



Drugs for Neglected Diseases *initiative*
Iniciativa Medicamentos para Enfermedades Olvidadas

June 10, 2021

Delay in Availability of Results

Study: Phase 2 Randomized, Multicenter, Double-blinded Safety and Efficacy Study to Evaluate Oral Fexinidazole Dosing Regimens for the Treatment of Adult Patients with Chronic Indeterminate Chagas Disease

Sponsor Code: DNDi-FEX-12-CH

Eudra CT number: 2016-004905-15

Follow-up was completed and all study sites were closed by March, 2020. A quality control check of the parasitological analysis was initiated as a normal procedure and completed in May, 2020. The quality control check determined that some of the reagents used in the parasitological analysis may have had slight external contamination. Although this did not appear to impact the initial study results, the sponsor decided to submit all samples to a second analysis in an independent laboratory. However, transfer of the study samples to the new laboratory was delayed by several months due to the COVID-19 pandemic. The samples were eventually transferred and are currently under analysis in the second laboratory. Once complete, the new results will undergo verification, statistical analysis, and quality checks prior to being made available; completion of this process is expected by late 2021.