

# How long does it take to develop a new drug?

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The process of developing new drugs, from the first-in-human study to marketing authorization, typically spans over several years. However, detailed information on the exact timelines and differences across clinical indications has been scarce, particularly for infectious diseases. In this issue of the Lancet Regional Health–Europe, HK de Jong and colleagues report the outcome of their research into *factors associated with acceleration of clinical development for infectious diseases* that aims to fill this gap by analysing development times for anti-infective interventions that received marketing authorization from the European Medicines Agency (EMA) between 2021 and 2022.<sup>1</sup>

This study examined 81 projects and found that the median development time from first-in-human study initiation to obtaining marketing authorisation was 7.3 years. However, there was considerable variability, with the fastest project taking only 8 months and the slowest extending to 223 months. The analysis revealed that vaccines and drugs against COVID-19 had the shortest development timelines, followed by interventions against Ebola virus disease and Hepatitis A-E. Interestingly, no significant differences in development times were observed between vaccines and drugs.

The primary factor contributing to shorter development times was the declaration of emergency emergent infectious disease (EID) and the use of conditional marketing authorisation (CMA). COVID-19 vaccines benefited significantly from these mechanisms, leading to expedited approval processes when compared with other interventions.

When comparing for anti-infectives with other indications albeit under different regulatory authorities, only minimal differences in development timelines were observed. The median clinical development time for 608 innovative drugs was also 7.3 years.<sup>2</sup>

As interventions against COVID-19 were developed and approved much faster than all other indications the authors conducted sensitivity analyses excluding COVID-19 vaccines and drugs. In this case, the following factors were shown to contribute to shorter timelines: emergency outbreak settings declared by WHO, accelerated regulatory review and granting of a

CMA, development of new combination therapies including already approved drugs, indications targeting well-defined, narrow patient populations with high medical needs where initial marketing authorisation was granted on for a narrow indication based on phase 2 study data (eg multi-drug resistance TB or Hepatitis C), adaptive study design and the use of surrogate endpoints, and disease prevalence and access to patients participating in clinical studies.

One key limitation of this work is the limited availability of data, only 81 development projects could be included and analysed. Therefore, the quantification of the factors contribution to the development timelines was not possible. It would be important that this research is continued to provide answers on the evolution of the development timelines over time, on the impact of ever-increasing regulations and requirements, and how the development and use of innovative study designs and acceptance of surrogate endpoints can optimize the development process.<sup>3,4</sup> Additionally, comparing differences between stringent regulatory agencies, particularly the EMA and the US FDA, would be valuable. Most neglected tropical diseases are also infectious disease<sup>5</sup> that affect low-and middle-income countries (LMIC) disproportionately. It would be important to investigate whether existing review and approval mechanisms for global health interventions, such as the EU's EU-M4All<sup>6</sup> and Switzerland's marketing authorisation for Global Health products (MAGHP)<sup>7</sup> can accelerate development and approval timelines in LMIC to benefit patients in these regions.

In conclusion, the development of anti-infective vaccines and drugs is characterized by long and variable timelines but not different from other indications. This variability is influenced by WHO emergency declaration and public health needs, the type of marketing authorisation granted, availability of resources, and the nature of the disease. Even within the category of infectious diseases, development times are not uniform, as they vary according to differences in disease characteristics, study endpoints, and patient populations. Transparency in the approval process is crucial, and the study by HK de Jong et al. is an essential step toward understanding and improving the development timelines for anti-infective interventions.

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