Progress report 2015

Department of Clinical Trial Data Management

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Outline of Department

The Department of Clinical Trial Data Management was established in 2007 and carries out educational and research activities on Clinical Data Management (CDM) in collaboration with The Department of Biostatistics and The Clinical Research Support Center in University of Tokyo.

As compared to the situation of CDM in the United States and Europe, technical aspects (data collection, entry, check…) have been mainly focused in Japan. However, the essence of CDM which is to ensure quality of clinical data to appropriate level for fair and scientific evaluation, has not been recognized in many educational activities. CDM should be defined as a technical system to conduct clinical trials scientifically, ethically and efficiently and to draw correct conclusion and also as an academic discipline with theory and practice that applies statistics, quality control and clinical knowledge. It can optimize the whole clinical trial process, keep the level of data quality and cost appropriately.

One of our missions is to promote research on CDM aimed at improving the quality of clinical trials. Another important mission is to provide educations to clinical data managers under the new educational system which can look around all the clinical trial process to adapt rapid change of medical environment and recent improvement of e-clinical trials.

Educational activities


2. Division of Biostatistics, Tohoku University Graduate School of Medicine - Department of Clinical Trial Data Management, Graduate School of Medicine, The University of Tokyo Joint seminar on Data Management. February 5 2016. A2 Healthcare Corporation, Tokyo, Japan

Research activities

1. Medical research consultation
We conducted medical research and biostatistical consultation to medical researchers and hospital staffs. Number of consultation requests in 2015 were below:
Table 1. Number of consultation request in 2015.

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<tr>
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<th>New item</th>
<th>Continued item</th>
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<tbody>
<tr>
<td>Biostatistical consultation</td>
<td>9</td>
<td>5</td>
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<tr>
<td>Medical research consultation</td>
<td>0</td>
<td>2</td>
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2. Data management and Statistical analysis support

We are supporting various clinical studies which are conducted in the University of Tokyo Hospital. For example our department supports “A clinical study of an oncolytic herpes simplex type 1 (HSV-1) G47delta for patients with castration resistant prostate cancer” which are conducted at Translational Research Center (TRAC) and Department of Urology in the University of Tokyo Hospital respectively. Moreover, we also have collaborative works with other universities and medical institutions for several clinical research. Finally, as the collaborative department of the Clinical Research Support Center (CresCent), we also involved in their projects as biostatisticians and clinical data mangers.

3. SCDM Academia Task Force

As a member of Society for Clinical Data Management Academia Task Force, we are involved in a project which is fostering global network on academia data managers.

Research Achievements

Publication (English only)


International Conference Presentation