Tasks Required of the Expert Panel

Panel Tasks
- Task I: Survey existent technologies and products
- Task II: Develop preliminary selection/inclusion criteria for pre-proposals
- Task III: Describe products with the capability to be developed for combat use
- Task IV: Advise what criteria should be used to evaluate the potential technologies/products
- Task V: Prioritize the current products
- Task VI: Suggest how to further evaluate the leading candidates
- Task VII: Communicate process and findings

Sponsor Responsibilities
- Provide all available information
- Review Draft Final Report for factual accuracy and compliance to the Scope of Work
Tasks Required of the Expert Panel

Task I

Survey existent technologies and products

– W81XWY-BAA-AFRRF: public call for information on Candidate Technologies for Advanced First-Responder Resuscitation Fluids (AFRRF)
  • LSRO has assembled a database of Pre-Proposal responses
– Review LSRO literature search for completeness
Tasks Required of the Expert Panel

Task II

Develop preliminary selection/inclusion criteria for pre-proposals

- **Product Requirements:** Potential to improve fluid resuscitation in combat injury situations, e.g.
  - Fluid conservative treatment with hypotensive endpoints
  - Stable for prolonged periods at ambient temperatures (≤130°F)
  - May support oxygen carrying capacity
  - Mitigates or negates post-shock, post-resuscitation syndromes
  - Compatible with blood products
  - Suitable for administration by first responder medical personnel
  - No mental or physical post-resuscitation impairment
  - No impairment of coagulation capability
Develop preliminary selection/inclusion criteria for pre-proposals

• Inclusion criteria to consider:
  – Has the potential to:
    • Increase survival in an extended evacuation situation
    • Reduce morbidity in an extended evacuation situation
  – Meets one or more of the example requirements

• Exclusion criteria
  – Monitoring devices will not be reviewed
  – Devices that assist fluid resuscitation will not be reviewed
Tasks Required of the Expert Panel

Task III

Describe products with the capability to be developed for the intended purposes

• A list of all candidate technologies meeting the inclusion criteria will be supplied to the Sponsor
Tasks Required of the Expert Panel

Task IV

Advise what criteria should be used to evaluate the potential technologies/products

• Develop a standard evaluation system based on generally accepted scientific criteria

• Set standards of evidence for weighting the candidates
  – Include:
    • Phase of development
    • Non-military development resources (market)
    • Scientific merit

• Sponsor will have the opportunity to review and comment on the evaluation system and standards of evidence
Tasks Required of the Expert Panel

Task V

Prioritize the current products

• Utilize the evaluation system to prioritize the pre-proposals that were submitted

• Rank highest those products most warranting an investment of Sponsor resources
Tasks Required of the Expert Panel
Task VI

Suggest how to further evaluate the leading candidates

- Additional types of experiments that might indicate functionality in a combat injury environment
  - Broad stroke, general
  - In vivo and in vitro testing
  - Potential criteria for reviewing future fluids
  - Sponsor acknowledges the lack of a “validated pre-clinical trauma model” and does NOT expect the panel to debate this matter
  - Sponsor acknowledges the need to perform experiments in multiple species prior to human use
Tasks Required of the Expert Panel

Task VII

Communicate process and findings

• In the Final Report, include:
  – Selection algorithm for inclusion of pre-proposals
  – List of all candidate technologies meeting the inclusion criteria
  – Details of the evaluation system for ranking pre-proposals
  – Prioritized list, including weighted scorecards, of pre-proposals
  – Additional experiments to support the utility of the product in a combat injury environment
  – Potential criteria for evaluation of future resuscitation fluids/technologies for use in a combat injury environment
  – Likely FDA approvable civilian indication that is analogous to the combat indication
  – Data/literature cited

• Level of detail to include in the Final Report
Sponsor Responsibilities

• Provide all available information
• Be accessible for questions
• Review Draft Final Report for factual accuracy and compliance to the Scope of Work