



# JGS GROUP

## A Holistic Approach

**JGS is a strategic clinical, regulatory and reimbursement consultancy for MedTech and Life Science companies. We uniquely combine programs for development, implementation and commercialization. With our capacity to execute your customized commercialization plan, we decrease your time to market and help you impact lives globally with a holistic approach.**

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**Educational  
Webinar:  
Commercializing  
Your Device in  
the U.S.**

**JGS Group offers two types of educational webinars:**

- 1. A complete high-level overview of a holistic approach to US commercialization including:**
  - Reimbursement
  - Regulatory
  - Clinical Trial Design and Implementation

- 2. A general overview of the commercialization process in the US.**

# JGS REIMBURSEMENT WORKSHOP

This workshop will include and overview of coding, coverage and payment in the US.

Highlights will include:

- Coding 101
- Payment methodologies
- Evidence based medicine
- Discussion of how regulatory path and clinical design can affect reimbursement
- Case study

# JGS REGULATORY WORKSHOP

This workshop will include and overview of the FDA clearance process.

Highlights will include:

- Choosing a predicate for a 510K
- Classes of devices
- Regulatory requirements
- US Agent
- Submission process
- Discussion of how regulatory decisions & clinical evidence can affect reimbursement
- Case study

# JGS CLINICAL TRIAL DESIGN WORKSHOP

This workshop will include an overview of how to design a clinical trial for regulatory, reimbursement, & practice acceptance purposes.

Highlights will include:

- Best type of study design
- Patient population
- Data endpoints
- Discussion of how clinical design can affect regulatory and reimbursement
- Case study

Studies designed for clearance from the FDA do not fulfill the requirements for coding, coverage and payment or physician acceptance. A well designed study can fulfill requirements for FDA clearance, reimbursement coverage and physician acceptance.



# JGS GROUP



Jen Murray has been at the forefront of the reimbursement industry for more than 23 years and is the founder of the JGS Group, Inc., a full-service reimbursement consulting group. Since 2001, JGS has provided reimbursement consulting for new and innovative technologies ranging from start-ups to Fortune 100 companies. Prior to launching the JGS Group, Jen held several positions at Covance. She has served as Covance's representative for the National AIDS Advocacy Program, working directly with the Clinton administration on the Ryan White Fund, an initiative to secure alternative funding for AIDS/HIV patients. Jen has authored various articles on reimbursement-related issues in such publications as the FDANews, Medical Device and Diagnostics Manufacturer's Magazine, and Drug Information Association News.

She has spoken at conventions and workshops all over the world. She was appointed to the FDA News Advisory Panel in 2003 and is currently serving on the Board of Maryland Innovations Initiative (MII). Jen holds a Bachelor of Arts in Sociology and Psychology from Villanova University.

For more information and to request a customized educational webinar for your MedTech and Life Science companies please contact,

**Susan Murray  
Vice President,  
International Commercialization  
[susan@jsgroup.com](mailto:susan@jsgroup.com)  
949.394.6741**