



How are
digital health
applications
assessed?

Since 2020, clinicians can prescribe and SHI funds will reimburse medical apps and digital health treatments (DiGAs).



To make such treatments available to patients as quickly as possible, the regulatory agency, BfArM, has developed the DiGA fast track process to speed up reimbursement.

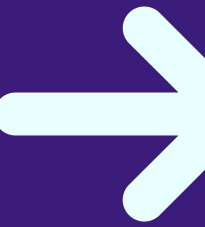


Federal Institute
for Drugs
and Medical Devices





Manufacturers submit an application. The BfArM then checks within 3 months whether the products meet the necessary requirements.



Fast track process



Manufacturer

Offers advice



Submits application



Federal Institute
for Drugs
and Medical Devices



Assessment

Requirements

on safety, functionality, quality, inter-
operability, data protection and security

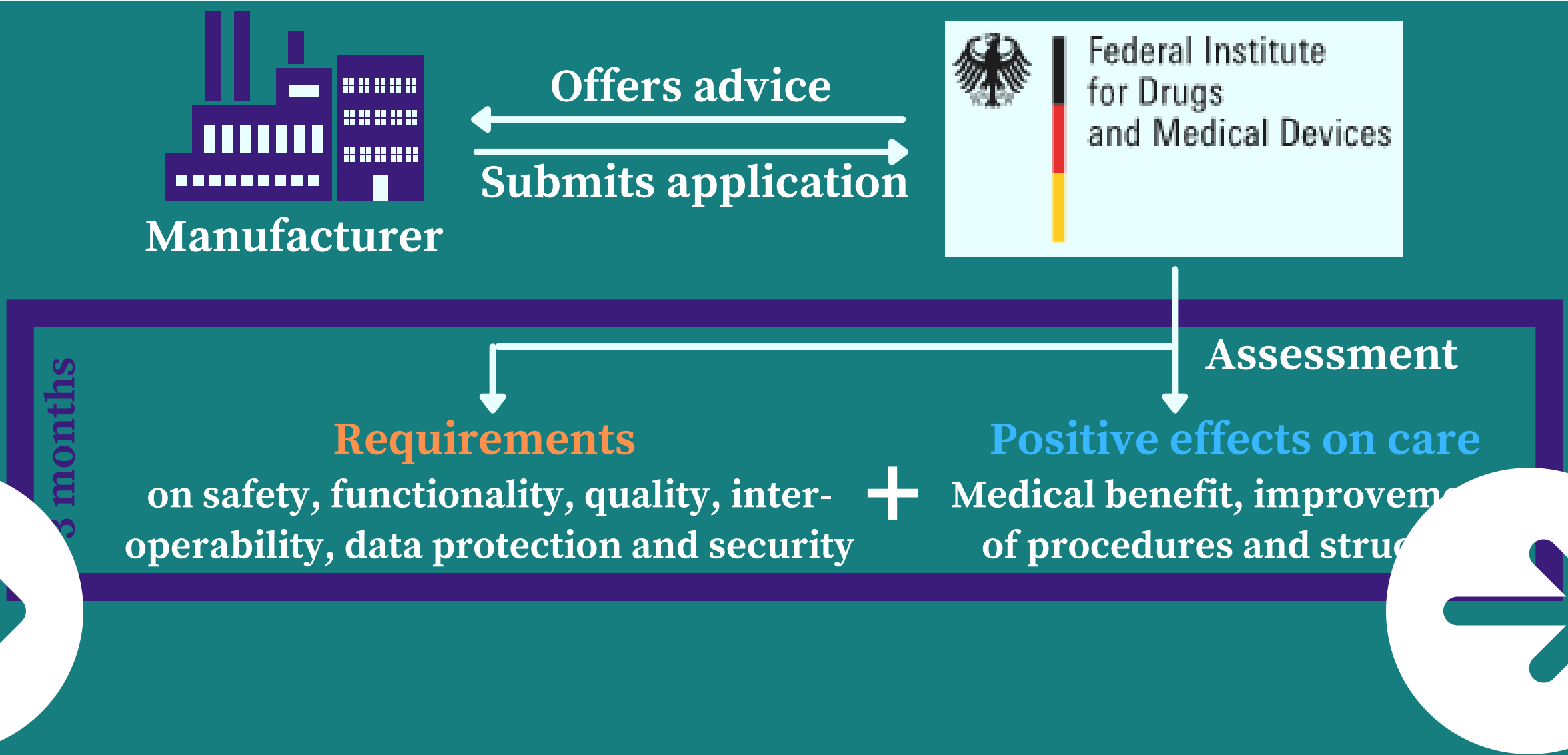
3 months



The manufacturers must
also prove that the DiGA
has a positive effect on
patient care.



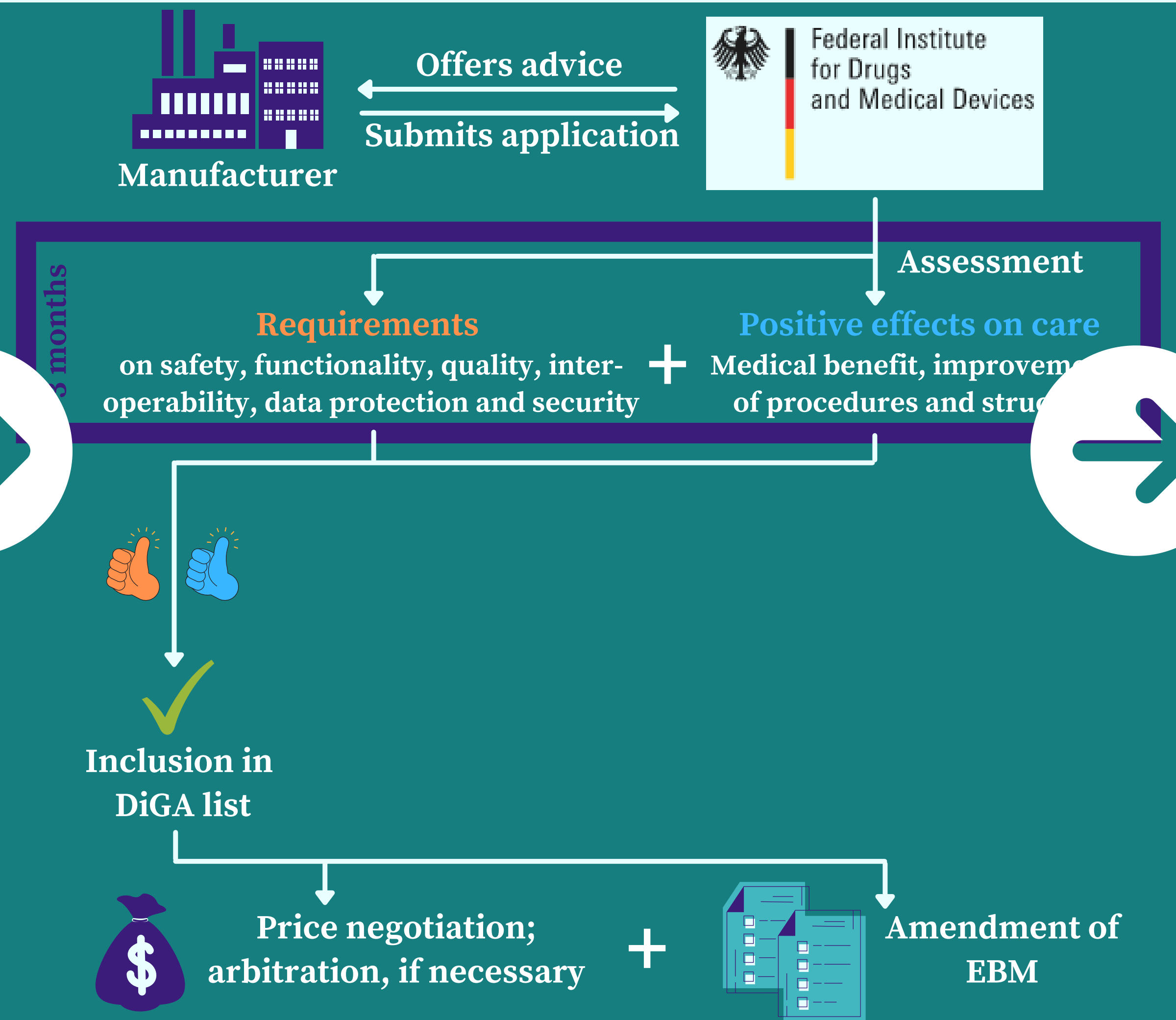
Fast track process



If the assessment was successful, the product can be included in the DiGA list and can be prescribed and covered by SHI funds.



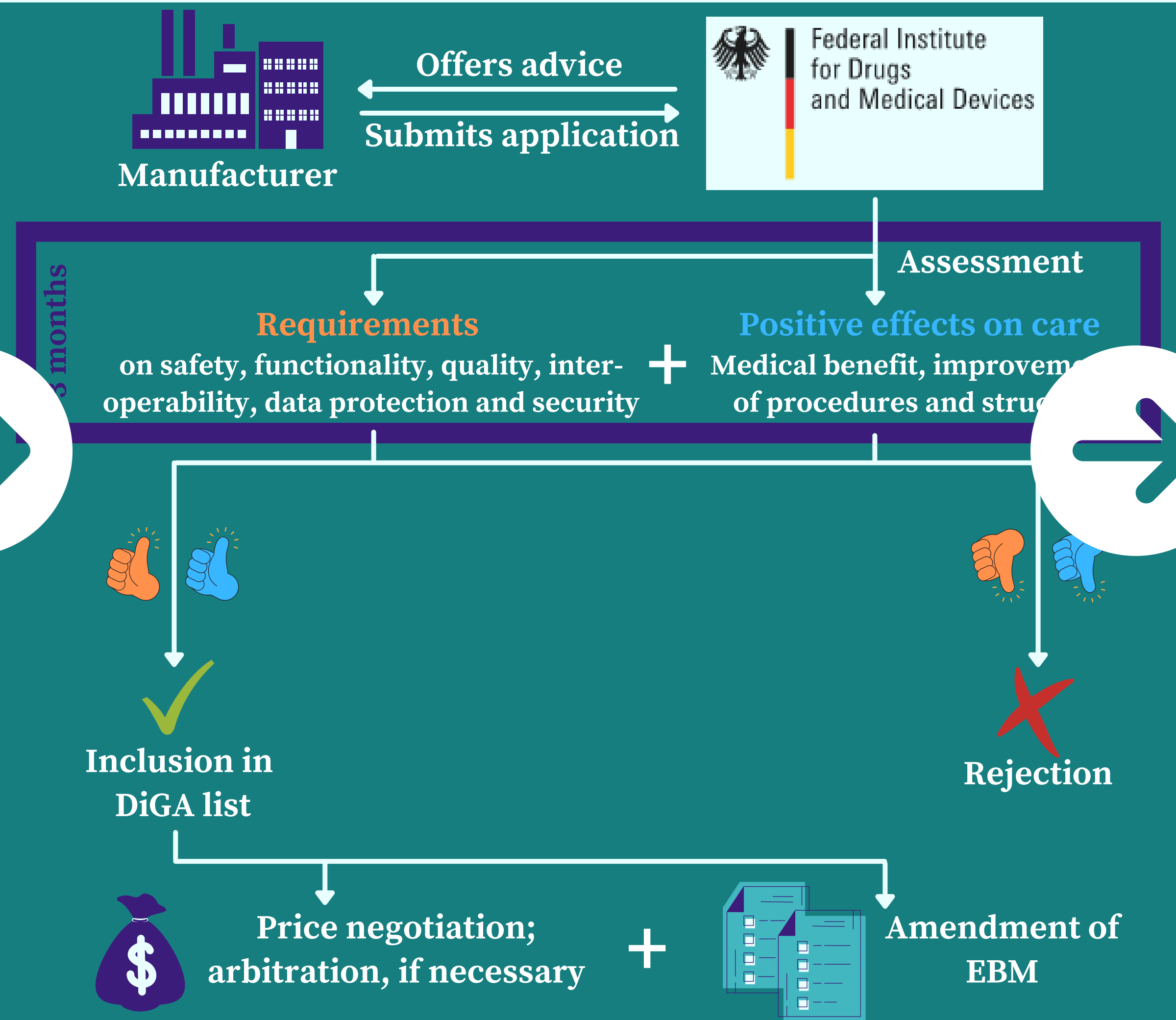
Fast track process



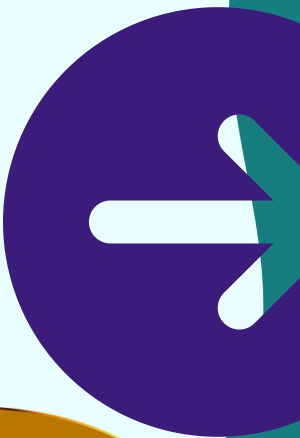
If the requirements are not fulfilled, and/or no positive effects on care were demonstrated, the BfArM will reject the DiGA.



Fast track process



Lastly, if the evidence on a positive effect on care is not available yet but the other requirements are fulfilled, a manufacturer can apply for provisional inclusion and can complete the necessary study within 12 months.



Fast track process



Manufacturer

Offers advice

Submits application



Federal Institute
for Drugs
and Medical Devices

3 months

Requirements

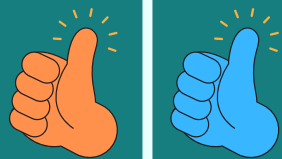
on safety, functionality, quality, inter-
operability, data protection and security



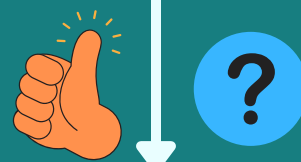
Positive effects on care

Medical benefit, improvements
of procedures and structure

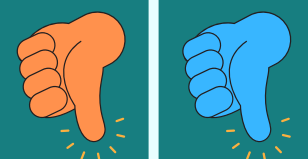
Assessment



Inclusion in
DiGA list



Provisional inclusion



Rejection

12 months

Trial phase

Plausible justification of
positive health care effects,
evaluation concept



Price negotiation;
arbitration, if necessary



Amendment of
EBM