Why are non-rodents not socially housed during cardiovascular telemetry recordings on safety pharmacology studies?

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Introduction

- Cardiovascular assessment of new chemical entities in a non-rodent species - most commonly dogs, minipigs or non-human primates (NHP) - is a regulatory requirement prior to first administration in humans, frequently performed *via* telemetry recordings.
- Although test animals are commonly socially housed before and in between recording sessions, a 2015 survey by the NC3Rs and SPS confirmed that the majority were individually housed during cardiovascular recordings[1].
- Since this time, wider availability of technologies that transmit on different frequencies (allowing recordings from multiple animals simultaneously) have addressed one of the major barriers for social housing identified previously.
- We have therefore conducted a new survey to track the implementation of this refinement and to investigate current concerns.

Data collection and demographics

- Data were collected using Survey Monkey. The survey was sent to one individual per organisation, identified with responsibilities for running or outsourcing safety pharmacology telemetry studies.
- Responses were received from 36 facilities worldwide (18 biopharmaceutical companies, 16 contract research organisations (CROs) and 2 consultants), with 50% of respondents from Europe and 42% of respondents from North America.
- In 2015, 33 facilities responded to the survey. 23 facilities responded to both the 2015 and 2017 surveys. Comparison of responses within individual facilities across 2015 and 2017 was not performed.

Results

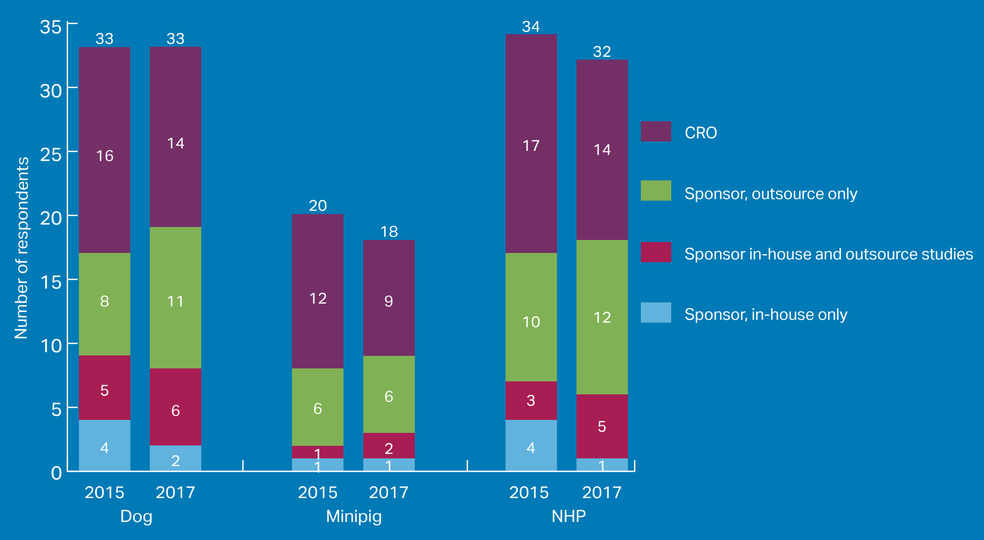


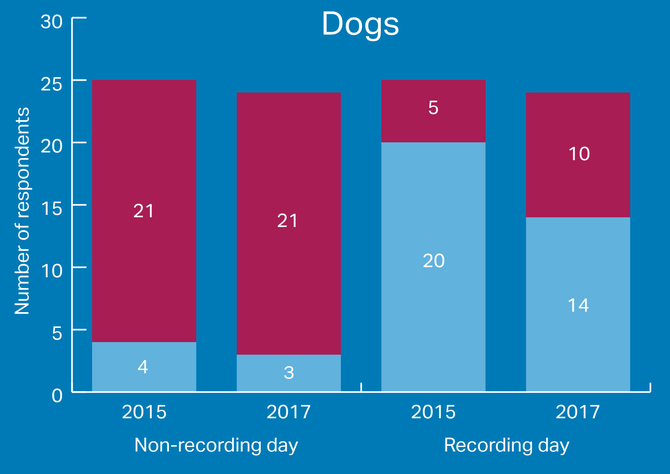
Figure 1: Number of respondents for each species in 2015 and 2017.

A similar number of responses were received for each species in 2015 and 2017.

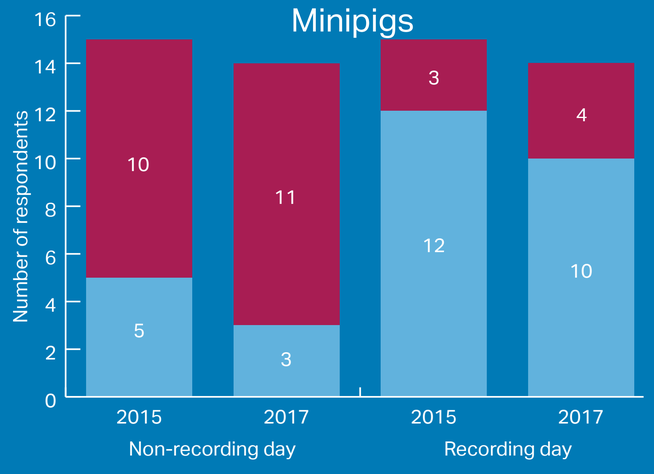
Fewer CRO responses were received in 2017.

There was a slight increase in the number of sponsors outsourcing studies in 2017 (although this may be a reflection of different contributing facilities for the two surveys).

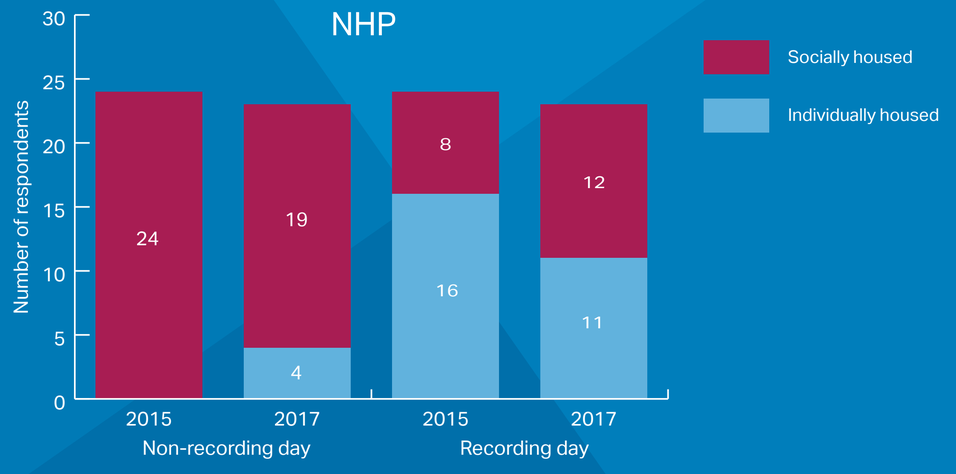
Figure 2: Housing conditions for dogs, minipigs and NHP on telemetry recording and non-recording days



In 2015, 20% of respondents socially housed their dogs during telemetry recordings. This increased to 42% in 2017.



In 2015, 20% of respondents socially housed their minipigs during telemetry recordings. This increased to 29% in 2017.



In 2015, 33% of respondents socially housed their minipigs during telemetry recordings. This increased to 52% in 2017.

Figure 3: The animals on socially housed studies:

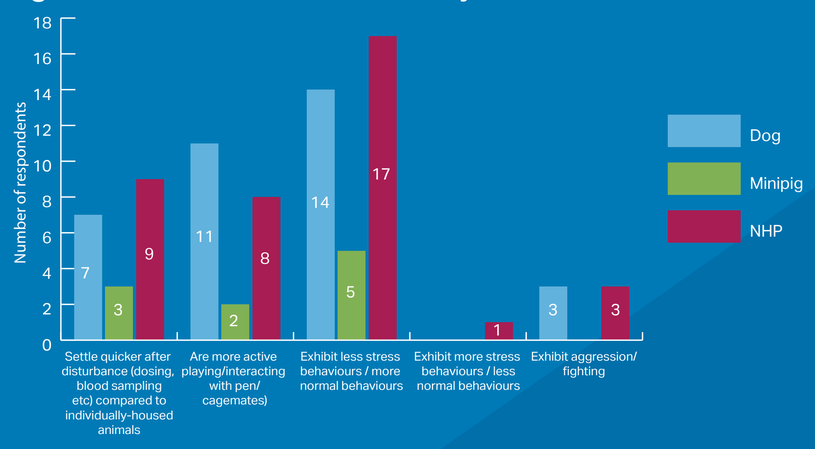


Figure 4: The data from socially housed animals is:

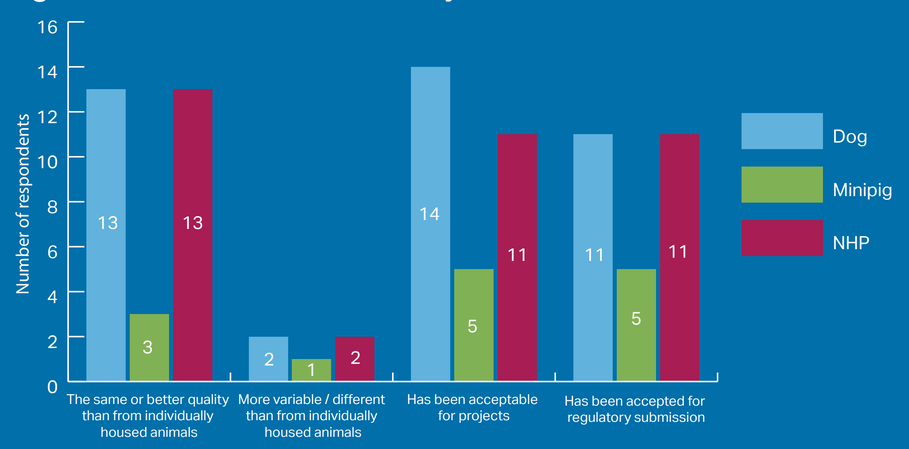
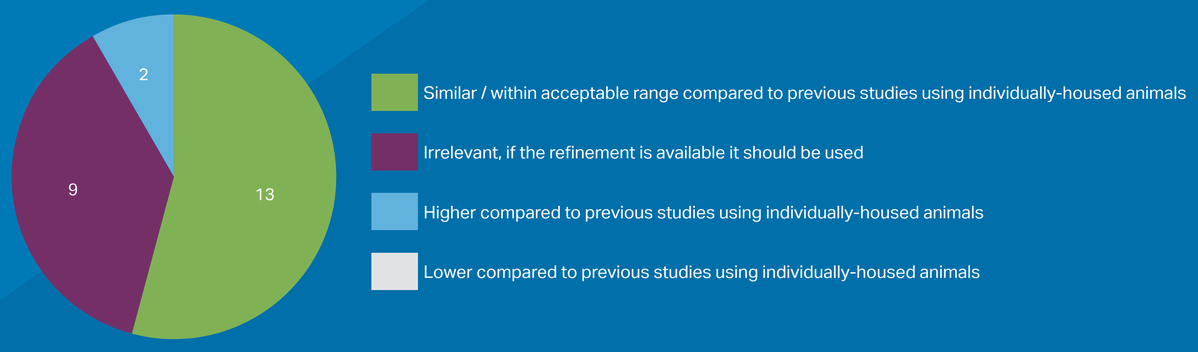


Figure 5: The financial cost of socially housed studies is:



3Rs Impact

Potential to refine the housing conditions of thousands of non-rodents during telemetry recordings within safety pharmacology studies worldwide.

Conclusions

- Many respondents have yet to upgrade to technologies allowing social housing during telemetry recordings.
- Continued concerns around study design, contamination risk and data sensitivity are highlighted.
- Companies with experience of social housing reported improvements in animal welfare indicators, similar or better quality data and similar study costs.
- Increasing the implementation of this refinement across the industry requires additional investment in infrastructure and hardware, combined with further discussions and sharing of best practice and data from companies already socially housing.

Reference

1. Prior *et al*. (2016) *J. Pharm. Tox. Meth.* 81:75-87