Shortening Development and Approval Timelines for Novel Medicinal Products

With These Special Designation(s)

The FDA and EMA offer expedited regulatory approval pathways to accelerate the development of therapies intended to treat serious conditions and unmet medical needs. We recommend that you build a strategic regulatory plan and leverage the right pathways to drive faster and more efficient drug development.

Below we highlight the benefits of twelve key special designations, many of which reduce clinical development and review timelines. Overall, these regulatory pathways can save time and reduce the cost of bringing therapies to market—and to patients—sooner.

BENEFITS OF KEY SPECIAL DESIGNATIONS

DESIGNATION	GEOGRAPHY	POTENTIAL BENEFIT
Orphan Drug Designation	US	> 7-year marketing exclusivity > Federal financial incentives > No submission fees
Orphan Drug Designation	EU	> 10-year marketing exclusivity > Fee reductions and access to centralized European review
Breakthrough Therapy (BT)	US	> Shortened clinical development time > Intensive guidance on efficient drug development > Initial comprehensive multidisciplinary BT meeting > Rolling review of application documents
PRIME (PRIority MEdicines)	EU	> Shortened clinical development time > Assigned rapporteur > Potential for Accelerated Assessment
Fast Track (FT)	US	> Expedited development and review timelines > Rolling review of application documents
Qualified Infectious Disease Product Designation (QIDP)	US	> 5-year exclusivity extension > Fast Track designation (must be specifically requested) > Priority Review (first application)
Regenerative Medicine Advanced Therapy (RMAT)	US	> Shortened development and review timelines > All Breakthrough Therapy designation features, including early interactions to discuss potential surrogate or intermediate endpoints > Potential opportunities to support Accelerated Approval and post-approval requirements
Priority Review (PR)	US	> Shortened review timeline (6 months compared to 10-month standard review)
Accelerated Approval	US	> Shortened development and approval timeline based on using surrogate endpoint for approval for serious condition or unmet medical need
Emergency Use Authorization (EUA)	US	> Quick approval during “emergency” until full approval
Accelerated Assessment (AA)	EU	> Assigned rapporteur and EMA’s CHMP may shorten review timeline from 210 down to 150 days
Conditional Marketing Authorization (CMA)	EU	> Earlier approval using less data – can shorten development and approval time and be renewed annually until complete approval
Real Time Oncology Review (RTOR)	US	> Shorter review cycle possible due to earlier submission and review of preliminary data for oncology indications

Get Trusted Regulatory Guidance from the Experts at Veristat

Special designations and expedited pathways can potentially accelerate the speed at which your products are developed or approved. However, these are not always granted. Work with the trusted experts at Veristat to ensure a seamless regulatory strategy and submission plan for both U.S. and global registrations. Veristat teams have prepared more than 160 marketing applications that have resulted in more than 80 regulatory approvals to date from various regulatory agencies around the world.

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