



Pambio-Noranco, 12.08.2021

Premature termination of a trial

Sponsor Study n.: 16I-Prg06

Eudract n.: 2016-002777-35

Study Title: *“Prospective, double-blind, randomised, placebo controlled, phase III clinical study assessing the efficacy of natural progesterone 25 mg/bid administered subcutaneously in the maintenance of early pregnancy in women with symptoms of threatened abortion.”*

The writer IBSA Institut Biochimique SA, as Sponsor, informs that the study was closed prematurely due to the delay in sites activation and the extremely low patient's enrollment rate.

In total, 4 subjects were included in the study (3 in the Cattolica center and 1 in the Bari center). Given the small number of subjects recruited, no statistical analysis was performed and therefore no study results are available.

Best regards

IBSA Institut Biochimique SA

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