

EXECUTIVE SUMMARY

ACTION ITEM: APPROVAL FOR PURCHASE AND IMPLEMENTATION BY ARIZONA CANCER CENTER OF ONCORE ONCOLOGY RESEARCH MANAGEMENT SYSTEM IN THE AMOUNT OF \$575,054.

ISSUE: The University of Arizona requests Board approval of the purchase and implementation of the Oncore Oncology Research Management System from PercipEnz Technologies, Inc. at a cost of \$575,054 for a five year period. Pursuant to a directive announced at the Board's September 26-27, 2002 meeting, ABOR review and approval is required for projects exceeding \$500,000.

BACKGROUND:

- The purpose of this project is to provide a solution for the Arizona Cancer Center's need for a clinical trial management system that will be appropriate for reporting purposes to the National Cancer Institute.
- As the Arizona Cancer Center approaches the competitive renewal of its National Cancer Institute (NCI) Cancer Center designation, its Scientific Advisors have recommended for the last two years that it implement a functioning, web-based clinical research management system before its application for renewal is submitted and the NCI performs its site visit.
- PercipEnz Technologies, Inc.'s Oncore Oncology Research Management System is the only product that was specifically designed for NCI Cancer Centers and is the sole product available for NCI designated cancer centers that meets the NCI's requirements.
- The Board's directive requires that the Board must receive for review a summary that includes a project overview, deliverables, some indication of service or what the economic benefits will be to the particular group of interest for the project, project origin responsibilities, project management time lines, opportunities for collaboration among the universities, a summary of proposed costs, indications of marginal operating costs, and evaluation criteria. That information follows in a separate report.

RECOMMENDATION/CONCLUSION:

RESOLVED: That the Board hereby approves the purchase and implementation of the Oncore Oncology Research Management System from PercipEnz Technologies, Inc. at a cost of \$575,054 for a five year period.

Contact: Michele Norin, Executive Director, Central IT Units
(520) 621-5972, norin@arizona.edu
Margie Barber, Dir. of Admin. and Finance, Arizona Cancer Center
(520) 626-0027, mbarber@azcc.arizona.edu

University IT Project Justification SUMMARY SHEET

<i>Institution</i>	<i>Contact Name and Phone</i>
The University of Arizona	Michele Norin, 520-621-5972
<i>College or Unit</i>	<i>Date Submitted</i>
Arizona Cancer Center	April 9, 2007

Project:

Arizona Cancer Center Purchase and Implementation of Oncore Oncology Research Management System

Project Overview:

PercipEnz Technologies, Inc. will provide the Oncore Oncology Research Management System. This system will provide a solution to the Arizona Cancer Center's critical need for a clinical trial management system that will be appropriate for reporting purposes to the NCI. As the Arizona Cancer Center approaches the "competitive renewal" of our NCI Cancer Center designation, our Scientific Advisors have recommended for the last two years that we have a functioning, web-based clinical research management system before our application is submitted and the NCI performs their "site visit." The Oncore Oncology Research Management System is the only product that was specifically designed for NCI Cancer Centers.

Deliverables:

Installed hardware and software to support oncology research

One time conversion of protocol data, subject registration data, Serious Adverse Events (SAE) related data, and committee activity data

Recommended configuration to comply with Health Insurance Portability and Accountability Act (HIPAA) regulations

Two day immersion training program

Two day onsite Oncore Oncology Research Management System training program

On-call operational support Monday through Friday, 8:00am – 5:00pm

Service and Economic Benefits:

Oncore, through a collaborative product development process with 17 of the nations leading cancer centers, has been able to gather, distill and fine-tune the best ideas from world-class research institutions to deliver solutions addressing one of the key operational challenges facing us - clinical research protocol management. Their product is a dynamic and robust research informatics program driven by a complete understanding of clinical research operations -- an understanding that comes from their years of close collaborations with world-

class research centers. Oncore's functionality has constantly evolved over the last 7 years, and has kept pace with evolving priorities and they have been able to recognize and address the nuances in organizational needs and differences in organizational structures and processes between the various national centers.

The price quoted to the Arizona Cancer Center was certified to be less than or equal to the pricing given to PercipEnz's most favored customer or other governmental agencies. In addition, we have verified the cost of this product independently with other NCI centers, and we were able to get a two year price break due to the size of our patient accruals.

Project Roles and Responsibilities:

The following services would be provided by PercipEnz Technologies, Inc.:

1. Installation of the hardware and software.
2. A one-time conversion of the Cancer Center protocol data, subject registration data, Serious Adverse Events (SAE) related data, and committee activity data into Licensee's Oncore implementation.
3. Recommendations on how to use the security and access control capabilities of the Software in order to comply with HIPAA regulations.
4. A standard (2) two-day Immersion Training Program for (2) two licensee staff members at Licensor's facilities in Madison, WI.
5. A standard (2) two-day onsite Oncore Oncology Research Management System training sessions for the Licensee key users and trainers. Remote, web-based training for new features and capabilities in upgrades to the Software will also be provided.
6. Second-tier, end-user and operational support Monday through Friday, excluding holidays, between the hours of 8:00 a.m. and 5:00 p.m. Central Standard Time (CST).

No U of A personnel will be required for the design or development of the software, as this is a commercially available, fully developed product. Arizona Cancer Center personnel (Margie Barber, Linda Johnson and Michael Lukach) will interface with the PercipEnz Technologies, Inc. personnel once the product is purchased to monitor the system installation and insure proper transfer of existing patient clinical trials accrual data into the new system.

Sources of Funding:

Arizona Cancer Center indirect cost return, contracts, and gift funds will be used to purchase the system.

Project Management Timeline:

Data will be converted, software will become accessible and training made available when the procurement process is completed and initial payments have been made.

Opportunities for Collaboration

The Oncore Oncology Research Management System is specifically designed to support cancer research making it very unique to the University of Arizona.

In addition to addressing the critical needs for collaboration among cancer researchers, this product can also be used for non-oncology (e.g., cardiology and diabetes) research. Due to the complexity of oncology research, some of the functionality built into the Oncore product is not necessary for the other disciplines. Accordingly, PercipEnz created the "Enterprise Research Management" version of Oncore at the request of academic medical center Deans and research institute Directors to insure that a "system-wide" approach could be used for clinical research across all disciplines for health sciences research protocols. The new "Enterprise" model will address all non-oncology research, all systems will work with each other to provide the appropriate controls and data necessary for collaborative research projects, as well as providing a solution that will address clinical research for the University of Arizona Health Sciences colleges both at the Tucson campus and at the new Phoenix campus. All of these considerations are of critical importance to Keith Joiner, M.D., Vice Provost, Medical Affairs and Dean, College of Medicine, and Edward Shortliffe, M.D., Ph.D., Dean, College of Medicine-Phoenix.

Summary of Proposed Costs

Costs will include annual charges for software licensing and ongoing support, and one-time charges for hardware and consulting, as follows:

Five Year Total Cost

FY 06/07	FY 07/08	FY 08/09	FY 09/10	FY 10/11	Total
\$147,054	\$ 92,000	\$112,000	\$112,000	\$112,000	\$575,054