HIV/TB co-infection - Enrolment TB-disease form

Center/Cohort name: _____

Patient ID code: _____

Please read Instructions before completing the form

This form is completed by:

Name (in print): _____ Date of completion of this form (dd-mm-yyyy) |__|__|-|__|__|-|__|__|__|__|

Position: |__| Physician: |__| Nurse: |__| Other, describe: _____

Date when the patient was last seen at the clinic (dd-mm-yyyy) |__|__|-|__|__|-|__|__|__|__|

Section A. Background demographics and basic clinical information

Date of Birth (dd-mm-yyyy): |__|__|-|__|__|-|__|__|__|__| Gender: |__| 1=Male, 2=Female

Risk factors for **TB** acquisition (tick all that applied) (x)
- ___(0) None
- ___(1) History of injecting drug user (IDU)
- ___(2) In prison within last 2 years
- ___(3) Alcohol abuse
- ___(4) Recent TB in the family /surroundings
- ___(5) Travelling in TB endemic area specify: _____
- ___(9) Other specify:_____

Originating from (x)
- ___(1) Same country as centre
- ___(2) Other European country specify:_____
- ___(3) Any other country specify: _____
- ___(9) Unknown

Ethnicity(x)
- ___(10) White
- ___(20) Black
- ___(21) Black African
- ___(22) Black Caribbean
- ___(30) Hispanic
- ___(40) Asian
- ___(50) American
- ___(60) Indigenous
- ___ (#) Combination of any of the previous, specify numbers: _____
- ___(98) Data collection prohibited
- ___(99) Unknown

If the patient is IDU

Is the patient currently active IDU? |__| Yes |__| No |__| Unknown

Is the patient currently receiving methadone? |__| Yes |__| No |__| Unknown

if Yes, please indicate dose |__|__|__| mg

if No, is the patient currently receiving any other substitution therapy?

|__| Yes |__| No |__| Unknown

if Yes, please indicate drug name: _____ and dose: |__|__|__| mg

Height (999cm = unknown) |__|__|__| cm

Most recently measured weight |__|__|__| kg

Date of measurement (dd-mm-yyyy) |__|__|-|__|__|-|__|__|__|__|

Not available: |__|

Section B. TB History: previous (to the current) TB diagnosis

1. Has patient experienced TB in the past (not on TB-treatment for at least 2 months at the time of current TB case):

☐ **Yes** ☐ **No** ☐ **Unknown**

If Yes, please answer the following questions. If No or Unknown, please continue to Section C

2a. Date of previous (most recent) TB diagnosis (dd-mm-yyyy): ☐☐-☐☐-☐☐☐☐

2b. Date when the last TB treatment was ended (dd-mm-yyyy): ☐☐-☐☐-☐☐☐☐

3. Clinical presentation: ☐ **Pulmonary** ☐ **Extrapulmonary** ☐ **Disseminated** ☐ **Unknown**

4. Previous anti-TB drug treatment: ☐ **Yes (at least one month of therapy)** ☐ **No** ☐ **Unknown**

5. Treatment outcome of the previous TB disease:

☐ **Cure**
Patient who is culture/sputum smear-negative in the last month of treatment and on at least one previous occasion

☐ **Treatment completed**
Patient who has completed treatment but does not meet the criteria to be classified as a cure or a failure

☐ **Treatment failure**
Patient who is sputum smear-positive at 5 months or later during treatment

☐ **Defaulted/interrupted treatment**
Patient whose treatment was interrupted for 2 consecutive months or more

Section B. TB History: previous (to the current) TB diagnosis

6. Drugs used for previous TB treatment and results of last resistance test for Previous (to the current) TB diagnosis:
Please indicate all that apply

Resistance test performed (If Yes, please insert results below): ☐ **Yes** ☐ **No** ☐ **Unknown**

	Drug used (index X)	Resistance test results: Date the specimen was obtained (dd-mm-yyyy)	Susceptible	Intermediate	Resistant
Ethambutol	☐	- -	☐	☐	☐
Isoniazid	☐	- -	☐	☐	☐
Pyrazinamide	☐	- -	☐	☐	☐
Rifampin	☐	- -	☐	☐	☐
- Rifapentine	☐	- -	☐	☐	☐
- Rifabutin	☐	- -	☐	☐	☐
Amikacin/Kanamycin	☐	- -	☐	☐	☐
Capreomycin	☐	- -	☐	☐	☐
Ciprofloxacin	☐	- -	☐	☐	☐
Cycloserine	☐	- -	☐	☐	☐
Ethionamide/Prothionamide	☐	- -	☐	☐	☐
Levofloxacin	☐	- -	☐	☐	☐
Moxifloxacin	☐	- -	☐	☐	☐
Ofloxacin	☐	- -	☐	☐	☐
Para-aminosalicylic acid	☐	- -	☐	☐	☐
Streptomycin	☐	- -	☐	☐	☐
Other, specify:_____		- -	☐	☐	☐
Other, specify:_____		- -	☐	☐	☐
Other, specify:_____		- -	☐	☐	☐

Section C1. Current TB diagnosis

1. Date of current TB diagnosis (dd-mm-yyyy): |__|__| - |__|__| - |__|__|__|__|

2a. Has the patient ever received Isoniazid chemoprophylaxis? ☐ Yes ☐ No ☐ Unknown

If Yes, please indicate:

approx. date of start (dd-mm-yyyy): |__|__| - |__|__| - |__|__|__|__|

approx. date of stop (dd-mm-yyyy): |__|__| - |__|__| - |__|__|__|__|

2.b Has the patient ever received any other anti-TB chemoprophylaxis? ☐ Yes ☐ No ☐ Unknown

If Yes

please indicate the drug name(s): _____ **and**

approx. date of start (dd-mm-yyyy): |__|__| - |__|__| - |__|__|__|__|

approx. date of stop (dd-mm-yyyy): |__|__| - |__|__| - |__|__|__|__|

3. Clinical symptoms (several answers are possible): ☐ Fever ☐ Weight loss ☐ Cough with expectorate ☐ Dry cough

Other symptoms: _____

_____

4. Symptoms duration: ☐ < 1month ☐ 1-3 months ☐ >3 months ☐ Unknown

5a. Has the patient experienced any of the following?

- Initiated antiretroviral therapy/regimen **or**
- Reintroduced the same or a different antiretroviral therapy/regimen **or**
- Changed antiretroviral therapy for reasons other than toxicity

☐ Yes ☐ No

If Yes, please continue to question 5b
if No, please continue to section C2

5b. Has the patient developed any of the following?

- TB diagnosis after initiation of cART **or**
- Worsening of TB diagnosed prior to cART initiation

☐ Yes ☐ No

If Yes, please complete IRIS event form (please see instructions for definition)

Section C2. Laboratory tests performed for the current diagnosis of TB and thereafter.

1. Use the ID numbers below to indicate what kind of tests have been done since enrolment

ID	Test
1	Microscopy
2	Culture
3	PCR/Nucleic Acid Amplification
4	Histology

ID	Specimen used
A	Sputum
B	Bronchoalveolar lavage fluid
C	Pleura fluid
D	Cerebro-spinal Fluid
E	Biopsy
F	Other, specify: _____

Please provide all available results

Test ID	Specimen ID	If specimen ID is E (biopsy), please specify the tissue:	Date the specimen was obtained (dd-mm-yyyy)	Result Positive	Result Negative	Result Unknown
☐	☐	_____	- -	☐	☐	☐
☐	☐	_____	- -	☐	☐	☐
☐	☐	_____	- -	☐	☐	☐
☐	☐	_____	- -	☐	☐	☐
☐	☐	_____	- -	☐	☐	☐
☐	☐	_____	- -	☐	☐	☐
☐	☐	_____	- -	☐	☐	☐
☐	☐	_____	- -	☐	☐	☐

2. If culture of the samples were not taken, please indicate why (several answers are possible):

- ☐ **Patient did not produce sputum**
- ☐ **TB culture not routinely performed on smear+ samples in our centre**
- ☐ **TB culture not available in our centre**
- ☐ **Patient refused to perform BAL/induced sputum/biopsy**
- ☐ **Patient was too sick to perform BAL/induced sputum/biopsy**
- ☐ **BAL/induced sputum not available in our centre**
- ☐ **BAL/induced sputum not offered to this patient. If so, please state reason:**

  _____
- ☐ **Patient has extrapulmonary TB without lung involvement**
- ☐ **Obtaining other material not possible / allowed in our centre**
- ☐ **Obtaining other material not indicated in this patient. If so, please specify or state reason:**

  _____

Section C3. Clinical presentation of current TB disease (several answers are possible)

Pulmonary (several answers are posssible)	Extrapulmonary (several answers are possible)
☐ Larynx	☐ Pleura
☐ Tracheobronchial tree	☐ Lymphatic intrathoracic
☐ Lungs	☐ Lymphatic extrathoracic
Chest X-Ray/CT-scan description:	☐ Spine
☐ Upper lung zones	☐ Bones/joints other than spine
☐ Middle lung zones	☐ Meningitis
☐ Lower lung zones	☐ CNS other than meningitis
☐ Unilateral infiltrates	☐ Genito-urinary tract
☐ Bilateral infiltrates	☐ Peritoneal/digestive
☐ Miliary	☐ Skin
☐ Cavitation	☐ Unknown
☐ Pulmonary fibrosis and shrinkage	☐ Other, specify:
☐ Interstitial infiltrates	_____
☐ Intrathoracic lymphadenopathy	
☐ Pleural effusion	
☐ No cavitation	
☐ No abnormalities	
☐ Unknown	
☐ Other, specify:	
_____	

Section D. Drugs used for TB disease and resistance test

Please use these following abbreviations to fill out the lines below detailing the drugs used by the patient.
If a drug is not on the abbreviations list, then please specify the full name. Please use multiple lines for multiple resistance testings.

ETHA:	Ethambutol	AMIK:	Amikacin/ Kanamycin	MOXI:	Moxifloxacin
ISON:	Isoniazid	CAPR:	Capreomycin	OFLO:	Ofloxacin
RIFM:	Rifampin	CIPR:	Ciprofloxacin	PARA:	Para-aminosalicyclic acid
RIFP:	Rifapentine	CYCL:	Cycloserine	STRE:	Streptomycin
RIFA:	Rifabutin	ETHI:	Ethionamide/ Prothionamide	B6:	B6-vitamin (pyridoxine)
PYRA:	Pyrazinamide	LEVO:	Levofloxacin	PRED:	Prednisolon or other Steroids

Frequency

1. Every day
2. Twice weekly
3. Thrice weekly

Reason for discontinuation

1. Resistance
2. Treatment failure
3. Hypersensitivity reaction
4. Toxicity

4.1. Toxicity - GI tract
4.2. Toxicity - lever
4.3. Toxicity - kidneys
4.4. Toxicity - CNS
4.5. Toxicity - peripheral nervous system

90. Toxicity - not mentioned above
91. Patient's wish/decision, not specified above
92. Physician's decision, not specified above
93. Other causes, not specified above
93.1. Completed recommended duration of therapy
99. Unknown

Please provide all available data

1. Resistance test performed: ☐ Yes ☐ No ☐ Unknown

Drug use						Resistance test results*			
2. Drugs used for current TB disease	**Daily dose (mg)**	**Frequency** (insert number from list below)	**Date of start (dd-mm-yyyy)**	**Date of stop (dd-mm-yyyy)**	**Reason for discontinuation** (insert number from list above)	**Date the specimen was obtained (dd-mm-yyyy)**	**Susceptible**	**Intermediate**	**Resistant**
______	☐	☐	- -	- -	☐	- -	☐	☐	☐
______	☐	☐	- -	- -	☐	- -	☐	☐	☐
______	☐	☐	- -	- -	☐	- -	☐	☐	☐
______	☐	☐	- -	- -	☐	- -	☐	☐	☐
______	☐	☐	- -	- -	☐	- -	☐	☐	☐
______	☐	☐	- -	- -	☐	- -	☐	☐	☐
______	☐	☐	- -	- -	☐	- -	☐	☐	☐
______	☐	☐	- -	- -	☐	- -	☐	☐	☐
______	☐	☐	- -	- -	☐	- -	☐	☐	☐
______	☐	☐	- -	- -	☐	- -	☐	☐	☐
______	☐	☐	- -	- -	☐	- -	☐	☐	☐

* **Please list ALL drugs tested for resistance, even though patient didn't receive these drugs for treatment**

3. If resistance test was not performed at baseline specimen, please indicate why:

☐ **TB culture was not done**

☐ **TB culture negative / contaminated / failed to grow**

☐ **Resistance test is not routinely done in our centre**

☐ **Resistance test is not available in our centre**

☐ **Other, specify:** ______________________________

4. If initial therapy was not RHZ based, please indicate why:

- ☐ **Suspected MDR-TB**
- ☐ **Confirmed MDR-TB**
- ☐ **Increased liver enzymes**
- ☐ **RHZ not available**
- ☐ **RHZ is not standard first line regimen in our hospital / country**
- ☐ **Other, specify: _____**

Section E. Clinical outcome for the current TB case

1. Please indicate <u>one</u> of the following outcomes:

☐ **Cure**
Patient who is culture-/sputum smear-negative in the last month of treatment and on at least one previous occasion

☐ **Treatment completed**
Patient who has completed treatment but does not meet the criteria to be classified as a cure or a failure

☐ **Treatment failure**
Patient who is culture-/sputum smear-positive at 5 months or later during treatment

☐ **Died (please fill in section F)**
Patient who dies for any reason within one year from the date of diagnosis

☐ **Defaulted/interrupted treatment**
Patient whose treatment was interrupted for 2 consecutive months or more

☐ **Transferred out/lost to follow-up**
Patient who has been transferred to another recording and reporting unit and for whom the treatment outcome is not known

☐ **Patient is still receiving anti-TB treatment**

Please see instructions for definition

Section F. For patients who died

1. Time of death (dd-mm-yyyy) ☐☐-☐☐-☐☐☐☐

2. Autopsy performed (index X)

- ☐ (1) Yes
- ☐ (2) No
- ☐ (3) Unknown

3. Presumed cause of death: (more than one answer is possible)

- ☐ (1) TB-related
- ☐ (2) HIV-related
- ☐ (2.1) AIDS defining event (other than TB)

  Please specify: _____
- ☐ (2.2) Invasive bacterial infection
- ☐ (3) Liver failure
- ☐ (3.1) Hepatitis related
- ☐ (3.2) Liver failure not related to hepatitis
- ☐ (4) Renal failure
- ☐ (5) Pancreatitis
- ☐ (6) Cardiovascular disease
- ☐ (6.1) Myocardial infarction
- ☐ (6.2) Stroke
- ☐ (6.3) Other cardiovascular disease
- ☐ (7) Complications to diabetes mellitus
- ☐ (8) Suicide
- ☐ (9) Drug overdose
- ☐ (90) Other

  Please specify: _____
- ☐ (99) Unknown

Has Causes of Death (CoDe) form been completed? ☐ Yes ☐ No

- if No, please complete a CoDe form.