Remap

# Day Two
## World EPA 2025

Our overview of:

the keynote and insights emerging from the global market access landscape

# Highlights

1

Payers recognise the importance of specific pathways for orphan drugs, such as the UK's HST and early access schemes, in helping new treatments secure reimbursement.

2

Greater patient involvement in rare diseases is essential for improving access, but national policies do not always support this. There is also uncertainty over how much the JCA will help address these challenges.

3

Payers see the need for more alignment in HTA processes to reduce inefficiencies and duplication, with the JCA offering opportunities for improvement.

# Highlights

4

It remains unclear whether the JCA will improve patient access across the EU, as affordability, rather than HTA processes, is the main barrier to innovation.

5

NICE is updating national processes to manage increasingly complex treatments, including extending NHS funding deadlines, which could improve patient access and support NHS sustainability.

6

These changes to NICE’s approval process may also result in funding delays, even for treatments with high unmet needs, depending on budget impact. The industry must monitor how this could affect both current and future treatments.

# The Key Takeaways

### REIMBURSEMENT

- There is an increased perception of value-based agreements having the potential to mitigate risk and uncertainty for payers and maximise reimbursement outcomes for manufacturers.

### MARKET ACCESS

- Manufacturers should take a proactive approach, using advanced technology, partnerships, and existing tools early to streamline market access, reduce delays, and enhance value demonstration.

### REAL WORLD EVIDENCE

- Manufacturers stress early cross-functional collaboration in clinical trials, uniting manufacturers, payers, and regulators to align development with payer expectations, reduce evidentiary gaps, and ease reimbursement decisions.

### HTA

- As complex technology submissions rise, NICE continues refining processes to sustain UK healthcare and the life sciences sector.

# Observations

## HTA

- NICE is implementing processes such as; extending NHS funding timelines beyond three months based on project nature and expected patient and healthcare benefits.

## MARKET ACCESS

- Affordability and uncertainty remain key access barriers, but outcome-based agreements and cost-management tools help mitigate risks. Identifying where and how to apply them is crucial for future access strategies.

## REAL WORLD EVIDENCE

- Artificial intelligence is significantly enhancing Real-World Evidence (RWE) strategies. Innovations such as predictive modelling, natural language processing, and automated patient mapping for external control arms are streamlining the generation of high-quality RWE, which is becoming increasingly actionable for payers.

# For The Future

### REIMBURSEMENT

- The potential for value-based agreements having a positive impact on reimbursement outcomes for products currently available in the pipeline.

### HTA

- Ongoing developments in mechanisms to ensure healthcare sustainability with the entry of complex treatments into healthcare.

### MARKET ACCESS

- Patient advocacy groups shape reimbursement by influencing product value perceptions. Manufacturers should engage them early to co-develop value narratives that address payer concerns and JCA uncertainties.

### REAL WORLD EVIDENCE

- As JCA frameworks evolve, Real-World Evidence (RWE) will be key, especially for rare diseases with limited trial data. AI and big data can enhance evidence integration, strengthening reimbursement cases in complex therapies.

# Manufacturer Considerations

## REIMBURSEMENT

- Manufacturers should consider increasing pricing flexibility and mechanisms to address both risks highlighted by the manufacturer and payer concerns to ensure optimal outcomes, as a lack of flexibility improves.

## HTA

- Managing complex treatments will support sustainable NHS access, but manufacturers should anticipate longer funding timelines, potentially affecting current and future pipelines.

## REAL WORLD EVIDENCE

- AI-driven tools, with human oversight, can speed up evidence generation and improve decision-making. Manufacturers must integrate them strategically.

## MARKET ACCESS

- As policy frameworks evolve, manufacturers should proactively evaluate existing access pathways, such as cross-border health, to maximize opportunities for growth.