

INAD Protocol Submission Transcript

Hello, my name is Lea Cranford and I will be presenting the INAD protocol template. Once you have completed your document information, firm information, responsible official and submitter information. You click to the next screen and it will ask you to select the INAD submission type. You are going to select Protocol – No data the E submission. Then it will offer the submission classifications codes. This webinar reviews the target animal division protocols. So we are going to choose Effectiveness for this demonstration. You could also choose Target Animal Safety. Then you are going to select which review division you are submitting to. I am going to choose 110. Then the next question is: “Is this information intended to amend a submission currently pending and under review by CVM?” I am going to choose no we are submitting a brand-new protocol.

The next screen is general information in regards to your protocol. Is this in response to a previous CVM Protocol Non-Concurrence Letter? For our demonstration purposes, I am going to select yes, which lights up the next question: In the protocol non-concurrence letter referenced above, did CVM offer you a shortened review time? I am going to choose yes for demonstration, which also illuminates the next question: and we are asked to please provide a submission number in which you received a shortened review time. We are going to say protocol number thirteen.

However, for this example we are going to assume that this is not in response to a protocol non-concurrence letter and you will notice that these questions are not illuminated. The next question is What type of protocol are you submitting. For example purposes we are going to start with Other; unclassified. Other, unclassified will illuminate the next text box and you can type in what type of protocol it is. For example we will type in Pilot Study. Then you will type in the Study ID number. The next question is: Is the submitted protocol an essential part of the basis for making the approval decision. Because it is a pilot study, the answer may be “no”. Then are you requesting protocol review and concurrence from CVM? Yes.

Let’s go back to choose a Field study protocol type. Again, you are still asked to include the study and trail number ID. And then you are asked, Is this submitted protocol considered an essential part of the basis of making the approval decision. The answer is yes. Are you requesting protocol review and concurrence from CVM? Yes.

Next is the product description screen. Please refer to the product description webinar.

Protocol Background Information. This is where you include the protocol title, the version number of a protocol is applicable. Let’s say this is the second version.

Then you are at to attach the protocol in PDF form. You click the plus button, you choose your submission, and it shows up on here. Then you click the next button. It comes to the comment section. If you have any additional instructions regarding your protocol, please type them here, or you can also attach a cover letter here. The cover letter can include, your additional instructions, or comments, or history regarding the protocol. And that completes the protocol template.

Melissa Glenn: Alright so, as I said at the beginning of the submission, while you may labor over developing a protocol for a very long amount of time, actually putting together that information for review by CVM is relatively straightforward.

We are not due to start our next webinar until 1:45, for Food Use Authorization. So, we have plenty of time if there any questions or if you would like to discuss any of the aspects of either the eye opening an new INAD submission or submitting a protocol. We would be happy to take your questions in the chat pod, or if you like to come off mute, we can discuss your questions verbally as well.