# Are digital therapeutics reshaping the HTA framework for health technologies?

HTA33

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## Background

The health technology assessment (HTA) frameworks weigh the value of new technology against health benefit as measured by clinical outcomes, with many frameworks focusing on predetermined monetary thresholds. Patient-reported outcomes (PROs), beyond the traditional quality of life (QoL), are rarely determinants in the decision-making process. With the emergence of digital health therapeutics (DHTs) there has been a growing awareness of the impact of patient's experience on the course of the disease and long-term treatment outcomes. Several European countries are in the process of changing traditional assessment frameworks to adapt to the specificities of digital health solutions. Examples of countries with a DHT assessment framework are the UK, Germany, and France, with Germany being considered a pioneer, having already introduced a statutory framework for DHTs. This research aims to gain insights into how HTA authorities consider patient-related insights for drugs vs. DHTs and whether the new HTA framework for DHTs may encourage HTA bodies to incorporate and evaluate more patient-centric data for traditional drugs moving forward.

## Methods

The European Medicines Agency (EMA) database was search for drugs approved via an accelerated pathway in Europe between 2018 and 2022. A total of 9 innovative drugs in various therapeutic indications were identified. The HTA evaluations for the selected drugs were retrieved from HTA agencies in 3 countries (i.e., UK, France and Germany). Subsequently, DHTs reimbursed in these countries up to 2022 were identified, and their HTA evaluations were analyzed. Narratives on patient-related insights, including PROs, for both drugs and DHTs were analyzed.

## Results

Of the drugs approved via the accelerated pathway, 16/20 HTA evaluations included PRO/QoL data. Additionally, 10/20 HTA reports included insights from patient groups during the appraisal (**Figure 1**). Conversely, all HTA evaluations for digital therapeutics (42/42) included assessment of patient-related insights, including a mix of DHT functionality (41/42), good data practices (41/42), and PRO/QoL (34/42) (**Figure 1**).

In the rationale for the decision, a total of 13/20 HTAs for drugs included QoL as arguments and 7/20 HTAs mentioned other patient-centric arguments beyond the traditional PRO data. Conversely, the patiented-focused insights above and beyond the PRO/QoL (related to ease of use, functionality, satisfaction, reduction of therapy-related efforts, well-being, quality of care etc.) were determinants for DHTs reimbursement in all analyses (42/42) (**Table 2**).

**Figure 1: QoL/PRO and other patient-centric outcomes assessed in the HTAs for drugs and DHT**

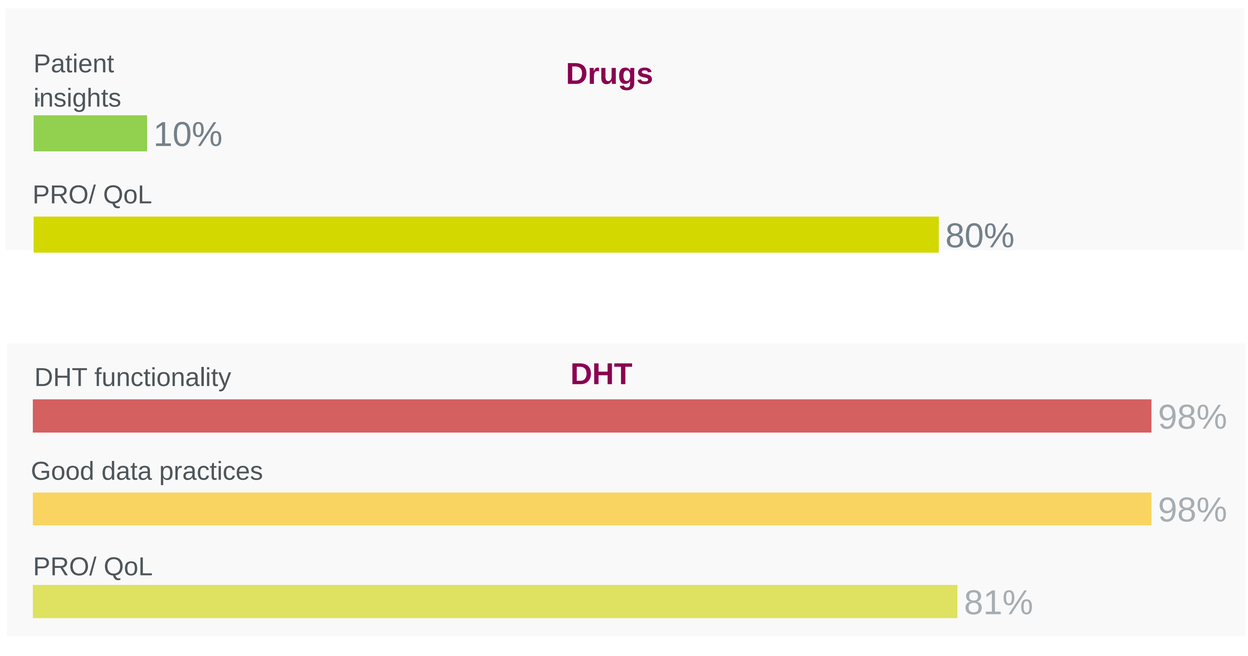


**Table 2: Comparison of determinant factors for the HTA decisions for DHTs vs. drugs**

| | Drugs | | | DHT | | |
|---|---|---|---|---|---|---|
| |  |  |  |  |  |  |
| **ADDED* CLINICAL BENEFIT** | | | | | | |
| **ADDED* COST-EFFECTIVENESS** | *Not a determinant on HTA decision-making* | | | *Not a determinant on HTA decision-making* | | |
| **ADDED* HUMANISTIC BENEFIT (PRO/QoL)** | | | | | *Not a determinant on HTA decision-making* | |
| **EASE OF USE/ FUNCTIONALITY*** | *Not a determinant on HTA decision-making* | | | | | |

* While clinical/humanistic benefit and cost-effectiveness data involves a comparison of additional value with the SoC/control arm, ease of use/functionality relates to the DHTs intervention only, with no comparison vs. SoC/control arm

**Key: importance in decision-making:** High | None | Medium

## Conclusions

As DHTs are increasingly being evaluated and funded in many parts of Europe, they are shifting the HTA paradigm leading to the incorporation of new patient-centric decision-making that places patients' ability to use and understand technologies in direct relationship with clinical outcomes. As such, instead of being passive recipients of care, patients are increasingly participating in their own health, translating into new health outcomes being assessed as part of the HTAs. With the expansion of DHTs, the patient-centered focus seen in the DHT assessment may inspire further innovations on how patient-centered outcomes are assessed in the HTAs for drugs, beyond the PRO/QoL outcomes and consulted patients' inputs.

## REFERENCES

[1] Bertrand J et al 2011. Development of a complex parent-metabolite joint population pharmacokinetic model. The AAPS journal 13 (3): 390-404.

[2] Taft DR et al 1997. Application of a First-Pass Effect Model to Characterize the Pharmacokinetic Disposition of Venlafaxine after Oral Administration to Human Subjects. Drug Metabolism and Disposition, 25, no. 10 (1997): 1215-1218.

[3] Zhou X et al 2018. Structural and Practical Considerations in the Development of a Parent-Metabolite Model. PAGE 27 Abstr 8660.

[4] Bellu G 2007. DAISY: A new software tool to test global identifiability of biological and physiological systems. Computer methods and programs in biomedicine 88(1): 52-61.