Comparison of Breakthrough therapy designation and MHRA processes

Breakthrough therapy designation characteristic	Equivalent MHRA activity
Holding meetings with the sponsor and the review team throughout the development of the drug.	The MHRA offers a scientific advice service in face to face meetings, which can be requested during any stage of the development of a medicinal product.
Providing timely advice to, and interactive communication with, the sponsor regarding the development of the drug to ensure that the development program to gather the nonclinical and clinical data necessary for approval is as efficient as practicable.	Following a scientific advice meeting, a final scientific advice letter is sent to the company within 30 working days of the meeting. The MHRA has launched an 'Innovation Office', aimed at providing regulatory advice and to support research and development. The EU system also provides extensive guidance to applicants outlining requirements
Taking steps to ensure that the design of the clinical trials is as efficient as practicable, when scientifically appropriate, such as by minimizing the number of patients exposed to a potentially less efficacious treatment.	National scientific advice covers aspects such as endpoints, trial duration, target population, choice of comparator and statistical methodology. EMA scientific advice provides similar advice The MHRA's dedicated clinical trial unit carries out timely approval of clinical trial applications, 100% within statutory timelines. The MHRA has strong expert representation on European committees including Committee on Human Medicinal Products (CHMP) and Scientific Advice Working Party (SAWP).
Assigning a cross-disciplinary project lead for the FDA review team to facilitate an efficient review of the development program and to serve as a scientific liaison between the cross-discipline members of the review team (i.e., clinical, pharmacology-toxicology, chemistry, manufacturing and control (CMC), compliance) for coordinated internal interactions and communications with the sponsor through the review division's Regulatory Health Project Manager.	Internal MHRA procedures are in place to ensure quality and consistency of the final scientific advice letters (multi-disciplinary in house review group). MHRA has dedicated product life cycle assessment teams (PLATs) for different therapeutic areas, comprising clinical, non-clinical and pharmaceutical assessors and the same specialist assessors handle products throughout the licensing process. The MHRA clinical trials unit works alongside the PLATs and are also present at scientific advice meetings, along with statistical and standards/inspection colleagues as required.

Involving senior managers and experienced review staff, as appropriate, in a collaborative, cross-disciplinary review	National scientific advice meetings are carried out by experienced staff and procedures have management oversight. European scientific advice is similarly prepared by experienced assessors and adopted through CHMP.
FDA publishes the number of requests made, granted or denied since the enactment of FDASIA on July 9, 2012, but not the specific products or the 'indication' for which the investigational medicine received the breakthrough designation. Under FDA regulations, it cannot disclose information submitted to an investigational new drug (IND) filing.	Names of specific products undergoing advice are not released, however numbers of advice procedures are released.