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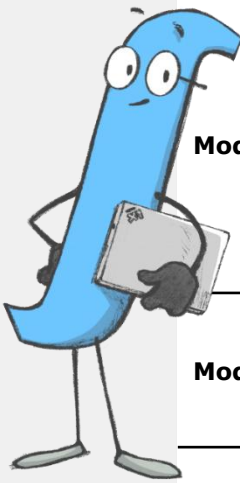
Implementing EU HTA at National Level: Adjustments to the AMNOG Module Template

The following information is based on the G-BA information event ***"Countdown to EU HTA: What Changes Lie Ahead for the AMNOG Process?"*** held on 22 May 2025. This summary outlines the key points of the event in the context of national implementation of the EU HTA Regulation. It highlights the planned adjustments to the AMNOG dossier template. Please note that these changes are still subject to final approval – a decision by the G-BA is expected in July 2025.



Module	Reference option?
Module 1	All required information in Module 1 must be provided without referencing the JCA dossier.
Module 2	To be completed without references: • Section 2.1.1 (Administrative information on the medicinal product) • Section 2.2 (Approved Indications) *Throughout all other sections, references to the JCA dossier may be made as appropriate.*
Module 3	To be completed without references: • Section 3.1 (Definition of the appropriate comparator therapy) • Section 3.2.3, 3.2.4, 3.2.5 (Patient numbers) • Section 3.3 (Costs of therapy for the GKV) • Section 3.4.1 (Requirements from the SmPC) • Section 3.5 (EBM) • Section 3.6 (Proportion of study participants in Germany) *Throughout all other sections, references to the JCA dossier may be made as appropriate.*
Module 4	To be completed without references: • Section 4.2.1 (Research question) • Section 4.4 (Final Assessment of the documentation demonstrating added benefit) *Throughout all other sections, references to the JCA dossier may be made as appropriate.*
Module 5	The file must be placed in the designated subdirectory and must include a reference to the JCA dossier. Please ensure compliance with the current coding specifications.

- References should indicate the lowest available level of document structuring (e.g., section, subsection).
- When referring to tables or figures, the corresponding table or figure number must be specified.

Editorial update of the appropriate comparator therapy

Patient-individual therapy

Therapy according to doctor's instructions

Individualized therapy

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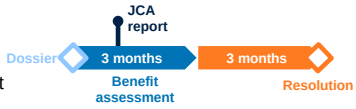
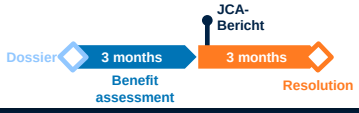
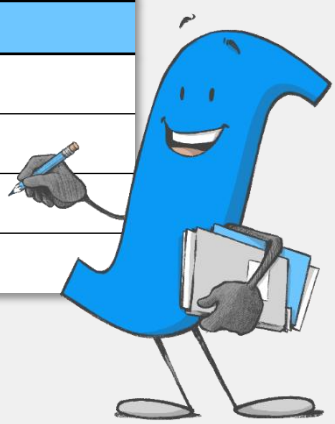
Availability of the JCA report at the time of dossier submission	IQWiG benefit assessment	Consultation Process	Resolution / Justification
Scenario 1: JCA report is available at the time of dossier submission 	✓ JCA report is considered.	✓ JCA report is considered. ✓ The G-BA provides both a link to the publicly accessible EC webpage containing the JCA dossier and report, as well as a reference to the PICO relevant for the benefit assessment.	✓ JCA report is considered.
Scenario 2: JCA report is available after dossier submission but before the publication of the benefit assessment 	× There is no legal obligation for IQWiG/G-BA to consider the JCA report; however, both institutions are involved in the report development through the JCA Subgroup.		
Scenario 3: JCA report is available after the start of the consultation procedure. 	× JCA reports published after the start of the consultation procedure cannot be formally considered.		

Current dossier template	New dossier template (from ~July 2025)
Safety endpoints	
• Overall rate of AE differentiated by severity	• Severe adverse events with CTCAE ≥ 3 – Clarification – already corresponds to practical implementation in Module 4
• A priori defined adverse events of special interest (AESI) as well as predefined SOC-wide adverse event analyses (e.g., as SMQs)	✓ **Requirement no longer applies**
Subgroup analyses	
• If the available information indicates potential additional effect modifiers, these **may** also be included with justification. • Results from a priori planned subgroup analyses defined in the study protocol for patient-relevant endpoints must always be presented.	• Restriction to subgroup analyses for gender, age, disease severity or stage, and center and country effects – If multiple definitions or operationalizations exist for disease severity, the selection must be justified. • If available information suggests additional potential effect modifiers, these **should** also be included with justification. • Results from subgroup analyses of stratification factors defined in the study protocol must always be presented. • As a general rule, the definition and operationalization of subgroups, including cut-off values, should be based on a priori planned subgroup analyses specified in the study documentation.
Requirements for searching clinical trial registries and results databases	
• International Clinical Trials Registry Platform Search Portal (ICTRP Search Portal)	✓ **Requirement no longer applies**
• WHO search portal	✓ **Requirement no longer applies**
• Pharmaceutical Information System (AMIS / AMIce)	✓ **Requirement no longer applies**
• Not previously required	➢ **NEW:** Clinical Trial Information System (CTIS) (Harmonization with the JCA Dossier)



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