Ⅱ期

平成 30 年度

武蔵野大学大学院　薬科学研究科薬科学専攻　修士課程　　入学試験問題　（1 月 21 日）

［ 英語 ］ 下の文章を読み、問 1～問 5 に答えよ。

Historically, drug development focused on regulatory strategies designed for specific regulatory regions. In that context, MRCTs had been recognised as an efficient way to enable recruitment of the planned number of trial subjects within a reasonable timeframe when either the disease and/or condition was rare (e.g., an enzyme deficiency disorder), for special (e.g., elderly, paediatric) populations, or when very large numbers of subjects were required (e.g., cardiovascular outcome studies, vaccine efficacy studies). ①More recently, global regulatory strategies are also used to plan and conduct studies more efficiently to facilitate more rapid availability of drugs to patients worldwide.

MRCTs allow for an examination of the applicability of a treatment to diverse populations. The intrinsic and/or extrinsic factors that are believed or suspected to impact upon responses to the drug can be further evaluated based on data from various regions using a single protocol. For example, the impact on the treatment effect of genetic differences or different distribution of gene polymorphisms in drug metabolising enzymes or the molecular target of a drug can be examined in exploratory and/or confirmatory MRCTs that include subjects with different intrinsic factors across regions. Accumulated knowledge of the impact of intrinsic and extrinsic factors and global sharing of experiences in various regions may promote inclusion of additional regions in MRCTs.

The primary reason for performing MRCTs is to evaluate the overall treatment effect based on data from subjects in all [　　]. However, intrinsic and/or extrinsic factors may be expected to impact subjects' responses to drugs differently across [　　] and should be considered when planning MRCTs. If major differences in treatment effects are expected, available data should be assessed to decide, whether it is appropriate and feasible to conduct the MRCT. Even in the case of expected major differences in treatment effects, it may still be possible, to conduct MRCTs by excluding some [　　] or a defined subgroup within a region, after careful consideration. Additional strategies to study a disease and/or drug in the excluded [　　] should be considered (see ICH E5). If MRCTs are the source of data in the bridging strategy based on the ICH E5 guideline, MRCTs could provide more robust evidence than single regional trials for extrapolation of study results. ②In some cases, single-region studies may be appropriate, such as in the evaluation of drugs to treat or prevent a disease that is prevalent in a single region (e.g., anti-malarial drugs, vaccines specific to local epidemics, or antibiotics for region-specific strains).

MRCTs can facilitate simultaneous global development of a drug and reduce the number of clinical studies conducted separately in each region, thereby minimising unnecessary duplication of studies. Although MRCTs require more coordination during the planning stage and possibly increase start-up

time, their use may provide a pathway for earlier access to new drugs worldwide by facilitating earlier approval across regions, thereby avoiding significant lag in the availability of new drugs in some regions.

As shown in the illustrative examples in Figure 1, the timing of clinical drug development across different regions can be synchronised by the use of MRCTs, in comparison to local studies conducted independently in each region. Figure 1 also illustrates the use of MRCTs in the overall design of the drug development programme, not only in the confirmatory stage, but also as an option in the exploratory stage, where it is feasible. Early identification of relevant intrinsic and extrinsic factors could set a good foundation for planning confirmatory MRCTs.

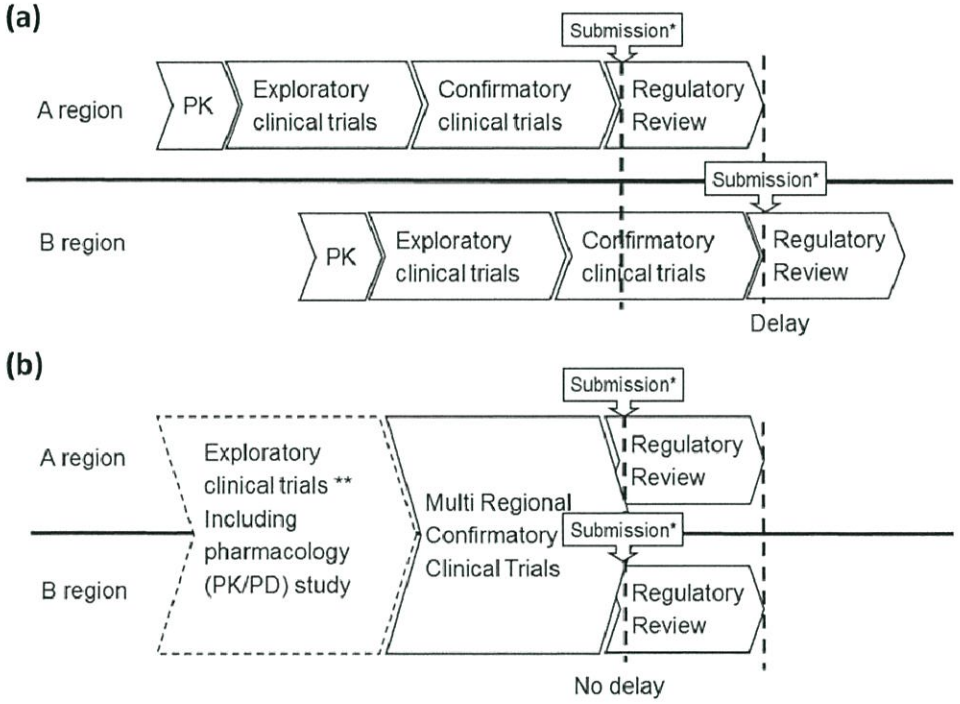

Figure 1. Illustrations of clinical drug development workflow across regions for drug submission and regulatory review in independent and global strategies.

（ICH-E17 General Principles for Planning and Design of Multi-Regional Clinical Trials より引用）

MRCTs: 国際共同治験 (multi-regional clinical trials)， paediatric: 小児, cardiovascular: 心血管系, intrinsic: 内因性， extrinsic: 外因性， submission: 承認申請

問 1　下線部①を和訳しなさい。

問 2　4 つの [　] 内に共通に入る本文中の 1 語を記しなさい。

問 3　下線部②を和訳しなさい。

問 4　本文に記述されている MRCTs の利点と欠点を記しなさい。

問 5　Figure 1 の (a) および (b) にそれぞれ適切なタイトルを記しなさい。