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NON-TECHNICAL SUMMARY

Early safety assessment, investigatory and efficacy studies

Project duration

5 years 0 months

Project purpose

- (b) Translational or applied research with one of the following aims:
  - (i) Avoidance, prevention, diagnosis or treatment of disease, ill-health or abnormality, or their effects, in man, animals or plants
- (c) Development, manufacture or testing of the quality, effectiveness and safety of drugs, foodstuffs and feedstuffs or any other substances or products, with one of the following aims mentioned in paragraph (b)

Key words

safety, pharmacology, drug development, physiology, efficacy

Animal types	Life stages
Mice	Adult
Rats	Adult
Guinea pigs	Adult

Retrospective assessment

The Secretary of State has determined that a retrospective assessment of this licence is not required.

Objectives and benefits

Description of the projects objectives, for example the scientific unknowns or clinical or scientific needs it's addressing.

What's the aim of this project?

The aim of this project is to help pharmaceutical companies assess the effects of their potential new medicines on the heart, lungs, brain, kidneys, or the gastrointestinal system. The project will also allow pharmaceutical companies to test whether their new medicine works as intended.

Potential benefits likely to derive from the project, for example how science might be advanced or how humans, animals or the environment might benefit - these could be short-term benefits within the duration of the project or long-term benefits that accrue after the project has finished.

Why is it important to undertake this work?

This project aims to understand whether new candidate medicines have the potential to cause unwanted effects on major body organ systems and whether the medicines are working as intended (drug efficacy).

During early research phases, in vitro laboratory tests (e.g. cells in culture, biochemical assays) are used to check whether a new drug could be helpful in treating disease and to see if the drug may cause any side effects. Whilst helpful, these in vitro assays on their own can't replicate the complexity of the whole-body system. In a human or animal, a drug's effects might depend on interactions at multiple organ systems, e.g. via actions at the liver, kidney and heart or may depend on actions in the brain or via interactions with hormones. Such a multi-system environment cannot be captured in an in vitro test. Therefore, any potential drug that shows promise in early in vitro experiments must be subsequently tested in a living organism. Rodents have proved to be a useful model for humans and are preferable to using large animals such as dogs, monkeys or pigs at this early stage.

Under this licence new medicines (e.g. medicines to treat pulmonary fibrosis, Alzheimer's disease, hypertension, cirrhosis, kidney disease and obesity) will be tested in rodents with the aim of identifying undesirable effects on the heart, lungs, brain, kidneys, or the gastrointestinal system. Both early screening studies and investigational studies to determine mechanisms of observed effects will be performed. Studies to assess the potential drug efficacy of new medicines will also be conducted. These studies provide essential information to ensure that medicines entering clinical trials are safe and effective thereby protecting the health of clinical trial volunteers and patients.

What outputs do you think you will see at the end of this project?

The project will generate new information for pharmaceutical companies developing new medicines to treat human disease.

By testing their candidate medicines in small animals and examining the effects on organ systems, the companies will obtain important information on the drug's efficacy – is the drug doing to the body what it is designed to do such that it will be helpful in treating human disease?

The studies may also produce important information on the safety of the drug – does the drug have the potential to cause harmful side effects to humans? The drug may be benchmarked against competitor or existing drugs in these studies to compare safety profiles.

All study results will be provided to the companies in the form of a final report. These efficacy and safety outputs will be used by the companies developing the drugs to determine whether the drug should progress to the next phase and ultimately whether the drug should be tested in human clinical trials.

Publishing data on the results of our tests in the wider scientific community is often difficult whilst the drug is in development, but we will publish manuscripts where opportunities arise and will also publish manuscripts relating to the methods we use involving animals and any refinements we make which will be of benefit to the scientific community.

Occasionally, we will provide animals implanted with specialist telemetry devices for other UK companies to use for the assessment of the effects of potential new medicines on vital organ systems.

Who or what will benefit from these outputs, and how?

The companies developing the potential new medicine will benefit immediately from the data that we produce and submit to them in the final report. The data may help the company decide if the drug candidate is showing the desired effects and whether it is worth continuing with the development of the drug, whether improvements should be made or whether the whole project be terminated. An early decision based on this data can save the company a lot of wasted time and resource on developing unsuitable drugs and also avoid performing unnecessary later phase animal experiments.

The companies may also benefit in the short-term from the outputs of our safety studies. If no potential side effects are identified the company can progress the drug to the next phase of development with more confidence that doses will be tolerated by the study animals. If our studies identify potential side effects that could pose a risk to humans, this data can be used by the company to assess the risk of further development. This may lead to the continuation of the project but with a better idea of potential risk, deselection of the current drug and selection of a better candidate, or discontinuation of the project if there are inherent safety risks with the mechanism of action of the drug or class of chemical.

Progression of safer pharmaceuticals will reduce the severity and/or incidence of adverse effects in later stage regulatory preclinical animals studies and will contribute to the safety of clinical trials, reducing the chances of side effects in healthy volunteers and patients. It is expected that these benefits would be realised within the lifetime of this licence since most compounds tested would be preclinical candidates which, if successful, could be expected to progress into clinical trials within 2-4 years.

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How will you look to maximise the outputs of this work?

Outputs of the work will be delivered to the sponsoring companies as a report. Some of these reports will be used in regulatory submission documents for drugs that progress to human clinical trials. Where possible, we will publish data from the studies performed, in collaboration with companies, in high quality journals. There are often restrictions surrounding publications of live project compounds but opportunities for publication often exist once approval is granted or on data for compounds that do not proceed to clinical trials.

Any refinements that we make to our protocols and animal models will be presented at relevant scientific meetings and also disseminated by publication in a relevant journal so that others may learn from our experiences. We have a track-record of publishing our refinements.

Species and numbers of animals expected to be used

- Mice: 235
- Rats: 595
- Guinea pigs: 335

Predicted harms

Typical procedures done to animals, for example injections or surgical procedures, including duration of the experiment and number of procedures.

Explain why you are using these types of animals and your choice of life stages.

Rats are commonly used in drug safety studies because their major body systems are well understood and there is extensive knowledge about how they respond to different types of medicines.

Mice may be used if for some reason they are a more appropriate species than the rat, e.g. if their expression of a drug target is more similar to humans than rats. Genetically modified mice that carry the human version of certain receptors can be used when there are important differences between rodents and humans. These mice help researchers study medicines more reliably when the normal rodent receptor doesn’t behave the same way as the human one.

Guinea pigs are used preferentially for studies on the electrical activity of the heart as the expression of ion channels in the guinea pig heart is more representative of the human situation compared to rats and mice and it has been shown to be a predictive species for drug effects in humans. Guinea pigs are also a more appropriate species to use if the drug is suspected to cause effects on the airway (e.g. asthma medications) since the smooth muscle in the airway responds to stimuli in a way that is closer to humans than other small animal species.

Disease model animals may be used in some studies since they are bred to develop the specific condition without the requirement for surgery or drugs and provide a stable, reproducible and physiologically relevant model of the disease (e.g. spontaneously hypertensive rats as a model for high blood pressure, or diet-induced obese mice for obesity).

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Using a small animal model also means only a small amount of the test drug is needed, which is especially helpful to the companies in the early stages of drug development when drug synthesis is expensive.

Adult animals will generally be used since most drug tested will be for indications in adult humans.

Typically, what will be done to an animal used in your project?

Animals in this project may take part in studies performed under anaesthesia where they do not recover, studies where they are anaesthetised and then recover afterwards, or studies carried out while the animals are conscious.

Example - Terminal anaesthesia: Animals will be anaesthetised and cannulae (thin flexible tubes) implanted in blood vessels to measure blood pressures or for intravenous (i.v.) dosing of the test compounds or other substances. Cannulae may also be placed in the bladder or ureters to collect urine. Breathing may be measured using a small sensor that tracks airflow or movement on the skin. In some cases, an animal's breathing may be supported by a ventilator.

Researchers may also place small electrodes on the chest to record heart activity (ECG), on the head to record brain activity (an EEG), or place electrodes or strain gauges on parts of the digestive system to measure stomach and gut activity (an EGG) or muscle contractions. Following surgery, the animals will be allowed to stabilise and then one or more doses of the test drug will be given to assess its effects over time on the measured parameters. The animals remain anaesthetised for the whole experiment and recordings may be made for up to 4h (or very occasionally up to 7h), after which time the animal is humanely killed without regaining consciousness.

Example - Recovery anaesthesia: In some studies, animals are given anaesthesia and allowed to recover afterwards so that small monitoring devices can be surgically implanted. These devices allow researchers to measure important body functions, such as blood pressure, using a tiny tube placed in a major artery (such as the aorta, femoral, or carotid artery), electrical activity of the heart (ECG) using small leads placed under the skin or in the chest muscles, brain activity (EEG) using small electrodes attached to the skull, stomach and gut activity (EGG) using electrodes placed on the surface of the digestive organs (usually the stomach). The body of the implant device is usually secured within the abdomen or under the skin. Animals are monitored closely throughout and after the surgery and are given medication to minimise the pain that may be experienced afterwards. Once they have recovered from surgery (after approx. 2 weeks) they may be dosed (usually orally) with test pharmaceuticals and the effects on measured parameters over time is recorded remotely without having to disturb the animals. If a test drug needs to be given directly into a vein, or if multiple blood samples are needed over time, animals may undergo surgery under anaesthesia to place a small tube (cannula) into a vein. They recover from this procedure before the study continues. Animals may be used on a maximum of 6 studies (24 doses) and a recovery period of 2 weeks between studies is usually allowed.

Example - Conscious animal studies: To assess whether a test drug might be useful in treating a human disease, normal (non-implanted) animals are dosed with the drug for up to several weeks and general effects on the animals are measured (e.g. body weight, behaviour). In most studies, blood samples are taken from the animals at intervals to measure how much of the test drug is in the body and to measure other chemicals in the blood that may indicate whether the drug may have a beneficial

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effect on a disease. Usually, the blood is taken via a tail prick, or via an implanted cannula. Some studies in conscious animals may require collection of urine and will require the animal to be singly housed either in cages with water repelling sand or, when more quantitative data is required, temporarily in specialised cages that allow researchers to collect accurate volumes of urine. Typically, animals are housed in the metabolism cage for up to 6 hours but, when necessary, this may be extended to 24 hours.

What are the expected impacts and/or adverse effects for the animals during your project?

Some adverse effects may come from the dosing procedure itself. Animals may receive the drug by mouth or by injection, which requires brief restraint and may cause short lasting discomfort. Methods of restraint that minimise suffering of the animals will be used preferentially and animals will be habituated to handling. Small blood samples are also often needed to measure how much of the drug is in the body, or for other purposes, and are usually taken with a quick prick to the tail.

Some animal may experience adverse behavioural effects as a result of side effects caused by the test drugs. These include weight loss, piloerection (raised fur), hunched posture and subdued behaviour. When they occur, the adverse effects of the drugs will be expected to occur around the time of the maximum concentration in the blood and will be of short duration dissipating as the drug is cleared from the body. However, we do not expect to see many adverse side effects since the companies will usually have prior data from studies in live animals, in which they have explored the doses that can be given safely to animals. When there is no prior tolerability information, a pilot study will be performed under this licence in a small number of animals to assess the tolerability of the drug and possible adverse effects. This will ensure safe and relevant doses are administered to the animals in successive studies. To ensure the safety of a drug is thoroughly assessed it is usually necessary to dose the animals at the doses equivalent to the human dose and at doses above the normal human dose.

A small number of animals may need surgery to implant monitoring devices or tubes for i.v. injections or blood sampling. After surgery, animals may show mild discomfort or reduced activity for a few days, and some weight loss is common. Pain relief medicines are always given.

Some animals may need to be housed alone for short periods, for example after surgery (1-2 days), during certain monitoring studies, or when collecting urine samples. When this happens, animals are kept next to each other so they can still see other animals.

Expected severity categories and the proportion of animals in each category, per species.

What are the expected severities and the proportion of animals in each category (per animal type)?

Rats: Non-recovery: 50%; Moderate adverse effect 30%; Mild adverse effects 20%

Guinea Pigs: Non-recovery: 85%; Moderate adverse effects 15%

Mice: Non-recovery: 20%; Moderate adverse effects 30%; Mild adverse effects 50%

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The majority of animals used in this project will be used in non-recovery procedures only.

Approximately 30% of rats and 30% of mice and 15% of guinea pigs may experience moderate adverse effects due to surgical implantation of telemetry devices or vascular catheters. Mild adverse effects are likely to be experienced during dosing of test compounds and blood sampling although occasionally these could be moderate.

Examples of mild adverse effects include slight weight loss, partial piloerection (slight raised fur), transient hunched posture and subdued behaviour or transient discomfort due to dosing restraint or blood sampling. Examples of moderate adverse effects include more marked weight loss, marked piloerection (marked raised fur), intermittent hunched posture, subdued behaviour even when provoked, intermittent tremors (marked but not continuous).

What will happen to animals used in this project?

- Killed
- Used in other projects
- Kept alive at a licensed establishment for non-regulated purposes or possible reuse

Replacement

State what non-animal alternatives are available in this field, which alternatives you have considered and why they cannot be used for this purpose.

Why do you need to use animals to achieve the aim of your project?

Companies developing drugs will use non animal laboratory methods to make an early assessment of whether a drug works as intended and to assess its safety. However, in vitro assays, including cells in culture or microfluidic ‘organ on a chip’ devices can’t replicate the complexity of the whole-body system. Models that behave as closely as possible to humans or real human disease are required. Therefore, to understand if a potential new drug has the desired effect in the body or to investigate how it affects the function of vital organs, either directly or indirectly, it is still necessary to use a whole living animal in which all organ systems are present and their physiology is intact. This is in accordance with international regulatory guidelines that specify that before human clinical trials, safety data should be generated in two animal species, one of which must be a rodent.

Which non-animal alternatives did you consider for use in this project?

The replacement checklist was used (April 2025) to assess whether non-animal alternatives could be used for this project. Search terms included: 'NAMS', 'organ on a chip', 'animal alternative', 'hiPSC-CM','iPSC-CM', 'organoid', 'cardiovascular', 'safety pharmacology' and 'toxicology' in various combinations. Some options exist and these in vitro/ex vivo assays are already being used to select the compounds that will be tested in animals in this licence as part of the usual screening cascade that occurs in the early stages of drug development. Non-animal alternatives such as these have already reduced the demand for some of the projects conducted under this licence. For example, tests on

heart cells grown in the lab allow drug development companies to screen for possible heart rhythm problems without using animals. Some selection between candidate drugs can now usually be made based on these in vitro results, rather based on in vivo data from multiple studies, and often only the final selected compounds are tested in animals. These in vitro data will be used alongside any in vivo data generated under this licence to form an integrated risk assessment used ultimately to minimise the risk to volunteers and patients in clinical trials.

Why were they not suitable?

In vitro/ex vivo assays, including stem cell derived assays, organs on a chip and organoids are useful in the screening and selection process of pharmaceutical development and can provide information about potential direct effects of a test substance on an organ system. Some of this in vitro data can also be used to feed in-silico models which can be used to predict effects in humans. However, they cannot yet replicate the complexity of the intact animal or human, lacking the interrelated organ systems and regulatory mechanisms (hormonal and nervous system) that control the organs and the effects of a drug are therefore often different in vitro versus in the whole animal or human situation. For a thorough assessment of the effect of a drug on vital organ function, non-animal alternatives, whilst useful, must still be followed-up by testing in an intact animal. Studies in non-protected species such as fruit flies and nematodes are not appropriate because of marked differences in organ systems and metabolism compared to humans.

Reduction

Explain how the numbers of animals for this project were determined. Describe steps that have been taken to reduce animal numbers, and principles used to design studies. Describe practices that are used throughout the project to minimise numbers consistent with scientific objectives, if any. These may include e.g. pilot studies, computer modelling, sharing of tissue and reuse.

How have you estimated the numbers of animals you will use?

As a Contract Research Organisation, the number of animals used will primarily be based on the number of studies performed for Sponsors. The estimates are based on actual numbers used in previous years on similar project licences.

We know from our historical data and ongoing collaboration with our statistical partner that for anaesthetised non-recovery studies and conscious telemetry studies a group size of n=4-6 is sufficient for detecting clinically relevant changes in physiological parameters. For tolerability studies and sampling studies (for drug blood concentrations) smaller groups sizes of n=2-3 are usually sufficient. Efficacy studies can produce more variable data and larger group sizes of n=8-10 are required.

What steps did you take during the experimental design phase to reduce the number of animals being used in this project?

Study directors working under this licence have extensive experience of designing these study types and aim to use the minimum number of animals that allows the study to reach its objective. We also

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have an ongoing collaboration with statisticians in a partner company who perform statistical health checks and advise on the design of the study, the number of animals per group, randomization and the method of statistical analysis.

Prior data analysed by our partner, and in preparation for publication, has shown that test substance effects on physiological parameters can be detected with acceptable sensitivity in small groups of animals (n=4-6) in non-recovery studies. Increasing the group size to n=8 improves the sensitivity of detection only marginally. The good sensitivity with small group sizes is likely to be due to the fact that the measurement of safety endpoints and efficacy biomarkers is conducted under terminal anaesthesia which may reduce the variability. We will continue to utilise this technique so that animal numbers are reduced.

Our previously published data has also shown that small drug-induced effects on physiological parameters can be detected with acceptable sensitivity in conscious animals using telemetry with a group size of n=4-6. Again, increasing the group size to n=8 has only marginal benefits in terms of the power of detection. We routinely use optimal data summarising techniques (e.g. superintervals) in conscious animal studies which contributes to the good sensitivity.

What measures, apart from good experimental design, will you use to optimise the number of animals you plan to use in your project?

All studies will be designed to maximise the amount of useful data obtained using from each animal. Pilot studies will also be used where necessary to ensure that safe and optimal doses are selected for the main studies. This will prevent studies having to be repeated, and animals used unnecessarily, due to poor dose selection.

Assessment of the safety of a test drug usually requires a dose-response to be investigated (at therapeutic levels and above). In non-recovery studies and conscious animal studies multiple doses of test drug will be tested in the same animal where possible rather than using separate animals for each dose. In conscious studies this will be achieved by using cross-over designs and appropriate washout periods between doses.

It may be possible in some studies to incorporate physiological endpoints from multiple organ systems into the same study, potentially negating the need for separate studies. E.g, cardiovascular and respiratory endpoints in a single terminally anaesthetised study; cardiovascular and EEG recordings in a single conscious telemetry study.

Animals implanted with telemetry devices or animals used for blood sampling may may be re-used in more than one regulated procedure. This reduces the total number of animal undergoing implantation surgery and reduces the total number of animals used. Prior to being re-used animals are checked to ensure recovery from prior procedures and their cumulative suffering is assessed.

Blood sampling may also be included alongside the safety assessment, especially in non-recovery studies, to allow the effects of test drugs to be correlated to the concentration of drug in the blood/plasma. This may make separate blood sampling studies unnecessary. Samples of tissues or body fluids taken at the end of the study may be frozen and stored for further analysis.

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In some non-recovery studies, it may be possible to obtain efficacy data alongside safety data in a single study

Refinement

Give examples of the specific measures (e.g., increased monitoring, post-operative care, pain management, training of animals) to be taken, in relation to the procedures, to minimise welfare costs (harms) to the animals. Describe the mechanisms in place to take up emerging refinement techniques during the lifetime of the project.

Which animal models and methods will you use during this project? Explain why these models and methods cause the least pain, suffering, distress, or lasting harm to the animals.

The majority of animal procedures used in this project will be performed under non-recovery terminal anaesthesia. This is the default model and will be used where possible since the use of terminal anaesthesia minimises pain, suffering and distress to the animals.

There are situations where studies in anaesthetised animals are not possible, e.g. if drug effects are expected to occur over a longer time period than can be measured under anaesthesia, if drug effects are expected to occur after repeated dosing or if the drug has to be administered orally. In such circumstances, a conscious animal method is used.

Telemetry is the gold-standard method for assessment of drug-induced changes in cardiovascular parameters and the electroencephalogram (brain activity) in conscious freely-moving animals. Telemetry has also been used in rodents to monitor the electrogastrogram (stomach activity). These techniques allow the assessment of drug effects in an unperturbed physiological system and allow effects of drugs to be measured over longer time periods.

Animals may also be dosed to assess the concentration of test drug in the blood/plasma or to assess the effects of test drugs on blood biochemical and clinical pathology parameters, hormone levels or specific markers in safety or efficacy studies. In most cases this will be performed in conscious animals since the samples need to be taken over longer periods of time than possible in an anaesthetised study. The number of blood samples and the volume of blood taken will be minimised by using a micro sampling technique, where possible, which also minimises the distress and restraint required.

When dosing in conscious animals is required, information about the tolerability of the test drug will usually already exist and doses will be selected accordingly. Where prior tolerability data is absent, a pilot study will be performed ahead of the main study in separate groups of animals using an ascending dose design. Suffering of the animals will be minimised by using a small group size for assessing each dose (usually n=2) and using small dose escalations, escalating only if the previous dose was tolerated. The results of this study will enable confident setting of tolerated doses for the main study which will minimise suffering of the larger group of main study animals.

Most drugs are administered orally but if they need to be administered intravenously to conscious animals, it will usually be more appropriate to surgically implant a venous cannula for dosing (approx.

10% of telemetry studies). An implanted intravenous catheter may also be used when repeated blood samples are required (e.g. >6), at short intervals as it will cause less suffering than repeated needle punctures (as described above).

Animals that are kept for re-use will be maintained in good physiological state by allowing them access to socialisation pens or cages.

Why can't you use animals that are less sentient?

This project requires that the models used are ones which closely mirror human physiology. Adult rodents are used standardly for the assessment of safety or efficacy of new medicines according to international regulatory guideline since their major organ systems (e.g. heart, lungs, brain and central nervous system) are well characterised and similar to humans. Less sentient invertebrates, such as fruit flies or nematodes, exhibit more differences in physiology compared to humans and are less likely to predict the potential effects of a test drug in humans. The majority of studies performed under this licence will however be conducted under terminal anaesthesia preventing an animal's perception of pain.

How will you refine the procedures you're using to minimise the welfare costs (harms) for the animals?

Procedures will be conducted under non-recovery anaesthesia where possible, minimising harms to the animals.

Animals will be group housed as standard and provided with specific materials to provide enrichment. Rats are housed in large two tier cages, guinea pigs in open floor pens, and mice in standard ventilated cages. We also have a socialisation programme in place where rats are housed in larger groups in a multi-storey playpen for periods of time. This will be utilised for animals that are kept for longer periods of time (e.g. re-used telemetry animals). Any periods of restraint or single housing required during a study will be kept to the minimum required to achieve the study objectives.

Doses that cause some adverse effects may be required to be given to animals so that a full dose response safety profile is explored. In all studies, adverse effects experienced by the animal and the number of animals per group will be kept to the minimum to achieve the objectives. Where animals receive multiple doses of a test medicine, sufficient recovery time will be allowed between successive doses. Dosing will be conducted by trained licencees and flexible oral dosing catheters will be the default catheter that is used for any oral dosing.

Capillary microsampling will be used preferentially in all studies when blood samples are required. This technique reduces animal suffering since the volume of blood collected per sample (usually approx 20-30uL) is smaller than standard samples and the collection process is more rapid and requires less animal restraint. Sampling in mice and rats can usually be performed by one person with the animal being supported in one arm. Guinea pigs usually require a handler to provide adequate support and a sampler. When repeated blood samples are required (e.g. >6), at short intervals, it will usually be more appropriate to implant a venous cannula for blood sampling rather than repeated needle punctures.

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Appropriate anaesthetics and analgesics will be used during and after any recovery surgical procedures required. Peri- and post-operative monitoring is performed closely using a detailed score sheet immediately after surgery for 3-5h with additional checks as required. Enhanced welfare checks with pain scoring are performed for a week after surgery followed by standard daily welfare checks. Animals are expected to make a rapid and uneventful recovery from surgical implantation of telemetry devices. Animals will be humanely killed in the event of any unexpected post-surgical complications that cannot be easily remedied using only minor interventions.

Cumulative harms will be assessed continuously and controlled through study design, welfare monitoring, application of refinements and use of predefined humane endpoints to ensure that overall suffering is minimised and remains within authorised limits.

What published best practice guidance will you follow to ensure experiments are conducted in the most refined way?

We follow the advice of the NC3Rs and Procedures with Care website for dosing and blood sampling

https://researchanimaltraining.com/article-categories/procedures-with-care/

https://nc3rs.org.uk/

Dose volumes will be used according to standard published guidelines (Morton et al., 2001)

Standard published guidelines will be followed for blood volume removal (NC3Rs website) and capillary microsampling will be the default method used.

PREPARE guidelines are followed when planning studies and ARRIVE guidelines are followed when publishing data.

https://norecopa.no/prepare/

https://arriveguidelines.org/arrive-guidelines

Morton DB, Jennings M, Buckwell A, Ewbank R, Godfrey C, Holgate B, Inglis I, James R, Page C, Sharman I, Verschoyle R, Westall L, Wilson AB; Joint Working Group on Refinement. Refining procedures for the administration of substances. Report of the BVAAWF/FRAME/RSPCA/UFAW Joint Working Group on Refinement. British Veterinary Association Animal Welfare Foundation/Fund for the Replacement of Animals in Medical Experiments/Royal Society for the Prevention of Cruelty to Animals/Universities Federation for Animal Welfare. Lab Anim. 2001 Jan;35(1):1-41[I.

How will you stay informed about advances in the 3Rs, and implement these advances effectively, during the project?

We receive updates from the NC3Rs and read animal science journals (IAT Journal, Laboratory Animals) which are good sources of useful information on animal welfare. We implement any appropriate changes to methodology that will have positive impact on the animals' welfare. We will also liaise with the establishment 3Rs manager to keep informed of local advances.

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We also strive to continually improve the welfare of animals by making refinements in our facility and publishing outcomes. Examples under a previous licence include publishing our outcomes in rodent telemetry and vascular access button surgery and the use of a rodent socialisation cage.

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