FORUM

Start EU-HTA 2025

Current project status and milestones

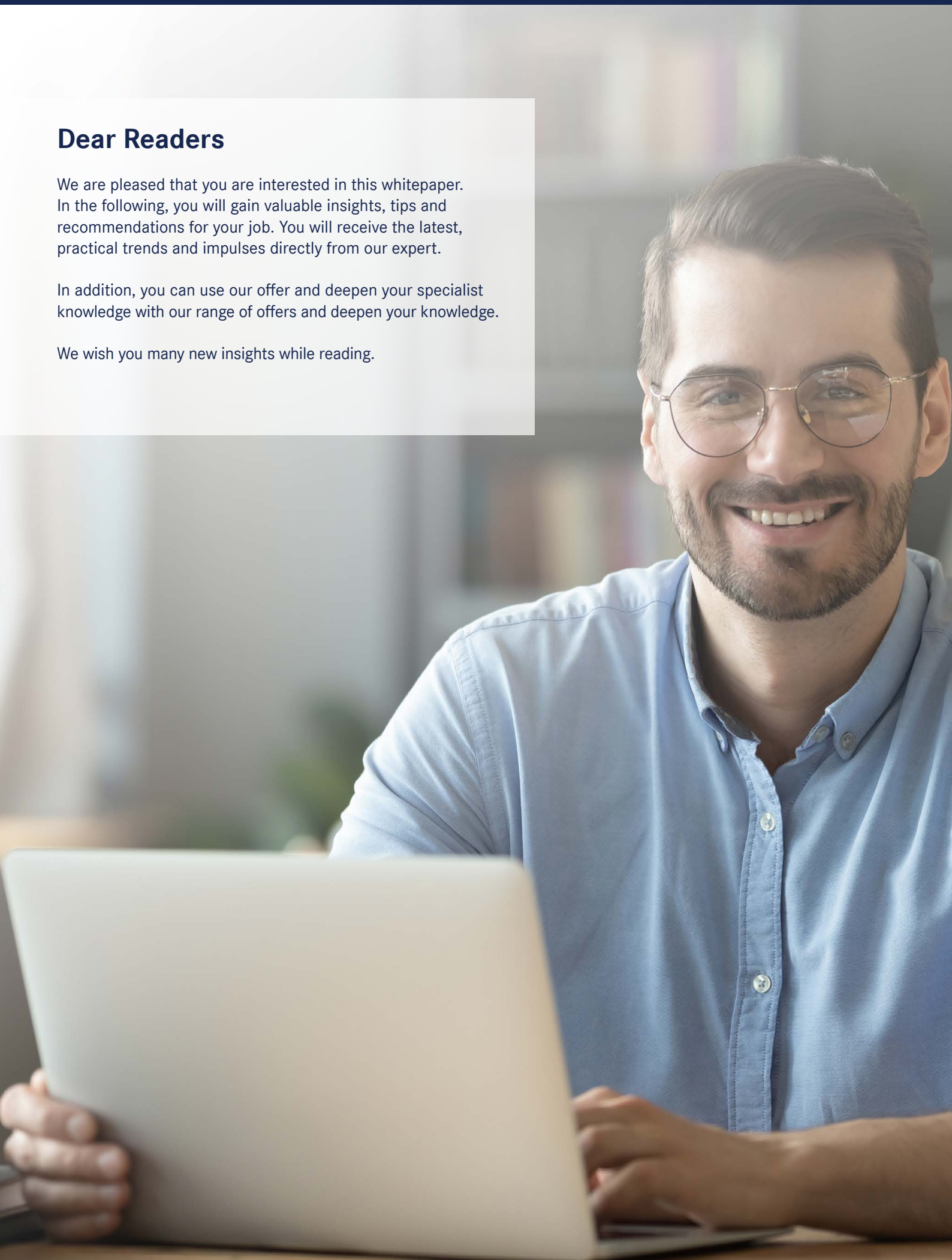
Dr med Olaf Pirk

Dear Readers

We are pleased that you are interested in this whitepaper. In the following, you will gain valuable insights, tips and recommendations for your job. You will receive the latest, practical trends and impulses directly from our expert.

In addition, you can use our offer and deepen your specialist knowledge with our range of offers and deepen your knowledge.

We wish you many new insights while reading.



Current project status and milestones

EU-HTA launches with first product groups and indications in 2025.
This white paper outlines the genesis and current status of the Regulation and its implementation rules as well as the milestones up to the start of the process. It also discusses the central body – the coordination group.

About the author

Dr med Olaf Pirk
is a trained physician, health economist and systemic consultant. In the past 20 years he has mainly worked as a consultant on market access for new medicines and medical devices, on health economics and health policy issues as well as on questions of health care management.

Cross-border healthcare should promote cooperation

Directive 2011/24/EU on the „Application of patients' rights in cross-border healthcare"

- Regulations on the reimbursement of cross-border healthcare
- Cooperation between European health systems

Article 15

- Support voluntary cooperation of national HTA institutions
- To support Member States in providing and efficiently exchanging objective, reliable, timely, transparent, comparable, and transferable information on the relative effectiveness of health technologies (Joint Assessment)
- Objective: avoid duplication of work

The first approaches of a joint assessment have already been established here.
The challenge is the „harmonisation" of 27 member states.

Source: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32011L0024

A new approach was needed to promote cooperation in health care.

Year	Event
Until 2017	IMPACT ASSESSMENT Strengthening of the EU Cooperation on HTA • Study on impact analysis of policy options for strengthened EU cooperation on HTA • Mapping of HTA methodologies in EU and Norway • Mapping of HTA national organisations, programmes and processes in EU and Norway
January 2018	Proposal for a Regulation on health technology assessment (31 January 2018, EU-Kommission)
October 2018/February 2019	Approval of the report by the European Parliament with 200 amendments. Parliament adopted the report in a vote on 14 February
March/June 2021	Mandate to start negotiations in the European Council; Agreement in Parliament, Council and the Permanent Representatives
Winter 2021/2022	Approval in the plenary of the European Parliament and entry into force of the EU HTA Regulation

The regulation has been in force since January 2022 with the following main points

REGULATIONS

- Joint clinical assessments of medicinal products (JCA)
- Joint scientific advice to manufacturers (also parallel HTA/EMA consultations)
- Identification of new health technologies (horizon scanning)
- Voluntary cooperation in other areas (e.g. non-clinical aspects)

Source: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32021R2282

The regulation contains the following key points for the EU Member States (MS) for a common HTA

- Mandatory mechanism for submitting the required data at EU level.
- Data already submitted by manufacturers at EU level may not be requested again at national level
- Supplementary data may be requested at national level
- Maximum transparency on submitted data and exchange via national HTAs
- Ensure high quality of the Joint Clinical Assessment (JCA)

Source: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32021R2282

The regulation has been in force since January 2022 with the following main points

REGULATIONS

- Joint clinical evaluations of medicinal products (Joint Clinical Assessment - JCA)
- Joint scientific advice to manufacturers (also parallel consultations HTA/EMA)
- Identification of new health technologies (horizon scanning)
- Voluntary cooperation in other areas (e.g. non-clinical aspects)

Source: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32021R2282

The regulation contains the following key points for the EU Member States (MS) for a common HTA

- Binding mechanism for submitting the required data at EU level
- Data already submitted by manufacturers at EU level may not be requested again at national level
- Supplementary data may be requested at national level
- Maximum transparency of submitted data and exchange of data via national via national HTA
- Ensure high quality of the Joint Clinical Assessment (JCA) (Joint Clinical Assessment, JCA)

Source: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32021R2282

The Coordination Group (CG) is the central body in the process of the EU-HTA

- The CG works independently and transparently. The highest quality standards of evidence-based medicine are to be guaranteed
- The members are appointed by the member states
- The Commission supports the CG and formally adopts the necessary legal acts (implementing acts, e.g. codes of practice, format templates, etc.). The Commission does not take decisions on joint clinical evaluation, joint clinical deliberations, their acceptance, preparation or methodology
- The CG establishes subgroups to prepare the decisions. They are responsible, among other things, for the design of processes and methods
- Development of methods and procedures and their updating
- Joint scientific assessments
- Joint scientific consultations
- Horizon scanning

Source: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32021R2282

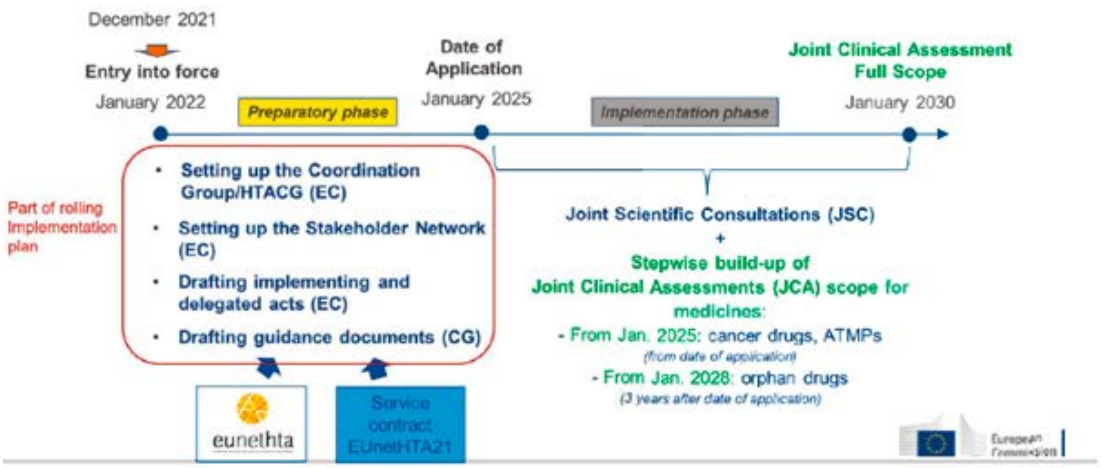
By the start of the evaluation phase

(3 years after entry into force), the evaluation phase shall include the following

- Rules of Procedure of the CG (Art 3/6a)
- Methodological guidelines in accordance with international standards of evidence-based medicine (Art 3/6d)
- Rules of Procedure for Joint Clinical Evaluations (Art 3/6e)
- Rules of Procedure for Joint Scientific Advice (Art 3/6f)
- Procedure for designation of author/co-author of JCA (Art 3/6f)
- Highest possible quality requirements for procedures according to international standards of evidence-based medicine (Art 3a)

Source: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32021R2282

The preparatory phase is still underway and the coordinating group is working out all the necessary requirements for the start.



Other offers:

Practical regulatory affairs and vigilance knowledge

Our regulatory courses and conferences provide practical information on the fundamentals and trends in marketing authorisation, regulatory maintenance and post-marketing surveillance. More information.

e-Learning – Click and learn

The FORUM Institut offers a flexible form of training with quality e-learning courses. You decide for yourself when and where to learn. Test free now.

In-house seminars – Tailored solutions

All our seminars are also perfect for in-house training. Request a personalised quotation now.

FORUM · Institut für Management GmbH · Vangerowstraße 18 · 69115 Heidelberg · Germany
Phone: +49 6221 500-500 · Fax: +49 6221 500-555 · www.forum-institut.com