The Importance of Expediting New Technologies Amid New FDA Legislation

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Up until this point, animal testing has been a ubiquitous practice in the realm of biomedical research. Now, a new law has been signed that no longer requires the testing of drugs on animals before they are given to participants in human trials.

What exactly does that mean for the drug development process? The new FDA Modernization Act 2.0, recently signed by US president Biden, will allow alternatives to animal testing, thereby paving the way for new approaches, innovative technology, and human alternatives. It will facilitate faster drug approvals and expedite innovation in drug technology, propelling research to new heights.

A positive result for clinical trials

The new legislation is a turning point in the pharmaceutical industry as it'll allow researchers to embark on their work with newfound freedom. It is a positive and encouraging change as clinical trials are a crucial part of the drug development process and animal testing has not been short of drawbacks. Not only has it been a controversial topic due to the ethical dilemmas caused by animal suffering, but there are additional limitations for which the new law can offer better alternatives in the long-run.

Focusing on translational pharmacology & accelerating new technology

What are the tools that research needs to concentrate on to tackle the challenges encountered in clinical trials? A promising alternative is translational pharmacology with a focus on new technology using human tissue instead of animal cells. Translational pharmacology focuses on the implementation of the findings from molecular and preclinical studies into clinical practice by improving clinical target identification, enhancing the reliability of early preclinical studies, and optimising the selection of drug dosages.

It holds a significant advantage in that it can evaluate and characterise the pharmacological potency of a compound and provide relevant insights into a new treatment much sooner than other approaches such as reverse translational research or phenotypic screening. This curbs the conventional five-year period to assess project feasibility and enables earlier identification of potential side effects and the likelihood of passing phase II. It gives researchers the possibility to discontinue a project if necessary rather than investing a decade of their time.

In fact, 90% of clinical drug development fail because they are considered too dangerous or ineffective on the cell culture. If research manages to bring that number down, it can speed up the drug process while also providing safer and more efficient drugs. To encourage investment in new technologies, stakeholders must be informed about the drug development process, its requirements, and the promising opportunities that lie ahead.

In relation to translational pharmacology stands the acceleration of new technology. Instead of animal testing, we need to focus on the use of human tissue. Working directly on biological tissue rather than on a cellular model provides vital information about the clinical reality of pharmacology. This will lower the risk of drugs reaching the market with unexpected undesired effects or loss of therapeutic activity. Hence, working directly on human tissue from the preclinical phase allows a transition to clinical development with guaranteed efficacy and safety of drug candidates.

Examples of such advancements to work with this type of tissue include label-free proprietary technologies such the NPOT® or PIMS® in which the entire efficacy and safety experiments are performed ex vivo on patient material.

These new technologies allow for the inclusion of more than 400 patients per week to explore a drug candidate's pharmacology and assess its efficacy and safety, validating the mode of action and identifying the off-target mechanism. In addition, it enables drug developers to determine and validate the responder and non-responder patient groups for phase IIa, thereby securing its success and paving the way for phase IIb for the validation of successes and failures in biomarkers. Ultimately, the drug candidate is developed for a specific disease and a clearly defined group of patients.

As with any technology, there are still limitations. High development costs, unknown long-term effects, and the need for regulatory approval are some of the challenges the industry faces. In order to tackle these struggles and ensure safety and further drug advancement, money needs to be invested in this industry. Companies that already offer alternative methods need to be supported and invested in as those are the ones that will provide safer therapies, better outcomes, and more efficient and cost-effective deliveries.

Linking new technology with a patient-centric approach

The need to invest in these technological advancements is intertwined with the one to invest in the patient-centric approach. Being able to provide personalised medical care not only facilitates higher patient satisfaction but can also build trust between the patient and the healthcare providers. It seeks to find the right treatment at the right time, resulting in the most suitable care for the patient. The outcome is an overall improved efficiency as personalised medicine offers better healthcare delivery while also reducing healthcare costs as unnecessary testing and treatments can be avoided.

The goal is to offer the patient the best possible outcome and develop new therapies as precision medicine bridges the gap between scientific research and patient care. Not only does this type of treatment aim to understand a drug's mechanism of action but it also strives to identify the most effective therapies for different patient populations. The patient-focused approach considers factors such as individual variability and health outcomes when developing and testing new drugs.

Investing in this type of treatment and new technology is essential both for overcoming the old ways of animal testing but also for boosting advancements in the drug development process. It goes beyond the changing of animal testing as these innovations promise more than that. Since they are adapted to individual needs, we can expect a better quality of life and increased survival rates and this is what drives us to find the medicine of tomorrow.