

## **SERVICE PROVIDER AGREEMENT**

This Service Provider Agreement (the "**Agreement**"), dated as of July 16, 2003 (the "**Effective Date**"), is made by and between Boston Scientific Corporation, a Delaware corporation with offices at One Boston Scientific Place, Natick, Massachusetts 01760 ("**BSC**"), and Leader Technologies Incorporated., a Delaware corporation with offices at 921 Eastwind Drive, Suite 118, Westerville, Ohio 43081 ("**Leader**").

WHEREAS, Leader has developed products and technical expertise in providing various product-related services, such as installation, implementation, training, maintenance, hosting, support and business development services, and

WHEREAS, BSC desires to have Leader provide such services in connection with its proprietary software licensed by Leader to BSC, and Leader desires to provide such services in accordance with the terms set forth herein;

NOW, THEREFORE, in consideration of the mutual promises and obligations set forth in this Agreement, the parties, intending to be legally bound, agree as follows:

### **1. DEFINITIONS.**

As used herein, the following terms shall have the meanings indicated:

1.1 "**External Business Partners**" means those Leader third parties listed on Exhibit B, as may be modified from time to time upon mutual agreement of the parties, which parties have executed an instrument, in the form of Exhibit C, agreeing to be bound by the terms and conditions of this Agreement [Covered in Exhibit C]

1.2 "**Confidential Information**" means any information disclosed previously or in the future by one party to the other party, either directly or indirectly, in writing, orally or by inspection of tangible objects (including without limitation documents, business plans, source code, software, documentation, financial analyses, marketing plans, forecasts, suppliers, customer names, customer lists, customer data, product plans, products, services, inventions, processes, designs, drawings, engineering or hardware configuration information, know-how, trade secrets, or any other proprietary or business information), which is designated as "Confidential," "Proprietary" or some similar designation, or other information, the confidential or proprietary nature of which is reasonably apparent under the circumstances. Confidential Information shall also include information disclosed to a party by a third party pursuant to a nondisclosure obligation.

1.3 "**Marks**" means the trademarks, service marks, trade names, logos and other proprietary words and symbols of Leader and its External Business Partners.

1.4 "**Leader Technology**" means any and all data models, data integration tools or technology, data processing systems or mechanisms, computer code, including objects and tools, trade secrets, know-how, processes, inventions, discoveries, original works of authorship and derivative works thereof, developments, concepts, improvements and trademarks that Leader has prepared, developed, acquired or otherwise obtained rights in prior to the Effective Date or may thereafter prepare, develop, acquire or otherwise obtain rights in other than the Deliverables.

1.5 "**Delay**" shall have the meaning set forth in Section 3.2.

1.6 "**Deliverable**" means designs, computer software (in source code and object code form), documentation, drawings, applications, software services and all other deliverables that are created or developed by Leader in connection with the provision of Services hereunder.

1.7 "**Services**" shall have the meaning set forth in Section 2.4.

1.8 "**Statement of Work**" shall have the meaning set forth in Section 2.3.

## 2. **SERVICES; CHANGE ORDERS.**

2.1 Installation, Implementation and Training Services. Leader shall provide the installation, implementation and training services and Deliverables set forth in **Exhibit A** in accordance with the schedule and other terms set forth in such exhibit.

2.2 Maintenance, Hosting and Support Services. Leader shall provide the maintenance, hosting and support services and Deliverables set forth in **Exhibit A** in accordance with the schedule and other terms set forth in such exhibit.

2.3 Statements of Work. From time to time, Leader and BSC may agree on additional services to be performed, and in that case, shall prepare a statement of work ("**Statement of Work**") that outlines the additional services to be performed. Each Statement of Work, upon execution by both of the parties hereto, will be a new agreement.

2.4 Services. Leader shall perform for BSC the services ("**Services**") described in the exhibits attached hereto and each Statement of Work.

2.5 Change Orders. Any changes to the scope of Services or the Deliverables shall be mutually agreed upon in writing executed by authorized representatives of both parties ("**Change Order**"). The parties acknowledge that such changes may affect both the schedule and costs set forth in an exhibit or Statement of Work. At a minimum, each Change Order shall document (i) the change requested and its effect on the Deliverables, (ii) any adjustments to the schedule set forth in the exhibit or Statement of Work, and (iii) any increase or decrease in the costs specified in such exhibit or Statement of Work.

## 3. **LEADER RESPONSIBILITIES.**

3.1 Responsibilities. Leader shall perform those tasks and assume those responsibilities set forth in the exhibits and Statements of Work, and to the extent Leader fails to do so, BSC will not be responsible for paying for the affected services. BSC acknowledges and agrees that Leader's performance is dependent on BSC's timely and effective satisfaction of all of BSC's material responsibilities hereunder and timely decisions and approvals by BSC. Leader is entitled to rely on all decisions and approvals of BSC in connection with the Services provided hereunder.

3.2 Failure to Perform Responsibilities. In the event BSC fails to perform its material responsibilities under Section 3.1 or materially impedes Leader's performance of the Services (a "**Delay**"), Leader shall, upon specific notice to BSC with respect thereof, be excused from any delay or non-performance of its obligations under this Agreement, beginning upon the date the Delay arises, to the extent such Leader delay or non-performance results from such Delay; provided that Leader shall work with BSC to minimize the impact or potential impact of any such Delay. BSC shall continue to pay Leader for Services actually performed by Leader prior to and during any such period of Delay by BSC. Leader acknowledges that such Delays may affect the fees payable by BSC pursuant to the applicable exhibits and Statements of Work.

## 4. **LICENSE GRANTS.**

4.1 License to Deliverables. Leader grants to BSC a non-exclusive, non-transferable (except as provided in Section 11.1) license to use the Deliverables for its internal business purposes; which shall include independent third parties approved by BSC who participate in the internal business purpose, subject to the terms and conditions of this Agreement. BSC may not re-sell the Services for any purpose other than its internal business purpose.

4.2 Terms and Restrictions. BSC shall not: (i) reverse engineer, disassemble, decompile, or decode the Deliverables; (ii) derive source code, methodologies or proprietary algorithms from the Deliverables; (iii) modify the Deliverables or otherwise create any derivative work from the Deliverables; or (iv) sell, assign, sublicense or otherwise transfer the Deliverables, except as provided in Section 11.1.

## 5. PROPRIETARY RIGHTS.

5.1 Leader Technology. Leader shall retain all right, title and interest, including all intellectual property rights, in and to all Leader Technology.

5.2 Deliverables. Unless otherwise specified in an exhibit or Statement of Work, Leader shall own all right, title and interest, including all intellectual property rights, in and to all Deliverables, except for the license rights granted to BSC pursuant to Section 4.

5.3 Marks. Each of Leader and its External Business Partners shall retain all right, title, and interest in its respective Marks, and all goodwill arising from BSC use of such Marks shall inure to the benefit of the Leader or its External Business Partners, as applicable. BSC shall not challenge the Marks or the registration thereof or attempt to register any trademarks, service marks, trade names, logos or proprietary words or symbols confusingly similar to the Marks.

## 6. COMPENSATION.

6.1 Fees. BSC shall pay Leader the compensation set forth in the exhibits and Statements of Work for the performance of the Services. Such fees may be on a usage basis, a time and materials basis, or on a milestone basis, or otherwise as agreed by the parties.

6.2 Expense Reimbursement. BSC shall pay, to the extent incurred by Leader in the performance of the Services, and with prior written approval from BSC: (1) reasonable out-of-pocket expenses such as long-distance telephone charges, postage, and shipping costs; and (2) reasonable travel, lodging and living expenses incurred by Leader's personnel, and (3) other pass-through costs such as printing, webcasting, etc.

6.3 Taxes. BSC shall pay or reimburse Leader for any taxes, such as sales, use or excise taxes, and similar charges of any kind imposed by any federal, state or local governmental entity for Deliverables and/or Services provided under this Agreement, excluding only taxes based solely upon Leader's income.

6.4 Payment Terms. All fees quoted and payments made shall be in U.S. Dollars. Leader shall submit monthly invoices, and BSC shall pay all such amounts within thirty (30) days after the date of invoice. Leader may not invoice until services are performed.

6.5 Late Payment. Any amounts due hereunder and not paid within thirty (30) days of the date of invoice shall accrue interest at the rate of one and one-half percent (1.5%) per month or the maximum rate permitted by applicable law, whichever is less, determined and compounded on a daily basis from the date due until the date paid.

## 7. LIMITATION OF LIABILITY.

IN NO EVENT SHALL LEADER'S LIABILITY ARISING OUT OF THIS AGREEMENT OR RELATING TO THE SERVICES OR DELIVERABLES PROVIDED HEREUNDER EXCEED THE TOTAL AMOUNT OF FEES RECEIVED BY LEADER HEREUNDER REGARDLESS OF WHETHER BASED UPON CONTRACT, TORT OR ANY OTHER LEGAL THEORY. IN NO EVENT WILL LEADER BE LIABLE FOR ANY CONSEQUENTIAL, INCIDENTAL, INDIRECT, SPECIAL OR PUNITIVE DAMAGES WHATSOEVER (INCLUDING WITHOUT LIMITATION, DAMAGES FOR LOSS OF PROFITS, LOSS OF USE, BUSINESS INTERRUPTION, LOSS OF DATA OR OTHER PECUNIARY LOSS), IN CONNECTION WITH OR ARISING OUT OF THE FURNISHING, PERFORMANCE OR USE OF THE DELIVERABLES OR SERVICES PERFORMED HEREUNDER, WHETHER BASED UPON CONTRACT, TORT OR ANY OTHER LEGAL THEORY, INCLUDING NEGLIGENCE, EVEN IF LEADER HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

## 8. CONFIDENTIALITY.

8.1 Non-use and Non-disclosure. Neither party shall use the Confidential Information of the other party for any purpose other than in accordance with this Agreement. Neither party shall disclose the Confidential Information of the

other party to anyone other than its employees and contractors who legitimately need access to it and who have signed proprietary and confidentiality agreements comparable in scope to this Section 8. Each party shall use the same degree of care to protect the Confidential Information of the other party as it uses to protect its own confidential information of like nature, which in no circumstances shall be less than reasonable care.

8.2 Exceptions. Confidential Information shall not include information (a) already lawfully known to the receiving party if the receiving party does not then have a duty to maintain its confidentiality, (b) developed independently by the receiving party, (c) generally known to the public through no fault of the receiving party; (d) lawfully obtained from a third party not obligated to preserve its confidentiality; (e) required to be disclosed by law, regulation or order of a court of competent jurisdiction or other governmental authority.

8.3 Remedy for Breach. The parties acknowledge that either party's breach of Section 8.1 would cause the other party irreparable injury for which it would not have an adequate remedy at law. In the event of a breach, the non-breaching party shall be entitled to injunctive relief in addition to any other remedies it may have at law or in equity.

## 9. **WARRANTY; DISCLAIMER.**

9.1 Warranty. Leader represents and warrants that the Services shall be provided in a workmanlike manner in accordance with applicable professional standards. With specific regard to data security, Leader shall secure all data transmissions from client machines to the Leader server with 128-bit Secure Socket Layer connections. All BSC files shall be encrypted on Leader servers at at least 128-bit encryption for each file and those files shall be stored on at least 128-bit encrypted hard drives. All files are backed up on a redundant basis: once an hour for a day, once a day for a week, once a week for a month, and once a month for a year. Access to the root directories on Leader servers shall be restricted only to authorized Leader personnel on a need-to-know basis. Currently three (3) Leader systems administrators have root access; this number may fluctuate as required by internal systems administration and maintenance requirements. All Leader systems administrators are bound by proprietary and confidentiality agreements that commit them individually to maintain and protect all customer data as a trade secret property of the customer in perpetuity. Leader collocation facilities are secured by both key and key lock box access. The collocation facility is further secured by intrusion and fire detection as well as both backup generator and battery continuous power systems.

9.2 Disclaimer. EXCEPT AS SET FORTH ABOVE, LEADER MAKES NO WARRANTIES, WHETHER EXPRESS, IMPLIED OR STATUTORY, WITH RESPECT TO THE SERVICES PERFORMED UNDER THIS AGREEMENT OR ANY EXHIBITS OR STATEMENTS OF WORK, OR THE DELIVERABLES, AND LEADER SPECIFICALLY DISCLAIMS ALL IMPLIED WARRANTIES OF MERCHANTABILITY, NON-INFRINGEMENT AND FITNESS FOR A PARTICULAR PURPOSE.

## 10. **TERM AND TERMINATION.**

10.1 Term. The term of this Agreement shall commence on the Effective Date and shall continue in full force and effect for a period of two (2) years, unless earlier terminated in accordance with Section 10.2 below. Thereafter, on an annual basis, the parties may mutually agree to renew this Agreement for one (1) year terms.

10.2 Termination. This Agreement may be terminated as follows:

(a) By Leader or BSC, immediately upon written notice of termination to the other party, in the event of a material breach of this Agreement by the other party, if such breach continues uncured for a period of thirty (30) days after written notice of such breach is provided to the breaching party; or

(b) By Leader or BSC, immediately upon written notice of termination to the other party, in the event the other party: (i) becomes insolvent; (ii) makes an assignment for the benefit of creditors; (iii) files a voluntary bankruptcy petition; (iv) acquiesces to any involuntary bankruptcy petition; (v) is adjudicated bankrupt; or (vi) ceases to do business.

(c) By BSC for convenience with 30 days prior written notice.

10.3 Effect of Termination. Upon the expiration or termination of this Agreement for any reason: (i) BSC shall immediately pay to Leader all amounts due and outstanding as of the date of such termination or expiration; and (ii) each party shall return to the other party the originals and all copies of such other party's Confidential Information in its possession or under its control.

10.4 Survival. The respective rights and obligations of the parties under Sections 4.1, 4.2, 5, 7, 8, 9.2, 10.3, 10.4 and 11 of this Agreement shall survive the termination or expiration of this Agreement.

## 11. MISCELLANEOUS.

11.1 Assignment. Either party may assign this Agreement in connection with a merger, corporate reorganization or sale of all or substantially all of its relevant assets. Subject to the foregoing, this Agreement shall bind and inure to the benefit of the parties, their respective successors and permitted assigns.

11.2 Amendment; Waiver. No modification, amendment or waiver of any provision of this Agreement shall be effective unless in writing and signed by the party to be charged. The waiver of any breach or default of this Agreement will not constitute a waiver of any subsequent breach or default, and will not act to amend or negate the rights of the waiving party.

11.3 Governing Law. This Agreement is made under and shall be governed by and construed in accordance with the laws of the State of Delaware, without regard to its conflict of laws provisions.

11.4 Notices. Any notice or communication required or permitted to be given hereunder may be delivered by hand, deposited with an overnight courier, sent by confirmed facsimile, or mailed by registered or certified mail, return receipt requested, postage prepaid, to the address for the applicable party first written above, or at such other address as may hereafter be furnished in writing by either party hereto to the other. Such notice will be deemed to have been given as of the date it is delivered.

11.5 Independent Contractors. The parties are independent contractors. Neither party shall be deemed to be an employee, agent, partner or legal representative of the other for any purpose, and neither party shall have any right, power or authority to create any obligation or responsibility on behalf of the other.

11.6 Severability. If any provision of this Agreement is held by a court or tribunal of competent jurisdiction to be contrary to law, such provision shall be changed and interpreted so as to best accomplish the objectives of the original provision to the fullest extent allowed by law, and the remaining provisions of this Agreement shall remain in full force and effect.

11.7 Headings and References. The headings and captions used in this Agreement are used for convenience only and are not to be considered in construing or interpreting this Agreement.

11.8 Complete Understanding. This Agreement including all exhibits constitutes the final, complete and exclusive agreement between the parties with respect to the subject matter hereof, and supersedes any prior or contemporaneous agreement.

11.9 Counterparts. This Agreement may be signed in one or more counterparts, each of which shall be deemed an original and together which shall constitute one instrument.

11.10 Force Majeure. The obligations hereunder of each party shall be suspended while and to the extent that such party is prevented from complying herewith in whole or in part by any event beyond the reasonable control of such party, which for purposes of this Agreement shall include, without limitation, acts of God, earthquakes, unavoidable accidents, laws, rules, regulations or orders of government authorities, acts of war (declared or not), hostilities, blockades, civil disturbances, embargoes, strikes or any other similar event or cause.

11.11 Subcontractors. BSC expressly consents to Leader's use of subcontractors in connection with the performance of Services hereunder, provided that for purposes of this Agreement, Leader shall be responsible for such

subcontractors' performance of that portion of the Services that have been subcontracted to them. Leader will provide prior notice to BSC in the event that a subcontractor is utilized that has not been previously approved and added to the list of Leader External Business Partners in Appendix B.

11.12 Export Restrictions. BSC agrees to comply fully with all relevant export laws and regulations of the United States to ensure that no information or technical data provided pursuant to this Agreement, including, but not limited to, the Deliverables, is exported or re-exported directly or indirectly in violation of law.

IN WITNESS WHEREOF, the parties hereto have caused their duly authorized representatives to execute this Agreement as of the Effective Date:

**Boston Scientific Corporation**

By: Janet McKelly

Print Name: Janet McKelly

Title: CIO

**Leader Technologies Incorporated**

By: Michael T. McKibben

Print Name: MICHAEL T. MCKIBBEN

Title: CEO

## **EXHIBIT A**

### **INSTALLATION, IMPLEMENTATION, TRAINING, MAINTENANCE, HOSTING AND SUPPORT SERVICES**

#### **Boston Scientific Corporation, ELECT Clinical Trials Leader2Leader™ Collaboration System**

#### **SYSTEM INITIALIZATION & TRAINING**

1. Document workflow, frequency, and special user requirements; delivered by BSC.
2. User names, user groups and leaderboard workspace names; provided by BSC.
3. User, user groups and leaderboards (folders) set up by Leader with confirmation of appropriate structure from BSC.
4. Orientation of BSC ELECT Leader2Leader™ systems administrator on account management, permissions, password changes, help system, teleconferencing services, operator support, security, encryption, professional service support, potential firewall issues, etc.; provided by Leader.
5. Written and electronic step-by-step user guides; prepared by Leader.
6. Two (2) training webinars; presented by Leader to personnel selected and approved by BSC.

#### **MONTHLY USER LICENSE**

1. 10-user license.
2. Help desk and technical support.
3. Additional 10 user licenses (this trial only).
4. Up to 1GB storage.
5. Re-negotiate per user license fee once requirement exceeds 20 users with the agreement that the price per user will decrease the more users we add assuming no additional feature or support requirements.

#### **DELIVERABLES**

1. 128-bit secure Internet-based Leader2Leader™ file sharing system delivered substantially in accordance with the ELECT specification entitled ELECT Collaboration Requirements in Exhibit D. At minimum, this will be enabled by access to multiple Digital Leaderboards™ and the Leader Files™ tool on non-host accounts. The host account will also have the Leader Admin™ and Leader Manage Board™ tools enabled for managing the network and user accounts.
2. Support both internal and approved external users.
3. Upon expiration of agreement or termination, CD of data and data wipe of the Leader system.

#### **COSTS**

1. \$750 per month for up to 20 users; billed monthly.
2. Maintenance fee of 17.5% of monthly fee.
3. Additional storage over 1GB: \$7.50 per GB per month; charged in per GB increments (e.g., any increment between 1 GB and 1.999 GB is charged for an additional GB, etc)
4. Per diem professional service rate and billing frequency to be negotiated on a case by case basis based upon the Statement of Work.

## **MAINTENANCE SERVICE LEVELS**

### **1. Maintenance Service Level Commitments**

#### **1.1. Application Hosting**

##### **1.1.1. Environment**

All Hardware, Software, and Internet connectivity services provided as part of Application Hosting are designed, implemented, and supported to maintain a monthly service level of 99.8% uptime or greater.

Uptime is defined as the time during which the majority of the site is available to users, within normal operating parameters.

For the purposes of calculating uptime, all circumstances beyond Leader's direct and immediate control, or failure by any third party to perform in accordance with the terms and conditions agreed to by such third party, will be excluded from such computations. For example, if Citynet collocation services were to lose backbone connectivity for a period of two hours, those two hours will not be counted against any uptime calculation.

##### **1.1.1.1. Hardware**

The hardware may include items such as: application, database, and storage servers; routers, switches, and load balancers; power supply and backup equipment; firewalls; testing and troubleshooting equipment; and other hardware required for BSC operation and support.

##### **1.1.1.2. Software**

This includes the operating system, application development platform, application functionality, analysis tools, and other platform components required for Leader operation and support.

##### **1.1.1.3. Internet Connectivity**

All application hosting includes connectivity to the Internet. (BSC's low initial volume requirements are not anticipated to be an issue here.).

##### **1.1.1.4. Third Party Maintenance, Upgrades, and Additions**

All hardware and software components may, at the sole discretion of Leader be covered by Third Party Maintenance or Upgrade agreements.

Leader may, from time to time, at its sole discretion, upgrade software components to enhance or improve service.

Leader may, from time to time, at its sole discretion, add new software components to enhance or improve service.

#### **1.1.2. System Administration**

In order for Leader to provide effective System Administration, all customers must abide by reasonable systems administration policies and procedures that may from time to time be established by Leader. BSC requires a 5 day notice of any scheduled maintenance. Notice can be sent to Dave Hahn at [hahnd@bsc1.com](mailto:hahnd@bsc1.com)

##### **1.1.2.1. Performance Monitoring and Tuning**

Leader will monitor system performance, including responsiveness, and make necessary modifications to the system to ensure optimal performance.



**1.1.2.2. Maintenance Compliance**

All software will be updated with the latest patches, as deemed necessary by Leader. All hardware will be monitored for recalls or additional necessary features, as well as periodic regularly scheduled maintenance, as per manufacturer or industry standard recommendations.

**1.1.2.3. Security**

Hardware and software security will be the responsibility of Leader. Security includes firewall administration and maintenance, as well as security patches.

**1.1.2.4. Network**

Leader will ensure network connectivity and serve as the main contact for Internet or other network connectivity issues.

Leader should be designated as the technical contact for all DNS related activities, and will serve in the capacity thereof.

**1.1.2.5. Backups**

All data and web servers will be backed up nightly and incrementally using a robust configuration of network-based backup servers.

**1.1.3. Database Administration**

**1.1.3.1. Performance Monitoring and Tuning**

Leader will monitor database system performance, including responsiveness, and make necessary modifications to the system to ensure optimal performance.

**1.1.3.2. Report Writing**

Any data and activity reports offered as standard reports by Leader will be made available to BSC. Any additional reports requested by BSC will be handled as a Statement of Work.

**1.1.4. Disaster recovery**

Leader will keep and periodically test a disaster recovery plan. This may include multiple personnel, additional equipment, and software.

**1.2. Help Desk**

Leader will provide advanced technical and domain support through email and telephone. The helpdesk for all Leader customers, including BSC, will consist of a full-time support technician, a dedicated support telephone number, an issue tracking system, and email support.

Between the hours of 9 AM to 5 PM Eastern Time Monday through Friday, excluding United States holidays, henceforth called "Standard Business Hours", all support calls should first be triaged by Leader. Specifically, BSC will provide Level 1 technical support and call triage (i.e., answering non-technical and lower level technical questions). Leader will be available to BSC staff via email and telephone to provide Level 2 and Level 3 technical support through BSC staff members on a 24 x 7 basis.

Support calls originating after Standard Business Hours will be considered After Hours Support calls and will be available to BSC on a 24 x 7 basis. These calls will be directed to an After Hours Support number, which will then page the on-call Leader Support Technician. Once the page has been received, the Support Technician will respond to the page within 20 minutes.

Whether Standard or After Hours, all inquiries will be time stamped and logged, and will be processed or escalated within four (4) hours.

The help desk function will be supported by a software system to track, at a minimum, date, time, incident number, inquiry type, incident description, and incident resolution.

Periodically, frequent inquiries will be summarized in a frequently asked questions document and made available to BSC. To enable Leader to better track issues related to BSC, Leader will track all queries it receives through the help desk tracking system, and enter reported bugs in a bug tracking tool.

**EXHIBIT B**

**LEADER EXTERNAL BUSINESS PARTNERS**

Citynet Holdings, LLC (collocation provider)

AnySystem.com (equipment provider)

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## **EXHIBIT D**

### **ELECT COLLABORATION REQUIREMENTS**

#### **Summary**

The ELECT trial has needs to send/receive sensitive lab data between business partners. This data is relatively small in volume (hundreds) and frequency (weekly). The data is used to track the status of core lab readings and to provide for reconciliation between company systems. For ELECT, the actual data will not be transmitted, but tracking files will be.

As such, the type of collaboration the ELECT trial is pursuing is some internet-based, secure file-sharing capabilities. While it could be expanded to include sites, the scope of these requirements is limited to just our core lab partners.

#### **Requirements**

##### **User Counts**

##### **External users:**

Angio core lab	2
ECG core lab	2
National PI	1
Sites	7

##### **Internal users:**

Data Management	2
Safety Group	1
Monitoring	2
Clinical Staff	3

Total 20

##### **File Volumes**

File volumes are expected to be very small over a two-year period.

<b>File</b>	<b>Frequency</b>	<b>Size Each</b>	<b>Total Size</b>
Angio Tracking File (lab-produced)	1/week	50k	10MB
ECG Tracking File (lab-produced)	1/week	50k	10MB
Enrollment File (BSC-produced)	1/week	30k	6MB
Weekly Report (BSC-produced)	1/week	2MB	100MB
Newsletter (BSC-produced)	1/month	5MB	120MB
Document Updates (BSC-produced)	as needed	20MB	20MB
Miscellaneous files	as needed	-	200MB
<b>TOTAL</b>			<b>&lt;500MB</b>

## Security

To properly restrict access to various folders, and to account for additional studies, the following user groups should exist.

Group	Description
ELECT_BSC_DM	ELECT trial, BSC Data Management
ELECT_BSC_SAFETY	ELECT trial, BSC Safety Group
ELECT_BSC_CLINICAL	ELECT trial, BSC Clinical Team
ELECT_BSC_MONITOR	ELECT trial, BSC Monitoring Team
ELECT_ANGIO_LAB	ELECT trial, Angio Core Lab
ELECT_ECG_LAB	ELECT trial, ECG Core Lab
ELECT_SITE_COORD	ELECT trial, site coordinator
ELECT_SITE_PI	ELECT trial, primary investigator

In addition, the following requirements should exist.

1. Access to files/folders must be restricted by a user/password scheme as well as role(s).
2. BSC must approve access for any user prior to granting them access to the system.
3. The password must expire – and user be forced to change – every 60 days.
4. Each user should be allowed to have multiple roles assigned to their login.
5. Transmission of any data files must use at least 128-bit encryption.

## Folders

The following folders are proposed:

Folder	Content, access
ELECT	
Core Lab – Angio	Data files produces by Angio Core Lab ELECT_ANGIO_LAB: read/create/update/delete ELECT_BSC_DM: read/delete ELECT_BSC_SAFETY: read ELECT_BSC_CLINICAL: read
Core Lab – ECG	Data files produces by Angio ECG Lab ELECT_ECG_LAB: read/create/update/delete ELECT_BSC_DM: read/delete ELECT_BSC_SAFETY: read ELECT_BSC_CLINICAL: read
Sites	Currently empty, but could contain site-specific subfolders. ELECT_BSC_CLINICAL: read/create/update/delete ELECT_SITE_COORD: read ELECT_SITE_PI: read
Sponsor	Sponsor-generated files
Enrollment	Enrollment files produces by BSC. ELECT_ANGIO_LAB: read ELECT_ECG_LAB: read ELECT_BSC_DM: read/create/update/delete ELECT_BSC_SAFETY: read ELECT_BSC_CLINICAL: read ELECT_SITE_COORD: read ELECT_SITE_PI: read



**Leader**

**LEADER TECHNOLOGIES INC.**

921 Eastwind Drive, Suite 118  
Westerville, Ohio 43081  
Phone: 614-890-1986  
Fax: 614-864-7922

**Invoice**

Date	Invoice #
8/16/2003	101103-59...

**ATTN: Lynn Mattice**  
**Boston Scientific**  
**One Boston Scientific Place**  
**Natick, Massachusetts 01760**

P.O. NO.	TERMS	DUE DATE
		8/26/2003

ITEM	DESCRIPTION	AMOUNT
LeaderFile	Monthly Usage Fee	750.00
LeaderFile	Monthly Maintenance	131.25
Total		\$881.25



**Leader**

**LEADER TECHNOLOGIES INC.**

921 Eastwind Drive, Suite 118  
Westerville, Ohio 43081  
Phone: 614-890-1986  
Fax: 614-864-7922

**Invoice**

Date	Invoice #
9/17/2003	101103-59...

**ATTN: Lynn Mattice**  
**Boston Scientific**  
**One Boston Scientific Place**  
**Natick, Massachusetts 01760**

P.O. NO.	TERMS	DUE DATE
		9/27/2003

ITEM	DESCRIPTION	AMOUNT
LeaderFile	Monthly Usage Fee	750.00
LeaderFile	Monthly Maintenance @ 17.5%	131.25
Total		\$881.25