Questions by Thematic Areas

Authorities and general framework

1.1 - What is the National Regulatory Authority (NRA) for clinical trials? *
1.2 - What are the main regulations governing health research? *
1.3 - What are the main regulations governing the authorization of clinical trials? *
1.4 - Is the approval of a Research Ethics Committee (REC) required?
1.5 - Must the approval of a Research Ethics Committee (REC) be obtained prior to submission to the National Regulatory Authority (NRA)?
1.6 - Is there an accreditation system for Research Ethics Committees (RECs)?
1.7 - Is there a public registry of Research Ethics Committees (RECs)?
1.8 - Is it established which types of research must be authorized by the National Regulatory Authority (NRA) before commencement?

Sponsor roles and obligations

2.1 - Does the regulation define the sponsor of a clinical trial?
2.2 - Is the sponsor required to have a legal representative or a legal entity domiciled in the country?
2.3 - Are the requirements that the sponsor must meet to act as such established?
2.4 - Are the requirements that the sponsor must meet when acting through a Contract Research Organization (CRO) established?
2.5 - Are there specific requirements for the selection of research sites or units?
2.6 - Are there specific requirements for the selection of investigators?
2.7 - Are requirements regarding insurance and compensation for participants established?

Initial authorization of the clinical trial

3.1 - Is the essential content of the submission for initial authorization established?
3.2 - Is the submission process established (platform, format)?
3.3 - Are the official regulatory timelines for the review chronology defined?
3.4 - Must fees be paid for the evaluation of the trial?
3.5 - Is public registration of the clinical trial mandatory before commencement?
3.6 - Are there mechanisms for recognition of evaluations conducted by National Regulatory Authorities of other countries?
3.7 - What is the sequential order of steps that the sponsor, institution, and principal investigator must follow from the beginning of the process to authorization for study initiation? *

Management of the investigational product (IP)

4.1 - Are labeling requirements for the investigational product (IP) established?
4.2 - Is proof of Good Manufacturing Practices (GMP) required for the investigation product (IP)?
4.3 - Does trial approval include authorization to import/use the investigational product (IP)?

Conduct and closure of the trial

5.1 - Safety Reports: Are the requirements, channels, mechanisms, and timelines for reporting SAEs and SUSARs established?
5.2 - Is the submission of annual safety reports required?
5.3 - Is the submission of periodic follow-up reports required?
5.4 - Is it established which types of protocol amendments require prior approval from the National Regulatory Authority (NRA) and/or the Research Ethics Committee (REC)?
5.5 - Are there obligations regarding post-trial access to the research intervention?

Additional specific regulations

6.1 - Is there a personal data protection law applicable to clinical trials?
6.2 - Are there specific regulations or guidelines for clinical trials with vaccines?
6.3 - Are there specific regulations or guidelines for the collection and/or use of samples for research?
6.4 - Clinical trials for specific situations: Are there specific regulations or guidelines for other types of clinical trials?

***** Available only in the “Search by Country” feature.