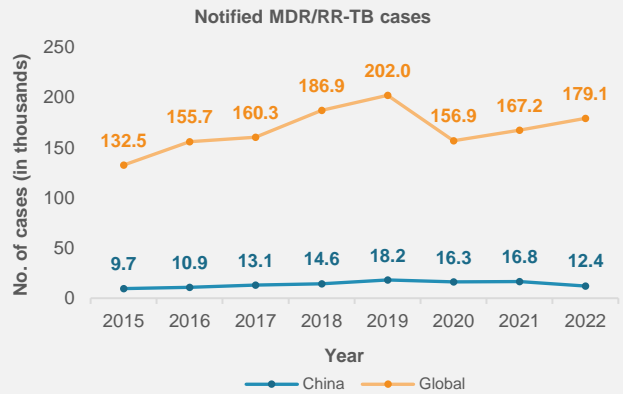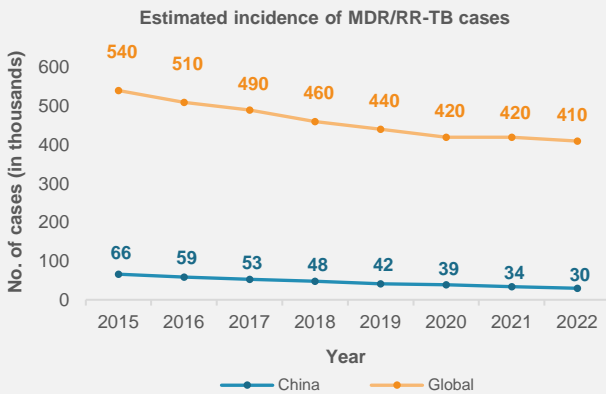# MDR/RR-TB LANDSCAPE IN CHINA

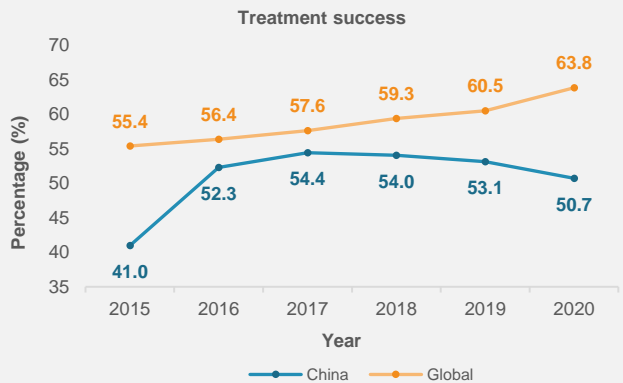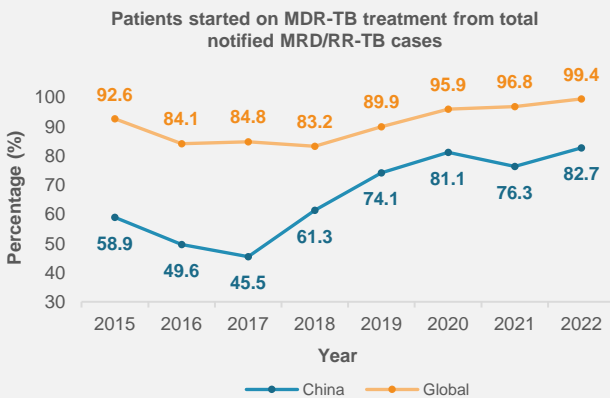## CHINA'S BATTLE AGAINST MDR/RR-TB: PROGRESS, TREATMENTS, PIPELINE & INITIATIVES

With **~160,000 deaths** in 2022, multidrug-resistant/rifampicin-resistant tuberculosis (MDR/RR-TB) represents a global challenge in the field of medicine. As per WHO, China ranks **5th** among the 30 high MDR/RR-TB burden countries, with an estimation of **~30,000 incidence cases** in 2022, contributing **~7.3%** to the global MDR/RR-TB burden. In 2022, **~3%** of new and **~20%** of previously-treated TB cases had MDR/RR-TB in China, against the average global of **~3.3%** and **~17%** respectively.

CURRENT SCENARIO

As per WHO's estimates, the incidence of MDR/RR-TB cases in China decreased at a CAGR of **~10.7%** between 2015 and 2022, compared to the global rate of decrease of **~3.9%**. Moreover, the rate of notified MDR/RR-TB cases in China, which is **~4.4%**, is lower than the global rate of **~5.5%.**

Estimated incidence of MDR/RR-TB cases

Global: 540, 510, 490, 460, 440, 420, 420, 410
China: 66, 59, 53, 48, 42, 39, 34, 30
Years: 2015–2022

Notified MDR/RR-TB cases

Global: 132.5, 155.7, 160.3, 186.9, 202.0, 156.9, 167.2, 179.1
China: 9.7, 10.9, 13.1, 14.6, 18.2, 16.3, 16.8, 12.4
Years: 2015–2022

The percentage of MDR/RR-TB patients starting therapy rose significantly from **~59%** to **~83%** between 2015 and 2022, with a CAGR of **~5%**. However, in 2021, China's treatment success of **~51%**, was still lower than global success rate of **~64%**, indicating the need for newer and effective treatment options.

Patients started on MDR-TB treatment from total notified MRD/RR-TB cases

Global: 92.6, 84.1, 84.8, 83.2, 89.9, 95.9, 96.8, 99.4
China: 58.9, 49.6, 45.5, 61.3, 74.1, 81.1, 76.3, 82.7
Years: 2015–2022

Treatment success

Global: 55.4, 56.4, 57.6, 59.3, 60.5, 63.8
China: 41.0, 52.3, 54.4, 54.0, 53.1, 50.7
Years: 2015–2020

EXISTING TREATMENTS

It has been observed that the strategies for treating MDR-TB vary in different hospitals across China. The treatment regimens can be standardized, empirical, or individualized.

Inexpensive standardized regimen (low concentration isoniazid and rifampicin resistance): 6 months (intensive phase) of amikacin-fluoroquinolones-cycloserine-protionamide-pasiniazid-pyrazinamide, followed by 12 months (continuation phase) of fluoroquinolones-cycloserine-protionamide-pasiniazid-pyrazinamide.

Standardized treatment regimen (MDR-TB): 6 months (intensive phase) of amikacin (capreomycin)-levofloxacin (moxifloxacin)-cycloserine (p-aminosalicylic acid, ethambutol)-protionamide-pyrazinamide, followed by 18-months (continuation phase) of levofloxacin (moxifloxacin)-cycloserine(p-aminosalicylic acid, ethambutol)-protionamide-pyrazinamide.

A recent clinical trial, which utilized two 9-month, all-oral regimens have reported a significant improvement in the treatment outcomes:
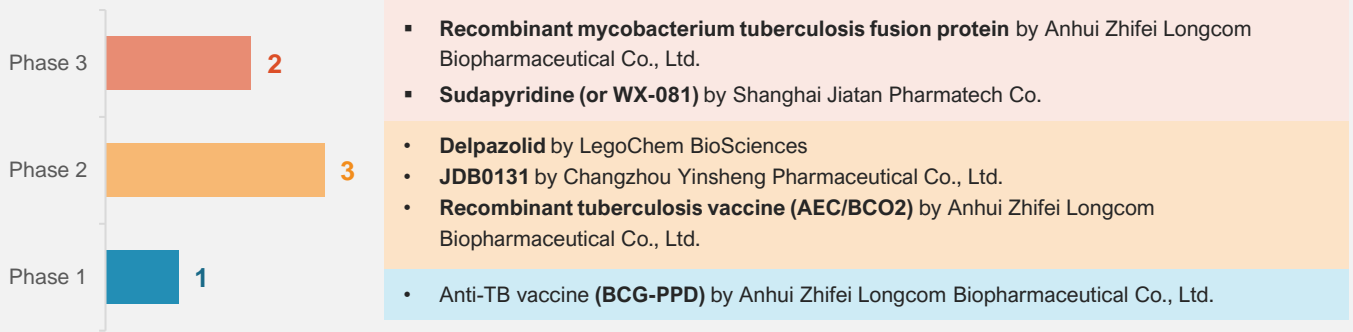
Regimen A: (bedaquiline + linezolid + moxifloxacin + cycloserine + pyrazinamide).

Regimen B: (linezolid + moxifloxacin + cycloserine + clofazimine + pyrazinamide).

SEAL-MDR Study – This is an ongoing study implemented to evaluate the safety and efficacy of all-oral shortened regimens for MDR-TB.

DRUG PIPELINE

Since 2017, **6** candidates have been undergoing clinical trials in China, as potential therapies for MDR/RR-TB.

Phase	Count
Phase 3	2
Phase 2	3
Phase 1	1

Phase 3
- **Recombinant mycobacterium tuberculosis fusion protein** by Anhui Zhifei Longcom Biopharmaceutical Co., Ltd.
- **Sudapyridine (or WX-081)** by Shanghai Jiatan Pharmatech Co.

Phase 2
- **Delpazolid** by LegoChem BioSciences
- **JDB0131** by Changzhou Yinsheng Pharmaceutical Co., Ltd.
- **Recombinant tuberculosis vaccine (AEC/BCO2)** by Anhui Zhifei Longcom Biopharmaceutical Co., Ltd.

Phase 1
- Anti-TB vaccine **(BCG-PPD)** by Anhui Zhifei Longcom Biopharmaceutical Co., Ltd.

KEY GOVERNMENT INITIATIVES TO TACKLE MDR/RR-TB

With the MDR-TB's emergence, China has devised dedicated strategies such as pivotal programs to address its MDR/RR-TB burden.

Programmatic management of drug-resistant tuberculosis 'PMDT' (2006-2014) – Aimed to establish a comprehensive and standardized approach for managing MDR-TB by improving its diagnostics, treatment, and prevention.

China National Health Commission and Gates Foundation TB Prevention and Control Project (2009-2019) – Phase 3 commenced in 2016 and focused on increasing diagnostic capacity and standardization, treatment, and patient management processes.

The 13th 5-Year National Tuberculosis Prevention and Control Program (2016–2020) - Emphasized on expanding RR-TB detection through rapid molecular technology. The number and detection rate of RR-TB cases increased from **~10,000 (14.3%)** in 2015 to **~18,000 (28.7%)** in 2019. The use of rapid molecular tools increased **~3-fold** between 2015-2019.

Despite the progress in controlling MDR/RR-TB over the past decade, China needs to improve its treatment success rate to achieve its 2035 target of 90% reduction in TB incidence and a 95% reduction in TB deaths from 2015–2035. This can be achieved by development of newer, effective drugs and sustained government funding towards mass-screening, diagnostics, and implemental research.

Right from understanding key issues to advising you through the right set of insights and recommendations, Aranca provides research, consolidation, and insightful analysis to aid in-depth understanding of therapy and effective decision-making.

HOW CAN ARANCA HELP?

01 **Epidemiological Analysis:** Prevalence and diagnosis of diseases based on geography, gender, race and ethnicity, etc.

02 **Diagnosis and Treatment Paradigm:** Analysis of diagnosis and treatment algorithm adopted in clinical practice

03 **Current and Future Landscape:** Current treatments and latest pipeline landscape assessment for a particular therapy area

04 **Humanistic, Economic Burden, and Unmet Need Analysis:** Impact of a disease on the patient's mental and economic well-being

05 **Health Technology Assessment:** Analysis of various HTA decisions published by various countries

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