Proficiency Testing Workgroup 3/31 and 4/14 Meetings Report

Presented at 4/16/2020 CSTF Steering Committee Meeting

Attendance

Ryan Zboralski, Ecology
Sara Sekerak, Ecology
Alyssa Peter, Ecology
Qingfen Gu, WSDA
Steve LaCroix, DOH
Nick Poolman, WSLCB
Bonnie Luntzel, Praxis
Jay Burns, Treeline Analytics
Steve Loague, Integrity Labs
Kyle Shelton, Medicine Creek Analytics

3/31 Meeting

Old Business

Ryan initiated the meeting with going over the 3-27 Steering Committee meeting, particularly their reaction to our desire to expand our data mining to all cannabis labs in the state. He mentioned there was no Objection so he mentioned that after the meeting he would draft an email for distribution and then circulate that to the group for review before sending to all the labs. After that, his next update was on his communications with the other states and Canada regarding Cannabis PTs. Unfortunately, due to the COVID-19 situation, these communications have effectively ceased.

Study Size, Field of Testing and PT Frequency

The next item for discussion the discussion of how to handle the limited study size of the in-state model. Nick mentioned that the size of the study is not as critical if there is a reference lab used to determine the true value. However, if the "true value" of the study uses a group average response, (as eluded to in Ty's presentation due to the unknown concentration of the starting material) of the study, there would be a minimum. In his presentation, Ty mentioned that seven was his minimum. Sara and Jay agreed that this is likely not an in the long term. If a single in-matrix provider is present, it is likely that the accrediting body would require labs to participate. The minimum participation question only would be an issue if there were multiple providers within the state.

The next item on the agenda was the field of testing that the in-state model should consist of. The group agreed that making a more concrete decision on this was dependent on the results from our data mining spreadsheet. Distribution of the spreadsheet to all cannabis laboratories within the state took place on 4/1/2020. Although participation is optional, the group is hopeful that most labs will participate by the deadline of 4/14/2020. Even with the pending results of the study, Kyle mentioned that the study should have as many in-matrix options as possible. In his experience, hemp flower (substituted for THC-dominant cannabis flower) and oil (substituted for other THC-containing extracts) do not accurately represent samples that the laboratory actually test. This prompted a question from Ryan: When a lab is participating in a PT that is covering multiple fields of testing is a lab receiving several small quantities of PT material, (one for each test), or one large lot that is divided up for all the fields of testing? Jay

mentioned it is currently the former of the two options. Jay followed up by saying he would hope in the future the second option would be the case.

Another critical piece to the in-state model is the frequency that the PT study occurs. Ryan asked the labs what their current schedule was, and what LCB/RJ Lee required. Nick said that labs LCB requires labs to have PTs done 6 months prior to their audit. Kyle mentioned that Medicine Creek tends to lump their PTs in short-succession of one another in order to minimize the impact on standard production. Steve Loague mentioned that his lab cannot afford to do this model and sprinkles their PTs throughout the year. He followed up mentioning that Cannabis PTs are unreasonable expensive; roughly 2-3 times more expensive than environmental PTs. Kyle agreed, but added that if costs come down staggering might not be required.

Trial Study and Survey

Jay brought up the idea of a Trial Run of the in-state model with Ty Garber of Phenova. This would allow the PT Workgroup, and Taskforce as a whole, to get a real idea of what the challenges in implementing a permanent model would be. Ryan mentioned pushing out a survey to all labs gauging interest would be critical in maximizing involvement. All members agreed if we went down this route, the Steering Committee would need to approve (both of the survey and the trial study). Steve Loague mentioned an approximate price of the study would be critical to know prior to sending the survey out. Ryan said he would reach out to Ty, but that the team should start constructing the Survey now to gauge interest as well as gather answers to other questions the workgroup has. The questions the workgroup agreed upon are:

1. Is your lab currently staggering PT analyses or batching them together?
    a. Staggering
    b. Batching
    c. Comment box
2. How many PT fields of testing do you perform within a year?
3. Have you ever participated in a PT study for the same field of testing over multiple matrices?
    a. Comment Box: If yes, which fields of testing and matrices?
    b. No
4. In order to streamline, and reduce the cost, of a PT program, which of the following cost ranges most closely represents your current annual expenditures on PTs?
    a. $3,500 and below
    b. $3,501 to $5,000
    c. $5,001 and above
5. Would you be interested in participating in a trial study of a Potency PT in a THC-dominant Cannabis flower?
    a. Yes
    b. If no, why not

After finalizing the questions for the survey, Ryan asked each non-ecology member of the work group what their Objectives would be for this trial study. Identifying these objectives would help the Workgroup and Taskforce decide if the trial was a success and worth repeating. The group did not have any disagreements on the following objectives:

- cost and distribution to the labs
- Licensing challenges
- PT is truly in-matrix
- Areas for increased efficiency
- Sourcing challenges
- Provide evidence in order to achieve buy-in from labs that are not represented on the workgroup or taskforce
- The PT provider's capability of providing what the workgroup and taskforce want

After identifying these objectives. The group agreed that feedback from the participating labs was critical in the review of the study. Bonnie mentioned that Praxis has a "Vendor Validation Checklist" that they use internally that would be a great place to start. She has added the document to Box for the group to view. This checklist will be adapted at our next meeting to suit this study. The group agreed to distribute this checklist to the participating labs one month after close of the study.

The location that will host Ty is also a very critical piece. The best location would be the Department of Agriculture's lab in Yakima since they have the needed equipment and SOPs. They also would be free of a possible conflict of interest. Ryan told the group he would start a project proposal document and add it to box in order for the team to collaborate on it.

4/14 Meeting

Data Mining Discussion

The meeting kicked off with a review of the results to the data mining exercise from last meeting. Ryan mentioned that the Master spreadsheet has lab names omitted in order to give individual labs anonymity. Five laboratories participated, yielding results that both confirmed some of the group's suspicions, and disproved some others. Having this data available to us will allow us to have a sanity check when it comes to our recommendations to the legislature. Although the group wishes a larger portion of the laboratories participated, we respect the reasons from the other labs for not participating. The spreadsheet will live on Box for the group to see and Ryan will update it if further data comes in.

Trial Study Location Concerns

Next up for discussion was the furthering of the discussion on the location of both the trial study and future study. Since Ty Garber of Phenova is currently the only provider of a true in-matrix PT model we are working on, he has been a resource for us to how the model functions in other states and Canada. Ty clarified that for Oregon he does NOT use the ORELAP lab, but one of the participating labs to create his PT material. Ty transfers custody to ORELAP once he is completed and then ORELAP handles the distribution and long-term storage of excess/back-up material. Ryan apologized for misleading the group in prior meeting about the relationship between Ty and ORELAP.

This prompted a question to the group, "Do the lab representatives have concerns with having Ty (or another PT provider utilizing this model) being hosted at a lab participating in the study?" Ryan emphasized that this was not the primary choice but it could be a possible outcome if unable to utilize a

neutral site. The group was in consensus that for the trial run, utilization of a participating lab was acceptable if no other option was available. However, all the labs had varying positions on location. All agreed the optics were bad, but not all were against the idea. Jay was most against a participating lab hosting Ty due to a combination of bad optics and possibilities for labs that fail to accuse the host lab of interfering or receiving preferential treatment. Bonnie agreed with Jay's concerns, but mentioned she would be willing to consider hearing what Ty has done in Oregon to quell similar concerns, and making a decision at that point. Kyle agreed with Jays concerns, but did not object if there was no other option. Steve League had no concerns about a conflict of interest and believed we should do what is most convenient for Ty, or whomever is serving his function. The group still wishes that the Department of Agriculture laboratory in Yakima, or some other neutral site, generates the PT material (or hosts whomever is generating the material).

Grading Sheet Construction

In order for the Trial run of the in-state PT model to work, a way to assess this study is required. Ryan reminded the group that this trial study is as a 'Proof of Concept'. The laboratories are not going to have the results of the study count for, or against them in accreditation. Although the cannabinoid results are important, they are not the primary objective of this trial; the primary objective is to ensure the success of this model prior to the use of it for accreditation. As an example: we do not want to find out on the first study that the workgroup's recommendations in regards to transportation of material were insufficient to preserve the integrity of the study; thus invalidating the study.

Stating with Praxis' "Vendor Validation Checklist" provided by Bonnie, the group went through each of the parameters and decided if it should remain, modify, or removed.

Before:

1	Quality of Supplies/services
2	Pricing
3	After Sale Service and Support
4	Delivery Times
5	Responsiveness to Inquiries
6	Compliance with ISO
7	Terms of Invoices
8	Professionalism

After:

Quality of Supplies
Quality of Services
Pricing
Responsiveness to Inquiries
Delivery Times
Terms of Invoices
Professionalism

Scoring of each item is on a scale of importance ranging from Not Important (0) to Very Important (2), as well as a non-applicable option. Each item also has a 5-tiered grading system of the result ranging from Unacceptable (1) to Excellent (5). An average score of the seven parameters will also be available at the bottom of the grade sheet. The group also added a comment box at the bottom where the person filling out the grading sheets can make comments that might be necessary to explain grades. When the distribution of the grading sheet takes place, a note will be included saying that the person serving as the point of contact for the labs in regard to the grading, may follow-up in regards to the scores. However, the labs will remain anonymous to the remainder of the workgroup.

Three items arose during work on this grade sheet. First, the workgroup noted that if other entities are involved in carrying out the trial (such as a 3rd party courier), they would need to also be graded. Second, the workgroup wanted to allow the steering committee to see this grade sheet and have the opportunity to add any input they have. Last, the involved agencies would likely need a second similar, yet separate, grading sheet to evaluate the study.

Licensing challenges

Nick mentioned that one of the most critical pieces to this trial study is the licensing challenges. Since whoever is conducting the study is technically selling marijuana, they are required to have a license. Nick listed all the available types of licenses, but mentioned that either the “Lab” or “Scientific Researcher” would be most applicable. Ryan asked what the time-frame for acquiring a license would be. The labs all mentioned it was roughly a six month process for them, but since a PT provider would have a more limited scope, it could take less time.

Jay asked if there was any possibility for an exception. Nick said yes, but it would be a significant challenge to everyone involved. Sara asked if the licensing issues persist if the trial study is funded, and carried out at an agency (or agencies). Nick mentioned that agencies have more coverage and if the agency(s) are willing to shoulder that liability(s) licensing could be significantly easier. Due to the time allotment in the meeting, Ryan noted that this is a critical piece to both the trial study, and the permanent model. The group will dedicate time at the next meeting to delineate the specific license requirements Ty would need in this trail study.

Action Items

1. Update the Steering Committee to our work on the trial study and ask if they would like to add any input to the scoring sheet.
2. Submit the PT survey to the steering committee for approval before distribution.
3. Continue monitoring the evolving COVID-19 situation and adjust our meetings if/as necessary.