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| **Supplemental Digital Content 1 - Table 1: Diagnostic criteria for TB IRIS\*** | |
| 1 | Initiation, reintroduction or change in antiretroviral therapy/regimen or therapy for opportunistic infections (OI). |
| 2 | Evidence of:   1. an increase in CD4+ cell count as defined by ≥ 50 cells/mm3 or a ≥ 2- fold rise in CD4+ cell count, and/or 2. a decrease in the HIV-1 viral load of >0.5 log10 \*\* and/or 3. a weight gain or other investigator-defined signs of clinical improvement in response to initiation, reintroduction or change of either antiretroviral therapy/regimen or OI therapy |
| 3 | Symptoms and/or signs that are consistent with an infectious or inflammatory condition. |
| 4 | These symptoms and/or signs cannot be explained by a newly acquired infection, the expected clinical course of a previously recognized infectious agent, or the side effects of medications |
| 5 | For purposes of data collection the infectious/inflammatory condition must be attributable to a specific pathogen or condition. A Clinical Events form should be completed 16 weeks (+ 4 weeks) after initial report if diagnosis confirmed or changed from initial report |
| \* *Generic criteria, AIDS Clinical Trial Group (ACTG), 2005*  \*\* *Because of the frequent lack of baseline VL assessments in this settings, an undetectable viral load at the time of IRIS event was considered as satisfactory for this condition* | |