

PUBLIC NOTICE ON THE MEASURES FOR THE IMPLEMENTATION OF AIFA'S DETERMINATION N° 9/2012, CONCERNING THE INVESTIGATIONAL MEDICINES' SAFETY MONITORING

With reference to the public notice regarding the "Measures for the implementation of AIFA's Determination n° 9/2012, concerning the investigational medicines' safety monitoring" <u>published on the AIFA website on January 31st 2014</u>, AIFA informs that from July 1st 2018 <u>dsur@aifa.gov.it</u> is the mail where the sponsors of interventional clinical trials, or delegated contract research organizations, have to send the annual DSURs to AIFA.

The above-mentioned mail replaces <u>DSUR ITA@aifa.malcert.it</u> (used until March 31st 2018) and <u>dsur@pec.aifa.gov.it</u> (used from April 1st 2018 until June 30th 2018) for all intents and purposes.

It should be noted that the transmission to AIFA of DSURs through other channels (fax, CD ROM, other email accounts) will not be considered valid or acquired acts except in case of malfunctioning of certified mail systems and in any case with permission of AIFA.