



#### One FOUR All

Only TAMM Net offers the integrated solutions you need to succeed

- Managed Markets and Reimbursement
  - Quality and Regulatory
  - Federal Market Development
    - Research Funding





#### While others say they can

## WeDo.

We are experts in dealing with the federal government, and work in 4 important areas:

- Research funding
- Reimbursement
- Regulatory
- Federal market development

Experience is nothing without talent and dedication, and these won't go far without skill and industry contacts. At TAMM Net, you will find these attributes in abundance. A highly skilled team of professionals who'll work tirelessly to ensure an excellent experience, our talented team wants nothing more than to deliver the right solutions for biomedical manufacturers.

You will work with people like **Mary Beth Mundy**, RHIA, CCS-P, who has over 20 years of experience in reimbursement and medical device coverage. **Darrell R. Galloway**, Ph.D, a retired U.S. Navy Captain who served as Director, ChemBio Defense at the Defense Threat Reduction Agency, throughout a life of service. You'll also work with **Blix Winston**, MPA, MS, whose 27 years of experience with the FDA give him a broad range of contacts and insider knowledge about the agency, or **Cham Dallas**, Ph.D., an extensively published professor at the University of Georgia who has obtained millions of dollars in research funding from numerous federal agencies, and **Janan Van Osdell**, who has over 20 years of experience in regulatory affairs, and clinical research trial design and management in the medical device and pharmaceutical industry. And of course **Art Spalding**, the founder of TAMM Net, an industry veteran.

From strategic direction — creating opportunities and conducting research using government resources — to regulatory affairs, reimbursement, and federal market development, our mission is to ensure flawless execution of every detail.

Talent, dedication, skill. Many claim it, few attain it.



#### First things first,

# get funded

## the government is here to help

Do you need resources to conduct clinical research? Have you applied for grants and been rejected? Have you considered all of the right sources for funding? These are challenges we know how to overcome.

TAMM Net can help by crafting a funding strategy for you approaching multiple sources, including the Department of Defense, DTRA, DARPA, BARDA, NIH, FDA, CDC, private foundations, and others you may not know. With ready access to these resources, TAMM Net will find the funds you need to take your product from design to pivotal trial and, as needed, introduce partners to pursue contracts.

The inside knowledge of which agency would be most interested in your specific product is one of the many value added services TAMM Net colleagues bring to the project. How to deal with the federal government is another specialty in its own right.

#### TAMM Net has the connections to expand your nondilutive funding possibilities

We know the individuals who manage many of the key agencies and institutions. We have knowledge and experience in communicating funding requests to match the mission of each government agency. By integrating their needs with our clients' product capabilities, we develop personalized, effective grant or research funding strategies. We know what to say, and how to say it for each funding source. TAMM Net will:

- Present multiple options for funding to pursue simultaneously
- Guide you in contract negotiations
- Work with potential principal investigators
- Help write grants or proposals
- Introduce your product to the right decision makers
- Perform literature searches

#### Tasks we routinely perform for our clients:

- SBIR applications and post-award management
- Acquisition of funding from government sources, such as DoD, NIH, and CDC
- Shaping of RFPs
- Opportunity capture
- Foundation grants
- Integration of payer needs
- Research activity coordination
- Research protocol writing
- Expert clinical research program management with government organizations like the Henry Jackson Foundation, VA hospitals, and military treatment facilities



#### We are regulars at

# Solving

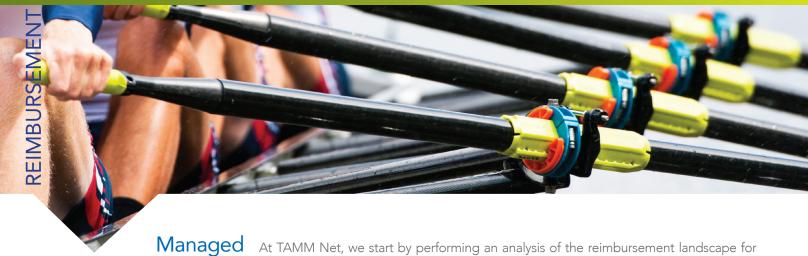
quality and regulatory issues

From pathway assessment and strategy to final clearance or approval, TAMM Net has the knowledge and relationships to expedite the regulatory process. Our professionals can guide you to develop your quality system or custom design and write it. Then, we will train your team on implementation and compliance.

We strategically negotiate the appropriate regulatory application with the FDA to obtain a successful outcome. We consult with the FDA. We perform facility audits for both Good Laboratory Practices (GLP) and Good Manufacturing Practices (GMP), and also perform system and process validations. Whether you need to outsource your VP Regulatory Affairs, or just need a facility audit, TAMM Net has the expertise.

### Regulatory tasks we routinely perform for our clients:

- Develop regulatory strategy
- Coordination with research activities
- File regulatory documents
- Perform compliance auditing: GMP, GLP
- Conduct regulatory auditing and validation software including MDDS
- Assist in preparing and submitting: IND, IDE, 505(b)(2), 510(k), PMA, ANDA, 513, BLA, and NDA
- Perform due diligence for competitive issues



and reimbursement

At TAMM Net, we start by performing an analysis of the reimbursement landscape for your product and its competition or related procedures. We provide you with candid recommendations and opinions on what is likely or not likely to be acceptable to payers, so that together we can develop an approach that has the greatest chance of success. Our relationships with payers, and the ability to relate to them in a manner that they understand, brings value to our clients. We conduct health economic analyses and produce publications to support the value of your product and quantify the size of the market. Claims data can be used to validate call points and sites of care.

TAMM Net prioritizes payers by commercial impact on your market segment to begin the process of gaining coverage. By working with your thought leaders, we obtain appropriate coding and coverage through societies and CMS. We communicate proper coding and product introductions to private insurers nationwide and work with individual plans to ensure coverage. Then, we work with payers to incorporate your product into their clinical treatment guidelines.

We are your call center performing prior authorizations and responding to questions from the field and headquarters. In the field, TAMM Net assists sales force training and develops reimbursement guides for reps and providers. This work includes content for internal and external websites and other materials.

#### Reimbursement tasks we routinely perform for our clients:

- Analysis, planning, and execution
- Integrate reimbursement into a pivotal trial Market preparation
- Attain proper coding via AMA, CMS, AHA, and the BCBS Association
- Communicate proper coding to insurers
- Get treatment into clinical pathways
- Payer assessment

- Health economic analysis
- Conduct competitive analysis
- Support field sales and providers
- Develop the reimbursement call center
- Claims data analysis
- Help resolve reimbursement issues



The government purchased

over \$19B

in healthcare in 2010

From the departments of Defense and Veterans Affairs to Indian Health Service, there are hundreds of U.S. hospitals that require no reimbursement and are often early adopters of new technology. TAMM Net prepares you by analyzing your product segment and competitive sales, purchasing vehicles like set-asides, and training your company to maximize its sales to these purchasers. It is not a fast process, but with the proper guide, you can realize significant sales from federal purchasers. From filing applications to negotiations, TAMM Net can help obtain a Distributions and Pricing Agreement (DAPA), and get you on the Federal Supply Schedule (FSS). We train your company in how to maintain compliance with appropriate government regulations. Once sales start, we can represent you at standardization committees, which can be leveraged into national contracts. We work in the field to guide your sales force through each facility and process, to identify and introduce fertile targets. TAMM Net works with all federal branches to facilitate sales through multiple mechanisms.

#### **Keys to success:**

- Focus company resources to meet federal government requirements
- Introduced strategic partners
- Know which facilities use your product
- Access to key decision makers
- Create an organization that is government savvy
- Register in DUNS and SAM
- Understand the government revenue cycle
- Develop policies and procedures for government proposals and compliance
- Implement sales training program to meet federal purchasing requirements

#### Value. Integrity. Hard work. Achievement.

These are words everyone at TAMM Net takes very seriously. We know they are overused, and underutilized. We take genuine pride in providing our clients the solutions they need to succeed, and the value they need to grow. Your success translates into our success, making you the reason TAMM Net's business continues to grow through referrals from satisfied clients. You are the reason TAMM Net is in business and continues to thrive.

We invite you to learn more about TAMM Net, and discover how we can help you achieve your goals.



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