

## Uncertainty: Friend or Foe?

The EAA was approached to present on Feb. 15<sup>th</sup> to the Oncology Group of the German Trade Association LAWG (<https://lawg-deu.de>) its perspective on 'Uncertainty'. Four key elements were highlighted (presentation available [HERE](#) at [www.euaac.org](http://www.euaac.org)):

### **A humanistic perspective on 'uncertainty':**

Uncertainty is an essential element of all our lives and cannot be avoided. While events that occurred in the past cannot be changed, a key characteristic of the future is change and related uncertainty. Uncertainty generates both, opportunities and challenges, resulting in a wide array of emotional responses ranging from hope to fear. How we approach and manage uncertainty largely impacts our success as individuals and that of society in the future. Compared to more conservative, or older, communities, young populations and innovative societies tend to be ready to accept higher levels of uncertainty. However, a trade-off of this 'agile learning attitude' is the potential risk of failure.

### **A Health Technology Assessment (HTA) perspective on 'uncertainty':**

As stipulated by the EU HTA Regulation '*HTA is able to contribute to the promotion of innovation, which offers the best outcomes for patients and society as a whole.*' Thus, the related risk is twofold:

- i) promoting innovation that does not offer best outcomes and
- ii) not promoting innovation that does offer best outcomes.

While HTA is often perceived as a means to ensure that an additional benefit is not falsely assigned, its perspective should therefore reach beyond. As pointed out by the HTAi-DIA Working Group, discrimination of i) nonpreventable vs preventable uncertainties and ii) uncertainties vs related risks are important elements when approaching the HTA perspective on 'uncertainty' ([Hogervorst et al. 2023](#)).

Finding the right balance across the two underlying types of risk – '*to the benefit of patients and the society as a whole*' - is the topic of the EAA Spring Convention 2024 @ Erasmus University in Rotterdam on April 18/19<sup>th</sup> (see: [www.euaac.org](http://www.euaac.org)).

### **The quest for certainty and the three pillars of Evidence-based Medicine (EbM):**

EbM is our means to reduce uncertainty in medicine. It is based on a triade of information: i) data; ii) clinicians' perspective; iii) patients' perspective. While assessment of evidence is a stepwise process, in the early phase of developing innovative health technologies only limited experience prevails on the side of clinicians and patients. Furthermore, 'Conflict of Interest' regulations pose the risk that existing experience might be sidelined with those few individuals having experience and expertise on an innovation being excluded. Thus, undoubtedly available data are the 'first among the three equals' when leveraging EbM in our quest for certainty. Consequently, HTA is at risk of becoming dominated by technical – i.e., methodological – discussions and losing sight of the patients' and clinicians' perspective. Therefore, the EAA strongly advocates for an inclusive societal dialogue to be included alongside each of the upcoming EU HTA assessment reports. Leveraging the available data as the evidence basis, but integrating patients' and clinicians' input in the assessment in order to have the right perspective on both the wanted and unwanted effects of a new medicine, is suggested.

**The opportunity of European leadership:**

With the EU HTA Regulation being applied from Jan 12<sup>th</sup>, 2025, these joint EU procedures will create the most impactful HTA globally. No other global market has introduced an HTA process reaching out to 27 member states. A balanced approach to uncertainty will be required to turn this opportunity for leadership by the [EU Health Union](#) into a success. Uncertainty is an essential part of our (health) future. It is neither friend nor foe - but our approach to uncertainty, and our willingness and skill to balance the opportunities and challenges that come with any innovation will determine the excellence of patient care across Europe in future.

*The Faculty of the European Access Academy*

*Monday, February 19<sup>th</sup>, 2024*