

Figure 1: Study flow diagram of patients with suspected active TB

The final four boxes show the number of patients with available IGRA results.

^aPatients with previously diagnosed TB were excluded from analyses because IGRA results cannot be reliably interpreted in previously treated patients. The decision to exclude was taken by the expert diagnostic panel and study management group in consultation with the independent Study Steering Committee before unblinding of IGRA and next-generation IGRA results.

^bUpon advice from the Study Steering Committee, and following consultation between the study management group and data management groups, 66 patients were excluded from analyses. Patients recruited from one study site (n = 40) were excluded because they all had diagnoses of confirmed or highly-probable TB (categories 1 and 2) due an error of implementation of recruitment criteria at this site, i.e. the natural spectrum of patients with *suspected* TB was not being recruited. A further subset of patients (n = 26) were, upon review, considered by the expert diagnostic panel to be ineligible (before unblinding IGRA results) on the basis that they were being investigated for TB (due to an incidental abnormal chest x-ray, known contact with active TB, or screening for anti-TNF treatment), but did not present with symptoms or signs suggestive of TB.