In Situ Global Clinical Trials Network, LLC

Research Support Services Proposal

GUIDESTAR®

OPTIMIZING RESEARCH

November 23, 2016

The GuideStar Difference

GuideStar's team of experts is passionate about helping hospitals, health systems and physician practices bring clinical trials to the communities they serve. Evaluating and supporting research programs is our only focus, and our seasoned, professional team is well-versed in all aspects of clinical trial programs.

What GuideStar Delivers

Expertise

GuideStar brings a unique blend of healthcare and clinical trial management expertise for successful navigation within community healthcare providers and the research industry.

- Strategic leadership and guidance
- Strong support team
- Singular focus on clinical research
- Highest standard of operational and financial performance
- Extensive experience in multi-specialty trials
- Proven track record
- Research infrastructure insight
- Industry thought leader

Assessment

GuideStar assesses all aspects of clinical research site operations and provides recommendations and plans for optimal performance, enhanced compliance and increased efficiencies.

- Comprehensive site evaluation
- Regulatory and finance audits
- Financial management assessment
- Research staff evaluation
- FDA readiness assessment
- Patient recruitment/ enrollment review

Support

GuideStar provides comprehensive clinical trial operations support to hospitals, health systems and physician practices.

- Support existing operation
- Trial contract and budget negotiation
- Stringent financial management
- Research informatics
- Regulatory compliance
- Clinical trial pipeline
- Physician compensation model development

GuideStar Services

Clinical Trial Pipeline Services

Bringing the right trials to In Situ—those that are of interest and provide the opportunity for good enrollment—is heavily dependent on communications with the pharmaceutical companies. GuideStar nurtures its relationships and maintains a positive reputation in the industry, thus allowing for increased access to clinical trials.

GuideStar has developed a streamlined process for building solid clinical trial pipelines. From identifying trials appropriate for the hospital's patient population to facilitating pre-award communications with sponsors, GuideStar is focused on delivering trials that will yield solid enrollment volume.

Deliverables

- Develop a detailed profile of each physician
- Develop a comprehensive profile of the practice's capabilities, patient population and volume
- Proactively communicate with pharmaceutical trial sponsors
- Manage pre-award document process
- Facilitate confidentiality agreements
- Facilitate Feasibility questionnaires
- Manage sponsor correspondence
- Facilitate agenda development for on-site prequalification meetings
- Manage sponsor communication until time of trial award

Service Fees

Implementation Fee for up to 10 Physicians (one time)	$ 1,900
Per Additional Physician	$ 250
Per Trial Payment	$ 1,650

(50% to be paid when site selection visit is scheduled, 50% to be paid upon trial award)

Accelerated Trial Start-Up

Efficient and timely trial start-up is essential to a clinical research program. Trial start-up involves contract and budget negotiations, as well as regulatory processing, which all must simultaneously be completed to ensure the trial is activated within the industry-standard of eight to 12 weeks from trial award.

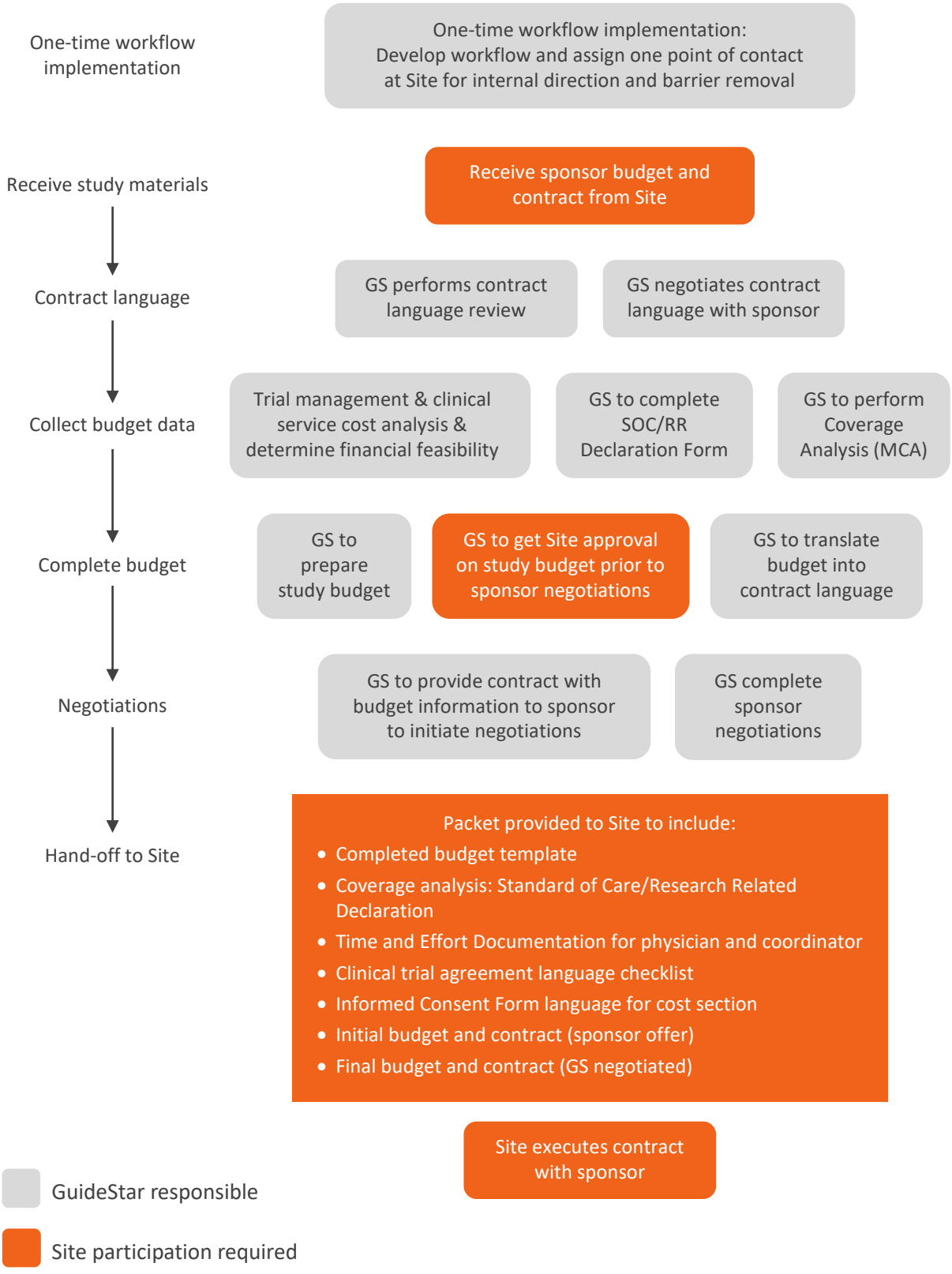
Clinical trial budgets and contracts are the foundation for financial success of a research program. Ensuring all trial expenses are covered by the sponsor requires intensive protocol review and a strong financial background. Equally important is negotiating the most appropriate language and terms in the clinical trial agreement to protect the practice and physician, as well as ensuring payment terms are reasonable.

GuideStar's financial team is certified in trial contracting and will work directly with sponsors to negotiate the best possible financial arrangement on behalf of In Situ.

In addition, the clinical trial must go through regulatory processing at the local, sponsor and IRB levels to ensure all requirements are in place to protect human subjects participating in the trial. GuideStar's specialists will manage the initial regulatory processes including working with In Situ's research staff and Principal Investigators to complete documents required of the site and manage the submission of all materials to the trial sponsor and IRB.

GuideStar will develop efficient workflows and communication mechanisms resulting in expedited regulatory processing and contract and budget reviews. Additionally, GuideStar will customize metrics for monthly performance reporting. Per trial metrics will include profit margin, negotiated margin and activation timeline.

Budget and Contract Processing Flow



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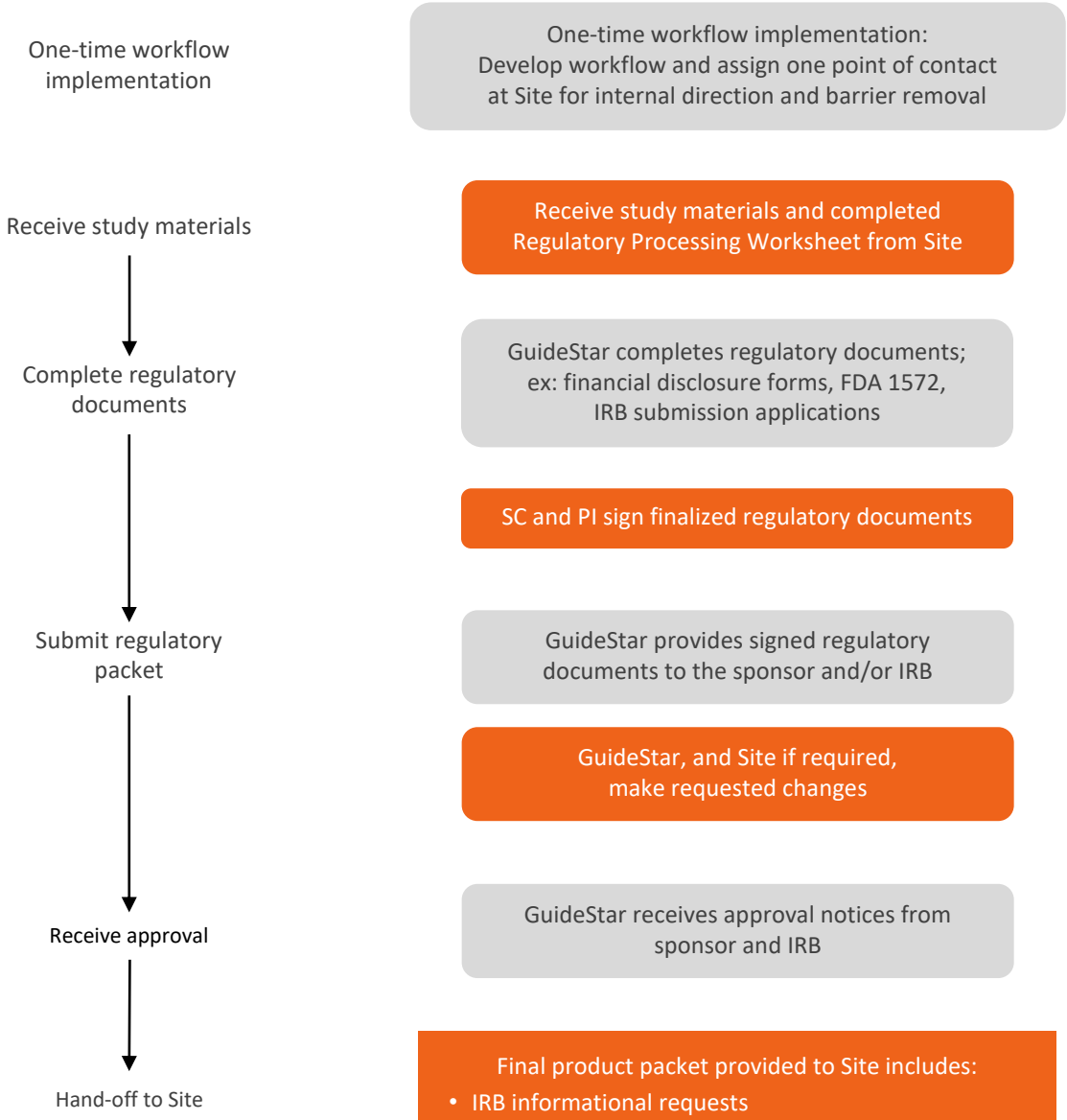
Regulatory Processing Flow



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Deliverables

Budgets and Contracts Negotiation:

- Cost and financial feasibility analysis
- Budget development
- Coverage analysis
  - Determination of overall clinical trial qualification for Medicare coverage
  - Review clinical events specified in the protocol and determine if they are covered services by Medicare
  - Perform declaration of standard of care and research related events
  - Complete MCA form to document the CMS National Coverage Decision process and coverage for subsequent budget preparation
- Time and Effort Documentation for Physician
- Time and Effort Documentation for Study Coordinator
- Clinical trial agreement language review and modification based on the organization's legal language requirements
- Final budget negotiation and budget section translation into the clinical trial agreement

Regulatory Processing:

- Draft sponsor and IRB required forms, obtain required signatures and submit final versions. Forms include:
  - FDA Form 1572
  - Financial disclosures
  - Site contact information
  - Delegation of authority logs
  - Initial IRB submission forms
  - IRB waiver of authorization
- Prepare, obtain approval and submit informed consent form documents in compliance with Federal, State and local regulatory requirements.
  - Ensure organization-specific requirements and/or language are included in each trial's ICF
  - Acquire trial sponsor approval of system-specific ICF prior to initial submission to IRB
- Process, submit and file regulatory documents required by trial sponsors including:
  - Protocol signature page
  - Investigator brochure receipt
  - Delegation of authority log

Service Fees

Accelerated Trial Start Up: Contract and Budget Negotiation and Regulatory Processing Implementation Fee	$	2,100	one time
Contract and Budget Negotiation* and Regulatory Processing	$	3,525	per trial
Registry Trials	$	1,525	per trial
Additional study arms	$	975	per arm
Contract and Budget Negotiation Only			
Contract and Budget Negotiation*	$	2,945	per trial
Additional study arms	$	975	per arm
Regulatory Processing and Budget Negotiation Only			
Regulatory Processing and Budget Negotiation*	$	3,025	per trial
Additional study arms	$	975	per arm
Budget Negotiation Only			
Budget Negotiation*	$	2,610	per trial
Additional study arms	$	975	per arm
Regulatory Processing Only			
Regulatory Processing	$	1,175	per trial
Multiple IRB processing and submission	$	675	per add'l IRB
Coverage Analysis Only			
Coverage Analysis	$	1,010	per trial

**Budget negotiations include performing Coverage Analysis*

GuideStar will make reasonable efforts to have its cost included in the trial budgets as start-up fees for sponsor reimbursement.

Note: Proposed fees are based on GuideStar's established standards of practice as outline above. Additional requested responsibilities and services can be negotiated.

Research Revenue Cycle Management

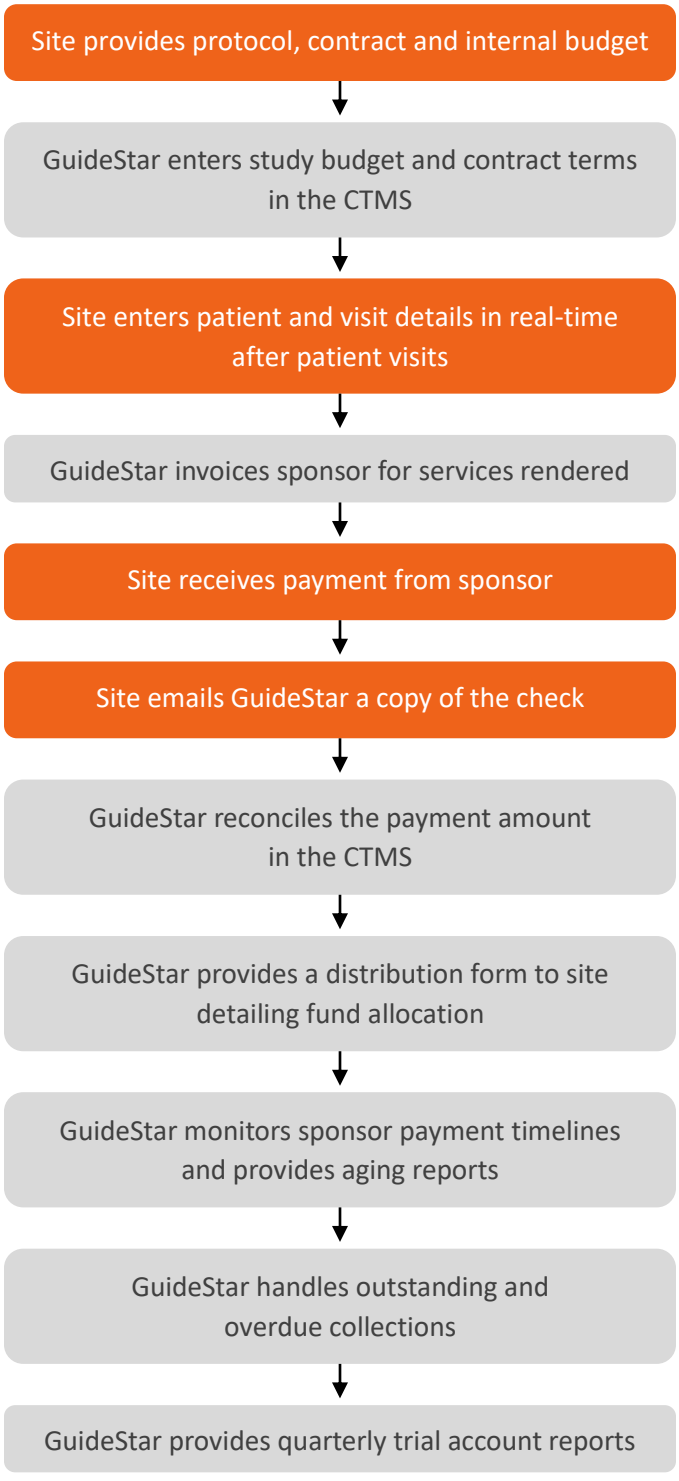
Just as important as timely and efficient trial start up is ensuring the site is paid for the work being done for that trial. Once a trial is initiated, aggressive management of the finances should begin. From ensuring all start-up funds are invoiced immediately and collected, to trial account reconciliation, strong focus on finances will result in positive cash flow making a site with successful patient enrollment profitable.

GuideStar provides complete research revenue cycle management in order to provide sites the tools necessary along with the expert level of services for optimal revenue outcomes, including access to a Clinical Trials Management System. Because so much of the revenue depends on the staff's diligence in the use of the CTMS, GuideStar also provides process and entry training for the user-friendly system.

Deliverables

- Clinical Trials Management System
  - Customization and implementation for the site
  - On-Site Staff Training
  - CTMS and post award management SOPs
- Invoicing and Collections
- Real-Time Research Revenue Cycle Management and Reporting
  - Trial account reconciliation
  - Profit and Loss Reporting on Trials

The Research Revenue Cycle Flow



Service Fees

Implementation and Training

One GuideStar professional on site for one business day	$ 5,300

Percentage of earned revenue

GuideStar negotiated trial budgets	20% all non-start up earned revenue
Non-GuideStar negotiated trial budgets	20% earned revenue

By charging a percentage of earned revenue, the site incurs no risk with GuideStar's services. GuideStar will not get paid the percentage until collections are successful. Coupled with optimal budget negotiations performed by GuideStar, the site will increase earnings. Because GuideStar provides the CTMS, the site has no licensing fees.

Note: Proposed fees are based on GuideStar's established standards of practice as outline above. Additional requested responsibilities and services can be negotiated.

Travel expenses incurred by GuideStar in providing any of its services are to be reimbursed by In Situ.

By engaging GuideStar, In Situ can be assured that it is working with a quality leader in clinical trials operations that will provide critical data and information necessary for strengthening and growing research based on the practice's goals and resources.

Proposal valid for 90 days

The GuideStar Team

Senior Management Team

Kristin P. Hutchins, MHA — President and Chief Executive Officer

Ms. Hutchins has served as a healthcare executive for more than 15 years with particular expertise in the areas of strategic business growth, operational efficiency, organizational management, healthcare financing, and technology development. She was previously president of a large regional managed care company, as well as a healthcare investment firm. She has served on numerous private and governmental boards in the healthcare industry. Ms. Hutchins received her Master of Health Administration from Tulane University and her Bachelor's degree in Biology from the University of Wisconsin-LaCrosse. She served as a faculty preceptor in Health Systems Management at Tulane and an adjunct faculty member of Phoenix University.

Rhonda J. Paz, PhD, CRCP — Chief Operating Officer

Dr. Paz is responsible for strategizing and implementing new service lines and products as well as the formation of expert operational units to support the variety of service needs of client research sites. She oversees all staff units, ensuring that operating goals and performance metrics are achieved. She has more than 25 years of leadership experience in clinical research. Prior to joining GuideStar, she was the Associate Center Director for Scientific Administration of the Louisiana Cancer Research Consortium, where she was responsible for establishing a centralized administration to oversee and manage scientific programs, internal grant programs, research informatics, as well as research facilities. Prior to that, she was the Director of Clinical Research for two prestigious medical centers, overseeing the implementation and operations of the clinical research programs. Her experience makes her uniquely adept at program development, start-up and re-engineering of research operations. Dr. Paz holds a PhD in Health Administration, as well as a Bachelor's in Business Administration and Management. She has earned a designation of Certified Contract Research Professional and is active in several industry organizations.

Senior Management Team (cont.)

Shirley Trainor-Thomas, MHSA — Chief Marketing Officer

With experience in both clinical trials operations and hospital management, Ms. Trainor-Thomas focuses on developing solid relationships with physicians and hospitals, as well as the pharmaceutical, biotech and device industries. Her career is founded in healthcare management overseeing business development, managed care contracting, ancillary services and physician practices in large community hospitals. Ms. Trainor-Thomas earned her Master's in Health Sciences Administration from the Medical University of South Carolina. She received her undergraduate degree from the University of South Carolina. She is an active member in the American College of Healthcare Executives.

Christine A. Miller, CPA — Chief Financial Officer

Ms. Miller administers all aspects of financial reporting, cash management, budgeting and forecasting for GuideStar. She provides decision support to strategic planning and imposes financial discipline and rigor on the company's operations. In her role, Ms. Miller oversees the analyses of research site financial activity and provides thorough financial reporting to include recommendations. She spent almost 20 years in the health insurance industry, serving as a financial accountant for a large health insurer and a hospital-owned HMO, and as a financial officer for a regional managed healthcare company. She earned her Bachelor of Business Administration in Finance/ Management from Loyola University in New Orleans and is a Certified Public Accountant.

Gregory E. Vaughan — Chief Technology Officer

Mr. Vaughan is responsible for overseeing clinical trial management system implementations and building IT infrastructures for enhanced clinical site data management and financial reporting. He has spent his career at the leading edge of technological innovation and administration and has served in technology positions across a diverse set of industries, with the past 15 years specifically in healthcare. Over the span of his career, Mr. Vaughan has focused on such initiatives as application development, employing technology to maximize corporate productivity, company-wide system integration, and cultivating internal proficiencies in EDI, OCR, and healthcare claim processing automation. Greg received his Bachelor's degree from the University of Louisiana at Lafayette.

Board of Directors

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James A. Hardy

Technology Development Consultant

Founding Director, Office of Technology Development, LSU Health Sciences Center

Kristin P. Hutchins, MHA

President and Chief Executive Officer, GuideStar Clinical Trials Management

Alan M. Miller, MD

Director of the Charles A. Sammons Cancer Center and Chief of Oncology,
Baylor Healthcare System

Ed Michael Reggie, MBA

Chairman of the Board, GuideStar Clinical Trials Management

Managing Director, Future Factory

Board member, New Orleans BioInnovation Center

Thank you.

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