Ohio | Department of Development

Final Proposal Evaluation

2011

Third Frontier Medical Imaging Program

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This Report written by:

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Proposal Review Team

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- Paula Dunnigan, Project Leader
- Chuck Meadows
- Bill Munk
- Reed Slevin

❖ EXTERNAL REVIEWERS

Imaging Experts

- Tracy Lynn Faber

  B.S.E. (Case), Ph.D. in Biomedical Engineering (UTHSCD); Professor of Radiology, Emory University; specializes in methodology for quantifying information in medical images; American Society of Nuclear Cardiology; Editorial Board, *Journal of Nuclear Cardiology*

- John Oshinski

  Ph.D. in Mechanical Engineering, Georgia Institute of Technology; Associate Professor, Division of Radiology, Emory University; Director, MR Research Center, Emory School of Medicine; Co-Chair, NIH Workshop on High Field Cardiac MRI; Founding Member, Society of Cardiac Magnetic Resonance

Clinical Experience and Business Background
(End-User Perspective)

- Gordon Butler

  M.D., Northwestern; Residency in Radiology, UTSMC; Technology Analyst, Accenture, LLC

- Brian Cox

  M.D., UTHSC; M.E. Biomedical Engineering, Vanderbilt University; Residency in Radiology, UTSMC; Medical Device Licensing Associate, Vanderbilt University

- Erin Moody-Buethe

  M.D., UTHMC; M.B.A., UTD; Residency in Diagnostic Radiology, UTSMC; Project Manager for MRI device company with responsibility for device modifications, FDA and CE approvals, and beta testing

Overview of Proposal Evaluation Process

- Two-stage evaluation process
- The evaluation process is objective and robust. Its consistency has been evaluated through rescoring. Results were found to be independent of the composition of the individual review panels and consistent year-to-year.
- The objective of the **First Stage Evaluation** is to rank the proposals on the basis of which best meet the RFP requirements and then to select the highest-ranking proposals for more in-depth evaluation.
  - The cut-point is based on significant score differences and best use of evalution resources. Taratec recommends a cut-point and ODOD selects the cut-point.
- The objective of the **Second Stage Evaluation** is to rank the highest-scoring proposals from the First Stage on the basis of the quality of investment for the State of Ohio.
  - Ohio job and revenue creation/retention that is likely to occur within 3–5 years
  - Company viability and business functions that are planned in Ohio
  - Potential of the project to contribute to a cluster of related companies in an industry that Ohio is trying to build

Proposal Evaluation Process

❖ FIRST STAGE EVALUATION

- Conflict of Interest evaluation for each reviewer
- Each proposal is read by 3 reviewers (internal and external)
- Proposal is scored by each reviewer using a scoring instrument based on the RFP criteria
- All scores from each reviewer are entered into a database
- Reviewers provide written comments on areas of concern or those requiring clarification
- A list of proposals ranked on the basis of their average scores is produced
- Taratec meets with ODOD to establish the competitive range (cut-point) for each competition
- Proposals scoring above the cut-point advance to the Second Stage Evaluation

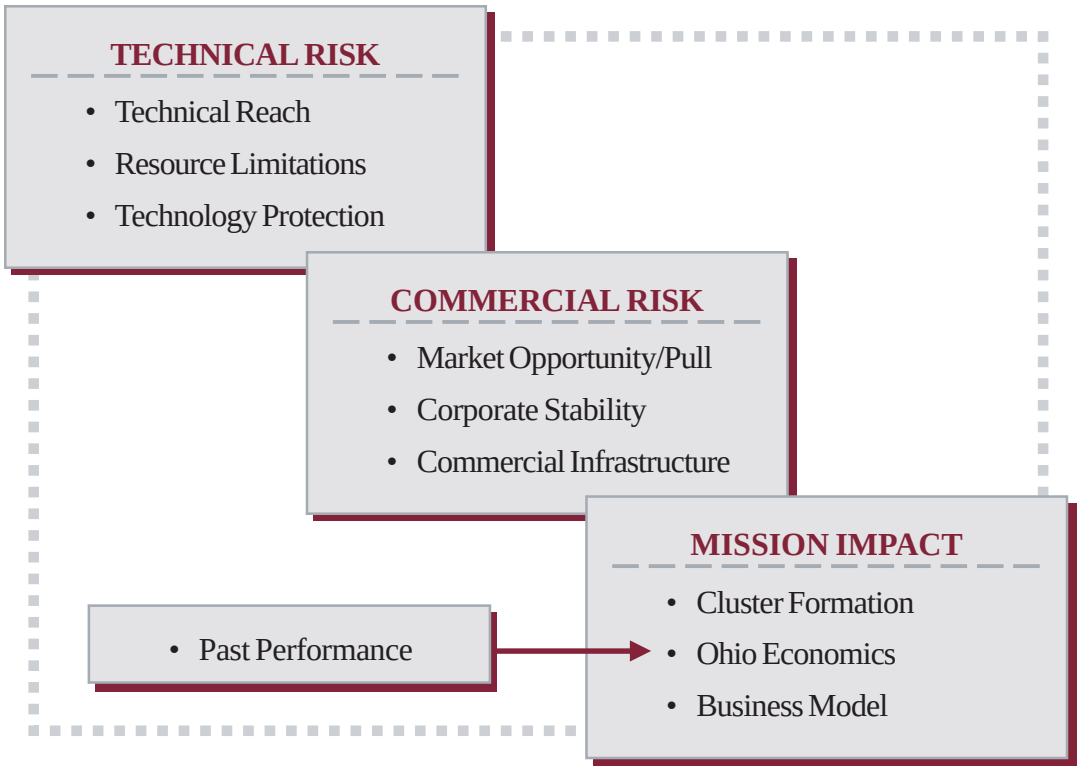
❖ SECOND STAGE EVALUATION

- Reviewer comments are integrated into the construction of a customized set of written questions for each applicant
- Applicants have one week to submit written responses
- Face-to-face meeting (90 minutes) for reviewers and applicants to discuss issues
- Final trade secret identification by applicants
- Preparation of 2-page project write-up and 2-page confidential summary
- Risk-benefit scoring by the entire review team
- Scores entered into the database
- Final recommendations developed
- Preparation of materials for consideration by the Third Frontier Commission

SUMMARY OF FIRST STAGE EVALUATIONS

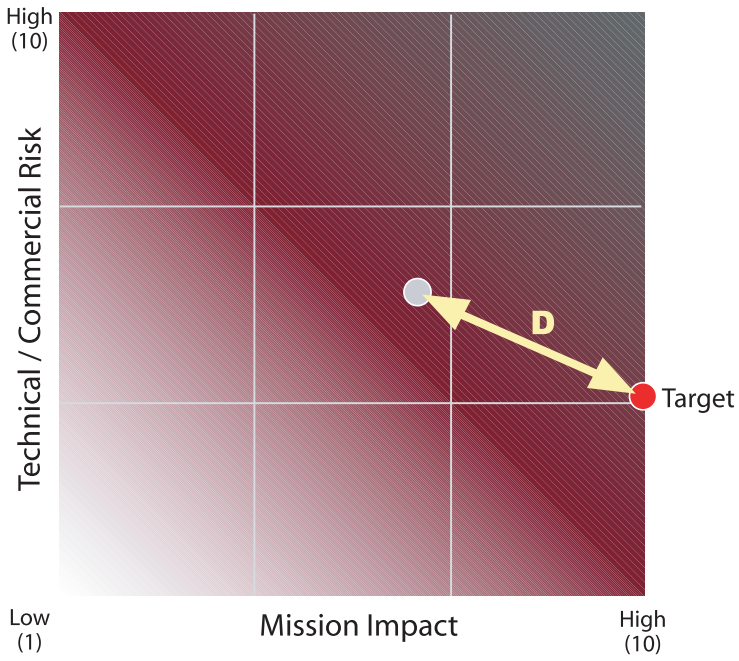
	TFBP	**TFMIP**	Total
Proposals Received	35	**17**	52
Proposals Recommended for 2nd Stage	18	**9**	27
Highest Score Recommended	82.3	**77.7**	
Lowest Score Recommended	59.0	**59.3**	
Highest Score Not Recommended	54.0	**56.7**	
TFRDF Available	$7M	**$7M**	$14M
Cumulative TFRDF Requested	$18M	**$8.9M**	$26.9M

SECOND STAGE EVALUATION FACTORS



Scoring Methodology *(continued)*

- Two 2-dimensional scoring matrices
  - One for Technical Risk
  - One for Commercialization Risk
  - Both risks are plotted against Mission Impact
- Target for Technical Risk is (10, 3.5)
- Target for Commercial Risk is (10, lowest value)
- Project's final score is based upon sum of D1 and D2



2011 TARGETS

	Technical Risk	Commercial Risk	Mission Impact
Biomedical	3.50	2.40	10.00
Medical Imaging	**3.50**	**2.33**	**10.00**

Target Definition for Ohio's Third Frontier Cluster Programs

The targets for Technical Risk, Commercial Risk, and Mission Impact have been set based on the profile of projects that are most likely to meet the intent of the Third Frontier Cluster Programs to develop new technology businesses that will produce economic development in Ohio in the 3- to 5-year timeframe. These targets were set after consultation with ODOD and the Third Frontier Commission.

Mission Impact

Ohio is seeking to fund the projects that will result in the highest economic development impacts for the dollars invested. Therefore, the target for mission impact has been set at the maximum of 10.

Technical Risk

Since economic development results are desired in a relatively short timeframe, projects selected for funding should be relatively mature, i.e., in the late Incubating or Demonstrating Stage with a functional prototype.

Projects that contain relatively little technical challenge, represent product line extensions, or are close to market are likely to score low on technical risk, i.e. 1 or 2. These types of projects would be candidates for internal funding by the applicant company, could attract investment, or would be bankable. They would not have the level of risk intended for this program.

At the other end of the spectrum, there will be projects that are still in early stages of development and have a number of significant technical and cost issues remaining to be resolved. These projects are frequently classified as Imagining or early Incubating Stage. They are likely to have technical risk scores in the range of 7–10. These projects would be candidates for federal R&D funding in the form of SBIRs or NIH grants. Only after they reach greater technical maturity would they be attractive candidates for the Third Frontier Cluster Programs.

The ideal level of technical risk for these three cluster programs has been set at 3.5. It is believed that this level of technical risk presents the optimum probability of achieving the intended economic development outcomes within the targeted timeframe.

Commercial Risk

The cluster programs are intended to serve the needs of both start-up companies and companies that have on-going business.

Existing companies frequently have well-developed distribution channels and some degree of financial stability resulting in low commercial risk scores. However, they may require assistance in new product development to reach a level of product maturity that will allow them to compete for scarce internal resources. Proposals from these companies will typically have commercial risks that score in the range of 1.5–2.5.

It was decided that these companies should not be penalized for having "too low of a commercialization risk." Therefore, for each competition, the target for commercial risk is set as the floor or at the lowest value of all proposals in the competitive range. This ensures that no proposal is penalized for having the ability to bring its product into the marketplace.

2011 TFMIP

Third Frontier Medical Imaging Program

Summaries of Proposals in Competitive Range

Recommendations for Funding
2011 Third Frontier Medical Imaging Program (TFMIP)

RECOMMENDED FOR FULL FUNDING

	OTF NO.	APPLICANT	SECOND STAGE SCORE	OTF $ REQUESTED	OTF $ CUMULATIVE
1.	TFMIP 11-606	Imalux Corporation	88.5	$ 987,000	$ 987,000
2.	TFMIP 11-615	Quality Electrodynamics	78.9	$1,000,000	$1,987,000
3.	TFMIP 11-612	Case Western Reserve University	71.9	$ 999,649	$2,986,649
4.	TFMIP 11-604	Case Western Reserve University	68.2	$1,000,000 (+ $580,000 WCF)	$3,986,649
TOTAL FUNDS REQUESTED					**$3,986,649**

2011 Third Frontier Medical Imaging Program Final Round Scores

SCORE		City	County	OTFRD $ Requested	OTFRD $ Cumulative	WRIGHT $ Requested	WRIGHT $ Cumulative
Targets - Mission Impact: 10 Commercial Risk: 2.33 Technical Risk: 3.5							
88.5	**TFMIP 11-606** Imalux Corporation Commercialization of an Innovative Medical Imaging System for Early Cancer Detection Technical Risk: **3.4** (R: 3.67 L: 3.33 P: 3.00) Commercial Risk: **4** (P: 3.00 S: 5.00 I: 4.00) Mission Impact: **9.09** (C: 7.67 E: 10.0 M: 8.67)	Cleveland	Cuyahoga	$987,000	**$987,000**	$0	**$0**
78.9	**TFMIP 11-615** Quality Electrodynamics Development and Commercialization of a Novel Imaging System to Determine Organ Viability Technical Risk: **4.73** (R: 6.67 L: 3.00 P: 4.33) Commercial Risk: **3.67** (P: 5.00 S: 2.67 I: 3.00) Mission Impact: **7.75** (C: 8.33 E: 6.67 M: 9.33)	Mayfield Village	Cuyahoga	$1,000,000	**$1,987,000**	$0	**$0**
71.9	**TFMIP 11-612** Case Western Reserve University PET/CT and PET/MR scanner options for Positron Emission Mammography Technical Risk: **6.40** (R: 8.00 L: 5.67 P: 4.67) Commercial Risk: **2.34** (P: 3.67 S: 1.67 I: 1.00) Mission Impact: **7.17** (C: 7.00 E: 6.33 M: 9.00)	Cleveland	Cuyahoga	$999,649	**$2,986,649**	$0	**$0**
68.2	**TFMIP 11-604** Case Western Reserve University Cardiac Perfusion with Computed Tomography Technical Risk: **7.27** (R: 8.67 L: 6.33 P: 6.33) Commercial Risk: **2.33** (P: 4.00 S: 1.33 I: 1.00) Mission Impact: **7.00** (C: 8.00 E: 5.67 M: 8.67)	Cleveland	Cuyahoga	$1,000,000	**$3,986,649**	$580,000	**$580,000**
61.9	**TFMIP 11-627** FMI Technologies Inc. Commercialization of the ScintiStar Cardiac LPX PET/CT for MyocardialPerfusion Imaging and CT Calcium Scoring for Global Markets Technical Risk: **6.6** (R: 7.00 L: 6.33 P: 6.33) Commercial Risk: **5.8** (P: 5.33 S: 5.67 I: 7.00) Mission Impact: **6.67** (C: 5.67 E: 7.67 M: 5.67)	Akron	Summit	$1,000,000	**$4,986,649**	$1,000,000	**$1,580,000**
60.9	**TFMIP 11-609** Hyper Tech Research, Inc. Manufacturing of Conduction Cooled Specialty MRI MagnetsUsing Magnesium Diboride Superconducting Wire Technical Risk: **6.60** (R: 8.00 L: 5.67 P: 5.67) Commercial Risk: **5.4** (P: 6.00 S: 5.33 I: 4.33) Mission Impact: **6.33** (C: 6.33 E: 6.00 M: 7.00)	Columbus	Franklin	$999,999	**$5,986,648**	$0	**$1,580,000**
52.6	**TFMIP 11-633** Advanced Imaging Research MRI Compatible, Neonate Imaging Sub-System Technical Risk: **6.27** (R: 6.00 L: 7.33 P: 4.67) Commercial Risk: **6.2** (P: 7.00 S: 6.00 I: 5.00) Mission Impact: **5.25** (C: 4.67 E: 5.67 M: 5.00)	Cleveland	Cuyahoga	$1,146,250	**$7,132,898**	$0	**$1,580,000**

2011 Third Frontier Medical Imaging Program Final Round Scores

SCORE		City	County	OTFRD $ Requested	OTFRD $ Cumulative	WRIGHT $ Requested	WRIGHT $ Cumulative
Targets - Mission Impact: 10 Commercial Risk: 2.33 Technical Risk: 3.5							
49.1	**TFMIP 11-610** Cleveland Clinic Foundation Ophthalmic Imaging Center	Cleveland	Cuyahoga	$999,996	**$8,132,894**	$0	**$1,580,000**
48.1	**TFMIP 11-632** Tursiop Technologies, LLC High-performance nanotechnology-based imaging coils forprostate imaging applications	Cleveland	Cuyahoga	$781,222	**$8,914,116**	$0	**$1,580,000**

49.1 — TFMIP 11-610

Technical Risk: **6.93**	Commercial Risk: **8.2**	Mission Impact: **5.92**
R: 7.67 L: 6.33 P: 6.67	P: 8.00 S: 8.33 I: 8.33	C: 4.33 E: 7.00 M: 5.33

48.1 — TFMIP 11-632

Technical Risk: **6.33**	Commercial Risk: **7.2**	Mission Impact: **5**
R: 7.33 L: 6.67 P: 3.67	P: 7.00 S: 8.00 I: 6.00	C: 4.33 E: 5.00 M: 5.67

Ohio Department of Development

2011 TFMIP Evaluation Summary

Third Frontier Medical Imaging Program

Imalux Corporation

Commercialization of an Innovative Medical Imaging System for Early Cancer Detection

TFMIP 11-606 Final Score: 88.5 Rank: 1

Previous Ohio Investment

At the time of its initial TFAF grant application in 2002, Imalux had developed a working prototype of its device for a new medical imaging technology known as optical coherence tomography (OCT). This equipment was intended for use by clinicians in screening for cervical cancer. The device had been tested extensively and had produced results in agreement with pathology findings. Imalux received a TFAF grant of $542,000 to build additional prototypes and a probe protector and to conduct additional clinical testing of equipment. The company planned to purchase standard optical components and to build or have built proprietary imaging devices. Imalux was successful in obtaining 510 (k) approval from FDA for this equipment in 2004, and commercialized the device in mid-2005. To date, Imalux has manufactured and sold 50 units (35 used for use in clinical trials) resulting in total sales of $560,000 creating 8 jobs. Imalux has leveraged the OTF grant to raise $17M in federal grants and private equity investments.

Project Description

In 2004, Imalux designed, built and received FDA 510(k) clearance for marketing its non-destructive, OCT device —the "Niris® Imaging System". This first generation prototype system uses a fiber optic probe with a beam of near infrared light to capture a static image of a tissue surface and the 2.5mm deep underlying region of that tissue. This static, real-time image enables a physician to identify diseased tissue (60% of cancerous tissues are normally <1.4 mm deep) before it is visible on the surface, allowing for earlier and more accurate detection and diagnosis of cancerous, pre-cancerous, inflammatory, and degenerative structural changes of suspected tissues in the cervix, bladder, mouth, larynx, trachea, bronchi, esophagus, lungs, stomach and intestines. In this 2-year project, Imalux will begin commercialization of an improved production version of the Gen1 prototype system, the Enhanced NirisR. This second generation version (Gen2) generates a dynamic image at 8 frames/second (12 times faster than the Gen1 prototype system) and will be ready for market release in Year 2. In addition, Imalux will complete design work and make pre-production units of the third generation, Advanced NirisR. This Gen3 version will produce an even better dynamic image (25 frames/second) for "movie like" video imaging allowing more advanced applications such as guided surgeries. Plans are for limited release of the Gen2 and Gen3 systems by the end of the project.

Key Issues

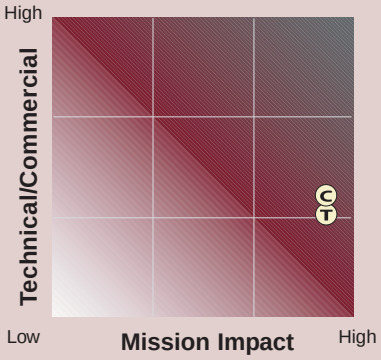
- Imalux has been able to attract significant investor support and will be closing its fourth investor round in 2011. While the NinrisR system will be introduced in the next 2 to 3 years with or without an OTFMIP award, the proposed funding will accelerate the commercialization schedule for the Imalux systems allowing earlier market entry and increased market capture.
- The market share projections are not unreasonable, but appear aggressive based on the current status of the commercial infrastructure and partnership relationships.

Technical Risk

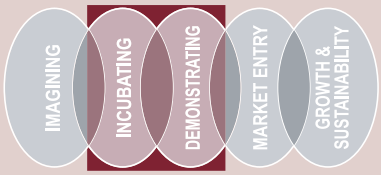
Overall Score = 3.40

Technical Reach

As a result of positive market feedback, Imalux developed Gen2. GVI will make preproduction units of Gen2, Imalux will expand its capabilities and make the preproduction probes for Gen2, and the Cleveland Clinic (CC) will perform clinical validations. GVI and Imalux will ramp up to production quantities for market release in 2012. Under a separate NCI SBIR grant, Imalux developed a proof-of-concept, bench-top Gen3 system using an advanced, proprietary high speed imaging sensor bench top system. GVI will make preproduction units of Gen3, Imalux will make the preproduction probes for Gen3, and the CC will perform clinical validations. Imalux will release the limited preproduction Gen3 systems for clinical trials by the end of the 2-year project. The Gen1 system has received FDA 510(k) clearance for marketing as a class II device, so Imalux be-



Stage of Development



County Location

Funds Requested

TFRDF Request:	$ 987,000
WCF Request:	$ 0
TOTAL Request:	$ 987,000
Cost Share:	$1,165,400

Collaborators

- Cleveland Clinic
- GVI Medical Devices, Inc.

lieves that the Gen2 version will not require additional FDA clearance. Gen3 likely will require FDA clearance and a submission will be ready by project end.

Resource Limitations

Imalux has very capable technical abilities, and the CEO has prior successful experiences with medical device startup companies. Imalux will rely upon the expertise of the suppliers for overcoming the challenges of their respective components, and the Cleveland Clinic and CWRU for the clinical trials and evaluations. Imalux has raised $17M in equity capital investments to date, and forecasts the need for $7M to achieve full commercialization. Imalux already has $245,000 grant, $2M in Round C equity, and $1M bridge financing from investors. Imalux anticipates another $3M equity investment, and the $1M OTF grant to fill out the $7M for commercialization. Imalux is providing the required cost share, with additional support from GVI.

Technology Protection

Imalux owns 26 issued US patents and has several patents pending. The Imalux OCT technology platform is based upon technology from the Institute of Applied Physics (IAP) of the National Academy of Sciences, Russia. This patent portfolio covers a variety of proprietary technologies that enable Imalux to deploy devices with high image quality at an affordable cost. Imalux has an open contract with IAP for developing additional IP. Imalux has a signed manufacturing agreement from Optiphase (CA), a critical vendor, for use of its fiber optical interferometer patented technology. Imalux secured exclusive licensing rights for technology related to the disposable sheath, and manufactures its own probes that are a central, proprietary element of the Niris family of products. The technical knowledge relating to probe manufacturing is a closely guarded Imalux trade secret. Imalux has received FDA clearance and ISO and CE Mark certification for the current product.

Commercialization Risk

Overall Score = 4.00

Market Opportunity/Pull

As a result of positive feedback from Gen1 at 21 hospitals worldwide, Imalux contends there is a established market pull. Of the $2B plus estimated market size, Imalux estimates the maximum potential market size in the USA is $821M. There are other OCT related companies in the medical arena (St. Jude Medical, Zeis Meditech, Michelson Diagnostics, Topcon Medical, Tomophase Corporation, etc.), but their FDA clearances limit them to anatomical areas not targeted by Imalux. The main competition will come from standard, current biopsy practices. Imalux believes its base system prices (module and probe) and disposable sheath prices (razor and razor blade model) will allow it to compete successfully in the urology, ENT, and gynecology markets.

Corporate Stability

The predecessor to Imalux was formed as a medical device developer and manufacturer in 1996 in Cleveland, Ohio by a team that included the Russian inventors and a Cleveland law firm. Over the next several years, the group received seed funding to conduct investigational studies at The Cleveland Clinic Foundation, file a series of U.S. patents, and commercialize the Niris OCT Imaging System. In 2010, Imalux generated revenues of approximately $1M, mostly in the form of grants and projects, and became revenue positive in 2011.

Commercial Infrastructure

Imalux currently has a 2,300 square foot office and lab area in the BioEnterprise facility and 9 employees. Imalux manufactures the probes in-house, plans to expand production capability, and distribute them from this Cleveland facility. Imalux outsources most component manufacturing to CMO's, including GVI, who will expand its pilot and production-scale capabilities at its Twinsburg, OH plant. Imalux will establish a direct sales and service force for USA hospitals and institutions, engage strategic partners for clinical offices in the USA, and set-up 2 service facilities. Imalux will use strategic partners and dealers for international sales and service.

Mission Impact

Overall Score = 9.09

Cluster Formation

Imalux is working with Ohio hospitals for conducting clinical trials (Cleveland Clinic, Case), utilizes Ohio contract manufacturers (Robins Industries, GVI), and purchases products and services from over 150 Ohio-based supply chain companies.

Ohio Economics

Revenues from the Gen1 system will increase in 2011 with Gen2 and Gen3 sales generating revenues beginning in years 2 and 3. Imalux projects that total revenues from Gen2 and Gen3 in Year 3 will reach about $20M, growing to over $70M in year 5. Imalux and GVI will add 17 jobs during the project period, growing to 31 in Year 3 and 75 in Year 5. The year revenue projections represent an approximate 10% market capture of potential hospital sales for the initial 3 market segments being targeted. Without OTFMIP support, the timing of the Ohio impacts will be delayed, and the revenue projections will be reduced by at least 50%.

Business Model

Imalux plans to be a developer of medical imaging devices, will manufacture the proprietary probes and outsource complete device manufacturing. It will augment its direct sales force with partners and with organizations that have sales and marketing networks in the appropriate domestic and international markets. Partnerships may involve joint ventures, exclusive distribution rights, and licensing. Most component production is planned at contract manufacturing organizations, while the production of the anatomically specific probes will be done in-house.

Prior Ohio Investments

- Development of OCT in Management of Cervical and Vulvar Cancer, 2002, $542,000

Ohio Department of Development

2011 TFMIP Evaluation Summary

Third Frontier Medical Imaging Program

Quality Electrodynamics, LLC

Development and Commercialization of a Novel Imaging System to Determine Organ Viability

TFMIP 11-615 Final Score: 78.9 Rank: 2

Previous Ohio Investment

Quality Electrodynamics (QED) has received five grants since 2006, including an Ohio Rapid Outreach Grant and Training Grant, a New Energy and Industrial Technology Development Organization (NEDO) grant, a GCIC grant focusing on the commercialization of a 32-channel MRI cardiac array coil and most recently a 2010 OTFMIP award for RF coils for the Siemens 7T MRI system. Dr. Fujita, Founder, President & CEO of QED, was also involved as a collaborator and co-investigator with Ohio State University, Case Western Reserve University, and Philips Medical Systems in the Wright Center for Innovation in Biomedical Imaging (WCIB) Third Frontier Grant (2003) focused on the development and commercialization of Ultra High Field (UHF) MRI systems, and its Phase II grant, the Biomedical Research and Commercialization Program (2006).

The 2010 project has just gotten underway and is on schedule for meeting its objectives and milestones. Overall QED has transitioned from a start up technology development organization in 2006 to a product manufacturer now employing over 70 staff with annual revenues well over $10M.

Project Description

In this 2-year project, QED proposes developing a turn-key RF coil package for donor kidney imaging to determine the renal viability of the kidney before transplantation. The package, called the vMRI system, includes a temperature-controlled kidney cradle assembly with transmit and receive coils; interfaces for integrating the vMRI to major OEM MRI systems; and optimized MRI/S (magnetic resonance spectroscopic imaging) protocols. Project tasks include a design phase leading to preliminary vMRI prototype to be tested at Toshiba and CCF sites; a Beta level prototype construction and testing phase in which the vMRI is integrated into Toshiba MRI unit and performance validated; and a production phase in which 3 pre-production units will be built, the system UL certified and a pilot production run made. By the end of the project, the new RF coil will be released for production and market entry.

Key Issues

- The business potential for the vMRI system in the renal transplant market is growing, but in itself is relatively modest over the next 5 years. However, the ultimate potential for determining transplant viability is much larger and the demand is great as the success rate in transplant procedures is increasing.
- The OEM collaborators in the project do not currently have manufacturing operations in Ohio, but have committed to be vMRI system purchasers and to assist in system marketing. Toshiba has established Toshiba Medical Systems USA in Mayfield Village to enhance its ability to interface with QED and the imaging expertise in NE Ohio.

Technical Risk

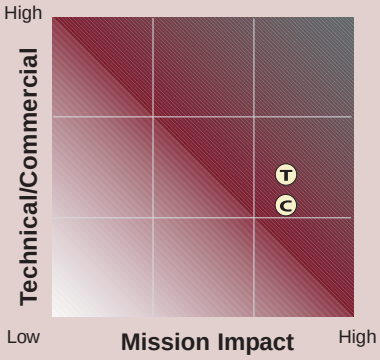
Overall Score = 4.73

Technical Reach

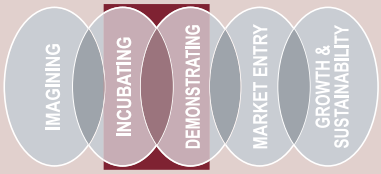
QED will use its extensive background in coil development to design the high-field coil. The disposable cold static state (CSS) device that holds the kidney during the measurement has been prototyped and the OEM collaborators will assist QED in developing the clinical protocols and tailoring the MRI sequences to be executed. The clinical study will be designed to be large enough to cover a variety of donor profiles and histology. QED expects to reach market entry by the end of the proposed project with a clinically validated vMRI system.

Resource Limitations

QED's project team has the skills and capabilities to design and develop the vMRI proposed. QED indicates the project funding and collaborating Case, Clinic and OEM support ensure the availability of sufficient resources to carry the vMRI technology to market entry.



Stage of Development



County Location

Funds Requested

TFRDF Request:	$1,000,000
WCF Request:	$ 0
TOTAL Request:	$1,000,000
Cost Share:	$1,002,000

Collaborators

- Cleveland Clinic Foundation, Glickman Urological Institute
- Case Western Reserve University, Department of Radiology
- Toshiba Medical Systems
- Canon, Inc. (Tokyo, Japan)

QED will be responsible for both the short- and long-term financing needed for full commercialization and does not expect to seek outside capital investment.

Technology Protection

Two patent applications (filed 12/2010 and 1/2011) form the basis for the vMRI system. In addition the vMRI relies on QED's unique and trade secret RF coil and compact preamplifier designs. All IP and trade secrets will remain at QED in Ohio.

Commercialization Risk

Overall Score = 3.67

Market Opportunity/Pull

The vMRI proposed fulfills an unmet market need for determining the viability of kidney transplants. The opportunity is supported by the growing gap between demand and useable transplants. Currently there are over 85,000 patients waiting for a kidney transplant in the U.S. alone. Based on the number of hospitals performing renal transplants that could use a vMRI system, the U.S market is currently estimated to be about $10M and growing. Globally the market potential is about $35M. QED is an OEM coil supplier to both Toshiba and Siemens, and these MRI system manufacturers are committed to integrate vMRI into their MRI/S systems. Other applications for transplant viability determinations represent a total potential market of several hundred million dollars.

Corporate Stability

QED was founded in 2006 and has rapidly become a world leader in the development and manufacture of high quality RF coils for MRI imaging systems from 0.35 to 7 Tesla. It is internally funded and profitable. Its sales in 2010 grew by over 40% and exceeded $15M. QED has strategic partnerships with several MRI system OEMs and has received national recognition for its growth and business potential.

Commercial Infrastructure

QED has a 27,000 square foot facility in Mayfield Village, OH that houses all of its business operations. It established sales/marketing channels and partner agreements with leading MRI system OEMs to assist in product distribution and co-branding of the vMRI system. QED is ISO certified and compliant with all necessary regulatory certifications (FDA, CE Mark, etc.).

Mission Impact

Overall Score = 7.75

Cluster Formation

QED leverages the imaging expertise resident in Ohio, including the talent from the medical institutions/colleges in NE Ohio. QED has established itself as part of Ohio's medical imaging/biomedical supply chain and also utilizes others in that supply chain for subcomponents for the vMRI system. Clinical work at the Cleveland Clinic, a committed end-user of the vMRI, is planned. A potential for Canon, a collaborator on the project, to start a new venture (R&D Center) in Ohio exists, but this remains speculative at this time.

Ohio Economics

QED projects revenues from the renal application of the vMRI in Year 3 to be about $1M growing to over $10M by Year 5 for capital equipment, disposables and service contracts. QED plans to add 14 employees during the project period and a total of 22 by Year 3 and 38 by Year 5. By Year 5 QED expects to introduce vMRI products for other transplant applications.

Business Model

QED will manufacture the vMRI systems in Ohio. It will follow its successful model used for its current MRI coil business and market systems directly to transplantation hospitals and its global MRI system OEM partners. Once the product has established a reputation for determining renal transplant viability, other applications will be addressed.

Prior Ohio Investments

- 7 Tesla High-Density MRI RF Coil Development and Commercialization, 2010, $1,000,000

Ohio Department of Development

2011 TFMIP Evaluation Summary

Third Frontier Medical Imaging Program

Case Western Reserve University

Positron Mammographic Imaging

TFMIP 11-612 Final Score: 71.9 Rank: 3

Previous Ohio Investment

Philips was a collaborator on a BRTT-Wright Center of Innovation award to OSU that contributed to the development of the Philips 7T MRI research system ($17.1M). Cumulative sales of that system have reached $85M and the program has sustained 17 engineering positions. Philips was also a collaborator on a 2006 BRCP award of $7.9M. This project contributed to the development of the Philips Ingenuity TF PET/MR system. Sales of the Ingenuity product are $45M, and Philips hired 13 engineering positions to support this product. As a result of these awards, Philips decided to keep development of new imaging devices and manufacturing in Ohio. It established the Philips Healthcare Global Advanced Imaging Innovation Center in Cleveland in 2010 with a $33.4M investment (plus a $5M OTF award) and is considering an investment of a similar amount in a second phase of the center.

OSURF received a 2009 Wright Project award of $3M to purchase a Philips Brightview SPECT/xCT unit with improvements from Philips and to upgrade the physical facilities where it would be installed. This project was projected to lead to a sales increase of $150M by 2017 for Philips and an annual increase of $50M for Cardinal Health's radiopharmaceutical business resulting in the creation of 20 jobs at the SPECT Center and 300 jobs at the industrial partners. The project has been delayed and the space will not become available until July 2011.

Philips received a 2010 TFMIP award of $1M to develop an upgrade for the Philips Gemini TF PET/CT scanner to allow it to quantitatively measure myocardial blood flow. That project was expected to increase PET/CT sales by $49M in 2013 and another $49M in 2015 leading to the creation of 5–7 new production jobs. That project has just gotten underway.

Project Description

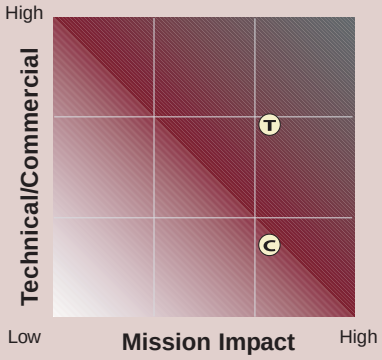
A key objective of this project is to develop positron mammographic imaging (PMI) to evaluate MR findings to assess if they are actually cancer. The project is focused on improving the spatial resolution of PET. Initially, PMI will be developed using a PET/CT system, but the technology also will be applicable to PET/MR systems that may be technologically and medically superior to PET/CT but currently have limited availability.

This project will involve developing an optimal positioning system for PET breast imaging that is MR compatible. The positioning system is expected to involve a modification of the system used by Invivo, a company recently purchased by Philips. High spatial-resolution image reconstruction algorithms will be developed at Case along with optimized imaging protocols. The performance of this product modification will be evaluated in phantom testing and clinical trials at University Hospitals. Case anticipates submission of a 510(k) by the end of this 2-year project.

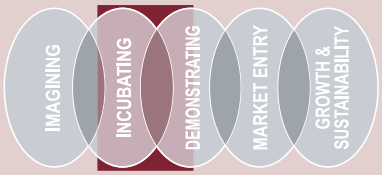
The goal of the project is to create and commercialize product options that are optimized for breast imaging using the Gemini PET/CT, Gemini TF PET/CT, Ingenuity PET/CT (a newer platform introduced in 2010), and PET/MR scanners. Philips plans to review the results from this project and its own internal work and will make a decision on committing to a platform for PET/CT and/or PET/MR. Product release could occur within 6–12 months of FDA approval.

Key Issues

- Mammography is used as a screening method for evaluating the presence of breast cancer in asymptomatic women. PMI would be applied to high-risk women and/or would be used for staging, restaging, and monitoring response to treatment after initial diagnosis.
- Philips has customers that require breast imaging capability on the Philips Ingenuity TF PET/MR and planned to introduce the capability at its initial release. However, during clinical validation, unanticipated technical issues arose causing Philips to release this unit without this capability.
- The resources available to Philips have been stretched by the introduction of the Ingenuity line in late 2010. The purchase of



Stage of Development



County Location

Funds Requested

TFRDF Request:	$ 999,649
WCF Request:	$ 0
TOTAL Request:	$ 999,649
Cost Share:	$1,000,613

Collaborators

- University Hospitals—Case Medical Center
- Philips Healthcare

the Invivo Corporation will minimize the cost of developing the PMI capability, and this Ohio investment is expected to push the development of this capability ahead by 2–3 years.

Technical Risk

Overall Score = 6.40

Technical Reach

This project is in the early incubating stage. It will be a hardware and software add-on for existing PET/CT and PET/MR systems. While PET breast imaging data is routinely obtained today using current imaging equipment, it provides two-dimensional images of a single breast. Better patient positioning and high spatial-resolution image reconstruction are needed to detect smaller lesions that may be located close to the chest wall. Fusing of MRI and PET breast images has been reported, but additional developmental work is needed on the Philips hardware, software, and clinical protocols before clinical evaluations can be done.

Resource Limitations

The combined staff of Philips and Case presents a strong technical team. University Hospitals has the full complement of radiologic equipment relevant to this project including a Philips Gemini TF PET/CT. An additional big-bore version and an Ingenuity PET/MR (only the second unit in the U.S.) will be available when UH's new cancer hospital opens in Spring 2011. Plans for obtaining regulatory approval and beginning commercialization of this product option are described but are contingent upon satisfactory product performance at the end of this project.

Technology Protection

Philips has an extensive patent portfolio covering its existing product line. Specific IP related to PMI has not been described. Case, as the lead applicant, is planning to execute a research agreement with Philips and University Hospitals covering IP ownership of innovations made during this project.

Commercialization Risk

Overall Score = 2.34

Market Opportunity/Pull

Breast cancer is the most common malignancy in women in the U.S. and is second only to lung cancer as a cause of cancer death. PET imaging of breast cancer represented 17% of all oncology studies in 2008, and it was the fastest growing segment with an increase of 65% between 2003 and 2008. Improved spatial resolution and the ability to identify much smaller tumors are expected to accelerate this growth. The installed number of systems to which this project would be applicable is approximately 1,000 units. With a price of $100K per retrofit the potential retrofit market $100M. The availability of this option might also increase Philips' market share for new units that is roughly 20–25% of an $800M market.

Corporate Stability

Philips Healthcare is one of the world's largest manufacturers of imaging equipment including x-ray, ultrasound, CT, MRI, and PET. Philips Medical Systems has 1,100 employees and a 1M square foot facility in Cleveland. This facility is the location of all of Philips' North American training. It is the company's global headquarters of nuclear medicine, high field imaging, PET, CT, and refurbishment.

Commercial Infrastructure

All expertise required for the commercialization of the PMI option is available at Philips Healthcare's facility in Highland Heights, OH including sales, marketing, and distribution. Philips has the ability to produce this product in Ohio and to sell it throughout the world. If this option results in increased sales of the Gemini and/or Ingenuity lines, production increases will occur in Ohio.

Mission Impact

Overall Score = 7.17

Cluster Formation

This project will enhance the Philips Healthcare Global Advanced Imaging Innovation Center by strengthening the collaboration between Case, University Hospitals, and Philips. The product will be developed at Case with assistance from Philips and clinically evaluated at University Hospitals. After product introduction, it is expected to increase demand for a product currently produced in Ohio, and this may increase sales for Ohio supply chain participants.

Ohio Economics

Philips recognizes that software does not drive job creation. This project will create economic development impacts by direct sales of retrofits for the Gemini and Ingenuity units and by increasing overall sales for these PET/CT units because of their greater utility. The proposal indicated that the retrofit option was projected to generate sales of $19M in 2013, $12.9M in 2014, and $9.3M in 2015 with the creation of 3–4 jobs. Pull-through sales due to the availability of the breast imaging option for the Gemini and Ingenuity units are expected to add $9M annually and will create additional manufacturing jobs.

Business Model

All of Philips' manufacturing of high-end CT is done in Ohio. Philips also maintains major operations in Ohio including sales, distribution, customer support, and training. It is believed that Philips makes extensive use of an Ohio supply chain in its CT manufacturing, but details on level of Ohio participation were not provided.

Prior Ohio Investments

- Wright Center of Innovation in Biomedical Engineering, (OSU with Philips as a collaborator), 2003, $9.1 million
- The Biomedical Structural, Functional and Molecular Imaging Enterprise, (OSU with Philips as a collaborator), 2006, $7,878,957
- The Molecular Imaging SPECT Technology Center, (OSURF with Philips as a collaborator), 2009, $2,999,924
- PET/CT Scanner Optimized for Quantitative Myocardial Blood Flow, (Philips), 2010, $999,175

Ohio Department of Development

2011 TFMIP Evaluation Summary

Third Frontier Medical Imaging Program

Case Western Reserve University

Cardiac Perfusion with Computed Tomography

TFMIP 11-604 Final Score: 68.2 Rank: 4

Previous Ohio Investment

Philips was a collaborator on a BRTT-Wright Center of Innovation award to OSU that contributed to the development of the Philips 7T MRI research system ($17.1M). Cumulative sales of that system have reached $85M and the program has sustained 17 engineering positions. Philips was also a collaborator on a 2006 BRCP award of $7.9M. This project contributed to the development of the Philips Ingenuity TF PET/MR system. Sales of the Ingenuity product are $45M, and Philips hired 13 engineering positions to support this product. As a result of these awards, Philips decided to keep development of new imaging devices and manufacturing in Ohio. It established the Philips Healthcare Global Advanced Imaging Innovation Center in Cleveland in 2010 with a $33.4M investment (plus a $5M OTF award) and is considering an investment of a similar amount in a second phase of the center.

OSURF received a 2009 Wright Project award of $3M to purchase a Philips Brightview SPECT/xCT unit with improvements from Philips and to upgrade the physical facilities where it would be installed. This project was projected to lead to a sales increase of $150M by 2017 for Philips and an annual increase of $50M for Cardinal Health's radiopharmaceutical business resulting in the creation of 20 jobs at the SPECT Center and 300 jobs at the industrial partners. The project has been delayed and the space will not become available until July 2011.

Philips received a 2010 TFMIP award of $1M to develop an upgrade for the Philips Gemini TF PET/CT scanner to allow it to quantitatively measure myocardial blood flow. That project was expected to increase PET/CT sales by $49M in 2013 and another $49M in 2015 leading to the creation of 5–7 new production jobs. That project has just gotten underway.

Project Description

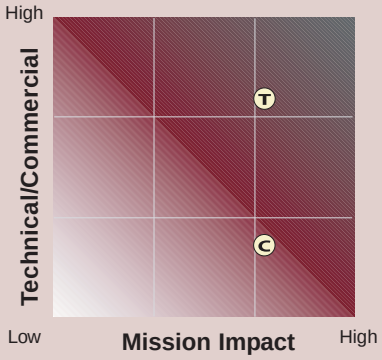
The proposed project will focus on expanding the performance of the existing Philips Brilliance iCT scanner to include the ability to perform coronary anatomy, function, and quantitative myocardial perfusion assessments during one single cardiac CT angiography scan. This will be a Class II medical device that will require 510(k) clearance from FDA prior to market entry. It is intended for use in emergency rooms and chest pain centers for entry-level cardiac imaging examination.

Technical tasks in this project include developing product specifications, evaluating the ability to lower x-ray dose, reducing beam hardening artifacts, and visualizing results. This work will be done at Case with assistance from Philips staff. The cardiac imaging product will be evaluated in large animal models of cardiac injury (pigs) by the end of the second year of the project. Small clinical studies will be done at University Hospitals during the third year of the project and will be followed by finalization of the cardiac perfusion and scar assessment product.

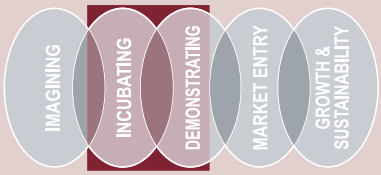
The Wright Capital funds will be used to purchase a freezer ($12K), a high-performance computer workstation ($13K), a microscope with slide scanning capability ($85K), x-ray angiography equipment for animal studies ($350K), and an Extended Brilliance Workstation ($120K). This equipment will be installed at Case.

Key Issues

- Because this project involves a different imaging modality than the myocardial blood flow project already funded by the OTFMIP in 2010, it appears that a different product group within Philips is seeking Third Frontier funding to improve its ability to do cardiac imaging. A better understanding of Philips' long-term strategic plan in the area of cardiac care is needed to place the importance of this project in context, especially since future requests for OTF funding to improve cardiac imaging capabilities may come from other product groups within Philips.
- Third Frontier funding is needed to accelerate development of this product. Philips currently has 1.5 FTE engineers working on CT perfusion. This project would allow a Case professor, 2 post-docs, and several graduate students and trainees to augment their efforts. A product might be released



Stage of Development



County Location

Funds Requested

TFRDF Request:	$1,000,000
WCF Request:	$ 580,000
TOTAL Request:	$1,580,000
Cost Share:	$1,581,856

Collaborators

- Philips Healthcare
- University Hospitals—Case Western Reserve University

in 3 years with the grant but could require 4–6 years without the grant.

- It is difficult to tell if this project is driven by an academic institution, a product group within Philips, or Philips Healthcare. Most of the project funding will go to Case to perform the product development and develop large animal models. The commitment from Philips Healthcare to support the costs associated with the commercialization of this product is claimed but not substantiated.
- This product is at an early stage of development with only a product concept and preliminary measurements completed. Three years are anticipated for product development and testing. Details pertaining to regulatory approval and commercialization were not presented.

Technical Risk

Overall Score = 7.27

Technical Reach

This product is still at the proof-of-concept stage. Significant development and optimization will be required. The magnitude of the remaining technical challenges was not discussed, but reducing the radiation exposure appears to be important. Although this project is designed to produce a full cardiac perfusion and scar assessment product, Philips may decide to release a cardiac product with fewer features at an earlier time.

Resource Limitations

This is a strong technical team, but the proposal lacks details and commitments from Philips pertaining to the regulatory approval and commercialization of the CT cardiac imaging product. University Hospital's purchase of a 256-channel Brilliance CT and a multi-energy Philips CT targeting next generation cardiac applications are both listed as A-level metrics resulting from this project. Without these resources, completion of the work plan as proposed does not seem possible.

Technology Protection

Case, University Hospitals, and Philips Healthcare are currently in the final stages of negotiating a research agreement that includes intellectual property management. Philips claims to own 18 patents related to this project, but their scope was not identified. It is not clear if they relate to the Brilliance iCT, which is already a commercial product, or to the cardiac imaging product that will be developed in this project.

Commercialization Risk

Overall Score = 2.33

Market Opportunity/Pull

CT has the greatest access/lowest cost of any advanced imaging modality. The worldwide market for CT sales and service is estimated at more than $5B annually. This project is targeted at the Brilliance iCT, a 256-slice unit introduced in 2007. Extension of this work to existing 64-slice units and to a 128-slice unit still in development may be possible.

Corporate Stability

Philips Healthcare is one of the world's largest manufacturers of imaging equipment including x-ray, ultrasound, CT, MRI, and PET. Philips Medical Systems has 1,100 employees and a 1M square foot facility in Cleveland. This facility is the location of all of Philips' North American training. It is the company's global headquarters of nuclear medicine, high field imaging, PET, CT, and refurbishment.

Commercial Infrastructure

Philips has the ability to make CT products in Ohio and to sell them throughout the world. Its existing infrastructure should be sufficient to support this product line addition.

Mission Impact

Overall Score = 7.00

Cluster Formation

This project will enhance the Philips Healthcare Global Advanced Imaging Innovation Center by strengthening the collaboration between Case, University Hospitals, and Philips. The team hopes to create a paradigm for preclinical/clinical validation of cardiac imaging that can be copied to other imaging modalities and therapeutics. The product will be developed at Case with assistance from Philips and clinically evaluated at University Hospitals. After product introduction, it is expected to increase demand for a product currently produced in Ohio, and this may increase sales for Ohio supply chain participants.

Ohio Economics

Work during this project will include job creation at Case consisting of 1.5 post docs, 1 clinical fellow, and 2 student trainees and an intern at Philips. By the end-of this 3-year project, the product development will have been completed. Employment projections are for 15–20 created or retained jobs within 3 years and 20–30 created or retained jobs within 5 years. The upgrade is expected to be a retrofit for the installed base of Philips Brilliance iCT units and will generate revenues of $5–10M annually. If the upgrade allows Philips to increase its share of the premium CT market or increases the size of this market due to greater dedicated CT adoption in chest pain centers and emergency rooms, the project eventually could have an additional upside potential of $20–50M annually. The project schedule does not address the date of market entry but Year 4 or 5 looks most likely for full claims with lesser claims being available in Year 3.

Business Model

All of Philips' manufacturing of high-end CT is done in Ohio. Philips also maintains major operations in Ohio including sales, distribution, customer support, and training. It is believed that Philips makes extensive use of an Ohio supply chain in its CT manufacturing, but details on level of Ohio participation were not provided.

Prior Ohio Investments

- Wright Center of Innovation in Biomedical Engineering, (OSU with Philips as a collaborator), 2003, $9.1 million
- The Biomedical Structural, Functional and Molecular Imaging Enterprise, (OSU with Philips as a collaborator), 2006, $7,878,957
- The Molecular Imaging SPECT Technology Center, (OSURF with Philips as a collaborator), 2009, $2,999,924
- PET/CT Scanner Optimized for Quantitative Myocardial Blood Flow, (Philips), 2010, $999,175

Ohio Department of Development

2011 TFMIP Evaluation Summary

Third Frontier Medical Imaging Program

FMI Technologies, Inc.

Commercialization of the ScintiStar Cardiac LPX PET/CT for Myocardial Perfusion Imaging and CT Calcium Scoring for Global Markets

TFMIP 11-627 Final Score: 61.9 Rank: 5

Previous Ohio Investment

FMI Technologies, Inc. has not received prior funding from OTF.

Project Description

FMI is developing imaging equipment that combines three modalities: positron emission tomography (PET), computed tomography (CT), and single photon emission tomography (SPECT). The system is designed to be 1/5 the cost and 1/5 the size of current whole body PET/CT systems. FMI believes that it will provide 7x to 10x improvement in quantifying myocardial perfusion for detection and treatment of cardiovascular disease. This equipment is intended for use at cardiology centers, community hospitals, and outpatient centers. It will be used to perform PET myocardial perfusion imaging, scar reconstruction and imaging, and CT calcium scoring

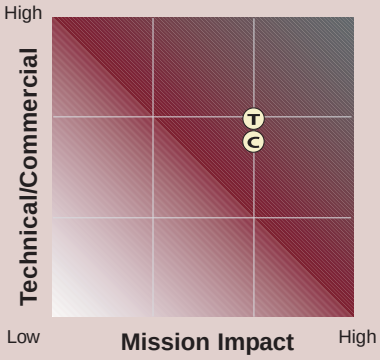
FMI is developing both a 64-slice and 16-slice CT system for cardiac imaging. Two different units are planned. The first will have a high power x-ray system as its source and is known as the ScintiStar HPX CT. A PET subsystem eventually will be added to this unit to form the ScintiStar Cardiac PET/CT system. The Cardiac 100 unit will have half the number of PET modules as the Cardiac 200 unit. The second is a 16 slice unit known as the ScintiStar Cardiac LPX (low performance x-ray) PET/CT. Eventually the company plans to produce a 16 slice ScintiStar HPX CT.

FMI and a Hangzhou China investment group have signed a term sheet and bridge loan agreement ($1.5M). The total value of the deal is $18M and it covers both A and B rounds of fund-raising. FMI is required to produce a prototype of the ScintiStar HPX CT-64 slice unit in 12 months (January 2012) that is ready for full-scale engineering testing and capable of meeting quality and quantity manufacturing levels. The fully functional LPX-CT is due in 16 months (May 2012).

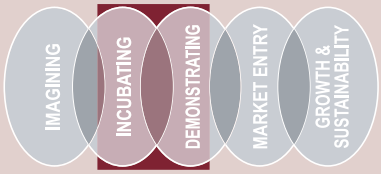
In this project, prototypes of the ScintiStar Cardiac LPX PET/CT will be built by FMI and evaluated in phantom and clinical studies to be conducted at Kettering Medical Center, Cleveland Clinic Heart and Vascular Institute, Akron General Medical Center, and Summa Health Systems.

Key Issues

- A significant portion of the cost share for this project ($430K) is coming from Lantheus and consists of inclusion of the ScintiStar Cardiac System in its Phase 3 clinical trial of the Flurpiridaz F-18, a new imaging agent. FDA has already given approval for the Phase 3 clinical trial of Flurpiridaz, to assess myocardial perfusion using PET, and this trial is expected to begin in 2Q 2011. Inclusion of the ScintiStar Cardiac System is dependent upon receiving 510(k) clearance, which is not scheduled until 2Q 2012. Development of the imaging analysis software, calcium scoring, and myocardial perfusion imaging for the ScintiStar is not expected to be complete until 3Q 2013.
- FMI projected that OTF funding would accelerate LPX market entry by 1 year. FMI believes that its first product, ScintiStar HPX CT, will be ready in 2012 without Third Frontier funding. With OTF funding, the LPX system can move forward. If the company does not receive OTF funding, the LPX system will be developed later.
- The rare earths and crystals that are used to produce the high-resolution detectors come from China. FMI plans to construct the detectors in Akron, and the final unit will be assembled and marketed in China. With control of the unique raw material and market for the product residing in China, it is uncertain how much leverage there will be to keep the detector IP and manufacturing in Ohio.



Stage of Development



County Location

Funds Requested

TFRDF Request:	$1,000,000
WCF Request:	$ 0
TOTAL Request:	$1,000,000
Cost Share:	$1,828,418

Collaborators

- Lantheus Medical Imaging (N. Billerica, MA)
- Cleveland Clinic
- Akron General Medical Center
- Summa Health System
- VP Innovation Center
- Wright State University
- Northeastern Ohio Universities—College of Medicine
- Northeastern Ohio Universities—College of Pharmacy

Technical Risk

Overall Score = 6.60

Technical Reach

A ScintiStar Cardiac PET/CT unit will be built in Akron, and initial phantom and physics testing will be done as part of this project. No animal or clinical test results have been provided to demonstrate the performance of the equipment, and it does not appear that an alpha prototype is fully functional at this time. FMI has built a PET detector using its new technology and has generated laboratory data showing good resolution on capillary tubes.

Resource Limitations

FMI is depending upon expertise from Wright State in the area of image processing and image analysis. The references provided did not show recent experience addressing the unique problems associated with cardiac imaging of a beating heart. Considering the narrow window for product performance that is necessary to secure the next tranche of Chinese investment, this lack of prior cardiac imaging experience raises the risk associated with this project. Examples of the team's successful prior business experience were not presented.

Technology Protection

FMI has two patents pending that relate to breast and neuro imaging. No information was provided in response to a written question about the company's intellectual property that directly relates to cardiac imaging. The company provided a legal opinion that stated that the company was free to make, use, sell, and import into the U.S. the ScintiStar products or components consistent with the product description in the letter. The letter also indicated that FMI would manufacture the ScintiStar family of products in China for the Chinese market.

Commercialization Risk

Overall Score = 5.80

Market Opportunity/Pull

FMI claims that the potential worldwide market for its cardiac multimodal systems is $3–4B over the next decade with a potential of 6,000–8,000 systems in the U.S and double that in worldwide markets. The Chinese investment demonstrates significant market pull for the product in China, particularly in rural locations where low-cost imaging systems are needed. However, this investment is contingent upon FMI's ability to demonstrate the performance of this product by January 2012.

Corporate Stability

FMI is an early stage product development company. The company raised $3.3M in angel investments prior to the Chinese investment, but it lacked the resources to build pre-production units. The $18M Chinese investment has stabilized the company, and a bridge loan of $1.5M allowed the hiring of 16 people. This staff will have to build functioning units within a very short timeframe in order to access the major portion of the Chinese investment. FMI is housed in an incubator in Akron where developmental work will be done.

Commercial Infrastructure

FMI is working on an agreement with Lantheus Medical Imaging to provide a direct sales channel for ScintiStar Cardiac PET/CT system to the U.S. and European markets. Lantheus is located in MA and has offices in Puerto Rico, Canada, and Australia that are staffed by 700 employees. The company sells imaging contrast agents to cardiologists and centers and would provide access to key decision-makers. However, there is no evidence that Lantheus has had experience selling or servicing capital equipment. This capability will have to be developed within FMI.

Mission Impact

Overall Score = 6.67

Cluster Formation

FMI provided an extensive list of Ohio manufacturers that would provide components and subassemblies, and claimed that approximately 85% of the expected material cost would come from Ohio suppliers. However, only the first few units will be produced in Ohio, with subsequent production and assembly shifting to China. No potential supply chain members are collaborators in this project, but clinical trials at multiple Ohio institutions will occur as part of the project.

Ohio Economics

By 2013, FMI projects that this project will create 25 new jobs in Ohio growing to 62 jobs by 2015. FMI projects that its total sales will be $11M in 2013 and $48M in 2015. Of this amount, it appears that the value of the Ohio-produced components is expected to be approximately $4M in 2013 and $18M in 2015.

Business Model

FMI intends to have operations in Akron, Ohio where its engineering and some of its component manufacturing functions will be housed. Its detector production and clinical development will be housed in Dayton, Ohio. The company has already established an office in Hangzhou, China for the China ScintiStar HPX. Manufacturing and assembly of the larger components like the gantry and processors will be done there. FMI intends to rely on Lantheus Imaging to market and sell its equipment in the U.S. and Europe.

Prior Ohio Investments

- None

Ohio Department of Development

2011 TFMIP Evaluation Summary

Third Frontier Medical Imaging Program

Hyper Tech Research, Inc.

Manufacturing of Conduction Cooled Specialty MRI Magnets Using Magnesium Diboride Superconducting Wire

TFMIP 11-609 Final Score: 60.9 Rank: 6

Previous Ohio Investment

Hyper Tech has received 5 previous OTF awards totaling $7.3M. The earliest awards, which began in 2002, were intended to develop and commercialize long-length wire containing magnesium diboride superconductors. Later awards were targeted at commercializing the wire for MRI magnets and converting it into fault current limiters for grid applications. The two most recent awards (for $6M) are still in progress, but the first three awards (for $1.3M) are complete.

Hyper Tech has successfully developed a manufacturing process for producing long lengths of superconductive magnesium diboride wire and is supplying the wire to MRI OEMs. It formed a subsidiary company, Hyper Tech Energy, to develop and market the wire and the superconducting fault current limiters as a complete system for U.S. and world markets. The ODOD database shows that Hyper Tech has created 21 jobs and raised $7.3M in total leverage, mainly in the form of federal awards and industry dollars. Product sales have totaled $23,052 as of 12/31/2010.

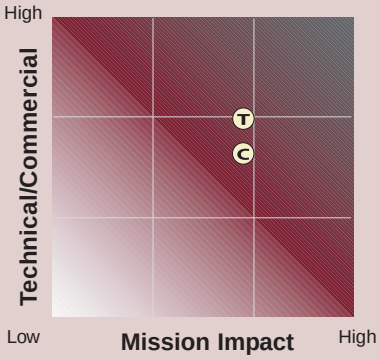
Project Description

A potential shortage of helium has been predicted, and helium is the key material used to cool MRI magnets. Currently MRI magnets are made from niobium-titanium superconductors that must be cooled to 4 deg. K. Hyper Tech makes wires from magnesium diboride, a superconductor that can operate at 39 deg K and is compatible with dry conduction cooling. For non-helium MRIs, the large MRI companies would purchase magnesium diboride wires from a company like Hyper Tech and make their own background magnets. The goal of this 3-year project is to allow Hyper Tech to expand its market opportunities by becoming a commercial supplier of magnesium diboride-based MRI magnets and their affiliated cryogenic cooling system.

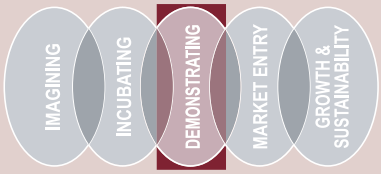
During this project, Hyper Tech will design and build a demonstration magnet for ViewRay's MRI. Hyper Tech will also investigate the feasibility of building other magnesium diboride MRI magnets—one for Aurora for breast imaging and one for Winged S&S for orthopedic and a variety of other diagnostic procedures. OTF funds would help Hyper Tech to develop magnet design and production capabilities and to generate price quotations for potential customers.

Key Issues

- The adoption rate of non-helium magnets for MRI coils using magnesium diboride wire will be strongly influenced by the price and availability of helium. This market has developed much more slowly than originally anticipated.
- Although Hyper Tech may be successful in the technical portions of this project, this is not likely to be sufficient to cause major MRI manufacturers to change designs of their MRI imaging equipment. Shifting from helium-cooled magnets to dry conduction-cooled magnets will require extensive product redevelopment and revalidation. End-users will require extensive data on image quality and long-term performance of the restructured MRI equipment.
- Forecasts for Ohio job generation and sales revenue are small because Hyper Tech is working only with the smaller MRI OEMs. In the previously funded RCP project, Hyper Tech supplied wire to Siemens, GE, and Philips, the major MRI OEMs. These companies have internal magnet development programs.
- ViewRay is a venture start-up that has raised over $50M and is expected to have commercial sales beginning in 2011. It does not yet have FDA clearance. ViewRay plans to use coils from the UK in its products. Hyper Tech claims to have the potential to convert ViewRay's systems over to magnesium diboride magnets in the 2014–2015 timeframe.



Stage of Development



County Location

Funds Requested

TFRDF Request:	$ 999,999
WCF Request:	$ 0
TOTAL Request:	$ 999,999
Cost Share:	$1,217,728

Collaborators

- The Ohio State University (OSU)
- Case Western Reserve University

Technical Risk

Overall Score = 6.60

Technical Reach

Prior to the start of this OTF, Hyper Tech will have completed the preliminary design and modeling objectives of its 2009 projects for the double donut, split magnet system, and cryogenic system that will be used in the proposed project. In Year 1 of this project, Hyper Tech will optimize the imaging guided (split solenoid) magnet design and work on demonstrating persistent coils. During Year 2, Hyper Tech will work on modeling other types of specialty MRI magnets for Aurora and Winged S&S, and will work on developing magnet coil fabrication techniques for the full-size image guided (split solenoid) magnet. Parallel to the magnet fabrication in Year 2, Hyper Tech and Eden Cryogenics will construct the cryostat and cryogenic parts. Hyper Tech anticipates that the magnet testing and shimming will take place during Year 3, and that it will be ready to accept purchase orders or receive funding for more prototypes at the end of the project.

Resource Limitations

This is a strong technical team with experience in producing magnesium diboride wire and cryocooling systems. Through contracts with the Department of Defense, National Aeronautics and Space Administration, National Institutes of Health, Massachusetts Institute of Technology, and the State of Ohio, Hyper Tech has put together a combined investment of more than $10M for product development and now has an backlog of $4M which appears to consist primarily of federal and industry grant awards.

Technology Protection

Hyper Tech has developed and patented continuous tube forming and filling (CTFF) process to make a powder metallurgy-based magnesium diboride superconductor wire (patent No. 6,687,975). Hyper has applied for a patent covering persistent magnesium diboride joints, a key component for MRI magnets. Hyper Tech also has several unique magnesium diboride coil fabrication techniques that can possibly result in additional patent applications.

Commercialization Risk

Overall Score = 5.40

Market Opportunity/Pull

The U.S. market for specialty MRI magnets is estimated to be about $250M annually, and the world market is approximately twice as large. Hyper Tech's initial market entry for magnets will likely be through purchase orders from ViewRay, Aurora, and/or Winged S&S (MagnaVu). Hyper Tech identified only one other manufacturer of magnesium diboride wire, Columbus Superconductor (Genoa, Italy), who also has an affiliated organization that makes magnesium diboride magnets. Hyper Tech claims its wire has 2-3 times the performance of the Columbus Superconductor wire enabling a magnet using Hyper Tech wire to require 2-3 times less superconductor wire in the same magnet design.

Corporate Stability

Hyper Tech is a privately held R&D company founded in 2001. It is funded by grants and contracts from NIH, DOD, NIST, DOE, NASA, and OTF. Hyper Tech currently has 23 employees and was profitable in 2010. Its revenue jumped from $2M in 2009 to $5.3M in 2010. In February 2010, the company moved into a new 45,000 square foot facility in Columbus, OH. The facility has two clean rooms and a third is under construction. It will house over $2.5M of equipment to produce and test magnesium diboride superconducting wire.

Commercial Infrastructure

Hyper Tech's current manufacturing capacity for magnesium diboride wire is 12,000 km/yrand is expandable to be sufficient for production needs for the next 3 to 5 years. Hyper Tech's sales force currently consists of one person, the company's president and CEO. Additional sales and marketing staff will be required once a functional prototype becomes available.

Mission Impact

Overall Score = 6.33

Cluster Formation

This project would support two Ohio clusters. Ohio has a large cluster of companies and universities that are focused on the MRI imaging industry. Hyper Tech would be a supplier to this industry. Ohio also has an important industrial base and infrastructure to support cryogenic systems and components. Hyper Tech plans to utilize the cryogenic cluster, including Eden Cryogenics and others, for its supply chain.

Ohio Economics

Additional revenues or jobs at Hyper Tech will be dependent upon an MRI company placing purchase orders for magnesium diboride coils. Assuming ViewRay purchases 150 systems to be made between 2102 and 2015 (with shipments beginning in 2014), Hyper Tech and Eden Cryogenics forecast sales and new job generation beginning in 2014. By 2015, Hyper Tech projects sales of $12M with 34 cumulative FTE's (24 at Hyper Tech and 10 at Eden).

Business Model

Hypertech plans to make the wire, wind the coils, and assemble and test the magnet system in Ohio. Eden Cryogenics, an Ohio company, will fabricate the vacuum cryostats. Local machines shops will machine the coil formers. The cryocooler will have to be purchased from a Japanese supplier, although Ohio suppliers may participate at some point in the future. The infrastructure to support sales, marketing, distribution, and customer service remains to be developed. Target customers for the magnets and dry conduction cooling systems appear to be the smaller MRI companies since the major MRI OEMs will likely develop their own technology in this area.

Prior Ohio Investments

- Magnesium Diboride for Next Generation MRI, 2009, $5,000,000
- Wires and Coils for Superconducting Fault Current Limiters, 2009, $1,000,000
- Commercialization of Fault Current Limiter Coils and Components, 2007, $350,000
- Business and Marketing Development for Commercializing Magnesium Diboride Superconducting Wires for Medical, Power, and Propulsion Applications, 2005, $174,756
- Development and Commercialization of Low Cost, Long Length Magnesium Diboride Superconductors, 2002, $800,000

Ohio Department of Development

2011 TFMIP Evaluation Summary

Third Frontier Medical Imaging Program

Advanced Imaging Research, Inc. d.b.a. Sree Medical Systems

MRI Compatible, Neonate Imaging Sub-system

TFMIP 11-633	Final Score: 52.6	Rank: 7

Previous Ohio Investment

Neither Advanced Imaging Research, Inc. nor Sree Medical Systems has received prior funding from OTF.

Project Description

The goal of this project is to develop a neonatal incubator and custom radio-frequency (RF) coil arrays to perform high-resolution brain/cardiac MRI in premature babies and infants with congenital defects. This is an engineering-intensive project that will produce a neonatal transport/MRI incubator and several models of 16/32 channel Infant COCOONs containing head, chest, and spine coil arrays that will be compatible with GE, Siemens and Philips 1.5T and 3T MRIs. OTF funding and cost share would be used to support new engineering capability at Sree and to purchase time on the MRI equipment at Case and the Cleveland Clinic.

Prototypes of the incubator and the non-magnetic trolley will be produced in this project along with 6 different types of MRI coil arrays. The incubator will have forced air warming, skin temperature monitoring, and humidity control (30–70% RH). The coil arrays will be suitable for brain, cardiac, and spine imaging. By the end of the project, the prototypes will be finalized, safety testing will be complete, and an FDA submission will be made.

Key Issues

- Although the company has been in business for 15 years, Sree declined to provide either a capitalization table or financial statements. Sree claimed that it had the necessary resources to cover the cost share for the proposed project, but did not provide supporting evidence for that claim.
- Sree indicated that the high humidity, oxygen-rich environment within the incubator was likely to affect the MRI coils. The work plan for this project does address long-term coil performance and does not include specific tasks to resolve this issue.
- The Sree incubator will be designed to only accommodate the Sree coils. Sree plans to void the warranty if other coils are used in the incubator. Although one major MRI OEM is developing (with OTF funding) pediatric coils and another has pediatric MRI coils in the market, Sree believes that the three MRI OEMs will be willing to promote the Sree product. Evidence of strong OEM involvement in the project was not provided.
- LMT is already in the market offering the MRI incubator. Sree worked with LMT on product development and in overcoming the MRI compatibility issues. Sree's indicates its competitive advantage is its cost structure, the Euro-USD exchange rate, and its customer service attitude.

Technical Risk

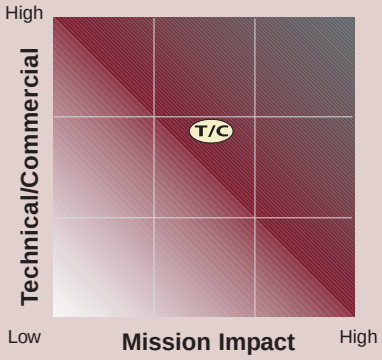
Overall Score = 6.27

Technical Reach

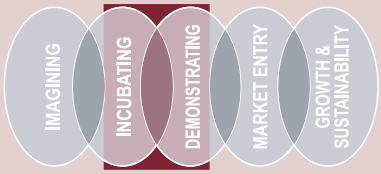
The applicant presented MRI images made using the Sree head and chest coils on neonates in Canada. The comments from the cardiac radiologists were very positive and indicated good coil performance. The incubator and trolley still appear to be in the early prototype stage and their performance has not been demonstrated. The applicant has had experience with another MRI incubator producer, and should be able to manage any technical issues that arise.

Resource Limitations

Sree Medical plans to commercialize this product with 24 months after successful completion of this 2-year project. The resources needed for commercialization are not identified, and it appears that the company plans to sustain itself on product sales or to seek equity-based financing from angel investors, private firms, or venture capitalists. Its president is the only Sree employee who is identified, and while he has good technical credentials and has won grant support, there is no evi-



Stage of Development



County Location

Funds Requested

TFRDF Request:	$1,000,000
WCF Request:	$ 0
TOTAL Request:	$1,000,000
Cost Share:	$1,000,000

Collaborators

- Cleveland Clinic Foundation
- University Hospitals—Case Medical Center

dence that he has been successful in growing a medical device business or in attracting the resources to support it.

Technology Protection

Sree's president is the inventor and Advanced Imaging Research is the assignee on 6 patents covering RF coils for MRI imaging. Sree has filed for U.S. protection on IP related to this project, including two applications related to coils (2004), one for MRI compatibility (2004), and one for the neonate imaging sub-system (2005). The company plans to seek foreign patent coverage. Sree Medical has chosen to retain some technology related to coil design, preamplifier design, and software as a trade secret.

Commercialization Risk

Overall Score = 6.20

Market Opportunity/Pull

This product is expected to fill a void and to offer safe transport and optimum pediatric imaging for very small babies with MRI. End-users for the incubator and custom RF coil arrays are expected to be in the departments of radiology, cardiology, and pediatrics-neonatology. No information was presented on the size of the current market that has been created by an existing manufacturer of an MRI incubator or by companies offering pediatric MRI coils. Sree's pediatric coils have performed well in initial testing at BC Children's Hospital in Vancouver, Canada and purchase orders of close to $1M have been received.

Corporate Stability

Advanced Medical Systems is a privately held company that was founded in 1996 and is focused on producing coils and devices for pediatric MRI imaging. Since January 2010, it has been doing business as Sree Medical Systems. The company sells neonatal head and cardiac MRI coils and claims to have sales revenue in the range of $1–2M annually, but was not revenue positive in 2010. The company has operated with private funds and roughly $6M in grants from NIH. It employs a staff of 5–10, and it occupies an 8,000 sq ft facility in Cleveland that houses a CNC machine shop, R&D, manufacturing, and other business functions.

Commercial Infrastructure

Sree Medical operates a light manufacturing assembly facility where housings and electronic components are procured from vendors and assembled in-house. The company plans to subcontract cable manufacturing, and electrical and mechanical assemblies. Present staffing is not described, and it appears that this grant will be needed to provide the staff to complete the product R&D. Sree has 1 to 2 direct sales people that cover the U.S. The company also claims to have distributors covering Canada and several countries in Europe and plans to establish additional distributors to cover other major world markets.

Mission Impact

Overall Score = 5.25

Cluster Formation

Sree Medical plans to use Ohio vendors for components when possible, but many MRI components are not available in Ohio. None of the potential participants from an Ohio supply chain are participating in the project. Sree Medical plans to develop devices in-house and to test them on the 1.5/3T MRI scanners at the Cleveland Clinic and Case. Testing will involve electrical, mechanical, and MRI testing, but none of the project tasks involves patients.

Ohio Economics

Sree anticipates that the incubator will be ready for market introduction by September 2012. It projects annual sales of the incubator and coils at $4.7M in 2013, 2014 and 2015 with significant increases thereafter. The company plans to fill 6–8 positions in the first three years and then will increase to between 20–30 employees as sales staff is added in the 2015–2017 timeframe.

Business Model

Only small-scale assembly operations are likely at Sree with initial incubator sales projected to be less than 10 incubators/year for the first three years and 10–20 incubators/year after that. Coil production will be slightly larger with increasing to over 25 coils/year for each model. Sree hopes to form relationships with the MRI OEMs to assist in marketing its incubator product with coils that are compatible with each OEM's equipment. The company plans to use a combination of in-house sales and customer support and distributors.

Prior Ohio Investments

- None

Ohio | Department of Development

2011 TFMIP Evaluation Summary

Third Frontier Medical Imaging Program

Cleveland Clinic

Opthalmic Imaging Center/OptoQuest

TFMIP 11-610 Final Score: 49.1 Rank: 8

Previous Ohio Investment

This project is a result of the Third Frontier $6M BRTT award to the Cleveland Clinic that created the Age-related Macular Degeneration Center of Excellence (AMD-iPAC) that, through 2010, has generated over $30M in research and commercialization funding, spun-off or relocated 4 companies to the area (including OptoQuest its the first spinoff). AMD-iPAC and created or maintained over 100 jobs in Ohio.

Project Description

In this 3-year project, the Cleveland Clinic Opthalmic Imaging Center (OIC) will develop seven new products in 2 project areas involving Optical Coherence Tomography (OCT). OCT is a non-contact, non-destructive imaging modality that provides high-resolution images of various tissues. In this proposal the OCT is used to generate images of the front and rear portions of the eye. Project 1 will develop the Corneal Elastography Device (CED), an add-on device with software for an existing OCT system that applies a known mechanical stress to the cornea, optically records the x-y-z displacements, measures viscoelastic properties, and generates a topographic map of the cornea. OptoQuest will commercialize the CED and software, plus clinical services for CED generated reports. Project 2 will develop an Integrated Intraoperative OCT (II-OCT) Platform that consists of four products: a modified OCT imaging system that can be used during an eye surgery; software that processes and evaluates the OCT images for real-time display during the surgical procedure; a series of surgical instruments that can be used during the surgery that do not interfere with the OCT images; and contrast agents to enhance OCT imaging during surgery. The products from the II-OCT Platform will be commercialized through future spinoffs of the OIC.

Key Issues

- The seven products are in different stages of development, with some in the early Incubating Phase that are not likely to reach market entry within the timeframe targeted by the OTFMIP.
- The business and commercializing plans for the seven products are also in various stages of development. While the Cleveland Clinic has years of successful experiences in forming business and commercialization plans for start up companies, the business and commercialization plan for the early stage products have not been developed.

Technical Risk

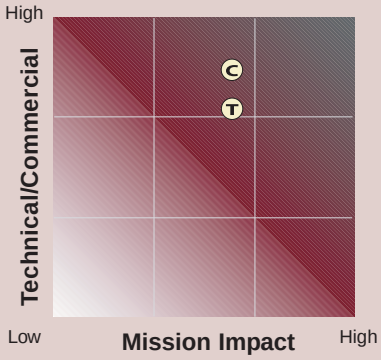
Overall Score = 6.93

Technical Reach

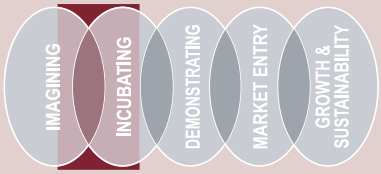
With respect to the first project proposed, CWRU has completed the initial design of a fully functional, bench-top prototype CED and will optimize the design for large-scale production. Key human tissue experiments and pilot clinical studies will be performed to support an FDA 510(k) submission during year 2 or 3. Proof-of-concept data on the computational modeling software will be generated for use in simulation-based surgical algorithm design. The second project involves four earlier stage product developments that will be conducted in parallel by separate team members/groups. CCF/OIC predicts some products will be ready for market entry by the end of the third year, and all will be ready for market entry by the end of the fifth year from project initiation.

Resource Limitations

The teams, along with the collaborators and contracted suppliers have the technical skills to overcome the technical obstacles of both project areas. While the Cleveland Clinic has a successful history of assembling management teams for spinoff companies, the full management teams for OptoQuest and the future spinoff company, have not yet been established. CCF is supplying the bulk of the cost $1.32M cost share and CCF/OIC plans to raise another $14.6M in additional grants and investments from potential partners during the project to support product commercialization.



Stage of Development



County Location

Funds Requested

TFRDF Request:	$ 999,996
WCF Request:	$ 0
TOTAL Request:	$ 999,996
Cost Share:	$1,363,498

Collaborators

- OptoQuest Corporation (GCIC)
- Case Western Reserve University
- Topcon Medical Systems (Oakland, NJ)
- Bioptigen (Durham, NC)
- Farm Design (GCIC)
- Peregrine Instruments (New Britain, PA)

Technology Protection

OCT was originally developed at major academic centers including MIT, Case Western Reserve, and Duke University, so the platform concept for OCT is largely available through the public domain. Intellectual property in this area is based largely around methods for use and specific modifications to the imaging modality. OptoQuest has licensed the use of existing patents, patents pending, and the know-how related to corneal elastography from the OIC, CWRU and Duke. Software relating to the projects will be treated as confidential trade secrets and will not be patented. Patents will be sought for the other product areas when it appears appropriate.

Commercialization Risk

Overall Score = 8.20

Market Opportunity/Pull

CCF/OIC estimates an aggregated peak market opportunity of approximately $285M for the seven products. Two of the collaborators, Topcon Medical Systems and Peregrine Instruments, are next stage developers that sell related products to the target markets.

Corporate Stability

OptoQuest is a fully owned virtual company spin-off from the Cleveland Clinic that was founded 3 years ago by ophthalmologists from the Cole Eye Institute and is housed at the Opthalmic Imaging Center. The CCF/OIC is exploring several options for the most appropriate business structure and commercialization program that will carry the other four products through commercialization.

Commercial Infrastructure

OptoQuest will utilize the infrastructures of the OIC. Since partnering and funding are integral components to the commercialization plans, the company infrastructures are still in development. OptoQuest realizes it will have to form a strategic partnership choice early on. The spinoff organization(s) for the II-OCT Platform products has(have) not been formed to date, but will also utilize the infrastructures of the OIC. The Cleveland Clinic has years of successful experiences in forming biomedical and/or technology start up companies.

Mission Impact

Overall Score = 5.92

Cluster Formation

The project proposed aligns with the medical imaging cluster, targeting optical imaging. CCF/OIC will use Ohio resources for the development efforts in the seven product areas, but since all seven products proposed will be commercialized through strategic partners, these may be companies outside of Ohio. The two collaborating product distributors in the project are based outside Ohio.

Ohio Economics

CCF forecasts it will generate $14.6M in grants and investments for the seven project areas in the first three years after the start of the project. In the same three years, CCF forecasts it will generate $3.1M in sales revenues and will have generated a cumulative of 44 jobs in Ohio. By year five after the beginning of the project CCF forecasts it will generate $33M in sales revenues through OptoQuest and the future spinoff companies, and will have generated a cumulative total of 76 jobs in Ohio.

Business Model

The business plans/models vary with each product. OptoQuest intends to develop the CED for clinic use using strategic partnerships for marketing, sales and distribution of the device. OptoQuest plans to keep R&D, contract manufacturing and clinical/regulatory work for the CED in Ohio. For the CED software system, OptoQuest will keep R&D and implementation personnel in Ohio and sell licenses for the software. OptoQuest will also set up a Clinical Testing Service for the CED system at OIC. The business plans and models for the remaining four products will be developed during the project. CCF/OIC predicts it is likely that two spinoff companies will emerge for the Intraoperative OCT and the surgical instruments. Contrast agents and image processing software will likely be licensed assets to larger industrial partners with established marketing, sales and distributions channels while research and development in these areas continues at the OIC.

Prior Ohio Investments

- Age-related Macular Degeneration Center of Excellence (AMD-iPAC), 2005, $6,000,000

Ohio Department of Development

2011 TFMIP Evaluation Summary

Third Frontier Medical Imaging Program

Tursiop Technologies, LLC

High-performance Nanotechnology-based Imaging Coils for Prostate Imaging

TFMIP 11-632	Final Score: 48.1	Rank: 9

Previous Ohio Investment

Tursiop Technologies, LLC has not received prior funding from OTF.

Project Description

In this 18-month, 3-phase project, Tursiop proposes developing a high-performance MRI prostate imaging coil using its proprietary carbon nanomaterial technology to replace the currently used copper wire. Its ultimate objective is to enable enhanced image-based MRI diagnosis of prostate disorders and for imaging guided therapy planning applications for the Philips 1T Panorama high-field, open MRI system. In the initial phase, Tursiop will refine the clinical application needs, review the interface specifications with Philips, design and build prototype coils, perform functional phantom tests, optimize the prototype coil and, if possible, obtain initial human imaging results. In the second phase, a pre-production prototype will be built, verification tests performed, regulatory submission data prepared, marketing materials developed and the FDA submission made. The final phase involves obtaining vendor and purchasing agreements and manufacturing ramp up to support approximately 60 units/year.

Key Issues

- The path to market for the coil proposed in this project is well defined as it integrates with specific installed Philips systems. However, that installed base is limited and saturation will occur in few years limiting sales growth. The extension of the Tursiop coils to other applications and or vendors will require additional development work and resources, and their sources are not yet established.
- While Philips is an active participant in the project, the benefits from the nanomaterial-based coil would seem to provide a potential competitive advantage for its products that would result in higher interest and a more significant financial role in the technology.
- The Tursiop coil will be reusable and will be expected to have improved imaging performance over the competitive disposable coils now used. However, it will be significantly more expensive and will require sterilization after each use. The number of sterilization cycles the coil can tolerate has not been validated and this along with the sterilization cost will affect the cost/benefit for the end-user.

Technical Risk

Overall Score = 6.33

Technical Reach

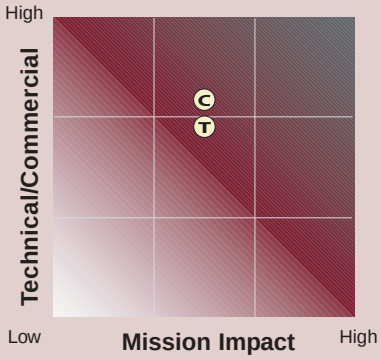
Tursiop has produced prototype coils (1.5Tesla) designed to meet prostate imaging requirements that have demonstrated a significant boost in performance using clinically relevant phantoms, but these coils did not find a commercial market. In this project the coil design and optimization for a specific Philips MRI system integration and imagining application will be established and the regulatory submission data generated.

Resource Limitations

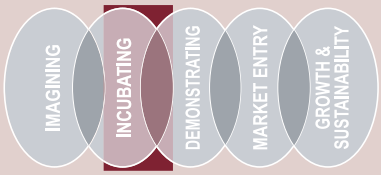
Tursiop principals have background and experience in MRI systems, coil design and medical device and software development. Tursiop has obtained 510(k) clearance for one of its products and is in the process of obtaining ISO medical device certification. Collaborator Philips Healthcare is a leading supplier of MRI systems. Tursiop projects that the OTFMIP project funding will be sufficient to reach market entry. The cost share requirement is fulfilled through labor support provided by Tursiop and Philips and a portion through anticipated revenues from early product sales. Product sales after the project are expected to be sufficient for Tursiop to create a self-sustaining business.

Technology Protection

Tursiop has a patent portfolio of over 6 issued patents and several pending patents in the area of nanotechnology-based imaging coils. It also has specific trade secret IP relevant to the tech-



Stage of Development



County Location

Funds Requested

TFRDF Request:	$	781,222
WCF Request:	$	0
TOTAL Request:	$	781,222
Cost Share:	$	800,500

Collaborators

- Philips Healthcare

nology proposed. Tursiop indicates its IP position establishes its freedom to operate globally in its sphere of interest.

Commercialization Risk

Overall Score = 7.20

Market Opportunity/Pull

Tursiop contends its technology fulfills an unmet market need and this is supported by Philips participation in the project. Philips currently has an installed base of 180 Panorama 1T systems that are all candidates for new coils. It is expected that 2 to 3 coils per system are needed to allow coil rotation for sterilization. Thus the potential market from the installed Philips units alone is well in excess of $15M. While the proposed project is aimed at a specific Philips MRI system, the Tursiop coils have potential applications across all MRI system platforms. The projected coil cost and need to withstand multiple sterilization cycles are potential market acceptance barriers.

Corporate Stability

Tursiop has been in business for approximately 3 years and is a privately funded company residing at BioEnterprise. It contends its private equity funding is sufficient to maintain its engineering and other staff and operations. The company's full-time employment appears to range from 2 to 5 personnel. Tursiop's current revenues consist of grants and private investor funding.

Commercial Infrastructure

The commercial path for the Philips product proposed is straight forward as the product will be applied to Philips installed Panorama systems in the field and will be directly handled by Tursiop in conjunction with Philips marketing and sales organization. Expansion beyond Philips' applications will require an infrastructure that is to be developed during the project period. That infrastructure will consist of a mix of supply agreements with platform vendors and direct sales to customer sites. Tursiop plans to produce its coils using Ohio contract manufacturing for parts relevant to image coil assembly.

Mission Impact

Overall Score = 5.00

Cluster Formation

Tursiop adds a new MRI coil developer and supplier to Ohio's imaging cluster. It offers a new coil technology based on nanomaterials over traditional copper coils. Tursiop is collaborating with Ohio's Philips Healthcare and plans to use Ohio suppliers for industrial parts, plastic components and electronics.

Ohio Economics

Tursiop projects that its sales revenues from the Panorama 1T application will be between $1M and $5M over the 3 to 5 year timeframe set by the OTFMIP. This will create 8 jobs at Tursiop. A much larger potential exists for Tursiop if the coils are adapted to other Philip's lines and other MRI producers. However, it is premature to quantify projections for other applications or the timing of their market entry.

Business Model

Tursiop plans to produce multiple coil lines for multiple system vendors across various field strengths and applications at its Cleveland facility. It indicates that the business will be supported through existing funding and sales growth. While no acquisition plans have been discussed or planned, there is a history of the larger MRI producers acquiring coil developers.

Prior Ohio Investments

- None