
Art. 1st The Resolution of the Collegiate Board of Directors - RDC No. 205, of December 28, 2017, becomes effective with the following changes:

"Art. 10...............................................................................................................

I - request for a pre-submission meeting, if the interested party deems it necessary, for the presentation of the DDCM, specific clinical trial dossier or substantial modification due to protocol inclusion;

II - holding a pre-submission meeting, if the interested party deems it necessary, for the presentation of the DDCM, specific clinical trial dossier or substantial modification by inclusion of the protocol, within sixty days after the request by the interested party;

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Art. 2 This Resolution comes into force from December 1, 2022.

ANTONIO BARRA TORRES
CEO

(*) (CODOU No.) Republished because it was published in the DOU on 12/1/2022, Section 1, page 120, with an error.

This text does not replace the one(s) published in the Official Gazette.