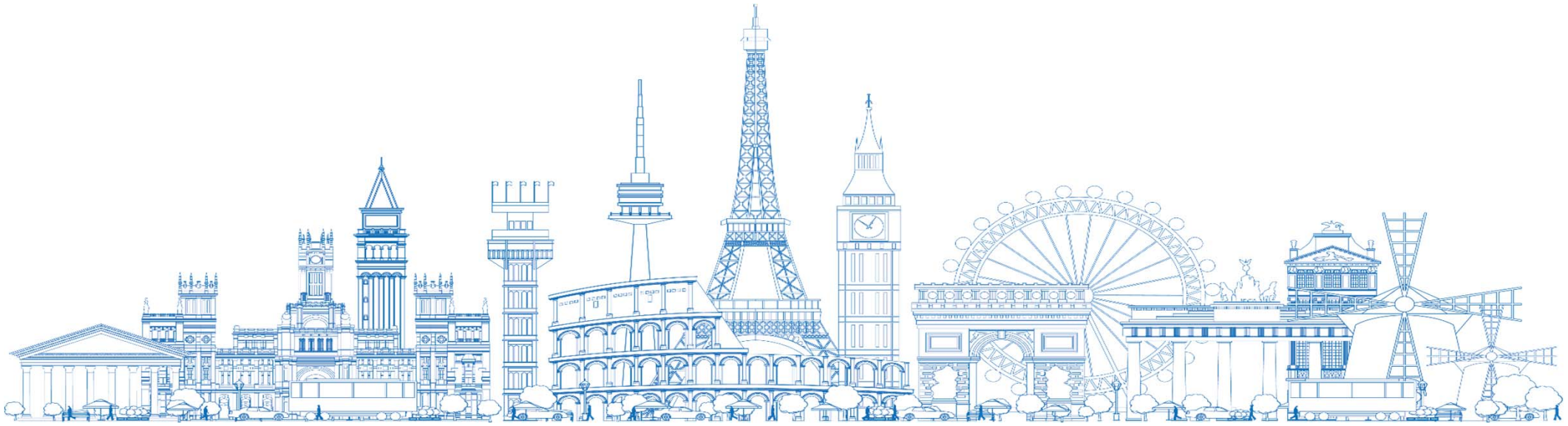

Challenges in demonstrating the value of COVID-19 technologies – industry perspective

Nicola Trevor
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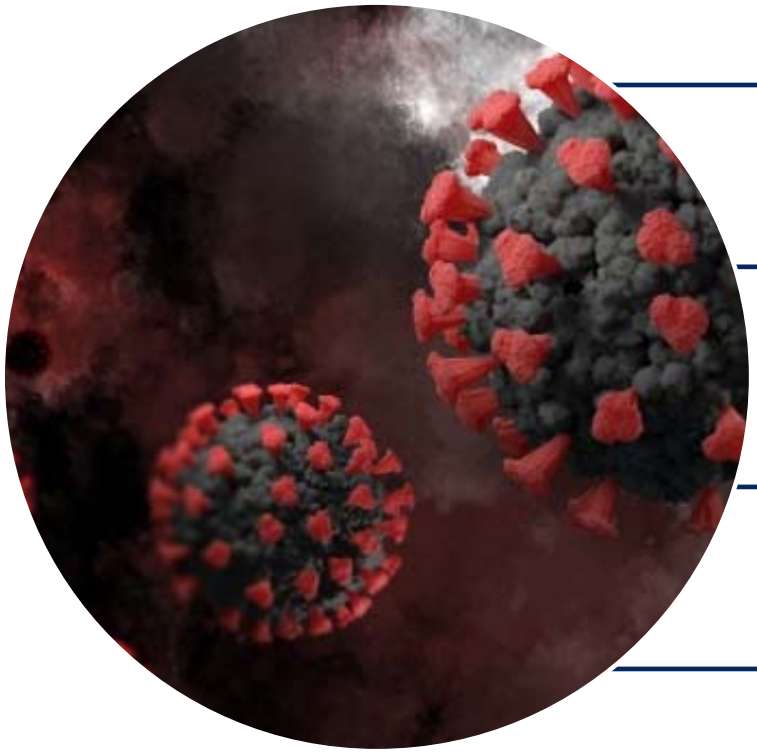
Agenda

- Impact of COVID-19
- Shared challenges for HTA
- The amplification factor
- Recommendations

[1]NICE appraisals from 2000 to June 2016 (https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance/data/cancer-appraisal-recommendations), [2]Janssen systematic search of NICE website

Impact of COVID-19



Substantial impact on global economy

Bureaucracy busting

Digital development

Significant impact on health and wellbeing

Shared challenges for HTA

- Rolling HTA review
- Outcomes based pricing
- Value Based Healthcare

Wider context

Clinical effectiveness

- Generating reliable clinical evidence with evolving disease understanding/acute unmet need
- Surrogate endpoints
- Generalisability

- Evolving treatment pathways
- Clinical vs Economic benefit
- Innovation vs Uncertainty

Decision making

Cost effectiveness

- Modelling what matters (complex versus simple modelling)
- Generating reliable economic data
- Perspective (payer/societal)

Janssen supports the evolution of HTA methods to address current access challenges facing urgently needed/innovative 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.

The amplification factor

HTA challenges for innovative therapies in areas of high unmet need are amplified with COVID-19 technologies:

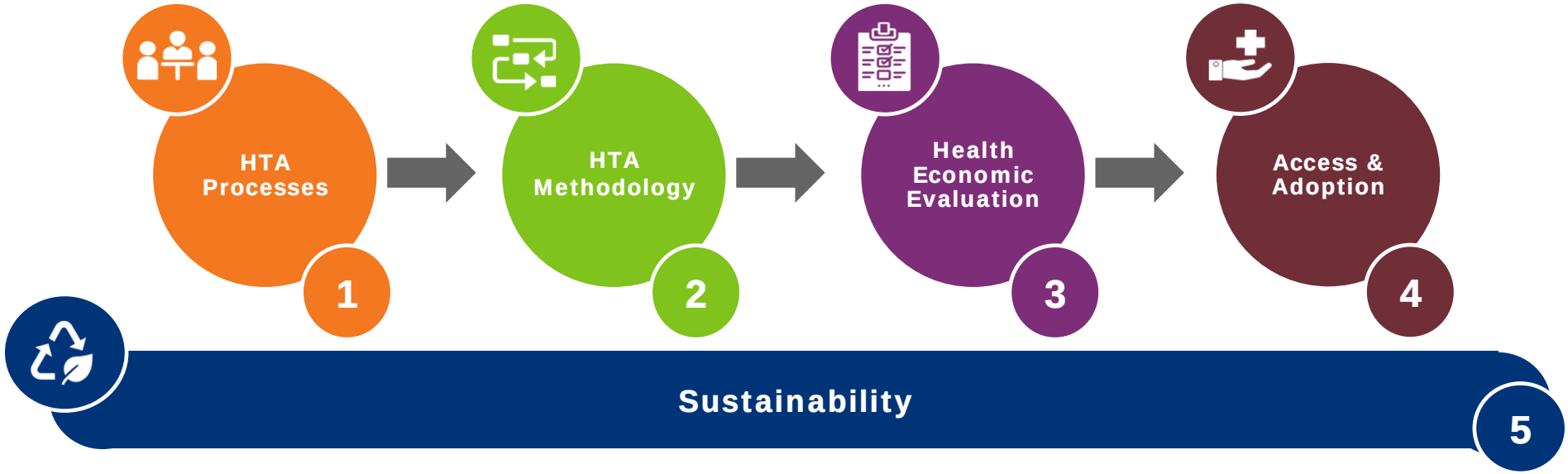
- Advanced therapeutic medicinal products (cell and gene therapy)
- Early interventions for dementia and Alzheimers
- Histology independent therapies
- Digital technologies

All these ‘challenging technologies’ are associated with similar challenges to COVID-19 technologies:

- Rapidly evolving science, high unmet need, high uncertainty in long-term outcomes, service implications, political pressure

Collaboration is needed between multiple stakeholders to address challenges to patient access across Europe

Recommendations



HTA assessments with iterative processes of continual assessment, as more evidence becomes available.

Assessment of clinical benefit conducted independently to price negotiations to ensure value recognition.

Greater acceptance of observational data for relative efficacy assessment where RCTs are not possible.

HTA agencies and regulators alignment on acceptance of surrogate endpoints where long-term outcomes are not feasibly captured within the time frame of a trial.

A broad perspective pragmatically factoring in productivity gains and losses.

Over-reliance on long-term extrapolation of outcomes should be avoided & beyond the QALY approaches implemented.

Alternative payment and financing strategies to manage short-term affordability.

Investment in electronic health records systems could provide incentives to enable outcomes-based reimbursement.

Evidence generation plans collaboratively developed.

Multi-stakeholder collaborations are essential at every stage to enable timely patient access