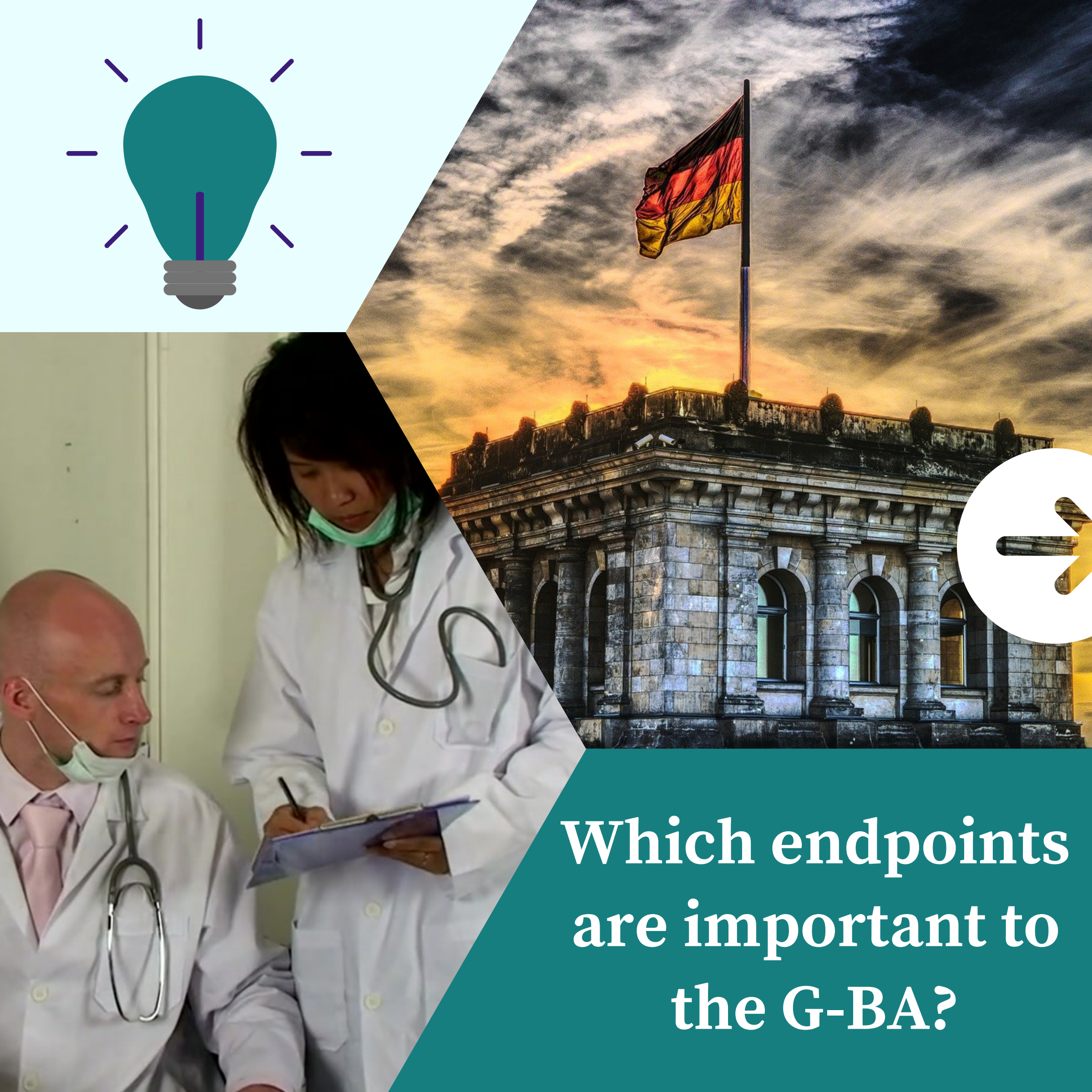
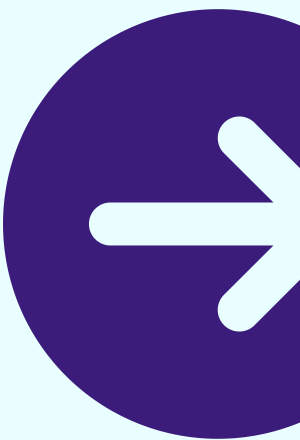




**Which endpoints
are important to
the G-BA?**

The G-BA follows strict criteria, applied in a hierarchical step-wise manner, to determine whether a product has an additional benefit.



Only when the first criterion is met, the next one will be reviewed. If the submitted data does not meet one criterion, the G-BA will automatically give “No additional benefit (proven)”. →



Criteria

Did the pharmaceutical company submit a dossier?

Are the included clinical studies acceptable?

Is the intervention being compared with the ACT?

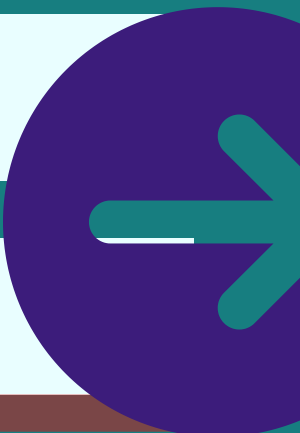
Does the study population reflect the population covered by the label?

Is the study duration appropriate?

Are the endpoints patient-relevant and acceptable?

Is there a statistically significant benefit?

The G-BA determines the additional benefit



The G-BA assesses
3 types of outcomes:

- Mortality
- Morbidity (symptoms and side effects)
- HRQoL

3

Patient relevance is crucial for the acceptance of an endpoint. These endpoints reflect how a patient feels, how they can perceive their functions and activities, or whether they survive.



The G-BA assesses the extent of the additional benefit for each endpoint individually, and then determines the overall additional benefit.



Guideline to determine extent of additional benefit

Extent of additional benefit				
Improvement in therapy-relevant benefit, which has not previously been achieved vs the ACT		Major Sustained and great	Considerable Marked	Minor Moderate and not only marginal
Outcome category	Mortality (OS) Increase in survival time	Major	Moderate	Any
	Morbidity Symptoms or late complications Serious / severe	Long-term freedom from	Alleviations of	Any reduction in
	Non-serious / non-severe	–	Important reduction in	Reduction in
	Side effects / AEs Serious / severe AEs	Extensive avoidance	Relevant avoidance	Any statistically significant reduction in
	Non-serious / non-severe AEs	–	Important avoidance	Relevant avoidance of
HRQoL Improvement		Major	Important	Relevant

Adapted from IQWiG methods