



B. McLAUGHLIN
ASSOCIATES, INC.

A Helping Hand in Clinical Research

BMA Core Capabilities Presentation

This presentation is provided to you by BMA. The presentation is meant to enhance discussions between your organization and BMA. The substance of this presentation is confidential and is legally privileged.

overview

BMA is a solutions-focused CRO providing expertise in clinical trial study management, data management, auditing, cold chain management and monitoring.

- ✓ **18 years of building a reputation...not simply relying on one**
- ✓ **growth driven by repeat business through word of mouth marketing and referrals**
- ✓ **experienced, cross-trained, dedicated staff and management with an average of 7 years with BMA and 11 years in industry**
- ✓ **diverse supplier – WBENC Certified woman-owned, small business**
- ✓ **FDA Inspected – Routine Audit in Spring 2010 with NO findings, 483s or recommendations**



**B. McLAUGHLIN
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locations



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value proposition

BMA's primary objective is to provide quality support at cost effective rates. Understanding your need to get products to market faster with accurate and timely data, our innovative services and industry experienced, cross-functional staff allow us to meet this goal, ultimately enhancing your ability to be a competitive industry leader.

*Our Value Proposition is centered around excellence of service with a firm focus on quality and efficiency. **Our company size and structure allow for a hands-on approach and expertise, ensuring that your project timelines are met with great success.***



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18 years of therapeutic expertise

<u>Biologics</u>	Cancer Breast Lung (Non-Small Cell) Melanoma Myeloid Leukemia, Acute Diphtheria Hepatitis B	HSV HPV Influenza Pertussis Polio Tetanus
<u>Cardiovascular</u>	Atrial Fibrillation Congestive Heart Failure (CHF) Congestive Heart Failure (CHF), Pediatric Coronary Heart Disease	
<u>CNS</u>	Cancer – Brain Insomnia Restless Leg Syndrome, Adolescent Progressive Multifocal Leukoencephalopathy	
<u>Dermatology</u>	Psoriasis Wound Healing	
<u>Endocrinology</u>	Diabetes Type 1 Diabetes Type 2 Diabetes Type 2, Pediatric	
<u>Gastroenterology</u>	Cancer – Gastroesophageal	
<u>Hematology</u>	Idiopathic Thrombocytopenia Purpura Lymphocytic Leukemia, Chronic Non-Hodgkin's Lymphoma Thromboembolism Prevention	
<u>Infect. Disease</u>	Diphtheria Hepatitis B Hepatitis C HSV	Otitis Media Pertussis Pneumonia Polio

<u>Musculoskeletal Disease</u>	Cancer – Sarcoma, Soft Tissue	
<u>Nephrology</u>	Cancer – Renal Cell Hepatitis C Liver Disease, Chronic	
<u>Oncology</u>	Brain Breast Cervix Colorectal Esophagus Gastric Head and Neck Kaposi's Sarcoma Lung (Non-Small Cell) Lung (Small Cell)	Lymphocytic Leukemia Melanoma Myeloid Leukemia, Acute Non-Hodgkin's Lymphoma Other Ovary Prostate Renal Cell Soft Tissue Solid Tumors
<u>Ophthalmology</u>	Cancer Safety Follow-up	
<u>Other</u>	Chemo-Induced Nausea & Vomiting Post-Surgical Nausea & Vomiting	
<u>Respiratory</u>	Asthma Cancer – Lung Chronic Obstructive Pulmonary Disease	
<u>Urology</u>	Benign Prostatic Hyperplasia Cancer – Prostate	
<u>Women's Health</u>	Cancer Breast Cervix Ovary HPV	

200+ clinical trials

Therapeutic Expertise	Phase				Study Management	Data Management	Audit and/or Monitoring	Cold Chain Support
	I	II	III	IV				
Biologics			◆		▪	▪	▪	▪
Cardiovascular		◆	◆	◆	▪		▪	
CNS	◆	◆	◆		▪	▪	▪	
Dermatology	◆		◆		▪	▪		▪
Endocrinology		◆	◆	◆	▪	▪	▪	
Gastroenterology		◆	◆		▪	▪		
Hematology	◆	◆	◆		▪	▪	▪	▪
Infectious Disease		◆	◆		▪	▪	▪	
Musculoskeletal Disease			◆		▪			
Nephrology		◆	◆		▪			
Oncology	◆	◆	◆	◆	▪	▪	▪	▪
Ophthalmology			◆		▪		▪	
Other		◆	◆	◆	▪		▪	
Respiratory	◆	◆	◆	◆	▪	▪	▪	▪
Urology			◆		▪	▪		
Women's Health	◆	◆	◆		▪	▪	▪	▪

why BMA?

sized by design, we offer...

Valued Service – High quality, specialized support with a personalized approach. Tailored service, consistency and expertise not always found in a larger organization.

Flexibility – Through strategic partnerships, BMA has the ability to ramp up quickly or scale back and maintain a skilled staff pool. Once an MSA is in place, BMA can begin project work very quickly, sometimes in less than 24 hours.

Innovation – Routinely create and implement new processes and/or improve upon existing client processes



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why BMA?

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Partnership – Integration of BMA operations with client's team utilizing laptops, client and CRO systems and training. Very experienced in working with and auditing other vendors, CROs and sites.

Big Picture Approach – Results-driven, cross-functional team members provide greater insight and understanding of the projects as a whole, not just our designated tasks

Continuity – Lower attrition rates allow for dedicated staff to be maintained throughout the course of the project, providing greater stability and fostering strong team relationships



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capabilities: **study management**

- Creation, Collection & Review of Regulatory Documentation
- Negotiation of Clinical Study Contracts & Patient Budgets
- Informed Consent Creation, Review, Language Negotiation & Maintenance
- Work Directly with Central IRBs on Behalf of Sponsor
- Maintenance of Sponsor CTMS Systems & Databases
- Trial, Site and Patient Management
- In-house and On-site Monitoring
- Site Consultation & Support



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capabilities: auditing

- Sponsor, Vendor and Investigator Site Study File Review
- During Study Conduct (in-stream), at Study Closure, Prior to Archive, Pre-FDA Audit or Submission
- Study Related Investigator Files, Country/Central Trial Master Files
- At Sponsor, Investigator Site or BMA Locations
- File Review for completeness and accuracy, as well as all due diligence efforts and documentation



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capabilities: data management

- Full and Niche Data Management Support
- Paper CRF and eDC Capabilities
- Data Discrepancy Query & Data Form Collection (paper and eCRF)
- Data Reconciliation, Collection, Tracking (samples, labs, slides, images, etc.)
- Patient Listing and Narrative Review
- SAE, Lab Normal Range & Lesion Cleaning
- Clinical Scientist & Submission Support
 - Narrative Review/QC, Patient Listing Review, Data Reconciliation, Query Generation



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capabilities: cold chain support

- Development of Study-Level Cold Chain Procedures and Creation of Monitoring Documentation
- Delivery of Customized Training to Sponsor, Monitoring Teams and Sites on Best Practices
- Selection/Recommendation of Investigational Product Shipping and Monitoring Equipment
- Liaise and Coordinate with Sponsor Selected Complementary Vendors (Shipping, warehouse, etc.)
- Risk Mitigation Through Assessments of Site Cold Chain Storage Capability
- Evaluation of Existing Site Temperature Monitoring Systems for Sponsor Compliance
- Ongoing Site Monitoring for Cold Chain Compliance
- Dissemination of Study Specific Temperature Monitoring Devices
- Preparation and Management of Transport and Storage Deviation Reporting
- Temperature Deviation Identification, Follow-up, Quarantine and Corrective Action



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capabilities: **monitoring**

- Certified Field Monitors (ACRP, SoCRA)
- Site Feasibility, Qualification & Selection Support
- Initiation, Interim & Closeout Visits
- Source Documentation Review & Data Verification
- Regulatory Compliance Support & Review
- Participation & Presentation at Investigator Meetings
- Identification & Addressing of Protocol Deviations & Violations
- Study Supply Inventory
- Reporting of Adverse Events & Serious Adverse Events



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case study: study management

opportunity

Large oncology vaccine trial that was part of a sponsor initiative to save money and deeply save time to site initiation. Sponsor started trial internally, but lacked the resources to get sites up and running to meet Upper Management's proposed timelines. Sponsor needed to outsource a portion of the sites to a company that could come on board quickly to send out initiation packets and collect and review regulatory and IRB documents, including Informed Consent Form (ICF) review.

plan

BMA assumed 40% of the total study sites for 26 weeks. Tasked to prepare Initiation packet documents and binders, verify site information, disseminate packets and procedure manuals, as well as collect, review and track regulatory documents for sponsor regulatory approval and review ICFs pre- and post-IRB submission.

results

92% of BMA managed sites were ready for site initiation within 26 weeks. Average of 22 weeks from initial packet shipment to regulatory approval for BMA versus 27 weeks for sponsor.



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case study: study management

opportunity

Sponsor had 82 sites that needed to be ready to enroll in a very short time for a high profile cardiovascular study. Sponsor had a limited study budget and departmental resources and needed a company that could come on board quickly and execute results. BMA was contracted to distribute, collect and review regulatory documents.

plan

Following federal guidelines, sponsor SOPs, processes, and guidance documents in conjunction with BMA SOPs, BMA prepared Study Initiation Pack (SIP) documents, created SIP binders, verified site information and disseminated Initiation packets for sponsor. Also collected, reviewed and tracked regulatory documents for Sponsor Regulatory Approval.

results

Regulatory Documents disseminated, collected, reviewed, tracked and confirmed as accurate in an average of 34 days. Sponsor met target initiation deadlines ahead of schedule and within budget. BMA completed all work within 5 months, more than 5 months ahead of sponsor projections (bulk of the time spent within the first 3 months). Speed and time savings translated into a cost savings of over 60% of the original Sponsor projected budget.



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case study: auditing

opportunity

Sponsor had a large, Phase III oncology trial that had been ongoing for 3 years, was on its 7th amendment and was being submitted for FDA approval. Via internal sponsor review, it was noted that the paper Investigator, Central and Country Regulatory files were missing documents and/or inappropriately filed. BMA was contracted to audit Investigator files and review and file thousands of pages of loose documents as well as perform due diligence. In anticipation of an on-site FDA inspection, the files had to be inspection ready in 3 months.

plan

Following federal guidelines, sponsor SOPs, processes, and guidance documents in conjunction with BMA SOPs, a team of BMA auditors reviewed all of the miscellaneous documents in comparison to the files, performed a thorough review of all Investigator and Central/Country files, liaised with sites, monitors and internal personnel to resolve document discrepancies and carried out a full due diligence effort.

results

BMA reviewed all documents, files and performed due diligence according to sponsor requirements within the sponsor's timeframe. BMA was asked to be involved with the pre-inspection preparedness and was an integral conduit during the time of inspection. No 483's were observed during inspection and the drug subsequently received approval. From recommendations made by the BMA auditors and with our support, the department developed new Investigator, Country and Central file filing guidelines. Additionally a central file room, internal audit team and audit process were developed.



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case study: contracts & budgets

opportunity

First time that sponsor contracts group had outsourced contract and budget negotiations. Imperative that CRO work as a seamless extension of sponsor team without sites recognizing a difference between CRO and sponsor. Negotiate and finalize contracts and budgets with sites quickly in order to meet an impending study start.

plan

Utilizing sponsor SOPs, guidance documents and training in conjunction with BMA SOPs, BMA negotiated contract language and per patient budgets. Given autonomy to approve budgets within the criteria set forth by the sponsor and abiding by standard-of-care amounts. Developed thorough understanding of direct and indirect costs associated with performing the study. The goals were to reduce delays in internal and external budget review and approval. Identified all costs, including "hidden" costs and confirmed that budgets were within range and in sponsor required format.

results

Met sponsor proposed timelines, negotiating per patient budgets for 124 sites in an average of 36 days and Clinical Study Agreements for 124 sites in an average of 38 days. Through our training and negotiating skills, negotiation was successful and assured that mutual agreement was achieved by all parties.



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case study: data management

opportunity

During the review of sponsor's oncology drug submission, FDA requested that slides for a subset of subjects be re-submitted to a central pathology lab for re-assessment. Sponsor needed specimens collected from 20 countries, 75 sites totaling about 608 slides. Sponsor expectation was that 20% of the needed slides would be recovered.

plan

Assisted in locating and returning slides from the sites including facilitating activities and tracking communication regarding return of slides. Centrally maintained all communication and documentation of efforts. Facilitated related activities such as shipment of return materials (often requiring knowledge of international shipping and customs requirements related to the shipment of human specimen samples). Provided ongoing progress reports to Study Management.

results

Proposed deadline of 2 months was met with a 95% response rate from sites regarding the status of the slides. Exceeded sponsor expectations of a 20% return by facilitating the recovery and return of 80% of the outstanding slides.



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sample client feedback

“Our collaboration with BMA has been incredibly successful and I hope we will consider such collaboration proactively for future studies.” *Director, Vaccines Development Unit*

“It was my absolute pleasure working with you on this initiative. You were always very quick to respond to all of my requests and managed to keep on top of the details of every single physician and their patients. I know that you also responded to questions from sites in a similar efficient fashion.” *Director, Clinical Development, Oncology*

“You did a great job, coming in at a difficult time and catching on right away. [We] thought you asked great questions and we were impressed with your overall understanding of our processes and ability to identify issues and query appropriately. We were very happy with your work.”
Sr. Clinical Data Scientist

“You seamlessly handled all our requests and managed the sites wonderfully. I never worried about something being taken care of.” *Lead Study Manager, Oncology*

“I appreciate all the help you have provided in answering questions and reviewing consents as I prepared this study for IRB review. I really feel like you and your colleagues have been the best I have worked with in the many studies we have opened here.” *Research Specialist (Inv. Site)*



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Our success has resulted from an unchanged approach that has stood the test of time - provide unwavering quality, commitment, excellence and value to our clients in order to support their clinical trial needs



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contact BMA today

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