



CIC Progress Toward Open Connectivity Standards in Point of Care Testing

Report by the Connectivity Industry Consortium (CIC)
at the Open Committee Meeting of the
AACC POC Division
Industrial Liaison Committee
Emery J. Stephans, Chair
July 25, 2000
AACC San Francisco, California



Chair's Summary

Emery J. Stephans, Chair

POC Industrial Liaison Committee

AACC2000
25 July 2000
-2-

- Ms. Cathy Burzik, President, Ortho Clinical Diagnostics gave the keynote address
 - Compared the CIC's one-year mission (and good progress to date) with her experience with the seven-year struggle in imaging to establish industry-wide standards
- CIC on track against its targeted completion date of Spring 2001 (work initiated in late February 2000)
- Significant technical progress made on definition of technical standard and toward a pilot connectivity experiment. See in charts from presentations given by:
 - Suzanne Cross, CIC President
 - Jeff Perry, CIC VP and Chief Technical Officer
 - Mike Higgins Agilent Technologies
- Provider Review Committee status
 - Represents user community in CIC; Dr. James Nichols is Chair
 - User requirements defined and accepted
 - Liaison with AACC set up
 - Working closely within CIC to support work and track progress



Report on Overall CIC Progress

Suzanne Cross
CIC President

CIC Progress as of July 2001

- CIC organization
 - Fully staffed and operating
 - California non-profit corporation
 - 100% member funded
 - Bylaws, board of directors, officers
 - Working committees
 - Health care provider representation
 - Over 30 industry members collaborating to develop a standard
- CIC Vision
 - Exeditiously develop, pilot, and transfer the *foundation* for a set of seamless 'plug and play' POC communication standards ensuring fulfillment of the critical user requirements of bi-directionality, device connection commonality, commercial software interoperability, security, and QC / regulatory compliance.”

CIC Progress as of July 2001

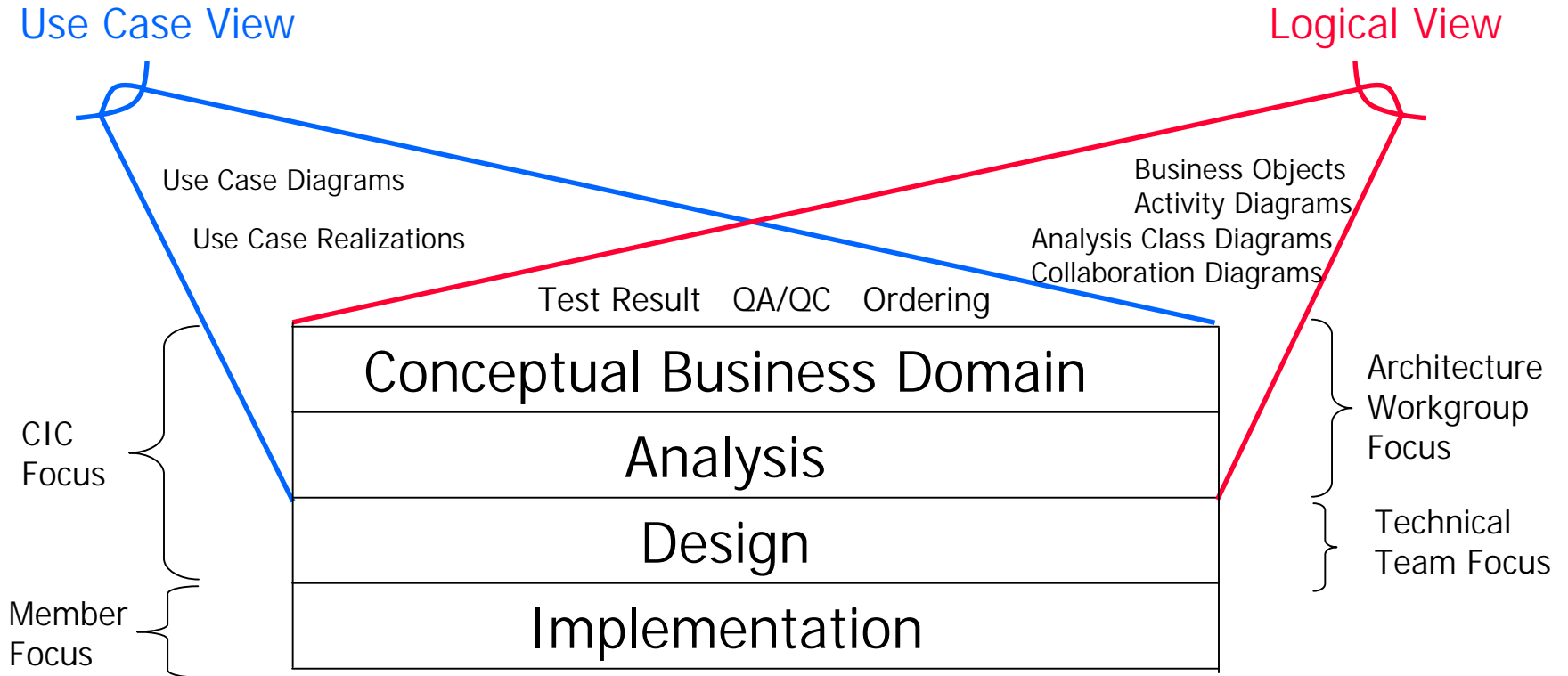
- Official start: February 2000
- Desired outcome:
 - Broad-based vendor and provider adoption
 - The recognized and accepted method for POC connectivity
 - Universal use
- Target completion: 12-15 months
 - February-May 2001
- Work proceeding on schedule
- “Sunset” built into CIC charter
 - CIC will transfer completed standard to a permanent standards-development organization for maintenance and further enhancement
- Next public checkpoint:
 - November 2000 at MEDICA in Dusseldorf, Germany
- CIC website:
www.poccic.com



Report on Technical Progress

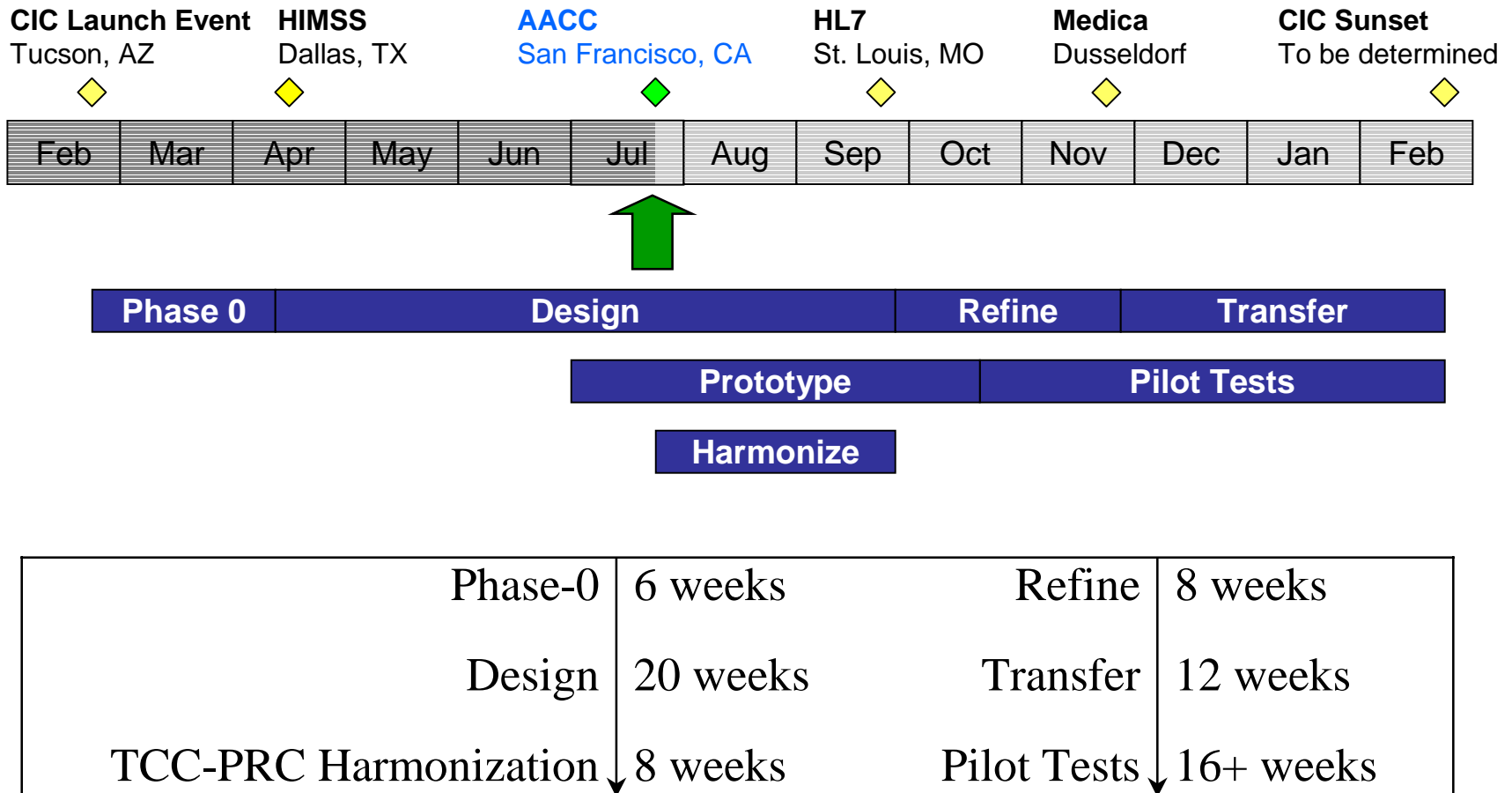
Jeff Perry
CIC Vice President and
Chief Technical Officer

CIC Development Process

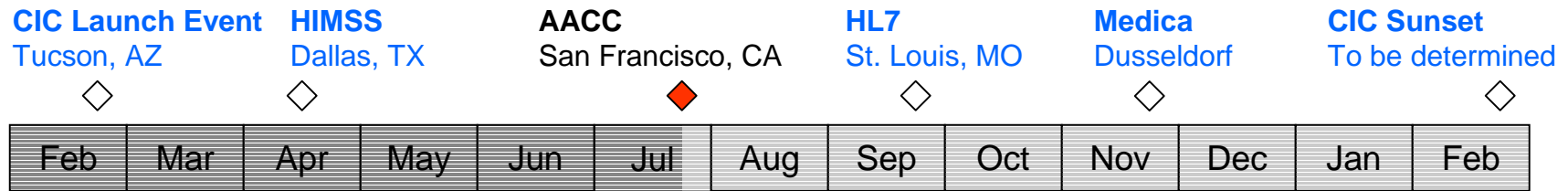


Note: Lessons and observations from Design and Prototyping work are fed back to refine the Architecture

Timeline and Phases



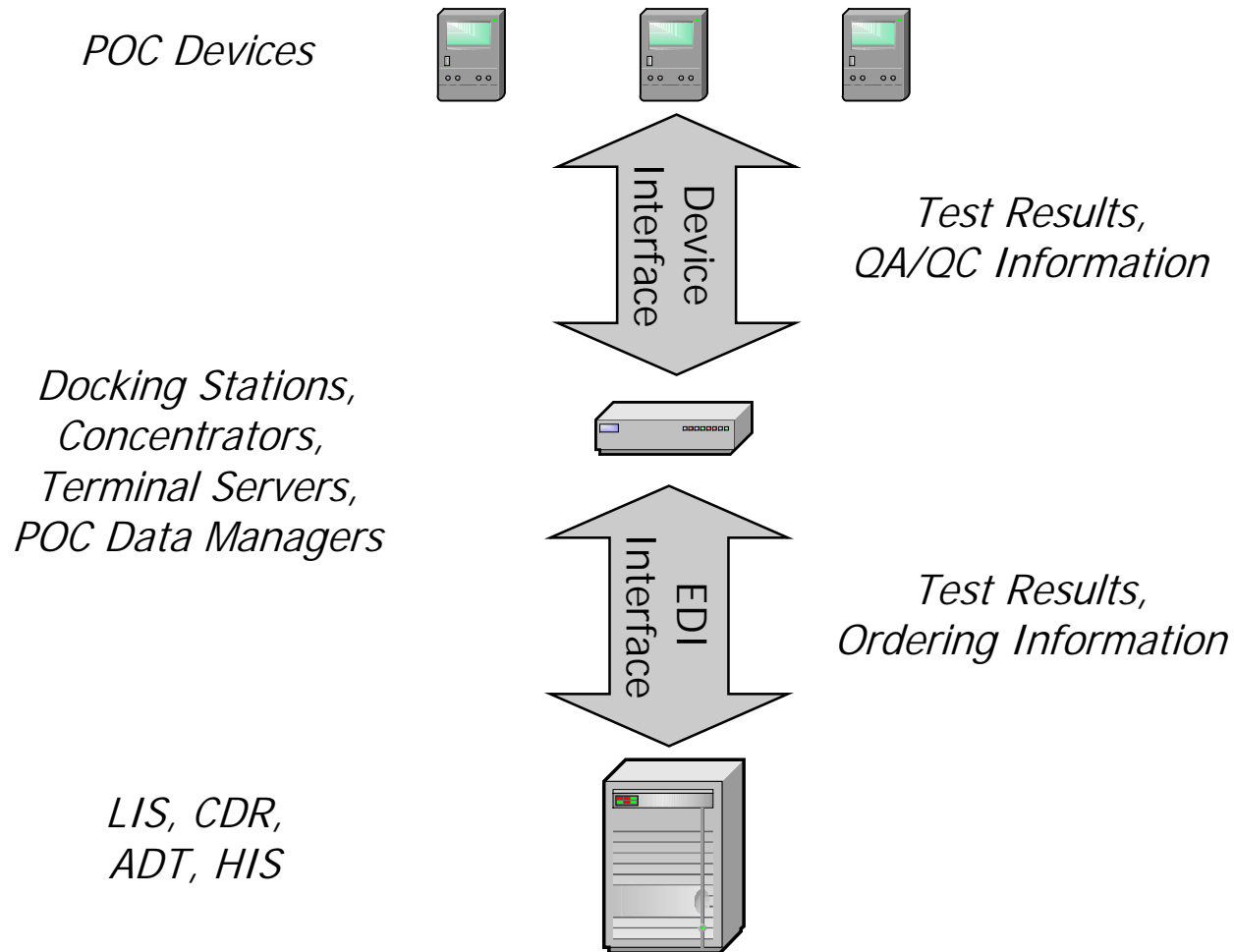
Development Milestone Accomplishments



Development Milestone - July 27, 2000

- Bayer Diagnostics sponsors CIC Technical Meeting in San Francisco.
- 48 member organizations
- Simple Patient Test Result message drafts completed
- "CIC Compatibility" proposal drafted
- Standards development process validated

Two Technical Focus Areas



Interfaces: Built on Proven Standards

Device Communication Interface

— (D)

- HL7/IEEE Information Model
- HL7 V2.X Abstract Syntax
- ER or XML Encoding

- Point-to-Point
- Cabled or Optical
- Intermittent Connection Use Model
- Multi-Analyte, Multi-Device
- Partial Message Attribution
- Leverage IEEE 1073.3.2 (MIB)

Observation Reporting Interface

— (R)

- Tied to site LAN infrastructure
- Point-to-Point, TCP/IP - *or* -
- Multi-Point, Message Queuing
- Multi-Analyte, Multi-Device
- Full Message Attribution
- Leverage IEEE 803.x



Decentralized Diagnostics Demonstration Project

*Tools for improving patient outcomes and
reducing cost*



Matthew D. Collier
President and CEO
Avocet Medical



Agilent Technologies

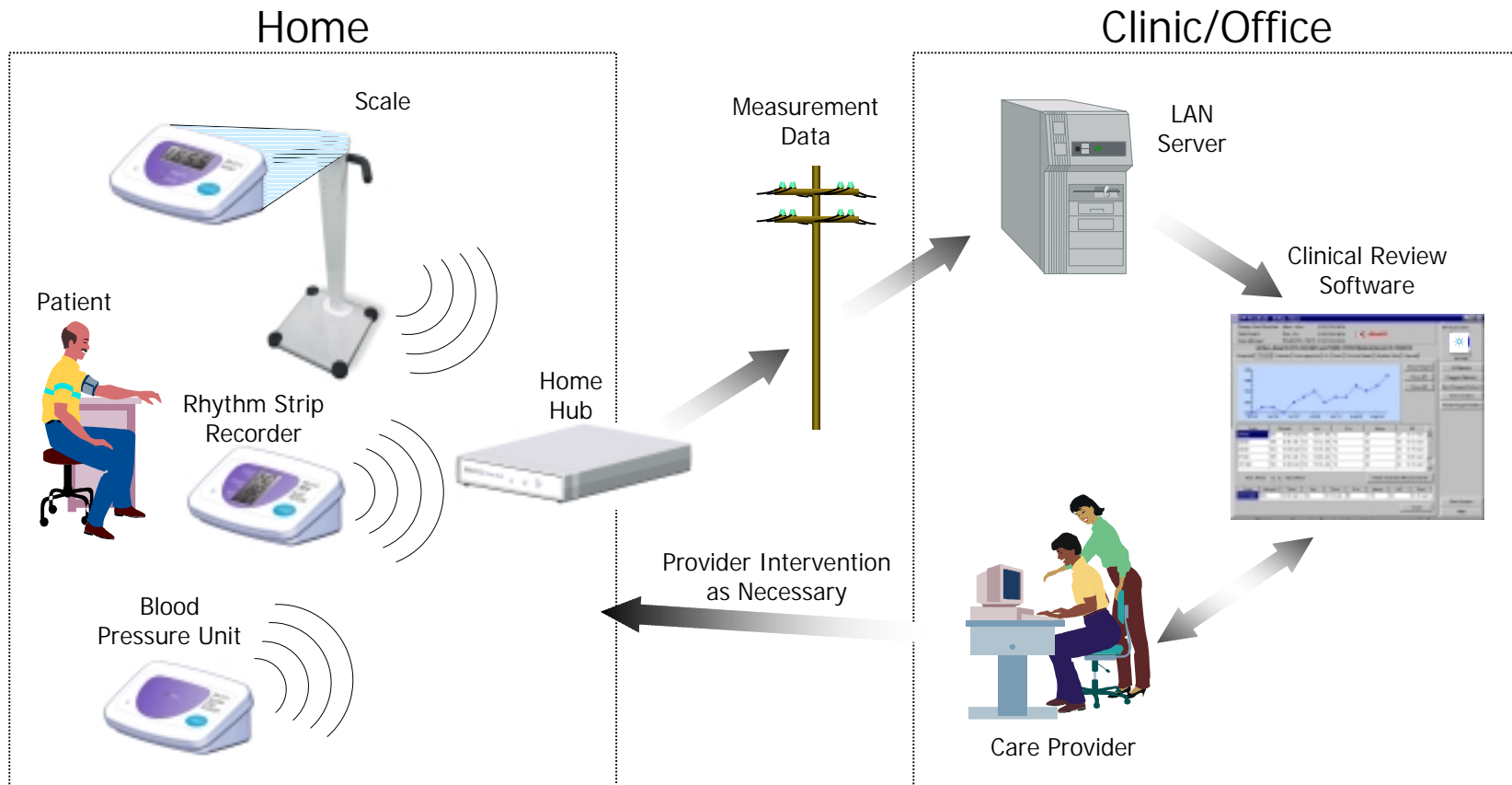
Michael C. Higgins, Ph.D.
Medical Department
Agilent Laboratories



KAISER PERMANENTE

Daniel Witt, PharmD
CPAS Chief
Kaiser Permanente

Example for Decentralized Diagnostics *Agilent's solution for CHF (Coronary Heart Failure) patients*



Clinical Pharmacy Anticoagulation Service (CPAS) *Kaiser Permanente, Colorado Denver/Boulder*

CPAS Objectives:

- Assist the physician and patient in systematic management of anticoagulation therapy;
- Decrease the possibility of untoward effects due to anticoagulation therapy failure or complications, including hospital admissions, emergency department visits, and medical office visits;
- Improve quality and consistency of care through development and implementation of anticoagulation therapy guidelines.

Outcome	CPAS	Traditional Care
Hospitalization		
Major bleeding	0.90% (6/663)	1.29% (4/331)
Thromboembolism	1.66% (11/663)	2.57% (8/331)
Total	2.71% (17/663)	3.86% (12/331)
Death	0.15% (1/663)	0.64% (2/331)

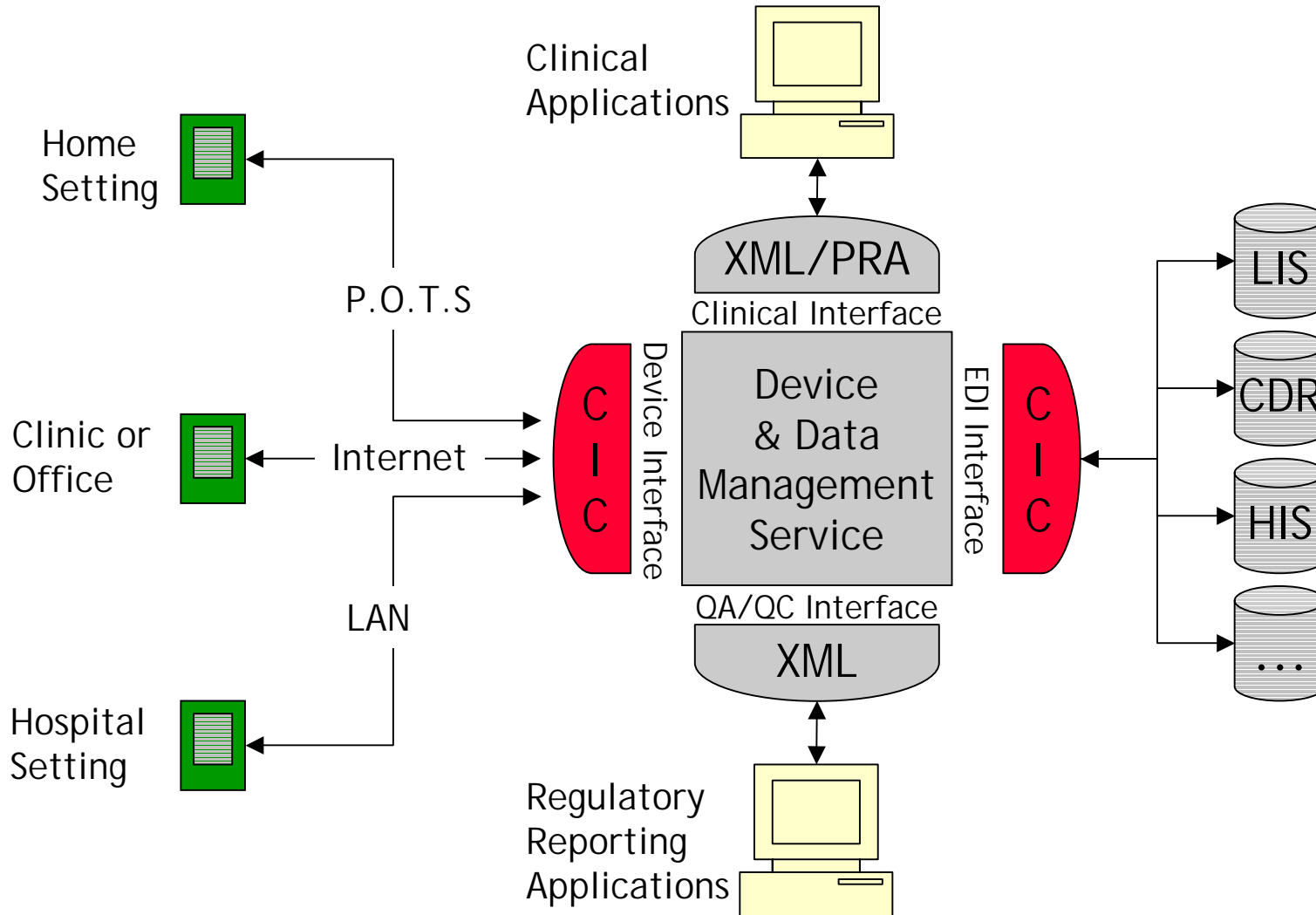
Source: The Permanente Journal /Summer 1999/Volume 3. No. 2

Avocet Prothrombin Time Meter

- FDA cleared for home use
- Range:
 - Numeric values between 0.7 and 7.0
 - **INR Lo** shown for values below 0.7
 - **INR Hi** shown for values above 7.0
- Sample Volume:
 - One hanging drop of capillary whole blood
 - 15 μ L 3.8% citrated venous whole blood
 - 10 μ L plasma proficiency material
- Battery Life: Approximately 50 tests depending on ambient temperature



POC Information Management Architecture



K-P Distributed Diagnostics Pilot

Description: Home monitoring solution for anticoagulation therapy that integrates seamlessly into the existing patient care process.

Goals: Determine the

- Clinical value,
 - Technical feasibility,
 - Business model viability
- of providing Internet-based connectivity for decentralized diagnostics.

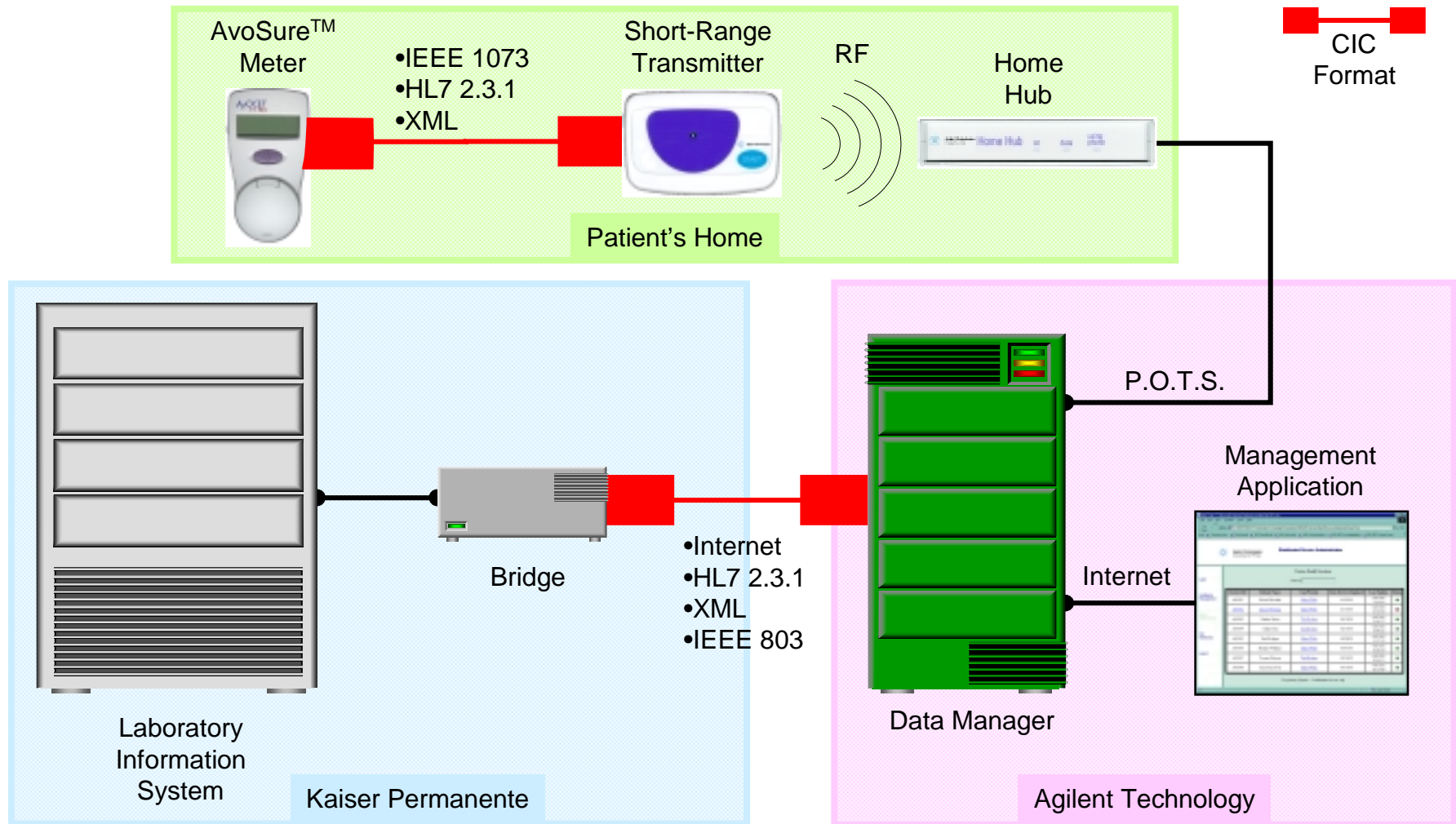
Study Population: Twenty randomly chosen CPAS patients with limited access to central laboratory facility.

Study Duration: Twelve months

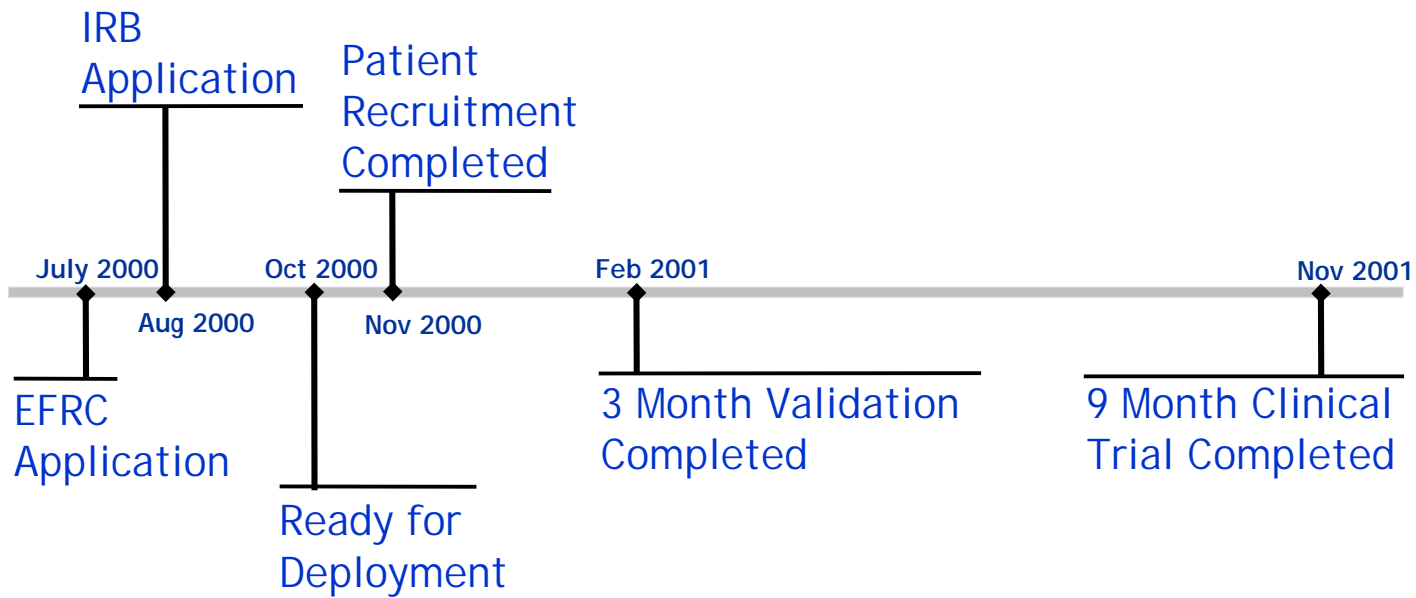


Kaiser Permanente Pilot System

Standards-based connectivity



Time Line





Report from the Provider Review Committee

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Provider Review Committee Membership

- James Nichols – Chair, Johns Hopkins
- Jim Fisher – Banner Health
- William Ganschow – Univ of Iowa
- Maurice Green – UCSF Stanford – Individual Consultant
- Doug Hirst – Bradford Hospitals – U.K.
- Ellis Jacobs – Mt. Sinai, AACC Liaison
- Jay Jones – Penn State Geisinger
- Forrest Kneisel – USAIP – Individual Consultant
- Gerald Kost – UC Davis - Individual Consultant
- Brent Lowensohn - Kaiser Permanente
- Petrie Rainey – Univ of WA - Individual Consultant
- Debra Russell – St. Vincent Medical Center
- Paula Santrach – Mayo Clinic

User Needs: Top Priority

- Bi-directional connectivity
- Plug and play – any device to any database
- Use existing infrastructure
- Conservation of IP addresses
- Ability to meet regulatory guidelines
- Compatibility with LIS order generation
- Interoperability with commercial software
- Security
- Connectivity must not impede timely result
- Ease of use

User Needs: Other Important Considerations

- Seamless download – no operator interaction
- Configurable use model – applies to all use scenarios
- Instrument dock to LIS integration – no intervening laptops, computers, etc
- Ability to force downloads
- Ability to qualify results

User Needs: General Principles

- Security of data and access
- International considerations
- Access to data
 - Multi-level (nurse, POCT coordinator, director)
 - User-defined
 - Site dependent

Consortium Expectations

- Download communication protocols (getting data from POCT devices):
 - Port Configuration
 - Gender
 - Language (i.e. ASCII, etc)
 - Order of fields (i.e. device ID, date, time, etc)
 - Communication/data confirmation protocol
- Upload communication protocols (to send updates, date/time, expiration dates, lot numbers to POCT devices, etc)

Provider Review Committee: User Requirements Document

- Requirements-document is a compilation of consumer needs in order of priority
- Users with experience in POC testing provide input into hospital, community and home self-testing needs
- The Provider Review Committee is a mix of academic POCT directors and liaisons to professional laboratory and informatics organizations

Provider Review Committee Liaisons

- Laboratory and Informatics Organizations provide and fund a liaison to CIC PRC
- Provides a conduit for information between the CIC and the organization for feedback on standards development and proposals
- Allows feedback from larger group of experts than just the members of the PRC
- AACC liaison approved – Dr. Ellis Jacobs is representative
- Will send out invitations to other organizations ASAP

Access to Speakers

Name	Title	Affiliation	E-mail
Suzanne Cross	CIC President	Ortho Clinical Diagnostics	scross@ocdus.jnj.com
Jeff Perry	CIC Vice President and Chief Technical Officer	Agilent Technologies	jeff@labs.agilent.com
James Nichols	<ul style="list-style-type: none">• Chair, CIC Provider Review Committee• Chair, AACC POCT Division	Johns Hopkins	jnichols@jhmi.edu
Emery Stephans	<ul style="list-style-type: none">• Chair, AACC POC Industrial Relations Committee• President, EAC	EAC, Enterprise Analysis Corp.	emery@eacorp.com