Issues Brought Up by Japanese Medical Device Industry

Insight from the results of surveillance on clinical trials conducted for JFMDA member companies

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On behalf of clinical evaluation committee WG2, JFMDA
Clinical Data for Application in JAPAN (2011~2015)

Number of items

Composition

Japan Trial  Overseas  Clinical evaluation  Global Trial  Other

2011 2012 2013 2014 2015

2011 2012 2013 2014 2015

From PMDA HP

December 7, 2017  HBD EAST 2017 Meeting  2/12
Clinical Data for Application in JAPAN ②
(2011~2015)
### Results from surveillance (1)

**Notification of Clinical Trial (financial year) in JAPAN (2010~2015)**

<table>
<thead>
<tr>
<th>Field</th>
<th>Notification of Clinical Trial (financial year)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2010</td>
</tr>
<tr>
<td>Cardiovascular</td>
<td>1</td>
</tr>
<tr>
<td>Dialysis</td>
<td>3</td>
</tr>
<tr>
<td>Radiopharmaceuticals</td>
<td>1</td>
</tr>
<tr>
<td>Ophthalmologic</td>
<td>2</td>
</tr>
<tr>
<td>Orthopedic</td>
<td>1</td>
</tr>
<tr>
<td>Thoracic Surgery</td>
<td>2</td>
</tr>
<tr>
<td>Endoscope</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td></td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>9</td>
</tr>
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</table>
## Results from surveillance (2)

### Number of Site of Clinical Trials in JAPAN (2010~2015)

<table>
<thead>
<tr>
<th>Field</th>
<th>Numbers of Site</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Cardiovascular</td>
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</tr>
<tr>
<td>Dialysis</td>
<td>1</td>
</tr>
<tr>
<td>Radiopharmaceuticals</td>
<td>3</td>
</tr>
<tr>
<td>Ophthalmologic</td>
<td>1</td>
</tr>
<tr>
<td>Orthopedic</td>
<td>1</td>
</tr>
<tr>
<td>Thoracic Surgery</td>
<td>2</td>
</tr>
<tr>
<td>Endoscope</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td></td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>3</td>
</tr>
</tbody>
</table>
Results from surveillance (3)

Target Sample Size of Clinical Trials in JAPAN (2010~2015)

<table>
<thead>
<tr>
<th>Field</th>
<th>Target Sample Size</th>
<th>≤ 20</th>
<th>21~40</th>
<th>41~100</th>
<th>101~200</th>
<th>≥ 200</th>
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</thead>
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<td>Cardiovascular</td>
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<td>9</td>
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<tr>
<td>Dialysis</td>
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<td>6</td>
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<td>1</td>
<td></td>
<td></td>
<td>4</td>
</tr>
<tr>
<td>Radiopharmaceuticals</td>
<td></td>
<td>3</td>
<td>1</td>
<td>3</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ophthalmologic</td>
<td></td>
<td>3</td>
<td>2</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Orthopedic</td>
<td></td>
<td>3</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Thoracic Surgery</td>
<td></td>
<td>1</td>
<td>1</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Endoscope</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Other</td>
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<td>4</td>
<td>2</td>
<td>1</td>
<td></td>
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<tr>
<td>Total</td>
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<td>12</td>
<td>16</td>
<td>18</td>
<td>9</td>
<td>4</td>
<td>6</td>
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</table>
## Results from surveillance (4)

### Global Clinical Trials in JAPAN (2010~2015)

<table>
<thead>
<tr>
<th>Field</th>
<th>Global Study</th>
<th>Only Japan</th>
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</thead>
<tbody>
<tr>
<td>Cardiovascular</td>
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</tr>
<tr>
<td>Dialysis</td>
<td></td>
<td>12</td>
</tr>
<tr>
<td>Radiopharmaceuticals</td>
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<td>2</td>
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<tr>
<td>Ophthalmologic</td>
<td></td>
<td>6</td>
</tr>
<tr>
<td>Orthopedic</td>
<td></td>
<td>4</td>
</tr>
<tr>
<td>Thoracic Surgery</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Endoscope</td>
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<td>1</td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td>8</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>13</strong></td>
<td><strong>52</strong></td>
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</tbody>
</table>
## Total cost and Breakdown per Protocol

<table>
<thead>
<tr>
<th></th>
<th>Total (n=21)</th>
<th>Cardiology (n=3)</th>
<th>Ophthalmology (n=5)</th>
<th>Orthopedic (n=5)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean</td>
<td>23,253.1</td>
<td>62,816.3</td>
<td>16,970.0</td>
<td>17,353.0</td>
</tr>
<tr>
<td>Max.</td>
<td>137,950</td>
<td>137,950</td>
<td>36,379</td>
<td>58,376</td>
</tr>
<tr>
<td>Median</td>
<td>13,417</td>
<td>40,255</td>
<td>13,417</td>
<td>7,129</td>
</tr>
<tr>
<td>Min.</td>
<td>2,422</td>
<td>10,244</td>
<td>5,364</td>
<td>2,836</td>
</tr>
</tbody>
</table>

Unit: 10K Yen, ( ): Protocols

## Total cost and Breakdown per Patient

<table>
<thead>
<tr>
<th></th>
<th>Total (n=21)</th>
<th>Cardiology (n=3)</th>
<th>Ophthalmology (n=5)</th>
<th>Orthopedic (n=5)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mean</strong></td>
<td>458.4</td>
<td>333.0</td>
<td>144.2</td>
<td>265.8</td>
</tr>
<tr>
<td><strong>Max.</strong></td>
<td>2,245</td>
<td>457</td>
<td>289</td>
<td>721</td>
</tr>
<tr>
<td><strong>Median</strong></td>
<td>289</td>
<td>412</td>
<td>106</td>
<td>178</td>
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<tr>
<td><strong>Min.</strong></td>
<td>43</td>
<td>130</td>
<td>75</td>
<td>43</td>
</tr>
</tbody>
</table>

**Unit: 10K Yen, ( ): Protocols**

Composition of clinical trial cost

- Site payment and others (e.g., PMDA consultation fee)
- Final visit and preparation of clinical study report (including audit)
- Operation and management of clinical trials
- Preparation of clinical trials before starting

Conclusion

• Clinical trial with five or less institutions per trial was 67%.
• Multicenter trials with more than 15 institutions was 12.7%.
• Clinical trials whose target number of patient was from 21 to 100 accounted 52%. On the other hand, there were also 18% of the clinical trials with 20 or fewer patients enrollment.
• 20% of clinical trials was global trials.
• In many cases, the other expenses such as operating costs were greater than the procedure costs to the trial site.

Many of the trials conducted in Japan were small and domestic trials, few global trials. One of the causes may be that the trial cost in Japan is higher than in foreign countries. Cost can be reduced by improving the over-quality of the trial. If so, global trial might be increased also in Japan.
Thank you for your attention!