



Summary of Participant Breakout Sessions

There were participant breakout sessions hosted on both days of the *USDA NBAF Stakeholders and Partnerships Conference* focused on asking direct questions and collecting specific input from conference attendees. USDA also hosted a breakout session dedicated solely to federal partner engagement and collaboration. The purpose of each of these breakout sessions was to encourage discussion regarding specific questions inspired by each of the plenary session presentations.

Breakout Sessions 1 and 2

Breakout Sessions 1 and 2 focused on the following seven questions. Feedback was collected from participants. Each question below contains sub-bullets summarizing the most common responses and major themes from the stakeholders in attendance. This section does not contain any official perspectives, nor responses from USDA. USDA will provide responses through our NBAF website at (<https://www.usda.gov/nbaf>), this section is included as a summary of the discussions held during the conference.

- **Question 1: Do you have any questions about the construction timeline of NBAF?**
 - Stakeholders were curious to know the start date for the BSL-4 agent work, the timeline for the BDM, and when activities are planned to kick off at NBAF.
 - Some stakeholders expressed concern about whether the facility would complete construction by December 2020 based on what could be seen from an external view of the construction site.
 - Although the stakeholders expressed that the timeline seems appropriate, they asked about certification, validation, and what happens if there are unforeseen delays.
 - Given there are certain activities that USDA cannot control, stakeholders wanted to know about the USDA plan for addressing Federal Select Agent Program (FSAP) requirements.
- **Question 2: Do you have any questions or concerns regarding the transition of NBAF from DHS to USDA?**
 - Many stakeholders inquired about the status of hiring for NBAF operational positions. A request was made for a list of positions and the types of employees being hired for NBAF.
 - Several stakeholders wondered how USDA will ensure the appropriate and necessary amount of operations and maintenance (O&M) funds are available to keep NBAF running annually.
 - A few stakeholders expressed concern about the continuation of the biodefense mission with DHS holding a less prominent role in the management of the facility. Stakeholders would like to ensure USDA continues to advance the biodefense mission and has the funding to continue that line of business.
- **Question 3: Do you have any questions or comments regarding transition activities and operational planning activities for NBAF?**
 - Stakeholders had many questions about select agent registration strategy, timing, and phased approach toward working with pathogens.

- Stakeholders recommended having USDA APHIS Center for Veterinary Biologics (CVB) involved early and often in the technology transfer process to provide consultations and recommendations on NBAF operational and partnership opportunities during the transition from PIADC and stand-up of NBAF.
- Stakeholders inquired whether there are projects that can be immediately started to show progress.
- Stakeholders in attendance raised several questions about potential continued DHS presence, Federal Bureau of Investigation (FBI) integration at NBAF, and if the BDM will be staffed at the same pace, and schedule, as the rest of the facility. Further, biologics industry stakeholders expressed the desire for integration in the planning of the approach toward the protection of intellectual property for NBAF partnerships.
- Stakeholders inquired about the square footage of the BDM and expressed concern that there is not enough to respond to a major outbreak if vaccine production is required.
- **Question 4: What are your hopes for NBAF?**
 - Multiple stakeholders stated a hope for the NBAF mission to include international outreach and direct engagement during international disease outbreaks to respond before outbreaks reach the United States.
 - Many stakeholders expressed hope for NBAF to be an open and transparent place that is not shrouded in secrecy.
 - Many stakeholders expressed a desire for research and operational funds to be separate and delineated at NBAF
 - Many stakeholders stated a desire for NBAF to have a strong collaborative outlook and to seek collaboration from industry and outside partners.
 - Stakeholders stated a hope for NBAF to consider non-endemic diseases that are not currently on the USDA priority list.
 - Stakeholders recommended an early success story for advocacy efforts on the Hill. For the BDM, this would be something akin to phase 1 studies.
 - Stakeholders also commented on beginning student training as early as possible and asked whether this would be before all select agents are in place.
- **Question 5: What are your concerns for NBAF?**
 - Stakeholders stated concern that there is not a guarantee that products developed in the BDM will be funded/supported by NBAF all the way to production. Industry stakeholders stated that they are hesitant to invest in a product that may sit on a shelf.
 - Stakeholders stated large pharmaceutical companies are not as interested in developing stockpiles as they are in ensuring persistent markets.
 - Stakeholders shared a common understanding that the BDM is the crown jewel of NBAF, but that there is no insight currently into the funding that will be set aside for the BDM.
 - Stakeholders stated USDA research priorities may not always match industry priorities. An example was provided that African Swine Fever (ASF) is a lower priority for biologics industry than for USDA. This could result in conflict in future.
- **Question 6: Do you have any questions or comments regarding the expansion of the PIADC mission?**
 - Stakeholders inquired about a plan for epidemiology/surveillance training and outbreak response and expressed that there is a real opportunity for engagement with USDA.

They asked whether the epidemiology capacity at NBAF is intended to be like the Centers for Disease Control and Prevention (CDC) Field Epidemiology Training Program (FETP)/Epidemic Intelligence Service (EIS) as there may be an opportunity for collaborative efforts with CDC.

- **Question 7: Do you have any questions or comments regarding the mission of the BDM and its capabilities?**
 - Stakeholders asked if there is a timeline for the BDM facilities to be compliant with European Union (EU) Good Manufacturing Practice (GMP) certification.
 - Stakeholders raised concerns that it may be difficult to manage expectations, and that people may think that having access to the BDM means that there will be products developed immediately.
 - Stakeholders also raised several questions about whether the BDM is biosafety level three (BSL-3) or biosafety level two (BLS-2); the process for industry engagement with the BDM; and if there will be a request for proposal (RFP) process.
 - Stakeholders expressed additional concerns regarding project closure and what steps will be taken to ensure that no effort is lost between projects (e.g. a research partnership between ARS and partner), how technology transfers will happen, how a facility will be turned around between projects, and whether ARS can hold onto part of the royalties or if the money goes directly back into NBAF or into general holding accounts.

Breakout Session 3

Breakout Session 3 consisted of the following four questions. Each question contains sub-bullets summarizing the most common responses and major themes from the stakeholders in attendance. This section does not contain any official perspectives, nor responses from USDA. USDA will provide responses through our NBAF website at (<https://www.usda.gov/nbaf>), this section is included as a summary of the discussions held during the conference

- **Question 1: What types of partnerships do you want to see at NBAF?**
 - Stakeholders expressed an interest in allowing small companies to have access to BDM partnership opportunities.
 - Stakeholders expressed that they are unlikely to invest heavily in a project at the BDM unless some sort of ROI can be realized.
 - Stakeholders expressed a desire for an international market for products created at the BDM. The regulatory framework of the BDM is a key component for consideration.
 - Stakeholders stated there is a clinical study site not yet defined (by location or agency) and asked about how testing/challenge studies may occur at NBAF.
 - Stakeholders inquired about how the BDM would have helped the development of the FMD Leaderless vaccine.
- **Question 2: How would your organization use the BDM?**
 - USDA wants to know partners' desired goals for the BDM in order to develop the BDM staffing plan, operating model, and equipment lists that best reflect how stakeholders would like to use the space. Stakeholders would like to know the BDM staffing plans, operational model, and equipment before they can explain or envision how they could use the space.

- Many stakeholders stated that their ability to work/partner in the BDM will depend on the layout, production capability, equipment, and availability of dedicated staff, among other topics.
- Stakeholders stated that some capacity should be reserved for niche markets, alternative species, and smaller companies and that when it comes to clinical evaluation, the facilities should reach full capacity quickly. Priorities should be set, and these should be very clear, or the facility will be overwhelmed quickly.
- Stakeholders asked whether there is a vision for anticipated capacity (e.g., if BDM is expected to be used 50% of the time, or more/less).
- Stakeholders shared that technical expertise needs to include substantial in-house expertise and that trade secrets are not a limiting factor. There should not be a limit on the potential for innovation—establish the best possible process.
- Stakeholders raised the point that companies must understand that protection of the animal population also protects their client pool.
- Stakeholders discussed that individual projects would require conversations about intellectual property (IP), etc. at the time of outset. The operational model selected should not dictate this.
- **Question 3: Does your organization prefer a specific BDM operating model?**
 - Consistent with responses to Question 2, general feedback from stakeholders was that they prefer to be informed of the BDM operating model so that they can plan accordingly for potential partnerships opportunities.
 - Stakeholders from the industry perspective stated that there are different kinds of models that industry requires at different times. The operating model may need to change depending on the project and the need.
 - Stakeholders asked whether there is flexibility in the BDM operational models and stated the overall desire is collaboration and partnership wherever it makes sense at NBAF. It will be difficult to create a one-size fits all approach. The needs will be on a case-by-case and company-by-company basis.
 - Stakeholders expressed concerns for the timelines on what the science program is going to look like at NBAF and if this will be open for comment.
- **Question 4: How can USDA partner with your organization?**
 - Stakeholders stated that the BDM will need to support private industry by taking a product all the way to licensing, and de-risking the process as much as possible through support with regulatory navigation.
 - Multiple stakeholders stated that USDA will need to de-risk the technology transfer process as much as possible and engage with stakeholders prior to publishing to allow for domestic and international patent considerations.

Session 4: Federal Partner Engagement and Collaboration

At the end of day two of the conference, USDA hosted a federal partner discussion that centered around the following six questions. A brief summary of the responses to these questions is included within sub-bullets underneath each question.

- **Question 1: How can NBAF work with you to strengthen overall federal effort around "diseases?"**

- Stakeholders noted that while their agency has a focus on human pathogens, partnering with NBAF and private industry to get work done for disinfectants, vaccines, and diagnostics would be beneficial for all.
- Stakeholders noted in the discussion that engaging with the public health medical countermeasure enterprise would strengthen an overall federal effort around diseases. There is an opportunity for these activities to be leveraged at NBAF, especially related to zoonotic diseases.
- Stakeholders mentioned that initiatives with Defense Threat Reduction Agency (DTRA), Defense Advanced Research Projects Agency (DARPA), etc. are all options for expansion at NBAF and a coordinated mechanism in how they might engage with the Department of Defense (DoD) would be beneficial.
- **Question 2: What are their experiences with similar partnerships? What has worked and what hasn't worked?**
 - One stakeholder stated that USDA-APHIS Wildlife Services has experience partnering with other USDA entities. The agreements that are required for successful partnerships are typically collaborative.
 - Another stakeholder stated that Interagency Agreements (IAA) are an option, but perhaps a Memorandum of Understanding (MOU) would be more flexible to allow the scientists and laboratorians to collaborate across the aisle more easily.
 - A stakeholder referenced that 2-3-year product licensing timeframes are normal, but there is precedent for expediting this process down to a matter of months - as was the case of vaccine development during the 2014/2015 avian flu outbreak.
 - One stakeholder stated that USDA and DoD have a long history of working together to support the Warfighter, and that diethyltoluamide (DEET) is a prime example.
 - Another stakeholder stated that with regards to RVF, DoD and the Department of Health and Human Services (HHS) have previously collaborated, were able to secure funding, and the partnerships that were established were tremendously valuable. RVF is one area where DoD and HHS may be interested in working with NBAF, as well as vaccine testing.
- **Question 3: What are their concerns about NBAF?**
 - One stakeholder noted that with the move from an island to a university community, they would work with USDA to continue integration with the intelligence community and can assist with protection of intellectual property.
 - One stakeholder stated that the Department is making good strides on counterterrorism efforts at the USDA Headquarters level, as well as at the ARS and APHIS levels.
 - Another stakeholder mentioned that funding to pay for an international patent is a limiting factor to partnerships.
 - One stakeholder mentioned that personnel reliability, onboarding, and operations could be more efficient for USDA. NBAF represents an opportunity to streamline duplicative processes for topics like sharing, streamlining, and fast-tracking background investigations and clearances.
 - A stakeholder stated that a lot of the discussions around the BDM appeared vaccine-centric; however, USDA would benefit from planning for a foray into biotherapeutics.
- **Question 4: What are their hopes for NBAF? What opportunities exist?**

- Stakeholders stated the capability of working with BSL-4 agents brings a potential opportunity to collaborate with CDC, National Institutes of Health (NIH), and DoD on agents of common concern.
- One stakeholder stated that they are looking forward to engagement in terms of the opportunities leveraging the NIFA portfolio. NIFA will offer agricultural biosafety and biosecurity opportunities in an upcoming Request for Information (RFI) that may be relevant to the NBAF mission space.
- **Question 5: Should we consider using the BDM for programs beyond NBAF?**
 - One stakeholder mentioned the need to start early in the process working with CVB. There is a desire for a knowledgeable and permanent group at NBAF dedicated to helping steer the regulatory approach and process as products are developed and as partnerships are made regarding the BDM.
 - Another stakeholder stated that there was a suggestion in their breakout session to have a process to help support incoming companies (i.e., some kind of “Manager” to help a group/company go through the regulatory process).
 - Multiple stakeholders agreed that they heard recommendations in their breakout sessions to actively curate opportunities for large and small companies.
- **Question 6: What further discussions are needed?**
 - One stakeholder stated that there is a concern about having a large enough team to start up research programs at NBAF and to maintain dual operating capability for any length of time.