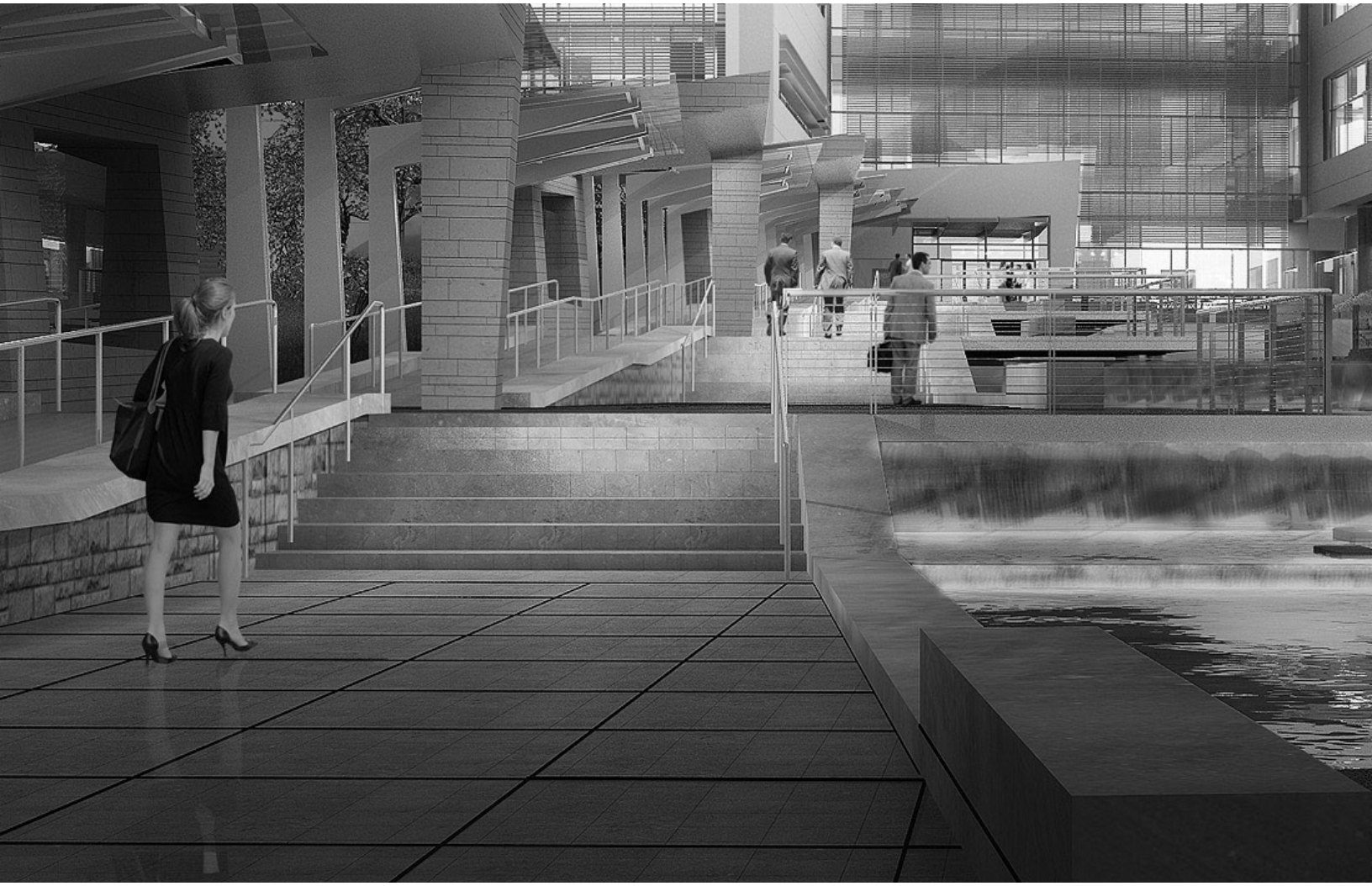
NBAF
NATIONAL BIO AND AGRO-DEFENSE FACILITY
Diagnostics • Vaccines • Training

NBAF STAKEHOLDERS AND PARTNERSHIPS CONFERENCE REPORT MAY 22-23, 2019



USDA

EXECUTIVE SUMMARY

BACKGROUND

The United States Department of Agriculture (USDA) National Bio and Agro-Defense Facility (NBAF) Stakeholders and Partnerships Conference was held on May 22-23, 2019, in Kansas City, Missouri. The conference served as a platform to update NBAF stakeholders and potential NBAF partners on the progress of NBAF construction and the operational plan for the facility. Stakeholders in attendance included representatives from livestock industries; biologics, pharmaceutical, and animal health industries; local and regional development organizations; academia, and the United States Government (USG). This USDA NBAF Stakeholders and Partnerships Conference Report provides a summary of the activities and outcomes from the 2- day conference, including a summary of presentation sessions, breakout discussion sessions, main themes, questions captured, and input received from attendees.

OVERVIEW

The plenary presentations of the conference consisted of four sessions:

1) NBAF Stand-Up and Transition from Plum Island Animal Disease Center (PIADC)
2) USDA Priorities and Capabilities at NBAF
3) Implementation of NBAF Mission: Technology Transfer, Biologics Development Module (BDM), and Partnerships
4) Federal Partner Engagement and Collaboration

These sessions focused on major NBAF topics to enhance attendee understanding of the NBAF mission, to communicate construction activity details and progress, and to initiate attendee engagement in opportunities for collaboration at NBAF.

Both days of the conference included participant breakout sessions in which USDA asked direct questions to collect specific and detailed input from attendees. The solicited discussion topics included the construction timeline of NBAF, transition activities and operational planning activities, general concerns about the project, partnership models, and the specific goals and capabilities of the BDM. The fourth breakout session focused on Federal partner engagement and collaboration. During this session, attendees discussed the intended capacity for Federal entity partnership with NBAF, as well as potential opportunities for collaboration.

Executive Overview Continued

SUMMARY OF OUTCOMES

A key outcome of the USDA NBAF Stakeholders and Partnerships Conference was that it introduced stakeholders to the USDA intentions and opportunities for establishing partnerships and collaborations to fully utilize the capabilities of NBAF. This outcome highlighted the important role NBAF will play in strengthening the country's ability to conduct animal research on important diseases; develop vaccines; diagnose emerging diseases; and train veterinarians, scientists, and laboratorians. Another outcome included identification of key contacts among industry, academia, and other Federal agencies who will be instrumental to successful establishment of partnerships and collaborations at NBAF. The conference enabled USDA to gather substantial input from key stakeholders, and this input will be critical for decision-making on NBAF partnership development and achieving the full potential of the BDM and NBAF.

NEXT STEPS

USDA recognizes that an important aspect of standing up NBAF, as not only a replacement facility for PIADC, but also as a facility with expanded capabilities and mission, is to listen and be aware of the ideas and priorities of the many officials, stakeholders, and collaborators involved with the evolving bio and agro-security community.

As USDA and partners continue to move toward full operational capability at NBAF, this Stakeholder and Partnerships Conference was a valuable opportunity to gather input from a wide representative cross-section of stakeholders, collaborators, and customers. USDA will continue to listen to and solicit input on NBAF; this input can be submitted to USDA by email at NBAF@usda.gov. Furthermore, presentations from the May 2019 conference can be reviewed at the USDA NBAF website (https://www.usda.gov/nbaf), and responses to questions and issues raised from this conference will be posted on the NBAF website. This will support the identification of specific and tangible areas where partners can provide expertise and support toward full realization of the USDA mission for NBAF.

Additionally, USDA envisions an annual stakeholder event focused on sharing information and soliciting input from our valued stakeholders, partners, and customers.

OVERVIEW OF THE CONFERENCE

On May 22-23, 2019, the USDA Animal and Plant Health Inspection Service (APHIS) and the USDA Agricultural Research Service (ARS) hosted the USDA NBAF Stakeholders and Partnerships Conference in Kansas City, Missouri. The purpose of this conference was to engage and encourage collaboration with potential partners for NBAF and to introduce intended partnership opportunities between the facility and prospective stakeholders. Attendees of this conference included a cross-section of Federal, academic, and industry stakeholders with the potential to enrich the NBAF mission and programs through future strategic partnerships and initiatives to further the efforts of APHIS and ARS.

The conference was divided into four sessions across 2 days and included topics such as an overview of the NBAF purpose and mission, construction status updates, NBAF operational stand-up approach and transition from PIADC, a description of USDA diagnostic and research priorities and capabilities at NBAF, technology transfer vision, BDM operational models, and Federal partner engagement and collaboration opportunities. The USDA NBAF Stakeholders and Partnerships Conference was a valuable opportunity to introduce potential partners to NBAF and to identify potential areas for collaboration.

OBJECTIVES FOR THE CONFERENCE

- To update and inform partners of intended research, diagnostic, and training programs for NBAF.
- To introduce NBAF partners to USDA's approach for standing up the facility and transitioning operations from PIADC.
- To discuss and collaborate with NBAF partners on pathways for the implementation of the NBAF Mission, including technology transfer, use of the BDM, and strategic partnerships.
- To collect and solicit stakeholders' feedback on operational models for the BDM, methods to promote collaboration within the BDM, and ways to bolster industry engagement.
- To explore opportunities for engaging USG partners who share the bio and agro-defense mission.

SUMMARY OF PRESENTATION SESSIONS

Session 1: NBAF Stand-Up and Transition from PIADC

Both days of the USDA NBAF Stakeholders and Partnerships Conference included plenary presentations focused on major topics to enhance attendee understanding of the NBAF mission, opportunities for collaboration, and stand-up/transition status. Below are brief summaries and key takeaways from each presentation.

WELCOME

Ms. Courtney Knupp, Chief of Staff, USDA Research, Education, and Economics

Ms. Knupp described NBAF as a USDA facility that will be a premier center for animal disease diagnostics and research. NBAF is committed to developing partnerships across academia, industry, the private sector, and USG sectors, as well as to developing expanded capabilities that will enable dynamic and flexible responses to disease threats. NBAF will have 24/7/365 support for national and global diagnostic activities.

Ms. Knupp highlighted the BDM as a section of the facility that will advance early - stage development and technology transfer of veterinary medical countermeasures. Ms. Knupp reinforced that stakeholders were invited to participate in the conference to provide USDA with input on the notional BDM operational models and to better gauge industry operational requirements for this type of facility.

KEYNOTE

Dr. Gerald Parker; Associate Dean for Global One Health, College of Veterinary Medicine & Biomedical Sciences, Texas A&M University

Dr. Parker emphasized that there are emerging and reemerging infectious disease outbreaks present in the United States and globally. For example, currently there is a significant outbreak of measles—a preventable disease—occurring within the United States. Emerging and reemerging diseases can have a significant economic impact. He opined that the United States needs to invest upwards of $5 billion on the prevention of diseases in order to mitigate the potential $60 billion economic impact from an actual disease outbreak.

Dr. Parker discussed “Disease X,” a hypothetical unknown pathogen. This example scenario represents the knowledge that a serious international epidemic could be caused by a pathogen currently unknown to cause human or animal diseases. The World Health Organization has also included “Disease X” on priority research and development blueprints. According to Dr. Parker, “Science is the foundation of the United States preparedness enterprise,” and he believes NBAF will play a role in the preparedness and response of the United States to “Disease X.”

Session 1 Continued

NBAF ROLE IN USDA HOMELAND SECURITY MISSION

Ms. Jessica Fantinato, Acting Director, USDA Office of Homeland Security

Ms. Fantinato reviewed the high-level USDA organizational chart and the diverse group of mission spaces across the Department. She described the role of the USDA Office of Homeland Security as the link between policy and field staff that is tasked with developing the policies with the presidential administration and determining the implementation approach for USDA priorities. She conveyed that NBAF is a national security asset.

NBAF CONSTRUCTION UPDATE

Mr. Timothy Barr, Program Manager, NBAF, Department of Homeland Security (DHS)

Mr. Barr emphasized that the completion of construction activities at NBAF will be accomplished in December 2020 and that commissioning activities are currently ongoing. He described operational planning activities that have been occurring between USDA and DHS for many years and noted that DHS and USDA have been working together from the initial planning stages of NBAF. Mr. Barr reiterated that DHS has and will continue to have a role on several operational planning groups and facilitating NBAF stand-up.

USDA TRANSITION ACTIVITIES AND PRIORITIES

Dr. Elizabeth Lautner; Associate Deputy Administrator, USDA-APHIS;
Dr. Steven Kappes; Associate Administrator, USDA-ARS

Dr. Lautner and Dr. Kappes described ongoing USDA activities for standing up operations and scientific programs at NBAF. They noted that USDA is soliciting input from stakeholders on priorities, capabilities, and collaboration for NBAF. USDA is actively seeking feedback on the BDM operational model.

Dr. Lautner and Dr. Kappes described in detail the hiring approach for NBAF operational staff, as well as the new capabilities that will be present in the biosafety level four (BSL-4) and BDM spaces of the facility. They emphasized the future opportunity to leverage partnerships through the Animal Health Corridor and universities, as well as continuing DHS/USDA collaboration through the NBAF Homeland Security mission.

Session 2: USDA Priorities and Capabilities at NBAF

FOREIGN ANIMAL DISEASE DIAGNOSTIC LABORATORY (FADDL) OVERVIEW

Dr. Kimberly Dodd; Director, FADDL, USDA-APHIS

Dr. Dodd provided an overview of the current mission areas at PIADC for APHIS. She outlined the expanded mission for FADDL, highlighting the approach for implementation of the FADDL program at NBAF, and the transition of diagnostic programs from PIADC to NBAF.

USDA'S ROLE IN BIO AND AGRO-DEFENSE AND ARS' SCIENTIFIC PROGRAM OVERVIEW

Dr. Cyril Gay; National Program Leader, USDA-ARS

Dr. Gay described the ways in which NBAF fills a critical role in preparing for and responding to disease outbreaks. He reviewed recent laws, regulations, and strategic plans developed by USG, highlighting the need to focus on agro- and bio-terrorism. Dr. Gay then described ARS program expansion at NBAF, including strategic objectives and criteria for selection of priority diseases.

OVERVIEW OF BDM MISSION AND CAPABILITIES

Dr. Cyril Gay; National Program Leader, USDA-ARS

Dr. Gay reviewed the original NBAF Biodefense Research and Development System, including the pipeline from basic research through veterinary medical countermeasure (MCM) product launch.

Dr. Gay noted that the NBAF BDM is the first USG facility dedicated to the development of veterinary MCMs, and that the BDM will provide specialized and dedicated staff to support translational research. The BDM will be a conduit for the rapid transfer of technologies to support the U.S. biodefense enterprise and will serve as a dedicated space where USG and the biotechnology and pharmaceutical industries might work together to develop veterinary MCMs.

NBAF TECHNOLOGY TRANSFER

Ms. Mojdeh Bahar; JD, Assistant Administrator, Office of Technology Transfer, USDA-ARS

Ms. Bahar highlighted NBAF capacity to facilitate partnerships and to allow for the adoption of research outcomes for broad U.S. public benefit. Ms. Bahar emphasized the possibility for enhancing U.S. economic development, global competition, and sustainable economic security through NBAF partnerships and technology transfer approaches. Ms. Bahar noted that USDA has different mechanisms to enter into a

Session 2 Continued

variety of partnerships regardless of the sector. There are legal requirements around technology transfer, but USDA has a variety of mechanisms to promote partnerships and meet partner needs.

Session 3: Implementation of NBAF Mission: Technology Transfer, BDM, Partnerships

ARS' LEADERLESS FOOT-AND-MOUTH DISEASE (FMD) VACCINE AND 3B ELISA: SUCCESS THROUGH PUBLIC-PRIVATE PARTNERSHIPS

Dr. Luis Rodriguez; Research Leader, USDA-ARS

Dr. Rodriguez discussed the high-level process for FMD vaccine development that is used today. This development process requires an animal biosafety level three (ABSL-3) facility for testing. The ARS team at PIADC has engaged in productive partnerships for decades in order to move products forward to achieve their scientific missions. This will be enhanced in NBAF due to the increased capabilities in the biocontainment areas such as the BSL-4 and BDM.

RIFT VALLEY FEVER (RVF) – VACCINES AND PARTNERSHIPS WITH KANSAS STATE UNIVERSITY (KSU)

Dr. William Wilson; Research Scientist, USDA-ARS

Dr. Wilson discussed the partnership between the ARS team at the Arthropod-Borne Animal Disease Research Unit, KSU, and the Biosecurity Research Institute (BRI) to begin the USDA RVF program in Manhattan, Kansas. Dr. Wilson outlined how current RVF studies have revealed the possibility that white-tailed deer could serve as a host for RVF if it entered into the United States.

INDUSTRY PERSPECTIVE ON BDM/WORKING WITH USDA

Dr. Will McCauley; Director, Veterinary Biologics Animal Health Institute

Dr. McCauley highlighted industry needs regarding the BDM and working with USDA. The central theme of potential industry participation at NBAF is that veterinary biological manufacturers are accountable to shareholders and must demonstrate return on investment (ROI) of their research and development portfolio. While industry acknowledges social responsibility and commitment to animal and human health, the reality is that a competitive market exists, and industry will prioritize projects that have an ROI. This will be an important consideration for USDA when identifying the proper operational model for the BDM. Dr. McCauley noted that the cost of inputs must be less than the value of outputs. USDA can lower input costs through cost-sharing agreements, reduced regulatory requirements on pre-license work, and clear expectations for projects.

Session 3 Continued

BDM ANALYSIS OF ALTERNATIVES

Mr. Steve Lewis; Project Manager, Merrick & Co.;
Dr. Lauren Richardson; Associate Director, Merrick & Co.

Mr. Lewis and Dr. Richardson reviewed the NBAF BDM Operational Model Alternatives Analysis Report, which was compiled to assess the current veterinary biologics market needs and potential ways in which the facility may operate. Mr. Lewis and Dr. Richardson stated that USDA is evaluating all operational models for partnership and collaboration, including Government-owned, Government operated models and Government-owned, contractor-operated models.

U.S. ARMY MEDICAL RESEARCH AND MATERIEL COMMAND WALTER REED ARMY INSTITUTE OF RESEARCH (WRAIR) OVERVIEW OF THE PILOT BIOPRODUCTION FACILITY (PBF)

Mr. Richard Millward; Associate Director, WRAIR PBF, United States Army

Mr. Millward highlighted his relevant experiences at the WRAIR PBF and described lessons learned and opportunities for the NBAF BDM. Mr. Millward discussed the larger capabilities at the PBF that attracted more clients to the facility to make the most use of the size and resources available in the space. Mr. Millward also explained how the PBF used cooperative agreements with external entities to fill the pipeline for utilization of the space.

KSU PERSPECTIVE ON PARTNERSHIPS

Dr. Dana Vanlandingham; Associate Professor, Arbovirology, KSU

Dr. Vanlandingham described KSU as a resource and potential partner for NBAF. Dr. Vanlandingham discussed current capabilities at the KSU Biosecurity Research Institute (BRI), including workforce development and training capabilities (hands-on and online); expertise in research and technical knowledge; facilities support; research support; commercialization; and relationships and networking in the local area and region.

Session 3 Continued

NBAF TRAINING

Dr. Kimberly Dodd; Director, FADDL, USDA-APHIS

Dr. Dodd described APHIS workforce development which will include expanding the FADDL mission at NBAF and will require training to build expertise in the new programmatic areas. Dr. Dodd highlighted three workforce development programs that are underway or in development to support NBAF training and new hires:

1) NBAF Scientist Training Program
2) NBAF Laboratorian Training Program
3) Career development opportunities for current staff

USDA NATIONAL INSTITUTE OF FOOD AND AGRICULTURE (NIFA) BIOSECURITY INITIATIVES

Dr. Michelle Colby; National Program Leader, USDA-NIFA

Dr. Colby discussed flagship grant programs that could be relevant to NBAF stakeholders, researchers, employees, and partners. These included:

- NIFA Foundational Program Area - Tactical Sciences for Agricultural Bioscience
- Small Business Innovations Research Program
- National Needs Fellowships to support new graduate student recruitment and training

SUMMARY OF PARTICIPANT BREAKOUT SESSIONS

Breakout sessions were hosted on both days of the USDA NBAF Stakeholders and Partnerships Conference to focus 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 & 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 the NBAF website (https://www.usda.gov/nbaf).

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 begin at NBAF.
- Some stakeholders expressed concern about whether construction would be completed at the facility 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 requirements.

QUESTION 2: DO YOU HAVE ANY QUESTIONS OR CONCERNS REGARDING THE TRANSITION FROM DHS TO NBAF?

- 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 funds are available to keep NBAF running annually.

Sessions 1 & 2 Continued

- 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 in that mission area.

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 raised several questions about potential continued DHS presence, Federal Bureau of Investigation integration at NBAF, and if the BDM will be staffed at the same pace and schedule as the rest of the facility. Biologics industry stakeholders also 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 space to respond if vaccine production is required to mitigate a major disease outbreak.

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 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.

Sessions 1 & 2 Continued

- 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 training would begin before all select agents are in place.

QUESTION 5: WHAT ARE YOUR CONCERNS FOR NBAF?

- Stakeholders stated concerns that there is not a guarantee products developed in the BDM will be funded/supported by NBAF all the way to production. Industry stakeholders stated 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 current insight into the funding that will be set aside for the BDM.
- Stakeholders stated USDA research priorities may not always match industry priorities; for example, African swine fever is a lower priority for the biologics industry than for USDA. This could result in conflict in the 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 (D) Field Epidemiology Training Program/Epidemic Intelligence Service as there may be an opportunity for collaborative efforts with CDC.

Sessions 1 & 2 Continued

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 Good Manufacturing Practice certification.
- Stakeholders raised concerns that it may be difficult to manage expectations, and that people may think that having access to the BDM means products will be developed immediately.
- Stakeholders also raised several questions about whether the BDM provides biosafety level three (BSL-3) or biosafety level two (BSL-2) containment; the process for industry engagement with the BDM; and if there will be a request for proposal 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 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 the NBAF website (https://www.usda.gov/nbaf).

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 side 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.

Session 3 Continued

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 factors.
- 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 percent 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 and associated issues 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 indicated they prefer to be informed of the BDM operating model so that they can plan accordingly for potential partnership opportunities.
- Stakeholders from industry 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 this be open for comment.

Session 3 Continued

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 develop disinfectants, vaccines, and diagnostics would be beneficial for all.
- Stakeholders noted that engaging with the Public Health Emergency 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 the Defense Threat Reduction Agency, the Defense Advanced Research Projects Agency, and others 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 are an option, but perhaps a memorandum of understanding would be more flexible to allow the scientists and laboratorians to collaborate across the aisle more easily.

Session 4 Continued

- A stakeholder referenced that 2- to 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 Deployed Warfighter Protection Research Program, and that diethyltoluamide (DEET) is a prime example of a successful partnership.
- Another stakeholder stated that with regards to RVF, DoD and the Department of Health and Human Services (HHS) have previously collaborated and 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; vaccine testing is another.

QUESTION 3: WHAT ARE THEIR CONCERNS ABOUT NBAF?

- 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, 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 that may be relevant to the NBAF mission space.

Session 4 Continued

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.

SUMMARY OF PARTNERSHIP OPPORTUNITIES

A significant part of the NBAF mission is the opportunity to leverage industry, academic, and USG partnerships. Whether through the APHIS mission within FADDL, National Veterinary Services Laboratories, ARS research programs, or through the new facility capabilities within BSL-4 or BDM spaces, NBAF is poised to develop and cultivate long term partnerships with the agricultural and veterinary biotechnology industries, academic institutions, and Federal strategic partners alike.

Industry Opportunities

There are three key capabilities of NBAF where industry stakeholders highlighted a desire for potential partnerships: the BDM, the BSL-4 spaces, and the BSL-3 animal space.

Many industry stakeholders were excited and curious about the opportunity to work within and partner on projects within the NBAF BDM. There was a stated desire to work with USDA to determine a way for research and development collaboration on agents that require BSL-3 or higher containment. Many stakeholders stated a desire for the ability to form partnerships to leverage the NBAF BDM but stated that the overall vision for the BDM would need to be driven by USDA and de-risked as much as possible for industry participation. Industry stakeholders stated a key decision factor for partnering within the BDM would be if USDA de-risked the research and development process as much as possible, streamlined the regulatory process significantly as a result of working within the BDM, and if USDA offered an expedited technology transfer process for products developed within the BDM. Industry partners stated that there is an opportunity to collaborate, but the process would need to be highly collaborative and streamlined to ensure the best opportunity to ensure ROI for industry partners.

Small industry stakeholders corroborated these desires from some of their larger counterparts represented at the conference. However, smaller companies were specifically interested in the utilization of the BDM for research and validation purposes and the opportunity to collaborate with the NBAF scientific staff. Representative stakeholders from biologics/pharmaceutical companies stated an interest in working with scientific personnel at NBAF and were more focused on expedited technology transfer considerations such as licensing and contractual efficiencies unique to working in the space.

With regards to the BSL-4 capability of NBAF, stakeholders were curious to know if the BDM would have the capability to perform challenge studies with BSL-4 agents. Stakeholders expressed the desire to understand if the BDM and NBAF containment space could be used for challenge studies with BSL-4 agents for research, with an eye toward CVB licensure. Industry stakeholders also stated the desire to collaborate with NBAF personnel early in the technology transfer process. Many industry partners remarked that their organizations do not have facilities for working

in BSL-3 or BSL-4 environments. Thus, industry considers the BSL-3 and BSL-4 capability of NBAF as unique and valuable for partnership, assuming they can take a product that requires high containment research capability through technology transfer and to production scale to realize an ROI. This is a critical question that will especially impact animal health companies that do not have access to other facilities to perform such challenge trials. This key topic is being discussed at USDA in terms of the model of operation for the BDM. Final decisions have not been made at this point.

Federal Partner Engagement and Collaboration

Federal stakeholders who participated in the conference discussed benefits of exploring myriad approaches to partnerships. The Session 4: Federal Partner Engagement and Collaboration section above highlights in detail the potential opportunities. The following were the most common themes for partnership and collaboration:

- Proactive MCM development for both human and animal health sectors.
- Collaboration with DoD and associated agencies, especially with utilization of the BDM and BSL-4 spaces.
- Ongoing biosecurity and biodefense strategic initiatives and collaborations with other agencies.

CONCLUSION AND SUMMARY OF OUTCOMES

The USDA NBAF Stakeholders and Partnerships Conference was a successful and key milestone toward partnership development for NBAF. USDA engaged with industry, academic, and Federal stakeholders to inform and solicit input from a representative group of future potential collaborators. USDA made a concentrated effort to both provide information and solicit feedback throughout the 2 days of the conference. From an outcome perspective, industry stakeholders provided a significant amount of insight, information, and input that will be critical for establishing effective partnerships envisioned for NBAF generally, and within the BDM specifically. Academic and Federal stakeholders agreed that the conference illuminated planned capabilities for the facility and intended capacity for partnerships. Participants agreed that the conference was beneficial, engaging, and an important step toward cultivating long-term collaboration opportunities with a broad array of stakeholders. USDA objectives for this conference were met and the input received will inform development of NBAF operational models and priorities.

Responses to the topics, questions, and issues raised at the NBAF Stakeholders and Partnerships Conference will be collected and reported through the USDA NBAF website (https://www.usda.gov/nbaf). USDA has a designated website to stimulate and continue stakeholder engagement with partners and collaborators around NBAF topics. This will be a “live” document that will grow as more responses are developed and stakeholder comments can be made to enable dialog around specific issues. In addition, we invite your questions and comments through email at NBAF@usda.gov.

APPENDIX 1: ACRONYMS

A

ABSL-3	Animal biosafety Level three
APHIS	Animal and Plant Health Inspection Service
ARS	Agricultural Research Service

B

BDM	Biologics Development Module
BRI	Biosecurity Research Institute
BSL-2	Biosafety level two
BSL-3	Biosafety level three
BSL-4	Biosafety level four

C

CDC	Centers for Disease Control and Prevention
CVB	Center for Veterinary Biologics

D

DEET	Diethyltoluamide
DHS	Department of Homeland Security
DoD	Department of Defense

F

FADDL	Foreign Animal Disease Diagnostic Laboratory
FMD	Foot-and-mouth disease

H

HHS	Department of Health and Human Services

K

KSU	Kansas State University

M

MCM	Medical Countermeasure

N

NBAF	National Bio and Agro-Defense Facility
NIFA	National Institute of Food and Agriculture

Appendix 1 Continued

P

PIADC	Plum Island Animal Diseases Center
PBF	Pilot Bioproduction Facility

R

ROI	Return on Investment
RVF	Rift Valley Fever

U

USDA	U. S. Department of Agriculture
USG	United States Government

W

WRAIR	Walter Reed Army


NBAF
NATIONAL BIO AND
AGRO-DEFENSE FACILITY
Diagnostics • Vaccines • Training