

EORTC-JCOG Quality of Life workshop in Japan

# A Challenge of Joining the EORTC QOLG from Japan

Kobe University Hospital Cancer Center  
Naomi Kiyota, MD, PhD

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# Agenda

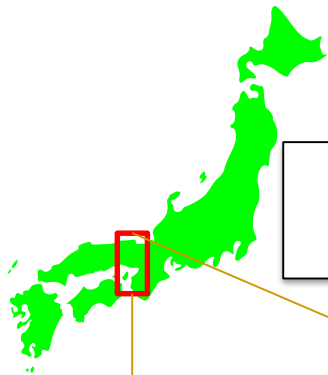
- Introduction
- Why am I interested in HR-QOL
- Participation in EORTC-QOLG from Japan
- Conclusions

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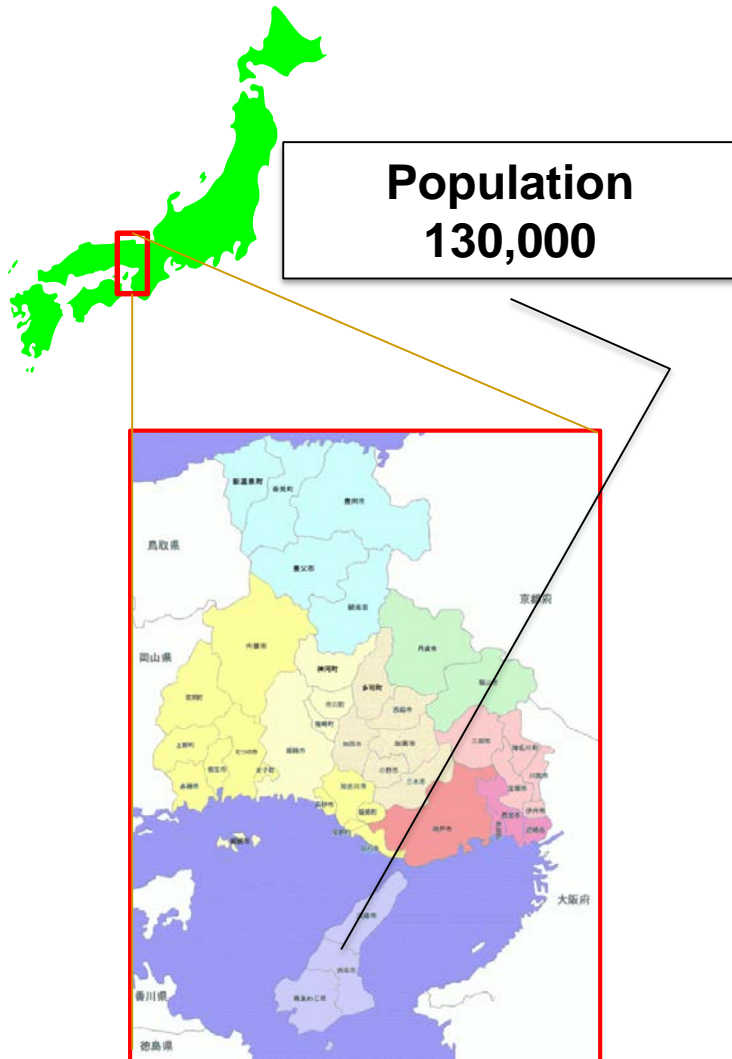
# Kobe City, Hyogo, Japan



**Population  
1.5 million**



# Awaji island, Hyogo, Japan





# Kobe University Hospital



- ❑ Founded in 1869
- ❑ 920 beds
- ❑ 37 clinical divisions



# Kobe University Hospital

## Department of Oncology/Hematology



- Clinical activity of our department
  - ▣ In patient: 40 beds, 15,000 pts/year
  - ▣ Out patient treatment unit: 28 beds, 11,000 pts/year

# JCOG Head and Neck Cancer Study Group

- Group Chair: Ryuichi Hayashi (Head and Neck Surgeon)
- Group Coordinator: Naomi Kiyota (Medical Oncologist)
- Established in 2011
- 31 institutions in Japan participate
- Ongoing trials
  - JCOG1008: post operative CRT for high-risk HNSC
  - JCOG1212: super selective iaCRT for maxillary sinus cancer
  - JCOG1601: prophylactic ND for early tongue cancer



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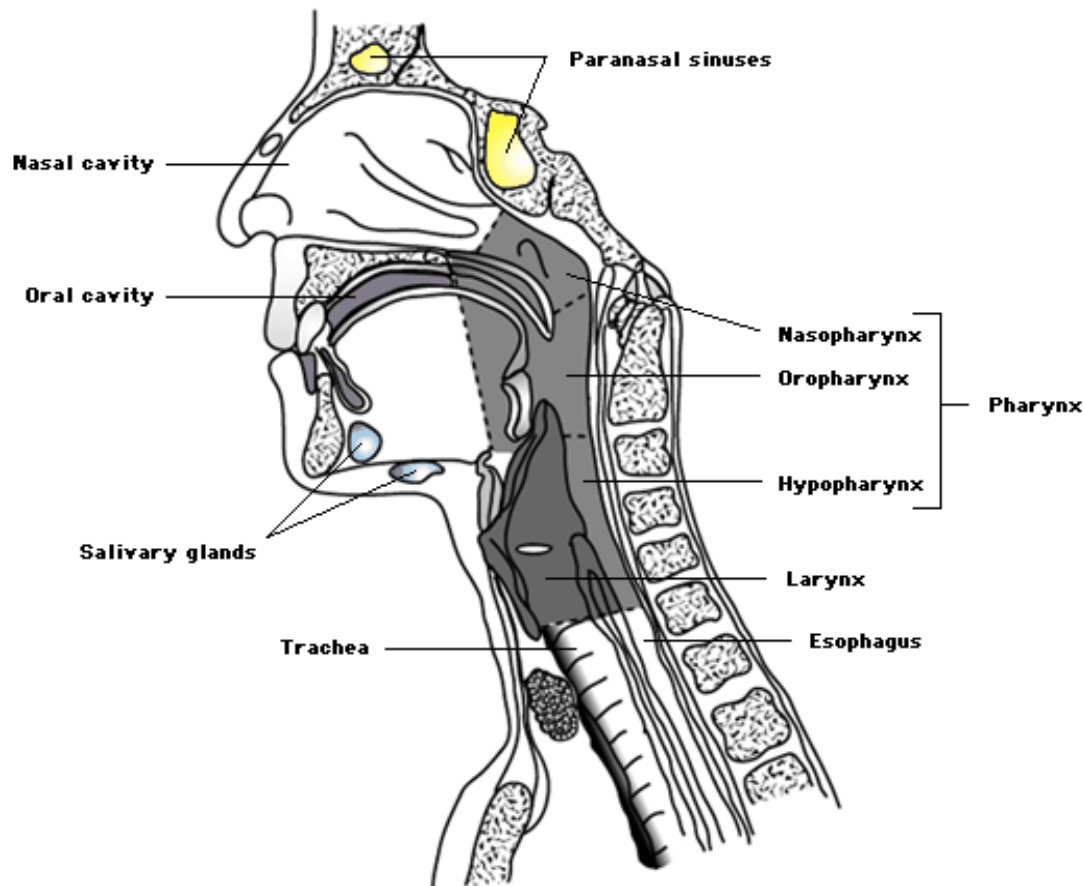
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# Head and Neck Cancer

- Affects fundamental functions of human being



# Incidence of HNC by Primary Sites

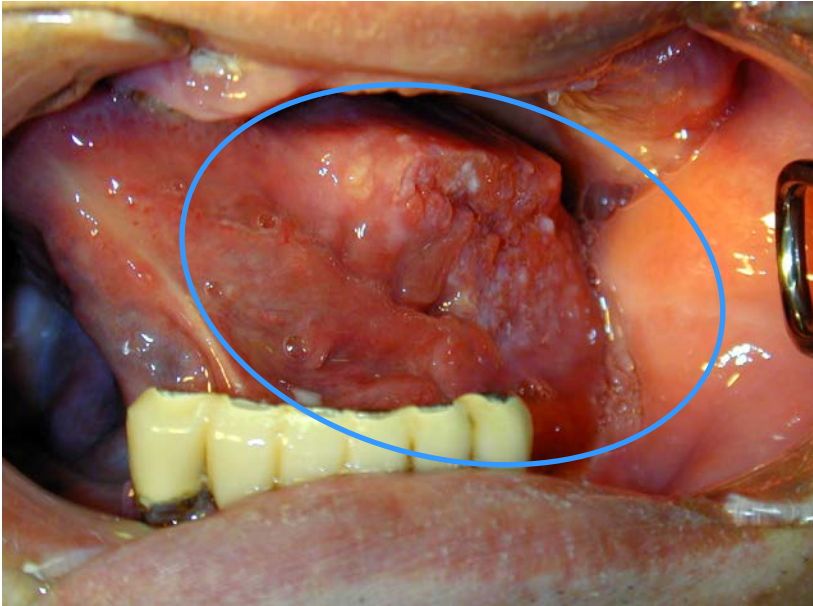
- Head and Neck Cancer Registry of Japan (2003 and 2013)
  - Proportion of oral cavity is decreasing
  - Proportion of oropharynx is increasing

Primary	2003	2013
Oral cavity	59.1 %	29.5 %
Larynx	15.7 %	20.4 %
Hyopharynx	9.6 %	19.8 %
Oropharynx	8.4 %	14.7 %
Nasopaharynx	2.2 %	3.2 %
Paranasal sinus	5.1 %	7.0 %

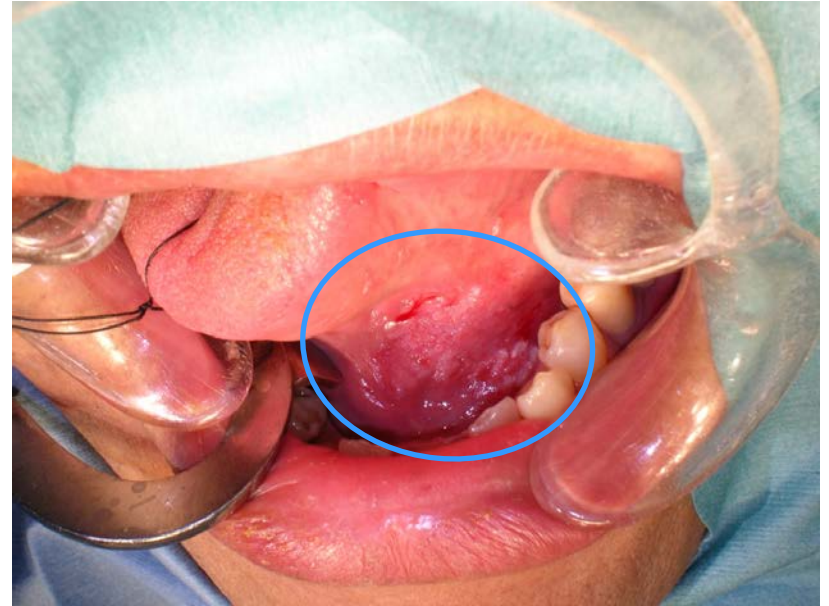
Head and Neck Cancer Registry of Japan, Clinical Statistics of Registered Patients, 2013



# Oral cavity cancer



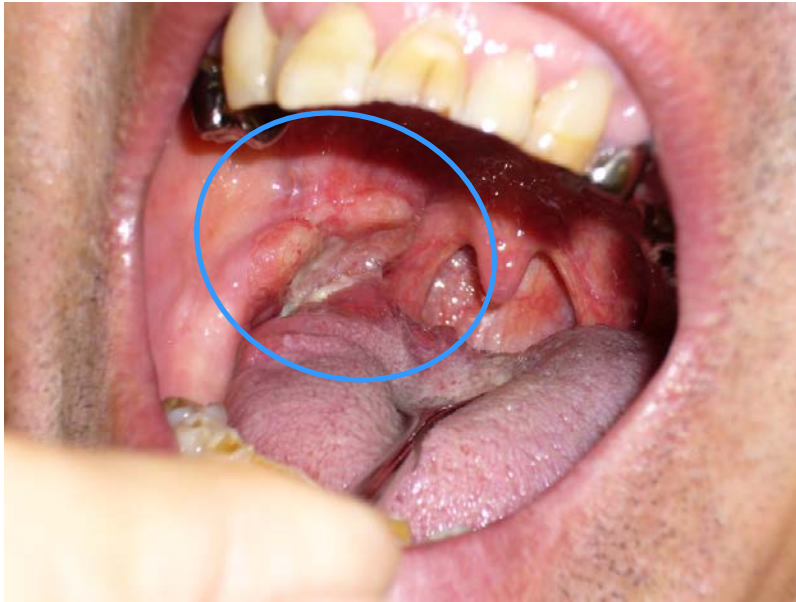
**Oral tongue**



**Oral floor**

With courtesy of Professor Akihiro Homma

# Oropharyngeal cancer

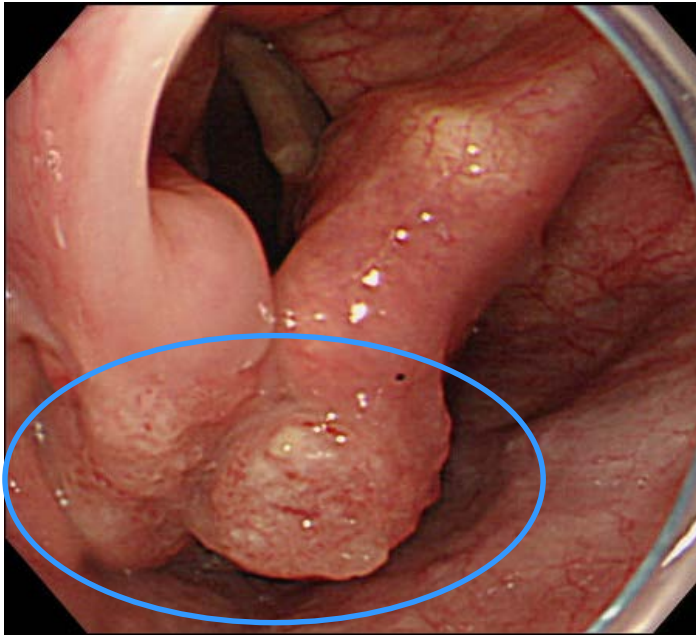


**Oropharynx**

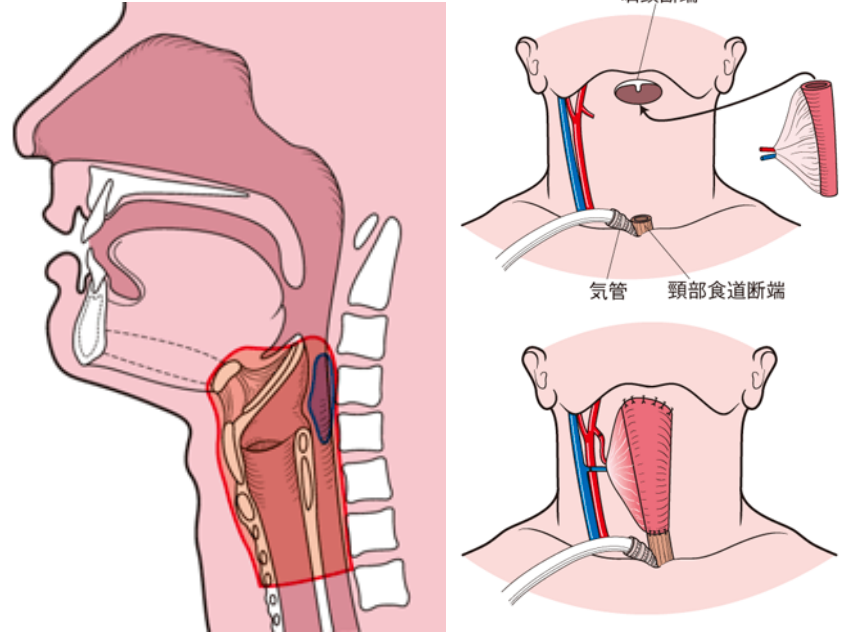


**Reconstruction with  
Rectus abdominis muscle flap**

# Hypopharyngeal cancer



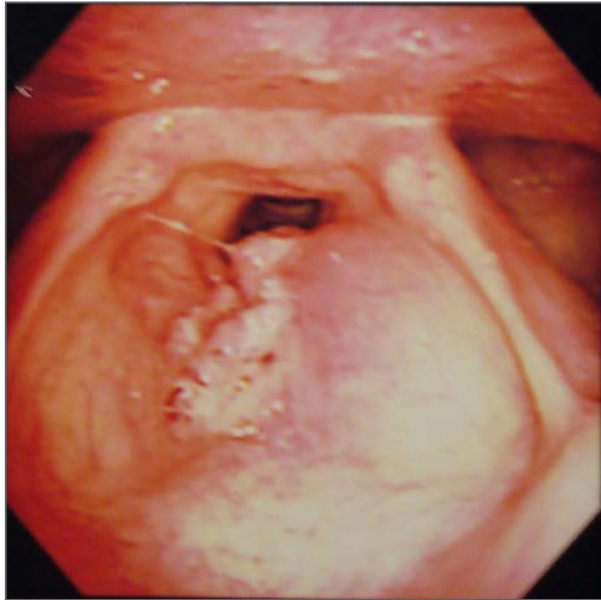
**Hypopharynx**



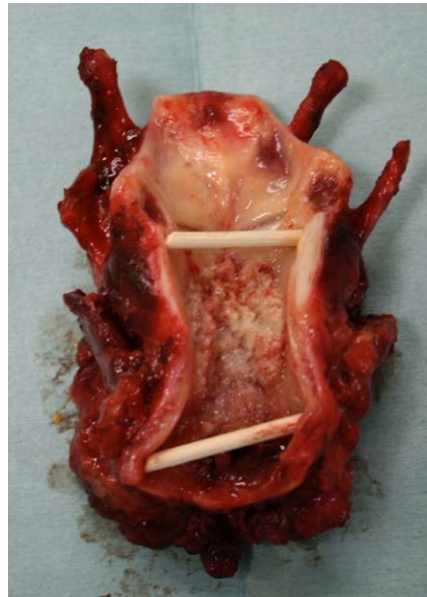
**Free jejunum transfer after  
Total pharyngoesophagectomy**



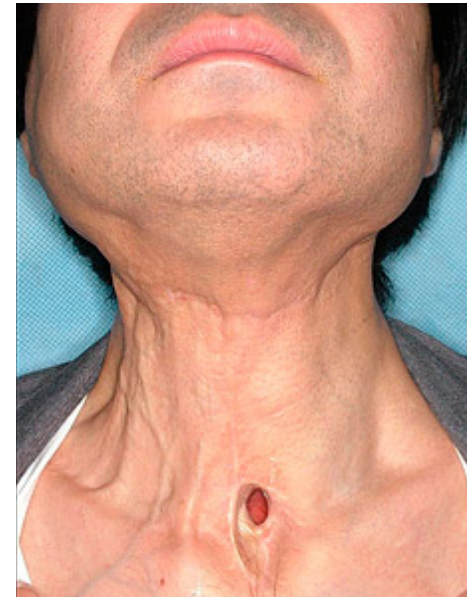
# Laryngeal cancer



**Larynx**



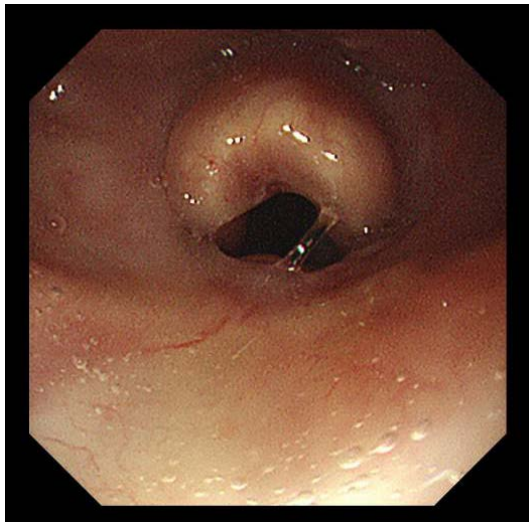
**Total laryngectomy**





# Functional impairment after CRT

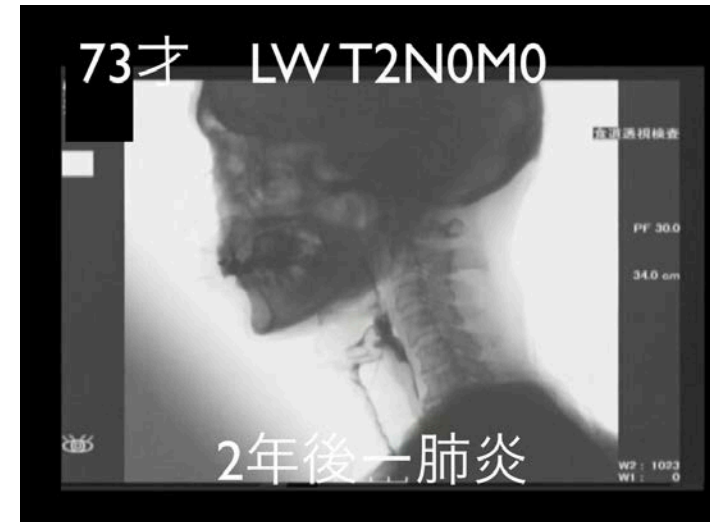
- CRT sometimes causes severe late toxicities
- Affect QOL of Head and neck cancer patients



**Pharyngeal stenosis**



**Poor clearance of  
sticky saliva**



**Aspiration**

# Why am I interested in HR-QOL?

- Head and neck cancer patients often suffer from problems specific to their cancer and treatments
- Sometimes difficult to evaluate with CTCAE
  - Restriction in speech
  - Difficulty in eating and swallowing
  - Quality of taste and smell
  - Disfigurement and dysfunction after surgery or (chemo-) radiation
  - Etc.



# Why am I interested in HR-QOL?

- e.g. Difficulty in eating and swallowing by CTCAE v4.0

AEs	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Dysphagia	Regular diet	Altered eating/swallowing	Severely altered eating/swallowing	Life threatening	Death

- EORTC-HN35; many items related to eating/swallowing
  - ❑ Have you had problems swallowing liquids?
  - ❑ Have you had problems swallowing pureed food?
  - ❑ Have you had problems swallowing solid food?
  - ❑ Have you had problems opening your mouth wide?
  - ❑ Have you had trouble eating?
  - ❑ Have you had trouble eating in front of your family?
  - ❑ Have you had trouble eating in front of other people?
  - ❑ Have you had trouble enjoying your meals?

# Why am I interested in HR-QOL?

- Some strange Japanese translations of QOL modules
  - Have you had problems having close physical contact with family or friends?
  - 家族や友人と肉体的接触を持つのに苦労しましたか？
  - Most of the Japanese pts fully understand this question
- Participation in EORTC HNG meeting since 2008
  - Most of the EORTC studies evaluate HR-QOL
  - Joint study between EORTC and JCOG was planning



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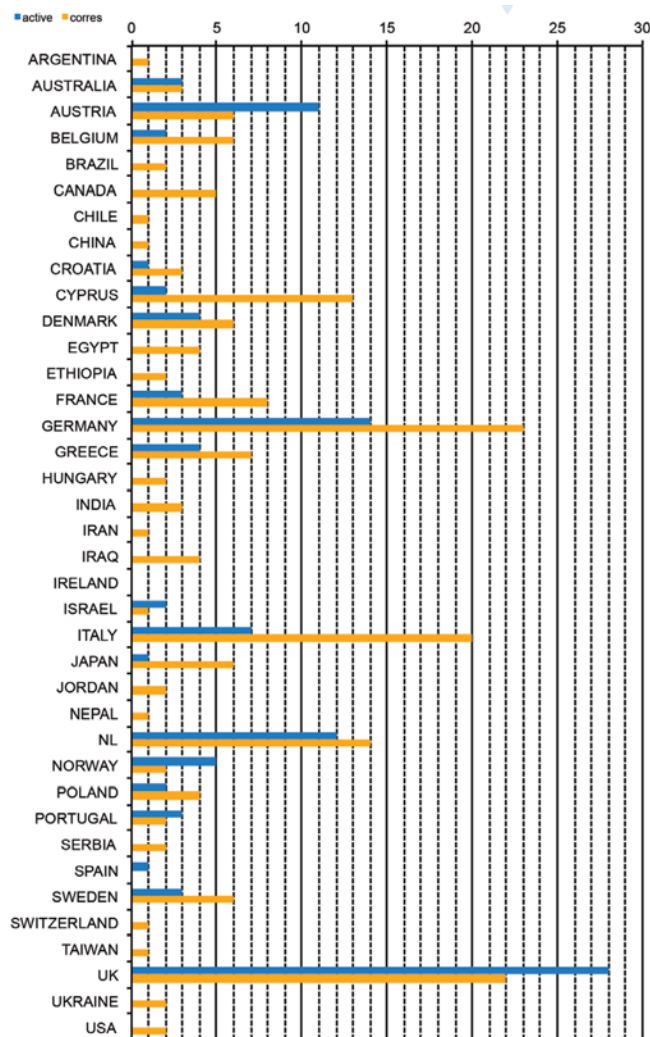
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# Participating countries in EORTC-QOLG



- 38 countries, mainly from Europe
- 316 members
  - Active members, 112
  - Corresponding members, 204
- 7 countries from Asia
  - China
  - India
  - Iran
  - Iraq
  - Japan; one active member from Asia
  - Nepal
  - Taiwan

# Translation and validation

List of translations available by language – validated modules and C30

Languages	QLQ-C30	BM22	BN20	BR23	C15-PAL*	CR29	CX24	ELD14	EN24	GINET21	HCC18	HN35	INFO25	IN-PATSAT32	LC13	LMC21	MY20	OES18	OG25	OH15	OV28	PR25	STO22
Afrikaans	T		T	T	T	T				T	T				T		T				T	T	T
Albanian	T																						
Amharic	T			T			T																
Arabic	T	T	T	T	T	T									T	T	T						T
Arabic (Egypt)												T											
Arabic (Israel)											T	T						T			T	T	
Arabic (Lebanon)													T										
Bengali	T			T	T		T					T			T	T						T	T
Bosnian	T			T	T										T								
Bulgarian	T		T	T	T			T		T					T	T					T	T	T
Burmese	T																						
Catalan	T				T																	T	
Cebuano	T			T							T	T			T								T
Chinese Mandarin (China)	T	T	T	T	T	T				T	T	T	T	T	T	T	T				T	T	T
Chinese Mandarin (Malaysia)	T			T	T						T	T			T	T					T	T	T
Chinese Mandarin (Singapore)	T		T	T	T	T					T	T			T	T	T				T	T	T
Chinese Cantonese (HK)	T	T	T	T	T	T					T	T			T	T	T				T	T	T
Chinese Mandarin (Taiwan)	T	T	T	T	T	T	T	T			T	T	T	T	T	T	T				T	T	T
Croatian	T			T	T	T	T	T	T	T	T	T	T	T	T	T					T	T	T
Czech	T		T	T	T	T				T	T	T			T	T	T				T	T	T
Danish	T		T	T	T	T	T	T	T	T	T	T	T	T	T	T	T				T	T	T
Dutch	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
Estonian	T		T	T	T						T	T			T						T	T	T
Finnish	T		T	T	T						T	T			T	T	T				T	T	T
French (Europe)	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
French (Canada)	T	T	T	T	T						T	T	T		T	T	T				T	T	T
Ganda	T																						
Georgian	T			T								T											
German	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
Greek	T	T	T	T	T			T		T	T	T			T	T				T	T	T	T
Greenlandic	T																						
Gujarati	T			T	T							T			T	T							T
Hebrew	T		T	T	T	T					T	T			T	T				T	T	T	T
Hindi	T	T	T	T	T		T				T	T	T		T	T	T				T	T	T
Hungarian	T		T	T	T	T					T	T	T		T	T	T				T	T	T
Icelandic	T				T	T								T									
Iloko	T														T								
Indonesian	T		T		T										T								T
Italian	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T	T
Japanese	T	T	T	T	T	T					T	T	T		T	T	T	T	T	T	T	T	T
Kannada	T			T	T							T			T	T							T
Kazakh	T		T																				

## ■ EORTC-QLQ-C30

- Translated into over 90 languages
- Used on over 3,000 trials

## ■ Japanese version

- QLQ-C30
- Disease-specific modules
  - Breast (BR-23)
  - CRC (CR-29)
  - HNC (HN-35)
  - Lung (LC-13)
  - Gastric (STO-22)
  - etc.

Updated June 2016



# Development of questionnaires in EORTC

- Phase I: Generation of relevant QOL issues
- Phase II: Conversion of the QOL issues into a set of items
- Phase III: pilot testing of new item list or module
- Phase IV: Large-scale international field testing, validation

# Development of questionnaires in EORTC

- Phase IV: Large-scale international field testing, validation
  - Should be tested in a large, international group of patients
  - To determine
    - acceptability
    - reliability
    - validity
    - responsiveness
    - Cross-cultural applicability
  - After completing Phase IV, it will be made available for general use

# Translation Procedures (1)

- Translation process into Japanese
  - two initial forward translations
    - English to Japanese, by native Japanese speakers
  - reconciled version
  - two backward translations
    - Japanese to English, by native English speakers
  - interim translation and an interim report
  - pilot testing and a report after pilot testing
  - final translation

# Translation procedures (2)

## ■ Example of translation procedures in THY phase I



甲状腺がん患者さんの QOL(生活の質)を検討するにあたって、どのような項目が重要かを調査しています。

以下の項目をみて、それぞれの項目について、あなたがどのくらい重要かと思うかをチェックして下さい。また、あなたがその中でも特に重要と感じた 25 項目をチェックして下さい。

		重要と思う程度				特に重要な項目 25項目をチェック
		全くない	少し	多い	非常に多い	
31	employment	1	2	3	4	
32	being judged	1	2	3	4	
33	being a burden to others	1	2	3	4	
34	social support from families and friends	1	2	3	4	
35	social support from health care providers	1	2	3	4	
36	sudden attacks of tiredness	1	2	3	4	
37	mentally exhausted	1	2	3	4	
38	physically exhausted	1	2	3	4	
39	problems with weight gain	1	2	3	4	
40	problems with weight loss	1	2	3	4	

Forward translation



Backward translation



甲状腺がん患者さんの QOL(生活の質)を検討するにあたって、どのような項目が重要かを調査しています。

以下の項目のそれぞれについて、あなたにとってどのくらい重要かと思うかをチェックして下さい。また、あなたがその中でも特に重要と感じた 25 項目をチェックして下さい。

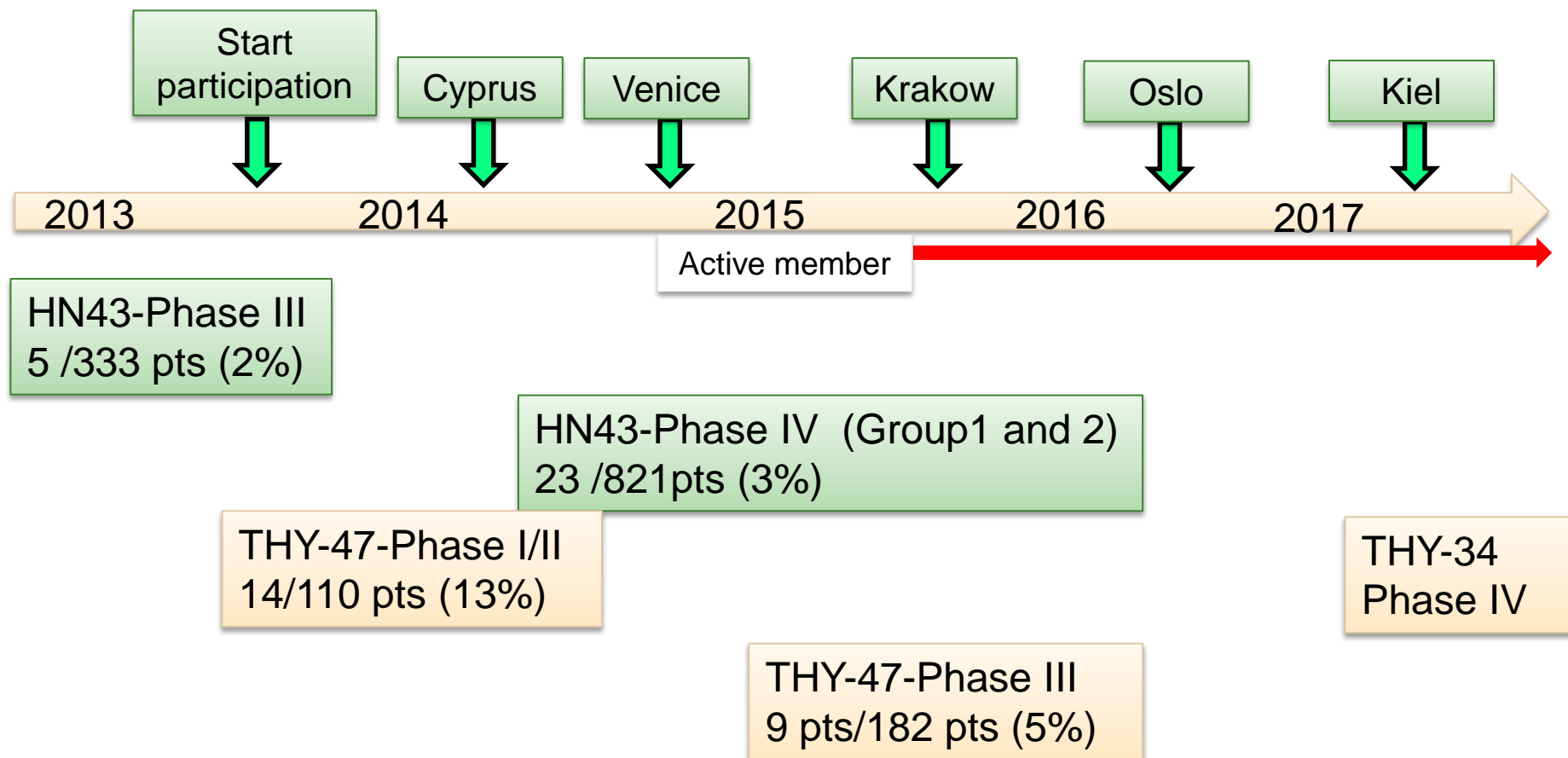
Q		重要と思う程度				特に重要な項目 25項目をチェック
		全くない	少し	多い	非常に多い	
31	雇用	1	2	3	4	
32	評価されること	1	2	3	4	
33	他人への負担となること	1	2	3	4	
34	家族や友人からの社会的支援	1	2	3	4	
35	医療サービス提供者からの社会的支援	1	2	3	4	
36	疲労感に突然襲われること	1	2	3	4	
37	精神的に疲れた	1	2	3	4	
38	肉体的に疲れた	1	2	3	4	
39	体重増加の問題	1	2	3	4	
40	体重減少の問題	1	2	3	4	

# To introduce EORTC-QOL modules into Japan

- Translation of completed form of questionnaire into Japanese
  - Merit
    - Easy and time-sparing
    - Needs small sample size for validation
  - Demerit
    - No reflection of Japanese subset (JPN subset)
- Participation in development process of questionnaire
  - Merit
    - Reflection of JPN subset
    - Direct communication with EORTC QOL-G
  - Demerit
    - Needs larger sample size to reflect JPN subset
    - Translation of protocol, CRF and ICF into Japanese is troublesome

# Actual participation in EORTC-QOLG from Japan

- Around 5% of total sample size
- More enrollment to reflect characteristics of JPN subset





# EORTC Thyroid Cancer Module - Phase I/II -

EORTC Spring Meeting 2014  
Limassol (Cyprus)



# EORTC Thyroid Cancer Module - Phase IV -



**EORTC Autumn Meeting 2017  
Kiel**

# Some contributions to EORTC-QOLG from Japan

- Updated head and neck cancer module (HN-43)
  - Phase III: published in 2014
  - Phase IV: completed accrual and the manuscript submitted
  - HN-43 will be available for general use, soon.

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## ORIGINAL ARTICLE

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### Measuring quality of life in patients with head and neck cancer: Update of the EORTC QLQ-H&N Module, Phase III

Susanne Singer, PhD,<sup>1\*</sup> Cláudia Araújo, MD,<sup>2</sup> Juan Ignacio Arraras, PhD,<sup>3</sup> Ingo Baumann, MD,<sup>4</sup> Andreas Boehm, MD,<sup>5</sup> Bente Brokstad Herlofson, MD,<sup>6</sup> Joaquim Castro Silva, MD,<sup>7</sup> Wei-Chu Chie, PhD,<sup>8</sup> Sheila Fisher, MD,<sup>9</sup> Orlando Guntinas-Lichius, MD,<sup>10</sup> Eva Hammerlid, MD,<sup>11</sup> María Elisa Irrarrázaval, MD,<sup>12</sup> Marianne Jensen Hjermstad, PhD,<sup>13</sup> Kenneth Jensen, MD,<sup>14</sup> Naomi Kiyota, MD,<sup>15</sup> Lisa Licitra, MD,<sup>16</sup> Ourania Nicolatou-Galitis, MD,<sup>17</sup> Monica Pinto, MD,<sup>18</sup> Marcos Santos, MD,<sup>19</sup> Claudia Schmalz, MD,<sup>20</sup> Allen C. Sherman, PhD,<sup>21</sup> Iwona M. Tomaszewska, MD,<sup>22</sup> Irma Verdonck de Leeuw, PhD,<sup>23</sup> Noam Yarom, MD,<sup>24</sup> Paola Zotti, MD,<sup>25</sup> Dirk Hofmeister, PhD,<sup>26</sup> on behalf of the EORTC Quality of Life and the EORTC Head and Neck Cancer Groups

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Head Neck, Published online 2014. DOI 10.1002/hed.23762

# Some contributions to EORTC-QOLG from Japan

- Novel thyroid cancer module (THY-34)
  - Phase I/II: published in 2016
  - Phase III: published in 2017
  - After evaluating Phase IV, it will be made available for general use

Research	S Singer et al.	EORTC QLQ-THY phase III	24:4	197-207
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## The EORTC module for quality of life in patients with thyroid cancer: phase III

Susanne Singer<sup>1,2</sup>, Susan Jordan<sup>3</sup>, Laura D Locati<sup>4</sup>, Monica Pinto<sup>5</sup>, Iwona M Tomaszewska<sup>6</sup>, Cláudia Araújo<sup>7</sup>, Eva Hammerlid<sup>8</sup>, E Vidhubala<sup>9</sup>, Olga Husson<sup>10</sup>, Naomi Kiyota<sup>11</sup>, Christine Brannan<sup>12</sup>, Dina Salem<sup>13</sup>, Eva M Gamper<sup>14</sup>, Juan Ignacio Arraras<sup>15</sup>, Georgios Ioannidis<sup>16</sup>, Guy Andry<sup>17</sup>, Johanna Inhestern<sup>18</sup>, Vincent Grégoire<sup>19</sup>, Lisa Licitra<sup>4</sup> on behalf of the EORTC Quality of Life Group, the EORTC Head and Neck Cancer Group, and the EORTC Endocrine Task Force

# Some contributions to EORTC-QOLG from Japan

- Phase I/II study for Novel thyroid cancer module
  - Patients enrollment from 8 centers of 7 countries
  - Germany, Austria, Netherland, UK, Poland, Italy, Portugal, Japan
- Difference between European countries and Japan
  - Issue ‘ unanswerd questions about disease and treatment ’
    - 86% of Japanese patients selected this as relevant concern
    - 36% of all patients selected this issue
    - May related to cultural or racial difference of JPN subset
  - Most of the Japanese patients received tyrosine kinase inhibitors
    - 78% of all patients never received tyrosine kinase inhibitors
    - Single institution of medical oncology department from Japan

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# Present status and future direction of collaboration with EORTC-QOLG from Japan

- Present status
  - Some achievements from the collaboration
    - Be an active member from Japan
    - Contributions to new HN and THY modules
  - Problems
    - Still small enrollment from Japan
    - Participation from single institution
    - No organizational activity for this collaboration
- Future directions
  - Establishment of organized participation from Japan
  - Recognition and prevalence of PRO/HR-QOL in Japan

# Thank you for your attention !!



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