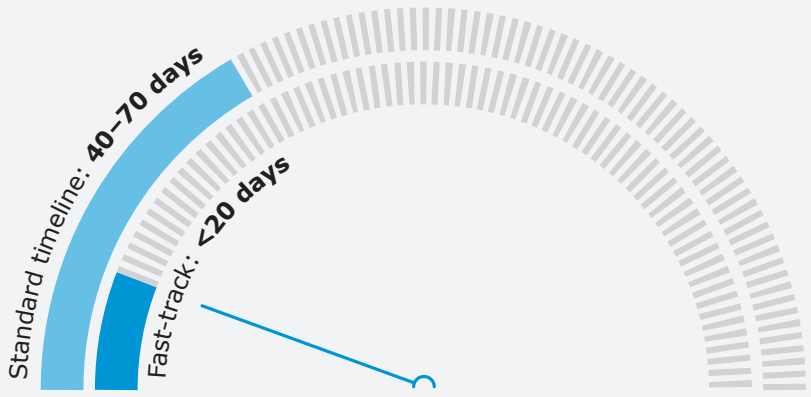
EMA

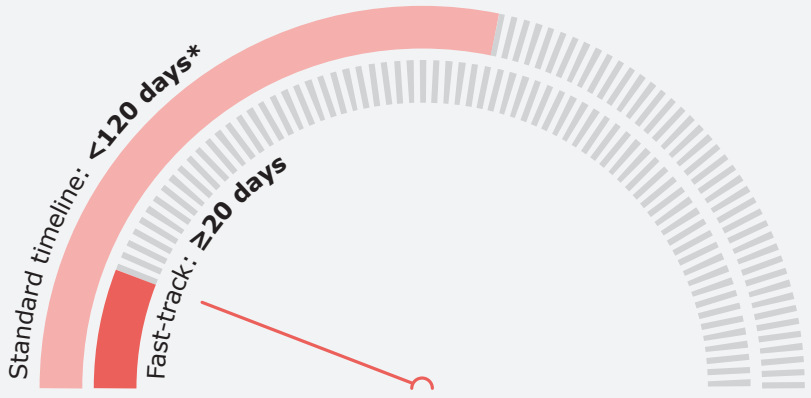
Fast-track procedures for treatments and vaccines for COVID-19

EMA is fully mobilised to support the development and marketing authorisation of safe, effective and high-quality therapeutics and vaccines against COVID-19. The Agency has put in place rapid review procedures related to COVID-19 to deliver assessments of high-quality applications from sponsors in the shortest possible timeframes while ensuring robust scientific opinions.



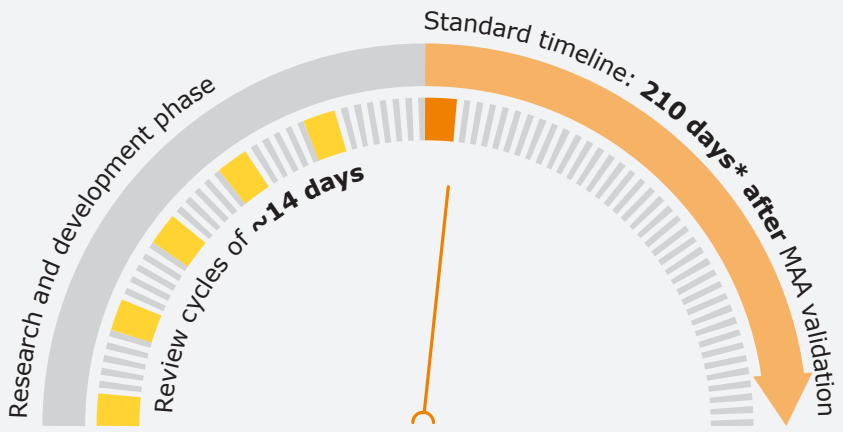
Rapid scientific advice

EMA provides developers with prompt advice to guide on the best methods and study designs to generate the scientifically robust evidence needed to determine the safety, efficacy and quality of treatments and vaccines against COVID-19 in the shortest time possible.



Rapid agreement of PIPs

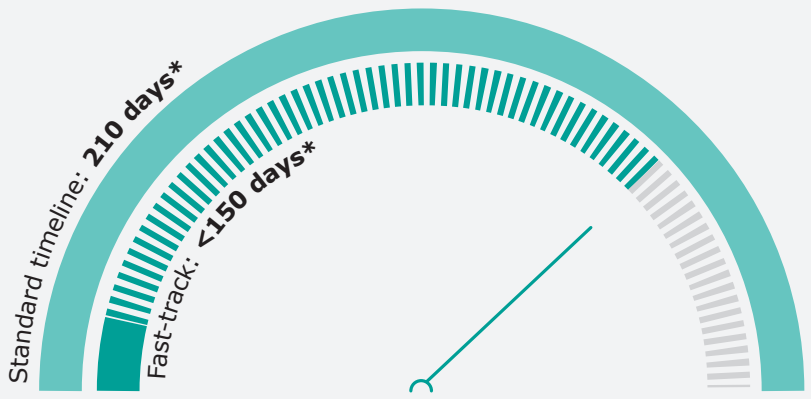
The needs of children have to be considered in the development of every medicine through a paediatric investigation plan (PIP) that is agreed by EMA. During the COVID-19 pandemic EMA expedites the review of applications for agreement of a PIP (or deferrals or waivers as appropriate) for treatments and vaccines against COVID-19 to ensure that development programmes can progress swiftly.



Rolling review**

In a public health emergency, EMA assesses data for promising medicines or vaccines as they become available. Through rolling review, EMA can exceptionally start evaluating data while the development is still ongoing. When the medicine's development is progressed enough for a marketing authorisation application (MAA), the formal assessment procedure can take place in a very short timeframe, because the data have already been scrutinised during rolling review.

Each rolling review cycle requires around 2 weeks, depending on the amount of data



Accelerated assessment

This procedure allows EMA to review the marketing authorisation applications for products of major interest for public health in a shorter timeframe than usual to speed up their approval and availability. It is an option when rolling review is not applicable, where there is an urgent public health need. In practice, assessment timelines will be reduced to the absolute minimum.

* Excluding time given to companies to provide responses
** An ad hoc procedure used in the context of a public health emergency

Extension of indication and extension of marketing authorisation

Medicines that are already authorised for other diseases may also work against COVID-19. EMA is ready to apply further flexibility in shortening review times for applications to extend indications for already approved medicines, which are being developed or repurposed for treatment or prevention of COVID-19.

Compassionate use of potential treatments for COVID-19

Compassionate use programmes can be set up by individual EU Member States to give access to treatments under development that have not received a marketing authorisation. EMA gives recommendations on how these medicines should be used for treating COVID-19 to support a harmonised approach across Europe.