
The principle investigator/program director for this project is Laurence H. Baker, DO, Executive Director-SARC.
The recipient business officer for this project is Denise Reinke, MS, NP, Administrative Director-SARC.

The period covered by this grant was from 8/01/2006 to 7/31/2007.

Background Statement:

SARC is a non-for-profit, 501.c.3 organization, whose mission and vision is to advocate for the collaboration on the design of clinical trials in sarcoma, to further the knowledge regarding the diagnosis and treatment of sarcoma and provide accurate and up to date information to physicians, patients and families.

Sarcomas are a heterogeneous group of rare diseases that affect 10,000-12,000 Americans each year. Unique as a group of cancers, sarcomas occur at any age, from newborn, child, young adult to senior citizens.

Clinical trial research in sarcomas gives us new insights into causation, treatment and prevention of sarcomas. SARC believes that in order to achieve the best outcomes for sarcoma patients, two important components are required:

1. Sufficient institutional expertise in the diagnosis and treatment of sarcoma
2. Multidisciplinary team of dedicated sarcoma experts.

SARC as a collaborative group of sarcoma specialists affiliated with over 24 major cancer centers throughout the U.S. and partnered with multiple European sites is uniquely positioned to provide the structure and expertise to accomplish the following objectives. These objectives, as stated in our project application are:

1. Assist in the development of the infrastructure for the continued growth and spectrum of clinical research advocated by SARC
2. Facilitate biannual meeting of SARC investigators
3. Develop a preclinical research base that would design and conduct research that would improve on the process of drug treatments selected for clinical research trials.

SARC has accomplished all of the stated objectives identified in our original proposal (see Table 1, list of SARC participating investigators and their affiliated institutions at time of our application and Table 2, list of current participating investigators and their affiliated institutions as of 7/31/2007). There has been significant growth of collaborative effort to achieve better outcomes for sarcoma patients.

While the use of conventional therapies have been employed in the treatment of sarcomas, these have had limited and less than substantial success. SARC has initiated several new clinical trials that employ novel targeted therapies in the last year (see Table 3 for complete list of current SARC trials).

SARC has hosted 2 biannual meetings for sarcoma specialists, in June of 2006 at the ASCO(American Society of Clinical Oncologist) in Atlanta, and November of 2006 at the CTOS(Connective Tissue Oncology Society) meeting in Venice. These meetings had a very significant attendance by sarcoma researchers from the U.S. and Europe. The meetings had an educational component as well as a collaborative agenda to enhance clinical trial participation and design. (See Tables 4 & 5 for program agendas for the SARC sponsored meetings at ASCO and CTOS). The attendance at the ASCO meeting was approximately 90 and the attendance for the CTOS meeting was approximately 350.

The markedly increased attendance of pediatric and surgical oncologist at these meetings is evidence of the success of the efforts of SARC to enhance collaborative practice across medical disciplines.
Actual attendance would be difficult to provide as in particular for the ASCO meeting, the meeting room was filled to standing room only. Interest in new treatment modalities and updates on current therapies continues to grow as SARC has been increasingly recognized as a strong organization dedicated to improving outcomes for sarcoma patients and for its ability to engage key medical providers in this endeavor.

SARC has secured a grant to help fund new clinical investigators research and funding to support a Developmental Therapeutics Committee to provide direction and assistance in the development of new novel therapeutic agents for clinical trials. This is a very significant accomplishment which will engage prominent Phase I researchers in experimental therapeutic investigation. The establishment of a sarcoma tissue bank will greatly facilitate this research effort as well as the securing of key biomarkers during the conduct of early clinical trials. SARC will facilitate basic research to move quickly and safely to Phase II and Phase III clinical trials utilizing unique data analysis and by expediting the conduct of clinical trials.
<table>
<thead>
<tr>
<th>Table 1: SARC Participating Investigators and the affiliated Institution</th>
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</thead>
<tbody>
<tr>
<td>1. James Butrynski, MD</td>
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<tr>
<td>a. University of Washington</td>
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<tr>
<td>2. Sant Chawla, MD</td>
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<tr>
<td>a. Century City Hospital</td>
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<tr>
<td>3. Arthur Staddon, MD</td>
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<tr>
<td>a. Pennsylvania Oncology</td>
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<td>4. Martin Blackstein, MD</td>
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<tr>
<td>a. University of Toronto</td>
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<tr>
<td>5. Amir Shahlaee, MD</td>
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<tr>
<td>a. University of Florida</td>
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<tr>
<td>6. William Tap, MD</td>
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<tr>
<td>a. UCLA*</td>
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<tr>
<td>7. Dennis Priebat, MD</td>
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<tr>
<td>a. Washington Cancer Institute*</td>
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<tr>
<td>8. Chris Ryan, MD</td>
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<tr>
<td>a. Oregon Health Science</td>
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<tr>
<td>9. Meg Von Mehren, MD</td>
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<tr>
<td>a. Fox Chase Cancer Center</td>
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<tr>
<td>10. Robert Benjamin, MD</td>
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<tr>
<td>a. MD Anderson Cancer Center*</td>
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<tr>
<td>11. Robert Maki, MD, PhD</td>
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<tr>
<td>a. MSKCC*</td>
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<td>12. Scott Schuetze, MD, PhD</td>
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<tr>
<td>a. University of Michigan*</td>
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<td>13. Lee Helman, MD</td>
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<tr>
<td>a. NCI-Pediatric Branch*</td>
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<tr>
<td>14. Gina D’Amato, MD</td>
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<tr>
<td>a. Moffitt Cancer Center</td>
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<tr>
<td>15. Michael Fanucchi, MD</td>
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<tr>
<td>a. Emory</td>
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<tr>
<td>16. George Demetri, MD</td>
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<tr>
<td>a. Dana Farber</td>
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<tr>
<td>17. David Harmon, MD</td>
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<tr>
<td>a. Massachusetts General</td>
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<tr>
<td>18. Scott Okuno, MD</td>
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<tr>
<td>a. Mayo Clinic</td>
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</tbody>
</table>

* indicates founding participating PI and institution
<table>
<thead>
<tr>
<th>Institution</th>
<th>Participants</th>
</tr>
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<tbody>
<tr>
<td>Arkansas Children's Hospital</td>
<td>Kimo Stine, MD</td>
</tr>
<tr>
<td>Carolinas Hem/Onc</td>
<td>Michael Livingston, MD</td>
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<tr>
<td>Cedars Sinai Medical Center</td>
<td>Charles Forscher, MD</td>
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<tr>
<td>City of Hope National Medical Center</td>
<td>Warren Chow, MD</td>
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<tr>
<td>Cleveland Clinic</td>
<td>Thomas Budd, MD</td>
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<tr>
<td>Dana-Farber Hospital [DF]</td>
<td>George Demetri, MD</td>
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<tr>
<td>Emory University</td>
<td>TBD</td>
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<tr>
<td>Fox Chase Cancer Center [FCCC]</td>
<td>Margaret von Mehren, MD</td>
</tr>
<tr>
<td>H. Lee Moffitt Cancer Center and Research Institute</td>
<td>Gina Z. D'Amato, MD</td>
</tr>
<tr>
<td>Huntsman Cancer Institute</td>
<td>R Lor Randall, MD</td>
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<tr>
<td>Johns Hopkins Medical Center</td>
<td>David Loeb, MD</td>
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<tr>
<td>Massachusetts General Hospital [MGH]</td>
<td>David Harmon, MD</td>
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<tr>
<td>Mayo Clinic</td>
<td>Scott Okuno, MD</td>
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<tr>
<td>MD Anderson Cancer Center [MDACC]</td>
<td>Shreyaskumar Patel, MD</td>
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<tr>
<td>Memorial Sloan Kettering Cancer Center [MSKCC]</td>
<td>Robert Maki, MD</td>
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<tr>
<td>National Cancer Institutes/NIH</td>
<td>Lee Helman, MD</td>
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<tr>
<td>Oregon Health and Science University [OHSU]</td>
<td>Christopher Ryan, MD</td>
</tr>
<tr>
<td>Pennsylvania Onc/Hem Associates</td>
<td>Arthur P. Staddon, MD</td>
</tr>
<tr>
<td>Sarcoma Oncology Center</td>
<td>Sant Chawla, MD</td>
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<tr>
<td>Stanford Comprehensive Cancer Center</td>
<td>Charlotte Jacobs, MD</td>
</tr>
<tr>
<td>Texas Children's Cancer Center [TXCCC]</td>
<td>Alberto Pappo, MD</td>
</tr>
<tr>
<td>UCLA Cancer Center</td>
<td>William Tap, MD</td>
</tr>
<tr>
<td>University of Florida Health/Science Ctr [UFL]</td>
<td>Amir Shalaee, MD</td>
</tr>
<tr>
<td>University of Michigan Cancer Center [UM]</td>
<td>Scott Schuetze, MD, PhD</td>
</tr>
<tr>
<td>University of Washington</td>
<td>Doug Hawkins, MD</td>
</tr>
<tr>
<td>Vanderbilt University Medical Center</td>
<td>James Whitlock, MD</td>
</tr>
<tr>
<td>Wake Forest</td>
<td>Paul Savage, MD</td>
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<tr>
<td>Washington, DC Cancer Inst. (Medstar)</td>
<td>Dennis Prieval, MD</td>
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</tbody>
</table>
Open Trials as of July 31, 2007

SARC 003 Gemcitabine/Docetaxel in Bone Sarcoma
SARC 004 Neoadjuvant Imatinib in DFSP
SARC 005 Adjuvant treatment of women with high High Risk Uterine Leiomyosarcoma
SARC 006 MPNST: Sporadic versus NF1 associated
SARC 007 Perifosine in chemoinsensitive sarcoma
SARC 009 Dasatinib in metastatic sarcoma
SARC Meeting
Atlanta, GA
June 2, 2006
8-12 noon
Marriott Hotel

8:00-8:10 Welcome
Larry Baker

Chawla-Rosenfeld Developmental Therapeutics Symposium

8:10-8:30 Preclinical Models: rapamycin/rapamycin analogs alone and in combination
Peter Houghton

8:30-8:40 Commentary on Peter Houghton’s presentation/moving to phase I
Anthony Tolcher

8:40-9:00 “Adaptive Randomization in Sarcoma Trials”
Peter Thall

9:00-9:15 Discussion
Peter Houghton

Trial Updates
9:15-9:25 Gleevec in sarcomas
Rashmi Chugh
9:25-9:35 Metastatic STS gemcitabine vs gemcitabine/docetaxel
Robert Maki
9:35-9:45 Bone sarcoma gemcitabine/docetaxel
Beth Fox
9:45-9:55 Neoadjuvant Gleevec in DFSP
Scott Schuetze
9:55-10:05 Adjuvant treatment of high risk uterine leiomyosarcoma
Martee Hensley

10:05-10:15 BREAK

10:15-10:25 MPNST
Brigitte Widemann
10:25-10:35 Perifosine in chemoresistant sarcomas
Dejka Steinart
<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
<th>Presenter(s)</th>
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<tbody>
<tr>
<td>10:35-10:50</td>
<td>New Lilly Compound</td>
<td>Robert Ilaria</td>
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<tr>
<td>10:50-11:05</td>
<td>Pulmonary Metastasis</td>
<td>Greg Kurt/Lee Helman</td>
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<tr>
<td>11:05-11:15</td>
<td>Dasatinib/STS</td>
<td>Scott Schuetze</td>
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<tr>
<td>11:15-11:25</td>
<td>GIST (Dasatinib/AMG 706)</td>
<td>Jon Trent</td>
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<tr>
<td>11:25-11:35</td>
<td>ET743 collaboration with European Study group</td>
<td>Larry Baker</td>
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<tr>
<td>11:35-12 noon</td>
<td>Business Meeting</td>
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</tbody>
</table>
8:00-8:15 Opening Remarks
Larry Baker

Chawla/Rosenfeld Developmental Therapeutics Symposia
8:15-8:45 mTOR inhibition/IGFR
Lee Helman
8:45-9:15 Operationalizing the Choi Criteria
Haesun Choi
Robert Benjamin
Scott Schuetze

SARC/European Collaboration
9:15-10:00 “SMART” Trial SARC008
Sarcoma Maintenance Assessment Randomized Trial
Larry Baker

10:00-10:15 BREAK

Ongoing Trials
10:15-10:25 SARC003
Combination gemcitabine/docetaxel in Ewing’s Sarcoma, Osteosarcoma and Chondrosarcoma
Shreyas Patel
10:25-10:40 Statistical Update SARC003
Kyle Wathen
10:40-10:45 SARC004
Preoperative imatinib in DFSP
Scott Schuetze
10:45-10:55 SARC005
Adjuvant treatment of high risk uterine leiomyosarcoma
Robert Maki
10:55-11:05 SARC006
Treatment of malignant peripheral nerve sheath tumor in sporadic vs nfl associated
Lee Helman
11:05-11:15 SARC007
Perifosine in chemoresistant sarcoma
Dejka Steinart
11:15-11:25 SARC009
Dasatinib in selected sarcoma subtypes
Scott Schuetze

SARC Organization
11:25-11:35 Participation in SARC trials
Robert Maki
11:35-11:45 New Concept: Submission Procedure and Review
Robert Maki

11:45-12:00 Business Meeting
October 28, 2007

To the Department of Energy,

No Special Status Report or Scientific/ Technical Report has been compiled for the attached Grant #DE-FG02-06ER64251 since there would be nothing to report.

Jim Arkison
Financial Manager
SARC
FEDERAL CASH TRANSACTIONS REPORT

(See instructions on back. If report is for more than one grant or assistance agreement, attach completed Standard form 272A.)

1. Federal sponsoring agency and organization element to which this report is submitted
   U.S. Department of Energy-Office of Science Chicago Office

2. RECIPIENT ORGANIZATION
   Name
   SARC

   Number and Street
   24 Frank Lloyd Wright Drive, P.O. Box 406

   City, State and ZIP Code
   Ann Arbor, MI 48106

3. FEDERAL EMPLOYER IDENTIFICATION NO.
   86-1087705

   FROM (month, day, year) 8/1/06 TO (month, day, year) 7/31/07

   a. Cash on hand beginning of reporting period 0.00
   b. Letter of credit withdrawals
   c. Treasury check payments 241,000.00
   d. Total receipts (Sum of lines b and c) 241,000.00
   e. Total cash available (Sum of lines a and d) 241,000.00
   f. Gross disbursements 241,000.00
   g. Federal share of program income
   h. Net disbursements (Line f minus line g) 241,000.00
   i. Adjustments of prior periods
   j. Cash on hand end of period 0.00

11. STATUS OF
   FEDERAL

12. THE AMOUNT SHOWN ON LINE 11], ABOVE, REPRESENTS CASH REQUIREMENTS FOR THE ENSUING DAYS

13. OTHER INFORMATION
   a. Interest Income 0.00
   b. Advance to subgrantees or subcontractors

14. REMARKS
   (Attach additional sheets of plain paper, if more space is needed)

15. CERTIFICATION
   I certify that to the best of my knowledge and belief that this report is true in all respects and that all disbursements have been made for the purpose and conditions of the grant or agreement.

   AUTHORIZED CERTIFYING
   SIGNATURE
   TYPED OR PRINTED NAME AND TITLE
   Denise K. Reinke, Administrative Director

   DATE REPORT SUBMITTED
   October 19, 2007

   TELEPHONE (Area Code, Number, Extension)
   734-930-7600

   This space for agency use

STANDARD FORM 272 (Rev. 7-97)
Prescribed by OMB Circulars A-102 and A-110
FINANCIAL STATUS REPORT

1. Federal Agency and Organizational Element to Which Report is Submitted
   Procurement Services Division
   DOE, Idaho Operations Office

2. Federal Grant or Other Identifying Number Assigned By Federal Agency
   DE-FG02-06ER64251

3. Recipient Organization (Name and complete address, including ZIP code)
   SARC
   24 Frank Lloyd Wright Dr., P.O. Box 406, Ann Arbor, MI 48106

4. Employer Identification Number
   86-1087705

5. Recipient Account Number or Identifying Number

6. Final Report
   □ Yes □ No

7. Basis
   □ Cash □ Accrual

8. Funding/Grant Period (See instructions)
   From: (Month, Day, Year) August 1, 2006
   To: (Month, Day, Year) July 31, 2007

9. Period Covered by this Report
   From: (Month, Day, Year) August 1, 2006
   To: (Month, Day, Year) July 31, 2007

10. Transactions
    Report the transactions for the budget period - not the whole project

    a. Total outlays
       $241,000

    b. Recipient share of outlays
       0

    c. Federal share of outlays
       241,000

    d. Total unliquidated obligations
       0

    e. Recipient share of unliquidated obligations
       0

    f. Federal share of unliquidated obligations
       0

    g. Total federal share (Sum of lines c and f)
       241,000

    h. Total Federal funds authorized for this funding period
       241,000

    i. Unobligated balance of Federal funds (Line h minus line g)
       0

11. Indirect Expense
    a. Type of Rate (Place "X" in appropriate box)
       □ Provisional □ Predetermined □ Final □ Fixed
    b. Rate
       25.000%
    c. Base
       $192,800
    d. Total Amount
       $48,200
    e. Federal Share
       $48,200

12. Remarks: Attach any explanations deemed necessary or information required by Federal sponsoring agency in compliance with governing legislation.

13. Certification:
    I certify to the best of my knowledge and belief that this report is correct and complete and that all outlays and unliquidated obligations are for the purposes set forth in the award documents.

Typed or Printed Name and Title
Denise K. Reinke, Administrative Director

drinking@sarctrials.com 734-990-7300

Signature of Authorized Certifying Official

Date Report Submitted
October 19, 2007

NSN 7640-01-318-4387
269-202

Standard Form 269A (Rev. 7-97)
Prescribed by OMB Circulars A-102 and A-110