| Sponsor validatio | n | Name: | | | | Date: | | | |
|---|--|-------------------------|--------------------|----------------------|-------------------------------|----------------------------------|---|----|------------------|
| ★ PC Console | | | | | | | | | ? |
| Protocol No.: 201312055 | Library: Oncology | | | PI: Thomas, Maria | | | Sponsor: RTOG - Radiation Therapy Oncology Group | | |
| Protocol Target Accrual: 1636 | | | Accrual To Date: 1 | | | Protocol Status: OPEN TO ACCRUAL | | | |
| RC Total Accrual Goal (Upper): IRB Expiration: 05/20/2016 | | | | | | | | | |
| Select Protocol | Details Management Staff Spo | onsor IND/IDE | ClinicalT | rials.gov / C | TRP | | | | |
| Main » | Sponsor Details History | | | | | | | | |
| | | 2 | | 3 | | Grant/Contract | | | |
| Treatment » | Sponsor | Sponsor Protocol No. | Role(s) | Principal Sponsor | Grant No. [Fund Acct. No.] | NIH/NCI Info | Title | PI | Department |
| Institution | RTOG - Radiation Therapy Oncology Group | 1304 / nsabp b-51 | | Y | | | | | Other Department |
| Accrual | | | | | 1 | ļ | | | |
| Status » | Data Table 4 Report Setting | | | | | | | | |
| | Sponsor type override | | | | | | | | |
| Reviews » | | | | | | | | | |

1. Sponsor name(s)

 Sponsor Protocol number – Cooperative Group numbers should appear here as well

Protocol : _____

 If Investigator Initiated, WU should be Principal Sponsor. Otherwise, the Primary Financial Sponsor should be the Principal Sponsor

Protocol : _____

- 1. Sponsor name(s)
- Sponsor Protocol number Cooperative Group numbers should appear here as well
- If Investigator Initiated, WU should be Principal Sponsor. Otherwise, the Primary Financial Sponsor should be the Principal Sponsor

| Update Protocol | Database Protocol ID:74 | 156 | | |
|--|--|----------------|-----------------------------|---------------|
| Title | 2440400110.00 | | | |
| | dy: A Randomized Phase : | TTT | PRMC Number | |
| Clinical Trial Evaluati and Regional Nodal XRT | ng Post-Mastectomy Chest and Post-Lumpectomy Reg: | twall ^ | 13-X414 | |
| | ith Positive Axillary No | odes | WU-IRB Number | WU-IRB Legacy |
| Before Neoadjuvant Chem Pathologically Negative | otherapy who Convert to | | 201312055 | |
| Neoadjuvant Chemotherap | | | | , |
| | | | Coordinating Group # 2 | |
| | | \sim | RTOG V 1304 / ns | abp b-51 |
| CTRP # | ClinicalTrials.Gov # | | Financial Tracking # | |
| NCI-2012-03198 | NCT01872975 | | 3274-941832 | |
| Study Coordinator | Regulatory Coordinator | | IND/IDE Number | |
| Shahab, Omar (Muhammad) | Felts, JoAnna (Joey) | | ⊖Yes ◉No ⊖Exemp | ot |
| (314)747-5059 shahabm@wudosis.wustl.edu | (314)747-3276 jfelts@dom.wustl.edu | | ✓ cIRB | |
| Phase | Date Submitted to PRM | C: | Initial WU-IRB Approval | |
| | 12/3/2013 | | 12/12/2013 | |
| | , | | Current WU-IRB Approval | |
| Externally Peer Reviewed | | | 6/5/2015 | |
| Locations (Check all that apply) | | | HSC Expiration | |
| | County 🗹 BJH - St. Peters 🗹 BJH | - South County | 5/20/2016 | |
| Study Type | Primary Purpose | - | Study Category | |
| Cooperative Group 🗸 | Treatment (TRE) | ~ | Therapeutic | ~ |
| Managing Group | Tags | | | |
| CTO-RadOnc | ~ | | | |
| Investigator Initiated | Therapeutic | Interventional | Scope | |
| O Yes | Yes | Yes | Nation | al |
| | ○ No | ○ No | ○ Local | |
| Study Section | Accrual Opened | | Accrual Closure | |
| 1.Agent or Device | ✓ 2/21/2014 | | | |
| _ | Projected Accrual Closu | ire | Length of Accrual | |
| ✓ Show on Summary 4 | - | | 5 yrs | |
| Original BJH Target Accrual | | | | |
| 10 | | | | |
| National Target Accrual | Current BJH Target Acc | crual | 1 yr Target Accrual | |
| 1636 | 4 | | 2 | |
| % Accrual Completion | Current Total Accrual | | Current BJH Only Accrual | |
| | 1 | | 1 | |
| Comments: | | | Nat'l StudyWide Accrual | |
| 2.26.14: checked WC box | per SM. AD | | 53 | |
| | | \sim | | |
| | | | Date StudyWide Updated Thro | ugh |
| | | | | |

| New Sponsor | | | | | | | | |
|---|----------------------|--------------------------|-----------|--------------------------|--|--|--|--|
| ID A Protocol Number Sponsor | Final Contract Rec'd | Contract Required | Holds IND | Primary Financial | | | | |
| 5861 1304 / nsabp b-51 RTOG - Radiation Therapy Oncology Group | 02/21/2014 | True | False | False 3 | | | | |
| New Grant | | | | | | | | |
| ID 🔺 Primary Investigator Grant Number Project Title Sponsor Project Begin Date Project End Date Status | | | | | | | | |
| | | | | | | | | |