WHO ARE PAYORS AND WHAT INFORMATION DO THEY NEED?

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Who are payers

- Payers decide the funding of patient treatment. They may be governmental, public or private institutions or organisations of individuals
- Payers have a wide range of backgrounds; clinical, pharmacists, health economic, budget managers. They are under increasing pressure to deliver good quality, affordable healthcare
- The global population is increasing and getting older, they are becoming more learned about healthcare and pose more questions and have greater demands. However, budgets are tighter, spending is more stringent. The payer has to make decisions which balance these two faces

Limited resources – unlimited expectations

France pledges reform after diabetes drug scandal

French Health Minister Xavier Bertrand has promised a complete revamp of the country's medical regulatory system.

Week ending Friday, November 29, 2002

Germany passes unpopular healthcare reform (Reuters) –

The German parliament passed healthcare reform on Friday to overhaul the country's cash-strapped insurance system and plug a threatened 11-billion-euro shortfall in the public health system next year.

NICE to lose powers to decide on new drugs

The medicines watchdog, NICE, is to lose its power to turn down new medicines for use on the NHS. The plans, called value-based pricing, are set to come into effect in 2014.

Drug price reforms cloud outlook for German pharma

It is anything but a happy new year for German pharma. The government's drug price reforms, which have now been enacted, will make a "severe" dent in the sector's revenues, noted Cornelia Yzer, general manager of the German pharmaceutical association, the VFA.

Austerity budget measures introduced in Italy

June 2010 saw the introduction of reimbursement limits for off-patent drugs, generic drug price cuts and a requirement for doctors to prescribe the cheapest equivalent drug.

Payer requirements

- It is no longer the case that a phase III trial meeting its primary endpoint is enough. A drug will face questions, barriers and request for different types of evidence:

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Different markets have varying payer needs

- There is heterogeneity across the world in how the healthcare systems of markets are set-up, and the process in which drugs are reimbursed and prescribed. Broadly we talk of 5 payer archetypes:

Cost effectiveness	A rational methodology of comparing value for improved outcomes	
Comparative clinical effectiveness	Comparing the clinical evidence for similar products to assess value and benefit	
Budget optimisation	Given a fixed budget, what is the best way of allocating theses limited resources	
Competitive rationalisation	Maximising profit whilst achieving healthcare benefit	
Patient-led markets	The patient has influence over purchase	

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Evidence needs in the cost effectiveness markets

In these markets, payers will only reimburse drugs if they meet value criteria; if they are cost effective. The evidence requirements payers need in order to achieve this include:

1. All costs to the healthcare system associated with the disease and/or your drug considered in both the clinical setting and the real world (healthcare resource utilization)
2. Data around costs, resource utilization and pricing at a market level
3. The unmet need of the target patient population
4. An assessment of cost benefit – typically cost effectiveness. This will provide a metric to determine if the drug meets reimbursement criteria

Evidence needs in comparative clinical effectiveness markets

In these markets comparison against competitors and especially against the current standard of care is required. The intention of these payers is to maximise health benefits whilst optimising formulary listings. The evidence requirements to achieve this include:

1. Direct comparison with key comparators – this may be outside of the pivotal trials if necessary
2. Indirect evidence through a mixed treatment analysis, based on a systematic review of evidence

This evidence is used to inform the price bands and the drug formulary tiers in the US.

Evidence needs in budget optimising markets

- In these markets a fixed amount of money is allocated to the budget holder for specific disease areas and at a local practice level
- The budget impact decisions often have to be made at a local level meaning that the budget impact models must be flexible
- Systematic reviews are needed to generate market specific inputs which are critical drivers of a budget impact analysis
- Budget impact analyses are increasingly required by national payer agencies and managed care organizations to estimate the financial consequences of adopting and diffusing a new healthcare intervention within a particular setting of care

Evidence needs for competitive rationalisation market

This payer archetype looks at those payers who focus on maximising profit. They will look for evidence of changing health policy and will ask question around:

- How to save costs
- Can we get the patient to pay more
- Fee for service initiative

1. Literature reviews looking at economical and societal burden of illness are crucial for these payers to generate evidence to reimburse on a lower tier
2. Evidence of the drug working in a large scale RWE trial will allow the sought after broader access

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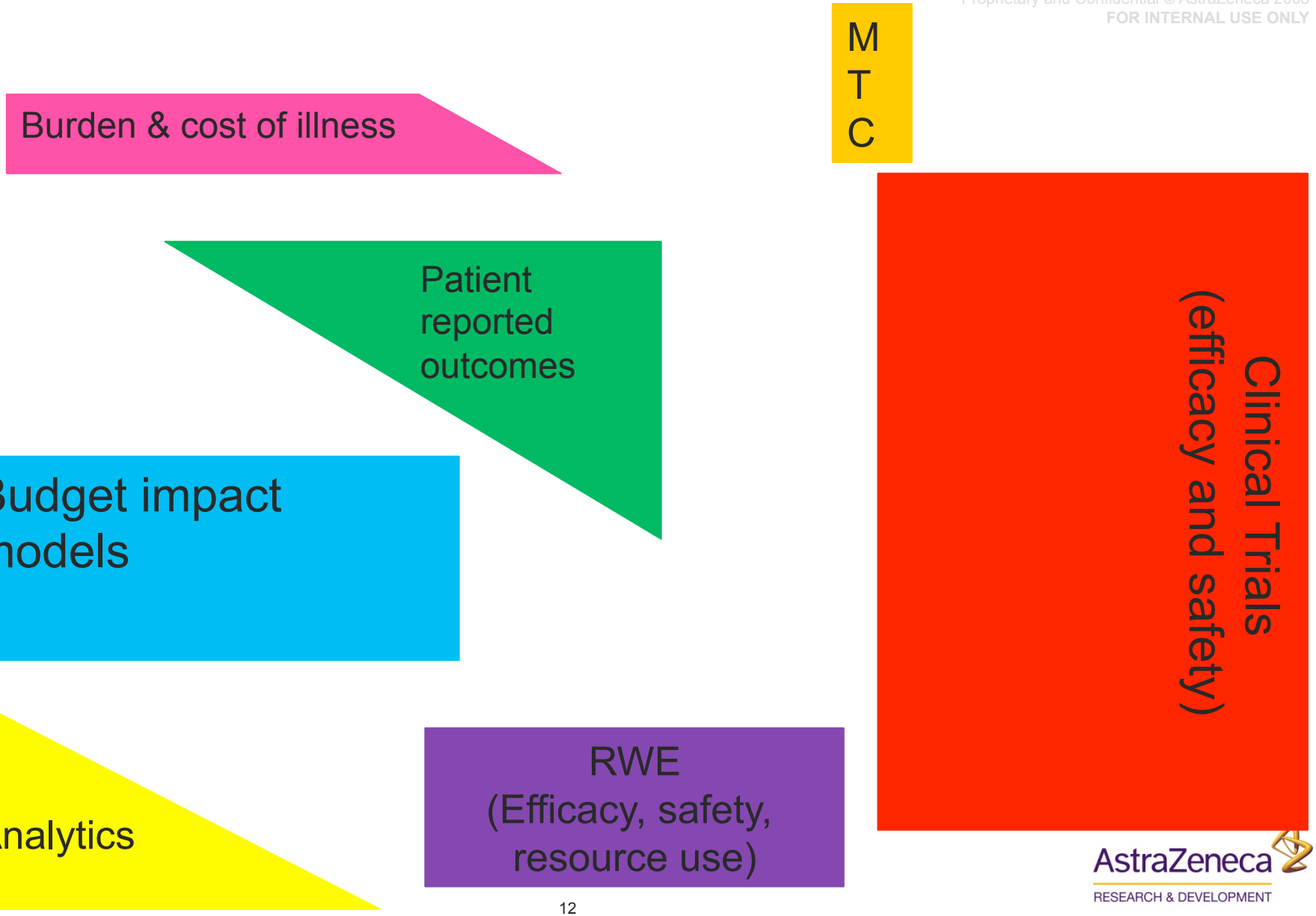
Evidence needs for patient led markets

In this market the patient has greater say and influence over the treatment they receive. The patient is often the payer. It is important to present evidence which resonates with the patient.

1. Patient reported outcomes in trials give the patient their own perspective before using the drug.
2. Burden of disease & burden on the caregiver. If you include endpoints which show that the patients caregiver and family will be less impacted it will be evocative to the patient
3. Comparative effectiveness. Statistical significance is less important here – evidence of how option A compares against option B is easy to understand and quantifiable from the patient perspective

Different types of evidence and analytics



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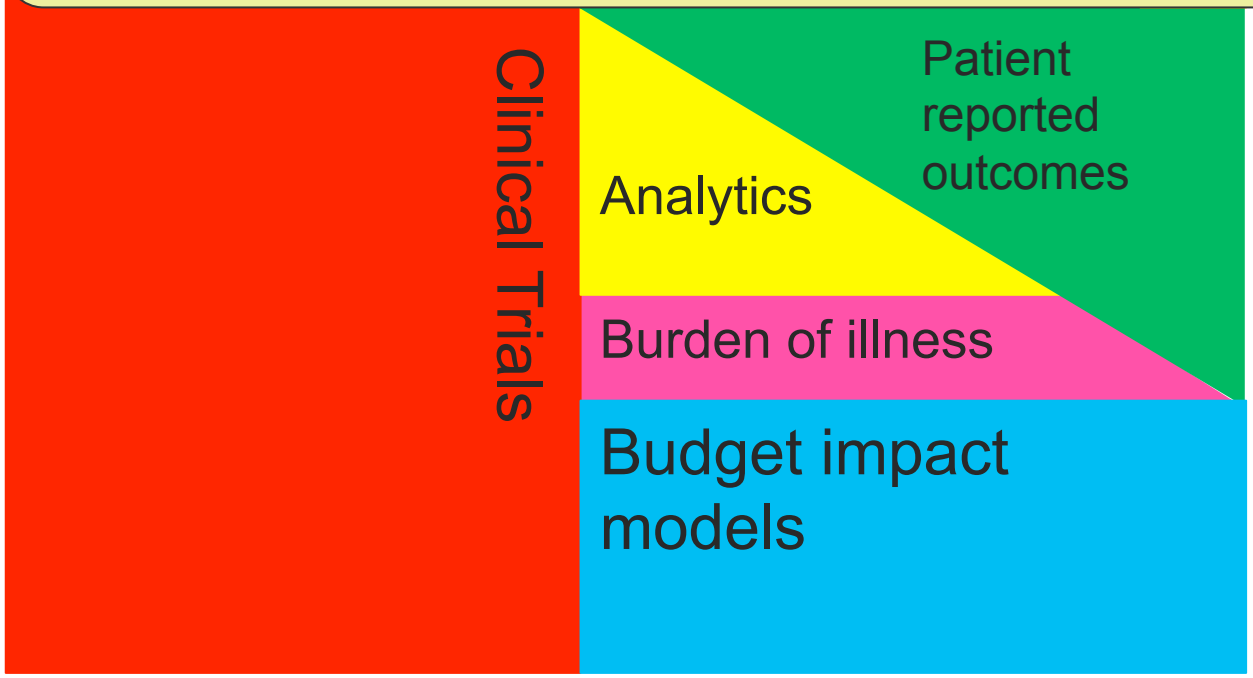
Different types of evidence and analytics

The pieces of evidence on their own are useful. But when you put them together and create the full picture for the payer the story becomes clear and the payer requirements are fully supported



Combine all the pieces together and you get a complete picture of what evidence needs a payer has

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