Communication In Drug Development



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Course Objectives:

By the end of this course, you will understand the need for a fully formed external communication strategy alongside excellent clinical development. From articulating the value proposition to potential investors while fundraising to appropriate positioning to be reported by the investment community when discussed alongside competitors.

It will also become clear the value of standardized communication through developing and evolving a lexicon and publication strategy. How to develop core claims starting with epidemiology, mechanism of action, through to superiority and points of differentiation claims

Introduction

As the strive for precision medicine intensifies, due to opportunities presented by the unlocking of the human genome, development of medicines continues at pace for rare diseases, improving overall survival in cancer, treatment for new conditions, such as (COVID), and delivering drugs only to patients pre-disposed to get a response.

Coupled with the processing power of AI, we can now successfully identify the most appropriate therapeutic targets, develop a substance structure that selectively and effectively binds to these targets, and safely modulate these targets to produce the desired therapeutic response.

This is only attainable if there is a seamless and effective communication amongst relevant sectors involved in drug discovery and development process. Effective communication is arguably the most important element of drug development.

A well developed external communication strategy is vital to ensure that the investment community have enough information to appropriately position your product versus competitors and leverage any differentiating factors to support raising capital, educate the prescribing community, support the work of patient advocates and help healthcare systems plan for the incorporation of this new product**.**

Moreso, effective communication in drug development ensures that all stakeholders, including regulatory agencies and manufacturing partners, are aware of the progress of the project and any potential challenges or issues that may arise. This can help to prevent delays and other problems that can occur when key stakeholders are not kept informed.

Hence, we will consider an extensive guide on how to foster and implement effective communication in the drug development process. Similarly, we will explore some of the basic principles to ensure effective communication in the drug development process.

Module 1. Early Asset Communication Strategy.

- ***Objectives:*** To find the appropriate doses.
- To develop proof of concept studies.
- To design registration trials.

Early asset strategy refers to a company's approach to developing and commercializing its early-stage assets, such as new drugs or other products. In the context of drug development, early asset strategy refers to the strategies and tactics that pharmaceutical companies use to identify and develop new drug candidates. This can include a wide range of activities, such as conducting market research to identify unmet medical needs, sourcing new drug candidates from external partners or through in-house research and development, and implementing clinical development plans to bring new drugs to market.

The aim of early asset strategy in drug development is to help pharmaceutical companies identify and develop new drugs that have the potential to address unmet medical needs and generate revenue for the company. This can involve a significant amount of time and resources, as well as careful planning and coordination across multiple teams and functions within the organization.

Ultimately, early asset strategy helps to identify the best path forward for the drug product, in terms of development, regulatory approval, and commercialization. An early asset strategy typically involves a number of different components, including:

- ❖ Identifying the key target markets for the drug product
- ❖ Developing a plan for clinical trials and regulatory approval
- ❖ Identifying potential partners and collaborators, such as manufacturing partners or distributors
- ❖ Developing a marketing and sales plan for the product

- Estimating the potential costs and revenues associated with the drug product

All of this is done to provide a clear and comprehensive plan for the development and commercialization of the new drug product, with the aim of maximizing its potential value and minimizing risks.

1.1. Steps Involved in Developing an Early Asset Strategy

To achieve a successful early asset strategy, steps involved in developing an early asset strategy will vary depending on the specific product and circumstances, but there are some key steps that are common to most strategies. These steps include:

- Identifying the key target markets for the product. This involves analyzing the potential demand for the product, as well as identifying any potential competitors and the key drivers of demand in the target market.
- Determining the correct doses as well as appropriate dosing regimen for the new drug product.
- Developing a plan for clinical trials and regulatory approval. This involves identifying the specific clinical trials that will be required to demonstrate the safety and effectiveness of the product, as well as the regulatory requirements that must be met in order to bring the product to market.
- Identifying potential partners and collaborators. This can include manufacturing partners, distributors, and other companies that can provide valuable support and expertise in the development and commercialization of the product.

Finally, the goal of these steps is to develop a comprehensive plan for the development and commercialization of the product, with the aim of maximizing its potential value and minimizing risks. This can help to ensure that the product has the best chance of success in the marketplace.

Early asset strategy also involves educating both the internal and external stakeholders, publication strategy, communicating with investors, and literature references, amongst others. All of these we will discuss in subsequent modules.

Summary

Early market strategy in drug development entails setting solid foundation for the drug development process. It involves identifying unmet medical needs and then developing drugs, at correct doses, that will seamless meet this need, and also ensuring all relevant sectors, stakeholders and regulatory bodies are not left in the dark.

Module 2. Investor Communication

Objectives: To keep investors informed about the progress of the drug development process.

- To provide transparent and accurate information about the potential risks and rewards of investing in the company.
- To manage investors' expectations and build confidence in the company's ability to deliver value.

Keep in mind the following knowable elements when pitching your program to potential investors:

- The proposed timeline for the development process
- The estimated cost for the entire project
- Other available means of sourcing funds
- The possible risks involved
- Estimated ways to mitigate and reduce the risks.

Conversely, presenting a well-defined program to potential investors and promptly responding to their inquiries can increase their trust in the sponsor, reduce the risk associated with its management team, and guarantee that investors have faith in their investment.

2.1. Key Factors To Consider When Pitching To Investors

When it comes to investor communication in drug development, there are several key factors that companies/sponsors should consider:

- Timing: It's important to provide regular and timely updates to investors throughout the drug development process. This can help to keep investors informed and engaged, and can also help to build trust and confidence in the company.
- Transparency: Companies should be transparent and open about the progress of the drug development process, including any challenges or setbacks that may be encountered. This can help to build credibility with investors and can also help to manage expectations.
- Relevance: The information provided to investors should be relevant and specific to the drug development process. This can help to ensure that investors have a clear understanding of the progress of the drug and the potential risks and rewards associated with it.

2.2. Tips for Communicating Effectively With Investors

Although there is no specific way or method of pitching your proposition to potential investors, there are proven ways to do it.

1. **Develop a Comprehensive Plan**

The importance of developing a comprehensive plan cannot be overemphasized. Apart from it serving as a roadmap for the development process, it is also what you will present to potential investors when pitching your program to them. Developing a working plan is how you make potential investors see value in your program.

If you cannot convince them that your program is lucrative enough for them to invest in, they will never see value in the key messages and information about the program, including nonclinical studies, clinical trials, chemistry, manufacturing, and controls tasks, as well as required regulatory milestones, amongst others.

As the sponsor, you should clearly describe the road to any possible value-creating regulatory and development milestones and lay out the program for investors. Doing this will help ensure that all relevant information is communicated in a consistent and organized manner.

Preferably, it is best to present these components of the development plan in a visual manner. A visual framework that depicts the entire expected development program while acknowledging potential downstream adjustments makes it easy for potential investors to establish the connection between the development program and the intended commercial strategy.

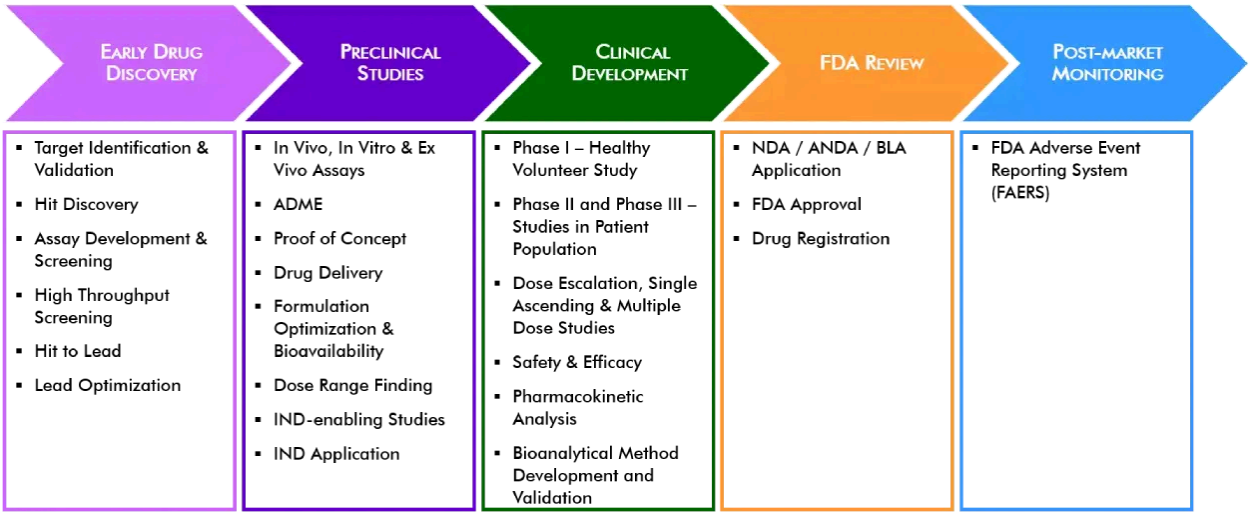


Image alt text - Drug Development Pathway

2. **Hold Presentations and Webinars.**

Hold presentations and webinars to provide more detailed information and updates on the drug development process. This is preferred if you pitch to a group of stakeholders or maybe fundraisers. It is a good opportunity to share more in-depth data and analysis and to answer questions from investors.

3. **Do not Fret Over Negative Feedback.**

You will definitely get negative comments, but don't gloss over it!. The Food and Drug Administration agency will sometimes point out the risks and gaps in the sponsor's strategy or plan of drug development. Sometimes investors will identify the loopholes and risks in your strategy.

outline the identified risk, discuss how it might affect the program, and provide specifics on the mitigation strategy. Acknowledging the risks and describing plans on how to mitigate them will

not only boost your integrity and reputation with your investors, but also it shows you are willing and ready to make corrections where necessary based on their recommendations.

Below are some examples of how it is possible to present negative FDA feedback in a pitch:

"The agency has said that our formulation includes an unqualified excipient. We plan to run a short study to collect data on the safety of this excipient that we can include in our IND application. This means that the earliest we can start our clinical trial is 6 months from now."

"The FDA signaled that our supportive nonclinical safety data is insufficient. If we move straight into an IND, there is a risk that we could get placed on a clinical hold. We feel it would be best to run additional nonclinical studies prior to submitting the IND. With the addition of these studies, we are targeting Q1 to open the IND."

4. **Highlight The Positive.**

Just as you shouldn't ignore the negative comments you get from the FDA, you should include the positives you get from the FDA in your pitch. It makes your proposition more appealing to your potential investors. Investors will be glad to know that the FDA has nice things to say about the program they are investing in. For example, if the program will be shorter than the proposed duration, lower in cost, or have some special designation, highlight it in your pitch.

Below are a couple of examples of how to go about it

"The FDA agreed that our product falls under the 505(b)(2) pathway. The agency has found our proposed abbreviated clinical program, consisting of a single Phase 1 trial, sufficient to support an NDA. We will not have to do large Phase 2 or 3 trials."

"The agency deemed our justification for orphan drug designation (ODD) reasonable and requested that we submit an ODD application. If we receive ODD, we will get a range of perks, including a waived PDUFA fee on our NDA and exclusivity."

5. **Provide Regular Updates**

You should provide regular and timely updates to investors throughout the drug development process. This can include sharing data from clinical trials, discussing any challenges or setbacks, and highlighting any milestones that have been achieved. In fact, they will be willing to put more money into the project should the need arises.

6. **Be Responsive**

You should be responsive to investors' questions and concerns and be willing to provide additional information and clarification as needed. This helps build trust and confidence and supports the program's long-term success.

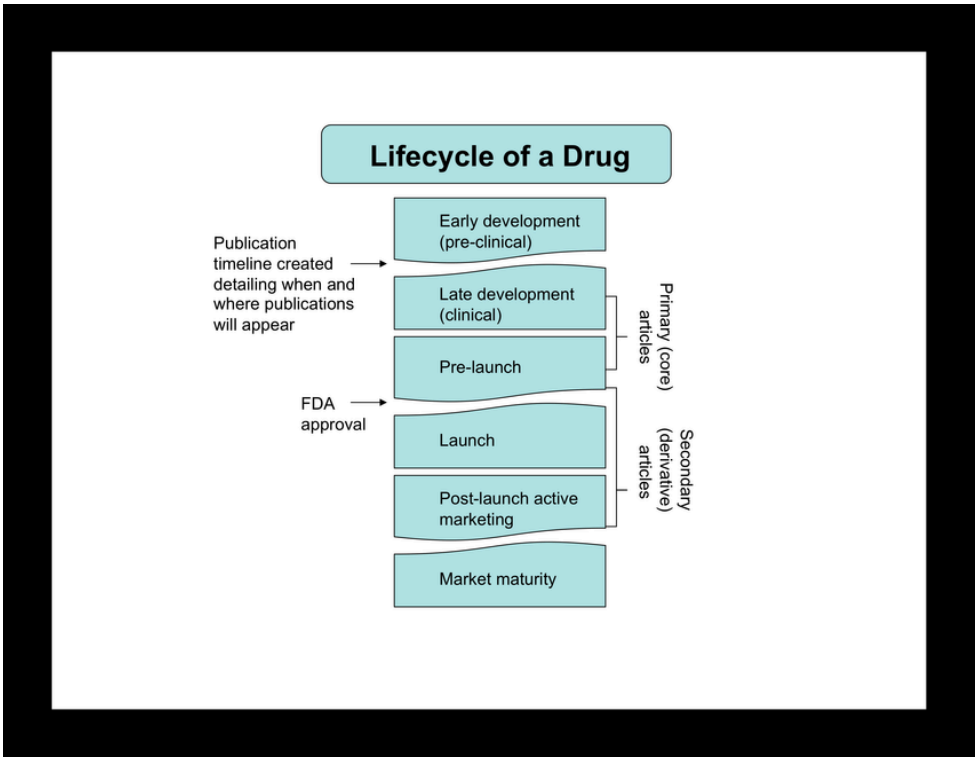
Summary

Investor communication refers to the strategies and tactics used to provide information about a drug and its development progress to potential investors. This may include presenting information about the drug's potential benefits, market potential, and development timeline and providing updates on key milestones and other developments related to the drug's development and commercialization.

Module 3. Publication Strategy.

Objectives: To disseminate the results of clinical research to the scientific and medical community.

- To build credibility and recognition for the company and its drug candidates



Alt image text - A diagram of publication timeline in drug development.

The publication is an important element of the drug development process. The outcome of comprehensive and resources-consuming years of clinical research and studies are documented in publications for professional and public use. Hence, proper measures should be put in place for successful publications.

3.1. The need for publication strategy

Typically, a publication strategy will include a timeline for submitting research findings to scientific journals, presenting the results at conferences, and other forms of dissemination. The strategy may also include plans for releasing interim results, such as during the clinical trial process, as well as final results when the drug is approved for use.

It is important that the publication strategy be transparent and consistent so that researchers and the public can easily access and understand the results of the research.

Below are some advantages of an effective publication strategy:

- First, a well-designed publication strategy can help to ensure that the research findings are accurately and effectively communicated to the public and the media. This can educate the public about the drug and can also help to address any concerns or misconceptions that may arise.
- Second, a publication strategy can help to support the development of new drugs and treatments by providing researchers with access to the latest research findings and enabling them to build on the work of others. This can help to drive progress and innovation in the field of drug development.

Publications require early planning to prevent the loss of scientific data and timely communication of relevant data. However, in recent times, striking a balance between a credible vehicle for information and faster publication has become a major concern. This is due to the clashing issues regarding transparency and authorship disclosures.

When publishing in the field of drug development, it is important to include information about the drug's design and development process, including any preclinical and clinical trials that were conducted. The results of these trials, including any efficacy and safety data, should be included in the publication. It is also important to discuss the potential applications of the drug and its potential impact on patients and the overall healthcare system. Additionally, the publication

should include a discussion of the limitations of the study and any future directions for research in the field.

Let’s consider the steps to publishing scientific data during the drug development process.

3.2. Publishing Scientific Data In Drug Development

To publish scientific data in the drug development process, you will need to follow the guidelines and requirements of the chosen publication outlet, which typically involves writing a manuscript that includes an introduction, methods, results, and discussion section. It is important to present the data clearly and concisely and to provide appropriate context and interpretation of the results.

Before submitting the manuscript for publication, it is important to carefully review the guidelines for the chosen outlet and ensure that the manuscript meets all requirements. This may include formatting the manuscript according to specific guidelines, providing appropriate citations, and including any necessary supporting materials, such as figures or tables.

Once the manuscript is ready for submission, it will typically be reviewed by the publication's editorial team and then sent out for peer review. This process can take several weeks or months and may involve revisions to the manuscript based on feedback from reviewers.

Once the manuscript has been accepted for publication, it will typically be published online and made available to the public. Sometimes, the publication may also be printed in a journal or physical format.

Below is a summary of the steps you can follow to develop a publication strategy in drug development:

- Identify the key research findings and milestones that will be important to disseminate, such as the results of clinical trials and other studies related to the drug.
- Determine the appropriate outlets for publishing the research, such as scientific journals, conferences, or other venues.

- ❖ Develop a timeline for submitting the research findings for publication, taking into account any regulatory or ethical considerations that may impact the timing of the release.
- ❖ Consider plans for releasing interim results, such as during the clinical trial process, as well as final results when the drug is approved for use.
- ❖ Create a plan for communicating the research findings to the public and the media, including any key messages or talking points that should be emphasized.
- ❖ Ensure that the publication strategy is transparent and consistent and that all relevant research findings are made available in a timely and accessible manner.
- ❖ Monitor and evaluate the effectiveness of the publication strategy, and make any necessary adjustments as needed.

However, note that, in the medical and scientific world, the number of publications you have to your name is not as important as the quality of the publications. Hence, you should carefully choose your publishing outlet, and the quality of the content must be top-tier. You can always enlist the help of an excellent scientific writer and statistician.

There are many publishing outlets today, but your field and a profound communication plan will inform your publication strategy and outlets.

The following questions will help you get started:

- ❖ What is the aim or objective of the communication? What do you hope to achieve?
- ❖ Who is the target audience for this research?
- ❖ What is the correct channel to reach your audience, or that helps you achieve this objective?

Summary

Generally, a publication strategy refers to a plan or set of guidelines that outline the approach and methods used to disseminate research findings and other information about a drug to the scientific community and the general public.

Module 4. Scientific Communication Platform

Objectives: To provide a centralized platform for sharing information and resources related to the company's drug candidates.

- To provide key statements and supporting information to guide the development of drug messaging.
- To facilitate collaboration and exchange of ideas among internal scientists and researchers.

The Scientific Communication Platform (SCP) creates a form of alignment for communications and messaging across different internal and external stakeholders. It can play a crucial role in drug development by enabling researchers to share their findings with other researchers and the broader scientific community, facilitating the exchange of ideas and collaboration. They can also help to ensure that the latest research is readily available to regulators and other decision-makers, allowing them to make informed decisions about the safety and effectiveness of potential drugs.

Since their inception some decades ago, SCPs have evolved to keep pace with the ever-dynamic spheres and needs of drug messaging. And although the format and quality of content is continually improving, the objective on which SCPs was founded remains the same; "To provide a strategic foundation for a product's medical communication plan and all initiatives generated from it by integrating scientific data, expected upcoming data, and treatment landscapes through coordinated scientific themes."

4.1. The Roles of Scientific Communication Platform

The roles of scientific communication platforms in drug development are as follows:

1. Facilitating the sharing of research findings: Scientific communication platforms enable researchers to share their findings with other researchers and the broader scientific community, facilitating the exchange of ideas and collaboration.
2. Exploring in details the unmet needs, the disease burden, mechanism of action and efficay of the potential drug in development.
3. Improving transparency and accountability: By providing a public record of the research and clinical trials conducted, scientific communication platforms can help improve transparency and accountability in the drug development process.
4. Providing a compedium of the most relevant references required to support scientific claims. However, do note that only the most relevant references are added in the SCPs.
5. Enhancing collaboration and communication: Scientific communication platforms can facilitate collaboration and discussion of available clinical data among researchers, clinicians, regulators, and other stakeholders, helping to accelerate the drug development process.

4.2. Stages of Scientific Communication Platforms

The stages of scientific communication can vary depending on the specific context and the platform used. However, in general, scientific communication platforms in drug development are as follows:

1. **Pre-publication:** This stage involves the preparation of studies and literature reviews for publication, including the review and editing of the manuscript by the authors and any peer reviewers.
2. **Submission and review:** After the manuscript has been prepared for publication, it is submitted to the scientific communication platform for review. The platform's editorial team will review the manuscript to ensure that it meets the platform's standards for quality and relevance.

3. **Publication:** If the manuscript is accepted for publication, it will be published on the scientific communication platform, typically in the form of an article or report.

4. **Dissemination and promotion:** Once the research has been published, the platform will promote it to relevant audiences, such as other researchers, clinicians, and decision-makers, through various channels, such as email newsletters, social media, and conferences.

5. **Impact and engagement:** The final stage of the scientific communication process is the impact and engagement of the research, which can be measured through metrics such as the number of citations, downloads, and social media shares. This stage is important because it helps to determine the relevance and significance of the research and its potential impact on the field

4.3. The Required Components of a Typical Scientific Communication Platform.

There are different scientific platforms, However, some components are typical to every scientific platform..

- **Lexicon:** A lexicon in drug development include terms related to the various stages of the drug development process, such as pre-clinical research, clinical trials, regulatory review, and marketing and sales. It also includes terms related to specific aspects of drug development, such as drug design, mechanism of action, and toxicology.

  It can be useful for researchers, clinicians, regulators, and other stakeholders who need to understand the technical language and terminology used in the field. It can help ensure that everyone uses the same language and terminology and prevent misunderstandings and confusion. A lexicon may be published as a standalone reference book or included as part of a scientific communication platform or other resources.

- **Key Scientific Statements:** Also, your sentences and phrases (properly referenced) must provide a foundation for planning and organizing tactics.

- **Analysis:** You are required to provide a comprehensive analysis. The analysis is done to evaluate the strength of the evidence supporting existing scientific claims using the gap analysis and look for additional viewpoints on the clinical usage of the product in the published literature and abstract database. Basically, analysis summarizes published data, target audiences, the present scientific framework, and the amount of support; it quantifies the mapping of messages to scientific assertions to identify gaps.

- **Situational Analysis:** you will also be required to analyze the disease space. This is more like an overview of the problems and opportunities in the disease state your drug product intends to fill, the method of treatment, and the product, together with a SWOT analysis, as supported by the scientific literature.

In summary, the key component of a scientific communication platform focusing on sharing research findings and data on essential pillars, such as the unmet needs in the market, mechanism of actions, disease burden, efficacy, safety, pharmacokinetics, etc., of the drug product.

Summary

In summary, scientific communication platform boarders on the sharing of key stakeholder goals, general strategy and vital clinical data gathered during the process of drug development. It focuses on some essential pillars, including the unmet needs in the market, the drug's MOA, efficacy, safety, dosing and pharmacokinetic parameters, and defined value.
This platform is updated regularly to contain emerging data pre and post the development phase.

Module 5. Evolved Scientific Communication Strategy

Objectives: To provide a guideline for communicating scientific terms to the target audience.

- To communicate with non-experts in a simple and understandable manner

In the early stages of drug development, the asset strategy typically focuses on identifying and developing a small number of promising drug candidates that have the potential to address unmet medical needs. The goal of the asset strategy at this stage is to maximize the potential value of the drug candidate by advancing it through preclinical and clinical testing as efficiently as possible.

As the drug development process progresses, the asset strategy may evolve to take into account new data and insights that are generated through preclinical and clinical testing. For instance, if a drug candidate demonstrates strong efficacy in early clinical trials, the asset strategy may shift to focus on optimizing the dosing and administration of the drug, or identifying additional patient populations that may benefit from treatment.

The insights and data generated must be communicated not only with the scientific community, but also with the target audience of the drug product; the non-experts. Hence, Evolved Scientific Communication Strategy (ESCS) is a concept that bridges the gap between scientists, medical practitioners, drug developers, and non-expert audiences.

The goal of evolved scientific communication strategy is to effectively communicate details of the drug product, including the pharmacology, toxicology, pharmacokinetics, etc, in basic ways that a non-expert will understand.

It emphasizes using clear, concise language and engaging storytelling to make complex scientific concepts accessible and interesting to a broader audience, which, in turn, enhances public understanding of science and promotes the use of evidence-based information in decision-making.

5.1. Component of Evolved Scientific Communication Strategy

The specific components of the ESCS may vary depending on the context in which it is being used, but in general, it emphasizes the following:

- Clear, concise language: Using simple and straightforward language that is easy for a non-expert audience to understand. As much as possible, avoid "technical medical terms" where necessary.
- Engaging storytelling: Using storytelling techniques, such as narrative arcs and relatable characters, to make complex scientific concepts more interesting and engaging.
- Contextualization: Providing relevant context and background information to help the audience better understand the presented scientific information.
- Visual aids: Using visual aids, such as graphs, charts, and images, to help illustrate and clarify complex scientific concepts.
- Interactive elements: Using interactive elements, such as Q&A sessions or hands-on demonstrations, engages the audience and encourages participation.
- Tailoring the message: Customizing the communication approach to fit the specific audience and context to make the information as accessible and relevant as possible.
- Evaluating effectiveness: Regularly evaluating the effectiveness of the communication approach and making adjustments as needed to improve it.

The target is your audience and not your fellow professionals. Ensure you employ the components listed above while communicating the specifications and details of your drug to your audience.

Summary

The Evolved Scientific Communication Strategy (ESCS) provides a template for communicating data and insights generated from the preclinical and clinical stages of drug development with the target audience.

Module 6. Finalize Unbranded Mechanism of Action (MOA) Messages.

Objectives: To communicate a drug's mechanism of action (MOA) clearly and accurately in an easy and understandable way.

- To provide an unbiased and objective description of the MOA of a drug, without promoting or highlighting the specific brand or manufacturer of the drug.

6.1. Mechanism of Action (MOA) Drug Message

It's important to know that until a drug has passed all the phases of the clinical trials and approved by the regulatories bodies, such as Food and Drug Administration (FDA), European Medicines Agency (EMA), etc., a drug cannot be branded. And for the drug to be approved, one of the criteria is that the mechanism of action must be well understood and communicated appropriately.

MOA message will describe the specific targets or pathways that the drug interacts within the body and how those interactions lead to the desired therapeutic effect. For example, a MOA message for a drug used to treat high blood pressure might describe how the drug works to relax the smooth muscles of the blood vessels, leading to a decrease in blood pressure.

Unbranded MOA messages can give healthcare providers and other stakeholders a general understanding of how a drug works without promoting a specific brand. This can be helpful for ensuring that healthcare providers and regulatory bodies have the information they need to make informed decisions about the drug's use and for facilitating discussions about the drug's potential benefits and risks.

Ultimately, unbranded MOA messages can play a valuable role in drug development by providing important information about a drug's mechanism of action without promoting a specific brand.

6.2. Writing an Unbranded Mechanism of Action (MOA) Message.

- Start by clearly defining the key terms and concepts involved in the drug's mechanism of action. For example, if the drug is a protein inhibitor, define what proteins are and how they function in the body.
- Use simple, easy-to-understand language to describe the drug's MOA. Avoid using technical jargon or complicated terms that may be difficult for a general audience to understand.
- Provide relevant examples or illustrations For example, use a diagram to show how the drug binds to a target protein or provide a real-life scenario to illustrate how the drug works in the body.
- Keep the message focused and concise. Avoid providing unnecessary details or going into too much technical detail, as this can make the message difficult to understand.
- Make sure to accurately and thoroughly describe the drug's MOA. This is important for providing healthcare providers and other stakeholders with a complete understanding of how the drug works.

Below are a couple of examples:

- XYZ (name of the drug) works by activating a specific enzyme known as lipoprotein lipase, which helps to break down fat in the body and improve metabolism. In individuals with obesity or other metabolic disorders, the activity of this enzyme is often impaired, leading to the accumulation of excess fat in the body. By increasing the activity of this

enzyme, XYZ helps to improve metabolism and facilitate weight loss, leading to improved overall health and reduced risk of obesity-related complications such as diabetes and heart disease.

- X (name of the drug) is designed to bind to and block the activity of a receptor known as the TNF receptor, which is involved in the immune system and plays a role in the development of inflammation. In patients with autoimmune diseases such as psoriasis and psoriatic arthritis, the activity of this receptor is overactive, leading to excessive inflammation and tissue damage. By blocking the activity of this receptor, X helps to reduce inflammation and improve symptoms in these patients.
- ABC (name of the drug) targets a specific enzyme known as a protease, which is involved in the processing of proteins in the body. In certain types of cancer, this enzyme is overactive, leading to the production of abnormal proteins that can drive the growth and proliferation of cancer cells. By inhibiting the activity of this enzyme, ABC helps to slow the growth of tumors and improve survival rates in patients with cancer.

6.3. Elements That Must Be In Your Unbranded MOA Message

There are a few key things that should be included to provide a clear and accurate description of the drug's MOA:

- A clear and concise definition of the key terms and concepts involved in the drug's mechanism of action.
- A description of the specific biological or chemical process by which the drug produces its effects on the body. This should be written in simple, easy-to-understand language and provide enough detail to give the reader a clear understanding of how the drug works.

Including these elements in your unbranded MOA message can clearly and accurately describe the drug's mechanism of action without promoting a specific brand.

6.3. What to Avoid When Writing a MOA Message.

There are a couple of things to avoid to ensure the message is effective and easy to understand. Below are a few:

- Avoid using technical jargon or complicated terms that may be difficult for a general audience to understand. Instead, use simple, easy-to-understand language to describe the drug's MOA.
- Don't make exaggerated or misleading claims about the drug's MOA or potential effects. This can damage the credibility of the drug and the company and lead to negative consequences.

Summary

In summary, understanding the mechanism of action (MOA) is an important requirement in drug development. And even more important is the ability to communicate the MOA in a way that perfectly conveys the message to the target audience. Not only is understanding the unbranded MOA message a vital requirement for approval of the drug, but it also enables better dosing through monitoring of the drug's effects on the target pathway in patients.

Module 7. Core Claims and Brand-related Messages

Objectives: To provide a consistent and compelling message about the brand, including its unique characteristics and advantages over other similar drugs on the market.

- To support the regulatory approval process for the drug by providing clear and detailed information about its key benefits and claims.

Core claims are statements that describe the key benefits of the drug, such as its effectiveness in treating a certain condition or its unique features, built on the safety and efficacy data generated during trials. Core claims are used in campaigns, and as the drug product goes through different post-marketing studies and post-marketing surveillance, the claims are updated accordingly.

7.2. Benefits of Core Claims and Brand-related Messages

There are several benefits to having an agreed set of core claims and brand-related messages in drug development. These include:

- **Clarity and consistency:** They help ensure that all members of the team are on the same page and working towards the same goals.
- **Improved communication:** They provide a common language that can be used to communicate with a variety of audiences, including regulatory agencies, prescribers, payers and patients. This can help improve the effectiveness of communication and make it easier to convey the key benefits and value of the drug.
- **Differentiation:** In a crowded and competitive market, Well-developed core claims and brand-related messages can help a drug stand out and secure buy-in of key decision makers.

- **Increased value**: By focusing on the key benefits and value of the drug, they help increase its perceived value, which can be important for pricing and negotiation.

7.3. Tips For Writing and Finalizing Core Claims and Brand-related Messages

- Develop clear, concise, and scientifically accurate statements that describe the drug's mechanism of action, effectiveness, safety, and other key attributes. These statements should be written in plain language that can be easily understood by the target audience and should avoid using technical or jargon-heavy language.
- Review the claims and messages with legal and regulatory teams to ensure that they are compliant with all relevant laws and regulations. This may involve checking for accuracy, consistency, and compliance with guidelines from regulatory agencies such as the Food and Drug Administration (FDA) in the United States.
- Test the claims and messages with potential customers or patients to gather feedback and make any necessary revisions. This can help to ensure that the messages are effective and resonate with the target audience.
- Finalize the claims and messages in a format that can be used in marketing materials and other communications about the drug. This may involve organizing the claims and messages into a logical structure, and providing them in a format that can be easily used by marketing teams, sales representatives, and other members of the drug development team.

7.4. Components of Good Core Claims and Brand-related Messages

When writing your core claims and brand-related messages, your goal is marketing and advertisements. It must be appealing to your target audience. As such, certain components will make your core claims and brand-related messages unique.

The components of a good core claims message in drug development may include the following:

- **Scientific accuracy**: The claims and messages should be based on valid and reliable scientific data and should accurately reflect the results of clinical trials and other research studies.
- **Compliance with regulations:** The claims and messages should be compliant with all relevant laws and regulations, including guidelines from regulatory agencies such as the Food and Drug Administration (FDA) in the United States, and the The European Federation of Pharmaceutical Industries and Associations (EFPIA).

For your brand-related message, some key components to pay attention to include:

- **Brand differentiation:** The brand-related messages should effectively differentiate the brand from competing products and should help to promote the unique features and attributes of the brand.
- **The target audience:** The brand-related message should clearly identify the target audience for the drug, such as a specific patient population or healthcare providers. This can help ensure that the message is tailored to the needs and concerns of the intended audience.
- **The key benefit:** The brand-related message should highlight the key benefit of the drug, such as its effectiveness, safety, or convenience. This can help differentiate the drug from competitors and give potential customers a reason to choose it.

- **The value proposition:** The brand-related message should clearly articulate the value proposition of the drug, such as how it can improve patient outcomes or reduce healthcare costs. This can help demonstrate the value of the drug and make it more appealing to potential customers.
- **Supporting evidence:** The brand-related message should be supported by evidence, such as clinical trial results, expert endorsements, or real-world data. This can help provide credibility and trustworthiness to the message.

Overall, good core claims and brand-related messages in drug development should be based on scientific data, be clear and simple, be compelling and persuasive, be compliant with regulations, effectively differentiate the brand from competitors, and communicate the key benefits and value of the drug to the target audience.

Summary

Core claims refer to all claims (benefits) a product's promotional materials can use, along with references for each claim, and brand-related messages simply entails marketing materials used to promote the brand of the developed drug. While each core claim has to be backed with references, brand-related messages don't require references.

Communicating both the core claims and brand-related messages is essential for the commercialization and marketing of your drug product to healthcare providers and potential patients.

Module 8. Launch Messaging and Tactics

Objectives:

- To ensure that the launch of the drug is successful by implementing effective marketing and communication strategies.
- To support the commercialization of the drug by promoting its brand and key features to potential customers, including healthcare providers and patients.

8.1. Effective launch planning

Launch messaging and tactics refer to the strategies and tactics used to promote a new drug once it has been approved for sale by regulatory agencies. These may include various activities, such as:

- **Marketing campaigns**: Marketing campaigns may be used to raise awareness of the new drug and generate interest among potential customers. This may include advertising in traditional media (such as television, print, and radio), as well as digital media (such as social media and online advertising).
- **Sales force training:** A sales force may be trained to effectively communicate the key benefits and value of the new drug to potential customers, such as healthcare providers or patients. This may include training on product knowledge, sales techniques, and communication skills.
- **KOL (Key Opinion Leader) management:** KOLs are experts in their field who are respected and influential among their peers. KOLs may be used to help promote the new drug and provide endorsements and testimonials.
- **Public relations**: Public relations efforts may be used to generate positive media coverage and build buzz around the new drug. This may include press releases,

interviews with key stakeholders, and other activities to raise awareness and generate interest.

The goal of launch messaging and tactics is to effectively introduce the new drug to the market and generate interest among potential customers, such as healthcare providers and patients. By carefully planning and executing launch messaging and tactics, drug developers can help ensure the success of their new product in the market.

8.2. Elements of A Good Launch Messaging and Tactic

The components of strong launch messaging and tactics in drug development may include:

- Clear and compelling messaging: The launch messaging should be clear, concise, and compelling and should effectively communicate the key benefits and value of the drug to the target audience.
- Targeted marketing campaigns: The launch tactics should include targeted marketing campaigns that are tailored to the specific needs and concerns of the target audience. This may include a variety of activities, such as advertising, sales force training, KOL management, and public relations efforts.
- Evidence-based support: The launch messaging and tactics should be supported by evidence, such as clinical trial results, expert endorsements, and real-world data. This can help provide credibility and trustworthiness to the message.
- Ongoing monitoring and evaluation: The launch tactics should include ongoing monitoring and evaluation to ensure that they are effective and achieving the desired results. This may include tracking key metrics, such as sales, market share, and customer feedback, and making adjustments as needed.
- Flexibility and adaptability: The launch tactics should be flexible and adaptable, and should be able to be adjusted as needed based on the results of the monitoring and

evaluation. This may include making changes to the messaging, tactics, or target audience to improve the effectiveness of the campaign.

Finally, the components of strong launch messaging and tactics in drug development should be designed to effectively promote a new drug and drive its success in the market.

Let's get right to helping you write a solid launching messaging.

8.3. Tips For Writing a Launching Message

The most important thing is getting your message across in a manner that concisely describes the details of the drug while also conveying your brand's identity. Below is how you do that!

- Identify the target audience: The first step is to identify the target audience for the drug product. This may include a specific patient population, healthcare providers, or other stakeholders. Understanding the needs and concerns of the target audience can help ensure that the messaging is tailored to their interests.
- Determine the key benefits: The next step is to determine the key benefits of the drug product. This may include its effectiveness, safety, convenience, or other advantages over competing products. Identifying the key benefits can help focus the messaging and give potential customers a compelling reason to choose the product.
- Develop a value proposition: The third step is to develop a value proposition that explains how the drug product can provide value to the target audience. This may include improving patient outcomes, reducing healthcare costs, or offering some other benefit that is important to the intended audience.
- Craft the messaging: The final step is to craft the messaging using clear, concise, and persuasive language. The messaging should be tailored to the target audience and should highlight the key benefits and value proposition of the drug product. It should be supported by evidence, such as clinical trial results, expert endorsements, or real-world data.

Precisely, writing a launch messaging for a drug product involves identifying the target audience, determining the key benefits, developing a value proposition, and crafting the messaging using clear and compelling language. Below are a couple of examples of a good launch message:

- [drug name] is a revolutionary new treatment for chronic pain that is safe, effective, and easy to use. Clinical trials have shown that it can significantly reduce pain and improve the quality of life for patients. Ask your healthcare provider if [drug name] is right for you."
- [drug name] is the first and only drug of its kind to treat anxiety without causing drowsiness or other common side effects. In a recent study, [drug name] was shown to be twice as effective as other anxiety medications, and was well-tolerated by patients. Talk to your doctor about [drug name] today."
- [drug name] is a breakthrough medication for people with high cholesterol. It works by targeting the root cause of cholesterol build-up, and has been shown to reduce cholesterol levels by up to 50% in clinical trials. Ask your doctor if [drug name] is right for you."

These examples of launch messaging for a new drug effectively communicate the key benefits and value of the drug to the target audience, and use clear and persuasive language to persuade potential customers to take action.

Avoid the following when writing your drug launching messaging:

- Using overly technical or complicated language: The messaging should be easy to understand and relatable to the target audience, and should avoid using overly technical or complicated language.
- Focusing too much on the drug itself and not enough on the patient's needs: The messaging should focus on the benefits of the drug for the patient, and how it can help to address their specific needs and concerns. Precisely, it must be patient-oriented.
- Not differentiating the drug from competitors: The messaging should highlight the unique features and benefits of the drug, and should set it apart from competitors in the market.

- Not testing the messaging with the target audience: It's important to test the messaging with a representative sample of the target audience to ensure that it resonates with them and effectively communicates the value of the drug.

8.4. Marketing Campaign For New Drugs

Marketing campaigns for new drugs typically involve a variety of strategies and tactics to educate potential patients and healthcare providers about the drug, its benefits, and how it can be used to treat a specific medical condition. This can include advertising in medical journals and on websites, direct mail campaigns, and outreach to healthcare providers through sales representatives. It's important for the marketing campaign to accurately and transparently communicate the potential risks and benefits of the drug to ensure that patients and healthcare providers have the information they need to make informed decisions.

The components of a marketing campaign for a new drug typically include the following:

- Identifying the target audience: This involves understanding the demographics, needs, and preferences of the patients and healthcare providers who are most likely to be interested in the new drug.
- Developing messaging and branding: This involves creating a compelling and differentiated message that highlights the key benefits of the new drug and sets it apart from competitors. It also involves developing a brand identity that reflects the drug's positioning and value proposition.
- Selecting channels and tactics: This involves choosing the most effective channels for reaching the target audience, such as advertising in medical journals, direct mail, and sales representative outreach. It also involves deciding on the specific tactics to be used, such as print ads, online ads, webinars, and in-person events.
- Implementing the campaign: This involves executing the various tactics and activities included in the campaign, such as creating and distributing advertising materials, organizing events, and training sales representatives.

- Monitoring and evaluating performance: This involves tracking the effectiveness of the campaign by measuring key metrics such as brand awareness, sales, and customer satisfaction. It also involves making adjustments to the campaign as needed to improve its performance.

8.5. What to Avoid During Marketing Campaign

There are certain pitfalls to avoid in order to ensure that the campaign is effective and compliant with regulations. Some things to avoid include:

- Making false or misleading claims about the drug's benefits or risks: It's important to be transparent and accurate in all communications about the drug, and to avoid making exaggerated or unfounded claims.
- Using channels or tactics that are not appropriate for the target audience: It's important to carefully select channels and tactics that will reach and resonate with the intended audience, and to avoid using channels or tactics that may not be effective or appropriate.
- Failing to comply with regulations: Marketing campaigns for new drugs are subject to various regulations, including those related to advertising, privacy, and data protection. It's important to ensure that the campaign complies with all applicable regulations to avoid legal and reputational risks.
- Not monitoring and evaluating performance: It's important to regularly track the effectiveness of the marketing campaign and make adjustments as needed to improve its performance. This can help to ensure that the campaign is delivering the desired results and achieving its goals.

8.6. Benefits of a Solid Marketing Campaign

If planned and done very well, a good marketing campaign for a new drug can bring a number of benefits, including:

- Increased brand awareness and recognition among potential patients and healthcare providers.
- Improved understanding of the drug's benefits and how it can be used to treat a specific medical condition.
- Increased sales and revenue for the drug.
- Improved customer satisfaction and loyalty among patients and healthcare providers.
- Differentiation from competitors and positioning as a leader in the market.

Ultimately, a well-planned and executed marketing campaign can help to build trust and credibility for the drug and the company, which can help to establish long-term relationships with patients and healthcare providers.

Summary

Launch messaging and tactics refer to the strategies and techniques used to communicate information about a drug to healthcare providers and potential patients and to promote the drug's brand and key features in order to support its successful commercialization.

Conclusion

Conclusively, effective communication is critical in the development and marketing of new drugs. It's important to accurately and transparently communicate the potential benefits and risks of the drug to patients and healthcare providers, and to create messaging that resonates with the target audience and sets the drug apart from competitors.

This can help to build trust and credibility for the drug and the company and can support the success of the marketing campaign and the overall drug development process.

Moreso, you should always prioritize simplicity, even when you are communicating with your fellow experts. Avoid technical terms where necessary, and convey your message in a way that appeals to your target audience. This is so key! If imbibed, effective communication will make your development process seamless, and ensure you follow strictly with the guidelines and regulations from relevant agencies and officials.

We have talked about the relevance of effective communication to every stage of drug development and provided templates and guidelines to help you ensure effective communication in your program. This guide is not exhaustive, as there are new guidelines and regulations released everyday to guide drug development, however, it will give a solid start to ensuring and fostering a seamless communication flow in your drug development program.