Supplementary Appendix

This appendix has been provided by the authors to give readers additional information about their work.

Supplement to: Slamon D, Eiermann W, Robert N, et al. Adjuvant trastuzumab in HER2-positive breast cancer. N Engl J Med 2011;365:1273-83.

(PDF updated October 12, 2011.)

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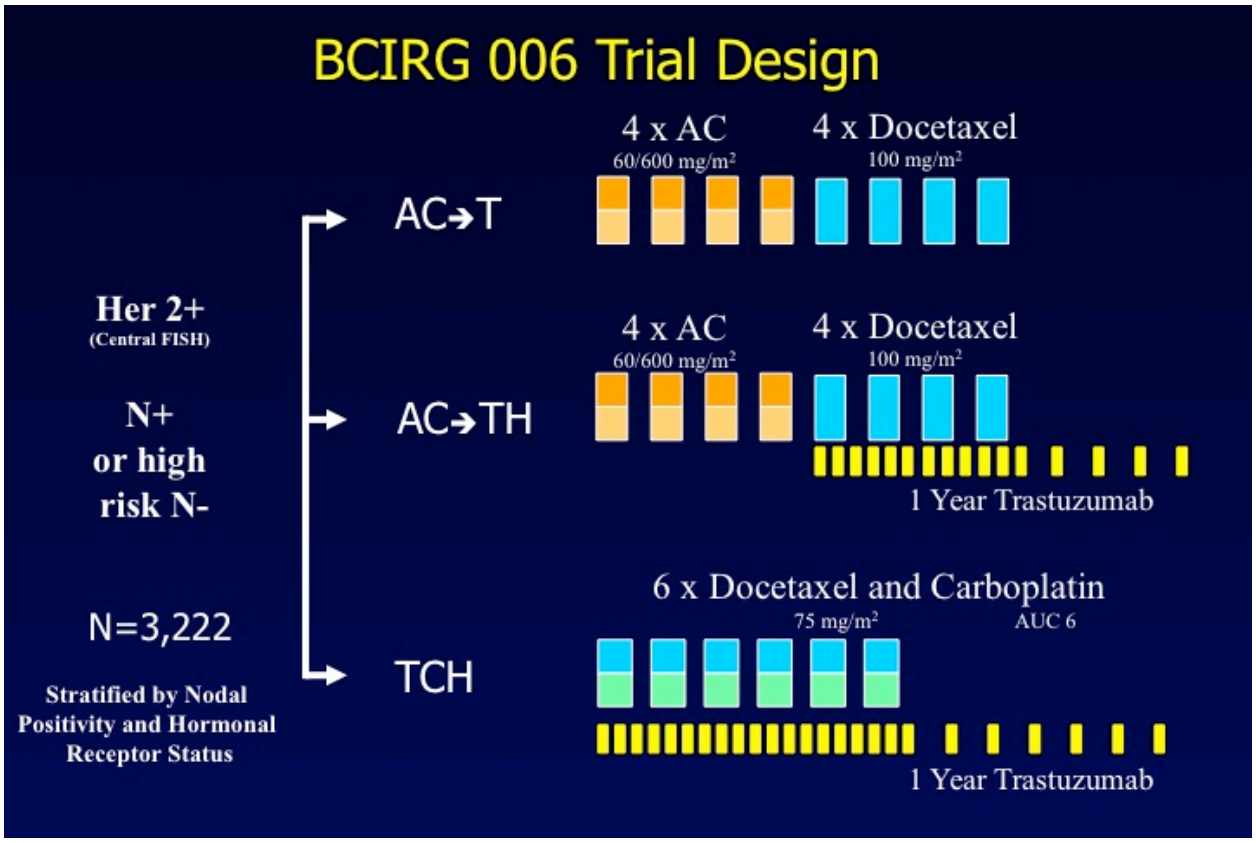
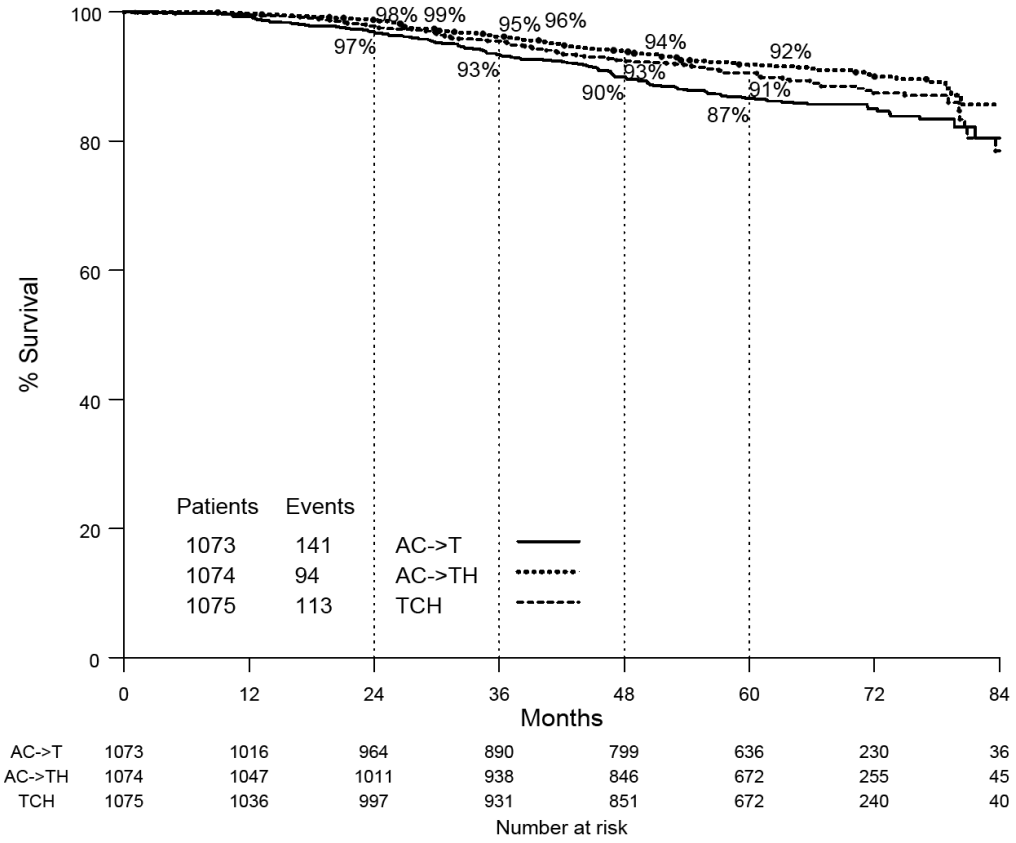
SUPPLEMENTAL TEXT

For patients randomized to the AC→TH arm, guidelines for initiating trastuzumab therapy following the initial four cycles of AC and before trastuzumab were predefined in the protocol. These trastuzumab "pre-start" guidelines were based on a subject's asymptomatic decline of LVEF (absolute decrease from baseline) and/or the degree of decrease below the calibrated lower limit of normal (LLN) for LVEF determined by the treating institution. Those patients who had either a decrease of ≥15 points from baseline and below the LLN or who experienced a decline that was ≥16 points from baseline regardless of the LLN, for two consecutive echo/MUGA determinations performed two weeks apart were not started on trastuzumab.

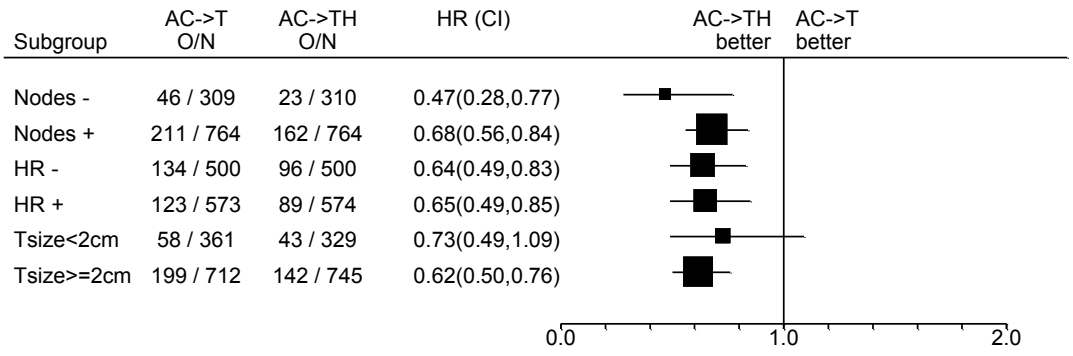
SUPPLEMENTAL FIGURES



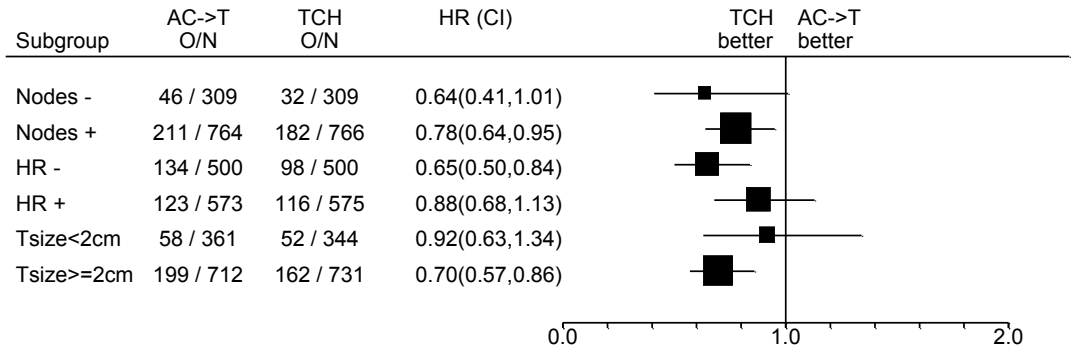
Supplemental Figure 1 - Study design of the BCIRG-006 trial. A= anthracycline, T=docetaxel, C=cyclophosphamide in the AC→T and AC→TH arms. C=carboplatin in the TCH arm. H=trastuzumab in the two experimental arms.



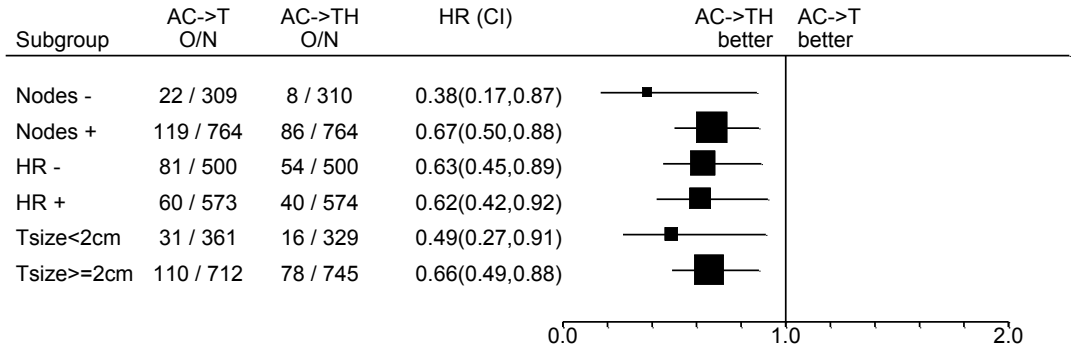
Supplemental Figure 2 – Kaplan-Meyer analysis of the relative overall survival of the three treatment arms.



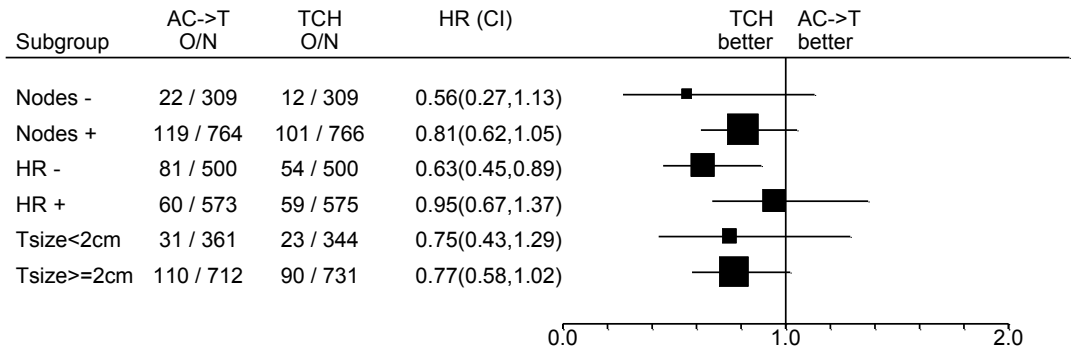
Supplemental Figure 3a – Forest plot of disease free survival for BCIRG-006 patients, AC-TH versus AC-T, stratified by nodal status (node negative or node positive), hormone receptor status (HR+ or HR-) and tumor size (<2cm or ≥2cm).



Supplemental Figure 3b – Forest plot of disease free survival for BCIRG-006 patients, TCH versus AC-T, stratified by nodal status (node negative or node positive), hormone receptor status (HR+ or HR-) and tumor size (<2cm or ≥2cm).



Supplemental Figure 3c - Forest plot of overall survival for BCIRG-006 patients, AC-TH versus AC-T, stratified by nodal status (node negative or node positive), hormone receptor status (HR+ or HR-) and tumor size (<2cm or ≥2cm).



Supplemental Figure 3d - Forest plot of overall survival for BCIRG-006 patients, TCH versus AC-T, stratified by nodal status (node negative or node positive), hormone receptor status (HR+ or HR-) and tumor size (<2cm or ≥2cm).

SUPPLEMENT Table 1A
Analysis of Disease-Free Survival (DFS) by Nodal Status at Randomization

Node-Negative Disease					
	# patients	**# DFS events**	**HR (95% C.I)**	**p value**	**5-year DFS (%)**
AC→ T	309	46	1 (ref)		85
AC→ TH	310	23	0.47 (0.28-0.77)	0.0028	93
TCH	309	32	0.64 (0.41-1.01)	0.057	90
Node-Positive Disease					
	# patients	**# DFS events**	**HR (95% C.I)**	**p value**	**5-year DFS (%)**
AC→ T	764	211	1 (ref)		71
AC→ TH	764	162	0.68 (0.56-0.84)	0.0003	80
TCH	766	182	0.78 (0.64-0.95)	0.013	78
≥4 Positive Nodes					
	# patients	**# DFS events**	**HR (95% C.I)**	**p value**	**5-year DFS (%)**
AC→ T	350	133	1 (ref)		61
AC →TH	350	99	0.66 (0.51-0.86)	0.0017	73
TCH	352	101	0.66 (0.51-0.86)	0.0016	72

SUPPLEMENT Table 1B
Analysis of Disease-Free Survival (DFS) by Tumor Size at Randomization

Size < 1 cm					
	# patients	**# DFS Events**	**HR (95% C.I)**	**p value**	**5-year DFS (%)**
AC→T	58	16	1 (ref)		72
AC→TH	46	6	0.36 (0.14-0.93)	0.034	86
TCH	44	6	0.45 (0.17-1.16)	0.096	86
Size ≥1 and <2 cm					
	# patients	**# DFS events**	**HR (95% C.I)**	**p value**	**5-year DFS (%)**
AC→T	303	42	1 (ref)		86
AC→TH	283	37	0.88 (0.57-1.38)	0.59	87
TCH	300	46	1.11 (0.73-1.69)	0.64	86
Size ≥ 2 cm					
	# patients	**# DFS events**	**HR (95% C.I.)**	**p value**	**5-year DFS (%)**
AC→T	712	199	1 (ref)		71
AC→TH	745	142	0.62 (0.50-0.76)	<0.0001	82
TCH	731	162	0.70 (0.57-0.87)	0.0009	79