Japan Clinical Oncology Group (JCOG)

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What is ‘JCOG’?

• Japan Clinical Oncology Group
  – The largest cooperative group in Japan
  – Funded by National Cancer Center and the Ministry of Health, Labour and Welfare, Japanese government
  – Headquarters: National Cancer Center, Tokyo

• Multi-disease, Multi-disciplinary treatment
  – Commercial drugs, surgery, radiotherapy
  – Combined modality treatment

• Multi-center phase II / phase III trials
What is ‘JCOG’? -cont.

- No legal entity (no corporate body) as JCOG
  - Informal consortium based on research grants
    - No counterpart of US Cooperative Group Program
    - Consists of 33 research grants (33 PIs)
    - Not authorized as JCOG by MHLW

- NPO was established in Oct 2006 to support JCOG Data Center and Operations Office
History of JCOG

• Initiation
  – 1978: initial research grant

• Organization as a cooperative group
  – 1990: Named as “Japan Clinical Oncology Group”
    • “JCOG Statistical Center” established - 1 staff

• Re-organization
  – 1996: Statistical Center reorganized - 4 staffs
  – 1998: renamed as “JCOG Data Center” - 7 staffs
  – 2000: 15 staffs
  – 2009-: 40 staffs (Data Center + Operations Office)
16 Subgroups (Study Groups)

Lymphoma Study Group 1978 –
Japan Esophageal Oncology Group 1978 –
Lung Cancer Study Group 1982 –
Gastric Cancer Surgical Study Group 1984 –
Gastrointestinal Oncology Study Group 1985 –
   > merged into Stomach Cancer Study Group 2011 –
Breast Cancer Study Group 1985 –
Lung Cancer Surgical Study Group 1986 –
Gynecologic Cancer Study Group 1995 –
Colorectal Cancer Study Group 2001 –
Urologic Oncology Study Group 2001 –
Bone and Soft Tissue Tumor Study Group 2002 –
Radiation Therapy Study Group (intramural) 2003 –
Brain Tumor Study Group 2003 –
Hepatobiliary and Pancreatic Oncology Group 2008 –
Gastrointestinal Endoscopy Study Group 2011 –
Head and Neck Cancer Study Group 2011 –
Dermatologic Oncology Group 2012 –

No leukemia group, no pediatric cancer group.
Organizational Structure

- **Executive Committee**
  - Data Center
  - Operations Office
  - Biobank Office

- **Standing Committees (11)**
  - Protocol Review
  - Data and Safety Monitoring
  - Audit
  - Education and Training
  - Conflict of Interest
  - Radiotherapy
  - Pathology
  - Regulatory Affairs
  - Translational Research
  - Diagnostic Radiology
  - Clinical Research Professional

- **Ad hoc Committees (2)**
  - Geriatric Research
  - Operative Complication

- **16 subgroups**
- **190 hospitals (institutions)**
- **638 sites (investigators)**

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- Clinical Oncology Research and Education (NPO-CORE)
Activity

• Number of trials
  • Open 40+/-
  • On protocol drafting 10+/-
  • On follow-up 20-30
  • Analysis – publication 10-20 total 70-100
    – Accrual: 2500 – 3000/year

• Budget & Funding for JCOG
  – 2000 2001-
    • Disease Groups, Institutions $1.5M -> 5.5M
    • Committee Activities, Seminars $0.2M -> 0.5M
    • Data Center/Operations Office $0.4M -> 2.0M
    • Total $2.1M -> 8.0M
JCOG Lung Cancer Study Group

42 Hospitals

Ongoing study: 4

Since 1982
Total study: 62
phase III: 19
## Phase 3 Studies for SCLC

<table>
<thead>
<tr>
<th>Study No.</th>
<th>Objective</th>
<th>Treatment</th>
<th>No. Pts</th>
<th>Ref</th>
</tr>
</thead>
<tbody>
<tr>
<td>JCOG8502</td>
<td>LD&amp;ED</td>
<td>CAV vs PE vs CAV/PE</td>
<td>300</td>
<td>JNCI 1991</td>
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<tr>
<td>JCOG9104</td>
<td>LD</td>
<td>PE+seqRT vs PE+conRT</td>
<td>231</td>
<td>JCO 2002</td>
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<tr>
<td>JCOG9106</td>
<td>ED</td>
<td>CAV/PE vs CODE</td>
<td>227</td>
<td>JCO 1998</td>
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<tr>
<td>JCOG9511</td>
<td>ED</td>
<td>CDDP+ETP vs CDDP+CPT</td>
<td>154</td>
<td>NEJM 2002</td>
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<tr>
<td>JCOG9702</td>
<td>Elderly ED</td>
<td>CDDP+ETP vs CBDCA+ETP</td>
<td>220</td>
<td>BJC 2007</td>
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<tr>
<td>JCOG0509</td>
<td>ED</td>
<td>CDDP+CPT vs CDDP+AMR</td>
<td>284</td>
<td>JCO 2014</td>
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<tr>
<td>JCOG0605</td>
<td>2nd line</td>
<td>NGT vs weeklyPEI</td>
<td>180</td>
<td>Lancet Oncol in press</td>
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<tr>
<td>JCOG1201</td>
<td>Elderly ED</td>
<td>CBDCA+ETP vs CBDCA+CPT</td>
<td>85/370</td>
<td>Ongoing</td>
</tr>
<tr>
<td>JCOG1206</td>
<td>HGNEC</td>
<td>Surgery f/b CDDP+ETP vs CDDP+CPT</td>
<td>114/220</td>
<td>Ongoing</td>
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# Phase 3 Studies for elderly NSCLC

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<tr>
<td>JCOG9812</td>
<td>III</td>
<td>RT vs CBDCA+RT</td>
<td>46</td>
<td>JJCO 2005</td>
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<tr>
<td>JCOG0207</td>
<td>IIIB&amp;IV</td>
<td>weeklyDTX vs weeklyCDDP+DTX</td>
<td>127</td>
<td>JJCO 2015</td>
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<tr>
<td>JCOG0301</td>
<td>III</td>
<td>RT vs CBDCA+RT</td>
<td>200</td>
<td>Lancet Oncol 2012</td>
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<tr>
<td>JCOG0803</td>
<td>IIIB&amp;IV</td>
<td>DTX vs weeklyCDDP+DYX</td>
<td>276</td>
<td>JCO 2015</td>
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<tr>
<td>JCOG1210</td>
<td>IIIB&amp;IV</td>
<td>DTX vs CBDCA+PEM f/b PEM</td>
<td>369/430</td>
<td>Ongoing</td>
</tr>
</tbody>
</table>

Ongoing study results.
A phase III study comparing gefitinib and inserted cisplatin and pemetrexed with gefitinib as a first-line treatment for patients with advanced non-squamous non-small-cell lung cancer harboring EGFR activating mutation

AGAIN study: JCOG1404/WJOG8214L

NSCLC
- stage IV & relapse
- EGFR mutation (+)
- PS: 0-1
- N=500

Randomize

Gefitinib
- 8wks
- Until PD

CDDP 75mg/m2 d1
PEM 500mg/m2 d1
- 3 cycles

2wks Rest

Gefitinib
- Until PD

Primary Endpoint: OS

Accrual 3 year; follow-up 3 year
- α: 0.05 (one side); β: 0.20
- 3-year survival rate: 45% vs 55%
- HR: 0.749
- Sample size (events): 482 (297)