MSLs Past:
Does History Repeat Itself?

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The Medical Science Liaison Research Group
Supporting Brands Across the Product Lifecycle

- REMs Support
- MSL’s/Medical Affairs
- On-Call Specialists
- CNE Teams
- TeleConnect Call Centers
## Concurrent Changes Affecting MSLs

<table>
<thead>
<tr>
<th>From</th>
<th>To</th>
</tr>
</thead>
<tbody>
<tr>
<td>Science discussant</td>
<td>Clinical knowledge director</td>
</tr>
<tr>
<td>Peer (either real or envisioned)</td>
<td>Commodity</td>
</tr>
<tr>
<td>Prized, individualized, and valued KOL</td>
<td>Commoditized again. One of many sources of information.</td>
</tr>
<tr>
<td>informational asset</td>
<td></td>
</tr>
<tr>
<td>Relationship centric</td>
<td><strong>Value centric</strong></td>
</tr>
<tr>
<td>Unbranded (ie, undifferentiated)</td>
<td>Branded AND differentiated</td>
</tr>
</tbody>
</table>
Key Question

Are we now organized for maximum information harvesting and knowledge production (and do we measure employees for their knowledge contributions)?
The Role of the MSL Has Continued to Evolve...From Tactician to Strategist

1. Gradually moving from traditional field medical affairs specialist to clinical research educator and knowledge director
2. Increasingly commoditized (crossing the outsourcing threshold)
3. Strategically envisioned and deployed, but tactically measured?
MSL Characteristics

- Ability to travel 60-70% of the time
- Usually terminally degreed (PhD, MD, PharmD)
- High capacity for relationship development
- Clinically, emotionally, compliance, and business intelligent
- Understand their strategic role as knowledge managers
- Possess superb presentation skills
Focus on Internal and External Stakeholders

- KOL development and management
- Academic institutions
- Investigators
- Advocacy groups
- Managed care/government

- Competitive intelligence
- Medical information
- HEOR
- Commercial and brand management
- Market research
- Publication planning
- R&D and medical affairs

Critical strategic value as integrator

MSLs
Things Done

**MSL Functions**
- REMS
- Scientific exchange
- Clinical trial site ID, enrollment
- Institutional targeting
- Advisory boards
- KOL relationship development
- Competitive intelligence
- Professional meeting attendance
- Formulary presentations (hospital, MC)
- Sales support
- Internal stakeholder teams
# Recommendations For Pre-launch Activities, Launch and Post-launch Activities

<table>
<thead>
<tr>
<th>Pre-launch</th>
<th>Launch</th>
<th>Post-launch</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trial data capture and discussions</td>
<td>Drug data discussions</td>
<td>Phase IV and IISs</td>
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<tr>
<td>Publications</td>
<td></td>
<td></td>
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<tr>
<td>Disease state education</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tier 1 KOL identification, segmentation, development, and management</td>
<td></td>
<td>Tier 2</td>
</tr>
<tr>
<td>Advocacy development</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medical information</td>
<td>Revisions</td>
<td>Revisions</td>
</tr>
<tr>
<td>Competitive intelligence</td>
<td></td>
<td></td>
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<tr>
<td>Market intelligence</td>
<td></td>
<td></td>
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<tr>
<td>Congress attendance</td>
<td></td>
<td></td>
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<tr>
<td>Guideline activity</td>
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</tbody>
</table>
Training and Compliance
Historical MSL Training

- Clinical intelligence
  - 1960s - present

- Business intelligence
  - 1970s - present

- Emotional intelligence
  - 1990s - present
Our MSL Training Today

- AMCP Dossier
- Preceptorships
- REMS
- Resource use intelligence
- Compliance intelligence
- Emotional intelligence
- Business intelligence
- Clinical intelligence
- IPad Skills and Applications
Draft Guidances As *de facto* Law

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**Guidance for Industry**

*Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices*

**DRAFT GUIDANCE**

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit comments to Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD, 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft guidance document, contact (CDER) Joan-Ah Kang at (301) 795-1200; (CBER) Office of Communication, Outreach and Development at 800-833-4709 or 301-827-1800; (CVM) Dorothy McAdams at (240) 276-9300; or (CDRH) Deborah Wolf at (301) 795-5732.

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U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Drug Evaluation and Research (CDER)  
Center for Biologics Evaluation Research (CBER)  
Center for Veterinary Medicine (CVM)  
Center for Devices and Radiological Health (CDRH)

December 2011  
Procedural
Compliance Understanding and Applications

- **Laws and Rules**
  (FDC Act, Kefauver-Harris, PDMA, PDUFA, FCA, Anti-Kickback Statute, Lantham Act, HIPAA, Physician Payments Sunshine Act, FDA Guidance on Unsolicited Medical Request)

- **Agencies and Organizations**
  (FDA, HHS, OIG, PhRMA, AMA, ACCME, AdvaMed, SEC)

- **Interpretation and Risk Tolerance**

- **Quality Control, Checks and Balances**

Awareness

Action
## Our Healthcare Compliance Policies Handbook for Medical Science Liaisons (MSLs)

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<tr>
<th>Section 1</th>
<th>Introduction</th>
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<tr>
<td>Section 2</td>
<td>Laws, Regulations, and Industry Guidance</td>
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<tr>
<td>Section 3</td>
<td>Promotional vs. Scientific Exchange of Information</td>
</tr>
<tr>
<td>Section 4</td>
<td>Relationships/Interactions with Internal Groups</td>
</tr>
<tr>
<td>Section 5</td>
<td>MSL Role and Interactions with Client Customers</td>
</tr>
<tr>
<td>Section 6</td>
<td>Responding to Medical and Off-Label Inquiries</td>
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<tr>
<td>Section 7</td>
<td>Business Meals and Hospitality</td>
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<tr>
<td>Section 8</td>
<td>Educational and Medically Relevant Items</td>
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<tr>
<td>Section 9</td>
<td>Speaker Programs</td>
</tr>
<tr>
<td>Section 10</td>
<td>Service Arrangements</td>
</tr>
<tr>
<td>Section 11</td>
<td>Participation in Medical Conferences and Conventions</td>
</tr>
<tr>
<td>Section 12</td>
<td>Support for Continuing Medical Education</td>
</tr>
<tr>
<td>Section 13</td>
<td>Adverse Drug Experiences and Product Complaints</td>
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<tr>
<td>Section 14</td>
<td>Communications</td>
</tr>
<tr>
<td>Section 15</td>
<td>Health Insurance Portability Accountability Act</td>
</tr>
<tr>
<td>Section 16</td>
<td>Interaction with Government Employees and Media</td>
</tr>
<tr>
<td>Section 17</td>
<td>State Laws</td>
</tr>
<tr>
<td>Section 18</td>
<td>Reporting Compliance Concerns</td>
</tr>
</tbody>
</table>
MSL Measurement Needs to Reflect a Blend of the Tactical (Quantitative) and Strategic (Qualitative)

<table>
<thead>
<tr>
<th>T/Quant</th>
<th>S/Qual</th>
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</thead>
<tbody>
<tr>
<td>1. Advisory board participation (KOLs)</td>
<td>1. CI and market research analyses</td>
</tr>
<tr>
<td>2. Clinical expertise measures</td>
<td>2. Informational integrator</td>
</tr>
<tr>
<td>3. Clinical papers published and presentations delivered</td>
<td>3. Leadership capabilities</td>
</tr>
<tr>
<td>4. CME faculty participation (KOLs)</td>
<td>4. Listening skills</td>
</tr>
<tr>
<td>5. Formulary presentations</td>
<td>5. Managing conflict</td>
</tr>
<tr>
<td>6. IIT/IST enrollments (KOLs)</td>
<td>6. Networking strengths</td>
</tr>
<tr>
<td>7. Presentation skills and feedback</td>
<td>7. Planning</td>
</tr>
<tr>
<td>8. Publication planning participation (KOLs)</td>
<td>8. Prioritization</td>
</tr>
<tr>
<td>9. Research sites recommended</td>
<td>9. Problem solving</td>
</tr>
<tr>
<td>10. Speaker bureau participation (KOLs)</td>
<td>10. Teaching and training</td>
</tr>
<tr>
<td>11. Time spent with KOLs</td>
<td></td>
</tr>
<tr>
<td>12. Unsolicited information requests handled</td>
<td></td>
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</tbody>
</table>

Quantitative measurement can miss or underestimate true MSL value as it focuses more on tactical numbers (doing) than strategic value (thinking and problem solving)
# Recommended MSL Performance Metrics

<table>
<thead>
<tr>
<th>Quantitative</th>
<th>Qualitative</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Unsolicited information requests documented and handled</td>
<td>1. Internal stakeholder evaluations</td>
</tr>
<tr>
<td>2. Time spent with KOLs</td>
<td>2. External stakeholder evaluations</td>
</tr>
<tr>
<td>3. Advisory Boards managed and leveraged</td>
<td>3. New organizational knowledge developed</td>
</tr>
<tr>
<td>4. IIT/IST enrollments (KOLs)</td>
<td>4. Regional plans developed and initiated</td>
</tr>
<tr>
<td>5. KOLs participating in speaker bureau</td>
<td>5. Leadership displayed</td>
</tr>
<tr>
<td>6. SOPs established or revised</td>
<td>6. Problem-solving skills displayed</td>
</tr>
</tbody>
</table>
## Objectively Assessing Knowledge Strength

<table>
<thead>
<tr>
<th>Factor</th>
<th>Ranking</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of publications</td>
<td>1</td>
</tr>
<tr>
<td>Number of clinical trials</td>
<td>2</td>
</tr>
<tr>
<td>Specialty training</td>
<td>3</td>
</tr>
<tr>
<td>Academic affiliation</td>
<td>4</td>
</tr>
<tr>
<td>Number of speaking engagements</td>
<td>5</td>
</tr>
<tr>
<td>Number of prescriptions</td>
<td>6</td>
</tr>
</tbody>
</table>
Indicators of Knowledge

A candidate's education and academics, including

- Specialty
- Title
- Academic title
- Medical school
- Residency
- Fellowship focus
- Fellowship institution

Key association memberships

- Editorial board positions
- Editorial journal impact factors
- Scientific advisory board positions
- Guideline committee involvement
- Research grants and funding
- Prizes and awards
- Other activities (international guidelines, governmental policy)
Indicators of Intent To Communicate

- Key associations memberships
- Editorial board positions
- Editorial journal impact factors
- Scientific advisory board positions
- Guideline committee involvement
- Industry involvement
- Advisory boards
- Speakers bureau involvement
- PR media activities
- Spokesperson's role
Indicators of Innovation

- Fellowship focus
- Key association memberships
- Editorial journal impact factors
- Guideline committee involvement
- Fellowship institution
- Editorial board positions
- Scientific advisory board positions
Indicators of Industry Affinity

Scientific Advisory board positions

Clinical trials analysis: investigator position, sponsor, or study

Research grants and funding

Secondary analyses with a specific agent

Consulting and advisory activities

Primary intervention studies with specific interventions

Publications where the focus was a specific intervention (on-label and off-label use)
Publications Analysis

Frequency of authoring position

Actual article types published including:
- Letters
- Editorials
- Case reports
- Reviews
- Retrospectives
- Post-hoc analyses
- Case series
- Practice guidelines
- Prognostic studies
- Preclinical studies
- Clinical trials

Frequency of citations (ie Google Scholar)

Journal impact factor of publications

Immediacy of publications

Total number of publications
Early Agenda: Some of the Items to Cover First

- Clear identification of KOLs and territories
- Use of MSLs across the life cycle
  - Roles, goals, and expectations
- The value proposition
- Compliance
  - Interactions with and support of Commercial
  - How other teams work
- Metrics
Compliance

The importance of clear compliance direction and leadership

- The perils of disregarding compliance

Compliant organizations

- Do’s
- Don’ts

Helping field medical and commercial work together intelligently
The Initial Result of Compliance?

- Celebrex/Vioxx yields heightened FDA safety focus with subsequent fewer approvals and larger trials requirements
- A rush to funding and trials data transparency and availability
- Beginnings of limited academic center access
- High focus on eliminating any conflict of interest and ensuring independence
- Significant ACCME and general CME changes (Pfizer now funds CME only through nonprofits, Stanford refuses commercial support)
- MSLs only responding to unsolicited medical information requests

Risky behavior became risk averse behavior
How Does This Role Affect MSL/KOL Relationships?

The MSL WAS proactive in catalyzing KOL’s reactions (owned the stimulus/response, framed and steered the discussion.)

The MSL must NOW be reactive in response to KOL’s proactive and unsolicited questions and requests (KOL now owns the stimulus/response. MSL’ must both plan the discussion as well as explain the rules of the road.)
“T” Thinking Helps To Generate Value...MSLs
As Strategists, Not Tacticians

• “T” thinkers are no longer in tactical, reactive mode only
  – Planning will be as important as execution

• They create and lead more initiatives to assist other disciplines and stakeholders

• They’re better and broader
  communicators and links across the organization

Connected to broad knowledge across other fields

Deep knowledge of one or two fields

Deep knowledge of one or two fields