New EU HTA Regulations: Why It Matters to You and How Phastar Can Help You Be Prepared

EU HTA What's Changing

EU HTA regulations are changing the way we conduct HTA submissions with EU regulators. **Prior to the introduction of this legislation,** submission to each member state's regulatory body could be done in a staggered approach. **This won't be the case with EUnetHTA**.

The **new process will require the submission of a single HTA dossier to EUnetHTA** (a consortium of countries). This dossier will **address the questions of interest from all the regulators** and will require the production of a **single submission package** which will include an **EUnetHTA Project Plan** as well as results from additional analyses conducted to complement the main clinical study report.

How It Impacts You

These analyses are **expected to generate a large body of evidence** and are likely to include **investigation of new subpopulations, subgroup analyses, additional endpoints and/or indirect treatment comparisons.** The **PICO framework** is central to the specifications and will require **careful consideration of feasibility, validity, and scientific rigour.**

In addition, **submissions are expected to be completed within a relatively short timeframe**. Thus, to ensure effective submissions, sponsors will require **detailed plans to be in place prior to the completion of the main clinical trial reporting.**

How Phastar Can Help You Be Prepared

Understanding the Journey

The journey of drug development is intricate, and at Phastar, we understand that each stage represents a pivotal milestone on your path to success.

Navigating Uncertainty

There is still a lot of uncertainty around the process, but at Phastar, we understand clinical trials and have expertise in the additional analyses often required for other HTA processes.

Maintaining Momentum

To maintain the momentum and progress of clinical development pipelines under the new EU HTA legislation, effective planning and access to top-tier expertise are crucial. This includes the ability to immediately understand the nuances of the design, analyses, endpoints, and data for your trial.

Tailored Solutions

Our experiences in applying our statistical and analytical skills to provide tailored solutions support robust HTA submissions (e.g., submissions to G-BA). Our proficiency in managing large datasets ensures data integrity and quality.

Leveraging Expertise

By leveraging our extensive expertise in clinical trials and data analysis, Phastar can provide robust support to sponsors facing these regulatory shifts. Our team is adept at:

Generating high-quality evidence across various endpoints

Conducting detailed subgroup and sensitivity analyses

Performing indirect treatment comparisons

Comprehensive Support

Whether dealing with a small number of PICOs that can be addressed by simple analyses of existing ADaM datasets, or many PICOs with new complex endpoint derivations and requirements for Multi-level Network Meta-Regression to compare the medicine with other interventions, Phastar is well-prepared to help.

EUnetHTA

What's New?

- One dossier
- Extra analyses
- New timelines
- One regulatory body for EU

Why?

- Reduces timelines
- Increased importance of planning prior to completion of trial(s)

What's Next?

- Plan ahead to mitigate impact on timelines
- Work with a company familiar with nuances of the clinical trial

For more information on how Phastar can support, get in touch - https://phastar.com/contact-us/