"Decade of Equal Opportunities for Women and Men"
"Year of Dialogue and National Reconciliation"

COMMUNICATION No. 003-2018-OGITT/INS

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Within the framework of the implementation of the Clinical Trials Regulations (DS N°021-2017-SA) and the Manual of Clinical Trials Procedures (MAN-INS-001.V03), it is reported that they are now available in the REPEC. , the forms for reporting Progress Reports and Final Reports, so that those administered can comply with presenting the integrity of the requirements established in articles 2, 104 and 105 of the Regulations*.

FOR-OGITT-054: Clinical Trial Progress Report

It must be sent by the sponsor or its legal representative in the country, on a quarterly or semiannual basis, counting from the date of authorization of the clinical trial in Peru. The maximum submission period is up to seven (07) calendar days after the end of the quarterly or semiannual period.

FOR-OGITT-055: Notification of the Final Report of the research center

It must be submitted within thirty (30) calendar days following the closing visit carried out by the monitor.

FOR-OGITT-056: Notification of the National Final Report

It must be submitted within sixty (60) calendar days following the date of presentation of the final report of the last research center. In the case of CTs carried out only in Peru, in addition to the data in this form, the national final report includes the results and conclusions of the study (Annex 02 of MAN-INS-001.V03: Guide for the report of results and conclusions of the clinical trial).

FOR-OGITT-057: Notification of the International Final Report

It must be presented within twelve (12) months after the completion of the CE in all research centers internationally. The final results and conclusions of the study must also be attached (Annex 02 of MAN-INS-001.V03: Guide for the report of results and conclusions of the clinical trial).

The instructions are available on the REPEC main page, section FORMULARIOS, GUÍAS Y ANEXOS

* The REPEC will import the list of deviations and/or adverse events based on the reports that were made with the electronic forms available for each case. For the purposes of the Progress / Final Report, it will not be required to enter information from notifications made with old forms (Word or Excel), that is, those that were sent before the electronic version was available for reporting deviations or adverse events. **The effective date of this form is immediate.**

Note
For inquiries about Clinical Trials, call 51(1) 748-1111, annex 2191 or to the email consultaensayos@ins.gob.pe.