

# STP

## Tailored Treatment Investigations

Premenopausal patients with endocrine-responsive disease (ER  $\geq$  10% and/or PgR  $\geq$  10%)

**SOFT:** Suppression of Ovarian Function Trial (IBCSG 24-02; BIG 2-02)

**TEXT:** Tamoxifen and Exemestane Trial (IBCSG 25-02; BIG 3-02)

**PERCHE:** Premenopausal Endocrine-Responsive Chemotherapy Trial (IBCSG 26-02; BIG 4-02)

North American Intergroup and Breast International Group (BIG) participation

Coordinating Group: International Breast Cancer Study Group (IBCSG)

Pharmaceutical Partner: Pfizer



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## Tailored Treatment Investigations

Premenopausal patients with endocrine-responsive disease (ER  $\geq$  10% and/or PgR  $\geq$  10%)

### Three protocols for two subpopulations:

A. For patients who **remain premenopausal** within 6 months **after chemotherapy**, or those for whom tamoxifen alone is considered adequate Rx:

**SOFT**: tamoxifen vs.  
OFS + tamoxifen vs.  
OFS + exemestane

*OFS = ovarian function suppression using triptorelin x 5 years or surgical oophorectomy or ovarian irradiation.*

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B. For patients who **should receive ovarian function suppression from the start:**

**TEXT:** triptorelin (+/- CT) + tamoxifen vs. triptorelin (+/- CT) + exemestane

**PERCHE:** OFS + (tam or exe) vs. OFS + CT + (tam or exe)

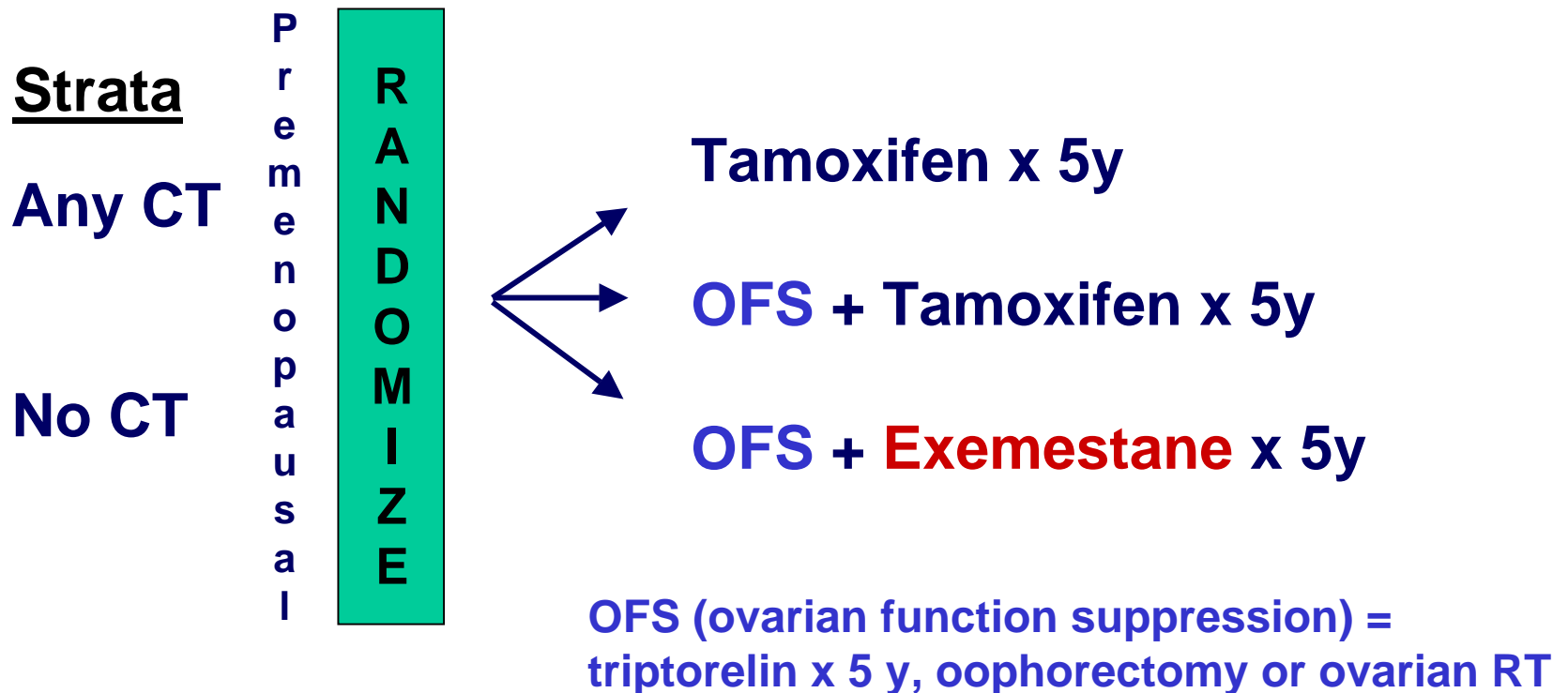
Patients may enroll in both PERCHE (to select +/- CT) and TEXT (to select tam or exe).

*CT = chemotherapy. OFS = ovarian function suppression using triptorelin x 5 years or surgical oophorectomy or ovarian irradiation. For TEXT, OFS = triptorelin x 5 years, but surgical oophorectomy or ovarian irradiation is allowed after 6 months.*

# SOFT [IBCSG 24-02, BIG 2-02]

Premenopausal, ER and/or PgR  $\geq 10\%$

Patients who **remain premenopausal** within 6 months **after CT**, or receive tamoxifen alone as adequate treatment



**Target sample size: 3000 patients**

# SOFT

- Study Chairs: P. Francis (BIG)  
G. Fleming (N. America)
- Target: 3000 patients
- 600 women/year for 5 years + 1.9 FU
- First patient entered: December 2003
- Entered through Sept 30, 2004: 75

# TEXT [IBCSG 25-02, BIG 3-02]

Premenopausal, ER and/or PgR  $\geq 10\%$

Patients who **should receive OFS from the start**  
of adjuvant therapy

R  
A  
N  
D  
O  
M  
I  
Z  
E

**Triptorelin + Tamoxifen\* x 5y**  
(+/- CT\*\*)

**Triptorelin + Exemestane\* x 5y**  
(+/- CT\*\*)

\* to begin  $\geq 6$  weeks after start of triptorelin or after CT

\*\* +/- CT by investigator choice or PERCHE trial randomization

**Target sample size: 1845 patients**

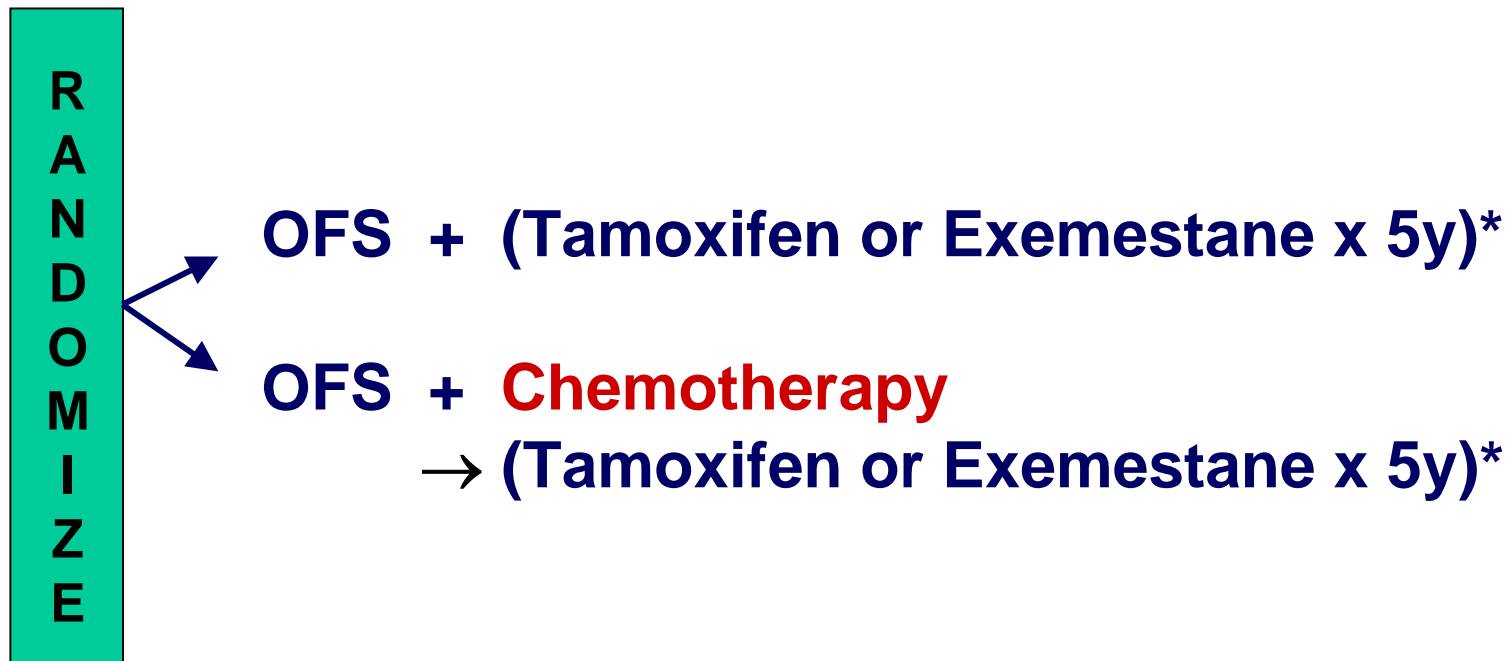
# TEXT

- Study Chairs: O. Pagani (BIG)  
B. Walley (N. America)
- Target: 1845 patients
- 410 women/year for 4.5 yrs + 2.4 FU
- Choice of +/- CT may be made by previous randomization in the PERCHE trial
- First patient entered: November 2003
- Entered through Sept 30, 2004: 147

# PERCHE [IBCSG 26-02, BIG 4-02]

Premenopausal, ER and/or PgR  $\geq 10\%$

Patients who **should receive OFS from the start**, and for whom CT is a randomized option (lower risk)



\* endocrine agent by investigator choice or TEXT trial randomization

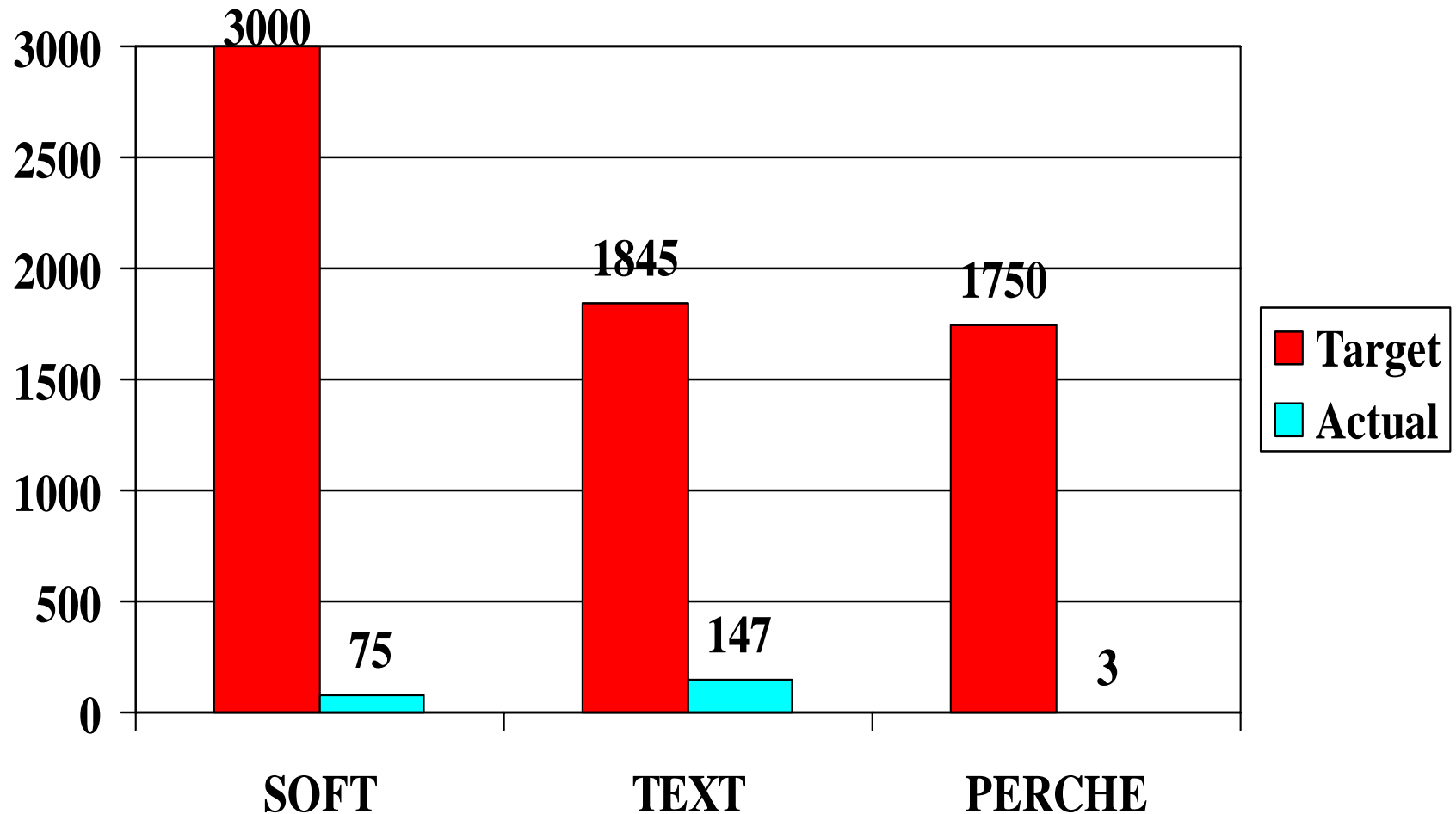
**Target sample size: 1750 patients**

# PERCHE

- Study Chairs: R. Torrisa (BIG)  
E. Perez (N. America)
- Target: 1750 patients
- 250 women/year for 7 yrs + 2.4 FU
- First patient entered: June 2004
- Entered through Sept 30, 2004: 3

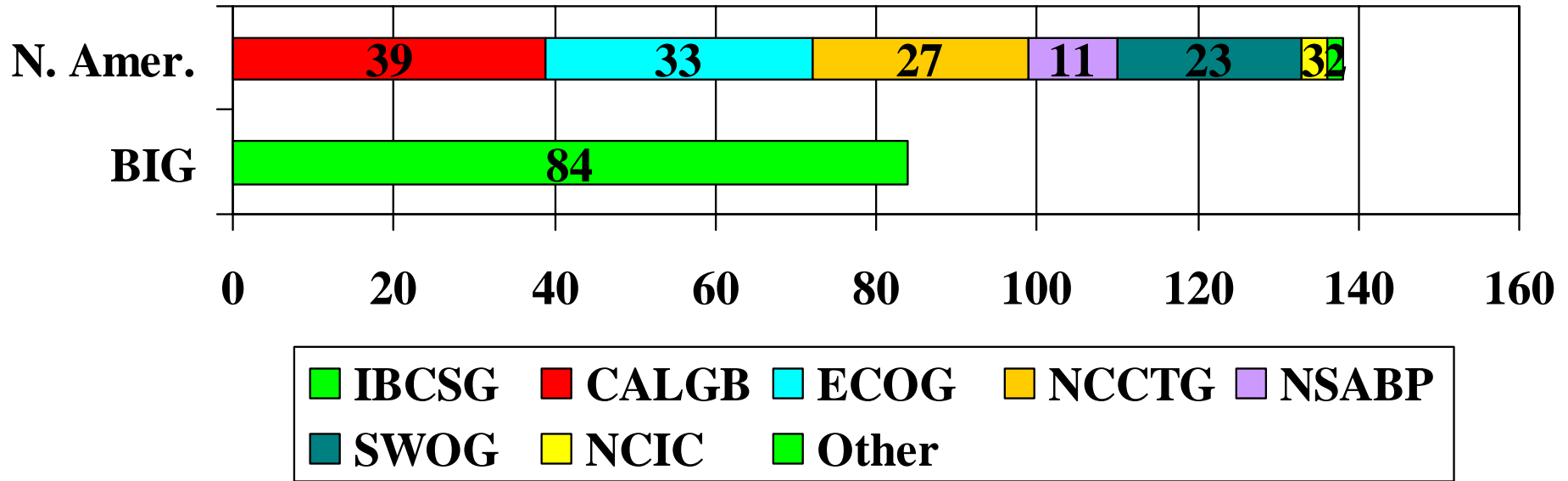
# STP Target and Actual Accrual

(through September 30, 2004)

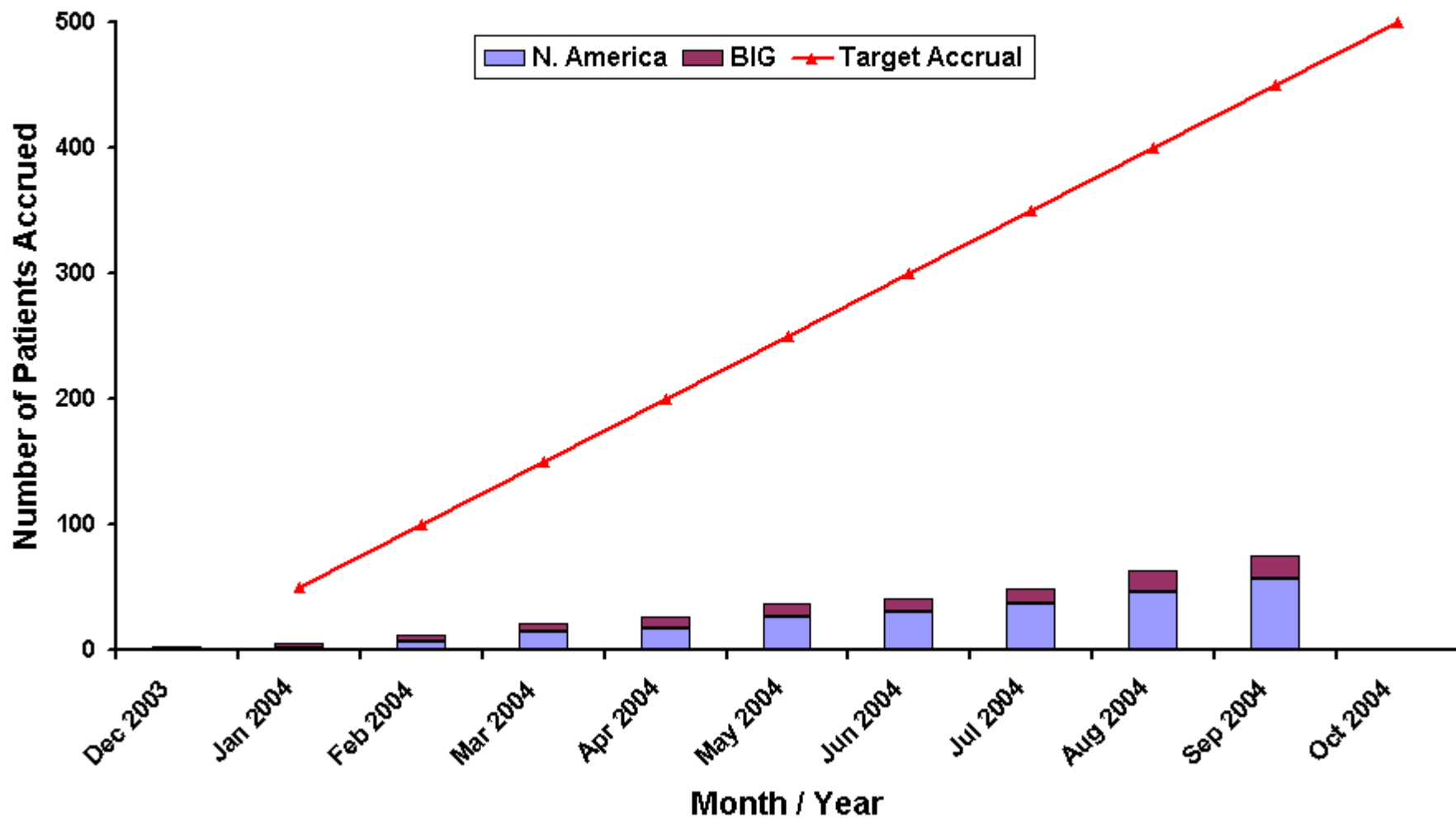


# STP Accrual

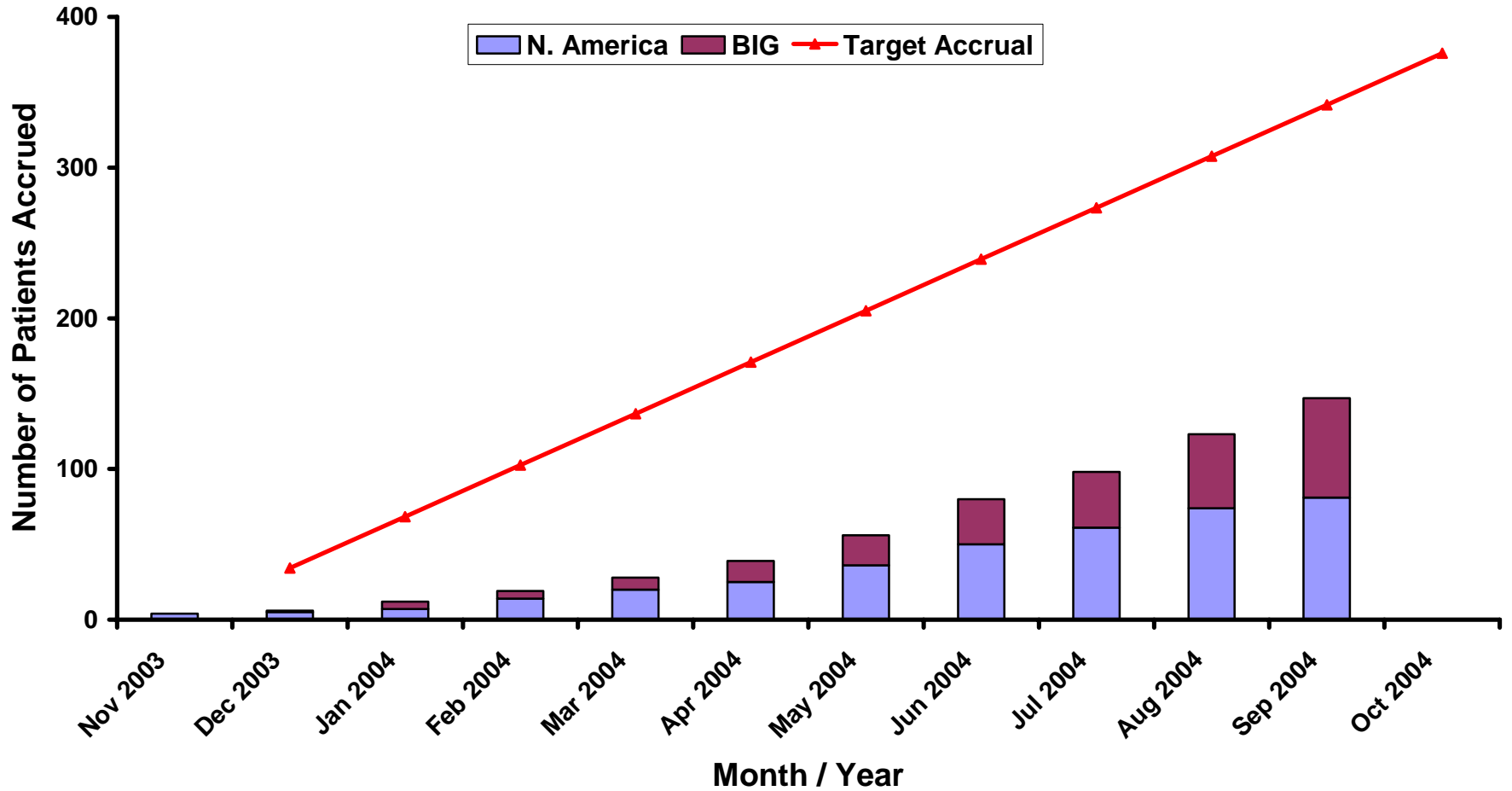
(through September 30, 2004)



**IBCSG Trial 24-02 (BIG 2-02) SOFT**  
**Cumulative Accrual through 30 Sep 2004**  
Accrual Goal: 3000 Patients (50/month)



**IBCSG Trial 25-02 (BIG 3-02) TEXT**  
**Cumulative Accrual through 30 Sep 2004**  
Accrual Goal: 1845 Patients (34/month)



**IBCSG Trial 26-02 (BIG 4-02) PERCHE**  
**Cumulative Accrual through 31 Aug 2004**  
Accrual Goal: 1750 Patients

