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**Form I: DOTS-Plus Case Registration Form, page 1 of 5**

1. Patient ID number (unique)

2. TB case registration #

2.1 Date of contact: \_\_\_ / \_\_\_ / \_\_\_  
Day Mo Year

2.2 Date of record: \_\_\_ / \_\_\_ / \_\_\_  
Day Mo Year

**Demographic**

**3. Patient name**

3.1 Surname 1 \_\_\_\_\_

3.1 Surname 2 \_\_\_\_\_

3.2 First name \_\_\_\_\_

3.2 First name 2 \_\_\_\_\_

4. Date of birth \_\_\_ / \_\_\_ / \_\_\_  
Day Mo Year

4.1 Place of birth \_\_\_\_\_  
City, Province

5. Sex  M  F

6. Citizenship  Peru  RF  Haiti  Other

6.1 Race \_\_\_\_\_

7. Address  Current  Previous  Homeless

7.1 Region \_\_\_\_\_

7.2 District \_\_\_\_\_

7.3 City/village \_\_\_\_\_

7.4 Street \_\_\_\_\_

7.5 Building # \_\_\_\_\_ Apt. # \_\_\_\_\_

7.6 Postal Code \_\_\_\_\_

7.7 Telephone # \_\_\_\_\_

8. Health Center \_\_\_\_\_

8.1 Health Center Address \_\_\_\_\_

9. Civil Status  Married  Living together  Single  Divorced/Separated  Widowed

10. Social status  Employed  Retired  Student  Unemployed

**11. Past medical history**

	yes	no	unknown		yes	no	unknown
a HIV/AIDS	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	i Psychiatric disorder	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
b Diabetes mellitus	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	j Chronic lung disease	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
c Alcoholism	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	k Cardiovascular disease	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
d Substance abuse	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	l Active hepatitis/cirrhosis	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
e Tobacco use	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	m Chronic renal insufficiency	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
f Gastric ulcer	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	n Massive hemoptysis (> 250 cc)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
g Seizure disorder	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	o Respiratory insufficiency	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
h Depression	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>				

**12. Contact History**

Name of Contact	Relationship	Date of first TB diagnosis	Age when first diagnosed	Living with patient when contact had TB	Multiple treatments?	Died During Treatment?	Current Condition*

\* C=cured  
T=in treatment  
S=symptomatic without treatment  
D=died

Comments: \_\_\_\_\_



Patient name

Patient ID

**17. Physical Exam**

Date:  /  /  Presenting Complaint: \_\_\_\_\_

Date of most recent symptoms:  /  /  Illness onset  Acute  Chronic

Cough  Expectoration  Loss of appetite  Fever  Night sweats  Dyspnea

Loss of weight: Previous weight \_\_\_\_\_ Date  /  /

Massive hemoptysis: Date of hemoptysis  /  /

Other presenting complaints \_\_\_\_\_

**17.1 Vital Signs**

Blood pressure \_\_\_\_\_ (mm Hg) Respiratory frequency \_\_\_\_\_ (/min) Heart rate \_\_\_\_\_ (/min) Temperature \_\_\_\_\_ (°C)

**17.2** Weight \_\_\_\_\_ (kg) Height \_\_\_\_\_ (cm)

**17.3**

System	Normal	Abnormal	Describe Abnormalities
General health	<input type="checkbox"/>	<input type="checkbox"/>	
Skin	<input type="checkbox"/>	<input type="checkbox"/>	
Head/neck/oropharynx	<input type="checkbox"/>	<input type="checkbox"/>	
Cardiovascular	<input type="checkbox"/>	<input type="checkbox"/>	
Thorax and lungs	<input type="checkbox"/>	<input type="checkbox"/>	
Abdomen	<input type="checkbox"/>	<input type="checkbox"/>	
Genito-urinary	<input type="checkbox"/>	<input type="checkbox"/>	
Extremities	<input type="checkbox"/>	<input type="checkbox"/>	
Neurlogical	<input type="checkbox"/>	<input type="checkbox"/>	
Lymph nodes	<input type="checkbox"/>	<input type="checkbox"/>	
Endocrine	<input type="checkbox"/>	<input type="checkbox"/>	

Comments: \_\_\_\_\_

**Form I: DOTS-Plus Case Registration Form, page 4 of 5**

Patient name

Patient ID

**Investigations**

**18. Bacteriology**

**Smear** (Specify other tissue or body fluid)

dd/mm/yy	Lab #	Result

Site: Sputum   
 Other  \_\_\_\_\_

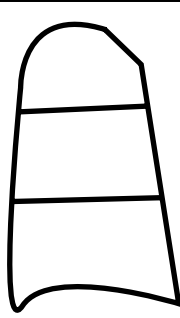
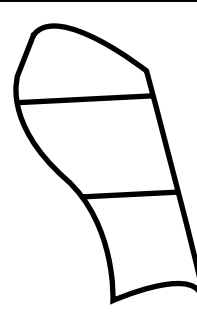
**Culture** (Specify other tissue or body fluid)

dd/mm/yy	Lab #	Result

Site: Sputum   
 Other  \_\_\_\_\_

**19. Chest x-ray** date: \_\_\_ / \_\_\_ / \_\_\_  
Day Mo Year

	Type of examination	Mark each affected zone
<input type="checkbox"/> Done <input type="checkbox"/> Not done <input type="checkbox"/> Digital copy	<input type="checkbox"/> Chest X Ray <input type="checkbox"/> Tomogram <input type="checkbox"/> CT Scan	1 Cavity 2 Fibrosis 3 Infiltrate 4 Pneumothorax 5 Pleural effusion 6 Tuberculoma 7 Disseminated

**19.1 Other CXR findings** \_\_\_\_\_

**20. Laboratory results** date: \_\_\_ / \_\_\_ / \_\_\_  
Day Mo Year

	AST	ALT	Bilirubin	Creatinine	K+	Mg+	HCT	B-HCG	HIV-ELISA	TSH	Urine Prot.
Normal values											

**21. DST results** date: \_\_\_ / \_\_\_ / \_\_\_ (Enter code: 1=Sensitive 2=Intermediate 3=Resistant 4=Pending)  
Day Mo Year

	Lab ID	Sample ID #	INH Low	INH High	RIF	PZA	EMB	SM Low	SM High	THA	KM	CS	CM	PAS	AMK	RFB	CPX	OFX	AMX-CLV	Other
Local Lab																				
Ref Lab																				

**Form I: DOTS-Plus Case Registration Form, page 5 of 5**

Patient name

Patient ID

**Management**

**22. Initial TB medication**

Date of treatment initiation: \_\_\_ / \_\_\_ / \_\_\_ (Expected duration of treatment in months MUST BE RECORDED)  
Day Mo Year

Drug	Dose			Frequency Per Week (1-7)	Duration (months)
	AM	PM	Nite		
Isoniazid					
Rifampicin					
Pyrazinamide					
Ethambutol					
Streptomycin					
Ethionamide					
Kanamycin					
Cycloserine					
Capreomycin					
PAS					
Clofazimine					

Drug	Dose			Frequency Per Week (1-7)	Duration (months)
	AM	PM	Nite		
Amikacin					
Rifabutin					
Ciprofloxacin					
Ofloxacin					
Rifater (H+R+Z)					
Rifinah (H+R)					
Thiacetazone					
Levofloxacin					
Prothionamide					
Clarithromycin					
Other					

**23. Supplementary drugs**

24. Information collected by (print): \_\_\_\_\_

Signature \_\_\_\_\_ Date \_\_\_\_\_

25. Information entered by (print): \_\_\_\_\_

Signature \_\_\_\_\_ Date \_\_\_\_\_

26. Information checked by (print): \_\_\_\_\_

Signature \_\_\_\_\_ Date \_\_\_\_\_

**Notes**

## Form 2: Checklist for Initial Evaluation and Treatment Surveillance

Patient name

Patient ID

### Initial Evaluation

- Initial physician evaluation
- AFB
- Culture
- Susceptibility testing
- Chest radiograph
- Laboratory analysis (includes liver function tests, creatinine, blood urea nitrogen, complete blood count, HIV,  $\beta$ -HCG for women)
- Health promoter evaluation (includes socioeconomic interview, home visit)
- Family planning
- Contact screening
- Initiation of empiric regimen
- Evaluation of susceptibility testing and adjustment to definitive regimen

### Routine Surveillance

#### During treatment

- Monthly AFB
- Monthly culture
- Monthly weight (may be weekly for malnourished patients)
- Chest radiograph every six months
- Physician evaluation every month for six months, then every three months
- Creatine and electrolytes monthly for 3 months, then every 3 months during injectable phase; in patients who are 50+ years old and/or have co-morbid disease, every week for first month, then at least monthly
- Starting at six months: evaluation for discontinuation of parenteral
- Starting at 18 months: evaluation for completion of DOTS-Plus treatment

#### After treatment completion:

- AFB and culture at three and six months after treatment completion
- Clinical follow-up as needed

### Forms for Patient Evaluation and Surveillance

- DOTS-Plus Case Registration Form
- DOTS-Plus Regimen Summary Sheet
- DOTS-Plus Smear and Culture Summary Sheet
- DOTS-Plus Weight Surveillance Sheet
- DOTS-Plus Susceptibility Data Summary Sheet
- DOTS-Plus Adverse Reaction Summary Sheet
- DOTS-Plus Treatment Administration Sheet
- Evaluation at Completion of DOTS-Plus Treatment



**Form 4: DOTS-Plus Smear and Culture Summary Sheet**

Patient name

Patient ID

Health center \_\_\_\_\_

Date of treatment initiation: \_\_\_ / \_\_\_ / \_\_\_  
Day Mo Year

Month	Date of sample	Smear result	Culture result	Culture ID #	# days culture read
Initial					
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					
15					
16					
17					
18					
19					
20					
21					
22					
23					
24					
25					
26					
27					
28					
29					
30					

Observations:

**Form 5: DOTS-Plus Weight Surveillance Sheet**

Patient name

Patient ID

Health center

Date of treatment initiation:  /  /   
Day Mo Year

Month	Weight (kg)	Date of weight	Height (cm)
Initial			
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			
11			
12			
13			
14			
15			
16			
17			
18			
19			
20			
21			
22			
23			
24			
25			
26			
27			
28			
29			
30			
31			
32			
33			
34			
35			
36			



**Form 7: DOTS-Plus Adverse Reaction Summary Sheet**

Patient name

Patient ID

Health center

Date of treatment initiation: \_\_\_ / \_\_\_ / \_\_\_  
Day Mo Year

Adverse reaction	Date of presentation	Date of resolution	Description	Severity 1=asymptomatic 2=does not affect daily activities 3=limits daily activities 4=life threatening, hospitalization 99=unknown	Intervention switch date	Was change made in TB regimen? If so, date and description of change	Outcome 1=complete resolution 2=partial resolution 3=no change 4=worse 99=none reported









**Form 9: Evaluation at Completion of DOTS-Plus Treatment, page 1 of 6**

Patient name

Patient ID

Health center \_\_\_\_\_

Date of treatment initiation: \_\_\_ / \_\_\_ / \_\_\_  
Day Mo Year

Evaluating physician \_\_\_\_\_

# months in treatment \_\_\_\_\_

# months receiving injectable \_\_\_\_\_

If > 8 months, reason for continuation of injectable \_\_\_\_\_

Date of previous evaluation \_\_\_\_\_

Date of treatment completion \_\_\_\_\_

Date of current evaluation \_\_\_\_\_

Patient present at evaluation?  Yes  No

Date of last positive smear \_\_\_\_\_

Date of last positive culture: \_\_\_\_\_

Current regimen (please complete regimen surveillance sheet to date) \_\_\_\_\_

Adverse reactions (please complete adverse reaction surveillance form to date) \_\_\_\_\_

Hospitalizations since previous evaluation?  Yes  No

If yes, hospital \_\_\_\_\_

Dates \_\_\_\_\_

Indication \_\_\_\_\_

Outcome \_\_\_\_\_

Hospitalizations since previous evaluation?  Yes  No

If yes, hospital \_\_\_\_\_

Dates \_\_\_\_\_

Indication \_\_\_\_\_

Outcome \_\_\_\_\_

Hospitalizations since previous evaluation?  Yes  No

If yes, hospital \_\_\_\_\_

Dates \_\_\_\_\_

Indication \_\_\_\_\_

Outcome \_\_\_\_\_

Surgery since previous evaluation?  Yes  No

If yes, hospital \_\_\_\_\_

Date \_\_\_\_\_

Procedure \_\_\_\_\_

Surgeon \_\_\_\_\_

Indication \_\_\_\_\_

Outcome \_\_\_\_\_

**Form 9: Evaluation at Completion of DOTS-Plus Treatment, page 2 of 6**

Patient name

Patient ID

**Review of DOT**

Total number of doses prescribed since previous evaluation \_\_\_\_\_

Total number of doses missed since previous evaluation \_\_\_\_\_

Number of doses suspended due to adverse reaction \_\_\_\_\_

Number of doses missed/refused by patient \_\_\_\_\_

Number of doses missed due to health worker \_\_\_\_\_

Number and cause(s) of other missed doses: \_\_\_\_\_

How many doses per day does the patient receive in health center? \_\_\_\_\_

How many doses per day does the patient receive at home? \_\_\_\_\_

Reason for receiving at home: \_\_\_\_\_

Is the patient currently working?  Yes  No

If yes, was patient working when he/she started treatment?  Yes  No

if no date resumed work \_\_\_\_\_ Occupation: \_\_\_\_\_

Is the patient currently studying?  Yes  No

If yes, was patient studying when he/she started treatment?  Yes  No

if no date resumed class \_\_\_\_\_ Type of study \_\_\_\_\_

Is the patient able to perform activities of daily living?  Yes  No

If yes, was patient able to when he/she started treatment?  Yes  No

if no, when activities resumed \_\_\_\_\_

**Review of systems** (check the following that apply)

- |  |  |  |   |
|--|--|--|---|
| <input type="checkbox"/> Cough           | <input type="checkbox"/> Sputum              | <input type="checkbox"/> Poor appetite | <input type="checkbox"/> Weight loss    |
| <input type="checkbox"/> Dyspnea at rest | <input type="checkbox"/> Dyspnea on exertion | <input type="checkbox"/> Night sweats  | <input type="checkbox"/> Vertebral pain |
| <input type="checkbox"/> Bronchospasm    | <input type="checkbox"/> Back pain           | <input type="checkbox"/> Other: _____  | <input type="checkbox"/> Other: _____   |
| <input type="checkbox"/> Hemoptysis      | Date of most recent hemoptysis _____         | Quantity in ml _____                   |   |

**Physical exam:**

PE: BP \_\_\_\_\_ HR \_\_\_\_\_ RR \_\_\_\_\_ Weight \_\_\_\_\_

**Form 9: Evaluation at Completion of DOTS-Plus Treatment, page 3 of 6**

Patient name

Patient ID

**Radiographic evaluation**

Date of chest radiograph \_\_\_\_\_ Number of affected lung zones (of 6) \_\_\_\_\_

Mark each affected lobe:  Upper left zone  Upper right zone  
 Middle left zone  Middle right zone  
 Lower left zone  Lower right zone

Pulmonary extent of infiltrates and cavities	Left lung	Right lung
<33%		
33-66%		
>66%		

Pulmonary extent of all radiographic characteristics	Left lung	Right lung
<33%		
33-66%		
>66%		

Note presence or absence of each radiographic characteristic:

	Present	Absent	
Cavity			# of cavities: _____ diameter of largest cavity (cm): _____
Heterogeneous infiltrate			
Fibrosis			
Retraction of adjacent structures			
Miliary			
Nodes			# nodes: _____ diameter of largest node(cm): _____ Presence of hiliary nodes: _____
Masses			# masses: _____ diameter of largest node(cm): _____
Pleural effusion			
Pleural plaques			
Bula or pneumatoceles			
Pneumotorax			Size of PTX (cm): _____
Hydrotorax			Size of HTX (cm): _____

Improvement from initial radiograph? \_\_\_\_\_

Impression/plan: \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

**Form 9: Evaluation at Completion of DOTS-Plus Treatment, page 4 of 6**

Patient name

Patient ID

**Review of treatment outcome**

Did the patient smear convert?  Yes  No If yes, date of first negative smear \_\_\_\_\_

Remained smear negative?  Yes  No If patient did not remain smear negative, date of first recurrent positive smear? \_\_\_\_\_

If completed treatment smear negative, date of final smear conversion \_\_\_\_\_

Did the patient culture convert?  Yes  No If yes, date of first negative culture \_\_\_\_\_

Remained culture negative?  Yes  No

If patient did not remain culture negative, date of first recurrent positive culture? \_\_\_\_\_

If completed treatment culture negative, date of final culture conversion \_\_\_\_\_

**Condition at completion (check only one):**

**Cured**

Subsequent death, if known?  Yes  No

If yes, date & cause of death \_\_\_\_\_

Subsequent treatment, if known?  Yes  No If yes, date of treatment initiation \_\_\_\_\_

If known, regimen \_\_\_\_\_

**Abandoned**

Date of abandonment \_\_\_\_\_

Reason for abandonment \_\_\_\_\_ Date of last smear prior to abandonment \_\_\_\_\_

Smear status  Pos  Neg  Unknown

Date of last culture prior to abandonment: \_\_\_\_\_

Culture status  Pos  Neg  Unknown

Subsequent death, if known?  Yes  No If yes, date & cause of death \_\_\_\_\_

Subsequent treatment, if known?  Yes  No If yes, date of treatment initiation: \_\_\_\_\_

If known, regimen \_\_\_\_\_

(continued >)

**Form 9: Evaluation at Completion of DOTS-Plus Treatment, page 5 of 6**

Patient name

Patient ID

Condition at completion continued (check only one):

Deceased

Date of death \_\_\_\_\_

Died of TB?  Yes  No

If no, cause of death \_\_\_\_\_

Date of last smear prior to death \_\_\_\_\_

Smear status  Pos  Neg  Unknown

Date of last culture prior to abandonment: \_\_\_\_\_

Culture status  Pos  Neg  Unknown

Failed

Date failure determined \_\_\_\_\_

Was regimen reinforced?  Yes  No

Was treatment irregular?  Yes  No

Was repeat DST performed?  Yes  No

Did the DST show amplification of resistance pattern?  Yes  No

Subsequent death, if known?  Yes  No

If yes, date & cause of death \_\_\_\_\_

Subsequent treatment, if known?  Yes  No

If yes, date of treatment initiation \_\_\_\_\_

If known, regimen \_\_\_\_\_

Not known

Observations, including efforts made to recover patient \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**Form 9: Evaluation at Completion of DOTS-Plus Treatment, page 6 of 6**

Patient name

Patient ID

**Follow-up Plan**

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Smear results at three months \_\_\_\_\_

Smear results at six months \_\_\_\_\_

Culture results at three months \_\_\_\_\_

Culture results at six months \_\_\_\_\_

Was patient evaluated by clinician after completion of treatment?  Yes  No

date \_\_\_\_\_ complaint \_\_\_\_\_ action \_\_\_\_\_

date \_\_\_\_\_ complaint \_\_\_\_\_ action \_\_\_\_\_

date \_\_\_\_\_ complaint \_\_\_\_\_ action \_\_\_\_\_