



Clinical Trial Sites – Global Capability Assessments MSF Meeting New York

11 and 12 January 2007

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Global Clinical Trials Capacity

- Can global clinical trial capacity meet GCP/GLP registration standards to meet current and future needs?
- No objective assessment of the situation has been done
- Benefit sites directly, sponsors of clinical trials, and ability to generate resources to build global clinical trial capacity



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Clinical Trial Sites – Assessing and Building Infrastructure

Objectives

- Assess global site capacity for conduct of Ph. II (including Early Bactericidal Activity studies) and Ph. III GCP/GLP TB drug trials
- Develop user-friendly database of assessed clinical trial sites, including laboratories, for utilization by a broad audience



Clinical Trial Sites – Assessing and Building Infrastructure

Approach

- Develop comprehensive site and laboratory evaluation questionnaire
 - **Primary clinical site**
 - **Pharmacy**
 - **Information systems, communication and data management**
 - **Laboratory: Mycobacterium & Safety; QC/QA**
 - **Regulatory and Ethics Committee (IRB or IEC) environment and procedures; Importation requirements**
 - **Satellite site(s) – if applicable**
 - **Tb & HIV Specific Information**
- Conduct assessments – clinical and lab (*M.tb* and safety labs)
- Design, develop and deploy database



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Clinical Trial Sites – Assessing and Building Infrastructure

Activities

- 2 CROs hired
 - PPD for S. America
 - Quintiles for Asia, Africa, N. America and Europe
- 2 internationally-recognized *M. tb* lab experts hired to ensure quality of TB lab evaluations
 - Dr. Kathleen Eisenach, University of Arkansas for Medical Sciences, USA
 - Dr Frederick Sirgel, Medical Research Council, South Africa,



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Sites Assessed





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Per site summaries

- For each clinical site and each laboratory:
Estimated time required to ready site for participation in a registration-standard, Phase III TB drug trial or an EBA trial –specified):
 - < 6 months
 - 6-12 months
 - 1-2 years
 - >2years
- Capacity-building recommendations



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Global Distribution and Time Required to Ready Site and Lab for Participation in a Phase III TB Drug Registration Trial

	< 6 MONTHS	6 to 12 MONTHS	1 to 2 YEARS	> 2 YEARS
Africa	3	7	8	1
Asia	1	2	1	0
Latin America	1	4	3	0
North America	0	6	0	0
Europe	1	0	0	0
Eastern Europe	0	0	6	0
TOTAL	6	19	18	1



User-friendly Database

- All data will be stored in a single manageable database, accessible via an online administration system
- System will consist of two main areas
 - Site/Laboratory Information
 - Supporting Documents and Policies
- Database will be made accessible to broad audience of relevant stakeholders



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Next Steps

- Populate database with clinical site and laboratory assessment data and supporting documents
- Open information to broad audience of relevant stakeholders (drug sponsors, trialists, sites)
- Project completion Q1, 2007
- Additional assessments and updates to be conducted as resources allow



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the development of better and faster
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