PotomacRiver
PARTNERS

PANEL DISCUSSION

Stage Appropriate Ethics & Compliance Considerations to Strengthen Development to Commercial Readiness

Wednesday, August 5, 2026 | 1:30pm – 2:15pm

Disclaimer. The views and opinions expressed during this presentation are those of the panelists and are based on their individual experiences. They do not necessarily reflect the views, policies, or positions of their respective companies.

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SECTION ONE

Compliance 101

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KEY US LAWS AND CODES

Food, Drug, and Cosmetic Act (FDCA)
Prevents selling misbranded drugs

False Claims Act (FCA)
Prohibits misleading statements to sell a product

Prescription Drug Marketing Act (PDMA)
Regulates sample distribution and management

OIG Guidance for Pharmaceutical Manufacturers*
Mandates Compliance Program Expectations

Anti-Kickback Statute (AKS)
Prohibits exchanging value as reward for purchases

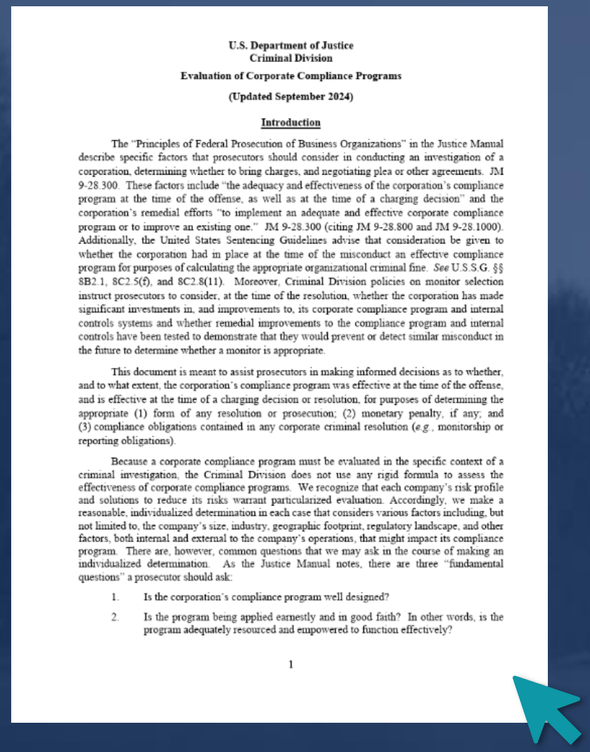
Health Insurance Portability & Accountability Act (HIPAA)
Protects patient privacy

Sunshine Act and State Transparency Laws
Required disclosure of HCP, Hospital, and Research Spend

PhRMA Code on Interactions with HCPs*
Defines appropriate conduct with HCPs

** While not "laws", state laws have required adherence to these "voluntary" guidelines*

DOJ'S EVALUATION OF CORPORATE COMPLIANCE PROGRAMS



U.S. Department of Justice
Criminal Division

Evaluation of Corporate Compliance Programs

(Updated September 2024)

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, Criminal Division policies on monitor selection instruct 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.

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. Is the corporation's compliance program well designed?
2. Is the program being applied earnestly and in good faith? In other words, is the program adequately resourced and empowered to function effectively?

1

Source: U.S. Department of Justice, Criminal Division — Evaluation of Corporate Compliance Programs

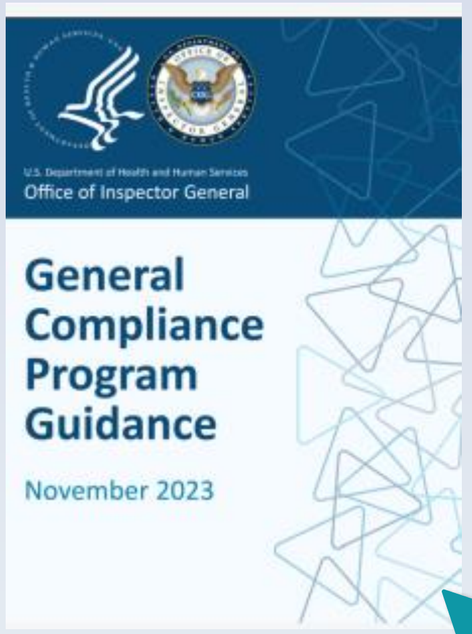
1 Is the corporation's compliance program well designed?

2 Is the program being applied earnestly and in good faith?

3 Does the corporation's compliance program work in practice?

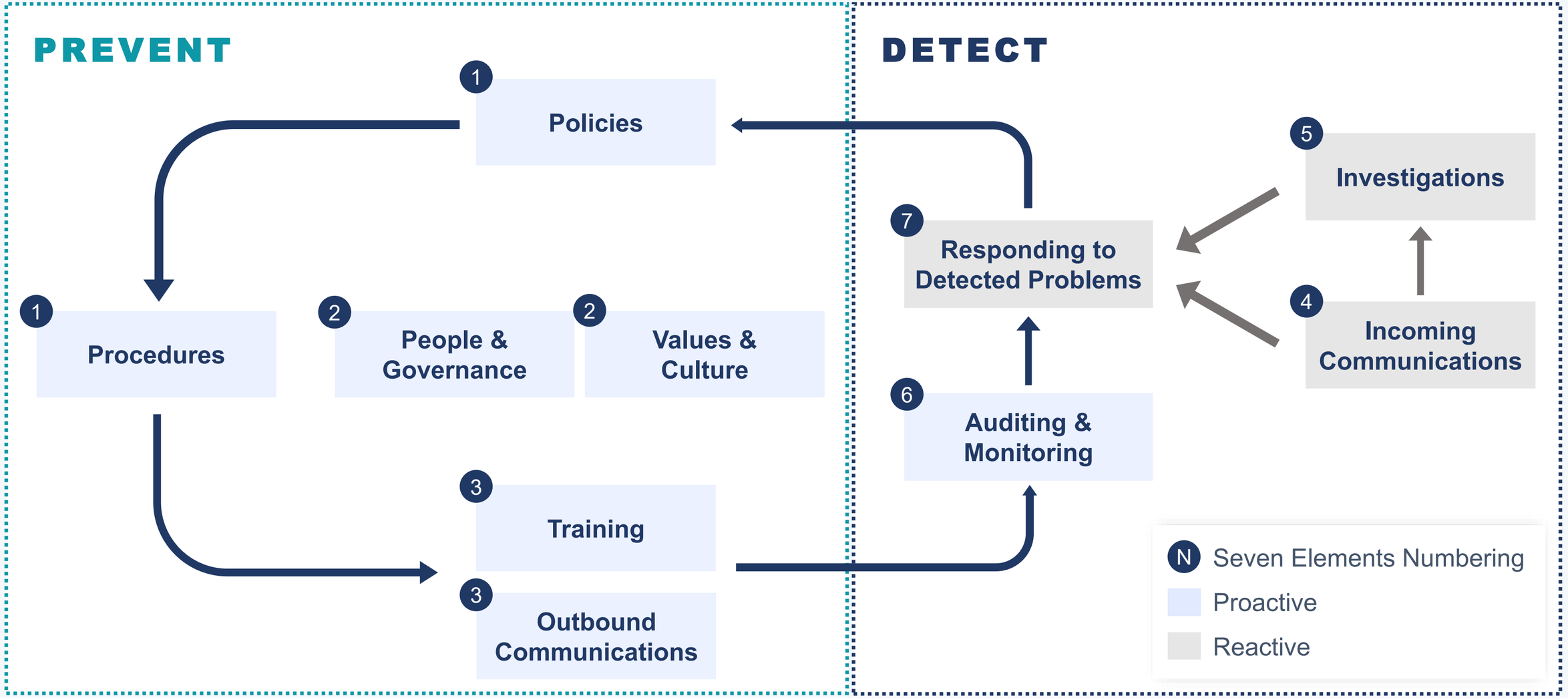
OIG SEVEN ELEMENTS OF AN EFFECTIVE COMPLIANCE PROGRAM

1. Written Policies and Procedures
2. Compliance Leadership and Oversight
3. Training and Education
4. Effective Lines of Communication with the Compliance Officer and Disclosure Program
5. Enforcing Standards: Consequences and Incentives
6. Risk Assessment, Auditing, and Monitoring
7. Responding to Detected Offenses and Developing Corrective Action Initiatives



Source: HHS Office of Inspector General — General Compliance Program Guidance, November 2023

SEVEN ELEMENTS LIFECYCLE



CONSEQUENCES OF NON-COMPLIANCE

GILEAD

Gilead to Pay $202M Over Speaker-Program Kickbacks

Honoraria, meals, and travel to high-prescribing HCPs through **speaker programs** induced HIV-drug prescriptions, leading to **false claims**. Gilead admitted to portions of the misconduct. Began as a whistleblower suit brought by a physician.

APRIL 2025

Source: DOJ

QOL Medical

QOL Medical Pays $47M for a Free-Testing Scheme

Free diagnostic tests were used to target and induce Sucraid prescriptions, which the government called illegal remuneration causing **false claims**. The **CEO was charged individually**. The settlement included a **corporate integrity agreement**.

NOVEMBER 2024

Source: DOJ

Takeda

Takeda Settles for $13.6M, Earns Cooperation Credit

Speaker honoraria and high-end meals allegedly induced Trintellix prescriptions. Takeda then earned DOJ **cooperation and remediation credit** for voluntarily producing key materials, ending the program, and addressing the misconduct.

MAY 2026

Source: DOJ

SECTION TWO

Panel Discussion

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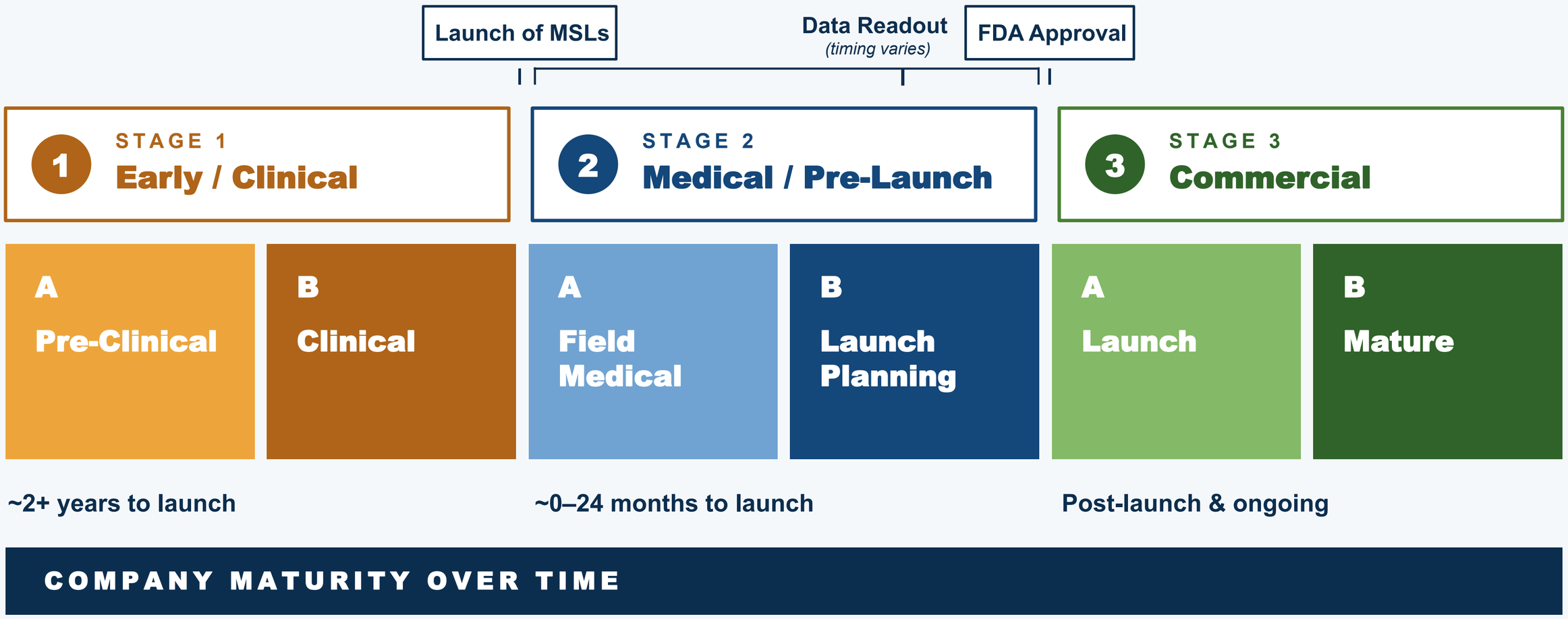
THE COMPANY LIFECYCLE: THREE STAGES, SIX PHASES



STAGE 1: EARLY / CLINICAL 2+ YEARS TO LAUNCH

KEY CONSIDERATIONS

- Which foundations do you need first, and which can wait?
- How do you influence leadership to prioritize or invest in compliance?
- How do you identify other key advocates?
- How do you avoid corporate policies from reinforcing that compliance is a “check-the-box” exercise?

PANELIST

Jen Fitzpatrick

Sionna Therapeutics

COMPLIANCE FOCUS BY OIG ELEMENT

OIG ELEMENT	PHASE A) PRE-CLINICAL	PHASE B) CLINICAL
People & Governance	Name Compliance owner	Plan governance and fractional CCO as you scale; Focus on culture
Policies & Procedures	Core corporate policies (Code, ABAC, document framework)	HCP interactions, 3rd-party due diligence, Quality System
Training & Education	Compliance training for executives and Board	Onboard new hires as team grows
Lines of Communication	Stand up hotline / inbox	Emphasize tone at the top
Monitoring & Auditing	Ad-hoc; Observe activities to learn risks	Scope risk-based “testing” (e.g., correct use of templates)
Enforcement & Discipline	Begin integration with HR	Align disciplinary roles and consistency (job descriptions, incentive-comp)
Response & CAPA	Case-by-case process	Define CAPA methodology; Set up tracking/filing system (e.g., Excel)
IT Systems	Quality Management System (QMS)	LMS within Quality

STAGE 2: MEDICAL / PRE-LAUNCH ~0–24 MONTHS TO LAUNCH

KEY CONSIDERATIONS

- What are some of the key changes you need before hiring Field personnel?
- How does that change by type of Field person – MSL, Managed Care, Rep?
- When is optimal time for a full-time CCO? What factors might influence the decision to be earlier or later?
- What must be fully built before your first sale vs. what can follow?

PANELIST

Greg Montalbano

Daiichi Sankyo

COMPLIANCE FOCUS BY OIG ELEMENT

OIG ELEMENT	PHASE A) FIELD MEDICAL	PHASE B) LAUNCH PLANNING
People & Governance	Formalize the CCO role and recruit FTE	Scale compliance team to meet growth plan; Make budgetary decisions on headcount vs. outsourcing
Policies & Procedures	Medical policies; Patient Advocacy (esp. for rare disease companies)	Commercial policies (promotion, payor, speaker programs) and SOPs
Training & Education	Leadership training; Functional Area training / advisory	Rep onboarding and credentialing (e.g., HIPAA)
Lines of Communication	Socialize “speak-up” and the CCO post-hire	Tone at the middle; First culture survey
Monitoring & Auditing	Test key controls / high-risk areas (e.g., attend an Ad Board, Congress)	Build the post-launch monitoring plan; Gain access to systems/data
Enforcement & Discipline	Review incentive-comp structures	Formalize investigations protocol
Response & CAPA	Pilot CAPA on monitoring findings	Pilot CAPA on investigations
IT Systems	CRM, Concur (with HCPs), LMS (non-Quality), MedComms	HCP Engagements; Promo Materials; Transparency; Federal and state price reporting

STAGE 3: COMMERCIAL POST-LAUNCH

KEY CONSIDERATIONS

As your company evolves, how is your program changing with it?

How do you avoid programs evolving into having too much information and bombarding stakeholders?

Once “prevent” elements are in place, how do you scale up “detect” elements? What data is critical?

What other things help move a program from formalized to DOJ’s ideal?

PANELIST

Jim Fraser

BeOne Medicines

COMPLIANCE FOCUS BY OIG ELEMENT

OIG ELEMENT	PHASE A) LAUNCH	PHASE B) MATURE
People & Governance	Annual refresh; Compliance as Business Partner; Structured Board reporting	Compliance Champions, Full program assessment; Trending over time
Policies & Procedures	Close gaps in policies; Deepen SOPs	Full document lifecycle management; Simplification and retirement
Training & Education	Rep onboarding live; NSMs; Deploy initial eLearning modules	Ongoing recertification / annual training; Evaluation of outcomes vs. completion
Lines of Communication	Track hotline trends; Hotline awareness and Speak Up campaigns	Report trends to the Board; Compliance Business Partners
Monitoring & Auditing	Live monitoring and transactional audits	Annual risk assessments, Aggregate reviews; Risk-based sampling
Enforcement & Discipline	Execute routine investigations; Develop resourcing for complex investigations	Consistent discipline across the org; Evaluation of bias
Response & CAPA	Formalize CAPA process	Track remediation and trends; Ensure preventive actions are working
IT Systems	Dashboards, Case Management; External Funding	More sophisticated / integrated systems; Enhance automation

CLOSING RECAP: STAGE ROADMAP

Early / Clinical
2+ years to launch

A) Pre-Clinical

- [ ] Name a Compliance owner
- [ ] Core corporate policies (Code, ABAC)
- [ ] Exec & Board training
- [ ] Stand up hotline / inbox; HR integration
- [ ] Ad-hoc risk observation
- [ ] QMS

B) Clinical

- [ ] Governance + fractional CCO; culture
- [ ] HCP interactions policy; 3rd-party due diligence
- [ ] Onboard new hires
- [ ] Emphasize tone at the top
- [ ] Risk-based testing; CAPA methodology
- [ ] LMS within Quality

Medical / Pre-Launch
~0–24 months to launch

A) Field Medical

- [ ] Formalize CCO; recruit FTE
- [ ] Medical & patient-advocacy policies
- [ ] Leadership & functional training
- [ ] Socialize speak-up & CCO
- [ ] Test key controls/high-risk areas
- [ ] CRM, Concur, LMS, MedComms

B) Launch Planning

- [ ] Scale team (build vs. outsource)
- [ ] Commercial policies & SOPs
- [ ] Rep onboarding & credentialing
- [ ] Tone at the middle; culture survey
- [ ] Monitoring plan; formalize Investigations
- [ ] HCP Engagements, Transparency, Promo Materials

Commercial
Post-launch

A) Launch

- [ ] Compliance as business partner
- [ ] Structured Board reporting
- [ ] Close policy gaps; deepen SOPs
- [ ] Rep onboarding; NSMs; eLearning
- [ ] Live monitoring & audits, formalize CAPA
- [ ] Dashboards, Case Management, Funding

B) Mature

- [ ] Full program assessment; track/report trends
- [ ] Document lifecycle management
- [ ] Recertification; annual training
- [ ] Risk-based sampling & reviews
- [ ] Consistent discipline; track remediation
- [ ] Sophisticated systems; enhance automation

The takeaway: build habits that prevent compliance problems, not a paper program for regulators.