

FREQUENT QUESTIONS

1.- Is a contract with the UHAP required to obtain a forecast?

It is not necessary to make a contract for the prediction by the UHAP-CCINSHAE.

2.- Is there still the alternative of submitting the direct procedure to COFEPRIS without requiring the forecast of a UHAP?

Yes, the evaluation by the UHAP is optional, but the traditional process in COFEPRIS continues in force.

3.- Who can guide me about the institution that can evaluate research protocols in areas that are not shown in the current list of UHAP's?

You can request guidance either by phone at the number: 5350-1900 Ext. 5001 or by email: beatriz.cano@salud.gob.mx

4.- What are the costs of the prediction by the UHAP's?

The cost of the prediction by Initial Protocol is: 60 thousand pesos

The cost for the evaluation of the institutional scientific committees will be: 40 thousand pesos

The cost per prediction of each Amendment or Inclusion of Center is: 3 thousand 500 pesos

NOTE: The cost is the same in all INSalud UHAP's.

5.- What is the response time from the UHAP's?

For any evaluation request, the response time is a maximum of 30 calendar days.

6.- How is the payment for the concept of prediction made in the UHAP's of the INSalud?

The payment will be made in the administrative area of each Institution, the UHAP staff does not have the faculties to directly make the collection for the forecast.

7.- Is it possible to carry out the evaluation process by the Committees, in parallel with the evaluation of the UHAP?

No, because the CCINSHAE does not have its own Committees.

8.- How can I find out what process my procedure is in?

The process of the forecast is 30 calendar days, it is suggested to wait the established time to obtain a response or contact the UHAP directly.

9.- If a protocol obtains a favorable opinion from the UHAP, is there a guarantee that COFEPRIS will authorize it?

No, COFEPRIS reserves the right of authorization in accordance with its guidelines and current Mexican legislation.

10.- How will COFEPRIS differentiate the procedures that have a UHAP forecast, to comply with the authorization time?

The user must notify the entry number of the procedure, directly to Dr. Rosa Legaspi to the email: uhap@cofepris.gob.mx

11. What are the UHAP's that will accept the opinion of Investigation Committees independent of them?

You should check directly with each UHAP.

12.- If the research will be carried out in more than one research center, how many Committees must approve the protocol before submitting it to the UHAP?

An approval is required for each research center by the Research Committee, Research Ethics Committee and Biosafety Committee (when applicable).

13.- What evaluation criteria will be followed for the protocols that belong to an international research program and that meet the ICH requirements, including characteristics of the population to be recruited, sample size, etc.?

Regardless of having international approval, the regulatory file must comply with all the requirements established by current Mexican legislation.

14.- When submitting the response to an Unsuitable prediction, how long will it take for me to obtain a final resolution from the UHAP?

The UHAP must issue the forecast within a maximum of 30 calendar days from the date on which the response is entered, this term may be reduced depending on the number of documents that have been modified.

15.- If an initial protocol was submitted directly to COFEPRIS, can the UHAP evaluate the amendments related to that protocol?

Preferably, only protocol amendments initially evaluated by the UHAP will be evaluated, otherwise the first procedure must enter the UHAP as Initial Protocol.