The Life Sciences Guide to the DOJ ECCP Updates

Veeva

In September of 2022, the United States Securities and Exchanges Commission (SEC) and Commodity Futures Trading Commission (CFTC) imposed a total of $1.8 billion in fines on 16 Wall Street firms.

The transgression? Instant messaging.

Specifically, the regulators targeted how employees at these firms conducted business with customers over platforms like WhatsApp and Signal, where messages were not preserved and could be deleted by an employee at will.

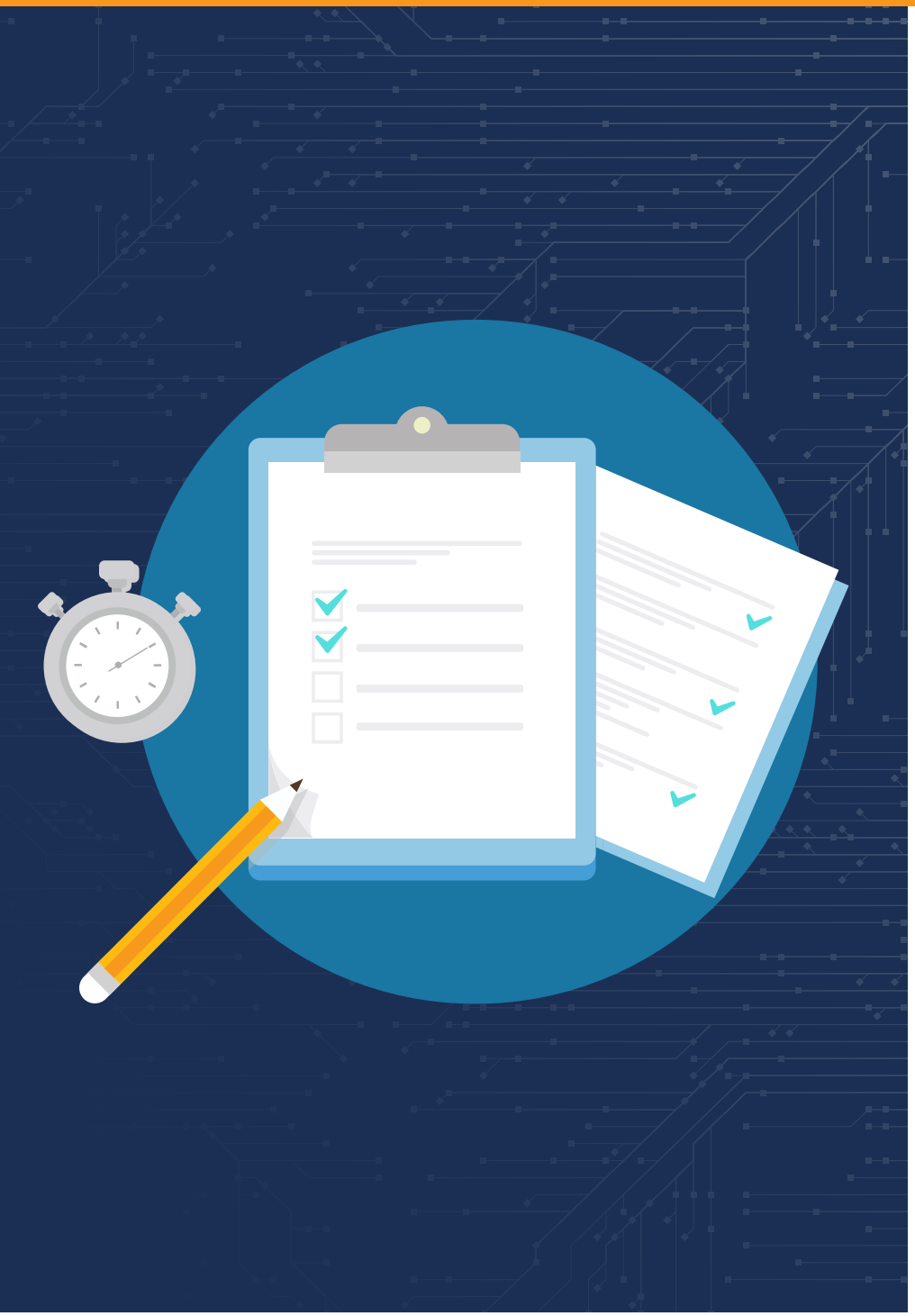
In a press release, the SEC called out these firms for "failing to honor their recordkeeping and books-and-records obligations." CFTC Commissioner Christy Goldsmith Romero even issued a stern warning: "[T]he era of evasive communications practices is over."

Following her comment, the United States Department of Justice (DOJ) updated its Evaluation of Corporate Compliance Programs (ECCP) in March of 2023, tightening its scrutiny of messaging apps across all industries.

So what does this update mean for life sciences, and what should biopharmas do about it? Let's delve deeper into its implications and the actions biopharmas may take in response.

$1.8B

in Regulatory Fines Split Across 16 Organizations and Affiliates



What is the Department of Justice's ECCP?

The ECCP is a document that prosecutors from the DOJ use to determine whether a company has sufficient compliance measures. The DOJ may use this document in investigations, charging decisions, or resolutions.

For example, suppose the DOJ suspects a company of an offense. In that case, prosecutors will use the standards set out in the ECCP to evaluate if it had a strong enough compliance program at the time of the suspected violation. If the company is ordered to take remedial measures, the corrective actions it must take are also based on the standards in the ECCP.

What does the ECCP say about messaging apps?

In this updated version of the ECCP, the DOJ explicitly designates a section for "messaging apps, including ephemeral messaging apps," where messages are designed to disappear after a set time. It also emphasized that "to the greatest extent possible, business-related electronic data and communications [must be] accessible and amenable to preservation" by the evaluated company.

When prosecutors judge how "accessible and amenable to preservation" a company's communications are, the ECCP asks them to consider three dimensions:

1. COMMUNICATION CHANNELS

This first dimension looks at whether a company's thought process around which communications channels to use has taken data preservation into account.

- First, prosecutors are asked to consider which channels a company has sanctioned for communications and whether special settings or configurations are mandated for each channel. They must also ensure sufficient rationale for allowing each channel to be used with these specific configurations.
- On top of channel selection, prosecutors are also asked to look into whether communications across each channel can be preserved. They must evaluate how each channel preserves and deletes information, the employee options for preservation and deletion in each channel, and the channel's data retention policies.

2. POLICY ENVIRONMENT

This dimension requires prosecutors to assess whether the company's business rules provide enough support for data preservation.

- Prosecutors are asked to scrutinize the policies surrounding replacement devices and whether a company has rules for retrieving and saving communications data from replaced devices.
- Another area they will look into is a company's code of conduct, privacy, and security, along with employment laws and policies, and whether they provide enough protection for communications data and the ability for the company to monitor and access said data.
- The final aspect prosecutors will look at is the company's track record of enforcement regarding devices and messaging apps. Simply establishing policies is not enough—the prosecutors must see that a company is truly following through on these policies.

3. RISK MANAGEMENT

This dimension looks at the company's response during and after transgressions of communications data preservation.

- When considering security, prosecutors will consider how the company maintains control and oversight over the communication channels used to conduct its business.
- Prosecutors will also examine the company's consequences for employees who interfere with or refuse access to communications data.
- Lastly, prosecutors will evaluate the organization's risk tolerance and see whether its policies around preserving and managing communications channels are reasonable given its business needs and risk profile.

How should I keep my organization compliant with the updated regulations?

Here are four recommendations for teams who are looking to stay current with this latest regulatory guidance.

1

Review business process for communications platforms

As the life sciences industry refines the omnichannel model, it's essential to incorporate compliance measures into existing channels such as email, text messages, messaging apps, and voice and anticipate emerging channels.

For each channel, there should be a thorough review of the policy areas highlighted in the ECCP:

- Regulations for employees who use these channels
- Consequences for employees who violate the channel regulations
- Processes to ensure the preservation of communications in each channel
- Methods for enforcing the business rules around each channel

During the review, establish a solid line of reasoning for policy decisions that thoroughly consider both business and compliance needs.

2

Reinforce business policies with customer-facing teams

Because the ECCP specifically mentions employee-level policies, consequences, and enforcement, preemptive training for customer-facing employees is important. This training can ensure they understand the level of discoverability in the channels they use and the significance of preserving business communications and complying with the company's data preservation policies.

In addition to training, biopharmas can also consider built-in guidance within the employee's workflow, such as help text in communications applications or on employee devices.

3

Enable compliance to detect and address transgressions

Preserving communication data serves the purpose of preventing and managing noncompliant communication.

To do that, compliance teams must have oversight of the communication activity in each channel and mechanisms to alert them when noncompliant communications happen. After the noncompliant activity is found, a process should be in place for compliance teams to take timely remedial action against each activity.

Without these three key compliance capabilities, it can be difficult for compliance teams to catch and respond to violations even with a more comprehensive set of communications data.

4

Implement solutions optimized for recordkeeping

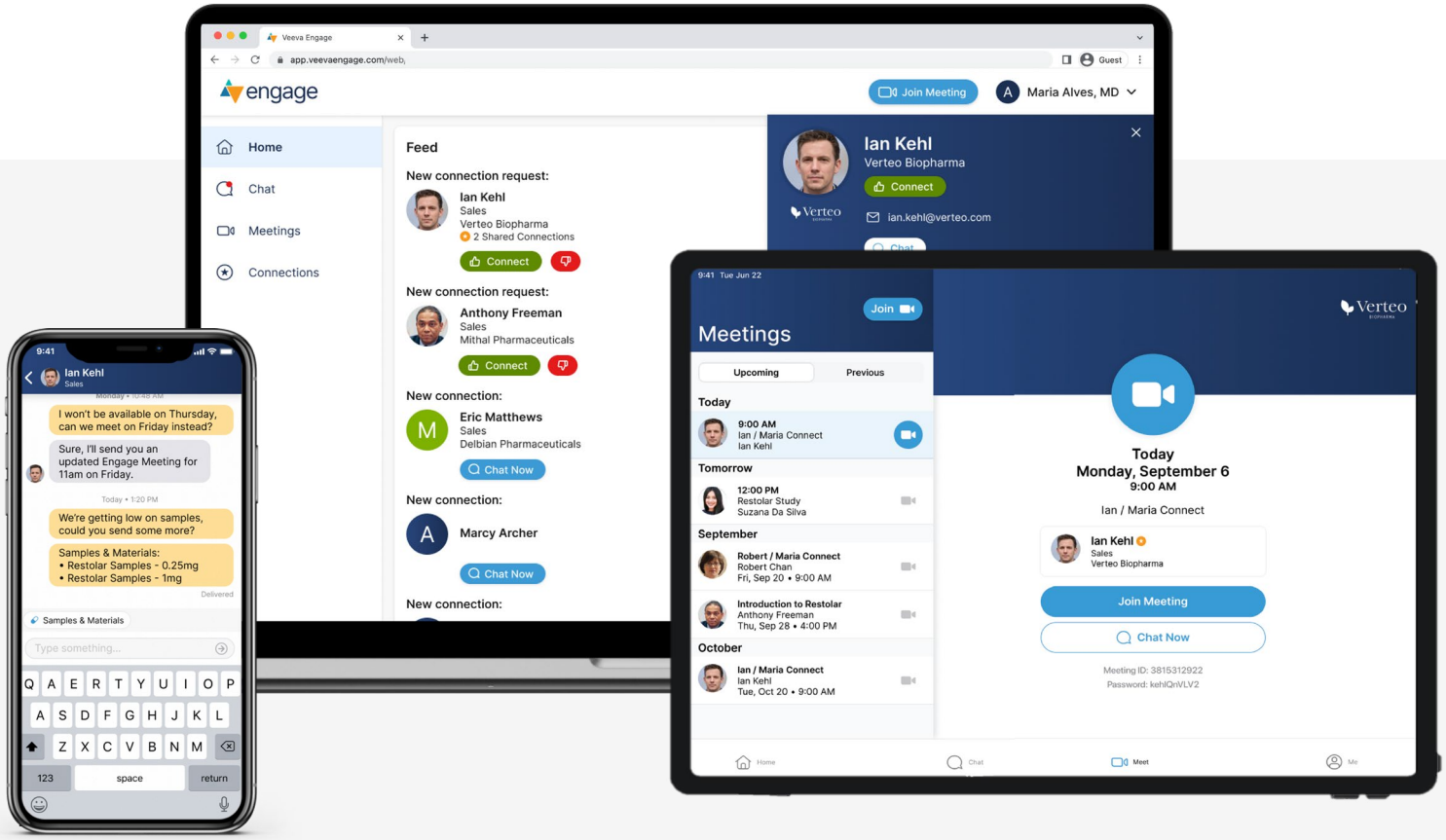
The right tools can make preserving communications easier, and the ECCP acknowledges this by making the recordkeeping capabilities of each communications channel a factor in its evaluation.

Many solutions on the market now provide full traceability of communications activity so that home office users can see what customer-facing teams are doing in the field.

Veeva Vault CRM Approved Email, for instance, has a complete log of emails sent and opened, as well as email content. For additional risk mitigation, it is fully integrated with Veeva Vault PromoMats and Veeva Vault MedComms, providing guardrails to ensure only MLR-approved content makes it to field teams.

For messaging, Veeva Vault CRM Engage provides complete visibility into conversations between field teams and HCPs. All chat activity is available for recordkeeping and monitoring purposes. Field teams can enrich messaging interactions by sending compliant links to approved brand content and track HCPs' content click-through. All activities between the field and customers are tracked for convenient monitoring.

On top of Vault CRM Engage, Veeva Vault CRM Approved Notes provides a monitoring layer to help compliance teams detect noncompliant messaging. Vault CRM Approved Notes can monitor any free text field in Vault CRM, along with Vault CRM Engage messages, for a list of flagged words and phrases. If any blocklist entries show up in a field or message, they will be flagged for compliance teams to do further review and mitigation.



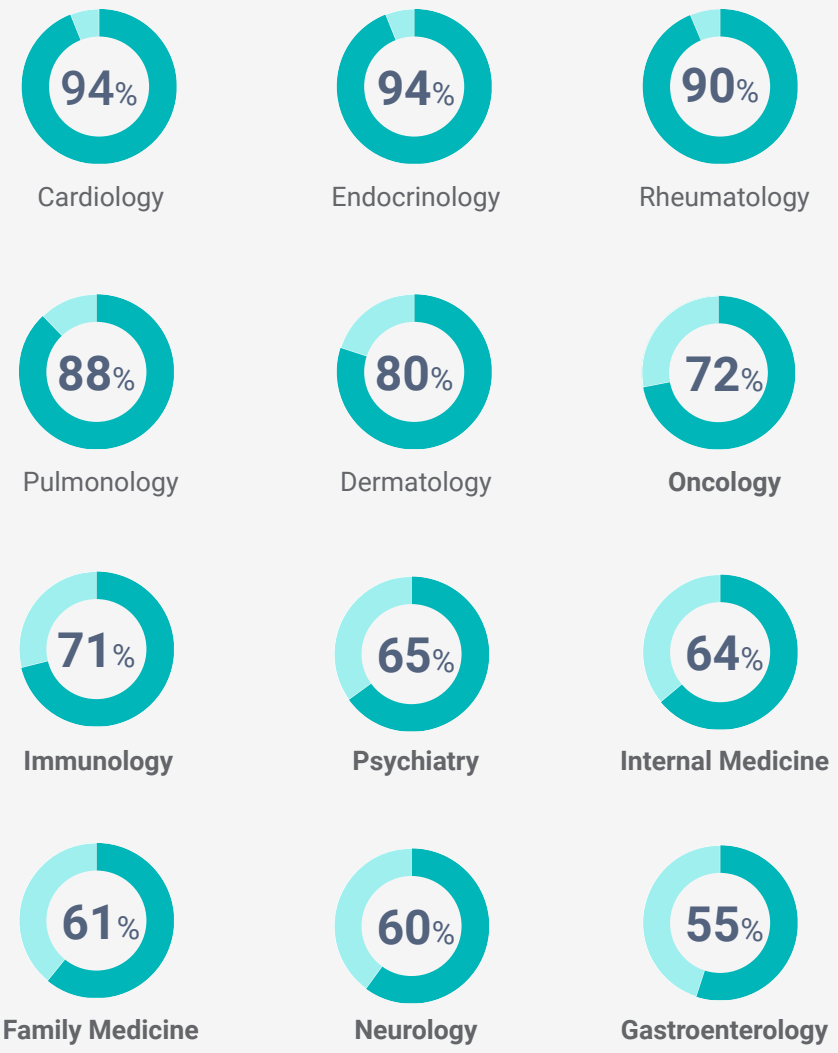
Compliance as a chance for new commercial opportunities

Today's HCPs expect a higher standard of customer service from the life sciences industry. Digital communication channels often play a critical role in enabling this higher standard of service, and this update to the ECCP helps remove uncertainty as to what constitutes their proper use.

Under these more precise directions, savvy organizations that want to put their customers at the center of their omnichannel strategy can activate channels they couldn't before. And with these channels comes a chance for commercial teams to re-evaluate strategy and discover new commercial opportunities.

According to Veeva Pulse Data from June 2023, 57% of targeted prescribers in the United States have used Vault CRM Engage to communicate with life sciences field teams. Adding this channel may help field teams better access these HCPs in a way that matches the HCPs' existing preferences while staying compliant.

Percentage of Targeted U.S. HCPs Using Vault CRM Engage, by Therapeutic Area



Veeva Pulse Data, June 2023

Better HCP engagement, better patient care

Opportunities like this with Vault CRM Engage create win-win situations for the life sciences company and the regulator, helping companies comply with regulations and increase reach simultaneously. More importantly, it also meets the HCPs' need for readily available service to deliver better patient care—the goal that HCPs, life sciences, and regulatory agencies all strive to achieve.

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