

ROK Study: Breast cancer survivorship cohort in Japan

-Study design and characteristics of 2,600 study participants-

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Rainbow of KIBOU

Background

Review 1: Risk factors for breast cancer occurrence

	WCRF / AICR Premenopause ¹⁾	WCRF / AICR Postmenopause ¹⁾	Japanese Clinical Practice Guideline Premenopause ²⁾	Japanese Clinical Practice Guideline Postmenopause ²⁾
Lactation	Convincing (↓)	Convincing (↓)	Convincing (↓)	Convincing (↓)
Adult attained height	Probable (↑)	Convincing (↑)	Probable (↑)	Convincing (↑)
Greater birth weight	Probable (↑)	Limited-no conclusion	Probable (↑)	Limited-no conclusion
Adult weight gain	Limited-no conclusion	Probable (↑)	Limited-no conclusion	Probable (↑)
Body fatness	Probable (↓)	Convincing (↑)	Probable (↓)	Convincing (↑)
Abdominal fatness	-	Probable (↑)	-	Probable (↑)
Physical activity	Limited-suggestive (↓)	Probable (↓)	Limited-suggestive (↓)	Probable (↓)
Smoking	-	-	Probable (↑)	-
Alcoholic drinks	Convincing (↑)	Convincing (↑)	Convincing (↑)	Convincing (↑)
Vegetables & fruits	Limited-no conclusion	Limited-no conclusion	Limited-no conclusion	Limited-no conclusion
Soya & soya products	Limited-no conclusion	Limited-no conclusion	Limited-suggestive (↓)	-
Vitamin C	Limited-no conclusion	Limited-no conclusion	Limited-no conclusion	Limited-no conclusion
Total fat	Limited-no conclusion	Limited-no conclusion	Limited-no conclusion	Limited-suggestive (↑)

1) World Cancer Research Fund / American Institute for Cancer Research. Food, nutrition, physical activity and the prevention of cancer: a global perspective. <http://www.dietandcancerreport.org/> (Accessed November 29, 2013)
2) The Japanese Breast Cancer Society. Clinical Practice Guideline of Breast Cancer 2. Epidemiology & Diagnosis. 2013.

Review 2: Risk factors for breast cancer recurrence & mortality

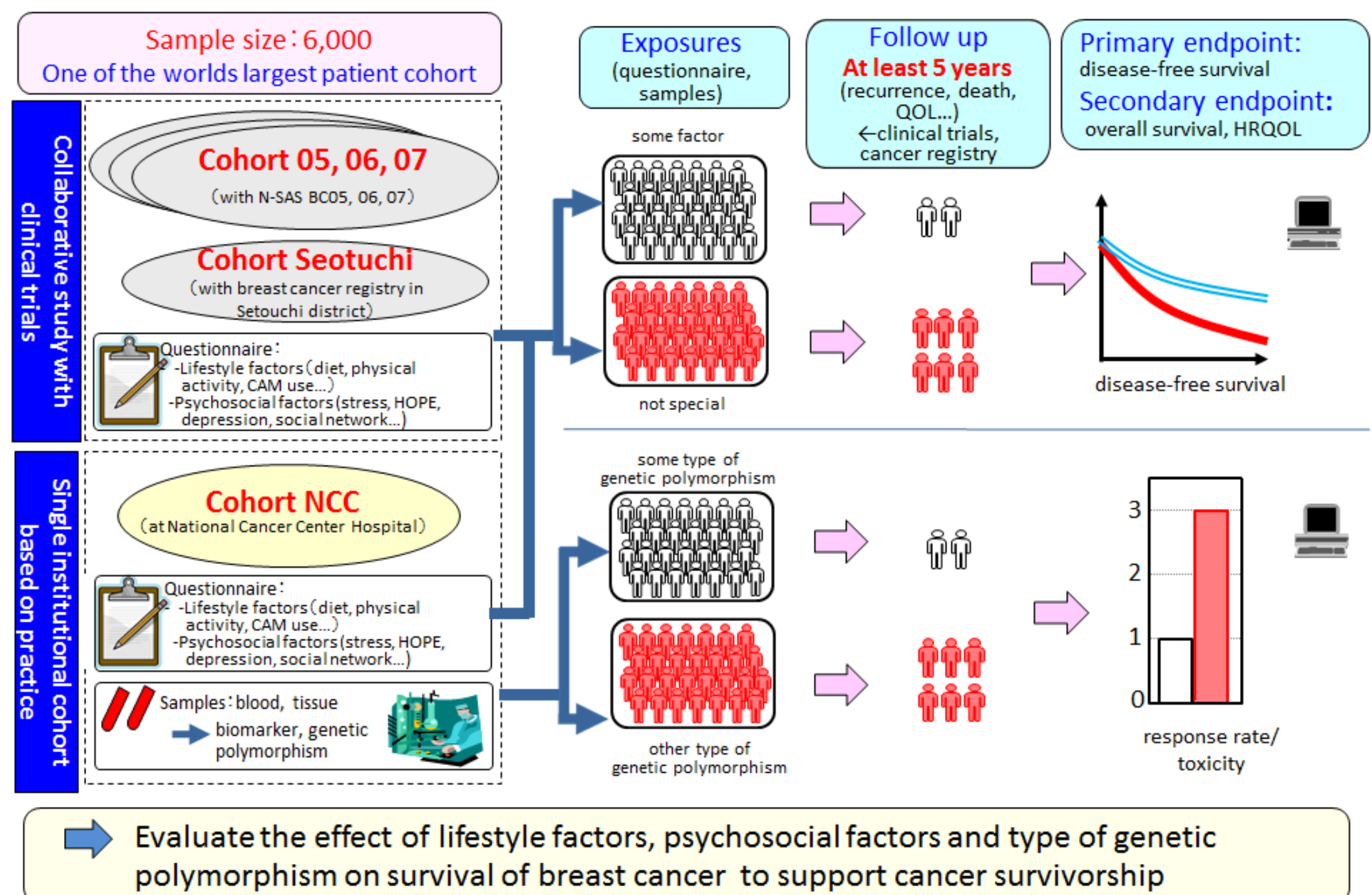
	Japanese Clinical Practice Guideline Postmenopause ¹⁾
Body fatness at diagnosis	Recurrence & death: Convincing (↑)
Body fatness after diagnosis	Death: Probable (↑)
Physical activity	Death: Probable (↓)
Smoking	Death: Limited-suggestive (↑)
Alcoholic drinks	Limited-no conclusion
Soya, soya products, Isoflavone	Limited-suggestive (↓)
Dairy products	Limited-no conclusion
Total fat	Limited-no conclusion

1) The Japanese Breast Cancer Society. Clinical Practice Guideline of Breast Cancer 2. Epidemiology & Diagnosis. 2013.

Objectives

- To investigate the effect of life style factors (diet, physical activity), psychosocial factors, CAM use on the effect of breast cancer prognosis including QOL, we started ROK Study Rainbow of KIBOU
- cohort studies for breast cancer patients.
- In this presentation, we describe the study design and enrollment status.

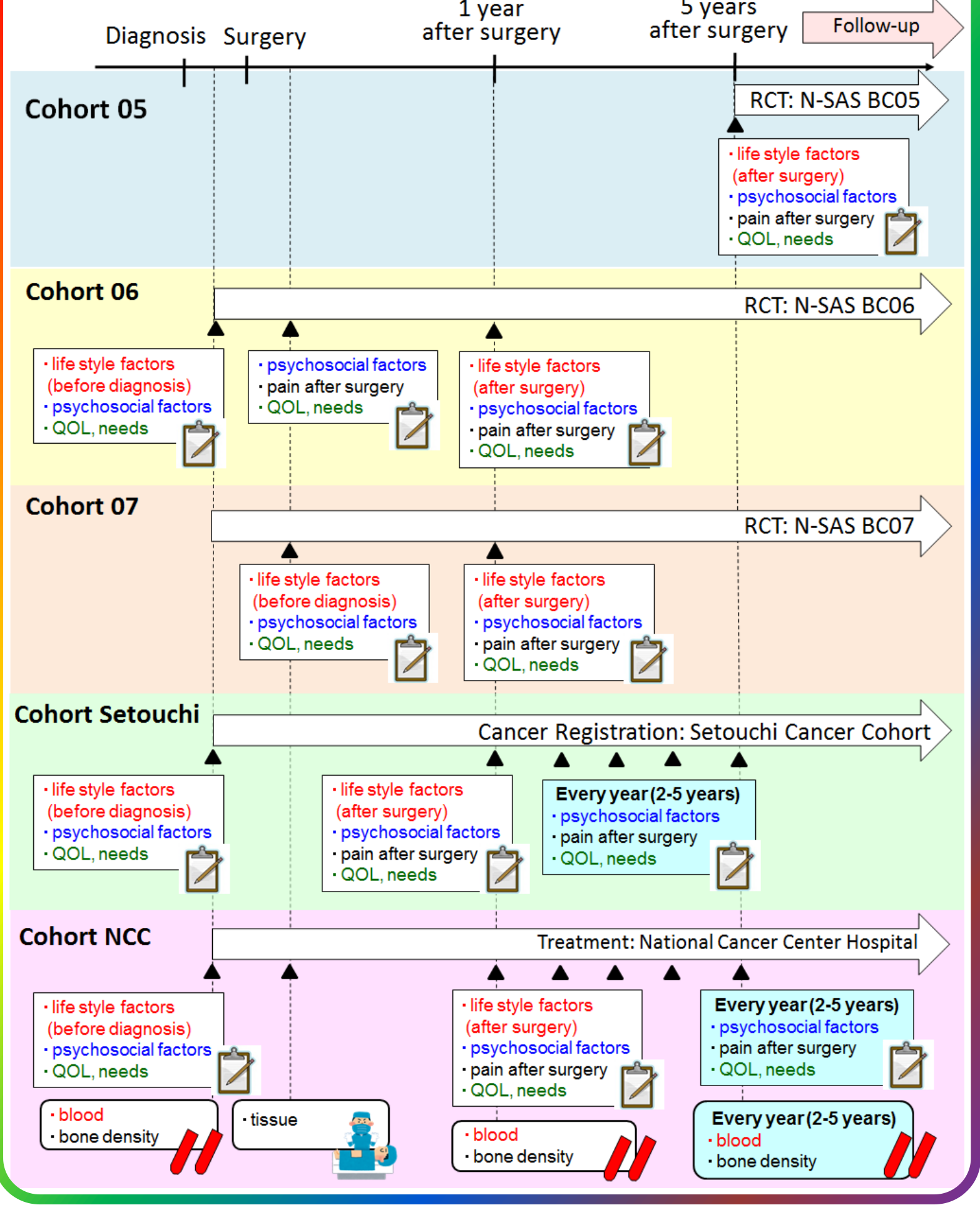
Study Design of ROK Study



ROK Study Consist of 5 Cohorts

Our study name	Collaborative study name	Sample size	Enrolment	Current condition (As of DEC 2, 2013)
Cohort 05	N-SAS BC05: Randomized Phase III Study to Assess the Efficacy of a Further 5 Years of Anastrozole Treatment for Postmenopausal Women	1,800	NOV 2007~ (Enrolling)	•120 institutions •1,505 patients enrolled (response rate: 94.6%)
Cohort 06	N-SAS BC06: Randomized Phase III Study of Adjuvant Endocrine-Therapy with or without Chemotherapy for Postmenopausal Breast Cancer Patients who Responded to Neoadjuvant	800	MAY 2008~ (Enrolling)	•126 institutions •733 patients enrolled (response rate: 95.8%)
Cohort 07	N-SAS BC07 (two studies) - Evaluation of Trastuzumab without Chemotherapy as a Postoperative Adjuvant Therapy in HER2 Positive Elderly Breast Cancer Patients: Randomized Controlled Trial - Cohort Study to Evaluate the Efficacy and Safety of Postoperative Adjuvant Therapy in HER2 Positive Elderly Breast Cancer Patients	200	OCT 2009~ (Enrolling)	•119 institutions •213 patients enrolled (response rate: 92.6%)
Cohort Setouchi	SBCC: Setouchi Breast Cancer Cohort Study conducted by Nonprofit Organization Setouchi Breast Project Comprehensive Support Organization	2,000	FEB 2013~ (Enrolling)	•13 institutions •373 patients enrolled ⇒373 baseline data ⇒299 questionnaires
Cohort NCC	All breast cancer patient treated at National Cancer Center Hospital	1,200	NOV 2010~ (Enrolling)	•314 patients enrolled ⇒313 samples (blood & tissue) ⇒264 questionnaires
TOTAL		6,000	Enrolling	3,138 patients enrolled and baseline data collected

Survey Items & Study Points



Questionnaire

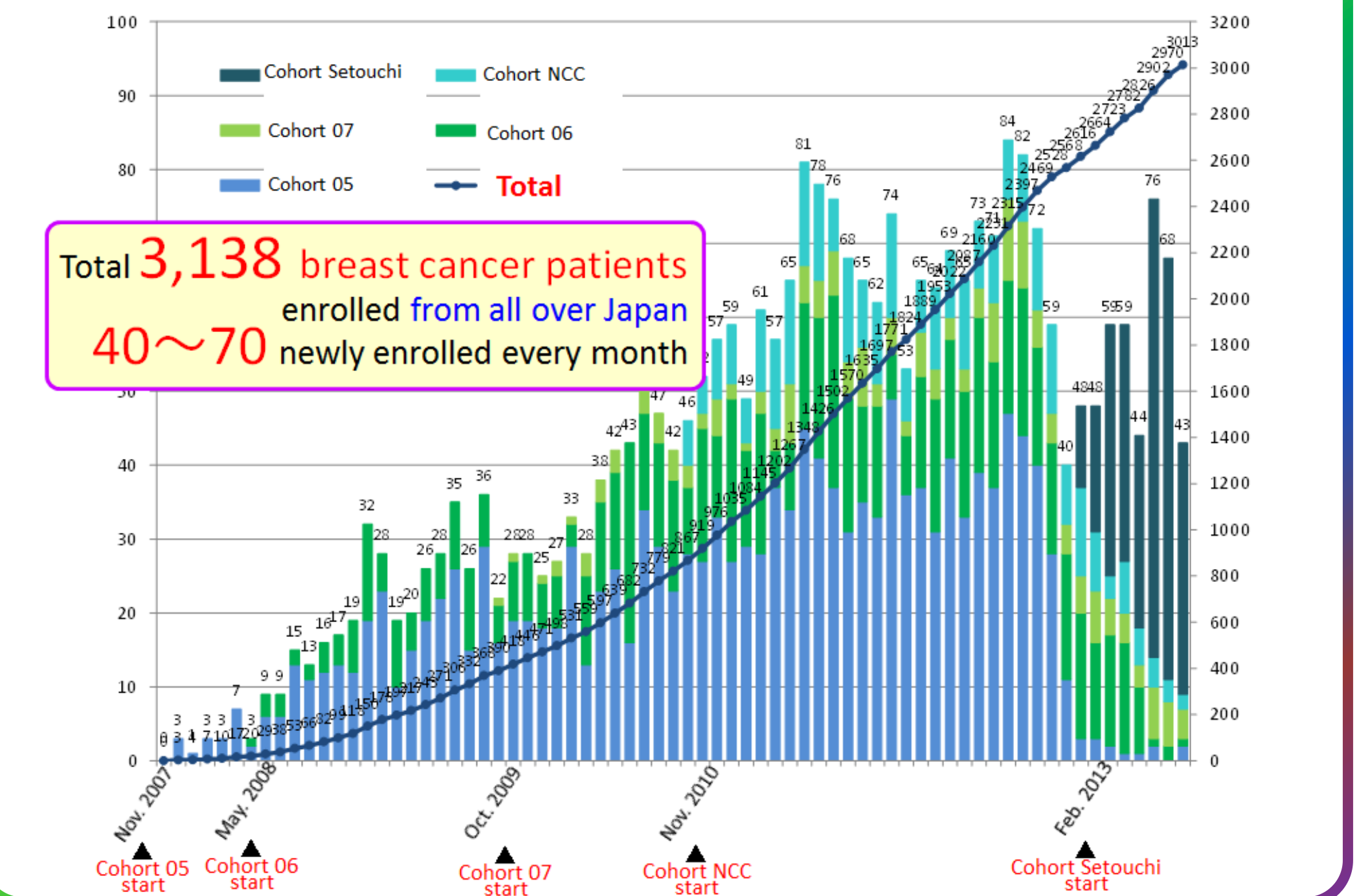
野菜の目安量 (実物大)
1日に食べている野菜の量と比べてください。1日1回の量の目安を覚えてください。写真より多ければ(1.5倍ほど) 多量(2) 少なければ(半分ほど) 少ない(1)の欄の数を覚えてください。

Frequency: less than once a month ~ over 7 times a day

Portion: half ~ half again as the picture

Life style before diagnosis: asked before surgery
Life style after diagnosis: asked one year after surgery

Enrollment (as of DEC 2, 2013)



Baseline data (as of SEP 30, 2013)

	ROK Study Total (n=2,920)	Cohort 05 (n=1,505)	Cohort 06 (n=750)	Cohort 07 (n=195)	Cohort NCC (n=258)	Cohort Setouchi (n=212)
Age						
Total	2,920	1,505	750	195	258	212
20-29	2	0	0	0	2	0
30-39	39	0	0	0	21	8
40-49	124	4	3	0	55	57
50-59	676	232	144	193	75	201
60-69	1,323	453	370	512	63	244
70-79	732	251	350	233	187	161
≥80	24	0	0	0	8	4
Location of institute						
Total	2,920	1,505	750	195	258	212
Hokkaido	185	62	99	6	14	7
Tohoku	478	145	43	29	86	115
Kanto	1,153	387	620	412	225	300
Chubu	447	150	187	122	36	44
Kinki	319	107	178	118	109	145
Chugoku	356	119	142	94	63	84
Shikoku	169	57	25	17	4	26
Kyushu	209	70	117	78	69	92
Marital status						
Total	2,981	1,505	750	195	258	212
married	1,831	69.5	1,069	71.3	90	51.7
divorced	162	6.2	82	5.5	56	7.8
separation	22	0.8	13	0.9	5	0.7
bereaved	378	14.4	209	13.9	89	12.4
unmarried	190	7.2	104	6.9	47	6.6
others	6	0.2	4	0.3	1	0.1
no answer	44	1.7	18	1.2	8	1.1
Current job						
Total	2,633	1,499	717	100	174	243
self-employed	204	7.7	108	7.2	65	9.1
full-time employee	2,088	144	9.6	88	12.1	2
part-time employee	429	16.3	255	17.0	123	17.2
housewife	1,184	45.0	699	46.6	310	43.2
unemployed	391	14.8	226	15.1	95	13.2
no answer	137	5.2	67	4.5	36	5.0
CES-D¹⁾						
Total	2,633	1,499	717	100	174	243
1-3	454	17.2	223	14.9	149	20.8
4-6	764	29.0	409	27.3	228	31.8
7	1,188	45.1	682	45.5	300	41.8
Herrh Hope Index²⁾						
Total	2,633	1,499	717	100	174	243
12-20	19	0.8	7	0.5	9	1.3
21-30	364	14.4	209	14.5	100	14.4
31-40	1,579	62.6	905	62.9	427	61.0
41	562	22.3	318	22.1	159	22.9

Conclusion

- Recruitment began in NOV, 2007, and as of DEC 2, 2013, 3,138 women with breast cancer have been enrolled.
- As baseline data, 3,014 questionnaire data, 313 blood samples and tissues have been collected.
- As it is now, approximately 50 women a month newly enrolled.
- Recruitment will be continued at least into 2018.
- The ROK: Rainbow of KIBOU Study will become one of the largest breast cancer cohorts in the world.

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<Disclosure Information> Yuri Mizota: I have no financial relationships to disclose.