Subject: US Regulatory: FDA Engagement
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Dear All,

Earlier this week, we managed to get an opportunity to talk with FDA regarding the GBIRd program, and the ongoing developments and interest in the US Regulatory process.

We talked with a Sarah Bembe of the USDA, assigned to engage with the program. She has shared some news that the FDA is going to be the regulating agency, and that we should be working with her moving forward. Although we cautioned that this was exploratory call with FDA, and that we do not yet know of any confirmed mouse construct, Sarah felt that it might be wise to open the engagement with the FDA officially (an INAD file) if only to have a more open and effective dialogue.

As this was just an exploratory conversation to clarify process, we only offered the direction of the program, the various partners, and what we hope its use pattern (for conservation) in the future could look like.

We did explore the concept of the SPONSOR, and who might be best to take this on, and what the requirements, obligations, and liabilities may be associated with that responsibility (eg. $103K annual fees!). Of interest is that the SPONSOR has to be a legal entity (University/Company/Non-Profit) but NOT a US government agency (such as USDA).

We did talk about and did receive some guidance about the diversity of the data requirements, and she did share this link that highlights the process overall (some of you likely are aware of this already): (https://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM113903.pdf).

What appears to be most pressing at this time is to determine who should be/could be/wants to be the SPONSOR for this program as it moves forward. Regardless of who takes it, the most important element is that the entity can and has the ability, and willingness to take on the diversity of engagement, and diversity (lab and field) of studies that are necessary for the eventual approval/registration approval that will lead to a release in the field.

We should schedule a call (next week?) to discuss next steps and review this, and designate the sponsor.

May I suggest the following agenda:

1. Review of FDA call with Sarah Bembe (GH and RS).
2. Discussion of who should be/could be/will be the SPONSOR and advantages/disadvantages of each model.
3. Determine next steps for the SPONSOR identification.
4. Harmonization of the US regulatory with the Aus/NZ Regulatory

Gregg