

# 1 IMPROVING ACCESS TO INNOVATION FROM INTERNATIONAL HEALTH 2 TECHNOLOGY ASSESSMENT

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11 The field of healthcare has evolved from an emphasis on evidence-based medicine,  
12 with a focus on efficacy, safety and tolerability, to the pursuit of evidence-based  
13 efficiency and sustainable innovation in many respects (healthcare budgets, carbon  
14 print....). This evolution can be attributed, in part, to the contributions of Health  
15 Technology Assessment (HTA) bodies, which have facilitated the incorporation of  
16 various factors into the decision-making process<sup>1</sup>. These factors include  
17 comparative effectiveness, quality of life, efficiency, budgetary impact and  
18 organizational impact, among others. Within the domain of healthcare, irrespective  
19 of the perspective of each entity (e.g. Food and Drug Administration, European  
20 Medicines Agency, etc.), there is an imperative for the presence of evidence and its  
21 assessment in the most transparent manner possible, with the objective of ensuring  
22 the incorporation of healthcare technologies.

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23 This has led to the conclusion that in order to promote innovation in health, as a tool  
24 to improve health systems and population's well-being, it is necessary to encourage  
25 early dialogue between the different stakeholders in the sector in the effort to  
26 optimize, accelerate and maximize the benefit of health technologies. Ensuring  
27 access to the most effective health technologies for the appropriate patients in the  
28 most efficient manner for the health system, while taking into consideration the  
29 technical and operational capacity of the health system, is also fundamental.

30 The HTA Group<sup>2</sup> has highlighted the need to establish a common framework  
31 defining what early HTA is, as a first step to provide a common anchor for  
32 researchers and developers to optimize their resources and being of benefit to  
33 society at large. Unlike other assessments, this is a process rather than a final  
34 milestone. We have to take into account that there are several phases of pre-  
35 concept, prototyping, clinical development and pharmaco-economic evidence  
36 before the technology is on the market, leading to the first version with minimum  
37 value (minimum viable technology), which can be improved by incremental  
38 innovation once it is on the market. For this reason, whether for the need to improve  
39 development, evidence or to obtain funding (angel investors, venture capital,  
40 investment funds, etc.), early HTA is a process that should help researchers shape  
41 their value proposition for society. It is not about generating value in a spurious way,  
42 as we are seeing in some cases with AI and other technologies<sup>3</sup>, which are  
43 sometimes based more on magnifying the benefit from an advertising arguments  
44 than on duly justified necessity, but to ensure that, in the development of health  
45 technologies, clinical and non-clinical aspects have been evaluated with the highest  
46 possible degree of evidence, to avoid surprises in HTA evaluations or, in the case  
47 of Europe, in the Joint Clinical Assessment (JCA)<sup>4</sup>.

48 Value assessment from an HTA point of view is under constant review. Long after  
49 the first definitions of HTA assessment and the publication of Drummon's book on  
50 Economic Evaluation of Health Care Programmes<sup>5,6</sup>, different definitions of value  
51 have appeared at the macro level, such as the one proposed by Michale Potter<sup>7</sup>, to  
52 the present day, where International Society For Pharmacoeconomics And Outcome  
53 Research (ISPOR) has proposed a flower of value<sup>8</sup> with petals that are even linked  
54 to value of hope, and other variants that try to emphasize the social perspective<sup>9,10</sup>.  
55 They are all aimed at the provision of health services and the uptake of health  
56 technologies, but they do not have such a clear focus on development through risk  
57 mitigation and optimizing market access as early HTA. To bridge this gap between  
58 the development process and final evaluation, many organizations have promoted  
59 initiatives or programs to assist researchers. In this regard, the FDA has the  
60 Breakthrough Therapy Designation and Breakthrough Device Program, a program  
61 that helps identify unmet needs by guiding development pathways, National Institute  
62 for Health and Care Excellence (NICE) has the Early Dialogue within its Scientific  
63 Advice Program, which includes the generation of evidence aligned with the  
64 requirements of HTA. Others have addressed the importance of improving  
65 integration and cooperation between three key processes in healthcare: regulation,  
66 HTA and the development of clinical guidelines<sup>11</sup>. Although these processes are  
67 independent, they share a common evidence base, and their alignment can be of  
68 great help to developers.

69 One of the keys to early HTA, and this is emphasized in the manuscript<sup>2</sup>, is that this  
70 process attempts to identify the essential elements where the evidence needs to be  
71 improved and to identify the key parameters that will be amenable to final decision  
72 making. Although the economic evaluation at this stage is not based on evidence

73 but on potential scenarios, it is a very useful exercise for the developer that allows  
74 him/her to focus on the development of his/her product. In the end, all aspects of  
75 early HTA, whether clinical, economic or other aspects linked to unmet needs  
76 among others, will help developers to understand the value of their product not only  
77 for themselves, but also for society and potential investors; key to providing value  
78 for money and rapid access to patients.

79 Within early HTA, health technology must be evaluated in each of the MIRE  
80 (Magnitude, budget Impact, Relevance and Efficiency) attributes to successfully  
81 demonstrate value.

82 **Magnitude:** The target therapeutic market is a critical consideration in the  
83 early stages of health technology development. It involves assessing the  
84 current and potential market, in line with potential competitors and unmet  
85 needs.

86 **Budget Impact:** Financial modeling is a valuable instrument in the initial  
87 stages of health therapy development, as it enables companies to simulate  
88 the potential market and the impact of the health technology on the market.  
89 Additionally, it facilitates the identification of the return on investment.

90 **Relevance:** Understanding the burden of disease is essential as it allows  
91 developers not only to assess the impact of the disease on patients and  
92 society, but also the clinical impact that the new technology may have.

93 **Efficiency:** The cost-effectiveness of a new technology is a critical  
94 consideration in its development, as it facilitates the identification of the  
95 potential market price and key parameters.

96 Although terminology has been subject to debate as exemplified by the difficulty of  
97 reaching consensus on a shared definition, its use is very useful. Employment may  
98 serve to heighten awareness among developers and to further cultivate  
99 collaboration between institutions, as well as public-private collaboration. Moreover,  
100 the term's usage in publications will facilitate the identification of use cases that may  
101 align with developers' needs.

102 There is a need to bring together the efforts of all those involved because, in  
103 addition to improving the health of society, investment in health technologies can  
104 generate improvements in economic growth, can even generate long-term savings  
105 and can be a focus for improving the equity of our healthcare systems. Given the  
106 different incentives available to investors, we must all be able to promote  
107 investment in health technologies because of their great added value. It is essential  
108 to acknowledge that investment in health technologies is not merely a financial  
109 expenditure; rather, it constitutes a strategic allocation of resources with the  
110 potential to generate substantial returns across diverse societal sectors and to  
111 make the system more robust/resilient to unforeseen events because it streamlines  
112 according to relevance and generates a clear and traceable path. A healthier society  
113 is a more equitable and wealthier society.

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## 115 REFERENCES

- 116 1 Henshall C, Schuller T. HEALTH TECHNOLOGY ASSESSMENT, VALUE-  
117 BASED DECISION MAKING, AND INNOVATION. *Int J Technol Assess*  
118 *Health Care* 2013;**29**:353–9. <https://doi.org/10.1017/S0266462313000378>.
- 119 2 Grutters JPC, Bouttell J, Abrishami P, Ahmed SYM, Cole A, Dawoud D, *et al.*

- 120 Defining early health technology assessment: Building consensus using  
121 delphi technique. *Int J Technol Assess Health Care* 2025.
- 122 3 Matheny M, Israni ST, Ahmed M, Whicher D, editors. *Artificial Intelligence in*  
123 *Health Care*. Washington, D.C.: National Academies Press; 2019.
- 124 4 Schuster V. EU HTA Regulation and Joint Clinical Assessment—Threat or  
125 Opportunity? *J Mark Access Heal Policy* 2024;**12**:100–4.  
126 <https://doi.org/10.3390/jmahp12020008>.
- 127 5 Drummond MF, Stoddard GL, Torrance GW. *Methods for the economic*  
128 *evaluation of health care programmes*. vol. 3rd editio. 1988.
- 129 6 Jonsson M, Alban A. Methods for the Economic Evaluation of Health Care  
130 Programmes, M. F. Drummond, G. L. Stoddard, and G. W. Torrance. Oxford:  
131 Oxford University Press, 1987, 182 pp., \$29.50. *Int J Technol Assess Health*  
132 *Care* 1988;**4**:. <https://doi.org/10.1017/s026646230000773x>.
- 133 7 Davidson A, Randall RM. Michael Porter and Elizabeth Teisberg on redefining  
134 value in health care: an interview. *Strateg Leadersh* 2006;**34**:48–50.  
135 <https://doi.org/10.1108/10878570610711288>.
- 136 8 Lakdawalla DN, Doshi JA, Garrison LP, Phelps CE, Basu A, Danzon PM.  
137 Defining Elements of Value in Health Care—A Health Economics Approach:  
138 An ISPOR Special Task Force Report [3]. *Value Heal* 2018;**21**:131–9.  
139 <https://doi.org/10.1016/j.jval.2017.12.007>.
- 140 9 Shafrin J, Kim J, Cohen JT, Garrison LP, Goldman DA, Doshi JA, *et al*.  
141 Valuing the Societal Impact of Medicines and Other Health Technologies: A  
142 User Guide to Current Best Practices. *Forum Heal Econ Policy* 2024;**27**:29–

- 143 116. <https://doi.org/10.1515/fhep-2024-0014>.
- 144 10 Neumann PJ, Garrison LP, Willke RJ. The History and Future of the “ISPOR  
145 Value Flower”: Addressing Limitations of Conventional Cost-Effectiveness  
146 Analysis. *Value Heal* 2022;**25**:558–65.  
147 <https://doi.org/10.1016/j.jval.2022.01.010>.
- 148 11 Hogervorst MA, Møllebæk M, Vreman RA, Lu T-A, Wang J, De Bruin ML, *et*  
149 *al*. Perspectives on how to build bridges between regulation, health  
150 technology assessment and clinical guideline development: a qualitative focus  
151 group study with European experts. *BMJ Open* 2023;**13**:e072309.  
152 <https://doi.org/10.1136/bmjopen-2023-072309>.
- 153