Background

It has been 20 years since the Ordinance on the Standards for the Implementation of Clinical Trials (GCP Ordinance) was enacted to streamline clinical trials in Japan. However, due to the ongoing evolution of clinical research coordinators (CRCs), the importance of clinical research coordinators (CRCs) has significantly increased. On the other hand, this has also led to significant increase in workload for the CRCs. To elevate this situation, a clinical research professional in the U.S. has developed a system called Tool for Operational Protocol Scoring (TOPS) that measures CRC operational workload and protocol complexity.

Purpose

1. To 'visualize' CRC's operational workload and protocol complexity using TOPS.
2. To utilize Numerical Rating Scale (NRS) and measure our workload of daily operations.
3. To view the workload of both TOPS and NRS, we will inspect the protocol complexity and our workload of daily operations.

Method

1. Survey Period: December 2017
2. Survey Participants: Among 500 CRCs at SSI, we investigated (※1)
3. Survey Method: The protocol complexity and the CRC's workload of daily operations in clinical trials supported by the CRCs were evaluated by using TOPS and NRS.
4. Number of responses: 92 respondents

Result

1. Surveyed Clinical trials
2. TOPS score & NRS scale
3. Ratio of TOPS category
4. Factor of the high score by TA

Consideration

To 'visualize' CRC's operational workload and protocol complexity using TOPS, and from the viewpoint of both TOPS and NRS, we inspected the protocol complexity and our workload of daily operations. In Neurology/Psychiatry, Oncology, Cardiology & Chir (Neurology/PhyMRI), and Respiratory showed similar trend in both TOPS and NRS. However, two or three factors 'universal' in all TA and various factors in each TA were observed. For example, PK study indicated a tendency of high workload in NRS score. We considered other factors that cannot be measured only by TOPS. Therefore, we will be able to consider the distribution of the CRCs' workload properly by confirming the results of a combination of NRS and TOPS scores as well as the accumulated data by disease group and the changes in those scores over time.