（様式 10）

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平成２８年度　医療研究開発推進事業費補助金
成果報告書

I.　基本情報

事　業　名：　（日本語）臨床研究品質確保体制整備事業
（英　語）Project for Securing High Quality Clinical Research

補助事業課題名：　（日本語）オールジャパンで臨む成育領域における国際水準の臨床研究推進と実施体制整備
（英　語）Development of all Japan academic research organization systems to promote international standard clinical researches in pediatric and perinatal field

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II.　成果の概要（総括研究報告）

国立成育医療研究センターでは、病院や研究所で見出された基礎・臨床研究成果について、網羅的・系統的にそのニーズを吸い上げ、特許等の知的財産権の取得や医師主導治験の実施等を支援する体制を強化した。シーズ管理については臨床研究推進委員会の下部組織として、開発企画部を中心に、臨床研究推進部、データ管理部、その他臨床研究実施に関与する職員で構成された開発戦略会議を開催し、シーズごとにプロジェクトリーダーを設定したチーム体制の構築及び支援シーズの進捗状況の確認、検討、計画の修正等の実務を行った。多施設連携を推進するため、小児治験ネットワーク等を活用して、小児臨床研究ネットワークを構築し、疾病登録・臨床情報データベースの構築をすすめた。臨床研究の品質保証、小児用製剤ラボの整備、人材育成・教育、情報・安全管理体制の整備等を進め、入口から出口まで臨床研究の適切な実施を支援する体制を強化した。組織の自立化のため新たに臨床研究支援に係る料金表を作成し、支援対価の受領体制を整備し運用を開始した。

臨床上の有用性が高いとされながら、治験実施企業のない小児未承認・適応外薬の開発の受け皿とし

ての治験・臨床試験実施体制を強化し、新たな治験・臨床試験を実施することも大きな課題である。平成 28 年には当センターで整備された小児用製剤ラボで治験用製剤を作成し、医師主導治験を開始した。また、小児用医薬品の開発について富山県庁や富山県薬業連合会など 7 者間で「小児用医薬品の開発促進に係る連携協定」を締結し、小児用製剤ラボを基盤として産学官の共同研究を推進した。現在 2 件の医師主導治験が症例登録中で、1 件の医師主導治験が終了し、平成 29 年度には新たに 3 件の医師主導治験を開始するための準備を進めている。さらに、医療機器において公知申請を 1 件準備中である。知的財産権の取得も積極的に進め、平成 29 年度は新たに 4 件の特許を出願した。

成育領域における All Japan の臨床研究実施体制を構築するための多施設連携を進めた。他施設からの臨床研究相談を積極的に受けいれ、平成 29 年度は 148 件と前年度比 3 倍の相談を受け付けた。教育分野においては臨床研究教育セミナーの外部公開をすすめ、新たに他施設と共同で小児周産期臨床研究ジョイントワークショップを開催した。

In 2016, we strengthened our existing policy of actively supporting physician-led clinical trials and securing patents and other IP rights over technologies and ideas originating in clinical and basic science research conducted in both the hospital and research arms of our institution. We have also developed a project management system to ensure the efficient conduct of research and development projects by assigning a project leader to each project, and forming a steering committee for research and development comprised of staff members tasked with overseeing various clinical trials. This steering committee meets once a month to share information with the aim of maximizing the efficient use of available resources. In order to facilitate multi-center collaboration, we developed a network of pediatric clinical researchers and broadened our disease registries and clinical databases. Quality assurance in clinical research, the development of pediatric drugs, training and education, and information and safety management were strengthened to ensure the appropriate conduct of clinical research. We also instituted a fee structure for these support services so as to enable this system to function as a self-sustaining organization.

Another important role that the NCCHD performs is conducting clinical trials of pediatric drugs which have a proven track record of efficacy abroad but have yet to be approved in Japan. In 2016, we commenced a physician-led clinical trial of an experimental drug developed in the NCCHD laboratory for pediatric use. There are currently two investigator initiated clinical trials in the recruitment, one was completed in March 2017. Three more clinical trials are scheduled to begin in 2017. Furthermore, four patent applications were submitted in 2017 by our institute
With the aim of developing a Japan-wide system governing clinical research in pediatric and perinatal medicine, we have been facilitating multi-center collaboration. In 2016, we provided 148 clinical research consultations, a figure three times higher than that of the previous year. We have also made clinical research education seminars available to professionals outside of the NCCHD, and organized a joint workshop in clinical research in pediatrics and perinatal medicine in collaboration with other institutions.

III. 成果の外部への発表

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（4）特許出願

特許出願番号の公開を希望しない。