome (ACS) vs. clopidogrel
Prospective cohort study in 45 073 ACS patients enrolled into Web system for enhancement of evidence-based care in heart disease between Jan. 2010 and Dec. 2013

Conclusion

Ticagrelor vs. clopidogrel post-ACS was associated with a lower risk of death, MI, or stroke, as well as death alone. Risk of bleeding was higher with ticagrelor.

These real-world outcomes are consistent with randomized trial results.

The study also demonstrate the ability to conduct pragmatic clinical trial by re-use high quality registry and EHR data in Sweden

European Heart Journal
doi:10.1093/eurheartj/ehw284

CLINICAL RESEARCH
Acute coronary syndromes

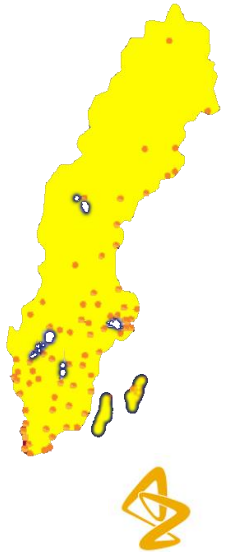
Outcomes in patients treated with ticagrelor or clopidogrel after acute myocardial infarction: experiences from SWEDEHEART registry

Anders Sahlén[1,2,3]*, Christoph Varenhorst[4], Bo Lagerqvist[4], Henrik Renlund[4], Elmir Omerovic[5], David Erlinge[6], Lars Wallentin[4], Stefan K. James[4], and Tomas Jernberg[1,2]

[1]Department of Medical Epidemiology and Biostatistics, Karolinska Institutet, Stockholm, Sweden; [2]Department of Cardiology, Karolinska University Hospital, Stockholm, Sweden; [3]National Heart Centre Singapore, 5 Hospital Drive, Singapore, Singapore 169609; [4]Department of Medical Sciences, Uppsala Clinical Research Center, Uppsala University, Uppsala, Sweden; [5]Sahlgrenska Academy, University of Gothenburg, Gothenburg, Sweden; and [6]Department of Cardiology, Clinical Sciences, Lund University, Lund, Sweden

Received 16 November 2015; revised 26 May 2016; accepted 8 June 2016

- A nationwide web-based registry including patients with myocardial infarction at all Swedish acute cardiac care hospitals (N=71)
- Includes 500 variables
- Monitoring and agreement between registry data and EHRs
- For research purposes, merged with the Swedish population registry (the vital status of all Swedish citizens) and the National Patient Registry (all diagnoses of all admissions to Swedish hospitals since 1987)



Using EHRs to supplement the placebo group in RCTs of severe diseases

Franzén et al. Respiratory Research (2016) 17:152
DOI 10.1186/s12931-016-0461-1

Respiratory Research

RESEARCH Open Access

Evaluation of the use of Swedish integrated electronic health records and register health care data as support clinical trials in severe asthma: the PACEHR study

Stefan Franzén[1], Christer Janson[2], Kjell Larsson[3], Max Petzold[4], Urban Olsson[5], Gunnar Magnusson[6], Gunilla Telg[7], Gene Colice[8], Gunnar Johansson[9] and Mats Sundgren[6,10*]

Rationale

In new drug development for severe asthma, it is a challenge from an ethical point of view to randomize severe asthma patients to placebo.

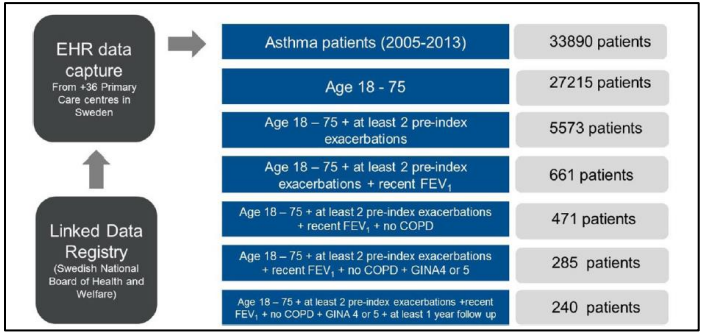
Objective

Evaluate the feasibility of **using EHR data to create a real-world reference population of uncontrolled asthmatic patients** to supplement the concurrent control/placebo group in long-term studies of asthma.

Method

EHR data from 36 primary care centres and a University hospital in Sweden were linked to Swedish mandatory health registers (2005–2013), creating a population covering 33 890 asthma patients. Logistic regression to estimate the propensity score (probability) of each RCT or EHR patient existing in the EHR cohort given their covariates.

- ✓ **We created an EHR-derived reference cohort of 240 patients, matching the placebo group (N = 151) in a RCT of severe asthma. The exacerbation rate (key end point) during follow-up in the EHR study population was 1.24 (weighted) compared to 0.9 in the RCT placebo group.**

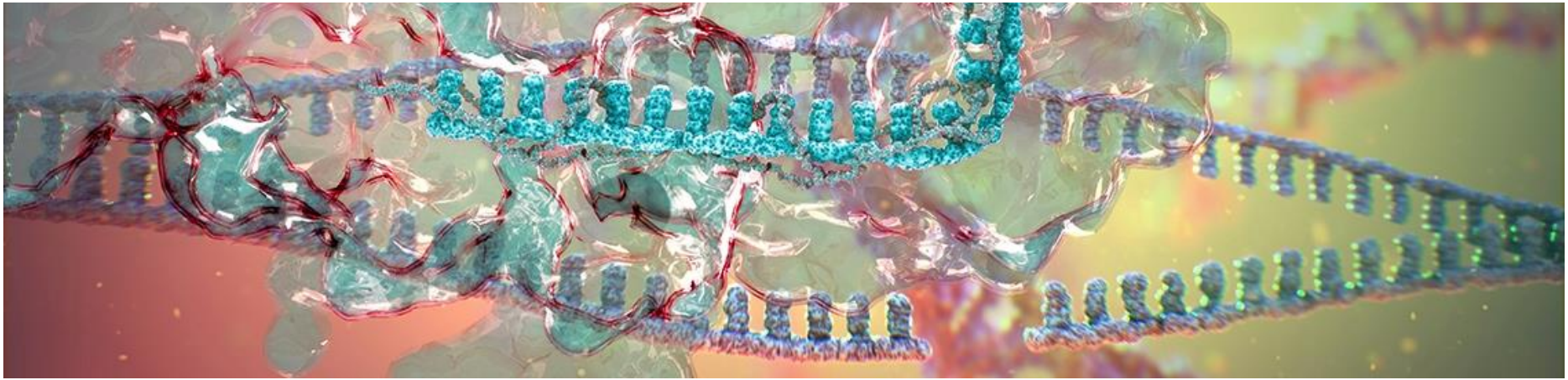


Placebo cohort (n= 151)
Completed AZ RCT (Phase II)
severe asthma

Conclusion

The study demonstrate that an adequate large number of severe uncontrolled asthma patients, comparable to the placebo group in a RCT, can be found in Swedish EHRs based on pre-defined criteria for uncontrolled asthma. Results indicate that EHRs provide an opportunity to supplement the control group in RCTs of severe diseases

Towards a common vision



Vision for the future health care & pharma

Tremendous opportunities for synergies between healthcare, payers, pharma and patients regarding the digitization of health data

We will see radical progress in clinical outcomes, care pathways, quality of care, personalized medicine and new medicines faster to patients at lower cost. We are not limited to just conducting clinical trials….

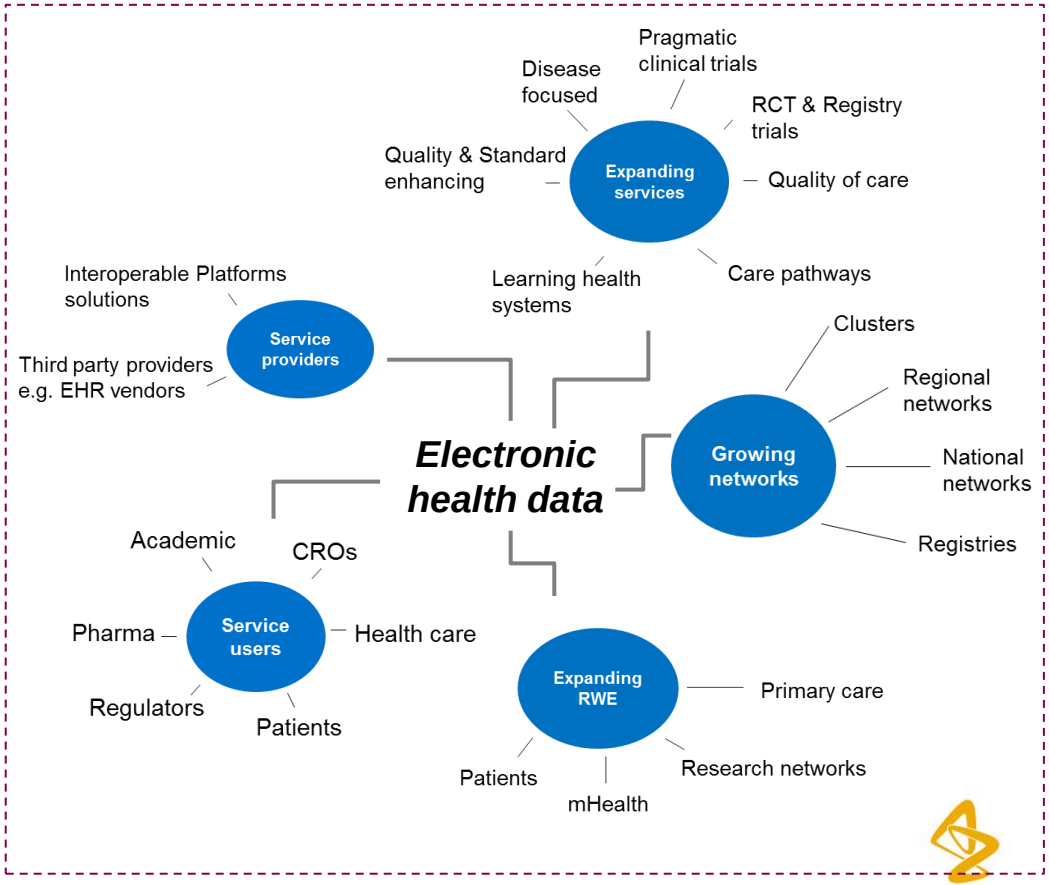
To make it happen we need new collaboration models and governance mechanisms, trust and technical platforms around trustworthy reuse of health data – **and it will revolutionize health care and new drug development**

How could the vision look like?

- With new collaborations that have started to shape with healthcare and industry
- Create connectivity of health data
- It demands trust, proper governance mechanism, new thinking, and a clear win-win philosophy all stakeholders
- The gains are huge for research, care and patients
- Time is ripe to start to work together

New collaborations & Governance mechanisms

Ensuring trustworthy use of health data



Thank you