The Department of Defense (DoD) has been working on advanced technologies to protect its warfighters against intentional and emerging biological threats for several years. The DoD's Next Generation Diagnostic Program concentrates its efforts on developing deployable diagnostics that can detect chemical, biological, radiological and nuclear agents as early and accurately as possible. Modern diagnostic technologies have helped all type of healthcare facilities to improve patient outcomes while simultaneously bringing economic benefits. The reality, however, is that a discussion about the added value of such technologies in far forward military settings needs to occur with medical personnel who would be asked to use the technologies in the different echelons of care.

The latest molecular biology and engineering advances included in the Next Generation Diagnostic System (NGDS) Increment (Inc) 1 enable further advances in quality, portability and rapidity of diagnostics. These technologies allow the detection of a wide range of pathogens of operational concern in deployed personnel, to enable effective patient treatment decision making at higher echelons of care. Currently, the DoD is developing the NGDS Inc 2 with advanced capabilities meeting the criteria for use as far as the Point-of-Wounding. The goal of this new generation of diagnostic systems is to increase the range of warfare agents while lowering the logistical burden of using diagnostic systems, to offer advantages over empirical assessment and help with earlier decision making in far forward military settings. Selection criteria will include issues such as the extent to which NGDS Inc 2 should be relied upon and what added advantage they offer over the current standard-of-care in lower echelons of care.

This meeting will provide a forum for a discussion about the added value of NGDSs, bringing together doctors with field experience, scientists who can speak to the promises and shortcomings of the technologies, and experts in the implementation of new scientific technologies into medical standards of care. The hope is that physicians will speak to the concerns they have with implementing the broad use to NGDSs in field-based settings. What would they like to know about the specificity and sensitivity of the tests? What type of new training would this involve? Do they have concerns about integrating test results with their observations? Are there concerns about making decisions on the basis of test results? In summary, the goal of the meeting is to discuss benefits and disadvantages of adopting NGDSs within the DoD infrastructure to help the early detection of biological threats.
### OPEN SESSIONS

**8:30am**  
**Welcome and Introductions; Meeting Overview** - Don Burke,¹ Dean, Graduate School of Public Health, University of Pittsburgh

**8:45**  
**CBDP Meeting Objectives for Discussion**  
CDR Franca Jones, Office of the Assistant Secretary of Defense for Nuclear, Chemical, and Biological Defense Programs

**9:00**  
**Moderator/Introduction - John Hardham, Zoetis, Inc., Committee Member**

**Summary Of Joint USFK Portal and Integrated Threat Recognition (JUPITR) Workshop Report** (15 minutes)  
Peter Emanuel, ECBC BioSciences Division Chief & JPEO-CBD JUPITR ATD Lead

**Summary of UPMC Work on Diagnostics for Use by Military in Different Settings** (15 minutes)  
Jennifer Nuzzo, Senior Associate, UPMC Center for Health Security

**9:30**  
**DoD Diagnostics Programs**  
This session will provide an overview of DoD efforts towards diagnostics tests in far-forward settings, including the NGDS program and the planned NGDS Increment 2 effort.

**Requirements for the family of systems** (10 minutes)  
LTC Mark E. Bohannon, Chief, Medical Branch, JRO-CBRND

**Description of NGDS Family of Systems** (10 minutes)  
Jennifer Dabisch, Deputy Joint Product Director, JPdM Diagnostics

**NGDS Increment 2 desired capabilities** (10 minutes)  
Phi D. Vu, Program Manager, JPdM Diagnostics

**Description of [fielded/ past] program: 24-Month Diagnostics and Biosurveillance Challenge** (10 minutes)  
Bradley Ringeisen, Head, Bioenergy and Biofabrication Section, U.S. Naval Research Laboratory  
Kathleen Quinn, Scientist, DTRA

**Questions and Answers**  
**Moderator: John Hardham**

---

¹ Committee chair.
<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
</tr>
</thead>
<tbody>
<tr>
<td>10:30</td>
<td>Break</td>
</tr>
</tbody>
</table>
| | **Perspectives on Medical Decision Making**
| | *Moderator – Doug Weibel, University of Wisconsin-Madison, Committee Member*
| | This session will describe perspectives in decision-making associated with NGDS 1 to identify a path forward for NGDS 2. By discussing the bullet point topics below, this session will enable the DoD to further develop and/or refine services CONOPS for the implementation of far-forward diagnostic systems.
| | • What types of decisions are made in far-forward situations (Role 1 and Role 2)?
| | • How are such decisions made?
| | • What additional information might improve decision-making?
| | • Discussion should focus on the importance of the specificity/sensitivity of the assays for decision-making upon results (treatment choice, quarantine, evacuation, etc.) as well as the consequences of false positive and negative results.
| 10:45 | **Training Issues Pertaining to Far-Forward Diagnostics** (15 minutes)
| | James Murray, Joint Biological Agent Identification and Diagnostic System (JBAIDS) Course Director, Army Medical Department Center and School
| | **Questions and Answers**
| | **When and How Do New Scientific Tools Get Incorporated into Military Care Guidelines?**
| | (15 minutes)
| | CAPT Cindy Wilkerson, Director, Center for Clinical Laboratory Medicine, Defense Health Agency
| | **Questions and Answers**
| | **Panel discussion and Solicitation of Input from Audience Participants**
| | **Will New Diagnostics Impact Decisions that Are Made?** (5 minutes each followed by discussion)
| | • LTC Kurt Schaecher, Chief, Research and Training Laboratory Operations, USAMRIID
| | • LTC Michael Ingram, Deputy Commander, USAMMDA
| | • Dr. Jim Karaszkiewicz, Senior Scientist/Senior Product Management Support to Force Health Protection, USAMMDA
| | • Medic Needs for Diagnostics: COL Ric Ong, Command Surgeon, 1st Special Forces Command(A)(P)
| | • COL Peter J. Weina, Chief, Department of Research Programs, Walter Reed National Military Medical Center
| | • Jim Sjovall, FHP Strategic Planner, USCENTCOM Surgeon’s office
<p>| 12:15 | Lunch |</p>
<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
</tr>
</thead>
</table>
| 13:15 | **What Can Human Factors Research Tell Us About Using New Information for Decision Making?** (30 minutes)  
Gavin Huntley-Fenner, Huntley-Fenner Advisors |
|       | **Questions for Speakers Above** (15 minutes)                                                
Moderator - Thomas Slezak, Lawrence Livermore National Laboratory, Committee Member |
| 2:00  | **Lessons Learned from Next Generation Diagnostic Systems Implementation and Use at All Echelons of Care**  
Moderator – Thomas Slezak |
|       | Are diagnostics being used as much as hoped? What are some of the reasons why or why not?  
Answers might include characteristics like specificity, coverage, fitting into decision maker thinking, ease of use and interpretation, multiplexing, etc. |
|       | **Panel discussion and Solicitation of Input from Audience Participants**                  |
|       | **Implementation of PCR-based technologies in military settings** (7 minutes each)         |
|       | • Allen Northrup, Principal, Northrup Consulting Group                                       |
|       | • Lcdr Benjamin Espinosa, Head, Operations Department, Biological Defense Research Directorate, Naval Medical Research Center - Frederick |
|       | • Ltc Kurt Schaecher, USAMRIID                                                              |
|       | • Bradley Ringeisen, Head, Bioenergy and Biofabrication Section, U.S. Naval Research Laboratory (including John Hannan, Chief, Threat Surveillance Branch, DTRA and Kathleen Quinn) |
|       | **Questions and Answers**                                                                   |
|       | **Implementation of PCR- and immunoassay-based technologies in field-based medical facilities in remote settings** (7 minutes each)  
• Christine C. Ginocchio, Vice President, Global Microbiology Affairs, bioMerieux  
• Joseph M. Campos, Director, Microbiology Laboratory, Molecular Diagnostics Laboratory, and Laboratory Informatics, Children's National Health System  
• Thomas Kozel, Professor, University of Nevada  
• Charlotte Gaydos, Professor, Division of Infectious Diseases, Johns Hopkins University  
• Roger Peck, Technical Officer, Technology Solutions Global Program, PATH |
|       | **Questions and Answers**                                                                   |
| 4:15  | **Break**                                                                                   |
| 4:30  | **Structured Discussion - Details to Be Provided** – Don Burke                             |
| 5:30  | **Adjourn**                                                                                 |
CLOSED SESSION: COMMITTEE AND STAFF ONLY, ROOM 100

Committee Only Discussion of Day 1 Meeting and Upcoming Meeting Topics
(Breakfast Available at 8:00)

OPEN SESSION, ROOM 100

Discussion with Sponsor and Committee Only
Meeting Recap
• Sponsor Thoughts
• Meeting Insights from Committee Members
• Summary of Meeting Insights

Committee and DoD Staff

Impacts of Previous Meetings
CDR Franca Jones

10:30
Break

Discussion with Sponsor and Committee Only
Upcoming Meeting Topics
• Biosurveillance
• July Topic

Committee and DoD Staff

12:15
Lunch

CLOSED SESSION: COMMITTEE AND STAFF ONLY, ROOM 100

1:00
Process Suggestions

1:15
Elaboration on Suggested Topics

2:00
Adjourn