SMDコンピテンシーのドメインリスト

Domain 1 - Discovery medicine & early development	• アンメットメディカルニーズの把握、新規開発候補の評価とTarget Product Profile作成に向けた臨床開発をデザイン化する
Domain 2- Clinical development & clinical trials	• 探索・検証臨床試験を企画・実施・評価し、論文発表や薬事申請文書を作成する
Domain 3 - Medicines Regulation	• 医薬品のライフサイクルを通しての適正使用とリスク管理のための臨床開発に必要な薬事・法制度を理解する
Domain 4 -Drug safety surveillance	• 患者と被験者に適切な情報を提供し、リスクを最小化するための市販後サーベイランスを評価・解釈する
Domain 5 - Ethics and subject protection	• 臨床試験の実施とコマーシャル活動における臨床試験倫理とビジネス倫理の基本を理解し、行動する
Domain 6 - Healthcare Marketplace	• 医薬品のプロモーションや臨床試験の企画において被験者保護に必要な倫理・法的基準を理解し、行動する
Domain 7 - Communication & management	• 効果的なコミュニケーションスキルや対人関係構築で成果達成に必要な人材管理やリーダーシップを発揮する

7つのドメイン

Competency総合評価

- Domain 1 - Discovery medicine & early development
- Domain 2- Clinical development & clinical trials
- Domain 3 - Medicines Regulation
- Domain 4 -Drug safety surveillance
- Domain 5 - Ethics and subject protection
- Domain 6 - Healthcare Marketplace

2科目以上選択

- Domain 7 - Communication & management

＝必修

7ドメインで合計57のコンピテンシーリスト

Domain-1:Discovery Medicine & Early Development

- C1. EVALUATION & ANALYSIS OF A DISEASE AREA WITHIN THE INDUSTRY CLINICAL DEVELOPMENT ENVIRONMENT & IDENTIFICATION OF UNMET THERAPEUTIC NEEDS.
- C2. EVALUATION OF THE CLINICAL & NON-CLINICAL PHARMACOLOGY & TOXICOLOGY EVIDENCE FOR A NEW CANDIDATE FOR CLINICAL DEVELOPMENT.
- C3. EVALUATION & APPLICATION OF THE REGULATORY & ETHICAL ASPECTS UNDERPINNING CLINICAL DEVELOPMENT
- C4. CREATION OF A CLINICAL DEVELOPMENT PLAN (CDP) FOR A NEW CANDIDATE INCLUDING A TARGET PRODUCT PROFILE (TPP).
- C5. THE DESIGN & EXECUTION OF EXPLORATORY STUDIES & EVALUATION OF THE RESULTING DATA AS APPLIED TO THE CLINICAL DEVELOPMENT PLAN .
- C6. THE EVALUATION OF THE ADVANCES MADE IN THE CLINICAL PHARMACOLOGY OF A NEW MEDICINE IN A STEPWISE MANNER WITH THE OVERALL CDP & THE TPP.
- C7. EXPLANATION OF THE STATISTICAL PRINCIPLES FOR THE DESIGN, CONDUCT & ASSESSMENT OF EXPLORATORY STUDIES.
- C8. JUSTIFICATION FOR THE VARIOUS END-POINTS USED IN THE CLINICAL DEVELOPMENT PROGRAMME.
- C9 APPRAISAL OF SUSPECTED ADVERSE EVENTS DURING EXPLORATORY DEVELOPMENT.

- 知識
- スキル
- 行動

各コンピテンシーを3面から定義

JAPhMed
The Japanese Association of Pharmaceutical Medicine
一般財団法人 日本製薬医学会

ドメイン1：創薬と早期開発（例）

必要な知識

スキル

態度・行動

ドメインを構成する複数のコンピテンシー

A1-Drug Development & Clinical Trials; D1=Discovery Medicine & Early Development			
Knowledge Syllabus topics	Applied knowledge The trainee should be able to demonstrate applied knowledge of....	Skills The trainee should demonstrate the ability....	Attitudes /Behaviours The trainee....
C1. EVALUATION & ANALYSIS OF A DISEASE AREA WITHIN THE INDUSTRY CLINICAL DEVELOPMENT ENVIRONMENT & IDENTIFICATION OF UNMET THERAPEUTIC NEEDS.			
2.3, 2.6, 2.7, 11.11, 11.12, 11.14.	• The causative factors, pathophysiology & main therapeutic options in one major organ-based disease. • The benefits & shortcomings of current therapy, thereby identifying new therapeutic needs in one major organ-based disease. • How advancing knowledge, such as pharmacogenomics & pharmacogenetics, may tailor therapy. • Searching the clinical literature. • How to evaluate & interpret the (literature) findings in the clinical development environment.	• To bring together scientists working on the underlying disease process, including academic & company experts on treatment options, & chemists developing new compounds that may fulfil unmet needs. • To contribute to proposed investigations & profiling of a new theoretical agent by applying key principles of efficacy, safety & economic value. • To conduct a clinical literature search. • To prepare a literature review of a specified disease area. • To write or review constructively a brief report describing: - the epidemiology & pathophysiology of the disease area; - therapies available & their mechanisms of action; - a summary of products under development in this area; - unmet medical / therapeutic need in this area.	• As part of a research team, consults with academic & clinical experts in the therapeutic area to learn therapeutic aims, achievements & needs. • Creates an idealised drug profile &, in doing so, recognises constraints in clinical practice & in healthcare provisions. • Recognises the breadth & depth of data requirements & the inherent limitations of information freely available in the public domain when making appropriate clinical development judgements. • Works as part of a team to ensure the fullest understanding of non-clinical, clinical & commercial data, & their relevance to the disease area review.
C2. EVALUATION OF THE CLINICAL & NON-CLINICAL PHARMACOLOGY & TOXICOLOGY EVIDENCE FOR A NEW CANDIDATE FOR CLINICAL DEVELOPMENT.			
1.2, 1.3, 1.4, 1.6, 1.7, 2.4, 3.1, 3.2, 3.3, 3.4, 3.5, 3.7, 3.8, 3.9, 3.10, 3.11, 4.1, 4.2, 4.3, 4.4, 4.5, 4.6, 5.1, 5.2, 5.3,	• Pre-clinical tests of a candidate drug's pharmacology & toxicology. • ICH Topic M3, Non-Clinical Safety Studies for the Conduct of Human Clinical Trials & Marketing Authorisation for Pharmaceuticals. • The clinical significance of in vitro & in vivo animal pharmacology including, for example, P450 studies. • Standard animal toxicology study designs & toxicokinetics.	• To understand the evidence for a candidate investigational product's potential value from pre-clinical studies in various species, either whole animal or isolated organ & tissue models, & in models of disease. • To relate longer-term animal toxicology to the potential therapeutic indications & dosages. • To use preclinical metabolism data to identify necessary clinical drug interaction studies.	• As a therapeutic / development team member, contributes to the stepwise decisions being made based on pre-clinical pharmacology & toxicology from the perspective of therapeutic needs & patient safety. • Recognises the benefits & pitfalls of extrapolating preclinical data to the predictions of drug effects in man. • Communicates the relevance of the preclinical