

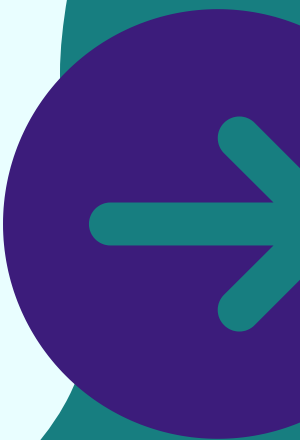


Surrogate
endpoints
accepted by
the G-BA

Surrogate endpoints can themselves be patient-relevant, but clinical trials often use them instead of patient-relevant endpoints.



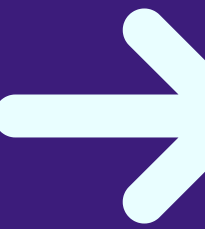
Surrogate endpoints,
that are not themselves
patient-relevant, will only
be accepted when they
have been **sufficiently
validated.**





VALIDATION

- They need to be validated
- using appropriate statistical methods
 - in the target patient population
 - for the same or a comparable intervention with the same mechanism of action.



There is no standard method or best practice to validate a surrogate endpoint, but the G-BA prefers the use of **correlation-based methods**.



cor-re-la'-tion
(-tiv), adj. [L. c
cor-res-pon

An NMA of several RCTs, which measure both the surrogate as well as the patient-relevant endpoint, needs to show a high level of correlation at the study and patient level.



Alternatively, the manufacturer can compare the effect on the surrogate endpoint with the so-called surrogate-threshold-effect (STE).

EFFECTS

