Calibrate Your Compliance Training

A Practical Framework

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Criminal Division

Evaluation of Corporate Compliance Programs

(Updated June 2020)

Introduction

The "Principles of Federal Prosecution of Business Organizations" in the Justice Manual describe specific factors that prosecutors should consider in conducting an investigation of a corporation, determining whether to bring charges, and negotiating plea or other agreements. JM 9-28.300. These factors include "the adequacy and effectiveness of the corporation's compliance program at the time of the offense, as well as at the time of a charging decision" and the corporation's remedial efforts "to implement an adequate and effective corporate compliance program or to improve an existing one." JM 9-28.300 (citing JM 9-28.800 and JM 9-28.1000). Additionally, the United States Sentencing Guidelines advise that consideration be given to whether the corporation had in place at the time of the misconduct an effective compliance program for purposes of calculating the appropriate organizational criminal fine. *See* U.S.S.G. §§ 8B2.1, 8C2.5(f), and 8C2.8(11). Moreover, the memorandum entitled "Selection of Monitors in Criminal Division Matters" issued by Assistant Attorney General Brian Benczkowski (hereafter, the "Benczkowski Memo") instructs prosecutors to consider, at the time of the resolution, "whether the corporation has made significant investments in, and improvements to, its corporate compliance program and internal controls systems" and "whether remedial improvements to the compliance program and internal controls have been tested to demonstrate that they would prevent or detect similar misconduct in the future" to determine whether a monitor is appropriate.

"Prosecutors, in short, should examine whether the compliance program is being disseminated to, and understood by, employees in practice in order to decide whether the compliance program is truly effective."

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This document is meant to assist prosecutors in making informed decisions as to whether, and to what extent, the corporation's compliance program was effective at the time of the offense, and is effective at the time of a charging decision or resolution, for purposes of determining the appropriate (1) form of any resolution or prosecution; (2) monetary penalty, if any; and (3) compliance obligations contained in any corporate criminal resolution (e.g., monitorship or reporting obligations).

Because a corporate compliance program must be evaluated in the specific context of a criminal investigation, the Criminal Division does not use any rigid formula to assess the effectiveness of corporate compliance programs. We recognize that each company's risk profile and solutions to reduce its risks warrant particularized evaluation. Accordingly, we make a reasonable, individualized determination in each case that considers various factors including, but not limited to, the company's size, industry, geographic footprint, regulatory landscape, and other factors, both internal and external to the company's operations, that might impact its compliance program. There are, however, common questions that we may ask in the course of making an individualized determination. As the Justice Manual notes, there are three "fundamental questions" a prosecutor should ask:

1

What is the purpose of Compliance Training?

Desirable Behaviors

Undesirable Behaviors

Training Guidance from the DOJ

- Needs analysis (Who and what should be trained?)
- Tailoring by role (functional and level)
- Appropriate format and language for audience
- Inclusion of lessons learned from prior incidents
- Process for asking training follow-up questions
- Measuring effectiveness (Testing-Remediation-Impact)

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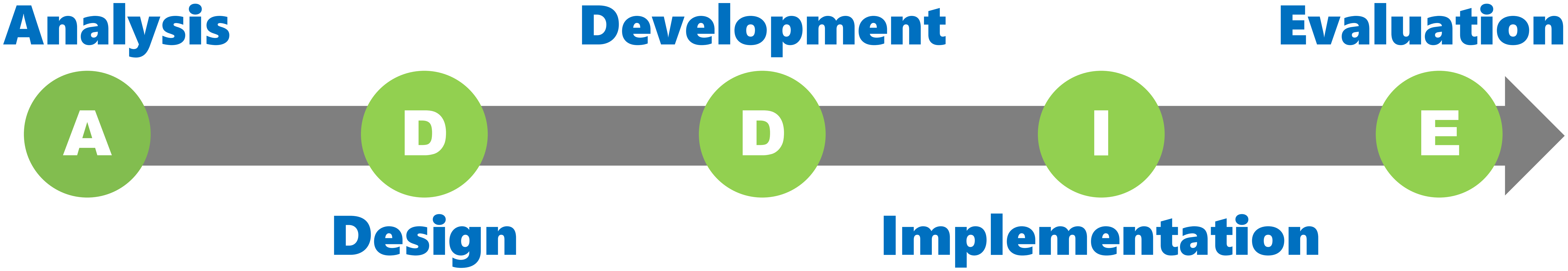
The ADDIE Model



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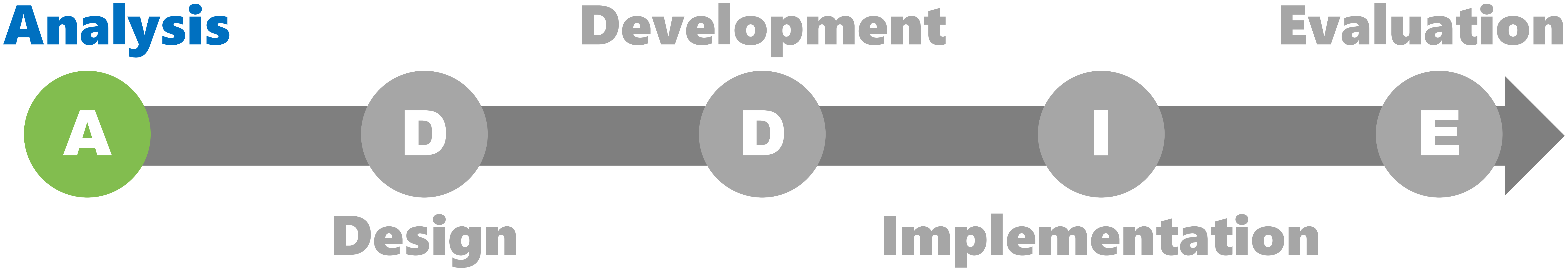


Training Needs Analysis: Two Types

Planning

- Forward looking
- Broad-based
- Applied to annual compliance training plan

Diagnostic

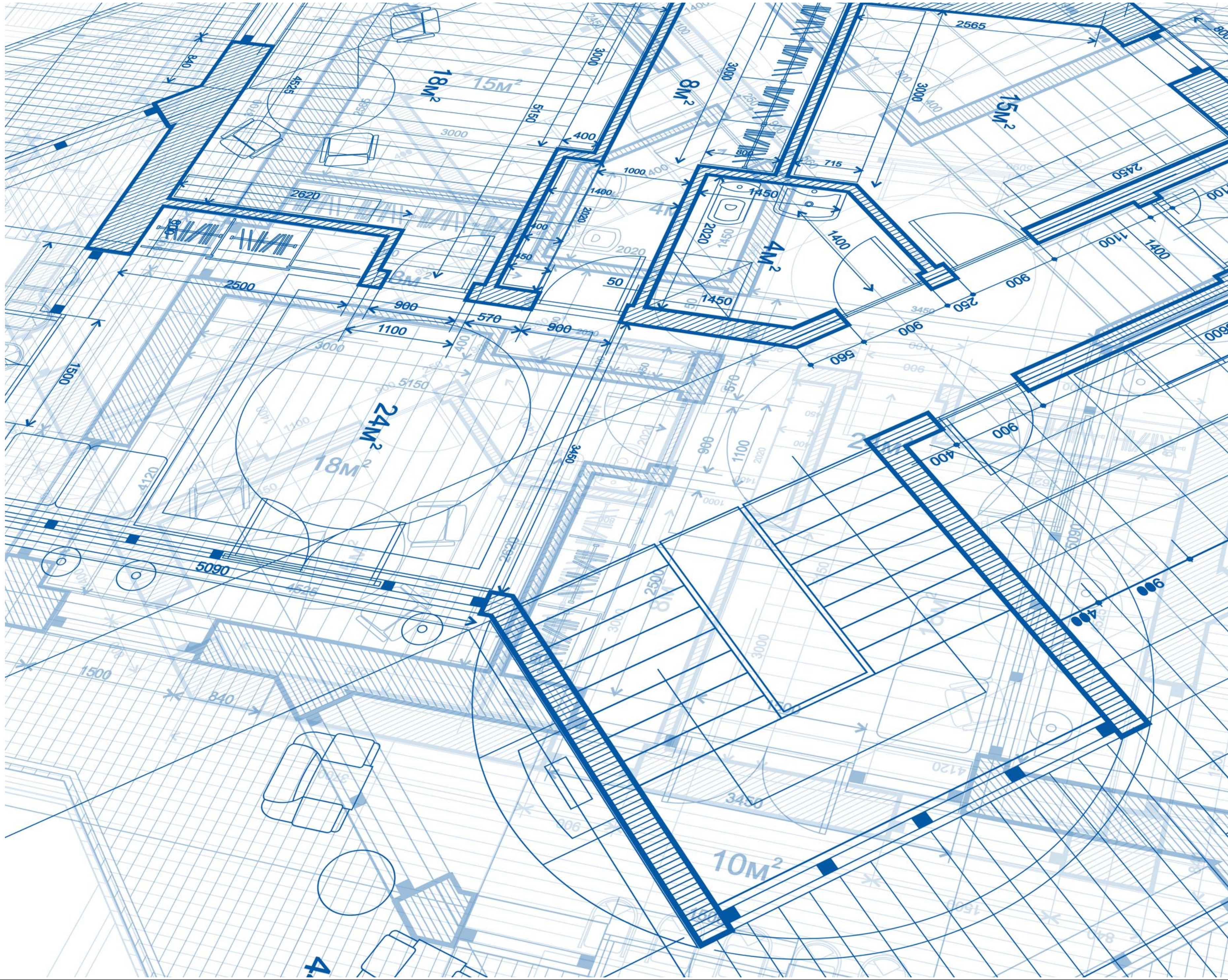
- Issue-focused
- Based on data
- Targeted toward specific problems/performance

Training Needs Analysis: Inputs

INPUTS	PLANNING	DIAGNOSTIC
Helpline/Hotline data	X	X
Monitoring and auditing	X	X
Formal risk analysis	X	
Input from the business	X	X
Performance reviews	X	
LMS and testing data	X	X
Surveys	X	X
Focus groups	X	X

Annual Training Plan

- Start with risk and frequency
- Focus on rules and principles
- Be strategic and tactical
- Make it function-specific
- Make it level-specific (including leaders)
- Include leader training
- Consider delivery methods

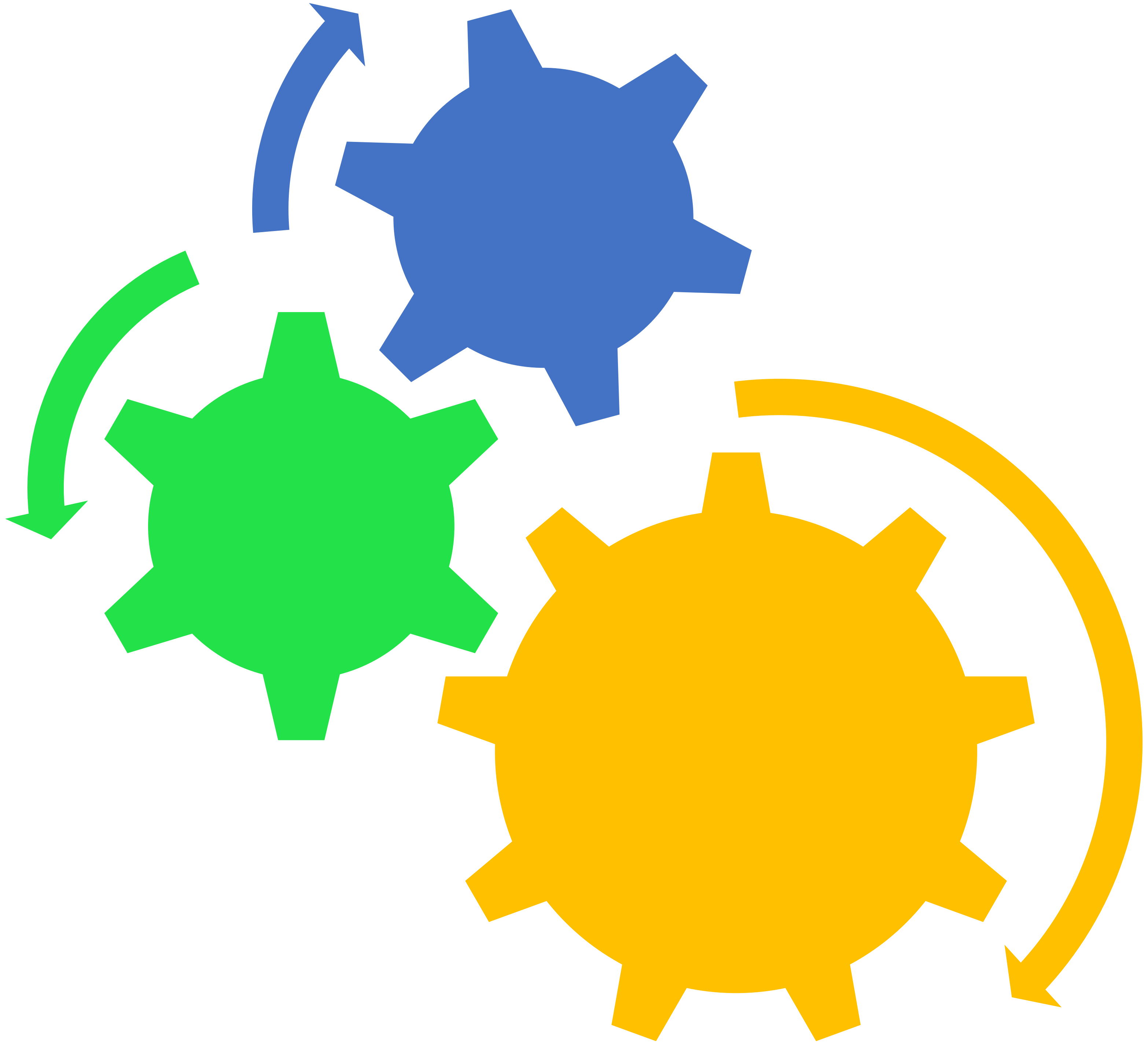


Training and Communications Plan 2020

	Q1	Q2	Q3	Q4
Mini Module Topics	Managing Suppliers	Interactions with HCPs	We Safeguard Confidential Information and IP	Annual Code of Conduct Training (Social Media, Interactions with Patients/Patient Advocacy, and Interactions with Government Officials/Payors)
External Funding Policy	OBIE OnD Live Trainings by BP (US and International) for affected employees Audience: Training required for those involved in the process (live training); awareness for all other employees (Corp Comm)			
Foundation Grants Policy	Very limited awareness (Katharine Jensen and Foundation Board)			
Medical-Commercial Interactions Policy		Vertex U. elearning training (5 min) for Medical and Commercial employees OBIE OnD Live Trainings by BP (US and International) for affected employees		
Patient Support Programs Policy			Vertex U. elearning training (5 min) for Medical, Commercial and International GAPP OBIE OnD Live Trainings by BP (US and International) for affected employees	
Social Media Policy				OBIE OnD See above (include in Annual Code training) re: Vertex U
Code of Conduct Refresh				Q2 2021
CAMPAIGN				
Integrity & Ethics Week		Brainstorming sessions begin		Late Sept - early Nov
Top 5 Quick Hits	Create and add to OBIE OnD w/ Push Notification: -Grants (create - push)	Create and add to OBIE OnD w/ Push Notification: -Med-Comm Interactions (create-push to commercial. GMA is under GMDA. Can't push.)	Create and add to OBIE OnD w/ Push Notification: -Patient Support Programs (create-push)	Revise existing content (per changes to existing policy) on OBIE OnD w/ Push Notification: -Social Media
Monthly Compliance Topic on Vnet and App (video, article, Ted Talk)-managed by individual on rotation	Select a modality to support and communicate via OBIE Vnet and App: -Grants -Managing Suppliers	Select a modality to support and communicate via OBIE Vnet and App: -Med-Comm Interactions -We Interact with Patients Appropriately	Select a modality to support and communicate via OBIE Vnet page and App: -Patient Support Programs -We Safeguard Confidential Information and IP	Select a modality to support and communicate via OBIE Vnet page and App: -Social Media - Interactions with GOs/Payors
OBIE Liaison Program (2 communications/quarter); Liaisons to also send	Breakfast/Lunch n Learn/Team Meeting with talking points on: -Grants -Managing Suppliers	Breakfast/Lunch n Learn/Team Meeting with talking points on: -Med-Comm Interactions -Interactions with HCPs	Breakfast/Lunch n Learn/Team Meeting with talking points on: -Safeguarding Confidential Information and IP -Patient Support Programs	Breakfast/Team Meeting with talking points on: -Code of Conduct Annual Training I&E Week Support
Quick Hit Compliance Topic Reminders - Template Emails	Aligns to the above schedule but comes from the BPs	Aligns to the above schedule but comes from the BPs	Aligns to the above schedule but comes from the BPs	Aligns to the above schedule but comes from the BPs
Adapting "Still Keeping it REAL in 2020" to broader audience	Display and announce REAL mural on 15th floor			

Diagnostic Needs Analysis: Factors that Drive Behavior

- Incentives and consequences
- Workplace barriers
- Personal motivation
- Clarity/lack of clarity on policy or procedure
- Communication of expectations
- Tools and resources available
- Knowledge and skill level

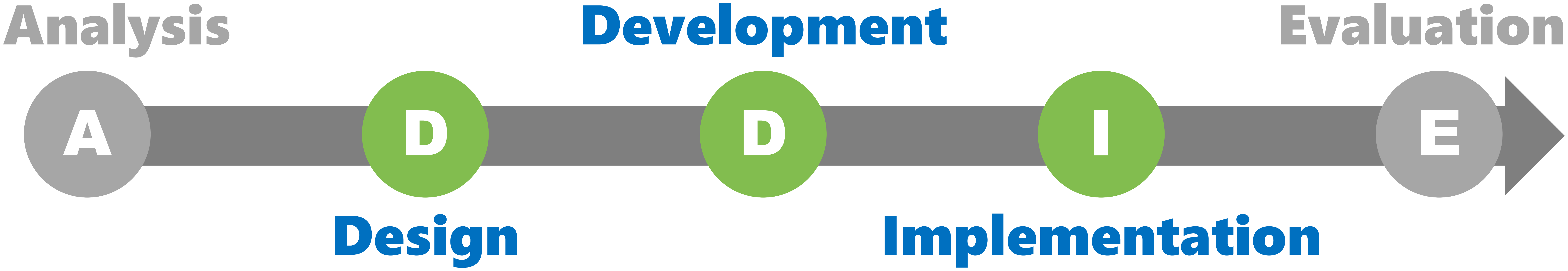


Diagnostic Needs Analysis: Is it a training issue?

Does the target audience have the **knowledge** and **skill** to perform?

If they do, it is not a training need.

The ADDIE Model



Training Guidance from the DOJ

- Needs analysis (Who and what should be trained?)
- **Tailoring by role (functional and level)**
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TAILOR BY ROLE

Sales Rep Position Risk

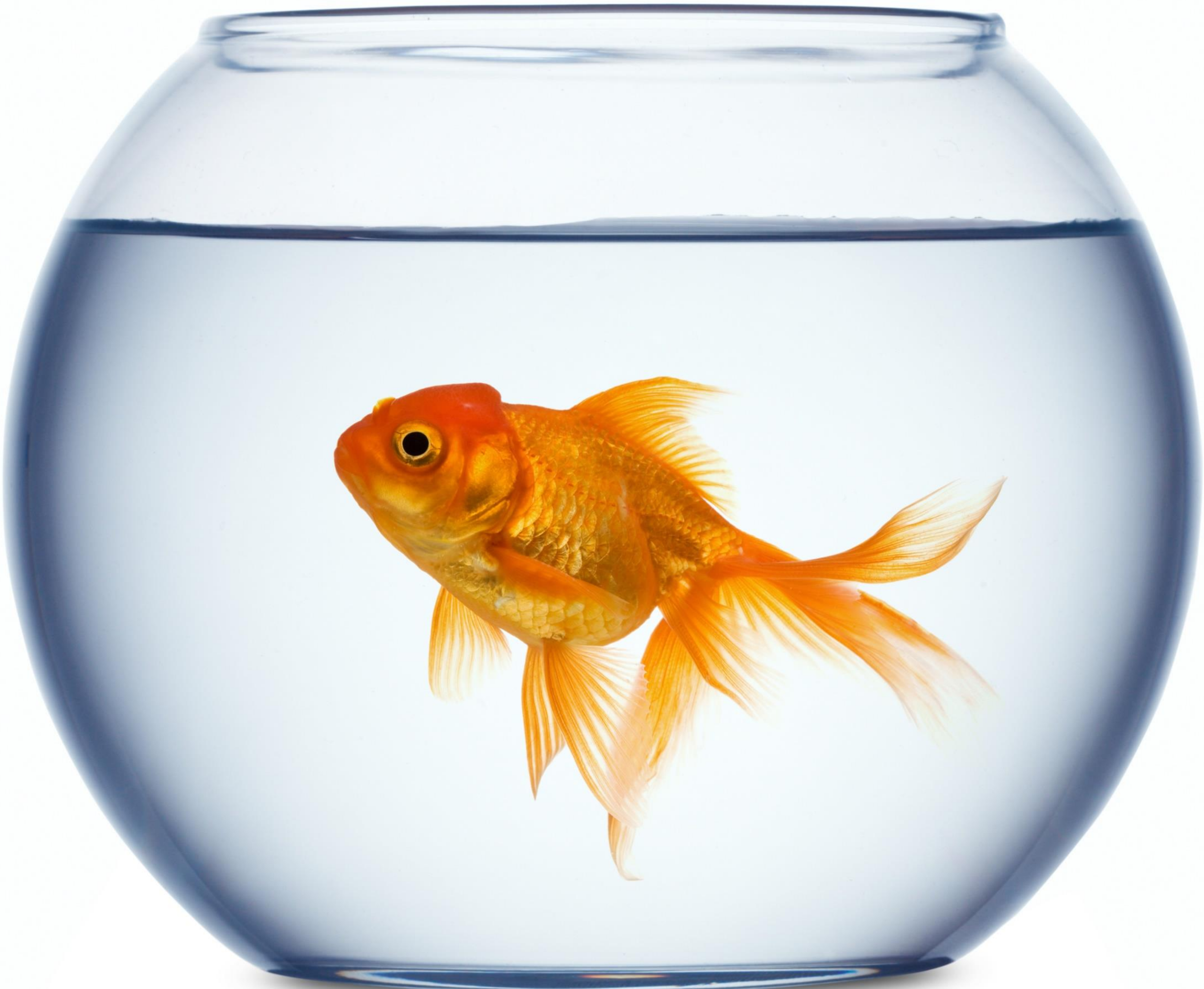
RESPONSIBILITIES
Develops business plan for assigned territory that is consistent with sales plans, strategies and objectives.
Conducts quality sales presentations to all targeted customers.
Understands and demonstrates targeting principles.
Leverages sample programs, literature and other items to ensure physician awareness of products.
Differentiates products from all competitors and responds to customer issues confidentially and appropriately.

Sales Rep Position: Lower Risk

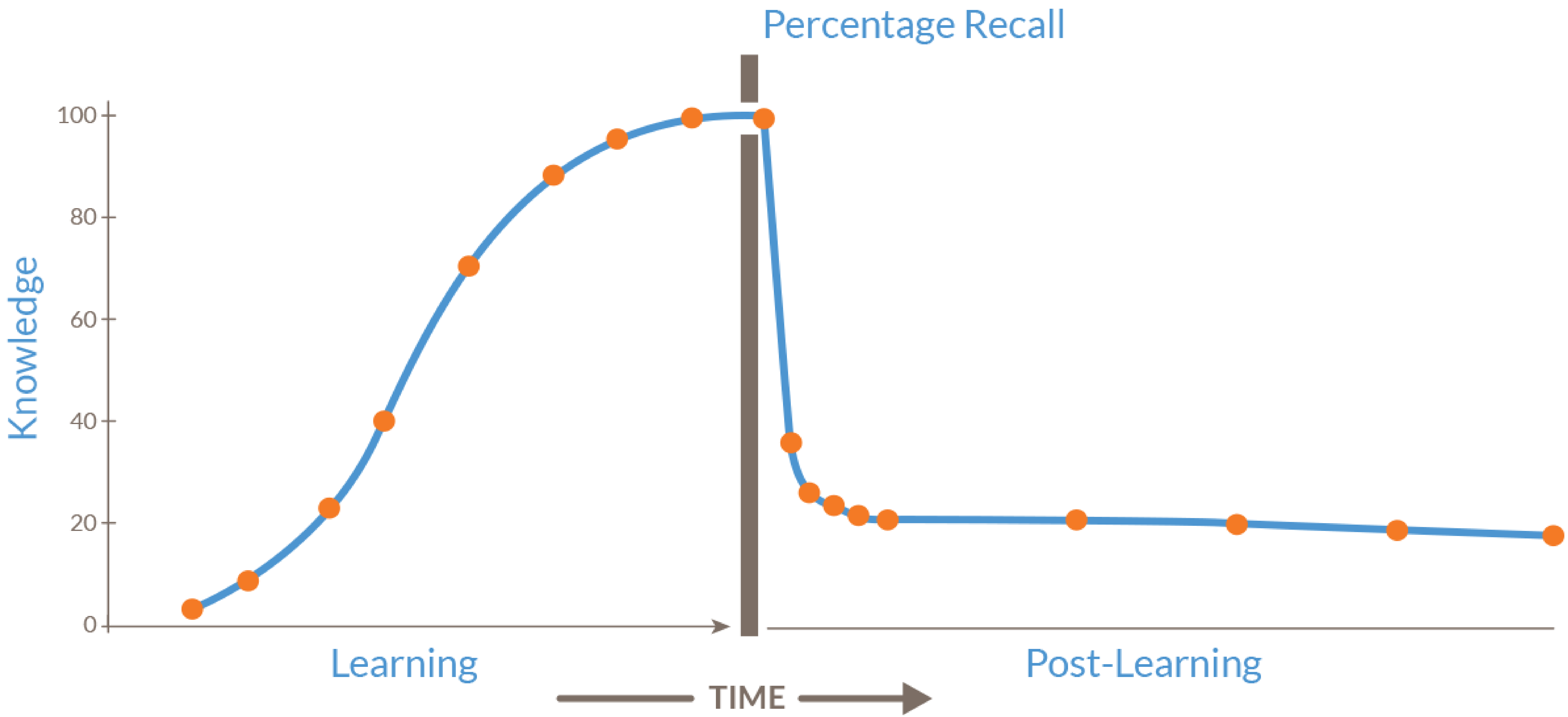
RESPONSIBILITIES
Develops business plan for assigned territory that is consistent with sales plans, strategies and objectives.
Conducts quality sales presentations to all targeted customers.
Understands and demonstrates targeting principles.
Leverages sample programs, literature and other items to ensure physician awareness of products.
Differentiates products from all competitors and responds to customer issues confidentially and appropriately.

Sales Rep Position: Higher Risk

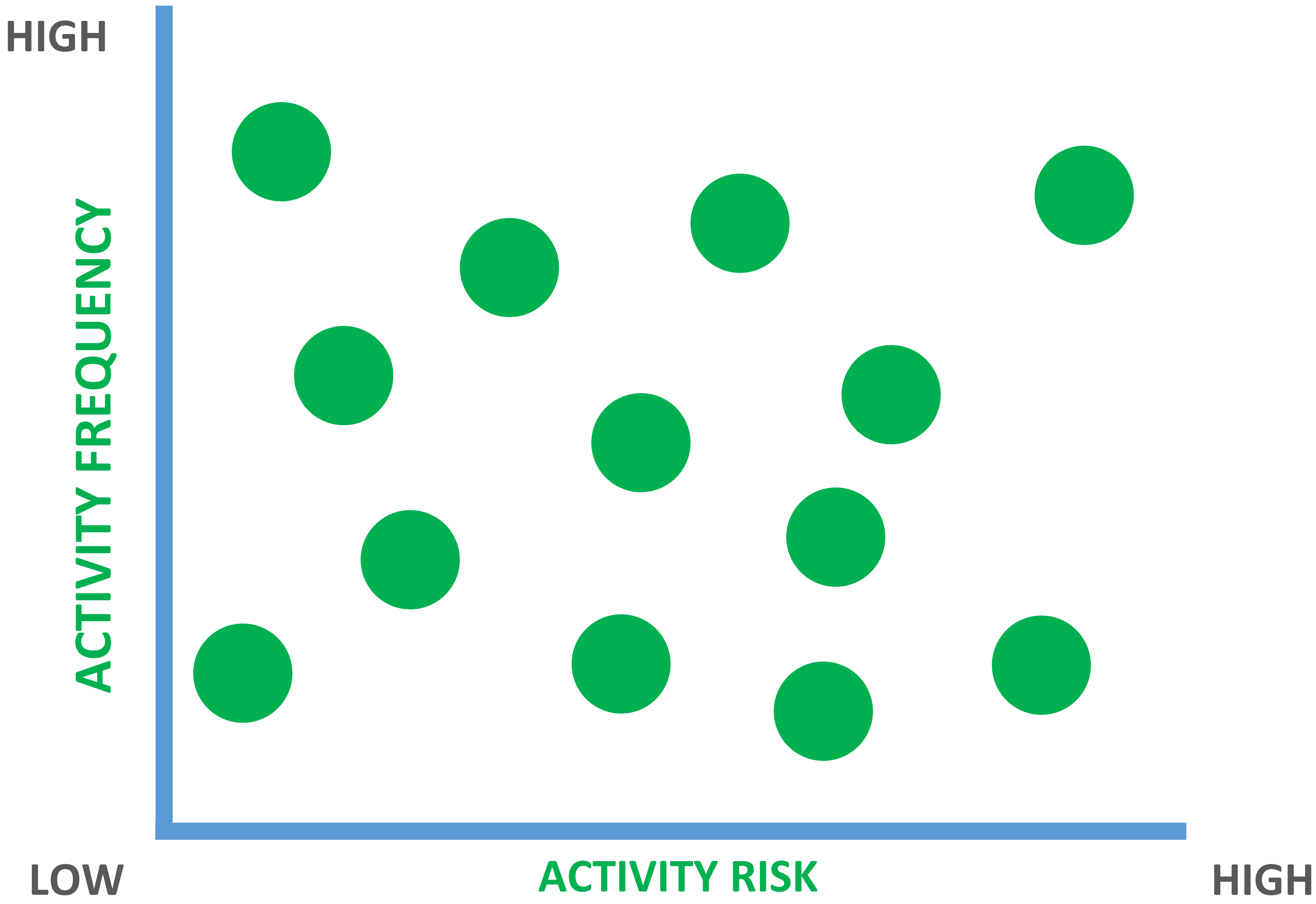
RESPONSIBILITIES
Develops business plan for assigned territory that is consistent with sales plans, strategies and objectives.
Conducts quality sales presentations to all targeted customers.
Understands and demonstrates targeting principles.
Leverages sample programs, literature and other items to ensure physician awareness of products.
Differentiates products from all competitors and responds to customer issues confidentially and appropriately.



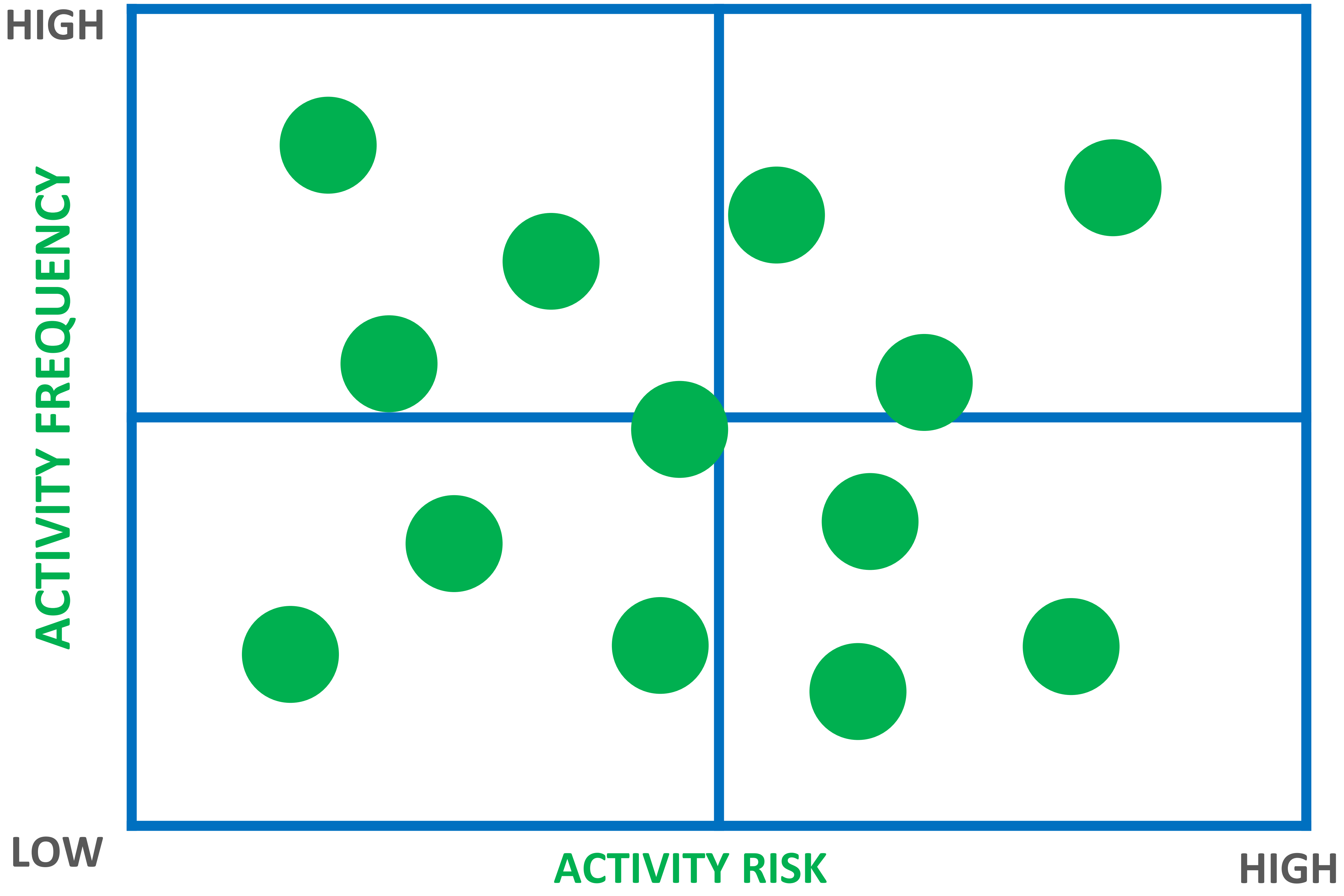
Ebbinghaus Forgetting Curve



Risk-Frequency Framework

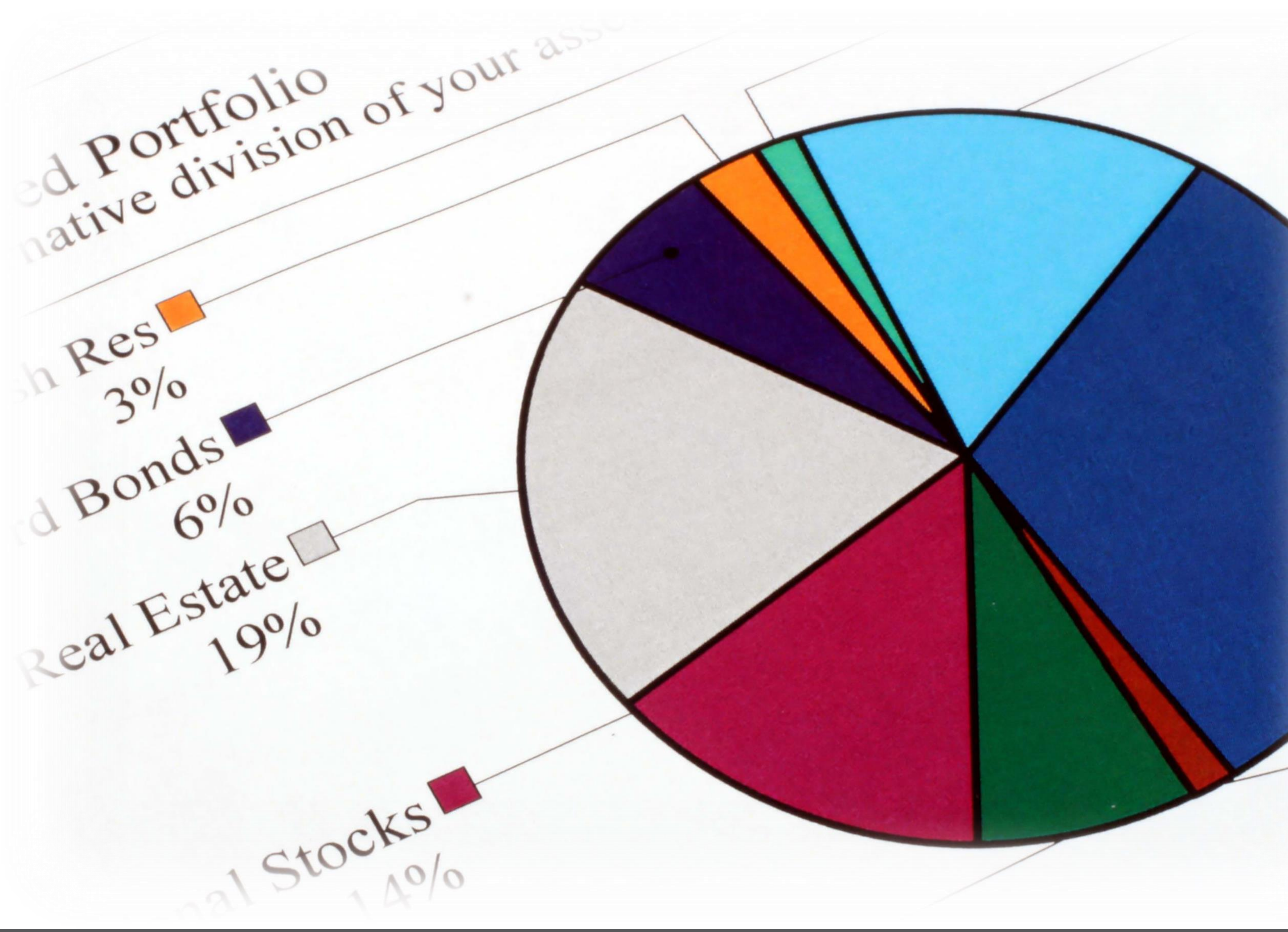


Risk-Frequency Framework



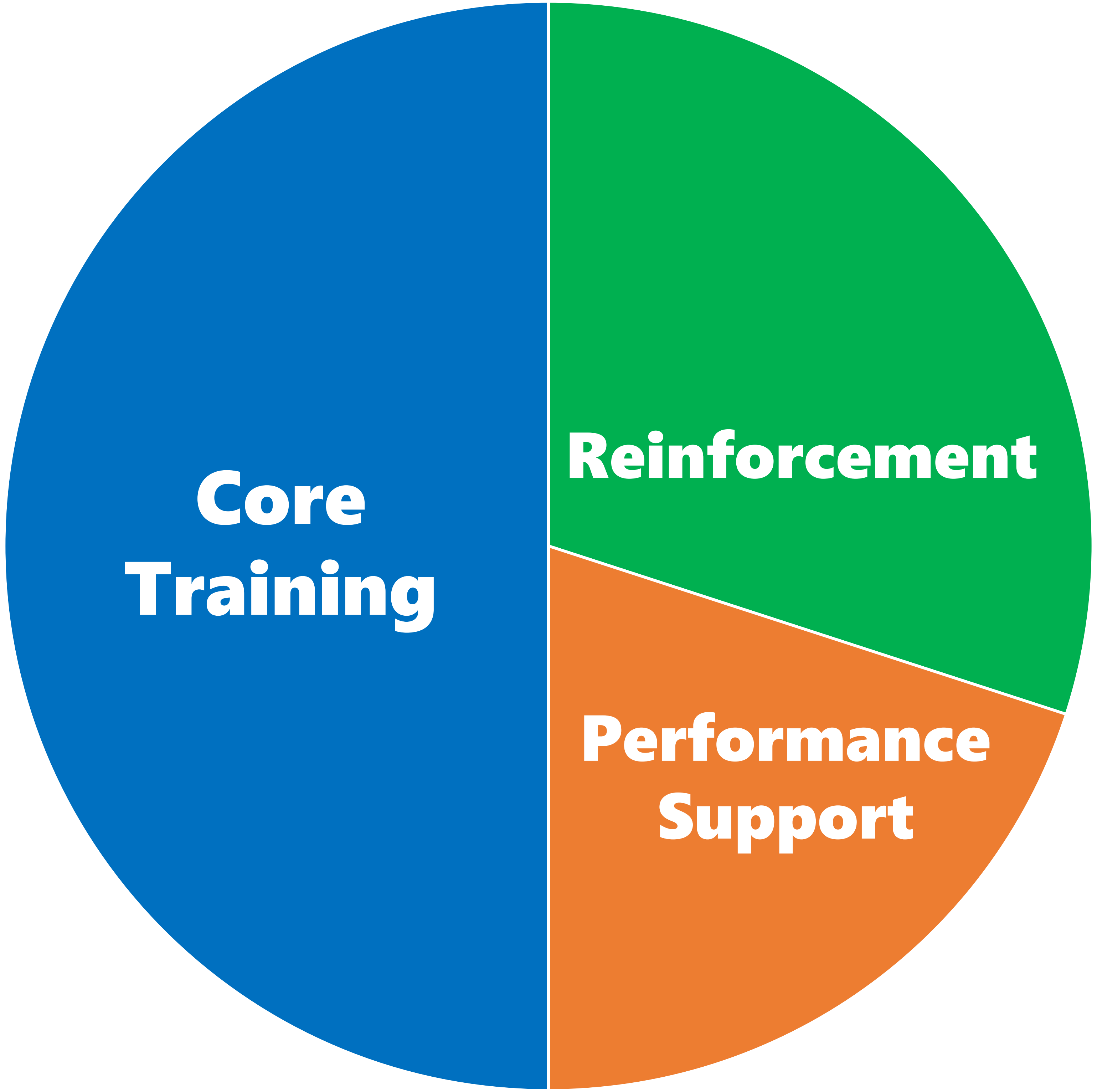
ACTIVITY FREQUENCY / ACTIVITY RISK	LOW	HIGH
HIGH	• Read & sign • Job Aids • Online reference	• Read & sign • Foundational eLearning • Quick reference • Live training • Coaching
LOW	• Read & Sign • Job Aids • Coaching • Online reference • Helpline	• Read & Sign • Foundational eLearning • Reinforcement eLearning • Job Aids • Quick reference • Live training • Coaching

Training Portfolio Model



Foundational Guidance

eLearning
Live Training
Workshops
Read-and-sign
Assessments



Risk-focused Training

Games
Microlearning
Digital Banners
Emails
Video
Assessments

Just-in-time Support

Infographics
Reference Guides/App
Video

Training Design Guidance

- Make it role-specific
- Focus on objectives
- Remember KISS (“Keep it short and simple.”)
- Use plain language
- Include scenarios/case studies
- Supply to real-world examples
- Consider the “point-of-need”
- Include contact information in all training
- Translate wherever necessary

Case Study:
Vertex Code of Conduct Training

Vertex Code of Conduct Training: Before

Vertex Code of Conduct Training: After

Goal: Transform 3-part, 215-minute training using modern approaches

CORE

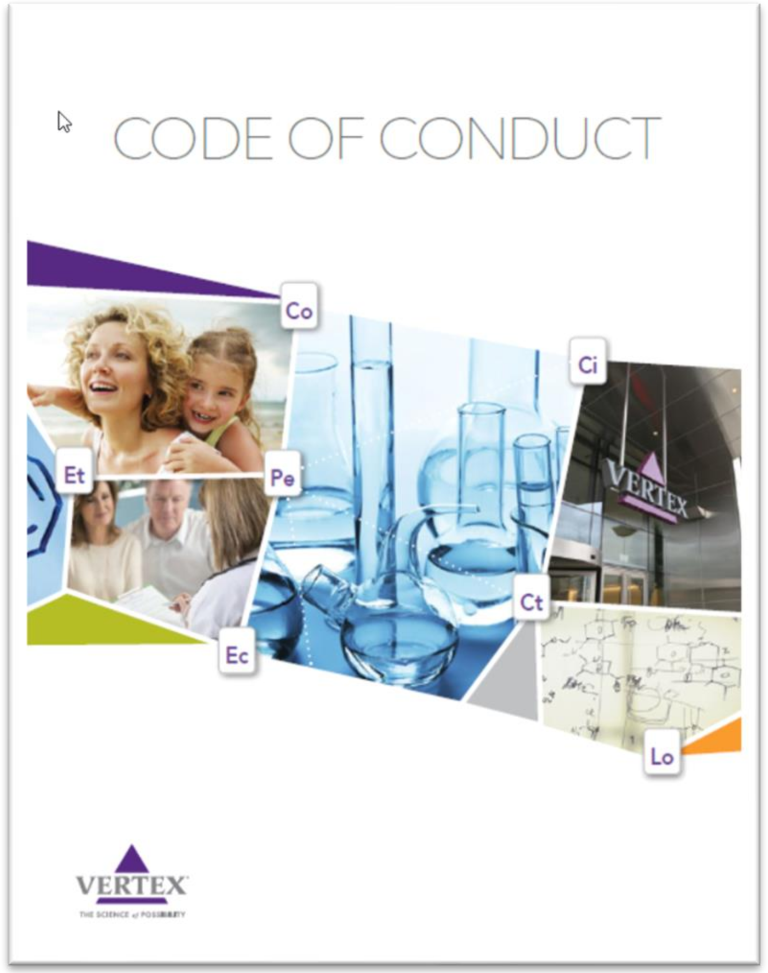
- CEO video for New Hires
- Read & Understand
- Link to PDF document

REINFORCEMENT

- Broke up the 21 parts - library
- Individual 5-minute videos
- Deploy topics as needed
- Code of Conduct annual refresher

PERFORMANCE SUPPORT

- Infographics in OBIE OnDemand App
- OBIE@vrtx.com
- OBIE Liaisons Intranet



Management and Leadership Training

Senior Leader (VP+)

Focus: Managing risk; strategic execution; risk tolerance

- Culture and tone-setting (R.E.A.L framework)
- Competition
- Cross-border interactions
- Third party risk
- Deceptive practices

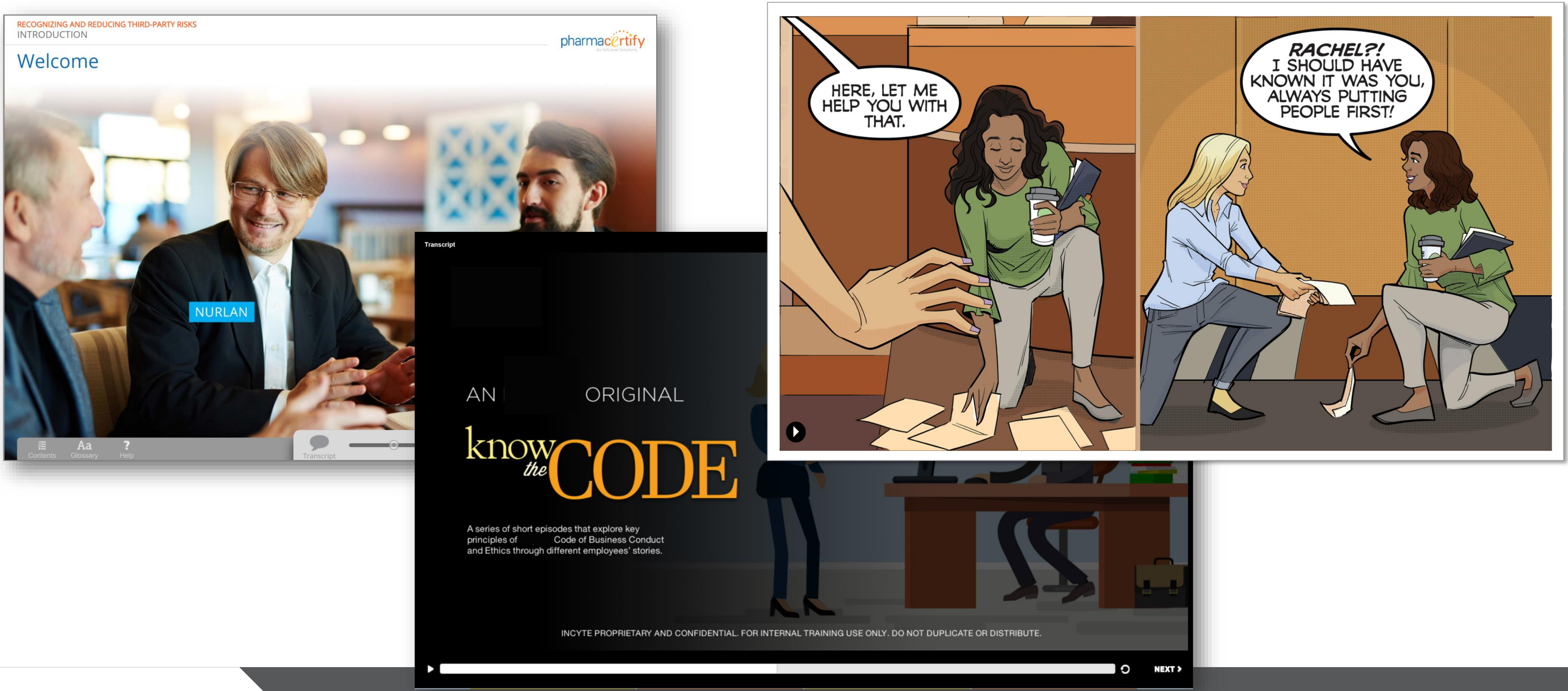
Core Leader

Focus: Understanding risk; tactical execution

- Auditing and monitoring
- Encouraging speak-up culture
- Compliance coaching for their team
- Applying R.E.A.L framework

Samples

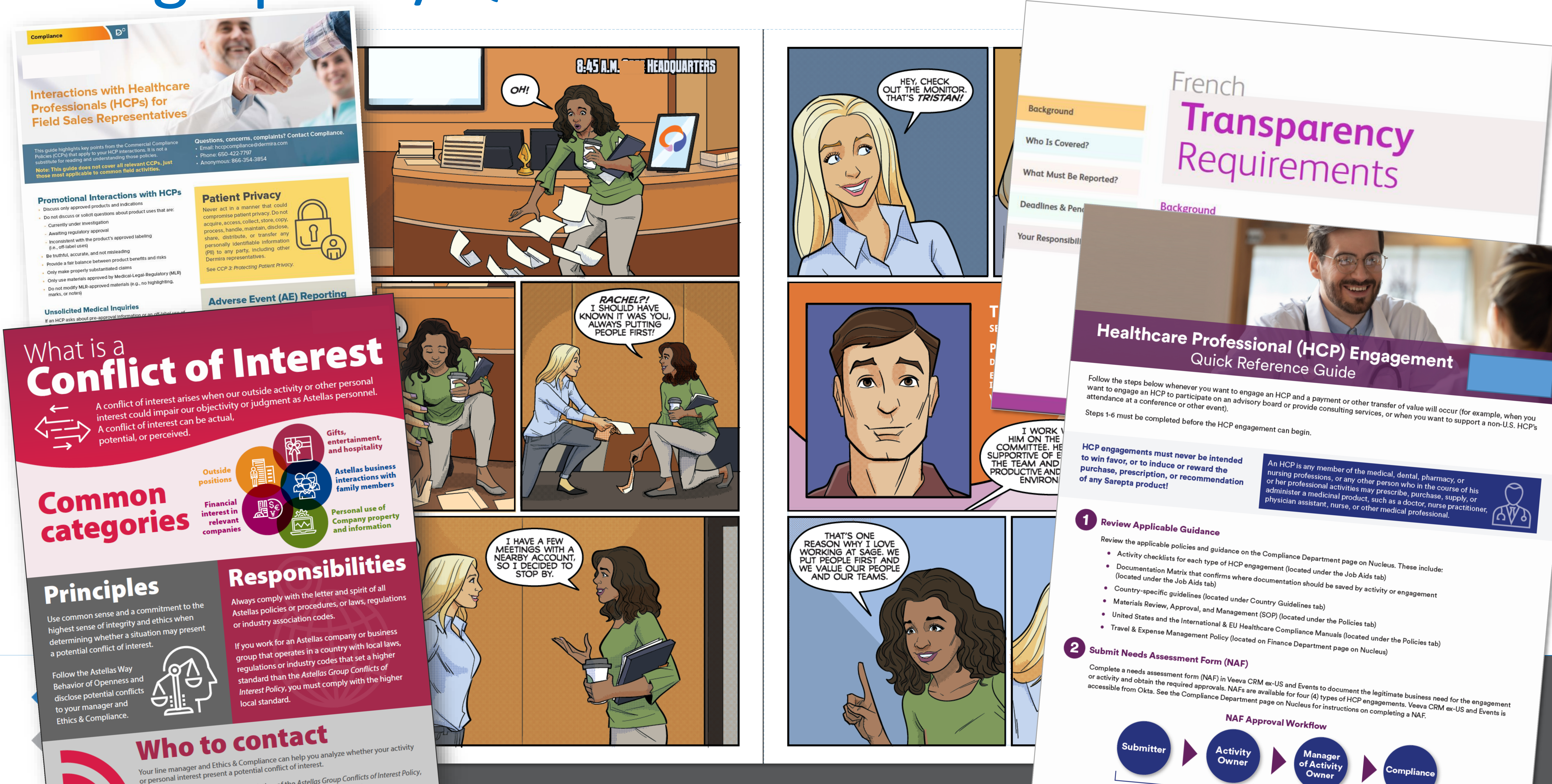
Microlearning Reinforcement



Games

Score: 400
SCRAMBLE
1 / 6
How often do cyber security hack attacks occur?
THE COMPLIANCE CHALLENGE
Interactions with HCPs
Promotional Speaker Programs
Gifts, Meals & Entertainment
Our Policies
Potpourri
Potpourri for 1000
A The meal could be reportable under the Physician Payments Sunshine Act
B Receipts should be provided in T&E with every meal
C All attendees and no-shows should be accounted for when submitting expenses in T&E
D All of the above
Submit
Exit
The Challenge
Which of the answers about providing meals to HCPs is correct?
Team John
Team Jenn
Team Bob
0
0
0
That's fine. In that case, what works for you in your heart patient wing?
But I think our drug is something Dr. Raymond would really be interested in
Compliance Reality Challenge
ComplianceRealityChallenge
COMPLIANCE MYSTERY: Timeline
Select each item on the timeline below to reveal a clue that will help you solve the mystery of what occurred. You may open and close each clue as many times as needed, but you must open all eight clues prior to continuing. Select Next to continue the Mystery Challenge.
OCTOBER 13 2016 Voicemail Transcript: Manager to BAM
OCTOBER 15 2016 Website screen: Product Theater details
OCTOBER 15 2016 Calendar screen: Conference events BAM plans to attend
OCTOBER 15 2016 Notes: BAM's handwritten notes from Poster Session
OCTOBER 15 2016 Printed list: Dinner attendees
OCTOBER 15 2016 Business Card: BAM's Business Card
OCTOBER 18 2016 Transcript: Call to gComm
OCTOBER 19 2016 Text Message Transcript: Marketer to BAM
Back
Next

Infographics/Quick Reference



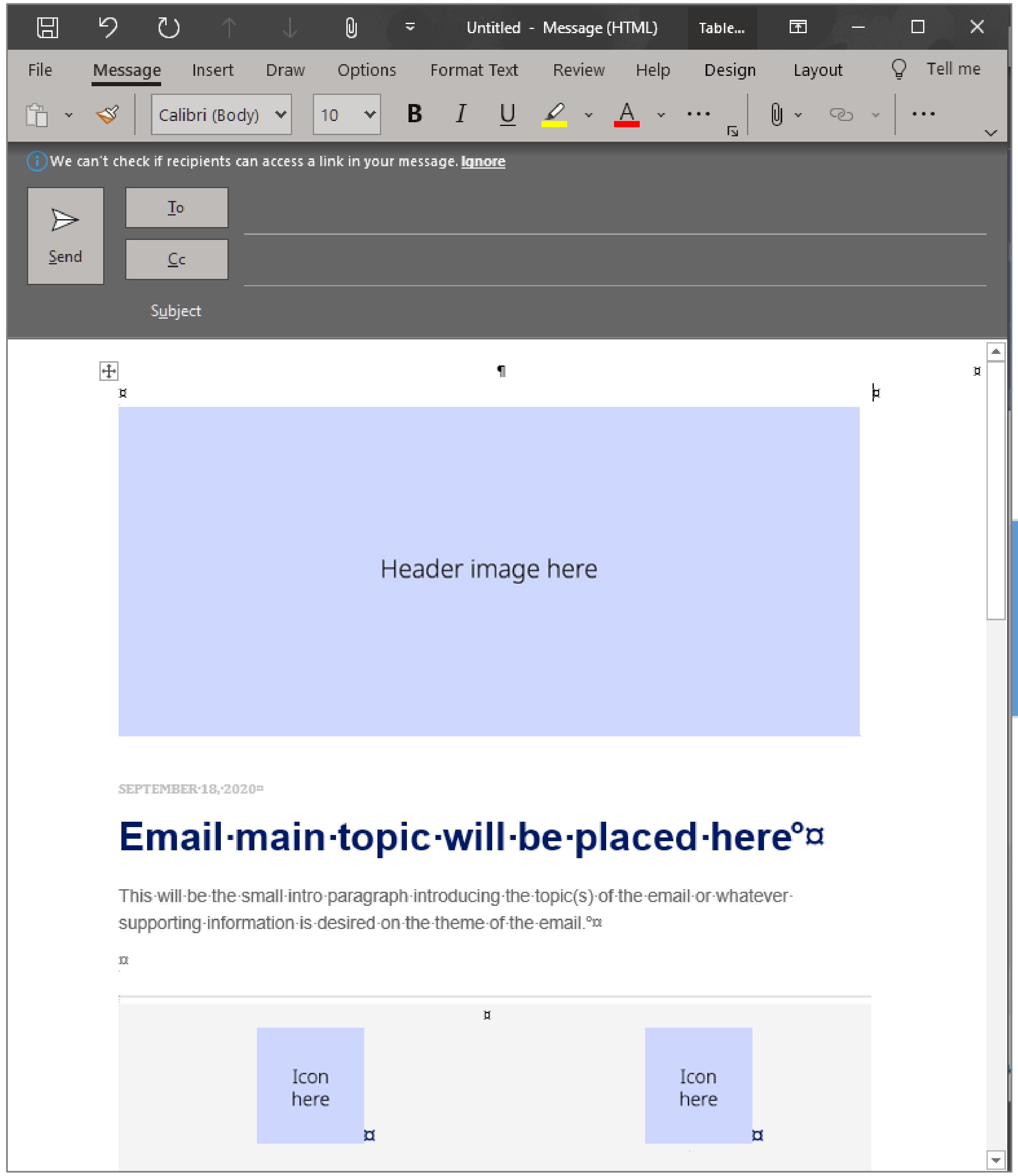
Posters

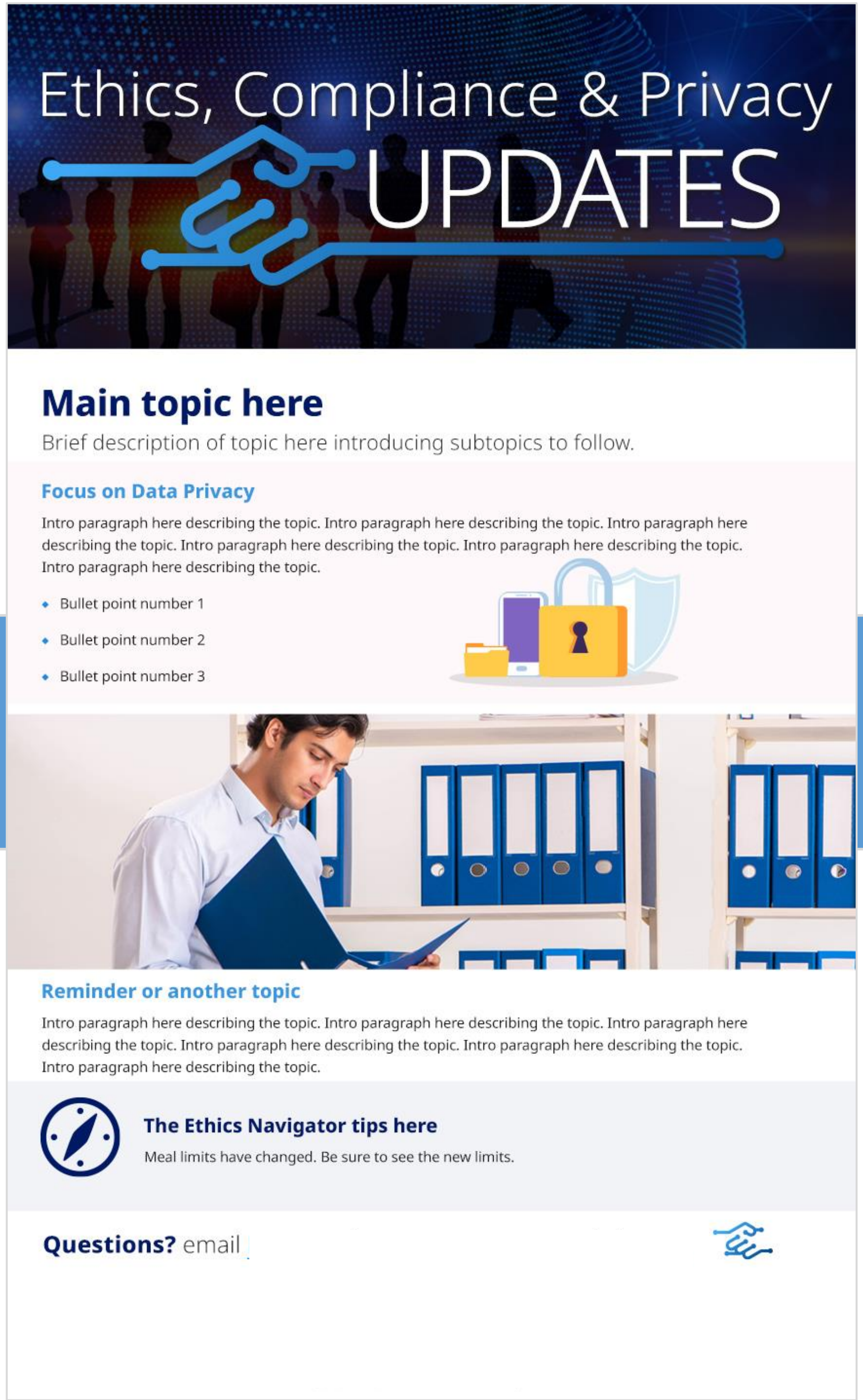
#DORIGHT
PUT PEOPLE FIRST
WE VALUE OUR PEOPLE AND OUR TEAMS.
ALWAYS TREAT EACH OTHER WITH RESPECT, HAVE OPEN AND HONEST CONVERSATIONS IN THE MOMENT, VALUE DIVERSITY AND INCLUSIVITY, AND MAINTAIN THE HIGHEST STANDARDS OF INTEGRITY.

Video

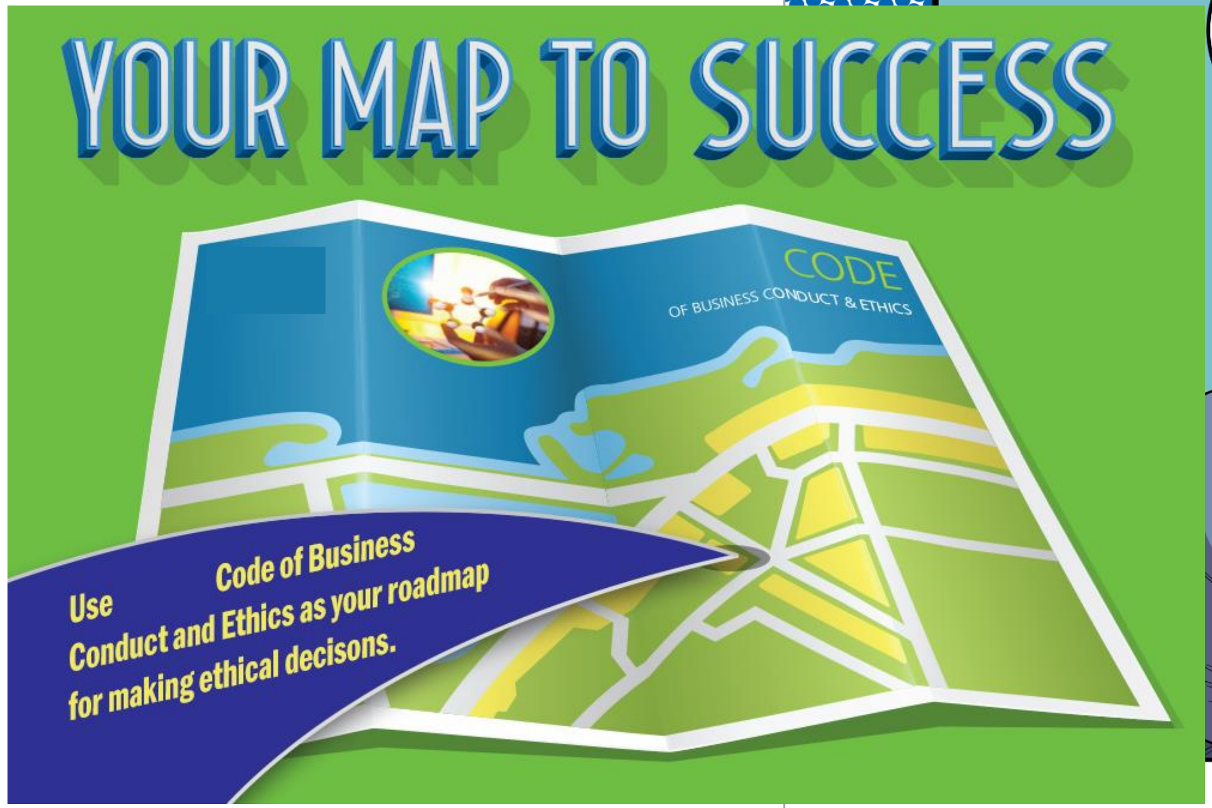

The California Consumer Privacy Act
Compliance Minutes
Think Before You Share
For internal use only.
0:07:00
DORIGHT
Our mission of saving and improving lives...
0:00:02
0:01:02
GOVERNMENT OR PUBLIC AFFAIRS
LEGAL
CORPORATE COMPLIANCE

HTML Email Blasts





Digital Banners



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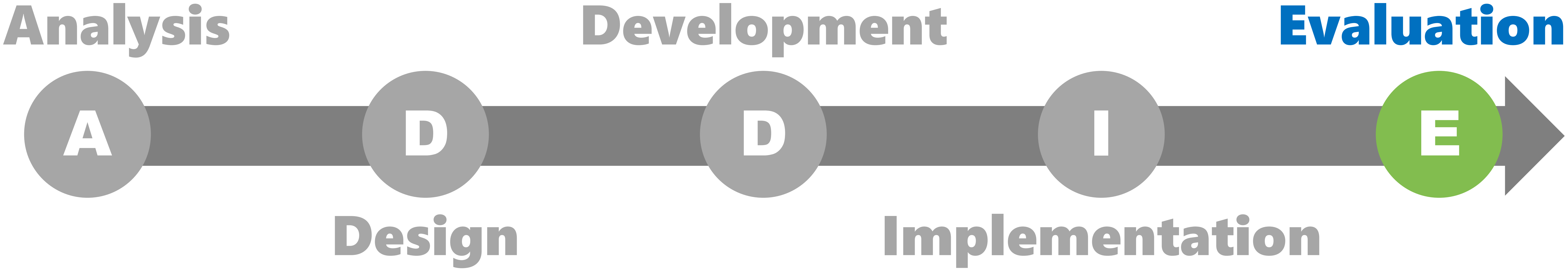

Evaluation

The Kirkpatrick Model

Possible Evaluation Approaches

Approach	Level 1	Level 2	Level 3	Level 4
Digital surveys	x			
Focus groups	x	x		
Formal assessment		x		
Baseline and post-training monitoring		x	x	
Helpline/hotline metrics			x	x
Compliance email metrics			x	x

Digital Surveys

GUIDANCE	BENEFITS	CHALLENGES
▪ 7-10 questions ▪ Make questions learner-centered using "I", "me", and "my" statements ▪ Ask perceptions of knowledge gains ▪ Be specific ▪ Use consistent and specific rating scale ▪ Allow open-ended comments as follow up for specific questions ▪ Position as an approach to help target future compliance training	▪ Efficient to produce and administer ▪ Enables metrics ▪ Anonymity	▪ Perceptions only ▪ Subjective measure ▪ Response rate

Survey Question Examples

Question	Strongly disagree	Disagree	Neutral	Agree	Strongly agree
I will be able to apply the skills and knowledge learned during this training in my role.	1	2	3	4	5
This course increased my knowledge of the policies in the Business Conduct Manual.	1	2	3	4	5
This course increased my knowledge of the principles that apply to interactions involving Commercial and non-Commercial personnel.	1	2	3	4	5

Focus Groups

GUIDANCE	BENEFITS	CHALLENGES
▪ Ask pre- and post-training levels perceptions ▪ Be topic-specific ▪ Use rating scale, if practical ▪ Possible include informal quizzes on subject matter (can use gaming approach) ▪ Ask follow up questions ▪ Position as an approach to help target future compliance training	▪ Natural give-and-take ▪ Opportunity for questions and discussion (two-way) ▪ Relatively easy to implement	▪ Subjective perceptions only ▪ Not anonymous ▪ Subject to group think

Focus Group Questions Example

General Questions

- What was the most valuable information you learned from the training?
- How would you recommend improving the training?
- What topics or situations would you like to see addressed in future training?

Content-specific Questions

- When is it permissible to make comparative statements about products?
- An HCP's office asks you to contact someone at EASE to find out the status of a patient's request.
  - Are you allowed to do that?
    - Why or why not?
- Exelixis' Twitter account tweets a picture of Exelixis employees participating in a volunteer event.
  - Can you retweet that post on your personal Twitter account?
    - Why or why not?

Assessment

GUIDANCE	BENEFITS	CHALLENGES
▪ Best using pre- and post-training assessments ▪ Validate questions, if possible ▪ Administer outside of LMS to enable question-level understanding of results ▪ Administer one week+ after training ▪ Position as an approach to help target future compliance training	▪ Efficient to produce and administer ▪ Provides an objective measure	▪ There may be trepidation on the part of learners ▪ Only measures long-term knowledge retention if issued repeatedly over time ▪ Possibility of answer sharing, a.k.a. cheating

Monitoring

GUIDANCE	BENEFITS	CHALLENGES
▪ Train observers/monitors ▪ Best to incorporate naturally, e.g., into ride-alongs ▪ Ensure common understanding of evaluation rubric(s) across observers ▪ Position as an approach to help target future compliance training	▪ Provides a clearer view of behavior change ▪ Opportunity for questions and discussion (two-way)	▪ Need to avoid "compliance cop" perception ▪ Must have solid and well-understood rubric ▪ Time consuming for observers ▪ Possibility of "cheating"

Q&A

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