

Clinical Issues is the Human Dimension of a Drug Project

Ronald Franklin*

Department of Diagnostics, University of Heilongjiang of Chinese Medicine, Yunnan, China

*Corresponding author: Ronald Franklin, Department of Diagnostics, University of Diagnostics, Yunnan, China, E-mail: franknald56@gmail.com

Received date: September 21, 2021; Accepted date: October 05, 2021; Published date: October 12, 2021

Citation: Franklin R (2021) Clinical Issues is the Human Dimension of a Drug Project. J Bio Med Sci Vol.10 No.S4:e002.

Description

The main feature of Translational Medicine is the bringing function between preclinical and clinical research. It aims at answering the following simple but tremendously important question, if a drug X works in rats, rabbits and even monkeys, how likely is it the drug will be beneficial to humans? Historically how did this simple and straightforward question, which is naturally inherent to all drug development processes, become of prime relevance in biomedical research. If all drug, device or test development components were closely connected within a common structure, the necessity to develop the discipline of Translational Medicine would probably not have become apparent. As it stands now, however the current emphasis on TM reflects the wide and strict separation of biomedical research into preclinical and clinical issues a situation best illustrated by the acronym which is used in pharmaceutical companies to describe their active investments into science as opposed to marketing. R stands for the research which is largely means preclinical drug discovery, and D stands for development, which is largely identical to clinical drug development. It is obvious that even the words behind R&D arbitrarily divide positions that share many similarities. Clinical development and clinical research are very congruent terms, and compounds are developed within the preclinical environment for example from the lead identification stage to the lead optimization stage.

In the drug industry the drug discovery and development process follows a linear stage progression. A major organizational transition occurs when a candidate drug is discovered to clinical development which is synonymous with trials in human. When this happens, it is often said that the discovery department has thrown a compound over the fence. The ironic or cynical expression exposes the main concern in this

context. Clinical issues that is the human dimension of a drug project are not properly and prospectively addressed in the early stages of preclinical discovery or even at the level of target identification or validation. Clinical researches are then surprised or even upset by what has been sent to be developed in humans. A chemical that had been shaped years earlier with too little or no clinical input or projections may turn out to be impractical or swallowing for example the compound dose may be too large or measured in grams instead of milligrams or may quickly prove to be too short-lived, requiring multiple dosing schemes that are far out of scope in many therapeutic areas.

Bridging this divide or improving the interface or animal data are typically lead to treatment of disease in humans. There is old dispute over free and basic sciences versus applied sciences, and universities in particular take pride in being independent and free in their choice of research areas and scientific strategies.

Unfortunately in drug discovery and development the assumption must be that a restricted, structured and therapy-driven process is the only way to cope with modern standards of drug approval requirements. Chance findings may trigger the initial steps of drug discovery, but those are rare in clinical stages.

Conclusion

The type R&D process has to reply on projections across this interface thus it has to focus its early discovery stages on later applications that is the treatment of the human diseases. This implies that throwing a drug over the fence is not optional if the final output is to be measured in terms of the number of approved new drugs being sold on the market.