GUIDANCE ON THE PAYMENT OF THE SINGLE FEE DURING THE TEMPORARY MANAGEMENT PHASE OF CLINICAL TRIALS ACCORDING TO EU REGULATION 536/2014, PENDING THE FULL IMPLEMENTATION OF THE MINISTERIAL DECREES OF REORGANISATION OF THE ETHICS COMMITTEES AND INTRODUCTION OF THE SINGLE FEE

This documents provides guidance on the payment of the single fee by the sponsors of commercial clinical trials submitted in accordance with the "Proposed guidance for the temporary management of clinical trials pursuant to EU Regulation 536/2014 pending the full implementation of the Ministerial Decree reforming the Ethics Committees and the single fee" published on 31st January 2022 on AIFA website

(https://www.aifa.gov.it/documents/20142/1619588/Proposta_operativa_gestione_temporanea_SC_EN.pdf).

The fee to be paid must include in a single rate the following: the fees currently in force for submitting to AIFA (including the amount currently paid to AIFA and the one currently paid separately to the Ministry of Health), and the fee currently in force for the Ethics Committee identified for the specific clinical trial, based on information published on the website of the Ethics Committee concerned.

If the Ethics Committee has not yet been identified or if only Part I of the dossier is submitted, the sponsor is allowed to pay the amount relating to the Ethics Committee fee with a second payment instalment.

Payment must be made by bank transfer to the following bank account number:

Banca Popolare di Milano
IBAN IT58-F-05034-03200-000000010455 (SWIFT CODE: BAPPIT21060)

The reason for the payment must include the EU number of the clinical trial (EU CT number) and, in the case of a substantial modification, also its unique code number generated by the CTIS Portal (where this is identified as "ID").

It should be noted that for the payments described above, it will not be temporarily possible to use the current AIFA (POL) fee payment system and sponsors will not be required to register on the OsSC portal or to be assigned a SIS code.