

ARTICLE

THE FUTURE OF TRANSLATIONAL MEDICINE

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Today, Translational Medicine is pivotal to the development of medicine in the 21st century. In the last ten years we have seen how the explosion of scientific knowledge and technological developments, triggered by the last World War, have rapidly grown.

The great paradox of medicine in this transitional period between two centuries is that, for the first time in human history, the entrepreneurial spirit of science has generated knowledge faster than society can incorporate it. We generate so much knowledge that it is difficult, not only to implement it, but replicate and validate it too.

Of course each new era faces challenges as society evolves, which must be overcome in the interest of progress. It is essential that the human community participates in these advances by identifying the barriers and designing efficient processes to navigate them.

In a society built on the fallacy that there are only two options: rapid success or failure. Translational Medicine illustrates that the age-old method of trial and error can offer a solid base upon which the great medical discoveries of the future can be made.

In fact, the history of medicine is full of examples of great advances that required long periods of maturation and a trial and error approach. Penicillin took more ten years to reach clinical use after its initial discovery. Shortly after his discovery Fleming thought that the lifetime of the drug in the body would be too short to produce a therapeutic effect and the first clinical trials failed because the doses used were subtherapeutic. It took almost five years to correct these first erroneous conclusions and finally Merck started its industrial development a further five years after that.

Translational Medicine generates a model of continuous evolution

The generation of scientific knowledge, focused on innovation in health intervention, results in a system that ensures knowledge is not diluted.

Translational Medicine creates a developmental playground where scientists can design experimental approaches, while maintaining a view of the implications their work may have

in the discovery of new therapies. This fact alone initiates a positive dynamic with transformational potential that mobilises basic scientists, technologists, researchers and clinicians along the same axis of inquiry, creating a space for cooperation and collaboration. It is a disruptive idea indeed, because traditionally scientists and doctors have developed their work in disconnected departments as a result of differences in language and culture, priorities and perspectives, preventing them from occupying a common space.

Thankfully Translational Medicine creates a defined path that allows researchers from different disciplines to walk together in harmony, transcending the barriers left behind by medicine's historical legacy.

Translational Medicine is, ultimately, a process. And, like so many innovative processes its course is non-linear. It is a perilous trail full of pitfalls, roadblocks and barriers, since each individual route must evolve across the mysterious landscape of human biology. Obviously, the goal is to advance the process and develop new interventions beneficial to the patient. Yet to this end a new generation of

pioneer is needed; those who have the capability, knowledge, mindset and adaptability to meet the challenges that emerge from the process and thus create a new paradigm in the history of science - transdisciplinarity.

Translational Medicine transforms science by pushing scientists to create a new language in which molecular biology, statistics, chemistry, clinical medicine, ethics and other disciplines meet and interact, generating new questions and new ways of addressing scientific problems. Today, more than ever, it is essential that translational medicine be reinforced within the research community and the medical community, as well as the pharmaceutical and medical technology industries.

The search for new drugs is at a historic moment of crisis. The process is becoming unsustainable, in spite of enormous technological advances, since the technological explosion has not been accompanied by a reinforcement of quality in experimental designs, especially in the discovery phases. The high level of failure at clinical trial in Phase II swallows up economic resources, generates exhaustion among researchers and clinicians and, more seriously,

'There is a nasty puzzle at the heart of modern biomedical research. On the one hand, the technologies that people think are important have become hundreds, thousands, or even billions of times cheaper. On the other hand, it costs nearly 100 times more to bring a drug to market today than it did in 1950. New drugs can be very expensive, yet the industry is closing labs and firing scientists. Our work goes some way towards explaining the puzzle. Governments, companies, and charities should focus on identifying and funding predictive methods, even if they don't match current scientific fashion.'

(Jack W. Scannell, Jim Bosley. **When Quality Beats Quantity: Decision Theory, Drug Discovery, and the Reproducibility Crisis.** PLOS ONE, 2016).

induces frustration among patients who see their hopes for a new drug, to treat their disease, disappear. It creates tremendous social distress because, at a time of global financial crisis, citizens perceive that vital resources are not being used efficiently. In a recent and visionary paper, Dr Jack Scannell, Associate Fellow of the Center for the Advancement of Sustainable Medical Innovation (CASMI), puts the issue in context:

Information is the key

The completion of the human genome in the year 2000 represented the moment when Translational Medicine began to be understood as a discipline, since it allowed us to dive into the biology of cellular processes in an exceptional way. We discovered new perspectives, approaches and targets and, as a result, started to address the challenges posed by complex diseases such as cancer, neuro-degenerative diseases or rare diseases, among others. Biomedical science produces enormous amounts of biological information, providing an excess of information which researchers must navigate. This is a process fraught with difficulties, in which the information technologies are the protagonists. The production of biological data, as well as how that data is sorted, stored and used is, without a doubt, the aim of the future development of Translational Medicine, as well as one of the greatest issues to be overcome by science and technology in the 21st century. The reclassification of pathological processes through the identification of molecular signatures creates a new classification of the human disease that is breaking down conceptual barriers and redefining how we understand disease. The repositioning of hierarchical classifications of diseases to molecular profiles, and not phenotypic manifestations, can only be strengthened if the biological information management systems are robust and efficient. With this in mind, the concept of FAIR data (Findable, Accessible, Interoperable, Reusable) has been developed, which should be a catalyst in the acceleration of outcome applicability. Future developments in Translational Medicine should be built on this strategy, where biological data is managed in a meaningful way to support a fast-track development process. This is particularly important in the pre-implementation phase where technological outcomes from different experimental models will determine the successful implementation of health care interventions.

Putting the patient at the centre of the process

Yet the key to the future of Translational Medicine is not centred exclusively on scientific or technological considerations. Rational analysis of the ethico-social landscape provides us with a guidance on how to advance forward, well into the next decade. The truth is societies are not transformed by technology alone, but by the way in which societal relations evolve in the wake of technological developments. If we were to consider a conceptual (not technological) revolution in the field of medicine in the 21st century, imagine a world where patients are empowered to take control of their health and how their health care system provides its services, on a preventative, diagnostic and therapeutic level.

Placing patients at the centre of the process transforms them into agents of change. They are the co-decision makers, helping to safeguard and foster constructive interaction between themselves and the healthcare system. Assuming responsibility for their own health will lead to medical innovation and, ultimately, create an open dialogue and mutual understanding between patients and the medical community. In fact, for some, patients are indispensable.

The debate around the price of medicines has to be conducted with patients to guarantee access to innovation at an affordable price. In this context, HTA strategies for implementing innovative therapies will be carried out with patients side-by-side. They are the ultimate users of health technologies and they can advocate and promote models for patient involvement among other stakeholders. Nothing will facilitate the dialogue among scientists, clinicians and society more effectively than the creation of a pathway, constructed together, and bound by a common objective.

In this way Translational Medicine can create a great testing ground, with the goal of developing an interactive space where scientists and citizens can commune, with mutual understanding, and become a pillar of social education.

The role of the RI in Translational Medicine: EATRIS as a driving force

Translational Medicine is a new discipline which needs an operational framework in order to progress. So, it is important to recognise the role of Research Infrastructure (RIs) as the threads of cohesion and dynamisation in the fabric of European science.

This organisational model creates a web of scientific capacities, characterised by transnationality and complementarity, and will play a key role in the development of medical innovation in Europe and knowledge excellence. European infrastructures are a great strategic move by the European Commission. Through this model, Member States can be directly involved in the governance of the system and the design of a holistic strategy.

It is anticipated that RIs will continue to play a fundamental role in the development of Translational Medicine, given that four of them (BBMRI, ELIXIR, ECRIN and EATRIS) have a direct impact on scientific activities within the medical arena.

The RIs guarantee a solid foundation for scientific development by creating a critical mass of complementary capacities to tackle ambitious challenges. They guarantee the incorporation of innovation and knowledge by bringing together the parties needed to push forward novel therapies in the European sphere.

The medicine of the 21st century need RIs as providers of excellent scientific services that are integral to the process of therapeutic innovation and gatekeepers of quality. RIs do not necessarily create structure themselves but synergise existing structures, and produce, through the creation of common projects, bottom-up alignment of the scientific strategies of EU Member States instead. Therefore, it is fundamental that the Member States perceive the RIs as allies to their own agenda, committed to their governance. It is in this space that EATRIS will shine. EATRIS' goal is to create harmony and synchronisation between the scientific and technological activities, as well as other stakeholders, that the medical RIs have been working on since their inception. It is important, that in the coming years, an environment is created where RIs can complement one another and provide mutual support to each other, in order to ensure

scientific advances are translated into the development of new interventions to improve the health of citizens.

One of EATRIS' most valuable assets is its capacity to foster collaboration with industry partners and bring them together with academic groups in order to accelerate therapeutic innovations. This mean high quality technical services are available to industry at the critical moments in the life-cycle of medicine development.

In addition, EATRIS participates actively in raising awareness of regulatory frameworks in academic and industry sectors, identifying barriers and solutions to accelerate regulatory processes in the development of new therapies.

Whilst other RIs focus their efforts on specific bottlenecks in the process EATRIS is dedicated to developing a holistic perspective of the process. This widening of the strategic spectrum focuses attention on the pipeline rather than on specific technologies. It is this focus that defines EATRIS as a driving force behind the concept of Translational Medicine, ensuring that Europe possesses an active framework in which science can respond to the greatest challenges posed by society. When we speak of the future of Translational Medicine, we must embrace the idea that it is a dynamic, living, evolving concept which, in the coming decades, will be the foundation of technological development and complicity for scientists, industry, citizens, policy-makers and health authorities.

The resources which society assigns to its citizens' health are not infinite and in a Europe which believes in equality of all men and women, equal access to health care must be guaranteed for all citizens regardless of their country, gender, or social class. It is an ethical imperative, therefore, that all those in the Translational Medicine community forge forward with conviction, rigour, generosity and transparency. The health of the next generations depend on the decisions we take today.

ABOUT EATRIS

The European Infrastructure for Translational Medicine (EATRIS) is a non-profit, permanent European research infrastructure consortium (ERIC) that comprises more than 90 research institutions in 12 European countries. EATRIS focuses on accelerating medical discoveries to clinical development through innovative use of infrastructure and scientific expertise provided by top-level European academic research centres. EATRIS is active in the fields of ATMP, biomarkers, imaging and tracing, small molecules and vaccines.

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