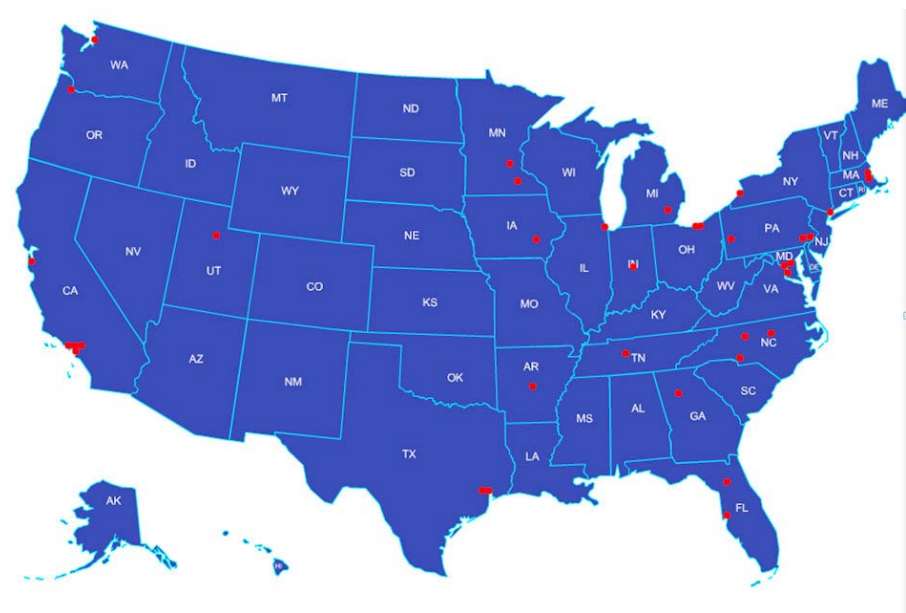


SARC

- Incorporated November, 2003
 - Non-profit organization (501c3)
- Mission
 - To provide a collaborative platform to make progress in the prevention, diagnosis and treatment of sarcoma
- Guiding principle
 - Those sites with a large volume of sarcoma patients seen by dedicated experts will perform the best quality research and most rapidly improve patient care

SARC Participants

- 40 centers across US
- Participation criteria
 - 80 new sarcoma patients annually
 - 20 if practice is limited to pediatrics
 - CTOS membership
 - Active research commitment and involvement



SARC Organization

- Board Directors led organization
- Operations office in Ann Arbor, MI
 - Project management staff
 - Finance
 - Medical Officer
 - Chief Operating Officer
- Statistical and Data Center in Seattle, WA
- Subcommittees
 - Executive
 - Developmental Therapeutics
 - Career Development
 - Participant
 - Concept Review Committee
 - SPORE
- Biannual member meetings (CTOS/ASCO)

Common Features of Studies

- Multi-center
 - Pediatric and medical oncology
- Rotating leadership for studies
- Novel agents and / or novel design
- Multiple subtypes of sarcoma permitted
- Biological correlative studies
- Discussions between lead and collaborating investigators yields final protocol
- Web-based patient registration and data capture

Funding Sources

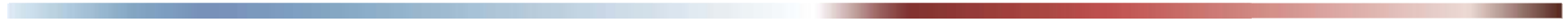
- Department of Defense
 - MPNST
- Pharmaceutical Partners
- Philanthropy

Global Collaboration

- Operational Logistics
 - Contracts and budgets
 - Contact for protocol/ eligibility/ enrollment questions
 - Central review process for pathology and images.
 - Insurance provider for sites
 - SAE submission and follow-up
 - Monitoring/auditing
 - Drug distribution

Lessons Learned

- SARC011
- N=305
- Median age
 - Ewing's age 27
 - 135 pt (23 pt under 18, range 3 -18 years)
 - Osteosarcoma age 34
 - 38 pt (8 pt under age of 18, range 15-18 years)
- Accrual “brisk”
 - Accrual completed for entire study in 20 months
- Importance of collaboration for accrual to both adult and pediatric population of subtypes



SARC001: Imatinib in multiple subtypes of metastatic sarcoma

- Primary endpoint:
- Overall study accrual
 - N= 241 patients
 - 4 years
 - Seven sites participated
- Osteosarcoma accrual
 - N= 27 patients
 - 6 sites
 - 3.5 years

SARC003: Gemcitabine/Docetaxel in metastatic bone tumors

- Primary endpoint
- Overall study accrual
 - N=
 - 4 years
 - 11 sites
- Osteosarcoma accrual
 - N=14
 - 1 year
 - 8 sites
 - Arm closed for futility

SARC009: Dasatinib in selected subtypes of metastatic sarcoma

- Primary endpoint
- Overall study accrual
 - N=
 - Activated 5/07 (remains open)
 - 18 sites
- Osteosarcoma accrual
 - N= 47
 - 2 years (paused several times for analysis)
 - 17 sites

SARC011: IGF-1R antibody in Ewing's, Osteosarcoma, Synovial, Rhabdomyosarcoma and other sarcomas

- Primary endpoint
- Overall study accrual
 - N= 305
 - 21 months
 - 39 sites (EU/Australia-18 sites, US-21)
- Osteosarcoma accrual
 - N= 38 (EU/Australia-6, US 32)
 - 8 months
 - 14 sites (EU/Australia-2, US-12)

SARC012: SRC-kinase inhibitor in metastatic osteosarcoma (lung only) following complete resection

- Primary endpoint
- Study accrual
 - N= 4
 - Open to accrual for 9 months
 - 12 sites open over the past 9 months
 - 4 patients accrued from 2 sites