Center for Veterinary Medicine (CVM)

Animal Biotechnology Info Rounds

AR6: Requesting a Meeting

Published May 2022

These slides provide general information about review process and procedures.
For questions or information related to a specific product, please contact CVM.

Overview

This document provides an overview of the three most common meeting types CVM offers developers of intentional genomic alterations (IGAs) in animals and animal cells, tissues, and cell- and tissue-based products (ACTPs). The meetings types covered here are:

- Pre-Investigational Development (PID) Meeting,
- Presubmission Conference (PSC), and
- Pre-Review Feedback Meeting.

For a given discussion topic or phase of development, there may be more than one meeting option that may be appropriate. CVM will assign a project manager (PM) to each product. We ask that you reach out to your PM prior to requesting a meeting to determine the most appropriate meeting type and how to submit the request.

Pre-Investigational Development (PID) Meeting

PID meetings are designed to allow developers to engage in early interactions with CVM and exchange information. These meetings can facilitate product development and help define the pathway to approval. PID meetings occur during the early stages of research and development so that the developer can use this information to direct their research and refine their development plan.

The meeting request is generally submitted under a Veterinary Master File (VMF) either in paper or electronically via eSubmitter. During the meeting, CVM and the developer will not make binding agreements.

After the meeting, CVM may send a Memorandum of Conference (MOC) on a case-by-case basis.

Presubmission Conference (PSC)

The purpose of the PSC is to establish binding agreements between the developer and CVM regarding the developer's development plan (e.g., the number and types of studies or information required for approval).

The developer submits the meeting request electronically via eSubmitter to an Investigational New Animal Drug (INAD) file. We ask that the request include any meeting materials (e.g., slide deck) and specific questions for CVM.

During the meeting, CVM and the developer establish binding agreements on the development plan, which assists the developer to efficiently work toward product approval.

After the meeting, CVM sends an MOC within 45 days.

Pre-Review Feedback Meeting

The purpose of a pre-review feedback meeting is to facilitate an efficient review process by providing an opportunity for informal, high-level feedback on upcoming submissions.

CVM and the developer can discuss questions about submission format, content, and level of detail of the submission to ensure high submission quality.

This meeting type is available to Veterinary Innovation Program (VIP) participants only. For more information on the VIP, please see

- the VIP webpage https://www.fda.gov/animal-veterinary/biotechnology-products-cvm-animals-and-animal-food/vip-veterinary-innovation-program)
- AR4: Veterinary Innovation Program https://www.fda.gov/media/152905/download

Pre-Review Feedback

We ask developers to submit pre-review feedback requests at least 30 days prior to submitting the corresponding submission. To request pre-review feedback, contact the appropriate team leader for the Cell and Tissue Products Team or Animal Biotechnology Team.

We ask that a request for pre-review feedback include:

- an outline and table of contents for a technical section,
- examples of information to be included in the technical section, and
- a description of methods for data analysis.

CVM provides pre-review feedback in-person, by phone, or by email. There is no MOC.

Scenario One

Firm XYZ is developing an equine bone marrow-derived mesenchymal stem cell product. XYZ is very early in development and would like to meet with CVM for the first time to discuss their product.

What meeting type is most relevant to XYZ?

Scenario One

Firm XYZ is developing an equine bone marrow-derived mesenchymal stem cell product. XYZ is very early in development and would like to meet with CVM for the first time to discuss their product.

What meeting type is most relevant to XYZ?

Pre-Investigational Development (PID) meeting

PID meetings provide the developer with information regarding relevant safety, effectiveness, and manufacturing considerations for their intended product. The developer can use the information obtained in this meeting to direct their research (e.g., design relevant proof-of-concept studies) and refine their development plan.

Scenario Two

Firm ABC is developing an IGA in trout. ABC has determined the alteration for which they will seek approval and has established proof of concept. ABC is interested in establishing an agreement with CVM regarding the types of studies required for approval and determining a product development plan.

What meeting type is most relevant to ABC?

Scenario Two

Firm ABC is developing an IGA in trout. ABC has determined the alteration for which they will seek approval and has established proof of concept. ABC is interested in establishing an agreement with CVM regarding the types of studies required for approval and determining a product development plan.

What meeting type is most relevant to ABC?

Presubmission Conference (PSC)

Binding agreements established at the PSC regarding the overall product development plan and the types of studies conducted to support approval allow the developer to proceed along a defined course of action.

Scenario Three

Firm GHI is developing an IGA in an animal that is intended to cause it to produce a human therapeutic product (biopharm animal) and previously had a PSC to discuss their overall development plan. GHI would now like to meet with CVM to establish an agreement on studies to support a specific technical section.

What meeting type is most relevant to GHI?

Scenario Three

Firm GHI is developing an IGA in an animal that is intended to cause it to produce a human therapeutic product (biopharm animal) and previously had a PSC to discuss their overall development plan. GHI would now like to meet with CVM to establish an agreement on studies to support a specific technical section.

What meeting type is most relevant to GHI?

Presubmission Conference (PSC)

A developer can request a PSC to discuss the overall product development plan and all technical sections; however, a PSC can also be used to discuss a specific technical section and establish binding agreements regarding the types of studies required to support that technical section.

Scenario Four

Firm QRS has an open INAD file for a canine stromal vascular fraction product, which is enrolled in the VIP. QRS is putting together a product characterization technical section submission and would like to ask questions related to submission quality and receive high-level feedback regarding any identified information gaps.

What meeting type is most relevant to QRS?

Scenario Four

Firm QRS has an open INAD file for a canine stromal vascular fraction product, which is enrolled in the VIP. QRS is putting together a product characterization technical section submission and would like to ask questions related to submission quality and receive high-level feedback regarding any identified information gaps.

What meeting type is most relevant to QRS?

Pre-Review Feedback

A developer with a VIP product can request high-level feedback regarding an upcoming technical section submission through pre-review feedback. Pre-review feedback allows the developer to address gaps in their submission prior to submitting the technical section. Pre-review feedback is intended to help reduce the number of review cycles needed to complete a submission.

Questions?

For general questions about the review process for IGAs and ACTPs, contact the ONADE Project Management team at CVM_PM_Biotech@fda.hhs.gov

For specific questions about eSubmitter, contact the eSubmitter help desk at cvmesubmitter@fda.hhs.gov

For all other general animal product-related inquiries, contact AskCVM@fda.hhs.gov


FDA
U.S. FOOD & DRUG
ADMINISTRATION