

# **Calibrate Your Compliance Training**

## **A Practical Framework**

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**Calibrate Your Compliance Training: A Practical Framework**

**June 15, 2021**

U.S. Department of Justice  
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."*

Introduction

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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:

# **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



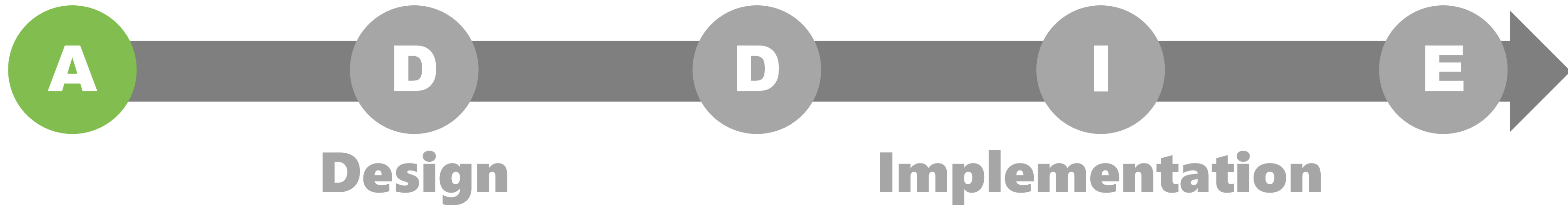


# The ADDIE Model

**Analysis**

**Development**

**Evaluation**



# 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

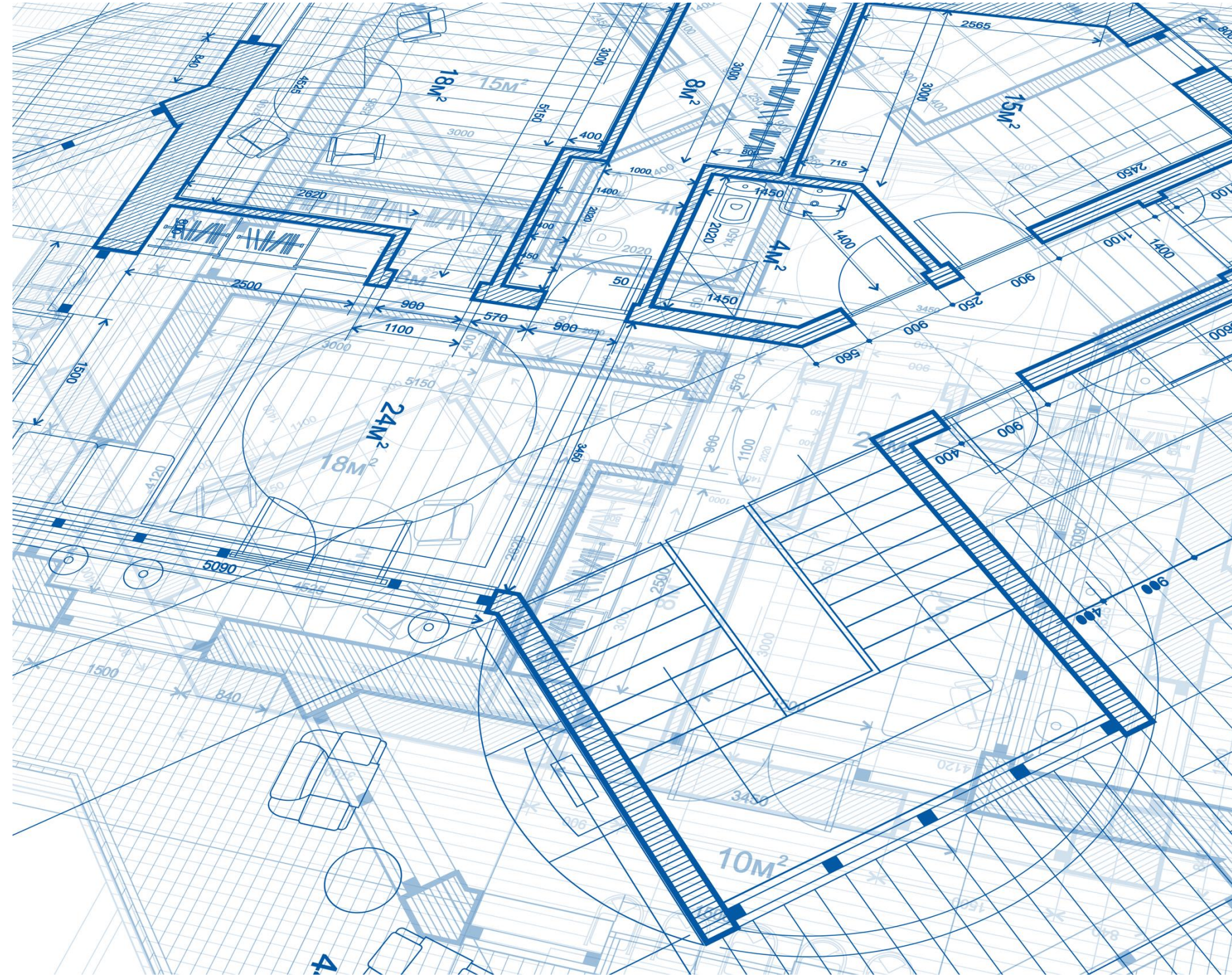
# Training Needs Analysis: Inputs

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

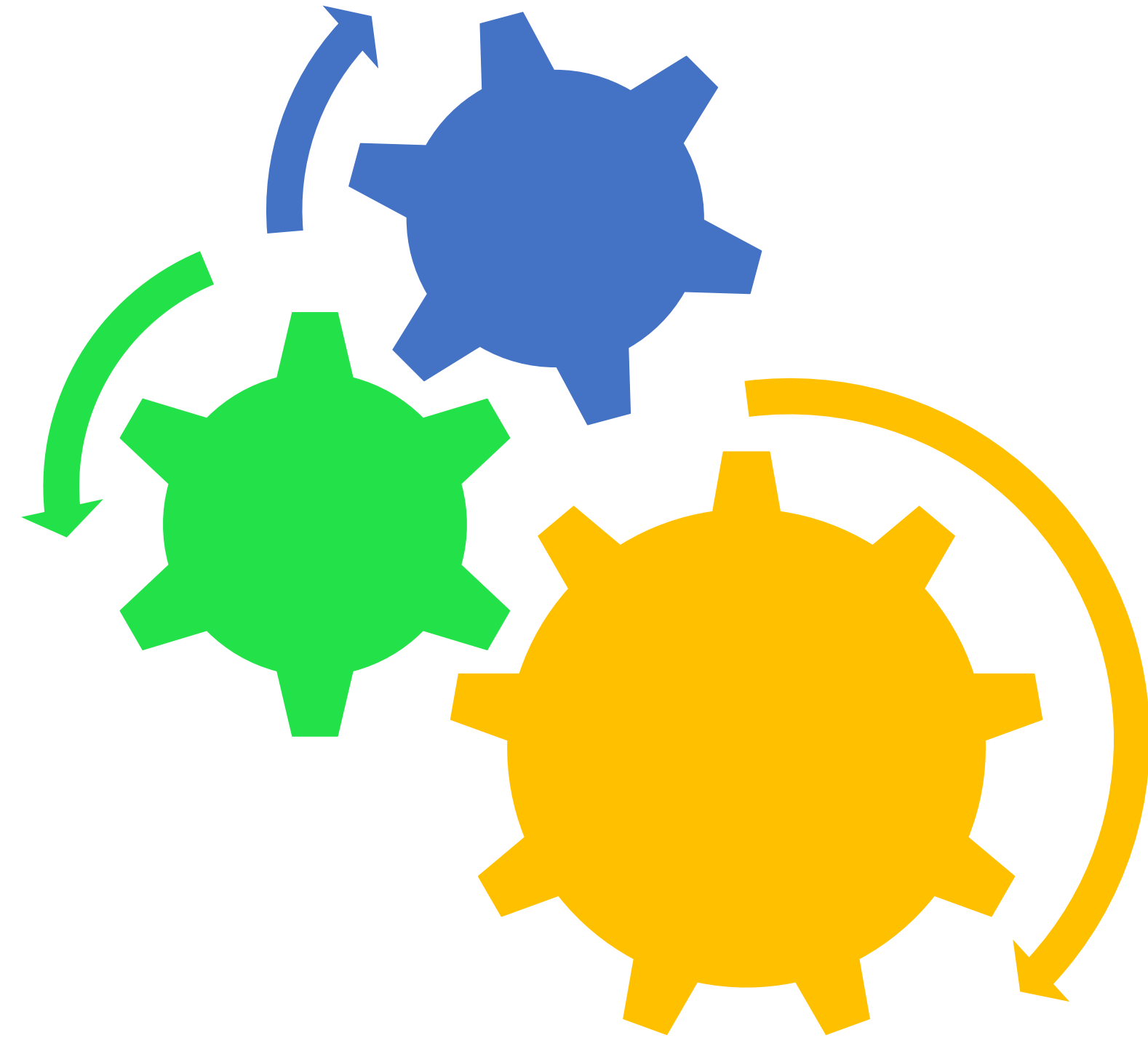




Training and Communications Plan 2020					
		Q1	Q2	Q3	Q4
	Mini Module Topics	Managing Suppliers	Interactions with HCPs	We Safeguard Confidential Information and IP	Annual Code of Conduct Training (Social Media, Interactions with Patients/Patient Advocacy, and Interactions with Government Officials/Payers)
	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/Payers
	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)**
- **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)



A person is shown from the chest up, wearing a vibrant green button-down shirt under a dark grey or black blazer. The blazer is open, and the person's hands are placed on the lapels, one near the bottom button and the other slightly higher. The background is a neutral, light-colored wall. A semi-transparent grey banner with the text "TAILOR BY ROLE" is centered across the middle of the image.

# 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.**

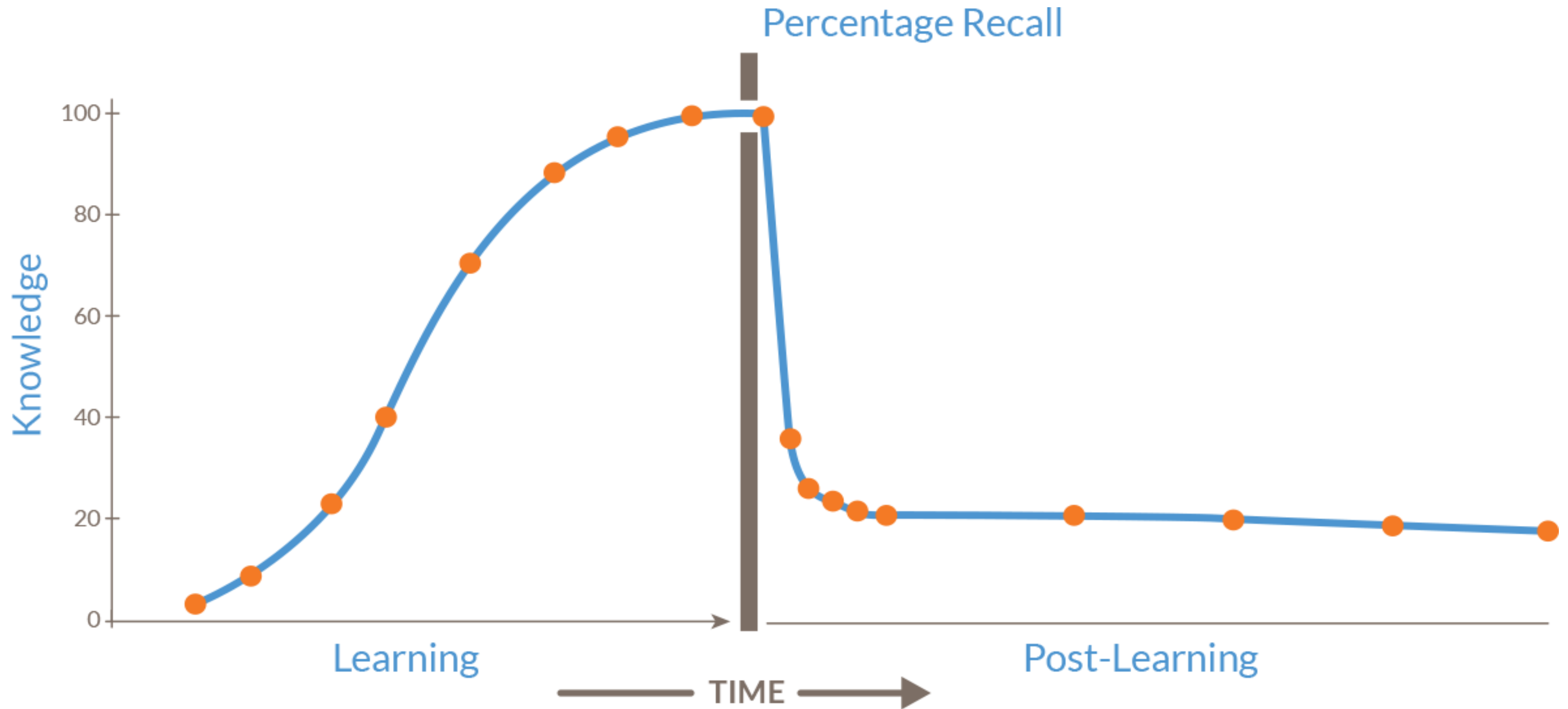
Understands and demonstrates targeting principles.

**Leverages sample programs, literature and other items to ensure physician awareness of products.**

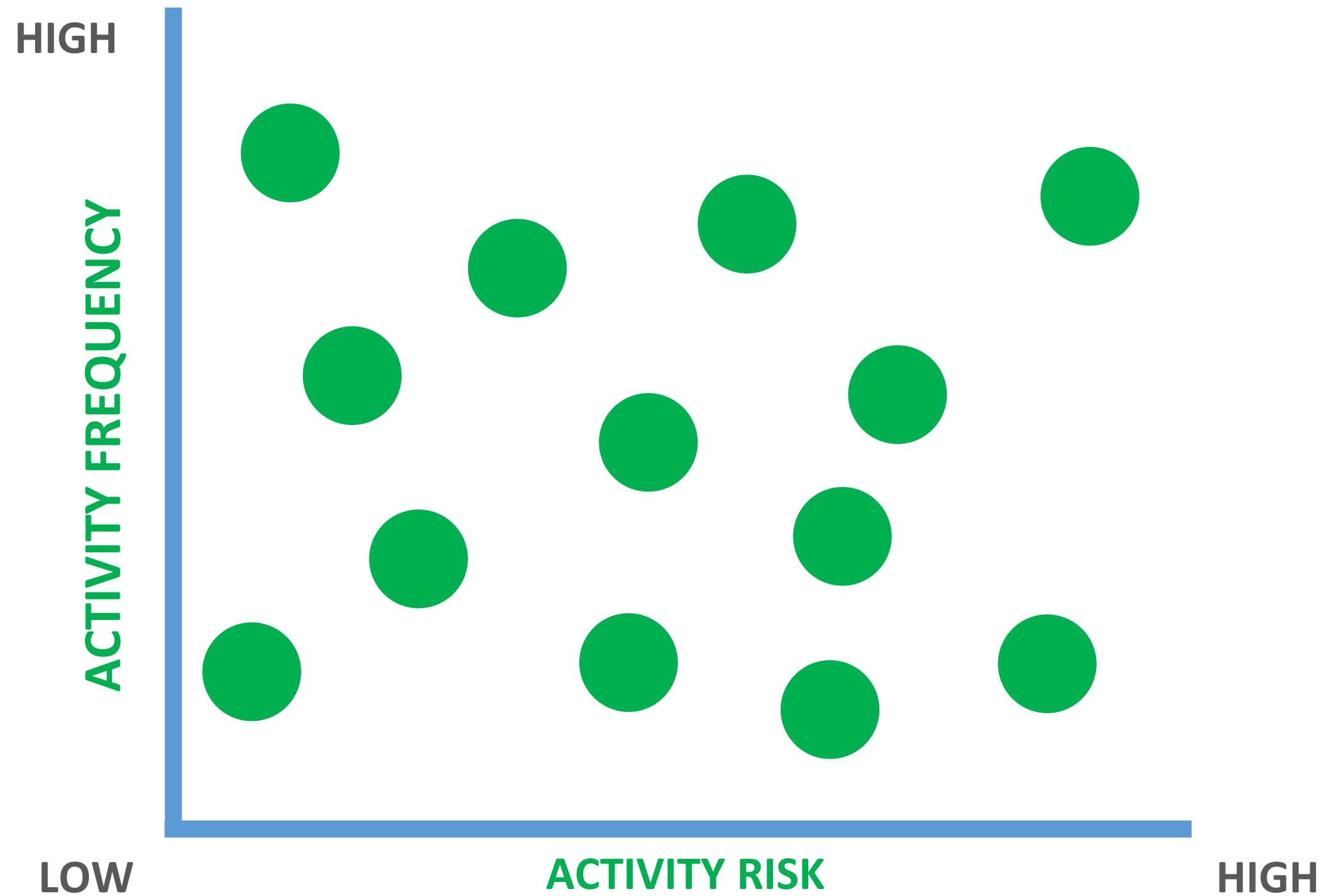
**Differentiates products from all competitors and responds to customer issues confidentially and appropriately.**



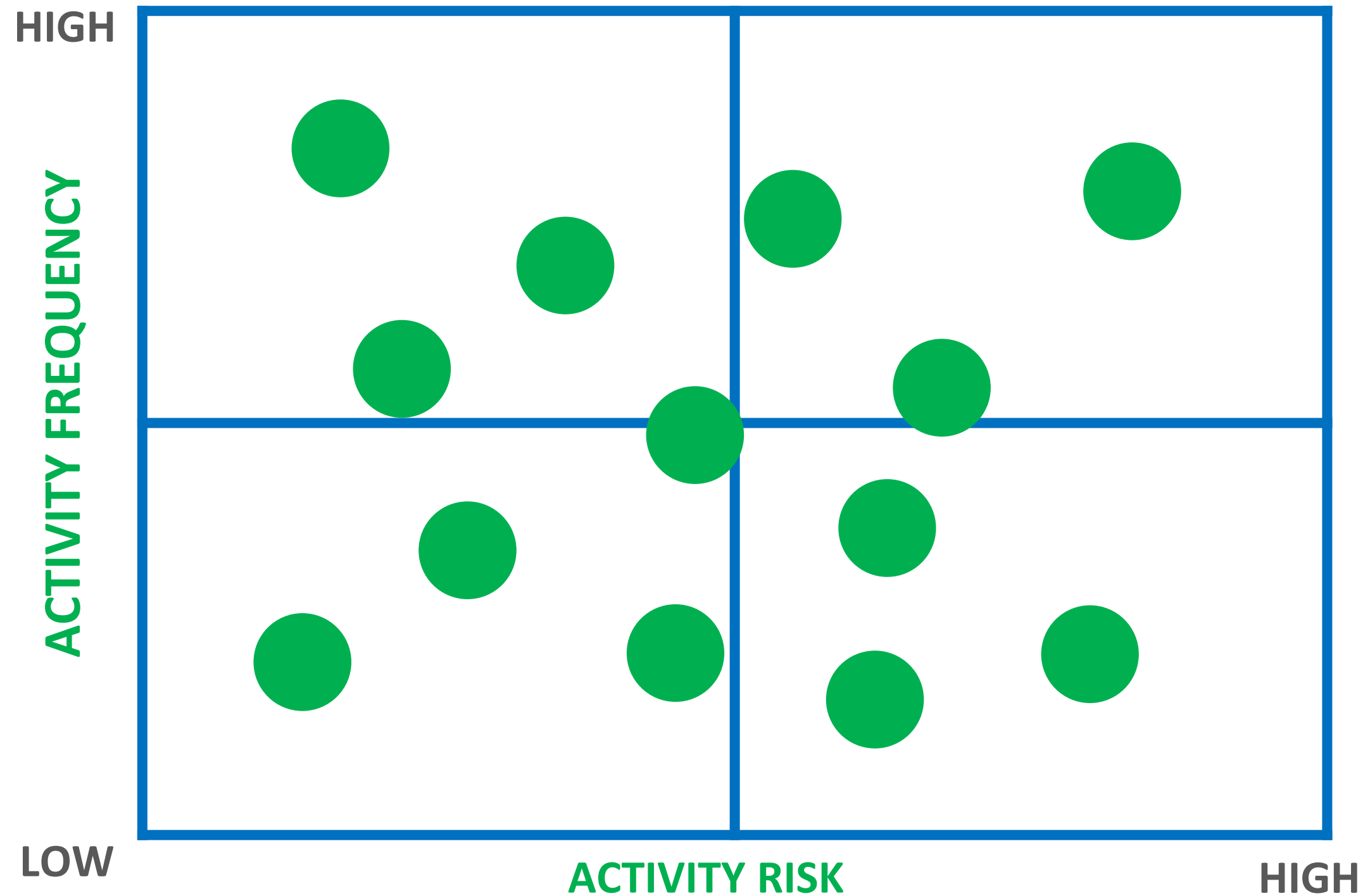
# Ebbinghaus Forgetting Curve



# Risk-Frequency Framework



# Risk-Frequency Framework



**HIGH**

**ACTIVITY FREQUENCY**

**LOW**

- **Read & sign**
- **Job Aids**
- **Online reference**

- **Read & Sign**
- **Job Aids**
- **Coaching**
- **Online reference**
- **Helpline**

- **Read & sign**
- **Foundational eLearning**
- **Quick reference**
- **Live training**
- **Coaching**

- **Read & Sign**
- **Foundational eLearning**
- **Reinforcement eLearning**
- **Job Aids**
- **Quick reference**
- **Live training**
- **Coaching**

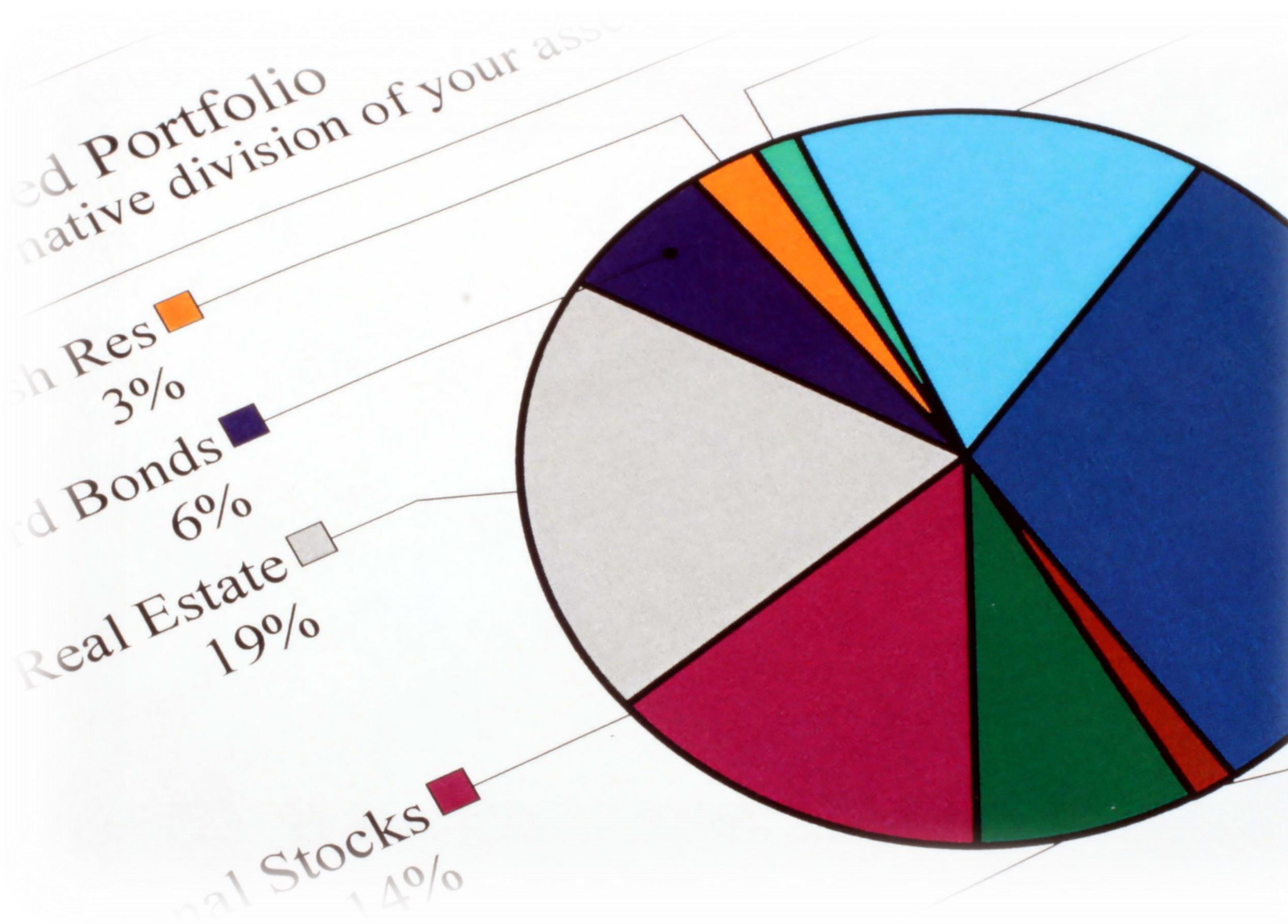
**LOW**

**ACTIVITY RISK**

**HIGH**

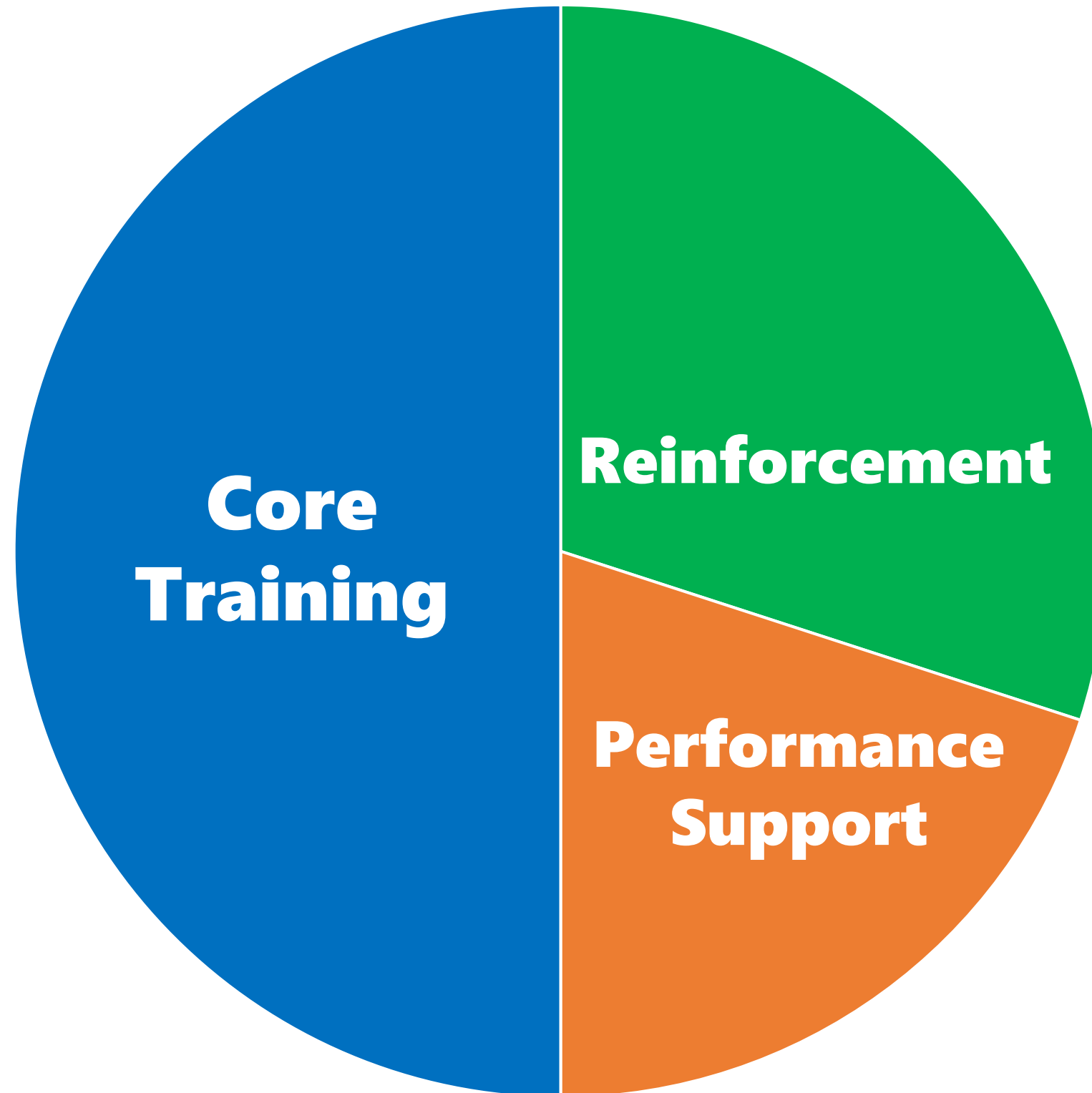


# Training Portfolio Model



## 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

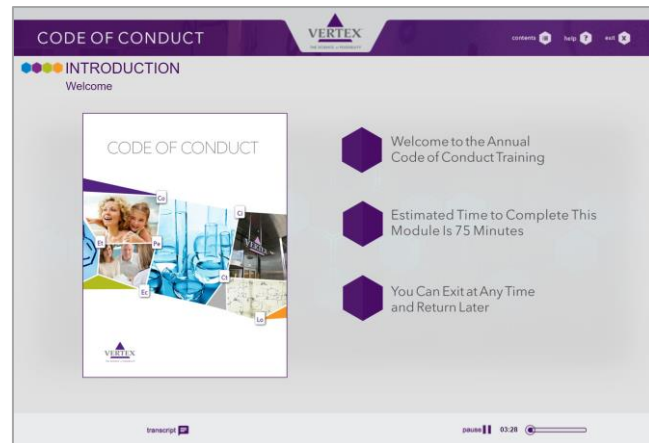
- Make it role-specific
- Focus on objectives
- Remember KISS ("Keep it short and simple.")
- Use plain language
- Include scenarios/case studies
- Supply to real-world examples
- Consider the "point-of-need"
- Include contact information in all training
- Translate wherever necessary

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# **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

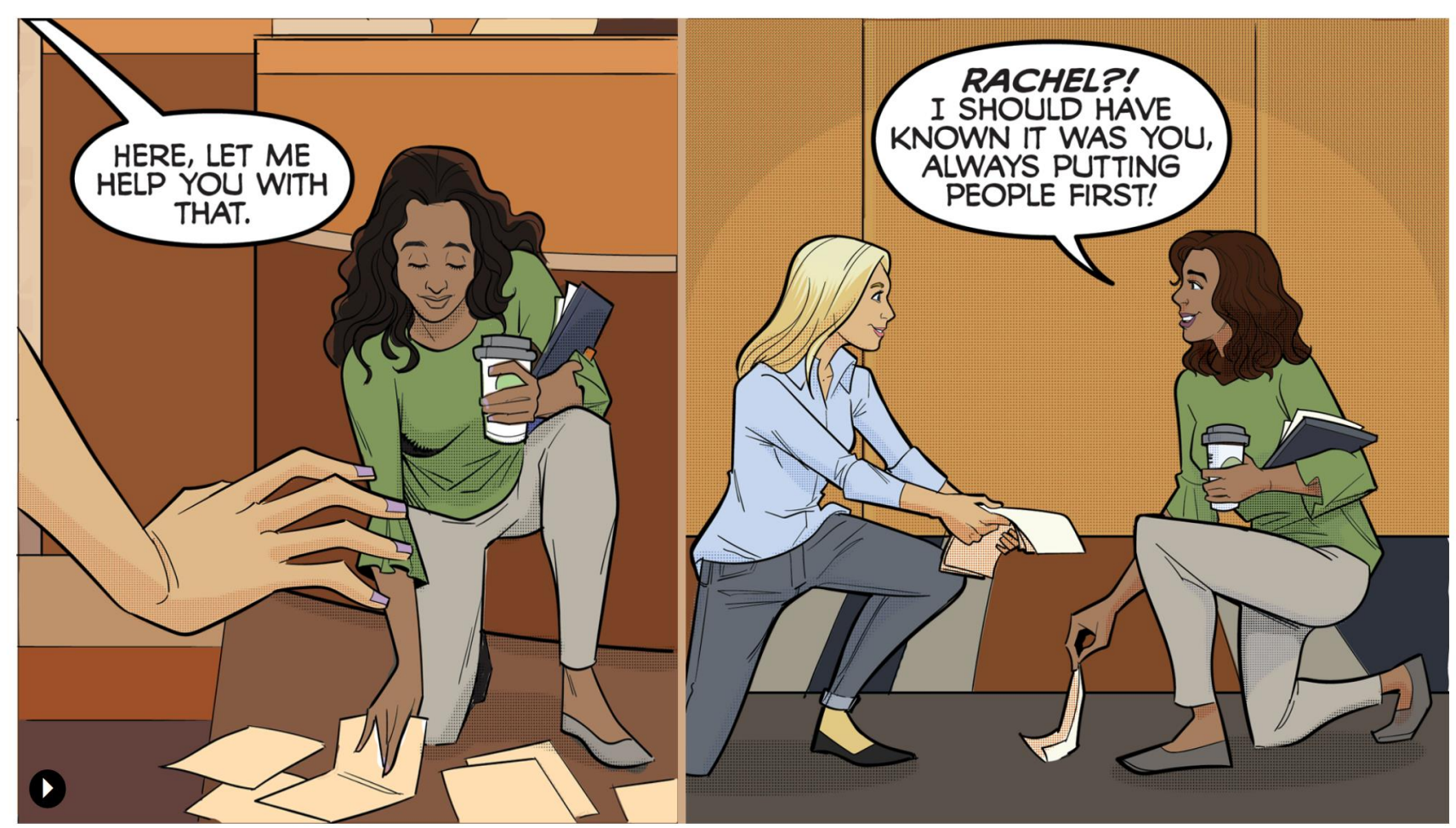
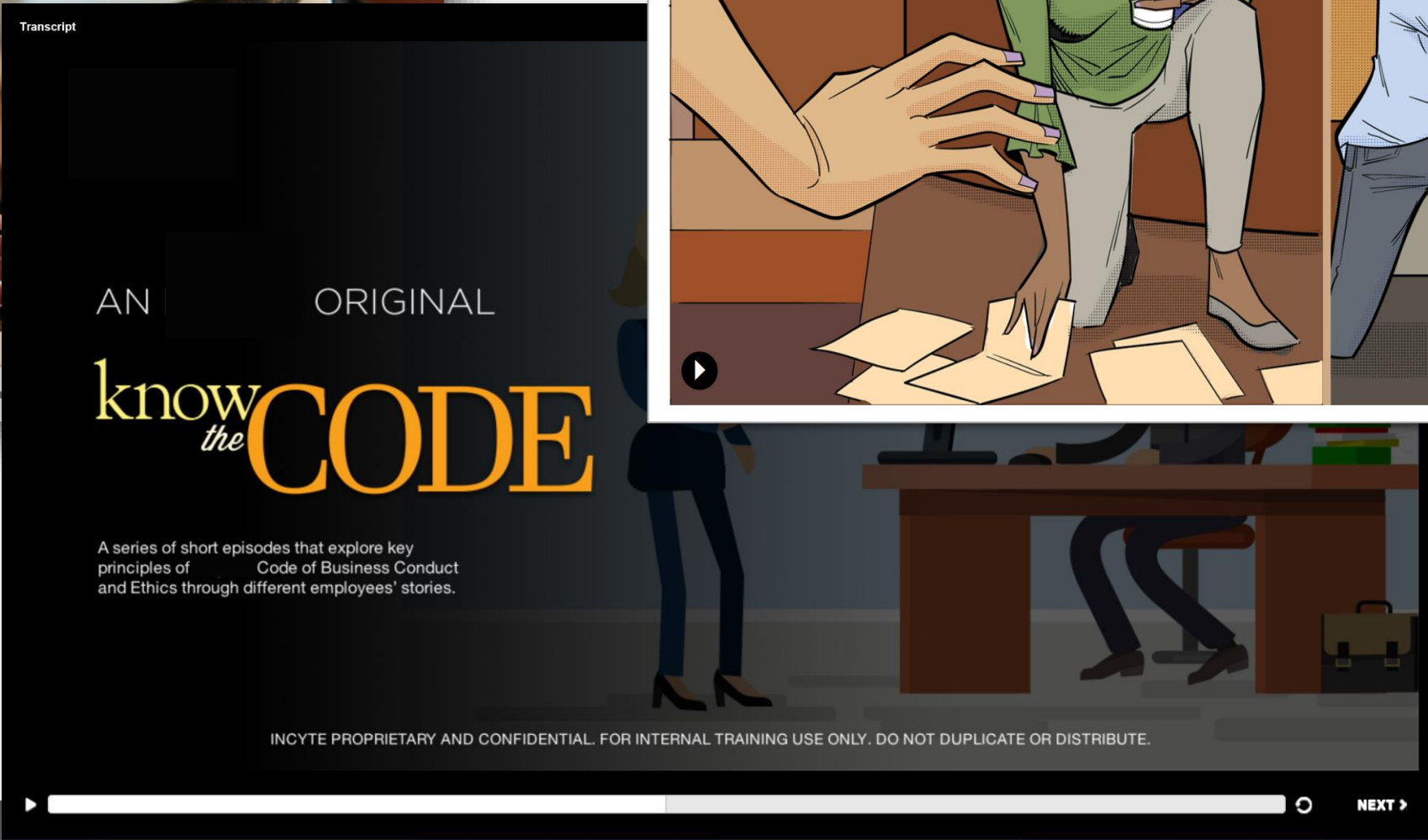
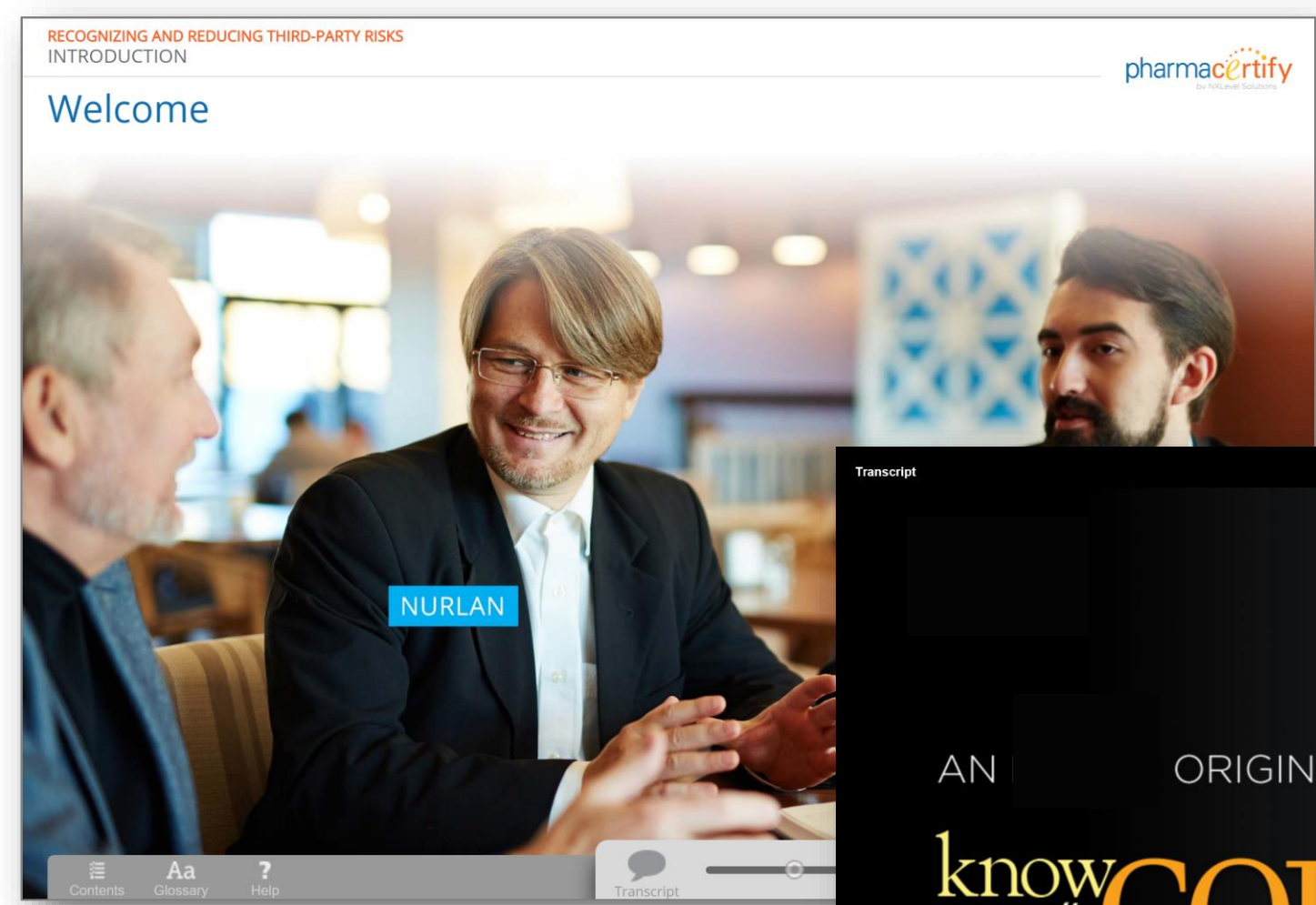
- Auditing and monitoring
- Encouraging speak-up culture
- Compliance coaching for their team
- Applying R.E.A.L framework

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# Samples



# Microlearning Reinforcement





# Games

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

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

Score: 400

SCRAMBLE

✓ 1 / 6

How often do cyber security hack attacks occur?

occur seconds Cyber every attacks

Compliance Reality Challenge

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

**Compliance**

## Interactions with Healthcare Professionals (HCPs) for Field Sales Representatives

This guide highlights key points from the Commercial Compliance Policies (CCPs) that apply to your HCP interactions. It is not a substitute for reading and understanding those policies.

**Note:** This guide does not cover all relevant CCPs, just those most applicable to common field activities.

**Questions, concerns, complaints? Contact Compliance.**

- Email: [hccpcompliance@dermira.com](mailto:hccpcompliance@dermira.com)
- Phone: 650-422-7797
- Anonymous: 866-354-3854

### Promotional Interactions with HCPs

- Discuss only approved products and indications
- Do not discuss or solicit questions about product uses that are:
  - Currently under investigation
  - Awaiting regulatory approval
  - Inconsistent with the product's approved labeling (i.e., off-label uses)
- Be truthful, accurate, and not misleading
- Provide a fair balance between product benefits and risks
- Only make properly substantiated claims
- Only use materials approved by Medical-Legal-Regulatory (MLR)
- Do not modify MLR-approved materials (e.g., no highlighting, marks, or notes)

### Patient Privacy

Never act in a manner that could compromise patient privacy. Do not acquire, access, collect, store, copy, process, handle, maintain, disclose, share, distribute, or transfer any personally identifiable information (PII) to any party, including other Dermira representatives.

See CCP 3: Protecting Patient Privacy.

### Unsolicited Medical Inquiries

If an HCP asks about pre-approval information or an off-label use of

## What is a Conflict of Interest

A conflict of interest arises when our outside activity or other personal interest could impair our objectivity or judgment as Astellas personnel. A conflict of interest can be actual, potential, or perceived.

### Common categories

- Outside positions
- Financial interest in relevant companies
- Gifts, entertainment, and hospitality
- Astellas business interactions with family members
- Personal use of Company property and information

## Principles

Use common sense and a commitment to the highest sense of integrity and ethics when determining whether a situation may present a potential conflict of interest.

Follow the Astellas Way Behavior of Openness and disclose potential conflicts to your manager and Ethics & Compliance.

## Responsibilities

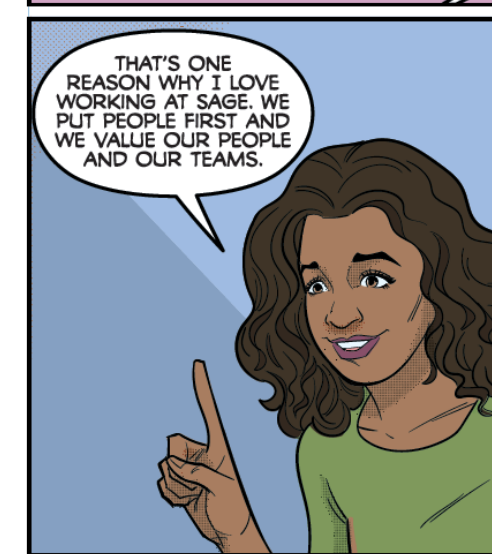
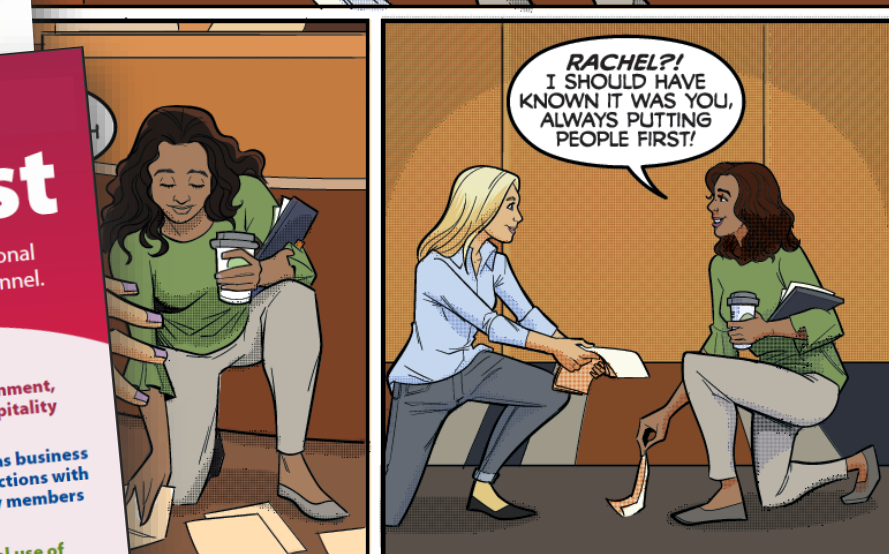
Always comply with the letter and spirit of all Astellas policies or procedures, or laws, regulations or industry association codes.

If you work for an Astellas company or business group that operates in a country with local laws, regulations or industry codes that set a higher standard than the *Astellas Group Conflicts of Interest Policy*, you must comply with the higher local standard.

## Who to contact

Your line manager and Ethics & Compliance can help you analyze whether your activity or personal interest present a potential conflict of interest.

of the Astellas Group Conflicts of Interest Policy.



## French Transparency Requirements

Background

Who Is Covered?

What Must Be Reported?

Deadlines & Penalties

Your Responsibilities

## Healthcare Professional (HCP) Engagement Quick Reference Guide

Follow the steps below whenever you want to engage an HCP and a payment or other transfer of value will occur (for example, when you want to engage an HCP to participate on an advisory board or provide consulting services, or when you want to support a non-U.S. HCP's attendance at a conference or other event).

Steps 1-6 must be completed before the HCP engagement can begin.

**HCP engagements must never be intended to win favor, or to induce or reward the purchase, prescription, or recommendation of any Sarepta product!**

An HCP is any member of the medical, dental, pharmacy, or nursing professions, or any other person who in the course of his or her professional activities may prescribe, purchase, supply, or administer a medicinal product, such as a doctor, nurse practitioner, physician assistant, nurse, or other medical professional.

### 1 Review Applicable Guidance

Review the applicable policies and guidance on the Compliance Department page on Nucleus. These include:

- Activity checklists for each type of HCP engagement (located under the Job Aids tab)
- Documentation Matrix that confirms where documentation should be saved by activity or engagement (located under the Job Aids tab)
- Country-specific guidelines (located under Country Guidelines tab)
- Materials Review, Approval, and Management (SOP) (located under the Policies tab)
- United States and the International & EU Healthcare Compliance Manuals (located under the Policies tab)
- Travel & Expense Management Policy (located on Finance Department page on Nucleus)

### 2 Submit Needs Assessment Form (NAF)

Complete a needs assessment form (NAF) in Veeva CRM ex-US and Events to document the legitimate business need for the engagement or activity and obtain the required approvals. NAFs are available for four (4) types of HCP engagements. Veeva CRM ex-US and Events is accessible from Okta. See the Compliance Department page on Nucleus for instructions on completing a NAF.

#### NAF Approval Workflow

Submitter → Activity Owner → Manager of Activity Owner → Compliance



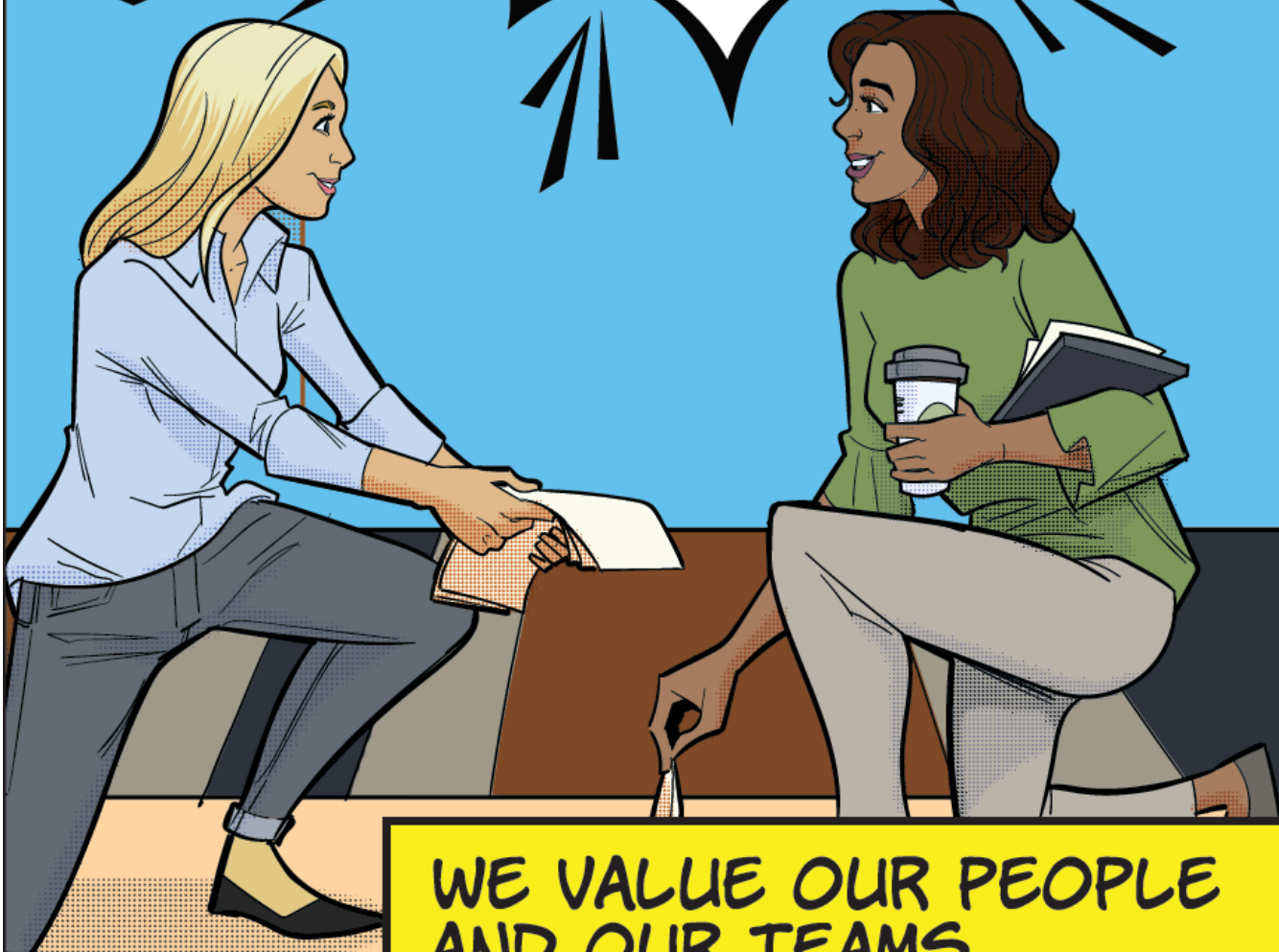
# Posters



Calibrate Your Compliance

#DORIGHT

**PUT PEOPLE  
FIRST**

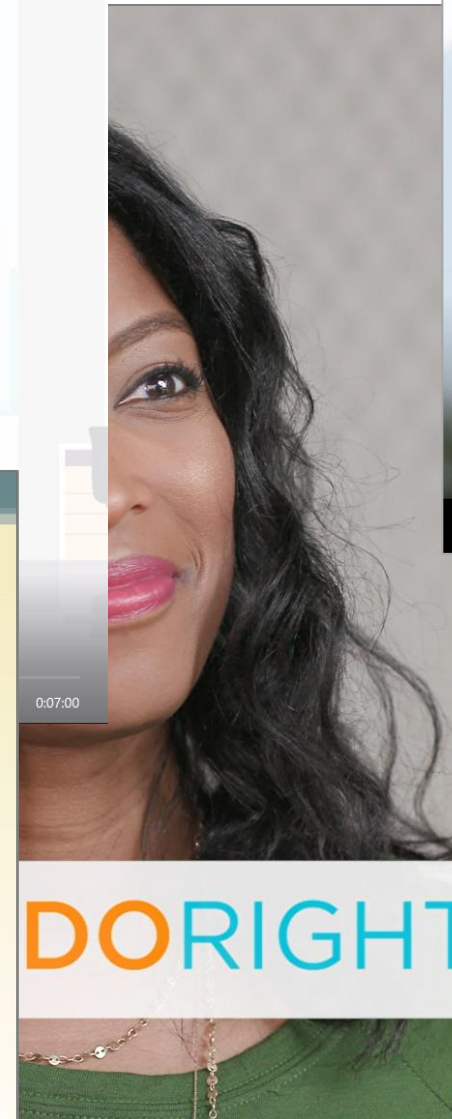


**WE VALUE OUR PEOPLE  
AND OUR TEAMS.**

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.

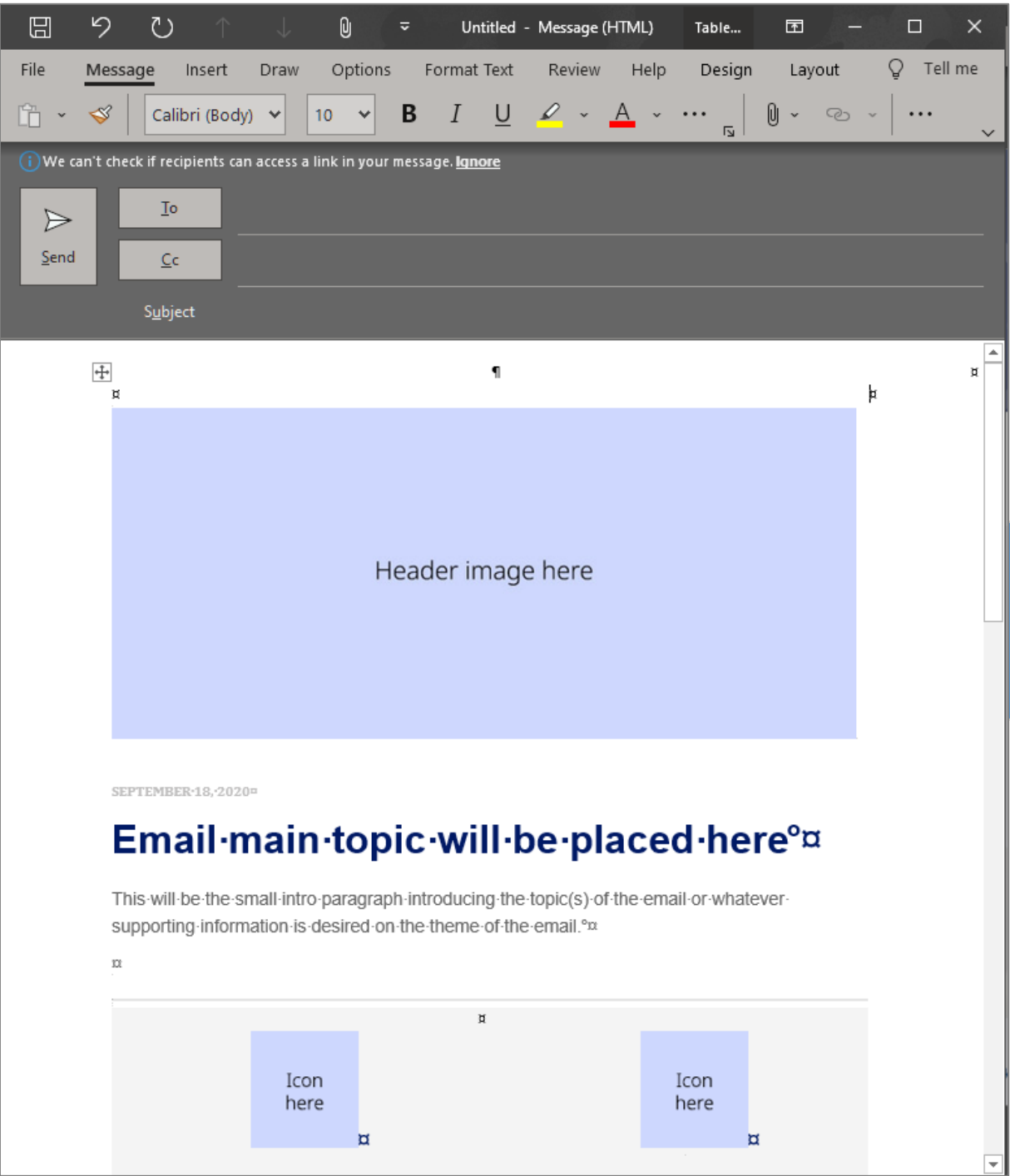


# Video





# HTML Email Blasts





# Digital Banners

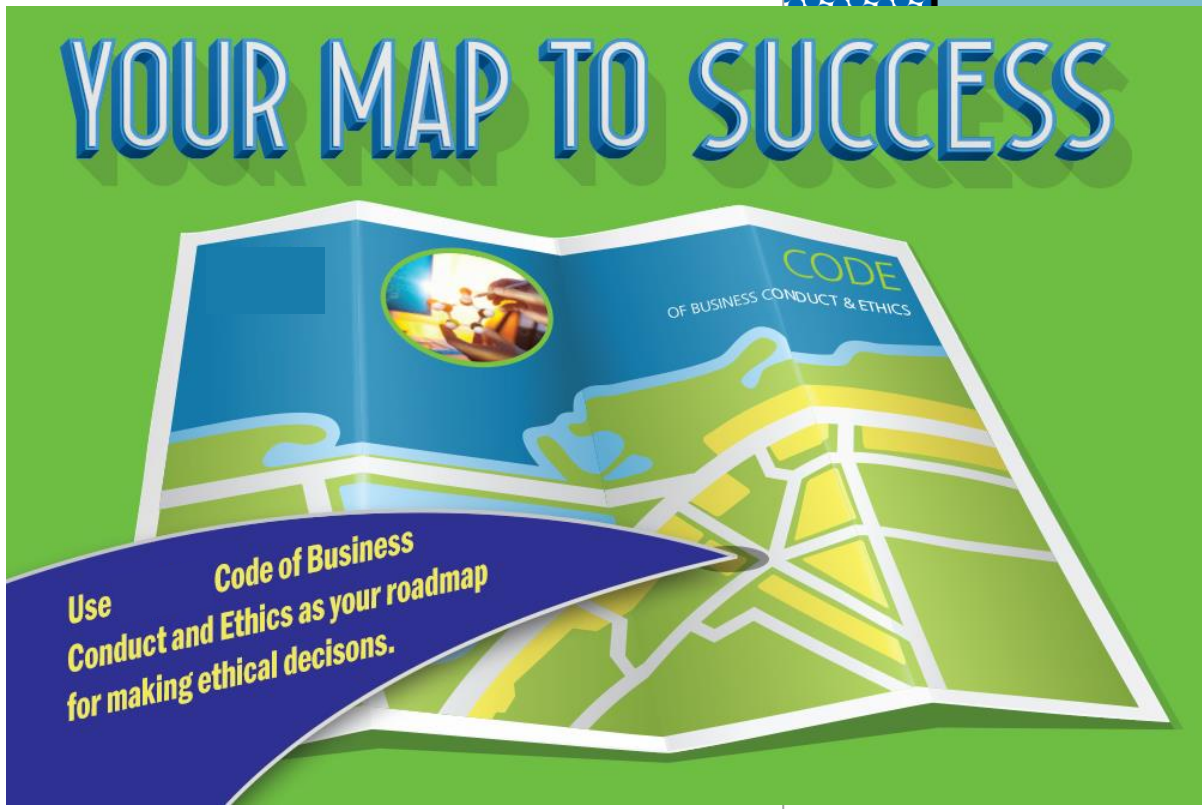
## CORPORATE COMPLIANCE & ETHICS WEEK

November 4-8, 2019



**SPEAK UP!**

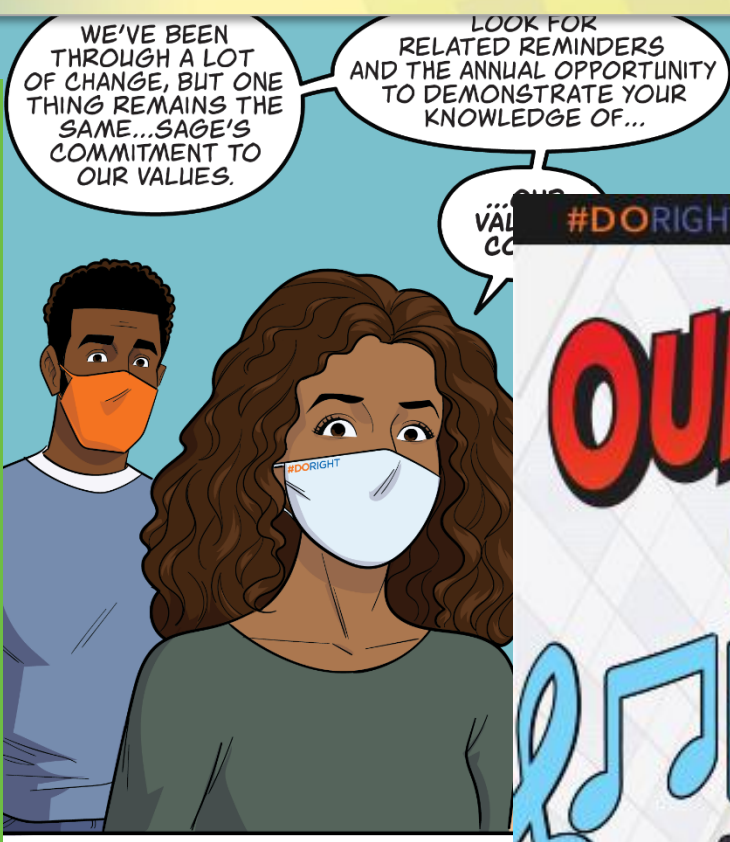
*We are committed to a speak-up culture!*



**YOUR MAP TO SUCCESS**

CODE OF BUSINESS CONDUCT & ETHICS

Use Code of Business Conduct and Ethics as your roadmap for making ethical decisions.



WE'VE BEEN THROUGH A LOT OF CHANGE, BUT ONE THING REMAINS THE SAME...SAGE'S COMMITMENT TO OUR VALUES.

LOOK FOR RELATED REMINDERS AND THE ANNUAL OPPORTUNITY TO DEMONSTRATE YOUR KNOWLEDGE OF...

#DORIGHT

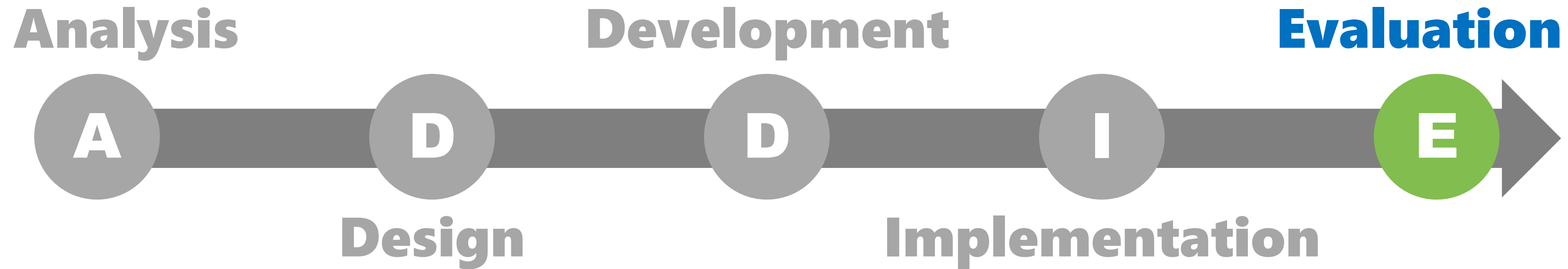


**OUR VALUES CODE REFRESH TRAINING**

SEE EXAMPLES OF OUR VALUES BEING LIVED OUT **LOUD!**

NOW AVAILABLE ON SAGEWISE

# The ADDIE Model





# 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
<ul style="list-style-type: none"><li>■ 7-10 questions</li><li>■ Make questions learner-centered using "I", "me", and "my" statements</li><li>■ Ask perceptions of knowledge gains</li><li>■ Be specific</li><li>■ Use consistent and specific rating scale</li><li>■ Allow open-ended comments as follow up for specific questions</li><li>■ Position as an approach to help target future compliance training</li></ul>	<ul style="list-style-type: none"><li>■ Efficient to produce and administer</li><li>■ Enables metrics</li><li>■ Anonymity</li></ul>	<ul style="list-style-type: none"><li>■ Perceptions only</li><li>■ Subjective measure</li><li>■ Response rate</li></ul>

# 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
<ul style="list-style-type: none"><li>■ Ask pre- and post-training levels perceptions</li><li>■ Be topic-specific</li><li>■ Use rating scale, if practical</li><li>■ Possible include informal quizzes on subject matter (can use gaming approach)</li><li>■ Ask follow up questions</li><li>■ Position as an approach to help target future compliance training</li></ul>	<ul style="list-style-type: none"><li>■ Natural give-and-take</li><li>■ Opportunity for questions and discussion (two-way)</li><li>■ Relatively easy to implement</li></ul>	<ul style="list-style-type: none"><li>■ Subjective perceptions only</li><li>■ Not anonymous</li><li>■ Subject to group think</li></ul>

# 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
<ul style="list-style-type: none"><li>■ Best using pre- and post-training assessments</li><li>■ Validate questions, if possible</li><li>■ Administer outside of LMS to enable question-level understanding of results</li><li>■ Administer one week+ after training</li><li>■ Position as an approach to help target future compliance training</li></ul>	<ul style="list-style-type: none"><li>■ Efficient to produce and administer</li><li>■ Provides an objective measure</li></ul>	<ul style="list-style-type: none"><li>■ There may be trepidation on the part of learners</li><li>■ Only measures long-term knowledge retention if issued repeatedly over time</li><li>■ Possibility of answer sharing, a.k.a. cheating</li></ul>

# Monitoring

GUIDANCE	BENEFITS	CHALLENGES
<ul style="list-style-type: none"><li>■ Train observers/monitors</li><li>■ Best to incorporate naturally, e.g., into ride-alongs</li><li>■ Ensure common understanding of evaluation rubric(s) across observers</li><li>■ Position as an approach to help target future compliance training</li></ul>	<ul style="list-style-type: none"><li>■ Provides a clearer view of behavior change</li><li>■ Opportunity for questions and discussion (two-way)</li></ul>	<ul style="list-style-type: none"><li>■ Need to avoid “compliance cop” perception</li><li>■ Must have solid and well-understood rubric</li><li>■ Time consuming for observers</li><li>■ Possibility of “cheating”</li></ul>



# Q&A

# **Calibrate Your Compliance Training**

## **A Practical Framework**

**Jennifer Anderson**

**Vertex Pharmaceuticals**

**Dan O'Connor**

**NXLevel Solutions/PharmaCertify™**



**Calibrate Your Compliance Training: A Practical Framework**

**June 15, 2021**