STP
Tailored Treatment Investigations

Premenopausal patients with endocrine-responsive disease (ER ≥ 10% and/or PgR ≥ 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

CTSU

IBCSG

Breast International Group

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Premenopausal patients with endocrine-responsive disease (ER ≥ 10% and/or PgR ≥ 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

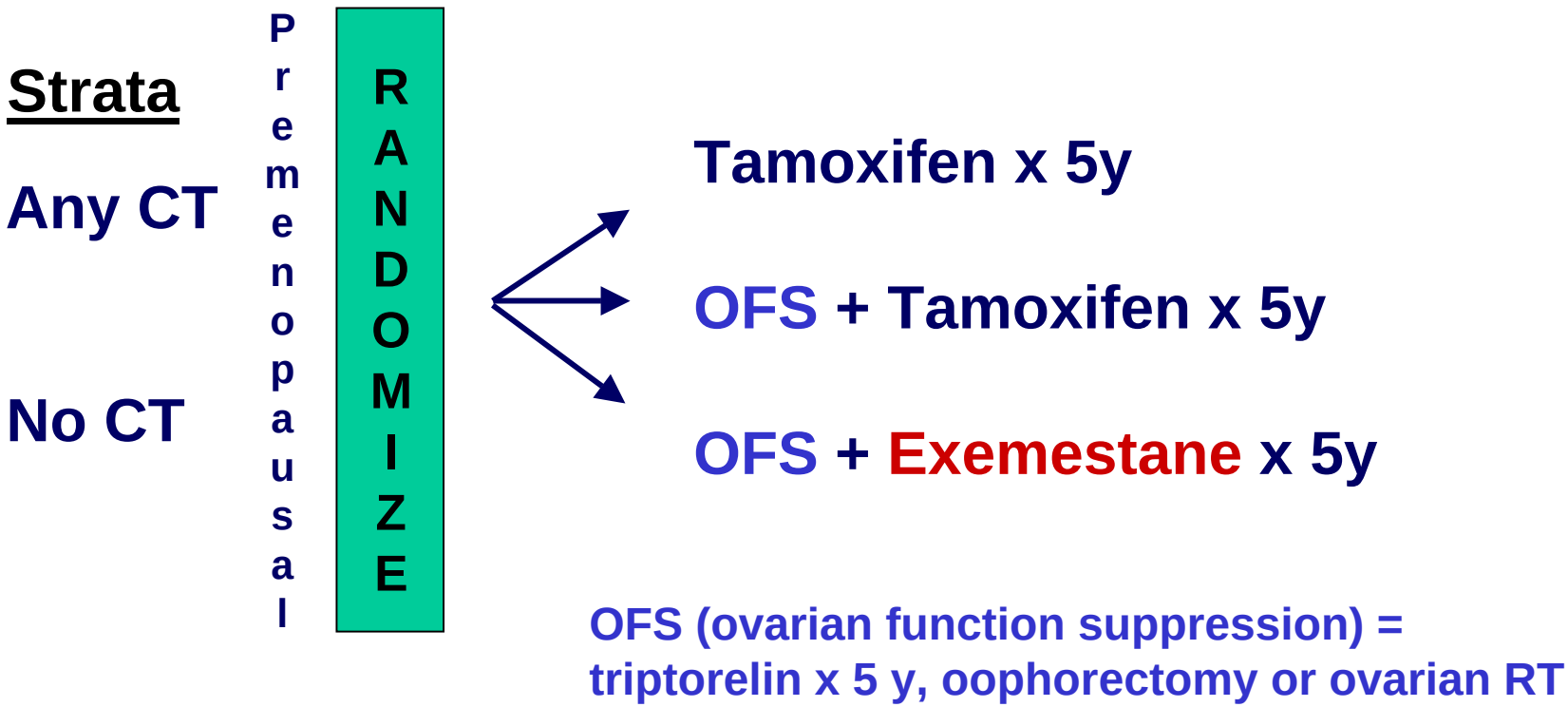
PERCHE: OFS + (tam or exe) vs.
OFS + CT + (tam or exe)

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 ≥ 10%

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



OFS (ovarian function suppression) = triptorelin x 5 y, oophorectomy or ovarian RT

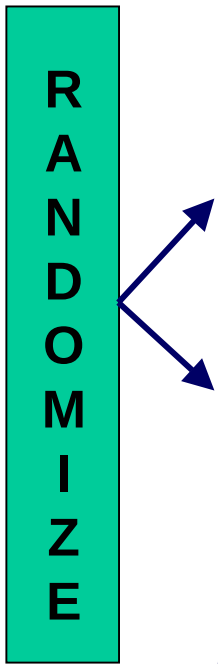
Target sample size: 3000 patients

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 ≥ 10%

Patients who should receive OFS from the start of adjuvant therapy



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

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

* to begin ≥ 6 weeks after start of triptorelin or after CT

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

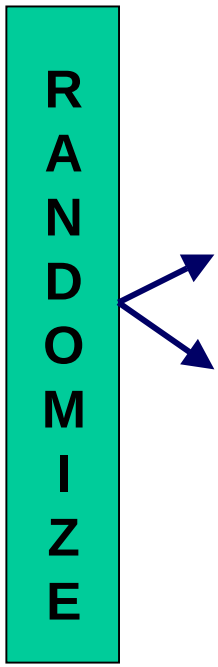
Target sample size: 1845 patients

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 ≥ 10%

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



OFS + (Tamoxifen or Exemestane x 5y)*

OFS + Chemotherapy
→ (Tamoxifen or Exemestane x 5y)*

*** endocrine agent by investigator choice or TEXT trial randomization**

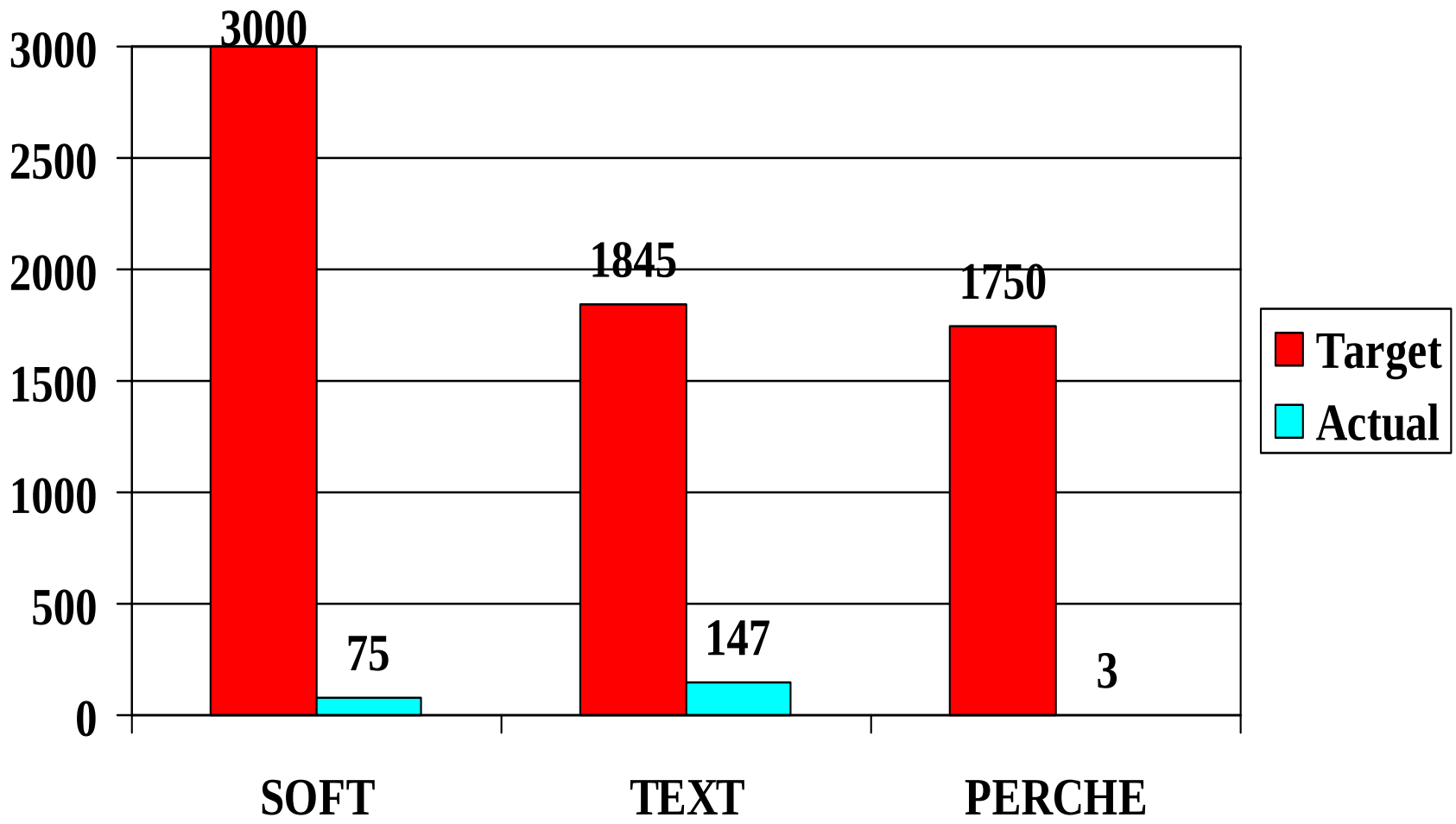
Target sample size: 1750 patients

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

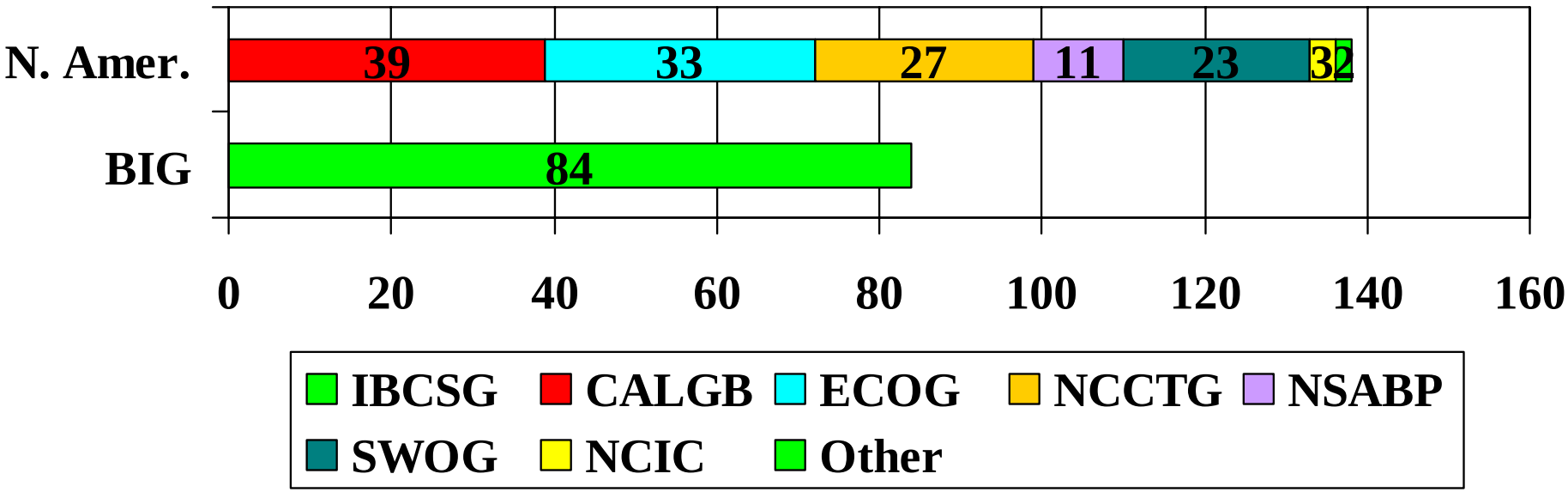
STP Target and Actual Accrual

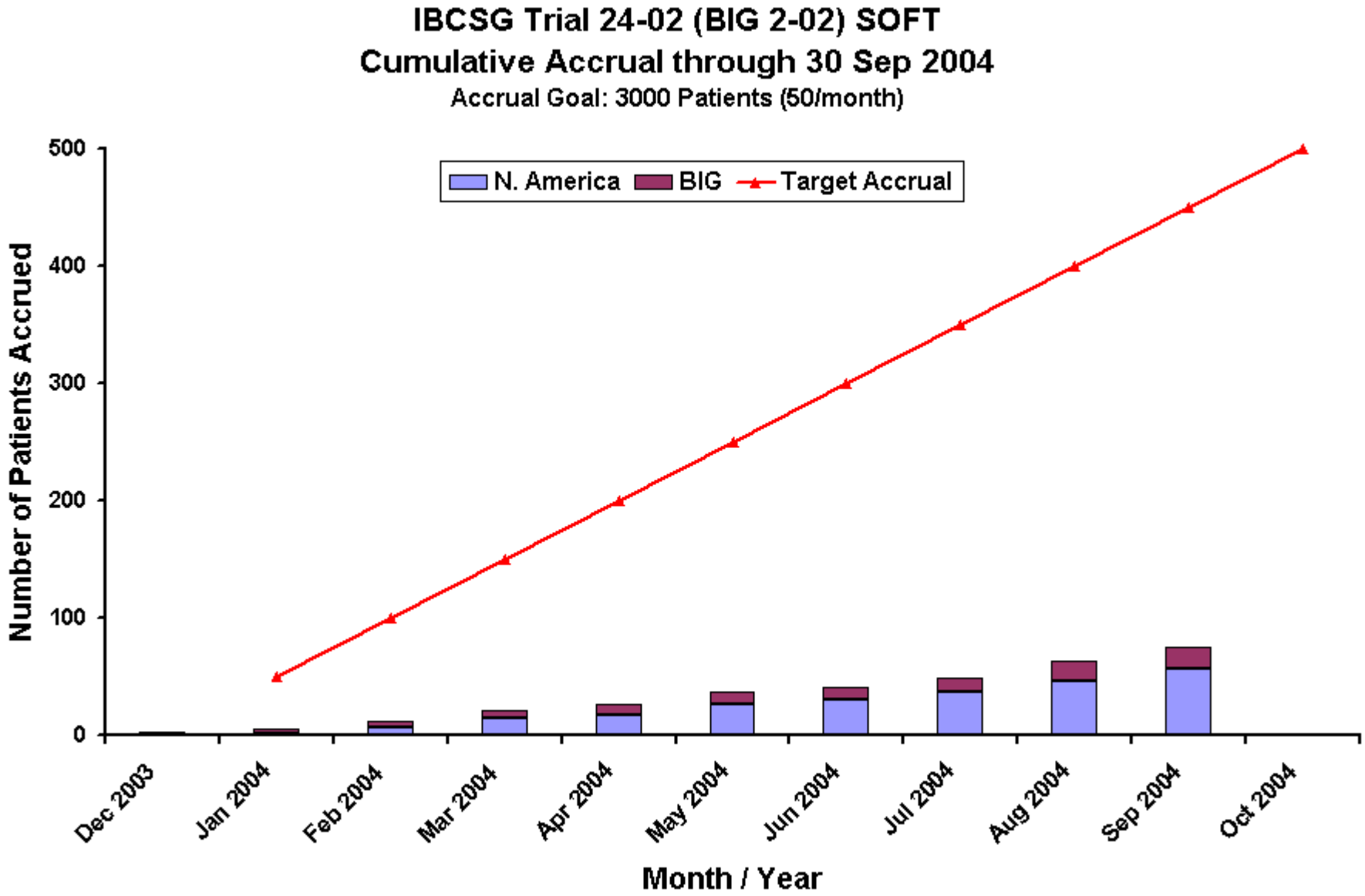
(through September 30, 2004)



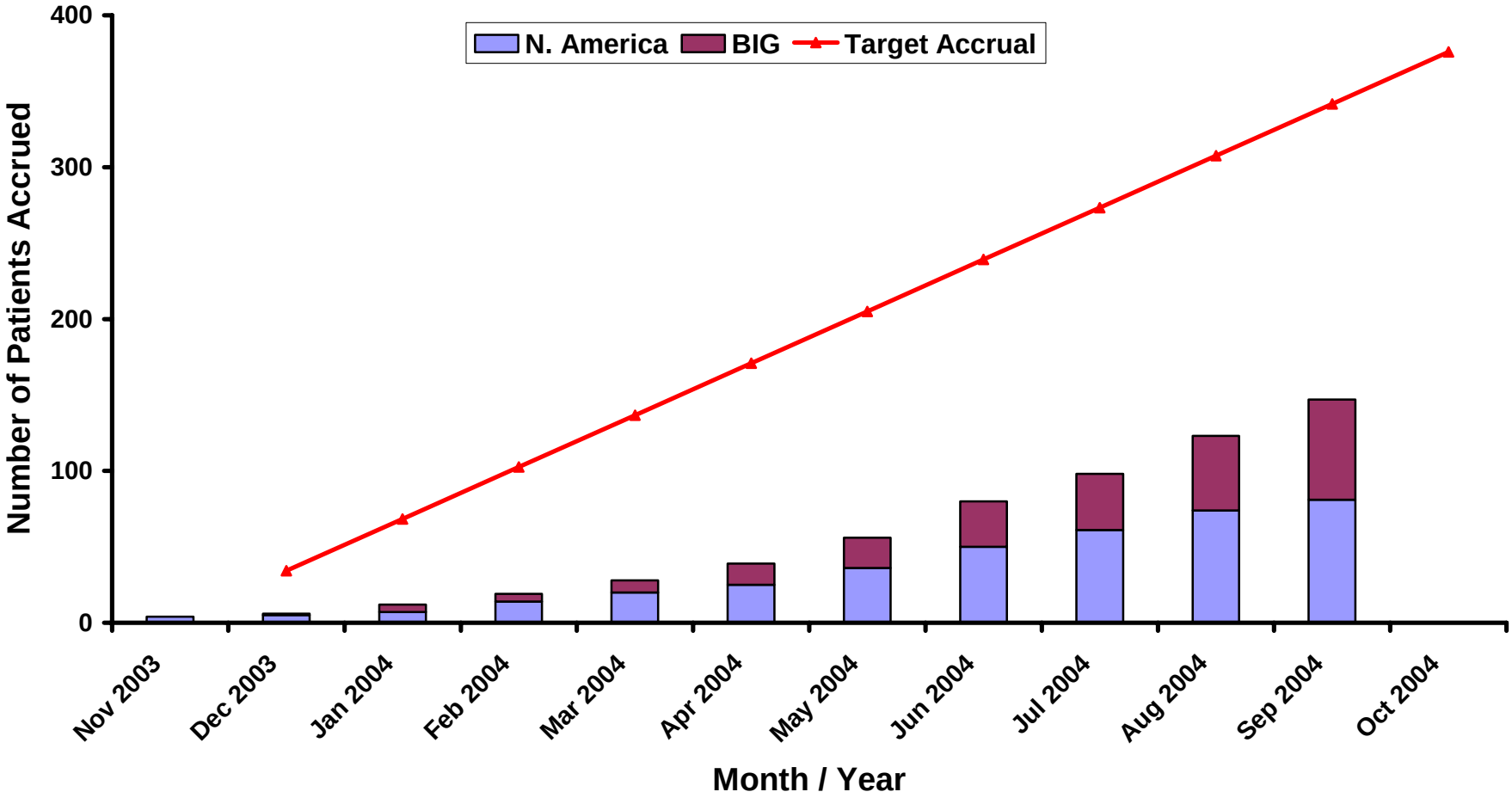
STP Accrual

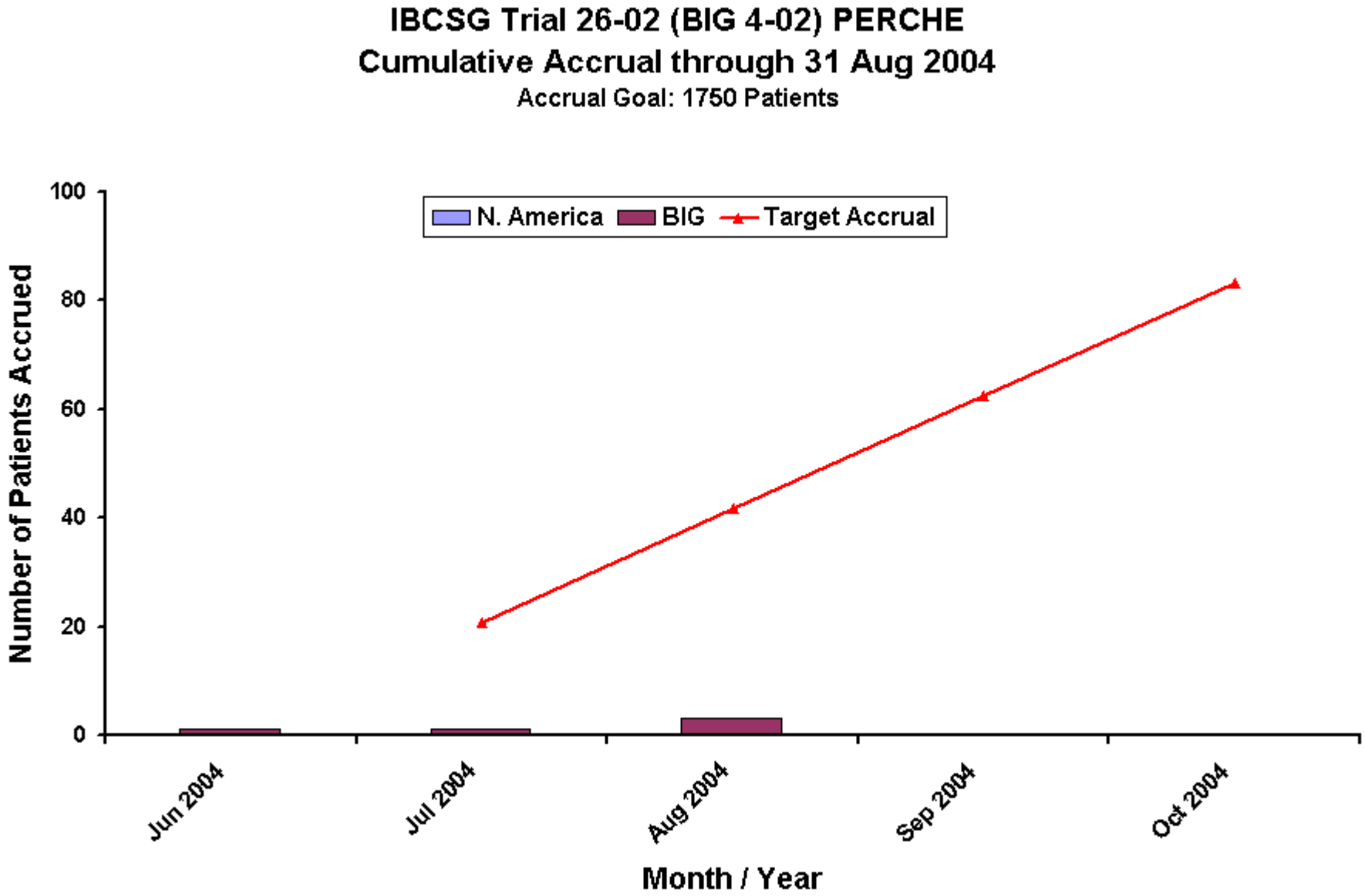
(through September 30, 2004)




IBCSG Trial 24-02 (BIG 2-02) SOFT
Cumulative Accrual through 30 Sep 2004
Accrual Goal: 3000 Patients (50/month)
N. America
BIG
Target Accrual
Number of Patients Accrued
0
100
200
300
400
500
Dec 2003
Jan 2004
Feb 2004
Mar 2004
Apr 2004
May 2004
Jun 2004
Jul 2004
Aug 2004
Sep 2004
Oct 2004
Month / Year

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
N. America
BIG
Target Accrual
Number of Patients Accrued
100
80
60
40
20
0
Jun 2004
Jul 2004
Aug 2004
Sep 2004
Oct 2004
Month / Year