

シンポジウム

平成26年度厚生労働科学特別研究事業 進捗管理班
(難治性疾患実用化研究・腎疾患実用化研究・慢性の痛み解明研究) 成果報告会

難病制圧に向けて — アカデミアにおけるイノベーション創出の現状と展望 —

主催：公益財団法人 先端医療振興財団 臨床研究情報センター
(2015年3月13日(金) 於：東京コンベンションホール)

Rare and Intractable Diseases Translational Research Conference 2014

Toward the New Horizon of Rare Disease

— Present status and scope of innovation in the academic sector —

Organized by: Translational Research Informatics Center,
Foundation for Biomedical Research and Innovation

(Friday, March 13, 2015 Tokyo Convention Hall, Japan)

Abstract

Since fiscal year 2012, MHLW (Ministry of Health, Labour and Welfare) has been recruiting Health and Labour Sciences Research Grants by applying a whole new recruiting guideline, for research focusing on drug and medical devices development. Regulatory science was rigorously applied to evaluate approved major research- Step 1 and 2; funded sufficiently to implement GMP (good manufacturing practice), GLP (good laboratory practice) and IND (investigational new drug application) trials based on the Pharmaceutical Affairs Law (PAL) in Japan. Additionally, the Program Directors and Program Officers took command by performing powerful R&D Project Management. As a result of these measures, among 34 approved research grants thus far, 16 have launched IND trials; 1 of which has obtained approval from the government, and 2 of which will submit an NDA within this fiscal year. Anticipating the kick-off of AMED (Japan Agency for Medical Research and Development) from April 1, 2015, our study group has been reviewing and upgrading the PDCA (plan-do-check-act) cycle to create an effective mechanism to drive R&D management. We have conducted a rigorous check and review of all sites, as well as documentation surveys for the purpose of maximizing all 126 approved funded research under the 3 grants project by the Specific Disease Control Division of MHLW. At this conference, progress has been reported mostly from the research based on PAL, in the Rare/Intractable Diseases Research Project. There was a symposium on establishing an all-Japan gene analysis medical treatment structure, as well as a Renal Diseases and Chronic Pain Research Project, to discuss remarkable research in the area. All other research has been reported in poster sessions.

Key words

rare disease, chronic kidney disease (CKD), pain, clinical genome sequencing, biobank

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