

HTA requirements in relation to the EU Regulation

Speaker

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TOPIC:

The REGULATION (EU) 2021/2282 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 15 December 2021 on health technology assessment and amending Directive 2011/24/EU (Text with EEA relevance) sets out the frame for cooperation of national Health Technology Assessments.

How does it work? Which kind of impact has the new regulation on the national decision making? Which steps are taken to reach the goal of a harmonised approach to a European Assessment?

Dr. Said will give an in-depth information about the involvement of Germany in the development of the process, the steps already taken e.g. by EUnetHTA 21 and the perspectives of the implementation of the regulation.

G-BA

The Federal Joint Committee (Gemeinsamer Bundesausschuss, G-BA) is the highest decision-making body of the joint self-government of physicians, dentists, hospitals and health insurance funds in Germany.

The G-BA must put every new active pharmaceutical ingredient through an early benefit assessment within six months after it is launched on the German market. During the early benefit assessment, the G-BA examines whether the drug is really something new: if it offers patients greater benefit than comparable treatments that are already available.

