Challenges and Lessons Learned from Implementation of STREAM Clinical Trial

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Background

Design and implementation of clinical trials for multidrug-resistant tuberculosis (MDR-TB) are complex. Documenting challenges and lessons learned from trial sites' perspective may ensure best practices are disseminated and implemented in future trials.

Methods

STREAM enrolled over 1,000 participants with MDR-TB in two stages from 15 sites in eight countries. We conducted a voluntary survey of trial staff at all sites to obtain information on challenges encountered and lessons learned from trial implementation. Summary statistics were generated for quantitative data and thematic analyses were done by two coders for qualitative data.

Results

Of 68 responses received, 47 (69%) were included in the analyses. Thirteen (87%) of 15 sites from all eight STREAM countries responded. Approximately half the respondents were investigators or trial coordinators, and 10% were fieldworkers or staff working with the community. Limitations in infrastructure was a challenge across key areas including laboratory, pharmacy, and trial administration. Complexities around import/export of drugs/samples, lack of prior experience, and inadequate training were also reported. Investment in infrastructure and capacity building, ongoing monitoring and robust oversight of processes, clear roles and responsibilities and improved communication/coordination, and meaningful engagement of stakeholders were all thought to be critical to successful implementation. Approximately half the survey respondents thought guidebooks on best practices for community engagement and trial administration would be beneficial, followed by one-third in favour of guidebooks for laboratory and pharmacy.

Conclusions

Existing frameworks for clinical trial implementation need to be reconceived – sponsors should increase upfront investments in the cross-cutting thematic areas identified here, work with sites to improve systems and processes, and take into account the local contexts for successful implementation of trials.

Cross-cutting Themes For Lessons Learned Across Distinct Areas of Trial Implementation

	Lab	Pharmacy	Community Engagement	Ethics & Regulatory	Trial Administration
Infrastructure	2	4			2
Capacity Building	8	2	8	3	3
Processes & Monitoring	3	6	3		6
Clarity of roles; Coordination	3	1			6
Stakeholder Engagement		1	6	4	

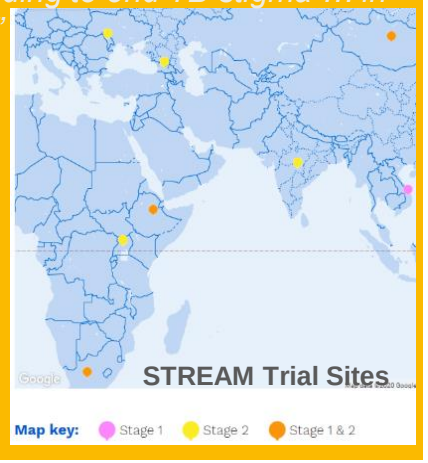
Increasing # of responses

- Infrastructure. *"….[ensure] supply of lab equipment & reagents."* *"Establish the required financial and human resource management systems before trial initiation"*
- Capacity building. *"Patience, capacity building at [Regulatory Authorit(ies)] RA & [Ethics Committee(s)] EC is a must to continue trials."*
- Processes and Monitoring. *"Meticulous check and calibration procedures [are necessary for laboratory]…lab monitoring & expert support, collaboration with lab scientists to help supervise the lab personnel"*
- **Coordination**

"Coordination between the [NTP], indoor wards, and DOT providers for seamless and uninterrupted provision of trial medicines"

- **Stakeholder Engagement**

"Our [community advisory board] gained experience working with MDR-TB patients and their families…. Engagement of all stakeholders through [the Community Engagement] general meetings makes [stakeholders] trust our CAB. [Also,] the MoH has recognised the STREAM CAB and given it funding to end TB stigma … in the workplace."



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