WHAT INFLUENCES THE PROBABILITY TO BE SUCCESSFUL IN AN ONCOLOGY HTA? AN ANALYSIS OF ONCOLOGY HTA DECISIONS IN GERMANY, SPAIN AND THE UK

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Background and objectives

Background

- HTA has become the key health policy instrument for managing new oncology drugs in Europe, but there might exist differences between countries.
- For HTA bodies and pharmaceutical companies, important to understand drivers of oncology-related HTA decisions.

Objectives

- Investigate the factors affecting decisions in oncology HTAs in Germany, Spain and the UK.
- Deep dive analysis for the case of Germany to gain insights into the drivers of a successful oncology HTA process.

Data sources (INGRESS HTA Databank)

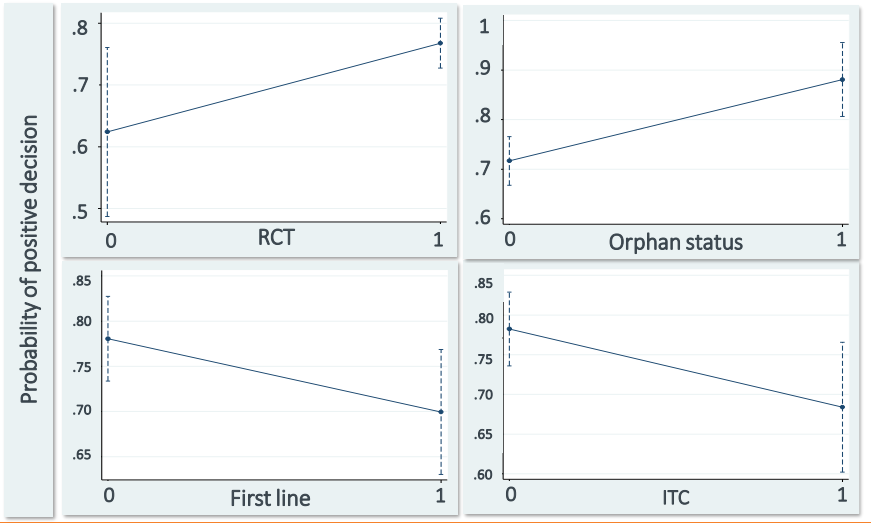
	Germany	Spain	United Kingdom
What is reviewed?	Dossiers and G-BA's assessments in oncology	AEMPS therapeutic positioning reports in oncology	Dossiers and NICE`s assessments in oncology
Timeframe	01/2012 – 03/2019	01/2013 – 03/2019	01/2001 – 03/2019
Coverage	Clinical evidence (RCT, single arm trials, ITC, PROs, comparators), clinical endpoints, RWE	Clinical evidence (RCT, single arm trials, ITC, PROs), clinical endpoints, cost-effectiveness	Clinical evidence (RCT, single arm trials, ITC, PROs), clinical endpoints, cost-effectiveness
Number of HTAs	N=153, 74% positive	N=72, 65% positive	N=211, 80% positive

Methods (Multivariate logistic regression)

Dependent variables	Independent variables
Large, considerable, minor, not quantified added benefit	First line treatment (Yes/No)
No added benefit, benefit less than alternative	RCT as main evidence (Yes/No)
Recommendation as per therapeutic positioning reports	Orphan status (Yes/No)
Rejection as per therapeutic positioning reports	Year of assessment
Recommended, optimized; CRF: recommended, optimized	Indication type (dummy var. for each indication)
Not recommended, only in research, terminated appraisal	ITC presented (Yes/No)
	Country of assessment

CRF: Cancer Research Fund | RCT: Randomized control trial | ITC: Indirect treatment comparison

Results of multivariate logistic regressions



Controls

- Country of assessment
- Year of assessment
- Indication type

Results

- RCT as main evidence and Orphan status → probability of positive decision by >10 pp.
- First line therapies and ITC → nearly 10 pp lower probability of positive decision.

Case of Germany

Deep dive in Germany

Due to diverse decision-making procedures, countries are hard to compare in all dimensions.

Therefore, deep-dive in one country (Germany) to gain insights into:

- Clinical and QoL endpoints
- Comparators
- Type of evidence presented

Finally, influence of these factors on the ultimate G-BA decision were assessed.

Variable definitions and methodology

Dependent variables	Comparators	Endpoints	Binary variables
Extent of benefit	BSC + Placebo	Overall survival Progression-free survival Response rate Quality of life	First line treatment
	Chemotherapy (ATC L01-)		RCT as main evidence
	Other medication (antigen/immune ATC LXX-L01) or therapies (e.g. ASCT)		Orphan status
	Comparator as SoC in at least one subgroup		Year
			Indication type
			RWE presented
			ITC presented
			Mutation-specific evidence presented

Levels	Binary classification of levels
Large= 4	Significant = 1
Considerable = 3	Considerable = 1
Minor = 2	Moderate or partial = 1
Not quantified = 1	No difference = 0
No add. benefit = 0	Worse = 0
> alternative = -1	

Method

Extent of benefit was analyzed as a function of other variables in an **ordered logit framework**.

What do the results mean for future submissions?

Ordered logit model	Extent of benefit	
Endpoints	**OR**	**P-value**
Overall survival (N=104)	6.734	(0.000)
Progression-free survival (N=83)	0.739	(0.507)
Response rate (N=64)	0.838	(0.685)
Quality of life (N=38)	5.074	(0.000)
Characteristics of technology		
First line (Yes/No) (N=41)	0.313	(0.007)
Orphan (Yes/No) (N=46)	2.692	(0.000)
Characteristics of evidence presented		
Mutation evidence (Yes/No) (N=59)	1.253	(0.598)
ITC presented (Yes/No) (N=37)	0.227	(0.004)
RWE presented (Yes/No) (N=146)	4.695	(0.087)
RCT presented (Yes/No) (N=122)	3.108	(0.028)
Comparators		
Chemotherapy (N=78)	0.610	(0.351)
Other medications/therapies (N=21)	0.702	(0.611)
BSC/Placebo (N=46)	0.884	(0.790)
Comparator as SoC in at least one subgroup (N=31)	1.347	(0.578)
N	**153**	
Pseudo R^2	**0.234**	

Limitations & conclusions

Limitations

- Cross-country comparison only in few respects → risk of **omitted predictors**
- **Only time-invariant healthcare system-level factors** are controlled (via country dummies).

Summary

- RCT & orphan drug → positive assessment
- ITC correlated with weak head-to-head evidence → negative decision probability.
- HTA bodies prefer treatments that are first introduced in late lines of treatment.
- Presenting convincing RWE → a positive HTA decision.
- OS and QoL → positive assessment in Germany.

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Do you have any questions?
Feel free to contact us!

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