博士後期課程Ⅱ期

令和 4 年度
武蔵野大学大学院　薬科学研究科　薬科学専攻 博士後期課程　入学試験問題 （1 月 9 日）
［ 英語 ］ 次の文章を読み、各問に答えよ。

Patients frequently use more than one medication at a time. Unanticipated, unrecognized, or mismanaged drug-drug interactions (DDIs) are an important cause of morbidity and mortality associated with prescription drug use and have occasionally caused the withdrawal of approved drugs from the market. ①In some instances, understanding how to safely manage a DDI may allow the Food and Drug Administration (FDA) to approve a drug that would otherwise have an unacceptable level of risk. Clinically relevant DDIs between an investigational drug and other drugs should therefore be: (1) defined during drug development as part of the sponsor's assessment of the (　②　) drug's benefits and risks; (2) understood via nonclinical and clinical assessment at the time of the (　②　) drug's approval; (3) monitored after approval; and (4) communicated in the labeling.

The goals of studies that investigate cytochrome P450 (CYP) enzyme- and transporter-mediated DDIs are to:

- Determine whether the (　②　) drug alters the pharmacokinetics of other drugs
- Determine whether other drugs alter the pharmacokinetics of the (　②　) drug
- Determine the magnitude of changes in pharmacokinetic parameters
- Determine the clinical significance of the observed or expected DDIs
- Inform the appropriate management and prevention strategies for clinically significant DDIs

After conducting in vitro drug metabolism and drug transporter studies, sponsors should determine the need for and timing of clinical DDI studies with respect to other studies in their clinical development program. Sponsors should assess the DDI potential before the product is administered to patients who are likely to take concomitant medications that could interact with the (　②　) drug. Furthermore, ③sponsors should collect enough DDI information to prevent patients from being unnecessarily excluded from any clinical study because of their concomitant medication use. Unnecessary restrictions on patient enrollment can result in clinical study populations that are not representative of the indicated patient population. Inadequate studies of DDIs can hinder the FDA's ability to determine the benefits and risks of an (　②　) drug and could result in restrictive labeling, postmarketing requirements or commitments, and/or delayed approval until

sufficient information on DDIs is available. Sponsors should summarize their DDI program at milestone meetings with the FDA. Potential discussion topics at these meetings include the planning, timing, and evaluation of studies to determine the DDI potential of the (　②　) drug.

（U. S. Food and Drug Administration, Guidance for Industry; Clinical Drug Interaction Studies-Cytochrome P450 Enzyme- and Transporter-Mediated Drug Interactionsより引用）

問 1　下線部①を和訳しなさい。

問 2　7 か所の (　②　) に共通に入る語（1 語）を、問題文から抜き出して記載しなさい。

問 3　シトクロム P450 およびトランスポーターを介する薬物相互作用試験の目的について、問題文の記載に基づいて日本語で記しなさい。

問 4　下線部③を和訳しなさい。

問 5　下線部③が適切に行われなかった場合の懸念について、問題文の記載に基づいて日本語で説明しなさい。