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Translational medicine: Achievements and challenges

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Despite tremendous efforts and investments, despite the cloning of the entire human genome, innovations at the patient level are becoming rare events. Failures to predict human efficacy/safety of new drugs from early discovery and development work are being blamed to cause early or late attrition of too many drug projects. The pressure of increasing R&D costs and low output in terms of critically novel drugs forced the Federal Drug Administration (FDA) to reconsider its own actions and those of major players in biomedical research in terms of time lines, costs, design and, ultimately, success. The 'critical path initiative' of 2004 represents a milestone in this context. It reflects a concerted action initiated by a regulatory authority criticized for its 'retarding' activities claimed to result in the low output syndrome described above. Though certainly not the first public initiative to address translational medicine issues as major concern, it was one of the most influential and respected ones. American universities addressed the challenge as well and established centers for translational medicine, e.g. at Duke or Pennsylvania University. In Europe, The European Organization for the Treatment of Cancer (EORTC) which is committed to making translational research a part of all cancer clinical trials, and the National Translational Cancer Research Network announced by the British government to facilitate and enhance translational research in the United Kingdom are working on this route. Almost all major drug companies have addressed the issue of translational medicine in one way or the other. The institutional structures range from independent departments of translational or discovery medicine to entirely 'embedded' dependent structures which are part of the drug discovery/development teams without central facilities. In general, US biomedical players have invested the most (NIH has announced to spend a total of up to 10 billion USD) and are at the forefront of translational institutionalization, with Europe lagging behind at very different distances as far as the individual countries are concerned. Commercialization of academic inventions has traditionally been much more efficient in the US than the EU, and translational medicine has a lot to do with expertise accrued during commercialization processes. One dimension and particular challenge of this novel science is certainly the assessment of the translational potential of an innovative project, thereby rating the risk of investment and creating a base for portfolio considerations. In a structured approach following pre-specified algorithms, the translatability potential of a given drug, device or diagnostic test project may be assessed by analysis of multiple variables. Biomarkers, disease models, test tube results, genetic and 'omics' data and other dimensions will be integrated into a translatability scoring system to achieve two goals:

- Quantitatively position the likelihood of translational success of a given project in the environment of competing projects to support stop/go decisions
- Develop a strategy for successful translation by the identification of weaknesses and the generation of a program for amelioration (e.g. biomarker development)

This approach is envisioned to help biomedical and drug companies, funding agencies, regulatory authorities, venture capital and academia to

- Detect promising projects with high potential for exploitation in the value chain
- Rate funding applications in regard to their translational potential and prioritize them
- thus, find a reasonable balance of more and less risky projects in a portfolio
- Define and implement a strategy for the development of translational aspects in given projects

By this reproducible process which even (but not only) produces numerical denominators, decision makers in biomedical or venture capital companies, funding agencies could add value to sometimes gut-feeling and expert opinion driven evaluation processes, and connect investment decisions to the evidence-based analysis of the translational soundness of a project. Academia might consider to partially re-shape research strategies if the route to out-licensing success and generation of revenues would be easier to travel in the light of this service.

Biography

Martin Wehling, MD, is full Professor of Clinical Pharmacology at the University of Heidelberg. He is also board certified internist (cardiologist) and has longstanding experiences in basic science (cell physiology, steroid pharmacology, nongenomic steroid actions), clinical trials (translating basic science into human studies) and clinical medicine (invasive cardiology, endocrinology). In 2004, he was appointed by AstraZeneca as Director of discovery (=translational) medicine. Returning to academia in 2007, he promotes translational medicine by aligning academic and private activities. Main tools are connecting distant players in the translational process, assembling, developing and profiling of biomarkers and developing smart translational plans to promote promising projects.

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