

The Future of Transparency: 5 Pillars for Global Success

October 15, 2015

pharmacertify

 **BRG**
Healthcare



Pete Sandford

Executive Vice
President and
Co-founder
NXLevel Solutions

Through its PharmaCertify™ division, NXLevel Solutions delivers innovative and practical learning and information solutions to compliance organizations in the pharmaceutical and medical device industries.



Katherine Norris

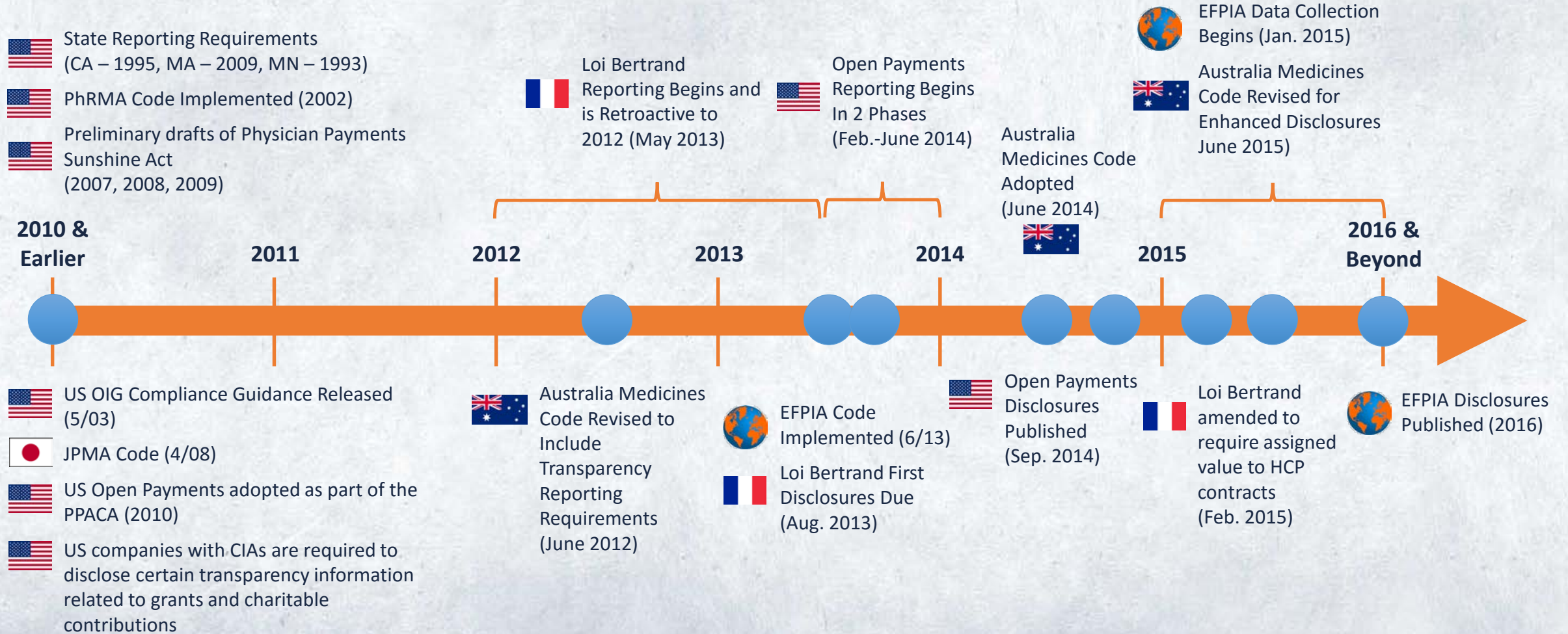
Director, Corporate
Compliance and Risk
Management
Berkeley Research Group

Berkeley Research Group, LLC is a leading global strategic advisory and expert consulting firm that provides strategic advice, independent expert testimony, litigation and regulatory consulting, authoritative studies, and document and data analytics to major law firms, Fortune 500 corporations, government agencies, and regulatory bodies around the world.

Our Agenda:

- A Brief History of Transparency Reporting
- Transparency Reporting today
- Five Pillars to Steer You Into the Future
- Q & A

Major Milestones in Transparency Reporting



Number of
countries
currently
publishing
data

4

Where are we now?



Number of
countries
publishing
data
in 2016

36

Number of
countries with
statutory
transparency
codes

6

Number of
countries with
voluntary
transparency
codes

37

11.41
MILLION

Total Records Published



6.49
BILLION

Total US Dollar Value



1,444

Total Companies Making Payments



1,121

Total Teaching Hospitals with Payment Records



607,000

Total Physicians with Payment Records



Open Payments Data*

THE
FACTS

*Data for 2014
Source: openpayments.cms.gov
June 30, 2015

30,000

Disputes on

25,000

Unique Records



The numbers
are **huge**

HCP & HCO Concerns

- Negative impact on ability to attain or keep research grants
- Reduced opportunities for research and consulting
- Worry about adhering to conflict of interest policies
 - Changing COI policies
 - Misinformation
 - Education and Awareness
- Time consuming registration, review and dispute processes
- Dissention with hospitals

Manufacturer Challenges

- Time and effort to resolve disputes
- Communication and training not “sticking”
- Managing recording and reporting from various business units
- Collection from third parties can be unreliable, resulting in data inconsistencies
- Poor understanding of actual requirements of law; incorrect assumptions = bad data
- Perception that transparency requirements are bureaucratic and not beneficial

Five Pillars for Global Success




Global Awareness

1




Managing Pre-Disclosure

2




Scalable and Aligned Business Practices

3



Rigorous Auditing and Analytics

4



Communication and Education

5

Polling Question:

What is your company's biggest concern about global transparency reporting?

Five Pillars for Global Success



Best Practices for Global Awareness

Think globally,
act locally...

- Where do you operate?
- What are the corporate structures in those countries?
- What legal and voluntary code disclosure requirements exist?
- Are your current businesses:
 - Subject to applicable requirements?
 - Aware of requirements?
 - Resourced?
 - Operating independently?
 - Using corporate-wide infrastructure?
- Who are your points of contact?



Putting Pen to Paper:
What Do You
Need to Know?

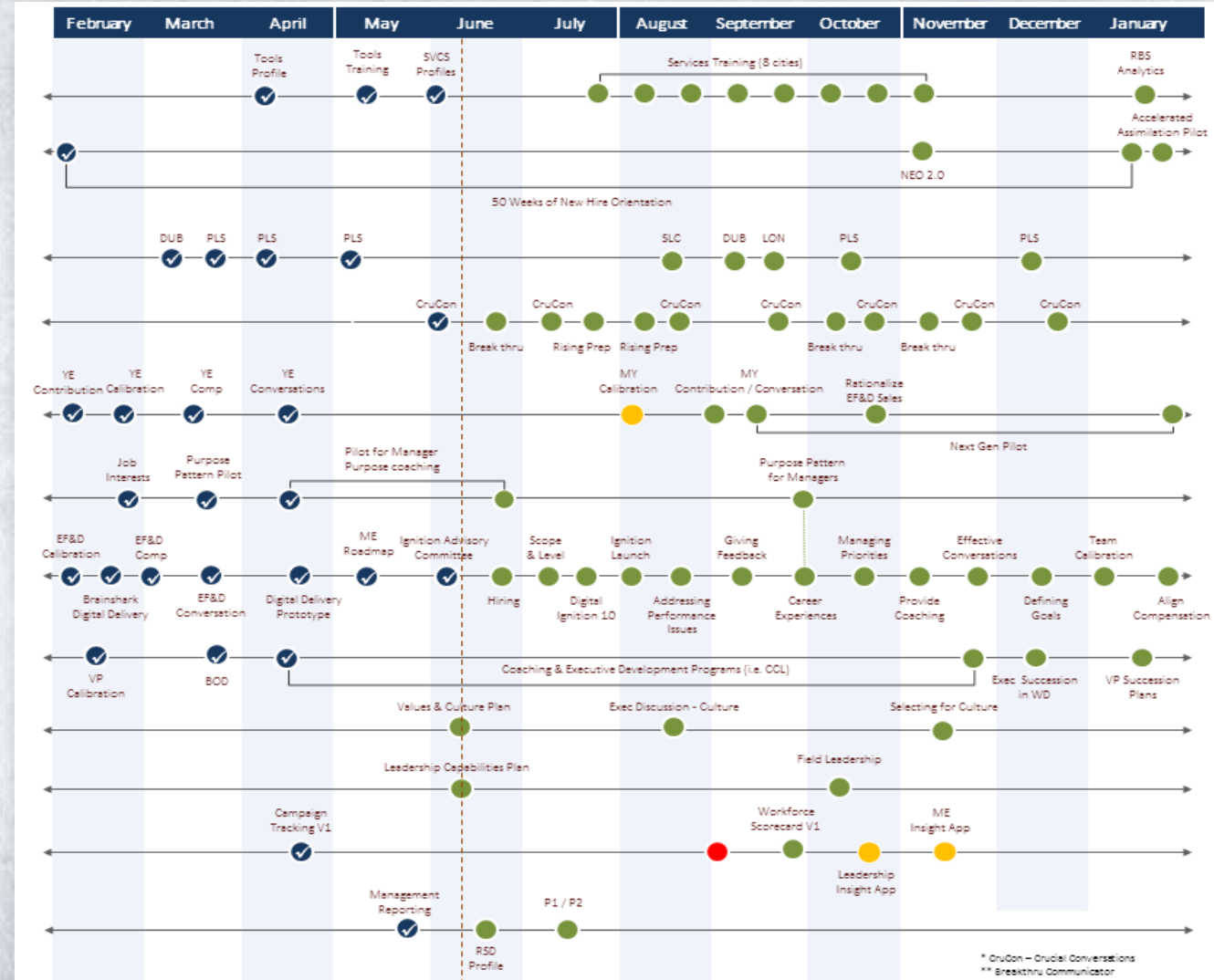
Form a global
transparency
steering
committee



Best Practices for Global Awareness



Establish and maintain a process & cadence for global environment scans



Country	Law or Industry Code	Individual or Aggregate Reporting	Applicability – HCPs, HCOs	Reported Items	TOV Thresholds	Notes
United Kingdom	Industry Code	Individual - encourages contractual agreement for individual disclosure	HCPs - physician, nurses, dentist, pharmacist HCO - medical societies	Travel, Education, R&D, Meals, Gifts, Hospitality	None at this time	NHS Contemplating HCP driven disclosures
France	Law	Individual	HCP - physician, nurse, pharmacist, medical students, software developers and more	Benefits (meals, gifts, travel, etc.) and Contracts with HCPs	Benefits - equal to or greater than €10 Contracts- Notification of contract and its value	
Portugal	Law	Individual	HCPs, HCO, Patient Organisations	Sponsorship, funding	€65	
Netherlands	Industry Code	Aggregate	HCPs, institutions, partnerships	Meals, contracts, travel etc. R&D excluded	TOVs over €500/ year	TOV data published in a central database. Data must be submitted in first 3 months of the year
Estonia	Law	Individual	HCPs	All non-clinical HCP engagements	In excess of €6.48	
Denmark	Law	Individual	HCPs	Name, address, and civil registration number of any physician or dentist associated with the company.		Additional detail about financial relationships may be requested by the Danish Medicines Authority.
	Law	Individual	HCPs	TOVs for marketing		

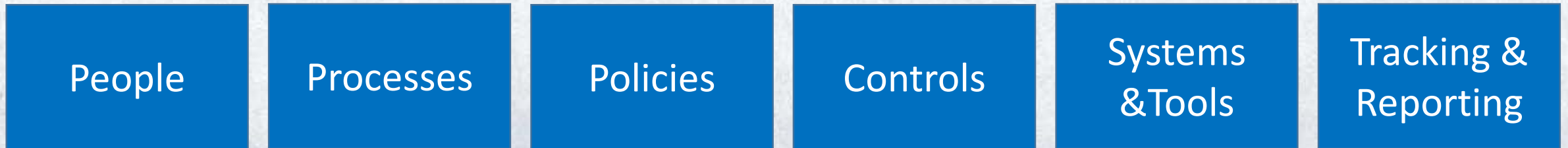
Proactively
adapt
to global
developments

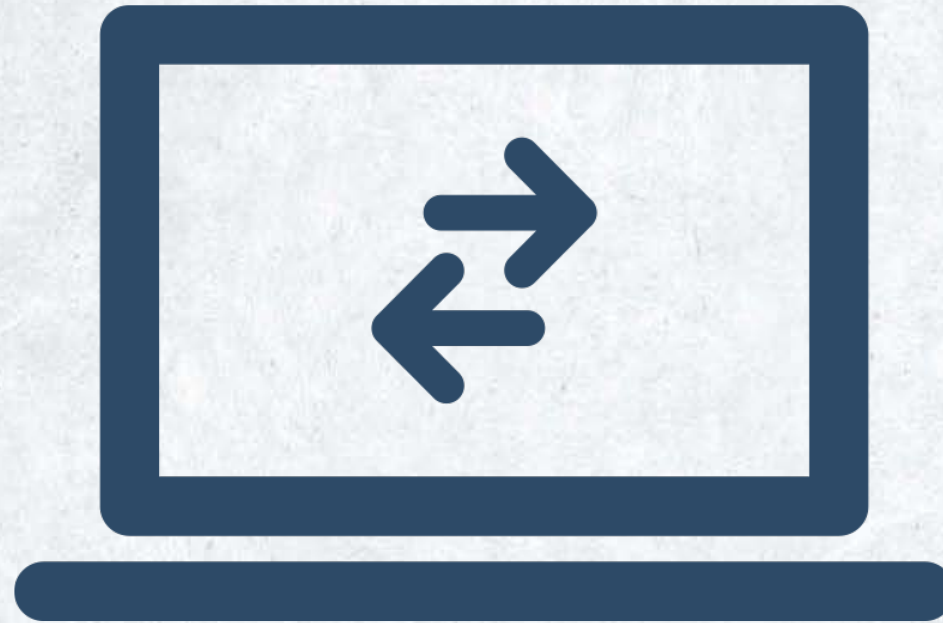
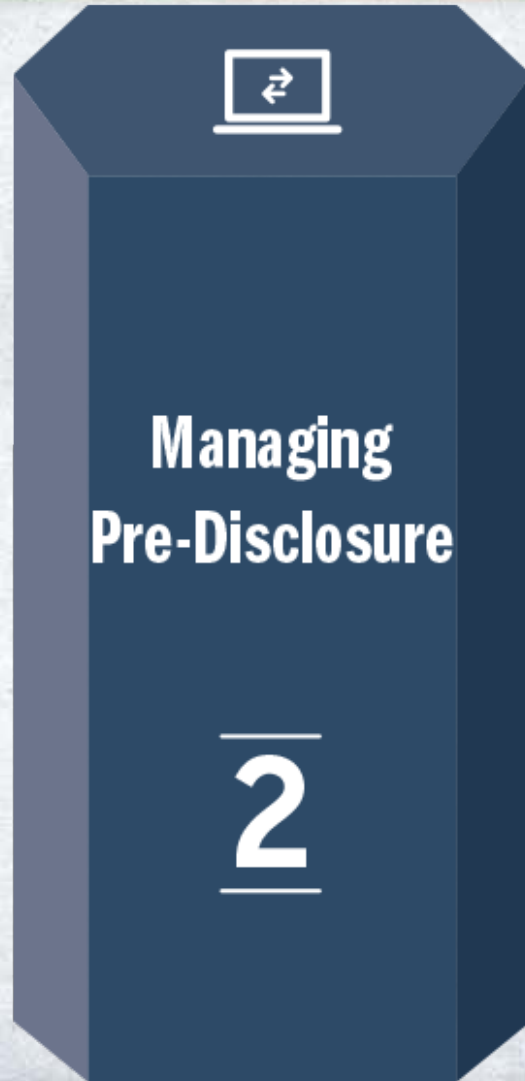


Managing Global Transparency: A Continuum



Variables





Why manage Pre-disclosure?

Data Accuracy

51 percent

of surveyed physicians who visited the
CMS Open Payments site

**found inaccuracies in
the data**

- 2014 MedPanel Survey of 461 Physicians

Dispute Channel

85 percent
of physicians would like a
channel to dispute
payments prior to
reporting and public disclosure.

- 2012 Regulatory Law Group Survey of 50,000 Physicians

Online Portal Access

61 percent
of physicians **would access**
an online portal to
proactively review and manage
financial data to be reported.

- 2012 Regulatory Law Group Survey of 50,000 Physicians

Polling Question

Does your
company have a
formal TOV
pre-disclosure
process in place?

Why Manage Pre-disclosure?



HOME ABOUT WHY?

TOVdisclosure.com™ is a streamlined and intuitive tool that enables manufacturers to share payments information with HCPs and HCOs before data is reported to CMS or other authorities. With TOVdisclosure.com™, payments data is updated continuously and aren't limited to one brief window of time for data review. Disputes are resolved early, before payments data is submitted. Conflicts are avoided and relationships with HCPs and HCOs are strengthened.

STEP 1

Transfer of Value data is shared with physicians through TOVdisclosure.com™.



STEP 2

HCPs review data and contact manufacturer with questions and disputes.



STEP 3

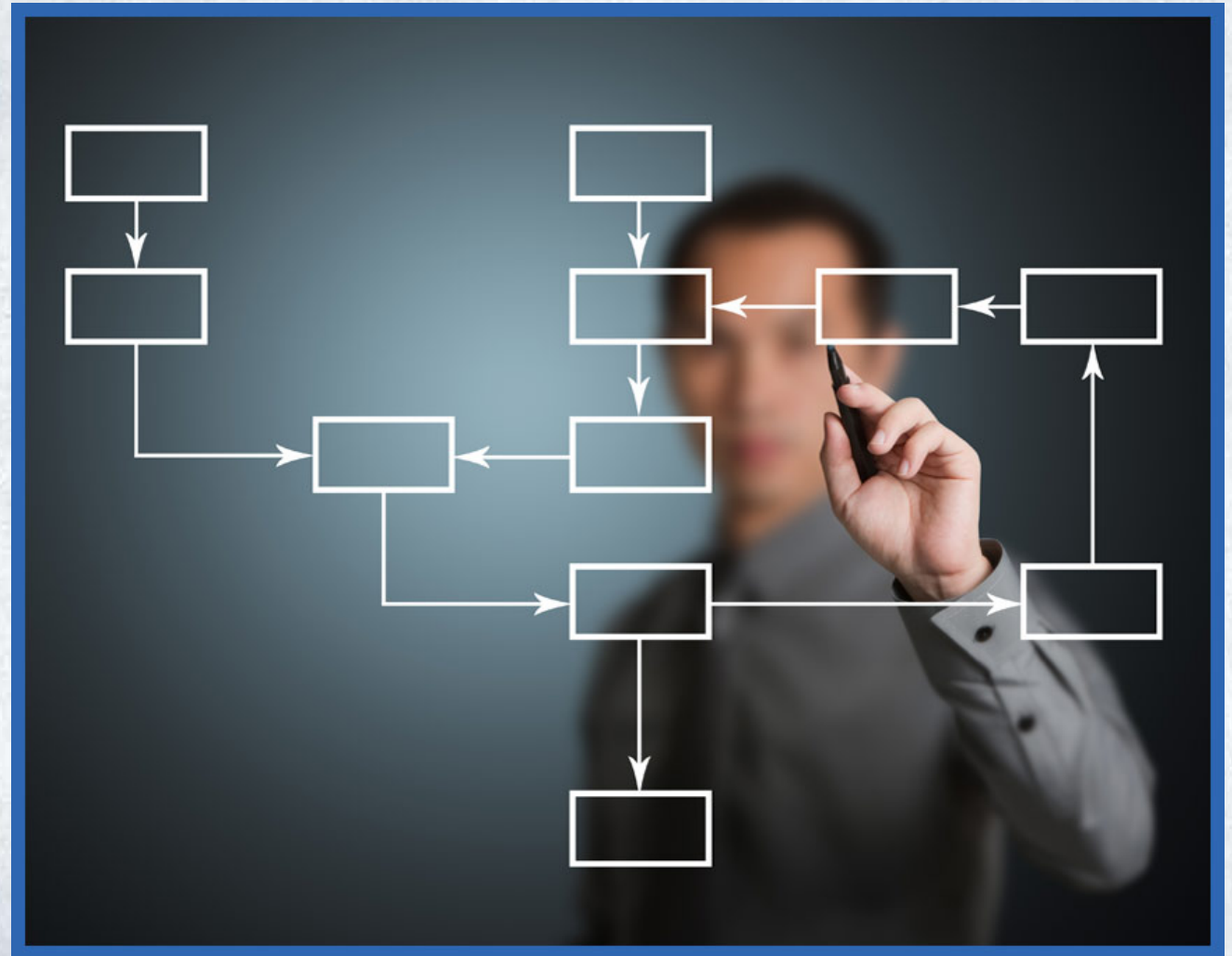
Disputes are resolved and data is finalized for submission.



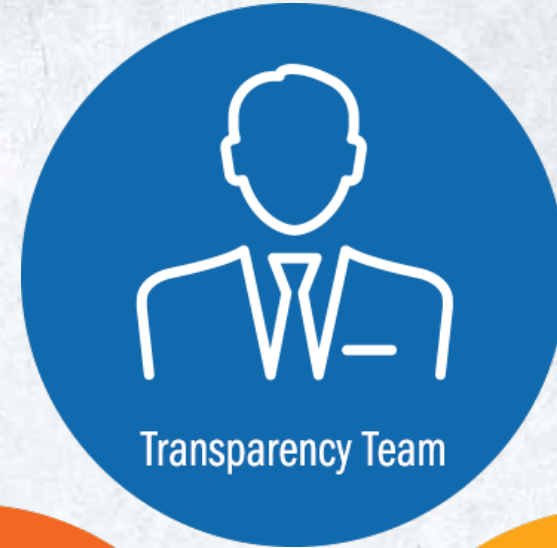
- To ensure data accuracy
- To resolve disputes before data goes public
- To build partnership
- To increase consent of HCP's where required

Best Practices for Managing Pre-disclosure

Develop and implement
SOP's in
partnership with
business
stakeholders



Establish a
communication
“triangle” with key
customers



Provide a
streamlined
platform
for HCP's
and HCO's
to view and
inquire

TCV DISCLOSURE™ HOME CHANGE PASSWORD LOG OFF

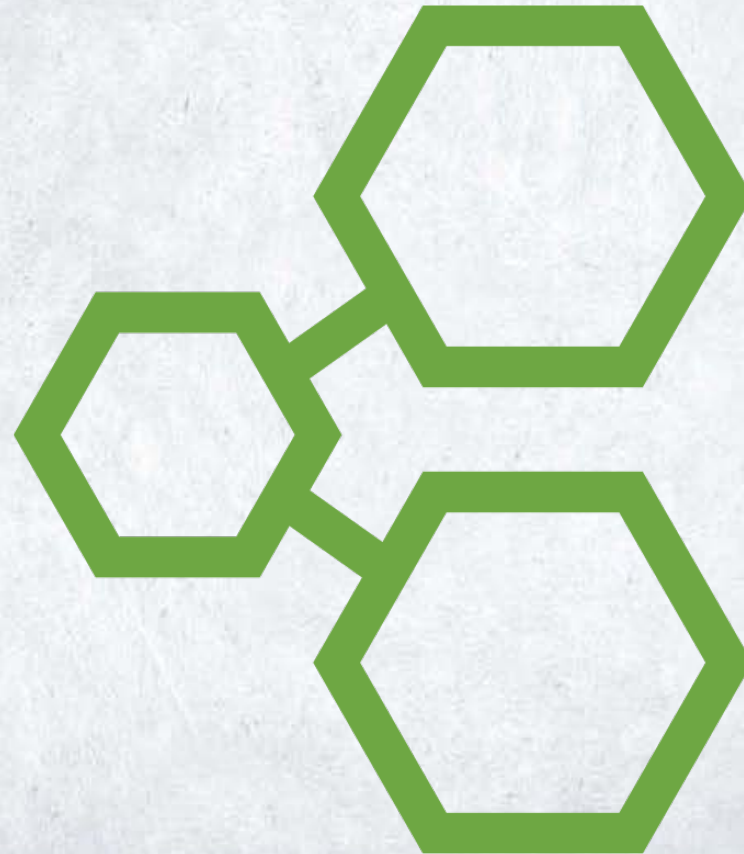
HCP Statement

Click on a payment below to view details and inquire.

HCP NAME:	AARON HELIGMAN, MD
NPI/SLN:	NY123456
PRIMARY BUSINESS ADDRESS:	600 S Paulina St Ste 524
CITY:	Chicago
STATE:	IL
ZIP CODE:	60612

Date	Payment ID	Nature of Payment	Amount	City	Product	Third Party Payment
1/15/2014	1234567	Food and Beverage	\$98.89	N/A	ERBITUX	N/A
1/15/2014	1234568	Travel and Lodging	\$265.35	TAMPA	ERBITUX	N/A
1/15/2014	1234569	Travel and Lodging	\$28.00	TAMPA	ERBITUX	N/A
1/15/2014	1234570	Travel and Lodging	\$290.08	TAMPA	ERBITUX	N/A
1/15/2014	1234571	Travel and Lodging	\$150.80	TAMPA	ERBITUX	N/A
1/15/2014	1234573	Speaker Fees	\$3,500.00	N/A	ERBITUX	N/A
1/16/2014	1234575	Speaker Fees	\$3,500.00	N/A	ERBITUX	N/A
1/16/2014	1234576	Food and Beverage	\$51.65	N/A	ERBITUX	N/A
8/15/2014	1234572	Travel and Lodging	\$50.00	TAMPA	ERBITUX	N/A

Five Pillars for Global Success



Best Practices for scaling and aligning business processes

Build and
follow a
roadmap



Great Falls Pharma – Global Transparency Assessment

Country	Voluntary Code	Statutory Requirement	Prior Consent	Individual Reporting	Company Website	Central Repository	Company Division
U.S.	Y	N	N	Y	Depends on CIA	Y	North America
U.K.	Y	N	Y	Y	Y	N	Vaccines Division, Main Pharma, Specialty Subsidiary
France	N	Y	Y	Y	N	Y	Distributor
Romania	Y	N	Y	Y	Y	Y	Distributor
Japan	Y	N	N	Y	Y	N	Direct Sales – World Wide
Portugal	Y	Y	Y	Y	N	Y	Distributor
Australia	Y	N	Y	Y	Y	Y	Australia Subsidiary
Canada	N	N	N	N	N	N	Main Pharma – Canada
CURRENT PROCESS	SFA, iPad, ERP	Legal, Compliance Tracking	N/A	Ag Spend System	N	Ag Spend System	US, Vaccines Division
COMPANY POLICY	Interactions with HealthCare Professionals – US Transparency Reporting - US	N/A	N	Transparency Reporting – US	Data Privacy and Information Governance – US/EU Safe Harbor	Data Privacy and Information Governance – US/EU Safe Harbor	ALL

Bridge the
gaps



Invest in
the right
**human
capital**



Driving alignment across the Global Organization



Do we all understand the objectives?

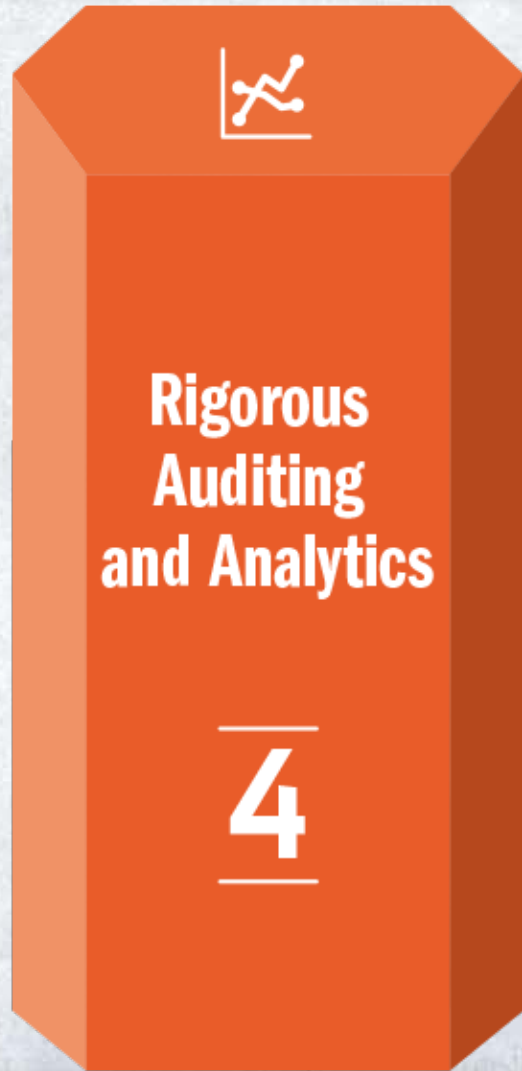
How do you account for them?

Do we have the right tools?

What are the unique business practices from country to country?

Does anything need to change?

Five Pillars for Global Success



Best Practices for Auditing and Monitoring

Develop an annual
**Audit +
Monitoring
Plan...**
...and stick to it.



What do your
efforts
reveal?

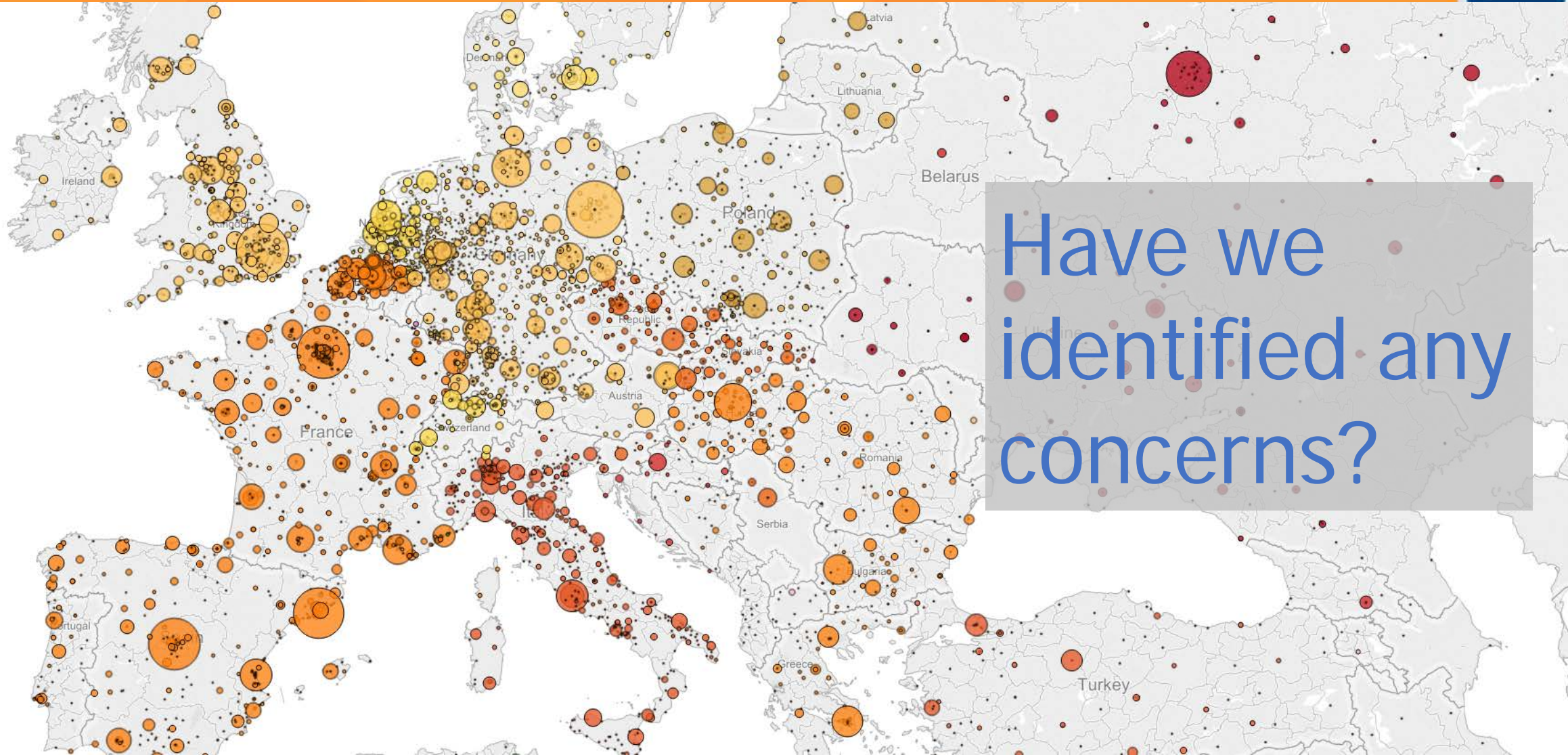


The Power of Analytics



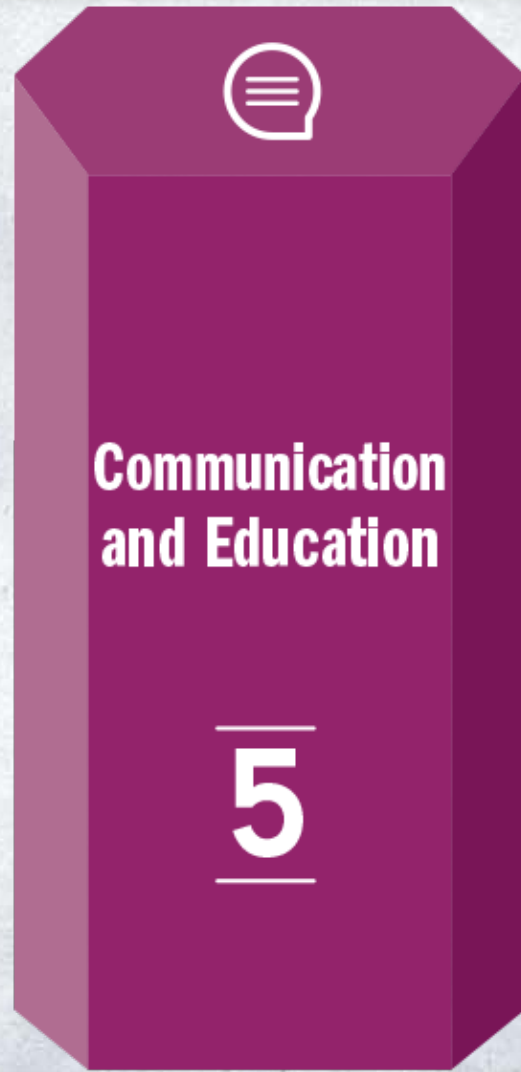
Where does your
FMV stack up?

Where do we spend?



Have we identified any concerns?

Five Pillars for Global Success



Why communicate and educate?



IFPMA



efpia*



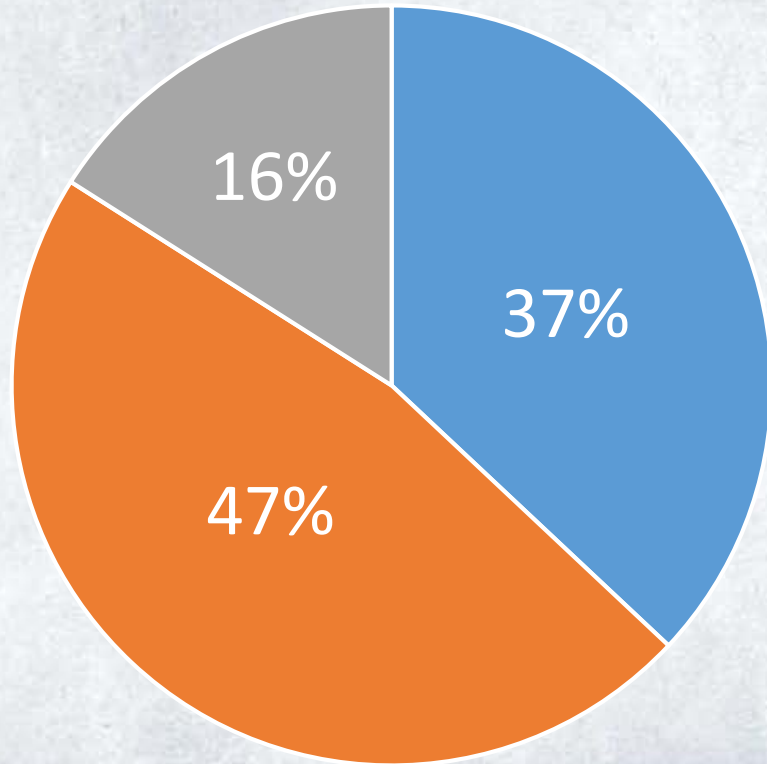
JPMA



Understanding of the U.S. Sunshine Act



Question: Please rate your familiarity with the Physician Payment Sunshine Act.



Only 37% of physicians were "very familiar."

Source: 2014 MedPanel Survey of 456 physicians

Why communicate and educate?



- Reinforce transparency as a positive development for manufacturers, healthcare providers, and patients
- Increase understanding of transparency requirements and scope by HCP's and HCO's
- Proactively share changes in healthcare regulations and company policies
- Educate internal and external stakeholders on their roles and responsibilities
- Increase willingness of physicians to consent to sharing their TOV information



Why communicate and educate?



Drive home the
concept that
transparency is
good for all



Best Practices for Communication and Education





Develop and implement a comprehensive plan
in collaboration with stakeholders



Address both
internal
and
external
constituents



Develop and deliver
targeted training
that includes
foundational
information
and **“how-to’s”**

Good Promotional Practices

Meals, Gifts, and Entertainment

Knowledge Check


Scenario | **Course of Action**

Terry, a new sales representative, will be taking over Dan's territory when Dan moves to a position in the home office. On this day, Dan is introducing Terry to Dr. Jeffries. During the conversation, Dr. Jeffries tells Terry that his practice is quite busy and he doesn't have much time to see sales representatives. He also tells Terry he hopes Terry will continue with the monthly golf outings that he had with Dan, as he found them to be the best time to discuss Terry's products.

As they leave the office, Terry questions Dan about the golf outings as he thought that sort of thing was not permitted. Dan tells Terry he pays for the golf outings out of his own pocket. If it is his money, Dan explains, no one can say anything about it. Dr. Jeffries is an important customer, and Dan tells Terry he should seriously consider doing the same.

What should Terry do?

Select the **Course of Action** tab to answer the question.



Select **Next** to continue.

pharmacertify
READY. LEARN. GROW.

Transcript 00:00 7 of 32

©2014 NXLevel Solutions. All rights reserved.

BACK NEXT

Integrate
existing
educational
materials



Embrace a
“touchpoint”
approach



Track
uptake
and adjust
your approach

The screenshot shows a reporting dashboard for 'Module: Certification Level 1'. It includes a sidebar with navigation icons, a main content area with a summary, a bar chart, and a user activity table. A right-hand sidebar contains quick reports and usage reports.

Module: Certification Level 1
All Results Filter this report

23 People Complete (Passmark) 80%
0h 3m 54s Average time spent

Question answers

Question	Correct	Incorrect
Q1	150	20
Q2	50	130
Q3	40	140
Q4	30	150
Q5	20	160
Q6	20	160
Q7	20	160

User View | Question View

PERSON	LAST ATTEMPT	TIME TAKEN	SCORE	ATTEMPTS	LOCKED	MARKING	STATUS
Alicia Winger		00:00:27		1			In Progress
Ayob Syed		00:00:08		71			In Progress
Ayob Syed	Oct 4, 2011 3:40:14 PM	00:09:55	100%	1			Complete
Charles Harder	Oct 4, 2011 1:17:07 PM	00:04:28	100%	1			Complete
Chris Balck	Sep 12, 2012 10:57:31 AM	00:05:12	100%	1			Complete
Chris Dobbertin		00:06:24		2			In Progress
Chris Race		00:00:00		0			Not Attempted
Christina Bebee Kemper	Oct 12, 2011 2:39:18 PM	00:14:06	100%	1			Complete
Christine Bacchus		00:00:09		1			In Progress
Christine Dorrien	Mar 13, 2012 8:48:06 PM	00:00:39	42%	5			Failed

1 to 30 of 71 records

pharmacertify

Quick reports: Learning Path, Courses, People, Teams, Modules, Assessment, Survey, Score or Tin Can, Compliance Summary

Usage Reports: Login activity, Never logged in, Courses purchased

Five Pillars for Global Success




Global Awareness

1




Managing Pre-Disclosure

2




Scalable and Aligned Business Practices

3



Rigorous Auditing and Analytics

4



Communication and Education

5

Thank you!



Pete Sandford

Executive Vice President and
Co-founder
NXLevel Solutions

psandford@nxlevelsolutions.com

Visit NXLevel Solutions in **Booth 204**
at the Sixteenth Annual
Pharmaceutical Regulatory and
Compliance Congress, October 21-23

Katherine Norris

Director, Corporate Compliance and
Risk Management
Berkeley Research Group

knorris@thinkbrg.com

Visit Berkeley Research Group in
Booth 6 at the Sixteenth Annual
Pharmaceutical Regulatory and
Compliance Congress, October 21-23