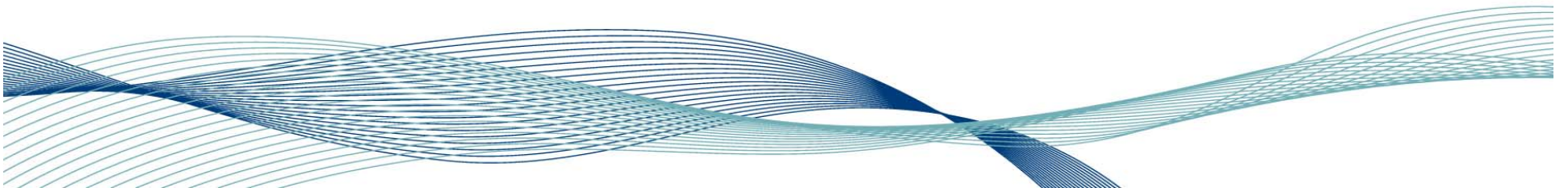




Speaker Programs: A Holistic Approach to Managing Risk

CBI Life Sciences Compliance Congress West
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Presenters



Jon Wilkenfeld

President at Potomac River Partners



Chris Hull

Consultant at Potomac River Partners



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Potential Challenges At Speaker Programs

Challenges can begin with any of the four roles



Reps



Speakers



Attendees



Bureau

Our Revelations from Conversations with Field Employees



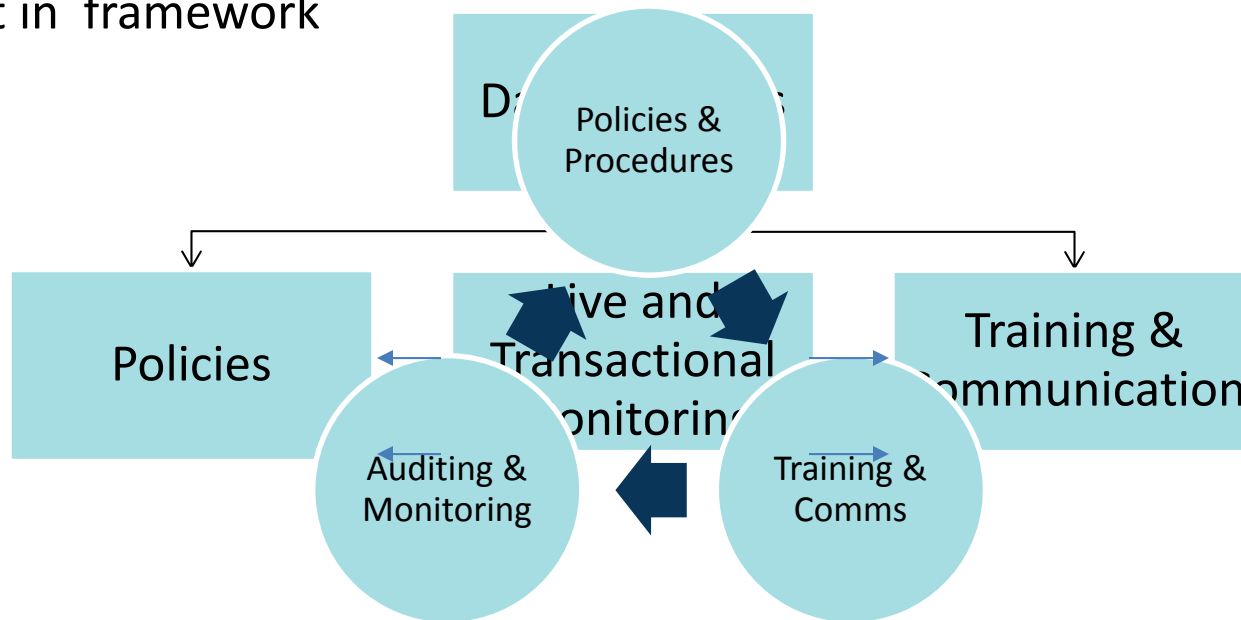
Compliance's Role: Provide the appropriate tools

Agenda

- Simplifying Policies
- Improving Traditional Training
- Developing Communications
- Holistic Approach to Monitoring

How to Mitigate the Risk Around Speaker Programs

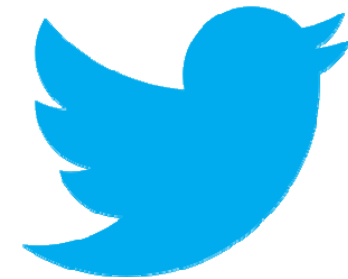
- Examine tools and resources across four major pillars:
 1. Simplifying policies
 2. Engaging training
 3. Providing “pull” communications
 4. Holistic monitoring
- A shift in framework



Traditional Compliance Framework

What Should be Done with Policies

1. Simplify language
 - OIG recommends that codes, standards, and policies have an accessible language “no more than 10th grade reading level” using the Flesch Kincaid measuring standard*
2. Make policies as short as possible
3. Make policies accessible (e.g., via tablet)
4. Highlight key points
5. Provide audience specific content



* Measuring Compliance Program Effectiveness: A Resource Guide, Element 1: Standards, Policies, and Procedures, Section 1.3

A Couple of Practical Examples

Conciseness

“It is your responsibility to determine that the individual has an Approved Attendee designation, utilizing the HCP Look-Up Tool ... Additionally, you must confirm that: (1) each Approved Attendee has appropriate responsibility for patient care; and (2) the program content is relevant to the Approved Attendee’s role”

vs.

Attendees must be part of the approved target audience:

- On-label **Prescribers**
- Non-prescribers for whom the information is relevant ~~to their job function~~

Audience Specific

“Speakers have a maximum twelve month speaker compensation cap of \$60,000 per year.”

Challenges with Traditional Training

Traditional training provides the what, not the how

X

Covers facts, not grey areas

X

Limited time
(duration and frequency)

X

Negative attitudes

X

Isn't retained; not portable

X

Little sales input (if any)

X

Discounts relationships

Areas Not Covered by Policies

Are there areas not covered in your policies that might be beneficial to train on?

Challenges involving reps

- Attendance minimum not met
- Medical Information Requests not completed
- Adverse Events not captured
- Prescribing Information not given
- Representative provides medical advice
- Samples being used to circumvent insurance approval

Challenges involving attendees

- Attendees discuss patients and include PHI
- Attendees seek advice on ongoing off-label use
- Attendee arrives at the end of the presentation
- On-call attendee leaves early
- All attendees share speaker's practice
- Attendee brings a non-HCP guest

Challenges involving speakers

- Speaker tries to provide unapproved handouts
- Speaker beings presenting unapproved deck
- Speaker attempts to skip safety slides
- Speaker goes off-label

Challenges involving logistics

- Projector doesn't work
- Speaker is a "no show"
- Private room, but noise is distracting

What You Can Do to Improve Training



Remember adult learning principles – what’s in it for me?

Customize content to audience - Speak audience language



Provide timely topics and real-world scenarios

Provide insight on how to respond



Add gaming to live training

Kahoot! is free to use!



Leverage interactive tools in e-learning

Rapid development tools (e.g., Articulate, Brainshark) can make training engaging



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Focus on Timely and Situational Communication

Challenges with Communications

- Time-sensitive inbound communications
- Inconsistent accessibility of outbound
- Reaching agreement on the gray areas

Improving Communications

- Simplify Information for specific audience and topic
- Utilize “push” and “pull” tactics
- Provide on-demand access via iPad

Monitoring Types

Live

Can provide insight into interactions or materials used

Looking at data that cannot be assessed after the fact

Transactional

Can provide insight into compliance with policies on receipts, contracts, sign-in sheets, etc.

Looking at individual data points

Aggregate/Analytics

Can provide insight into frequency, trends, or outliers

Looking at the full data set

Examples of How This Works

SPEAKER PROGRAM RISKS	TYPE OF MONITORING
COMMUNICATION	
<ul style="list-style-type: none"> • Use of approved deck • Response to questions 	<ul style="list-style-type: none"> • Live • Live
SPEAKER COMPENSATION	
<ul style="list-style-type: none"> • Contract in place before engagement • Follows FMV • Frequency of cancelled paid programs 	<ul style="list-style-type: none"> • Transactional • Transactional • Aggregate/Analytics
LOGISTICS	
<ul style="list-style-type: none"> • Venue was conducive to educational presentation • Meal costs only included food, tax, and gratuity • Rep frequently goes over meal limit 	<ul style="list-style-type: none"> • Live • Transactional • Aggregate/Analytics
ATTENDEES	
<ul style="list-style-type: none"> • Receipts accurately documented for transparency • Attendees all present for presentation • Frequency of presentations for single attendee 	<ul style="list-style-type: none"> • Transactional • Live • Aggregate/Analytics

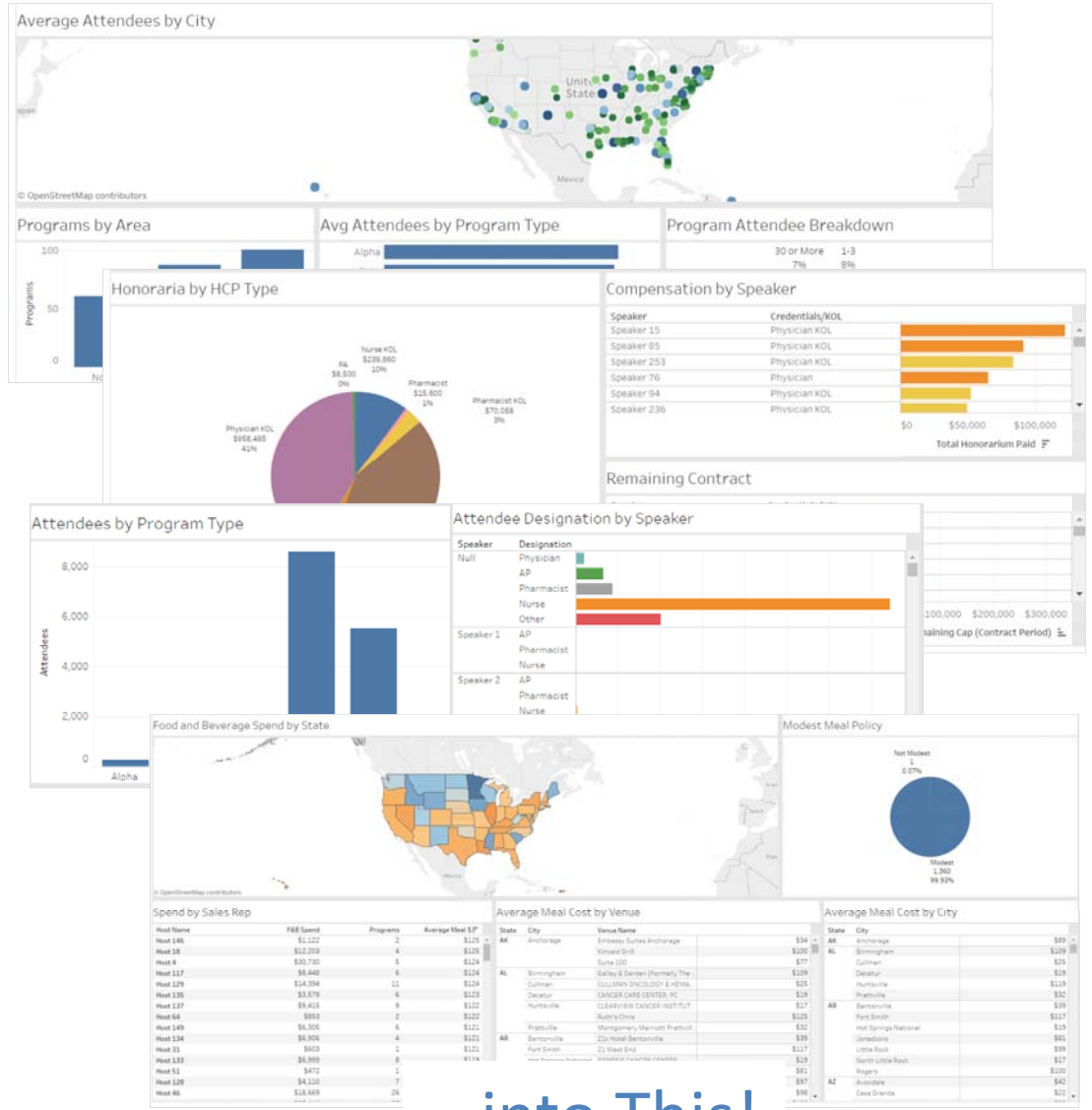
Building Dashboards to Monitor Aggregate Data

Owner	(123)555-0100	(123)555-0123	1st Street	Boston	
Francisco	Purchasin	(123)555-0100	(123)555-0123	2nd Street	Los Angeles
Christina	Purchasin	(123)555-0100	(123)555-0123	4th Street	New York NY
Donnell Martin	Owner	(123)555-0100	(123)555-0123	5th Street	Minneapolis MN
Pérez-Ola Francisco	Purchasin	(123)555-0100	(123)555-0123	6th Street	Milwaukee WI
Xie Ming-Yang	Owner	(123)555-0100	(123)555-0123	7th Street	Boise ID
Andersen Elizabeth	Purchasin	(123)555-0100	(123)555-0123	8th Street	Portland OR
Mortensen Sven	Purchasin	(123)555-0100	(123)555-0123	9th Street	Salt Lake City UT
Wecker Roland	Purchasin	(123)555-0100	(123)555-0123	10th Street	Chicago IL
Krschna Pieter	Purchasin	(123)555-0100	(123)555-0123	11th Street	Miami FL
Edwards John	Purchasin	(123)555-0100	(123)555-0123	12th Street	Las Vegas NV
Ludick Andra	Purchasin	(123)555-0100	(123)555-0456	13th Street	Memphis TN
Gnilo Carlos	Purchasin	(123)555-0100	(123)555-0456	14th Street	Denver CO
Kupkova Helena	Purchasin	(123)555-0100	(123)555-0456	15th Street	Honolulu HI
Goldschm Daniel	Purchasin	(123)555-0100	(123)555-0456	16th Street	San Francisco CA
Bagel Jean Philippe	Owner	(123)555-0100	(123)555-0456	17th Street	Seattle WA
Auker Mica Catherine	Purchasin	(123)555-0100	(123)555-0456	18th Street	Boston MA
Eggerer Alexander	Accountin	(123)555-0100	(123)555-0789	19th Street	Los Angeles CA
Li George	Purchasin	(123)555-0100	(123)555-0789	20th Street	New York NY
Tham Bernard	Accountin	(123)555-0100	(123)555-0789	21th Street	Minneapolis MN
Ramos Luciana	Purchasin	(123)555-0100	(123)555-0789	22th Street	Milwaukee WI
Michael	Purchasin	(123)555-0100	(123)555-0789	23th Street	Portland OR
Jonas	Owner	(123)555-0100	(123)555-0789	24th Street	Salt Lake City UT
	Purchasin	(123)555-0100	(123)555-0789	25th Street	Chicago IL
	Accountin	(123)555-0100	(123)555-0789	26th Street	Miami FL
		(123)555-0100	(123)555-0789	27th Street	Las Vegas NV

Turns this...

Sample of Speaker Program Dashboards:

1. Programs by Type
2. Types of Attendees
3. Avg. Attendees
4. Attendee Frequency
5. Food and Beverage
6. Speaker Compensation
7. Canceled Paid Programs
8. Monitored Programs



...into This!

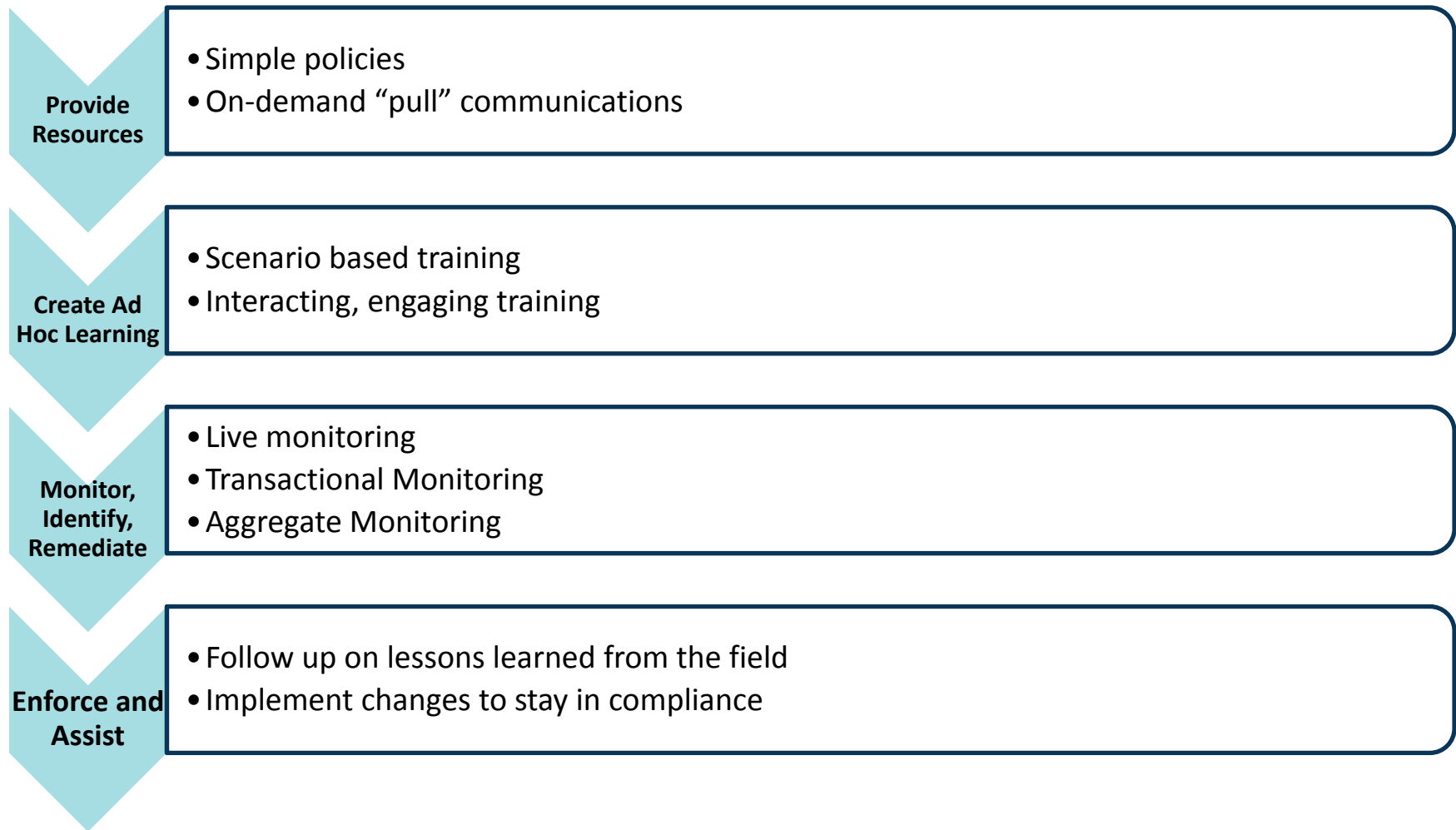


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Conclusion

A holistic approach to Speaker Programs can help minimize associated risks





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Contact Information



Jon Wilkenfeld
President

jwilkenfeld@potomacriverpartners.com
www.potomacriverpartners.com

Chris Hull
Consultant

chull@potomacriverpartners.com
www.potomacriverpartners.com