

附件 4

中华预防医学会科学技术奖项目公示内容

一、项目名称：耐药结核病精准诊疗关键技术研究及推广应用

二、推荐单位（专家）及推荐意见：

该项目聚焦国际重大传染病耐药结核病，开展了系列创新性研究，其主要创新点在于绘制我国流行耐药菌株的分子图谱，首创具有自主知识产权的耐药结核快速诊断试剂盒（MeltPro MTB），率先开展氯法齐明和利奈唑胺治疗耐药结核病的临床研究，建立了全过程耐药结核病患者管理平台。项目团队结合我国国情，制定了一系列针对耐药结核患者的技术文件，指导全国耐药结核患者的规范化治疗，惠及全国超过 300 家结核病医疗机构就诊的 20 万耐药结核病患者，将其治疗成功率由 48% 提高到 70% 以上。项目团队制定了结核病领域多部专著，提升了我国耐药结核领域的诊治水平，并且将国内的耐药诊断产品成功推广到国际市场，并把耐药治疗的中国经验写入国际指南，具有显著的经济效益和社会效益。同意推荐该项目为中华预防医学会科学技术奖（类别：应用研究类）（一等奖或二等奖）。

三、项目简介：（项目简要介绍，技术路线，创新点及项目产出。）

结核病是严重危害人民健康的重大传染病，耐药结核病尤甚，其发现率低、治愈率低、死亡率高，是我国结核病防治的首要挑战。研发推广适宜检测技术，探索新型治疗方案是成功控制耐药结核病的关键。针对上述难题，项目组在国家传染病重大专项等课题的资助下，密切结合临床需求，集成建立适宜我国耐药结核病诊治的新技术和新策略，实现耐药结核从“经验”到“精准”诊疗根本转变，取得原创性成果如下：

一、首次阐明我国耐药结核病分子流行病学特点，绘制流行耐药菌株基因图谱：开展全球规模最大的单中心结核分子流行病学研究，绘制我国流行分枝杆菌系统发生图谱，阐明北京基因型“南低北高”特征，揭示其近 30 年驱动我国耐药结核病传播。率先开展全国最大规模肺外结核患者流行病学研究，证实肺外结核耐药比例逐年攀升，揭示规范管理耐药肺外结核的重要性。首次开展全国结核菌株微进化全景式扫描，在国际首次报道结核耐药性相关的 100 个新基因，建立适宜我国耐药结核诊断的分子标志物组合。

二、首创具有自主知识产权的耐药结核快速诊断试剂盒（MeltPro MTB），在全国广泛应用：基于适宜诊断标志物组合，结合探针熔解曲线技术成功研制 MeltPro MTB 试剂盒，获 15 项国内外医疗器械注册证，性能达到国际水平，目前已用于超过 200 万患者早期筛查，是全国覆盖最广的耐

多药结核诊断产品，同时远销亚洲、欧洲和非洲。

三、率先在国内开展氯法齐明和利奈唑胺治疗耐药结核病的临床研究，经验写入世界卫生组织指南：作为全球最早三家团队之一建立氯法齐明和利奈唑胺治疗耐药结核病患者队列，将其治疗成功率由 48%提升至 70%以上，上述成果成为世卫组织将其列入核心药物的重要循证依据，据此制定国家耐药结核病的临床路径，规范超过 20 万名耐药患者临床治疗，有效提高预后。

四、运用人工智能、云计算和移动互联网等技术自主开发了耐药结核病患者信息管理与监测平台：建立全球最大的耐药结核患者队列，将患者管理监测和科学研究打通，开展全程、精准患者管理，将治疗失访率由 25%降低至 10%，惠及 5 万余名耐药患者。

本项目组发表 SCI 论文 56 篇，论文他引共计 1065 次。主编国家耐药结核病指南、规范和共识 10 部，开发耐药分子诊断产品 9 项，惠及 200 万就诊患者，产生直接经济效益 2.5 亿；制订国家耐药结核治疗方案，在全国 31 个省 300 个治疗点推广，20 万患者获益，引领和推进我国耐药结核病诊疗发展。

四、主要支撑材料目录（被引用论文题目及作者）

1. 申请、获得专利证明
2. 国家法律法规要求审批的批准文件

3. 应用证明
4. 代表性论文
5. 论文收录和被他人引用情况检索报告
6. 查新咨询报告
7. 科研基金、计划结题验收报告或证明
8. 科技成果登记证明
11. 曾获科技奖励证明
12. 其他证明

以下是被引用论文情况：

序号	文献信息	SCI 收录
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3.	Clofazimine for the Treatment of Multidrug-Resistant Tuberculosis: Prospective, Multicenter, Randomized Controlled Study in China Tang, Shenjie; Yao, Lan; Hao, Xiaohui; Liu, Yidian; Zeng, Linhai; CLINICAL INFECTIOUS DISEASES Year:2015 Volume:60 Issue:9 Page:1361-1367 Doi:10.1093/cid/civ027	收录
4.	Epidemiology of Extrapulmonary Tuberculosis among Inpatients, China, 2008-2017 Pang, Yu; An, Jun; Shu, Wei; Huo, Fengmin; Chu, Naihui; EMERGING INFECTIOUS DISEASES Year:2019 Volume:25 Issue:3 Page:457-464 Doi:10.3201/eid2503.180572	收录
5.	Role of pncA and rpsA Gene Sequencing in Detection of Pyrazinamide Resistance in Mycobacterium tuberculosis Isolates from Southern China Tan, Yaoju; Hu, Zuqiong; Zhang, Tianyu; Cai, Xingshan; Kuang, Haobin; JOURNAL OF CLINICAL MICROBIOLOGY Year:2014 Volume:52 Issue:1 Page:291-297 Doi:10.1128/JCM.01903-13	收录

6.	Prevalence and Molecular Characterization of Fluoroquinolone-Resistant Mycobacterium tuberculosis Isolates in China Zhang, Zhijian; Lu, Jie; Wang, Yufeng; Pang, Yu; Zhao, Yanlin ANTIMICROBIAL AGENTS AND CHEMOTHERAPY Year:2014 Volume:58 Issue:1 Page:364-369 Doi:10.1128/AAC.01228-13	收录
7.	Beijing genotype of Mycobacterium tuberculosis is significantly associated with linezolid resistance in multidrug-resistant and extensively drug-resistant tuberculosis in China Zhang, Zhijian; Pang, Yu; Wang, Yufeng; Liu, Changting; Zhao, Yanlin INTERNATIONAL JOURNAL OF ANTIMICROBIAL AGENTS Year:2014 Volume:43 Issue:3 Page:231-235 Doi:10.1016/j.ijantimicag.2013.12.007	收录
8.	Crystal structure of DNA gyrase B ' domain sheds lights on the mechanism for T-segment navigation Fu, Guangsen; Wu, Jinjun; Liu, Wei; Zhu, Deyu; Hu, Yonglin; NUCLEIC ACIDS RESEARCH Year:2009 Volume:37 Issue:17 Page:5908-5916 Doi:10.1093/nar/gkp586	收录
9.	Comparison of In Vitro Activity and MIC Distributions between the Novel Oxazolidinone Delpazolid and Linezolid against Multidrug-Resistant and Extensively Drug-Resistant Mycobacterium tuberculosis in China Zong, Zhaojing; Jing, Wei; Shi, Jin; Wen, Shu'an; Zhang, Tingting; Pang, Yu ANTIMICROBIAL AGENTS AND CHEMOTHERAPY Year:2018 Volume:62 Issue:8 Doi:10.1128/AAC.00165-18;e00165-18	收录
10.	Linezolid in the treatment of extensively drug-resistant tuberculosis Zhang, L.; Pang, Y.; Yu, X.; Wang, Y.; Gao, M.; INFECTION Year:2014 Volume:42 Issue:4 Page:705-711 Doi:10.1007/s15010-014-0632-2	收录
11.	Genotyping and molecular characteristics of multidrug-resistant Mycobacterium tuberculosis isolates from China Zhang, Zhijian; Lu, Jie; Liu, Min; Wang, Yufeng; Qu, Geping; Pang, Yu; JOURNAL OF INFECTION Year:2015 Volume:70 Issue:4 Page:335-345 Doi:10.1016/j.jinf.2014.11.008	收录
12.	Rapid diagnosis of MDR and XDR tuberculosis with the MeltPro TB assay in China Pang, Yu; Dong, Haiyan; Tan, Yaoju; Deng, Yunfeng; Cai, Xingshan; SCIENTIFIC REPORTS Year:2016 Volume:6 Doi:10.1038/srep25330	收录
13.	Clinical outcome of multidrug-resistant tuberculosis patients receiving standardized second-line treatment regimen in China Xu, Caihong; Pang, Yu; Li, Renzhong; Ruan, Yunzhou; Wang, Lixia; JOURNAL OF INFECTION Year:2018 Volume:76 Issue:4 Page:348-353 Doi:10.1016/j.jinf.2017.12.017	收录
14.	In Vitro Activity of beta-Lactams in Combination with beta-Lactamase Inhibitors against Multidrug-Resistant Mycobacterium tuberculosis Isolates Zhang, Dan; Wang, Yufeng; Lu, Jie; Pang, Yu ANTIMICROBIAL AGENTS AND CHEMOTHERAPY Year:2016 Volume:60 Issue:1 Page:393-399 Doi:10.1128/AAC.01035-15	收录

15.	Rapid Detection of Isoniazid Resistance in Mycobacterium tuberculosis Isolates by Use of Real-Time-PCR-Based Melting Curve Analysis Hu, Siyu; Li, Guoli; Li, Hui; Liu, Xiaoli; Niu, Jianjun; JOURNAL OF CLINICAL MICROBIOLOGY Year:2014 Volume:52 Issue:5 Page:1644-1652 Doi:10.1128/JCM.03395-13	收录
16.	In vitro synergistic activity of clofazimine and other antituberculous drugs against multidrug-resistant Mycobacterium tuberculosis isolates Zhang, Zhijian; Li, Tianzhi; Qu, Geping; Pang, Yu; Zhao, Yanlin INTERNATIONAL JOURNAL OF ANTIMICROBIAL AGENTS Year:2015 Volume:45 Issue:1 Page:71-75 Doi:10.1016/j.ijantimicag.2014.09.012	收录
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18.	Ethambutol Resistance as Determined by Broth Dilution Method Correlates Better than Sequencing Results with embB Mutations in Multidrug-Resistant Mycobacterium tuberculosis Isolates Zhang, Zhijian; Wang, Yufeng; Pang, Yu; Kam, Kai Man JOURNAL OF CLINICAL MICROBIOLOGY Year:2014 Volume:52 Issue:2 Page:638-641 Doi:10.1128/JCM.02713-13	收录
19.	Prevalence and molecular characterization of pyrazinamide resistance among multidrug-resistant Mycobacterium tuberculosis isolates from Southern China Pang, Yu; Zhu, Damian; Zheng, Huiwen; Shen, Jing; Hu, Yan; BMC INFECTIOUS DISEASES Year:2017 Volume:17 Doi:10.1186/s12879-017-2761-6	收录
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21.	Molecular typing and drug susceptibility of Mycobacterium tuberculosis isolates from Chongqing Municipality, China Zhang, Dan; An, Jun; Wang, Jianmin; Hu, Chuan; Wang, Zhengui; Pang, Yu INFECTION GENETICS AND EVOLUTION Year:2013 Volume:13 Page:310-316 Doi:10.1016/j.meegid.2012.10.008	收录
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23.	Rapid Identification of Clinically Relevant Mycobacterium Species by Multicolor Melting Curve Analysis Xu, Ye; Liang, Bin; Du, Chen; Tian, Xueshan; Cai, Xingshan; JOURNAL OF CLINICAL MICROBIOLOGY	收录

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24.	Evaluation of the MTBDRplus 2.0 assay for the detection of multidrug resistance among persons with presumptive pulmonary TB in China Tan, Yaoju; Li, Qiang; Wang, Qing; Sun, Huiping; Chen, Jin; Pang, Yu; SCIENTIFIC REPORTS Year:2017 Volume:7 Doi:10.1038/s41598-017-03473-7	收录
25.	Genotyping and Prevalence of Pyrazinamide- and Moxifloxacin-Resistant Tuberculosis in China, 2000 to 2010 Pang, Yu; Zhang, Zhijian; Wang, Yufeng; Wang, Shengfen; Song, Yuanyuan; ANTIMICROBIAL AGENTS AND CHEMOTHERAPY Year:2017 Volume:61 Issue:2 Doi:10.1128/AAC.02170-16	收录
26.	Molecular and phenotypic characterization of multidrug-resistant Mycobacterium tuberculosis isolates resistant to kanamycin, amikacin, and capreomycin in China Zhang, Z.; Liu, M.; Wang, Y.; Pang, Y.; Kam, K. M.; EUROPEAN JOURNAL OF CLINICAL MICROBIOLOGY & INFECTIOUS DISEASES Year:2014 Volume:33 Issue:11 Page:1959-1966 Doi:10.1007/s10096-014-2144-5	收录
27.	A 10-Year Comparative Analysis Shows that Increasing Prevalence of Rifampin-Resistant Mycobacterium tuberculosis in China Is Associated with the Transmission of Strains Harboring Compensatory Mutations Huo, Fengmin; Luo, Jingjing; Shi, Jin; Zong, Zhaojing; Jing, Wei; Pang, Yu ANTIMICROBIAL AGENTS AND CHEMOTHERAPY Year:2018 Volume:62 Issue:4 Doi:10.1128/AAC.02303-17	收录
28.	Determination of in vitro synergy between linezolid and other antimicrobial agents against Mycobacterium tuberculosis isolates Zou, Lin; Liu, Min; Wang, Yufeng; Lu, Jie; Pang, Yu TUBERCULOSIS Year:2015 Volume:95 Issue:6 Page:839-842 Doi:10.1016/j.tube.2015.07.003	收录
29.	High rate of drug resistance among tuberculous meningitis cases in Shaanxi province, China Wang, Ting; Feng, Guo-Dong; Pang, Yu; Liu, Jia-Yun; Zhou, Yang; SCIENTIFIC REPORTS Year:2016 Volume:6 Doi:10.1038/srep25251	收录
30.	Interpretation of Discordant Rifampicin Susceptibility Test Results Obtained Using GeneXpert vs Phenotypic Drug Susceptibility Testing Huo, Fengmin; Ma, Yifeng; Liu, Rongmei; Ma, Liping; Li, Shanshan; Pang, Yu OPEN FORUM INFECTIOUS DISEASES Year:2020 Volume:7 Issue:8 Doi:10.1093/ofid/ofaa279	收录
31.	Prevalence and treatment outcome of extensively drug-resistant tuberculosis plus additional drug resistance from the National Clinical Center for Tuberculosis in China: A five-year review Pang, Yu; Lu, Jie; Huo, Fengmin; Ma, Yifeng; Zhao, Liping; JOURNAL OF INFECTION Year:2017 Volume:75 Issue:5 Page:433-440 Doi:10.1016/j.jinf.2017.08.005	收录

32.	McSpoligotyping, a One-Step Melting Curve Analysis-Based Protocol for Spoligotyping of Mycobacterium tuberculosis Zeng, Xiaohong; Xu, Ye; Zhou, Yang; Li, Hui; Zheng, Rongrong; JOURNAL OF CLINICAL MICROBIOLOGY Year:2018 Volume:56 Issue:8 Doi:10.1128/JCM.00539-18	收录
33.	Genetic diversity of multidrug-resistant tuberculosis in a resource-limited region of China Zhang, Dan; An, Jun; Wang, Yufeng; Pang, Yu INTERNATIONAL JOURNAL OF INFECTIOUS DISEASES Year:2014 Volume:29 Page:7-11 Doi:10.1016/j.ijid.2014.05.020	收录
34.	Molecular Characterization of Prothionamide-Resistant Mycobacterium tuberculosis Isolates in Southern China Tan, Yaoju; Su, Biyi; Zheng, Huiwen; Song, Yuanyuan; Wang, Yufeng; FRONTIERS IN MICROBIOLOGY Year:2017 Volume:8 Doi:10.3389/fmicb.2017.02358	收录
35.	Is rifampin resistance a reliable predictive marker of multidrug-resistant tuberculosis in China: A meta-analysis of findings Liu, Zhengwei; Dong, Huali; Wu, BeiBei; Zhang, Mingwu; Zhu, Yelei; JOURNAL OF INFECTION Year:2019 Volume:79 Issue:4 Page:349-356 Doi:10.1016/j.jinf.2019.08.004	收录
36.	Highly Sensitive Detection of Isoniazid Heteroresistance in Mycobacterium tuberculosis by DeepMelt Assay Liang, Bin; Tan, Yaoju; Li, Zi; Tian, Xueshan; Du, Chen; JOURNAL OF CLINICAL MICROBIOLOGY Year:2018 Volume:56 Issue:2 Doi:10.1128/JCM.01239-17	收录
37.	Spoligotyping of Mycobacterium tuberculosis Complex Isolates by Use of Ligation-Based Amplification and Melting Curve Analysis Zeng, Xiaohong; Li, Hui; Zheng, Rongrong; Kurepina, Natalia; Kreiswirth, Barry N.; JOURNAL OF CLINICAL MICROBIOLOGY Year:2016 Volume:54 Issue:9 Page:2384-2387 Doi:10.1128/JCM.00857-16	收录
38.	Increased prevalence of levofloxacin-resistant Mycobacterium tuberculosis in China is associated with specific mutations within the gyrA gene Huo, Fengmin; Zhang, Fuzhen; Xue, Yi; Shang, Yuanyuan; Liang, Qian; Pang, Yu INTERNATIONAL JOURNAL OF INFECTIOUS DISEASES Year:2020 Volume:92 Page:241-246 Doi:10.1016/j.ijid.2020.01.021	收录
39.	Transregional movement of multidrug-resistant tuberculosis in north China: an underlying threat to tuberculosis control An, Jun; Gao, Mengqiu; Chu, Naihui; Huang, Hairong; Pang, Yu; SCIENTIFIC REPORTS Year:2016 Volume:6 Doi:10.1038/srep29727	收录
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41.	Para-aminosalicylic acid increases the susceptibility to isoniazid in clinical isolates of Mycobacterium tuberculosis Zhang, Tingting; Jiang, Guanglu; Wen, Shuan; Huo, Fengmin; Wang, Fen; Pang, Yu INFECTION AND DRUG RESISTANCE Year:2019 Volume:12 Page:825-829 Doi:10.2147/IDR.S200697	收录
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五、主要完成人及完成单位情况

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3	杜建	首都医科大学附属北京胸科医院
4	李庆阁	厦门大学
5	毕利军	体必康生物科技(广东)股份有限公司
6	唐神结	首都医科大学附属北京胸科医院
7	高孟秋	首都医科大学附属北京胸科医院
8	谭耀驹	广州胸科医院
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3	体必康生物科技(广东)股份有限公司
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5	厦门致善生物科技股份有限公司
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7	解放军总医院第二医学中心
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公示单位： 签章
年 月 日