

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
 - 1985: Constitutions & Bylaws, Protocol Review Cmte., Monitoring Cmte.
 - 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	–	No leukemia group,
Head and Neck Cancer Study Group	2011	–	no pediatric
Dermatologic Oncology Group	2012	–	cancer groups

Organizational Structure

K. Tobinai
@NCCH

JCOG Chair

Executive Committee

**Data
Center**

**Operations
Office**

**Biobank
Office**

16 subgroups

190 hospitals(institutions)

638 sites(investigators)

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

**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

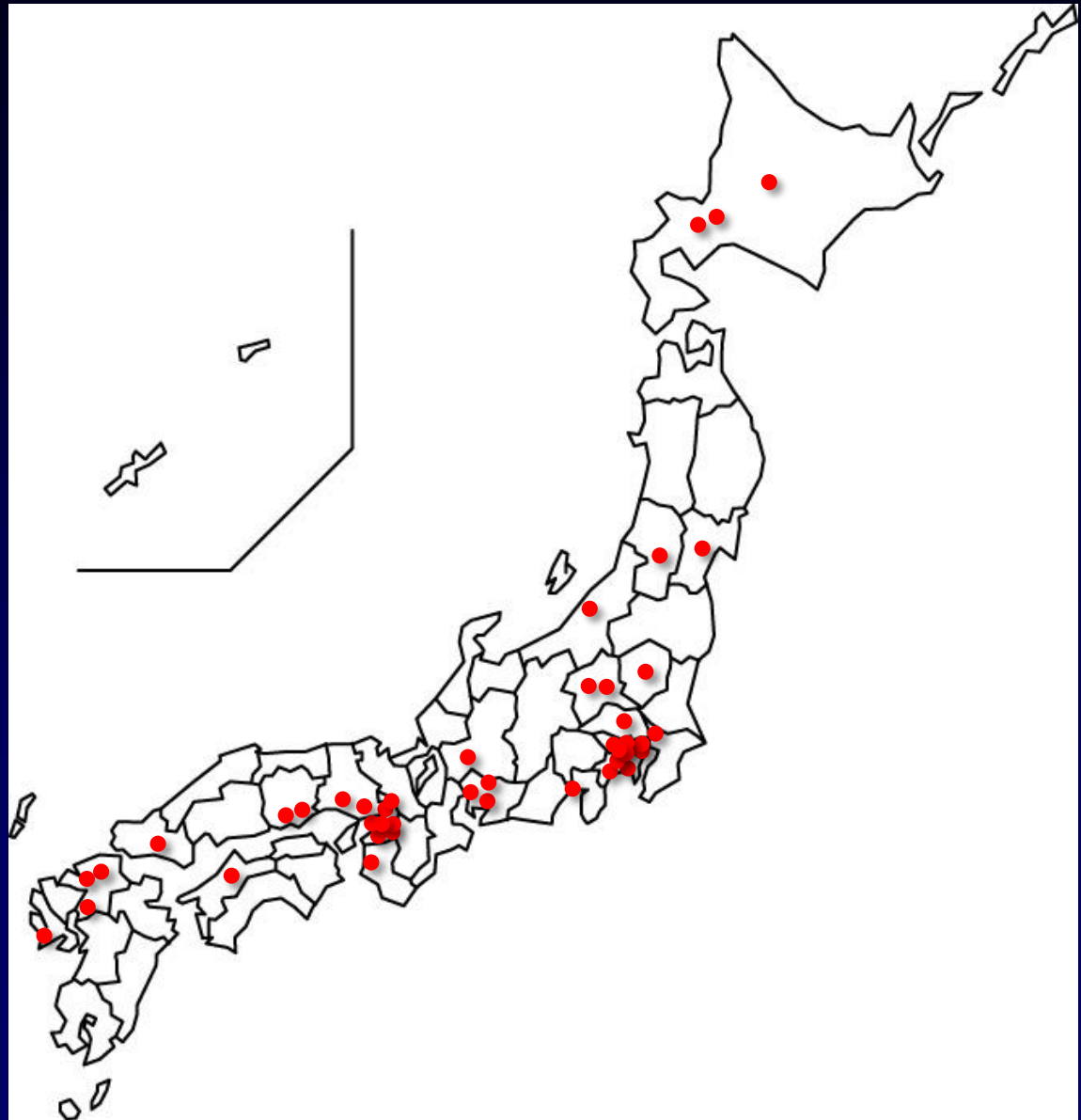
JCOG Lung Cancer Study Group

42 Hospitals

Ongoing study: 4

Since 1982

Total study: 62
phase III: 19



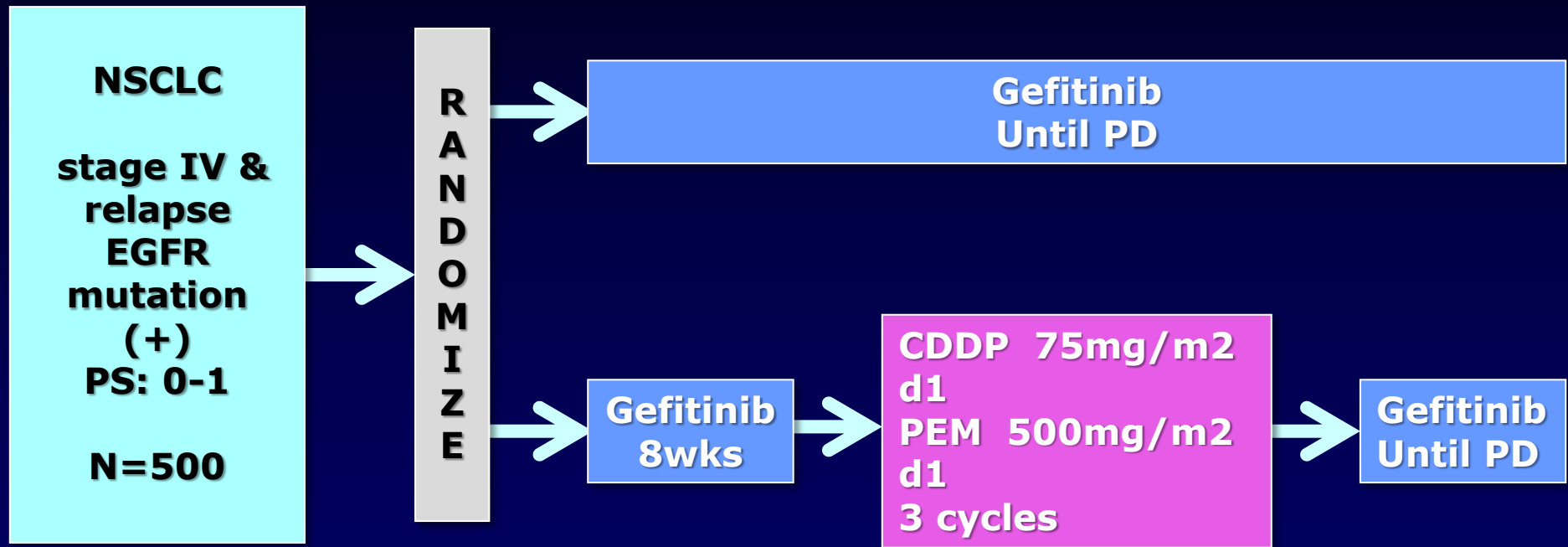
Phase 3 Studies for SCLC

Study No.	Objective	Treatment	No. Pts	Ref
JCOG8502	LD&ED	CAV vs PE vs CAV/PE	300	JNCI 1991
JCOG9104	LD	PE+seqRT vs PE+conRT	231	JCO 2002
JCOG9106	ED	CAV/PE vs CODE	227	JCO 1998
JCOG9511	ED	CDDP+ETP vs CDDP+CPT	154	NEJM 2002
JCOG9702	Elderly ED	CDDP+ETP vs CBDCA+ETP	220	BJC 2007
JCOG0202	LD	EP+TRT f/b EP vs IP	281	Lancet Oncol 2014
JCOG0509	ED	CDDP+CPT vs CDDP+AMR	284	JCO 2014
JCOG0605	2 nd line	NGT vs weeklyPEI	180	Lancet Oncol in press
JCOG1201	Elderly ED	CBDCA+ETP vs CBDCA+CPT	85/370	Ongoing
JCOG1206	HGNEC	Surgery f/b CDDP+ETP vs CDDP+CPT	114/220	Ongoing

Phase 3 Studies for elderly NSCLC

Study No.	Objective	Treatment	No. Pts	Ref
JCOG9812	III	RT vs CBDCA+RT	46	JJCO 2005
JCOG0207	IIIB&IV	weeklyDTX vs weeklyCDDP+DTX	127	JJCO 2015
JCOG0301	III	RT vs CBDCA+RT	200	Lancet Oncol 2012
JCOG0803	IIIB&IV	DTX vs weeklyCDDP+DYX	276	JCO 2015
JCOG1210	IIIB&IV	DTX vs CBDCA+PEM f/b PEM	369/430	Ongoing

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



Accrual 3 year; follow-up 3 year
 $\alpha:0.05$ (one side); $\beta:0.20$
3-year survival rate:45% vs 55%
 \Rightarrow HR:0.749
Sample size (events):482 (297)

2wks
Rest

Primary Endpoint: OS