RESIST-TB

Research Excellence to Stop TB Resistance

Site Development Report

Background

Successful clinical trials require access to adequate numbers of patients. For MDR-TB, factors that limit this capacity are availability of MDR-TB diagnosis, treatment, and monitoring. In addition, sites need to have institutional infrastructure that supports clinical trials (such as Institutional Review Boards), good recordkeeping, data management and transmittal capacity, laboratory capacity, and adequately trained staff. Currently, there is a shortage of such sites. Therefore, the RESIST-TB Site Capacity Working Group was formed in 2010 to look at ways to expand site capacity. The Working Group was led by Frank Cobelens and Nancy Dianis. The group determined that there were a number of sites with access to patients and interest in becoming trial sites, but that some or all of these lacked one or more of the capacities needed to become an effective clinical trial site.

Methods

In 2010, RESIST-TB advertised their intention to evaluate sites that had interest in being MDR-TB clinical trial sites but had not previously done so. Over sixty potential sites from various continents were identified. A questionnaire was prepared to determine areas where sites either had adequate capacity or needed site development activity, in the following areas: numbers of patients, ability to maintain patients in follow-up, laboratory capacity, clinical services, pharmacy capacity, availability of quality-assured drugs, research experience, data management capacity, regulatory oversight and good clinical practices training.[see Site Assessment Tool, below]

Results

Of the 62 potential sites examined, 24 were already participating in a network study and were judged not to need further site development; 27 did not respond to the questionnaire that was sent out, and 11 responded. These eleven potential sites were from Africa, Asia, Europe and the Americas. Results for these 11 sites are shown in Table 1.

Table 1: Site Capacity Survey Results

Site Characteristic	Number of patients or percent of sites with Capacity
Total MDR-TB patients treated in 2010	2806
Total XDR-TB patients treated in 2010	187
Site has mycobacteriology laboratory capacity	100%
Site has ties to the local NTP	100%
Site delivers DOT to patients	100%
Site has electronic data management capacity	70%
Sites performs patient follow-up for $\geq$ 12 months	80%
Clinical trial experience other than TB	80%

The RESIST-TB Site Capacity Development Working Group evaluated the patient populations, laboratory and research infrastructure available at each of potential clinical trial sites. Six clinical sites were identified as ready to implement trials; these were listed on www.sitefinder.tghn.org so that they could be accessed by potential clinical trial implementers. The RESIST-TB evaluation provides evidence of their readiness to implement an MDR-TB clinical trial.

The remaining five sites required additional training in the following areas: (1) Good Laboratory Practice; (2) Good Clinical Practice; (3) Good Pharmaceutical Practice (Table 2). The Working Group compiled a list of low-cost options for provision of training to these sites with the goal of bringing them to clinical trial readiness.

Table 2: Problem Areas

	AFRICA			ASIA					EUROPE	AMERICAS		
	Site A	Site B	Site C	Site D	Site E	Site F	Site G	Site H	Site I	Site J	Site K	
Problem Areas												Possible Solutions
Poor patient follow-up											Interested in RESIST-TB suggestions	Questionaire response: Do you have experience following up on MDR-TB patients after treatment of therapy - No
Lacking Good Laboratory Practice (GLP)		X				Interested in RESIST-TB suggestions - estimate pending	x					CDC online training course (free)
No X-Ray Services							X					
Lacking electronic systems for recording/reporting diagnosis and treatment			Interested in RESIST-TB suggestions **5-7 employees**									Data management training through ICSSC (need number of participants to confirm), CDC online training, CITI training program (requires subscription)
Lacking training in Good Clinical Practice (GCP)?						Interested in RESIST-TB suggestions - estimate pending	X					Online CITI training program
Equipt for MDR-TB clinical trials	x			x	x			x	x	x		

Future Directions

The site evaluation tool is provided on the RESIST-TB website so that other potential sites may perform a self-evaluation. Sites that wish to identify resources for receiving training may contact RESIST-TB at ***resisttb@gmail.com*** to earn about currently available training programs and materials.