



Pfizer's global development in China

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Development China / Global Product Development

Pfizer

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Our vision for global clinical trials and our development goal in China

- We ensure our global clinical trials reflect the demographics of the countries and communities where we conduct these studies, and the epidemiology of the diseases we intend to treat or prevent (我们确保开展的全球临床试验能够反映出所在国家和地区的人口学特征，以及目标治疗或预防疾病的流行病学特征)
- Our development goal in China is to join the global clinical trials in both exploratory and confirmatory stages and ensure the simultaneous regulatory approval in China (我们在中国的研发目标是加入探索阶段和确证阶段的全球临床试验，以确保在中国的同步批准)

The Challenges we are facing to join global clinical trials, especially in the exploratory phase

China Phase I study required prior to join global clinical trials
加入全球临床试验前，要求完成中国I期试验
Longer cycle time to initiate a clinical trial in China
临床试验启动时间长

VS

Short duration of expletory phase clinical trials
探索期临床试验的周期较短

Biomarker data and fast turnaround of data generation/transfer to support the PK/PD and E/R analyses
用于支持PK/PD和E/R分析的生物标志物数据，以及数据生成和传输的及时性

VS

HGRAC approval
中国人类遗传资源管理批准

Our proposal for simultaneous global development in China - E17 based

**Design and conduct confirmatory trials based on a E/R based scientific pooling strategy
China + Japan + more?**
基于科学的E/R分析，定义亚组人群合并策略，设计和开展确证性临床试验

**Q: Where is Chinese and Japanese located in the E/R curve
中国和和日本受试者E/R与总体人群的相似性**

2. Global strategy: representative example of MRCTs

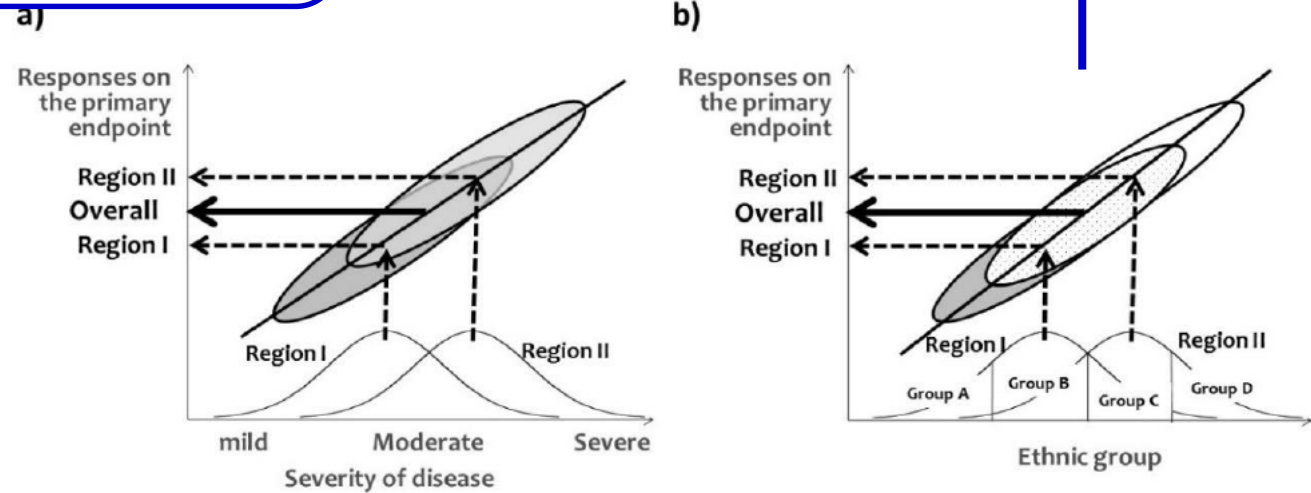
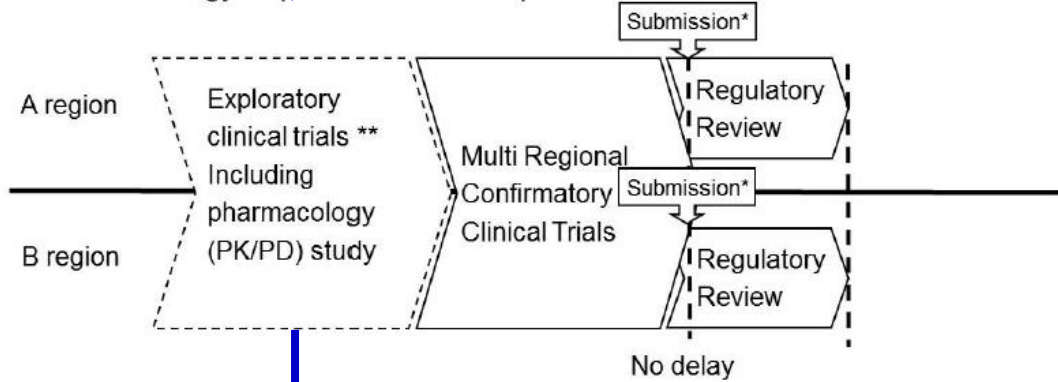


Figure 2. Illustration: primary endpoint modulated by intrinsic and extrinsic factors across regions; (2a) by severity of disease, (2b) by ethnic group.

**China and Japan to join the exploratory clinical trials
中国和和日本加入探索期临床试验**

**Analyze E/R including Chinese and Japanese subjects
包括中国和和日本受试者数据在内的E/R分析**



Thank You

