



Lower Your Compliance Risk – How  
Open Payments Data Can Assist

11th Annual Forum on

**Transparency  
& Aggregate Spend**

August 14, 2017

# Disclaimer

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The views expressed and ideas presented in this session are those of the speakers and are not necessarily shared by the presenters' employers.

Any examples provided are hypotheticals and should not be attributed to any individual company.

# Agenda

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- ❑ Introductions
- ❑ Overview of Open Payments Data Evolution
- ❑ Questions for Panel
- ❑ Q&A for Audience



# Introductions

OUR PANEL TODAY

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## **MODERATOR**

**Manny Tzavlakis**  
*Managing Partner*  
Helio Health Group

## **PANELISTS**

**Chuck Bell**  
*Director of Compliance*  
Kedrion Biopharma Inc

**Ben Yao**  
*Director, Transparency*  
Astellas US LLC

**Melissa Hunt, JD, LLM**  
*Associate Director, Compliance*  
Seattle Genetics

**Minna Bak**  
*Senior Manager*  
Helio Health Group

# Compliance Monitoring

## CURRENT LANDSCAPE

Pharmaceutical, medical device and biotechnology companies continue to receive **scrutiny from government entities and the public**, leading to increases in investigations, settlements, restrictions and the passing of additional laws and regulations for the industry.

The focus of many of these activities under examination include employee / agent **interactions and payments to healthcare professionals (HCPs) and healthcare organizations (HCOs)**.

Additionally, **public reporting** of certain expenditures to HCPs / HCOs have enabled other parties and industry competitors **access and evaluate these activities**, potentially increasing a company's risk for investigation.



Life Sciences companies are attempting to mitigate these risks by considering **predictive modeling and analysis** for proactive compliance monitoring.

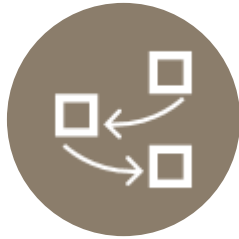
# Compliance Monitoring

## CURRENT LANDSCAPE



### Resources / Support

Are the right resources being allocated to enable success?



### Program Strategy

Does the strategy in place assess and identify risks optimally?

Are there areas that can be improved or enhanced to be more efficient?



### Risk Management / Assessment

Are risks being prioritized and triaged for resolution?

Have standardized process steps been pressure-tested to ensure efficient outcomes?



### Information Sharing

Are channels in place to provide executive levels with proper assessments?



### Internal Monitoring

Are internal auditing measures in place?

Is program efficiency measured and evaluated?

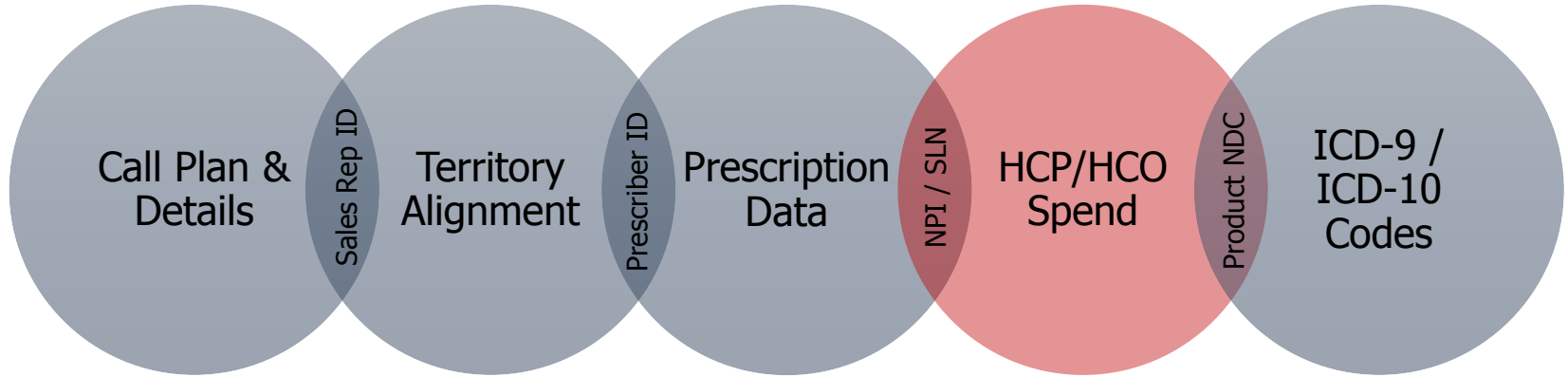


### Stability & Continuity

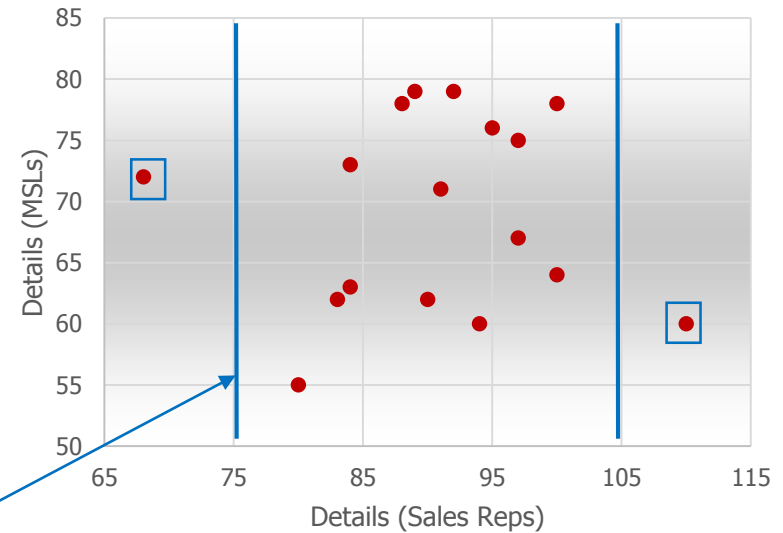
How to gain buy-in and adherence from company resources?

# Compliance Monitoring

IDENTIFY & PREPARE DATASETS



The key to gathering insightful information is to **prepare accurate data**. By gathering relevant datasets and normalizing the information, a Life Sciences organization can start to look at **outliers** as potential risk areas for Compliance.



Normalize datasets to define risk constraints

# Compliance Monitoring

## POTENTIAL COMPONENTS & DATA SOURCES

### Company / Internal Data

- Accounts Payable
- Call Notes & Details
- Clinical Trial Management System Data (Sites & PIs)
- CRM Application Data
- Customer Master
- Employee Expenses
- FMV Data
- HCP/HCO Contracting
- Field/MSL/Patient Support Territories, Plans and Lists
- Medical Literature
- Meetings & Event Data
- Needs Assessments
- Prescription Data
- Speaker Program/ Bureau Data
- **Transparency Spend Data (State, Open Payments, EFPIA)**
- Territory Alignment

### External Data

- AAMC Data & AMSA Data
- Clinicaltrials.gov
- EudraCT
- FDA Adverse Event Reporting System
- FDA Debarment List
- HEDIS & Quality Measures
- IDC-9 / IDC-10 Codes
- Market Access Data
- Medical Associate & Society Member Lists
- Medicare Part D Data
- NPPES (including Taxonomy)
- **Open Payments Data (Propublica)**
- Patient Support Forums
- PubMed
- Social Media Data
- State Licensure Data



# External Monitoring: HCP / HCO Spend

## CONSIDERATIONS



### Questions to Answer

- Is your company spend in line with competitor spend?
- Are there risks associated with the levels of spend activity for any prescribers?
- Are any sales reps violating state provisions for expenditures?

- Accounts Payable
- Call Notes & Details
- Customer Master
- Event Sign-In Sheets
- FDA Debarment List
- **Transparency Spend Data (State, Open Payments, EFPIA)**
- Territory Alignment

### Key Data Sources



### Example Metrics

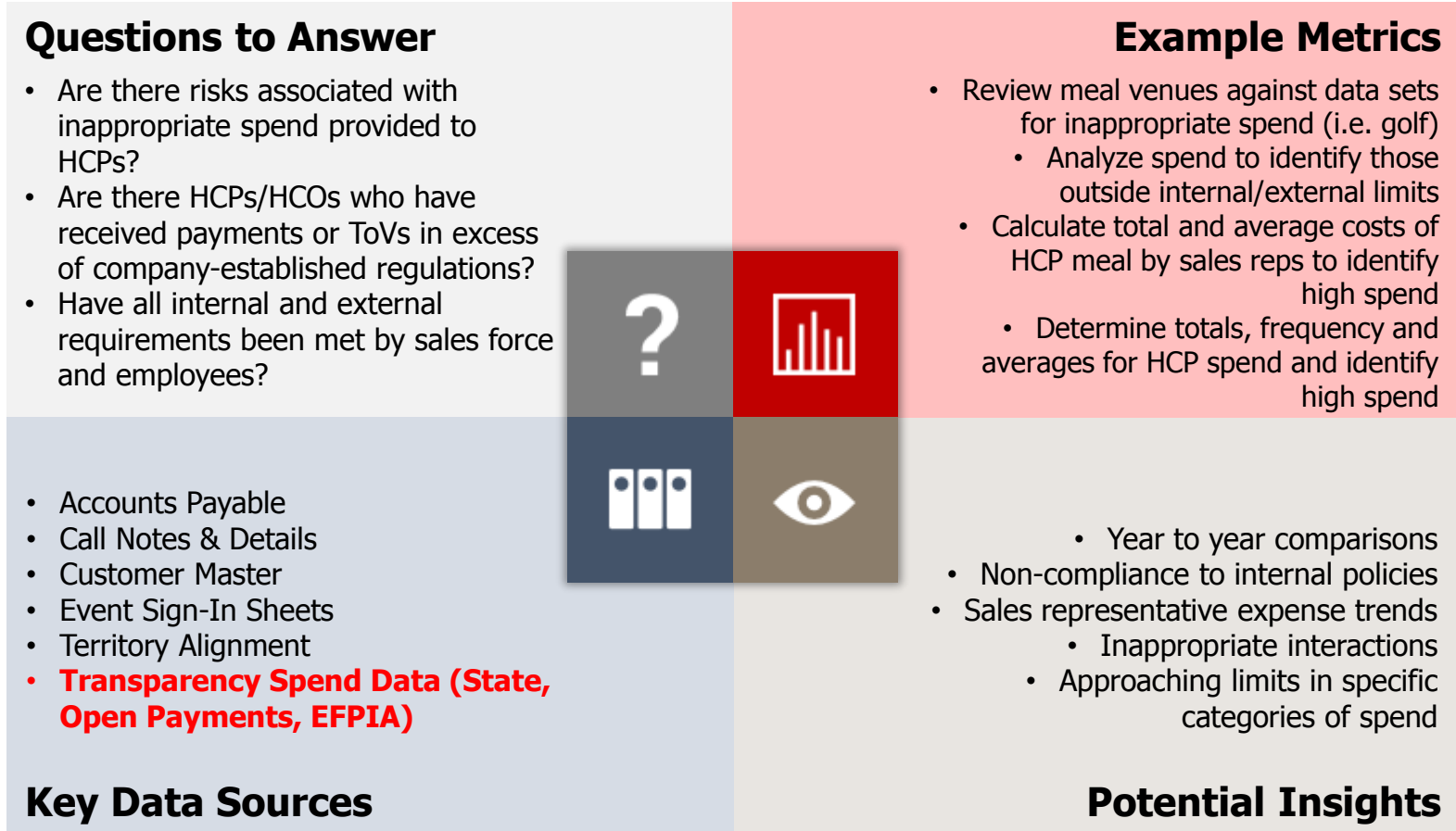
- Compare employee expenditures against data sets for inappropriate spend
  - Identify HCP activities that are restricted by certain states
  - Analyze spend by activity and benchmark with competitors to determine deviation from industry average

- Violations of state regulations
  - Competitor benchmarking

### Potential Insights

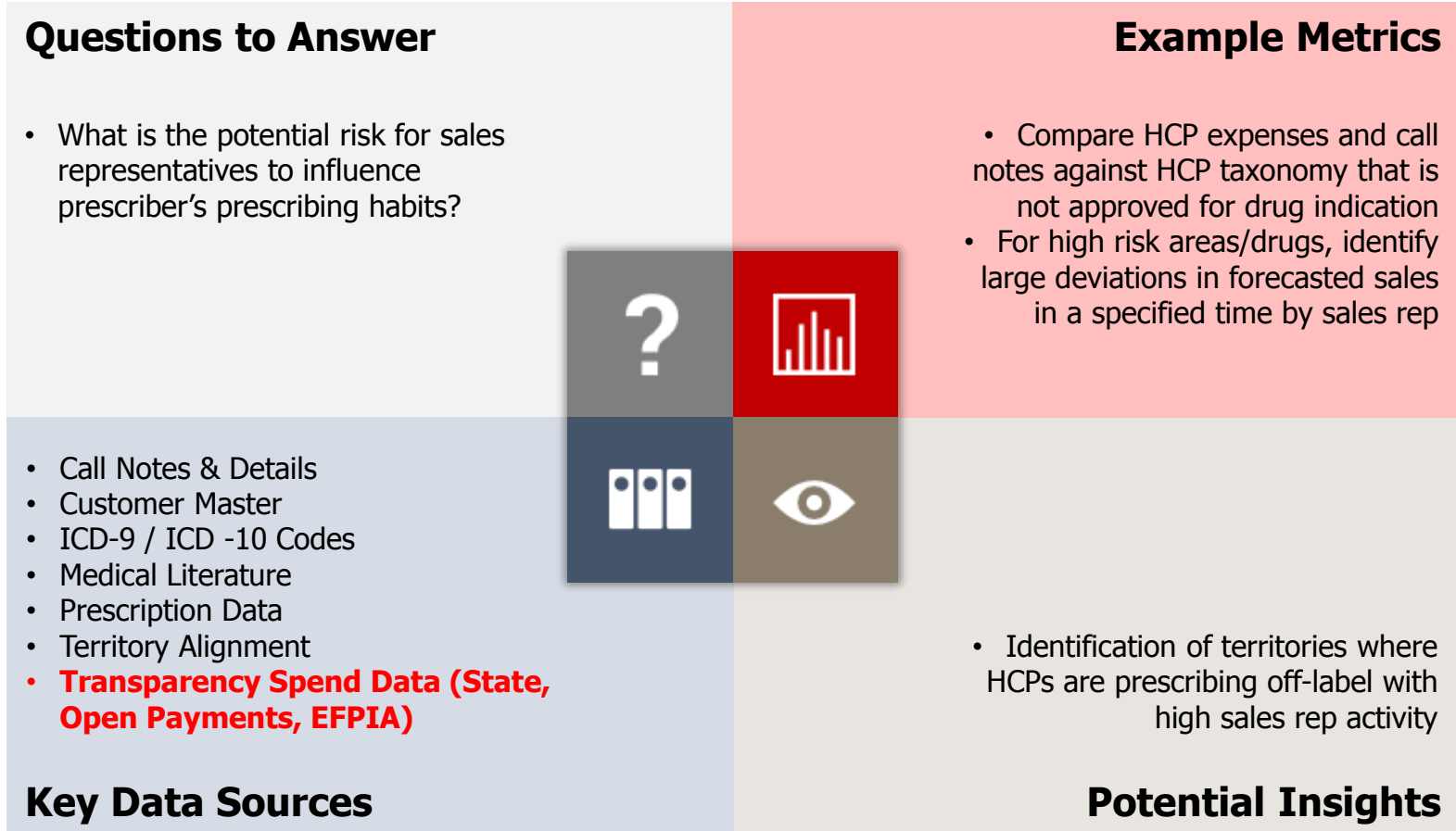
# Internal Monitoring: HCP / HCO Spend

## CONSIDERATIONS



# Off-Label

## CONSIDERATIONS



# Anti-Kickback & FMV

## CONSIDERATIONS

### Questions to Answer

- Are there risks associated with spend activities that can be interpreted as a kickback?
- Is there evidence to suggest prescriber behavior could be linked to potential kickbacks?
- Was HCP paid a consulting rate in accordance with company's standard FMV rates?

- Accounts Payable
- Call Notes & Details
- Customer Master
- FMV Data
- HCP/HCO Contracting
- Medicare Part D Data
- Meetings & Event Data
- Prescription Data
- Territory Alignment

- **Transparency Spend Data**

### Key Data Sources



### Example Metrics

- Calculate total HCP/HCO payments to consultants for high thresholds of payments
- Aggregate speaker programs and review for excessive usage of specific HCPs and regional program frequency
- Compare consultant hourly payment rate to FMV rate/rate card

- Validity of honoraria exceptions outside of approved FMV rates
- Appropriateness of spend with high prescribers

### Potential Insights

# Q&A – Session Panel

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Q&A

# Contact Us

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