

## The **BEST** Path for Blood Management Software: From Idea to Prototype to a Deployable Solution

**Ileana Hauge, Maj, US Air Force, BSC**

AFRRI, SRD

8901 Wisconsin Avenue

Bethesda, MD 20889-5603

USA

Telephone: 301-295-2950 or 301-295-0316, Fax: 301-295-1863

[Hauge@afri.usuhs.mil](mailto:Hauge@afri.usuhs.mil)

**Maria F. Trujillo, Ph.D.**

CAMRIS International

6931 Arlington Road Suite 575

Bethesda, MD 20814

USA

Telephone: 301-770-6000 ext 131, Fax: 301-770-6030

[Mtrujillo@CAMRISinternational.com](mailto:Mtrujillo@CAMRISinternational.com)

*A Global Profile Database for Blood Donor's Identity, Health, and Travel History (in its working version labelled the "**B**lue Evaluation Software" or **BEST**) prototype has been designed to meet specifications for US Air Force, US Navy, and US Army. **BEST** provides a working deployable interface between military needs and Commercial-Off-The-Shelf (COTS) blood software. Originally developed to work with one industry leading COTS, **BEST** can be customized to fit any leading compliant blood system COTS. **BEST** will be easy and flexible to deploy in the field and can be embraced by other civilian blood donor facilities, national security, emergency response national forces, and NATO allies.*

*The analytical basic design for this prototype's construction and customization includes specific data interfaces, electronic option donor questionnaires, identification barcode cards with local, remote, and global tasks related capabilities. This global profile software technology solution represents a clear innovation to the Armed Services Blood Program (ASBP) global profile database of blood donors and will be able to provide continuous and universal access to donors' information in a secure setting, to help ensure data integrity, reliability and proper records management. **BEST** will assure the data are filed continually with each donor visit, each blood collection, each infectious disease test, each component manufactured from every donation and the final disposition of every blood component, and others. Started as an idea to overcome day-to-day functionality shortcomings, and developed under a U.S. Air Force funded Small Business Innovation and Research (SBIR) project, **BEST** represents an innovative approach within real constraints to global profile software technology with both local and global field deployment potential capabilities.*

### 1.0 SMALL BUSINESS INNOVATION AND RESEARCH (SBIR) PROGRAM

The Small Business Innovation Research (SBIR) Program was established by the U.S. Congress in 1982 to fund Research and Development (R&D) through small businesses of less than 500 employees. Eligible projects must serve a Department of Defense (DoD) R&D need and have potential to develop into a product

## Report Documentation Page

*Form Approved*  
*OMB No. 0704-0188*

Public reporting burden for the collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Washington Headquarters Services, Directorate for Information Operations and Reports, 1215 Jefferson Davis Highway, Suite 1204, Arlington VA 22202-4302. Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to a penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number.

1. REPORT DATE <b>APR 2010</b>	2. REPORT TYPE <b>N/A</b>	3. DATES COVERED <b>-</b>	
4. TITLE AND SUBTITLE <b>The BEST Path for Blood Management Software: From Idea to Prototype to a Deployable Solution</b>		5a. CONTRACT NUMBER	
		5b. GRANT NUMBER	
		5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S)		5d. PROJECT NUMBER	
		5e. TASK NUMBER	
		5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) <b>AFRRI, SRD 8901 Wisconsin Avenue Bethesda, MD 20889-5603 USA</b>		8. PERFORMING ORGANIZATION REPORT NUMBER	
9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES)		10. SPONSOR/MONITOR'S ACRONYM(S)	
		11. SPONSOR/MONITOR'S REPORT NUMBER(S)	
12. DISTRIBUTION/AVAILABILITY STATEMENT <b>Approved for public release, distribution unlimited</b>			
13. SUPPLEMENTARY NOTES <b>See also ADA564622. Use of Advanced Technologies and New Procedures in Medical Field Operations (Utilisation de technologies avancees et de procedures nouvelles dans les operations sanitaires). RTO-MP-HFM-182</b>			
14. ABSTRACT <b>A Global Profile Database for Blood Donor's Identity, Health, and Travel History (in its working version labelled the Blue Evaluation Software or BEST) prototype has been designed to meet specifications for US Air Force, US Navy, and US Army. BEST provides a working deployable interface between military needs and Commercial-Off-The-Shelf (COTS) blood software. Originally developed to work with one industry leading COTS, BEST can be customized to fit any leading compliant blood system COTS. BEST will be easy and flexible to deploy in the field and can be embraced by other civilian blood donor facilities, national security, emergency response national forces, and NATO allies.</b>			
15. SUBJECT TERMS			
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT
a. REPORT <b>unclassified</b>	b. ABSTRACT <b>unclassified</b>	c. THIS PAGE <b>unclassified</b>	<b>SAR</b>
			18. NUMBER OF PAGES <b>12</b>
			19a. NAME OF RESPONSIBLE PERSON

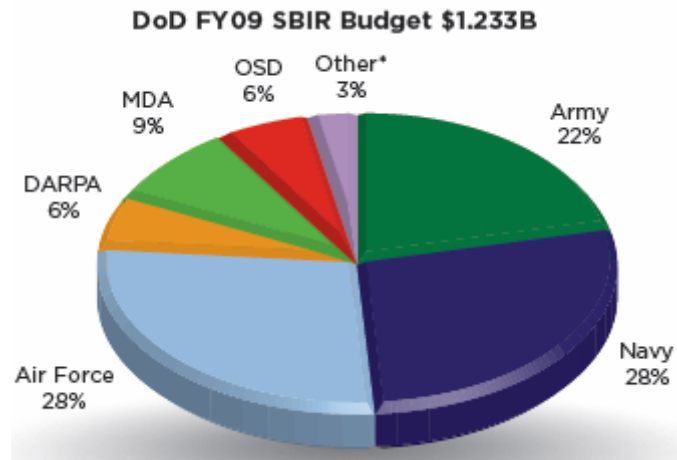
or service for commercial and/or defense markets. The DoD SBIR Program is part of a larger Federal SBIR Program administered by 11 Federal Departments and Agencies. See Figure 1 for the US DoD SBIR participation by component and Figure 2 for the US DoD SBIR budget by component [1].

**Participation At a Glance**

Component	SBIR FY09 Budget	STTR FY09 Budget
Army	\$265.6M	\$31.8M
Navy	\$339.9M	\$40.8M
Air Force	\$340M	\$40.7M
DARPA	\$70.4M	\$8.4M
MDA	\$111.4M	\$13.3M
OSD	\$69.7M	\$5.6M
Other*	\$34.8M	--

*\*Other includes DTRA, SOCOM, CBD, NGA, DLA and DMEA*

**Figure 1: The US DoD SBIR Participation by Component [1].**



**Figure 2: The US DoD SBIR Budget by Component [1].**

The purpose of DoD's SBIR and Small Business Technology Transfer and Research (STTR) programs is to harness the innovative talents of the United States small technology companies for U.S. military and economic strength. Each year, the DoD issues three SBIR solicitations which identify hundreds of topics from the DoD components that represent serious scientific and technical problems requiring innovative solutions. The topics are available online. Small businesses respond to solicitations by submitting Phase I proposals electronically during the four week open period.

To participate, a company must:

- Be a small business with 500 or fewer employees;
- Be independently owned and operated and organized for profit;
- Have its principal place of business in the U.S.;
- Be at least 51% owned by U.S. citizens or lawfully admitted permanent resident aliens.

In addition:

- The primary employment of the principal investigator must be with the recipient small business.
- A minimum of two-thirds of the research work must be performed by the proposing firm in Phase I and half in Phase II.

## The Process

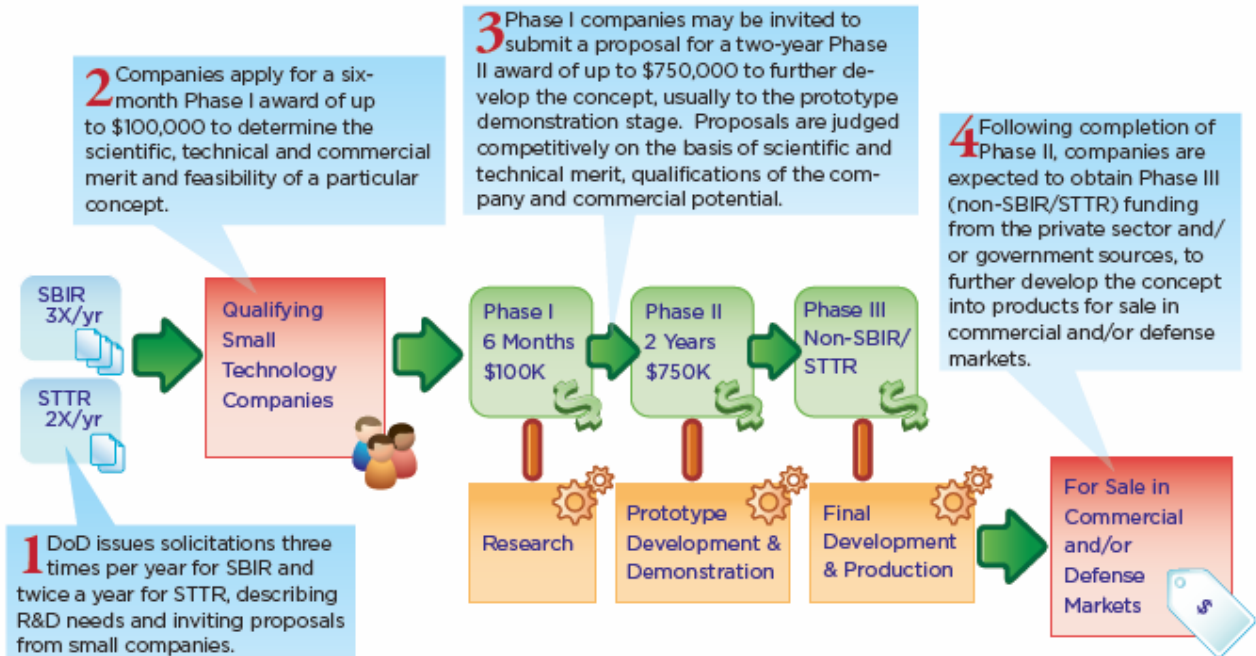


Figure 3: The US DoD SBIR Process.

The SBIR program is a 3-phased program as illustrated in Figure 3. Phase I contracts are typically for up to \$100,000 over 6 months. Phase II contracts are typically for up to \$750,000 over 24 months. Government scientists and engineers who are experts in a particular topic area review the proposals and evaluate them based on:

- Soundness, technical merit and innovation of proposed approach;
- Qualifications of the principal/key investigators and supporting staff;
- Potential for government or private sector commercial application.

During Phase I, the small business carrying out the SBIR work develops its technical design and also prepares a proposal for Phase II. The Phase II proposal includes a commercialization strategy explaining how the small business expects to rapidly move the technology to widespread commercial (Government or private sector) use. Logically following on the commercialization oriented work of Phase II, Phase III represents the successful culmination of a SBIR project. While Phase II success is measured by whether the prototype product or service developed by the small business can meet a need, Phase III success is indicated by the small business marketing and selling the products or services outside of the SBIR Program. Phase III revenues can be obtained from Government or private customers, and cannot use SBIR funds (these are reserved for Phase I and II projects). Phase II is typically a demonstration phase in which prototypes are built and tested in a period of performance. Finally, Phase III is the commercialization stage and the ultimate goal of the SBIR program. It refers to work that derives from, extends, or logically concludes efforts performed under prior SBIR funding agreements. Adding to the support provided under the previous phases, this final phase also provides the SBIR recipient reaching Phase II with authorization for non-competed or “sole source” contracts

from the Government for an extended five year period. Sole source is permitted because the normal competition requirements for government procurement are deemed to have been satisfied in Phases I and II. Phase III work may be for products, production, services, R&D, or any combination thereof. There is no limit on the number, duration, type, or dollar value of Phase III awards, and small business size limits that restrict awards to small businesses during Phases I & II do not apply to Phase III. This program therefore provides the government with access to technologies that result from small business innovation, while giving the recipient funding for design and development as well as facilitation to make public sector sales.

CAMRIS submitted a Phase I O063-H08-3234 proposal to the SBIR FY 2006.3 solicitation which was available as Pre-solicitation in August 2006, was posted online in September 2006 and closed in October 2006. There were 60 Office of the Secretary of Defense (OSD) topics among 160 overall SBIR DoD topics. There were 37 Phase I proposals submitted, of which four were selected to continue to Phase I. CAMRIS' proposal was the only one selected to continue under Phase II. CAMRIS is now initiating Phase III.

## 1.1 SBIR Phase I

An SBIR Purchase Order FA8650-07-M-6729 dated February 28<sup>th</sup> 2007, indicated a March 1<sup>st</sup> 2007 SBIR Phase I starting date for CAMRIS International and its initial participating technology subcontractor to develop a global profile software technology for the U.S. Air Force and the Armed Services Blood Program (ASBP).

Phase I included a proof of concept to provide universal access to donor identity, previous deferrals, and travel history to assist data filing continuity of the blood bank collection facilities managed by the Air Force Research Laboratories (AFRL) located in the Wright-Patterson Air Force Base (WPAFB) based in Ohio. The joint team led by Dr. Maria Trujillo from CAMRIS International and additional software specialists from the COTS provider analyzed how the COTS FDA 510(K) cleared blood donor management information system could be adapted to the specific needs of the DoD. Even though software systems to track donor identity, previous deferrals and travel history are commercially available from a number of firms including the initial subcontractor, the knowledge management needs of the U.S. Air Force and the DoD Armed Services Blood Program (ASBP) required and continue to require new and novel software development. In deployment, **BEST** with its COTS "engine" solves information retrieval problems and provides continuous and universal access to information in a secure setting. These systems ensure data integrity, reliability and proper record management so that data are filed continually with each donor visit, each blood collection, each infectious disease test, each component manufactured from every donation, and the final disposition of every blood component. As a result, the ASBP global profile database of blood donors is powered by the COTS system but adapted to the specific needs of the Armed Forces.

CAMRIS understood the challenge for Phase I as the development of the necessary software layers to meet the ASBP knowledge management needs while maximizing the proven benefits of a commercially leading COTS solution.

SBIR Phase I (May-Sep 2007) allowed CAMRIS to develop the **BEST** global profile software technology prototype. In Phase I of the SBIR project, the feasibility of **BEST** was demonstrated as it could be applied to the USAF and ASBP global profile database of blood donors. CAMRIS **BEST** solution enabled the team to start with FDA 510(K) cleared COTS powering the **BEST** solution, a clear innovation to the ASBP global profile database of blood donors. **BEST** has been designed to provide universal access to donor identity, previous deferrals, and travel history in order to assist data filing continuity of the blood bank collection

facilities of the USAF and the ASBP. **BEST** has been designed to provide continuous and universal access to information in a secure setting, help ensure data integrity, reliability and proper record management, such that data are filed continually with each donor visit, each blood collection, each infectious disease test, each component manufactured from every donation, and the final disposition of every blood component.

The project has come to grips with the practical constraints implicit in the development of this new technology thus laying a good foundation upon which a subsequent Phase II project can be successfully implemented. Phase I demonstrated the general feasibility of the concepts and illuminated the technical hurdles to be crossed in the future. Phase I efforts also demonstrated the team's capability for technological innovation, developing new commercial products, processes, and services to benefit the government and/or the public.

We started this six month SBIR Phase I project on March 1<sup>st</sup> 2007 with an accelerated timetable. We completed all of the proposed activities ahead of schedule, as follows:

**Table 1: SBIR Phase I Delivery Schedule.**

		<i>Scheduled</i>	<i>Status</i>	<i>Comments</i>
1. Determination of technical feasibility	Interim Report #1	April 30, 2007	COMPLETED on April 21 <sup>st</sup> 2007	9 days earlier
2. Design of GUI layer of BEST	Interim Report #2	June 29, 2007	COMPLETED on June 21 <sup>st</sup> 2007	8 days earlier
3. Demonstration of BEST prototype	First Demonstration in person in WPAFB	August 28, 2007	COMPLETED on June 5 <sup>th</sup> 2007	53 days earlier
	Second demonstration via Live Meeting and phone conference	August 28, 2007	COMPLETED on August 15 <sup>th</sup> 2007	13 days earlier
<b>Final Report</b>		<b>September 27, 2007</b>	<b>COMPLETED on September 9<sup>th</sup> 2007</b>	<b>18 days earlier</b>

We dramatically accelerated our completion rate in order to demonstrate functionality before Phase II recommendations took place. Phase I deliverables included one demonstration of **BEST**, however a second demonstration was added to highlight the Graphical User Interface (GUI) prototype features for global profile software technology, in particular the donor management module. Our two demonstrations: 1) in person on June 5<sup>th</sup> 2007 and 2) via Live Meeting and phone conference on August 15<sup>th</sup> 2007 allowed us to demonstrate the minimum set of specifications required for Phase I, in addition to full functionality of many other **BEST** features. During performance of Phase I, CAMRIS initiated what would normally be considered Phase II activities regarding commercialization considerations of **BEST**.

The minimum set of requirements and specifications for **BEST** in Phase I were defined as: 1) global donor deferral; 2) global lookback; 3) an interface with laboratory testing equipment; 4) accurate, timely, and readily available reports; and 5) cryovial shipment and storage management. **BEST** as demonstrated covered these six original requirements depicted in Table 2 below:

Table 2: SBIR Phase I Original Design Requirements.

<i>Six original design requirements</i>
Global donor deferral
Global lookback
Laboratory testing equipment interface
Accurate, timely, and readily available reports
Cryovial shipment and storage management
Total asset visibility

## 1.2 SBIR Phase II

Four scientists led by Program Manager Maj. Ileana Hauge from 711 HPW/RHPB WPAFB, Ohio and CAMRIS International received OSD funding on September 15<sup>th</sup> 2008 for the SBIR PHASE II “**BEST**” Global Profile database to support Donor’s Identity, Health, Travel History. This project was approved by OSD to be added to the Theater Medical Information Program (TMIP), which is a multibillion dollar program to meet multiple DoD and NATO military cyberspace safety needs. “**BEST**” is powered by the prototype FDA 510(K) cleared COTS to meet critical shortcomings of the Defense Blood Standard System (DBSS) and meet “unfulfilled needs” stated by ASBPO [5]. Compatibility to DBSS data has required a collaborative effort a team of computer engineer scientists from other DoD and government agencies. SBIR PHASE II “**BEST**” Global Profile database to Donor’s Identity, Health, Travel History incorporates specifications for Air Force, Navy, Army, and global requirements with easy deployment to the field, likely to be embraced by NATO allies. The SBIR Phase II award advances **BEST** from prototype through full deployability across military blood services. This unique project goes beyond SBIR goals, and builds new opportunities for United States DoD and NATO to lead future cyberspace missions. The team successfully completed their SBIR Phase II first year report (Sep 2008-2009) for contract FA8650-08-C-6834 for the development of the **BEST** software prototype. Currently **BEST** is still being designed to meet specifications for the US Air Force (USAF), US Navy, and US Army. **BEST** will be easy and flexible to deploy in the field and can be embraced by other civilian blood donor facilities, national security, emergency response national forces, and NATO allies. Noteworthy in this 12 month period is the completion and demonstration of the majority of the functional DoD requirements established for the **BEST** prototype. This global profile software technology solution represents a clear innovation to the ASBP DBSS database of blood donors and will be able to provide continuous and universal access to donors’ information in a secure setting, to help ensure data integrity, reliability and proper records management. **BEST** will assure the data are filed continually with each donor visit, each blood collection, each infectious disease test, each component manufactured from every donation and the final disposition of every blood component, and others. Goals achieved in the SBIR Phase II first year include: an executed data use agreement between CAMRIS/USAF, successful transfer of AFBP DBSS retired data to CAMRIS, the launching of a secure website for the public and working groups, and three live demonstrations of DoD requirements.

The CAMRIS team began regular (weekly) meetings December 22<sup>nd</sup> 2008 to discuss DoD requirements. Since then, a web-based workgroup area has been established by CAMRIS for online document sharing and collaboration <http://bestblood.camris.net/> (public username: Demo password: dBEST01!).

The CAMRIS team agreed on the technical scope of the **BEST** prototype as follows: ‘build’ refers to table definitions, user-definable rules and application configuration settings of standard commercially available software so that it can be run in an environment simulating DoD use. The term ‘build’ does not refer to analysis, design or coding of software or enhancements. The CAMRIS team identified and reviewed key

documents for requirements analysis. CAMRIS generated all the Standard Operational Procedures (SOPs), DBSS audits, and other documents that provided a basic understanding of requirements definitions for the original high-level specifications.

### **1.2.1 DoD Blood Donor Management Standard Operating Procedures and Processes (SOPs) as Basis for Specifications of a Modification Code Set for a COTS**

The objective of these activities was to provide a general description of the DoD Blood Donor Management processes and procedures using the legacy system DBSS v3.04. We did not focus on understanding information about policies, but rather focused on understanding DBSS v3.04 processes as “written descriptions of “how” a DoD facility using DBSS v3.04 turns the intent stated in the policies into actions to implement the applicable regulations, requirements and standards.” We organized procedures based on the processes. The documents referenced in the process-based procedure manual generated were then divided by donation and transfusion centers.

The following Standard Operating Procedures and Processes (SOPs) for DoD Blood Donor Management were created as part of the SBIR Phase II efforts based on AABB SOPs [3]:

- 1) GLOB - 001 - Global Description of DoD Blood Donor Management
- 2) GLOB - 002 - Reports Inventory DoD Blood Donor Management
- 3) GLOB - 003 - Data Conversion from DBSSv3.04 to COTS
- 4) SOP - 003 - DoD Blood Donor Management Blood Donor screening
- 5) PID - 001 - DoD Blood Donor Management Donation process
- 6) SOP - 009 - DoD Blood Donor Management Lookback case
- 7) SOP - 018 - DoD Blood Donor Management Lookback Reports (HCV Summary, Donor Implication, Person Implication, Transfusion Implication)
- 8) SOP - 018 - DoD Blood Donor Management Daily Donations and Donor Rare Qualities Reports
- 9) SOP - 018 - DoD Blood Donor Management Upload Report (Disposition, Projected Units Expiration, Inventory, Transfusion, and Shipment feeder)
- 10) SOP - 018 - DoD Blood Donor Management Product Reports (Destruction and Disposition)
- 11) BOR - DD2555 - DoD Blood Donor Management Blood Operations Report
- 12) SOP-020- DoD Blood Donor Management Mobile remote blood drives

These SOPs will have to be created and documented by any COTS vendor, and validated by DoD, for the necessary adaptation of any COTS to support DoD Blood Donor Management. These SOPs also constitute CAMRIS’ SBIR Data Rights. These rights are granted to and protected by DFARS 252.227-7018, Rights in Non-commercial Technical Data and Computer Software SBIR Program.

### **1.2.2 DoD Blood Donor Management COTS Design Requirements**

Based on our review of the requirement documents for DoD Blood Donor Management, we identified functions included in the initial system design that still had not been incorporated into the current DoD Blood



Donor Management processes. The following is the list of original design requirements that the **BEST** prototype was designed to comply with (✓= accomplished):

- 1.2.2.1 Global Donor Deferral ✓
- 1.2.2.2 Global Lookback ✓
- 1.2.2.3 Accurate, Timely, and Readily Available Reports ✓
- 1.2.2.4 Cryovial Shipment and Storage Management ✓
- 1.2.2.5 Laboratory Testing Equipment Interface ✓

#### 1.2.2.1 Global Donor Deferral

A global donor deferral capability would allow DoD blood donor centers to determine whether potential blood donors had been permanently or temporarily deferred from donating blood at any DoD Blood Program Organization. DBSS will identify and flag deferred donors, but the capability is limited to each individual facility. That limitation is significant for DoD because the DoD population is transient and could donate or receive blood products at many different locations. The advantages to having a global donor deferral capability is that it could reduce the time necessary to identify deferred donors, reduce unnecessary infectious disease testing, and save time spent by technicians in collecting and processing blood products that may ultimately have to be destroyed. In addition, the capability could decrease the possibility of the release of an inappropriate blood product. A global donor deferral capability was identified as an initial requirement for inclusion in DBSS version 2.00 and the required completion date was September 1999 in the Medical Readiness Strategic Plan 1998-2004 (the Strategic Plan), August 1998.[2]

The **BEST** prototype now complies with this functional requirement (Global Donor Deferral), and was demonstrated on February 23<sup>rd</sup> 2009. The demonstration included donor registration, screening and deferral functionality.

#### 1.2.2.2 Global Donor Lookback

A global lookback capability would allow the tracking of blood product disposition, blood donors, and blood recipients from a centralized location. The FDA requires a lookback capability to identify all donors and recipients of possibly infectious blood and any blood products that may have been donated by those individuals. It is performed for blood products that have tested positive for the human immunodeficiency virus, the hepatitis C virus, or the human T-lymphotrophic virus type-1. Currently, if a lookback must be performed, DBSS must be searched at every applicable facility to determine the source and recipients of the infectious blood products to ensure that the spread of the disease is contained and the recipients are treated. The advantages to having a global lookback capability are that it reduces the time necessary to search for blood products, donors, and recipients and could decrease the possibility of the release of an inappropriate blood product. A global lookback capability was identified as an initial requirement for inclusion in DBSS version 2.00 and the required completion date in the Strategic Plan was September 1999. [2]

The **BEST** prototype now complies with this functional requirement (Global Lookback) , and was demonstrated on July 13<sup>th</sup> 2009.

#### 1.2.2.3 Accurate, Timely, and Readily Available Reports

Accurate, timely, and readily available reports would reduce the need to manually create reports for internal and external uses. The thirteen (13) fixed facilities we contacted during this audit all reported problems with

DBSS reports. Users stated that the DBSS reports did not provide sufficient information for inventory management or planning purposes. In addition, only one (1) of thirteen (13) fixed facilities contacted had successfully generated an accurate feeder report for the DD Form 2555 “Blood Bank Operational Report” the quarterly report that contains all blood inventory and operations data for a Blood Program Organization. The Blood Bank Operational Report is the primary operational report for the Blood Program; the report data is consolidated by the Service Blood Program Offices and forwarded to the ASBPO. The ability for DBSS users and Blood Program management to obtain accurate and timely reports from DBSS would reduce the time necessary to compile report data and reduce possible reporting errors due to the manual recording of data or manual calculations.

The need for accurate, timely, and readily available reports was identified as an initial requirement for inclusion in DBSS version 1.00 and, although past system updates contained changes to reports, the problems had not been completely resolved by version 3.03. Of the 729 outstanding system requests, 90 concern DBSS reporting. However, as of May 2001, there were no report-related system requests approved for development or funding. The DBSS Project Office planned to correct this by surveying the user community for reports created at individual Blood Program Organizations that could have universal benefit to all users. [2]

The **BEST** prototype now complies with this functional requirement (Accurate, timely and readily available reports), and was demonstrated on July 13<sup>th</sup> 2009.

#### *1.2.2.4 Cryovial Shipment and Storage Management*

A cryovial shipment and storage management capability in DBSS would ensure that a cryovial can be easily identified and traced to its corresponding frozen red blood cell unit. Currently, cryovial inventories are maintained on various database programs, not DBSS, while frozen red blood cell inventories are maintained on DBSS. The cryovial inventory reports and DBSS frozen red blood cell inventory reports do not contain identical data, which makes it difficult to reconcile the two reports. A reconciliation of the reports is necessary to update the cryovial inventory when frozen red blood cell units are destroyed, used for training purposes, or shipped to another location. A cryovial shipment and storage management function in DBSS would ensure that the data reported for a frozen red blood cell unit and its cryovial are identical and would expedite the process of identifying cryovials for testing or for destruction. Cryovial shipment and storage management was identified as an initial requirement for inclusion in DBSS version 1.00 and, in November 1994, subsequent to the deployment of DBSS version 1.00, a system change request was submitted for the function. As of June 2001, the system request had been approved, but was assigned a low priority. [2]

The **BEST** prototype now complies with this functional requirement (Cryovial shipment and storage management), and was demonstrated on November 23<sup>rd</sup> 2009.

#### *1.2.2.5 Interface with Laboratory Testing Equipment*

The capability to record laboratory test results in DBSS through the use of an interface with the laboratory testing equipment would reduce the need for the manual entry of more than one million infectious disease test results annually. Some of the blood donor centers perform their own testing; however, most infectious disease testing is performed at centralized DoD or contractor testing sites that transmit the test results back to the blood donor center by facsimile. DBSS requires the test results to be entered twice and if there are any discrepancies between the data entered they must be reconciled. An automated interface with the testing equipment, whether the testing is performed at the blood donor center or at another site, would reduce the possibility of manual entry errors and reduce the risk of releasing inappropriate blood products. In addition,



since a blood product cannot be released until test results are entered, the interface could allow for faster release of blood products for transfusion or shipment. The laboratory testing interface was identified as an initial requirement for inclusion in DBSS version 1.00 and the required completion date in the Strategic Plan was March 1999. The function was funded for development in FY 2002 and FY 2003. [2]

The **BEST** prototype now complies with this functional requirement (Interface with laboratory testing equipment), and was demonstrated on November 23<sup>rd</sup> 2009.

**1.2.3 DoD Blood Donor Management COTS Design Specifications**

In sum, **BEST** requirements and specification definitions for the original high-level specifications were accomplished as follows:

**Table 3: SBIR Phase II Original DoD Design COTS Specifications.**

<ul style="list-style-type: none"> <li>• Global donor deferral</li>   <li>• Global lookback</li>   <li>• Accurate, timely, and readily available reports</li>   <li>• Cryovial shipment and storage management</li>   <li>• Laboratory testing equipment interface</li> <li>• Total asset visibility</li> </ul>	<ul style="list-style-type: none"> <li>• Basic donor registration in COTS donor management module</li> <li>• Donor screening in the Donor Doc application using Blood Donation Record DD Form 572.</li> <li>• Transmission of donor deferral, reported travel history, and physical exam results via the interface from COTS donor module</li> <li>• COTS donor recruitment module as it applies to ASBPO using donor groups are managed within DBSS. This new capability, which is not feasible with DBSS, allows facilities to create recruitment lists that exclude ineligible donors.</li> <li>• DD2555 Blood Bank Operational Report - Research, prototype, and coding activities were completed for the <b>BEST</b> custom report RPT_055. This report lists all components created from a single donor and identifies each component’s disposition.</li> <li>• Cryovial Shipment &amp; Storage was addressed by adding a new CRYOVIAL component. This component is created during the manufacturing process and is identified by the same Blood Unit Identification number as the parent donation. After creation, the cryovial may be located, transferred to another location, and used for subsequent testing.</li> <li>• Interfaces for laboratory equipment were successfully tested to COTS components of the <b>BEST</b> prototype.</li> <li>• Migration to an upgraded COTS donor module of <b>BEST</b> incorporated new functionality from a pre-release version that included capabilities to:             <ul style="list-style-type: none"> <li>○ Transfer products between locations</li> <li>○ Quarantine and/or discard either labelled inventory or components in process of manufacture</li> <li>○ Create Inventory Orders and to ship products to fill Inventory Orders</li> </ul> </li> </ul>
---	---

**1.3 Conclusion: The Phased SBIR – Why it Works in the U.S. for DoD**

This project started as an idea from Major Ileana Hauge (USAF/WPAFB) to overcome day-to-day shortcomings, and developed into a Small Business Innovation Research (SBIR) project. During Phase I, CAMRIS carried out 67% of the small business work which included the creation of a Phase II proposal

which included a commercialization strategy explaining how CAMRIS expected to rapidly move the technology to widespread commercial (Government or private sector) use. During Phase II, CAMRIS carried out 51% of the work in creating an innovative approach within real constraints to global profile software technology with both local and global field deployment potential capabilities.

Furthermore, CAMRIS considers the SBIR Phase III to represent the successful culmination of this SBIR project. While the Phase II success was measured by whether the **BEST** prototype developed by CAMRIS can meet a need, Phase III success will be indicated by the CAMRIS marketing and selling the products or services outside of the SBIR Program. Phase III revenues can be obtained from Government or private customers, and cannot use SBIR funds (these are reserved for Phase I and II projects). Phase II (now a few months from concluding in September 15<sup>th</sup> 2010) has been the demonstration phase in which prototypes are built and tested during the period of performance.

Finally, Phase III is the commercialization stage and the ultimate goal of the SBIR program. It will refer to work that derives from, extends, or logically concludes efforts performed under prior SBIR funding agreements, and can be funded by the commercial sector or government sources other than the SBIR Program. No further competition is required for a Phase III award as the competition requirements are satisfied in Phase I. Phase III work may be for products, production, services, R&D, or any combination thereof. There is no limit on the number, duration, type, or dollar value of Phase III awards and the small business size limits for Phase I & II do not apply. We are optimistic in the Phase III commercialization potential of the **BEST** prototype in the U.S. DoD and NATO.

## 2.0 REFERENCES

- [1] SBIR information and solicitation <http://www.sbir.gov/>.
- [2] Office of the Inspector General, Department of Defense, Report No. D-2002-010, October 22<sup>nd</sup> 2001.
- [3] AABB, Transfusion Service Manual of Standard Operating Procedures, Training Guides and Competence Assessment Tools, 2<sup>nd</sup> Edition, Edited by Lucia M. Berte, AABB Press, 2007.
- [4] AABB, Transfusion, Vol 48, No 7, July 2008.
- [5] AABB News, "Military Blood Program Looks at Dreams Fulfilled and Hopes for New Year", Pages 16-20, Vol 10, Issue No 12, December 2008.

