CERTARA | EVIDENCE & ACCESS

VALUE FRAMEWORKS & ICER – IMPLICATIONS FOR ACCESS

In the last couple of years, we have been witnessing the emergence of multiple criteria decision analysis tools and value frameworks for assessing benefits of new medicines especially in oncology and rare diseases

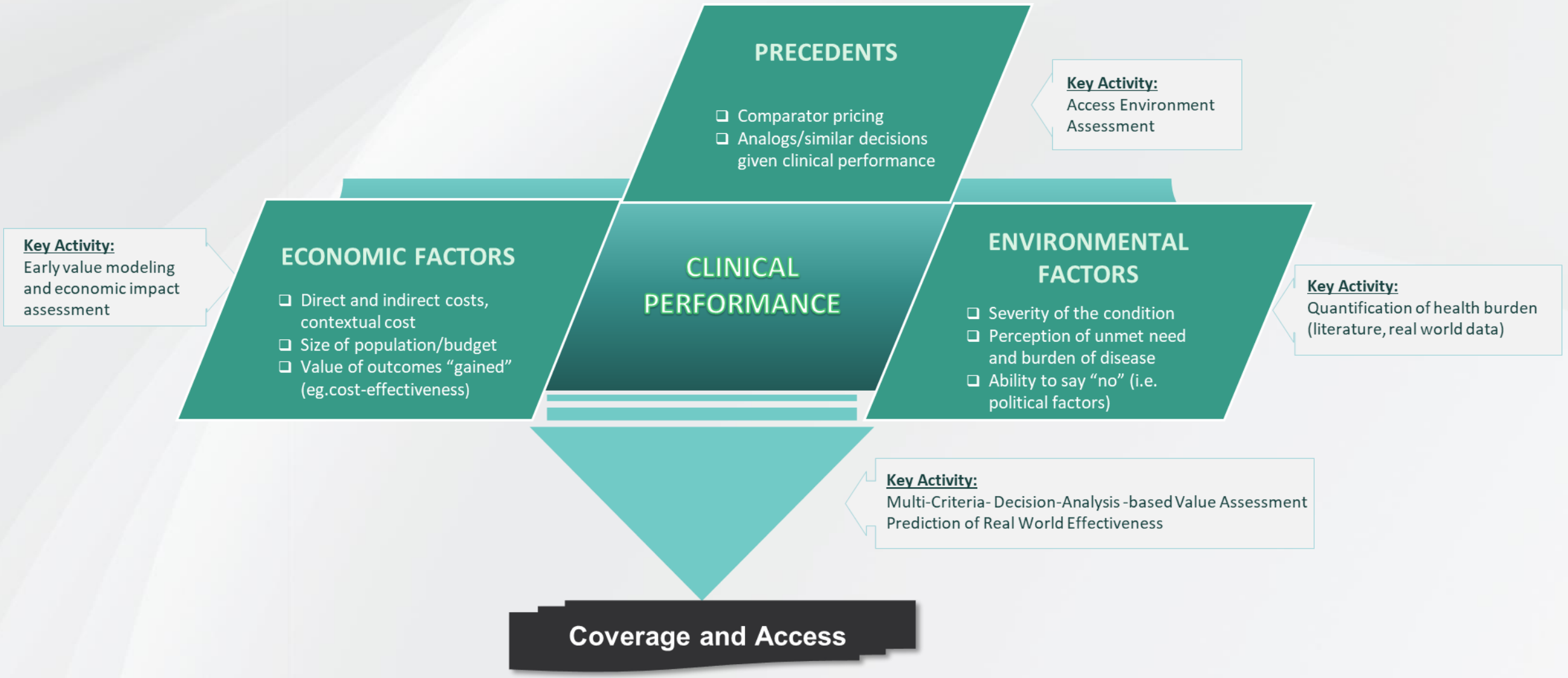
- Developing value frameworks as tools to **support a multi-dimensional assessment** of technologies allows transparent and participatory **deliberations and decision making**
- The majority of those published in the literature have been built following a review of literature, based on established processes and in consultation with stakeholders involved in listing and reimbursement decisions
- Their comprehensiveness varies, ranging from 4 to up to 20 criteria, which are often grouped in clusters/domains

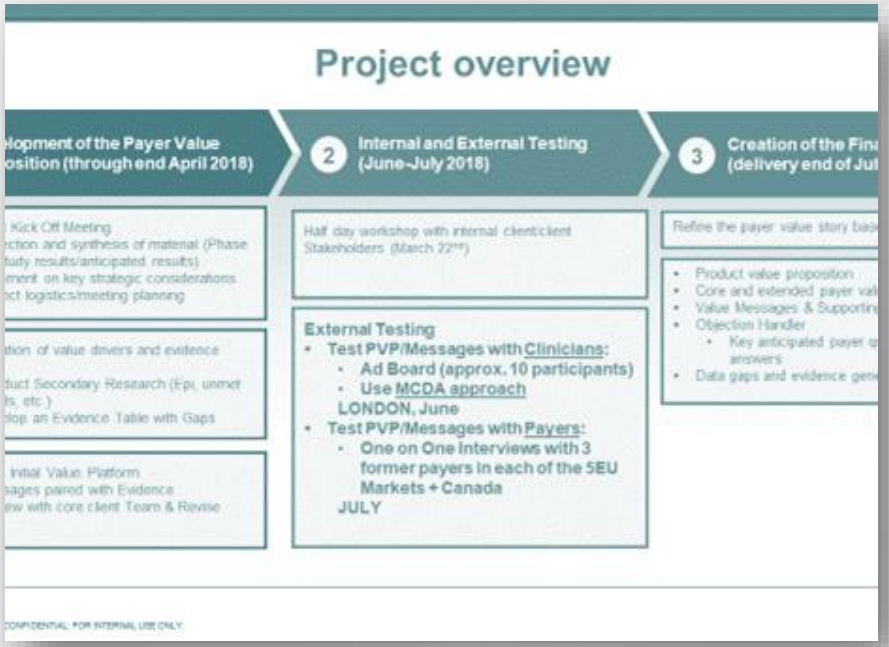
OUR PROCESS FOR VALUE FRAMEWORKS

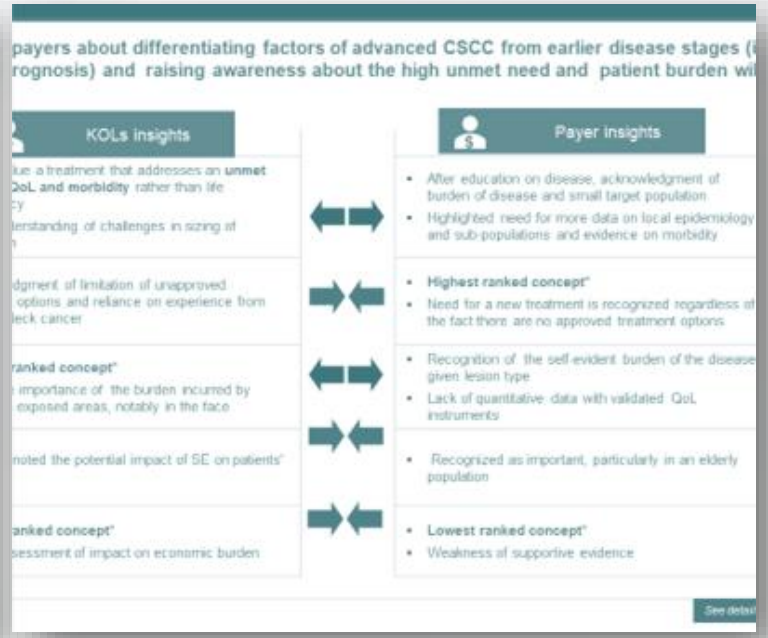
- Assess the value framework landscape to understand the range of frameworks developed, how they are being used, their strengths and weaknesses assessing different technologies and how they are aiding decision-making for your product defining their overall importance
- Use an existing or developed value framework and payer experts to determine decision makers' relative preferences for the drivers of value
- Collate extant evidence in alignment with an emerging or developed value framework to identify evidence gaps
- Support value dossiers and submissions by gathering insights on patients and clinicians' preferences using the principles and science of Multi-Criteria-Decision-Analysis to better understand what matters as part of their disease management
- Use expert advisory boards and an evidence manual to assess the performance of your technology against emerging or developed value frameworks

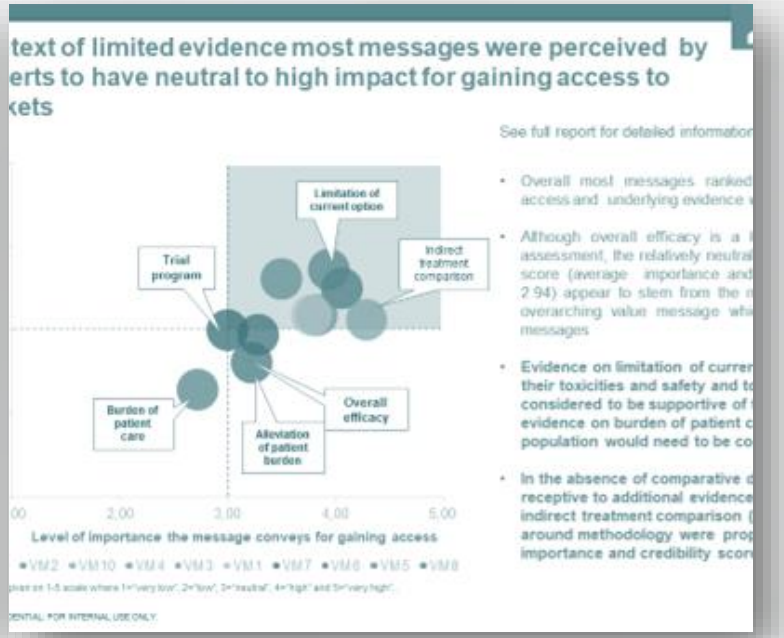
ACC-AHA ASCO DrugAbacus ICER NCCN Avalere

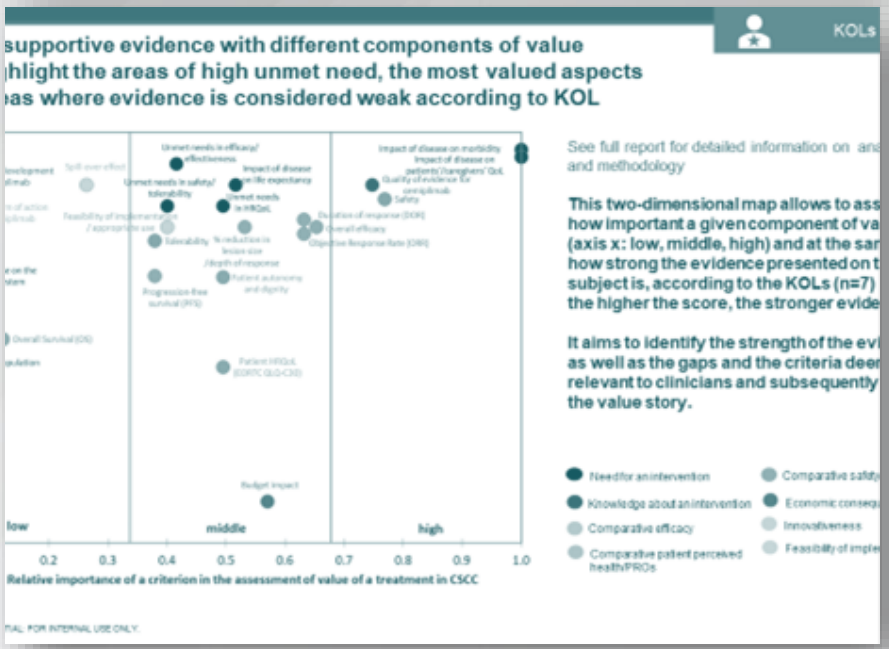
GUIDED BY A SIMPLE BUT PROVEN COMPASS FOR VALUE ASSESSMENT





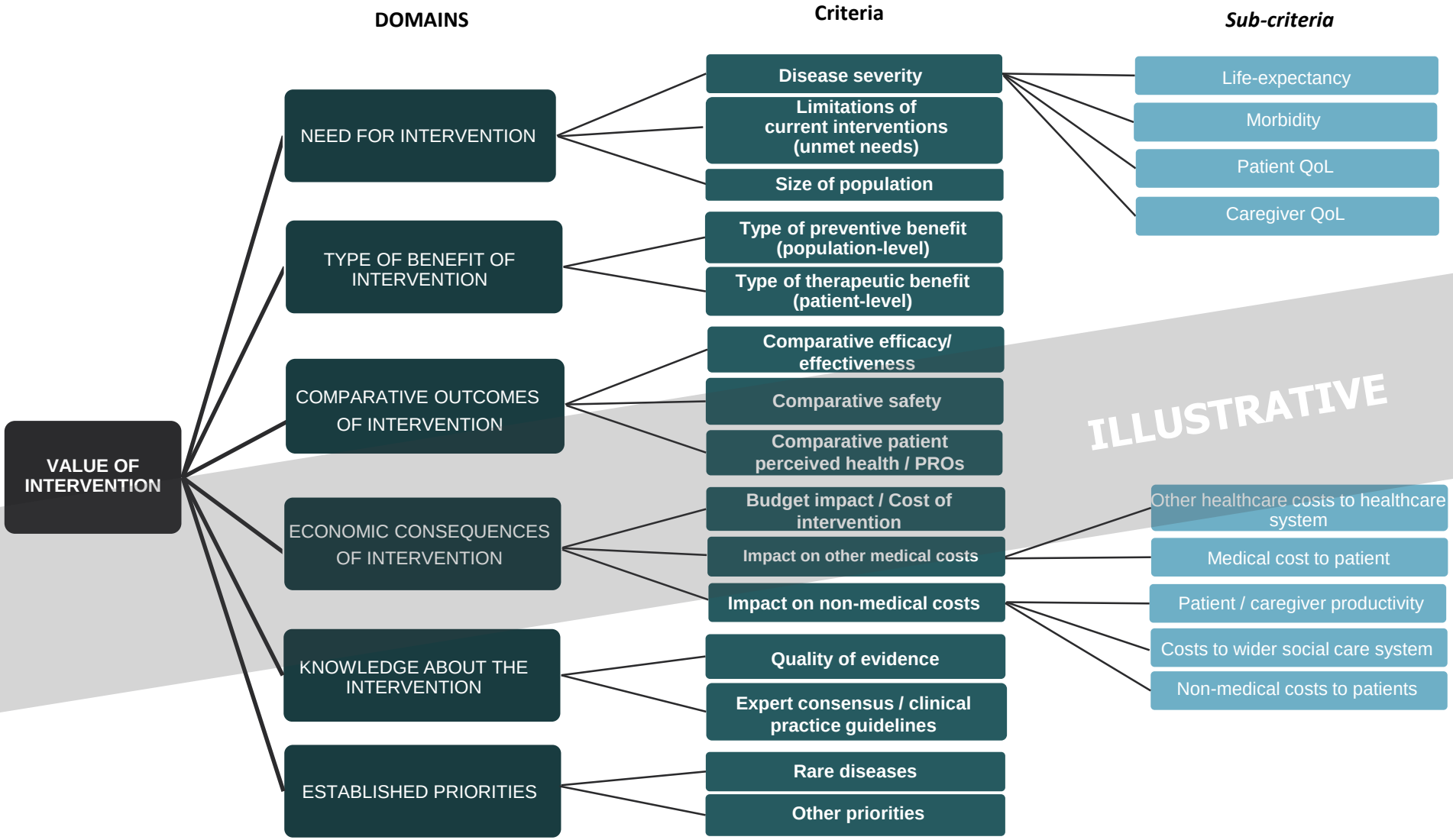






MCDA-DRIVEN AD-BOARDS TO AUGMENT YOUR VALUE STORY

Example MCDA Value Tree to enhance value dimensions



READY FOR ICER?

Pre-scoping | Week 0 | Week 7: final scope | Week 21: Draft Report | Week 27: Evidence Report | Week 30-32: Meeting & Final Report

INDIVIDUALLY CRAFTED, MULTI-PRONGED ENGAGEMENT STRATEGY

Employ Multi-Criteria-Decision-Analysis → **Assess Formulary Decision Making Impact** → **Enhance the Evidence Base** → **Appraise ICER Approach & Methodology** → **Payer Engagement for Value & Price Optimization**

Engagement tactics should be deployed at multiple points throughout the process and will inform response to ICER at all points of the review during open input periods

- Conduct MCDA (aimed at workshop and/ or publication)
- Offers sound, systematic and accepted methodological footing to take value perception beyond what is observed in trials and demonstrable in potentially limiting existing frameworks
- Can also be used as material during internal development of scenarios, segmentation, tactical playbooks
- Blends key criteria and weightings implicit in current value frameworks and other decision support frameworks

- Helps inform scenario-testing and internal objection handling materials for payer interaction in view of ICER recommendations
- Reveal weaknesses in current value story and point to need for additional evidence generation
- Simultaneously understand if payers expect to engage in risk-sharing discussions

- Fill in critical HEOR and real-world evidence gaps (identified through: MCDA; payer and stakeholder testing, scenario workshops)
- Address various questions on burden of illness, unmet need
- Include other dimensions to appropriately show value beyond narrow value frameworks, e.g. considerations around social willingness-to-pay to allow for more equitable evaluation

- During the engagement period, comments tend to zoom in on all assumptions, model inputs, patient population and sub-populations, efficacy data, methodology and comparators
- We can replicate ICER methodology, identify flaws, prepare for sound response during public commentary period
- We critically assess inputs and various ICER estimates of budget impact and the burden of illness metrics that undergird the analysis

- In view of the actual ICER analysis, conduct extensive payer testing to inform objection handling techniques and further payer engagement
- Explore possibility of innovative contracting and other innovative pricing schemes

Topic Announced	0	Open Input Period Begins Scoping Calls Begin	calls with mfrs., clinical experts, patient groups, clinical societies, and insurers. Mfrs. may begin to submit supplemental information through the open input period.
Draft Scope	1		
	2		
	3	Draft Scoping Document Posted Open Input Period Ends ICER Sends Request for Data	ICER sends formal requests for data to each mfr. Supplemental data requests may be sent during the following weeks on a case-by-case basis.
Final Scope	4	Public Comment Period	Mfr. and other stakeholders have 15 business days to comment on the draft scope.
	5		
	6		
	7	Scoping Calls End Final Scoping Document Posted	
Draft Evidence Report	8		
	9	ICER Shares Preliminary Model Assumptions and Inputs	ICER shares preliminary list of model inputs and assumptions; responses are due in 10 business days.
	10		
	11	Evidence Submissions Due	Supplemental evidence and alternative assumptions/inputs for modeling effort due.
	12		
	13		
	14		
	15	Preliminary Findings Shared with Manufacturers	After reviewing ICER's preliminary model findings, manufacturers may send supplemental data.
	16		
	17	Supplemental Data Submission Due	Supplemental data sent in response to ICER's preliminar results are due 11 business days after call.
	18		
	19		
	20		
	21	Draft Evidence Report Posted	
Evidence Report	22		
	23	Public Comment Period	Mfrs. and other stakeholders have 20 bu comment on the Draft Evidence Repor
	24		
	25		
	26		
Public Meeting	27	Evidence Report Posted	The relevant program voting report.
	28		
	29	Public Meeting	See section 1.7 fo during the pu
Final Report	30	Final Evidence Report and Meeting Summary Posted	

Document Release | Data Request

DURING THE ICER REVIEW WINDOW A WELL-ORCHESTRATED APPROACH LEADS TO TACTICAL PLANNING, INTERNAL AND EXTERNAL STAKEHOLDER MANAGEMENT

We prepare Clients to appraise key aspects of the ICER evaluation

Typical Client Considerations around the Report

- How adequate is existing evidence that is being considered?
- What are key assumptions and how are they derived?
- What are our views on the budget impact assumptions?
- Can we offer more substantial clinical expertise?
- Do we see a credible discussion of comparators?
- Are demonstrable cost offsets included?
- Do we wish to include comments on data accuracy/ consistency?
- Should we make an effort to offer an appropriate definition of value?
- Do we see the appropriate discussion of the disease burden?
- Appropriate review of Efficacy data and Safety data?
- Is there an impact on innovation that we want to highlight?
- What about the use of network meta-analysis?
- What is our view on the inputs of the model?
- Do we see any patient perspectives being included?
- How robust is the definition of the patient population/ subpopulation?
- Do we comment on specific limitations around Quality-adjusted life-years?
- Do we see adequate employment of sensitivity/scenario analyses?
- What is our position on utility data used?
- Does the analysis follow a reasonable time horizon?
- Are there overall concerns around the transparency on the methods for our product?
- Should we make an effort to highlight unstated limitations?

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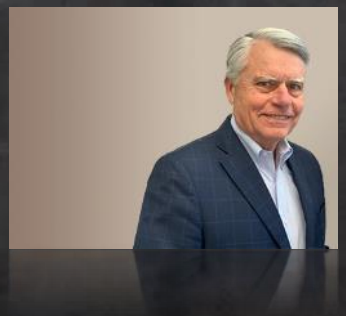
MEET OUR SENIOR US TEAM

Roman Casciano
MSc BSc
SVP, Certara Evidence & Access

+ 25+ years of market access and HEOR leadership
+ Co-Founder Analytica Int



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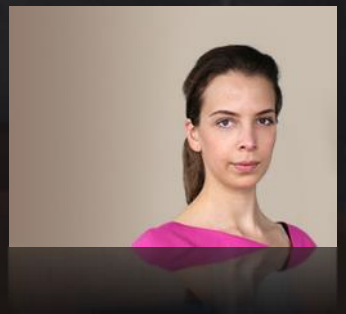
Vice President, US Market Access Strategy

+ Launched products into over 65 markets as head of a global marketing organization
+ Founder of Compass

Edward Gallagher
MS
Senior Consultant, Pricing

+ 20+ years' of pricing experience
+ Former head of Marketing Research and Pricing and Contracting in a major pharma



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+ Oversees all Basecase technology engagements and app development

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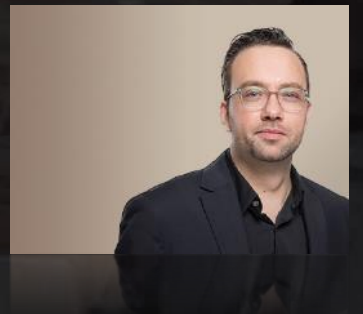

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Senior Director, US Access & Commercial Strategy

+ 12+ years' experience in product development, marketing & policy
+ Founded several ventures, led US division of global pharma networking and research firm

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Senior Director, US Market Access Strategy

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+ Oversees global BD team

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+ Experienced across all major therapeutic areas and care settings

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