

# A CLINIC BASED PROGRAM FOR ANTICOAGULATION MANAGEMENT USING AN OUTREACH PROGRAM AND PATIENT SELF-TESTING.

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## PROGRAM DESCRIPTION

A Coordinated Program for Patient-Specific Anticoagulant Therapy Management and Home Monitoring.  
 Contributing Partnership  
 University of Massachusetts - Memorial Medical Center  
 International Technidyne Corporation

## PROGRAM OBJECTIVES

Optimizing the delivery and management of anticoagulation therapy in a large university center with broad community outreach.

Optimize Patient Care

- Reduce Hospital Length of Stay (LOS)
- Reduce Costs
- Reduce Incidence of Adverse Events
- Facilitate Patient Return to Home

Historical Expectations of Moving Anticoagulation Management from Routine Medical Care (RMC) to Organized Anticoagulation Services (ACS)

### Analysis of Published Comparison Studies Adverse Events in Warfarin Therapy RMC versus ACS

# Studies/Type of Care	# of patients	Pt-years	Major Bleed	Thromboembolism
13 studies of ACS	14,105	19,362	4.4	4.8
6 studies comparing RMC and ACS				
RMC	480+	941.52+	10.9	16.2
ACS	562+	993.03+	2.8	2.4

Adverse event rate expressed as % per patient year

Ansell JE, Anticoagulation management as a risk factor for adverse events: Grounds for improvement. *J Thrombosis and Thrombolysis* 1998; 5:13-18.

## PATIENT DEMOGRAPHICS (N = 1100 + PATIENTS)

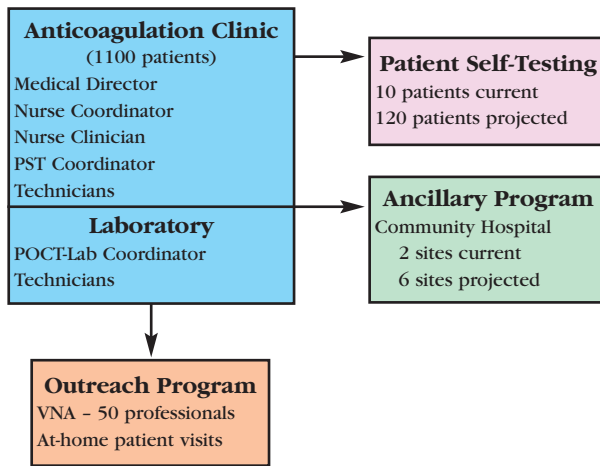
Indications for Anticoagulation

Atrial Fibrillation	50%
Treatment/prophylaxis of DVT	30%
Heart Valve Prosthesis	20%

## PROGRAM OPPORTUNITIES

- Patient Empowering Therapeutics
- Center of Excellence
  - Referral Center
  - Training Site
  - Care Coordinating Center

## PROGRAM COMPONENTS



## PT-INR TESTING AT THE POINT OF CARE (POC)

### Cooperative effort of the Laboratory and Clinic

- The laboratory staff is responsible for selection and validation of the POC System.
- The laboratory staff generated a comparison study protocol.
- The manufacturer provides protocol review and technical advice.
- Comparative testing is conducted by the clinic staff.
- Data analysis is conducted by the laboratory staff.
- The clinical staff defines operator interface requirements.
- The clinical team is responsible for selection of patient self-testers.

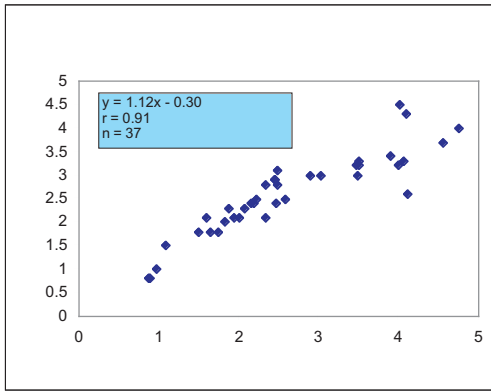
### POC System Selection



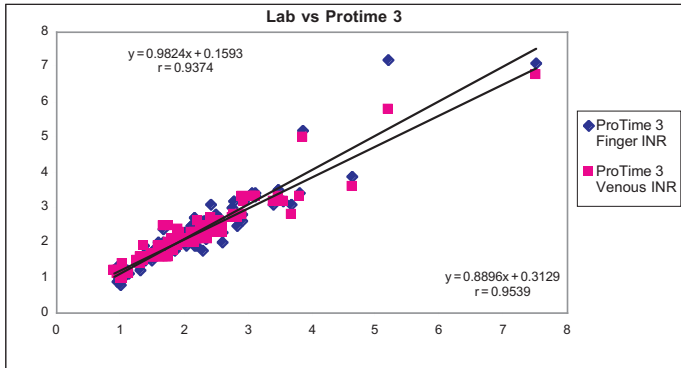
The ProTime® System includes the device, test cartridges and blood collection system (Tenderlett Plus LV)



The test cartridge includes a simultaneous measurement of the sample (e.g., patient) INR and two levels of integral controls. Patient INR values are displayed when controls meet pre-established ranges.



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