

Vitamin D and Type 2 Diabetes

Pharmacy Coordinating Center



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Cooperative Studies Program
Clinical Research Pharmacy Coordinating Center
Research and Development, Department of Veterans Affairs



Who we are



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Clinical Research Pharmacy Coordinating Center
Research and Development, Department of Veterans Affairs





VETERANS HEALTH ADMIN Office of Research & Development (ORD)

**Biomedical
Laboratory
R&D**

**Clinical
Science
R&D**

**Health
Services
R&D**

**Rehabilitation
R&D**

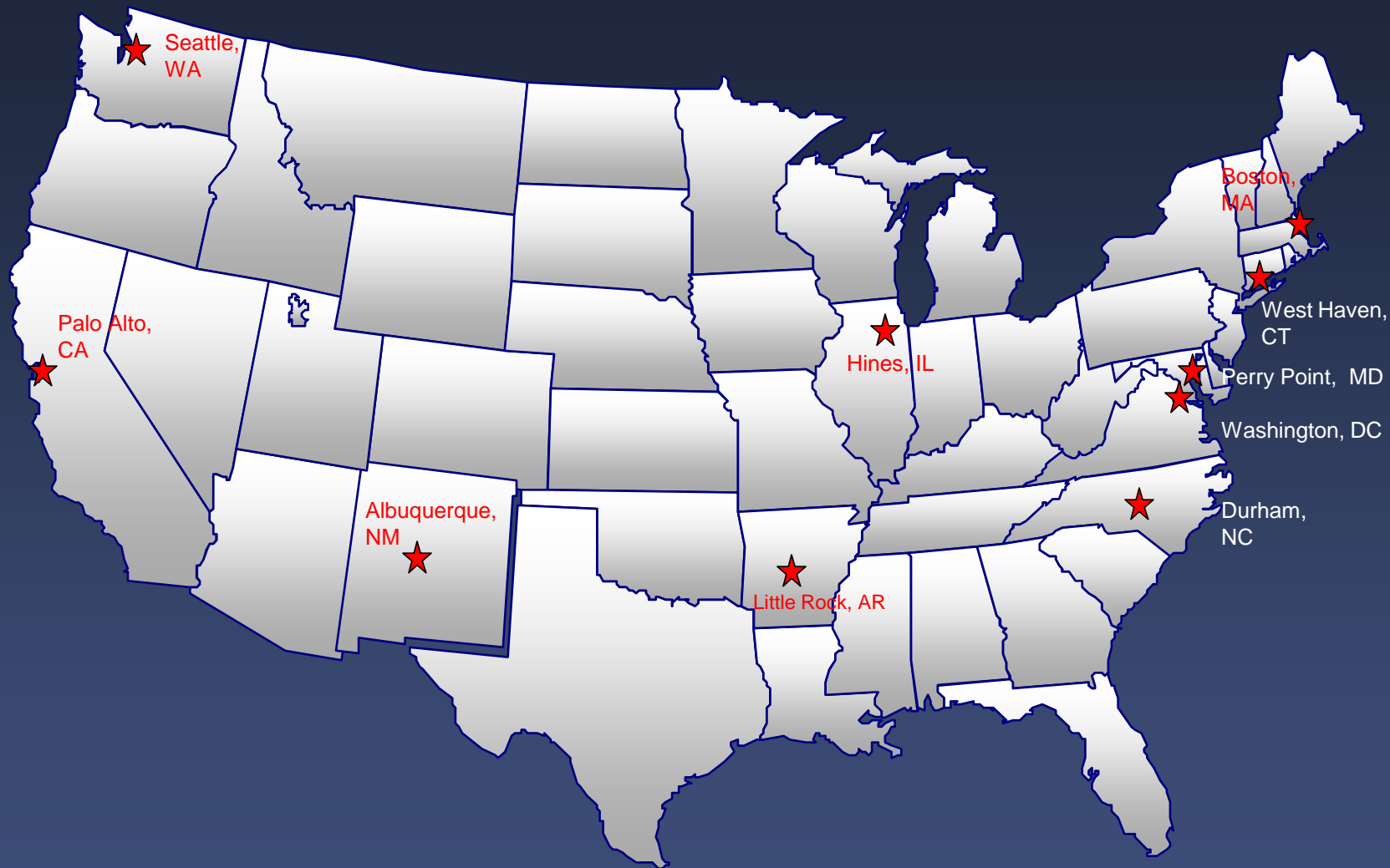
**Cooperative Studies
Program**



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CSP CENTER LOCATIONS



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VA CSP Clinical Research Pharmacy Coordinating Center

- ▲ FDA Registered Facility
- ▲ ISO 9001:2008 and 15378
- ▲ Commitment to Quality



*VA Cary
Organizational
Excellence
Trophy Award
2004*

*VA Circle of Excellence
Awards
2006, 2007, 2009*



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PCC Services-D2d

- ▲ Receipt
- ▲ Packaging
- ▲ Labeling
- ▲ Analytical Testing
- ▲ Shipping to sites
- ▲ Web based Inventory



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GRADE

Glycemia Reduction Approaches in Diabetes:
A Comparative Effectiveness Study

NIDDK
NATIONAL INSTITUTE OF
DIABETES AND DIGESTIVE
AND KIDNEY DISEASES

Action to Control Cardiovascular Risk in Diabetes

ACCORD

SPRINT

Systolic Blood Pressure Intervention Trial

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Therapies for Active Rheumatoid Arthritis after Methotrexate Failure



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FLAT

SUGAR



The NEW ENGLAND
JOURNAL of MEDICINE

HOME ARTICLES & MULTIMEDIA ▾ ISSUES ▾ SPECIALTIES & TOPICS ▾ FOR AUTHORS ▾ CME ▸

ORIGINAL ARTICLE

[A Correction Has Been Published](#) ▸ [A Correction Has Been Published](#) ▸

Glucose Control and Vascular Complications in Veterans with Type 2 Diabetes

William Duckworth, M.D., Carlos Abaira, M.D., Thomas Moritz, M.S., Domenic Reda, Ph.D., Nicholas Emanuele, M.D., Peter D. Reaven, M.D., Franklin J. Zieve, M.D., Ph.D., Jennifer Marks, M.D., Stephen N. Davis, M.D., Rodney Hayward, M.D., Stuart R. Warren, J.D., Pharm.D., Steven Goldman, M.D., Madeline McCarren, Ph.D., M.P.H., Mary Ellen Vittek, William G. Henderson, Ph.D., and Grant D. Huang, M.P.H., Ph.D. for the VADT Investigators
N Engl J Med. 2009; 360:129-139. | January 8, 2009 | DOI: 10.1056/NEJMoa0808431



Behind the Scenes

U.S. News & WORLD REPORT

CSP 558

Friday, May 4, 2007

Clinical Trials News: Using Robots to Regain Ground After a Stroke

By Sarah Baldauf
Posted 10/18/06

Blood-Letting Treatment Might Help Some Heart Patients

It appears to reduce harmful iron stores, especially for younger people

By Amanda Gardner
HealthDay Reporter

USA TODAY

CSP 403

Health and Behavior

Posted 6/1/2005 7:06 PM Updated 6/1/2005 9:30 PM

Shingles vaccine cuts cases by half

By Steve Sternberg, USA TODAY



U.S. Medicine

The Voice of Federal Medicine

Featured column

November, 2004

Advancing Veterans' Care Through Clinical Research



ABOVE: The Honorable R. James Nicholson (right), Secretary of Veterans Affairs, got a close look at some state-of-the-art equipment while touring the VA Clinical Research Pharmacy Coordinating Center. With him, from left, are: Mark Jones, Assistant Center Director; Dennis Raisch, Associate Center Director; and Mike Sather, Center Director.

washingtonpost.com

CSP 424

Heart Attack Study Casts Doubt On Routine Use of Angioplasty

By Rob Stein
Washington Post Staff Writer
Tuesday, March 27, 2007; A01

AP Associated Press

Piñon Press—September 2006

Brain pacemaker helps Parkinson's, but with risks

By CARLA K. JOHNSON



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DDC's Role in D2d

- ▲ Receive, label, & distribute study drugs
- ▲ Maintain drug inventory at clinical sites
- ▲ Stability testing of packaged drug
- ▲ Maintain interactive web response system (SPIRS-Study Pill Inventory and Randomization System).



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D2d Study Medication

- ▲ Vitamin D₃ 4000 IU Softgel and Placebo
- ▲ Supplier—Tishcon Corp.
- ▲ 2 year expiry date (1st batch-manufactured in April 2013)
- ▲ Excipients-Soybean Oil, gelatin, glycerin, purified water, corn oil



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D2d Study Medication

- ▲ 240 softgels per bottle (6 month supply)
- ▲ 120cc white HDPE bottle w/ childproof cap and foil tamper seal
- ▲ Silica desiccant packet



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Packaging/Labeling Configuration

- ▲ Bottle label will include
 - Unique 5-digit number
 - Barcode which can be used to document receipt in SPIRS
- ▲ Bottles will be packaged in 30 count kit box
 - 15 active/15 placebo randomly positioned



Bottle Label

D2d Study (P319)
Vitamin D₃ 4000 IU or Matching Placebo
Bottle 1XXXX
240 Softgels

Take One Softgel By Mouth Every Day

Store at 15°C to 30°C (59°F to 86°F)

D2d Study Coordinating Center
Tufts Medical Center, Boston, MA
617 – 636 – 3232

Distributed by VA Cooperative Studies Program CRPCC
Albuquerque, NM, 505 – 248 – 3203

Caution: New Drug – Limited By Federal Law To Investigational Use.



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Kit Box Label

D2d STUDY (P319)

Site 16 – UNIVERSITY OF NEBRASKA MEDICAL CENTER

Vitamin D₃ 4000 IU or Matching Placebo

240 Softgels Per Bottle

Store at 15° – 30°C (59° – 86°F)

Box #XXX

Contains Bottle Numbers:

1XXXX 1XXXX 1XXXX 1XXXX 1XXXX 1XXXX
1XXXX 1XXXX 1XXXX 1XXXX 1XXXX 1XXXX
1XXXX 1XXXX 1XXXX 1XXXX 1XXXX 1XXXX
1XXXX 1XXXX 1XXXX 1XXXX 1XXXX 1XXXX
1XXXX 1XXXX 1XXXX 1XXXX 1XXXX 1XXXX

Distributed by:
VA COOPERATIVE STUDIES PROGRAM CRPCC
ALBUQUERQUE, NM 87106
505 – 248 – 3203

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Tufts Medical Center
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617 – 636 – 3232



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Packaging Configuration Bulk Kit Box



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Study Drug Distribution

- ▲ All shipments via UPS (overnight)
- ▲ Site recipient will be notified via email from UPS with tracking number of pending delivery
- ▲ Initial and subsequent shipment quantities to be determined based on projected and/or current site enrollment data
- ▲ All shipments will include a Packing List detailing shipment contents



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Site Responsibilities

▲ Responsibilities

- Local Destruction of Study Medication in accordance with local policies
- Receiving/Dispensing Study Medication
- Study Medication Accountability in SPIRS



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Questions



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