

# Your CRO for Success



## YOUR FIRST CHOICE FOR QUALITY, COST-EFFECTIVE REGULATORY FILE AUDIT & FDA SUBMISSION SUPPORT



*Study closure and submission can be a stressful and challenging time. BMA will work with your team to create positive results.*

BMA will support your team during this critical period by reviewing and reconciling regulatory documents, investigator, country and central files, as well as support sites that may be audited as part of a submission.

**“ Get the most out of your study and resources by partnering with BMA ”**

Our goal is to provide world class support services that keep your projects on time, within budget and compliant to all regulatory authorities.



## Regulatory File Audit & FDA Submission Support

- FDA Regulations, Your SOPs & Policies
- Study & Investigator File Review and Documentation (Paper & Electronic)
- Global File Review Capabilities for Translated Documentation
- Safety Documentation Tracking & Reconciliation
- Discrepant & Missing Documentation Follow-up & Due Diligence
- For Drug & Biologics
  - Interim & Final Financial Disclosure Collection & Reconciliation
  - Interim & Final 1572 Reconciliation
    - 1572 vs. Utilized Local Laboratory Reconciliation
    - 1572 Regulatory Submission Reconciliation
- For Medical Device
  - Interim & Final Financial Disclosure Collection & Reconciliation
  - Interim & Final Investigator Agreement Reconciliation
- FDA Audit Request Investigation & Resolution
- Site Audit & Consultation

Contact us today to discuss your support needs.



**B. McLAUGHLIN**  
ASSOCIATES, INC.  
A Helping Hand in Clinical Research<sup>SM</sup>

1540 McDaniel Drive  
West Chester, PA 19380  
Tel: 610.430.1847

16515 South 40th Street, #125  
Phoenix, AZ 85048  
Tel. 480.659.9120

[Info@bmaresearch.com](mailto:Info@bmaresearch.com)

[www.bmaresearch.com](http://www.bmaresearch.com)