

Integrated Process Management Information Technology: The Next Generation in Medical Efficiency

Medical Automation Conference 2009



Premise for today's talk

There is a need for significant overhaul of current medical information technology to better support the complex processes of healthcare delivery. Novel process management paradigms will create solutions that span the breadth and depth of healthcare continuums from high volume high throughput automation to ad hoc decisions at the bedside supported by sophisticated decision support knowledge bases.



Who we are

Best of class provider of life science process management software; we apply “rigorous simplicity” to tame the deep complexity of molecular science.

Unsurpassed power in tracking lab samples, the “Achilles heel” of every lab operation

Rapid implementation: we operate at the speed of innovation

Adapts to changing customer circumstances

Customers pass regulatory audits with high marks

UNIConnect’s process management technology has the capacity and power to serve broad areas of healthcare delivery beyond the lab

Organic Lab Growth: Fueled by UNIFlow™



UNIFlow™ Processware from UNIConnect — Rigorous Simplicity for Laboratory Innovation and Management Success

- Bio-Molecular, HTS, Proteomics, Clinical Trials, Seeds, and more
- Step-by-step control and tracking for complex processes
- Fast implementation
- Easy configuration and modification
- Helps ensure compliance



See how UNIFlow can increase your laboratory success with a custom demo!

UNIConnect at a glance

We support the science and business of life science by delivering:

- disruptive process management software that extends far beyond labs: molecule > patient > health system
- empowerment to life science lab & IT professionals
- scalability in customer organizations by implementing, training, enabling clients to take control of their destiny and rise to new levels of achievement



Some thoughts on process and process management

Organizations create value as employees transform inputs of resources – the work of people, equipment, technology, product designs, brands, information and cash into products and services of greater worth. The patterns of interaction, coordination, communication, and decision making through which these transformations occur are processes.

– Clayton Christensen



If you can't describe what you are doing as a process, you don't know what you are doing. J.Edward Deming



A process

- a series of linked steps, often but not necessarily sequential, designed to ...
 - *cause* some set of outcomes to occur
 - transform inputs into outputs
 - generate useful information
 - add value

Brent C. James MD, Executive Director,
Institute for Health Care Delivery Research, Intermountain Healthcare



Process Management

Starts with knowledge of...

- Processes
- Systems (processes interacting together)
- Human psychology
- Variation
- A system for ongoing learning

Build a rational system to manage processes

What you get is quality improvement theory

Brent C. James MD, Executive Director,
Institute for Health Care Delivery Research, Intermountain Healthcare



Managing a process means....

- the right ***data***
- in the right ***format***
- at the right ***time*** (*and place*)
- in the right ***hands*** (*the clinicians who operate the process*)

Brent C. James MD, Executive Director,
Institute for Health Care Delivery Research, Intermountain Healthcare



The goal of personalized medicine is

To deliver

- THE RIGHT TREATMENT
- TO THE RIGHT PATIENT
- AT THE RIGHT TIME

-- Personalized Medicine Coalition

Is this possible without process management?



The idea of personalized medicine isn't new;

“It's far more important to know what
person the disease has
than what disease the person has.”

- *Hippocrates*

The potential to deliver it *IS new*.



An IT paradox and crisis:

Many technologies support the gathering, reporting, and storing of DATA. What we need is technology to support PROCESS, to help overcome

- Islands of automation
- Disjoint silo information systems
- Systems that cannot keep pace with organizational needs
- Manual workarounds
- Post-It notes and emails



IT issues that impact every aspect of healthcare

- Canned software doesn't fit
 - Processes FORCED to adapt to fit the software
 - Critical functionality is compromised
- Custom software comes with a high cost
 - It's expensive – often prohibitively so
 - Long development timeline results in lost productivity and opportunity



Programming: Why The Old Way Doesn't Work

- **Vendor Determines Features**

- Missing Features
- Unnecessary Features

-Or-

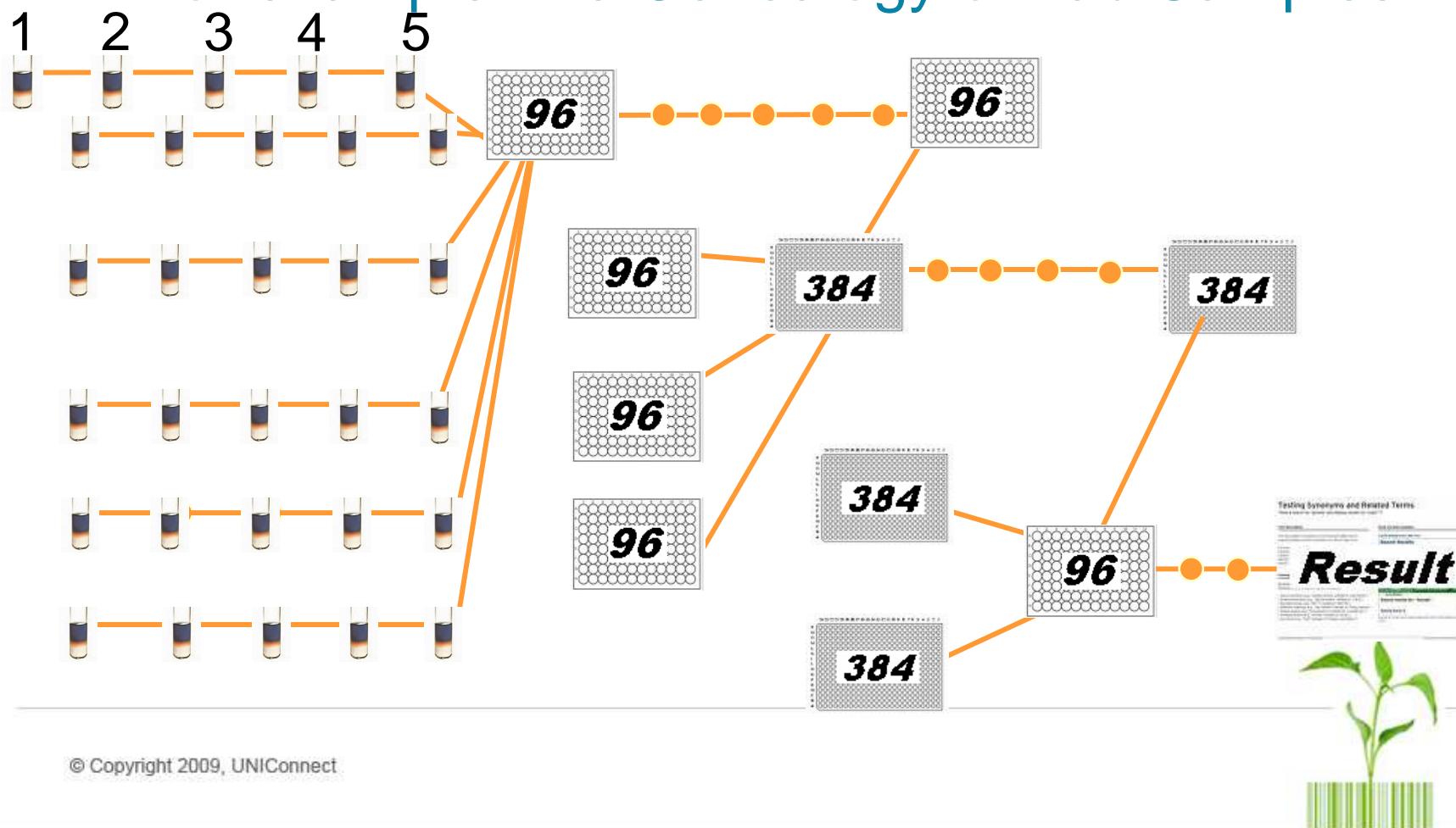
- **Every Installation Is Custom-programmed**

- Cost and Delay
- New Changes → New Projects
- Rate of Change Is Faster Than Rate of Implementation



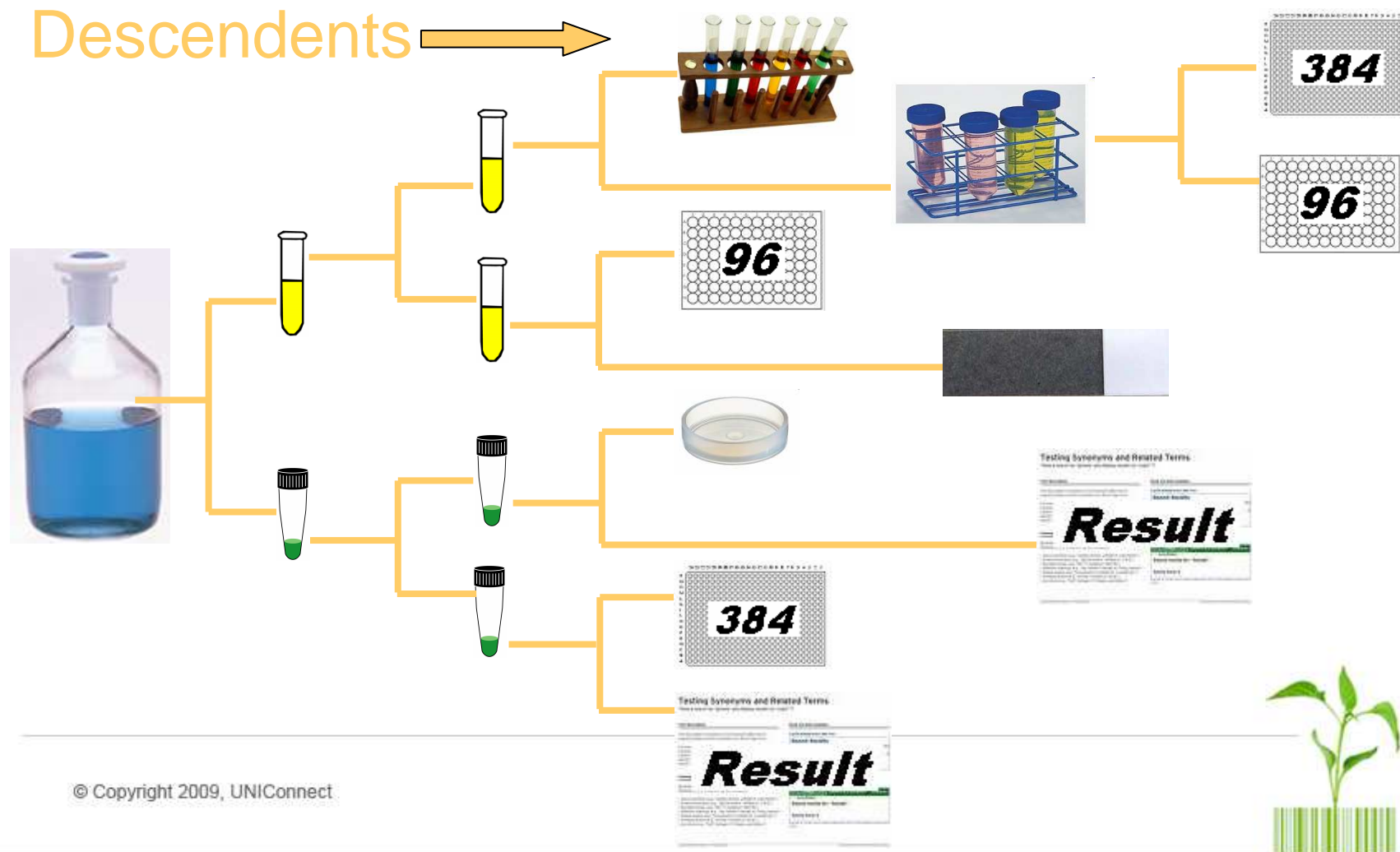
SOLUTION... managing complexity of processes

For example: the Genealogy of Lab Samples



The genealogy of a reagent

Descendents



Where Process Management Solves Problems Today:

- Molecular Diagnostics
- High Throughput Screening
- Biopharmaceutical
- Forensics
- Genetic Sequencing
- Clinical Trials
- Pain points along the discovery to delivery continuum
- Ancillary processes large and small



All Kinds Of Products

- Samples
- Tubes
- Plates
- Batches
- Patients
- Workers
- Instruments
- Documents
- Customers
- Projects
- Requests
- Issues

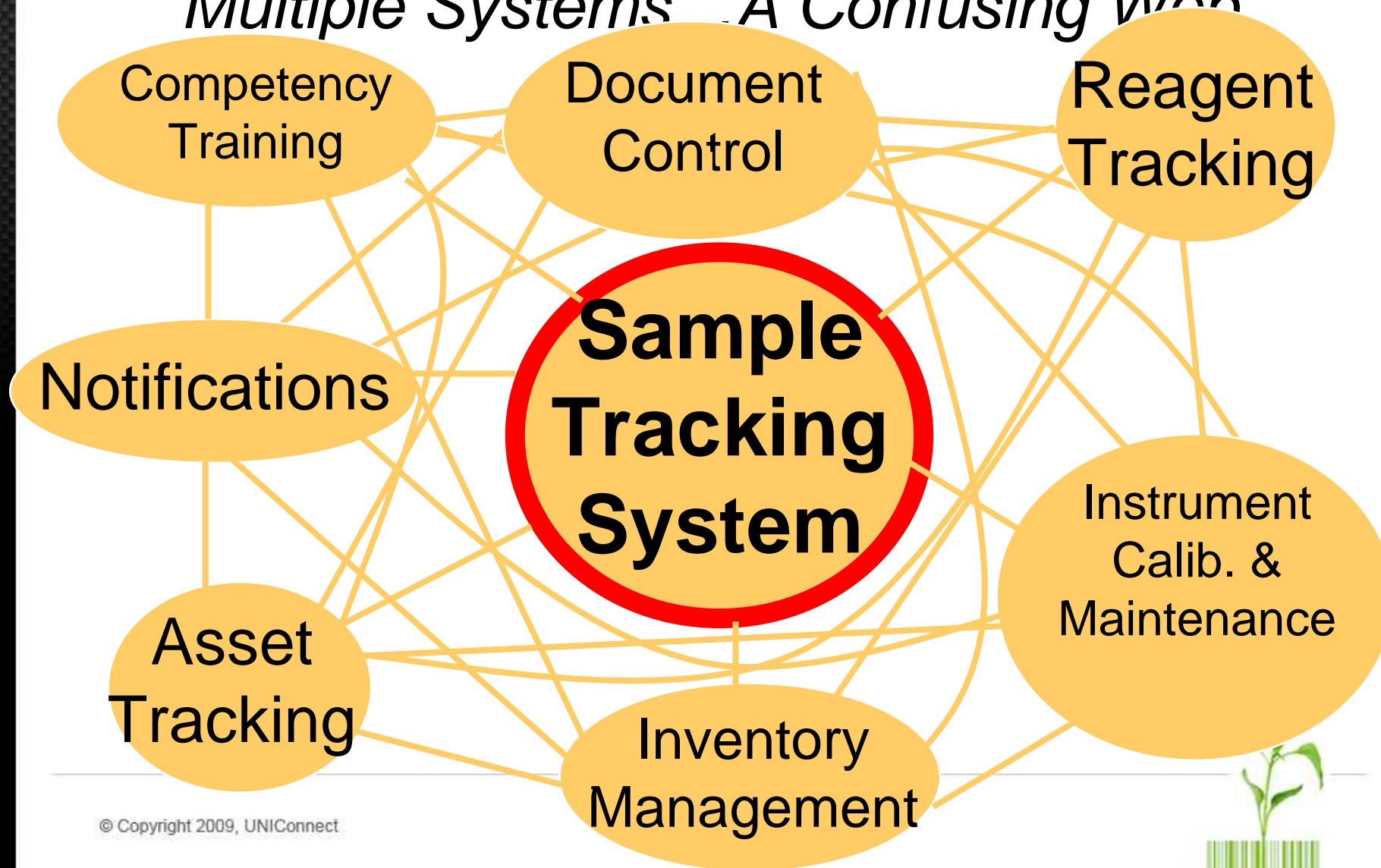


Components of software success

- Ideal solution for most companies has five key characteristics:
 - Conforms to your operation not the reverse
 - Adaptable by the customer
 - Timely, weeks, not months or years
 - Affordable for companies of all sizes
 - Comprehensive single platform



Multiple Systems A Confusing Web



One Platform: Comprehensive Automation

**Sample
Tracking
System**

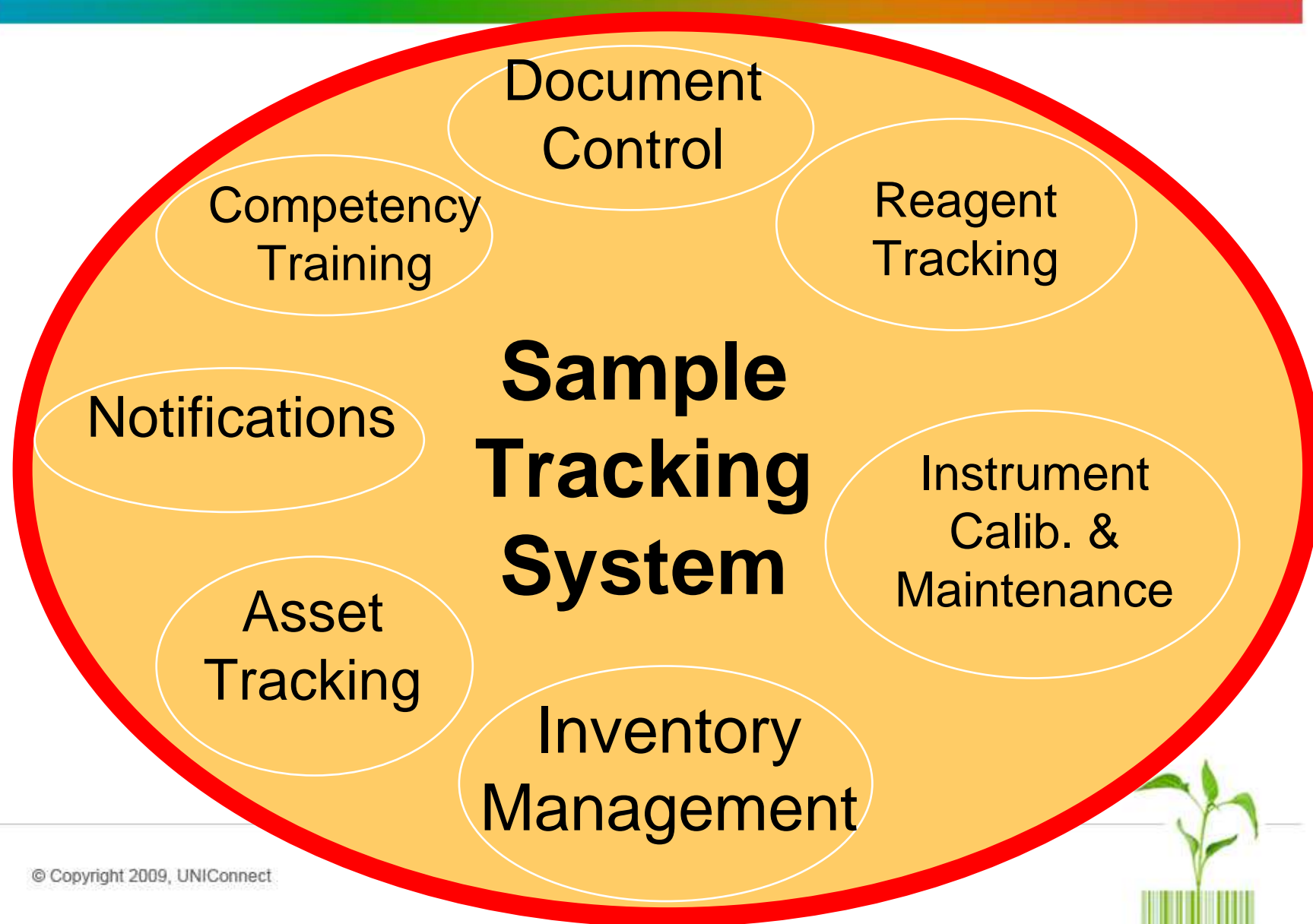


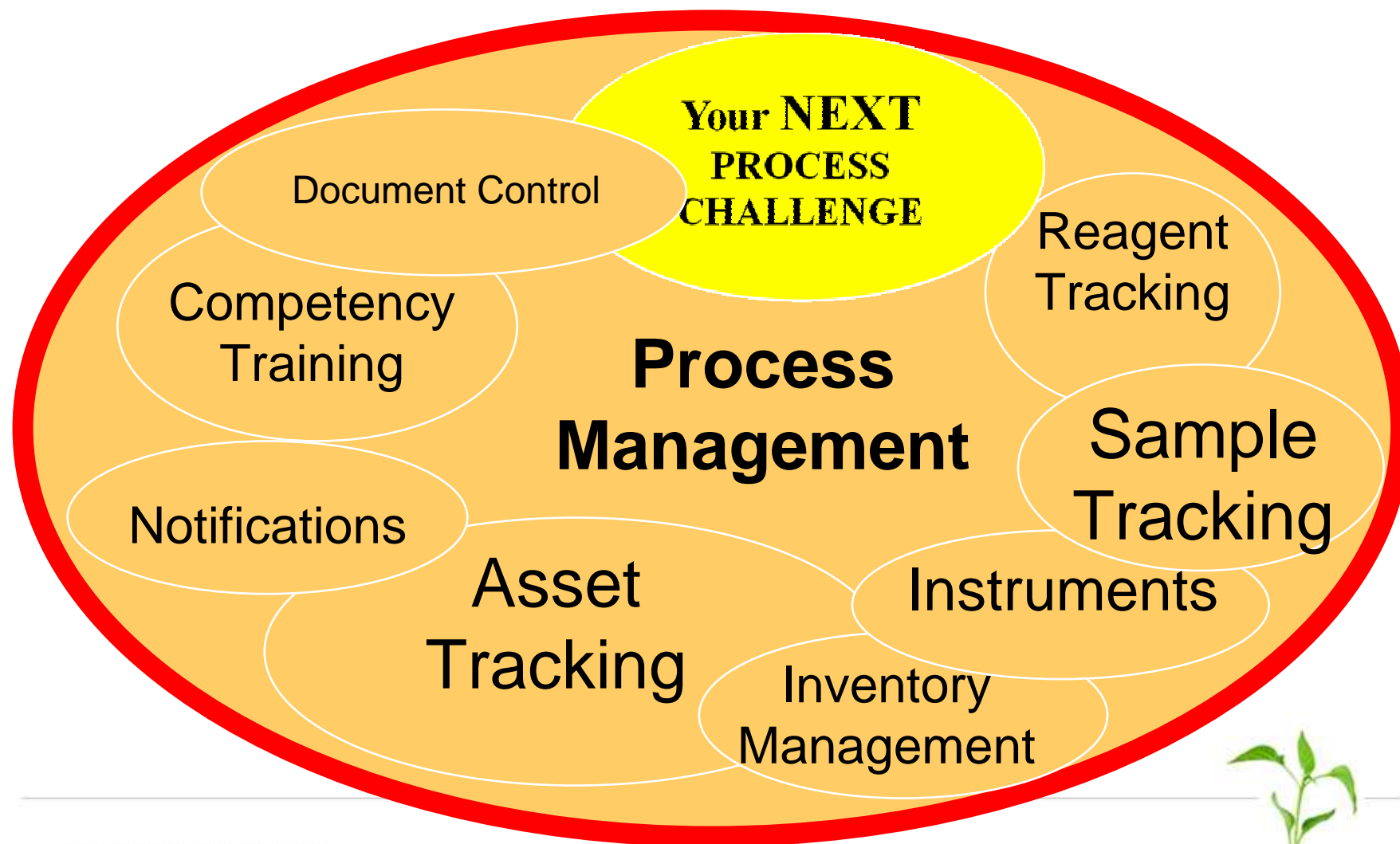
One Platform: Comprehensive Automation

Document
Control

**Sample
Tracking
System**







Software Platform Continuum

Generic

Specific



Software Platform Continuum

Generic

Specific

- Sample Storage
- Inventory
- Documents
- Notifications
- Instruments
- Sample Tracking
- Competency
- Reagents
- Assets
- Clinical Trials
- Customer Issues



Software Platform Continuum

Generic

Specific

**Sample Storage
Inventory
Documents
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Software Platform Continuum

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**Sample Storage
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Software Platform Continuum

Generic

Specific

Sample Storage
Inventory
Documents
Notifications
Instruments
Sample Tracking
Competency
Reagents
Assets
Clinical Trials
Customer Issues



Software Platform Continuum

Generic

Specific

Process
Management

Sample Storage
Inventory
Documents
Notifications
Instruments
Sample Tracking
Competency
Reagents
Assets
Clinical Trials
Customer Issues



Language To Define Any Process

Products

Steps

Content **Intermediate Steps:** Product

Workflow **•Always Custom**

•Always Changing

Properties and Acceptable Values

Resources and Qualifications



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Everything that follows are filler slides. We need more technical examples and we need to think about how not to be too self promoting.



Why UNIFlow is so different

- It wasn't developed in labs
- Unique “processware” originated from genealogy and genetics research
- Simplicity ensures that even the most complex requirements are covered
- Grows with customer needs rather than lagging behind



The unique advantages of UNIFlow

- Removes the tracking obstacles that often impede innovation
- Limits the constraints of uncertainty
- Grows at the speed of innovation – without missing a beat
- Empowers teams and clears the way to success
 - it's another arrow in the quiver





Molecular Dx

Create Dx Sample Request

Receive Dx Sample

1 Quality Review

1 Accession Dx Sample

1 Prepare Extraction Plate

Quantify Dx

1 Review Results

Rerun DNA

Prepare Assay Plate

Upload Assay Plate Results

Assay Quality Check

Review DNA

Create Score Report

Notify Doctor of Results

Store Dx Sample

2 Contact Customer

1 Review Rejected DNA

Other Step Groups:

- Dynamic Sample Management
- Molecular Dx**
- Sample Tracking
- Presentation

Create Dx Sample Request

Sample ID

Pre Authorization ☐

Patient Name: First M.I. Last Gender

Birthdate: Day Month Year

Submitting Clinic

Clinic Contact

Clinic Phone

E-Mail

Comments

Submit

Logout Reset



General Preparations

[Request Cells](#)

[Make Stock For Reagent Supplements](#)

[Create Media](#)

[Create FBS](#)

[Create Compound Stock Plates](#)

[Create Virus Stock](#)

[Make Stock Buffer Component](#)

[Create Buffer](#)

[Create Enzyme Stock](#)

Cell Preparation

[Create Cells](#)

[Receive Cells](#)

[14 Plate Cells](#)

Prepare Drugs


[Thaw Working Compound Plates](#)

[Prepare Dilution Plates](#)

Make Stock For Reagent Supplements

Media Supplement Barcode 

Supplement Type

Pen/Strep 

Manufacturers UPC

15140122 1302762

Manufacturers Cat #

15140122

Manufacturers Lot #

1302762


Expiration Date (mm/dd/yyyy)


11/30/2006

Storage Location

-20 Freezer 

Comments

5ml/tube 

2nd shelf-right 

Submit

Logout

Reset

“We change assays monthly – UNIFlow enables me to do this by myself in a couple of days. With other systems, this would take at least 3-6 months. In other words, we couldn’t do this without UNIFlow”

**Clinton Maddox, Biochemist
Southern Research Institute**





BioPharma

[Patient Registration](#)

[Administer Dose](#)

[Collect Blood](#)

[Separate Plasma](#)

[Receive And Store
Sample](#)

1 [Setup Extract Plate](#)

[Load Reader Plate](#)

[Analyze Extract](#)

[Prepare Report](#)

[Review report](#)

[Approve report](#)

Other Step Groups:

Sample Tracking
Presentation
Database Reports
Request Processing

Submit

Setup Extract Plate

Extract Plate EP101

Protein Precipitant PP101

Comments Dust in air during
prep.

Plasma Tubes

	1	2	3	4	5	6	7	8	9	10	11	12
A	PT101A											
B												
C												
D												
E												
F												
G												
H												

Submit

Logout

Reset





IS Project Initiation

Create Project Request

Evaluate Project Request

Edit Project Request

Chris IS Projects

[19](#) Mark IS Projects

[8](#) Keith IS Projects

[15](#) Kelli IS Projects

Other Step Groups:

MtDNA Sequencing

PCR Setup

Post-PCR

Analysis

Case Production

Housekeeping

R&D

IS Project Initiation

Chernobyl

Project Details

Project Type

System

Detailed Description of Project

Events not written to
events table but
written to
containerHistoryTable

Priority Level

Estimated Due Date

IS Team ONLY

By-pass Evaluation ☐

Assign Project To:

Submit

Logout Reset

AIS Prognostic Assay Test Result Form

PATIENT INFORMATION

Patient Name: Jane Sample **Specimen Barcode:** SCO-5001-01829A
Medical Record # or Patient #: MED-123 **Gender:** female **Cobb Angle:** 14
Physician Name: Dr Clinical Trial **Date of Birth:** 05 - Mar - 1997
Physician's: 2749 E. Parleys Way Suite 200 **Collection Date:** 09 - Dec - 2008
Report Date: 05 - Jan - 2009 10:03 AM
City: Salt Lake City **State:** UT **Zip:** 84109

ASSAY DESCRIPTION

ScoliScore AIS Prognostic Assay is performed on DNA extracted saliva. A multiplex PCR reaction and Taqman detection are used to determine the genotype for a panel of 53 single nucleotide polymorphisms (SNPs). The ScoliScore AIS Progression Score ranges from 1 - 200, is calculated using marker weighting factors and a simple accumulation algorithm.

ASSAY RESULTS

SNP ID #	GENOTYPE	SNP ID #	GENOTYPE	SNP ID #	GENOTYPE	SNP ID #	GENOTYPE	SNP ID #	GENOTYPE
RS12345	TT	RS12345	TT	RS12345	AA	RS12345	TT	RS12345	CG
RS12345	CC	RS12345	GG	RS12345	AT	RS12345	AC	RS12345	TT
RS12345	GA	RS12345	TT	RS12345	AG	RS12345	GC	RS12345	AC
RS12345	GG	RS12345	CC	RS12345	TT	RS12345	GT	RS12345	GG
RS12345	AA	RS12345	CC	RS12345	GG	RS12345	GG	RS12345	CC
RS12345	AC	RS12345	CC	RS12345	CC	RS12345	CC	RS12345	CC
RS12345	TC	RS12345	TT	RS12345	AA	RS12345	AG	RS12345	GG
RS12345	GG	RS12345	GG	RS12345	CC	RS12345	GC	RS12345	GC
RS12345	TT	RS12345	TT	RS12345	GG	RS12345	AG	RS12345	CC
RS12345	CC	RS12345	CC	RS12345	GG	RS12345	CA	RS12345	CC
RS12345	AA	RS12345	GG						

SCOLISCORE AIS PROGRESSION SCORE =
54
ASSAY INTERPRETATION


This score indicates this patient is at intermediate risk for progression to a severe curve by or before skeletal maturity. ScoliScore results should be interpreted with all other diagnostic information for the AIS patient. Interpretation of ScoliScore results for patients outside the intended use population may not be applicable.


ASSAY ACCURACY
NPV: 99%

(Negative Predictive Value)

Although rare, genotyping errors can occur due to misincorporation of DNA bases by the enzyme used to perform the test, sample misidentification, sample contamination or general laboratory errors.

Laboratory Director: Kenneth Ward, MD



This Laboratory Developed Test was developed and its performance characteristics determined by Axial Biotech Laboratories. The laboratory is regulated under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) as qualified to perform high-complexity clinical testing and has established and verified the test's accuracy. This test has not been cleared or approved by the U.S. Food and Drug Administration. The FDA has determined that such clearance or approval is not necessary. These results are adjunctive to an ordering physician's diagnosis.

CLIA Number: 46D1077919

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This test is performed pursuant to an agreement with Roche Molecular Systems, Inc.

05-Jan-2009 10:03 AM

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Business Model

- SaaS subscriptions
- Perpetual Licenses & Maintenance Contracts
- Service Contracts
- Support by UNIConnect and authorized integrators
- Train Customers to Become Independent
- Grow from lab to enterprise
- National to global presence
- BIO Business Solutions parameters to be negotiated
- BIO member benefits immediate and will evolve



Common problems, simple solutions

Problem

Complex processes

Growing needs

Documentation

Regulatory requirements

Legacy systems

Training downtime

Extensive customization

Solution



“I found the UNIFlow system running at Axial to be one of the best Molecular Dx-SPECIFIC systems I have ever seen.”

**Dr. Dan Farkas
CLIA Molecular Pathology Lab Accreditation Inspector
Sequenom Center for Molecular Medicine**

