



*cutting through complexity™*

# Pharmaceutical Regulatory and Compliance Congress

## Preconference II: The Next Step in Aggregate Spend Reporting

November 2, 2011

Advisory

# Background Assumptions

For the purposes of this discussion, let's assume:



# Aggregate Spend Next Steps

## Preparing The Public

### Covered Recipients

- Understanding:  
Disclaimer, confirmation
- Spend:  
Opportunity to review
- Recipient Information:  
Opportunity to review and update
- Tracking:  
Confirmation of understanding, spend, recipient information

### General Public

- Announcements:  
Website, press releases
- Message:  
Compliance, importance of relationships with HCP/Os
- Clarification:  
Timing, correction of errors
- Existing Announcements:  
Voluntary, Corporate Integrity Agreements

# Aggregate Spend Next Steps

## Continuous Monitoring

***Are people and systems doing what they are supposed to be doing?***

### Data Quality

- Completeness and Accuracy
- Lineage or History
- Frequency
- Exception Management

### Spend Activity

- Limits (Legislation, Organization)
- Prohibited Spend
- Corrective Action Plan
- Cross Functional Effort

### Other Compliance Risks

- Data to be highly scrutinized by government, media, others
- Identify actual or perceived risks
- Focus on how a third party might interpret the spend

### Anticipating Disputes

- Assess top recipients of spend compared to expectations
- Identify unconfirmed spend
- Audit trail of reported spend to source system / documentation

# Aggregate Spend Next Steps

## Deriving Value From The Data

### Analyzing Own Spend

- Assessing benefits
- Spend patterns (e.g. regional, activity)
- Efficiency of spend
- Discuss with the business

### Analyzing Other Spend

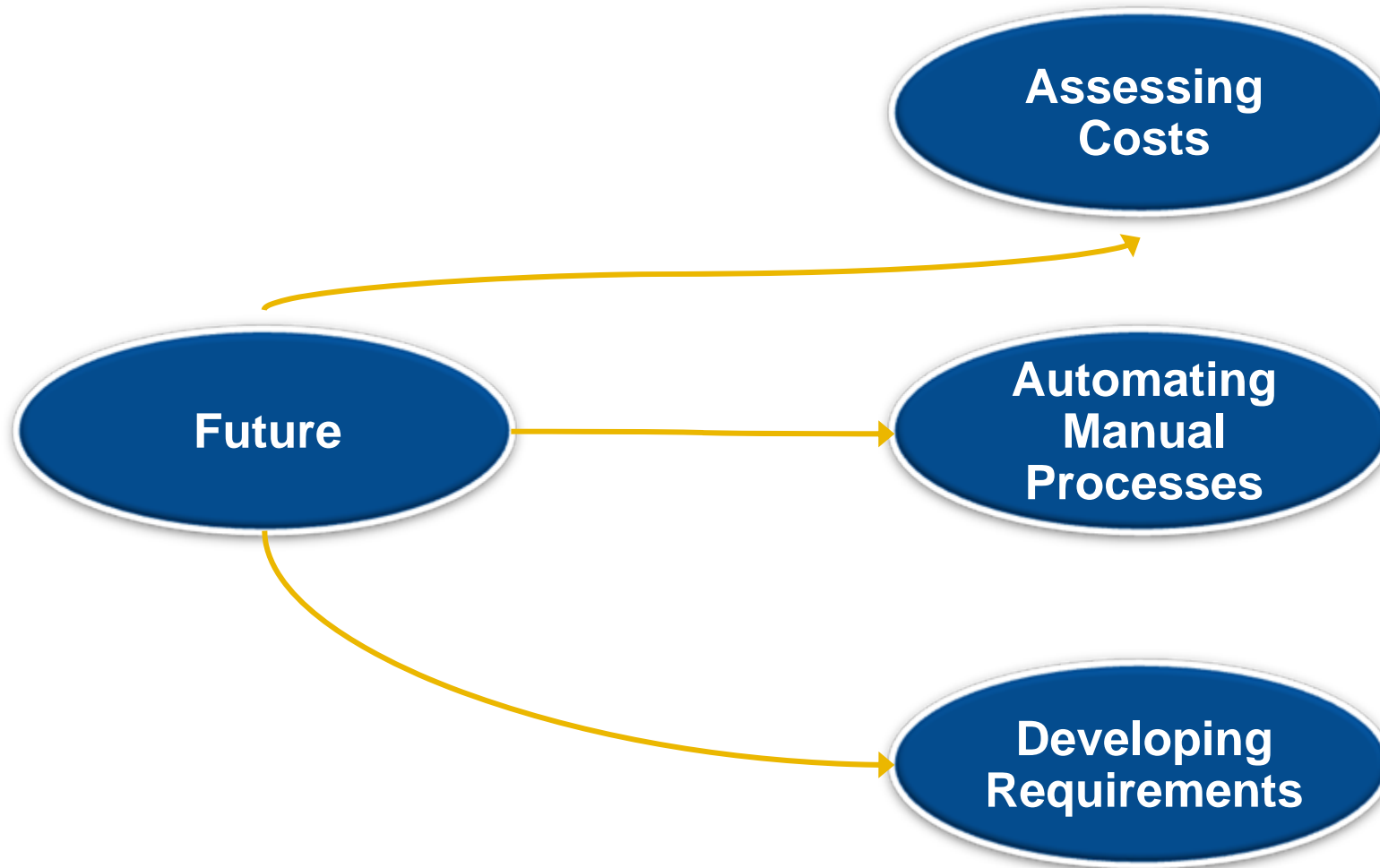
- Competitive intelligence
- Begin now
- Be prepared to track the data

### Oversight

- Importance of Compliance and Legal overseeing the use of data
- Focus on spreading awareness
- Assess who can best communicate the topics

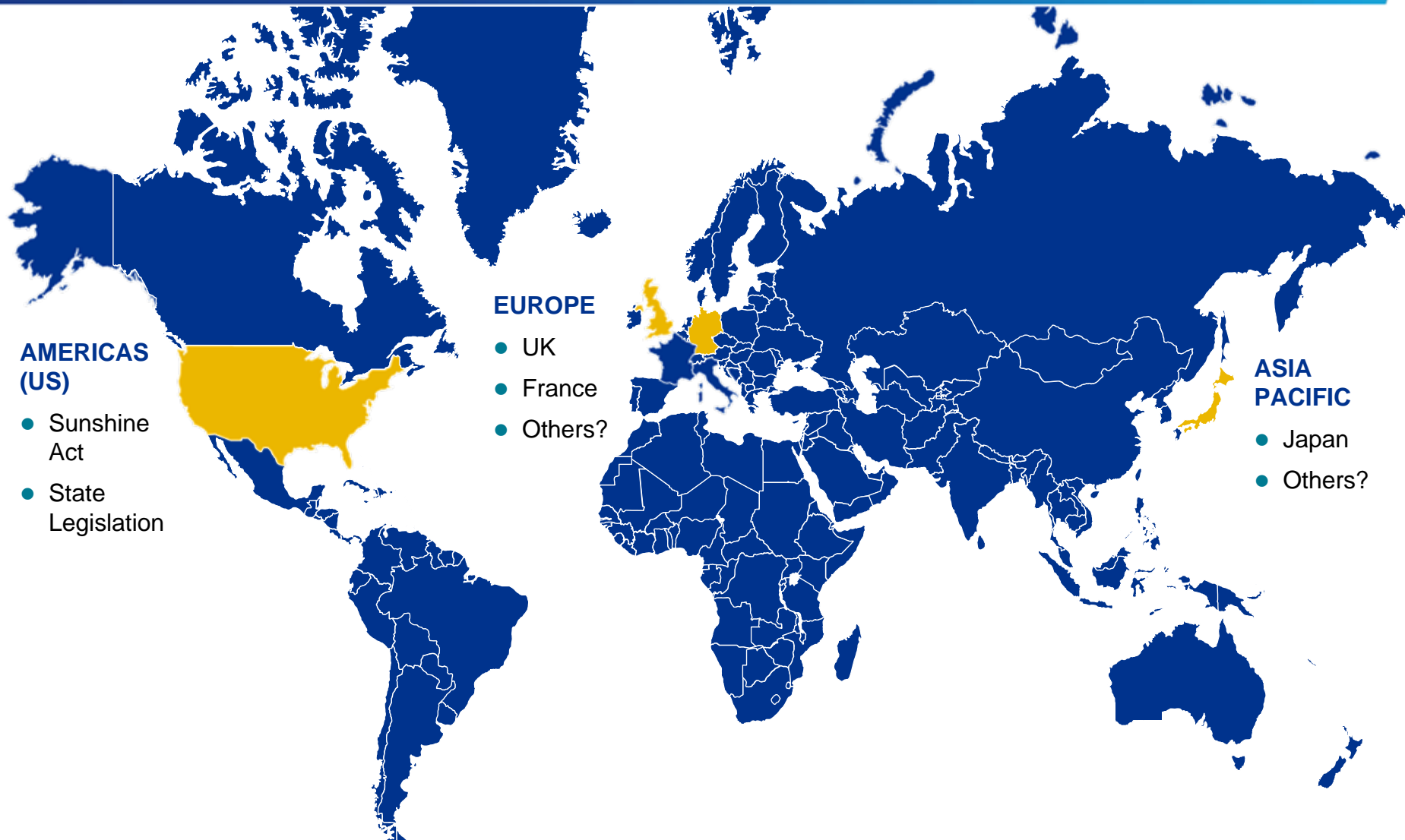
# Other Considerations

## Thinking Ahead



# Other Considerations

## Developing Global Requirements



# Aggregate Spend Next Steps

## Questions for the Panel

- 1) What is your organization's proposed procedure and infrastructure for preparing its **covered recipients** for the reporting of Aggregate Spend data (e.g. confirming understanding, spend amounts)?
- 2) How is your organization preparing the **general public** for the reporting of Aggregate Spend data (e.g. website announcements), what is the focus of the message (e.g. compliance, importance of HCP relationships), and who will be delivering the message?



# Aggregate Spend Next Steps

## Questions for the Panel

- 3) How will your organization be monitoring the **quality** of the spend data and/or the **spend activity** itself (e.g. against legislative / organizational limits or prohibited spend)?
- 4) What is your organization's plan and proposed level of effort (i.e. headcount) to monitor the output of your Aggregate Spend reports for **other compliance matters** – including actual risks and risks that may be perceived by a third party?

# Aggregate Spend Next Steps

## Questions for the Panel

- 5) In what ways does your organization plan (approach, predicted level of effort) to derive additional value from its **own data** captured under the Sunshine Act and individual state requirements? Who will be overseeing this process?
- 6) How is your organization preparing (approach, predicted level of effort) to analyze **other organizations' data** to be disclosed under the Sunshine Act and individual state requirements (i.e. beyond what is already available)?
- 7) To what extent is your organization tracking new and developing **global requirements** for Aggregate Spend?

# Thank You

**Andy Parks**

KPMG LLP

202-533-6082

[aparks@kpmg.com](mailto:aparks@kpmg.com)

[www.us.kpmg.com](http://www.us.kpmg.com)