

SITE ASSESSMENT TOOL

DATE:

SITE NAME and CONTACT DETAILS:

PRINCIPAL INVESTIGATOR:

Incidence of MDR-TB, XDR-TB, HIV Co-Infection

1.	Does your clinic/site treat MDR-TB patients with second-line anti-tuberculosis drugs, or is it planning to do so in the coming 12 months?	<input type="checkbox"/> yes – please continue <input type="checkbox"/> no – do not continue
2.	How many MDR-TB patients with no (known) previous exposure to second-line anti-tuberculosis drugs did your clinic/site treat in the past 12 months?	Number:
3.	How many non-newly diagnosed MDR-TB patients did your clinic/site treat in the past 12 months?	Number:
4.	How many MDR-TB does your clinic/site plan to treat in the coming 12 months?	Number:
5.	How many XDR-TB patients did your clinic/site treat in the past 12 months?	Number:
6.	What percentage of MDR-TB patients treated at your clinic/site have HIV infection?	Percentage: _____ %
7.	What is the treatment success rate (cure and treatment completed combined) among the MDR-TB patients treated in your clinic/site?	Percentage: _____ %
8.	What is the combined loss-to-follow-up and transfer-out rate among the MDR-TB patients treated at your clinic/site?	Percentage: _____ %

Ability to Follow Patients after Treatment

9.	Do you have experience following up MDR-TB patients after completion of therapy?	<input type="checkbox"/> yes <input type="checkbox"/> no
	<i>If YES to question #9, what percentage of patients have you been able to follow for 12 months? 24 months?</i>	Percentage (12 mos): _____ % Percentage (24 mos): _____ %
10.	What percentage of your patients with MDR-TB live within one hour's travel from your clinic?	Percentage: _____ %
11.	What modes of contact do you use to send information to or receive information from your patients?	Check all that apply: Phone Letter/ Postcard Email

Laboratory Capacity

12.	Does your clinic/site have access to a laboratory that performs:
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	a. microscopic sputum smear examination for acid-fast bacilli?	<input type="checkbox"/> yes – on-site <input type="checkbox"/> yes – at km distance <input type="checkbox"/> no
	b. mycobacterial culture?	<input type="checkbox"/> yes – on-site <input type="checkbox"/> yes – at km distance <input type="checkbox"/> no
	c. quality-assured ¹ susceptibility testing to first-line anti-tuberculosis drugs?	<input type="checkbox"/> yes – on-site <input type="checkbox"/> yes – at km distance <input type="checkbox"/> no
	<i>IF YES, please name the Supranational Reference Laboratory involved in external quality assurance.</i>	<i>Laboratory Name, Location</i>
	d. susceptibility testing to second-line anti-tuberculosis drugs?	<input type="checkbox"/> yes – on-site <input type="checkbox"/> yes – at km distance <input type="checkbox"/> no
	e. hematology tests: at minimum hemoglobin (Hb), haematocrit (Ht), white blood cell count (WBC)?	<input type="checkbox"/> yes – on-site <input type="checkbox"/> yes – at km distance <input type="checkbox"/> no
	f. biochemistry blood tests: at minimum sodium (Na), potassium (K), creatinin, alanine aminotransferase (ALAT), aspartate aminotransferase (ASAT), glucose, thyroid-stimulating hormone (TSH)?	<input type="checkbox"/> yes – on-site <input type="checkbox"/> yes – at km distance <input type="checkbox"/> no
	g. molecular susceptibility testing to INH and RIF? (e.g., Hain MTBDRplus)	<input type="checkbox"/> yes – on-site <input type="checkbox"/> yes – at km distance <input type="checkbox"/> no
	h. Molecular susceptibility testing to second-line anti-tuberculosis drugs? (e.g., Hain MTBDRsl or GeneXpert 2 nd -line)	<input type="checkbox"/> yes – on-site <input type="checkbox"/> yes – at km distance <input type="checkbox"/> no
13.	How many laboratory staff in your clinic/site have completed training on Good Laboratory Practice (GLP)?	Number:
14.	Is clinic/site management willing to make time and space available for remaining laboratory staff to be trained in GLP?	<input type="checkbox"/> yes <input type="checkbox"/> no

¹ participation in international external quality-assurance scheme (proficiency testing)

Other Clinical/Diagnostic Services

15.	Does your clinic/site have X-ray services?	<input type="checkbox"/> yes <input type="checkbox"/> no
16.	Does your clinic/site make use of an electronic system for recording and reporting diagnosis and treatment of (MDR) TB patients?	<input type="checkbox"/> yes <input type="checkbox"/> no
17.	Does your site have internet connection?	<input type="checkbox"/> yes <input type="checkbox"/> no
	<i>If YES, please specify which type of connection:</i>	Dial-up DSL Other

Anti-Tuberculosis Drugs

18.	Does your clinic/site have access to quality-assured ² first-line anti-tuberculosis drugs?	<input type="checkbox"/> yes <input type="checkbox"/> no
19.	Does your clinic/site have access to quality-assured ² second-line anti-tuberculosis drugs?	<input type="checkbox"/> yes <input type="checkbox"/> no
20.	Does your clinic/site treat MDR-TB patients with bedaquiline, delamanid or pretomanid?	<input type="checkbox"/> yes <input type="checkbox"/> no

² produced by internationally pre-qualified manufacturers

Clinical Trials Experience

21.	Has your clinic/site participated in clinical trials?	<input type="checkbox"/> yes <input type="checkbox"/> no
	a. Did any of these trials have a formal sponsor?	<input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> unknown
	b. Did your clinic/site work with a contract research organization (CRO)?	<input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> unknown
22.	Does legislation and regulation in your country allow the use of non-registered medication in the context of clinical trials?	<input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> unknown
	<i>If UNKNOWN, are you aware of clinical trials being conducted in your country that make use of non-registered medication?</i>	<input type="checkbox"/> yes <input type="checkbox"/> no
23.	Does your clinic/site have access to an Ethical Committee that reviews research proposals?	<input type="checkbox"/> yes <input type="checkbox"/> no
24.	Is clinic/site management willing to obtain approval from this or another Ethical Committee?	<input type="checkbox"/> yes <input type="checkbox"/> no
25.	How many clinical staff in your clinic/site have completed training on Good Clinical Practice (GCP)?	Number:
26.	Is clinic/site management willing to make time and space available for remaining clinic staff to be trained in GCP?	<input type="checkbox"/> yes <input type="checkbox"/> no
27.	Is it possible for your clinic/site to make available or hire a study coordinator with experience in clinical trials?	<input type="checkbox"/> yes <input type="checkbox"/> no
28.	Is it possible for your clinic/site to place a study coordinator from a different source?	<input type="checkbox"/> yes <input type="checkbox"/> no
29.	Does your clinic/site report to the National Tuberculosis Control Program in your country?	<input type="checkbox"/> yes <input type="checkbox"/> no
30.	Does your clinic/site have formal links with the National Tuberculosis Control Program in your country?	<input type="checkbox"/> yes <input type="checkbox"/> no
31.	Does your staff deliver Directly Observed Treatment (DOT) to patients enrolled in your clinic/site?	<input type="checkbox"/> yes <input type="checkbox"/> no