



China Compliance Roundtable

RDPAC Legal and Compliance Working Group
Best Practices Task Force

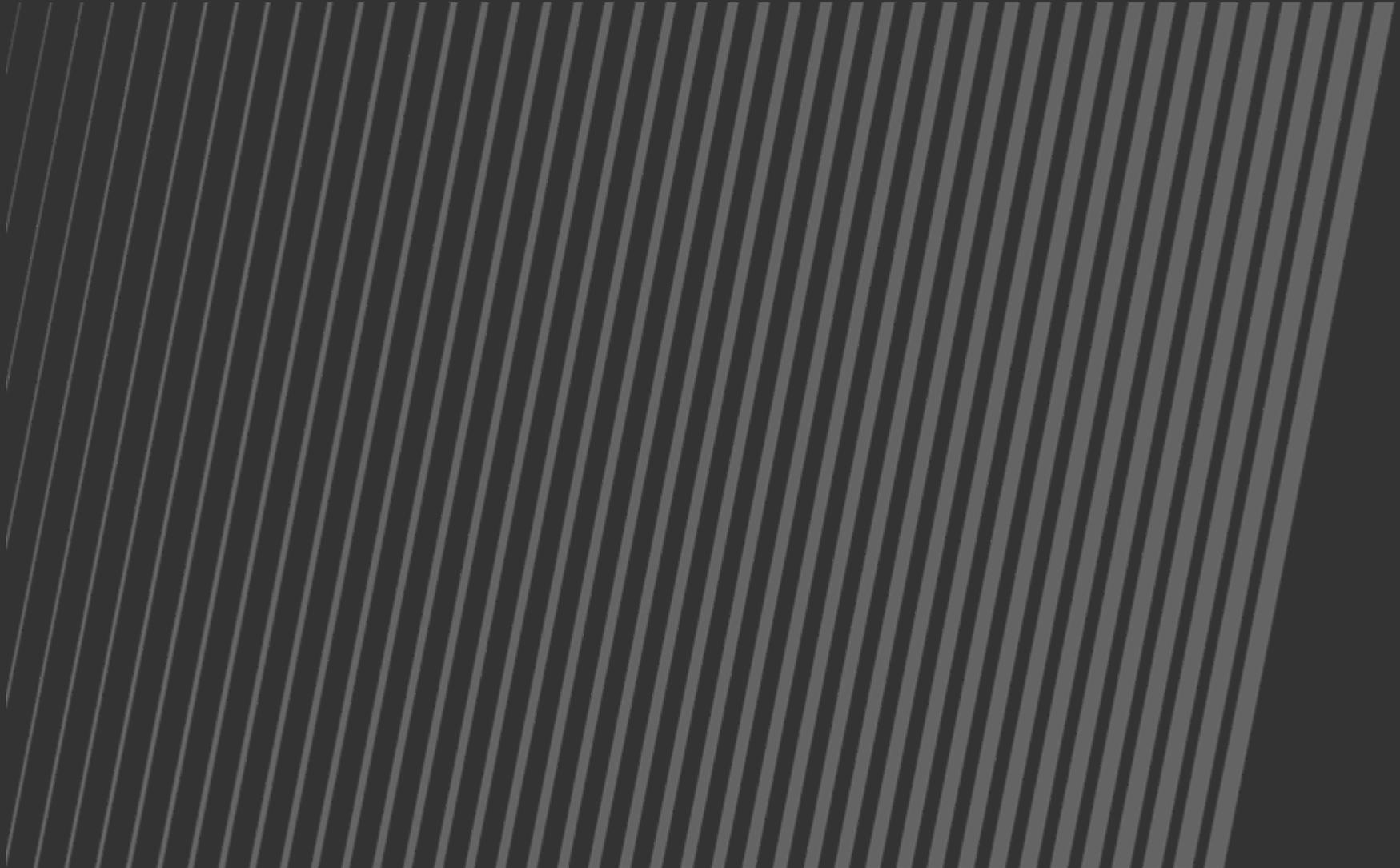
September 11, 2012

Agenda

1. **Status Report – the RDPAC Code**
2. **Emerging Trends – China 2012**
 1. **General**
 2. **T&E Management**
 3. **Speaker Management**
 4. **Event Vendor Management**
3. **Improvement Paths**



Status Report: RDPAC Code



RDPAC 2010 Code Revision

BACKGROUND

- ▶ To enhance compliance of the 2006 RDPAC Code;
- ▶ To address China-specific compliance.

HIGHLIGHTS OF THE 2010 REVISION

1. BROADENING OF THE SCOPE OF THE CODE

- ▶ The Code's introduction states that while the Code aims to “ensure its Members maintain high ethical promotional practices . . . this Code can also serve as a reference for related stakeholders including other pharmaceutical companies”.
- ▶ The Note to the provision further highlights this broadened scope by listing such individuals as the subcontractors, consultants, contractor-sales persons and public relations agents as “relevant employees of the Company”.

RDPAC 2010 Code Revision

2. MORE SPECIFIC RULES ON THE TRANSPARENCY OF PROMOTION

- ▶ The Code expressly refers to sample size in post-marketing surveillance studies as an indicator of the “scientific and educational purpose” of such study (relevance of data collected); as well as fees paid to healthcare professionals which could be abused if not following FMV. Also, Lucky draw is prohibited as part of the transparency requirement of the Code.

3. ETHICAL PRE-APPROVAL AND/OR OFF LABEL COMMUNICATION

- ▶ The Code addresses the globally established prohibition on the promotion of a product either before the registration approval or after approval but for uses outside of its approved label (and indication). The new Code further specifies that communications with healthcare providers regarding off-label/indication uses must come from or be supervised by medically qualified employees of the pharmaceutical company.

RDPAC 2010 Code Revision

4. SPEAKERS FEE

- ▶ Borrowed the “reasonable” standard (FMV) concept from US PhRMA Code;
- ▶ “Official agenda” required for mandatory documentation purpose;
- ▶ “Cap” of the fees paid to an individual HCP per year;
- ▶ Conducted Speakers Fee Survey in 2008 and 2010, to provide FMV reference of FMV for the Members;
- ▶ Encouraged wire transfer of such payment from the Company directly to avoid abuse of the payment.

5. MEETINGS VENUES, ACCOMMODATION EXPENSES

- ▶ Express reference to not using “theme venues associated with leisure activities” as a rule for venue-selection;
- ▶ Encouraged Companies to adopt “no-go” cities.

RDPAC 2010 Code Revision

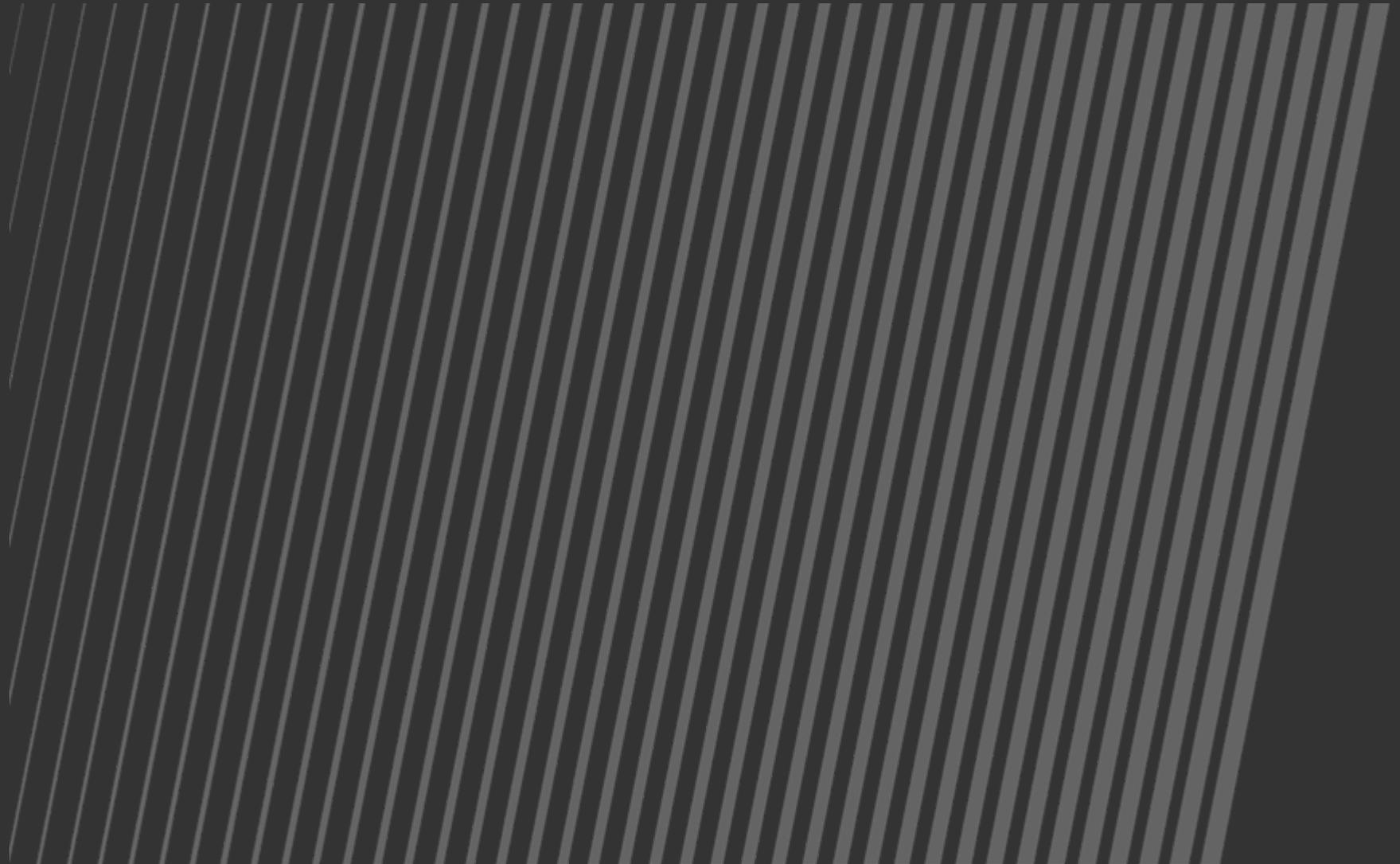
6. HOSPITALITY AND ENTERTAINMENT

- ▶ Emphasized the prohibition against the organization of and/or payment for or participation in certain activities as per se “stand alone” entertainment, including various sports, cultural and entertaining activities; e.g. sight-seeing.

7. COMPLAINT MECHANISM

- ▶ The Complaint Procedure has been improved to include external experts in the Hearing Panel: a practitioner recommended from Chinese Medical Doctor Association, external attorneys or auditors.
- ▶ Penalty for violation includes a fine, and/or exclusion of the RDPAC membership for 1-12 months – a more transparent procedure.

Emerging Trends – China 2012



Work of the Best Practices Task Force

- ▶ Part of the RDPAC Legal and Compliance Working Group
- ▶ Focused on practical strategies to achieve the standards set by the RDPAC Code
- ▶ Identifying leading practices among the member companies

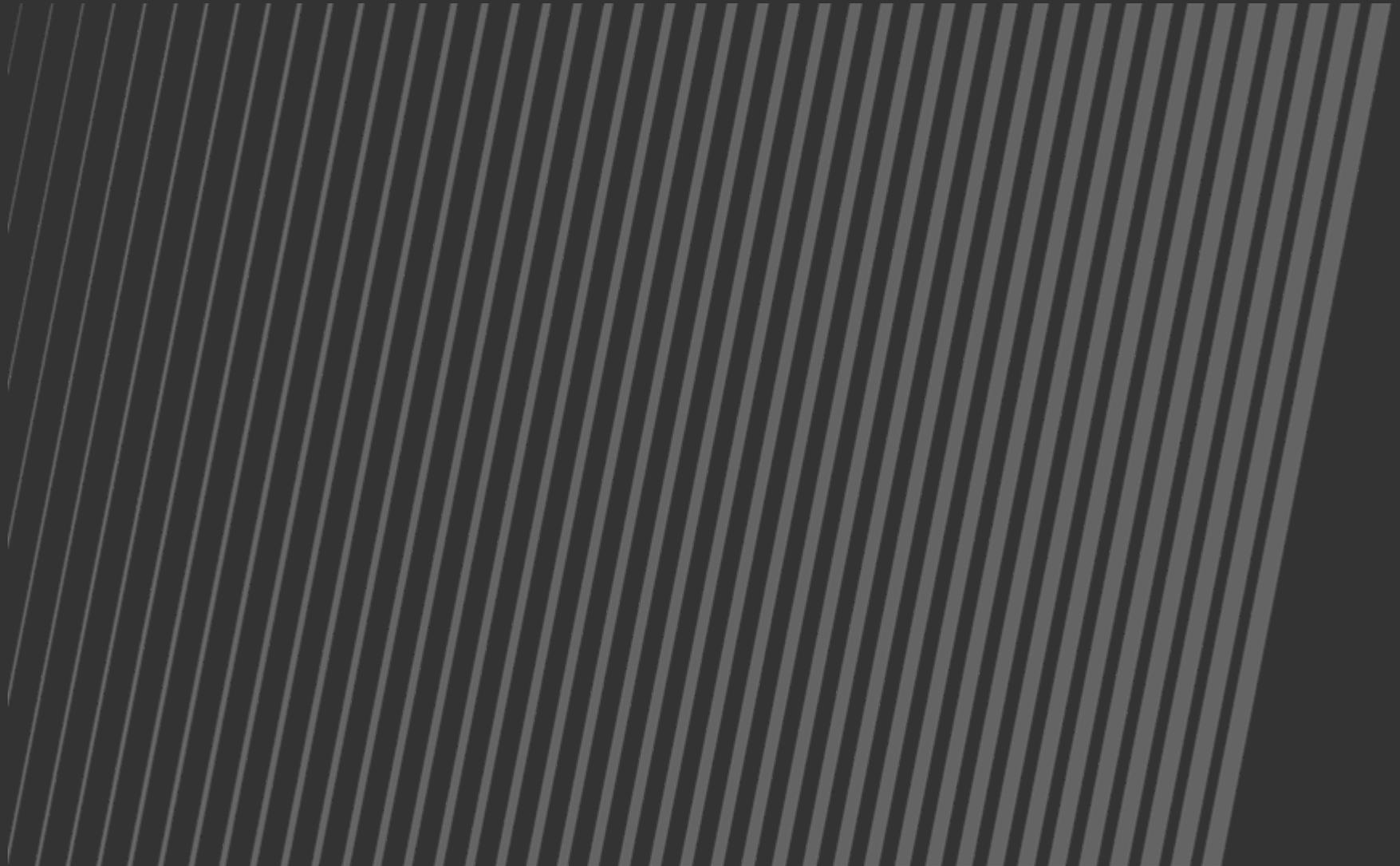
Task Force Focus Areas in 2012

Type of interaction	Process	RPDAC Code Link	Area of interest
Rep to HCP	Travel and entertainment management	Hospitality	<input type="checkbox"/> Use of corporate credit card <input type="checkbox"/> Expenses type and restriction <input type="checkbox"/> Requirement of supporting documents <input type="checkbox"/> Independent verification of expenses <input type="checkbox"/> Tracking and reporting
Company to HCP	Speaker management	Payment of speakers and Presenters, Fair market value	<input type="checkbox"/> Selection and validation of speaker <input type="checkbox"/> Criteria of speaker level <input type="checkbox"/> Contracting process <input type="checkbox"/> Payment type <input type="checkbox"/> Tracking and reporting
Vendor to HCP	Event vendor management	Hospitality	<input type="checkbox"/> Due diligence and acceptance <input type="checkbox"/> Training and education <input type="checkbox"/> Audit and monitoring <input type="checkbox"/> Payment type <input type="checkbox"/> Consequence management

Primary Lessons

1. “Best Practice” is a fast moving target
2. There is no single “Compliance Leader”
3. There is no one size fits all approach
4. China risk is unique, requires innovative approach
5. The tools available are developing rapidly

A. The General Compliance Function



General Trend 1: **Localization**

- ▶ Most member companies have dedicated China-based local compliance teams, up notably from recent years.
- ▶ Most of the local compliance officers report to either the Regional Compliance Officer or Corporate Compliance Officer directly, also a shift from previous, local reporting lines.
- ▶ Most prevalent skill sets are Legal, Finance and Audit, but there are examples of professionals coming from the Sales and Medical functions

General Trend 2: **Increased HQ Awareness**

- ▶ Member companies report increased awareness of China compliance challenges on the part of HQ
- ▶ HQ understanding still lags that of local team

B. Travel and Entertainment (“T&E”) Management

T&E Trend 1. Credit Cards are In

- ▶ First corporate credit card was introduced by Chinese banks in 2006.
- ▶ To minimize cash reimbursement, $\frac{3}{4}$ of LC Working Group Members now provide corporate credit cards to medical representatives to finance T&E expenses.
- ▶ Mostly due to high employee turnover, all of these credit cards are personal liability cards where the employees individually bear the ultimate liability to the bank.

T&E Trend 2. **Thresholds are Down**

- ▶ Earlier thresholds such as RMB 1,000 in previous years have steadily decreased to the RMB 300-500 range, with the ultimate direction of eliminating cash from the process.
- ▶ A growing number of companies have no minimum threshold for credit card use (though exceptions still occur).

T&E Trend 3. Card Data & Expense Claim Reconciliation

- ▶ Most credit card issuing members monitor ratio of credit card payments vs. cash payments.
- ▶ Many now reconcile bank credit card data with the internal T&E system.

T&E Trend 4. Increased Focus on Venue and Actual Cost

- ▶ Restricting the venue type for HCP events (i.e. luxury resort, known for sightseeing) in some way is now the norm.
- ▶ Offering a preferred meeting venue program, and explicitly disallowing meetings at certain resort locations, e.g. Sanya, Jiuzhaigou.
- ▶ On top of the tax invoice (“Fapiao”), POS slip, signed attendee list, agenda, etc., now requiring an Itemized bill from the vendor to support the performance of T&E claims

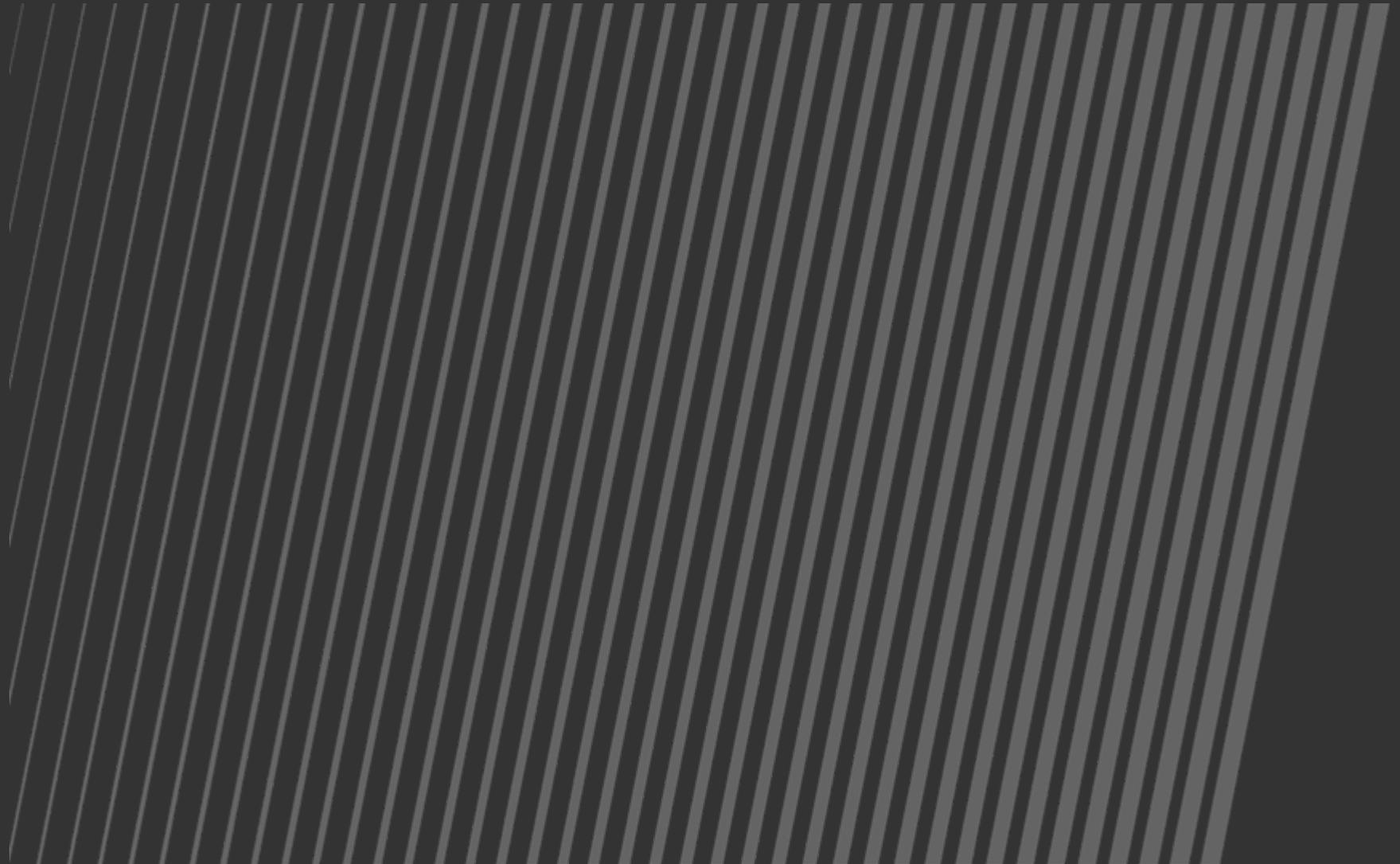
T&E Trend 5. **Greater Scrutiny of Invoices**

- ▶ For invoices, most companies now have built in validation checks with tax bureau databases before payment is authorized.
- ▶ Some currently perform 100% validity check of invoices, but the median invoice review coverage is around 50%.

T&E Trend 6. Focus on Monitoring and Training

- ▶ Compliance officers point to 2 primary tools as the most effective
 - ▶ **Training** to communicate the standards
 - ▶ **Auditing and Monitoring** to ensure actual adherence
 - ▶ **Credit cards** to create third party validation and transparency

C. Speaker Management



Speaker Management Trend 1. **Cash is On the Way Out**

- ▶ Pay speaker fees via wire transfer only, or at least a mix of cash and wire transfers.
- ▶ If paying by wire, almost all companies require that the speaker name match beneficiary name of the account.

Speaker Management Trend 2. **Tracking Aggregate Spend**

- ▶ Setting aggregate caps on the payments made to HCPs
- ▶ Performing a quarterly analysis of aggregate payments made to HCPs.
 - ▶ Facilitated by move to wire transfer payment

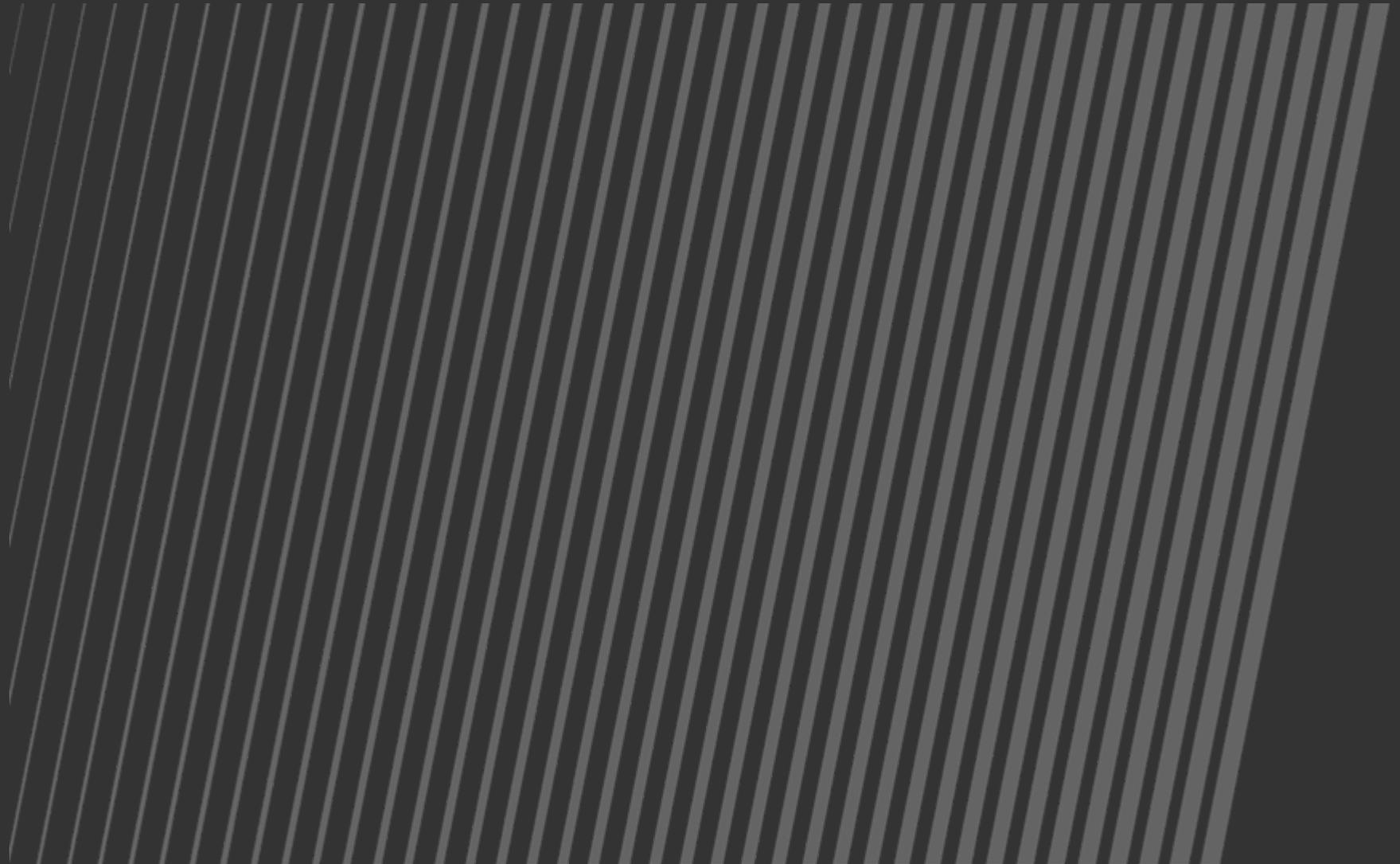
Speaker Management Trend 3. Rationalizing Speaker Fee Amounts

- ▶ Usually, speaker fee standards are determined on an event by event basis.
 - ▶ Many members consider the length of the speech delivered by HCPs to determine the actual cost calculation basis for speaker fee
 - ▶ Many also use industry benchmark surveys as a resource.

Speaker Management Trend 4. Requiring Performance for Payment

- ▶ Payment made to HCPs on the basis of Fee For Service:
 - ▶ No payment for HCPs' time to attend speaker training.
 - ▶ No payment to HCPs who attend case sharing session without delivering a presentation

D. Event Vendor Management



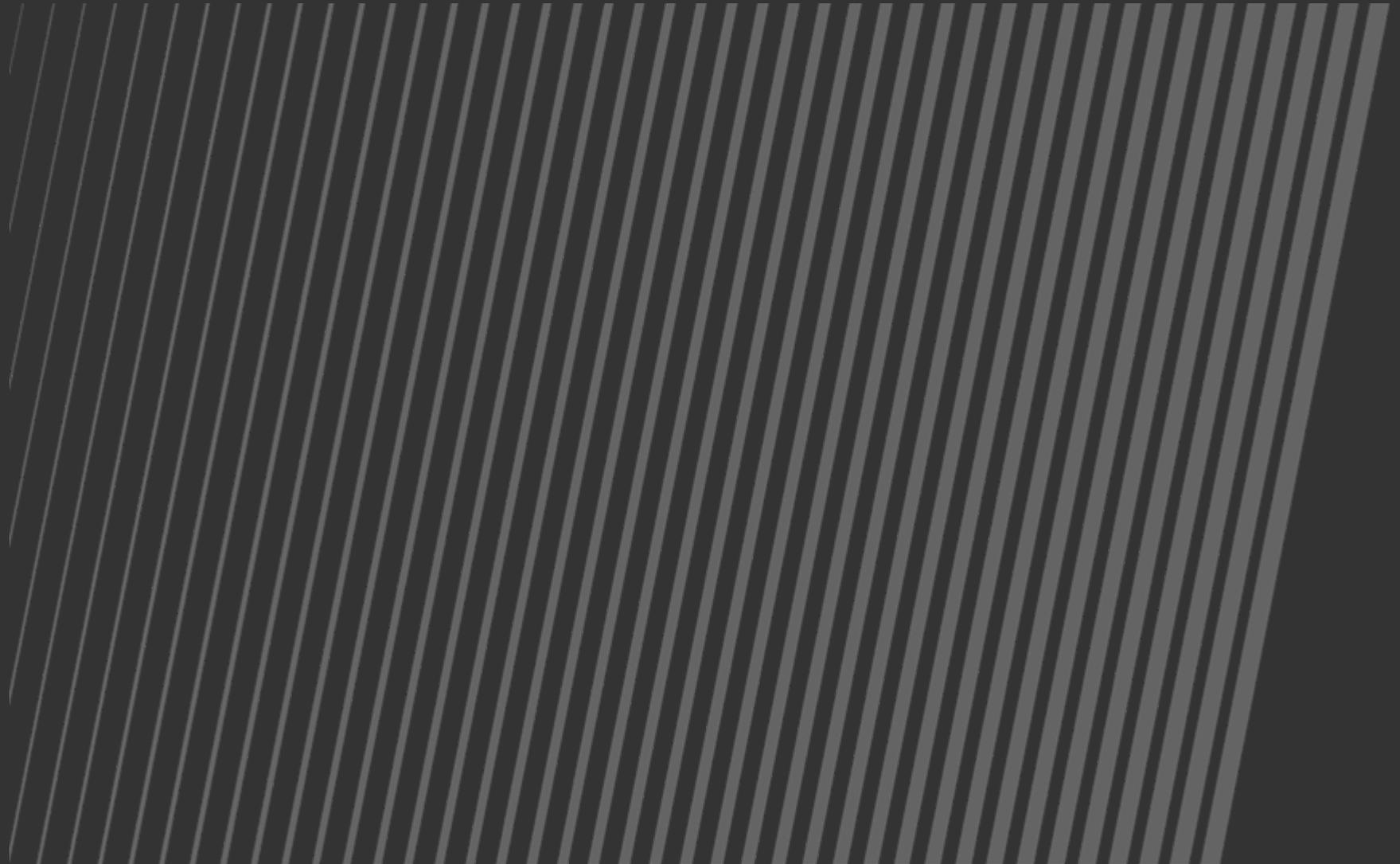
Event Vendor Management Trend 1. **Tightening Control of Event Providers**

- ▶ Centralized management and limited number of vendors based on performance and reputation.
- ▶ Restricting sub-contracting unless agreed to by the company.
- ▶ Requiring vendor to provide photocopies of original invoices or statements with the hotels and restaurants for the event organized on behalf of the company.
- ▶ Restricting vendors from providing cash advances or cash reimbursements to sales reps.
- ▶ Conducting direct payment to venues and transportation vendors whenever possible

Event Vendor Management Trend 2. **Tightening Control of Event Providers, Cont.**

- ▶ For company events, use is normally restricted to preferred vendors
 - ▶ However, for external sponsorship, it is still common to allow the organizer to assign vendors.
- ▶ Providing anti bribery or anti corruption training to the preferred events vendors (not externally appointed vendors)
- ▶ Requiring vendor ABAC compliance certification.
- ▶ Contractual requirement to the vendors regarding ABAC compliance
- ▶ Audit rights in the service agreement & exercising audit rights

E. Improvement Paths



Improvement Paths – Quick Wins

- ▶ Stop cash advances to sales team when a corporate credit card is available. Phase out cash payment. Provide lists of venues accepting cards in key markets.
- ▶ Identify top compliance champions within the existing sales force to help shift primary “ownership” of compliance to the top line business.

Improvement Paths – Quick Wins

- ▶ Increase local compliance/audit resources to enhance audit and monitoring of compliance.
- ▶ Establish an Events function to independently manage the process of vendor selection and meeting planning.

Improvement Paths – Quick Wins

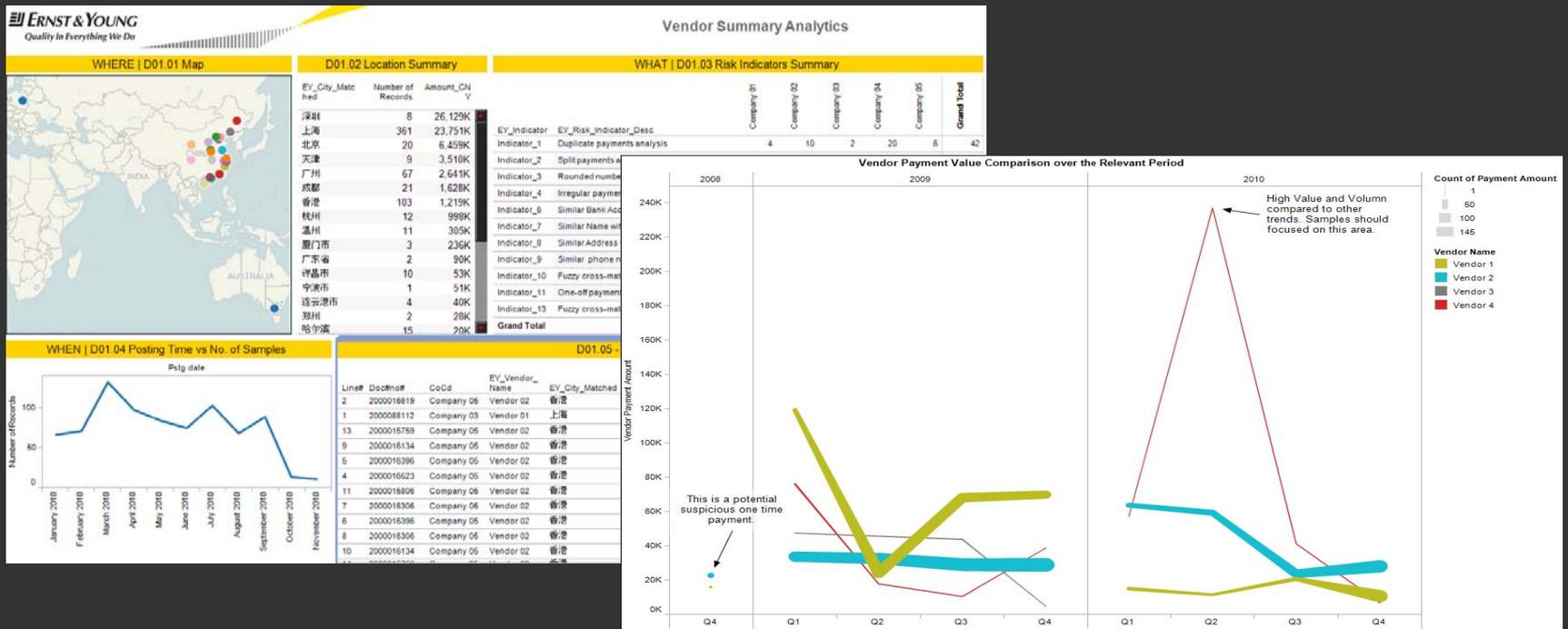
- ▶ Deepen compliance focus of third party due diligence efforts:
 - ▶ Move beyond the standard financial background check to questionnaire-driven, reputation driven screening
 - ▶ Identify third parties with high exposure of compliance risk.
 - ▶ Conduct different levels of substantial compliance review/assessment based on the level of the identified risks.

Improvement Paths – Quick Wins

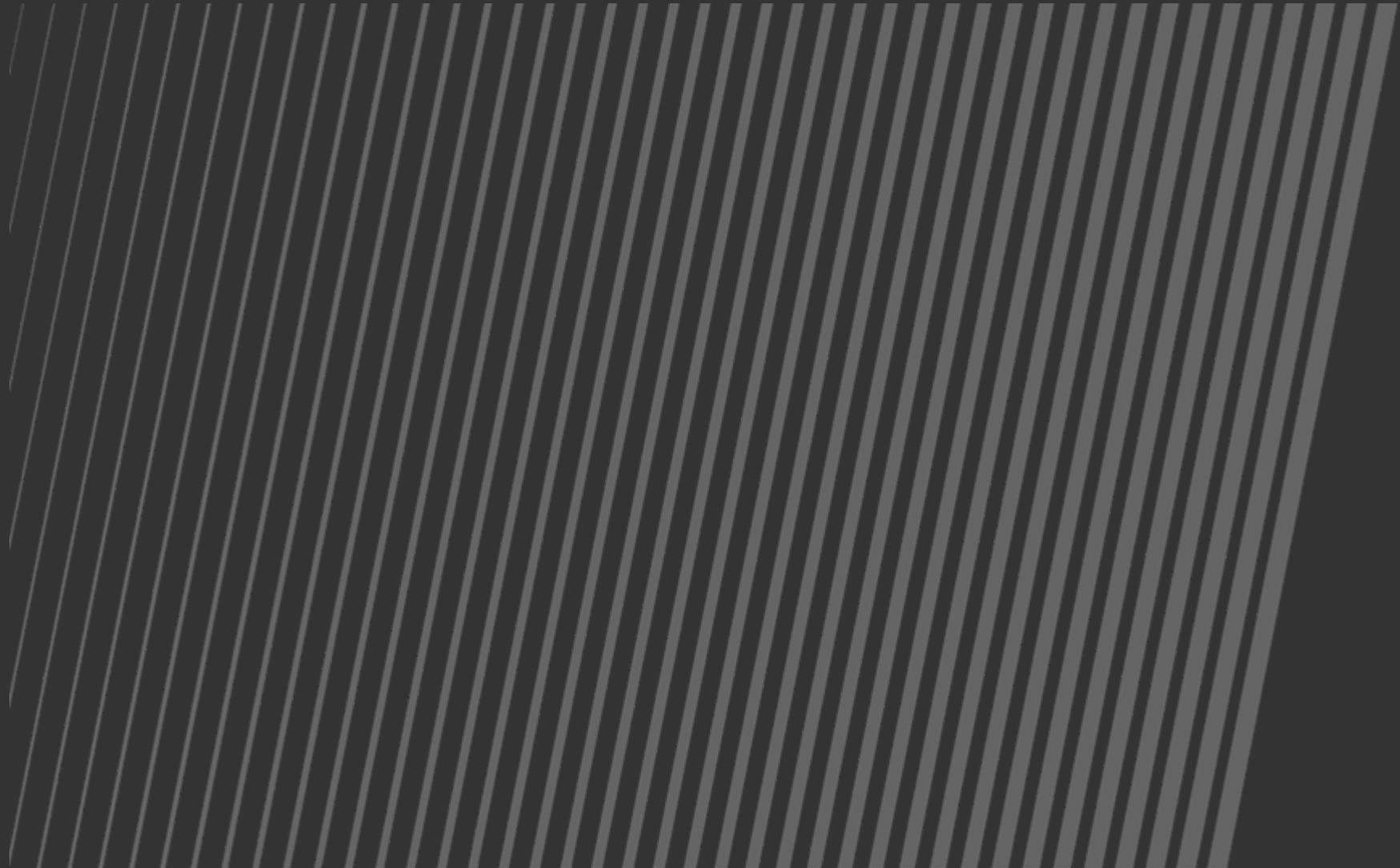
- ▶ Develop more consistent and rational criteria for determining HCP experience level to determine Fair Market Value
 - ▶ Sample “bundle of criteria” could include: # years of medical profession, # of publication per year, position in the national/provincial medical association, etc.

Improvement Paths – Longer Term

- ▶ Use technology as an enabler to manage high-volume transaction monitoring
 - ▶ Make compliance a module in the business intelligence platform
 - ▶ Use data to establish and track compliance KPIs for managers



Q&A



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