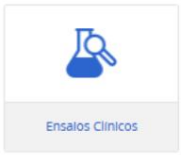
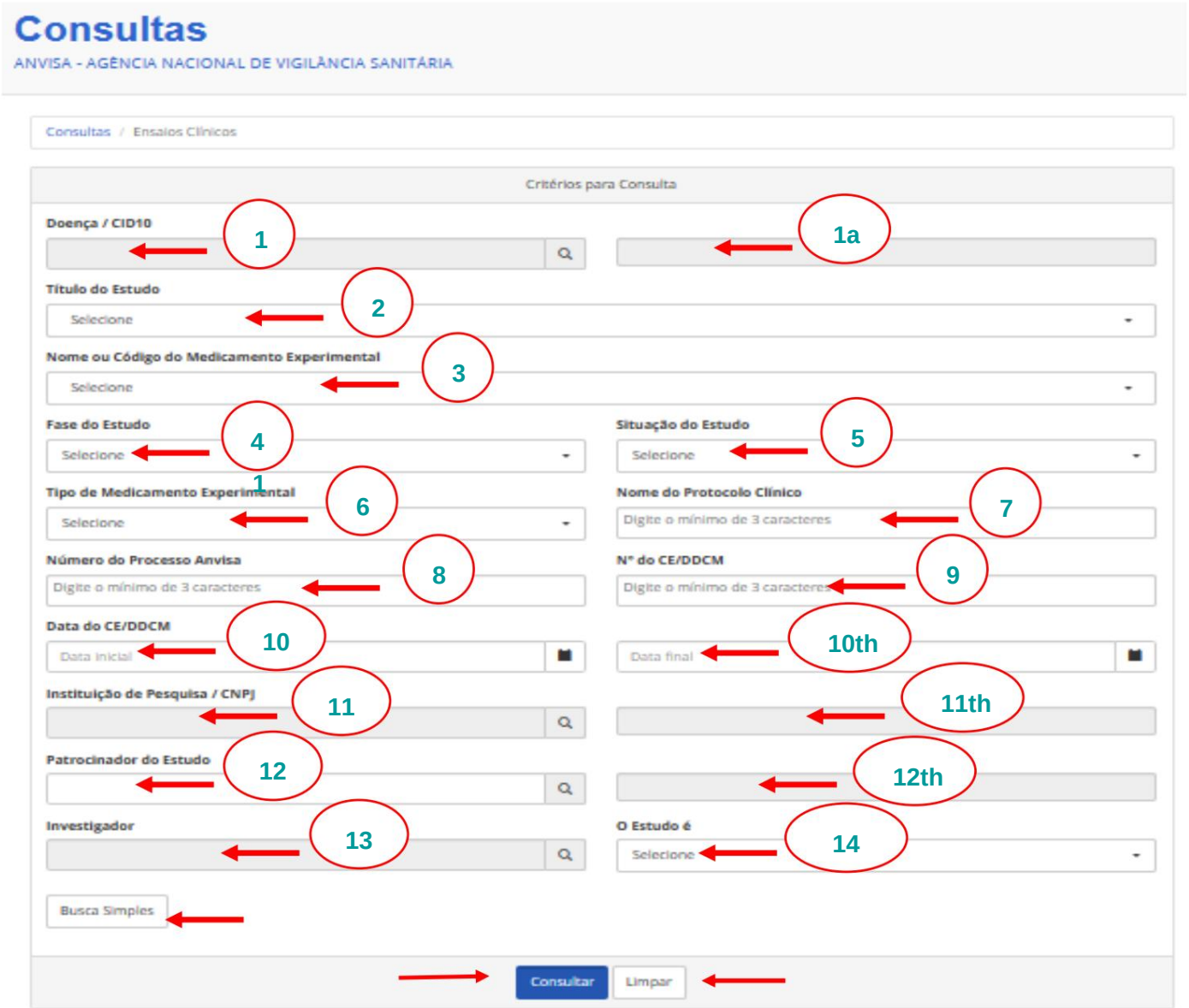
INSTRUCTION MANUAL FOR CONSULTING CLINICAL TRIALS

To consult the Clinical Trials authorized by Anvisa, access the link:

https://consultas.anvisa.gov.br/#/

Click on the icon





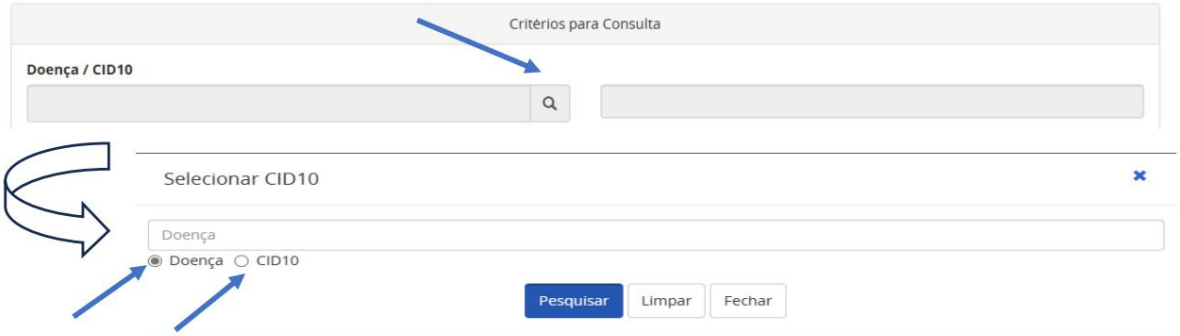
1. Step by step

1.1 Completing any of the fields on the screen above, using the criteria indicated, is sufficient to carry out the consultation.

1.2 Click on ***"Consult",*** after filling in the desired field.

1.3 In the step-by-step process described below, the ***"Disease/ CID".*** (1)

1.4 Click on the magnifying glass

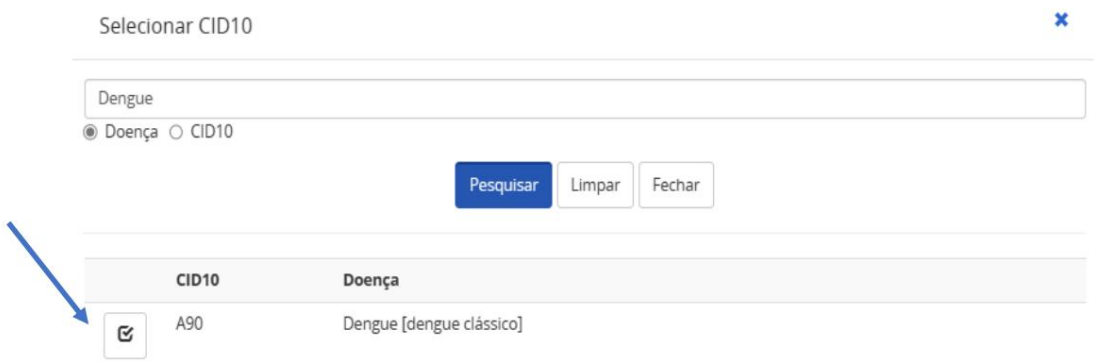


1.2 Select Disease or ICD10.

1.3 Enter the name of the disease or at least the first three letters of the name of the disease in the corresponding field and click on ***"Search",*** or

1.4 Enter the CID10 code in the corresponding field, if this was the selected option, and click ***"Search".***

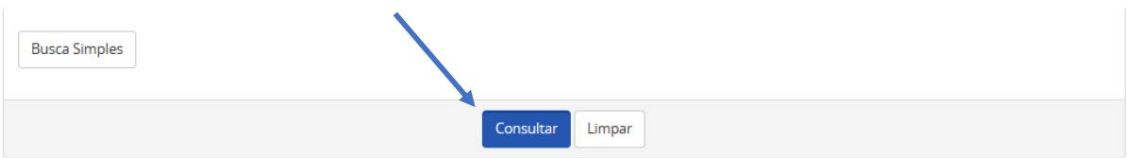
1.5 The system will present a list of diseases or ICD codes, according to the selected option, as in the following example.



1.6 Select the desired option, as indicated by the arrow above. In this case the system presented a single line/option.

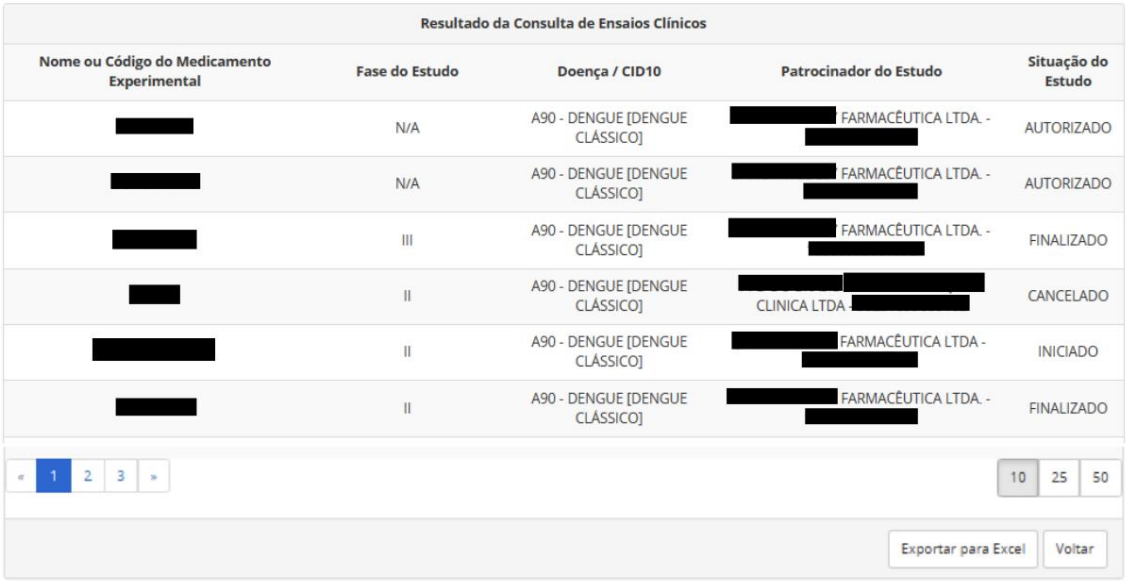
1.7 The name of the disease or selected ICD will appear in the field (1a)

1.8 Click on ***"Consult",*** at the end of the consultation screen.



1.9 The system will present a list of all clinical trials found in the Anvisa database *(Anvisa Clinical Research Control System* – SCPC), from 2015 onwards.

1.10 As can be seen in the example below, the first column contains the name or Code of the Experimental Drug, followed by the Clinical Trial Phase and the ICD code and name of the Disease and then the name of the company sponsoring the clinical trial and, in the last column, the current status of the Clinical Trial.



Resultado da Consulta de Ensaios Clínicos

Nome ou Código do Medicamento Experimental	Fase do Estudo	Doença / CID10	Patrocinador do Estudo	Situação do Estudo
[redacted]	N/A	A90 - DENGUE [DENGUE CLÁSSICO]	[redacted] FARMACÊUTICA LTDA. - [redacted]	AUTORIZADO
[redacted]	N/A	A90 - DENGUE [DENGUE CLÁSSICO]	[redacted] FARMACÊUTICA LTDA. - [redacted]	AUTORIZADO
[redacted]	III	A90 - DENGUE [DENGUE CLÁSSICO]	[redacted] FARMACÊUTICA LTDA. - [redacted]	FINALIZADO
[redacted]	II	A90 - DENGUE [DENGUE CLÁSSICO]	[redacted] CLINICA LTDA - [redacted]	CANCELADO
[redacted]	II	A90 - DENGUE [DENGUE CLÁSSICO]	[redacted] FARMACÊUTICA LTDA - [redacted]	INICIADO
[redacted]	II	A90 - DENGUE [DENGUE CLÁSSICO]	[redacted] FARMACÊUTICA LTDA. - [redacted]	FINALIZADO

« 1 2 3 » 10 25 50

Exportar para Excel Voltar

1.11 The list of clinical trials may be presented in Excel Spreadsheet format.
To do this, click on the ***"Export to Excel"*** option at the end of the query screen.

1.12 Below is a brief explanation of each of the criteria, in the order they appear on the screen above. The number highlighted with a red circle indicates the corresponding field on the initial query screen.

Name or Code of the Experimental Drug : *Experimental drugs are generally not yet registered and therefore do not have a commercial name, which is why they are identified by codes. However, it is not uncommon for already registered drugs to be investigated for other therapeutic indications, or for new populations, new pharmaceutical forms.*

and new associations, which make them experimental in these new conditions.

Study Phase : *Phase I clinical trials are the first clinical trials in humans (initial safety trials), mainly involving the administration of the drug to a few participants. Phase II clinical trials are conducted on a larger number of participants with the disease to be studied, with the main objective of evaluating the short-term safety, dose-response relationship and preliminary efficacy of the experimental drug. Phase III or comparative efficacy clinical trials are those in which the experimental drug is administered to a much larger population of patients than in the previous phases and generally aim to confirm the results.*

efficacy and safety results and demonstrate the benefit/ risk ratio of the experimental drug. In Phase IV, the drug is already authorized for marketing, based on the results of previous clinical trials, and the objective is to assess whether these same results will be observed in the majority of the target population.

Disease or ICD10 : *ICD is the International Classification of Diseases, created by the World Health Organization (WHO). Although the WHO has already published the new ICD11, which is an improved and fully digital version, ICD10 continues to be used.*

Study Sponsor : *Person, company, institution or organization responsible for initiating, administering, controlling and/ or financing a clinical study. The Sponsor may hire a CRO (Clinical Research Representative Organization) to partially or fully assume its responsibilities, together with Anvisa.*

Study status : *The clinical trial* ***"AUTHORIZED"*** *means that Anvisa has authorized the clinical trial to be conducted and the sponsor may start it at any time, provided that it is authorized by the National Research Ethics Commission (CONEP) and/ or local Research Ethics Committee (CEPs). If Anvisa does not authorize the clinical trial to be conducted, the system will display the clinical trial status as* ***"NOT AUTHORIZED".*** *The clinical research standard (RDC No. 9/2015) determines that the sponsor or ORPC must inform Anvisa when the clinical trial begins and ends. Therefore, as soon as Anvisa receives information about the start or end of the study, the system is updated to* ***"STARTED"*** *and* ***"ENDED"*** *to reflect the current status of the study. The Sponsor may request, at any time, the cancellation or temporary suspension of the clinical trial, and must present the appropriate justifications for this. Likewise, when justified, Anvisa may also, ex officio, cancel or temporarily suspend the clinical trial, which will appear in the query as* ***"CANCELLED"*** *or* ***"SUSPENDED".*** *In most cases, cancellations and suspensions of clinical trials occur at the request of the Sponsor.*

1.13 Click on the line of the clinical trial of interest to access detailed information.

1.14 The system will display the page with detailed information about the selected clinical trial, as in the following example.

Detalhes do Ensaio Clínico	
Patrocinador do Estudo	[redacted]
CNPJ	[redacted]
Número do Processo Anvisa	25351.[redacted]
Número do CE / DDCM	[redacted]
Nome ou Código do Medicamento Experimental	[redacted]
Classe Terapêutica	ANTIVIROTICOS
Tipo de Medicamento Experimental	SINTETICO/SEMISSINTETICO
Doença / CID10	A90 - DENGUE [DENGUE CLASSICO]
Nome do Protocolo Clínico	[redacted]
Título do Estudo	ESTUDO DE FASE 2, RANDOMIZADO, DUPLO-CEGO, CONTROLADO POR PLACEBO, [redacted] PARA AVALIAR A EFICACIA E A SEGURANÇA [redacted] PREVENÇÃO DA INFECÇÃO POR DENGUE [redacted].
Fase do Estudo	FASE II
Tipo de Estudo	POSSUI COOPERAÇÃO ESTRANGEIRA
Situação do Estudo	INICIADO

1.15 In addition to the information already mentioned above, the system will present other additional information:

Anvisa process number : *The Clinical Drug Development Dossier (DDCM), as well as the Specific Clinical Trial Dossier (DEEC), receive a process number when submitted to Anvisa. Since this is administrative information, it appears in the query only as complementary information. For each authorized DDCM, in addition to publication in the Official Gazette of the Union (DOU), the sponsor receives a Special Communication (CE) with the description of the authorized clinical trials and the list of clinical inputs to be imported* 8 9 10 .

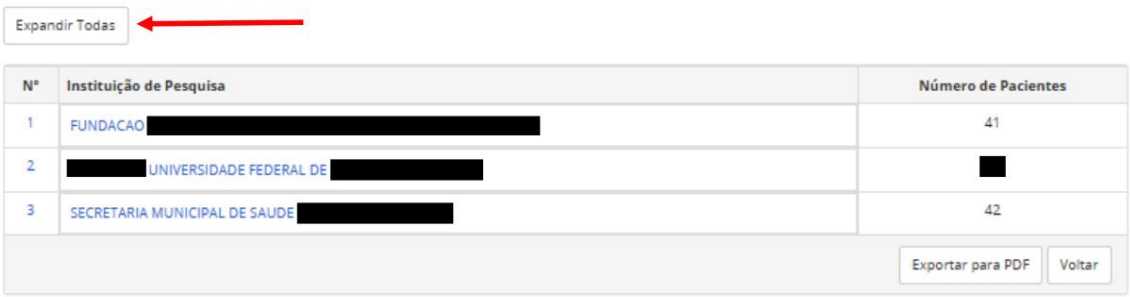
Type of experimental drug : *The category of the experimental drug is one of the characteristics that determine its level of complexity and the time required for analysis of the respective DDCM. There are four main categories of experimental drugs or products under investigation, namely: Biologicals, including vaccines, Synthetics or Semi-synthetics, Phytotherapeutics and Radiopharmaceuticals.* 6

Study Title and Clinical Protocol Name : *The study title describes the design and main characteristics of the study such as: study phase, objective (pharmacokinetics, pharmacodynamics, immunogenicity, safety, efficacy, etc.), type of control (placebo or active comparator), type of masking (blind/ double-blind or non-blind), centers where the study will be conducted (single center or multicenter, national and/ or international), etc. The clinical protocol is usually identified by a code and/ or acronym. Using the protocol name or code, it is possible to search for the clinical trial in international databases such as Clinicaltrials.gov* 7

Type of study : *This refers to the participation or not of foreign sponsors in conducting the clinical trial. Information on whether or not there is foreign cooperation in conducting clinical trials is provided by the sponsor itself, but the fact of having or not foreign cooperation or being sponsored by national capital makes no difference from the point of view of DDCM/ DEEC requirements and analysis.*

2. Consultation by Research Institution and Researchers

3.1 In the lower third of the page, the system will present the list of locations where the clinical trial (research institution) will be carried out and the number of participants that the sponsor plans to include in each location, as in the following example .



3.2 Click on ***"Expand All"*** to find out which investigators or researchers will be responsible for carrying out the clinical trial at each location indicated by the sponsor.

3.3 The list of Research Institutions and researchers can be accessed in pdf format. To do this, simply click on the ***"Expand to PDF"*** option.

3.4 When clicking on the ***"Research Institution"*** the system will direct you to the National Health Platform Register of Establishments of (https://cnes.datasus.gov.br/pages/estabelecimentos/consulta.jsp?search).

3.5 The CNES platform allows access to detailed information about the health establishments, including research centers.

3.6 CNES information is not under the governance of Anvisa.

3.7 Using the name of the institution or CNPJ, it is also possible to directly consult the Research Institution and the clinical trials being carried out at this institution.

3.8 In the same way, it is possible to find out about the clinical trials that a given researcher or investigator is participating.

Consultation of authorized clinical trials does not produce legal effects