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Medicines and Healthcare products Regulatory Agency
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Dear MHRA

Trial title: AX-8 - Prospective, multi-centre, randomised, placebo-controlled, double-blind, cross-over, phase IIa proof-of-concept trial to investigate the efficacy and safety of AX-8 tablets 5 mg in patients with chronic refractory cough and associated upper airway symptoms.		
EudraCT no: 2016-004803-30	IRAS project ID: 210459	Sponsor R&D ref no: R2060
Participating site: Castle Hill Hospital, Castle Road, Cottingham, HU16 5JQ		Principal investigator: Professor Alyn Morice

This is to notify you that the above study terminated in the set up phase.

The board of directors of the company developing AX-8 decided to stop this clinical trial at the set-up phase as there were significant doubts as to whether the adapted study design (as a result of the MHRA non-acceptance letter) would provide robust study results.

Furthermore, the phase 1 trial which showed unexpectedly systemic bioavailability of the drug, would require a considerably more extensive development program than originally planned.

Yours sincerely

James Illingworth
R&D Manager