

Axio Research



DATA MONITORING COMMITTEES IN CHINA

SCT, Boston

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Outline

- What is a Data Monitoring Committee and why is one needed?
- DMCs in China
- “China specific” characteristics
 - Advantages
 - Challenges

What is a Data Monitoring Committee and why is one needed?

- Periodic review during the study
 - Study conduct
 - Safety
 - Efficacy
- Potential investigator/sponsor bias
- An independent committee of experts

Clinical trials in China

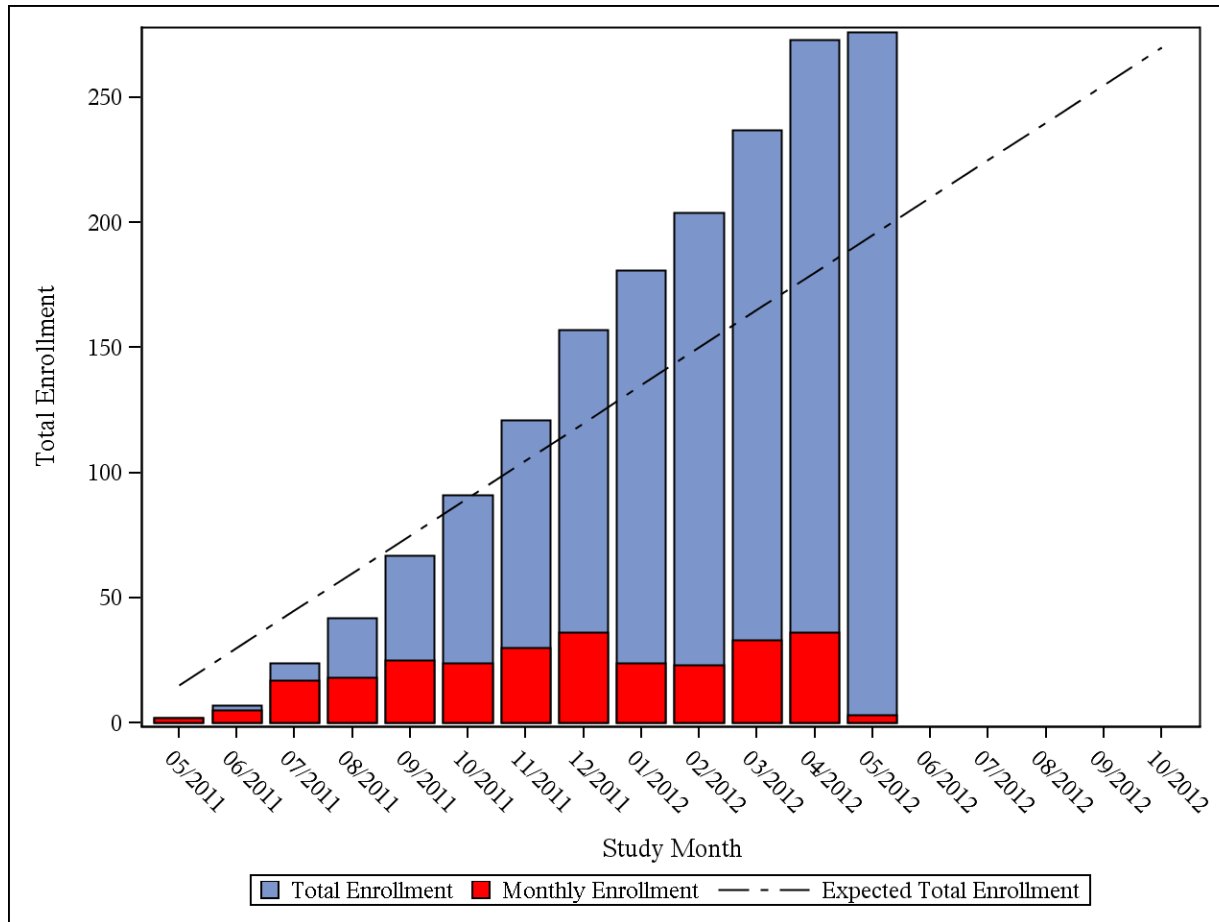
- **Government support**
 - Welcomes foreign investment
 - SFDA adopting ICH and FDA guidances
- **Patient population**
 - Large population in concentrated centers
 - Disease profile of interest
 - Healthcare limitations
- **Lower cost**

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DMCs in China

- A new concept
- “DMC guidelines” established in 2009
- Sponsors/DMC members with mixed background and limited experience
- “Pioneers” to improve regulatory guidelines

Advantage - Fast Enrollment



Advantage – Data Quality

- Investigators:
 - Famous, experienced, respected
 - Motivated
- Medical monitors: all physicians
- Thorough follow up

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Challenges

- Language barrier
- Communications
 - Email
 - Meetings
- Scheduling
- Courier delivery
- “Spoiled” doctors

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Thank you!

- “Despite twists and turns on the road ahead, the future is bright.”

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