（報告様式４）

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平 成 ２ ８ 年 度　委 託 研 究 開 発 成 果 報 告 書

I.　基本情報

事　業　名：（日本語）医薬品等規制調和・評価研究事業
（英　語）Research on Regulatory Science of Pharmaceuticals and Medical Devices

研究開発課題名：（日本語）再生医療実用化加速のための幹細胞等由来製品評価に最低限必須・共通の技術要件・基準に関する研究
（英　語）Study on a Minimum Consensus Package for evaluating Human Cell Therapy Products in order to accelerate realization of regenerative therapy

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実 施 期 間：平成２８年　４月　１日　～　平成２９年　３月　３１日

分担研究　（日本語）研究総括と製造・品質・非臨床・臨床試験等における MCP 策定のための分担研究および海外の動向調査
開発課題名：（英　語）Research managing and supervise; Study for developing a Minimum Consensus Package (MCP) on manufacturing, quality, non-clinical, clinical trials for human cell therapy products, Study on investigating an overseas trend for MCP.

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II. 成果の概要（総括研究報告）

本研究は、幹細胞等由来のあらゆる製品に最低限必須・共通の要件や基準・評価技術（ ミニマム・ コンセンサス・ パッケージ： ＭＣＰ）を提言し、現行指針と合わせて活用することにより、より合理的、効率的、効果的な製品開発を促進し、再生医療実用化の推進に寄与することを目的とした。平成 26 年度から平成 28 年度に至る研究の結果、以下①～⑫の事項につき MCP 試案を策定した。

① 一般原則：a）共通基本要件･基準の適用、b）臨床適用開始時の評価ポイント、c）臨床適用すべきか否かの判断、d）資料の範囲および程度、e）試験事項、試験方法、基準その他の技術要件

② 組織を取り扱う上での GTP（Good Cell/Tissue Practice）： a）目的・基本原則、b）用語の定義、c）研究の体制､研究機関の基準､d）ヒト細胞等の採取､e）ヒト幹細胞等の調製段階と安全対策等、f）ヒト細胞等の移植又は投与、g）見直し規定

③ 製品の製造方法及び品質試験・評価・管理：a）各段階の細胞の特性解析、特性指標の把握、適格性、b）その他の原材料、製造関連物質の適格性と品質管理、c）微生物安全性、d）製造工程の妥当性、一定性、e）最終製品（目的細胞）の純度/均質性/力価等の恒常的確保、f）安定性、g）製品レベルと製法レベルでの適切な組合せによる品質管理

④ 非臨床安全性試験における合理的、効率的に開発を進める方策のあり方

⑤ 非臨床有効性（POC）試験における共通基本要件･基準

⑥ 臨床試験：a)ヒトでの試験開始に際しての技術面（品質、非臨床安全性）での評価要件及び倫理面での要件、b)臨床試験時の考慮事項、c)市販後のフォローアップ

⑦ 細胞種別 MCP：自己細胞、同種細胞、体細胞、体性幹細胞、多能性幹細胞（iPS 細胞や ES 細胞等）

⑧ 細胞バンクの概念についての主要 3 項目。細胞バンクの技術要件：ａ） 作製方法､b） 特性解析､c） 保存・維持・管理方法、d） 更新方法を含む項目・内容その他の各作業工程や試験に関する手順等

⑨ 細胞特性解析：a)製品の作用本質が「細胞」であり、複雑な構造・物性と不可避的な不均一性を示す亜種細胞の集合体であり、変化しがちな生命体であること、b） 多種多様な細胞製品の開発、c） 細胞特性の全貌は、分子構造解析手法、各種理化学的、生物学的、免疫学的手法で必ずしも解析できないこと、d)最終細胞製品の特性は、ある特定の細胞原材料から、脱分化、（段階的）分化、細胞バンク／重要中間体の設定等を経て造り上げられる「各製造段階での細胞特性解析の集積により規定される」特長を持つこと、e） 各細胞特性は一定の加工過程の恒常性にも支えられていること、f） 最終製品の品質特性と安全性、有効性との意味のある関係づけを目指すこと、などの留意事項

⑩ ウイルス安全性 MCP についての主要な 9 つの留意事項

⑪ 造腫瘍性試験： 体性幹細胞、iPS/ES 細胞を原材料として最終製品に至る過程の鍵となる細胞それぞれにおける造腫瘍性試験の必要性、必要である場合に最低限どのような試験を実施し、どのように評価すべきかに関して a)目的、b） 試験対象、および c） 試験法：ⅰ)残存未分化細胞を検出測定するための未分化細胞マーカを指標にした *in vitro* 法、ⅱ)残存未分化細胞の検出・増殖性の観察及び増殖性形質転換細胞を検出するための超培養期間細胞培養における増殖性の観察、ⅲ)足場非依存的増殖を検出するための軟寒天コロニー形成試験、ⅳ)免疫不全動物を用いた *in vivo* 法の提示

⑫ 非臨床段階での製品の抗原性回避方策や抗原性試験のあり方について、２つの主要留意事項

本研究により、学・産の研究・開発、再生医療安全性確保法下での臨床研究等の医薬品医療機器等法下での開発への切れ目のない移行、行政での薬事戦略相談や承認審査などが円滑に進行し、再生医療実用化を加速するなど、その成果は厚生労働行政上きわめて大きな意義をもつと期待される。

（英文）

The major objective of the study is to highlight the important regulatory considerations that are unique to human cell derived and substantially manipulated cell therapy products (hCTPs). To develop novel hCTPs and to translate them more efficiently and effectively into products that contribute more to human health care, it is essential that they be based on a sound scientific rationale. Manufacturers and control authorities should take into account common scientific core elements, as well as the specifics of the cell source, mfg. process, product administration procedures, and diseases in question. As a part of such an endeavor, it is critical to share a common recognition among interested parties with respect to the essential scientific and technological elements for CMC, nonclinical and clinical studies of all types of substantially manipulated hCTPs. In other words, a challenge should be made so that we can develop a minimum consensus package that encompasses scientific principle/concepts, general considerations and technical requirements commonly applicable to all hCTPs.

It was explained that a minimum consensus package should encompass scientific principle/concepts, general considerations, and essential core scientific and technological elements. Further detailed explanations of the minimum consensus package were made regarding 1) general principles, 2) general consideration on sound scientific requirements for product development, evaluation and control, 3) CMC, 4) nonclinical safety, 5) nonclinical efficacy, and 6) clinical study including monitoring and follow-up after marketing authorization. CMC elements included: 1) justification of the source and selection of human cells that serve as raw materials, including autologous or allogeneic donor screening criteria and eligibility; 2) suitability and quality control of raw materials and manufacture-related substances other than the target cells; 3) the expected function and safety of non-cellular components constituting the final products together with the cells; 4) establishment of a relevant cell line, cell bank, and/or critical intermediate(s); 5) processing of the cells; 6) preparation of the desired cell products; 7) formulation (preparation of the final product); 8) characterization and understanding of specific profiles of cells at critical stages (e.g., starting, bank, intermediate, and final stage); 9) verification of a manufacturing process and constancy of the manufacture as well as process control; 10) comparability assessment after changes in a manufacturing process; 11) product stability; 12) quality control of final products on the basis of product aspects (including setting of specifications) and process aspects; and 13) setting storage and a transport procedure for the cells/products at critical steps. It was emphasized that all interested parties including basic and clinical researchers, industry, as well as regulators could use such a "minimum consensus package" as a common platform for their activities concerning hCTPs for product development, evaluation, and control. For an individual case, various add-on packages might be set by taking into account the product specific profile, target disease, development stage, experiences of use, among other factors. The overall concept was that cell therapy could be promoted efficiently, effectively and reasonably through the use of such a "minimum consensus package" plus add-on packages for individual cases.

Finally, we deeply hope that our presenting minimum consensus package makes a sizable contribution to promote greater progression for regenerative therapy.

III. 成果の外部への発表

（１）学会誌・雑誌等における論文一覧（国内誌 27 件、国際誌 192 件）

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（4）特許出願

該当なし