FRPath.org
Where the Roads to Accelerated Assessments Converge

FRPath.org FRP Summary		
Country: USA	**Agency Name:** US FDA	
Name of FRP: Breakthrough Therapy Designation		
Is this FRP Proposed or Active? Active		
Year FRP was officially enacted: 2012		
1. Facilitates activities during development	**2. Accelerates the regulatory review process**	**3. Relies on or recognizes a prior regulatory decision**
☒	☒	☐

Is a Guidance or SOP describing how to apply this FRP publicly available?	Yes- see reference below
When should the FRP be requested?	With IND or after Ideally, no later than the end-of-phase 2 meeting
Does the agency provide assistance/advice to the sponsor?	Yes- for selected submissions
For which types of product(s) can this FRP be used? E.g. NMEs, generics, biologics, biosimilars, all products	NME, biologics
Must the product address an unmet medical need or serious condition?	Yes
If a fee is required, what is the amount (in US$ equivalent)	None
Total target (agency) time for assessment (calendar days)	Variable
Total target (company) time for responses to agency questions (If stated)	Variable

Select one of the following

Is this a verification review (a recognition pathway)?	**Is this an abridged review (selected dossier portions)? (a reliance pathway)?**	**Is this a full review of all parts of the dossier?**
☐	☐	☐

If this is a reliance or recognition pathway, what are the accepted reference agencies?	Not applicable
How many reference agency decisions are required?	Not applicable
Does this FRP require submission of Assessment Reports from prior decisions?	Not applicable
Is a CPP (Certificate of Pharmaceutical Product) required for approval?	Not applicable
Can an alternate form of reference documentation to the CPP be used? If so, what types of documents?	Not applicable
If this process is through a Regional Regulatory Initiative, which countries	Not applicable

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participate in this process?	
Does the product have to have been marketed in another country? For a specific amount of time? If so, for how long?	Not applicable
How are queries to the companies sent?	As they arise
Are external reviewers (e.g. non-agency) involved in the assessment?	No-all done internally
Post-authorization study commitments	Negotiable
For how long is the initial approval or designation valid?	See Details Section below
Details	FDA to respond to designation request within 60 calendar days of receipt of the request. Designation may be rescinded if it no longer meets the qualifying criteria for breakthrough therapy
Date of latest update	10August2019
References	Guidance for Industry Expedited Programs for Serious Conditions – Drugs and Biologics. https://www.fda.gov/media/86377/download Section 506(a) of the FD&C Act, as added by section 902 of FDASIA Conrad R et al: Breakthrough Therapy Designation: CDER analysis of requests 4 years into the program. TIRS 2017:51(4);509-515 Damle N et al: FDA's expedited programs and their impact on the availability of new therapies. TIRS 2017:51(1):24-28

Definitions:

Verification review: A checklist review based on recognition of a prior regulatory decision. Recognition is the routine acceptance of the regulatory decision of another regulator or other trusted institution. Recognition indicates that evidence of conformity with the regulatory requirements of economy A is sufficient to meet the regulatory requirements of economy B.

Abridged review: An abbreviated review of selected portions of the dossier and the reliance on prior assessment decisions. Reliance is the act whereby a regulatory authority in one jurisdiction may take into account/give significant weight to work performed by another regulator or other trusted institution in reaching its own decision

Full review: A comprehensive review of all components of the dossier. This may or may not be CPP-dependent.