ONCOLOGY

APPLIED EARLY ECONOMIC MODELLING FOR COMBINATION THERAPIES IN ONCOLOGY: NOVEL VALUE-BASED PRICING APPROACH

WORKSHOP
For distribution to ISPOR Asia Participants
SEPTEMBER 05, 2016
CONFIDENTIAL

OVERVIEW

1700 – 1710
INTRODUCTION
1. Speaker Introductions
2. Objectives

1710 – 1730
RATIONALE / CHALLENGES
1. Early Economic Modelling
2. How it works

1730 – 1745
CASE STUDY
1. Multiple Myeloma

1745 – 1800
Q&A
1. Questions / Answers
Today, the session will be run by two speakers.

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The objective of this session is to explore rationale for, as well as opportunities and challenges associated with early economic modelling in oncology

OVERALL PROJECT GOAL
To explore rationale for, as well as opportunities and challenges associated with early economic modelling in oncology

PROJECT OBJECTIVES

✓ To understand the environmental drivers for early economic modelling
✓ To understand the rationale for use of early economic modelling
✓ To evaluate the challenges and barriers associated with early economic modelling
✓ To understand the commercial and clinical implications of early economic modelling
✓ To explore a real-world example of how early economic modelling was used to extract actionable conclusions
Combination therapies in oncology are already coming to the market, with many more on the horizon.

### COMBINATION THERAPY
### OVERVIEW OF THERAPIES

<table>
<thead>
<tr>
<th>AVAILABLE THERAPIES</th>
<th>TAKE-AWAY (TA)</th>
<th>EMA LAUNCH</th>
</tr>
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<tbody>
<tr>
<td><strong>BASE</strong></td>
<td><strong>ADD-ON</strong></td>
<td><strong>MFG</strong></td>
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<tr>
<td>HER2+ BC</td>
<td>HER2+ BC</td>
<td>Roche</td>
</tr>
<tr>
<td>CLL + NHL</td>
<td>CLL + NHL</td>
<td>Gilead</td>
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<tr>
<td>MELANOMA</td>
<td>MELANOMA</td>
<td>Bristol-Myers Squibb</td>
</tr>
<tr>
<td>MULTIPLE MYELOMA</td>
<td>MULTIPLE MYELOMA</td>
<td>Amgen</td>
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<tr>
<th>FUTURE THERAPIES**</th>
<th><strong>TA</strong></th>
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<tr>
<td><strong>BASE</strong></td>
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*List is not comprehensive but representative of launches expected in upcoming months; research completed in April 2016

NHL: Non-Hodgkin's lymphoma
DEX: dexamethasone

SOURCE: CBPartners Prior Experience
Early economic models are based on the best available known information, as well as likely scenarios for the unknown variables.

**WHAT IS AN EARLY ECONOMIC MODEL?**
- It can assess anticipated cost-effectiveness in different subpopulations, across different comparators, and in different indications.
- NOT designed to be as robust as the cost-effectiveness models.
- Interface is flexible and designed to be exploratory to help shape an initial understanding of the likely drivers of cost-effectiveness.

**WHO SHOULD USE IT?**
- Should be designed for both health economists and non-health economists.
- Analysis modules:
  - Clinically supported price
  - Minimum efficacy necessary to support desired price
  - Sensitivity analyses
  - Cost-effectiveness accessibility curves
  - Expected value of perfect information

**WHAT IS THE PURPOSE?**
When designed for use in oncology, there are two questions answered:
1. Based on anticipated clinical data, what cost-effective price is supported?
2. In order to achieve a desired price for your asset, what minimum incremental overall survival (OS) / progression-free survival (PFS) relative to the current standard of care need to be achieved?

**WHAT DATA IS NEEDED TO USE THIS MODEL?**
- At a minimum:
  - Comparator data, including median or mean OS and PFS, dosing schedule and pricing
  - Key asset data, including pricing of marketed regimen components, survival assumptions
  - All other inputs necessary for the model to run properly are stored in a broadly applicable ‘base case’ and can be modified if necessary
  - E.g., AE rates / costing; utilities and disutilities; and, healthcare resource utilisation rates and costs

Early economic models can be useful in the clinical and commercial development of new health technologies.
Early economic models can be used to answer different key questions relative to ‘late’ economic models.

<table>
<thead>
<tr>
<th>EARLY ECONOMIC MODELS</th>
<th>QUESTIONS ANSWERED</th>
</tr>
</thead>
<tbody>
<tr>
<td>‘LATE’ MODEL</td>
<td>EARLY MODEL</td>
</tr>
<tr>
<td>What is the economic value of this asset?</td>
<td>How does economic positioning of the product affect go / no-go decisions for development?</td>
</tr>
<tr>
<td>What is the ICER for this product from the relevant market perspective?</td>
<td>What level of efficacy (and which endpoints), is required to demonstrate cost-effectiveness?</td>
</tr>
<tr>
<td>Which parameters drive costs and cost offsets for this product?</td>
<td>Which efficacy parameters are the biggest drivers of cost-effectiveness?</td>
</tr>
<tr>
<td>What is the economic value of this product at its anticipated price in this market?</td>
<td>What preliminary price can be supported for the product for the purposes of forecasting?</td>
</tr>
<tr>
<td>How do the PHASE III clinical outcomes translate into economic benefits?</td>
<td>Which endpoints should be investigated in Phase III clinical trials?</td>
</tr>
<tr>
<td>What is the relative cost-effectiveness in different sub-groups?</td>
<td>Which populations / indications should be targeted?</td>
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Early stage models aim to inform internal decisions related to product development, while late stage models aim to inform external decision-making on resource allocation.

As early models inform different types of decisions, they differ in terms of structure, complexity and certainty.

<table>
<thead>
<tr>
<th>EARLY ECONOMIC MODELS</th>
<th>COMPARISON WITH LATE MODELS</th>
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<tbody>
<tr>
<td>‘LATE’ MODEL</td>
<td>EARLY MODEL</td>
</tr>
<tr>
<td><strong>FLEXIBILITY</strong></td>
<td><strong>FLEXIBILITY</strong></td>
</tr>
<tr>
<td>LESS FLEXIBLE</td>
<td>MORE FLEXIBLE</td>
</tr>
<tr>
<td>As late stage models aim to answer specific questions their structure needs to be fixed, designed to consider costs and health outcomes in a specified population and indication</td>
<td>As early models aim to answer a wider set of questions their structure needs to be flexible to consider different indications and populations</td>
</tr>
<tr>
<td><strong>COMPLEXITY</strong></td>
<td><strong>SIMPLER</strong></td>
</tr>
<tr>
<td>MORE COMPLEX</td>
<td>Early models typically have a simpler structure, both because of the requirement to maintain flexibility and because less data is likely to be available</td>
</tr>
<tr>
<td>Late stage models are usually more complex to more accurately reflect disease progression and risks and incorporate all available data</td>
<td></td>
</tr>
<tr>
<td><strong>CERTAINTY</strong></td>
<td><strong>GREATER ACCURACY</strong></td>
</tr>
<tr>
<td>LESS CERTAIN</td>
<td>As the late stage models are more complex and populated with more accurate data the results are more certain and can be used to inform external decisions</td>
</tr>
<tr>
<td>The results of early economic models are less certain as they aim to be indicative of relative cost-effectiveness therefore they should not be shared externally</td>
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</table>
A range of factors can be considered in the development of an early model for a product portfolio.

**EARLY ECONOMIC MODELS**

**DISCUSSION**

- Preliminary data/estimates of progression-free survival, response rate, and overall survival can be valuable inputs on which to base the model calculations.

- Partitioned survival analysis with generalisable health states (e.g., progression-free, progressive, death) can facilitate generalisability across a portfolio of products.

- Depending on the model objectives, a variety of analyses are available for early model outputs, including deterministic sensitivity and value of information analyses.

**MODEL INPUTS**

**MODEL STRUCTURE**

**MODEL OUTPUTS**

Before early economic modelling begins, structural considerations must be aligned upon.

**INTERFACE STRUCTURE / ANALYSIS MODULES**

- What are the pros / cons of employing a partitioned survival vs. a Markov model?
- Will a typical 3-state model satisfy the broadest possible set of analogues?
- What should be the base case market from a costing perspective?
- What are the key interface study endpoints?
- Which analyses should be performed within the interface, and how should these vary based on the intervention question posed?

**INTERVENTION QUESTIONS / SCENARIOS**

- What are the key questions the interface should help to answer?
- How many scenarios should the user be able to investigate at one time?

**HARD-CODED VS. MODIFIABLE INPUTS**

- What variables should be user-modifiable vs. hard-coded? How will this vary based on the intervention question being asked?
Once built, the model’s utilisation will follow a specific flow in order to elicit the desired information for the asset.

**DEFINE STRUCTURAL INPUTS**
- Nature of intervention arm
- Nature of comparator arm
- Utility for PFS and PD states

**DEFINE COMPARATOR DATA**
- Median OS
- Median PFS
- Cost of comparator regimen

**DEFINE INTERVENTION QUESTION**
- Option A: With these data, what value-based price is supported?
- Option B: If we want to achieve a price of $X, what OS and PFS data need to be achieved?

**ENTER INTERVENTION DATA**
- Expected median OS
- Expected median PFS

**RUN ANALYSIS**
- Desired price

**INTERPRET RESULTS**

Repeat process for alternate scenarios

SOURCE: CBPartners Prior Experience

Several visualisations are possible for the early economic model interface outputs.

**EARLY ECONOMIC MODEL VALUE interface**

(A) **VALUE-BASED PRICE**
- Implicit assumption of WTP of USD 100,000 / QALY

(B) **INCREMENTAL COST EFFECTIVENESS RATIO**
- Distribution of likely ICER values

POTENTIAL SCENARIO VARIABLES
- Choice of comparator
- Expected state utilities
- Intervention adverse event profiles
- Intervention patient subpopulations

SOURCE: CBPartners Prior Experience
Solving for the minimum relative efficacy (with OS and PFS as variables) to achieve our desired price will require two-dimensional visualisation.

A value of information analysis can help to inform whether further investment in research is likely to be cost-effective.

1. PERFORM PSA-BASED NMB ANALYSIS
2. PERFORM PATIENT LEVEL EVPI ANALYSIS
3. TRANSFORM TO POPULATION LEVEL EVPI

- A population-based EVPI can help to prioritise research investment across different indications
- EVPI analysis can also be structured to isolate the impact of further research on a specific variable (e.g. QoL, decrease in hospitalisations, etc.)
The following sources are recommended to be queried in order to arrive at the set of data that will be used to develop the model inputs for the proof-of-concept exercise.

**SEARCH STRATEGY**

**SUGGESTED SOURCES**

**LITERATURE**
- Embase, PubMed
  - Epidemiological and clinical data; clinical practice guidelines

**CONGRESS ABSTRACTS**
- ASCO
  - American Society of Clinical Oncology
- ESMO
  - European Society for Medical Oncology
- ISPOR
  - International Society for Pharmacoeconomics and Outcomes Research

**DATA ON FILE**
- Sanofi
  - Latest data from on-going studies

**REGULATORY / ACCESS LANDSCAPE**
- HAS
- NHS
- CADTH
- Updated market landscape for asset and its competitors; utility data (NICE / SMC submissions)

**OVERVIEW**

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<tr>
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<td>2. How it works</td>
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The following case study is a real-world example of a product being considered for approval in MM indications.

In this analysis, ≥2L MM indications PRODUCT X achieves a cost-effective price at a WTP of GBP 20,000 / QALY.

**KEY POINTS**

- For PRODUCT X, a threshold of £20,000 / QALY can generate a sustainable price for the product’s acquisition costs due to the baseline therapy not being taken into progression and administered for a median of seven cycles.
- When BASELINE is discounted, the acquisition costs decrease and the price of PRODUCT X increases slightly.
- Acquisation and administration costs of the intervention are the main driver behind the relative difference in costs, while terminal care costs are generally similar across both arms.
In this analysis, 22L MM indications PRODUCT X cannot achieve a cost-effective price at a WTP of GBP 20,000 due to the high costs of the baseline therapy.

**KEY POINTS**

- For PRODUCT X, only a very high WTP can generate a positive value for PRODUCT X's acquisition cost, as the increased costs from BASELINE due to increased PFS vastly increase PRODUCT X-independent acquisition costs.
- Acquisition costs of the non-PRODUCT X components of the comparator therapy are the main driver behind the relative difference in costs, while monitoring and terminal care costs are generally similar across both arms.

**TOTAL COSTS RESULTS**

<table>
<thead>
<tr>
<th>Product</th>
<th>Acquisition Costs</th>
<th>Administration Costs</th>
<th>Monitoring Costs</th>
<th>AE Costs</th>
<th>Terminal Hosp Costs</th>
</tr>
</thead>
<tbody>
<tr>
<td>BASELINE</td>
<td>£38,643</td>
<td>£55,160</td>
<td>£1,808</td>
<td>£0</td>
<td>£3,381</td>
</tr>
<tr>
<td>PRODUCT X + BASELINE</td>
<td>£7,717</td>
<td>£1,996</td>
<td>£1,230</td>
<td>£0</td>
<td>£3,460</td>
</tr>
<tr>
<td>BASELINE (35% disc)</td>
<td>£120,000</td>
<td>£40,000</td>
<td>£60,000</td>
<td>£80,000</td>
<td>£100,000</td>
</tr>
</tbody>
</table>

**SOURCE:** CBPartners / SANOFI Prior Experience

In a classic cost-effectiveness market like the UK, only one positive decision made by NICE had no known rebates or restrictions.

**NICE (ENG) HTA REVIEW SUMMARY**

- The manufacturer rebates the full cost in patients after 26 cycles (28 days).
- Lenalidomide (REVLIMID)
- Palidomide IMNOVID

**OCT 2007**
- VELCADE/dex (Vd) Bortezomib
- (≥2L, MM)

**DEC 2011**
- VELCADE (Vd) Bortezomib
- Thalidomide
- (1L, MM)

**MAR 2012**
- No rebate or risk-sharing agreement was stipulated, but VELCADE was only recommended in 1L if stem cell transplant is not appropriate and thalidomide is contraindicated.

**JUL 2014**
- No rebates or restrictions

**MAR 2015**
- Palidomide IMNOVID

**SOURCE:** CBPartners / SANOFI Prior Experience
The main reason for the negative decision for POM in >2L was that the ICER was above GBP 50K after the manufacturer was requested to revise their assumptions.

### NICE (ENG) HTA REVIEW

POM + LD dex was compared to 3 comparators in >2L

- **POM + LD dex**
- **BORTEZOMIB + LD DEX**
- **THALIDOMIDE + HD DEX + CYCLOPHOSPHAMIDE**
- **BENDAMUSTINE + THALIDOMIDE + LD DEX**

### ASSUMPTIONS

- **OS**: 0.977 years
- **Median PFS**: 0.307
- **EFFICACY**: 2.225 Mean LYS gained

- **OS**: 0.422 years
- **Median PFS**: 0.249
- **EFFICACY**: 1.166 Mean LYS gained

Uncertainty around the clinical evidence and inappropriate assumptions for the utility values and cost assumptions were the main criticisms of the manufacturer's model.

### MAIN CRITICISMS FROM NICE

- The SLR submitted missed key studies
- Some of the comparators (high dose dex) were inappropriate
- The discounted price bortezomib was not applied (they assumed list price)
- Uncertainty around the disutility with IV drug use was not considered and favoured POM
- There was no justification for only including disutility for adverse events in 2% of patients
- The disutility values applied for adverse events underestimated the effect of adverse events
- The Kaplan-Meier plots for OS in the manufacturers submission over estimated survival for POM and underestimated survival for comparators

### IMPLICATIONS FOR SUBMISSIONS

**ENG; CLINICAL INPUTS**

<table>
<thead>
<tr>
<th>DO</th>
<th>DO NOT</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CLINICAL EVIDENCE</strong></td>
<td>Ensure the model is based on most robust clinical evidence available</td>
</tr>
<tr>
<td><strong>SELECTING INPUTS</strong></td>
<td>Be consistent; justify selection of inputs for OS / PFS / ORR</td>
</tr>
<tr>
<td><strong>COMPARATORS</strong></td>
<td>Select comparators based on market authorisation / current practice</td>
</tr>
<tr>
<td><strong>COMPARATORS COST ASSUMPTIONS</strong></td>
<td>Consider the price expected to be applied in practice</td>
</tr>
<tr>
<td><strong>COMPARATOR EVIDENCE</strong></td>
<td>Ensure efficacy data is obtained from comparable clinical trials</td>
</tr>
</tbody>
</table>

SOURCE: CBPartners / SANOFI Prior Experience
There are also lessons regarding the model structure and assumptions that should be considered when developing evidence for a product under development.

### IMPLICATIONS FOR SUBMISSIONS

**ENG: MODEL STRUCTURE AND ASSUMPTIONS**

<table>
<thead>
<tr>
<th>DO</th>
<th>Do not</th>
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<tbody>
<tr>
<td><strong>MODEL STRUCTURE</strong></td>
<td>Apply a transparent structure, e.g., Markov</td>
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<tr>
<td></td>
<td>Have an unnecessarily complex structure perceived as a 'black box'</td>
</tr>
<tr>
<td><strong>MAINTENANCE THERAPY &amp; DOSING</strong></td>
<td>Ensure the assumptions applied are consistent and justified</td>
</tr>
<tr>
<td></td>
<td>Apply dosing / maintenance therapy assumptions that favour intervention</td>
</tr>
<tr>
<td><strong>UTILITIES</strong></td>
<td>Source utility / dis-utility values appropriate to the indication</td>
</tr>
<tr>
<td></td>
<td>Omit dis-utilities for adverse events or apply dis-utility assumptions for IVs</td>
</tr>
<tr>
<td><strong>STOPPING RULES</strong></td>
<td>Consider alternative stopping-rules</td>
</tr>
<tr>
<td></td>
<td>Apply efficacy assumptions to non-responders w/o explicitly stating this</td>
</tr>
<tr>
<td><strong>SCENARIO ANALYSIS</strong></td>
<td>Consider appropriate and justified sub-groups</td>
</tr>
</tbody>
</table>

### IMPLICATIONS FOR SUBMISSIONS - FRA

**SUMMARY OF HAS DECISIONS**

- Based on clinical significant median OS (51.6 vs. 48.1 vs. 34), PFS (27.6 vs. 17.2/19.4) reported in a single phase III RCT

Decision based on clinical significant median OS (48.1 vs. 34), PFS (15.7 vs. 8), ORR (80% vs 57%) reported in a single phase III RCT

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An ASMR <III has been historically attainable with clinical significant ORR or PFS, even if OS is similar or not available yet and if only reported in a single RCT.

**SOURCE:** CBPartners / SANOFI Prior Experience
The outcomes of previous HAS decisions should also be considered when preparing to launch a new oncology product.

**IMPLICATIONS FOR SUBMISSIONS - FRA CURRENT ENVIRONMENT**

<table>
<thead>
<tr>
<th>DO</th>
<th>CURRENT ENVIRONMENT</th>
</tr>
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<tbody>
<tr>
<td><strong>CLINICAL EVIDENCE</strong></td>
<td>Demonstrate a clinically significant or substantial OS, PFS and ORR</td>
</tr>
<tr>
<td><strong>Submit phase II or phase II trials, and multiple studies if available</strong></td>
<td>Assume minor improvements in key clinical endpoints (OS, PFS, ORR) will secure access</td>
</tr>
</tbody>
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**FUTURE ENVIRONMENT**

<table>
<thead>
<tr>
<th>DO</th>
<th>FUTURE ENVIRONMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CLINICAL EVIDENCE</strong></td>
<td>Applying the same criteria for clinical evidence submitted to HAS, as detailed in the previous slide</td>
</tr>
<tr>
<td><strong>Develop economic evidence, applying HAS PE guidelines</strong></td>
<td>Assume demonstrating clinical benefit alone sufficient to gain access</td>
</tr>
</tbody>
</table>

**ECONOMIC EVIDENCE**

<table>
<thead>
<tr>
<th>Do not</th>
<th><strong>Assume that ICER &gt; €75k / QALY will be accepted</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ensure all modelling inputs are adequately justified</strong></td>
<td>Aim to demonstrate cost-effectiveness as ~ €75k / QALY</td>
</tr>
</tbody>
</table>

As an economic submission is expected to be required for future launches; hence, the implications of this should also be considered.

To date, CEESP do not appear to apply a formal WTP threshold:
- HAS has accepted interventions with ICERs as high as €300,000/QALY, but most of the interventions recommended have been around €75,000 / QALY, thus there is a growing consensus that decisions will be accepted around this WTP threshold, with some decisions accepted at a higher threshold.
- Compared to NICE, CEESP decisions are expected to be more flexible in respect to ICERs and more focused on robust methodology, clinical effect, burden of illness and budget impact.
- While price is not fixed based on the economic submission, price set in the economic dossier is expected to be an important starting point for eventual pricing negotiation with CEPS.

**SOURCE:** CBPartners / SANOFI Prior Experience
The HAS guidelines on economic evaluation are broadly aligned with the NICE for economic submissions.

### HEALTH ECONOMIC SUBMISSIONS

#### SIMILARITIES

**COMMON TO BOTH HAS & NICE GUIDELINES**

<table>
<thead>
<tr>
<th>DATA SOURCING</th>
<th>• Both require similar methods for data identification, production and validation, preferring systematic literature review</th>
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<tbody>
<tr>
<td>CLINICAL EVIDENCE</td>
<td>• Both require similar sources of clinical evidence (favouring head-to-head RCTs and meta-analysis)</td>
</tr>
<tr>
<td>UTILITY DATA</td>
<td>• Cost utility analysis is the preferred type of analysis in both</td>
</tr>
<tr>
<td>SUBGROUP ANALYSIS</td>
<td>• In both, subpopulations should be considered</td>
</tr>
<tr>
<td>TIME HORIZON</td>
<td>• Time horizon should be long enough to capture all differences in costs and outcomes</td>
</tr>
<tr>
<td>SENSITIVITY ANALYSIS</td>
<td>• Both require a sensitivity analysis, with probabilistic sensitivity analysis (PSA) being the preferred for both HAS and NICE</td>
</tr>
</tbody>
</table>

The guidelines for developing health economic evaluations are broadly similar in both countries in terms of the preferred type of analysis, data inputs and the approach to sensitivity and sub-group analyses.

**SOURCE:** CBPartners / SANOFI Prior Experience


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However, there are also some methodological differences in the HAS and NICE guidelines that should be considered when adapting models to FRA.

### HEALTH ECONOMIC SUBMISSIONS

#### DIFFERENCES

**DIFFERENCES BETWEEN NICE & HAS GUIDELINES**

| ANALYSIS | Only recommends cost-utility analysis | Accepts that sometimes cost per LY is more appropriate than cost / QALY |
| POPULATION | The population considered should match the market authorisation | All populations for whom health is directly or indirectly affected by the intervention |
| COMPARATORS | Comparators should have market authorisation | The intervention should be compared to all relevant comparator interventions, irrespective of market authorisation |
| UTILITY | Utility should be derived using EQ-5D data sourced from a UK population | Prefers EQ-5D data to be sourced from a French population but recognises French EQ-5D data is not always available |
| COSTS | Costs should be considered from a NHS and Personal Social Services (PSS) perspective only | In addition to costs from a NHS and PSS perspective, HAS considers patient travel and time costs, costs borne by other stakeholders and carer’s costs |
| DISCOUNTING | Future costs and outcomes should be discounted at 3.5% | Future costs and outcomes should be discounted at 4% |

**SOURCE:** CBPartners / SANOFI Prior Experience

In summary, early economic models serve a useful purpose to inform clinical development, commercial, and payer needs.

**EARLY ECONOMIC MODELS**
**SUMMARY**

**RECAP OF BENEFITS OF THIS EARLY ECONOMIC INTERFACE**

- The Interface is designed to consider a wide range of scenarios that can be applied to new drugs, alternative comparators, in different populations and for different indications / lines of therapy.
- It is intended to be used by the different organisational functions involved in different aspects of the product development process (HEOR, R&D, Pricing and Marketing).
- It can be used to inform decisions when planning research and acts as a platform to develop subsequent economic models.
- CSP & VBO analyses can both be used to inform go/no go decisions and develop the economic positions and pricing and targeting strategies.
- The results from both the CSP and VBO analyses can be further explored by analysing survival and costs, or conducting sensitivity or EVPI analysis.

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