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A COMPLETE GUIDE TO THE DRUG AND VACCINE LIFECYCLE AND COMPLIANCE

The drug and vaccine development process is a complicated and expensive affair that involves the dedication of more than a decade (an average of 12 years) to pre-clinical research and studies and then clinical trials. The results and objectives of these trials all need to be documented and submitted to the FDA to meet the compliance guidelines. Windward can automate this whole document generation process to meet all regulations set by the authorities (more about this below).

Here, we provide a guideline on the type of documents that should be prepared, when they need to be used, and to whom they must be submitted for compliance.

"CLINICAL STUDIES CARRIED OUT IN THE CLINICAL LIFECYCLE OF DRUGS AND VACCINES REQUIRE INNUMERABLE DOCUMENTS NECESSARY FOR EFFECTIVE PLANNING, ASSESSMENT, AND COMMUNICATION OF THEIR OUTCOME AND APPROVAL...ALL OF WHICH NEED TO PAINT A CONSISTENT PICTURE."

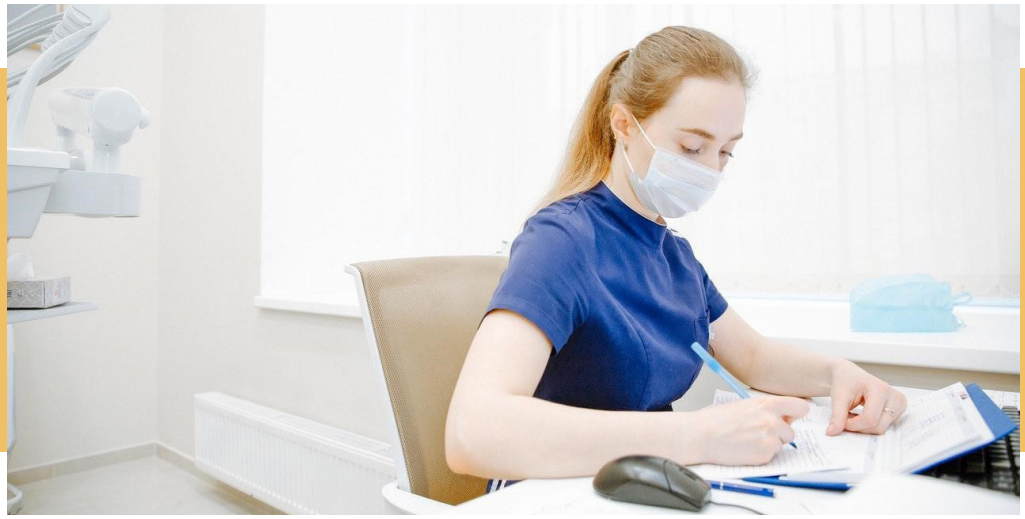
Error-Free Document Creation: The Key to Approval of Drugs & Vaccines

Documents play a central role in the compliance and life cycle of drug discovery, development, and distribution. They are key for designing, conducting as well as reporting trials carried out in animals and humans. Also, they are important for monitoring manufacturing quality, packaging, labelling, market performance, and safe usage of drugs. Also, ICH guidelines (more so ICH E6), gives a standardization of regulations within which the U.S., Japan, and the EU can mutually accept clinical data from regulators operating within their jurisdictions, outlining essential documents needed to advance in a clinical lifecycle while adhering to regulatory requirements.

Template Creation and Connecting to Multiple Datasources Just a Few Clicks Away

A majority of the necessary compliance and drug lifecycle documents are rather straightforward forms that need to be filled with appropriate information. Some are more complicated, requiring input from multidisciplinary teams to compile the necessary information.
This is where Windward's document automation can make a real difference.

It can connect with a wide range of datasources to populate the created templates. The good news is even new clinical investigators and drug developers in your company can collaborate and create the templates needed for generating documents at every stage to meet the compliance regulations set by the authorities. Even an individual employee in your pharma company can create the templates and tags needed for generating hundreds of documents by using the Windward add-in for Microsoft Office.



Documents Required Before Commencing A Clinical Trial

Before testing new therapy techniques or drugs/vaccines on humans, developers need to apply for approval through the submission of Investigational New Drug (IND) if in the United States or Investigational Medical Product Dossier (IMPD) if in a member state of the EU. To facilitate initial human trials, the submissions give an overview of manufacturing information, up-to-date data on animal studies inclusive of toxicity data, clinical study protocols (CSPs) that are meant to govern the actual studies as well as information on the actual investigators that shall be running the studies. Updates to the submissions must be carried out in tandem with the developments in the process. They must include any new data generated from human and animal studies.

According to the ICH E6, several key documents need to be generated to hold clinical trials. Key among them are informed consent forms (ICFs), Investigator Brochures (IBs), and CSPs. These are important as they:

1. Outline available scientific information on the product (IB)
2. Explain the train-of-thought behind each study (CSP)
3. Explain in detail the purpose of the study devoid of scientific jargon participants of the trial (ICF)
4. Give the investigational plan in detail while describing the analyses necessary for achieving the study objectives (CSP)

The necessary documents are usually an intricate compilation of information (data) building on one another to paint a clear picture of the aim of the trials and how investigators hope to achieve them. It is important to employ document automation software to coordinate the collation of input from various stakeholders and create flawless documents that are consistent with the aims and objectives of the proposed studies.

Whether it is the protocol or information amendment documents, safety reports or annual reports they can all be created in quick time without any errors by running Windward in your applications. You can thus meet all regulatory requirements and obligations and proceed with the clinical research study without any further delay by filing and maintaining IND documents quite effectively using Windward.

Documents Needed When Conducting Clinical Trials

Congratulations! you have initiated the clinical trials. However, you still have a lot more document generation ahead of you.

Thousands of documents are either updated or created in the clinical program life cycle, most of which are done while conducting clinical trials. Amendments to the CSPs are often made describing changes to planned studies or analysis. Often, this may be a result of impracticalities in original study designs necessitating the adaptation of activities into the feasible study design. Amendments might also be made due to the need to recruit more patients.

The Development Safety Update Report (DSUR) is an important document as it allows for the continuous collection and compilation of cumulative pharmacovigilance data collected while conducting clinical development programs. IBs need to be updated in readiness for the next stages of the study. Statistical analysis of trial data should be defined before viewing the data. These are outlined in the Statistical Analysis Plans (SAPs). Clinical teams need to have all the relevant documents in hand in advance. It can be rather frustrating to realize that a crucial document is missing just as you're about to submit a new study. Creating a proper mind map for all necessary documents for clinical studies allows for quicker document generation, thus avoiding unnecessary delays in the study. *What's not documented is considered undone in this phase!*

This is why you need to generate documents about every aspect of your clinical trials. And, Windward can help you come up with complete, consistent, credible, and well-corroborated clinical trial documents that are compliant with the regulations.

It's important to note that the intricacy of the compliance documents increases with the progress made in the development program. The first phase of clinical trials involves a small number of human subjects. The aim here is to investigate drug safety as well as its pharmacokinetics. The second phase of the trials is meant to assess the drug's initial efficacy on subjects suffering from target conditions. Dose finding trials are also conducted in this phase to determine optimal dosages in which the medicine can be administered. The third phase includes large scale trials aimed at undoubtedly demonstrating the product's effectiveness when administered at the designed dosage. This phase is important as it helps to improve the researchers' understanding of safety profiles.

CSPs from the first phase and reports of simple second phase studies are often easier to document and report as they don't have many assessments, making them less complicated to draft. CSPs of complex second and third phase studies contain several objectives including efficacy, pharmacokinetics, quality of life, and safety. They, therefore, contain assessments of each of the objectives from treatment groups or dose regimes and may even include sub-studies. The development of these documents may require months of deliberation before they can be compiled. The process of creating these documents often consists of the creation of multiple drafts and reviews or revisions as different stakeholders give their input on various phases of the trial.

IBs required at advanced stages of the clinical lifecycle are more complex and difficult to produce. The purpose of this document is to bring investigators tasked with various aspects of the study up to speed on PK, profiles, drug safety, and efficacy.

By the third phase, there exists a host of data that requires to be compressed and compiled into brochures that are as easy to read as they are informative to meet all regulatory guidelines. Demand on the entire development team shoots up with the rising intricacies of documents required in advanced developmental stages.

Windward matches this demand during all these different phases. It can help churn out hundreds of thousands of documents in just a few clicks while ensuring all the information presented in the IBs are error-free.

Documents Necessary During the Termination of Clinical Trials

A detailed Clinical Study Report (CSR) is necessary at the end of every trial. It contains a comprehensive description of study results, whether negative or positive. This report typically contains every single piece of information in the course of the study as well as descriptions of the study methodology inclusive of any changes to initial plans as stipulated in the CSP. The complexity of a CSR is also dependent on the complexity of the phase within which the trial was carried out. This also dictates the time taken to create it and the required manpower both in skill and disciplinary diversity that needs to be engaged. The amount of data that needs interpretation and evaluation is often the cause of the slow-paced nature of the process. That being said, teams working on this document or report need to be allocated a sufficient amount of time to process large amounts of information. Windward can play a key role in this process as it makes the document generation process fairly simple and swift with its intuitive and user-friendly features and interface.

It is mandatory that summaries of clinical trial results emanating from studies carried out in the EU or the US be published in online databases within a year of the trial's completion. This is in accordance with FDAAA 801 regulations in the US and EU guidelines for approval of clinical trials on drugs meant for human consumption. The EMA policy prohibits the publishing of reports about any test drug on public platforms that contain information that could lead to the identification of subjects within the study. Your investigators and researchers are therefore obligated to point out potential pitfalls that would arise from the inclusion of the wrong information in CSRs. Doing so helps to avoid time and cost-intensive processes that are associated with redaction as summaries are being created. Here, Windward's document automation software comes handy. You can set up specific handling for warnings and errors (either in the full report or per-tag basis) to ensure you generate error-free documents for complete compliance.

Documents Needed When Seeking Marketing Authorization

Once clinical development processes are complete, an application seeking marketing authorization needs to be made. This is done through the submission of a dossier containing a compilation of data from the clinical development process. The dossier typically includes summary documents that are written in accordance with common technical document (CTD) guidelines. CTD dossiers house a clinical section that comprises a clinical overview (Module 2.5) and summaries of biopharmaceutics, clinical pharmacology, clinical safety, and clinical efficacy (Module 2.7)

This dossier forms the backbone of the challenge posed to small lab researchers and big pharma employees of synthesizing numerous ideas as well as data into cohesive descriptions of that which is known of the drug. For example, the preparation of Modules 2.7 and 2.5 can be a year-long process depending on the intricacies of the drug and its intended use. The documents should be generated in such a way that regulatory reviewers can easily understand the available data gathered during clinical programs, and their interpretation with regards to the pharmacokinetic profile, safety, efficacy as well as the drug's relative risks and benefits.

Plans for monitoring and minimization of potential risks that are associated with using the medication referred to as Risk Evaluation and Mitigation Strategies (REMS) in the United States and Risk Management Plans (RMP) in the EU must be included in the application document. Submission of RMPs is mandatory while that of REMS is upon the FDA's request. To compile this document, the team involved needs to go through documents from all stages of the development program, assess key risks, and consider appropriate precautions to ensure proper monitoring as well as mitigation of the identified risks. A layperson's summary is required in the RMP. This guarantees patients' understanding of the risks involved in the treatments prescribed to them.

Windward can connect with multiple data sources during this stage to create these documents to ensure compliance and quick approval for marketing. And, you can generate documents in multiple output formats (PPTX, PDF, DOCX, and more) based on your needs.

Documents Necessary for Marketing

Publication of data gathered in clinical studies is done either as PDF documents, informative websites, patient information sheets among others. This is done to draw the attention of physicians, patients, health authorities, and practitioners to potential risks and benefits of the new drug. Stringent compliance rules are governing how marketing practices are conducted as well as the claims made in any of the publications about new drugs.

After introducing a drug to market, all reports of safety events must be recorded, compiled and assessed continuously. Doing so yields the Periodic Benefit-risk Evaluation Report (PBRER), formerly referred to as the Periodic Safety Update Report (PSUR). Guidelines for the compilation of this document are given by the ICH. PBRER is aimed at the harmonization of worldwide reporting procedures on the safety experiences of medicinal products after approval. The preparation of this document is often a race against time as annual submission deadlines are regulated.

PBRER can only be compiled after data summaries for a particular reporting period are obtained and final reports are produced. Standardization of data presentation and production can help to streamline documenting processes by enabling the focusing of efforts by various teams on the identification of safety signals rather than wasting time arguing over data presentation techniques. This standardization is made possible by the fact that formats for assessing data are often similar across the different phases of development. Windward can help come with these crucial reports and documents in the right formats regularly to ensure pharmacovigilance and compliance guidelines are met

Summary

Clinical studies carried out in the clinical lifecycle of drugs and vaccines require innumerable documents necessary for effective planning, assessment, and communication of their outcome and approval. A majority of the documents are an intricate collation of research and data. These also work alongside other documents, all of which need to paint a consistent picture.

To generate these documents fast and flawlessly, you can take advantage of Windward's document automation software. It will ease the pressure on the entire research and development team in your pharma company or lab research firm and ensure that documents generated correspond with their purpose and meet the compliance guidelines set forth by the authorities. Documents will be error-free and data-powered.

Try Windward today.