

# Evaluation of Digital Biomarkers in Nonclinical Research: Barriers to Information-Sharing



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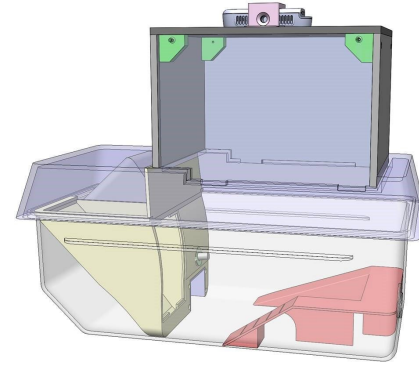
# Introduction/Hypothesis



- Behavior is the ultimate expression of health and welfare, but is rarely characterized in experimental animals because needed tools have been unavailable
- Artificial intelligence vision systems and machine learning now allow objective and *continuous* assessments of animal behavior before and after therapies or interventions through recognition of behavioral biomarkers
- Our productive collaboration with NIH scientists and sharing of large video files for algorithm development and validation is greatly limited by institutional network security rules and requirements

# Introduction/Hypothesis *(Continued)*

The White Oak Animal Program has innovated an assessment system for nocturnal rodents using depth cameras positioned above the cage on racks in the animal room



- Active collaboration for analysis and annotation currently requires computers or hard drives to be **physically transported** between the NIH and FDA campuses
- Currently there is no way to connect computers to one another's networks, nor an HHS interagency environment that would allow video storage, annotation and data-sharing

# Findings/Results



- FEDRAMP-approved cloud services would likely be prohibitively expensive for such projects
- Short-term storage of video for annotations and machine-learning could be handled on existing FDA or NIH servers, but currently, network access restricts access to only employees of one agency or the other
- Currently, a non-FDA computer for research cannot access the internet on the White Oak campus (no access to the guest network)
- Our collaboration with the NIH Institute of Biomedical Imaging and Bioengineering (NIBIB) does not require utilizing FDA's regulatory network nor use of computers that routinely access it

# Conclusion



- Collaboration and data-sharing on a separate (HHS) research network could safeguard FDA's regulatory network
- Data-sharing drop zones could facilitate enhanced collaboration between HHS agencies and mitigate cybersecurity threats if set up and managed appropriately
- Currently, FDA reviewer-scientists have few opportunities to perform data mining from images and video, and perform data assessments and biomarker algorithm development when it involves non-FDA collaborators and partners

# Thank you for your attention!

*Thanks also to*

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