

The following study was approved by AIFA and EC in October 2017:

EudraCT number	Sponsor code	Title
2017-001731-39	STRIM002- (205813)	Methodology study to investigate the utility of retroviral insertion site analysis in samples from subjects treated with Strimvelis™ gene therapy

However, the initiation of the study was delayed due to pending completion of the analytical method transfer and validation. During that time, the study protocol was amended to an observational study design (STRIM-005). The requirement for this study, fulfils a post approval commitment for Strimvelis, and therefore the new study design has been accepted by EMA.

The sponsor closed the clinical trial under the above EudraCT number in July 2019 and a new application for the observational study was submitted to the required ethics committee under a new protocol number (STRIM-005). Please note that STRIM-002 study did not start and therefore no results are available.