In patients with ER-negative disease (n = 304) goserelin was inferior to CMF for DFS (HR 1.61; 95% CI 1.20, 2.16) and the other two outcomes. With regard to overall safety, as reported previously, goserelin was well tolerated.
Conclusions: This follow-up analysis confirms the previously reported results from the ZEBRA trial and thus demonstrates that goserelin offers a well-tolerated effective alternative to CMF chemotherapy in the management of patients with ER-positive, node-positive early breast cancer.

O-4 Ovarian suppression (OS) and tamoxifen (TAM) as an alternative to chemotherapy in early breast cancer. Long-term results of the GROCTA02 trial

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Background: We have previously reported that comparable results can be achieved by 5 years of TAM combined with ovarian suppression or chemotherapy in pre-perimenopausal breast cancer patients affected by early breast cancer (JCO 18:2718–27, 2000). Here we report the updated results of this trial at a median follow-up time of 12 years.
Methods: Details have been published previously. In summary 124 women have been randomly assigned to receive TAM for 5 years in combination with some form of OS (most patients were given Goserelin injections for 2 yrs, but a few of them were restarded on Goserelin for one additional year when menses were restored) while 120 were given 6 cycles of "classical" (i.e. cyclophosphamide 100 mg/m^2 by mouth dd 1–14, every 4 weeks) CMF. In both groups, most of the patients were node positive (though about 15% of patients in each group were "high risk" node-negative) and all of them had ER positive tumours.
Results: At the time of the present analysis, in all 109 pts relapsed and 64 died. There was no statistically significant difference between groups either in progression-free or in overall survival (p = 0.7 for both comparisons). The comparability of results is confirmed by multivariate analysis (table below) which in addition shows that No of involved nodes and tumor grade are both independent predictors of recurrence and mortality risks.

	Recurrence			Death		
	HR	(95% CI)	P	HR	(95% CI)	P
Treatment						
CMF	1.0		0.8	1.0		0.8
TAM+OS	0.95	(0.64–1.40)		1.06	(0.64–1.77)	
Age						
⩽40 years	1.0		0.015	1.0	0.2	
>40 years	0.56	(0.35–0.89)		0.66	(0.36–1.21)	
Tumour size						
⩽2 cm	1.0		0.2	1.0		0.03
>2 cm	1.26	(0.85–1.86)		1.78	(1.05–3.01)	
No. of involved nodes						
0–3	1.0		0.002	1.0		0.055
>3	1.89	(1.27–2.84)		1.67	(0.99–2.81)	
Tumour grade						
G1–G2–Gx	1.0		0.02	1.0		0.015
G3–Gu	1.67	(1.07–2.59)		1.99	(1.15–3.44)	

Outcome analysis by prognostic strata confirms that comparable results were achieved by TAM plus OS or CMF, except in patients affected by undifferentiated tumors where both recurrence-free and mortality trends favoured those assigned to CMF (the difference in respect to mortality risk being statistically significant: p = 0.02)

Conclusions: The updated results of GROCTA 2 trial confirm that, even after a long follow-up, OS and TAM is an effective alternative treatment for ER positive breast cancer patients, irrespective of nodal status, though CT appears to be more appropriate to manage the women with less differentiated tumours.

O-5 Carcinoembryonic antigen cell adhesion molecule (CEACAM6) predicts breast cancer recurrence following adjuvant tamoxifen

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Tamoxifen has been the principal endocrine therapy for ERα-positive breast cancer patients and still remains the therapy of choice in the pre-menopausal setting. However, resistance and recurrence remain a serious problem. Our previous work has indicated that CEACAM6 was significantly up-regulated in tamoxifen-resistant (TAMr) MCF-7 derivatives compared to sensitive controls. The aim of this study was to determine the functional role of CEACAM6 in endocrine resistant breast cancer and to retrospectively test whether it was predictive of resistance in a large cohort of breast cancers with long term follow up. Up-regulation of CEACAM6 mRNA and protein in TAMr MCF-7 was confirmed by qRT-PCR and Western blotting. SiRNA-mediated silencing of CEACAM6 reduced clonogenicity of TAMr cells by ~3-fold ($p < 0.05$), and reduced anchorage-independent colony formation by ~10-fold ($p < 0.05$). Importantly, silencing of CEACAM6 partially restored sensitivity of TAMr cells to 4-Hydroxytamoxifen and restored their ability to proliferate in response to 17β-estradiol. CEACAM6 immunohistochemistry was performed on a tissue microarray comprising 108 relapsed primary human breast cancers and 243 tamoxifen-sensitive controls. Cytoplasmic and membranous staining was scored, with a maximum score of 3 indicating strong staining in >10% of cells. 57/108 (53%) of the relapsed group demonstrated strong to moderate CEACAM6 staining, which was significantly more than the non-relapsed group (76/243 (31.3%) OR = 2.46, 95% CI 1.54 to 3.91, $p < 0.0001$). In conclusion, our *in vitro* and clinical data support an important role for CEACAM6 in endocrine resistance and breast cancer recurrence.

O-6 Three years of the Breast Cancer Clinical Outcome Measures (BCCOM) project

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Data on over 45,700 primary symptomatic breast cancers diagnosed in 2002, 2003 and 2004 have been collected in the first three years of the project, including data on 374 male breast cancers. Each year, an average of 20,000 cases was sent to more than 200 UK consultant surgeons for checking.
In the absence of robust performance indicators, a set of measures has been developed by the BCCOM Project Steering Group. For example "the number and proportion of histologically node negative cancers for which more than seven nodes were harvested". BCCOM data indicate that 62% of invasive cases had known nodal status and that 52% were node negative. 59% (7,983 cases) of the node negative cancers had more than 7 nodes harvested. 46% of