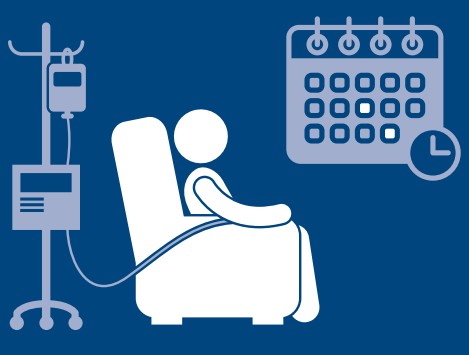
Accelerating Access to Innovative Cancer Therapies

Innovative therapies continue to improve outcomes for patients with cancer.

Whilst regulatory bodies have evolved their methods, Health Technology Assessment (HTA) agencies have largely remained static in their evidence requirements. This is one of the key reasons why patients still face delays in accessing these innovative therapies.[1]



Key areas of misalignment include:[1,2]

- Acceptability of the clinical evidence for decision-making purposes
- An over-reliance on the availability of mature overall survival data at the time of HTA

Collaboration between multiple stakeholders is needed to:

Reduce inter-country variation in access to innovation to tackle disparities in cancer outcomes between countries

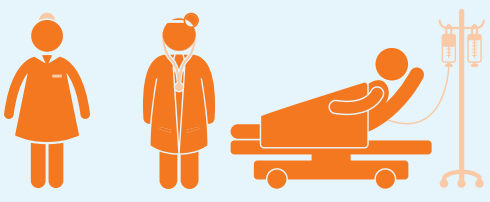
Improve the time to achieving patient access to innovative cancer treatments

Janssen supports the evolution of HTA methods to address current access challenges facing innovative cancer therapies. Changes to the way that innovation is valued and how uncertainty is considered, is essential in overcoming access challenges and reaping the benefits for patients.

Janssen's Key Recommendations

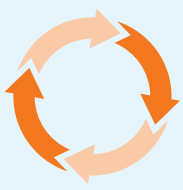
Applicability of solutions will vary depending on a country's reimbursement mechanisms and respective needs, which can be tailored accordingly.

1 HTA Processes



Clinical experts with relevant experience of treating patients should form part of the HTA decision-making process

Patients and carers should be systematically included in the HTA process



Evidence generation should be an iterative process when long-term outcomes are pending

Assessment of the clinical value of new treatments should be made independent of price

The HTA decision-making process should be predictable, timely and transparent

2 HTA Methodology

Value assessment criteria should be more flexible for innovative cancer treatments

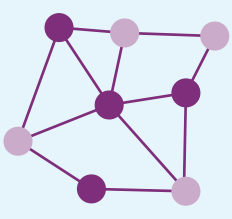
The requirements for validation of surrogate endpoints need to be more flexible for innovative cancer treatments

Greater emphasis should be given to the value of real-world data to inform HTA decision making

Estimates of relative efficacy should be derived through high quality indirect treatment comparisons in the absence of head-to-head trials

3 Health Economic Evaluation

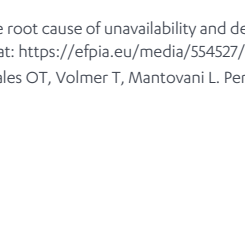
Non-healthcare costs and benefits should be considered in economic evaluations



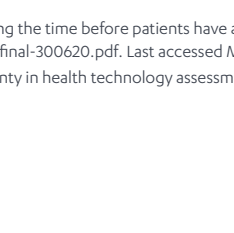
Frameworks for health economic modelling need improvement to better characterise the costs and benefits of treatment

Greater flexibility in cost-effectiveness thresholds are needed to recognise the value of innovation, where uncertainty exists

4 Access & Adoption



Adoption of innovative cancer therapies should be guided by diagnostic and/or biomarker testing, where available



Mechanisms that enable broader access to innovation are needed, such as outcomes-based payment models

Trusted partnerships between manufacturers and payers are needed to agree managed entry agreements in a timely manner

Working together with all stakeholders will help us progress towards achieving our common goal: that every patient receives the **right treatment** at the **right time** and in a sustainable way.

We need to:

- Find sustainable ways to fund solutions that achieve health targets and value-based outcomes
- Shift the focus from restricting expenditure to making long-term investments in earlier disease detection, prevention and delivery of effective cancer care
- Support a productive and profitable life sciences industry to encourage innovation.

By ensuring people can access the treatments they need when they need them, we are helping to build a healthy population and more sustainable future, since **healthy populations** are directly linked to **healthy economies**.

References

1. EFPIA. The root cause of unavailability and delay to innovative medicines: Reducing the time before patients have access to innovative medicines. Available at: https://efpia.eu/media/554527/root-causes-unavailability-delay-cra-final-300620.pdf. Last accessed March 2021.
2. Sola-Morales OT, Volmer T, Mantovani L. Perspectives to mitigate payer uncertainty in health technology assessment of novel oncology drugs. *J Mark Access Health Policy*. 2019;7:1562861.

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