


Speaker
Second Plenary Session
 The Reality of Real World Data and its Use in Health Care Decisions in Europe



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The reality of 'Real World Evidence'
An industry point of view


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ISPOR, November 7th 2011

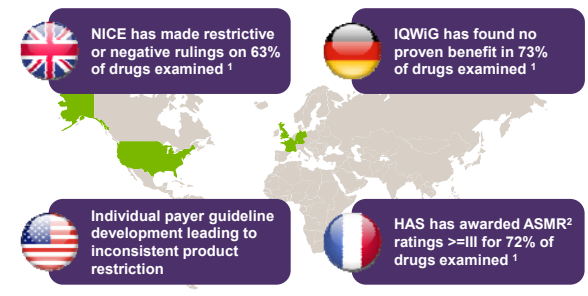






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Payers and HTAs are having a significant impact on our ability to deliver valuable medicines



-  NICE has made restrictive or negative rulings on 63% of drugs examined ¹
-  IQWiG has found no proven benefit in 73% of drugs examined ¹
-  Individual payer guideline development leading to inconsistent product restriction
-  HAS has awarded ASMR² ratings >=III for 72% of drugs examined ¹

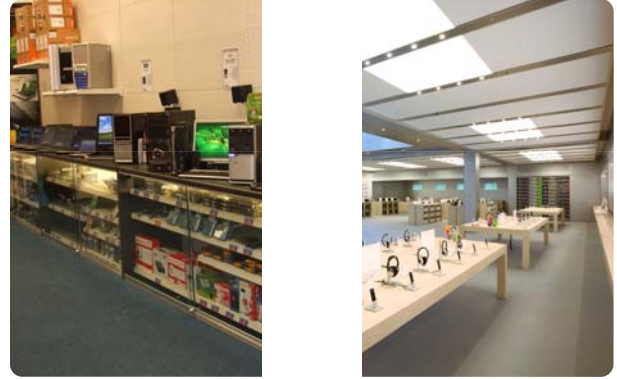
¹ Sample set comprised all products ever assessed by NICE UK (drugs that received EMEA approval)
² ASMR ratings of III and above imply price negotiation and drive towards price parity with comparator
 SOURCE: McKinsey HTA database

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Limited resources; unlimited expectations



Structural redesign of healthcare systems



Today payers are asking us to prove and promote the benefits that they will reimburse in their healthcare systems



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To help the patient, we need to help the payer.



Industry and Healthcare systems are undergoing paradigm shifts

We see an expansion from RCT with strict regulatory focus to a broader stakeholder focus where RCT are complemented by RWE
Evidence of differential benefit is key

Traditional focus on regulatory needs for Quality, Efficacy, and Safety

- Retrospective RCT data used for Value generation
- Stakeholders require dossiers to support market access

Payers have same priority in Medicine development as Patients, Regulators and Clinicians.

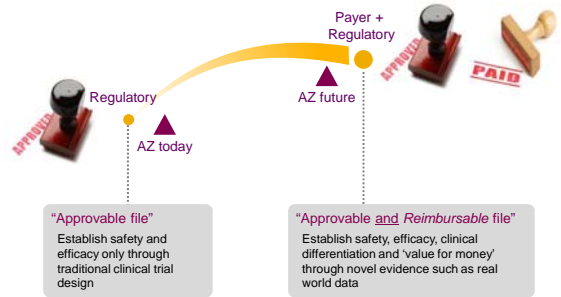
- Value defined by improved Healthcare Outcomes, effectiveness, safety, and economic evidence
- Evidence generated from Phase 3 and post approval studies using RCT and RWE
- Health Technology Assessments are required, but use common methodologies



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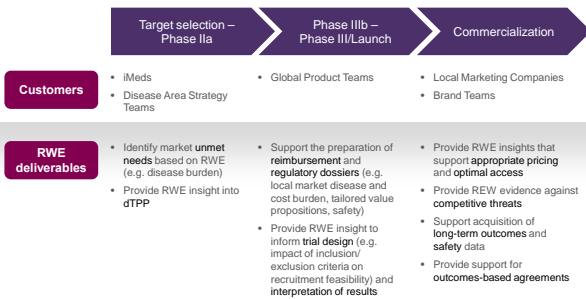
AstraZeneca goal: to be the industry leader in a payer-driven world



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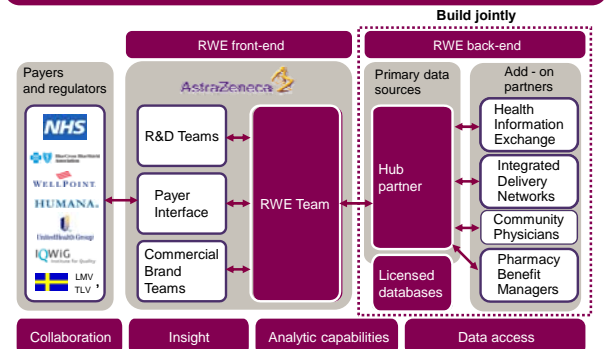
Real World Evidence has internal decision making impact from 'Discovery' through 'Commercialization'



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RWE capability requires skilled people, sophisticated data access, analytics and IT tools, and external partnerships



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Collaborating to generate Real World Evidence

Our aim is to develop and implement collaborations with payers to deliver a benefit to patients, payers and AstraZeneca

Partnership with Health Authority of Abu Dhabi

- Combine complimentary skills in data capture and analysis
- Improve understanding of CV disease burden

BRISA Project

- Murcian HA and AZ two year collaboration
- COPD Epidemiology Study with 400 researchers
- COPD recommendations development

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Trusted RWE capability is one option to reverse the growing data asymmetry and skepticism between payers and pharma

Skeptical of the value of our products

IQWiG

Found no proven benefit in 73% of drugs examined

Using their own RWE data to inform pricing and reimbursement decisions

medco

Mined its own claims database to study effect of Plavix with PPIs

TLV

Uses RWE for QALY-based pricing decisions

Real-World Evidence (RWE) capability

- Demonstrate the value of our medicines in the real world
- Balance the data asymmetry
- Part of Pharma organisational redesign and process change
- Behaviours

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Challenges ~ RWE Data access is geographically divergent



Readily accessible, strong claims orientation

Poor access



Depends on country

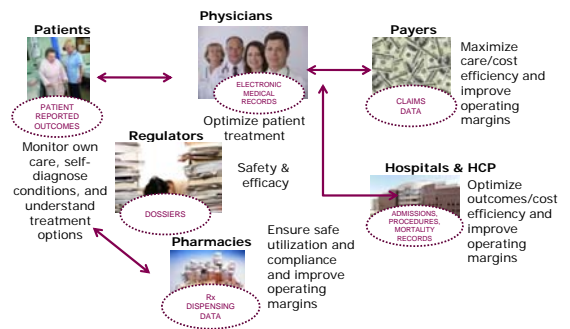
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Challenges ~ Pharma is one of many RWE stakeholders, all with historically divergent motivations.

Different stakeholders have different data-needs



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New rules



Next generation payer interactions

Organisation, process, and behaviour redesign to embed new ways of working with payers and policy makers



Understanding payers from the inside out

Trust-based interactions

Strategic collaborations



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