

講演録

ARO自立化への展望 — 研究開発エコサイクルの確立に向けて*1

福島 雅典

公益財団法人 神戸医療産業都市推進機構 医療イノベーション推進センター

Prospect for self-sustaining ARO (Academic Research Organization) — In view of establishing an R&D eco-cycle

Masanori Fukushima

Translational Research Center for Medical Innovation,
Foundation for Biomedical Research and Innovation at Kobe

Abstract

This is a status report by TRI (Translational Research Center for Medical Innovation) at the plenary meeting of the “Project for Translational and Clinical Research Core Centers,” which AMED (Japan Agency for Medical Research and Development) held on March 5, 2018.

In 2015, Japan made a significant reform to the mechanism for funding life science research & development (R&D) through a national project—AMED’s Project for Translational and Clinical Research Core Centers—to extend healthy life expectancy through medical innovation. The project’s origin dates to the national TR (translational research) promotion program in 2007 by MEXT (Ministry of Education, Culture, Sports, Science and Technology), which TRI has overseen. As a result, a powerful R&D pipeline was established in academia allowing us to establish a disease-specific portfolio strategy. The R&D pipeline of the Academic Research Organization (ARO) in Japan has added approximately 1,260 projects; of which 26 medical products were approved by the regulatory agency under the Pharmaceutical Affairs Law (PAL) of Japan as of August 2017. More than 150 products have a good chance to be approved in the next few years.

This establishment of an R&D pipeline brought us to a stage where we can calculate substantial Return-on-Investment (ROI) from licensing to pharma companies in each ARO. This is critical for establishing a self-sustaining ARO. Also, by sharing clinical data globally, with appropriate support by AI (artificial intelligence), it is possible to establish an eco-cycle based on global standardization and harmonization of clinical data. This approach will lead to the integration of medical practice and research, helping to create an ideal world in which to conquer incurable diseases.

Key words

ARO (Academic Research Organization), R&D pipeline, Return-on-Investment (ROI), sustainability, global data sharing

Rinsho Hyoka (Clinical Evaluation). 2018 ; 46 : 263-86.

*1 本稿は、2018年3月5日(月)開催の国立研究開発法人日本医療研究開発機構「革新的医療技術創出拠点プロジェクト」第二回全体会議で報告した内容をもとに記したものである。