

# **Summary of QoL/PRO assessment in JCOG studies**

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# JCOG trials between 1990-2004

Group	Randomize phase III (44)				Non randomized and/or phase I, II (72)							
Lung medical (38 trials)	J9104	J9106	J9202	J9511	J9008	J9009	J9011	J9110	J9111	J9201	J9302	J9306
	J9702	J9811	J9812	J0104	J9405	J9406	J9408	J9409	J9413	J9504	J9507	J9509
	J0202	J0207	J0301		J9510	J9512	J9515	J9601	J9605	J9606	J9608	J9704
					J9706	J9807	J0402					
Lung Sx (9)	J9209	J9304	J9403		J9101	J9805	J9806	J0201	J0204	J9805		
GI (11)	J9205	J9912	J0106		J9001	J9207	J9410	J9603	J9703	J9906	J9207	J0407
Gastric Sx (10)	J9206-1	J9206-2	J9501	J9502	J0001	J0210	J0302	J0405				
	J9701	J0110										
Esophageal (6)	J9204	J9907	J0303		J9407	J9516	J9708					
Colorectal (3)	J0205	J0212	J0404									
Breast (12)	J9114	J9208	J9401	J9404	J9107	J9113	J9503	J9602	J9803	J0306		
	J9802	J0111										
Lymphoma (19)	J9002	J9301	J9801	J9809	J9004	J9005	J9007	J9109	J9203	J9303	J9305	J9402
	J0203				J9505	J9506	J9508	J9705	J0112	J0406		
Gynecology (3)	J0102				J9412	J0206						
Urology (2)	J0209	J0401										
Bone & STS (1)					J0304							
Radiation (1)					J0403							
Brain (1)	J0305											

# JCOG trials between 1990-2004

Group	Randomize phase III ( <b>19</b> /44)				Non randomized and/or phase I, II ( <b>5</b> /72)							
Lung medical ( <b>8</b> /38)	<b>J9104</b>	<b>J9106</b>	<b>J9202</b>	<b>J9511</b>	J9008	J9009	J9011	J9110	J9111	J9201	J9302	J9306
	<b>J9702</b>	J9811	J9812	<b>J0104</b>	J9405	J9406	J9408	J9409	J9413	J9504	J9507	J9509
	J0202	<b>J0207</b>	J0301		J9510	J9512	<b>J9515</b>	J9601	J9605	J9606	J9608	J9704
					J9706	J9807	J0402					
Lung Sx ( <b>0</b> /9)	J9209	J9304	J9403		J9101	J9805	J9806	J0201	J0204	J9805		
GI ( <b>1</b> /11)	<b>J9205</b>	J9912	J0106		J9001	J9207	J9410	J9603	J9703	J9906	J9207	J0407
Gastric Sx ( <b>2</b> /10)	J9206-1	J9206-2	<b>J9501</b>	<b>J9502</b>	J0001	J0210	J0302	J0405				
	J9701	J0110										
Esophageal ( <b>0</b> /6)	J9204	J9907	J0303		J9407	J9516	J9708					
Colorectal ( <b>1</b> /3)	J0205	<b>J0212</b>	J0404									
Breast ( <b>7</b> /12)	<b>J9114</b>	<b>J9208</b>	<b>J9401</b>	<b>J9404</b>	J9107	<b>J9113</b>	<b>J9503</b>	J9602	<b>J9803</b>	J0306		
	J9802	J0111										
Lymphoma ( <b>3</b> /19)	<b>J9002</b>	<b>J9301</b>	J9801	J9809	J9004	J9005	J9007	J9109	<b>J9203</b>	J9303	J9305	J9402
	J0203				J9505	J9506	J9508	J9705	J0112	J0406		
Gynecology ( <b>0</b> /3)	J0102				J9412	J0206						
Urology ( <b>2</b> /2)	<b>J0209</b>	<b>J0401</b>										
Bone & STS ( <b>0</b> /1)					J0304							
Radiation ( <b>0</b> /1)					J0403							
Brain ( <b>0</b> /1)	J0305											

# QoL assessment in lung cancer

Study ID	Disease status	Accrual period	N	Tx	Phase	Questionnaire	QoL data management	QoL assessment outcome
J9104	Limited-disease	1991-1995	231	CRT	rIII	Modified EORTC QLQ-C30	Group (unknown)	<b>Terminated</b>
J9106	Limited-disease	1991-1995	227	Cx	rIII	Modified EORTC QLQ-C30	Group (unknown)	<b>Terminated</b>
J9202	Limited-disease	1992-1994	320	CRT	rIII	Modified EORTC QLQ-C30, Face scale	Group (unknown)	<b>Planned but not performed?</b>
J9511	Metastatic	1995-1999	154	Cx	rIII	Modified EORTC QLQ-C30	Group (unknown)	<b>Terminated</b>
J9515	Metastatic	1996-1999	105	Cx	rII	Modified EORTC QLQ-C30	Group (unknown)	<b>Unknown</b>
J9702	Metastatic	1998-2004	220	Cx	rIII	Palliation score (disease-specific symptoms score by MRC lung cancer working party and treatment related symptoms by FLIC)	Group (Dr. Kunitoh)	<b>Completed</b>
J0104	Metastatic	2002-2003	130	Cx	rIII	FACT-L (Functional Assessment of Cancer Therapy - Lung )	Exclusive coordinator (Dr. Ando)	<b>Completed</b>
J0207	Metastatic	2003-2006	126	Cx	rIII	FACT-L	Exclusive coordinator (Dr. Ando)	<b>Completed</b>

- **No completed trials** exist among trials started **before 1998**.
- Questionnaires were not returned directly to the QoL study coordinator except for J0104 and J0207.

# QoL assessment in GI cancer

Study ID	Disease status	Accrual period	N	Tx	Phase	Questionnaire	QoL data management	QoL assessment outcome
J9205	Gastric Metastatic	1992-1997	280	Cx	rIII	Unknown	Unknown	<b>Terminated</b>
J9501	Gastric Curative	1995-2001	523	Sx	rIII	Researcher's Original	Group (Dr. Sasako)	<b>Completed</b>
J9502	Gastric Curative	1995-2003	167	Sx	rIII	Researcher's Original	Group (Dr. Sasako)	<b>Completed</b>
J0212	Rectal Curative	2003-2010	701	Sx	rIII	IIEF (International Index of Erectile Function)	Group (Dr. Saito)	<b>Completed</b>

- QoL assessment was completed in 3 (75%) out of 4 trials.
- In J9501 and J9502, used questionnaire was not validated, was not returned directly to the QoL study coordinator.
- **QoL coordinator sent reminders** at each evaluation point in **all completed trials**.

# QoL assessment in lymphoma

Study ID	Disease status	Accrual period	N	Tx	Phase	Questionnaire	QoL data management	QoL assessment outcome
J9002	Non HL	1991-1995	447	Cx	rIII	Unknown	Unknown	<b>Terminated</b>
J9203	Non-ATL	1992-1995	45	Cx	II	Researcher Original	Unknown	<b>Terminated</b>
J9301	MM	1993-1998	210	Cx	rIII	Researcher Original	Unknown	<b>Terminated</b>

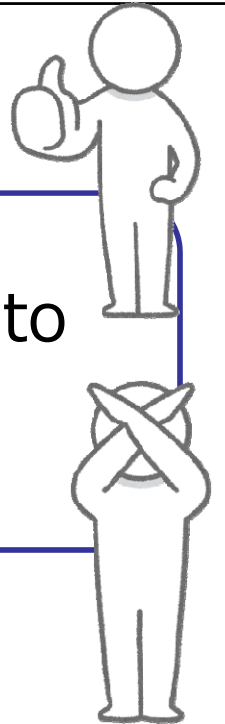
- **No completed trials** in QoL assessment.
- Used questionnaire was not validated and not returned directly to the QoL study coordinator .



# QoL assessment in Urology

Study ID	Disease status	Accrual period	N	Tx	Phase	Questionnaire	QoL data management	QoL assessment Outcome
J0209	Bladder Curative	2003-2009	130	Sx/Cx	rIII	FACT-BL*1	Group (Dr. Kakei)	<b>Completed</b>
J0401	Prostate Curative	2004-2011	210	RT/ hormonal	rIII	UCLA-PCI*2, SF-36*3	Group (Dr. Hinotsu)	<b>Completed</b>

- All QoL assessment was completed.
- Used questionnaire was validated and collected directly to the QoL study coordinator.
- QoL results have **NOT** been presented and published.



\*1 Functional Assessment of Cancer Therapy - Bladder cancer : <http://www.facit.org/FACITOrg/Questionnaires>

\*2 UCLA Prostate Cancer Index: Litwin, M. Medical care (1998): 1002-1012.

\*3 MOS 36-Item Short-Form Health Survey: <https://www.sf-36.jp/qol/sf36.html>



# QoL assessment in breast cancer

Study ID	Disease status	Accrual period	N	Tx	Phase	Questionnaire	QoL data management	QoL assessment outcome
J9113	Metastatic	1992-1995	28	Cx	I/II	Unknown	Unknown	<b>Terminated</b>
J9114	Metastatic	1992-1996	455	Cx	II	Unknown	Unknown	<b>Terminated</b>
J9208	Curative	1993-1998	97	Cx	rIII	Researcher's Original	Unknown	<b>Terminated</b>
J9401	Curative	1994-1999	129	Cx	rIII	Unknown	Unknown	<b>Terminated</b>
J9404	Curative	1994-1999	169	Cx	rIII	Kurihara's QoL questionnaire (QOL-ACD)*1	Unknown	<b>Terminated</b>
J9503	Metastatic	1995-1997	18	Cx	II	Unknown	Unknown	<b>Terminated</b>
J9802 (9803)	Metastatic	1999-2003	441	Cx	rIII	FACT-B*2, FACT-Taxane*3	<b>JCOG QoL Unit</b>	<b>Completed</b>

- All but J9802 was not completed.



\*1 Kurihara M et al., Development of Quality of Life Questionnaire in Japan: quality of life assessment of cancer patients receiving chemotherapy. *Psycho-Oncology*. 1999;8(4):355-63. (Quality of Life Questionnaire for Cancer Patients Treated with Anticancer Drugs)

\*2 Functional Assessment of Cancer Therapy – Breast cancer: <http://www.facit.org/FACITOrg/Questionnaires>

\*3 Functional Assessment of Cancer Therapy – Taxane: <http://www.facit.org/FACITOrg/Questionnaires>

営利目的での使用はご遠慮ください

# Questionnaire used for the evaluation of daily lives

Please check the most appropriate answer

1. Are you engaged in work now? /現在お仕事はしていますか？
2. Has your weight changed? / 体重の変化は？
3. Do you have an appetite? / 食欲は？
4. How are you sleeping? / 睡眠は？
5. **What do people around you (colleague, family) say and how do they look at you? / まわりの人（家族、職場の同僚など）はあなたを見てどのように言いますか？**
6. How do you feel about your condition? / あなた自身はご自分の状態をどのように思いますか？
7. What makes you most anxious about your treatment? Please check up to 3 from following lists.  
/これから受ける、あるいは今うけている治療で、何がいちばん不安ですか。3つまで選んで○をつけてください
8. Do you have anxiety about your disease, treatment or others? Could you please give details? /病気や治療のこと、またはそれ以外のことでも何か気になることはありませんか？前問と重複してもかまいませんので、具体的にお書き下さい。
9. Do you want to continue the current treatment?/今の治療を続けたいと思いますか？
10. Are you engaged in the same work as pretreatment?/お仕事は治療前と同じですか？
11. Do you feel there has been change in the relationship between you and your colleague/family before and after the treatment?/ 治療の前後で、ご家族あるいは職場の同僚などとの人間関係に変化がありましたか？
12. Was there anything particularly harsh or worrying about your treatment?/治療でつらかったこと、恐かったことは何でしたか？
13. **Do you have any opinions, problems or requests regarding your primary doctor? /上記以外でお困りのこと、ご意見、医師への希望などありましたらお書きください。**
14. Lastly, how would you rate your current daily living? Please circle the number between 1 and 10 that best applies to you./最後に、現在の生活状態を10段階評価し、該当する数字を○で囲んでください。

# Why did JCOG DC terminate QoL data management?

- JCOG Executive Committee in Nov 1997
- Dr.Fukuda presented the **miserable situation** regarding the QoL assessment
  - There were **no patient identifier** and **no study number** in most of the questionnaires kept at JCOG Data Center (JCOG DC).
  - Some of the questionnaires were **filled with patient's complaints**
    - “I was very uncomfortable answering those questions”
    - “I didn't understand how my answer would contribute to progress of the medical science”
    - “I had troubled answering a question about family because I was divorced”
  - Those complaints were not provided feedback to a primary doctor
    - No one including PI/SC acted upon these complaints
      - At that time, primary doctor received the questionnaire from patients
- More than 60% of the ongoing QoL assessments were terminated

# **After the termination of most QoL assessment in JCOG**

**From 1998 to 2002**

# Establishment of “JCOG QoL unit”

- “JCOG QoL unit” in JCOG DC was established in Dec 1997
  - To establish feasible and valuable QoL assessment method in JCOG with limited budget and human resources
- Committee structure:
  - Chair: Dr.Naohito YAMAGUCHI (Director@JCOG DC)
  - Secretary: Dr.Haruhiko FUKUDA (Deputy director@JCOG DC)
  - Dr.Kenji EGUCHI (@Sikoku CC)
  - Dr.Kojiro SHIMOZUMA (@Kawasaki medical univ.)
  - Dr.Noriyuki KATSUMATA (@NCCH)
  - Ms. Miyuki NIIMI (DM@JCOG DC)
  - Dr. Kimio YOSHIMURA (@NCC)

# Was QoL assessment feasible in JCOG study?

- **A feasibility study (J9803) was carried out by JCOG QoL unit**
  - Objectives:
    - To establish a method to manage QoL assessment including data management and reminders in JCOG QoL unit
    - To evaluate a feasibility of QoL assessment
- **Methods**
  - All patients enrolled in J9802 (rPIII) were consulted and registered to J9803
  - Questionnaire: FACT-B\*<sup>1</sup>, FACT-Taxane\*<sup>2</sup>
  - Assessment points: Baseline, 6 weeks, 18 weeks
    - **Prespecified window was  $\pm 1$  week** at 6 weeks and 18 weeks
  - Data management and reminders was done by JCOG QoL unit
    - 2 persons (1 from JCOG DC and 1 from investigator) were in charge of practice
    - Baseline questionnaire was distributed prior to patients enrollment and others were distributed 2 weeks before the assessment points in each patient
    - Reminders was sent if JCOG QoL unit did not receive questionnaire after 2 weeks of the planned assessment points

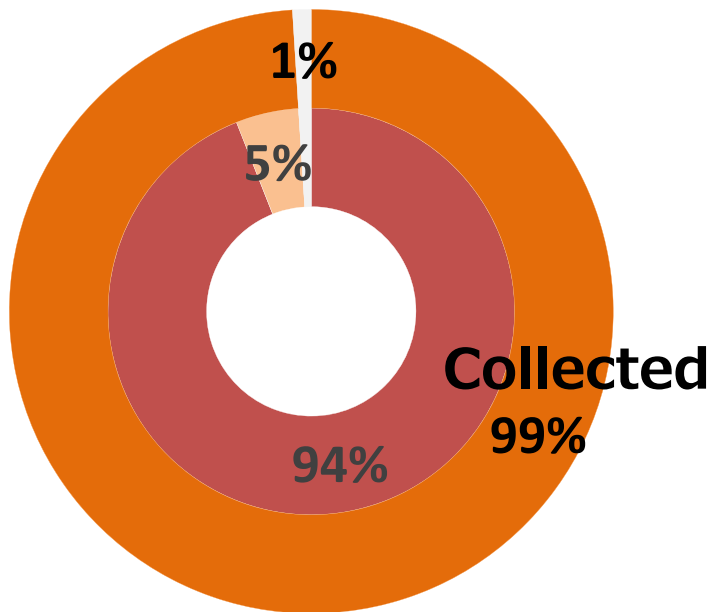
\*1 Functional Assessment of Cancer Therapy – Breast cancer: <http://www.facit.org/FACITOrg/Questionnaires>

\*2 Functional Assessment of Cancer Therapy – Taxane: <http://www.facit.org/FACITOrg/Questionnaires>

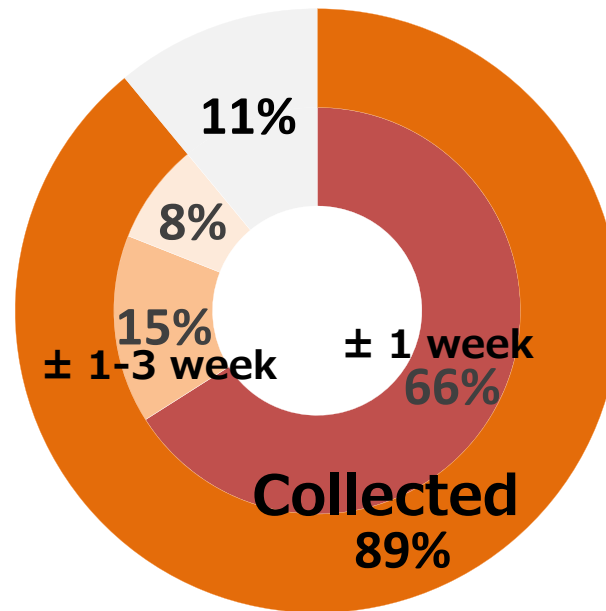
# Result of J9803

- A total of 150 patients were enrolled in this study

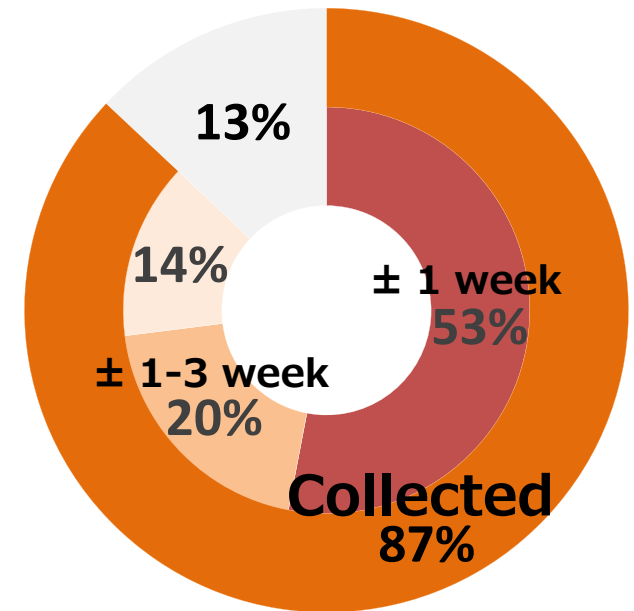
Baseline



6 weeks



18 weeks



- Collection rate was judged as sufficient if the window of 3 weeks was accepted
- Practical burden at JCOG QoL unit was more difficult than expected

# Having said that JCOG DC cannot support QoL data management...

- After most of the ongoing trials including QoL assessment were terminated in Nov 1997, some trials included QoL assessment
  - Lung medical: J9702, J0104, J0207
  - Colorectal: J0212 (rectal cancer)
  - Urology: J0209 (bladder cancer), J0401 (prostate cancer)
- There was an urgent need to establish a JCOG policy regarding the QoL assessment
  - Investigators might start QoL assessment independently without knowledge regarding appropriate QoL assessment



# Establishment of “JCOG QoL ad hoc committee”

- **“JCOG QoL ad hoc committee”** was established in Sep 2003
  - To establish a policy of QoL assessment in JCOG including required resources
- Committee structure :
  - Chair: Dr.Kunitoh (@NCCH)
  - Vice chair: Dr.Fukuda (@JCOG DC)
  - Secretary general: Dr.Sato (@JCOG OPS)
  - Secretary: Ms.Kaba, Dr.Yoshimura (@JCOD DC), Ms.Suzuki (@JCOG OPS)
  - Member (recommended by group chair)
    - Dr.Ando (from Lung medical), Dr.Watanabe(from Lung Sx), Dr.Yamada (from GI), Dr.Nashimoto, Dr.Tsujinaka (from Gastric Sx), Dr.Igaki (from Esophageal), Dr.Osumi(from breast), Dr.Wasada(from Lymphoma), Dr.Kasamatsu(from Gyne), Dr.Fujita(from colorectal), Dr.Kakei, Dr.Hinotsu(from urology), Dr.Chuuman(from Bone & STS), Dr.Ito (from radiation), Dr.Sonoda(from brain)
  - Advisor: Dr.Katsumata, Ms.Niimi

# What was discussed at the committee? (1/3)

## 1. What kind of questionnaire should be used?

- It must have been validated
- Use a questionnaire **with a patient self-reporting format**
  - Questionnaires must be returned directly to the QOL Study Coordinator without the questionnaires being seen by the primary physicians.
- Consideration should be made in a study-by-study basis on whether to use a generic scale or a disease-specific scale (or both).

## 2. In which trials should QoL be assessed?

- A QOL assessment is conducted **only in phase-III trials.**
  - Interpretation is quite difficult if there is no control arm
  - If the objective is to determine the feasibility of QOL assessment in clinical trials, it may be implemented in a single arm study

# What was discussed at the committee? (2/3)

## 3. What is required resources to perform QoL assessment?

- The sending and collection of QOL questionnaires should be arranged by the study group by appointing a **QOL Study Coordinator**.
- From the experience of J9803 feasibility study and J9702, QoL study coordinator should be a dedicated position to the task
  - Dr.Kunitoh presented his experience of QoL Study Coordinator in J9702
    - » He struggled with the QoL data management
- At the time, JCOG DC could not afford to allocate a person who was responsible for the QoL data management
- It is desirable to assign one QOL Study Coordinator for each group
- Considering accumulation of know-how, communication with the JCOG DC etc.
  - A different QoL study coordinator had been assigned in each study except for Lung medical group

# What was discussed at the committee?(3/3)

## 4. What is a recommended analysis method?

- **Binary data analysis is recommended** as the primary analysis method to compare the proportion of improvement exceeding a certain pre-specified threshold.
  - **Missing data are counted as negative values**
- The primary analysis method should be determined at the planning stage of the trial and described in the protocol

# Why wasn't it reach a consensus?

- **Whether QoL assessment should be included in all randomized phase III**
  - For : QoL is considered **as one of the main pillars** for endpoints
    - Japan (JCOG) **lagged behind** the rest of the world regarding QoL assessment
    - It is capable of introducing patients perspective into clinical research
  - Against : Whether “**QoL is important**” and whether “**QoL is measurable**” should be separate discussion
    - QoL assessment was **not a priority** compared with survival and toxicity
    - It should be discussed whether QoL assessment is **worth the time and effort.**
    - It is unclear how to use QoL data for **decision-making process** to conclude a standard treatment

## Japan Clinical Oncology Group

Policy No. 30  
 Title: QOL Assessment  
 Scope of Coverage:  
 Study group, QOL study coordinator, Protocol Review Committee (PRC) and Data Center

### QOL Assessment

#### 1. Current Situation and History

##### 1.1. Current Situation in QOL Assessment

As stated in the large monograph recently published by NCI (Cancer Outcomes Research: The Arenas of Application, J Natl Cancer Inst Monogr. 2004,(33)), the significance of outcome evaluation from the patient's point of view is widely recognized and various instruments exist in assessing Health-related Quality of Life (HRQOL). However, since HRQOL is inadequately measured, the results of the analysis have limited impact. On the other hand, the collection rate of QOL questionnaire in recent clinical trials in Japan is >90% and the differences in QOL between treatment arms have become to be detected.

##### 1.2. QOL Ad hoc Committee and Policy Development

In the QOL assessments conducted at JCOG in the past, despite significant burden to the researchers and the Data Center, there were almost no useful assessments in terms of the collection rate, reliability, usefulness of the data and methodology. Given this fact, implementation of full-scale QOL assessment study (JCOG9803) was planned and conducted, but a decision was made that QOL assessment was not feasible under the system at that time, when almost half of the planned accrual was done. However, there was increasing demand from researchers in various specialties to use QOL as a secondary endpoint in JCOG studies. Therefore, a QOL Ad hoc Committee, which included the investigators of each organ group at JCOG, was established to determine future directions for QOL assessment at JCOG. The QOL Ad hoc Committee held three meetings to discuss the definition of QOL assessments in JCOG and requirements for conducting QOL assessments.

#### 2. Objectives

The objectives of this policy are to define QOL assessment in JCOG and establish guidelines for implementation of QOL assessments.

#### 3. Definition of a QOL Assessment

In JCOG, a QOL assessment is defined as follows: If any of the followings are not applicable, the QOL assessment is outside of the scope of this policy.

##### 3.1. The Questionnaire to be used

Use a questionnaire with a patient self-reporting format. Whenever possible, use a questionnaire that has been validated. (An assessment where a primary physician/CRC interviews patients and completes the form is not designated as a QOL assessment.)

- Consensus through discussion in the committee are included
- QoL assessment in JCOG should be followed in the policy
  - Validated questionnaire
  - A patient self-reporting format
  - QOL Study Coordinator
  - Binary data analysis with missing data as negative value
- This policy was designed to be revised every 5 years
  - It has never been revised

# **After the establishment of JCOG QoL policy**

**From 2005 to 2017**

# JCOG trials between 2005-2017

Group	Randomize phase III (62)							Non randomized and/or phase I, II (43)				
Lung medical (9)	J0509	J0605	J0803	J1201	J1210	J1404	J1701	J0901	J1011			
Lung Sx (8)	J0707	J0802	J1206	J1413	J1508	J1708		J0804	J1211			
Gastric (15)	J0501	J0705	J0912	J1001	J1013	J1104	J1108	J0703	J1002	J1301C	J1401	J1704
	J1507	J1509	J1711									
Esophageal (8)	J0502	J1109	J1314	J1409	J1510			J0604	J0807	J0909		
Colorectal (11)	J0603	J0910	J1006	J1007	J1018	J1107	J1310	J0903	J1609INT			
	J1502C	J1503C										
HBP (8)	J1113	J1202	J1213	J1611				J0506	J0805	J1106	J1407	
GI endoscopy (7)	J1207	J1217						J0508	J0607	J1009	J1604	J1612
Breast (4)	J1017	J1204	J1607									
Lymphoma (8)	J0601	J1111C	J1411									
Gynecology (6)	J0602	J1311	J1412									
Urology (2)	J1019	J1403										
Bone & STS (3)	J0905	J1306	J1610									
Radiation (8)	J0701	J1408						J0702	J0906	J1015	J1208	J1315
								J1402				
Brain (7)	J0504	J1016	J1114C	J1303	J1308C	J1703		J0911				
H & N (4)	J1008	J1601						J0706	J1212			
Skin (3)	J1309							J1602	J1605			



# JCOG trials between 2005-2017

42% → 13%

7% → 2%

Group	Randomize phase III (8/62)							Non randomized and/or phase I, II (1/43)					
Lung medical (4/9)	<b>J0509</b>	J0605	<b>J0803</b>	<b>J1201</b>	<b>J1210</b>	J1404	J1701	J0901	J1011				
Lung Sx (0/8)	J0707	J0802	J1206	J1413	J1508	J1708		J0804	J1211				
Gastric (2/15)	J0501	J0705	<b>J0912</b>	J1001	J1013	J1104	<b>J1108</b>	J0703	J1002	J1301C	J1401	J1704	
	J1507	J1509	J1711										
Esophageal (1/8)	J0502	J1109	J1314	<b>J1409</b>	J1510			J0604	J0807	J0909			
Colorectal (1/11)	J0603	J0910	J1006	J1007	<b>J1018</b>	J1107	J1310	J0903	J1609INT				
	J1502C	J1503C											
HBP (0/8)	J1113	J1202	J1213	J1611				J0506	J0805	J1106	J1407		
GI endoscopy (0/7)	J1207	J1217						J0508	J0607	J1009	J1604	J1612	
Breast (0/4)	J1017	J1204	J1607					J1505					
Lymphoma (0/8)	J0601	J1111C	J1411					J0904	J0907	J0908	J1105	J1305	
Gynecology (0/6)	J0602	J1311	J1412					J0503	J1101	J1203			
Urology (0/2)	J1019	J1403											
Bone & STS (0/3)	J0905	J1306	J1610										
Radiation (1/8)	J0701	J1408						J0702	J0906	J1015	J1208	<b>J1315</b>	
								J1402					
Brain (0/7)	J0504	J1016	J1114C	J1303	J1308C	J1703		J0911					
H & N (0/4)	J1008	J1601						J0706	J1212				
Skin (0/3)	J1309							J1602	J1605				

Intergroup trial is included in the leading group  
 営利目的での使用はご遠慮ください

# QoL assessment in lung medical group

Study ID	Disease status	Accrual period	N	Tx	Phase	Questionnaire	QoL data management	QoL assessment outcome
J0509	Metastatic	2007-2010	284	Cx	rIII	Kurihara's QoL questionnaire (QOL-ACD)*1	Exclusive coordinator (Dr. Ando)	<b>Completed</b>
J0803	Metastatic	2008-2010	276	Cx	rIII	FACT-L	Exclusive coordinator (Dr. Ando)	<b>Completed</b>
J1201	Metastatic	2013-	370	Cx	rIII	FACT-L	Exclusive coordinator (Dr. Ando)	
J1210	Metastatic	2013-2017	430	Cx	rIII	FACT-L	Exclusive coordinator (Dr. Ando)	<b>Completed</b>

- QoL assessment was completed in all trials and performed according to JCOG QoL policy (by exclusive QoL coordinator, Dr. Ando)
- The results of QoL analyses were included in primary article (J0509, J0803)



\*1 Kurihara M et al., Development of Quality of Life Questionnaire in Japan: quality of life assessment of cancer patients receiving chemotherapy. *Psycho-Oncology*. 1999;8(4):355-63.  
 営利目的での使用はご遠慮ください

# QoL assessment in GI cancer

Study ID	Disease status	Accrual period	N	Tx	Phase	Questionnaire	QoL data management	QoL assessment outcome
J0912	Gastric Curative	2010-2013	921	Sx	rIII	EORTC QLQ-C30, EORTC QLQ-STO22	Exclusive coordinator (Dr. Ando)	<b>Completed</b>
J1018	Colorectal Metastatic	2012-	250	Cx	rIII	EQ-5D PRO-CTCAE	Exclusive coordinator (Dr. Ando)	<b>PRO-CTCAE was terminated</b>
J1108	Gastric Metastatic	2013-2017	101	Cx	rIII	EQ-5D	Exclusive coordinator (Dr. Ando)	<b>Completed</b>
J1315	Liver Curative	2017-	290	Rx/ Sx	nrIII	EQ-5D	Exclusive coordinator (Dr. Ando)	
J1409	Esophageal Curative	2015-	300	Sx	rIII	EORTC QLQ-C30	Exclusive coordinator (Dr. Ando)	

- QoL assessment was performed according to JCOG QoL policy (by exclusive QoL coordinator, Dr. Ando)

# Are we ready to perform QoL assessment in all randomized phase III trials?

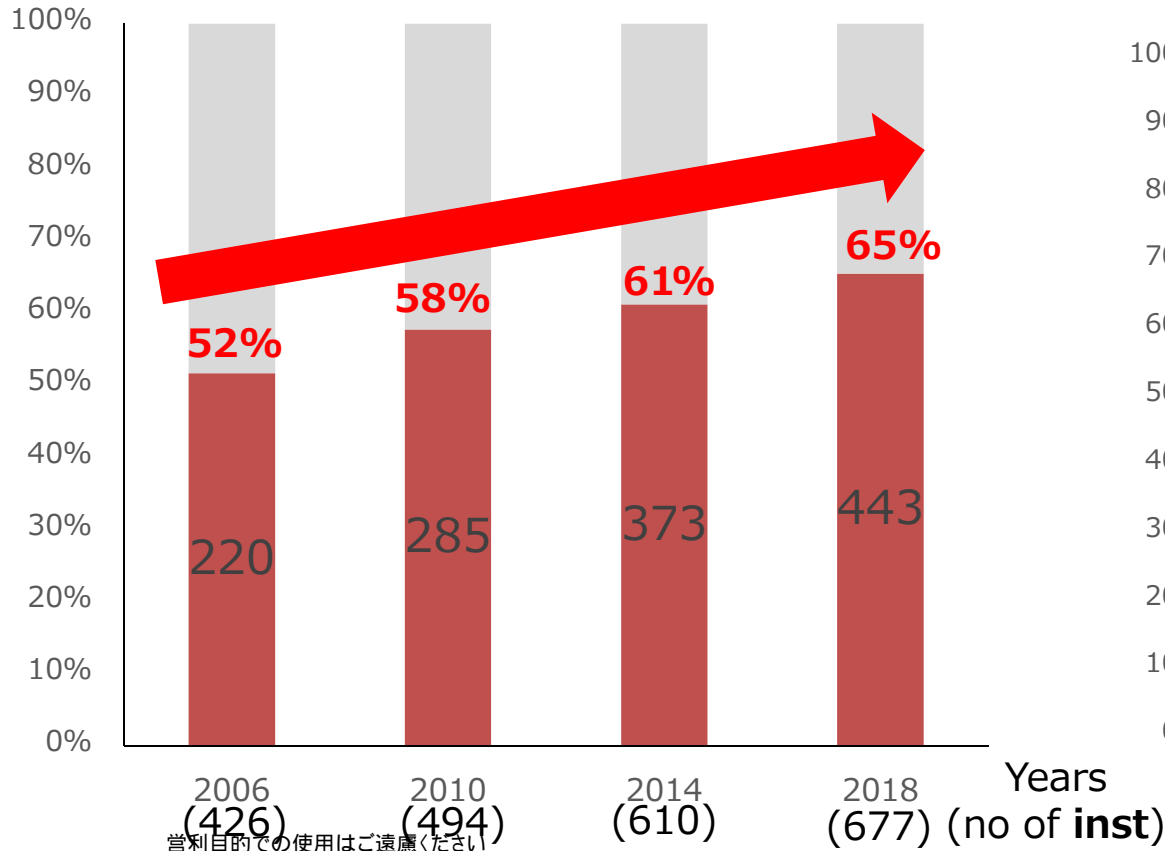
- It seems that JCOG is not fully ready to perform QoL
- Central (JCOG Data Center) issues
  - JCOG DC can afford to accept QoL data management compared to 10 years ago
    - Reminders can be easy to set up using current electronic system
    - Costs for data entry clerk is needed (may not be so expensive)
  - EDC system and introducing platform with Apps (ePRO) or Interactive Voice Response system may help collection of QoL data
    - Rental fee for tablet or system is needed (would be so expensive)
- Central issues may not be a barrier for QoL assessment as far as:
  - Investigators can get funds for QoL data management
  - We can receive support from Dr.Ando as a QoL Study Coordinator



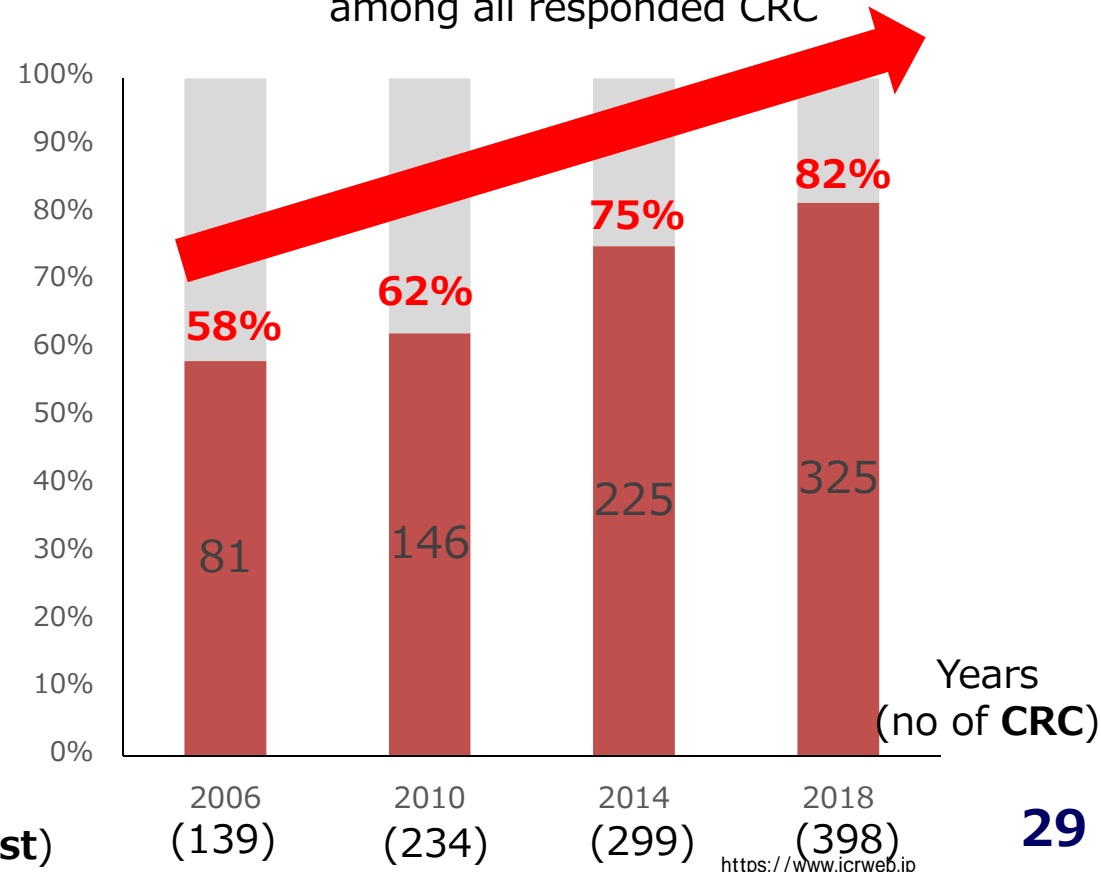
# Are we ready to perform QoL assessment in all randomized phase III trials?

- Local issues
  - Support from CRC has been improved but insufficient
  - Reminders cannot be omitted to maintain the quality of QoL data

Percentage of institution with **at least one CRC** registered in the institution



Percentage of **CRC who support JCOG studies** among all responded CRC



# Case studies: J0912 & J1018

J0912\*

cStage I gastric cancer

randomization

N=459

Open surgery  
(OP)

(standard)

N=462

Laparoscopic  
surgery (LAP)

(test)

J1018

cStage IV colorectal cancer  
≥ 70 years

randomization

FU+Bev

(standard)

FU+Bev+OXP

(test)

- Questionnaires: EORTC QLQ-C30, -STO22
  - Baseline, 30 days, 90 days, 1 year, 3 years
- Number of participating institutions = 33
  - QoL assessment was planned in 4 institutions considering feasibility
- Questionnaires: EQ-5D, PRO-CTCAE
  - PRO-CTCAE: Baseline, each courses within 6m
- PRO-CTCAE was terminated
  - PRO-CTCAE was considered as a heavy burden for investigators due to strict recall period of 7 days
  - The burden was considered as one of the reasons for poor accrual

# Future vision of QoL research in JCOG (my personal impression)

- It may be about time to revise QoL policy
  - DC seems to be ready to support QoL data management if valuable
    - The demand of QoL assessment has been increasing in clinical research
    - Results of JCOG trials should be supported by multiple parties
- Requirements (both JCOG DC/OPS and investigators)
  - Become familiar with QoL/PRO
    - Some investigators cannot answer a concrete questionnaire when we ask “What kind of questionnaires do you want to use?”
  - Secure sufficient funds
    - Required additional costs to coordinate QoL data management
  - Consider not only investigators burden but patient burden
    - EORTC “Item Library\*” would be an option

# Summary & Conclusion

- In 1990's, JCOG committed to QoL research but the majority of JCOG trials failed to complete QoL assessment
- While most of QoL assessment was completed thanks to Dr.Ando, the number of QoL research plummeted after the establishment of JCOG QoL assessment policy
- Both central and local systems should be improved to expand our commitment to QoL assessment in JCOG studies





**Thank you for your  
kind attention**