（報告様式４）

【16ek0510004h0003】

平成　29 年　5 月 29 日

平 成 28 年 度　委 託 研 究 開 発 成 果 報 告 書

I.　基本情報

事　業　名：（日本語）免疫アレルギー疾患等実用化研究事業（移植医療技術開発研究分野）
（英　語）Practical Research Project for Allergic Diseases and Immunology (Research on Technology of Medical Transplantation)

研究開発課題名：（日本語）本邦における造血細胞移植一元化登録研究システム及び研究データ質管理システムの確立研究
（英　語）Development of hematopoietic cell transplantation outcome registry study system and its quality management system in Japan

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実　施　期　間：平成 28 年 5 月 29 日　～　平成 29 年 3 月 31 日

分担研究　（日本語）WG 研究管理体制の構築
開発課題名：（英　語）Development of management system for working group studies

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所属 役職 氏名：（英　語）Research Institute for Radiation Biology and Medicine, Hiroshima University, Professor, Tatsuo Ichinohe

分担研究　（日本語）研究リレーショナルデータベースの構築
開発課題名：（英　語）Development of relational database for research

研究開発分担者　（日本語）東京都立駒込病院・小児科・医長　田渕　健
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分担研究　　（日本語）非血縁者間骨髄・末梢血移植の移植データ管理と組織適合性情報の解析
開発課題名：　（英　語）Data management for bone marrow or peripheral blood transplants from unrelated donors and analyses of HLA information.

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分担研究　　（日本語）非血縁者間臍帯血移植の移植データ管理と一元化
開発課題名：　（英　語）Data management and unification for cord blood transplants from unrelated donors

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分担研究　　（日本語）登録研究、統計解析の質管理、EZR
開発課題名：　（英　語）Registry studies, quality control of statistical analyses, EZR

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分担研究　　（日本語）ドナー安全性情報との連携
開発課題名：　（英　語）Data relation with donor safety information

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分担研究　　（日本語）QOL 横断的研究
開発課題名：　（英　語）Cross-sectional study of quality-of-life after hematopoietic cell transplantation

研究開発分担者　（日本語）学校法人聖路加国際大学・聖路加国際病院血液腫瘍科・医長　山下　卓也
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分担研究　　（日本語）登録データの品質保証方法の検討
開発課題名：　（英　語）Quality assurance of registry data

研究開発分担者　（日本語）名古屋大学医学部附属病院 先端医療・臨床研究支援センター・病院助教　鍬塚　八千代
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II. 成果の概要（総括研究報告）

・ 研究開発代表者による報告の場合

和文

世界的にも、造血細胞移植レジストリによる造血細胞移植の患者やドナーに関する情報の収集とその解析は、造血細胞移植医療の発展に貢献してきている。レジストリ（アウトカムレジストリとも呼ばれる）は、観察研究方法論を用いて、特定の疾患、状態、治療などにおいての効果までの情報収集をするものである。

当該研究機関（日本造血細胞移植データセンター）は、「移植に用いる造血幹細胞の適切な提供の推進に関する法律」に基づき、造血幹細胞移植の患者やドナーに関する情報の収集と基本的解析を実施している機関である。本研究では、移植医療の登録研究方法論を技術的に分析し、登録研究の効率と質を上げ、本邦の造血細胞移植一元化登録を研究登録データベースとして発展させることをその目的とした。

十分でかつ質の高い情報収集システムは造血細胞移植レジストリに不可欠なものである。Web データベースとして第二世代造血細胞移植登録一元管理プログラム（TRUMP2）を導入し、登録データの質をより効率的に管理できる方法を検討した。登録研究におけるデータ管理および統計解析の質の向上のために、データの取り扱いおよび統計解析の教育的なセミナーを開催した。登録研究でしばしば用いられる基本変数を作成するスクリプトを 2 種類の統計ソフト（Stata および R/EZR）に対応するものとして作成、論文公表し、研究者向けに公表の上その使用方法に関するセミナーを開催した。

同時に国内のテーマごと研究グループ（ワーキンググループ）を組織し、登録研究の活性化に努めるとともに、研究の進捗管理を行った。TRUMP で収集されていないが一部の研究に必要な調査項目に関して二次調査研究を実施し、その成果が論文公表された。TRUMP data を用いた研究として、2014 年からの 3 年間の公表論文数は 70 編を超えた。国際共同研究も積極的に推進し、この間 3 編の国際共同研究を

公表した。移植後の QOL 横断的調査研究を実施し、1000 名を超える患者の調査協力が得られた。

非血縁者間造血幹細胞移植の患者およびドナーの採血検体から得られた保存試料（検体）の検体保存体制を整備することにより、検体保存の質の向上と枯渇しない DNA 検体 repository を確立し、研究活用により適した検体保存体制を整備することを目的として、5000 ペア 10000 検体の DNA 抽出と DNA 増幅を完了した。

研究成果を一元的に管理し、わかりやすく社会に還元する仕組みを検討し、2014 年までに公表された研究に関しては、課題名および公開されている英文抄録の和訳を実施の上、JDCHCT web page に公開した。

英文

Globally, collection and analysis of information on diseases and post-transplant courses of allogeneic hematopoietic cell transplant (HCT) recipients have played important roles to the improvement of therapeutic outcome of HCT. Recipient registries, typically referred to as outcome registries, are organized systems that utilize observational study methods to collect uniform data to evaluate specified outcomes for a particular disease, condition or exposure.

Efficient and high-quality data collection system is essential for HCT outcome registries. The Japanese Data Center for Hematopoietic Cell Transplantation (JDCHCT) in collaboration with the Japan Society for Hematopoietic Cell Transplantation (JSHCT) introduced Second Generation Transplant Registry Unified Management Program (TRUMP2), a web-based program which will lead to better quality of data and more efficient data management.

Data management process throughout observational research includes generating and defining variables, defining study subjects and characteristics, and performing statistical analyses as designed. Extreme care should be given to quality management of data manipulation and statistical analyses throughout study process. We defined and introduced shared scripts to define variables according to unified definition for quality control and improving efficiency of HCT registry studies.

The JSHCT formed Working Groups for HSCT research. The JDCHCT supports Working Group activities, and also promotes collaborative studies with other research groups. We also collected additional information for specific studies. Quality of life studies were also performed with participation of more than 1,000 recipients. These activities to promote research contributed to increased publications using TRUMP data in this field, more than 70 publications from 2014 to 2016. Study proposal and approval process, study progress management process, and authorship guidelines are organized and managed accordingly.

Linking clinical data with immunological and genetic information can provide important insights into transplant biology. To build an infrastructure of DNA sample repository, we have completed DNA and amplification for 5,000 pairs (10,000 samples).

It is also extremely important to share publication information with public. We have developed publication information page in the JDCHCT website.

III. 成果の外部への発表

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（3）「国民との科学・技術対話社会」に対する取り組み

無し

（4）特許出願

無し