HIV-TB study — Event Checking Chart

TB Immune Reconstitution Inflammatory Syndrome (IRIS)

Name of centre and cohort _____

Patient ID code:_____ Gender: [ ] Male [ ] Female

Date of birth (dd/mm/yyyy):_____ Date of IRIS (dd/mm/yyyy):_____

INSTRUCTIONS:

- This form is to be used for reporting TB related Immune Reconstitution Inflammatory Syndrome (IRIS) only. The generic criteria for this diagnosis are on the last page of the form.
- $CD4^+$ cell count and HIV-1 RNA results reported on this form must also be reported on the appropriate HIV-Form, IF they are not reported by the electronic data transfer.
- In general, complete these forms either by writing "*X* ", filling out a numeric field, or by completing the information regarding the day, month, and year for time-variables. If the month is unknown, write only the year. If the month and year are both unknown, write "02/79".
- If an answer leads to a "STOP," do not answer any other questions and submit the form to CHIP.
- Please submit the completed form to CHIP via fax: **+45 35455758** or e-mail: **hivtb@cphiv.dk**

Please read Appendix 1 "Criteria for the Tuberculosis related Immune Reconstitution Inflammatory Syndromes (IRIS)" before completing this form

1- Has the study participant recently had one of the following occur?

- 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
↓
STOP
No Diagnosis of IRIS

a. **Indicate which event occurred:**
[ ] Initiated antiretroviral therapy/regimen
[ ] Reintroduced the same or a different antiretroviral therapy/regimen
[ ] Changed antiretroviral therapy for reasons other than toxicity

b. **Date antiretroviral therapy/regimen initiated/reintroduced or changed:**
(dd/mm/yyyy):_____

↓

2- Has the study participant experienced at least one of the following events in response to initiation, reintroduction or change of antiretroviral therapy/regimen?

- Evidence of an increase in CD4+ cell count of ≥50 cells/mm^3, or a ≥2-fold rise in CD4+ cell count **and/or**
- Evidence of a decrease in the HIV-1 viral load of >0.5 log_{10} **and/or**
- Weight gain or other investigator-defined signs of clinical improvement.

[ ] Yes [ ] No →
↓

Is the study participant being evaluated for an infectious/inflammatory condition at a time that is < 4 weeks after initiation, reintroduction or change in antiretroviral therapy/regimen?

[ ]-Yes → **Go to question 6.**
[ ]-No
↓
STOP. No Diagnosis of IRIS

Patient ID code:_____

3- Were any CD4+ cell count results obtained that documented an increase by ≥50 cells/mm3, or a ≥2-fold rise in the CD4+ cell count since the antiretroviral therapy/regimen was initiated/reintroduced or changed?

[ ]-Yes, [ ]-No → **Go to question 4**

↓

Documenting CD4+ cell count:

Indicate the date the blood specimen was obtained and the CD4+ absolute cell count that **documents the increase**:

a. Date specimen obtained (dd/mm/yyyy):_____

b. $CD4^+$ cell count that **documents increase**: _____(cells/mm^3)

Prior CD4+ cell count

Indicate the date the specimen was obtained and the result for the $CD4^+$ absolute cell count that was obtained **prior to or near** the time of the initiation/reintroduction or change in antiretroviral therapy/regimen.

c. Date prior specimen obtained (dd/mm/yyyy):_____

d. Prior CD4+ cell count: _____(cells/mm^3)

4- Were any HIV-1 RNA viral load results obtained that document a decrease of >0.5 log10 since antiretroviral therapy/regimen was initiated, reintroduced or changed?

[ ]-Yes, [ ]-No → **Go to question 5**

↓

Documenting HIV-1 RNA viral load result

Indicate the date the specimen was obtained and the result for the viral load that **documents the decrease**.

a. Date specimen obtained (dd/mm/yyyy):_____

b. HIV-1 RNA (copies/mL):_____

Prior HIV-1 RNA viral load result

Indicate the date the specimen was obtained and the result for the HIV-1 RNA that was obtained **prior to or near** the time of the initiation/reintroduction or change in antiretroviral therapy/regimen

c. Date specimen obtained (dd/mm/yyyy):_____

d. **Prior** HIV-1 RNA (copies/mL):_____

5- Has the study participant experienced any weight gain or other investigator-defined signs of clinical improvement since antiretroviral therapy/regimen was initiated, reintroduced or changed?

[ ]-Yes →
[ ]-No

↓

a. **Indicate which event occurred:**

[ ] Weight gain (Investigator defined significant weight gain)

[ ] Other Investigator-defined signs, specify

Specify:_____

Patient ID code:_____

6- Has the study participant had any signs/symptoms that meet the following conditions?

- Signs/symptoms are consistent with TB **AND**
- They cannot be explained by any other newly acquired infection, the expected clinical course of TB, or the side effects of antiretroviral therapy itself.

[ ]-Yes, [ ]-No → **STOP. No diagnosis of IRIS**

↓

a. New or worsening of a previously diagnosed TB

[ ] New TB diagnosis [ ] Worsening of a previously diagnosed TB

Please specify (several answers are possible)

[ ] Tuberculosis lymphadenitis

[ ] Tuberculosis abscesses with prominent acute inflammatory features

[ ] Pulmonary tuberculosis that is complicated by respiratory failure due to adult respiratory distress syndrome

[ ] Marked systemic inflammatory syndrome related to tuberculosis?

[ ] New or enlarging lymph nodes, cold abscesses, or other focal tissue involvement−eg, tuberculous arthritis

[ ] New or worsening radiological features of tuberculosis (found by chest radiography, abdominal ultrasonography, CT, or MRI)

[ ] New or worsening CNS tuberculosis (meningitis or focal neurological deficit−eg, caused by tuberculoma)

[ ] New or worsening serositis (pleural effusion, ascites, or pericardial effusion)

b. Date of New or Worsening TB diagnosis (dd/mm/yyyy):_____
(Date of Diagnosis of IRIS)

c. Indicate the certainty of TB diagnosis according to the definition in the Appendix 1 ”Criteria for the Tuberculosis related Immune Reconstitution Inflammatory Syndromes (IRIS)”

[ ] Confirmed [ ] Probable

7- Has patient received steroids during TB treatment? [ ] Yes [ ] No [ ] Unknown

If ***Yes***, please indicate: Drug name_____ Initial dose_____mg

Date of start (dd/mm/yyyy):_____ and stop (dd/mm/yyyy):_____

8- Has the patient needed surgery/ hospitalisation after New TB diagnosis/ Worsening of previous TB?

[ ] Surgery [ ] Hospitalisation [ ] None

Patient ID code:_____

9- Comment if there is other pertinent information relevant to this diagnosis:

_____

_____

_____

_____

_____

_____

PHYSICIAN REVIEW

I have reviewed this case and all supporting data and concur with the diagnosis.

_____

Physician's Signature *Date*

Name of reviewing physician:

Last Name: _____

First Name: _____