

The Role of Modern Experimental Biomedical - Translational Research in the Development of New Products with Clinical Applications. Ethical Justification, Implementation, Education and New Frontiers.

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Drug and new devices development in the medical arena is dependent on a variety of support structures. The introduction of a new molecule or drug or device, ideally begins with innovation responding to clinical need, progresses through engineering and development, is fostered by financing from a variety of sources, and reaches the markets through disparate commercial structures. Along the way, the drug is subject to scientific, clinical, engineering, and regulatory scrutiny and may be lost to the target community by recognition of a lack of validity, safety, or effectiveness, or by mismanagement of its development. It is critical to understand the method by which new products with clinical applications are funded in the period between concept and product launch. Data available reflect the stage of development and therefore reflect the stage of the investment as well as the terms of the development. Nonetheless, diligence must demonstrate at least the following parameters, as organized by stage of development :

1 – Seed stage : a logical mechanical, physiologic and engineering approach to well – defined clinical problem and need for which current solutions remain imperfect.

2 - Early stage : proof of concept as represented by computer modeling, prototype development with in vitro testing or early animal validation.

3 - Pre-clinical stage : demonstrated safety and efficacy in animal models with progression to phase I testing demonstrating safety in humans.

4 - Pre- launch stage : phase 2 and phase 3 trials demonstrating efficacy and ultimately effectiveness under tightly controlled circumstances.

The foundation stones of most regulations are the internationally established principles of replacement (avoid or replace the use of animals), reduction (minimize the number of animals used per experiment by resorting to other methods or strategy) and refinement (implementation of methods which ensure that animal suffering is minimized and improve welfare). These three principles are very important and are considered to be the common basis for scientists worldwide.

The aforementioned appraisal could guide the development and adoption of a universally lawgiving that meets international standards. In other words, new frontiers in biomedical – translational research and training for healthcare professionals.