The Researcher’s Journey:
The Discovery Phase of Drug Development
To develop a new drug, there is a long and difficult journey that any researcher must complete. This process often requires an extensive amount of time and money. In fact, according to the European Patients’ Academy, introducing a new drug to market requires an average of 12 years and $1 billion.\textsuperscript{[1]} According to the FDA, there are five steps to the drug development process: Discovery and Development, Preclinical Research, Clinical Research, FDA Review, and FDA Post-Market Safety Monitoring.\textsuperscript{[2]}

The discovery step of drug development requires in-depth research that will help a pharmaceutical uncover if their initial research looks promising enough to pursue further testing.

During this stage, researchers must aim to:

- Identify and understand their competitors
- Thoroughly research the ailment for which they are creating a drug
- Uncover their target molecule
- Comply with medical device regulations

This e-brochure will break down the critical steps of the discovery phase, with suggestions on how to complete the highlighted research.
Pharmaceutical research is not based solely on scientific discoveries. To complete the discovery phase, you must identify and understand your competitors through competitive research. This step serves to uncover critical competitor information that will ultimately help bring a drug to market successfully.

The competitive research process requires two slightly different approaches that can be conducted simultaneously. The first approach is identifying and understanding your current competitors. These are pharmaceutical companies that you have previously identified and possibly researched.

The second approach is discovering new competitors due to the nature of your research. It is possible that the scope of your research will introduce companies that have not been recognized as competitors. To identify these companies, conduct preliminary research about your ailment to see what other organizations currently offer a drug for your target ailment or are working toward the same drug.

Once you have an exhaustive list of current and new competitors, you can dig deeper into your research. For new competitors, it is helpful to have a general understanding of the company. Review case studies, key executive profiles, profit information and SWOT analyses. Additionally, consult other teams within your company – such as sales or marketing – as they may have existing research to contribute. Summarize your findings in a document that can be easily accessed by the entire research team.

After your initial investigation has been completed, aim to understand your competitors in the context of your current research. The goal of this research is to understand where your competitors are in trial, or if they have an approved molecule or medical device. Timely information such as this can be found in current trade periodicals or news sources. To make this process more efficient, set up a system to alert you anytime a competitor or your ailment is mentioned in the news. As changes occur, consult with your team and be prepared to revise your research strategy.
Solutions:

*Biotechnology Source™* and
*Business Source® Corporate Plus*

EBSCO offers research databases that will help you gather critical information on your competitors. To begin, utilize EBSCO’s *Biotechnology Source* to access thousands of full-text biotechnology and pharmaceutical journals, as well as the largest collection of full-text content indexed in MEDLINE, EMBASE and BIOSIS. This information will help you complete the initial research necessary to identify new and existing competitors in the pharmaceutical and biotechnology industries.

Additionally, *Business Source Corporate Plus* features tools that allow you to stay updated with your industry and competitors. The Current News View brings critical news content with ongoing updates throughout the day from news sources such as Associated Press, CNBC, CNN, NPR, Reuters and BusinessWire, as well as access to more than 1,300 newspapers with same day currency. With *Business Source Corporate Plus*, you can create custom alerts so that you never miss a relevant story.
Conclusion

Competitive intelligence research provides critical information that can help you begin the drug development discovery process. By identifying and understanding competitors, you will gain valuable insight into your industry and be better prepared to introduce a new drug to market. Closely monitoring your competitors will help you to revise your research and go-to-market strategy as you consider what appears to be working (or not) for your competitors.

EBSCO’s databases make competitive intelligence research easier than ever. Biotechnology Source offers the industry-specific information needed to begin your analysis, while Business Source Corporate Plus helps you dive deeper and stay updated on your market and your competitors.
Understanding the ailment for which you are creating a drug is critical to your research process. Prior to molecule target validation, you want to gather background information to gain a better understanding of your target disease. This data must be retrieved from reputable, relevant sources. Today, there are several strategies to support and supplement your initial ailment research.

**Translational Research**

Translational research, “the process of applying knowledge from basic biology and clinical trials to techniques and tools that address critical medical needs,” is an innovative way to collect information and make connections throughout your research. The goal of translational research is to “bridge the gap” between new or existing scientific knowledge and potential approaches to the prevention and treatment of a disease.

Translational research is constantly growing with new therapeutics. It has been used to explore complex diseases including chronic kidney disease, liver disease, and cancer. To bring a new drug to market, it is imperative that biotechnology and pharmaceutical companies work with translational scientists or experts in academia to develop their research plans. Additionally, research can be conducted independently using databases such as EBSCO's Biotechnology Source.
Part 2
Understanding the Ailment

Solution:
*Biotechnology Source™*

By utilizing databases, researchers can locate valuable information that will help them to thoroughly understand the nuances of a disease. For example, through *Biotechnology Source*, a researcher can find specific full-text articles that will outline the impacts of viral infections from a morphological perspective. In the screenshot on this page, a researcher has utilized *Biotechnology Source*’s Advanced Search feature to find academic articles relevant to their target ailment and has sorted their results by “Date Newest” to ensure that their information is timely.
In additional to translational research, pharmaceutical and biotechnology researchers must utilize data repositories and biobanking to collect critical information regarding an ailment. As technology advances, we can access more and more information relevant to our research. Specifically, within pharmaceutical and biotechnology research, “data sharing can enhance reproducibility and the generation of new knowledge.”

Data repositories are critical to the effective and safe sharing of clinical study data. There is a variety of data repositories, such as, “generic repositories for all kinds of life-science data, generic repositories exclusively for clinical research data and specific repositories for study data with a specific focus.” These repositories should be used extensively in your research to gather relevant data on your disease.

Biobanking

In additional to data repositories, biobanking can be utilized to support your research. By bringing together translational research and the information found in data repositories and biobanks, you will gain better insight into the ailment you are researching. Utilizing these methods of research will ensure that you are gathering relevant, timely information on your target ailment, helping you to make better informed decisions regarding your drug development process.
Conclusion

Understanding the ailment for which you are developing a drug requires in-depth research that can be completed using a variety of methods. Translational research helps to bring together existing scientific knowledge and new approaches to the prevention and treatment of a disease. Completing translational research can employ a multifaceted approach that utilizes field experts as well as independent research conducted via scientific databases. Additionally, data repositories and biobanking will help researchers locate critical information such as clinical study data. Through the World Wide Web, this information is now readily available to any pharmaceutical or biotechnology researcher.

To help facilitate this research, EBSCO’s Biotechnology Source offers thousands of full-text articles from reputable publications. By using EBSCO’s Advance Search feature, researchers can conduct translational research that helps them better understand the nuances of their ailment.
As you learn more about your target ailment, you must validate your molecular target. This step is critical in the drug development process. According to an article posted on Drug Target Review, “an in-depth biological understanding of a molecular target as one of the very early steps in the entire drug discovery and development process... can determine later success or failure of the emerging drug candidate.”

Molecular target validation can be defined as, “the process of physiologically, pathologically, and pharmacologically evaluating a biomolecule.” In order to develop a drug for your target ailment, you must identify the biological targets that are connected to the condition and validate that the molecular target is directly involved in the disease.

To validate the molecular target, perform studies in cells, tissues and animals to verify that the target can be influenced by medicine. This validation is important to identify the most promising approaches before further developing a potential medicine; increasing the effectiveness of research. When the molecule has proven to be valid, it must be characterized - “the molecule’s size, shape, strengths and weaknesses, preferred conditions for maintaining function, toxicity, bioactivity, and bioavailability must be determined.”

To help gather this information, researchers must be able to identify connections to their work from various pieces of literature – including both published and internal. However, due to the sheer volume of literature available, this can be a difficult task.

Literature-Based Discovery

To address this issue, Literature-Based Discovery (LBD) systems are utilized to identify connections between disjointed pieces of data. According to an article published in the Journal of Biomedical Informatics, LBD works in the following way:

• A starting term (such as “cancer”) is identified by the researcher.
• The LBD system uses a “correlation-mining approach” to identify terms associated with the starting term, known as “linking terms.”
• For each “linking term,” the LBD uses the same “correlation-mining” method to recognize additional terms that correspond with each linking term.
• The LBD system then orders these terms with a “ranking approach.”

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Solution: *EBSCO Discovery Service™*

A discovery platform such as *EBSCO Discovery Service*, takes the concept of literature-based discovery to the next level. While having access to full-text is extremely valuable, how that full-text is surfaced and how similar concepts and terminology are presented to the researcher creates a greater possibility to uncover the connections between literature that could lead to a scientific breakthrough.

The work done by subject matter experts in a field to curate and classify materials (journal articles, books, conference proceedings, dissertations, etc.) and develop field-specific controlled vocabularies has tremendous value. Subject indexing in *EBSCO Discovery Service* improves three core areas of literature discovery and retrieval.

**Improves Relevancy**

One of the main goals of a discovery platform is to connect users with the most relevant content for their research; subject indexes in discovery can help improve relevancy. Subject indexes contain highly detailed, controlled vocabularies, linking concepts with different terminology. A discovery platform like *EBSCO Discovery Service* includes complex mapping technology to connect and leverage controlled vocabulary, delivering the most relevant information to users.

**Provides Quality**

Subject indexes in discovery are only as good as their quality. A discovery service should utilize subject matter experts who perform quality checks on new topical subject headings for accuracy and appropriateness. In addition, continuous evaluation of indexing procedures and processes helps to avoid duplication or misspellings in subject headings, ultimately providing the best quality search experience in the discovery platform.
Delivers Depth

To deliver depth to the content that is available in a discovery platform, partnering and implementing top subject indexes in discovery brings content to the next level.

In addition to subject indexing, functionality of a discovery platform plays a key role in sifting through and providing a direct path to the right information.

For example, the screenshot on the right shows a target identification search within a clinical setting. In this example, the researcher has utilized the advanced search function within EBSCO Discovery Service to select multiple search terms. Additionally, the results have been filtered by Date Newest to ensure that the information presented is both timely and relevant for the researcher. Simple access to the full text PDF file as well as related subject terms helps the researcher to build connections.

EBSCO Discovery Service™
Solution (continued):

*EBSCO Discovery Service™*

Additionally, it is important to utilize real-world examples while conducting your research. In *EBSCO Discovery Service*, you can search case studies using the search feature. On the right is an example of how this can be completed.
Conclusion

Molecule target validation is a critical part of the drug development discovery phase. By identifying and validating a target molecule, you can save enormous amounts of money and time on your drug research and development processes.

Literature-based discovery can be utilized to execute this step. There are tools available that make literature-based discovery possible for the researcher. The subject indexing within EBSCO Discovery Service improves literature discovery and retrieval by providing improved relevancy, quality of content and depth of information.
Part 4
Medical Device Testing and Reporting

Medical Device Testing
As your understanding of your competitors, ailment and target molecule increases, you will begin to consider how medical devices will contribute to your execution of new drug development. Medical device testing must occur at this stage to ensure the technical feasibility of your proposed drug. According to an article published in Pacific BioLabs, "Medical device testing can cover a wide variety of areas – from qualifying materials and ensuring their safety for human use, to validating sterilization or cleaning and disinfection programs, and also ensuring that final products are free of microorganisms." [12]

Medical Device Reporting
During this stage, it is critical to understand the medical device regulation standards. According to the FDA, “Medical Device Reporting (MDR) is one of the postmarket surveillance tools the FDA uses to monitor device performance, detect potential device-related safety issues, and contribute to benefit-risk assessments of these products.” [13]
MDR Requirements

MDR set forth by the FDA highlight requirements for manufacturers, importers and device user facilities. These requirements include:

Manufacturers: Manufacturers must submit a report when they discover that their devices could have caused or contributed to death or injury. Additionally, they must report any device malfunctions that would likely contribute to or cause death or serious injury.

Importers: Importers must report to the FDA as well as the manufacturer if they discover that a device could have caused or contributed to a death or serious injury. If the imported device has malfunctioned and could have caused or contributed to a death or injury, then the importer must submit a report only to the manufacturer.

Device User Facilities: Device user facilities include hospitals, surgical facilities, nursing homes, outpatient diagnostic facilities, or outpatient treatment facilities. User facilities are required to report a possible medical device-related death to both the FDA and the manufacturer. Additionally, these facilities must report a medical device-related serious injury to the manufacturer, or to the FDA if the medical device manufacturer is unknown.

As medical device reporting evolves, regulations become stronger for manufacturers and other involved parties. In May of 2020, new regulations will be introduced titled The Medical Device Regulation 2017/745 and In vitro Diagnostic Devices Regulation 2017/746. These new requirements will affect all manufacturers selling their products throughout the European Union, the United States and beyond. This regulation will require systematic literature monitoring (SLM) of literature search (LS) at all three regulatory levels – specifying steps in which databases of scientific, peer-reviewed literature must be used for research.
To conduct MDR-compliant research, certain information must be gathered. EBSCO’s Biotechnology Source gives you immediate access to thousands of full-text journals including many industry leading publications and unique sources not found elsewhere on the web. This database provides relevant research on medical devices, access to full text and the ability to search within full text. These features will help assist any pharmaceutical or biotechnology company in meeting the new MDR requirements.
Conclusion

Conducting research on medical devices is critical to validating the feasibility of a proposed drug. MDR-compliant research must be completed to ensure that guidelines are being properly followed. With research databases, such as EBSCO’s Biotechnology Source, researchers can be sure that they are gathering relevant and reliable information.
Bringing it All Together with the Right Resources

The drug development process begins with research. From understanding competitors, to studying ailments, to validating molecular targets and testing and reporting medical devices, reliable and relevant information is needed at every stage.

EBSCO provides the content that you need to complete the discovery phase of drug development. The resources highlighted throughout this e-book will enable any researcher to complete their preliminary research with confidence.

To learn more about how EBSCO products can assist in the drug development journey, request to speak to an EBSCO representative today.


