Commentary

iMedPub Journals
www.imedpub.com

Translational Biomedicine
ISSN 2172-0479

2021
Vol.12 No.9:193

# Translational Medicines in Ecosystem

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**Received date:** September 09, 2021; **Accepted date:** September 23, 2021; **Published date:** September 30, 2021

**Citation:** Govindaraju RT (2021) Translational Medicines in Ecosystem. Transl Biomed Vol.12 No.9:193

## Introduction

Translational medicine is an ecosystem, connecting a group of independent but interrelated stakeholders to promote advances in healthcare. It is comprised of patients, academic and industrial research and development professionals, commercialization teams, investment capital, regulatory agencies which enforce government policies, ethics and health insurance payers. These stakeholders often have conflicting goals and objectives and are operating within an evolving ethical framework. In today's world that is so interconnected by technology, the new ideas and advances in healthcare echo across disciplines to create an extensive and interrelated system.

The primary role of medicine and health care organizations is to benefit patient health, including longevity, quality of life and affordability. Historically, drug discovery often has had roots in academic institutions. Some of the best examples of collaborations between academia and industry in the realm of drug discovery include Copaxone, Emtriva and Taxol. Research and commercialization platforms have become the primary catalysts for funding, with investment as a driver of the ecosystem.

Funding sources for the bio-industry include private or government grants, venture capital, private investors, corporate partnerships; public capital markets (IPOs), philanthropists, charity organizations and private foundations. However, newly established bio-industry companies such as biotechnology and pharmaceutical companies are often caught in the "Valley of Death" phase—the critical and challenging transition from developing a promising drug to securing funding for continued development and validation of its therapeutic and commercial potential. Navigating the "Valley of Death" is an integral part of the learning experience and can be rewarding if the process is managed successfully and effectively with a well-seasoned management team.

Many young bio-industry companies facing the "Valley of Death" phase saw an opportunity to mitigate these challenges when the "Right-to-Try" Act was passed by the U.S. Congress and signed by President Trump in May 2018. Right-to-Try laws were created with the intention of allowing terminally ill patients who have failed standard-of-care treatment to try experimental therapies (drugs, biologics, devices) that have completed at least Phase I testing of the Food and Drug Administration (FDA) regulatory process. The impact and the outcome of these laws on the ecosystem is too early to predict. The risks associated with the "Right to try" experimental drugs may be mitigated when the experimental drug is combined with an approved drug or the drug has gone through further studies such as the Phase II approval process. Funding may be further impacted by one or more factors such as the approval or disapproval of a drug by the FDA. Implementation of government policies such as the "Patient Protection and Affordable Care Act" (PPACA) will inherently impact one or more parts of the ecosystem. According to the upper echelon theory of management, the beliefs and background of chief executives affect the strategic choices and outcomes of their organizational collaborations. Cultural differences between academic institutions and bio-industries can include trust, intellectual property ownership and compensation. These challenges can be mitigated by cultivating and nurturing a flourishing relationship between academia and bio-industries with effective communication, transparency, trust, and confidence. Another challenge that academia often faces is the "over visionary syndrome". This may have less impact on bio-industries which must consider capital risk, market potential, time to commercialization, regulatory issues and reimbursement issues.