

TRANSLATIONAL RESEARCH

The Competence Center for Applied Biotechnology and Molecular Medicine defines the truth of translational research

The ambition of medical research often undergoes fashion seasons in the same way as the textile industry – one summer it's the mini-skirt and high heels and the next it is long, ruffled skirts and sandals. 'Translational medicine' is the latest trend in medical research. Modern research groups and networks all over the world claim that they are involved in and contributing to this area – knowing, of course, that this is well received, in particular by funding agencies. However, looking a bit closer, there often isn't actually much translation behind the proposed projects, and the research is performed as ever before – on the bench alone – and it will never make it to the bedside of a patient.

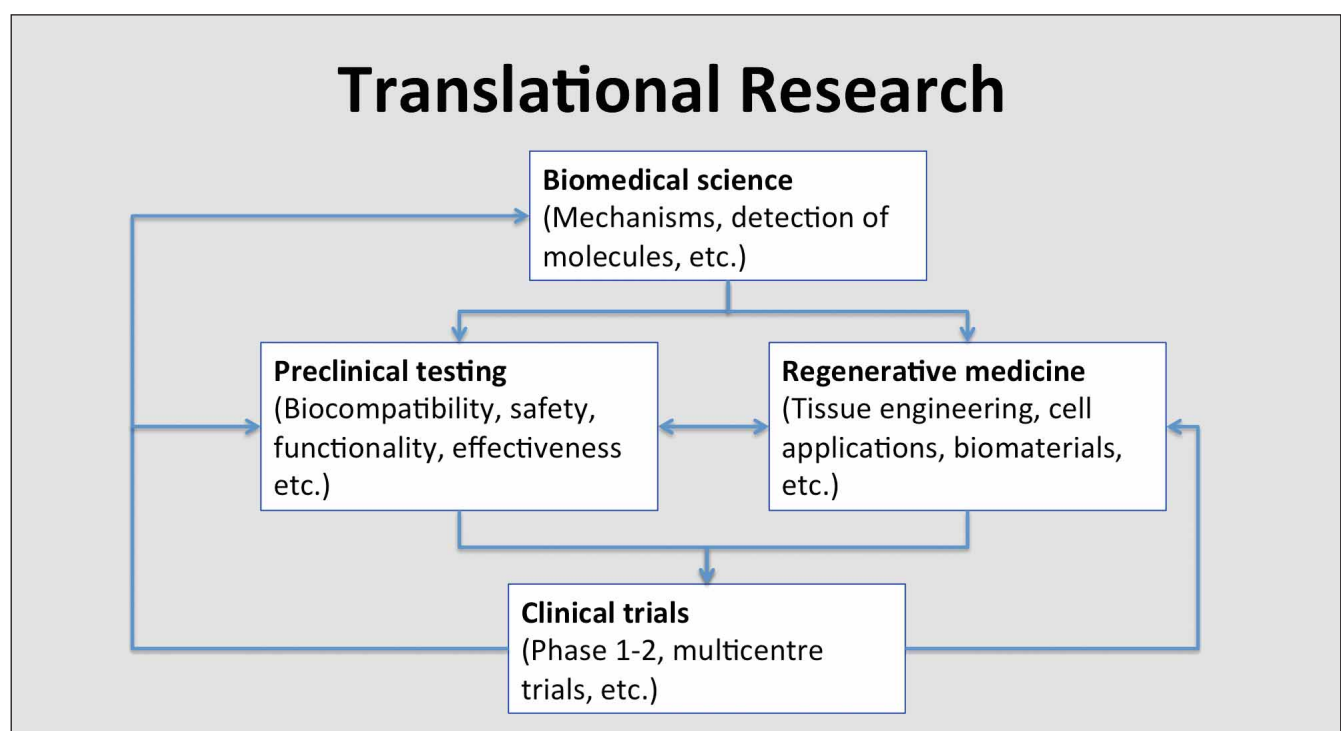
Misnomer

The expression 'translational medicine' is a misnomer to start with. Medicine always comprises the translation aspect from basic scientific knowledge into clinical applications for the benefit of patients. The phrase should be 'translational medical research', and then the word 'translation' has to be better defined. Translational medical research aims to improve the health of individuals and the community by 'translating' findings into diagnostic tools, pharmaceuticals, procedures, policies and

education, which basically indicates that knowledge gained from any area finally ends up with the patients for their benefit.

As an example: inventing a new pacemaker for heart patients is at best medical engineering but not yet translational research. This expression is only justified when the newly invented device undergoes all preclinical tests and finally receives permission to be used in a clinical human trial. The same is true for tissue-engineered constructs, such as in cell culture and bioreactors, engineered skin or vessel transplants. The translational aspect starts only after the proof of concept work has been done experimentally, e.g. at the point when the construct is implanted into an experimental animal in preclinical tests, with a very strong emphasis on, or in concrete preparation to perform, later human clinical use.

Ideally, the basic scientists in translational research (the researchers performing the animal experiments and the clinicians who at the end implant devices and tissue-engineered constructs or apply new medication in human patients) are involved from the very beginning of the innovation and plan the research throughout the experimental course as an interdisciplinary team. In an even more ideal translation, the clinician also provides material, such as biopsies, blood samples,





etc., from diseased patients for the basic scientists to investigate the mechanisms of the underlying disease or to study the benefit of the new treatment modality, thus driving the new innovation from the other end (from bedside to bench).

So translation is not a one-way street – it goes from ‘bench to bedside and back’. If a researcher claims translation, then the direction of research has to be clearly directed towards a treatment modality that can later be used to combat disease. Finding a molecular regulatory mechanism of a disease or new molecule that inhibits an enzyme alone has nothing to do with translational research yet. This is still very valuable basic research, but for its translation it needs more than that.

Realistic undertakings

In medical reality, translation also involves regulatory affairs on many levels. For example, any tissue-engineered construct that was tested in preclinical studies in experimental animals, and is finally regulatory approved for clinical trials, has to involve the production of tissues under GMP (good manufacturing practice), preclinical testing under GLP (good laboratory practice) and finally clinical testing under GCP (good clinical practice) conditions. All three levels involve rigorous procedural protocols that are accredited by the medical authorities in each country and, due to market reasons, often at the end by the FDA (Food and Drug Administration, USA). Apart from the protocols, procedures also require accredited infrastructures that form the basis of these procedures, which are the safety basis for later use in human patients. These are expensive and extensive undertakings, and thus many, if not the majority of, good research findings get lost during this translational process.

The Competence Center for Applied Biotechnology and Molecular Medicine (CABMM) at the University of Zürich, Switzerland, was founded in 2008 to cope with this challenge. It is an interdisciplinary centre with the aim to perform, co-ordinate and promote clinically-oriented experimental research in the fields of biotechnology, regenerative medicine and molecular medicine. The promotion of scientific exchange and collaboration between basic

scientists and clinically-oriented research groups, conducting joint research projects, and the transfer of gained project knowledge to sustain further development by filing patent applications and/or collaborations with industry are the core of the CABMM. In conjunction with the university hospitals, the University of Zürich is the only university, at least in Europe, that offers the full translation pipeline, including regulatory aspects with GMP (Swiss Center for Regenerative Medicine), GLP (Musculoskeletal Research Unit) and GCP (university hospitals).

In this context, the newly initiated Wyss Translational Center Zürich (in conjunction with the Swiss Federal Institute of Technology) further adds to the unique translational research competence by strictly focusing on the efficient translation of medical innovations and novel human-centric technologies in the fields of regenerative medicine and robotic technologies.



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