Ministry of Health
Health Surveillance Department
Department of Immunization and Communicable Diseases
General Coordination of the National Immunization Program

INFORMATION NOTE No. 71/2021-CGPNI/DEIDT/SVS/MS

Registration of vaccination data in the national Immunization database from clinical studies approved by Anvisa.

I - SUBJECT

Registration, in the national immunization database of the National Health Data Network (RNDS), of vaccine doses applied during clinical studies that supported the authorization for emergency use or approval of the sanitary registration of Covid-19 vaccines and other vaccines by the National Health Surveillance Agency (Anvisa).

II - JUSTIFICATION

The National Research Ethics Committee (Conep) decided that data from clinical research participants vaccinated in the context of studies with Covid-19 vaccines may be sent to the national immunization registry, as this procedure is compulsory for all Brazilian citizen, in accordance with Decree No. 78.231, dated August 12, 1976, which regulates Law No. 6.259, dated October 30, 1975, Ordinance GM/MS No. 69, dated January 14, 2021 and Law No. 14.124 dated March 10, 2021. Thus, there is no need to request authorization from research participants for the transfer of vaccination data to the national immunization registry. In future clinical trials with vaccines, Conep will request the inclusion of this information in the Informed Consent Form (ICF), as per document No. 0021581825.

In meetings with technicians from the General Coordination of the National Immunization Program (CGPNI), the SUS IT Department (DATASUS) and Anvisa, the guidelines contained in this Information Note were aligned.

III - PURPOSE

To define business rules for registration, in the RNDS national immunization database, of vaccine doses applied during clinical studies that supported the authorization for emergency use or approval of sanitary registration of Covid-19 vaccines and other vaccines by Anvisa.

IV - ANALYSIS

Between the development of a vaccine and its use in the vaccination activities developed by the PNI, it is required to meet the quality, safety and efficacy standards, whose analysis and registration of the products are the responsibility of Anvisa, as well as the regulations for the operation of the vaccine rooms and the registration of doses applied, in accordance with Law No. 9782/1999, which defines the National Health Surveillance System and creates the National Health Surveillance Agency, Law No. 9.787/1999, which provides for the health surveillance and other activities, Decree No. 8.077/2013, which regulates the conditions for the operation of companies subject to sanitary licensing, registration, control and monitoring, within the scope of sanitary surveillance, Law No. 14.124/2021, which defines the registration of individualized form, in an information system provided by the Ministry of Health, regarding the application of covid-19 vaccines and possible adverse events and other activities.

The accredited vaccination service for the application of vaccine doses during the clinical study must observe the following normative acts:

Anvisa Collegiate Board Resolution (RDC) No. 50/2002, which provides for the technical regulation for planning, programming, preparation and evaluation of physical projects of health care facilities;

RDC No. 63/2011, which provides for the requirements of good operating practices for health services;

RDC No. 197/2017, provides for the minimum requirements for the operation of human vaccination and vaccine registration services;

RDC No. 222/2018, which regulates good management practices of health services waste;

GRECS/GGTES/Anvisa Technical Note No. 1/2018, with questions and answers about RDC 197/2017;

Technical Note No. 12/2021/SEI/GRECS/GGTES/DIRE1/Anvisa, with recommendations for vaccination services during the Covid-19 pandemic period.

The doses of vaccines applied to volunteers in the context of clinical research must be registered in the national immunization database, after authorization for emergency use or approval of the health registration of these vaccines, to prove the individual's vaccination status, composition of PNI indicators, as well as to obtain of the Electronic Vaccination Booklet, the National Vaccination Certificate and the International Vaccination Certificate, when required.

For registration in the national immunization database of vaccine doses applied in participants in clinical studies approved by Anvisa, the following requirements must be observed:

The clinical study must have been approved, the results of which were used as a subsidy for the authorization of emergency use or approval of the health registration of Covid-19 vaccines or other vaccines, by Anvisa;

The sponsor will be responsible for the registration in the national immunization database, together with the accredited vaccination service for the application of vaccine doses during the clinical study, which shall proceed in accordance with the rules and legislation of the Ministry of Health;

All valid doses of the complete vaccine schedule approved in the clinical study must be registered (single dose, first dose, second dose, another if any). These doses will be computed to compose the vaccine coverage indicators, certificates and electronic vaccination booklet;

The registration will be through data transfer from the information system of the sponsor or the vaccination service to the RNDS national immunization database according to the information model for integration, available on the Ministry of Health's Services Portal (https://servicos-datasus.saude.gov.br);

The information template on the Ministry of Health's Services Portal must contain the fields for identification of data originating in the clinical study registered and approved by Anvisa:

Study protocol number at Anvisa;

Study protocol version number at Anvisa

Vaccine health registration number at Anvisa (emergency or definitive);

Study start date;

Study end date;

Strategy: research;

Other data provided for routine vaccination activities to identify the vaccinated person, the vaccine and the vaccination schedule.

Doses given as placebo should not be transferred to the RNDS national immunization database.

The institution responsible for recording the doses applied must be registered in the National Register of Health Facilities (CNES), in accordance with Ministry of Health Ordinances No. 2022, dated August 7, 2017 and No. 1.883, dated November 4, 2018.

The operator of the information system responsible for entering the doses applied must be previously registered in the Access Permission Registration System (SCPA) of the Ministry of Health, with the Municipal Health Department of the city where the clinical study was carried out.

The vaccinator responsible for administering the vaccine doses must be linked to the vaccine room of the institution responsible for the clinical study, through registration with the CNES.

The transfer of the data of all vaccinated individuals, participants of the clinical study approved by Anvisa, must be done at once, covering the period of beginning and end of the study, and a new corrective transfer may be made if it is necessary to update any data record showing inconsistency.

In order to facilitate the transfer of vaccination data to RNDS, information on batches and laboratories manufacturing COVID-19 vaccines or other vaccines applied to clinical trial participants should be registered in the Strategic Inputs Information System (SIES), of the Health Surveillance Department, from the Ministry of Health.

A filter option to identify the doses applied in each clinical study, individually or together should be indicated in the dissemination of data and vaccination indicators.

V - CONCLUSION

The doses of vaccines applied during the conduction of clinical studies that supported the authorization for emergency use or approval of the sanitary registration of Covid-19 vaccines and other vaccines, by Anvisa, must be registered in the RNDS to prove the citizen's vaccination status, PNI indicator composition, as well as to obtain the Electronic Vaccination Booklet and the National and International Vaccination Certificates.

The Information Template must be adequate to identify the doses of vaccines applied during the conduction of the clinical studies.

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