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

Center/Cohort name: _____

Patient ID code: _____

Please read Instructions before completing the form

This form is completed by:

Name (in print): _____

Position: ☐ Physician: ☐ Nurse: ☐ Other, describe: _____

Date of completion of this form (dd-mm-yyyy) |_ _-_ _-_ _ _ _|

Section A. Demography

Date of Birth (dd-mm-yyyy): |_ _-_ _-_ _ _ _|	Gender: ☐ 1=Male, 2=Female
Mode of HIV infection (x) ___(1) Homo/bisexual man ___(2) Injecting drug user ___(3) Homo/bisexual man + injecting drug user ___(4) Haemophiliac ___(5) Transfusion recipient ___(6) Heterosexual contact ___(7) Other, specify: _____ ___(8) Unknown	First seen at the department (dd-mm-yyyy) |_ _-_ _-_ _ _ _| **Most recent visit (dd-mm-yyyy)** |_ _-_ _-_ _ _ _|

Section B1. Previous HIV serological status (patient must have a pos. HIV-1 antibody test)

	Time (dd-mm-yyyy) of test		If known, time (dd-mm-yyyy) of
First date of documented pos HIV-1 ab	|_ _-_ _-_ _ _ _|	last neg. test	|_ _-_ _-_ _ _ _|

Section B2. BCG vaccination and Screening for TB

1. BCG vaccination ☐ Yes ☐ No ☐ Unknown

If Yes, state approx. year (yyyy) _____ **if more than one vaccination, please indicate the year of the latest**

2a. Tuberculin skin test performed ☐ Yes ☐ No ☐ Unknown

If Yes

indicate approx. date of the most recent test (dd-mm-yyyy) - -

indicate diameter of skin reaction / induration (mm) _____

2b. Interferon-based tests performed ☐ Yes ☐ No ☐ Unknown

If Yes, please indicate type of test: ☐ QuantiFERON-TB Gold ☐ QuantiFERON-TB Gold In-Tube

☐ T-SPOT.TB ☐ Other, specify _____

indicate approx. date of the most recent test (dd-mm-yyyy) - -

indicate result ☐ Positive ☐ Negative ☐ Indeterminate ☐ Unknown

2c. CD4 cell count

if available, provide CD4 absolute cell count closest to the date of tests performed in 2a and/or 2b

date of measurement (dd-mm-yyyy) - - **value** _____ **unit** _____

3. Chest X-Ray performed prior to present TB diagnosis ☐ Yes ☐ No ☐ Unknown

If Yes, date of last negative X-Ray (dd-mm-yyyy) - - ☐ Unknown

Section C1. Laboratory values

At the time of TB diagnosis	Date of measurement (dd-mm-yyyy)	Value	Unit
Haemoglobin level:	- -		
Platelet count:	- -		
ALT value:	- -		
AST value:	- -		
Bilirubin:	- -		
S-creatinine:	- -		
Albumin:	- -		
Basic phosphatase:	- -		
Lowest CD4 cell count ever measured:	- -		
CD4 cell count at time of TB diagnosis:	- -		
CD4 cell count at time of initiation of antiretroviral therapy:	- -		
Highest HIV-RNA ever measured:	- -		
HIV-RNA at time of initiation of antiretroviral therapy:	- -		

	Date of measurement (dd-mm-yyyy)	Value	%	Date of measurement (dd-mm-yyyy)	Value	%
Most recent CD4 cell counts:	- -			- -		
	- -			- -		
	- -			- -		
	- -			- -		

	Date of measurement (dd-mm-yyyy)	Value	Below level of detection (X)	Detection limit	Assay (see list)
Most recent HIV-RNA values measured:	- -				
	- -				
	- -				
	- -				
	- -				
	- -				
	- -				
	- -				

Assay:
1 - Roche
2 - Roche ultrasensitive
3 - NASBA
4 - Chiron/bDNA
9 - Other, please specify:_____

If CD4-cell count was not measured at the date of TB diagnosis or within a 6 months period before TB diagnosis, please indicate why:

- ☐ **CD4 count measurement is not available in our centre**
- ☐ **No funding to do a CD4 count**
- ☐ **Other (please specify)** _____

Section C2. Laboratory values

	Date (dd-mm-yyyy)	Type	Not done
Last HIV-subtyping performed:	- -		☐
Last HCV-subtyping performed:	- -		☐
Last HIV resistance testing performed:	- -	**Method used:**	

If a test was performed - please attach a copy of the resistance test report when returning the form

Hepatitis virology/serology, most recent test	Date	Positive	Negative	Unknown	Value	Unit
HBV antibody test	- -	☐	☐	☐		
HBVsAg	- -	☐	☐	☐		
HBV-DNA	- -	☐	☐	☐		
HCV antibody test	- -	☐	☐	☐		
HCV-RNA	- -	☐	☐	☐		

Section D. Antiretroviral treatment

1. Has the patient ever received antiretrovirals? **If No, index X [ ]**

If **Yes**, please update this section which should include all data on antiretrovirals used. (go to section E for other treatment).

2. Previous and/or present antiretroviral therapy

	Ongoing treatment: Date of start	Ongoing treatment: On drug at present visit indexed by X	*If stopped drug, indicate: a.date of stopping	*If stopped drug, indicate: ** b. reason for discontinuation
_____	- -		- -	
_____	- -		- -	
_____	- -		- -	
_____	- -		- -	
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_____	- -		- -	
_____	- -		- -	
_____	- -		- -	

3. Has any comment(s) on adherence to ART been made in the patient records since last follow-up?

[ ] No [ ] Yes

If Yes, please give date of comment(s) to the right (dd-mm-yyyy): - -

Perceived adherence in the 6 months preceding TB diagnosis:

"<70%", "poor", "inadequate", "not good", "intermittent"	anything inbetween	">95%", "perfect", "full", "excellent"
[ ]	[ ]	[ ]

Combination drugs:
- COM: Combivir (AZT/3TC)
- KIV: Kivexa (3TC/ABC)
- LPV: Kaletra (LPV/RTV)
- TRP: Atripla (TEN/EMT/EFV)
- TRU: Truvada (TEN/EMT)
- TZV: Trizivir (AZT/3TC/ABC)

Entry (fusion/CCR5) inhibitors:
- ENF: Enfurvirtide (Fuzeon/T20)
- MAR: Maraviroc

Integrase inhibitors:
- RGV: Raltegravir

NRTIs:
- ABC: Abacavir
- AZT: Zidovudine
- 3TC: Lamivudine
- D4T: Stavudine
- DDI: Didanosine
- EMT: Emtricabine
- TEN: Tenofovir

NNRTIs:
- EFV: Efavirenz
- ETV: Etravirine (TMC-125)
- NVP: Nevirapine

PIs:
- AMP: (Fos-)Amprenavir
- AZV: Atazanavir
- DAV: Darunavir (TMC-114)
- IDV: Indinavir
- LPV: Lopinavir/r

PIs:
- NFV: Nelfinavir
- RTV: Ritonavir
- SQH: Saquinavir hard gel capsule
- TPV: Tipranavir

Other:
- PBT: Participant in blinded trial

****Reason for discontinuation:**

1: Treatment failure (i.e. virological, immunological and/or clinical failure)
2: Abnormal fat redistribution
3: Concern of cardiovascular disease
3.1: Dyslipidaemia
3.2: Cardiovascular disease
4: Hypersensitivity reaction
5: Toxicity, predominantly from abdomen/GI tract
5.1: Toxicity - GI tract
5.2: Toxicity - Liver
5.3: Toxicity - Pancreas
6: Toxicity, predominantly from nervous system
7: Toxicity, predominantly from kidneys
8: Toxicity, predominantly from the endocrine system
8.1: Diabetes
9: Haematological toxicity
10: Hyperlactataemia/ lactic acidosis
90: Toxicity, not mentioned above
91: Patient's wish/decision, not specified above
92: Physician's decision, not specified above
93: STI - Structured Treatment Interruption
94: Other causes, not specified above
94.1: Drug out of stock
99: Unknown

Section D. Antiretroviral treatment

4. If patient was not on cART at TB diagnosis and did not initiate cART after 2 months of TB diagnosis, please indicate why:

- ☐ **Concerns of TB and cART drug interactions**
- ☐ **Concerns of TB and cART side effects**
- ☐ **cART is not indicated to this patient**
- ☐ **cART is not available in our clinic**
- ☐ **Patient refusing cART**
- ☐ **History of virological failure**
- ☐ **cART will be initiated later.**
  Please tick when:
  ☐ **3** ☐ **4** ☐ **5** ☐ **6 months after initiation of TB treatment**
- ☐ **History of virological failure**
- ☐ **Other, specify:** _____

5. Please state reason for choice of initial cART regimen:

- ☐ **Default regimen**
- ☐ **Based on guidelines for cART and TB treatment co-administration**
- ☐ **Based on HIV resistance pattern**
- ☐ **Based on available drugs**
- ☐ **Other, specify:** _____

Section E. Treatment against opportunistic infections

Center/patient code

1. Has the patient received drugs to prevent (both primary prophylaxis and maintenance therapy) or treat opportunistic infections at the time of TB diagnosis or thereafter? **If No, index X [ ]**

If **Yes**, complete this section (For drugs against opportunistic infections, only those used after enrollment in the HIV/TB study).

2. Present therapy	**Latest date of start (dd-mm-yyyy)**	**On drug at present visit (indexed by X)**	**If not on drug at pres. visit indicate date of stopping (dd-mm-yyyy)**
_____	- -	[ ]	- -
_____	- -	[ ]	- -
_____	- -	[ ]	- -
_____	- -	[ ]	- -
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CMV/HSV drugs
- CIDO: Cidofovir
- CONA: Continous Acyclovir
- CONF: Continous Famciclovir
- CONV: Continous Valaciclovir
- GANC: Ganciclovir
- FOSC: Foscarnet

Fungal drugs
- AMPH: Amphotericin B, i.v.
- CASP: Caspofungin
- FLUC: Fluconazole
- ITRA: Itraconazole
- KETO: Ketoconazole
- VORI: Voriconazole

HBV drugs
- ADEF: Adefovir dipivoxil
- ENTE: Entecavir
- TELB: Telbivudine

HCV drugs
- PINT: Peg-Interferon
- RIBA: Ribavirin

Immunomodulating therapy
- IL2: Interleukin 2
- GCSF: G-CSF
- INTF: Interferon
- PINT: Peg-Interferon

Mycobacterium drugs
- CLAR: Clarithromycin/azithromycin

Mycobacterium drugs
- ETHA: Ethambutole
- ISON: Isoniazide
- PYRA: Pyrazinamide
- RIFA: Rifabutine
- RIFM: Rifampicine

PCP/TOXO drugs
- ATOV: Atovaquone
- BACT: Bactrim (cotrimoxazole)
- CLIN: Clindamycin
- DAPS: Dapsone
- PENT: Pentamidine neb./inj.
- PYRI: Pyrimethamine
- SULP: Sulphadiazine

Section F. Opportunistic infections

1. Has the patient ever experienced any AIDS-defining opportunistic infections? **If No index X [ ]**

If **Yes**, complete this section

2. AIDS-defining opportunistic infections:	**Time of onset (dd-mm-yyyy)**	**Way of diagnosis (tick box)**		
		Definitive	**Presumptive**	**Autopsy**
_____	- -	☐	☐	☐
_____	- -	☐	☐	☐
_____	- -	☐	☐	☐
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DEM:	AIDS dementia complex	LEIS:	Leishmaniasis, visceral
BCNE:	Bacterial pneumonia, recurrent (>2 episodes within 1 year)	MCDI:	Microsporidosis diarrhoea (duration >1 month)
CANO:	Candidiasis, oesophageal	MC:	Mycobact. avium complex (MAC) or Kansasii, extrapulm.
CRCO:	Cryptococcosis, extrapulm.	MCP:	Mycobact. tuberculosis, pulm.
CRSP:	Cryptosporidosis (duration > 1 month)	MCX:	Mycobact. tuberculosis, extrapulm.
CMVR:	Cytomegalovirus (CMV) chorioretinitis	MCPO:	Mycobact. pulm., other type, specify (non-TB)
CMVO:	CMV - other location, specify	MCXO:	Mycobact. extrapulm., other type, specify (non-TB)
HERP:	Herpes simplex virus ulcers (duration >1 month) or pneumonitis/esophagitis	PCP:	Pneumocystis jiroveci pneumonia (PCP)
		LEU:	Progressive multifocal leucoencephalopathy
HIST:	Histoplasmosis, extrapulm.	SAM:	Salmonella bacteriaemia (non-typhoid) (>2 episodes)
WAST:	HIV wasting syndrome	TOX:	Toxoplasmosis, brain
ISDI:	Isosporiasis diarrhoea (duration >1 month)	FBLS:	Focal brain lesion

Section G. AIDS defining malignancies

1. Any AIDS defining malignancies? **If No index X [ ]**
If **Yes**, please complete this section

2. Any AIDS defining malignancies:

	Time of onset (dd-mm-yyyy)	Way of diagnosis (tick box)		
		Definitive	Presumptive	Autopsy
_____	- -	☐	☐	☐
_____	- -	☐	☐	☐
_____	- -	☐	☐	☐
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_____	- -	☐	☐	☐

KS: Kaposi´s sarcoma
CRVC: Cervical cancer

Non-Hodgkin lymphoma:
NHLB: Burkitt (Classical or Atypical)
NHLI: Diffuse large B-cell lymphoma (Immunoblastic or Centroblastic)
NHLU: Unknown/other histology
NHLP: Primary brain lymphoma (at diagnosis, involvement of the central nervous system without other organ affection - regardless of histology)