

# The Investigational New Animal Drug Program – Investigator Guide

This guide is intended to help the Investigator complete the required steps to participate in the INAD Program. The following topics are covered below:

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## Setting up an account

If you are brand-new to the INAD Program you will first need to set up an account. Please be aware that the Monitor’s account must be created before an Investigator account can be set up.

Visit our “[How to Enroll in the Investigational New Animal Drug Program](#)” page for step-by-step instructions to set up your account.

**Each facility can only have one Monitor and one Investigator on their account.** Other staff members can act as the Reporting Individual and enter information into the forms if needed, but only the Investigator’s contact information can be saved to the account. AADAP will reach out to this individual with study-related questions.

### New Investigator account – If brand new start here!

Visit our “[How to Enroll in the Investigational New Animal Drug Program](#)” page for step-by-step instructions on the enrollment process.

Go to the [INAD database homepage](#), and select “Facility/Investigator”.

Enter the requested account and facility information.

Select the study Monitor for the facility (this is why the Monitor’s account must be set up first).

You will need to enroll in each INAD you plan to use within a calendar year, see enrollment instructions below.

### New Investigator taking over pre-existing account

If a facility already has an account a new Investigator needs to take over the account, rather than create their own. This ensures that the new Investigator will have access to previously conducted

studies. To take over an account the previous Investigator will need to share the login information with the new individual. If the login information is unknown [contact AADAP](#).

Log in, select the “Account Info” tab on the upper-right of the page.

Update the contact information to reflect the new Investigator and change the username and password, then click the “Save Data” button.

## Yearly Enrollment

You must enroll each year that you would like to participate in the INAD Program. Enrollment lasts for one calendar year and participants are not limited to the number of studies conducted or the number of species they can treat using an INAD. Each non-USFWS facility/office will be required to pay \$700 to participate in the INAD Program for each INAD they plan to use per year.

To add enrollment go to “Account Info”; select the year; Drug/INAD you plan to use; the species you plan to treat; and provide an estimate of the number of fish you plan to treat (this estimate is only for the single calendar year). Be sure to click “Save Data” at the bottom of the page to save this information.

**\*You must enroll in the INAD for each species you plan to use** (this will not increase the fee). If you cannot find the species you wish to treat listed in the drop-down menu, first check the [INAD Fact Sheet page](#) to ensure that treatment for the species is available under the INAD. If treatment is allowed for the species but it is not listed, please [contact AADAP](#) with the species’ scientific and common names.

## Ordering the INAD

Once you are enrolled in the INAD Program you will be able to contact the drug suppliers to order the INAD. Contact information for each supplier can be found on the [INAD Fact Sheet page](#). Please note that some INADs do require that the study request be filled out prior to receiving the INAD. It is important to know that the INAD fee you pay does not pay for the INAD drug. Also, submitting a study request does not automatically order the drug.

The drug suppliers listed on the INAD factsheet pages are working on the specific formulations of drugs which are in the approval process. Therefore, only their product can be used under an INAD treatment.

## Submitting a Drug receipt

Each time you order an INAD drug you will need to submit a drug receipt. All drug receipts need to be submitted within 10 days of receiving the drug.

To submit a drug receipt, follow these steps:

- The drug receipt can be submitted from the Investigator’s account. From the Investigator’s Homepage select the “Manage/View Drug Inventory” located on the top banner.
- Click the “Receipt of Drug” in the brown box on the upper left of the “Manage/View Drug Inventory” page.
- Enter all information and click “Add To Drug Inventory” to save.
- Remember, you will need to repeat this process each time you receive the drug from the supplier.

You **can** transfer extra INAD drug to other facilities participating in the INAD Program.

- To transfer the drug, click “Manage/View Drug Inventory” from the Investigator’s Homepage;
- Select the inventory to transfer;
- Click the transfer button;
- Fill out the information; and click save.
- The receiving facility will then need to enter the received drug into their inventory.

## Submitting a Study Request

A Study Request will need to be submitted each time you plan to treat your fish. Before you submit a Study Request please review the [study protocol and factsheet](#) to ensure that the protocol laid out by the FDA is followed. You cannot start a treatment until a study number has been assigned, this allows AADAP the opportunity to ensure that the study protocol will be followed.

To initiate a Study Request, click “NEW STUDY REQUEST” from the top banner on the Investigator Homepage. **If the website loads for a prolonged period of time** (shows a spinning fish for longer than 1 min) you most likely are not enrolled in that INAD. Add the INAD enrollment and you should be able to continue without problems.

Select the Drug you plan to use at the top of the form.

Select the Fish Species Treated from the drop-down menu. If the species you plan to treat is not listed in the drop-down menu on the Study Request form, this means that you have not enrolled in the INAD to treat that species. For information on how to add fish species to your account see the “Yearly Enrollment” section.

Fill out all fields in the form.

Be sure that you select the **STUDY PROTOCOL OBJECTIVE** you plan to use.

In the STUDY DESIGN section, please provide a brief description of your planned study. The description should include the reason you feel fish should be treated, the treatment dates, the number of fish that will be treated, and if the fish are a threatened or endangered species.

*\*\*If you are aware of a deviation from the Study Protocol that you feel is unavoidable please let AADAP know prior to conducting the treatment.*

Once you have completed the form click “Submit for Approval” which will send the Study Request to your Monitor for review. AADAP will not have a chance to see the request until the Monitor reviews and advances it.

## Study Numbers

A study number is assigned to each Study Request by AADAP. The study number allows AADAP to track and reference each study.

**A new study number is needed (e.g., a new Study Request will need to be submitted) anytime a new therapeutic treatment is initiated.**

- If the start date of treatments will be staggered over multiple days, then each treatment will need its own study number.

**For anesthetic, marking, or spawning INADs there are different guidelines.** Generally, a new study number will be needed;

- if there are more than 30 days between treatments,
- different doses will be used,
- different levels of sedation will be used (handleable, surgery, or euthanasia)
- or the treatment crosses into the new year by more than two weeks

If these guidelines are not followed, AADAP will ask that you break your studies into multiple study numbers. Even if the treatment has already occurred AADAP may request additional study requests to be submitted, enabling the data to be better evaluated.

## Study Stages

The INAD process is broken into study stages. There are seven stages of the study process as described below. In **bold** you will see who is responsible for advancing the study in each stage.

Stage 1: Before treatment can begin, the **Investigator** must fill out and submit a Study Request to the Monitor.

Stage 2: The **Monitor** will review and advance the Study Request to AADAP.

Stage 3: **AADAP** will review the Study Request, assign a study number, and advance it to the next stage.

Stage 4: Treatment can now begin. Once the treatment is completed and all data has been collected, the **Investigator** then enters the data into the Results Report and submits it to the Monitor.

Stage 5: The **Monitor** will review the Results Report and advance the study to AADAP.

Stage 6: **AADAP** will review the study for the last time and determine if it can be approved.

Stage 7: The study will be archived in the database and accessible to study participants.

If information is missing, the protocol is not followed, or forms are not correctly filled out, both the Monitor and AADAP can send a study back to a previous stage.

## Submitting a Results Report

Once you have completed the treatment, a Results Report should be submitted **within 30 days**. If the INAD used required post-treatment evaluation or laboratory results, then the Results Report should be submitted within 30 days of receiving the results or beginning on the last day of the evaluation. Both the Monitor and AADAP will review your Results Report, if questions arise during the review both parties can reach out to you with questions. If multiple errors are found or information is missing both the Monitor and AADAP can send the study back for changes.

All incomplete studies can be found on the Investigator's Homepage. To submit the Results Report, click on the study and enter the required information. Please keep the following in mind while completing the Results Report:

- Please note that **data entered on the Study Request is automatically pre-populated** into the Results Report. It is **very important that you double check that this information** (i.e., number of fish treated,

treatment dates, number of treatment dates, treatment dose) **is correct**. If any changes occur, then the form will need to be updated to reflect what happened during treatment.

- Please be aware the changes made to the form are not saved unless all the required fields are completed. Therefore, we suggest having all study data available when completing the form.
- Some of the information (number of fish treated, dose, treatment dates) may be reported multiple times on the report, it is important that information matches. Inconsistently reported information will result in the Results Report being sent back for revisions.
- The number of treatment dates refers to the dates which the drug was administered, not the number of dates from the initial to final treatment.
- Any change from the FDA study protocol ([protocol and fact sheet can be found here](#)) will count as a deviation and will need to be documented in the Study Deviation section of the form. AADAP must report on all deviations from the study protocol to the FDA. If a deviation occurs AADAP may reach out to you for additional information.
- Disease related INADs will require mortality information to be reported. Mortality data will be required for five days of pre-treatment, treatment period, and ten days of post-treatment. Not reporting the pre and post treatment mortality data will be considered a deviation. If there was a reason this information was not collected it will need to be specified in the Study Deviation section of the Results Report.
- Mortality needs to be reported every day during the treatment period in the Mortality Record. If no mortalities occurred then enter 0, however each date needs to be evaluated and reported.
- Disease-related INADs also need to report the percent of fish saved due to the INAD treatment. Since controls are not used in the majority of INAD studies, one cannot truly calculate the percentage of fish which were saved due to the INAD treatment. However, we do ask that Investigators provide an estimate of the percentage of fish they believe were saved due to INAD use. This estimate can be based on past facility history or mortality rates prior to treatment.
- You will be asked to report the number of days before availability of treated fish for human consumption, this question enables us to determine whether the withdrawal period was fulfilled. Therefore, we ask that you enter a brief description (ex: number of days maintained on station, fish were lethally spawned, fish were never released, 30+ days). **NA is not an acceptable answer** to this question.

## Closing a cancelled study

If a study is cancelled or treatment does not occur the Investigator will need to close the study.

On the top of the Results Report there is a banner asking, “IF TREATMENT WAS INITIATED”. To cancel a study, select NO from that banner. You will then be asked to provide a reason. Your explanation can be brief. Be sure to click Save at the bottom of the page to complete this step.

Please keep in mind that studies must be advanced to Stage 4 in order to be cancelled.