

Dear EMA EudraCT team,

Subject:

EudraCT number	Sponsor code	Title
2018-004447-23	RVT1601-CC-04	Randomized, Double-Blind, Placebo-Controlled, Dose-Ranging, Efficacy and Safety Study with Inhaled RVT-1601 for the Treatment of Persistent Cough in Patients with Idiopathic Pulmonary Fibrosis (IPF): SCENIC Trial

On 5 October 2020, IQVIA received a letter from Rod Saponjic, Vice President of Clinical Operations at Respivant.

“The SCENIC clinical trial was a global Phase 2b clinical trial assessing the potential of inhaled RVT-1601 to treat IPF patients with persistent cough. Respivant enrolled 108 subjects of 180 planned before the study was terminated on 1 May 2020 due to the COVID-19 pandemic. Consequently, Respivant Sciences will be closing out the study”.

In this letter Respivant stated that Respivant will not be providing updates of the results of the study to EudraCT and Respivant will not be submitting a CSR for the RVT1601-CC-04 trial to Health authorities.

As a consequence of the termination of all clinical trial activities, Respivant ceased all business activities at the end of December 2020 and no longer exists as a legal commercial entity. As IQVIA was acting only in the EU Legal Representative capacity in relation to the SCENIC trial IQVIA are unable to obtain access to this sponsor’s trials within EudraCT nor to fulfil the responsibilities of the Sponsor with regard to provision of additional information relating to the results of trials sponsored by Respivant.

Would you need any more specific information relating to the SCENIC trial, you can contact Dominique Blankaert at Dominique.Blankaert@IQVIA.com.

Kind regards,

Zubin Thacker