Challenge meet **Solution**

TAMM Net®
Integrated Biomed Solutions

Only TAMM Net has the integrated solutions biomed needs to succeed

- Regulatory and Quality
- Managed Markets and Reimbursement
- Health Economics Outcomes Research
- Reimbursement Support / Call Center
- Prior Authorization Service
- Research

From concept through commercialization — regulatory affairs and quality management, reimbursement, prior authorization call-center, conducting research, accessing government resources and more — our mission is to ensure flawless execution of every detail.

(855) 826-6638 • info@tammnet.com • www.tammnet.com

Let TAMM Net help take your medical miracle to the market

Quality and Regulatory

- Develop regulatory strategy
- File regulatory documents
- Perform compliance auditing: GMP, GLP
- Preparing and submitting: IND, IDE, 505(b)(2), 510(k), PMA, ANDA, 513, BLA, and NDA
- Prepare SOPs comprising Quality System
- Prepare Risk Analysis
- Compile technical file
- Obtain CE Marking and ISO 13485 certificates from the Notified Body
- Complete the essential requirements
- Train staff on QMS
- Software Gap analysis, audit & validation
- Host quality system
- Software Risk assessment and files
- Health Canada filings
- CMC CMO selection
- Handling and Storage Requirements, Stability Plans, Impurity Profile, Formulation, etc.
- Advisory Committee Meetings

TAMM Net®
Integrated Biomed Solutions

Managed Markets and Reimbursement

- Analysis, planning, and execution
- Attain proper coding via AMA, CMS, and the BCBS association
- Gain CMS coverage for clinical trials
- Communicate proper coding to insurers
- Get treatment into clinical pathways
- Payer assessment
- Market preparation
- Conduct competitive analysis
- Health Economics
- Budget impact analysis and value propositions
- Claims data analysis

Reimbursement Support Call Center Activities

- Provide reimbursement call center
- Perform prior authorization
- Support field, providers, and headquarters
- Sales force training
- Reimbursement guides and content for websites
- Verification of coverage & benefits
- Pre-certification/pre-authorization of procedures
- Appeal/denial filings
- Documentation of medical necessity
- EOB and correspondence guidance
- Tools and templates for PA processes
- Peer-to-peer (P2P) call assistance
- Coding & coverage questions
- Pursuing positive coverage decisions

Research

- Integrate with regulatory & reimbursement requirements
- GAP analysis
- Nonclinical Planned studies
- Relevant model selection
- Safety margins & signals
- Development of Clinical Plan
- Dosing strategy (dose, duration, regimen)
- Manage Protocol Development and Study Design
- Clinical Trial Operations Under GCP
- Development of Statistical Plan
- Statistical Analysis of Study Data
- Development of Clinical Trial Support Materials, Data Capture Forms (eForms), & Data
- Investigator Selection/Site Selection
- Site Management
- Investigator Meetings/Site Training
- Study Monitoring