

Best Practices

for Interacting with U.S. Regulators (FDA - Food and Drug Administration)

Digital health regulations and interacting with the [United States Food and Drug Administration \(FDA\)](#) can seem intimidating at first, but, in reality, these regulators exist to ensure the safety and effectiveness of digital health products and can facilitate broad, national marketing authorizations for these products.

Regulatory requirements are in place to protect the public from potential risks associated with the use of these technologies, and satisfying regulatory requirements can instill public confidence in a product. Some digital health technologies may be subject to regulation as traditional medical devices, while others may not be. Even when a product is regulated as a device, it is important for developers to understand that there are various levels of device regulation, and regulatory requirements are tailored to the risk presented by the device. It is important for innovators and manufacturers of digital health technologies to be familiar with the relevant regulations and to work closely with the FDA to understand how their device will be classified based on risk.

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WHY DOES REGULATION MATTER?

An overview

In the rapidly changing landscape of digital health, innovation has often [outpaced regulations](#), especially for novel technologies and emerging industries. This mismatch creates more [uncertainty about the value of pursuing a regulated digital health product](#), making it easy for individuals, teams, and companies to follow a strategy that completely avoids regulatory oversight. However, working with regulators throughout the development of a product can lead to positive health and economic outcomes. Early demonstration of regulatory compliance also provides significant advantages of regulatory oversight from the lens of product and business differentiation. Going to market with a product cleared by the FDA can provide market advantages. Digital health innovators who take the time to work with the FDA to ensure evidence-based product safety and effectiveness are seen as more marketable and reliable by investors and payers, leading to more capital investment and a higher likelihood of payers' approval and consistent reimbursement.







Even though interacting with the regulatory agency may sound burdensome, the positive results are undeniably valuable. While meetings with the FDA can be time-consuming and require adequate preparation, they are critical to gain a clear understanding and direction from the agency and can provide developers much needed guidance for product development and regulatory submission strategy. Depending on the stage of development, the type of product, the regulatory process, etc., an innovator or a product developer may need to interact with different offices or divisions within the FDA. Therefore, one of the key elements of the design and development process of a digital health product is an interaction with the regulatory agency.

Overall, interacting with the FDA is an important part of gaining clarity on the regulatory requirements that apply to your product and ensuring the safety and effectiveness of your product. By being transparent, accurate, and proactive in your communications with the agency, you can help ensure a smooth and successful regulatory process.

Innovating in gray space with evolving digital health regulations may seem intimidating, especially for novel and innovative health technology solutions, but in reality, it is not rocket science.



Benefits of quality interaction and communication with the FDA

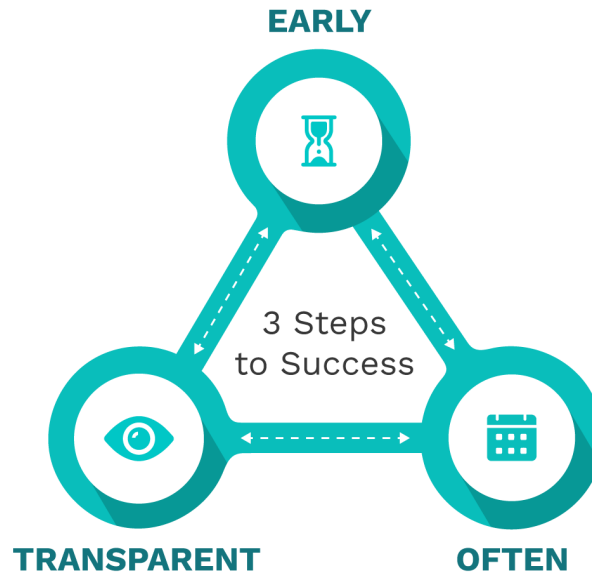
 <p>Shared Understanding</p>	 <p>Faster & (Likely) Better Outcomes</p>	 <p>Enhanced Efficiency</p>
<p>Clear and consistent communication ensures shared understanding between the agency and the industry about the regulatory status of a product, development issues to be addressed, and submission requirements (if any), allowing the two entities to work towards a common goal. Having a clear understanding and record of the regulatory status of your product can also facilitate outside investment in product development.</p>	<p>Clear and accurate communication with the FDA can help to clarify requirements and expectations, leading to a faster and more rigorous product development and oversight process. In particular, such communication can aid companies in understanding which product features pose the highest risk and regulatory burden, so that product development and design can be well-informed and strategically structured to deliver a high-value product.</p>	<p>Good communication can facilitate and streamline the regulatory review process (especially for new medical products by enabling fewer questions from the agency and fewer rounds of regulatory review), reducing the risk of delays or misunderstandings.</p>
 <p>Improved Relationships</p>	 <p>Enhanced Compliance</p>	 <p>Built Trust</p>
<p>Establishing strong, open lines of communication with the FDA can help to foster a positive working relationship and accountability between the agency and industry stakeholders. This relationship benefits multiple stakeholders and can accelerate access to high-value medical products for patients.</p>	<p>Effective communication can help to ensure that all parties are aware of the regulatory requirements and can work together to ensure compliance. Such communication can help developers avoid costly delays or legal issues that can arise from non-compliance.</p>	<p>Maintaining transparent and responsive communication with the FDA can help a company build trust with regulators and the public. This trust can be particularly important for companies that rely on public trust to sell their products.</p>



WHAT SHOULD I DO?

Three steps to successfully nail the interaction with the regulatory agency

To successfully ace the interaction with the regulatory agency, consider this triphasic approach. Your three steps to success entail:



When is a good time to start interacting with the FDA?

→ **EARLY:** *Early bird makes the nest right*

Consider reaching out to the agency as early in the process of the product development as you can. However, it is important to have at least your intended use and some basic product functionalities somewhat defined by the time you reach out, to ensure interactions are fruitful and the advice received is accurate and relevant across the product development lifecycle.

How often should I keep in touch with the FDA?

→ **OFTEN:** *Don't be a stranger after the first date*

When in doubt, reach out to the FDA. There are various engagement channels you can use. It is particularly important to reach out if you add new product features, change the design, or change how your product would be used as you proceed through the development process. This communication ensures advice from the FDA remains accurate and relevant to the final product.

How much should I share with the FDA?

→ **TRANSPARENT:** *Transparency goes a long way*

Be honest and up front about your product, evidence, approach to product testing, etc. – even if you are sharing future plans with the FDA. Additionally, it is critical to share the testing plans and data you have generated, and to make an argument for why you believe your product falls into or outside a certain regulatory category. Present your case to the FDA, being fully transparent.



WHAT SHOULD I KNOW?

Best practices for successful “non-written” communication(s) with the agency

1. Define the purpose of the interaction and have specific goals

Be clear as to the reason for the interaction and the specific questions that you are seeking to clarify with the FDA about your digital health product.

2. Select the right type of interaction to achieve your goals

Once you know what you hope to achieve, select the appropriate interaction type. If you want formal written feedback critical to your strategy that you can reference later or share with investors, you likely want to pursue a meeting. Familiarize yourself with the available meeting types and select the appropriate one for your issue.

If you are seeking informal feedback on a minor issue or process question, which is not critical to your product strategy, you may be able to communicate through more informal channels (i.e., e-mail, phone call).

3. Be intentional and use the appropriate tone

Be genuine and serious about interacting with the agency. Every communication must be treated as a formal communication, as it will become part of the administrative record.

4. Know the process and familiarize yourself with the relevant guidance and regulations

The FDA has established guidelines and regulations for development, testing, and marketing of various products. It is important to familiarize yourself with these guidelines and ensure that you understand and are in compliance with them before meeting with the agency.

The FDA has a structured review process for evaluating products. Familiarize yourself with this process by reviewing FDA guidance documents and policies, then prepare your questions accordingly. You do not want to waste valuable meeting time on something related to the review process that can be easily obtained by researching publicly available sources.

5. Plan before taking the leap

Have specific goals in mind and create a well-planned and well-edited meeting package (meeting request, briefing book on the issues, agenda, questions for the FDA, attendees who you would like to be present at the meeting, etc.) and a realistic meeting agenda beforehand. Share this meeting package and agenda with the agency ahead of time per the processes and timelines outlined in the guidance for the appropriate meeting type.

Ensure you have done your homework to collect all relevant information before reaching out. You will save time, energy, and back and forth if you are well-organized in your outreach.



6. **Plan your time wisely**

Traditionally, FDA meetings last only 60 minutes. As time with the FDA is limited, use the available time wisely.

Sometimes, you will receive only written feedback and will not be granted a meeting. Therefore, it is critical that you provide a robust meeting package and well-defined questions to get the feedback you need, whether it is in written form or in a meeting.

Assemble any relevant documentation or data that may be needed to support your request or position and submit it with your meeting request or meeting package.

7. **Seek, don't sleep (or wait)**

If you are uncertain about how to interact with the FDA, or have concerns about potential regulatory issues, consider seeking the guidance of a legal or regulatory affairs professional.

8. **Show, don't tell**

Be prepared to:

- Provide supporting documentation that concretely supports your positions and/or claims. Blanket statements or generalizations will not carry the day. The FDA may request additional information or documentation to support your product or request.
- Lead the call. Don't show up with empty hands. Determine whether or not you have all necessary information collected.
- Identify which member of your team is best poised to answer obvious questions. Assign roles and draft responses for these questions in advance.

9. **Take complete notes**

Proper documentation can help you demonstrate compliance with FDA regulations and can also be helpful if you need to make changes to your product or process.

The FDA will provide minutes for most meeting types. It is critical that you also take your own notes and minutes, as these can be shared with the FDA to avoid misunderstandings related to the advice provided during the meeting or the meeting outcome.

10. **Communicate clearly and transparently**

The agency values transparency and clear communication. It is important to provide complete and accurate information to the FDA and to be open and transparent about any challenges or issues that may arise during the development or marketing of a product.

It is also important to provide information in a well-organized manner, with a clear description of the product (including images, as appropriate), its potential intended uses, and the appropriate context for any test reports, data, and/or testing plans, so that a reviewer who is unfamiliar with the product can understand the product context and come prepared to the meeting. You do not



want to waste valuable meeting time answering basic questions about the product.

11. **Respond to requests promptly**

If the FDA contacts you or requests information from you, be sure to respond promptly and accurately. Delays in responding could result in regulatory action.

Best practices for successful “written” communication(s) with the agency

1. **Use clear and concise language**

Avoid using jargon or technical terms that may be unfamiliar to the FDA. Use plain language and avoid using unnecessary words or phrases.

2. **Be organized and thorough**

Present your information in a logical and organized manner, and be sure to include all relevant details.

3. **Attach relevant supporting documents**

Attach relevant files to the email instead of embedding them in the email body or adding hyperlinks, especially to any Google workspace document (e.g. Google document, Google spreadsheet, Google slides, etc.) that may be accessible to the agency server.

If you are submitting a document or request to the FDA, be sure to include any relevant supporting documents or data.

4. **Follow the required format**

Be sure to follow any specific formatting requirements or guidelines provided by the FDA. These guidelines may include requirements for font size or margins, or the use of specific forms or templates.

5. **Use an appropriate tone**

Use a professional and respectful tone in your communication with the FDA. Avoid using overly casual language or making inappropriate comments.

6. **Use proper grammar and spelling**

Pay attention to the grammar and spelling of your communication. Poorly written communication can be confusing or difficult to understand and may be viewed as unprofessional.

7. **Use appropriate citations**

If you are citing information from other sources, be sure to use proper citations and include any relevant references.

8. **Check for errors**

Before submitting your communication to the FDA, be sure to proofread it carefully to ensure that it is accurate and free of errors.



9. **Follow FDA guidelines**

Familiarize yourself with the FDA's guidelines for written communication and make sure to follow them closely.

10. **Use proper formatting**

Use headings, bullet points, and other formatting tools to make your document easy to read and understand.

WHAT SHOULD I AVOID DOING?

Things to avoid

✘ **Do not provide false claims or misleading information about your digital health product**

These claims include making false or misleading statements on product labels, in advertising, or in other interactions with the agency.

Do not make false or unsubstantiated claims, especially about the safety, effectiveness, or benefits of a product.

✘ **Do not assume you know the regulatory status of the product or regulatory obligations.**

You should present your case, but understand that the FDA may disagree. The FDA determines a product's status and obligations as long as the product is within its jurisdiction. The requestor may still be subject to other obligations.

✘ **Avoid withholding important information or trying to conceal information from the FDA.**

It is important to be transparent and forthcoming with the agency about any issues or concerns related to your product.

If there are issues with your product, it is important to report them to the FDA and to take appropriate corrective actions.

The FDA may also be able to advise as to how to mitigate risk or address product issues.

✘ **Do not ignore or fail to respond to requests or questions from the FDA.**

The FDA has the authority to regulate and enforce compliance with federal regulations, and failing to cooperate can result in penalties.

Additionally, if the FDA raises a concern in a meeting or communication, it will likely be raised again during the product review and could result in a failure to clear or approve the product for marketing if it is unaddressed.

✘ **Do not try to bribe or influence FDA employees.**

Using leverage of personal relationship/connections or more could potentially violate the law and result in criminal charges.



Additionally, all communications with the agency could be subject to Freedom of Information requests and could become public. Attempts to influence FDA employees have appeared after the fact in public news sources and can harm a company's reputation, even if the activity did not violate the law.

WHERE CAN I FIND ADDITIONAL INFORMATION?

Additional Resources

- [Regulatory Engagement Pathways Map for Digital Health Products](#)
- [Guide: Engagement Pathways to Communicate with U.S. Regulators](#)
- [Glossary of Key Terms](#)

Access DiMe's Digital Health Regulatory Pathway Resources



Identify your
regulatory pathway



Build your
regulatory strategy



Interact with
regulators

