

# ***Impacting R&D through pharma- payer collaboration: the AstraZeneca-HealthCore Partnership***

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# Outline

- Challenges faced by pharma R&D and the need for Real World Evidence (RWE)
- Gap in use of Real World Evidence (RWE) data for R&D
- How can we build data assets that can generate useful RWE?
- Case examples where RWE data have helped R&D



# Challenge I: Lack of Translational Science

- In FDA's view, the applied sciences needed for medical product development have not kept pace with the tremendous advances in the basic sciences.
- The new science is not being used to guide the technology development process in the same way that it is accelerating the technology discovery process.

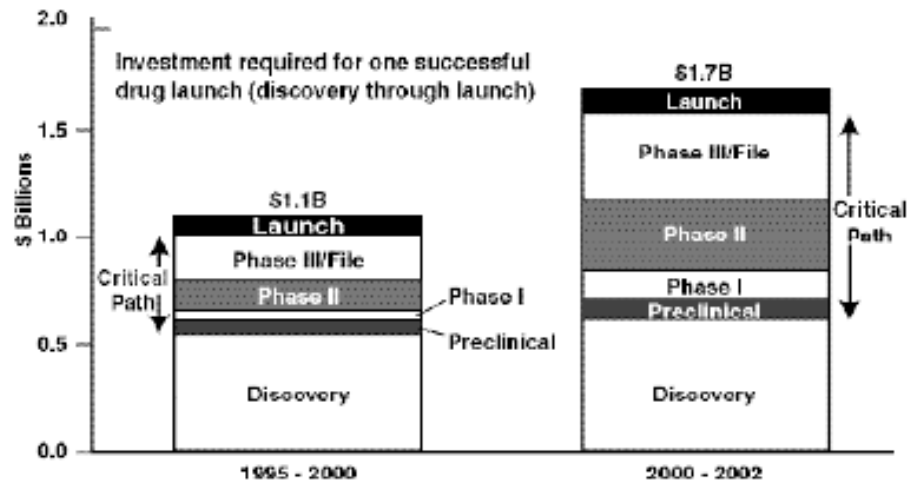


***Innovation or Stagnation: Challenge and Opportunity on the Critical Path to New Medical Products. FDA, March 2004***



# Challenge II: Costly Attrition in Late Stage Development

- Chance of new compounds entering Phase I & reaching market decreased to 8% as compared to 14% 15 years ago
- For drugs completing phase 2, the failure rate in phase 3 has increased to 50% as compared to 20% 10 years ago
- Cost for launching a successful drug keeps increasing



SOURCE: Windhover's In Vivo: The Business & Medicine Report.  
Bain drug economics model, 2003



## Challenge III: Long-term Safety – Needs Real World Evidence (RWE)

- Some drugs have been withdrawn from the market because of unexpected adverse effects that were not detected during Phase III clinical trials and were only apparent from long-term surveillance data from the wider patient community

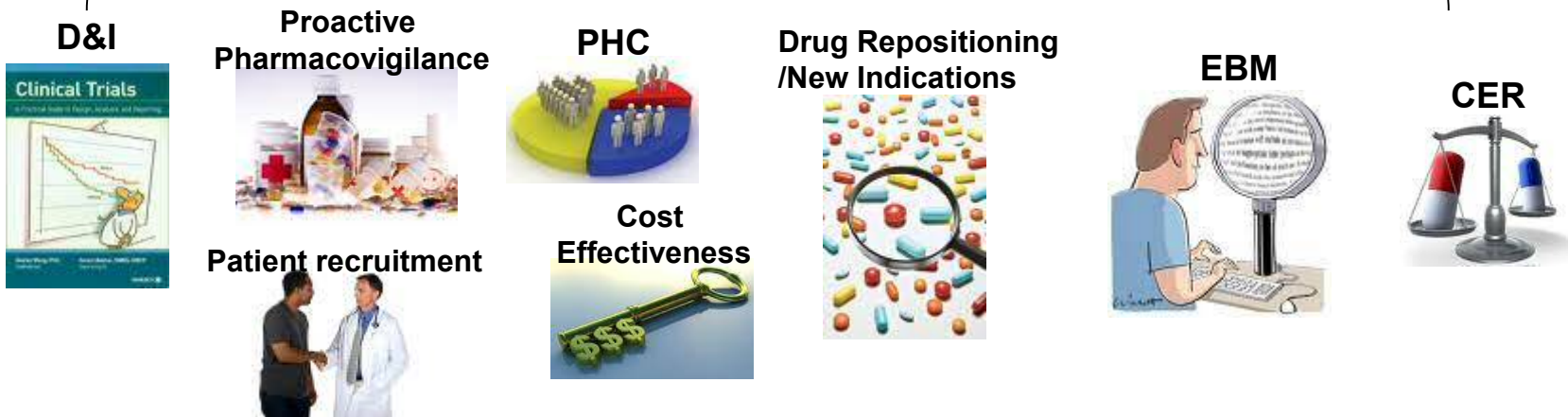
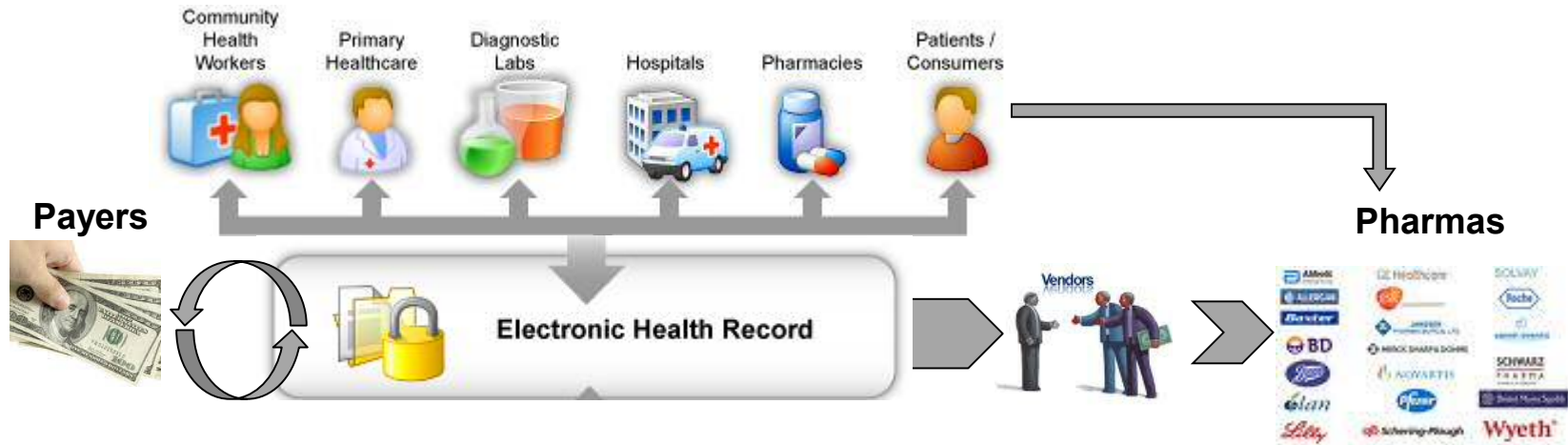


# Challenge IV: Comparative Effectiveness – Needs Real World Evidence (RWE)

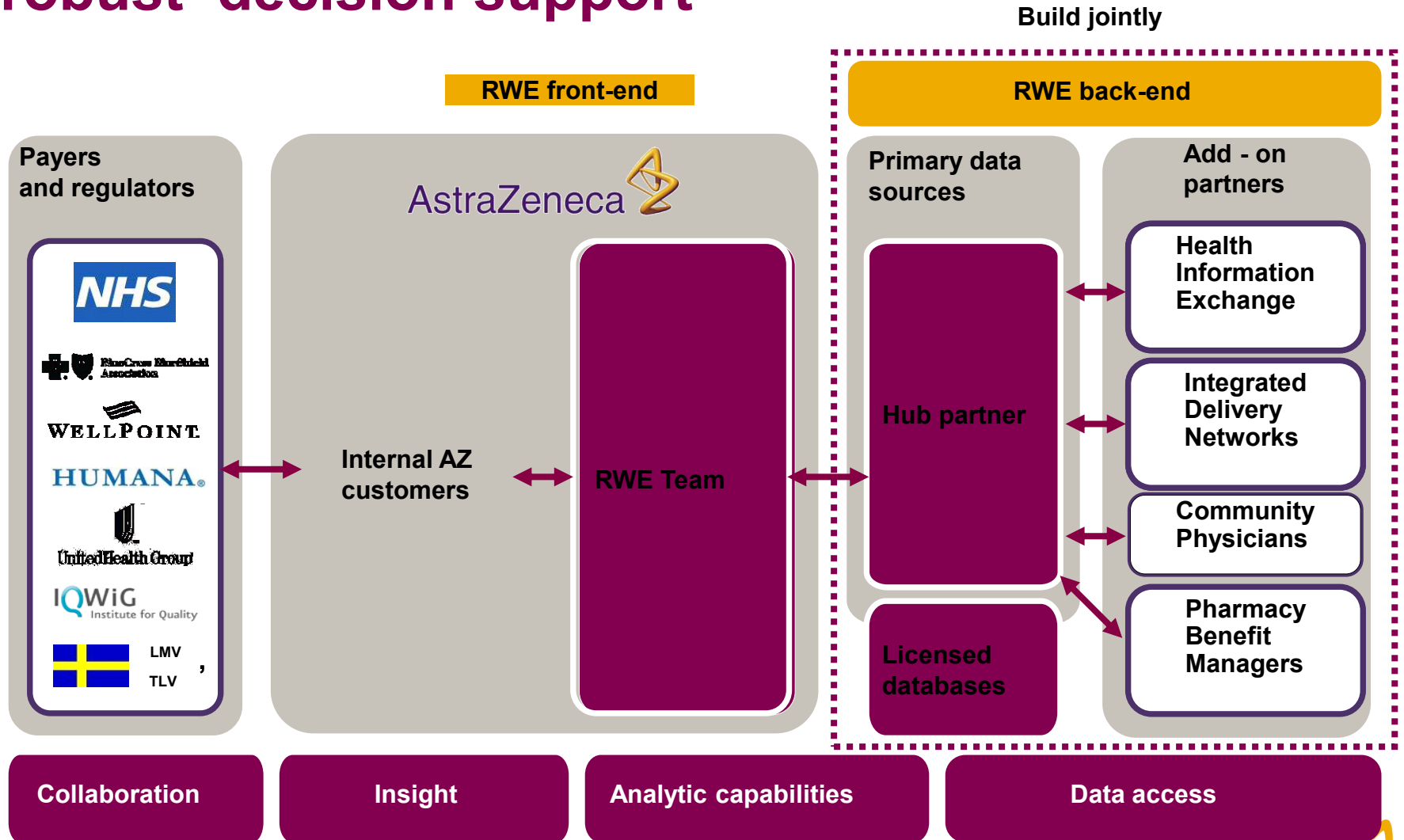
- Need to demonstrate comparative effectiveness
  - Cost effectiveness – **Payer's willingness to pay**
  - Clinical effectiveness (long term efficacy and safety) – CER research and patient reported outcome for decision making by healthcare providers and patients
- Other related issues:
  - Lack of standardization of data (EHRs/EMRs ) and analytical methods
  - Uncertainty in data quality and completeness in EHRs/EMRs
  - Uncertainty in regulatory environment



# Potential Use of RWE in Pharma R&D



# The RWE capability provides dedicated RWE analytics capability with enhanced data access for robust decision support





# THE WALL STREET JOURNAL.

Feb 3<sup>rd</sup>, 2011

## **AstraZeneca, WellPoint To Work On 'Real-World' Health Studies**

Drug maker AstraZeneca PLC (AZN) and health insurer WellPoint Inc. (WLP) have teamed up to conduct what they're calling "real-world" studies to determine the most effective and economical treatments for chronic illnesses and other diseases. The partnership is part of a movement toward greater use of comparative-effectiveness research...

# *"The Pink Sheet"*

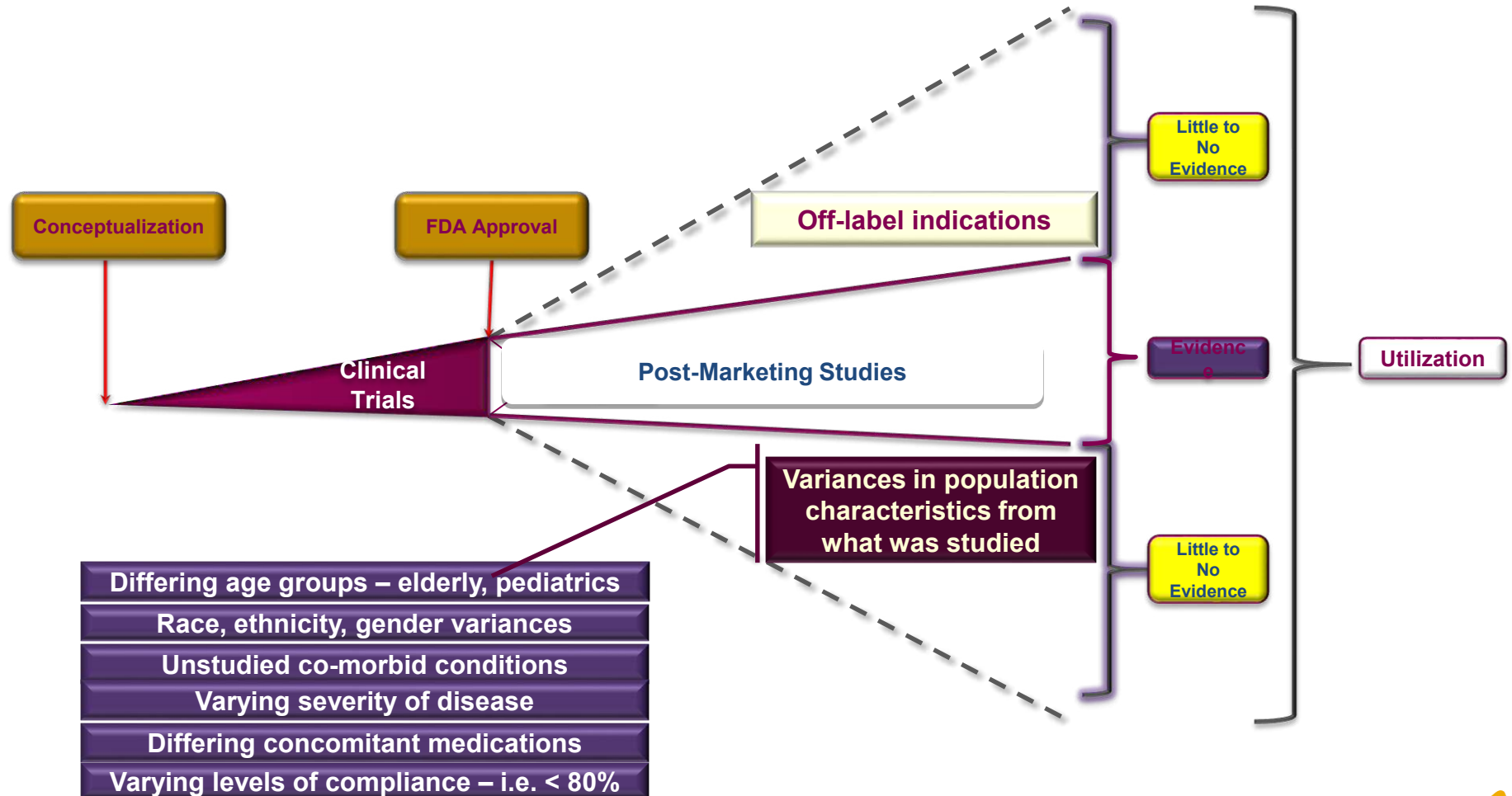
Feb 3<sup>rd</sup>, 2011

## **AstraZeneca, HealthCore Launch Outcomes Data Project, Seek Multi-Stakeholder Consortium**

AstraZeneca and Healthcore, WellPoint's clinical outcomes research unit, have begun an evidence-development partnership to generate "real world" data on the most effective and economic ways to treat disease, with a focus on chronic ailments ..., but also addressing areas such as oncology...

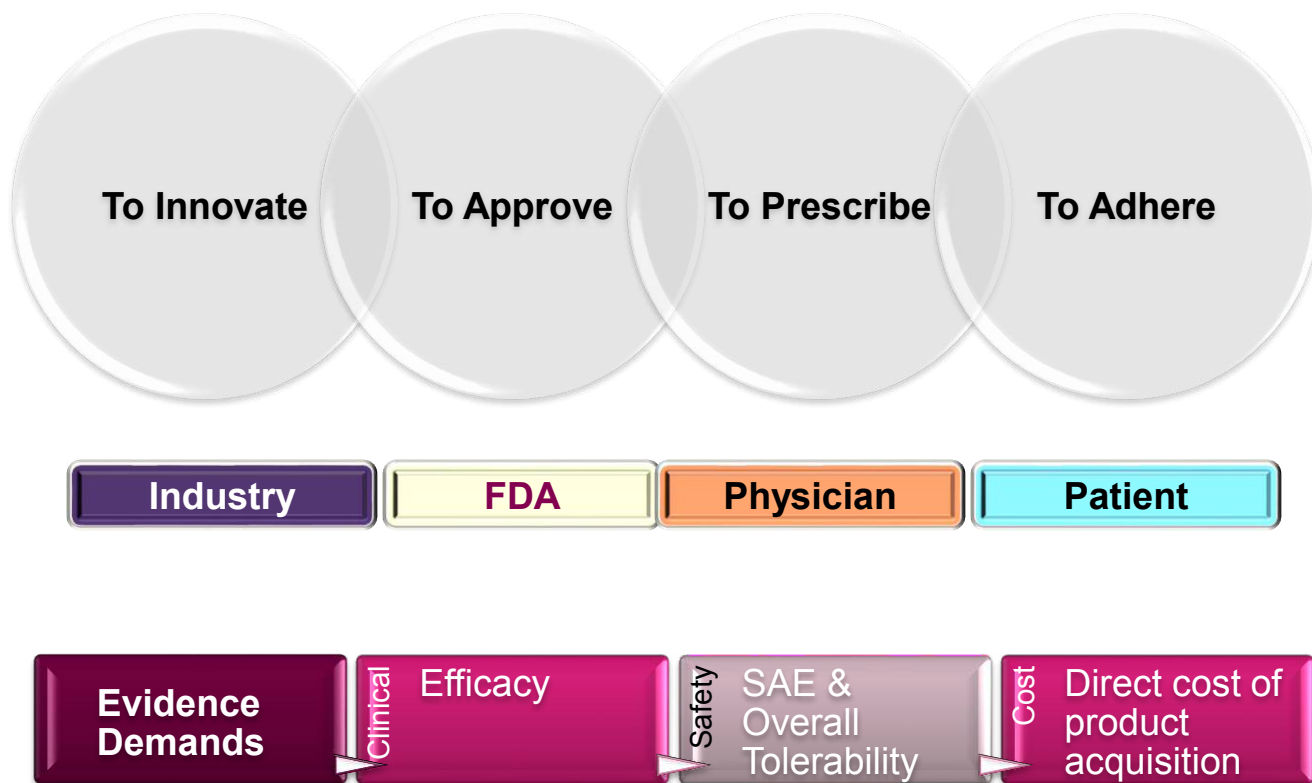


# Key Contributors to Evidence Gaps



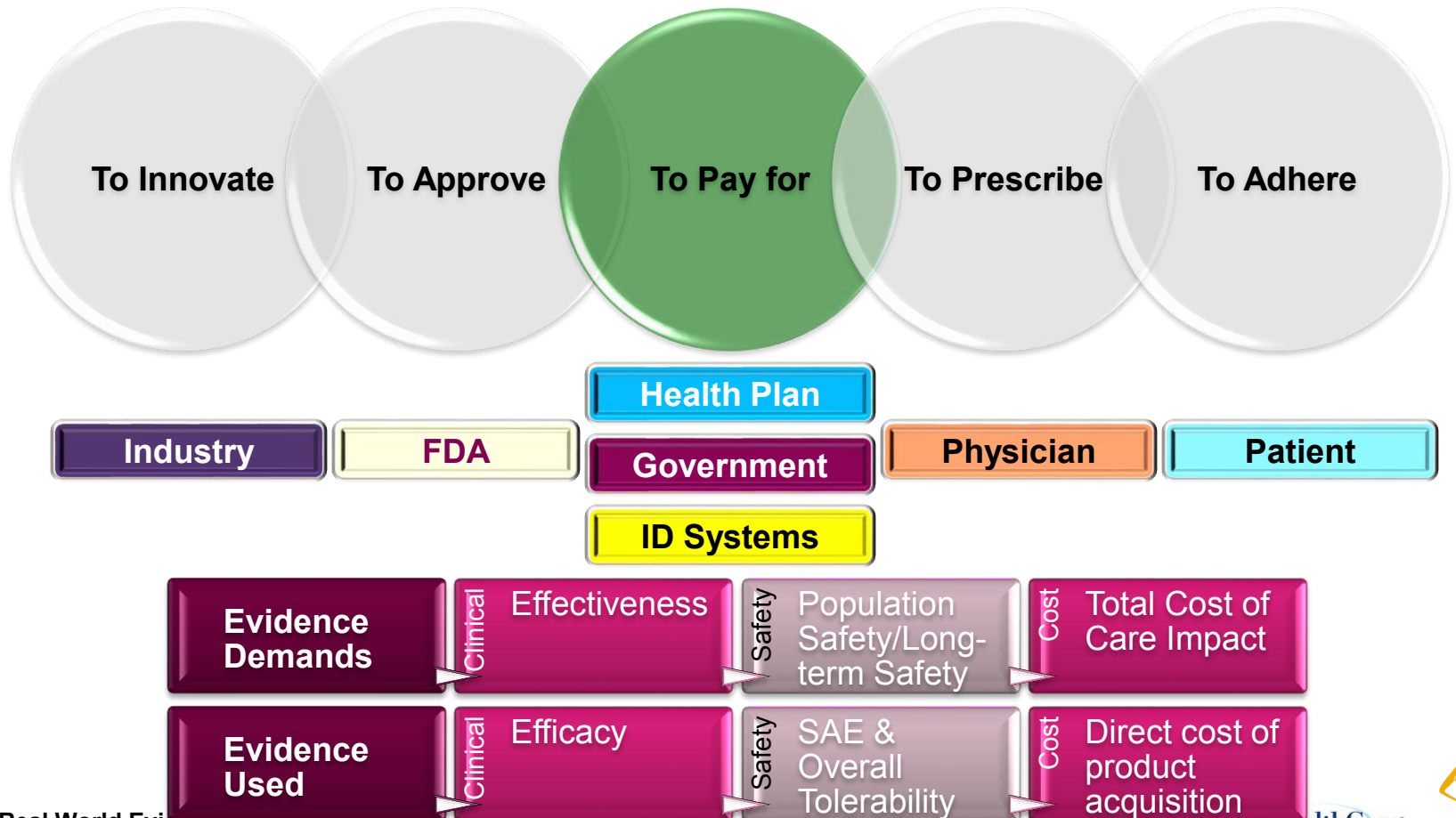
# Shifting Landscape

## Traditional Environment for Decision-Making



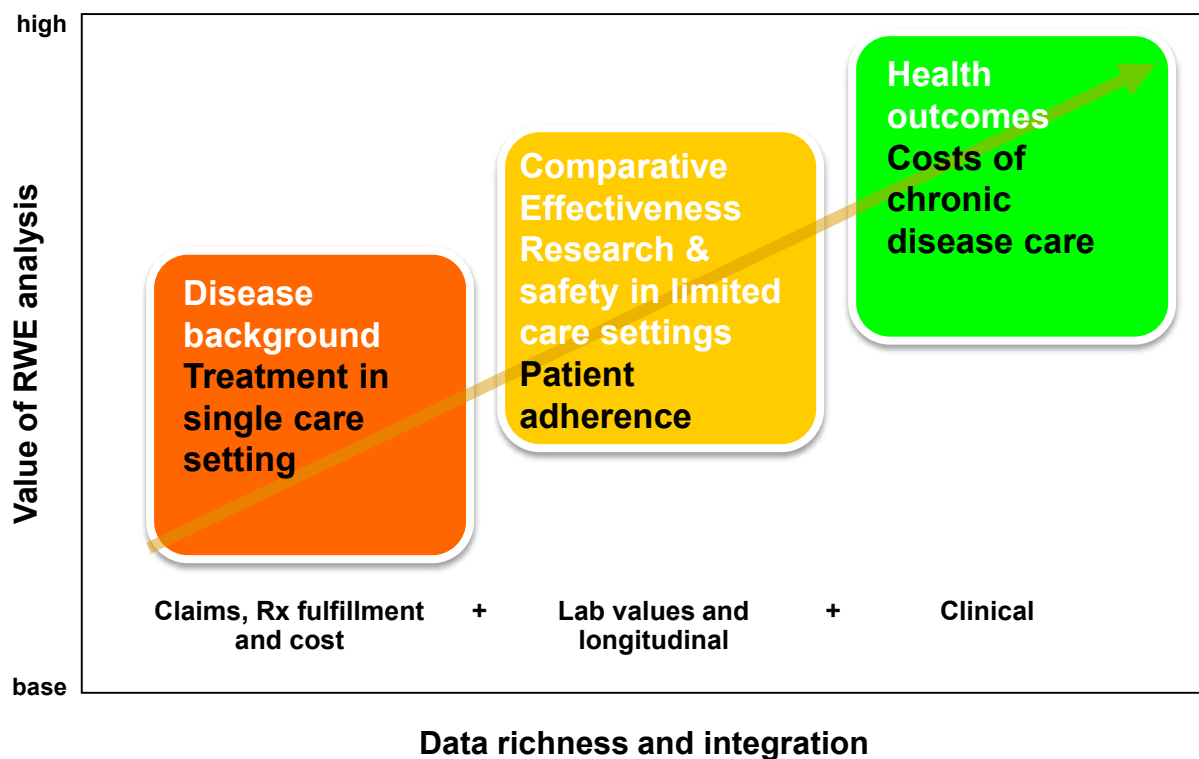
# Shifting Landscape

Emergence of the Payor in the Decision-Chain & the need for Industry to develop products that will get reimbursed

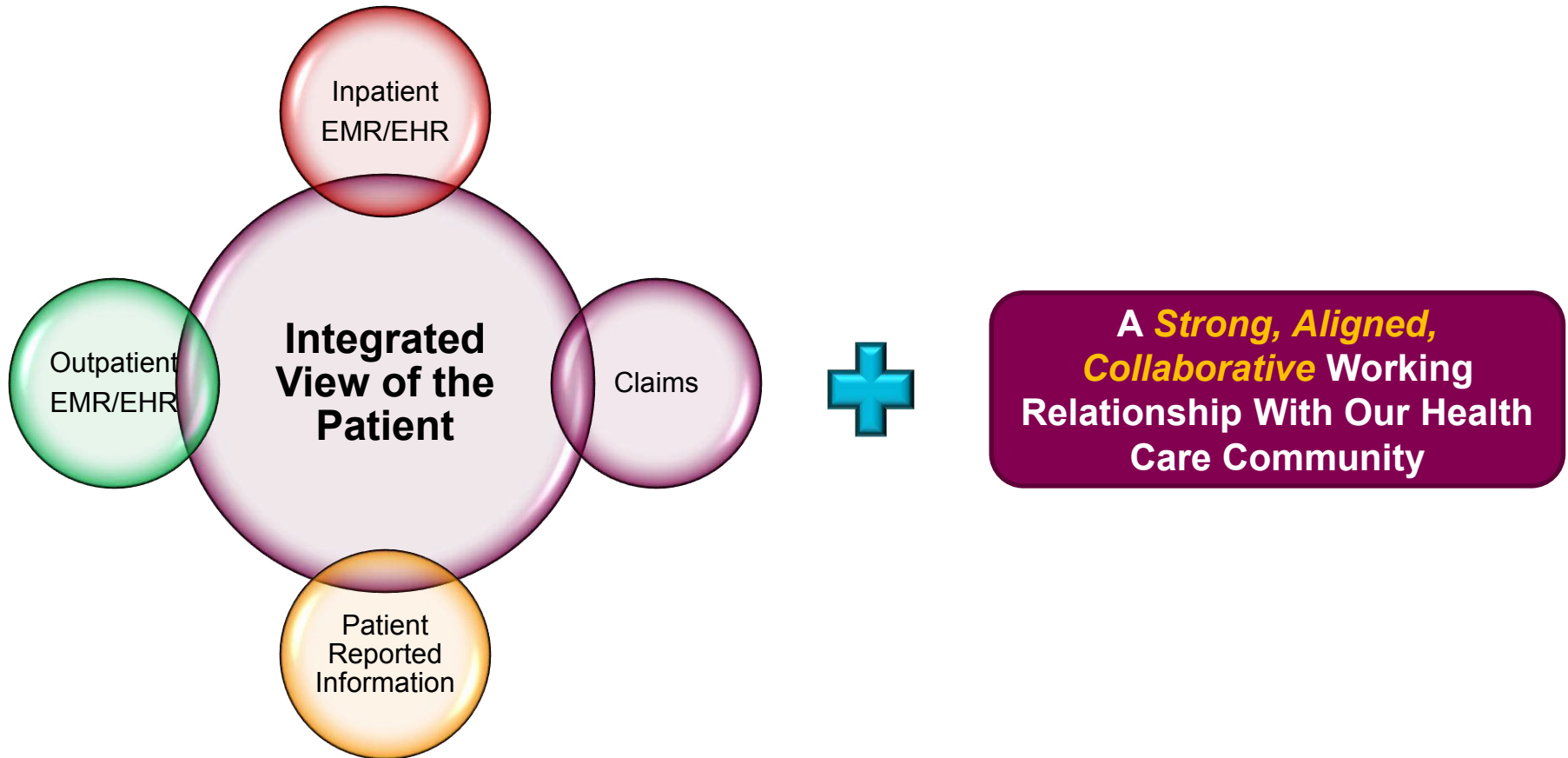


# The value of RWE data to customers

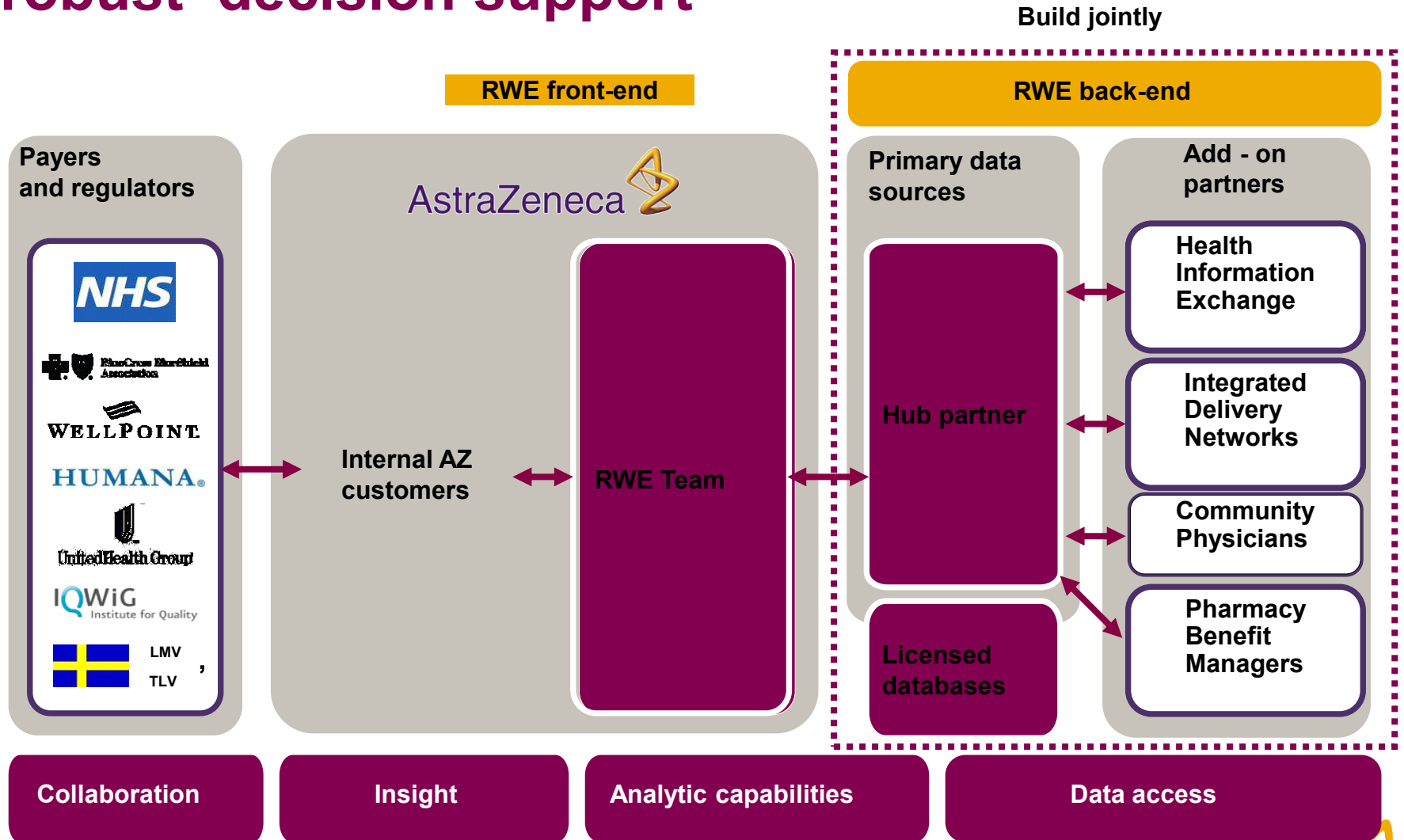
## Strong correlation between data integration and RWE value



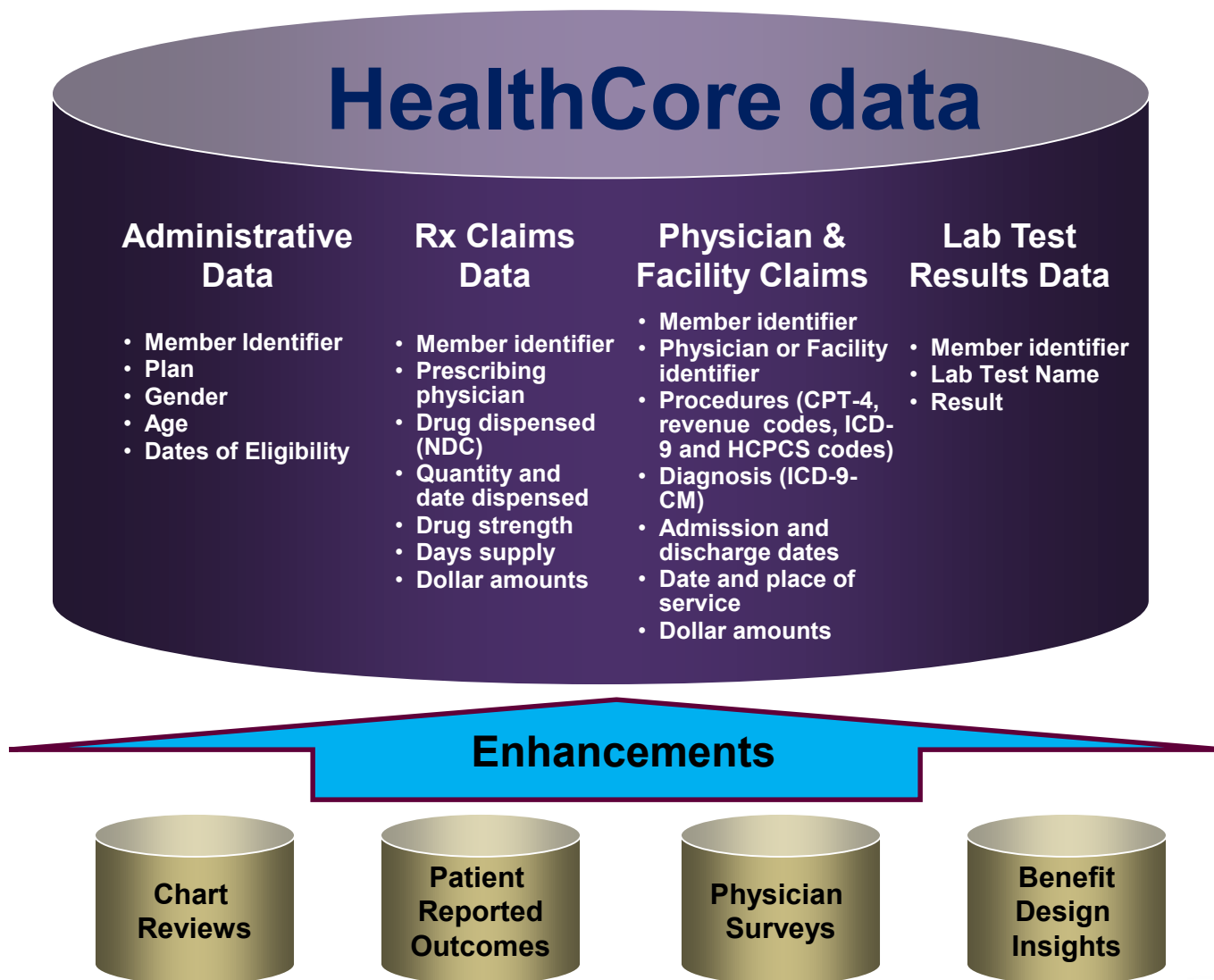
# Data integration is key to quality of RWE results



# The RWE capability provides dedicated RWE analytics capability with enhanced data access for robust decision support



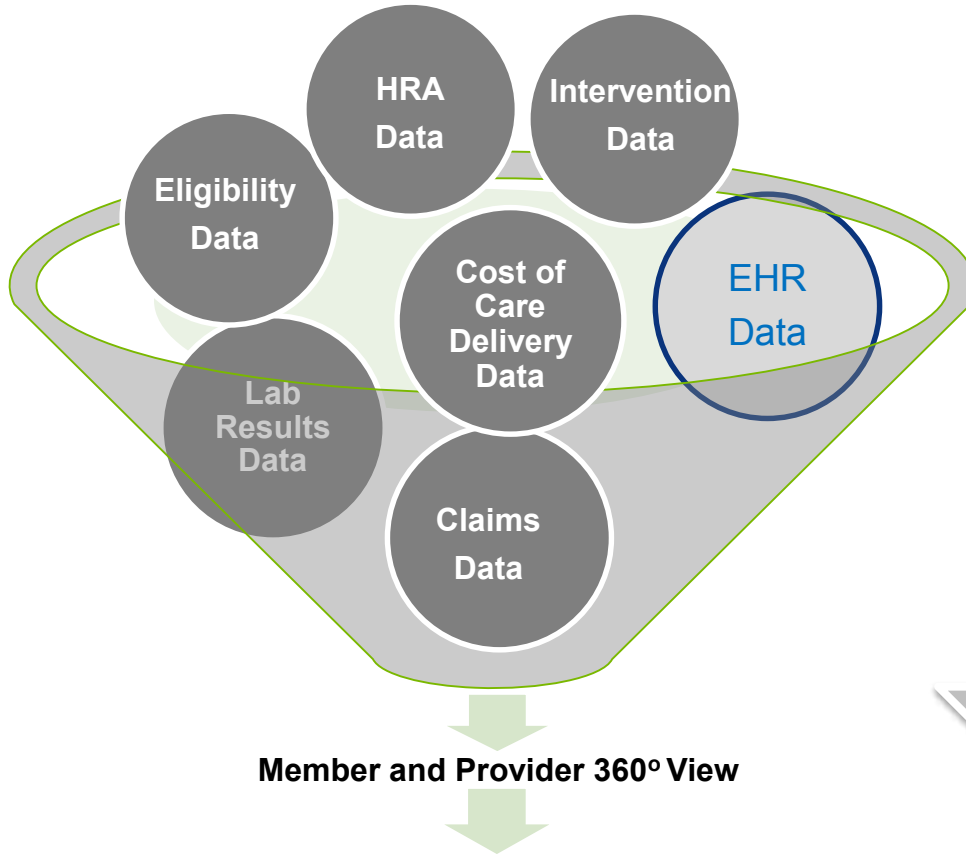
# Data Environment - Elements





# Advancing Outcomes Research

## Patient 360<sup>0</sup> Proof of Concept \*

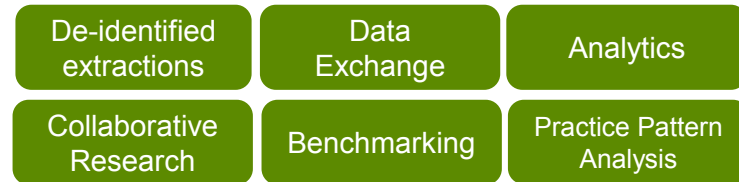
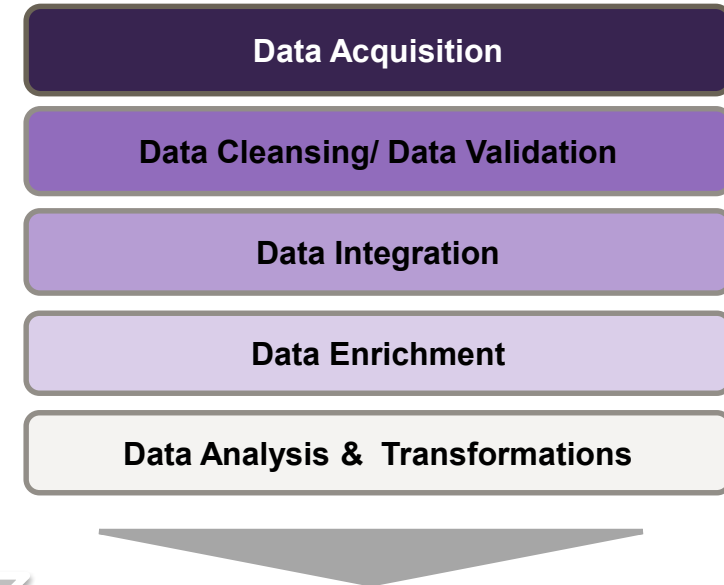


**Member and Provider 360° View**

**Understand true costs vs. reimbursed cost – risk based contracts**  
**Understand drivers of never events**  
**Insights into appropriate coding**  
**Systematic justification for denial of care**  
**Screen/identify/prevent population disease burden**

**Enhance/ Accelerate ECC Clinical  
Healthcare Services Capabilities**

### The value-chain



**\* Potential HealthCore service offerings subject to legal review and approval, and mutual agreement**



# Use of RWE for R&D

## Case Examples:

- Early drug development team requires data on treatment patterns in oncology to assess 'line of therapy fit' for their compound
- Market sizing for potential indications requires deep understanding of 'unmet need'- example: not all hyperlipidemics may be potential targets for a new compound but only those with unmet need/experiencing treatment failure may be targeted
- Comparative effectiveness studies on competing products enable R&D to assess value proposition potential of compounds

