THE NORTH AMERICAN 3Rs COLLABORATIVE

Participation in a New NA3RsC Workstream or Discussion Group

1. Workstream/Working Group Title	Translational Digital Biomarkers Hub
2. Name of group chair or co-chairs, if known	Szczepan Baran, Laura Schaevitz
3. NA3RsC Sponsor (if any)	Natalie Bratcher
4. Is this a strictly NA3RsC topic, or should other groups be invited?	NA3RsC only, for the time being
5. Relevant background: **Why is this work needed?** **Has any other group addressed it?** **Relevant publications, guidances?**	In vivo animal models provide valuable information to better understand human and animal diseases and to develop new medicines, devices and treatment modalities for disease. While the value of animal models in advancing science and medicine is well established, the scientific community is continually working to identify novel approaches that may lead to improved clinical translation and relevance of animal models. Furthermore, the scientific community is committed to the 3Rs (replacement, reduction, and refinement), which are rapidly evolving as a part of advancing optimal science and animal welfare. Emerging digital technologies increase the amount of information gained from both human and animal studies and offer unique opportunities and potential for scientific advancement. Intensive continuous monitoring in the animal's home environment enables measurement of spontaneous behavior and the ability to detect subtleties that may go unnoticed by clinical observations. These technologies may therefore improve in vivo study outcomes through improved detection methods that can be translated into valuable, actionable insights. However, the path to adoption of emerging technologies is not straightforward and digital biomarkers will likely face similar characterization, validation and regulatory challenges as traditional biomarkers. Although currently some individual institutions are working to solve these challenges, progress will be more efficient & beneficial through coordination between these institutions. Therefore, we propose a collaboration that will help to establish an improved understanding of the value of, and optimal implementation of digital biomarkers.

Commented [MRL1]: I don't see this addressed, I'm not sure if there's anything like this?

Commented [BNA2R1]: There are no relevant guidances that I'm aware of. Are there relevant publications that we want to include, or is the background sufficient for now?

Note: This scoping document is in draft form, with review comments included. Once the Working Group (WG) is formed, the WG will work together to finalize the document.

THE NORTH AMERICAN 3Rs COLLABORATIVE

6. Scope, focus, objectives of the group	The Translational Digital Biomarkers Hub will include early stage- and commercially available digital biomarker technologies and will engage end-users and those interested in learning more about how these technologies can be used to promote the 3Rs. The objectives for this hub are to: 1) showcase digital technologies & capabilities; 2) promote & support collaboration, sharing and opportunities for interactions within and between end-users (potential end-users); 3) create a data base by sharing summarized scientific data (precompetitive or blinded) collected from these technologies that can be used in practice to support data-driven refinements to animal welfare; 4) engage regulatory bodies (FDA & EMA) to identify a path for how to characterize and qualify digital biomarkers within the regulatory environment (i.e. path of acceptance of data from new technologies).
7. Target deliverables	1) Create a virtual knowledge exchange (on NA3RsC.org) where scientists and regulatory bodies can access information about translational digital biomarkers. – Provide a platform for presentation of non-infomercial information about technologies in static and live format. – Showcase publications using technologies and provide ongoing relevant updates. 2) Promote &, coordinate interactions and discussions among end-users (and potential end-users) of digital technologies to: – share learnings on: 1) how to onboard and engage with technologies, 2) how digital technologies are being evaluated, and 3) opportunities and needs to be shared with technology providers. – discuss and identify opportunities for evidence-based animal welfare refinements. – determine the ideal platform(s) for these discussions, provide infrastructure, solicit interested parties ways to promote collaboration between scientists and technology providers 3) Organize a digital biomarkers conference to bring technology providers and end-users together.
8. Type of expertise sought	• Scientists and stakeholders (including statisticians) interested in using translational digital biomarker technology for any purpose

Note: This scoping document is in draft form, with review comments included. Once the Working Group (WG) is formed, the WG will work together to finalize the document.

Commented [BNA3]: This will be done through deliverables 1 and 3 below.

Commented [BNA4]: What about adding the Guide for Animal Care and Use? What specifically would we include?

Commented [MRL5]: Would a good deliverable be to actually have a goal to develop a few documents related to this to post open-access on the website?

Some possibilities could include:
-A position statement on the use of translational digital biomarkers (?)
-A template for onboarding or SOPs (?)
-A review of current relevant publications that support this technology use
-A vision statement for an ideal technology development (related to the opportunities/needs)
-A case study of where this has been beneficial?

To me, I think it would be great to show not only that people are discussing these things, but they're actually producing content that can be useful to anyone even if they're not directly involved in the group.

Maybe this is too far ahead of where the technology is right now (and I'm still very new to all of this!), but I definitely think making it a goal to create 1-3 documents/downloads/statements would be great to help show impact.

And perhaps this falls under #1?

Commented [BNA6R5]: I agree that these would be great deliverables… I think a lot of this will depend on bandwidth of our members. Perhaps we prioritize deliverables and discuss feasibility once we have membership established and all stakeholders together to review?

Commented [BNA7]: Are there others we want to specifically include here? Data sciences?

THE NORTH AMERICAN 3Rs COLLABORATIVE

	This can include basic research, drug discovery and development, internal/regulatory decision makers and animal welfare evaluation • Technology providers interested in collaboration with scientists and stakeholders to facilitate new development and faster adoption of technology into the research market
9. Any restrictions on the number or role of members **If the size of the group is to be limited, enumerate the objective criteria that will be used for final selection.**	NA
10. Anticipated length of the project	Ongoing. 12 months – 5 years
11. Anticipated time commitment for members	Initially, members are anticipated to commit approximately 1 hour per month to teleconferences with end-users and quarterly teleconferences with technology providers. The frequency/duration of meetings will be revisited once membership is established. Outside of these scheduled meetings, members are expected to dedicate approximately 4-10 hours of work annually to this working group in some capacity (e.g., additional engagement, creating/reviewing deliverables, etc.).
12. What is needed for involvement?	– Name and contact information – CV, bio, or company descriptor – Statement of interest
13. Deadline for submitting nominations for involvement	March 25, 2020
14. Any other relevant information or requests	

Commented [BNA8]: Should there be a commitment for the technology providers to provide trial equipment/resources to the scientists for trials or validation? And for the scientists to commit time/resources to the tech providers to test the equipment in a reasonable amount of time?

Note: This scoping document is in draft form, with review comments included. Once the Working Group (WG) is formed, the WG will work together to finalize the document.