

Good essay about drug development and regulatory interactions

[Law](#), [Security](#)



DRUG DEVELOPMENT AND REGULATORY INTERACTIONS. An overview of drug interactions and activities in drug development. A drug is any component in the body other than food that is intended to affect the proper functioning of human bodies or the animals. Drugs can be used in various ways including diagnosis, treatment, cure and prevention of diseases in humans and animals. Drug development refers to the continuum stages that are involved at each stage of development. The authorities have to be involved in the drug development process with a view of ensuring the safety of human. The drug must be taken through stages in its development. The first stage is the non-clinical trial where the drug is discovered. The next stage is the clinical trial where the drug is formulated and scaled up for specifications. The drug is then developed, registered and taken to the market. The developers of a drug and the regulating body must team up so as to ensure that the drug is developed without any health implications risks. The regulators work to assess the benefit -risk ratio of a drug. if the drug is found to be unsafe or ineffective, and then the regulating authority cannot grant license. In the United States, there are laws that regulate drug. One example is the food and drugs and cosmetics (FD&C) Act that was enacted in 1906. The Act requires that before any developed drug reaches the marketing stage there is sufficient evidence that the drugs are safe. The regulators have to ensure a thorough inspection of the factories and ensure that the drug meets the standards for food. There is also Kefauver-Harris Amendments enacted in 1960 that provides that manufacturer have to prove the effectiveness of the drug before marketing it. In some cases, medical devices have been reported to cause deaths. That was the motive behind enactment of the Medical

Device Amendments in 1976 that ensures safety and effectiveness of new medical devices. The code of federal regulations contains several regulation areas, food and drugs included. The regulation on foods and drugadministration contains a national policy on drugs that prohibits abuse of drugs in the workplace and spells out uniform requirements for grants. During development of drugs there are several factors that must be considered. The disease, for which the drug is meant to diagnose, treats, cure or prevent. The unique characteristics of the disease must be considered taking into account any previous experience of the disease. The development pathway of the drug is then formulated with a keen consideration of the regulatory and intelligence insights, depending on the class of the drug. Attention is paid to the guidelines in the regulatory documents. The development of a drug must meet the quality, safety, multidisciplinary and efficacy aspects. The quality of drugs is determined by its test on stability; a drug that contains no impurities. The quality test must satisfy the chemical and pharmaceutical test. Safety of drugs relates to the clinical studies carried out. Efficacy implies that the drug must go through the dosage test in human to ascertain how much of it enough to accomplish its set objective. Of great importance is the pre- investigation new drug meeting that helps in communicating to the drug review authorities for purpose of the provision of necessary data to warrant an investigation on the new drug.

The pre-clinical developments aim at investigating the drug's safety standards by assessing its effect on the central nervous system and other major organs in the body. The aim is to generate data necessary to support

the first test in human. The drug developers have to prove to the regulators that the drug is effective by first testing it on animal models. The role of regulating agencies in the development of drugs is very crucial since they protect consumers from unsafe drugs. The regulators are also involved in research activities aimed at developing the regulatory bodies in terms of technology and being up-to-date with the current issues related to safety and efficacy of drugs and the various diseases that affect the human population. The toxicology study is carried out to support the clinical development and registration process. The study is carried out on the standard animals using the two-species rule, in particular rodents and non-rodents. The main issue is that the tests are done on small animals thus the efficiency of a similar quantity of dose in humans is not easy to determine. The FDA takes a period of thirty days to review the new developed drug. Once they are satisfied that the drug meets all the requirements they give an acceptance notification. In cases where the drug does not meet all the requirements, the body requires that the manufacturer cannot proceed with the clinical investigations. In some cases, the FDA issues a partial, implying that clinical investigations may proceed but with limitations. The clinical development has four main phases. The first phase is carried out on healthy human, and it is the drug's first trial on humans. There is intensive oversight by the clinic's staff. However the oncology test is not carried out on healthy individuals. The doses administered in the beginning are not as much, and they increase slowly. Some of the information sought in the first phase includes the drug-drug interaction, the food effect, bioavailability, effects on vital signs and the level of tolerability and safety.

Completion of the phase one gives enough confidence on the variables under investigation. It creates a rough idea in the mind of the investigator on the quantity of doses he needs to test on patients. At this stage the regulators are consulted to give the green light to the next phase. The second trial is carried out on patients to test the efficiency of the drug's dose response. The study in specific involves those patients with the disease that the drug under investigation is likely to an effect on. The population used is more than the population in the first phase. The result from this second trial eases the dose selection for phase three. The third phase is aimed at testing the drug's efficiency using even more population size of patients than in the second phase. In the United States, phase three is only granted permission to go through after the end of phase two meeting with the regulators. In Europe, phase there is conducted after successful meetings with selected national authorities. The last phase involves assessing the patients in phase three to ascertain the approval of the drug. Safety of the drug is monitored by spontaneous measurement of indicators such as the liver enzymes and spontaneous reports such as headaches.

The safety of drugs is monitored closely by the data and safety monitoring board which among other duties are responsible for reviewing accumulative data from the ongoing trials. This brings in the issue of transparency since the board is allowed access to the unblinded information. The access may result to interference with the trial process as the information can be distorted to bring about a false implication about the drug. The data analysis should be standardized, quantifiable and pre-specified. Once the board is satisfied that the data results show that the drug meets requirements such as in

safety and efficacy, the registration of the drug goes ahead. In the US, one has to submit a new drug application and the biologics licensing application. In the European countries, one must have the market authorization application. The meetings with the regulation authorities continue where the overall benefits and risks concerning the drugs are discussed. The submissions of the registration process are made in the common technical document that includes information such as data on quality, clinical and non-clinical data and all the administrative information. The document contains consistent location for the scientific study and provides the regulators with a format for assessing quality, performance and compliance. However, a common technical document does not provide for a list of required studies for approval. Having carried on the clinical and non-clinical trials, there should be a provision for the issues noted that may need a deeper study in the future. The aim of developing a drug should not focus only on the specific diseases but even the likelihood of filling the research gap in other fields. The technological advancement has made it easier for the documents to be stored in a better way, and it is now easier to retrieve a document from the regulator's portal. After the registration the draft product label is submitted. The label must be clear and unambiguous. The label provides information on the drug such as dosage, effects of over-dose, warnings and precautions and how the drug is supplied. In European countries, before any clinical trial is done one has to obtain authority from the regulating body of the concerned state. The regulatory authority sees to it that the drug meets the safety and efficacy standards. Ethics committee's opinion must be sought to ensure that the drug in question meets the ethical standards. An effective clinical trial

should have clear objectives as to the variables required to be tested, adequate subject selection and well defined methods of assessing the subject's responses. The clinical trial should also give room for comparison between the quantitative assessments of the effect of the drugs. The study results should be analyzed comprehensively in order to arrive at an accurate conclusion. In conclusion, the process of developing drugs is a crucial one and involves not only the sponsors but also the regulators. With an unregulated drug manufacturing, there may be many issues of unsafe drugs that contain impurities, substandard medical laboratories and equipment and an overall risk of drug abuse. The regulators however take a long period of time to respond to the applications by the sponsors. The time taken between the different phases feels like wasted time. The regulation needs to lessen the development process' time so as to give room for the researchers to carry out more research