

**Agencia Española de Medicamentos y Productos Sanitarios
AEMPS**

**REPORTING TO THE AEMPS OF SUSPECTED
UNEXPECTED SERIOUS ADVERSE REACTIONS
OCCURRED IN A CLINICAL TRIAL WHILE
EUDRAVIGILANCE IS NOT AVAILABLE**

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EudraVigilance (EVCTM) will not be available from 8th (00:00) to 21st (24:00) November 2017 due to preparations for the improved version go live. During that period, reporting of suspected serious adverse reactions to the Agencia Española de Medicamentos y Productos Sanitarios will be submitted by FAX. The sponsor will have to send those SUSAR reports to EVCTM since the 22nd November 2017.

Reporting to the AEMPS of suspected serious adverse reactions (SUSAR) occurred within a clinical trial has only to be done through Eudravigilance_CTM, as indicated in section “¿Deben notificarse al CEIm las sospechas de reacciones adversas graves e inesperadas? (Should suspected unexpected serious adverse reactions be reported to the CEIm?)” on the document “[Instrucciones de la Agencia Española de Medicamentos y Productos Sanitarios para la realización de ensayos clínicos en España](#) (Instructions of the Spanish Agency of Medicines and Medical Devices for conducting clinical trials in Spain)”.

It is foreseen that EudraVigilance (EVCTM) will not be available from 8th (00:00) to 21st (24:00) November 2017 in order to prepare the go live of the actualized version of such system. More related information is available on the document published by the European Medicine Agency (EMA) [EudraVigilance Go-Live Plan](#).

During that period, SUSAR reports to the Agencia Española de Medicamentos y Productos Sanitarios will be submitted to the FAX number +34 918 225 076. All SUSAR reported to AEMPS from the 8th (00:00) to the 21st (24:00) November 2017 will be submitted by the sponsor to EudraVigilance from day 22nd November.