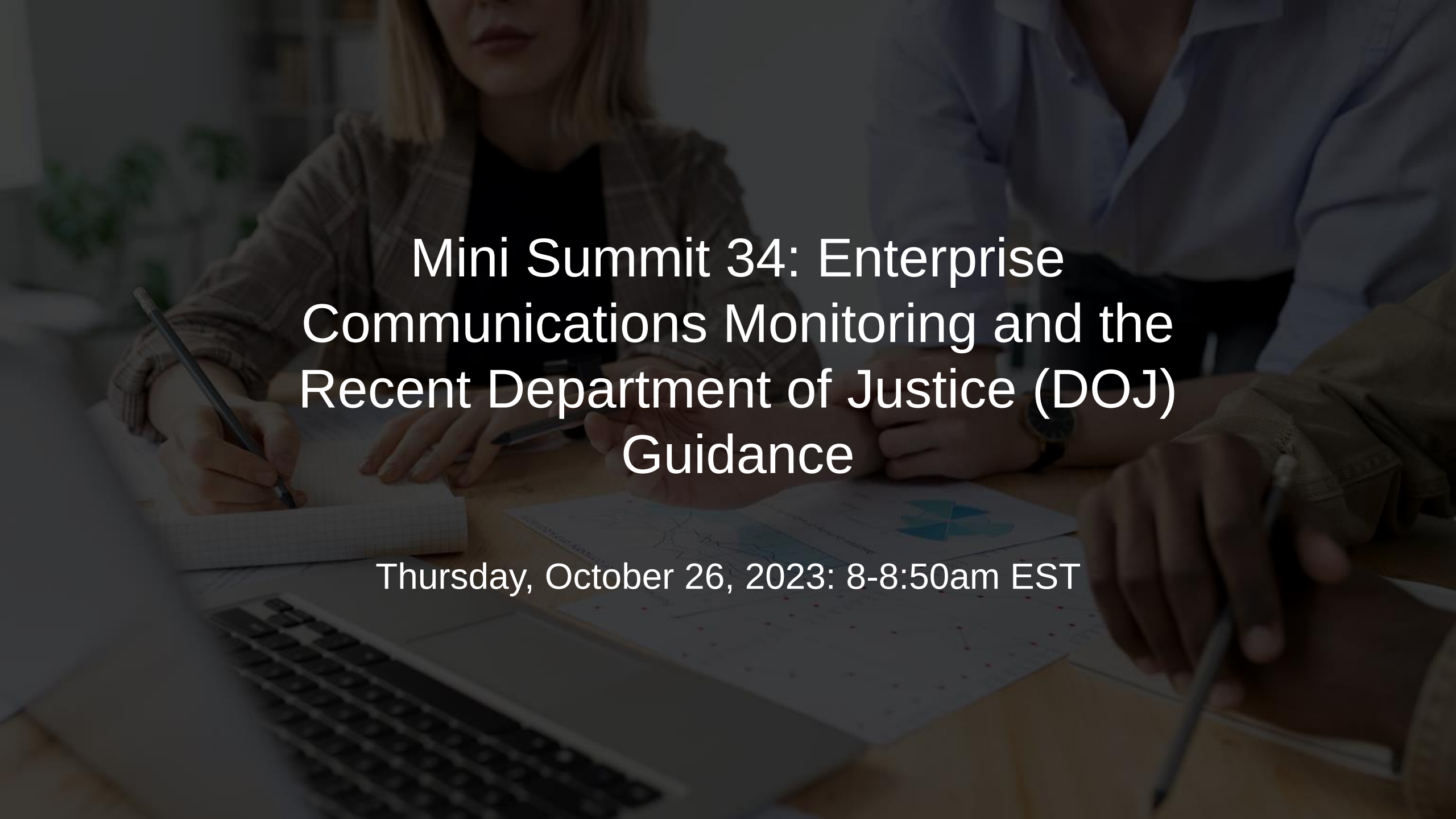


Mini Summit 34: Enterprise Communications Monitoring and the Recent Department of Justice (DOJ) Guidance

Thursday, October 26, 2023: 8-8:50am EST

Panelist

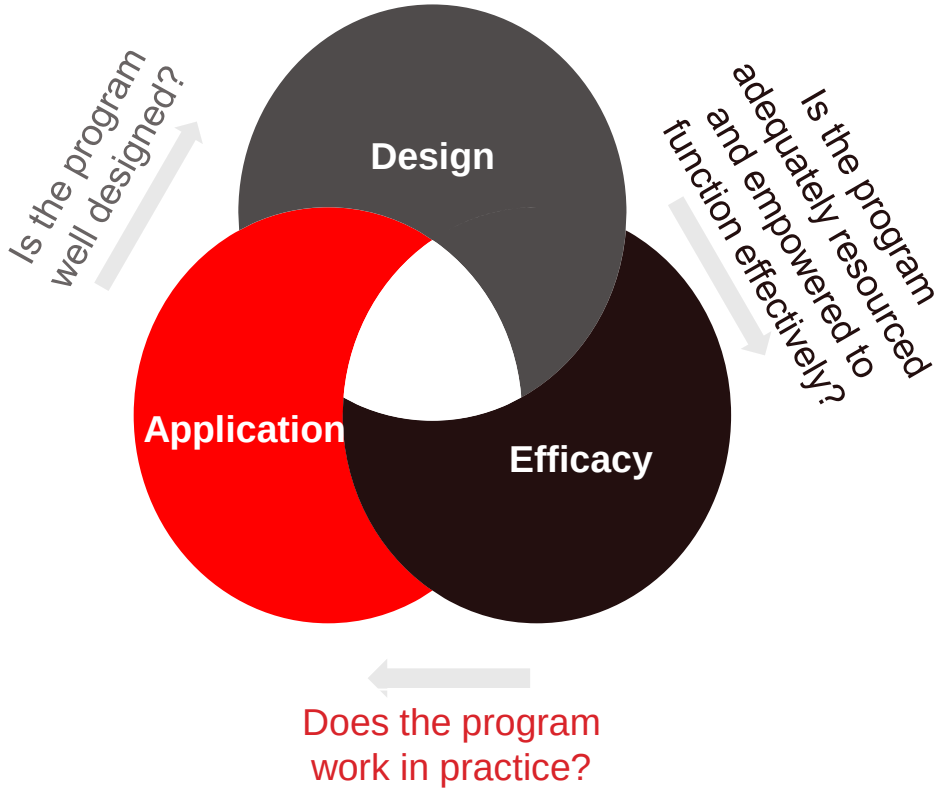
- Rachel Batykefer, *Vice President, CIA and Compliance Operations, Mallinckrodt Pharmaceuticals, Bridgewater, NJ*
- Sarah A. Franklin, JD, *Partner and Vice-chair, Life Sciences Investigations Practice, Covington & Burling, LLP, Washington, DC*
- Nichole Pinard, CPA, *Senior Director, Global Monitoring, Analytics and Digital Capabilities, Bristol Myers Squibb; Former Senior Director, Digital Transformation, Audit and Compliance, Princeton, NJ*
- Alexis Shaw, *Executive Director, Compliance, Paratek Pharmaceuticals, Malvern, PA*
- Marci Juneau, *Partner, HELIO Health Group, Atlanta, GA (Moderator)*

Disclaimer

- *The views expressed and ideas presented in this session are those of the speakers and are not necessarily shared by the speakers' employers.*
- *Any examples provided are hypotheticals and should not be attributed to any individual company.*

Background: DOJ Guidance

- Deputy Attorney General Lisa Monaco issued Monaco's Memo Oct. 28, 2021 on "initial revisions" to those policies and is the result of an evaluation process by the DOJ's corporate crime advisory group.
- Monaco Memo 2.0 on Sept. 15, 2022 included detail on "Further Revisions to Corporate Criminal Enforcement Policies" that will apply across all of the DOJ's components, including the Fraud Section (enforcing the U.S. Foreign Corrupt Practices Act (FCPA).
  - Included focus area was review and oversight of employee communications using personal devices and ephemeral messaging applications



- In March 2023, the DOJ Issued an updated "Evaluation of Corporate Compliance Programs" including the previous factors and expanding on certain areas that would 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
  - *As a part of this document section on "*Does the Corporation's Compliance Program Work in Practice?*" the DOJ has included additional detail on monitoring of communications.*

Overview: DOJ Considerations

What should be governed:

- Personal devices
- Communications platforms
- Messaging applications; including ephemeral messaging applications

What prosecutors look at:

- Effectiveness of communication of policies and procedures to employees
- Level of enforcement of policies and procedures
- Consistency of enforcement of policies and procedures

Factors Considered When Evaluating Communication Channels

Communication Channels

- Communication channels used to conduct business
- Practice variations by jurisdiction and business function
- Mechanisms to manage and preserve information contained within communication channels
- Requirements and actual preservation & deletion settings available to employees
- Rationale for determination of appropriate communication channels and settings

Policy Environment

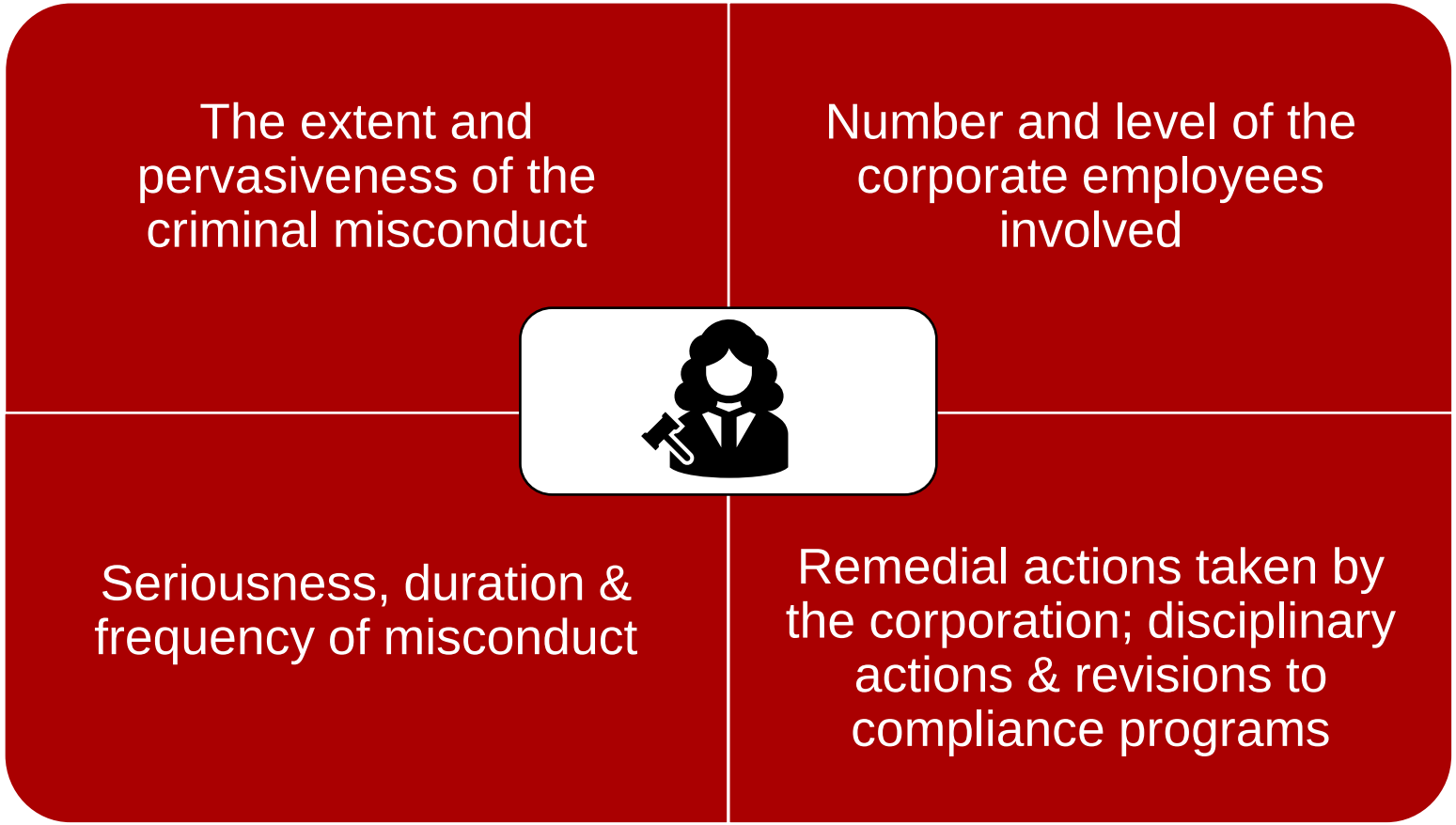
- Preservation of communication & data with replacement devices
- Codes of conduct, privacy, security and employment laws or policies to ensure security or monitor business-related communications
- Policies and rationale around BYOD
- Application & enforcement of data retention and business conduct policies
- Permitted exceptions/ limitations to established policies
- Existence & enforcement of policy on transfer of messages, data and information from private phones/messaging applications onto company record

Risk Management

- Consequences for employee refusal of company access to company communications
- Past enforcement of consequences
- Impairment of the company's compliance program, ability to conduct internal investigations, or respond to requests from prosecutors, civil enforcement or regulatory agencies using personal devices/ messaging applications
- Security management and communication channel control
- Reasonableness of company approach to permitting and managing communication channels

Analysis & Remediation of Underlying Misconduct

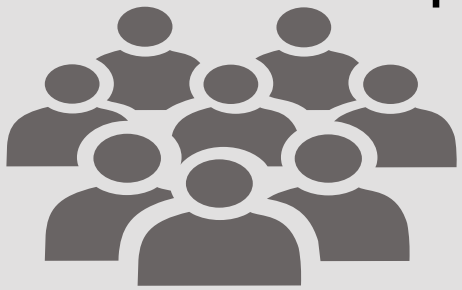
Prosecutors are encouraged by the DOJ to reflect on the following:



Recent Survey Results

Recent Survey on Monitoring- Conducted August 2023

Number of Participants



25

Types of Organizations

79 Pharmaceutical

8% Medical Device

8% Hybrid Device/Pharma

4% Biological

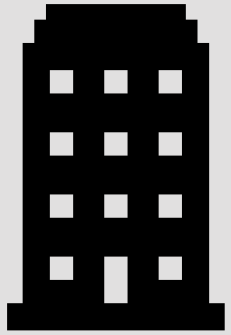
Size of Organization

60%

Small (Lower than Top 50 Biopharma)

20%

Mid-Size (Top 50 to 20 Biopharma)



20%

Large (Top 20 Biopharma or Higher)

Monitoring Internal Communications

When monitoring internal communications within your organization, which communication type do you monitor?

48%

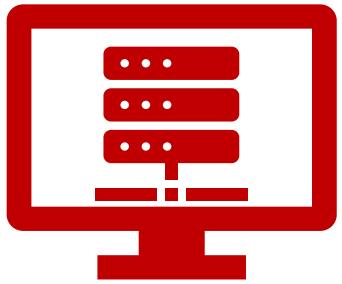
No Monitoring of Internal Communications

32%

Call Notes

24%

Email

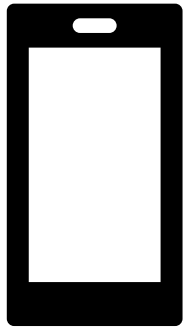


12%

Enterprise Chat (Teams, Slack, etc.)

0%

Voicemail



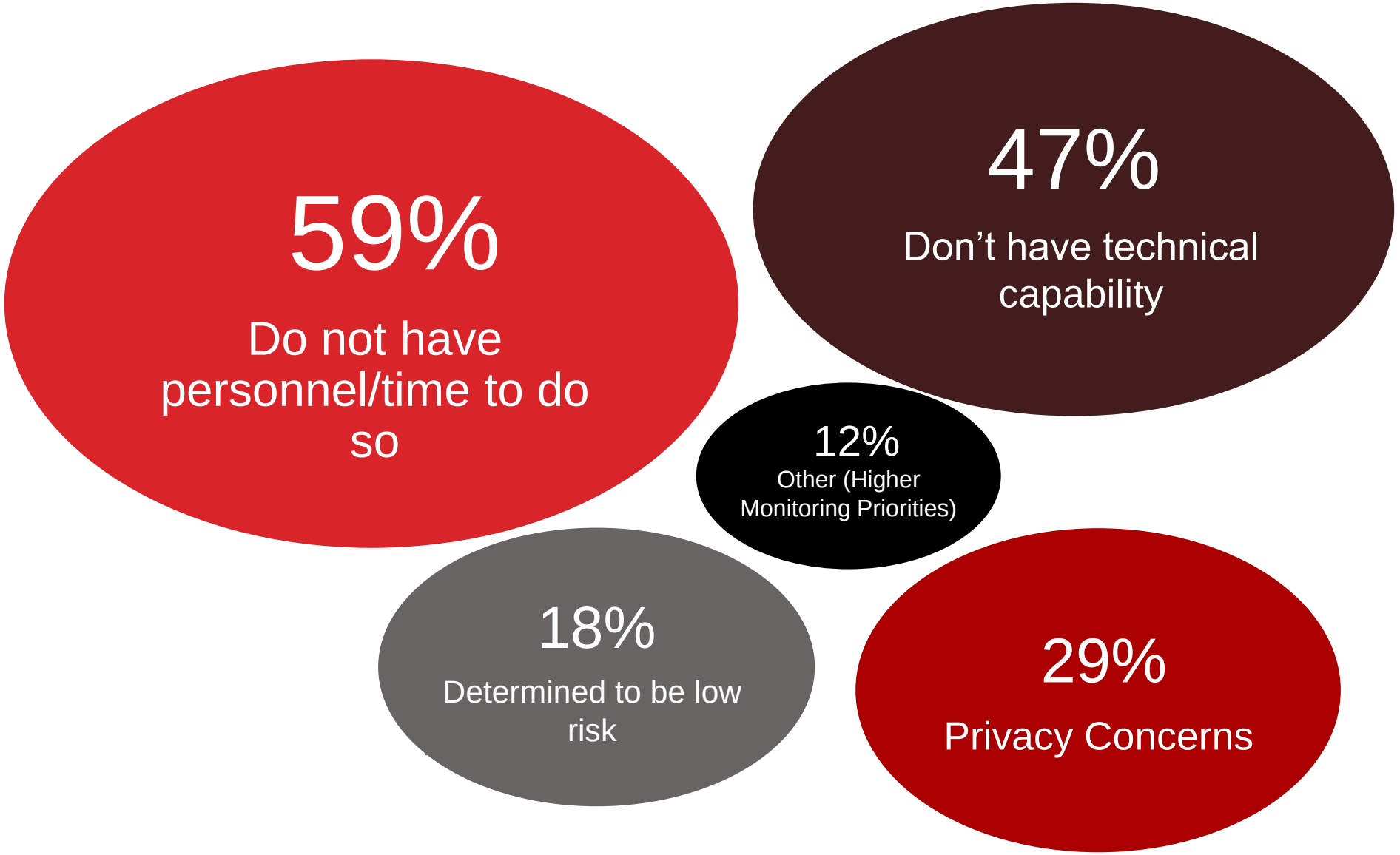
0%

Text Messages

**Note: Some respondents monitor other areas based on current risks or activities*

Monitoring Internal Communications

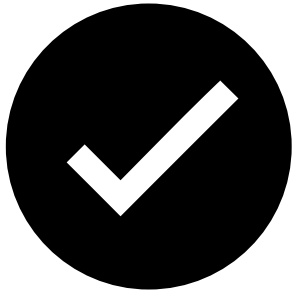
If you do NOT monitor internal communications, why not?



Policy on Personal Devices

Is your organization evaluating/monitoring employee devices under a BYOD (Bring Your Own Device) policy?

Yes



20%

40%

No, but considering based on DOJ Guidance

No

40%

Audience Survey Question

Audience Survey Questions

1. What Size is Your Organization

- Small (Lower than Top 75 Biopharma)
- Mid-Size (Top 75 to 30 Biopharma)
- Large (Top 30 Biopharma or Higher)

2. What Type of Organization Do You Work For?

- Pharma
- Medical Device
- Hybrid

Audience Survey Questions

3. What type of communications monitoring is your company currently performing? (Select all that apply)

1. Email
2. Text
3. Apps
4. Call notes
5. Other
6. None

Audience Survey Questions

4. What do you see as the biggest barrier to communications monitoring?

1. Technology
2. Culture/Politics at Company
3. Privacy
4. Cost
5. Effort/Personnel
6. Other

Audience Survey Questions

5. Is your company waiting for more guidance before beginning initiatives on comms monitoring?

1. Yes- we have not started comms monitoring
2. Yes- we have started communications monitoring but are waiting for additional direction/guidance
3. No- we are in the process of conducting communications monitoring