

Ai.Study™ User Documentation

End User Guide

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1 Getting started

Welcome to your Ai.Study™ User Guide. This document has been written to support researchers, animal technicians, Ethics / IACUC members, veterinary staff and facility managers understand how to use the Ai.Study system to support best practice experimental design, planning, and execution.

To access your Ai.Study system, please ask your System Administrator for the web address (also called a URL) for your site. It will be:

`https://[your organisation prefix].mysensalab.com`

where [your organisation prefix] will have been agreed with your System Administrator and / or person buying the Ai.Study system for you.

1.1 Using this document

We recommend that you browse this document to familiarise yourself with the main topics of interest to you and the features of the Ai.Study system.

1.1.1 Symbols used in this document

Symbols

Attention Symbols for Notes, Caution and Reference have been marked for users . This guide uses the following symbols and conventions:



Important

The **Important** symbol indicates prerequisite checks and important information



Note

The **Note** symbol indicates supplementary explanations and useful tips



Caution

The **Caution** symbol indicates critical notices and restrictions

1.2 Accessing help – online

In addition to this document, Ai.Study provides a link to online help too. This will be displayed as soon you visit your web address.

On your screen, bottom right, you will see the following button.

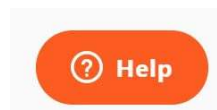


Figure 1: Help – accessing online help

If you click on this button, it provides a way for you to search content in this document, which is also online. The search will also search other documents produced by Somark, such as Frequently Asked Questions, Troubleshooting and many other resources we develop and maintain to help customers use Somark systems more effectively.

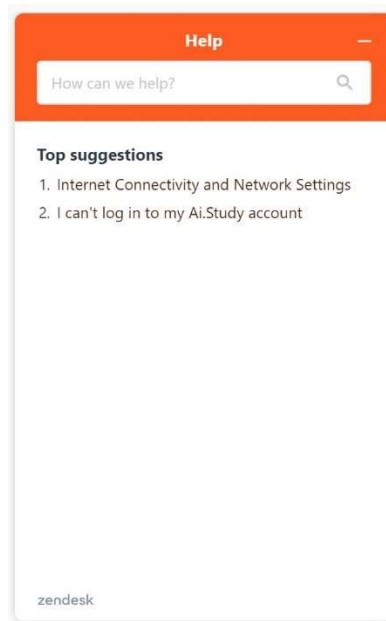


Figure 2: Help – searching online help

When you click on the Help button, the screen above will display. It will list the most commonly searched topics by our customers, as direct links to those topics. You can also input key words to search on in the field which says How can we help? with the magnifying glass icon.

Simply type the words to search on and press enter. If a match is found, it will display as shown below.

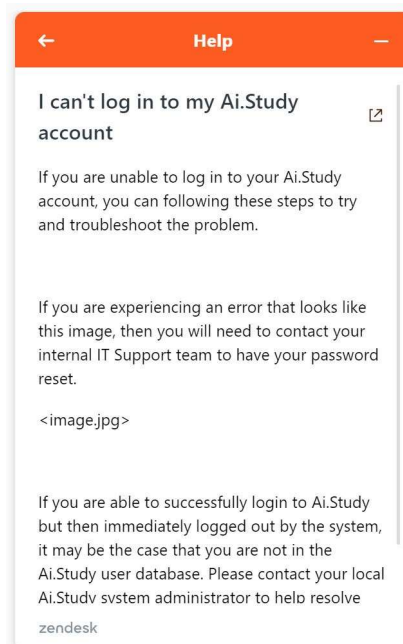
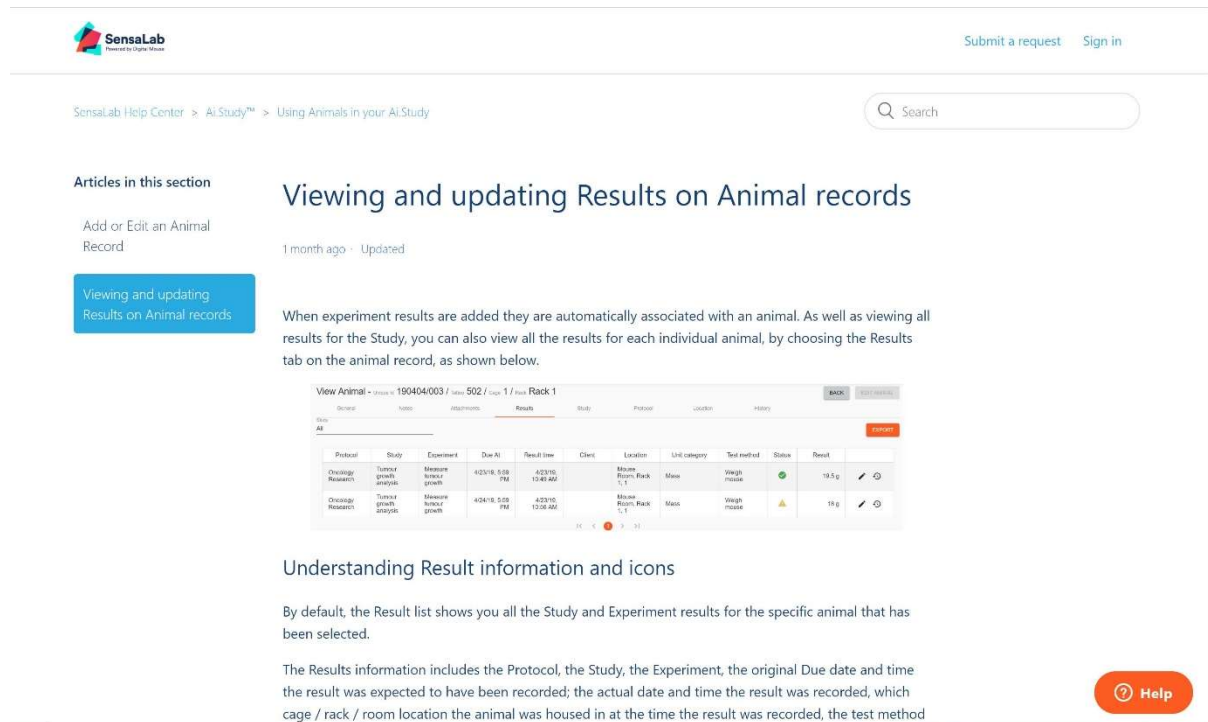


Figure 3: Help – search result – example

To return to the main search screen, press the arrow button .

To minimise the Help screen, press the button .

If you want to view the full article, click on the  button and this will open the full article in a new window on our Support Portal, as shown below.



The screenshot shows the SensaLab Support Portal interface. At the top, there's a header with the SensaLab logo, navigation links like 'Submit a request' and 'Sign in', and a search bar. Below the header, the breadcrumb trail reads 'SensaLab Help Center > Ai.Study™ > Using Animals in your Ai.Study'. The main content area is titled 'Viewing and updating Results on Animal records' and includes a sub-header 'Articles in this section' with a button 'Viewing and updating Results on Animal records'. The article text explains that experiment results are automatically associated with an animal and can be viewed by choosing the 'Results' tab. A screenshot of the 'View Animal' interface is shown, displaying a table of results for a specific animal (190404/003 / Rack 1 / Rack 1). The table has columns for Protocol, Study, Experiment, Due At, Result time, Client, Location, Unit category, Test method, Status, and Result. Two rows of data are visible, both for 'Challenge Research' and 'Tumour growth analysis' experiments, showing 'Measure tumour growth' results. The first row has a 'Pass' status and a result of '19.5 g', while the second row has a 'Fail' status and a result of '19 g'. Below the table, there's a section titled 'Understanding Result information and icons' which explains that the Result list shows all Study and Experiment results for the selected animal. It also notes that the Results information includes the Protocol, the Study, the Experiment, the original Due date and time the result was expected to have been recorded, the actual date and time the result was recorded, which cage / rack / room location the animal was housed in at the time the result was recorded, the test method, and a 'Help' button.

Figure 4: Help – full article on the Support Portal – example

1.3 What you need to start

1.3.1 What browser do you need?

You will need to use the latest Google Chrome Web browser to get the best experience when using Ai.Study. Please also make sure that you have the latest Google Chrome Browser installed when you come to login and use Ai.Study.

You will also need internet access to use Ai.Study, via your WIFI, Ethernet connection, or via a 4G cellular connection.

1.3.2 What device can I use to access Ai.Study?

Ai.Study is optimised for the best user experience with a standard computer or laptop and browser. You can access Ai.Study with the Google Chrome Browser on other devices, such as tablets and even smartphones, but the screens have not been adapted to resize for the smaller screens on these devices.

1.3.3 What login do you need?

Your organisation will have appointed a System Administrator who will help create and maintain your logins and your system reference data.

To login, your System Administrator will have input your usual email address and will be able to confirm this to you. Your password will be your usual password for that email address.

Your System Administrator will have assigned one or more “roles” to your profile. The role you have been assigned controls what menu options, records and data you can view and update. If you have any questions about your access rights, please speak to your System Administrator who is able to change your role profile.

1.4 How to log in

Input the web address for your site and add /login to the end, as shown below.

`https://[your organisation prefix].mysensalab.com/login`

This will display the following page.

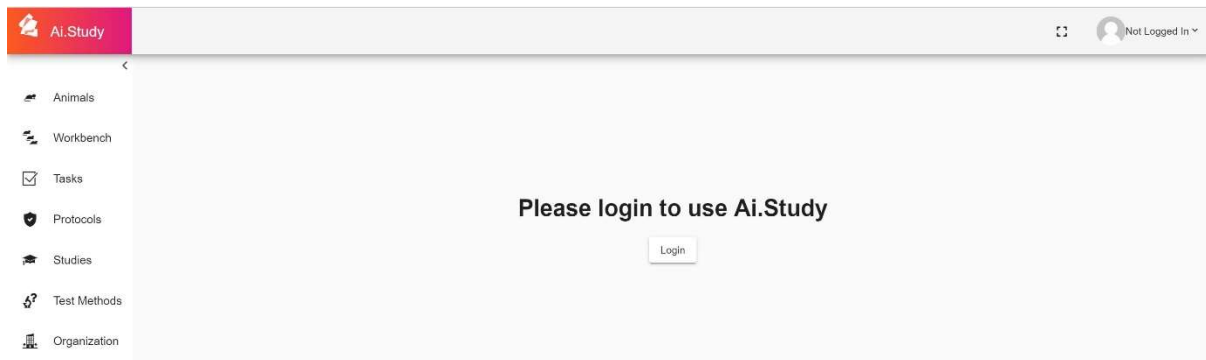


Figure 5: Login – not logged in page

Click on the Login button and the following page will display.

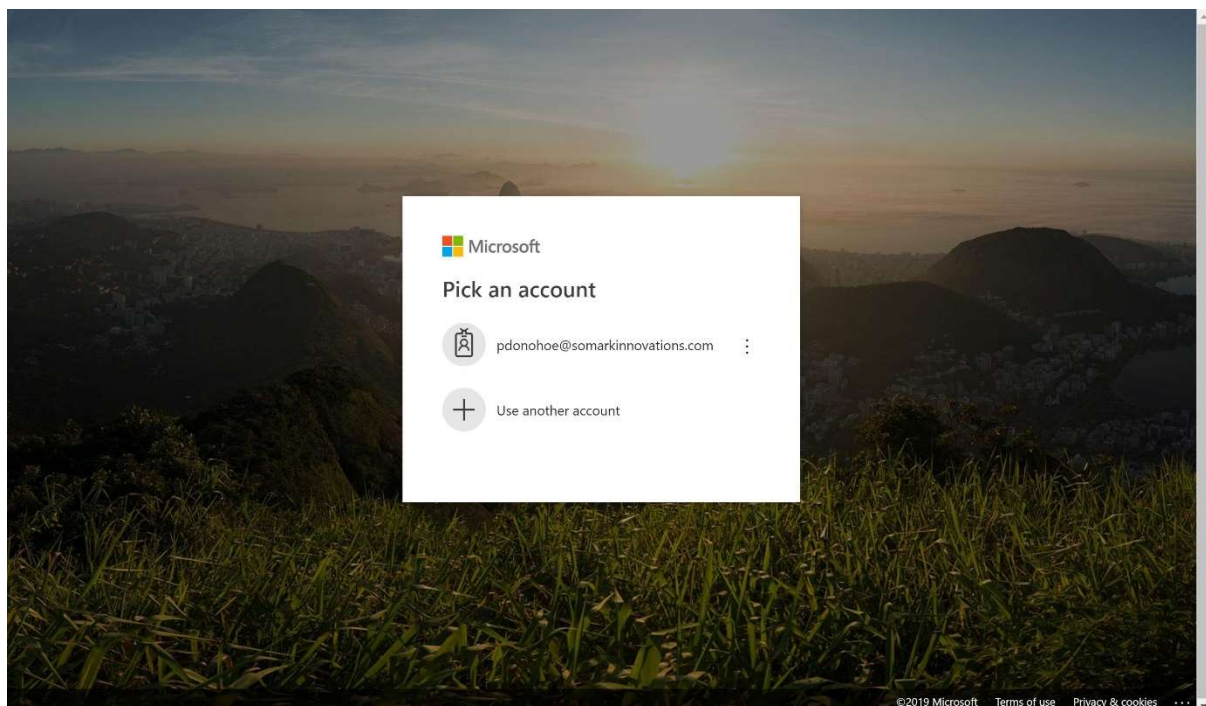


Figure 6: Login – choose account or use another account

If your usual login email address is not displayed, or the one your System Administrator used for your to log into Ai.Study, please select the “User another account” option and this will prompt you to enter the email address your System Administrator advised.

After you have selected an account from the screen above, or input your email address, you will be prompted to input your usual password.

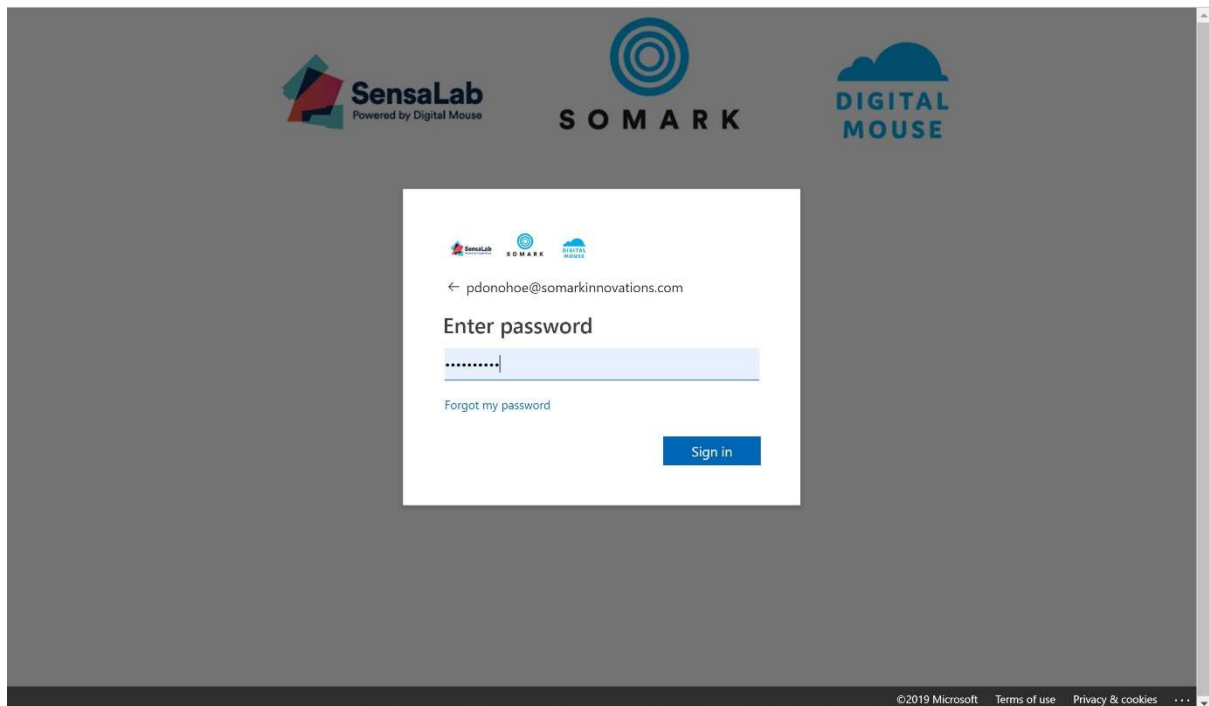


Figure 7: Login – enter password

Press the Sign in button to submit your password. This will be validated. If you have entered the Password incorrectly, the system will advise you and offer the option to re-enter it.

1.4.1 Forgotten password

If you have forgotten your password, you can usually reset it online using the “Forgot my password” link on the screen above. You will be asked for additional security questions which you set up at the time of creating your email account.

Note

Somark does not have access to your password. We cannot reset it for you. Please speak to your internal IT personnel if you are not able to reset your password and if your account has been suspended.

1.4.2 Successfully logging in

After entering the correct password, a “You are successfully logged in” message will briefly display.

Note

When you first login in, our system will retrieve your security profile and save this in our system. This may take a few seconds to complete. You may see a message displayed saying “Logging in . . .” This is quite normal and should close after a few seconds.

You may also see a message saying “Loading your profile . . .”. This is quite normal and is our system saving your profile. It too, should only display for a few seconds at most. If the screen gets stuck on this message, use the browser page refresh option  (which will be top left next to the Home icon).

The next screen displayed will be the Tasks list page as shown below.

[illegible]

Figure 8: Login – success – Task landing page

 Note

Your user login (email address) should display on the top right of the screen, if you have successfully logged in.

2 Ai.Study Overview

Ai.Study enables pre-clinical experiments to be designed, planned, scheduled and executed. It can also be used to support Breeding experiments or plans (although it is not a full colony management system).

Ai.Study can be used on its own, but the maximum benefit will be realised when used as part of the full Ai.Suite solution, which includes digital animal identification and automated data collection with Ai.Connect. Ai.Study ensures experimental data is collected and stored against the correct animal record.

Ai.Study was designed to help researchers move beyond paperlab notebooks and using Excel spreadsheets. It is also much more than an Electronic Lab Notebook. Not only does it enable you to store ALL your research data, results and files in one place, securely, it also enables you to design your research, to validate the quality of your data, to maintain a full, online history and audit trail of changes to your data and even to share access to it, if you so wish.

Ai.Study will also prompt you, if / when humane or ethical endpoints are close to, or have been reached. You can record and store any observation against both your animal records and as part of your study – whether captured by animal technicians, veterinary staff or your research team.

2.1 Additional key benefits

Ai.Study also delivers the following key benefits:

- You have complete control over configuring your Ai.Study to suit your needs. You can define the experimental methods you use, the types and models of rodent you work with and can maintain them yourself.
- You can access your research and data, any time anywhere – you just need a browser and internet access.
- You do not need to worry about how much data you store – there is no limit to the numbers of records you create or files you attach. Ai.Study will automatically scale to meet your needs.
- You have complete control over how can view and update your research. You control access rights to your research. You can grant view only access to people outside of your immediate team, for example, grant reviewers or colleagues with whom you collaborate (where ever in the world they are).
- Somark continually invest in improving the ease of use and the functionality of Ai.Study. It will grow with you and if you have suggestions about what you need it to do and how it can be improved, please let us know via your Account manager or via our Support Portal at <https://support.somarkinnovations.com> using the “Submit a request” feature.
- You do not need any IT experience or people to help you get set up and use Ai.Study. Our team constantly monitor and manage your Ai.Study to keep it running, performing and backed up.

2.2 Ai.Study Interface – what it looks like and how to use it

Features and information are arranged in cards and tables which you can navigate through using a navigation menu and tabs.

2.2.1 Menu options

You have two display options for your left hand menu.

The full description is like this:

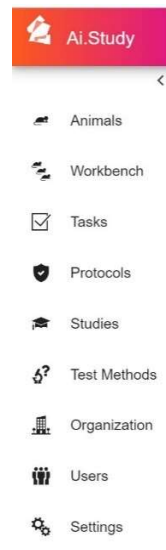


Figure 9: Menu options – full display

The icon only display looks like this:



Figure 10: Menu options – icon only display

You can toggle between the two options by selecting the < or > arrows at the top of the menu list. The icon only option provides a larger screen to display the main pages.

Note

The actual list of menu options you will see displayed does depend on your user profile. Only System Administrators will see the Test Methods, Organisation, Users and Settings menu options.

2.2.2 Record filter

Choose ▾ In screens with lists of records, where this device is present, you can choose to filter records with your selected preferences. The following screen will pop-up.

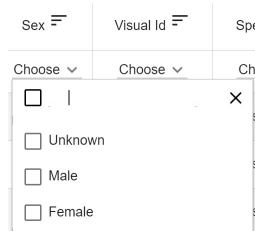


Figure 11: Record filter – selecting the record values to filter on

Select one or more values required to filter the list results so only matching records are displayed. You can also type values into the search field on the top line as an alternative way to filter values. This is useful when you have a long list of field values, such as strains, and want to narrow down the filtered values.

Where the field value selected is a date, the following pop-up will display to enable you to filter records by a date range.

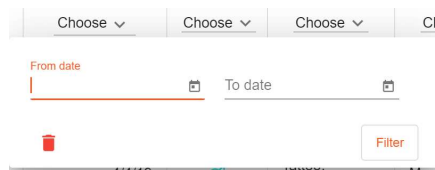


Figure 12: Record filter – selecting the record date values to filter on

2.2.3 Scrolling through lists and pages

When a list of values is presented, for example on the Animal list option, the Tasks list option or the Result list option, if there are more than 25 animal records, or 20 tasks or ?? results, the following option will be displayed to enable you to browse other pages of values.



Figure 13: Record browsing – selecting other pages to view

The buttons are explained below:

<< Return to the first page

< Go back one page

> Go forward one page

>> Skip to the last page

1 2 3 4 5 Click on the page number to skip to directly; the current page viewed is in orange



2.2.4 Icons – and what they mean

Species* 

The * next to a field label indicates that the field value is mandatory and a valid value must be entered before the record can be successfully saved.

The downward pointing arrow shown, indicates the field has a list of values from which one must be selected to complete the field.

 View or Edit a record

 Delete a record

 Reset (remove current) filters

 Used in the Workbench – move the cage from the Workbench back to its Rack

 Used in the Workbench – Add an animal to the cage

 Used in the Workbench – Mark the selected animal as culled

2.3 Features and records

2.3.1 Menu options and records

AI.STUDY™ FEATURES	DESCRIPTION	DETAILS	CONFIGURABILITY
 ANIMAL LIST	Displays a filterable list of the Animals in Ai.Study	- Complete listing of Animal Records restricted by user's system roles and study access. - Filters and Sort Ordering on list using animal attributes and location. - Search field to filter and find animal records. - Add Animal Records. - Import Animal Records. - View an Animal Record.	- Use Filters to filter data and change Sort Order - Use Search to filter the list
 ANIMAL RECORD	This feature enables individual records for each animal in the system to be defined. The records enable you to capture all attributes of the animal, notes, attachments and displays its location, recorded observations and its planned usage in a study or protocol.	- Access to view and edit the record is restricted by the user's system roles and study access. - Capture and view all animal attributes. - Capture multiple identification methods for an animal which includes a Visual and RFIDs. - Capture notes and add attachments to each individual animal record - View results from observations captured for a study or for other purpose - View the animal's purpose in a study and its associated protocol - Locate the Animal in the facility	- Strain, Genotype and Phenotype are managed configurable lists - Identification methods are configurable to use only organization approved methods
 WORKBENCH	This feature enables you to create and manage cages: allocate animals to cages, allocate cages to racks and allocate cages of animals to existing protocols. You can also select animals in a cage that should be recorded as culled.	- Create new cage - Allocate cage to rack - Allocate animals to or remove animals from a cage - Mark animals in a cage as culled - Allocate a cage of animals to a protocol	
 PROTOCOLS	This feature enables you to view a list of protocols and then to create and manage protocols or ethics licences to which approved studies can be attached. Protocols enables you to specify the number of animals permitted for study and allows you to track animal use and adverse mortality events.	- Create and approve a new protocol - Attach the detailed protocol application - Allocate the number of animals approved to the protocol - Track the use of animals on your protocol	

AI.STUDY™ FEATURES		DESCRIPTION	DETAILS	CONFIGURABILITY
	STUDIES	This feature enables you to view a list of studies and then to create and manage studies (or experiments).	- Create and approve a new study - Control who can view study data and who can input study results - Upload your experiment design (NC3Rs EDA file) - Define the phases, experiments and test methods within the study - Define ethical endpoints for selected test methods - Enrol animals to specific experiment groups within phases - Track the use of animals on your study - Upload study documents, such as SOPs, results files, study images etc. - Review the results of your experiments - Export your study results for analysis	
	STUDY TASKS	This feature enables you to view tasks to which you have access rights, to input study results directly to study tasks and to create and complete ad hoc tasks, including animal observation results and test results within a study.	- View and filter tasks by: - Time (past, overdue; due today, this week, in the next 2 weeks, in the next 4 weeks and completed) - Study, Phase, Experiment - Add an adhoc animal observation outcome - Add an adhoc experimental result - Add a result value to a scheduled study task	
	TEST METHODS	This feature enables your System Administrator to define the experimental procedures, observations, measurements, treatments and interventions permitted and used in your research.	- Add Animal Test Methods for specific animal species and body parts - Add Other Test Methods with freeform descriptions and references to external material documentation	
	ORGANISATION	This feature enables your System Administrator to define the location of racks within your organisation, so that the location of your animals can be tracked within their cages.	- Add your top level organisation name and address - Add any subsidiary organisational units and their addresses - Add animal and research facilities to your organisational units - Add buildings to your facilities - Add rooms to your buildings - Add levels or zones to your rooms, if you segment animals or research activities within a room	

AI.STUDY™ FEATURES		DESCRIPTION	DETAILS	CONFIGURABILITY
			Add racks to rooms, including reference data on the rack, such as manufacturer, types, make/model and capacity	
	USERS (USER MANAGEMENT)	This feature enables your System Administrator to manage access rights to Ai.Study – who can login and what rights they have to features and records in Ai.Study.	- Create new users, providing their login credentials - Disable and remove users to restrict access rights - Assign role profiles to users to control access to functions and records / data (animals / studies)	- Assign one of 3 profile options: - Administrator - Animal Technician - Ethics Committee
	SETTINGS	This feature enables your System Administrator to define key reference data to be used in your organisation. It also enables the organisation to enforce a particular study design standard by requiring evidence of best practice study design thinking by requiring an NC3Rs Experimental Design Assistant file to be uploaded to a study before it can be approved and activated.	- Define whether an NC3Rs EDA file is required as a prerequisite for study approval and activation - Define the permitted animal identification methods and details - Define the permitted animal strains, genotypes and phenotypes for use in studies	

2.3.2 Relationship between Features

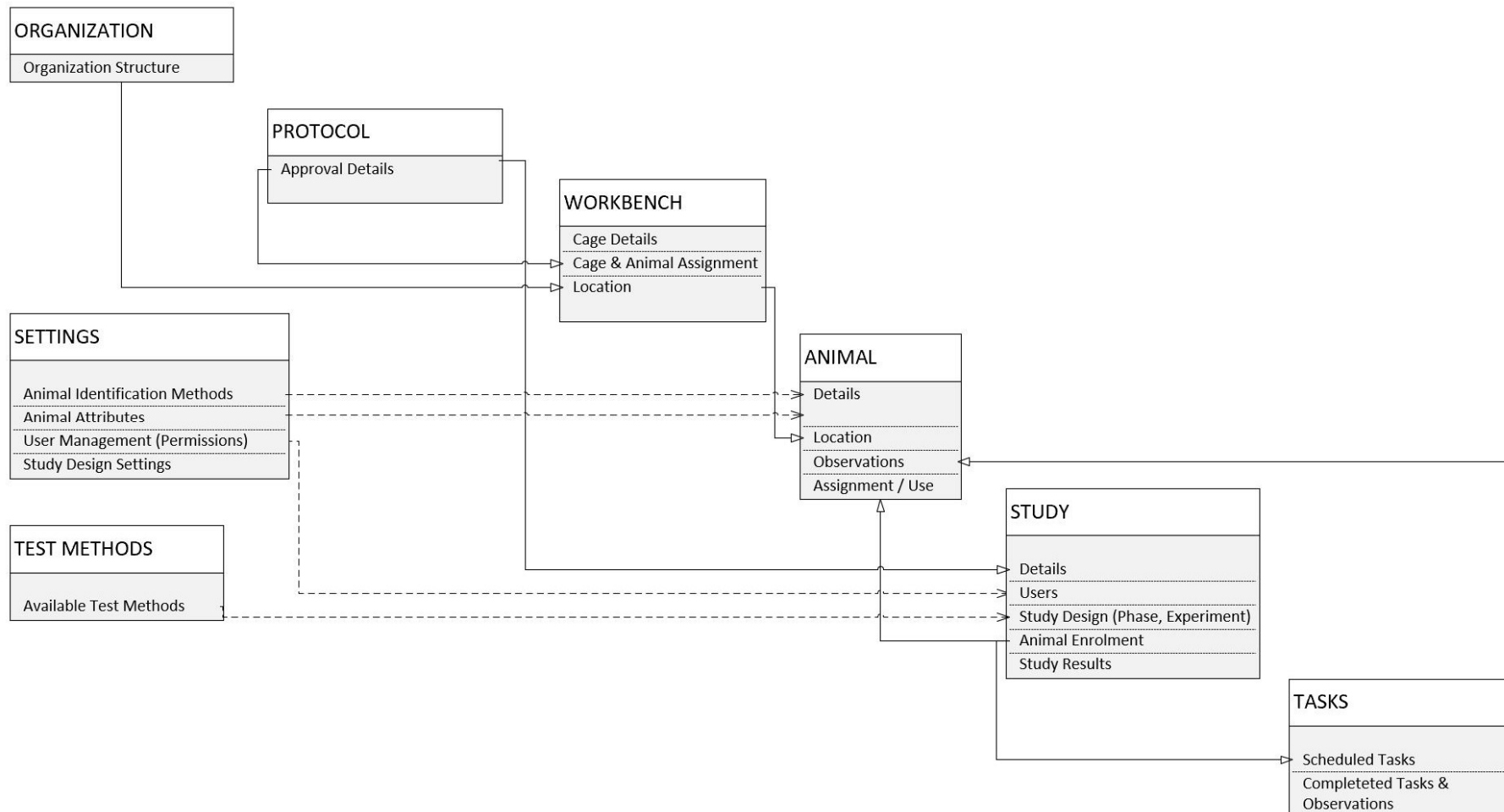


Figure 14: How Ai.Study features relate to each other

2.4 How to create and run experimental studies

2.4.1 Overview - Using Ai.Study to create and run experimental studies

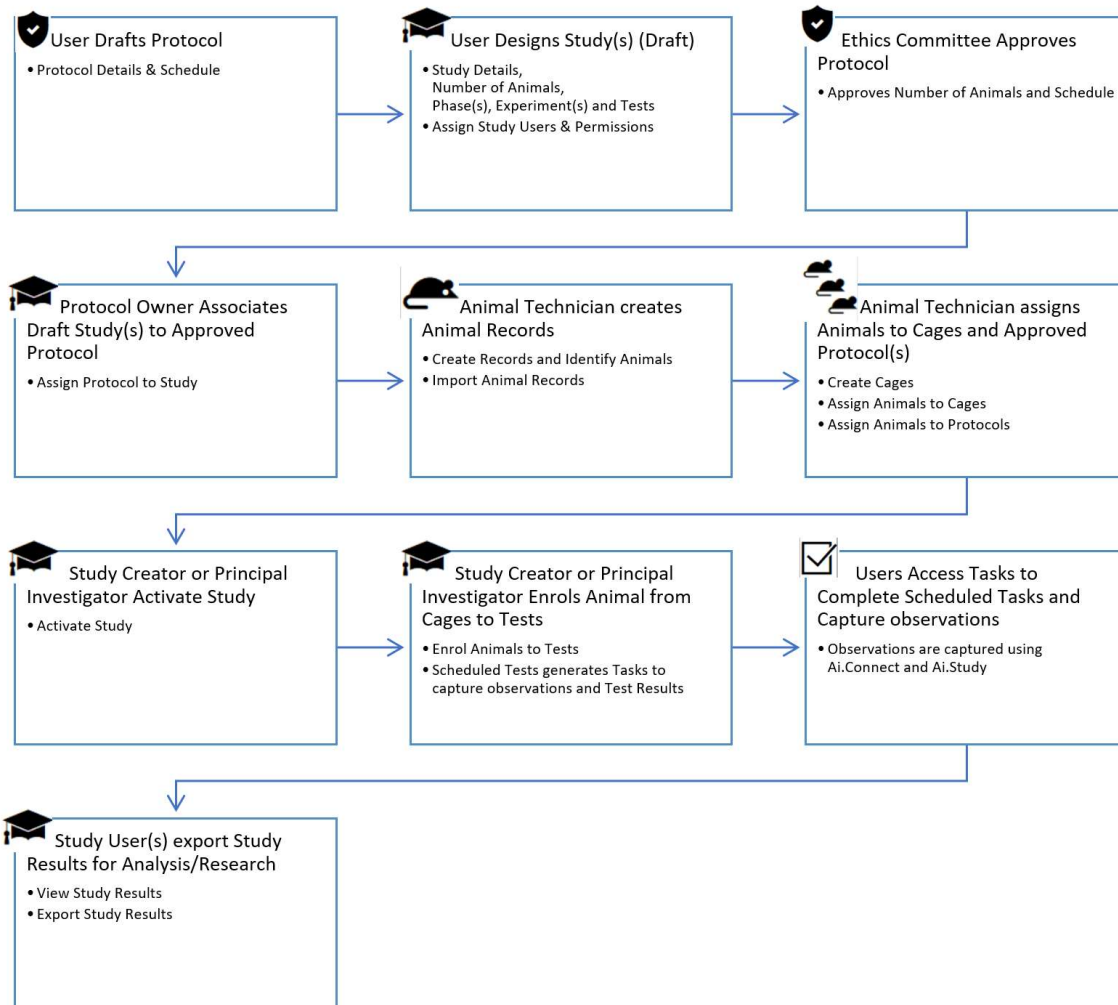


Figure 15: Studies – overview of how to create and run a study

Note

- If your organisation has decided to enable the NC3Rs EDA requirement, this means you must have uploaded a EDA or SVG file from the NC3Rs EDA service (see <https://eda.nc3rs.org.uk/>) before your study can be activated. The NC3Rs EDA provides a free service to help researcher design their experimental studies.

2.4.2 Introduction to Studies

Ai.Study is designed to enable researchers to design their experiments, plan the experiments setting times and frequencies of procedures, schedule the related work and then execute the study by capturing the experimental results – all in one, online, secure database system.

Studies can be drafted as part of the protocol review and approval process, giving Ethics Committee / IACUC members the opportunity to review the study design in advance of approving the Protocol.

As the preclinical research sector moves towards improved standards for reproducibility and rigour in experimental design, Ai.Study enables your organisation to quickly, painlessly and cost effectively adopt and implement emerging best practices being expounded by leading funding groups, such as the NIH, EMA and NHMRC; industry publisher, such as Nature, Cell and PLOS; as well as leading industry researchers and commentators.

Once created, approved and activated, experimental results are captured and associated to specific animals, and the reference information about that animal is available to the researcher when analysing results.

Supporting the expectations of leading funding and publishing groups, as well as the ARRIVE Guidelines, studies provide a complete audit trail of methods and results, which can be shared both on and offline.

Results data can be shared online by providing online, read only access to your specific study or offline via exported CSV files.

Studies enables researchers to control who can view the study information and who can update the results data in the system. This enables you to outsource experiments and data collection to external groups, such as CROs, and yet remain in control of the conduct of the study with full, real time oversight of the data collection process, methods and quality.

Studies can be drafted and made available for review online to peers and Ethics / IACUC members. Studies must be associated with an approved Protocol and cannot be activated and ready to use until the associated Protocol is approved.

For more on Protocols see section 4.

2.4.2.1 How Ai.Study supports best practices

For more information on how Ai.Study supports preclinical research best practices, please visit our Support Portal and follow the links below.

2.4.2.1.1 ARRIVE Guidelines

[How Ai.Study supports the ARRIVE Guidelines](#)

2.4.2.1.2 ALCOA+

[How Ai.Study supports ALCOA+ data integrity standards](#)

2.4.2.2 The structure of a Study

A study comprises the following structures:

1. Purpose
 - a. The protocol under which the study is to be approved
 - b. Objectives
 - c. Hypothesis
 - d. Rationale

- e. Start and end date
2. Phases
 - a. First define your experimental “phasing”
3. Experiments
 - a. For each phase, define your experiments or experimental groups.
 - b. Experiments capture the list of procedures, interventions, observations, treatments or measurements you will perform with your animals.
4. Test methods
 - a. Test methods are the list of procedures, interventions, observations, treatments or measurements that you will perform with your animals.
 - b. When you select the test methods for your experiment, you can specify the timing and scheduling of the tests: what day, what time, how frequent.
 - c. When you select certain test methods, you can also define “endpoints”. Endpoints are results from observations or measurements that exceed the minimum or maximum permitted value, as agreed with the Ethics committee, and that should result in the animal being culled or removed from study for restorative treatment.

In addition to the structure of the study, discussed earlier, you will also need to consider the following aspects for your study, which the system requires:

1. Staff and access rights
 - a. Who should be able to view your study information?
 - b. Who should be able to conduct the experiments and input study results?
2. How many animals are required to power the study?
 - a. How many animals are required in each experimental group?

The following section of this Guide explains how to create studies and offers some hints and tips on how to apply common best practices.

3 Studies

3.1 Adding a study

To add a new study or view an existing study, click on the menu icon . This will take you to the Studies screen below.

Studies						Q	ADD STUDY
Study title	Protocol Id	Principal investigator	Start date	End date	Status		
Choose	Choose	Choose	Choose	Choose	Choose		
VEGF1 Signalling					Draft		

Figure 16: Studies – List view and Add Study button

To view an existing study, click on the Edit icon.

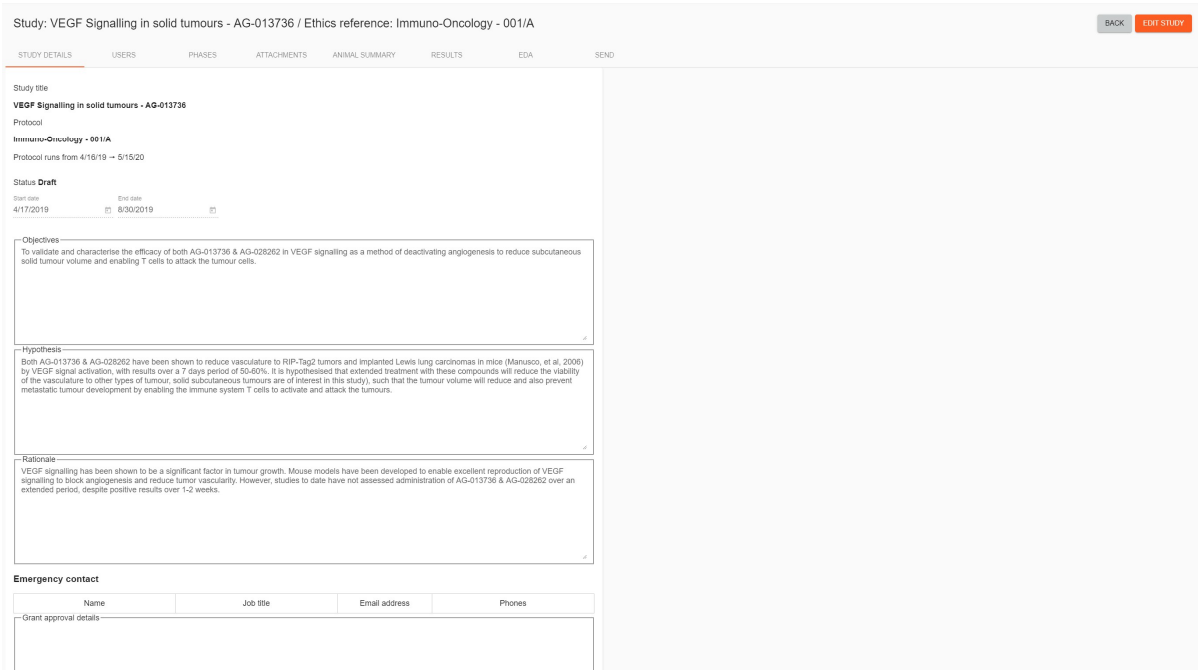
To add a new study, click on the Add Study button.

3.1.1 Completing the General section

The General Section provides an opportunity for the researcher to describe the Objectives, Hypothesis and Rationale for their study, in keeping with the emerging best practice being expounded by the NIH in the USA, EMA in Europe, NHMRC in Australia, and so on. As the preclinical research sector moves towards standards of compliance for animal based research, such as the

ARRIVE Guidelines, this section will have increasing importance as part of the review and approval process for new studies.

Importantly, this section enables the researcher to set out and document the justification for the study which is often a prerequisite for protocol / ethics / licence approval.



Study: VEGF Signalling in solid tumours - AG-013736 / Ethics reference: Immuno-Oncology - 001/A

STUDY DETAILS USERS PHASES ATTACHMENTS ANIMAL SUMMARY RESULTS EDA SEND

Study title
VEGF Signalling in solid tumours - AG-013736

Protocol
Immuno-Oncology - 001/A

Protocol runs from 4/16/19 - 5/15/20

Status **Draft**

Start date 4/17/2019 End date 8/30/2019

Objectives
To validate and characterise the efficacy of both AG-013736 & AG-028262 in VEGF signalling as a method of deactivating angiogenesis to reduce subcutaneous solid tumour volume and enabling T cells to attack the tumour cells.

Hypothesis
Both AG-013736 & AG-028262 have been shown to reduce vasculature to RIP-Tag2 tumors and implanted Lewis lung carcinomas in mice (Manusco, et al, 2006) by VEGF signal activation, with results over a 7 days period of 50-80%. It is hypothesised that extended treatment with these compounds will reduce the viability of the vasculature to other types of tumour, solid subcutaneous tumours are of interest in this study, such that the tumour volume will reduce and also prevent metastatic tumour development by enabling the immune system T cells to activate and attack the tumours.

Rationale
VEGF signalling has been shown to be a significant factor in tumour growth. Mouse models have been developed to enable excellent reproduction of VEGF signalling to block angiogenesis and reduce tumour vascularity. However, studies to date have not assessed administration of AG-013736 & AG-028262 over an extended period, despite positive results over 1-2 weeks.

Emergency contact

Name	Job title	Email address	Phones
Grant approval details			

Figure 17: Studies – General section – fields to complete

In defining the study's Objectives, Hypothesis and Rationale in advance of the study starting, the expectation is that post-study rationalisation of outcomes is avoided.

3.1.1.1 Objectives

This section is intended to offer an opportunity to describe the expected results of the study: what problem or opportunity is the study expected to address.

3.1.1.2 Hypothesis

This section should set out a testable hypothesis, and how it will be tested.

3.1.1.3 Rationale

This section should be used to explain why the research is necessary and appropriate, in particular, why the use of animal models is justified and what non-animal alternatives have been considered. It should address key questions, such as:

- Whether this is original research or is seeking to test or validate previously run studies
- How the use of the particular animal models and species is justified and what alternatives were considered (such as alternative lower level species or in-silico options)

3.1.1.4 Emergency contact

This section enables key contacts for the study to be recorded so that any staff working on the research know who to contact in the event of any key questions or concerns.

3.1.1.5 Grant approval details

If applicable, the source of study funding and the budget can be captured here.

3.1.2 Adding users

This section of the Study enables the researcher to specify both who is the Study creator and / or lead researcher / investigator and staff who can:

- Add study results to the animals enrolled in the study, known as a “Result creator”
- Only view study results and information, known as a “Result viewer”

User	Roles
Steven Blom Veterinary Technician	Result creator

Figure 18: Studies – Users section

The users must already be defined as users by the System Administrator and must have login's set up for them.

To add a user, ensure the Study is in Edit mode, and click on the Add user button. The following form will popup.

Add user

User *

Rose Lecciones

Roles

☒ Result creator

☐ Result viewer

CANCEL ADD

Figure 19: Studies – Add user to study form

Select the user from the list provided (which is populated by the users added to the system by the System Administrator) and select which role is required.

Note

- *A Result viewer will have read only access to your study information, including results. They will not be able to edit the study, add results or export any data to the CSV file. They will be able to view the animals enrolled to the study but will not be able to change the records. This is ideal for sharing your research with oversight groups, colleagues, peer review groups, publishers and funding groups and avoids the need to create a separate study file to email or upload to a shared site.*

3.1.3 Defining Phases

Phases can help you organise your experiments and study groups into collections in specific time periods.

The phase dates can overlap.

You may only have one phase into which all your experimental groups belong.

Common uses of phases are:

1. If you need to acclimatise your animals or prepare them before they are ready for experiments. This is common if you need tumours to be of a particular size, weight to have reached a critical level or even if you simply need to observe them for several days post shipping / identification / surgery to ensure they are healthy before assigning them to your study groups
2. You may have a phase of observations, procedures, interventions, such as injections and data collection over a key period. If you then have a sample that you wish to analyse, post study, e.g. for necropsy or observation post study, you may wish to keep the data sets separate, and can do this by creating a post intervention phase.

3.1.3.1 Adding a Phase

All studies must have at least one phase defined.

To add a phase, ensure your study is in Edit mode by clicking on the Edit Study button (which will change to an Update button).

Click on the Phases and Experiments tab to open the screen below.

Click on the Add phase button to add a Phase.

Study: VEGF Signalling in solid tumours - AG-013736 / Ethics reference: Immuno-Oncology - 001/A

BACK

UPDATE

STUDY DETAILS

USERS

PHASES

ATTACHMENTS

ANIMAL SUMMARY

RESULTS

EDA

SEND

Phases

ADD PHASE

Title	Planned date	
Baseline compound characterisation	Start date 4/17/19 End date 4/30/19	 

Figure 20: Studies – Add a Phase option

The form below will open when you select the Add Phase button.

Add phase

Title *
Necropsy

Start date
4/17/2019

End date
4/17/2019

Study runs from 4/17/19 – 8/30/19

CANCEL

ADD

Figure 21: Studies – Add a Phase form

Input a name for your Phase and define the start and end dates for the Phase and click the Add button to save it.

 Note

- Phases must start and end within the Protocol and Study start and end dates.

3.1.3.1.1 Acclimatisation and pre-study preparation

In some experiments, animals cannot be enrolled into a study group until they meet certain parameters – e.g. weight, age, tumour size etc.

If the researcher has this need, this is how they must design the study in our system:

3.1.3.1.2 Pre-study or acclimatisation phase

- Create your first phase – with start and end date. Name it – e.g. Acclimatisation phase (tumour development) etc.
- You can also create the next phase, which might be Study Phase – Compound testing
- There may be a third phase, which is Post Study Phase – Necropsy analysis
- You can have as many phases as you need.

Once you have your phases, click on the phase to add your experimental or study groups to that phase.

3.1.3.1.3 Pre-study or acclimatisation phase experiment groups

Based on your power analysis, you will have worked out the total sample size / number of animals you require for your research. Let's assume the research requires 4 groups of 25 animals each = 100 animals in total.

You need to ensure your protocol has approved sufficient numbers of animals for you to enrol 100 mice into your study.

If you have an acclimatisation phase, you may need to enrol more than the 100 mice into your phase 1 as not all 100% of the animals may reach the minimum criteria to be enrolled into a study phase. E.g. their tumours do not take; they do not reach the target weight; they do not recover from a procedure etc.

So, with an acclimatisation phase, you may simply have 1 Experiment, for example called Acclimatise animals – tumour volume or Acclimatise animals – weight target etc.

For this one experiment group you can enrol, or add, all your mice. In this experiment you will add the procedures you will perform, the observations you will undertake. E.g. inject tumour cell line; measure tumour, weigh etc.

3.1.3.1.4 Moving animals from acclimatisation phase experiment groups to study experiment groups

When an animal is acclimatised (e.g. has completed 3 days settling in, or the tumour size matches the minimum etc.) you can then move the animal from your current phase an experimental group to your study phase and new experimental group.

To do this you must un-enrol them from the current group so you can enrol them in the new group. See the section on Enrolling animals for information on how to perform this function.

3.1.4 Defining Experiments / Experimental Groups

Within a phase, we provide a facility for you to create your animal "groups". Based on your study design, typically you may have 2 main groups:

- Control groups (for example where sham / placebo compounds are injected or where no interventions are conducted, but for who observational data is to be collected)
- Study or treatment groups (these being the groups where animals are organised according to the variables of the research: e.g. sex, interventions, observations, dosing regime etc.)

3.1.4.1 Adding an Experiment

To add an experiment / experimental group, you must click to select the Phase to which the experiment will below, as shown below.

Study: VEGF Signalling in solid tumours - AG-013736 / Ethics reference: Immuno-Oncology - 001/A

BACK

UPDATE

STUDY DETAILS

USERS

PHASES

ATTACHMENTS

ANIMAL SUMMARY

RESULTS

EDA

SEND

Phases

ADD PHASE

Title	Planned date	
Baseline compound characterisation	Start date 4/17/19 End date 4/30/19	 

Experiments

ADD EXPERIMENT

Title	Planned date	
Control - Male	Start date 4/17/19 End date 4/30/19	 
Control - Female	Start date 4/17/19 End date 4/30/19	 
AG-013736 - Male	Start date 4/17/19 End date 4/30/19	 
AG-013736 - Female	Start date 4/17/19 End date 4/30/19	 

|< < 1 > >|

Figure 22: Studies – Add an Experiment to a Phase

Click on the Add experiment button to add an experiment. This will show the form below.

Add experiment

Title *

Dosing - Group 1

Start date

4/17/2019

End date

4/17/2019

Phase runs from 4/17/19 → 4/30/19

CANCEL

ADD

Figure 23: Studies – Add an Experiment form

Input a Title for the experiment. The following sections discuss how you might name your experiments and / or groups, for example, depending of whether you are blinding your study and / or creating control groups.

The start and end dates of the experiment must be within the start and end dates of phase to which it belongs.

Click on the Add button to save the experiment.

There is no limit to the number of experiments you can define.

If you have used a system, such as the NC3Rs EDA tool to design your experiments, you will already know how many experimental groups to create and how many animals will need to be enrolled in each group.

 Note

- Experiments will generally be defined according to the number and types of variable that you are studying, where the variable may be animal characteristic, such as gender, strain or age; treatment type, such as compound, dose level, cell line or other outcome group of interest.

- *Other variables, such as husbandry practices, diet, housing conditions, etc. should be recorded in the Notes section of the study, where they are common to all experiment groups. If any of these environmental conditions vary between groups, it may be appropriate to explicitly record these as declared and differentiated Test Methods, so that their effect can be analysed in the post study analysis.*

3.1.4.1.1 Experimental groups and sample size

If you have used the EDA tool, the study design will have helped you work out how many groups you need and how many animals in each group are required to have the correct power and sample size.

You can create as many study groups as you wish.

You can name the study groups as you wish, so you can distinguish the variables of each group. For example:

- Control group, male
- Control group female
- Group 1 – High dose, compound AG-013736, Male
- Group 2 – Low dose, compound AG-013736, Male
- Group 3 – High dose, compound AG-013736, Female
- Group 4 – Low dose, compound AG-013736, Female

3.1.5 Selecting Test Methods

Test methods are used in experiments to define the types of observation, treatment, intervention or measurement that is to be conducted. These include examples such as dosing, tissue collections, observations such as body condition scores, gait analysis or necropsy.

Test methods will have been pre-defined and loaded into the system by your System Administrator. Please contact your System Administrator if your experiment requires a new observation, measurement, treatment or procedure.

Study: VEGF Signalling in solid tumours - AG-013736 / Ethics reference: Immuno-Oncology - 001/A

STUDY DETAILS USERS PHASES ATTACHMENTS ANIMAL SUMMARY RESULTS EDA SEND

Phases ADD PHASE

Title	Planned date	
Baseline compound characterisation	Start date 4/17/19 End date 4/30/19	

Experiments ADD EXPERIMENT

Title	Planned date	
Control - Male	Start date 4/17/19 End date 4/30/19	
Control - Female	Start date 4/17/19 End date 4/30/19	
AG-013736 - Male	Start date 4/17/19 End date 4/30/19	
AG-013736 - Female	Start date 4/17/19 End date 4/30/19	

Tests ADD TEST

Test method	Planned date	Frequency
-------------	--------------	-----------

Enrolled animals ENROL ANIMAL

You cannot enrol animals to a study that is in Draft mode.

Unique Id	Visual Id
-----------	-----------

Figure 24: Studies – Add a Test Method

Test methods are organised in 2 categories:

- Animal
- Other

To add a Test Method to an Experiment, click on the Add button.

3.1.5.1 Adding a Test method

The Title of the Test enables you to define the specific variable information relating to the Experimental group, such as dosing level, cell line or even implantation site. If you are blinding your study, you can name your Test Method with a unique reference value to cross refer to your study variable which could be held in an offline file.

Add test

Test title
AG-013736 - Dose 0.25ml

Test method
Administer drug

Text
Free text Text

Schedule
Start date End date
4/17/2019 4/17/2019
Experiment runs from 4/17/19 - 4/30/19
Frequency
Once
Start time End time
00:00 23:59

CANCEL ADD

Figure 25: Studies – Add a Test Method form

Select the Test Method from the database list which is maintained by your System Administrator.

Depending on which type of Test Method you select, the next set of fields will vary. There are 3 main types:

- Free text
 - As shown in the example above, this type of Test Method does not require any further definition. On the Results input field, this type of method enables you to record a free form value, such as a Score (e.g. an MSG score or Body condition score), an Observation result etc.
- Measurement area
 - For experiments which require the capture of a length, width, height, area (square area) or volume (cubic value), Test Methods will have been defined with one or more input values to achieve the necessary result value to be captured.
- Measurement weight

- For experiments where the capture of weight value is required, the Test Method will have been defined to capture a weight as a mass value.

3.1.5.2 Defining a Test Method Schedule

When defining a Test Method as part of an experiment, you can specify the period during which the Test Method should be performed (the start and end date) as well as the Frequency and Timing.

When animals have been enrolled to the Experiment and the Study is saved, Ai.Study will automatically generate a complete set of scheduled tasks for each animal and each Test Method for the period set in this Schedule section.

Important

- *The timing of experiments has been demonstrated as a potential confounding variable, so care should be taken in choosing the date, time and frequency when scheduling experiments. Particular care should be given to animal circadian patterns and even post cage change acclimatisation considerations.*

Note

- *The dates and times of the tasks generated from the Test Method schedule will be set for the time zone in which the animal is housed, so the local time for the animal NOT the local time for the end user if they are in a different time zone.*

3.1.5.3 Defining a Test Method Frequency

The Frequency options are:

- Once
- Daily
- Weekly
- Bi-weekly
- Monthly

Note

- *If you need to perform an experiment, such as an observation or PK related blood draw, more than once per day, you should define more than one Test Method, with the same Test Method type, but perhaps entitled to distinguish the timing of the experiment, with each version timed appropriately.*

3.1.5.4 Defining a Test Method Timing

This option enables you to define a specific time period within a 24 hour period that you want the Test Method to be performed.

As indicated earlier, care should be given to the animals circadian rhythm with regard to timing of experimental conduct. Also, where a Test Method is to be repeated more than once in a 24 hour period, ensure the correct time period is defined for each Test Method.

3.1.5.5 When to use Animal Test Methods

A Test Method in the Animal category, specifies the body part to which the observation, treatment or procedure pertains and the species. Therefore, it is recommended that test methods that pertain to specific body parts and / or species should be created under the Animal category.

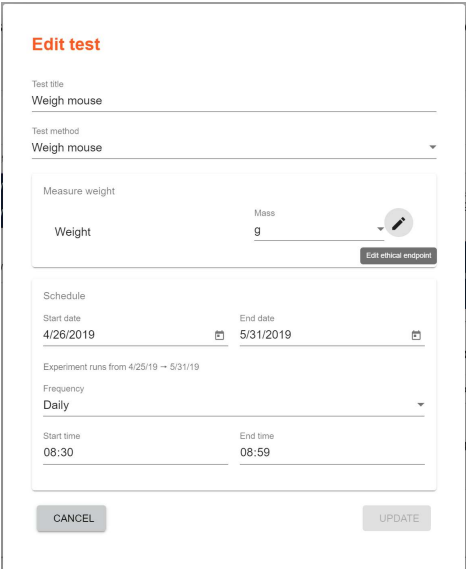
3.1.5.6 When to use Other Test Methods

A Test Method in the Other category, provides a freeform text description that describes the observation, treatment or procedure SOP. The freeform text can also be used to describe the composition of compounds and provide hyperlinks to catalogue information online.

3.1.6 Defining Ethical Endpoints

When selecting Test Methods, Ai.Study enables you to define “endpoints” – results, outcomes or observations that exceed a specified threshold, as defined in your SOPs and agreed with your veterinary staff, and which would result in the animal either being culled or removed from the study to recover.

To define an Ethical Endpoint, click on the Edit  icon, as shown below.



Edit test

Test title
Weigh mouse

Test method
Weigh mouse

Measure weight

Weight

Mass
g

Edit ethical endpoint

Schedule

Start date
4/26/2019

End date
5/31/2019

Experiment runs from 4/25/19 → 5/31/19

Frequency
Daily

Start time
08:30

End time
08:59

CANCEL **UPDATE**

Figure 26: Studies – Add an Endpoint to the Test Method

In the example given below, you can specify the maximum weight loss or gain the animal should experience, beyond which the endpoint threshold will be exceeded and the animal should be culled or removed from study. As shown below, you may also define warning thresholds, which may indicate early intervention is needed to retain the animal in the study or may suggest more detailed observation is required.

Edit test

Test title
Weigh mouse

Test method
Weigh mouse

Measure weight
Weight

Mass
g

Schedule
Start date
4/26/2019
End date
5/31/2019
Experiment runs from 4/25/19 to 5/31/19
Frequency
Daily
Start time
08:30
End time
08:59

Bodyweight threshold

High danger (%)
20

High warning (%)
10

Low warning (%)
10

Low danger (%)
20

In reference to the first recorded value

CANCEL OK

Figure 27: Studies – Define Ethical Endpoint values and thresholds

You can also set endpoints for tumour length, width and volume.

3.1.7 How Ethical Endpoints are notified

Endpoints are checked when you input results against the study tasks or create adhoc experiment results.

3.1.7.1 - Status – no ethical endpoint triggered

The green tick icon indicates the result is within defined thresholds.

3.1.7.2 - Status – warning – ethical endpoint is approaching maximum tolerance

When you see a study result with this ethical endpoint status, you should check to ensure the protocol for an endpoint that is nearing the maximum threshold has been actioned for this animal.

3.1.7.3 - Status – danger – ethical endpoint has been reached – action required

When you see a study result with this ethical endpoint status, you should check to ensure the protocol for breaching endpoints has been actioned for this animal.

3.1.8 Enrolling and unenrolling animals

3.1.8.1 Setting the Animal Summary

Before you can enrol animals to one of your Phase / Experiment groups, you must set the Animal Summary details to record the total number of animals that are to be used within your study.

The total number of animals to be used should have been calculated using a relevant power calculation. The NC3Rs EDA system can be used to help you calculate the total number of animals required.

To capture the animal total to be used, click on the Animal Summary tab.

Input the total number of animals in the field “Please enter the number of animals required to be issued to the study”.

Note

- The total number of animals entered onto your study cannot exceed the total number permitted under your licence / protocol. The value you enter in the field above is checked against the total value on your protocol record.

3.1.8.2 Enrolling animals

To enrol animals in your study, a few prerequisites must have been completed:

- Your study must belong to an approved Protocol record.
- Your study must have been activated (which means it must have been approved).
 - It cannot be in draft mode.
- You must have defined the total number of animals to be used on your study.
- You must have allocated the cages and specific animals to be used on your study to the protocol under which your study is approved.
 - To do this, see the Workbench function which explains how to assign cages and animals to protocols.
- You must have defined your study with relevant phases, experiment groups and test methods.

Once the above pre-conditions are satisfied, when you navigate through the phase and experiment groups, the Enrol button on the screen below will be activated.

Study: VEGF Signalling in solid tumours - AG-013736
Ethics reference: Immuno-Oncology - 001/A

BACK UPDATE

STUDY DETAILS USER ACCESS PHASES & EXPERIMENTS ATTACHMENTS ANIMAL SUMMARY RESULTS EDA ATTACHMENTS ARRIVE SEND

Phases

Add phase

Title	Planned date
Baseline compound characterisation	Start date 10/26/2018 End date 12/28/2018

Experiments

Add experiment

Title	Planned date
Control - Male	Start date 10/26/2018 End date 12/28/2018
Control - Female	Start date 10/26/2018 End date 12/28/2018
AG-013736 - Male	Start date 10/26/2018 End date 12/28/2018
AG-013736 - Female	Start date 10/26/2018 End date 12/28/2018

Experiment tests

Add test

Test method	Planned date	Frequency
Administer Injection - ID	Start date 10/26/2018 End date 10/27/2018	Once
Weigh mouse	Start date 10/29/2018 End date 12/28/2018	Daily

Enrolled animals

Enrol animal

Animal visual ID	Date of birth	Sex	Life status
Tattoo: A01	9/23/2018	♂	Alive
Tattoo: A02	9/23/2018	♂	Alive

Figure 28: Studies – Enrol animal

When you press the Enrol animal button, a list of available animals will display, as shown below.

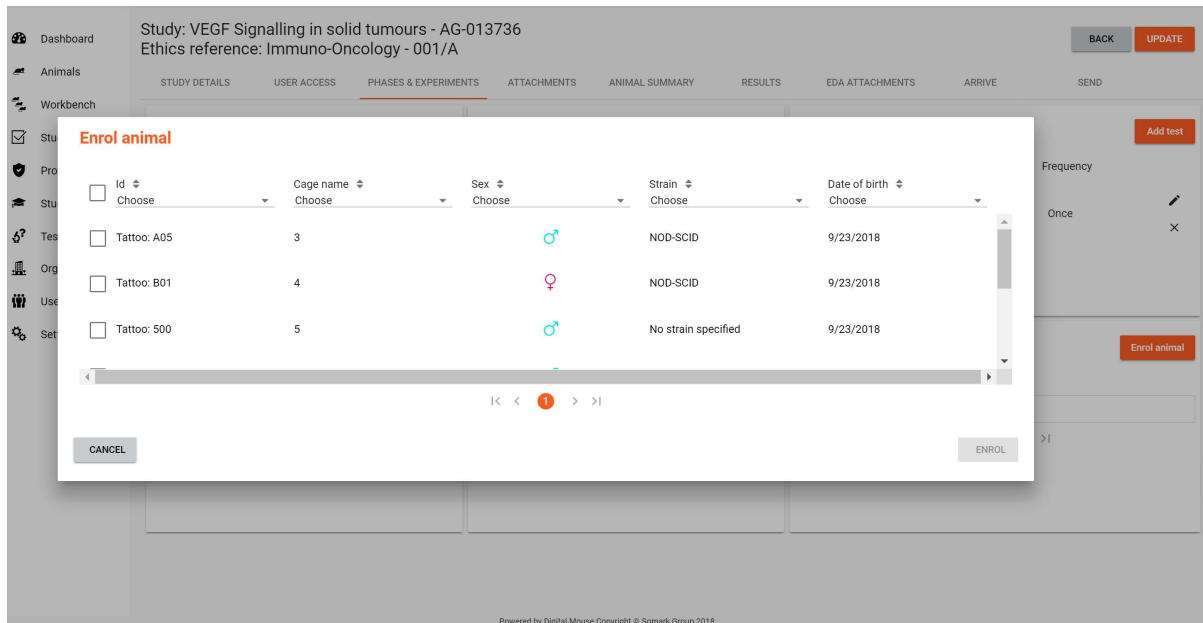


Figure 29: Studies – Enrol animal list

You can select one, several or all animals displayed by checking the tick box(es) on the left side of the screen. Press the Enrol button to add the selected animals to your experiment group.

3.1.8.3 Unenrolling animals

Access your study and experiment to view the currently enrolled mice – as shown in the example screen below. Make sure you press the Edit Study button (top right)

The screen will show an X next to each enrolled mouse. Click on the X shown below to un-enrol them.

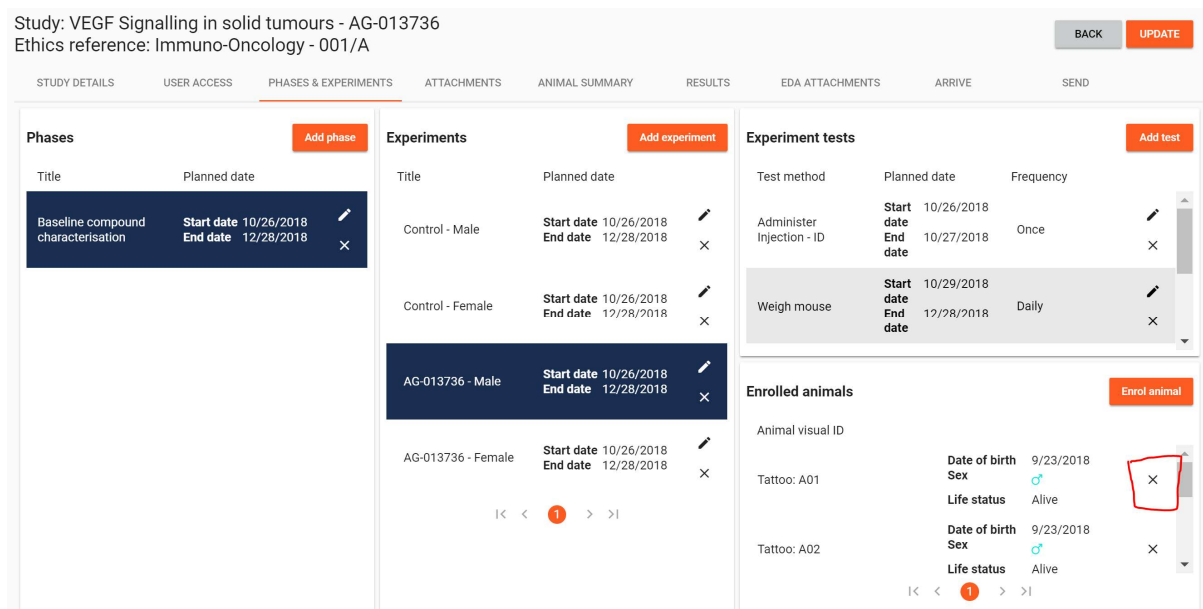


Figure 30: Studies – Unenrol an animal

You will be prompted to confirm you do want to unenroll them. Press OK to confirm.

Study: VEGF Signalling in solid tumours - AG-013736
Ethics reference: Immuno-Oncology - 001/A

STUDY DETAILS USER ACCESS PHASES & EXPERIMENTS ATTACHMENTS ANIMAL SUMMARY RESULTS EDA ATTACHMENTS ARRIVE SEND

Phases Add phase

Title	Planned date
Baseline compound characterisation	Start date 10/26/2018 End date 12/28/2018

Experiments Add experiment

Title	Planned date
Control - Male	Start date 10/26/2018 End date 12/28/2018
AG-013736 - Female	Start date 10/26/2018 End date 12/28/2018

Experiment tests Add test

Test method	Planned date	Frequency
Administer Injection - ID	Start date 10/26/2018 End date 10/27/2018	Once
Weigh mouse	Start date 10/29/2018 End date 12/28/2018	Daily

Unenrol Rodent

Are you sure you wish to unenrol this rodent?

CANCEL OK

Enrolled animals Enrol animal

Animal visual ID	Date of birth	Sex	Life status
Tattoo: A04	9/23/2018	♂	Alive
Tattoo: A05	9/23/2018	♀	Alive

Figure 31: Studies – Unenrol confirmation

You can then add this animal to a different Phase / Experiment group. When you click on the Enrol button, this animal just unenrolled will now appear, ready to add to your new Experiment group.

Dashboard Animals Workbench

Study: VEGF Signalling in solid tumours - AG-013736
Ethics reference: Immuno-Oncology - 001/A

STUDY DETAILS USER ACCESS PHASES & EXPERIMENTS ATTACHMENTS ANIMAL SUMMARY RESULTS EDA ATTACHMENTS ARRIVE SEND

Enrol animal

Id	Cage name	Sex	Strain	Date of birth
Tattoo: A05	3	♂	NOD-SCID	9/23/2018
Tattoo: B01	4	♀	NOD-SCID	9/23/2018
Tattoo: 500	5	♂	No strain specified	9/23/2018

CANCEL ENROL

Figure 32: Studies – Re-enrol animal to another phase / experiment

3.1.9 Generating, viewing and completing study tasks

Once you have created your Phases, Experiments and Test Methods, and after you have enrolled your animals, Ai.Study will automatically generate a schedule of study tasks – for each experiment, test method and each animal, with the time and date of the study task being automatically calculated based on the frequency and time you specified in the Test Method.

Tasks

ADD RESULT OR OBSERVATION

OVERDUE

TODAY

IN A WEEK

IN 2 WEEKS

IN 4 WEEKS

COMPLETED TASKS

Study

Phase

Experiment

Tumour growth analysis

Inject Cell lines

Measure tumour growth

Study	Experiment	Due At	Unique Id	Visual Id	Sex	Location	Unit category	Test method	Status	Result	
Tumour growth analysis	Measure tumour growth	4/23/19, 5:59 PM	190404/072	Tattoo: 571	♂	Mouse Room, Rack 1, 2	Mass	Weigh mouse			+ ×
Tumour growth analysis	Measure tumour growth	4/23/19, 5:59 PM	190404/079	Tattoo: 578	♂	Mouse Room, Rack 1, 10	Mass	Weigh mouse			+ ×
Tumour growth analysis	Measure tumour growth	4/23/19, 5:59 PM	190404/062	Tattoo: 561	♂	Mouse Room, Rack 1, 4	Mass	Weigh mouse			+ ×
Tumour growth analysis	Measure tumour growth	4/23/19, 5:59 PM	190404/070	Tattoo: 569	♂	Mouse Room, Rack 1, 2	Mass	Weigh mouse			+ ×
Tumour growth analysis	Measure tumour growth	4/23/19, 5:59 PM	190404/006	Tattoo: 505	♂	Mouse Room, Rack 1, 2	Mass	Weigh mouse			+ ×
Tumour growth analysis	Measure tumour growth	4/23/19, 5:59 PM	190404/080	Tattoo: 579	♂	Mouse Room, Rack 1, 10	Mass	Weigh mouse			+ ×

Figure 33: Tasks – Task list

To view the Study tasks, click on the Tasks menu option .

3.1.9.1 Understanding Task information and icons

The Task list show you the Study and Experiment and specific animal that the result of the test method is to be recorded against, as well as the time and date that the result should be captured from the animal and recorded in the system.

To help ensure the correct animal is selected for the result to be recorded, the animals sex and location (its room, rack and cage number), are provided.

3.1.9.1.1 - Status

By default, the status is as shown above. When a result is entered, the status

3.1.9.1.2 - Status – no ethical endpoint triggered

3.1.9.1.3 - Status – warning – ethical endpoint is approaching maximum tolerance

When you see a study result with this ethical endpoint status, you should check to ensure the protocol for an endpoint that is nearing the maximum threshold has been actioned for this animal.

3.1.9.1.4 - Status – danger – ethical endpoint has been reached – action required

When you see a study result with this ethical endpoint status, you should check to ensure the protocol for breaching endpoints has been actioned for this animal.

3.1.9.1.5 - Add result

You can record a study result against a scheduled task simply by clicking on the icon above. This will pop up a data capture form. The values to input will vary depending on what data the result requires, for example:

- Weight

Result date *
4/23/2019

Result time *
10:56

Weight
18 g

Ethical endpoints
Body weight threshold
Loss of $\leq 10.0\%$ from the first result (20g).

CANCEL ADD

Figure 34: Tasks – Record task result – example of bodyweight

- Measurement (area / volume)

Result date *
4/23/2019

Result time *
11:15

Width mm

Length mm

Ethical endpoints
None

CANCEL ADD

Figure 35: Tasks – Record task result – example of area value

- Free text

Result date *
4/23/2019

Result time *
11:42

Free text

Ethical endpoints
None

CANCEL ADD

Figure 36: Tasks – Record task result – example of free text value

3.1.9.1.6 - Discard task

If you select this option, to discard or remove a task from the list, you must record a reason why that task and study result will not be collected. When you select this option, the pop-up form below will display.

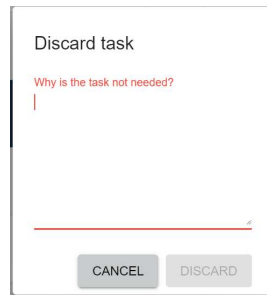


Figure 37: Tasks – Discard task

Please enter your reason and select the Discard button to save the value.

This keeps a record in the database and enables future analysis to understand why results are not being recorded, such as unexpected mortality of the animal; animal temporarily removed from the study (for example, to recover from an infection) and so on.

3.1.9.1.7 - Discarded task status icon

When a task is discarded, the Status icon will change to the above value.

3.1.9.1.8 - Correct result

When a task has a result captured against it, either from direct, manual input or automatically via Ai.Connect, the task list will show the above option, which enables the result to be changed. The following form will display when you click on this icon.

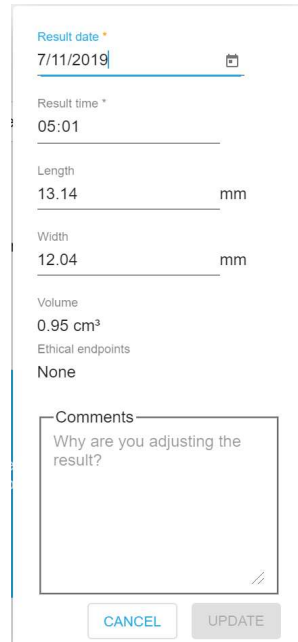


Figure 38: Tasks – Correct a result value – example of tumour measurement

The date and time will default to the time and date now, but can be set in the past.

You must enter a reason for why the original result is being changed, for example: the scales were not tared or calibrated for the original result capture.

All changes to results are captured in the history of the result, which is explained below.



3.1.9.1.9 - Show result history

When an experiment result is corrected, click on the above icon to display the history of the result information.

Study	Experiment	Due At	Unique Id	Visual Id	Sex	Location	Unit category	Test method	Status	Result	
Tumour growth analysis	Measure tumour growth	4/23/19, 5:59 PM	190404/071	Tattoo: 570	♂	Mouse Room, Rack 1, 2	Mass	Weigh mouse	✓	20 g	 
At 4/23/19, 10:49 AM Paul Donohoe entered the result Weight: 20 g ✓											

Figure 39: Tasks – Show result history

If a result has been changed, the history will also show the audit trail history of the change too, as shown in the example below.

Tumour growth analysis	Measure tumour growth	4/23/19, 5:59 PM	4/23/19, 10:49 AM		190404/003	Tattoo: 502	♂	Mouse Room, Rack 1, 1	Mass	Weigh mouse	✓	19.5 g	 
At 4/23/19, 11:57 AM Paul Donohoe corrected the result Result time 4/22/19, 9:49 AM Weight 19.5 g  Comments Balance was not tared correctly At 4/23/19, 10:50 AM Paul Donohoe entered the result Weight 20 g 													

Figure 40: Tasks – Show corrected result history

3.1.9.2 Viewing Study tasks by date range

When you select the Tasks option, the list will display all the tasks due Today, in the next 24 hours, as the default tab shown is Today's tasks, for all the studies to which you have access rights and assigned work.

You can view tasks that are Overdue, due in the next 7 days (In a Week), due in the next 14 days (In 2 Weeks), due in the next 28 days (In 4 Weeks) or all Completed tasks.

The list will show 20 tasks per page. To view the next list, scroll to the bottom of the page and use the number buttons or arrows to advance to another page.

3.1.9.3 Viewing Study tasks by Study, Phase or Experiment

You can also filter the list of tasks to show you only those relating to a specific

- Study – select a value from the list of Studies
- Phase – for the selected Study, select a value from the list of Phases for that study
- Experiment – for the selected Study and Phase, select a value from the list of experiments

3.1.9.4 Capturing Study Task Results

Section 3.1.12 explains how results can be captured against specific tasks, or can be recorded ad hoc. Section 3.1.12 also discusses how results can be captured manually via this function or automatically, via use of the Ai.Connect device (if you have purchased it).

3.1.10 Deciding on your Study design

3.1.10.1 Using the NC3Rs EDA service

We recommend you sign up for and use the NC3Rs Experimental Design Assistant to design your studies: <https://eda.nc3rs.org.uk/>

It is free to use and has all the tutorials and best practice guidance you need to ensure your research and experimental design is rigorous, statistically sound and well designed.

Our Ai.Study solution then ensures you can implement your design correctly, plan it effectively, schedule it efficiently and then execute it (i.e. collect, record and analyse results data) accurately and efficiently, ensuring data transparency, reproducibility and eliminating bias.



Figure 41: Studies – EDA file upload

The EDA file must be created in the <https://eda.nc3rs.org.uk/> system and then saved locally and uploaded to the Ai.Study using the EDA attachment function in Studies, shown above.

This enables research oversight groups, such as your Protocol or Licence holder or IACUC to be able to view the EDA file and the study design and compare this to how the Ai.Study experiment has been constructed, and complies with the EDA design recommendations.

3.1.10.1.1 Acclimatisation

The Phase feature of Studies enables you to define different stages of an experiment one of which is often “acclimatisation” or what is sometimes referred to as a “pre-study” phase.

This phase may be used to:

- Record that certain animal models are being bred in preparation for study, or
- Record that your animals must achieve certain parameters before being accepted for study, such as:
 - A minimum tumour size
 - A certain body weight range
 - Recovery from a particular surgery

3.1.10.1.2 Randomisation

If you wish to randomise your study, in simple terms, this means randomly allocated animals in your study to particular experimental groups.

First, calculate the total number of animals needed per study / experimental group

- Then sum the totals to give you your total animal count for the study
- Use the EDA tool to calculate this based on your planned experiment design

Second, you need to have all the animal records in the animal database (which you can create using the Import Animal function, or you can add manually via the Add animal button). You need to have assigned an individual identification code to each animal – which should be unique for each animal within your study. This can be visual or our RFID tag code, or both.

Next you have a choice: do you allocate your animals to cages before you randomise your animals or after?

If you have a pre-acclimatisation phase, you may wish to allocate your animals to cages first (e.g. animal 1-4 in cage 1, animals 5-8 in cage 2 etc.)

However, if you do not have a pre-study phase, you can run your randomisation process to determine which number animal belongs to which study group and then you can decide how you want to allocate your animals to which cages:

- You may wish to group animals in the same study group into the same cage(s), for example
 - Cage 1 houses 7, 21, 23, 36 and 60 or
- You may wish to house animals in an sequence so that animals 1-4 go into cage 1; 5-8 go into cage 2 etc.

Which approach is better?

- From a work management point of view, it makes sense to group animals into cages where the treatment / observation can be conducted in a streamlined efficient manner and, therefore, you should randomise your animals first, and then group them into cages so the test methods can be performed with groups of animals in the same cage

You should use the Workbench to allocate your animals to the required cages and racks.

Once the animals are in cages, you must use the Workbench to allocate your animals to the protocol to which your study is approved.

3.1.10.1.3 Randomisation method

There are many methods – Excel has one; flipping a coin is a method etc.

- Please refer to: <https://eda.nc3rs.org.uk/experimental-design-allocation> for more information

First you must establish how many animals in total your study requires:

- The EDA tool has an inbuilt sample size calculator which will help you determine this across all groups
- The EDA tool will produce an Excel file that randomly allocates the animals across the number of study groups your experiment requires

3.1.10.1.4 Control and treatment groups

Ai.Study uses the general term “Experiments” in the study function to refer to any control or treatment group that is needed to separate groups of animals according to the research parameters that are to be applied and tracked.

You can define as many Experiment or experimental groups as required. For example, you may have control groups defined by gender, model, age or any combination required.

For treatment groups, you may wish to define groups according to the dose level or other intervention variable, such as tumour cell line injected.

If you are not blinding, you may name each Experiment with specific variable information so that the groups are easily distinguished by the group name given.

3.1.10.1.5 Blinding

There are different approaches to blinding:

- Treatment application
- Measurement
- Analysis

Ai.Study supports blinding for each of these stages by enabling you to name your study groups and your treatments without any obvious indications of meaning.

If you wish to blind your technicians to the study group the animals belong to, you may wish to name the study groups without any meaningful labels, e.g.

- Study group 1
- Study group 2
- Etc.

If you wish to blind the technician to whether the treatment is a high level dose / low dose, you can name the test methods without meaningful labels, such as:

- Dose 1
- Dose 2
- Etc.

You will have to keep an offline record that maps the study group names and test method names to your actual experiment and treatment parameters. If you are analysing your study data by exporting the data to Excel, you can simply add columns into the spreadsheet with your study parameters.

3.1.11 Activating your Study

Before you can start to run your study, you must Activate your study.

The screenshot shows the 'Study: Tumour Dosing - 001 / Ethics reference: Oncology Research' page. At the top right are 'BACK' and 'UPDATE' buttons. Below is a navigation bar with tabs: STUDY DETAILS, USERS, PHASES, ATTACHMENTS, ANIMAL SUMMARY, RESULTS, EDA, and SEND. The 'STUDY DETAILS' tab is active. It contains a form with the following fields: 'Study title *' (Tumour Dosing - 001), 'Protocol' (Oncology Research), 'Protocol runs from 4/12/19 - 5/31/20', 'Status Draft', 'Start date 4/23/2019', 'End date 7/31/2019', and an 'ACTIVATE STUDY' button.

Figure 42: Studies – Activate study

The study can be successfully activated by clicking on the Activate study button, and confirming you are ready to start, the following actions must have been completed:

1. Associate your study to an approved Protocol – on the General tab, select from the list of Protocols
2. Record the number of animals to be issued to your study – on the Animal Summary tab, input the number in the first field
3. Upload your EDA file – if your organisation requires an NC3Rs EDA file to be present on your Study, on the EDA tab, upload your experiment design

3.1.12 Capturing Study results

The primary purpose of the Ai.Study system is to enable researchers to capture experiment results in a secure, auditable, scalable, low cost and easy to use manner. Ai.Study was designed to provide much of the flexibility found in using Excel spreadsheets, but with added validation and data authenticity.

Experiment results can be captured in several ways:

1. Using the Tasks function, researchers can input results against specific, scheduled experiments for specific animals
2. Also, using the Tasks function, researchers and animal technicians can capture unplanned experimental outcomes or observations
3. If you have purchased the Ai.Connect solution, when experimental measurements, such as bodyweights or caliper measures, are captured for a particular animal, this will automatically record the result in Ai.Study – against the correct animal and it will match the closest task by date and time
4. If you are capturing results in files, such as spreadsheets, images or video or audio files, you can add these results as attachments to the Study too, or to the specific animal.

The following sections explain how to capture experiment results using the tasks feature.

3.1.12.1 Capturing unplanned task results and observations

The Task function enables you to capture both unplanned or adhoc study results and animal observations.

3.1.12.1.1 Adding an experiment test result

To add a Test result for an experiment, select the option from the main screen to display the data capture screen below.

Add Result or Observation

BACK

ANIMAL OBSERVATION

TEST RESULT FOR AN EXPERIMENT

Protocol

Oncology Research

Study

Tumour growth analysis

Phase

Inject Cell lines

Experiment

Measure tumour growth

Animal

Visual Id	Strain	Sex	Species
Tattoo: 504	BALB/c	♂	Mouse

Select animal

Test method

Figure 43: Tasks – Results – Add test result for experiment – unplanned or adhoc

First select the protocol. Once selected, the system will populate the study, phase and experiment values, if there is only one option to select from. If there are more than one study in a protocol, or more than one phase in a study and more than one experiment in a phase, you must use the drop down list to choose the values you want to record the result against.

Next, click on the Select Animal button to see the list of animals enrolled into your experiment. This will pop up a list of animals – choose the one to record the result against.

Next, select the test method you wish to record the result against. Only the test methods in the experiment will appear in the list to choose from.

The data capture panel will appear to the right, as shown below. The field values that appear will depend on which test method you have selected.

Add Result or Observation

BACK

ANIMAL OBSERVATION

TEST RESULT FOR AN EXPERIMENT

Protocol

Oncology Research

Study

Tumour growth analysis

Phase

Inject Cell lines

Experiment

Measure tumour growth

Animal

Visual Id	Strain	Sex	Species
Tattoo: 503	BALB/c	♂	Mouse

Select animal

Test method

Weigh mice

Weigh mice

Result date *
4/17/2019

Result time *
17:54

Weight _____ g

Ethical endpoints
None

Comments

ADD

Powered by Digital Mouse. Copyright © Somark Group 2019

Figure 44: Tasks – Results – Add test result for experiment – example test method result capture

3.1.12.1.2 Adding an observation

Add Result or Observation

ANIMAL OBSERVATION

TEST RESULT FOR AN EXPERIMENT

Protocol

Oncology Research

Cage

Cage Name	Protocol Type	Location
1	Experimental	Mouse Room, Rack 1

Select cage

Animal

Visual Id	Strain	Sex	Species
Tattoo: 501	BALB/c	♂	Mouse

Select animal

Figure 45: Tasks – Results – Add Observation

When you select the Test Method – Observation from the list in the drop down field below the animal record, the page will display fields to enable you to capture the result. For observations, this will be freeform text plus more detailed comments, as shown.

Add Result or Observation

ANIMAL OBSERVATION

TEST RESULT FOR AN EXPERIMENT

Protocol

Oncology Research

Cage

Cage Name	Protocol Type	Location
1	Experimental	Mouse Room, Rack 1

Select cage

Animal

Visual Id	Strain	Sex	Species
Tattoo: 501	BALB/c	♂	Mouse

Select animal

Dull eyes/orbital tightening

Result date *
4/17/2019

Result time *
17:46

Free text

Ethical endpoints
None

Comments

ADD

Dull eyes/orbital tightening

Figure 46: Tasks – Results – Add Observation – results capture

Note

- Observations recorded in this way are not visible as completed tasks. They are recorded and can be viewed as a Result on the Animal record – see example below.

View Animal - Unique Id 190326/008 / Tattoo ROSEMOUSE000008 / Cage RRCage05 / Rack Rack3

General Notes Attachments **Results** Study Protocol Location History

Study: All

EXPORT

Protocol	Study	Experiment	Due At	Result time	Client	Location	Unit category	Test method	Status	Result	
Immuno-Oncology	VEGF1 Signalling	Control group	4/17/19, 2:59 AM	4/16/19, 5:46 PM		Room1, Rack3, RRCage05	Text	Administer Injection - IT	✓	Complete	✎ ↺
Immuno-Oncology			4/16/19, 5:47 PM	4/16/19, 5:47 PM		Room1, Rack3, RRCage05	Text	Dull eyes/orbital tightening	✓	MSG Score 3	✎ ↺
Immuno-Oncology			4/17/19, 7:55 AM	4/17/19, 7:55 AM		Room1, Rack3, RRCage05	Text	Dull eyes/orbital tightening	✓	MSG Score 3	✎ ↺
Immuno-Oncology			4/17/19, 7:57 AM	4/17/19, 7:57 AM		Room1, Rack3, RRCage05	Text	Dull eyes/orbital tightening	✓	MSG Score 3	✎ ↺
Immuno-Oncology			4/17/19, 7:57 AM	4/17/19, 7:57 AM		Room1, Rack3, RRCage05	Text	Dull eyes/orbital tightening	✓		✕
Immuno-Oncology			4/17/19, 7:57 AM	4/17/19, 7:57 AM		Room1, Rack3, RRCage05	Text	Dull eyes/orbital tightening	✓	MSG 3	✎ ↺

< > 1 >

Figure 47: Animals – Results – Observation

3.1.13 Capturing Study results from Ai.Connect

If your organisation is using Ai.Connect to collect experimental measurements, such as weights (e.g. animal bodyweights) or tumour lengths, widths and volumes, data captured from Ai.Connect will automatically match to the tasks in your study based on the nearest time due. Those tasks will be marked as completed and the results will be visible in the Results tab of your study (as well as on the Animal Results tab).

3.1.14 Exporting and analysing Study results

Ai.Study enables you to export your experiment results values to a CSV file. You may also select an option to include all other observations recorded against your experimental animals, such as health observations or other adhoc behaviour observations, treatments or procedures related to your animals.

Study: VEGF Signalling in solid tumours - AG-013736 / Ethics reference: Immuno-Oncology - 001/A

BACK EDIT STUDY

STUDY DETAILS USERS PHASES ATTACHMENTS ANIMAL SUMMARY **RESULTS** EDA ARRIVE

Phase: All

ADD NEW RESULT EXPORT ALL STUDY RESULTS EXPORT ALL STUDY RESULTS AND OBSERVATIONS

Study	Experiment	Due At	Result time	User	Unique Id	Visual Id	Sex	Location	Test title	Test method	Status	Result	
VEGF Signalling in solid tumours - AG-013736	AG-013736 - Female	7/15/19, 7:21 AM	7/15/19, 7:21 AM	Greg Golden	190404/042	Tattoo: 546	♀	Digital Research Inc, Digital Research - USA, The John Kitson Centre, Biologicals Facility, IW4, Rack 1, 000092	Weigh mouse	Weigh animal - mouse	✓	17.3 g	✎ ↺

Figure 48: Studies – Export study data - options

Select one of the Export buttons as shown, and the system will generate and download a CSV file to your computer.

3.1.15 Analysing your data

If you would prefer not to export your data to analyse (for example with tools such as SPSS or Graphpad), please contact your Account manager to discuss the options we can provide to help you analyse your data with other tools (such as R or Python) as well as predictive analytics tools (using machine learning).

We can also support you to integrate other sources of data, such as previous studies, colony data and data from your cages, racks and rooms.

3.1.16 Adding Attachments

Study: Tumour growth analysis / Ethics reference: Oncology Research

BACK UPDATE

STUDY DETAILS USERS PHASES ATTACHMENTS ANIMAL SUMMARY RESULTS EDA SEND

+ Choose X Cancel

UPLOAD

Name	Size	Type	Actions
------	------	------	---------

1

Figure 49: Studies – Attachments

When you click on the Choose button, the system will open your File manager / Explorer screen. This enables you to navigate to where your file is located – either on your local PC or on a network drive. Click on the Open button to choose the file. The name of the file will appear in the field below the Choose button and the Upload button will activate, as shown below.

Study: Tumour growth analysis / Ethics reference: Oncology Research

BACK UPDATE

STUDY DETAILS USERS PHASES ATTACHMENTS ANIMAL SUMMARY RESULTS EDA SEND

+ Choose X Cancel

protocol - io 001-a - approved.pdf 117 KB

UPLOAD

Name	Size	Type	Actions
------	------	------	---------

1

Figure 50: Studies – Attachments – Upload file

If you have selected the wrong file to upload, click on the Cancel button to remove it from the screen.

When you are ready to upload the file, click on the Upload button shown above.

Study: Tumour growth analysis / Ethics reference: Oncology Research

BACK UPDATE

STUDY DETAILS USERS PHASES ATTACHMENTS ANIMAL SUMMARY RESULTS EDA SEND

+ Choose X Cancel

UPLOAD

Name	Size	Type	Actions
protocol - io 001-a - approved.pdf	117 KB	.pdf	 

1

Figure 51: Studies – Attachments – Uploaded file

To remove a file, use the Delete icon .

Note

- Once you have deleted a file from Attachments, it cannot be recovered. It must either be re-attached or you must contact Somark's Help Desk to restore the attachment from a back up of your data.

To view a file, use the Download file icon . To view the file or show it in your local folder, use the arrow to display the options, as shown below.

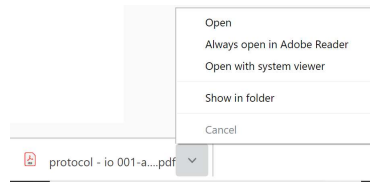


Figure 52: Downloaded file – Open or Show in folder options

3.2 Analysing data in files attached to your study

Ai.Study enables you to store ALL your research results in one, secure place. This includes images, video and audio files, as well as Excel files, PDFs and so on.

Using advanced tools from Microsoft, Somark can assist you to analyse all the content in these files without having to download them. Please contact your Account manager to discuss how we can help you extract insights from all your study files, with minimum effort and greater insight.

4 Protocols

Ai.Study provides a Protocol management function. We use the term Protocol to also mean Licence or Ethics Licence. The Protocol feature enables Ethics Committee members, Animal Care Use members or Licence Holders to control the approval of Studies attached to the protocol and the number of animals permitted for study.

A protocol may have one or more studies associated to it. A study cannot be activated until the protocol to which it is attached, is approved and the number of animals permitted has been defined.

4.1 Access to Protocols

The Protocol feature can be accessed from the menu by clicking on the Protocol icon .

Protocols							ADD PROTOCOL
Ethics Id	Short title	Type	Status	Approved	Approval	Expiry	
Choose	Choose	Choose	Choose	Choose	Choose	Choose	
001-A	Oncology Research	Experimental	Approved	500	4/12/19	5/31/20	

Figure 53: Protocols – View list of protocols / Add protocol

This will display a list of Protocol records and their status, as shown above. You can add a new Protocol, by clicking on the Add Protocol button, or edit an existing protocol using the  Edit icon.

4.1.1 Filters and Searching for a Protocol

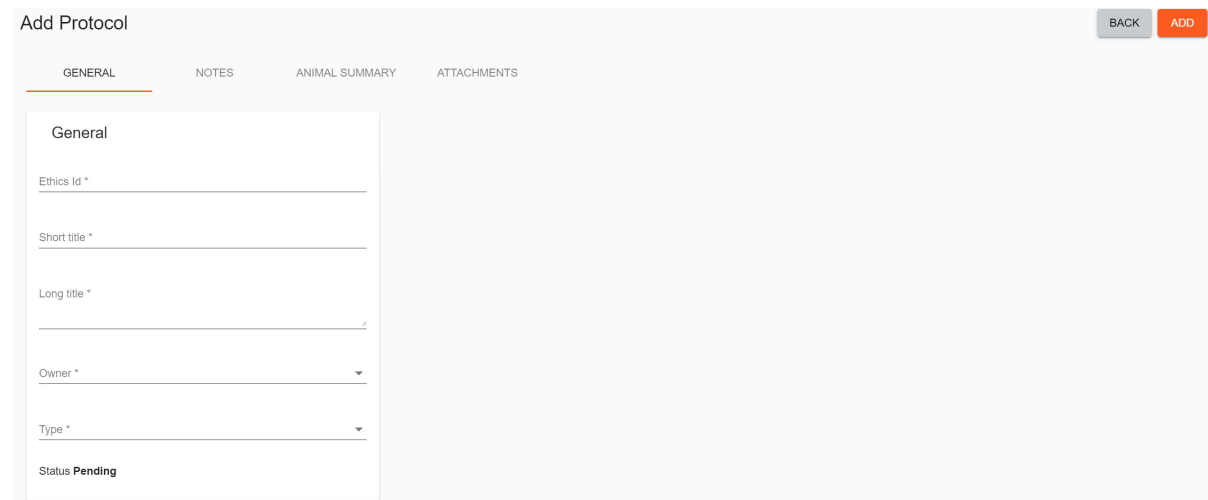
You can use the list filter option to select specific protocol records, based on your selection choice. This list screen also provides the option to sort records in ascending order or descending order using the  Sort icon.



The List Search field  allows you to input a search value and this will filter the list with records that match the search term. This field does not work with date searches. Please use the Choose filter option to filter records by dates.

4.2 Adding a Protocol

When the Add Protocol button is selected, the following input form is presented.



Add Protocol

BACK ADD

GENERAL NOTES ANIMAL SUMMARY ATTACHMENTS

General

Ethics Id *

Short title *

Long title *

Owner *

Type *

Status Pending

Figure 54: Protocols – Add a new protocol

The Status will default to Pending when a new Protocol is added.

To add a new protocol, you must input the following information:

- The Ethics ID – often also referred to as the Protocol or Licence ID
- A short title – less than 150 characters – i.e. the name of the protocol
- A long title – a short description of the protocol purpose
- The Owner – who is the person responsible for this protocol, including the animals approved and the studies and their experiments and procedures?
 - Who owns the licence?
- The Type? Is it for:
 - Breeding
 - Experiments
 - Training
 - Sentinels
 - Or Holding / Quarantine animals

If you select the Add button at this point, and have not input the number of animals approved under this protocol, you will see the  icon appear next to the Animal Summary tab label.

ANIMAL SUMMARY 

Figure 55: Protocols – Animal Summary – warning

This indicates you must input the total number of animals approved under the protocol for the full period of time the protocol will run.

4.2.1 Adding Notes and Attachments

The Notes section allows you to capture free text information about the protocol. This may include comments made during drafting, review or approval and any limitations or constraints for the protocol, such as the animal species and strains permitted for study.

The Attachments section allows you to upload any documents pertaining to the Protocol, such as the full application submission, details of approved procedures, Harm / Benefit analysis if required, other research on which this protocol may build, etc.

4.2.2 The Animal Summary

The most important detail to record for the protocol is the total number of animals that are approved for study for the entire duration of the protocol.

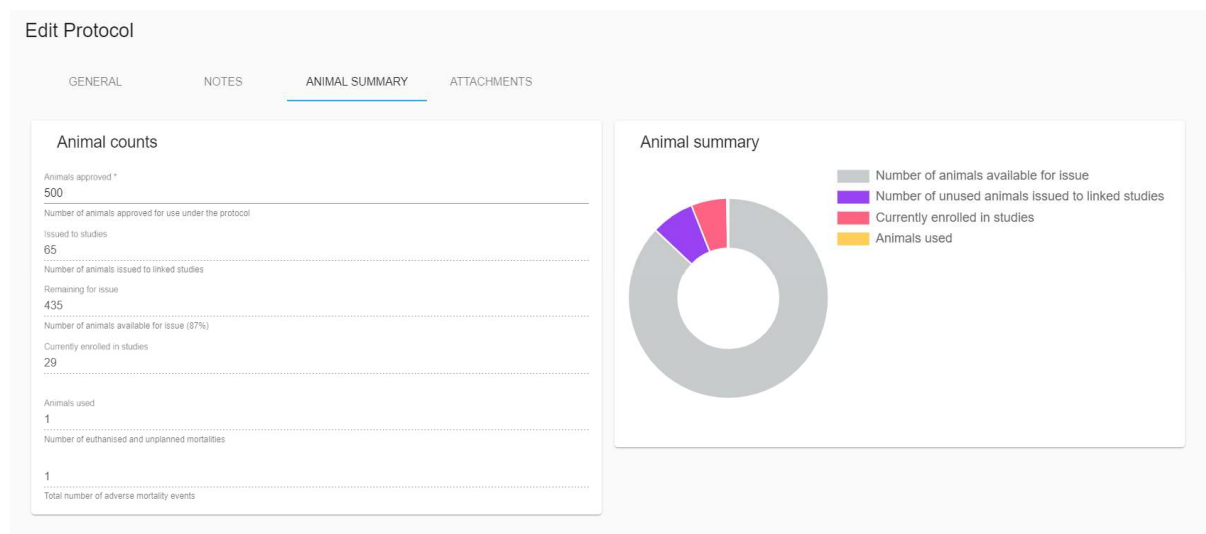


Figure 56: Protocols – Animal Summary – Animals approved

Enter the information in the first field, as shown above. This value can be amended while the Protocol status is Pending, but cannot be changed once the Protocol is approved.

The other fields:

- Issues to studies
- Remaining for issue
- Currently enrolled in studies
- Animals used, and
- Number of adverse mortality events

are automatically updated by the system when animals are enrolled into studies and culled.

4.3 Approving and Cancelling a Protocol

When you have completed the Animal Summary information, and the Protocol is ready to approve, click on the Approve button, as shown below.

Edit Protocol

GENERAL NOTES ANIMAL SUMMARY ATTACHMENTS

General

Ethics Id *
002 / 1B

Short title *
MR - Diabetes 1B

Long title *
Metabolic Research - Diabetes - Diet restriction - 1B

Owner *
Hafidh Jamaluddin

Type *
Experimental

Status Pending

REJECT APPROVE

Figure 57: Protocols – Approval button

Note

- Once you have approved your protocol, the current version of Ai.Study does not allow any further changes to it. Please ensure you have checked the protocol titles, added you notes you require and any attachments. Most importantly, make sure you have the correct number of animals input on the Animal Summary screen.

4.3.1 Date Selection

When a Protocol is selected for approval, you must specify the start and end date period for which the Protocol is approved.

Approving protocol

An approved protocol must have an approval and expiry date

Approval Expiry

CANCEL SAVE

Figure 58: Protocols – Approval date specification

Press the Save button to save and finalise the protocol record.

4.4 Assigning animals to Protocols

See section 6.4

5 Managing Animals in Ai.Study

5.1 Benefits of maintaining animal records in Ai.Study

Ai.Study requires that animal records are recorded and maintained. This is to ensure:

- The correct animals are enrolled into the study and all experimental results are assigned to an individual and correct animal record
- The system can keep track of compliance to permitted animal numbers on protocols and studies
- The system can alert animal care staff of specific individuals and their location that require health interventions, or in the case of humane end points, are culled as the protocol may require

There are additional benefits to the researcher too:

- Any and all interactions with the animal on the study can be captured to identify whether these interactions suggest any underlying variables in observed outcomes
- Specific environmental or animal model variables can be recorded and tracked to also identify whether these variables suggest any correlation to observed outcomes

5.2 Maintaining animal information in Ai.Study and your colony system

Since in most cases, the information Ai.Study requires about the animal (its attributes and location) are also maintained in a colony system, Ai.Study provides a bulk import function to upload data from your colony system into Ai.Study – see section 5.7.

Where endpoints or health interventions are identified during the course of the study, and these are recorded in Ai.Study, these conditions should be updated and reflected back into the colony system where further action and record keeping should be maintained.

For organisations who do not currently have or use a separate colony system, the Animal and Workbench function offer a simple, integrated colony management function. It is also possible to use the Study Tasks function to create and manage basic husbandry tasks, although these have to be defined first as Test Methods and then added to each study.

5.3 Access to Animal Records

To view the list of animals in Ai.Study, click on the menu item shown below.



Animals

5.4 Viewing Animal Records

To view an existing animal record, click on the View  icon. This will open and display the General tab, which provides common attributes about the animal, including both its visual and non-visual (RFID tag) identifying information.

You can also access the other features of the animal record:

- Notes
- Attachments
- Study
 - Which study the animal is enrolled to
- Protocol
 - Which protocol the animal is assigned to and who the animal “owner” is
- Location
 - Where the animal is housed
- Results
 - This feature presents scheduled experiment results plus any ad hoc observations or experiment results
- History

5.5 View Animal identity

When you view an Animal record, the top of the page will display identifying information about the animal – if it has been recorded.

View Animal - Unique Id 190404/003 / Tattoo 502 / Cage 1 / Rack Rack 1

Figure 59: Animals – View Animal identity

The Unique ID is an automatically, system generated and assigned unique animal record ID. If you animal has no visual or digital identifying information, you can use this value to find your animal and can use this value to refer to when working with colleagues so you know which animal is being addressed.

If a visual ID has been applied, this value is also display.

If the animal has been assigned to a cage and rack, this information will also display.

5.6 Filters and Searching for Animal Records

By default, when you select the Animals option, you will only see the first 25 records returned and only those animal records to which you have access rights to view and / or update (based on your role profile and which studies you are attached to as a user).

Animals ADD ANIMAL IMPORT ANIMAL

Unique Id	Cage name	Date of birth	Sex	Visual Id	Species	Strain	Genotype	Purpose	Life status	
Choose	Choose	Choose	Choose	Choose	Choose	Choose	Choose	Choose	Choose	
190404/055	5	4/4/19	♂	Tattoo: 554	Mouse	BALB/c		Experimental	Alive	
190404/074	6	4/4/19	♂	Tattoo: 573	Mouse	BALB/c		Experimental	Alive	
190404/075	6	4/4/19	♂	Tattoo: 574	Mouse	BALB/c		Experimental	Alive	
190404/076	6	4/4/19	♂	Tattoo: 575	Mouse	BALB/c		Experimental	Alive	
190404/077	6	4/4/19	♂	Tattoo: 576	Mouse	BALB/c		Experimental	Alive	
190404/097	6	4/4/19	♂	Tattoo: 596	Mouse	BALB/c		Experimental	Alive	
190404/096	7	4/4/19	♂	Tattoo: 595	Mouse	BALB/c		Experimental	Alive	
190404/095	7	4/4/19	♂	Tattoo: 594	Mouse	BALB/c		Experimental	Alive	
190404/094	7	4/4/19	♂	Tattoo: 593	Mouse	BALB/c		Experimental	Alive	
190404/093	7	4/4/19	♂	Tattoo: 592	Mouse	BALB/c		Experimental	Alive	
190404/092	7	4/4/19	♂	Tattoo: 591	Mouse	BALB/c		Experimental	Alive	
190404/091	8	4/4/19	♂	Tattoo: 590	Mouse	BALB/c		Experimental	Alive	

Figure 60: Animals – List view with filter options

As explained in section 2.2.2 Ai.Study User interface, you can use the Choose option above each column of data to filter the list of animal records displayed. Use the Reset filter option to clear your search filters and display the complete list.

Use the functions to skip to particular pages or scroll through pages.

Note

- If you cannot find an animal record in your list, it may be because other filters you have set, may remove it from your list. For example, if you set your Sex filter to Female, this will only display Female records, and it may be that you are looking for an animal by its ID value but can't see it.

5.7 Importing Animal Records

The Import animals button enables you to bulk upload multiple animal records to the system from a CSV template. The following screen is displayed.

Animal Import

Protocol
001-A-Oncology Research

Ethics Id
001-A

Short title
Oncology Research

Type
Experimental

Status
Approved

Approval
4/12/19

Expiry
5/31/20

Owner
Name
Paul Donohoe

+ Choose

Drop attachments here

CSV file template

Legend:
Total number of assigned animals remaining for use in this protocol (Blue)
Total number of animals used (Purple)
Total number of animals remaining for use in this protocol (Grey)

Figure 61: Animals – Import animals

First, you must select the Protocol to which the animals will belong and be added to. This will enable the system to check if the number of animals being added is within, or exceeds the maximum allowed under the protocol.

To import animals, first you must download the CSV template, which you can do by clicking on the



CSV file template

icon, top right of your screen.

This will download the animal-bulk-import.csv file to your local computer – usually to your Download folder.



Figure 62: Animals – Import animals – CSV download to your computer

You can open the file from your browser by clicking on the arrow next to the file name to show the options below

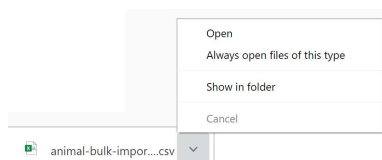


Figure 63: Animals – Import animals – CSV download to your computer – open file

5.7.1 Import animal CSV fields and values

The following table explains the fields that the CSV provides for you to complete. The values that must be present in the CSV file to successfully load are indicated with an M and *. All the other values can be updated on the individual record at a later time.

Field name	Explanation
Record Number	This is a user assigned number
*Species	Must be either "Mouse" or "Rat"
*Sex	Must be "Male" or "Female" or "Unknown"
*Date of birth	dd-mm-yyyy format for non US time zones or mm-dd-yyyy format for US time zones
Reason for death	Leave blank if Status is Alive. Note: The system will set the Life Status field value for the animal to Alive by default is this and the next 2 fields are left blank.
Date of death	Leave blank if Status is Alive
Is adverse death?	Must be False if animal is not alive; can be left blank or can be set to True if the animal has died unexpectedly during transportation, for example.
*Genetic status	Must be "Genetically modified" or "Non-genetically modified"
Primary visual method (M - must be the same as one of the configured visual identity items)	Please refer to your System Administrator for a list of the valid values for the Strains (or Models) that your organisation permits for the species of this animal
Primary visual ID value (M - must be the same as one of the configured visual identity items)	Please refer to your System Administrator for a list of the valid values for the Strains (or Models) that your organisation permits for the species of this animal
Primary visual ID provider (M - must be the same as one of the configured visual identity items)	Please refer to your System Administrator for a list of the valid values for the Strains (or Models) that your organisation permits for the species of this animal
Primary visual ID location (M - must be the same as one of the configured visual identity items)	Please refer to your System Administrator for a list of the valid values for the Strains (or Models) that your organisation permits for the species of this animal
Primary visual ID ink color (M - must be the same as one of the configured visual identity items)	Can't be mandatory??
Date of primary visual ID (Mandatory in the local date format - dd-mm-yyyy format for non US timezone mm-dd-yyyy format for US timezone)	
Health status	Up to 100 alphanumeric characters
Strain (also known as Model)	Please refer to your System Administrator for a list of the valid values for the Strains (or Models) that your organisation permits for the species of this animal. When the animal is genetically modified, you may wish to use the Line field below to capture a specific genotype and use this field to record a background strain
Line	Up to 195 alphanumeric characters. This value enables you to specify a particular name for a genotype variation of the main strain or model
Genotype (Must be a nominated item from the available genotype list for the environment)	Please refer to your System Administrator for a list of the valid values for the Genotypes that your organisation permits for the species of this animal
Phenotype (Must be a nominated item from the available phenotype list for the environment)	Please refer to your System Administrator for a list of the valid values for the Phenotypes that your organisation permits for the species of this animal
RFID (non-visual ID)	This field is provided when your facility or vendor pre-tags your animal with an RFID tag and the unique ID is known in advance.

Field name	Explanation
RFID date	dd-mm-yyyy format for non US time zones or mm-dd-yyyy format for US time zones
Supplier ID (Must be up to 424 alphanumeric characters)	
Supplier ID date	dd-mm-yyyy format for non US time zones or mm-dd-yyyy format for US time zones

5.8 Add or Edit an Animal Record

Use the Add animal button to add a new, individual animal record. Or, to Edit an existing animal record, use the View  icon to open an existing animal record and the Edit animal button to change or update the values. Use the Update button to save a changed animal record.

5.8.1 General

The first section of the Animal record enables you to define key attributes of the animal that will be enrolled into the study.

Add animal

General
Notes
Attachments
Re

General

Species *

Sex *

Date of birth

Age

Life status *

Health status

Strain

Line

Genetic status *

Genotype

Phenotype

Supplier

The name of the organisation that supplied the animal

Figure 64: Animals – General – Attributes

Field name	Explanation
* Species	Must be either "Mouse" or "Rat"
* Sex	Must be "Male" or "Female" or "Unknown"
* Date of birth (M - dd-mm-yyyy format for non US timezone mm-dd-yyyy format for US timezone)	dd-mm-yyyy format for non US time zones or mm-dd-yyyy format for US time zones
* Life status	Alive or Dead
Health status	Freeform text up to 100 characters
Strain	Please refer to your System Administrator for a list of the valid values for the Strains (or Models) that your organisation permits for the species of this animal.

Field name	Explanation
	When the animal is genetically modified, you may wish to use the Line field below to capture a specific genotype and use this field to record a background strain
Line (Must be up to 195 alphanumeric characters)	Up to 195 alphanumeric characters. This value enables you to specify a particular name for a genotype variation of the main strain or model
*Genetic status	Must be "Genetically modified" or "Non-genetically modified"
Genotype	Please refer to your System Administrator for a list of the valid values for the Genotypes that your organisation permits for the species of this animal
Phenotype	Please refer to your System Administrator for a list of the valid values for the Phenotypes that your organisation permits for the species of this animal
Supplier	Please record the facility / organisation who bred and supplied the animal

Use the Add button to create a new animal record.

5.8.1.1 Visual identity

First, the animal record must be created and added. When done so, the Add button on the panel below will turn from grey to orange, indicating you can add the Visual ID.

Visual identity Add

Method	Location	Value	Id date	Primary
--------	----------	-------	---------	---------

Figure 65: Animals – Visual Identity – Add button

Visual identity

Identification method ▼

Method provider ▼

Id value

Id Date

☐ Is Primary

CANCEL ADD

Figure 66: Animals – Add Visual Identity form

5.8.1.2 Non visual identity

The Non-visual identity RFID tag code and date tag inserted values can only be updated using the Ai.Connect – Associate Tag feature (which reads the tag in the animal's tail and updates the correct animal record automatically).

Non-visual identity

RFID		
Radio frequency tag code		Date the tag was inserted
Supplier Id		
Animal Id provided by the supplier		
Unique Id		
190404/003	4/12/2019	
Unique animal identifier	Date the unique Id was added	

Figure 67: Animals – Non visual Identity

The Supplier ID name can be added manually by editing the animal record.

5.8.2 Adding Notes

The Notes field enables you to record freeform text information about the animal. Every time a note is edited and changed, the History section will keep a record of the Note information over time, and who made the change with the date and time of the changes.

Note

- We recommend that you use the Tasks, Add Observation feature to record health or behavioural observations, as these can be exported with the animal history. Note information recorded in this feature is not exported with the animal record.

5.8.3 Adding Attachments

The Attachments feature enables you to upload a wide variety of file and documents to the animal record. This is useful to record images of health issues or individual image based experiment results, such as tumour images or behavioural video clips.

Note

- There is no limit on the amount of data and number of files you can upload and attach to animal records. However, there is an additional cost for use of storage above 50Gb.

5.8.4 Viewing and updating Results

When experiment results are added they are automatically associated with an animal. As well as viewing all results for the Study, you can also view all the results for each individual animal, by choosing the Results tab on the animal record, as shown below.

View Animal - Unique Id 190404/003 / Tattoo 502 / Cage 1 / Rack Rack 1

BACK EDIT ANIMAL

General Notes Attachments **Results** Study Protocol Location History

Study All

EXPORT

Protocol	Study	Experiment	Due At	Result time	Client	Location	Unit category	Test method	Status	Result	
Oncology Research	Tumour growth analysis	Measure tumour growth	4/23/19, 5:59 PM	4/23/19, 10:49 AM		Mouse Room, Rack 1, 1	Mass	Weigh mouse	✓	19.5 g	
Oncology Research	Tumour growth analysis	Measure tumour growth	4/24/19, 5:59 PM	4/23/19, 10:56 AM		Mouse Room, Rack 1, 1	Mass	Weigh mouse	⚠	18 g	

< > 1 >

Figure 68: Animals – Results list

5.8.4.1 Understanding Result information and icons

By default, the Result list shows you all the Study and Experiment results for the specific animal that has been selected.

The Results information includes the Protocol, the Study, the Experiment, the original Due date and time the result was expected to have been recorded; the actual date and time the result was recorded, which cage / rack / room location the animal was housed in at the time the result was recorded, the test method performed; the ethical endpoint status and the result value.

You can filter the list of results by Study, Phase and Experiment. To do this, click on the All option below the Study field label and this will display a list of Studies. When you select a study, this will then offer a choice of phases to select from. When you select a Phase, this will offer a choice of experiments to select from. As shown below.

View Animal - Unique Id 190404/003 / Tattoo 502 / Cage 1 / Rack Rack 1

General Notes Attachments Results Study Protocol Location History

Study Tumour growth analysis Phase Inject Cell lines Experiment Measure tumour growth

EXPORT

Protocol	Study	Experiment	Due At	Result time	Client	Location	Unit category	Test method	Status	Result	
Oncology Research	Tumour growth analysis	Measure tumour growth	4/23/19, 5:59 PM	4/23/19, 10:49 AM		Mouse Room, Rack 1, 1	Mass	Weigh mouse	✓	19.5 g	
Oncology Research	Tumour growth analysis	Measure tumour growth	4/24/19, 5:59 PM	4/23/19, 10:56 AM		Mouse Room, Rack 1, 1	Mass	Weigh mouse	⚠	18 g	

< > 1 >

Figure 69: Animals – Results list – filtered by Study, Phase and Experiment

5.8.4.1.1 - Status – no ethical endpoint triggered

5.8.4.1.2 - Status – warning – ethical endpoint is approaching maximum tolerance

When you see a study result with this ethical endpoint status, you should check to ensure the protocol for an endpoint that is nearing the maximum threshold has been actioned for this animal.

5.8.4.1.3 - Status – danger – ethical endpoint has been reached – action required

When you see a study result with this ethical endpoint status, you should check to ensure the protocol for breaching endpoints has been actioned for this animal.

5.8.4.1.4 - Discarded task status icon

When a result task is discarded, the discarded result task will display with no value and the status icon will display as above.

5.8.4.1.5 - Correct result

A Result can be corrected by clicking on the above icon. The values to input will vary depending on what data the result requires. For example, the case below enables a volume calculation to be amended by changing either the width or the length.

Result date *
7/11/2019

Result time *
05:01

Length
13.14 mm

Width
12.04 mm

Volume
0.95 cm³

Ethical endpoints
None

Comments
Why are you adjusting the result?

CANCEL UPDATE

Figure 70: Animals – Correct a result value – example of tumour measurement

The date and time will default to the time and date now, but can be set in the past.

You must enter a reason for why the original result is being changed, for example: the scales were not tared or calibrated for the original result capture.

All changes to results are captured in the history of the result, which is explained below.

5.8.4.1.6 - Show result history

To view the history of an experimental result recorded against the animal record, click on the  Show history icon. This will display the result history, as shown in the example below.

Protocol	Study	Experiment	Due At	Result time	Client	Location	Unit category	Test method	Status	Result	
Oncology Research	Tumour growth analysis	Measure tumour growth	4/23/19, 5:59 PM	4/23/19, 10:49 AM		Mouse Room, Rack 1, 1	Mass	Weigh mouse	✓	19.5 g	 
At 4/23/19, 11:57 AM Paul Donohoe corrected the result Result time 4/22/19, 9:49 AM Weight 19.5 g ✓ Comments Balance was not tared correctly At 4/23/19, 10:50 AM Paul Donohoe entered the result Weight 20 g ✓											

Figure 71: Animals – Result history

5.8.4.2 Exporting Results

Study results can be exported to a CSV file by clicking on the Export button, shown in the screen below.

View Animal - Unique Id 190404/003 / Tattoo 502 / Cage 1 / Rack Rack 1

General Notes Attachments **Results** Study Protocol Location History

Study
All

EXPORT

Protocol	Study	Experiment	Due At	Result time	Client	Location	Unit category	Test method	Status	Result	
Oncology Research	Tumour growth analysis	Measure tumour growth	4/23/19, 5:59 PM	4/23/19, 10:49 AM		Mouse Room, Rack 1, 1	Mass	Weigh mouse	✓	19.5 g	 
Oncology Research	Tumour growth analysis	Measure tumour growth	4/24/19, 5:59 PM	4/23/19, 10:56 AM		Mouse Room, Rack 1, 1	Mass	Weigh mouse	⚠	18 g	 

< < 1 > >

Figure 72: Animals – Result Export

5.8.5 Viewing and updating Study information

The Study information shown for an animal will update when the animal is enrolled into an Experiment via the Study function.

5.8.6 Viewing and updating Protocol information

The Protocol information shown for an animal will be set if it was imported via the CSV import process, or will be blank until it is assigned to a Protocol via the function in the Workbench. See section 6.4.

5.8.7 Viewing and updating Location information

The Location information shown for an animal will be blank until it is assigned to a Cage via the function in the Workbench. See section 6.3.2. When the Cage is assigned to a Rack, the Location information will also show the Rack and Room.

View Animal - Unique Id 190404/544 / Tattoo A01 / Cage Uncaged

General Notes Attachments Results Study Protocol **Location**

Location

The animal is not assigned to a cage.

Figure 73: Animals – Location – not in a cage

View Animal - Unique Id 190404/003 / Tattoo 502 / Cage 1 / Rack Rack 1

General Notes Attachments Results Study Protocol **Location** History

Location

Organisation
Somark Innovations

Facility
Mouse House

Building
Breeding Building

Room
Mouse Room

Rack
Rack 1

Cage
1

Figure 74: Animals – Location – in a cage

5.8.8 Viewing and updating History information

The History feature will record changes to the animals general attributes, study and location information, plus notes. It does not record a history of observations or experiment results – these are recorded in the Result section of the animal record.

View Animal - Unique Id 190404/003 / Tattoo 502 / Cage 1 / Rack Rack 1						BACK	EDIT ANIMAL
General	Notes	Attachments	Results	Study	Protocol	Location	History
Last seven days		3 changes					
At 4/17/19, 5:19 PM Paul Donohoe changed		Phase	from	None	to	Inject Cell lines	
At 4/17/19, 5:19 PM Paul Donohoe changed		Experiment	from	None	to	Measure tumour growth	
At 4/17/19, 5:19 PM Paul Donohoe changed		Study title	from	None	to	Tumour growth analysis	
Last thirty days		1 change					
At 4/12/19, 7:47 PM Paul Donohoe changed		Cage	from	None	to	1	
Older		0 changes					

Figure 75: Animals – History

6 Workbench – managing your animal housing

6.1 An introduction to Workbench

The Workbench feature provides two main functions:

1. It enables the creation of cages in which animals can be placed to ensure the animals enrolled in each study are correctly located in your facility, so researchers and animal technicians know where to find and retrieve the animals when needed for experiments.
 - a. We call this the “Colony” feature as it offers a simple colony management function, either replicating what you may already have in your colony system, or, if you do not have a colony system, a simple, integrated colony management service for you to use to manage your animals.
2. It provides a quick and easy way to allocate animals to protocols
 - a. This feature is accessed via the Protocol tab as shown below.

The Workbench information is organised based on how your System Administrator configured your organisation and its facilities, buildings, rooms and racks.

6.2 Locating a Cage

To view cages, you must navigate through your organisation by clicking on the relevant facility, building, room and rack. As you click, it will open the record and the structure below it.

To view a cage, click on the cage, which will highlight it in grey and a black arrow will display to the right of the cage name. Click on the black arrow to add the cage to the Workbench, and this will display the list of animals inside it.

Your System Administrator maintains your organisation information and racks.

By default, when you first access Workbench, the system will not have any cages created or assigned to racks. As well as importing the relevant animal records to the Animal database, creating cages and assigning them to the correct racks is the other first activity to perform with a new instance of Ai.Study.

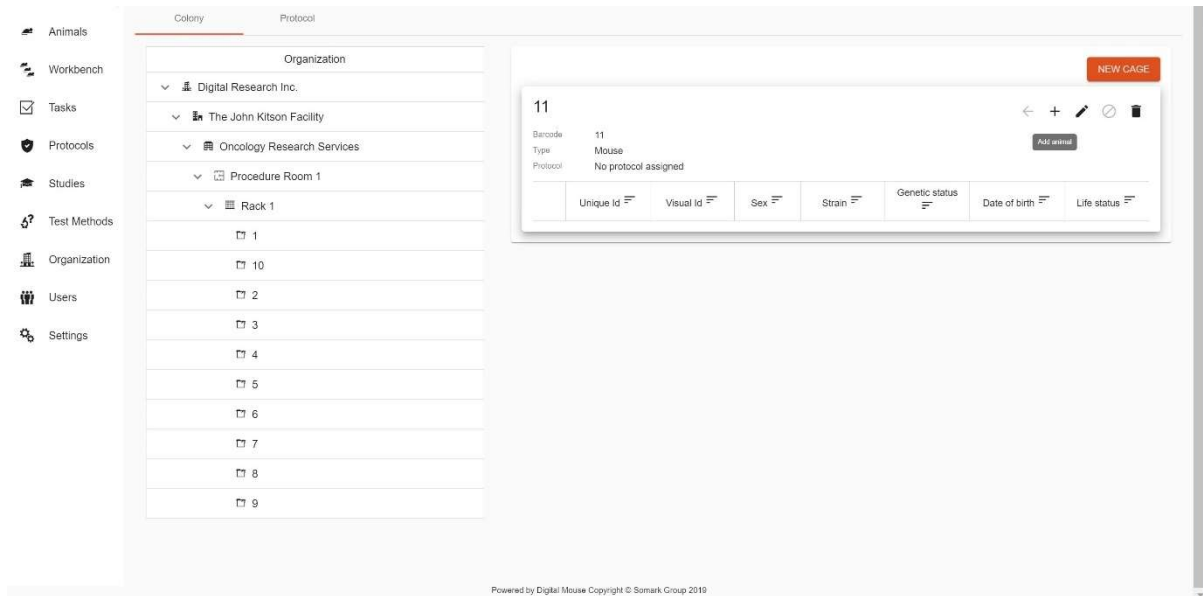


Figure 76: Workbench – Locating cages in rack

6.3 Working with Cages

6.3.1 Creating a New Cage

To create a new cage, click on the New Cage button. The following form will popup.

Figure 77: Workbench – Adding a new cage on the Workbench

It is recommended that the Cage name used is unique and corresponds to the value which staff will find written or printed on your cage cards.

The Capacity field is optional and is not validated, but can be used to set the maximum number of animals permitted in the cage.

6.3.2 Adding Animals to a Cage

Once you have created a cage, you can then add animals to the cage from the Animal records list.

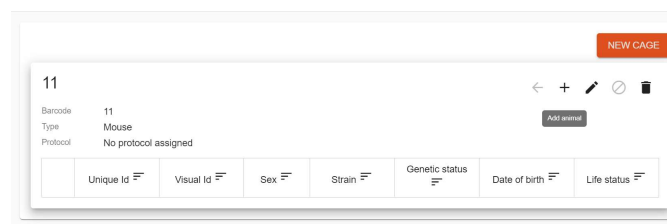
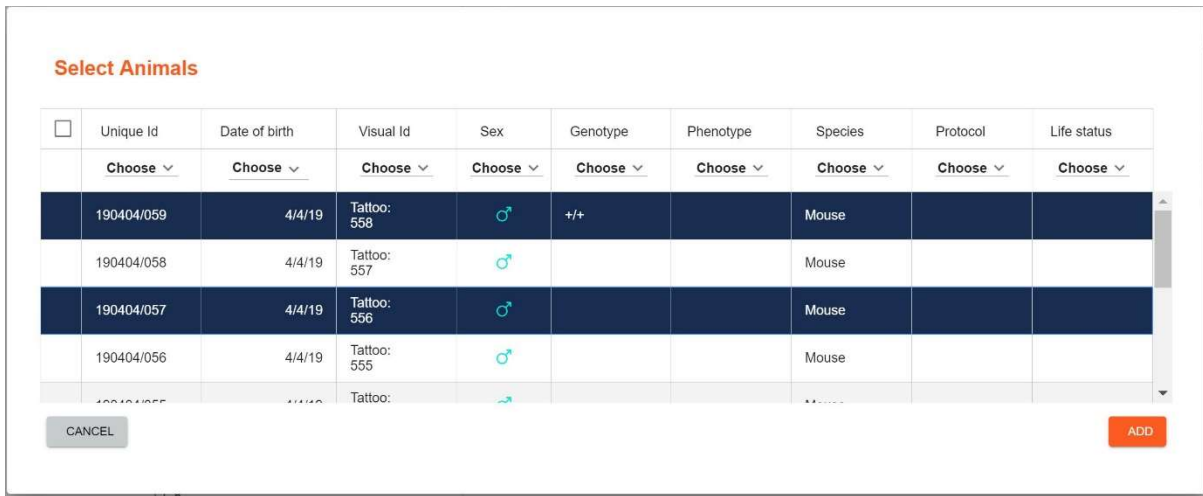


Figure 78: Workbench – Adding animals to a cage

Click on the Add animal  icon to display a list of animals, as shown below.



Select Animals

☐	Unique Id	Date of birth	Visual Id	Sex	Genotype	Phenotype	Species	Protocol	Life status
	Choose ▾	Choose ▾	Choose ▾	Choose ▾	Choose ▾	Choose ▾	Choose ▾	Choose ▾	Choose ▾
☒	190404/059	4/4/19	Tattoo: 558	♂	+/+		Mouse		
☐	190404/058	4/4/19	Tattoo: 557	♂			Mouse		
☒	190404/057	4/4/19	Tattoo: 556	♂			Mouse		
☐	190404/056	4/4/19	Tattoo: 555	♂			Mouse		
☐	190404/055	4/4/19	Tattoo: 554	♂			Mouse		

CANCEL ADD

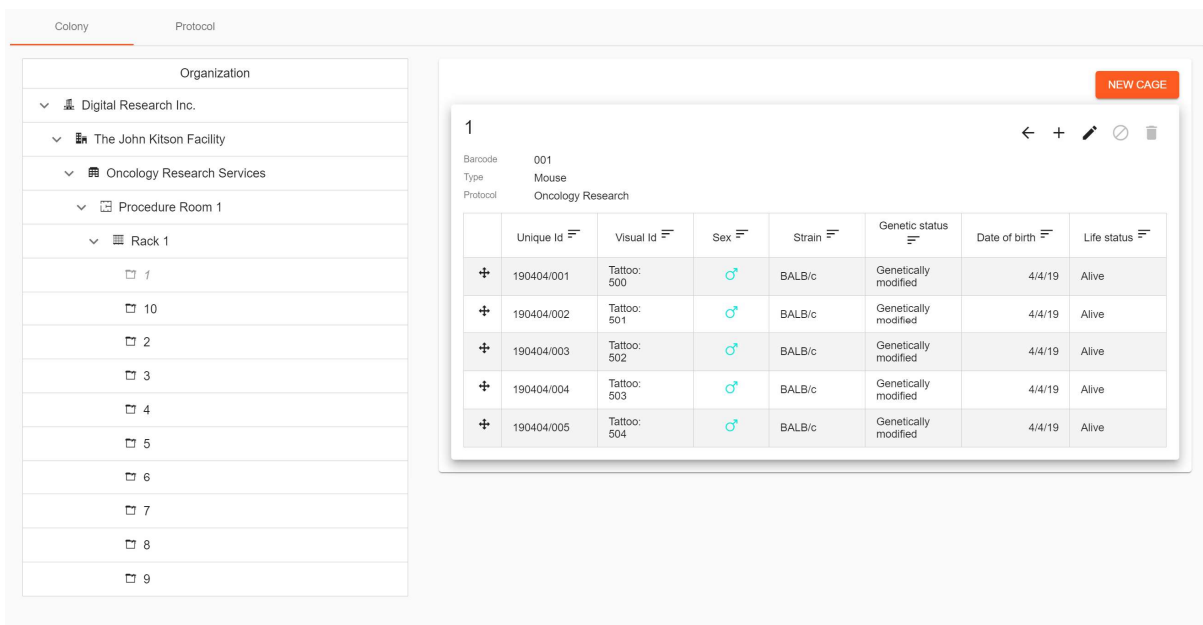
Figure 79: Workbench – Adding animals to a cage from a list

You can use the columns to filter the animals you are looking for to assign to your cage and narrow the list of animals displayed.

To select animals click on the row to highlight them, as shown above. The press the Add button to place them in the cage and return to the cage view, where the animals will now be listed.

6.3.3 Moving a new cage to a rack

When you have assigned animals to a cage, you can move the cage to your required rack. First, you must expand the organisation structure to reveal the rack in the correct room.



Colony Protocol

Organization

- Digital Research Inc.
 - The John Kitson Facility
 - Oncology Research Services
 - Procedure Room 1
 - Rack 1
 - 1
 - 10
 - 2
 - 3
 - 4
 - 5
 - 6
 - 7
 - 8
 - 9

1 NEW CAGE

Barcode 001
Type Mouse
Protocol Oncology Research

	Unique Id	Visual Id	Sex	Strain	Genetic status	Date of birth	Life status
+	190404/001	Tattoo: 500	♂	BALB/c	Genetically modified	4/4/19	Alive
+	190404/002	Tattoo: 501	♂	BALB/c	Genetically modified	4/4/19	Alive
+	190404/003	Tattoo: 502	♂	BALB/c	Genetically modified	4/4/19	Alive
+	190404/004	Tattoo: 503	♂	BALB/c	Genetically modified	4/4/19	Alive
+	190404/005	Tattoo: 504	♂	BALB/c	Genetically modified	4/4/19	Alive

Figure 80: Workbench – Moving a cage to the Workbench

To add the cage to a rack, click on the cage name or number (the number 1 shown in the example above) and hold your mouse down to drag the number across to the left so your cursor hovers over the rack name.

Release your mouse button to “drop” the cage onto that rack. It should now appear listed beneath that rack.

6.3.4 Moving a cage to the Workbench

To move a cage from a rack onto the Workbench – the space to the right of the organisation structure, navigate to the cage, move your cursor over the cage – which highlights it in grey with a right pointing arrow.

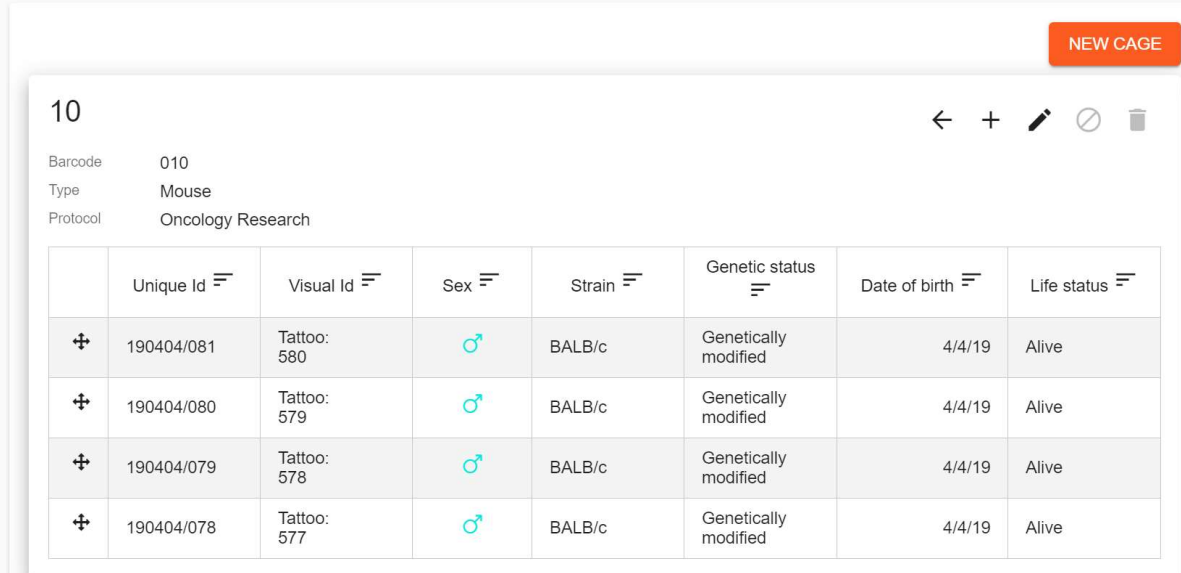
Click on the arrow and the cage will appear on the right hand side of the screen – on your workbench.

This will automatically display the animals housed within that cage.

You can move multiple cages to the Workbench to view them.

6.3.5 View Animals in a Cage

When a cage is moved to the Workbench, you can view a summary of information about the animals, as shown in the example below.



NEW CAGE

10

Barcode: 010
Type: Mouse
Protocol: Oncology Research

	Unique Id	Visual Id	Sex	Strain	Genetic status	Date of birth	Life status
+	190404/081	Tattoo: 580	♂	BALB/c	Genetically modified	4/4/19	Alive
+	190404/080	Tattoo: 579	♂	BALB/c	Genetically modified	4/4/19	Alive
+	190404/079	Tattoo: 578	♂	BALB/c	Genetically modified	4/4/19	Alive
+	190404/078	Tattoo: 577	♂	BALB/c	Genetically modified	4/4/19	Alive

Figure 81: Workbench – Viewing animals in a cage on the Workbench

6.3.6 Move Animals between cages

To move animals from one cage to another (for example, as part of a post randomisation re-allocation of animals to new cages), move both the current cage to the Workbench and the cage to which the animals will be moved.

If the cage to which the animals will be moved is new, use the New cage button to create a new, empty cage.

NEW CAGE

10

← + ✎ ⊘ 🗑

Barcode
010

Type
Mouse

Protocol
Oncology Research

	Unique Id	Visual Id	Sex	Strain	Genetic status	Date of birth	Life status
✚	190404/081	Tattoo: 580	♂	BALB/c	Genetically modified	4/4/19	Alive
✚	190404/080	Tattoo: 579	♂	BALB/c	Genetically modified	4/4/19	Alive
✚	190404/079	Tattoo: 578	♂	BALB/c	Genetically modified	4/4/19	Alive
✚	190404/078	Tattoo: 577	♂	BALB/c	Genetically modified	4/4/19	Alive

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Barcode
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Type
Mouse

Protocol
Oncology Research

	Unique Id	Visual Id	Sex	Strain	Genetic status	Date of birth	Life status
✚	190404/059	Tattoo: 558	♂	BALB/c	Genetically modified	4/4/19	Alive
✚	190404/058	Tattoo: 557	♂	BALB/c	Genetically modified	4/4/19	Alive
✚	190404/057	Tattoo: 556	♂	BALB/c	Genetically modified	4/4/19	Alive

Figure 82: Workbench – Moving animals from one cage to another

Click on the Move animal ✚ icon and hold your mouse cursor down, then drag the animal record to the other cage number (for example the number 11 in the example above) and then release your mouse click to “drop” the record into the new cage.

6.3.7 Removing a cage from a rack

To move a cage from one rack to another, simply drag the cage to the new Rack name (which needs to be open in your hierarchy).

To remove a cage from a rack and disposition it,

6.3.8 Marking Animals Dead in a Cage

The record that an animal has died or has been culled, move the cage to the Workbench, select the animal record to highlight it and then click on the Mark as culled ⊘ icon. This will display the following popup form to record the reason for the death or cull.



Figure 83: Workbench – Recording the reason for culling an animal

To save the animal status, press the Update button.

This will automatically update the Animal Summary information in both the Study and Protocol records to which the animal belongs.

6.4 Assigning a Cage and Animals to a Protocol

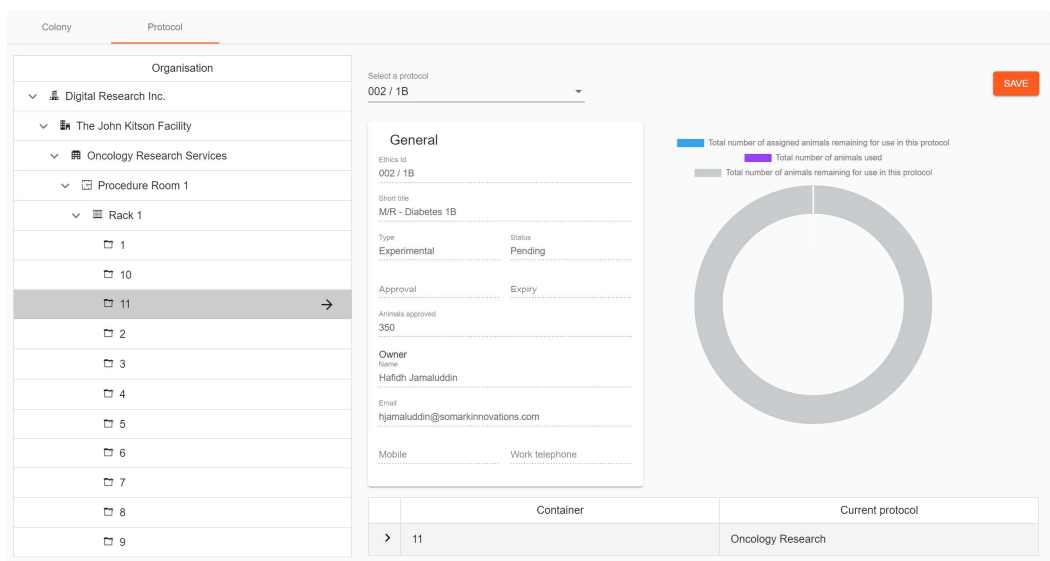
If you add an animal record manually, and did not use the Import Animal function, you must assign that animal to a protocol using the feature below in the Workbench.

To access this feature, select the Protocol tab in the Workbench screen to display the screen below.

By default, the organisation structure is not expanded and the Protocol value is blank.

Open the organisation structure to locate the cage of animals you wish to assign to a protocol.

Select the Protocol from the list.



Container	Current protocol
> 11	Oncology Research

Figure 84: Workbench – Assigning a cage to a protocol

Highlight the cage you wish to assign to the protocol and click on the arrow. This will add those animals to the selected protocol and update the animals total for that protocol.

Then press the Save button to commit this information to the system.

If the number of animals you are allocating to the protocol will take you over the maximum permitted animals on that protocol record, the system will tell you that you are over-committed and prevent the addition of those animals to that protocol.

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