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The coming-of-age of bedaquiline: a tale with an open ending

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Future strategic choices in the clinical development of bedaquiline should be guided by the need to generate high-quality evidence and ultimately improve outcomes of tuberculosis treatment, while preventing the emergence of drug resistance <https://bit.ly/3iAOCZr>

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Bedaquiline can probably be considered the biggest breakthrough in tuberculosis drug development of the past decades. The first compound of a new anti-tuberculosis drug class, diarylquinolines, bedaquiline binds the mycobacterial ATP synthase, inducing major conformational changes and ultimately impacting the bacterial respiration pathway [1, 2]. After being developed in 2005 [3], bedaquiline showed promising results in phase II trials [4, 5], and was granted accelerated approval in 2012 by the US Food and Drug Administration (FDA) and conditional approval in 2014 by the European Medicines Agency. In the following years, the access to bedaquiline has progressively increased, from compassionate to programmatic use [6, 7], although at an insufficient pace. Between July 2015 and December 2019, 51098 patients received bedaquiline worldwide: although remarkable, this figure only represents 11% of those who are estimated to need it according to the most recent recommendations by the World Health Organization (WHO) [8].