

Letter to Editor

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The critical need to include India in global infectious disease trials

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Since 2016, the number of clinical trials registered in the World Health Organization-International Clinical Trials Registry Platform has been steadily increasing. The number of clinical trials registered between 2018 and 2022 is 39 765 for BRICS countries. Though India's contribution increased from 33% to 40% in the interim, the number of infectious disease trials registered in India is low (325) compared to the number of oncology clinical trials (1 936)[1]. The number of phase 3 registrational antibacterial clinical trials conducted in India is also low (Table 1). This poses a serious public health challenge given the infectious disease burden in India[2].

Moreover, the cost of clinical development of antibacterial agents is increasing with more challenges of funding. The majority of anti-infective pharmaceutical innovation is driven mainly by small and medium-sized companies, with limited contributions from large firms, leaving a significant gap in funding for antibacterial development that underscores the need for federal support. Furthermore, though the cost of conducting clinical trials in India is 40%-70% less than in the United States of America and the European Union, in comparison to the United States of Food and Drug Administration and the European Medicines Agency, there is a relative drug lag of 43.2, 25.6, and 30.3 months, respectively, for drug approval by the Central Drugs Standard Control Organization of India[3].

To encourage clinical trials in India, the Indian Council of Medical Research has launched a nationwide Indian Clinical Trial and Education Network to provide more sophisticated sites for conducting clinical trials along with world-class phase 1 clinical sites to cater for the need of early-phase clinical trials. As part of combating antimicrobial resistance in Asia, including India, ADVANcing Clinical Evidence in Infectious Diseases, is a network of around 30 hospitals in Asia collaborating to conduct high-quality clinical trials in infectious diseases to improve the lives of seriously ill patients with infections caused by antimicrobial resistance[4]. Moreover, in India, along with international collaborators, the Clinical Research Network for Drug-Resistant Infections has been established to conduct high-quality clinical research, with harmonizing efforts to reduce antimicrobial resistance and to improve patient outcomes. By doing so, it will allow early access to medicines at lower costs for any unmet medical need and meet the United States of Food and Drug Administration requirements on diversity and inclusion of underrepresented populations or countries in clinical trials, including infectious disease trials.

In conclusion, all facts delineate the need for the inclusion of India in future clinical trials of infectious disease for faster access to effective new medicines. Moreover, it is not just about access to new drugs; conducting trials in India would ensure the safety and efficacy of new drugs in the Indian population. There is an urgent need to further facilitate the dialogue between the regulatory authorities of developed nations (*i.e.*, the US) and India.

Conflict of interest statement

The author declares that there is no conflict of interest.

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Table 1. Recent major antibiotic clinical trials, sponsor name, regulatory approval status, infection type and presence of Indian cities.

Antibiotic name	NCT No. & phase of clinical trial	Sponsor name	Infection type	Regulatory approval status	Indian cities involved
Gepotidacin	NCT04020341; Phase 3 NCT04187144; Phase 3	GSK GSK	Uncomplicated urinary tract infection	Approved by the USFDA	Ahmedabad, Varanasi & Surat Aurangabad, Chandrapur, Hyderabad, Mumbai, Nagpur, Nashik, New Delhi, Pune, Rajkot, and Surat
Cefiderocol	NCT03032380 & NCT02714595; Phase 3	Shionogi & Co., Ltd.	Nosocomial pneumonia caused by Gram-negative pathogens & carbapenem-resistant Gram-negative bacteria	Approved by USFDA & EMA	No site (s)
Cefepime-Taniborbactam	NCT03840148; Phase 3	VenatoRx Pharmaceuticals	Complicated urinary tract infections	Submitted to USFDA and received CRL	No site (s)
Cefepime/ Enmetazobactam	NCT03687255; Phase 3	Allecra Therapeutics	Complicated urinary tract infection	Approved by USFDA	No site (s)
Zoliflodacin	NCT03959527; Phase 3	Entasis Therapeutics & GARDP	Uncomplicated gonorrhoea	Not yet approved	No site (s)
Plazomicin	NCT02486627; Phase 3	Achaogen, Inc.	Complicated urinary tract infection	Approved by USFDA & EMA	No site (s)
Meropenem/ Vaborbactam	NCT02166476, NCT02168946; Phase 3	Melinta Therapeutics & The Medicines Company	Complicated urinary tract infection & acute pyelonephritis	Approved by USFDA & EMA	No sites (s)
Eravacycline	NCT01844856, NCT02784704, NCT01978938, NCT03032510; Phase 3	Tetraphase Pharmaceutical, Inc.	Complicated intra-abdominal infections & complicated urinary tract infections	Approved by USFDA & EMA	No sites (s)
Ceftazidime/ Avibactam	NCT01595438, NCT01599806, NCT01499290, NCT01500239, NCT01808092; Phase 3	Allergan	Complicated urinary tract infections & complicated intra-abdominal infection	Approved by USFDA & EMA	No site (s)
Sulbactam/ Durlobactam	NCT03894046; Phase 3	Entasis Therapeutics	Carbapenem-resistant *Acinetobacter baumannii*	Approved by USFDA	Ahmedabad, Gujarat, Belgaum, Hyderabad, Kolkata, and Pune

CRL: Complete Response Letter; EMA: European Medicines Agency; USFDA: United States of Food and Drug Administration; NCT: National Clinical Trial Number; GSK: GlaxoSmithKline.

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References

[1] Manoharan K, Jinson J, Ramesh K, George M. Clinical trial trends over the last 5 years among the BRICS (Brazil, Russia, India, China, and South Africa) nations. *Perspect Clin Res* 2024; **15**: 128-133.

[2] Liu Q, Jing W, Liu M, Liu J. Health disparity and mortality trends of infectious diseases in BRICS from 1990 to 2019. *J Glob Health* 2022; **12**: 04028.

[3]Konwar M, Maurya MR, Nishandar TB, Thatte UM, Gogtay NJ. An evaluation of drug lag for new drugs approved by the Indian regulator relative to the United States, European Union, and Japanese regulatory agencies: A 15-year analysis (2004-2018). *Perspect Clin Res* 2021; **12**: 159-164.

[4] National University of Singapore. *ADVANcing Clinical Evidence in Infectious Diseases (ADVANCE–ID) dated 22 November 2022.* [Online]. Available from: https://sph.nus.edu.sg/2022/11/advancing-clinical-evidence-in-infectious-diseases-advance-id/. [Accessed on 11 July 2024].

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