Investigator Initiated Trial (IIT) by Clinical Oncology Group

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Chief Operating Officer
West Japan Oncology Group
Clinical Studies in Japan

Clinical Study
(mainly by Investigators)

Clinical trials
(for drug approval)
Clinical Trial is to compare the New with the Old
Phase of Clinical Study

<table>
<thead>
<tr>
<th>Phase</th>
<th>Number needed</th>
<th>Safety</th>
<th>Efficacy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase I</td>
<td>15～30</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Phase II</td>
<td>Less than 100</td>
<td></td>
<td></td>
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<tr>
<td>Phase III</td>
<td>100 ～ Thousands</td>
<td></td>
<td></td>
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<tr>
<td>Phase IV</td>
<td>Thousands ～</td>
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</tbody>
</table>
Drug development

Pre-clinical

Clinical Phase

Phase I
Phase II
Phase III

Approved

Clinical Trial

A new standard

Phase IV
Post Marketing Research
Searching for new cancer treatment

- Single agent
  - Phase I
  - Phase II
  - Phase III
- 2 drug combination
  - Phase I
  - Phase II
  - Phase III
- 3 drug combination
  - Phase I
  - Phase II
  - Phase III

Radiation  Surgery  Standard Treatment
Clinical Oncology Groups in the World
WJOG History

- 1992 West Japan Lung Cancer Group
- 1997 West Japan Thoracic Oncology Group
- 1998 Central registration
- 1998 randomized phase II
- 1999 randomized phase III
- 2000 Non-Profit Organization
- 2004 Central office at Namba
- 2005 Presented WJTOG9904 at ASCO
- 2006 5 original papers
- 2007 West Japan Oncology Group
Conducting Clinical Trial

**Funding**

- Annual Fee
- Donation from persons
- Donation from Companies
- From the company With contract
- From the Government

**Study conduction**

- Hospital
- Hospital
- Hospital
Funding

- Annual Fee: Important, amount is small
- Donation from persons: Important, amount is small
- Donation from Companies: large amount, Conflict of Interest
- From the company With contract: Large amount, cannot obtain for all students
- From the Government: Large to medium amount, hard to get, procedure is not simple
From the companies’ standpoint

Donation:
Strategic investment from the long view

Contract study:
Direct investment from the short view
When does contract study come into existence?

Companies' benefit

Investigator's interest
We must consider the medical care situation in Japan. Almost all people have medical insurance. All prefectures have medical centers, almost all city have a city hospital and there are many national hospitals. These hospitals have enough medical equipment such as CT, MRI and sometimes even PET scan. These hospitals have at least one specialist in their medical stuff but minimum in total number.
We learned a lesson and gathered experiences.

We have information of quality of many hospitals and investigators.

We already have administration office, datacenter and many committees that are essential to conduct a clinical study even a clinical trial.
We believe WJOG could conduct clinical trials in certain conditions.