Application of the Data-Intensive Approach to Technological Innovation System for Sustainability: The case of regenerative medicine innovation in Japan

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This thesis examines the effectiveness of applying the data-intensive approach to analyse how technological transformation process takes place over time by using the analytical framework, Technological Innovation System. This is achieved by assessing system performance and identifying its system drivers and barriers, analysing dynamic interactions of different actors within and between system functions, and investigating characteristics of major actors in the system. To examine the effectiveness of the proposed approach, this thesis uses the case of regenerative medicine in Japan from 1990 to 2010. The current main challenge in the regenerative medicine field is that although there is political confidence that regenerative medicine has future value, how the field would progress in terms of science, technology, market conditions, societal responses and commercialisation is still relatively unknown.

The results show that expectation from the Japanese government towards the regenerative medicine technology has been continuously increasing since 2000 and that the governmental subsidies reach 4 billion yen in 2010. It also showed that society has already begun to consider the possible effects of regenerative medicine such as safety and risks, ethical issues and economic issues as if it has already been fully realised in society. On the other hand, the number of the applications of this technology for clinical trials is comparatively small and it can be observed that JACE is the only regenerative medicine product being commercialised on the market today. Further, an investigation on the institutional settings showed that the regenerative medicine technology is poorly aligned with current institutional settings. JACE was approved as medical device under the Pharmaceutical Affairs Act in 2007. This indicates difficulties in policymaking for health insurance, as JACE possesses characteristics of both drug and device. It can be said that absence of appropriate regulations for regenerative medicine product is causing the knowledge diffusion from creation to utilisation to be significantly slow. New and revision of regulatory framework for basic to clinical research, clinical trials as well as consideration of social, economic and ethical values for regenerative medicine pointed out by society are urgently needed to reform its innovation system.

Keywords: Data-Intensive Approach; Regenerative Medicine; Science, Technology and Innovation Policy; Systems of Innovation; Technological Transformations