RESOURCE SHEET NUMBER 6 –
NEW APPROACH METHODOLOGIES/NON-ANIMAL METHODS (NAMS)

NAMs are human-specific techniques that represent superior science. They are designed to provide results that are much more human relevant. They are not hampered by the non-predicative translation of one species to another. Game changing examples are organ-on-a-chip/micro-physiological systems technology and micro-dosing. NAMs are not a choice between an animal life or a human loved one, they provide an opportunity to use superior, cutting-edge new approaches that are specific to humans making them more accurate.

NAMs are available right now, for example, a liver on a chip has 87% accuracy for human toxicity. Compare this with 92% - 96% of drugs being abandoned at human trial stage. Half of those failures are due to unanticipated human toxicity and most of the rest are due to efficacy reasons not identified in non-predicative animal models. It is obvious we need to modernise our methods to accelerate new drugs to market and save effective medicine from being discarded that could save many human lives.

Conversely, adverse drug reactions kill thousands of people in the UK and costs NHS England billions each year. Tests on human cells and tissues can predict dangerous drug side effects where animal tests and even human trials fail.

The Government claims that the Animals in Scientific Procedures Act (ASPA 1986, revised 2012) protects animals used for science. ASPA states 'the principle of replacement is the principle that, wherever possible, a ***scientifically satisfactory*** method or testing strategy not entailing the use of protected animals must be used instead of a regulated procedure.' Further, the Government repeatedly states that animals are only used as a last resort principle and that their use is only permitted where no alternative exists. We know this is simply not the case. In practice a 'scientifically satisfactory' method is interpreted as one that has undergone regulatory approval and validation, thus creating an additional layer of compliance that is not explicitly required by the legislation. UK Law is routinely overridden by a global Regulator expectation. ***Animal use has never been validated/approved, and is certainly not scientifically satisfactory.***

In terms of chemicals the UK's scientific leaders are in broad agreement with a NAMs roadmap for chemical safety, however engagement from the policy and regulatory government departments is lacking and needs to be stepped up for a UK REACH.

It is currently scientifically satisfactory to replace and/or abandon ALL animal research immediately. Not only are there current NAMs replacements, but there is also the complete opposite, research that involves human volunteers, within a rigorous ethical framework ensuring the safeguarding of participants.

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Independent NAMs specialist committee and Project Licences (PPL)
At no stage from project conception by the animal researcher to Animal Welfare Ethical Review Body (AWERB) to the Home Office Inspectors or purely administrative, tick box, new ASRU licencing team are PPLs reviewed by a NAMs specialist. There is no requirement to provide evidence that replacement options have been thoroughly investigated. Instead, a view can simply be stated that the research outcome requires animal use. Even if Inspectors are consulted, most, if not all, come from an animal research background and thus are biased from the outset. Inevitably animal procedures will be approved where non-animal methods do exist. The last PPL application to be rejected was one in 2012, data is not held prior to 2011.

For our first Parliamentary debate in Jan 23 we proposed that the Home Office adds an advisory independent committee, comprising of specialists in various NAMs, as a step in the pathway to review PPL applications prior to the granting of Home Office approval. For every proposed, and actual, use of animals - given the time to pull evidence together - they could demonstrate that (a) the odds of the findings in animals being sufficiently and reliably human relevant are slim, and (b) that using human-specific methods would give more reliable, robust results. With the exception of s24 ASPA, this would require no change in existing legislation. If the government had a genuine commitment to making the UK a centre of excellence for science, this simple adjustment could put us right at the forefront of disease research allowing multiple drugs that do not make it past animal use to be accurately assessed for the human system and to make a difference to the patients that need them.

If the government is serious about moving on from, and avoiding, animal use in science, and using NAMs superior science, they would facilitate this. NAMs Specialists are ready to give their time voluntarily.

Here at Camp Beagle we do not claim to be scientists but we do have access to talk to the top NAMS specialists in the world, including one of the most respected NAMs toxicologists. We are incredibly grateful that these people take time out of their busy schedules to keep us focused on fact rather than fiction.

Often you will hear the time for change is not now as we need a replacement for a whole biological system. Yet the National Centre of 3Rs (NCR3s) are funding development of a virtual dog to predict human toxicity – there are huge amounts of data of toxic effects on dogs but they have a different biological system to humans, it’s just not translatable.

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Some examples of NAMs are:

Organoids
Organoids are cultures of stem cells capable of differentiating and spontaneously self-organizing into small 3D structures that mimic, to an extent, organs. Heart, lung, and other organoids offer screening platforms for drugs, as well as mechanistic insights. Researchers at the Center for Alternatives to Animal Testing at the Johns Hopkins Bloomberg School of Public Health have created brain organoids for studying neurodegenerative disease, electrophysiology, and even intelligence.

Organ on a chip
These microfluidic devices contain tiny channels lined with living cells and are designed to reflect the architecture and physiology of an organ. This involves capturing the basic elements required for biological activity, including various cell types, structures, and microenvironments, and recreating them in a matrix. By stringing organ-on-a-chips together in a biologically relevant fashion, researchers can create multi-organ systems or even a human-on-a-chip. Such efforts recently resulted in the first FDA (USA) approval of human trials for a drug candidate without preclinical animal efficacy data.

Human tissue
Studies on tissue derived from volunteers and surgical procedures offer opportunities to evaluate therapeutic interventions on accurate models of the disease. For example, researchers studying vitiligo, an autoimmune skin disorder, can directly assess how a potential intervention impacts autoimmune processes in skin tissue derived from people with vitiligo. Such experiments generate data that promote a level of precision medicine unattainable using animal models.

Phase 0 clinical trials
In Phase 0 trials, study participants are given sub-therapeutic levels of an investigational drug, followed by tests to identify changes in physiology. Despite the low dosage, data concerning potential toxicity and efficacy may be derived.

Digital Twins AI
The application of machine learning methods takes advantage of enormous amounts of data from patient records and previous clinical trials to generate predictive models of patient response to an intervention. In the future treatments will be personalised as even individuals of the human species react differently.

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In the UK organisations like Animal Free Research UK , FRAME and others fund NAMs development. Government funding is given to the National Centre of the 3Rs, this money is not we believe spent effectively – replacement could even be just one species to another.

https://www.animalfreeresearchuk.org/

https://frame.org.uk/

https://www.peta.org.uk/issues/animals-not-experiment-on/non-animal-research-methods/

https://animalfree-research.org/en/for-researchers/databases/