CFDA issued the draft of "Clinical Evaluation Basic Requirements for Clinical Exempt IVD Reagents" along with the 2nd batch of clinical exempt class II IVD reagents

On May 24,2017, CFDA issued the draft of "Clinical Evaluation Basic Requirements for Clinical Exempt IVD Reagents". The 2nd batch of clinical exempt class II IVD reagents (130 reagents) have been added to the original clinical exempt IVD reagents directory. China Med Device, LLC, specializing in providing turn-key solution for medtech companies entry into China, brings you up to date information on CFDA. If you have any feedback, please email us at info@ChinaMedDevice.com or visit us www.ChinaMedDevice.com

Key highlights are below.

1. Clinical Evaluation Comparison Method
2. Sample Selection and Sample Size
3. Basic Content of the Clinical Evaluation Report
4. Areas that need special attention

For the more detailed content, please click below.

According to Article 29 in the "Administrative Decree for the IVD Reagents Registration" (CFDA, No. 5), the clinical exempt IVD reagents will need the clinical performance evaluation based on the assessment of products' intended use, interference factors, comprehensive literature review and other non-clinical-trial methods.

"Clinical Evaluation Requirements for Clinical Trial Exempt IVD Reagents (Draft)"

According to Article 29 in the "Administrative Decree for the IVD Reagents Registration" (CFDA, No. 5), the clinical exempt IVD reagents will need the clinical performance evaluation based on the assessment of products' intended use, interference factors, comprehensive literature review and other non-clinical-trial methods.

5. Clinical Evaluation Comparison Method
    a. Choose approved products that have high reputation in current clinical application as the compared predicate reagent. Complete technical information of the predicate reagent should include methodology, clinical indications, main performance indicators, traceability of predicate device, recommended positive parameters, or reference interval etc. The predicate device registration information should be provided.
    b. Applicant should choose the reference methodology for comparative study test. Select reference laboratory for research. Reference methodology and

reference laboratory should have the certification recognized by the China National Accreditation Service for Conformity Assessment (CNAS)

c. According to the intended use of the product, applicants can also use patients' clinical diagnosis, disease progression, efficacy observation and other objective indicators for clinical performance studies.

6. Sample Selection and Sample Size
   a. Select clinical samples that cover the intended use and interference factors.
   b. The sample size of Class II product should not be fewer than 100. Clinical cases should fully reflect the products clinical safety and efficacy.
   c. The type of samples to be used for the evaluation should be consistent with the one in registration application. The comparable sample types are serum and plasma. One of the sample types can be selected for clinical evaluation. If there is no comparable sample type such as serum and urine, they should be evaluated separately.

7. Basic Content of the Clinical Evaluation Report
   a. report cover request
      Should include: the reagent generic name, test start date, test completion date, test site, signature of the principal investigator and the seal of the unit, signature of the person in charge of the statistic and the seal of the unit, the name of the applicant (seal), the applicant's Contact and contact information, report date.
   b. test sample Information
      Should include: testing reagents, compared reagents, other reagents used in conjunction with calibration, quality control, dilution, test equipment, etc. Including: the specific reagent name, manufacturer, specifications, batch number, expiration date, equipment should include Name, manufacturer, model and so on.
   c. Evaluation proposal
      Including: background information of the product, purpose of the evaluation, evaluation method, sample size, sample type, crowd selection, disease selection, interference samples, statistical methods, data processing.
   d. Evaluation results report
      (1) Describe the implementation of the evaluation proposal, such as the specific sample selection, the basic process of testing.
      (2) Testing data's statistical results
      (3) Statistical analysis of the testing data according to the test results, population distribution, disease distribution, interference samples, etc.
      (4) For the samples that have unmatched test results in comparative study, they should be rechecked in a reasonable way to analyze the results of the tests. If they do not need to be rechecked, applicants should explain the reasons in detail.
      (5) Test conclusions.

e. Evaluation data sheet
Should include at least the following: sample number, age, sex, tested reagents' test results, comparative reagent test results, recheck test results (if any), clinical diagnostic information (including interference sample information) etc.

f. Provide relevant clinical documents of the tested product.

g. Specify that the storage location of evaluation documents should reside in the institution itself.

8. Areas that need special attention:

a) The evaluation sample should be traceable.

The original documents of evaluation samples should include but not limited to: patient sample source, unique and traceable number, age, gender, department, very clear clinical diagnostic information, treatment tracking information (if any) etc.

b) Registration changes relating to clinical evaluation should be implemented according to this requirement.

c) If the applicant cannot do clinical evaluation based on the above requirements, they can also choose the clinical trial for clinical evaluation.