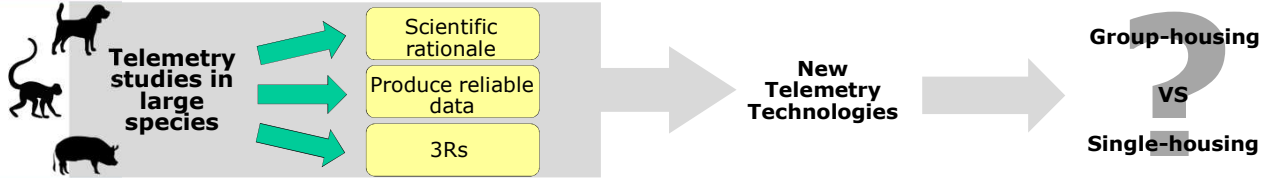


HOW NEW TELEMETRY TECHNOLOGIES AND STUDY DESIGNING CAN SUPPORT?

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INTRODUCTION



BENEFICIALS AND LIMITATIONS OF GROUP-HOUSING IN TELEMETRY STUDIES

Large animals group-housing installations equipped with HD video cameras



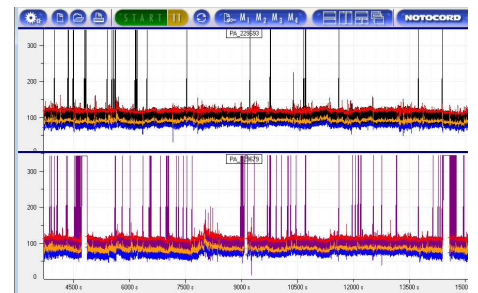
Prons (+)	Cons (-)
<ul style="list-style-type: none"> <li>Improved animal welfare</li> <li>Telemetry recording performed in daily housing conditions</li> <li>Multi-recording : 6 receivers (covering up to 12 animals)</li> <li>High quality signals, very little noise (no interferences between animals)</li> </ul>	<ul style="list-style-type: none"> <li>Incompatibility between animals = colony management</li> <li>Possible cross-contaminations</li> <li>Possible signal loss (minipig)</li> <li>Continuous IV infusion with jacket</li> </ul>

Examples of possible cross-contamination

- analytical contamination**
  - feces/urine contact or ingestion during elimination of the test compound
  - vomits/saliva (if test compound induces vomiting or hypersalivation after oral dosing)
  - automatic watering system
- behavioral contamination**
  - drug-induced behavioral changes impacting companion' behavior (e.g. hyperactivity, pain or distress)

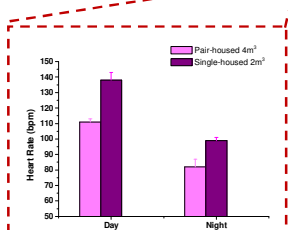
	Dog		NHP		Minipig	
CV Parameters	Single-housed	Pair-housed	Single-housed	Pair-housed	Single-housed	Pair-housed
MAP (mmHg)	100 ± 1	102 ± 3	92 ± 3	95 ± 4	104 ± 6	100 ± 8
HR (bpm)	74 ± 2	76 ± 3	138 ± 5	111 ± 2	79 ± 2	81 ± 18

(+) Positive impact of group-housed telemetry on baseline CV endpoints in NHP

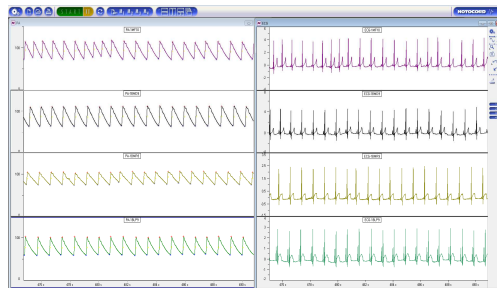


(-) signal loss during group-housed telemetry recording in minipigs (4 animals) due to animal behavior

(+) Group-housed telemetry did not impair the quality of signals



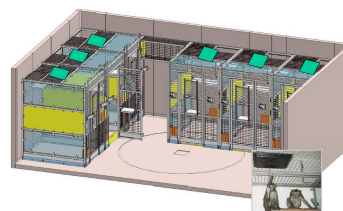
24% decreased in HR compared to single-housed



STUDY DESIGNING CAN COUNTERBALANCE LIMITATIONS OF GROUP-HOUSING

Management of implanted animal colony

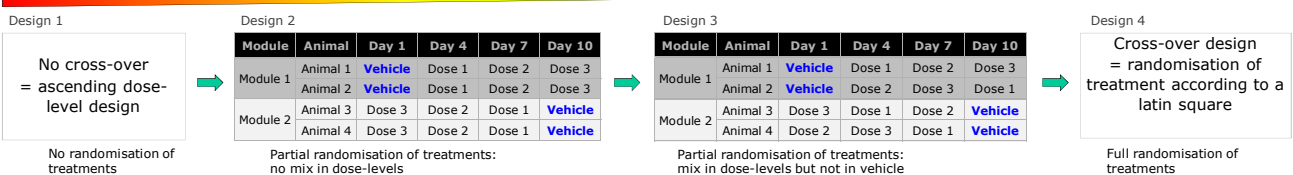
- Group size
  - pair-housing significantly decreases signal loss in minipigs
- Compatibility between animal's behavior
  - importance of habituation and training
  - no change between daily housing and housing during telemetry recording



Top view of a dog and primate daily housing and telemetry room showing 6 large modules with pair-housed animals

Randomization of treatments to address the risk of contaminations

Environmental impact



Cross-contamination risk

CONCLUSION

Telemetry studies should be designed according to (i) the scientific rationale and (ii) the data available regarding the test compound. The design of each study should be discussed upstream and the final design selected should take into consideration the following items:

- Group-housing: based on our experience, only a low number of studies really need to be performed in single-housing conditions
- Randomisation of treatments: in general, early pharmacology studies or dose range finding studies are performed in an ascending dose-level design to adapt the dose depending on the effects observed and cross-over designs (partial or complete) are used for regulatory Safety Pharmacology studies.