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Translational Researches Require Effective Protocols for Knowledge and Technology Transfer and Integration

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SUMMARY

Integration of several disciplines (nonclinical, preclinical and clinical researches) during drug discovery and development through learning and confirmation process needs a dynamic process; "translational medicine" (TM) to give a holistic understanding of the entire process. To achieve the highest impacts, however, effective standard protocols need to be performed.

As a matter of fact, the value and success of a process is usually judged by the merit of the final output(s), an integrative process which is the driving force of a new domain of science called "translational sciences" - the so called translational medicine (TM) in the field of medical sciences.

TM is referred to as the translation of basic research discoveries into clinical applications. More specifically, translational research takes the discoveries from basic research to a patient and measures an endpoint in a patient. Basically, translational research or TM encompasses not only the identification and validation of clinically relevant biomarkers, but also the conduct of nonhuman and nonclinical studies with the intent of developing principles for the discovery of new therapeutic strategies. In fact, this holistic insight into researches aims to combine different disciplines for achievement of a proposed aim. The impact of such approach is deemed to be significant in terms of drug discovery, in which TM influences not only the industry, but ultimately the society as well. Although the capacity of TM in research and development (R&D) still is not fully understood in many under development countries, it has been well appreciated by pioneer countries in terms of R&D. for example, in 2004, the United States Food and Drug Administration (FDA) released a report titled as "Innovation/Stagnation: Challenge and Opportunity on the Critical Path to New Medical Products", by which FDA addressed some important stoppages in innovative medical therapies submitted to the FDA for approval (Cosmatos and Chow, 2009). In short, the report underlined several issues in particular the urgent needs for modernizing the medical-product development process *per se* (through a critical path to make product development more predictable and less costly) as such intricate process is very expensive. FDA officials have highlighted that the FDA registration and approvals have been dramatically dropped - most of the failures at registration were due to the sponsor selecting the wrong dose or regimen for the test drug (Cosmatos and Chow, 2009). As result of which, the FDA aimed to initiate a national effort to advance medical- product development sciences that can turn discoveries into medical miracles. In fact, in recent years, many scientists and pharmaceutical companies have appreciated the impacts of TM not only for acceleration of clinical research and development but also for harmonization of different activities of various scientific disciplines. Many advanced technologies have been merged with TM. Of these, genomics and proteomics have shown to fasten the

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TM approaches for prime detection and final application of molecular biomarkers for cancer diagnosis, prognosis and prediction of therapy outcome (Cho, 2011, Mendrick, 2006).

Accordingly, translational proteomic/genomic medicine will assist the individualized clinical decision making - doing away with the use of race, ethnicity or ancestry as a proxy (Gurwitz and Lunshof, 2009). It is almost the same for translational regenerative medicine (Mason and Dunnill, 2007), as reported for translational models for musculoskeletal tissue engineering and regenerative medicine (Sah and Ratcliffe, 2009). National Institutes of Health (NIH) and FDA are now pursuing translational pathways that lead to clinical trials and therapeutic development.

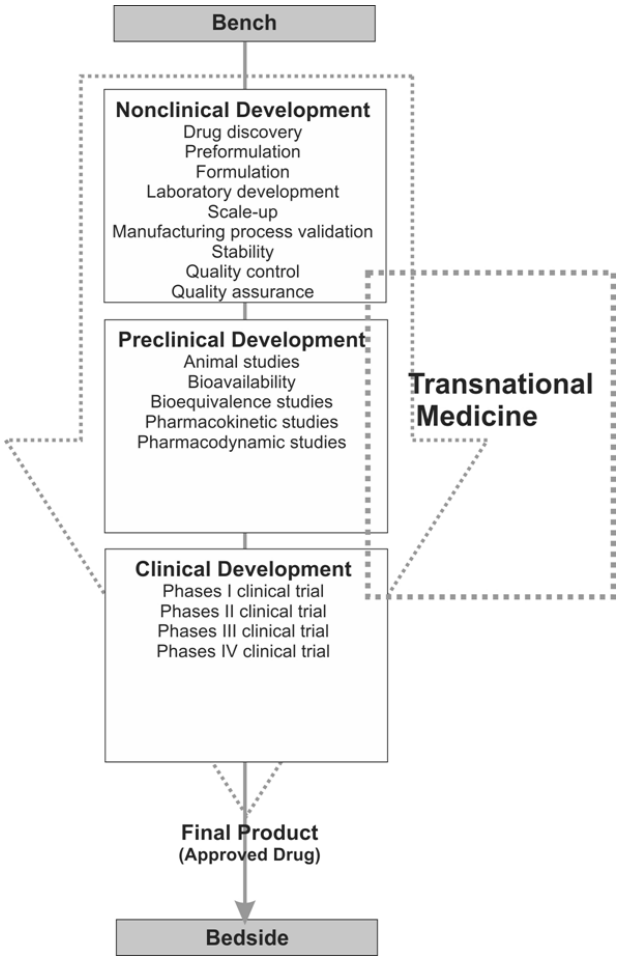

Fig.1. Integration of drug discovery and development via translational medicine (a bench to bedside approach).

To accelerate the translational pathways, in 2005, NIH released a new guide (NOT-RM-05–013), announcing its plan to solicit applications for Institutional Clinical and Translational Science Awards (CTSA) and to solicit applications for Planning Grants for CTSAs. The purpose of the CTSA initiative as part of the NIH Roadmap for Medical Research was mainly to assist the institutions to forge a uniquely transformative, novel, and integrative academic platform for Clinical and Translational Sciences. Such approach is believed to consolidate resources towards: 1) captivation, advancement, and cultivation of a team of well-trained, multi- and interdisciplinary investigators and research teams; 2) initiation of incubators for innovative research tools and information technologies, and 3) cooperation of multidisciplinary and interdisciplinary clinical and translational research and researchers towards a facilitative implementation of new knowledge and techniques to clinical practice at the frontlines of patient care (Cosmatos and Chow, 2009), an approach also called as a bench to bedside research activities.

Although TM provides the knowledge necessary to draw important conclusions from clinical testing regarding disease and the viability of novel drug mechanisms, its further advancement demands education and new sources of funding in a merged coalition of patients' advocacy groups, academia, drug regulatory agencies and industry (Littman *et al.*, 2007). What is more, Mankoff *et al.* (2004) underlined the major obstacles to effective TM in practice as: 1) the challenge of translating basic science discoveries into clinical studies, 2) the translation of clinical studies into medical practice and healthcare policy, and 3) the philosophical hurdles (Mankoff *et al.*, 2004).

So far, FDA has taken the lead in the development of a national "Critical Path Opportunities List" (http://www.fda.gov/oc/initiatives/criticalpath). The list consists of: 1) development of biomarkers, 2) clinical trial designs, 3) bioinformatics, 4) manufacturing, 5) public health needs, and 6) pediatrics. Of these, biomarker development is considered as the most important area for improving medical-product development (Flood *et al.*, 2011, Suh *et al.*, 2010, Litwin and O'Gorman, 2010, Mendrick, 2006).

Fundamentally, biomarkers are measurable characteristics that reflect physiological, pharmacological, or disease processes in animals or humans, in which detection of the specific biomolecule(s) can significantly lessen uncertainty of diagnosis and improve the medicaments (Chang, 2009). For example, many cancer patients are diagnosed at a late stage, in which the cancer is not often curable. Thus, early detection of cancer is going to be improved by implementation of cancer biomarkers, and this can provide tremendous opportunity for cancer patients through enhancing detection and treatment approaches. This also can favour development of personalized

medicines as the heterogeneity among diseases and patients may confer such potential. Despite some notable achievements, only a few biomarkers are routinely used in oncology.

Effective use of the biomarkers may face with some hurdles such as: 1) lack of methods, tools, and resources needed to discover and develop biomarkers; (2) lake of guidelines, standards, and oversight needed for biomarker development; and (3) methods and processes needed for clinical evaluation and adoption. These examples clearly highlight importance of TM in terms of intercommunications among various disciplines for makings guidelines, standards and practical protocols for transition of knowledge and technology between different fields. We must find out the ways to bring the novel systems (e.g., biophotonics, nanobiotechnologies, biomaterials and electrosensing) into a merged practice.

It is an obvious fact that basic scientists need to perform active intercommunication with clinicians through effective cooperation to maximize the corollaries of the basic research – it is exactly the same for clinicians too. In fact, preliminary and pilot nonclinical and nonhuman studies should be implemented for transition therapies developed using animal models to a clinical setting. This along with a good design (based upon both direct and lateral thoughts) may shed a guiding light upon clinical trials (the final stage of drug discovery). However, this needs scientific and sociocultural endeavours, because: 1) many scientists are not still aware of integrative translational researches particularly in developing societies, 2) TM is an intricate discipline that needs to be simplified, 3) there are no substantial guidelines and protocols for TM in different scientific categories, and 4) international collaborations (particularly among modern and under developing societies) are not adequate or effective due to many political issues while many societies are yet to explore their futuristic needs. Further, there is an increasing need for free publication platforms for accelerated dissemination of published papers that can significantly enhance knowledge upon TM (Omidi, 2011). This may also help knowledge and technology transfer process.

As concluding remarks, TM spans all the disciplines and activities that lead to making key scientific decisions as a compound traverses across the difficult preclinical–clinical divide, however for efficient transition of various disciplines we need to use simplified standardized protocol-based guidelines.

Ethical issues

None to be declared.

Conflict of interests

The authors declare no conflict of interests.

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