Abstract 15 July 2016

*Alessandro Spina- Monica Dias- Frank Petavy**

Notes on the anonymization of Clinical Study Reports for the purpose of ensuring regulatory transparency

In October 2014, the European Medicines Agency (EMA) adopted a Policy on the publication of clinical data for medicinal products for human use. This Policy is probably the first concrete and pioneering measure adopted by a pharmaceutical regulator to give effect to the objective of transparency of clinical trial information. As stated in the Policy, "*the protection of personal data is enshrined in EU legislation; it is a fundamental right of EU citizens. The policy has to ensure adequate personal data protection; it must be fully compliant with applicable regulations in the EU* […].*There are ways and means to anonymise data and protect patients from retroactive identification*". As part of the implementation of the Policy, EMA has developed a guidance document addressed to pharmaceutical companies on the anonymisation of clinical reports. This paper aims at discussing the scientific methodology and the technical and legal challenges for the anonymization of clinical study reports, also in light of the increasing importance of clinical trial transparency.

** The Authors are respectively Data Protection Officer (AS), Policy Officer (MD) and Scientific Administrator –Statistician(FP) at the European Medicines Agency (EMA). The views expressed in this paper are personal and may not reflect the official position of EMA*