Sponsor:	Istituto di Ricerche Farmacologiche Mario Negri IRCCS - Via Mario Negri 2, 20156 Milano
Study Title:	"*A RANDOMIZED, CROSS-OVER, BIOEQUIVALENCE STUDY OF EFAVIRENZ TABLETS 600 mg OF MYLAN SpA AND SUSTIVA® (EFAVIRENZ) TABLETS 600 mg OF BRISTOL MYERS SQUIBB AT STEADY STATE IN PATIENTS WITH HIV-1*"
Short Title:	-
Acronym:	EFAVIRENZ
EudraCT:	2015-003278-34
Phase:	IV
Start Date (mm/dd/yyy):	02/12/2015
Completion date (mm/dd/yyy):	16/12/2016
Reason for interruption:	Administrative difficulties
Keywords:	

Short Report

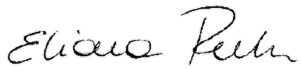
The Efavirenz study is a phase IV, single-center, randomized, open-label, cross-over design with two treatment groups. The aim was to evaluate the bioequivalence at steady state, in clinical practice, of Efavirenz (Mylan) and Sustiva® both administered in 600mg tablets to HIV-1 patients.

The study was authorized by AIFA on 02/12/2015 and was approved by the Coordinating Ethics Committee (Comitato Etico Aziendale Milano Area A, Milan) on 16/12/2015.

It involved a single experimental center, I Division of Infectious Diseases of the "Luigi Sacco" Hospital in Milan, (Principal Investigator Dr. Giuliano Rizzardini), active in recruiting since 12/05/2016. According to the study protocol, the overall duration of the project was approximately 5 months (divided into 4 months for the recruitment of 40 patients plus one month of treatment for each patient).

However, due to administrative and management difficulties of the experimental center, no patient has been enrolled in the EFAVIRENZ Study, consequently the sponsor decided to prematurely terminate the trial.

The formal communication of premature closure of the study was sent to the National Competent Authority (Italian Medicines Agency, AIFA) and to the Ethic Committee of the participating centre through a letter dated 16 December 2016.



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