

HEALTH-ECONOMIC EVALUATION OF IMPLEMENTING MICRODOSE CLINICAL TRIAL IN DRUG DEVELOPMENT

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[Purpose] To provide health-economic evidence to decision makers in pharmaceutical industries for implementing various MD methods to their drug development processes. **[Methods]** Different decision maker is supposed to be interested in different phases of drug pipeline. Moreover, there are various MD methods which pharmaceutical industries select regarding characteristics of their candidates. Therefore, our model was designed to calculate expected costs and numbers of compounds passed through each phase of drug development process for four strategies; the conventional strategy (non-MD) and 3 MD-integrated strategies (MD-LC-MS/MS, MD-AMS and MD-PET). For this purpose, we assumed two situations: situation 1) 100 drug candidates were allocated to these four strategies (non-MD for 70 candidates and each of the 3 MD-integrated strategies for 10 candidates) and situation 2) all 100 drug candidates were applied to each strategy. For both situations, we evaluated two outcome measures; the number of compounds pass through phase2 and that of approved ones. For each situation and outcome measure, we calculated incremental cost-effectiveness ratio (ICER), i.e., additional cost per one additional “successful” compound. **[Results and Discussion]** In situation 1, ICER of each outcome measure was JPY12.7bil. per additional approved compound and JPY6.0bil. per additional compound succeed in phase2 study, which were both lower than each threshold, which was set to the average cost of the conventional therapy (JPY24.4bil. per approval and JPY15.4bil. per phase2 success). In situation 2, the number of approved compound and overall costs increased in order to non-MD, MD-LC-MS/MS, MD-AMS and MD-PET (22.5 vs.26.0 vs.27.4 vs.29.6, JPY345bil. vs.JPY364bil. vs.JPY379bil. vs.JPY385bil.). ICERs for all 3 MD-integrated strategies were lower than threshold, JPY15.4bil. In many setting and even with various sensitivity analysis, implementing MD was thought to be cost-effective.