



US DEPARTMENT OF DEFENSE

# BLAST INJURY RESEARCH PROGRAM COORDINATING OFFICE

## Hemorrhage Control and Resuscitation

### Freeze Dried Plasma Investigational New Drug Application Submitted to US Food and Drug Administration

Freeze dried plasma (FFP) is a vital component for successful management of severe bleeding. Up to 30 percent of FFP supplied to the battlefield is unusable because of bag breakage during shipping and because of outdating after thawing (product expiration). Current doctrine does not position FFP forward of role of care -3 because of freezer requirements. Freeze Dried Plasma (FDP) will reduce waste of plasma by eliminating breakage and outdating after thawing and will reduce power, weight, and cube required for battlefield positioning of plasma by reducing or eliminating associated freezer requirements for FFP. FDP can be reconstituted (to return to liquid) in less than five minutes with sterile water for injection (FFP takes 25-35 minutes to thaw), thereby making the plasma available for transfusion virtually on demand. Most importantly FDP will permit positioning of plasma at more forward battlefield locations closer to the point of injury, potentially improving the clinical outcomes associated with severe bleeding. US Army Medical Materiel Development Activity (USAMMDA) plans to submit the FDP Investigational New Drug (IND) application to the US Food and Drug Administration in early FY17. USAMMDA has an ongoing Cooperative Research and Development Agreement (CRADA) with Vascular Solutions Inc. for the development of FDP. Under the terms of the CRADA, Vascular Solutions is responsible for conducting all of the manufacturing aspects of the FDP product development effort while USAMMDA conducts all of the required clinical testing under a US Army Office of the Surgeon General (OTSG)-sponsored IND. The Phase 1 clinical trial is expected to begin in December 2016.

