Exploration Laboratory Analysis

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2013 NASA Human Research Program Investigators’ Workshop
Overview

Exploration Laboratory Analysis (ELA)

FY12 Highlights

• Functional Requirements – High Priority Analytes
• Documentation:
  – Level I Functional Requirements
  – Operational Concept
• Selection and head-to-head competition of in-flight laboratory analysis (IFLA) instrumentation
• Small Business Innovative Research (SBIR) Projects
• *Strengthened collaboration with Human Health and Countermeasures (HHC)*
Exploration Laboratory Analysis (ELA) project supports:

Exploration Medical Capability (ExMC) risk –

- Risk of Unacceptable Health and Mission Outcomes Due to Limitations of In-flight Medical Capabilities

Derived ExMC Gap 4.05 –

- Lack of minimally invasive in-flight laboratory capabilities with limited consumables required for diagnosing identified Exploration Medical Conditions.
Gap to Requirements

- ExMC Gap 4.05
- SMEMCL
- Diagnosis
- Treatment

ELA Functional Requirements

SMEMCL – Space Medicine Exploration Medical Conditions List
HIGH PRIORITY ANALYTES
<table>
<thead>
<tr>
<th>Basic Metabolic Panel</th>
<th>Hematology</th>
<th>Liver/ Renal Panel</th>
<th>Urinalysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glucose</td>
<td>WBC Count</td>
<td>AST</td>
<td>Leukocytes</td>
</tr>
<tr>
<td>Sodium</td>
<td>Hgb</td>
<td>ALT</td>
<td>Proteins</td>
</tr>
<tr>
<td>Potassium</td>
<td>Neutrophils</td>
<td></td>
<td>Blood</td>
</tr>
<tr>
<td>Creatinine</td>
<td>Lymphocytes</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Under review*
# Functional Requirements

## HIGH PRIORITY ANALYTES*

### Research Requirements

<table>
<thead>
<tr>
<th>Bone</th>
<th>Cardio &amp; Muscle</th>
<th>Immune</th>
<th>Oxidative Stress</th>
<th>Hormones</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ca$^{2+}$</td>
<td>cTn</td>
<td>TNFα</td>
<td>NOS</td>
<td>Norepinephrine</td>
<td>Na$^+$</td>
</tr>
<tr>
<td>NTx</td>
<td>CK-MM</td>
<td>IL1β</td>
<td>SOD</td>
<td>Epinephrine</td>
<td>K$^+$</td>
</tr>
<tr>
<td>Creatinine</td>
<td>hsCRP</td>
<td>ILK-4</td>
<td>TRX</td>
<td>Cortisol</td>
<td>HgA1c</td>
</tr>
<tr>
<td>(urine mg/dL)</td>
<td>BNP</td>
<td>IL-6</td>
<td></td>
<td>Testosterone</td>
<td>K$^+$</td>
</tr>
<tr>
<td>CTx</td>
<td>ANP</td>
<td>IL-8</td>
<td></td>
<td>Estradiol</td>
<td>Ca$^{2+}$</td>
</tr>
<tr>
<td>OC</td>
<td>B2M</td>
<td>IL-10</td>
<td></td>
<td>Testosterone</td>
<td>Na$^+$</td>
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<tr>
<td>GPx</td>
<td>Helical Peptide</td>
<td>TGFβ</td>
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<td>Aldosterone</td>
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<tr>
<td>BSAP</td>
<td>Homocysteine</td>
<td>NF-kB</td>
<td></td>
<td>Renin</td>
<td></td>
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<tr>
<td>OPG</td>
<td>MMA</td>
<td>IFN gamma</td>
<td></td>
<td>Total Plasma</td>
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</tr>
<tr>
<td>OPG-RANKL</td>
<td>Myostatin</td>
<td>Neopterin</td>
<td></td>
<td>Proteins</td>
<td></td>
</tr>
<tr>
<td>sRANKL</td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>OP</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vitamin D</td>
<td></td>
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<td></td>
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</tbody>
</table>

*Under review
ELA Operational Concept and Level I Functional Requirements
Purpose

The operations concept:

(i) Constitutes the ELA portion of the ExMC Element Operation Concept Document

(ii) Provides the operational scenarios that will form basis for ELA system requirements

The ELA operational concept was presented and reviewed at the ExMC (Systems Requirements Review) SRR2 in August 2012
ELA Operational Concept

ELA System Configuration

User
- Crewmember
  - Sample acquisition
  - Sample preparation

Hardware
- Sample Analysis
  - Analyzer 1
  - Analyzer 2

Data Management
- Integral to hardware
  - Data processing, storage, transmission
  - Wired/wireless communication to PC

EMSD
- Wired/wireless integration hardware
  - Medical diagnosis, evaluation
  - Ground support
Exploration Laboratory Analysis (ELA) Project - Purpose

- Defines top-level operational requirements for the ELA project with respect to the Exploration Medical System (EMS).
  - For ExMC, Level I functional requirements support the:
    - Deep space exploration
  - For research, requirements for the intended HHC studies on ISS.
- Facilitate the diagnostics of several medical conditions.
- Track the development of hardware by the Human Research Program (HRP) elements, the National Space Biomedical Research Institute (NSBRI), and Small Business Innovation Research (SBIR) projects.
Exploration Laboratory Analysis (ELA) Project – Scope

- Defines requirements for clinical laboratory analysis equipment intended to:
  - Support medical operations based on Level IV standard of care (NASA-STD-3001)
  - Medical conditions outlined in the SMEMCL for a Near-Earth Asteroid (NEA) mission.
  - Address research needs that will accommodate a variety of biological specimens and provide a wide range of analytical capabilities

- Hardware selection will be based on:
  - Assessment of commercial-off-the-shelf (COTS) instrumentation
  - Evaluation of performers in the IFLA competition
IFLA Assays and Competition
IFLA Assays and Competition

- Follow-on to the Defense Venture Catalyst Initiative (DeVenCI)
- Four companies down-selected to participate in a run-off competition
  - DNA Medicine Institute (Phase III SBIR), Nanomix, OPKO (Claros), Rice Univ.
  - Joint-effort between HHC and ExMC
- Goal is develop and demonstrate four assays by April 30, 2013
  - NTx
  - IFN-γ
  - TNF-α
  - (25-OH) Vitamin D
- Competition will culminate with a demonstration at JSC
  - On-site analysis of 15 blind samples
Small Business Innovative Research (SBIR)
Phase I solicitation: X13.01 Smart Phone Driven Blood-Based Diagnostics

- Two performers completed Phase I contracts.
- A single Phase II performer, Intelligent Optical Systems, has been recommended for selection as Required to meet HRP Objectives (award pending funding appropriations).
- Phase II will seek to demonstrate at least two of the medical operations panels that are shown below:
  - Basic metabolic panel (Chem8)
  - Blood gas panel (PaO2, PaCO2, SaO2, HCO3, pH)
  - Cardiac panel (troponin I, CK-MB)
  - Liver/renal (total bilirubin, direct bilirubin, ALP, ALT, AST) panel
Future Work

Exploration Laboratory Analysis FY13

• Develop technology downselect plans for:
  – HHC run-off competition
  – ExMC ELA under the EMSD

• Develop ELA technology development plan for ExMC

• Manage the SBIR Phase II performance

• Market survey update