NSABP B-39/RTOG 0413
Eligibility – 1

Stage 0, I, or II, assuming

- **Tumor**
  - DCIS or invasive (ductal or lobular)
  - \(< 3\) cm
  - Final negative margins (no ink on tumor)

- **Lymph nodes**
  - 0-3 +LN
  - - SLN
  - +SLN bx -> AND (total # LN removed \(\geq 6\))
  - AND (# LN removed \(\geq 6\))
  - No axillary staging needed for DCIS
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Eligibility – 2

Receptor Status

- Pre-randomization ER analysis
  - “borderline” will be considered +ve
- Pre-randomization PR analysis if ER-

Timing

- Pt MUST be randomized withing 42 days of last breast/axillary surgery
Pre-randomization Volume Analysis

- CT of breast breast
- Contour
  - Whole breast reference volume
  - Lumpectomy
- Calculate ratio
  - \( \text{Lumpectomy cavity volume} < 0.30 \) (30%) whole breast reference vol
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Eligibility – 4

Other

• Consent signed

• > 18 y/o

• Prior malignancy OK if:
  – CIS cervix, colon, melanoma
  – Basal and squamous skin cancer
  – No prior breast cancer – EVER!
    • Prior excised LCIS OK

• Life expectancy > 10 years
  – Excluding breast cancer prognosis
• Extracapsular nodal extension
• Any positive NON-axillary LN
  – Note, intramammary LN staged as axilla
• Palpable or radiographic findings concerning for disease outside of index lesion
• Metastatic disease
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Ineligibility - 2

• Anti-endocrine therapy for more than 28 days prior to randomization
• Any prior chemotherapy or XRT
• Breast implants
• Collagen-vascular disease
• Pregnancy
• Psychiatric/Addictive disorders
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Whole Breast Reference Volume

Definition:

All tissue within the boundaries of standard whole breast tangential fields, excluding lung.
Whole Breast Reference Volume

• How to:
  – Place pt in tx position/immobilization
  – Place markers around breast + medial/lateral tangent borders
  – CT from mandible-lung base
    • Slice thickness ≤ 5 mm
  – Simulate field sizes for tangents
  – Contour lumpectomy cavity and all tissue within tangent beams
    • Eliminate lung tissue from whole breast volume
  – Cavity:Breast ≤ 30%