



Exploring the Compliance Aspects of Virtual / Digital Engagement and Deployment

6TH ANNUAL
LIFE SCIENCES

COMPLIANCE CONGRESS FOR
SPECIALTY PRODUCTS

VIRTUAL EVENT / **SEPT. 21-24, 2020**

Emerging Trends, Best Practices and Benchmarking for Managing Risks Associated with Complex, High-Touch Therapies

The logo features a circular graphic on the left composed of many small dots in various colors (blue, red, green, yellow) surrounding a central white pill icon. The text is arranged in a structured, multi-line format with varying font weights and colors (white, blue, red) to create a professional and modern look.

September 2020

Disclaimer

The views expressed and ideas presented in this session are those of the speakers and are not necessarily shared by the presenters' employers.

Any examples provided are hypotheticals and should not be attributed to any individual company.

Panelists

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Introduction

The coronavirus pandemic accelerated the pace of change in integrating virtual tools into specialty pharmaceutical company business models. It's important for compliance professionals to understand the degree to which the current business models have already changed and just how different they might still become.

In August 2020, Helio surveyed 29 life sciences companies to gain a better understanding of how these companies were evolving their compliance programs and tactics during the pandemic.

Survey Demographics

Introduction

Your Company is:

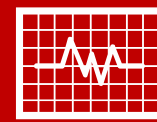
59%

Pharmaceutical



31%

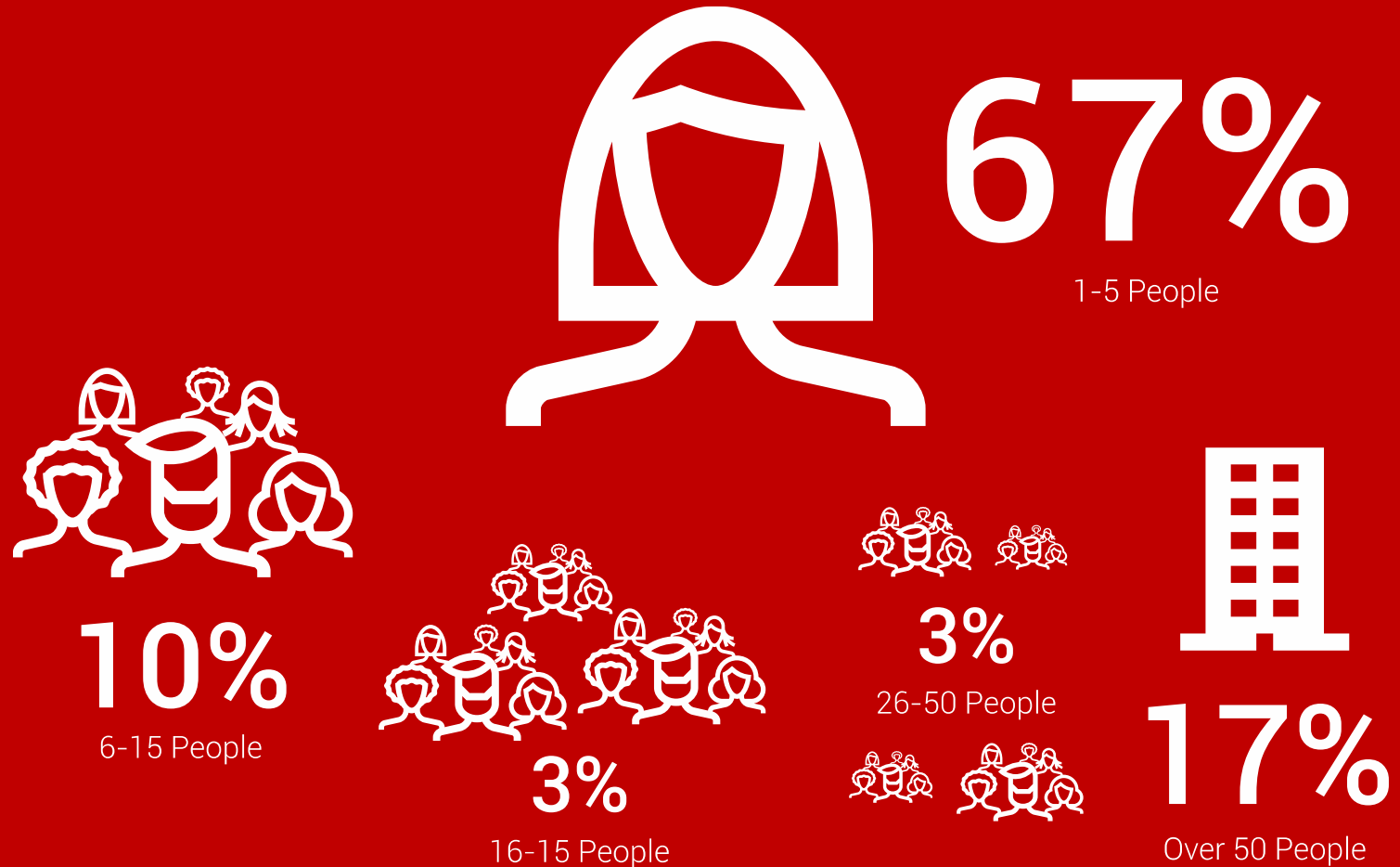
Biotechnology



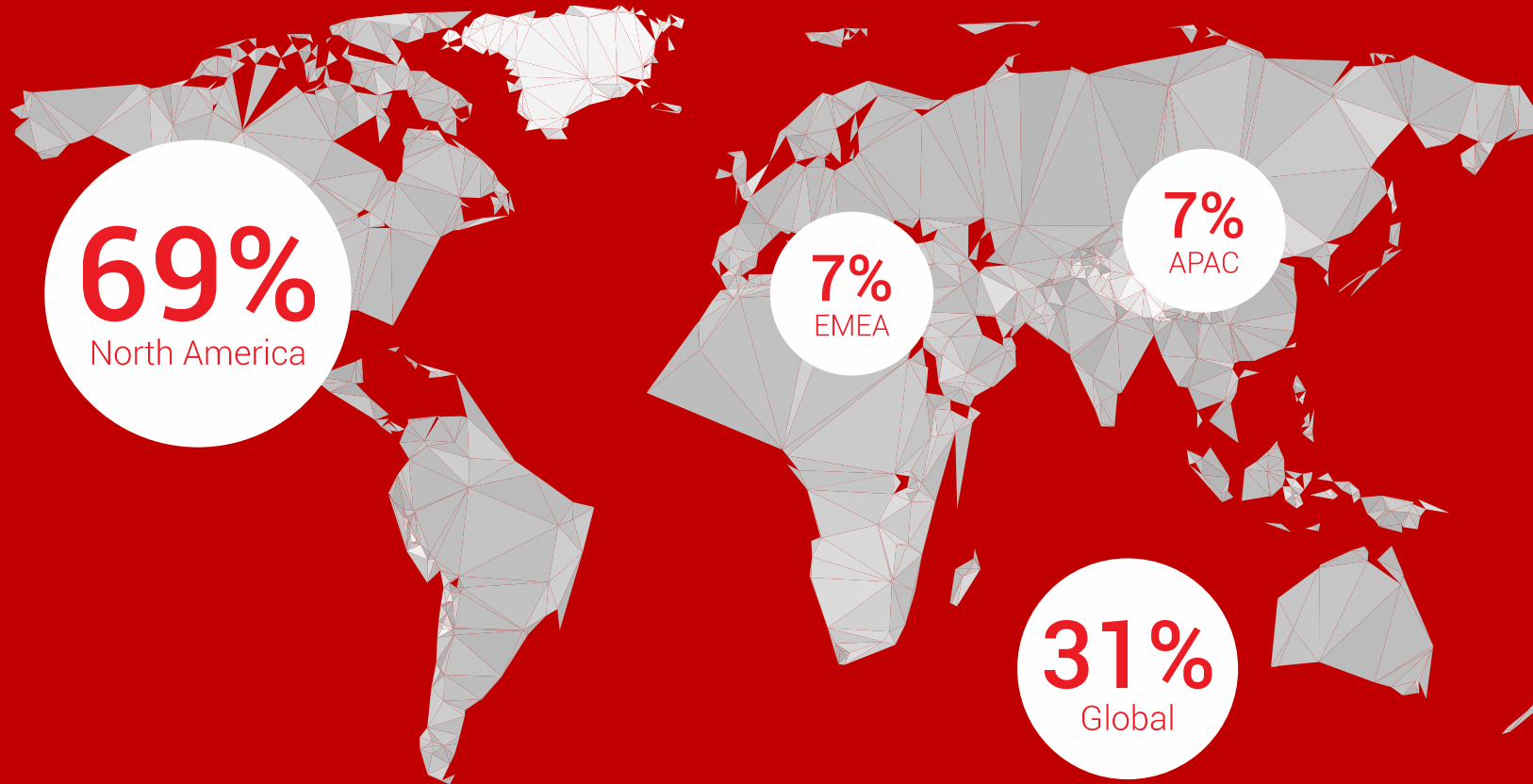
10%

Medical Device

How many people are in your Compliance Department?



Your geographical scope of activity is:



Your Company revenue is:

69%

Less than \$1B



14%

\$1B to \$5B

3%

\$6B to \$10B

14%

More than \$20B



Evolving Program Logistics



Monitoring &
Auditing



Privacy Concerns for
Digital Platforms

Where Are We At Today?

Helio was involved with a similar polling exercise¹ in May 2020.

The results of our most recent survey from August 2020 show that since the original survey there have been clear and significant changes in promotional and non-promotional activities and the related compliance risks.

¹ *GHC Response to Covid-19 Webinar Series Part IV*

Evolving Program Logistics

Evolving Program Logistics

**As a result of the pandemic, is your Company
conducting programs virtually?**

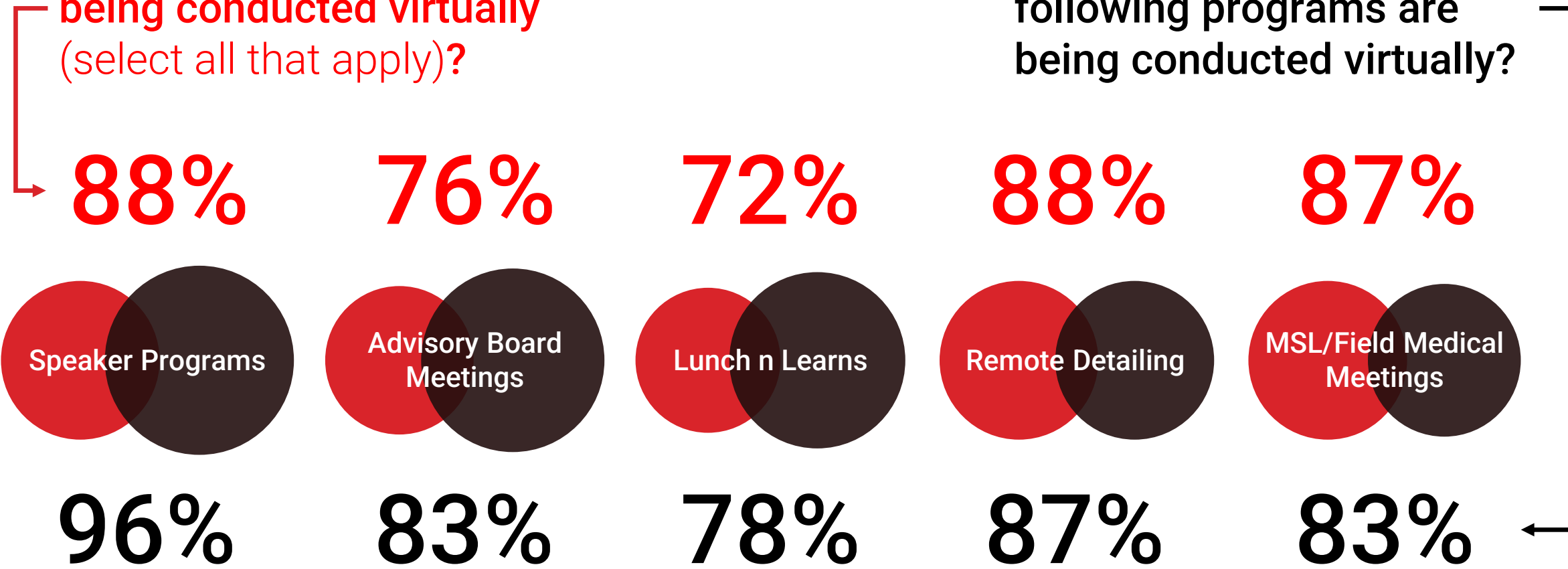
100% YES!

Evolving Program Logistics

What kind of programs are being conducted virtually
(select all that apply)?

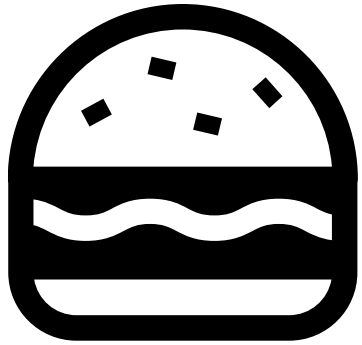
Evolving Program Logistics

What percentage of the following programs are being conducted virtually?



Evolving Program Logistics

If you are allowing meals, which virtual activities are you allowing meals for (select all that apply)?



72%

Lunch n Learns

64%

Speaker Programs



32%

Advisory Board Meetings

44%

Remote Detailing

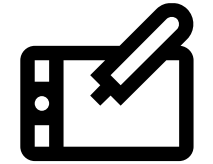
20%

MSL / Field Medical Meetings

24%

None of the Above

Are you tracking meals?



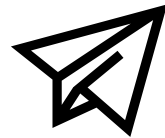
64%

Electronic Signature
or Scanned Sign-In
Sheet from Attendees



20%

Not Providing Meals



8%

Email Confirmation
from Attendees or
Office Staff



4%

Not tracking



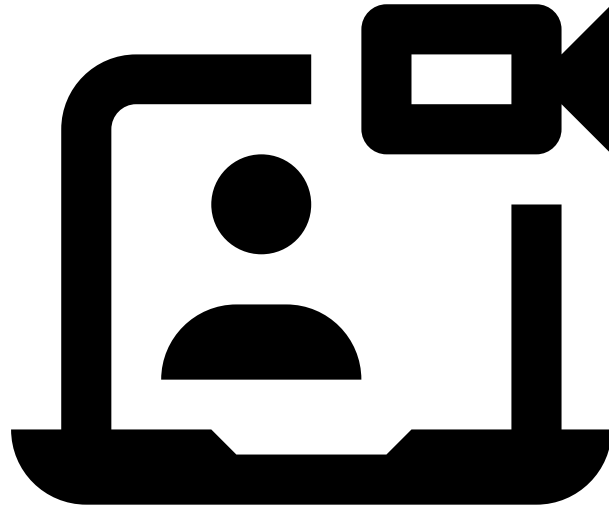
4%

Manual List Kept by
Company

Is your Company actively planning advisory board meetings to be virtual in the future?

76%

Yes



24%

Not Sure



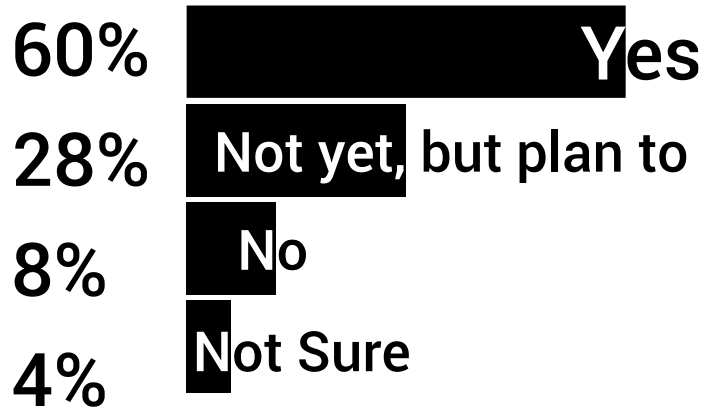
0%

No



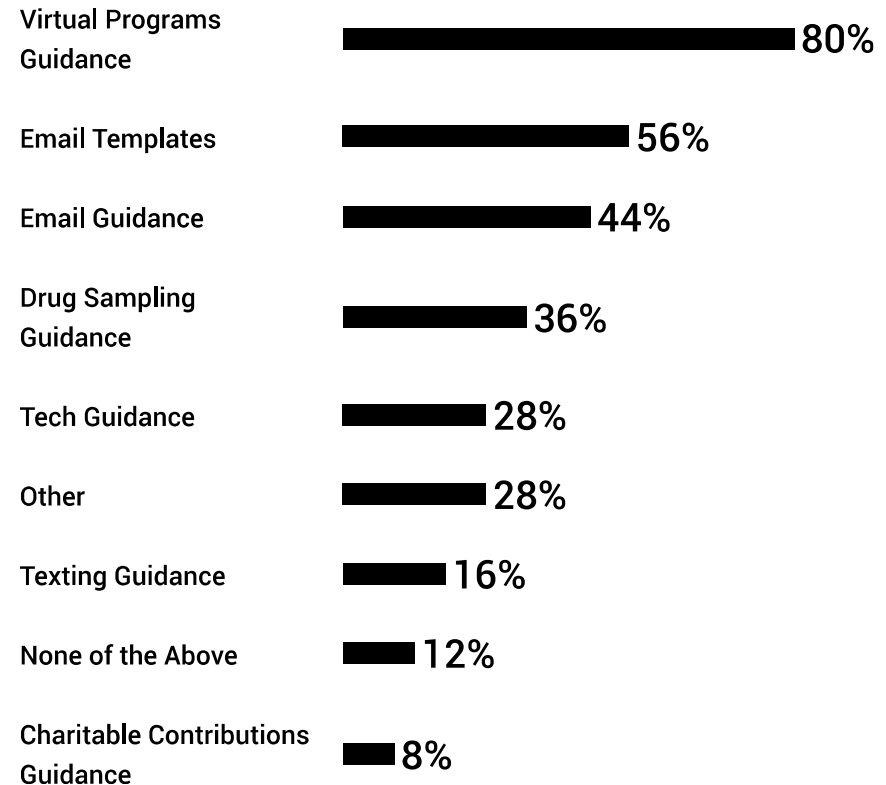
Evolving Program Logistics

As a result of the pandemic, has your Company revised any policies or SOPs?



Evolving Program Logistics

As a result of the pandemic, which ones have you developed additional guidelines (select all that apply)?



Evolving Program Logistics

As a result of the pandemic, have you seen an increase in the number of questions and/or requests for charitable contributions?

60%

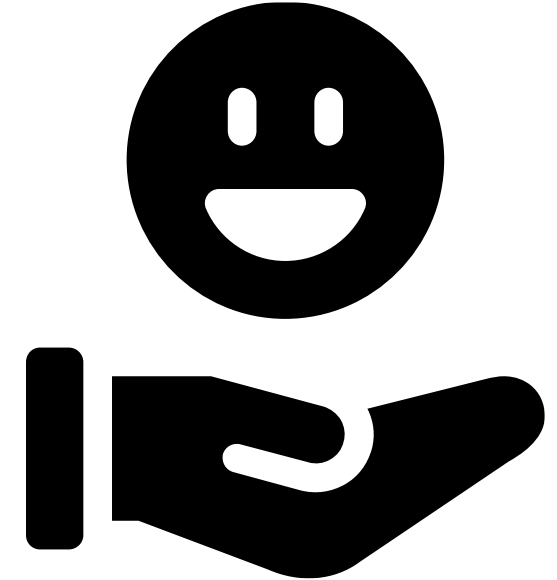
No

24%

Not Sure

16%

Yes



Evolving Program Logistics

As a result of the pandemic, has there been an increase in your unsolicited medical requests or requests to your medical team?

48%

Not Sure

40%

No

12%

Yes

Evolving Program Logistics

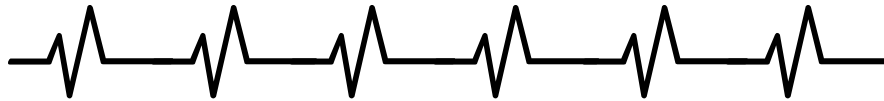
In the situation where patient support (e.g. nurse educators, field reimbursement managers) has not traditionally been virtual, has your Company migrated to a platform to virtually interact with patients?

24%



Yes

60%

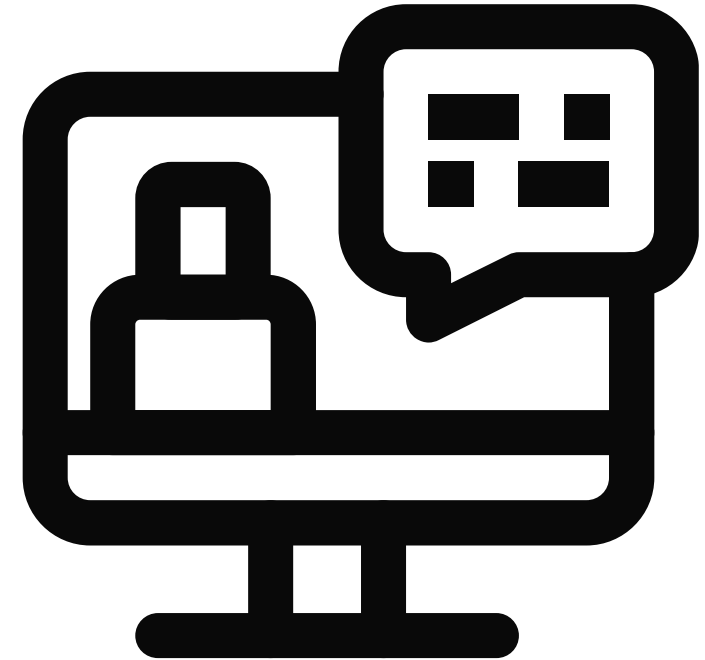


Not Applicable

16%



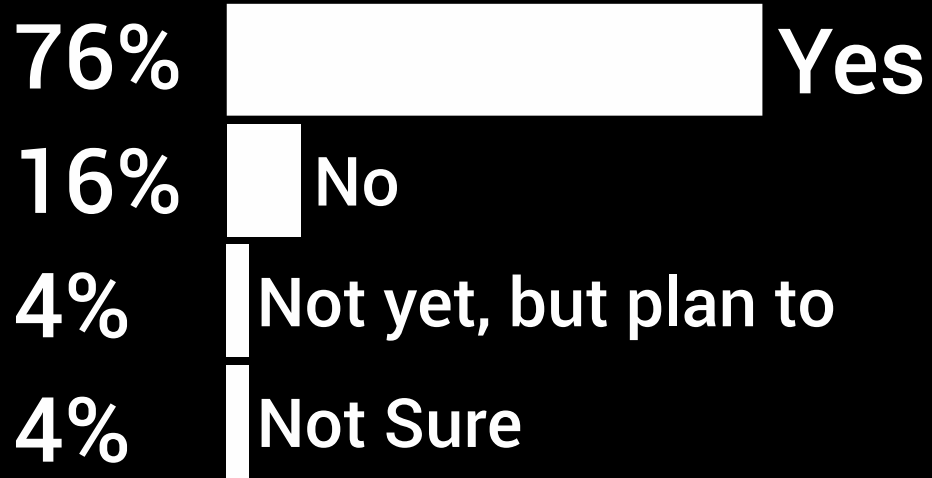
No



Privacy Concerns for Digital Platforms

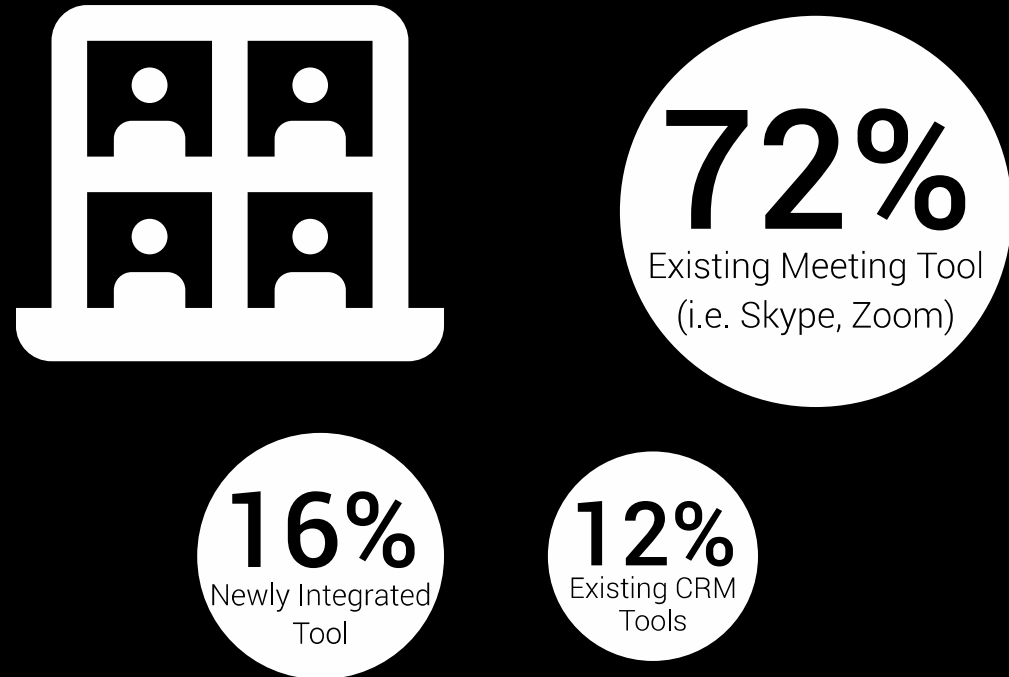
Privacy Concerns for Digital Platforms

Is your Company conducting training with employees for remote working?



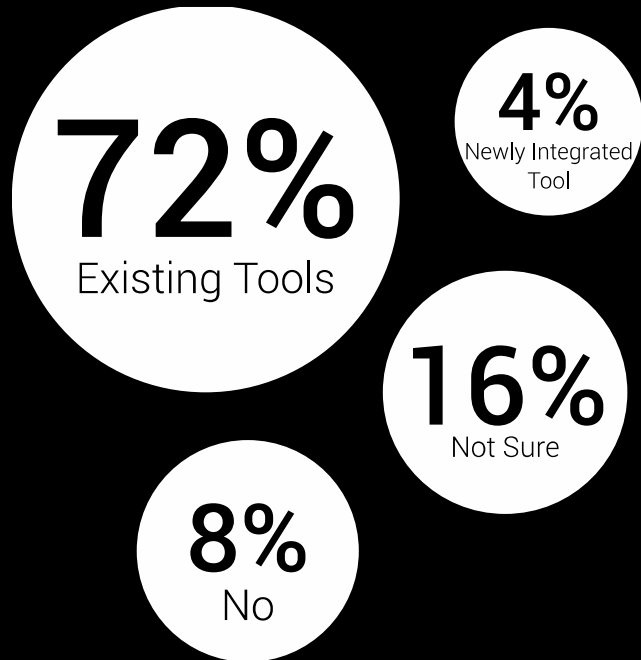
Privacy Concerns for Digital Platforms

What platforms are you using to host your digital programs?



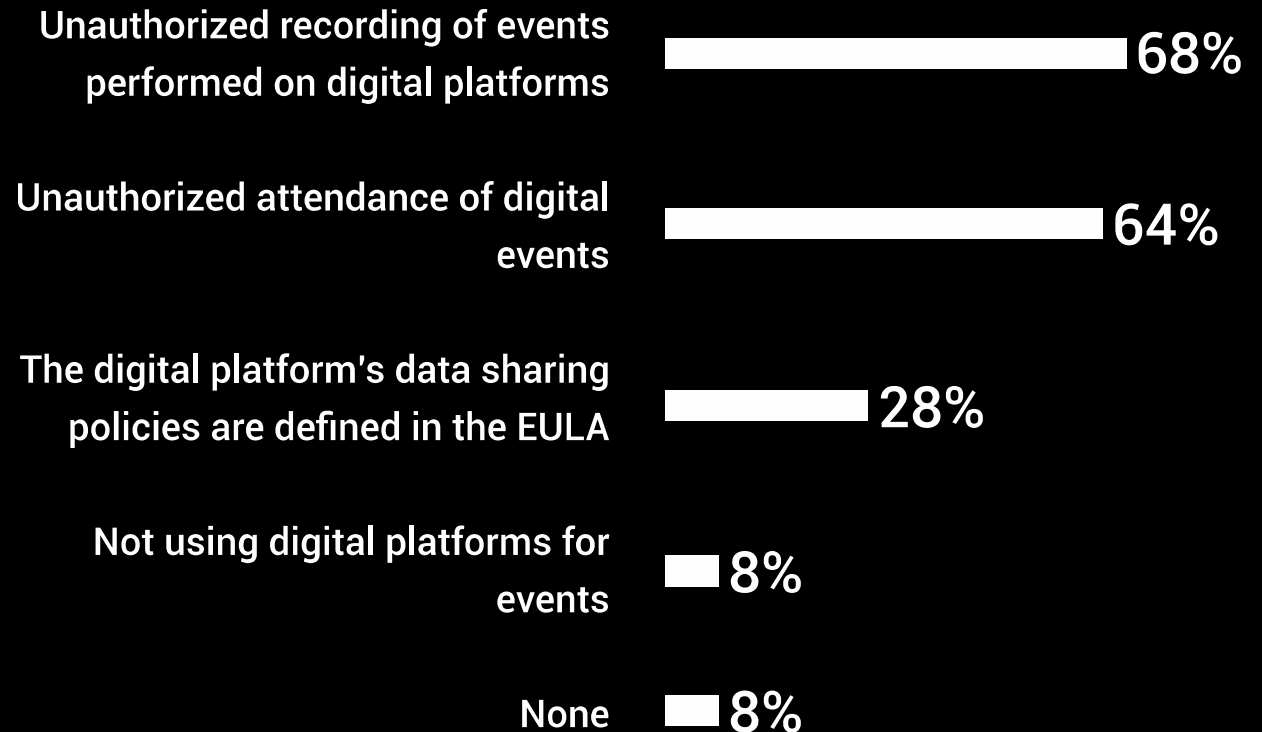
Privacy Concerns for Digital Platforms

Is your Company using any calendaring tools to assist with scheduling virtual meetings?



Privacy Concerns for Digital Platforms

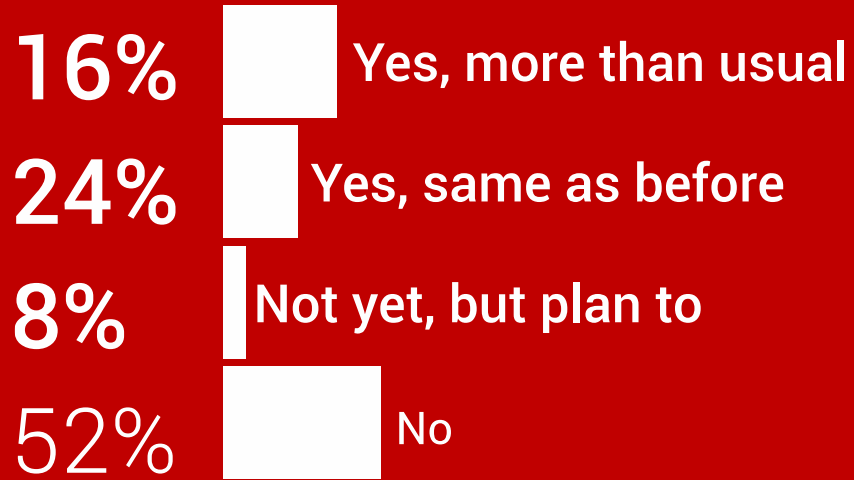
What privacy concerns do you have with your digital platforms (select all that apply)?



Monitoring and Auditing

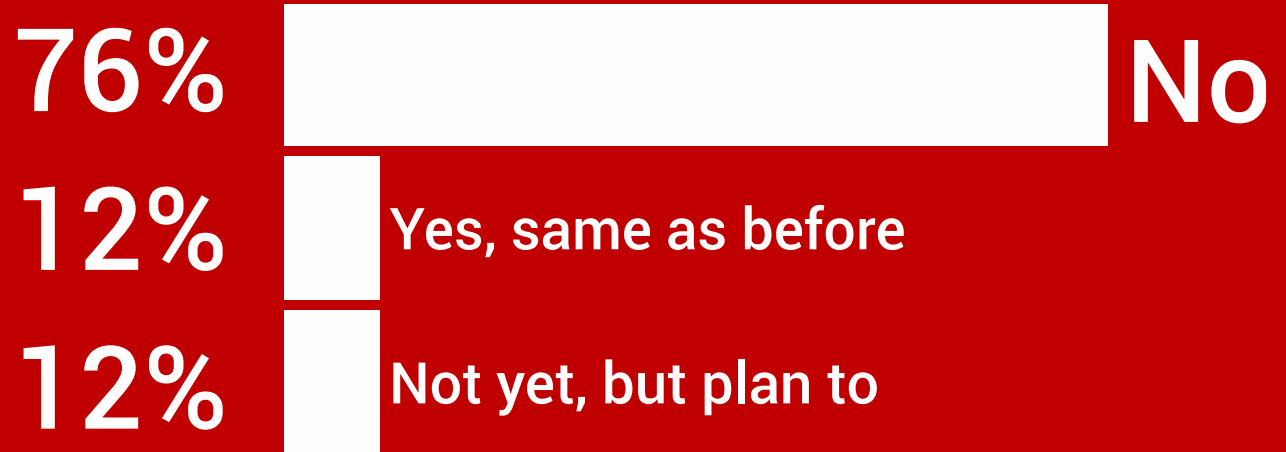
Monitoring and Auditing

Is your Company monitoring emails?

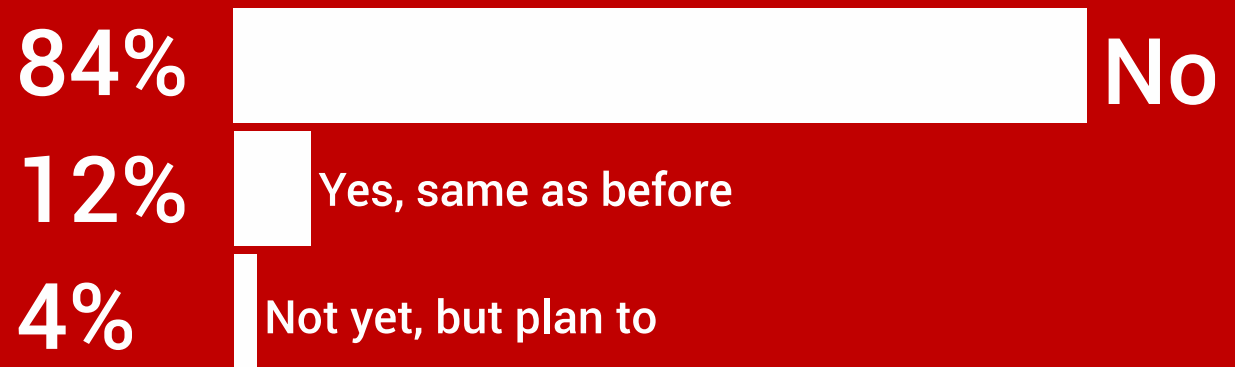


Monitoring and Auditing

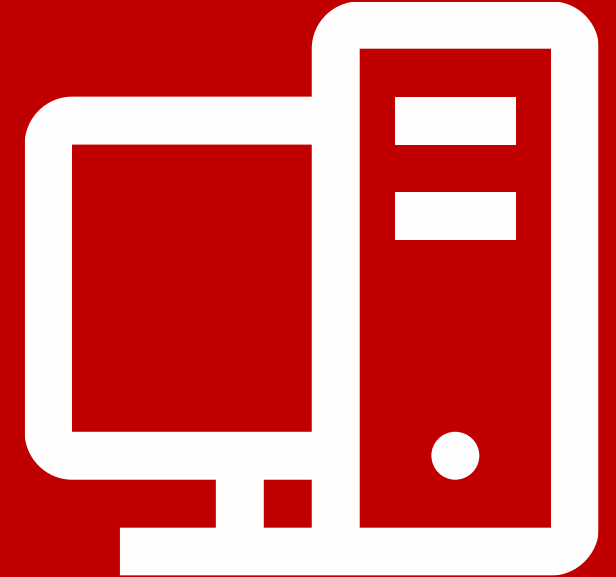
Is your Company monitoring external communications via texts or other messaging platforms (e.g. WhatsApp)?



Is your Company monitoring internal communications texts or other messaging platforms (e.g. Skype, Teams, company instant messaging, etc.)?



Is your Company conducting desk-based reviews (i.e. Transactional Monitoring) of programs?



52%

Yes, same as before

28%

Yes, more than usual

12%

No

8%

Not yet, but plan to

Monitoring and Auditing

Have you experienced challenges with monitoring virtual programs or interactions with HCPs?

40% Yes

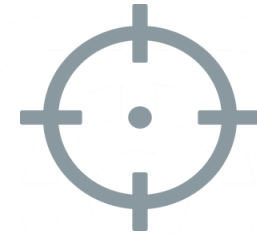
60% No



Virtual Activities



Monitoring &
Auditing



Where Should
Compliance Be Focused?

Moving Forward

Moving Forward

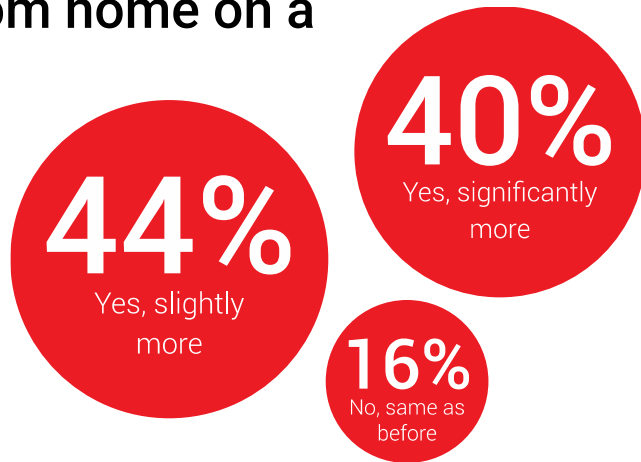
At what level do you think you will monitor these virtual activities?

80% Include in annual monitoring plan

20% Ad-hoc monitoring as needed

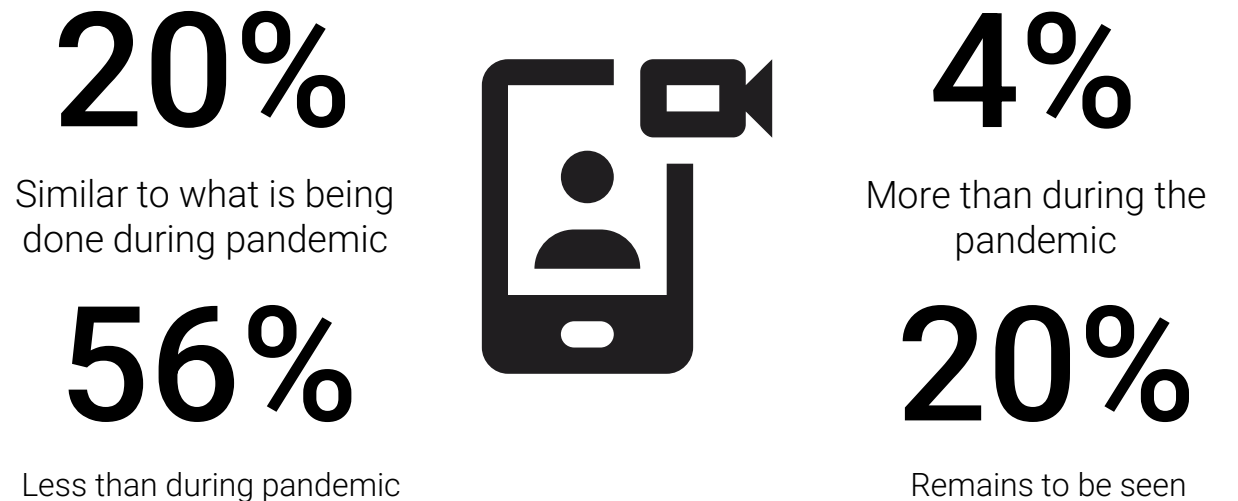
Moving Forward

As a result of the pandemic, will more of your Company personnel be working from home on a regular basis?



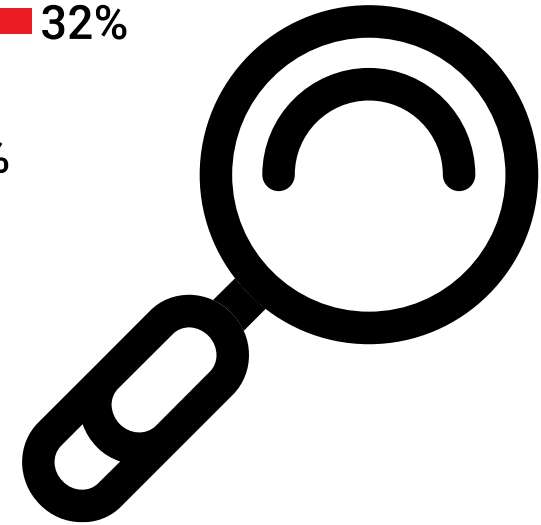
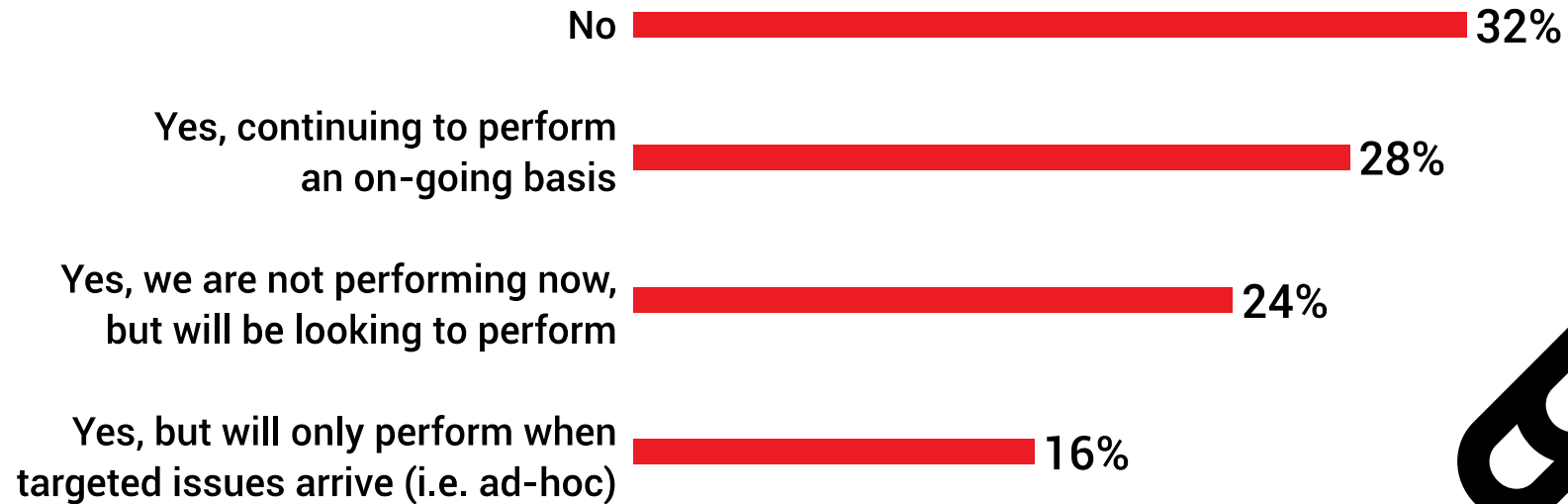
Moving Forward

At what level do you think your Company will continue virtual activities post-pandemic?



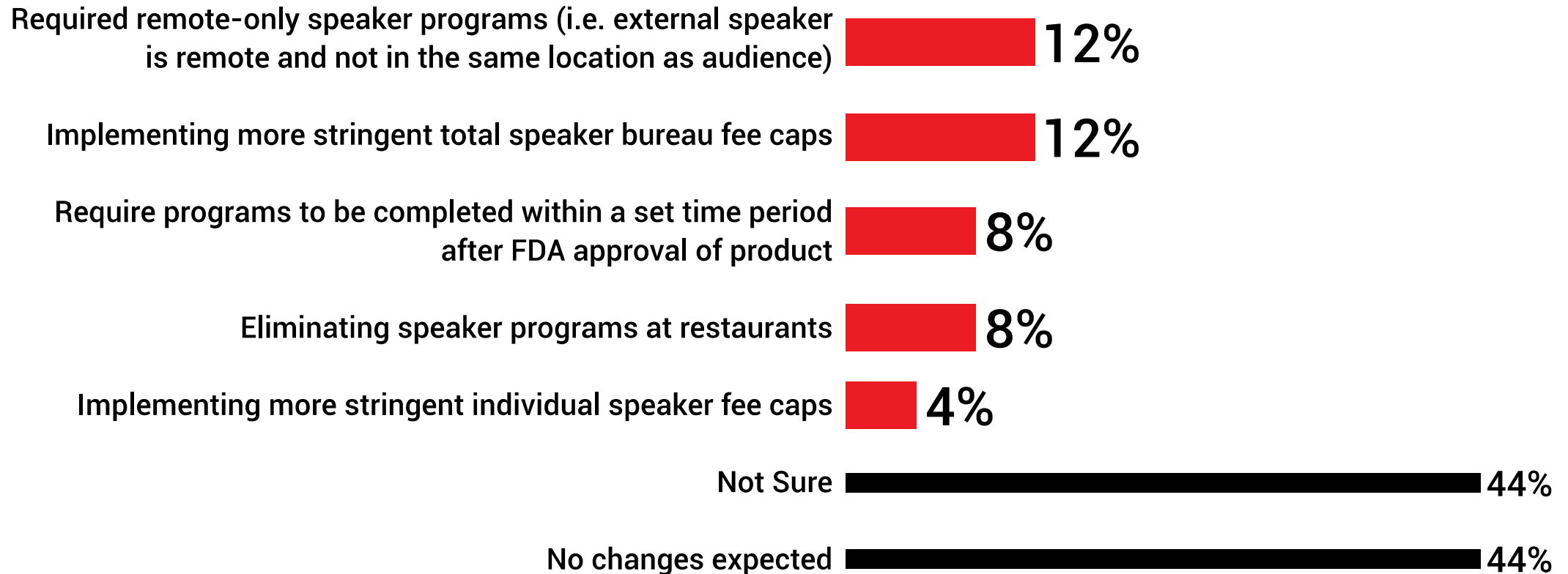
Moving Forward

Do you foresee your Company performing or continuing to perform ongoing (e.g. quarterly) email monitoring post-pandemic?



Moving Forward

The OIG recently issued a CIA mandating additional restrictions on speaker programs. In light of this, is your Company contemplating the following (select all that apply):



Where Should Compliance Be Focused?

With Commercial and Medical teams taking their activities and interactions with HCPs virtual, now more than ever, Specialty Pharmaceutical Compliance teams need to adapt and take proactive measures to provide updated guidance for new processes, update risk assessments, and conduct appropriate and effective monitoring of virtual activities.

To minimize risk and continue to evolve their Compliance programs, companies should be considering what data they are analyzing, how they are monitoring and auditing activities, and ensuring that documentation is fully updated as processes change.



Analyze Data

Understand

- Understand the volume and prevalence of new activities



Analyze

- Analyze data and look for trends or outliers (e.g., spend data, call reports, virtual speaker programs)



Review

- Review operational data capture processes to determine if updates need to be made to meet current demand



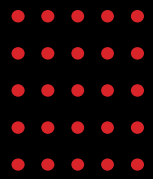
Review

- Review charitable contribution processes to account for COVID-19 related requests



Monitor & Audit

Refresh	Refresh risk assessment to identify potential new risk areas
Monitor	Monitor virtual programs and sales rep activities
Determine	Determine if current monitoring tactics are efficient and effective in monitoring the new ways of conducting business
Increase	Increase email/text monitoring of HCP and patient interactions to address the increased volume
Conduct	Conduct transactional reviews of various activities (e.g., virtual meals, HCP contractual arrangements, speaker programs, etc.)



Update Documentation



Review

Review existing policies and SOPs and identify areas in which updates need to be made to reflect current processes



Develop

Develop new or update existing training materials for virtual activities



Update

Update monitoring and auditing checklists to account for virtual program considerations

Concluding Thoughts

- Digital / Virtual interactions with customers have increased dramatically over the past six months.
- Creative and innovative / effective ways to virtually engage with healthcare professionals, payors, patients, and caregivers.
- Novel business models require novel compliance programs:
 - Agility and purposeful strategy is needed to effectively evolve risk assessments, policies, training, and monitoring.
 - In this respect, we are not looking to “flatten the curve,” we are looking to stay ahead of the curve.

Contact Us: Full Survey Results

Full results of Helio Health Group's "Challenges Posed by Field, Commercial, and Medical Personnel Changes to Virtual Activities in Response to the COVID-19 Pandemic" survey can be obtained by emailing us at info@heliohealthgroup.com.

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