The Critical Need for New Antibiotics

There are not enough antibiotics in development globally to meet current and anticipated patient needs.

There are only **43 antibiotics** in clinical development.*



* Total number of antibiotics in Phases 1-3 does not add up to 43 because new drug applications have been submitted for two drugs. Historical data show that, generally, only

1_{in}5

infectious disease drugs that enter Phase 1 trials will receive FDA approval.¹

Products can fail to receive approval for many reasons, including lack of effectiveness or safety concerns.

Antibiotics in Clinical Development With the Potential to Treat Infections Caused by Gram-Negative ESKAPE Pathogens[†]



There is a critical need for new therapies to treat deadly infections caused by Gram-negative ESKAPE pathogens²—bacteria that are often resistant to available antibiotics. Only a handful of new treatments with the potential to address these serious threats are currently in development.³

† One drug with a submitted new drug application also has the potential to treat Gram-negative ESKAPE pathogens.

Critical threat pathogens

The World Health Organization considers three bacteria—all of which are resistant to last-line carbapenem antibiotics—to be critical threats to public health. These pathogens—carbapenem-resistant/ESBL-producing Enterobacteriaceae (CRE), *Pseudomonas aeruginosa* (CRPA), and *Acinetobacter baumannii* (CRAB)⁴—often cause severe complications in hospitalized patients, with up to 50 percent of patients dying from bloodstream infections caused by CRE.⁵ There is an urgent need to address these critical threats, but only 15 antibiotics in development have the potential to treat infections caused by these bacteria.



Only 15 antibiotics in development have the potential to treat WHO's critical threat pathogens.



Endnotes

- 1 Biotechnology Innovation Organization, "Clinical Development Success Rates 2006-2015" (2016), https://www.bio.org/sites/default/files/Clinical%20Development%20Success%20Rates%202006-2015%20-%20BIO,%20Biomedtracker,%20Amplion%202016.pdf.
- 2 The ESKAPE pathogens—Enterococcus faecium, Staphylococcus aureus, Klebsiella pneumoniae, Acinetobacter baumannii, Pseudomonas aeruginosa, and Enterobacter species—cause many infections in the United States and show resistance to many currently available antibiotics. Within the ESKAPE pathogens are key Gram-negative bacteria, including K. pneumoniae, A. baumannii, P. aeruginosa, and Enterobacter species. These pathogens are particularly concerning due to the difficulty in discovering new therapies that can overcome current resistance. Stakeholders often highlight the Gram-negative ESKAPE pathogens as an area in which drug innovation is urgently needed.
- 3 An antibiotic is considered to have potential to treat Gram-negative ESKAPE pathogens if the drug has *in vitro* or *in vivo* data showing both activity against one or more Gram-negative species that are considered ESKAPE pathogens and the potential for clinically significant improved coverage of isolates of these species relative to currently available antibiotics. For additional information, see http://www.pewtrusts.org/en/multimedia/data-visualizations/2014/antibiotics-currently-in-clinical-development.
- 4 World Health Organization, "Global Priority List of Antibiotic-Resistant Bacteria to Guide Research, Discovery, and Development of New Antibiotics" (2017), https://www.who.int/medicines/publications/global-priority-list-antibiotic-resistant-bacteria/en/.
- 5 U.S. Centers for Disease Control and Prevention, "Antibiotic Resistance Threats in the United States, 2019" (2019), https://www.cdc.gov/drugresistance/pdf/threats-report/2019-ar-threats-report-508.pdf.

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For further information, please visit: pewtrusts.org/antibiotic-pipeline

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