



Design Principles for a Bio-banking System

the Wales Cancer Bank - a case study



Today's presentation

- I. The Wales Cancer Bank project
- II. IT project setup
- III. System design principles
- IV. Functionality and scope
- V. Current efforts - Future direction
- VI. Lessons learned



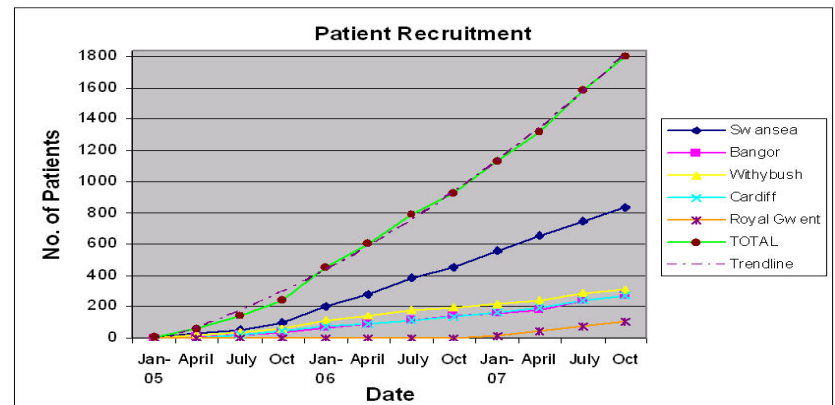
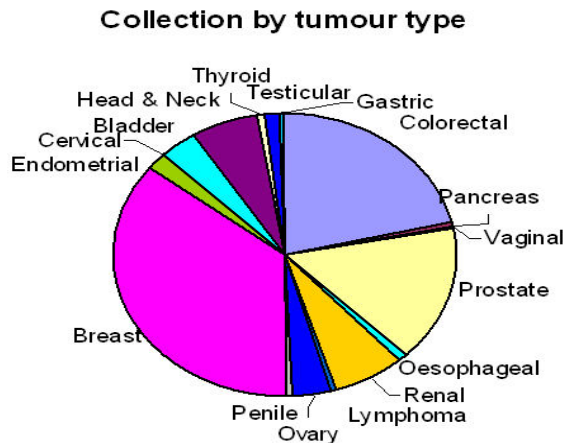
I. The Wales Cancer Bank (WCB) aim:

- To provide a population based collection of tissue and blood samples from all patients in Wales undergoing an operation where cancer is a possible diagnosis;
- In the hope that, eventually, the provision of a standardised, quality assured collection of tissue samples, linked to clinical outcome, will help identify novel profiles for prediction and prognosis which will lead to individualised and efficient treatment.



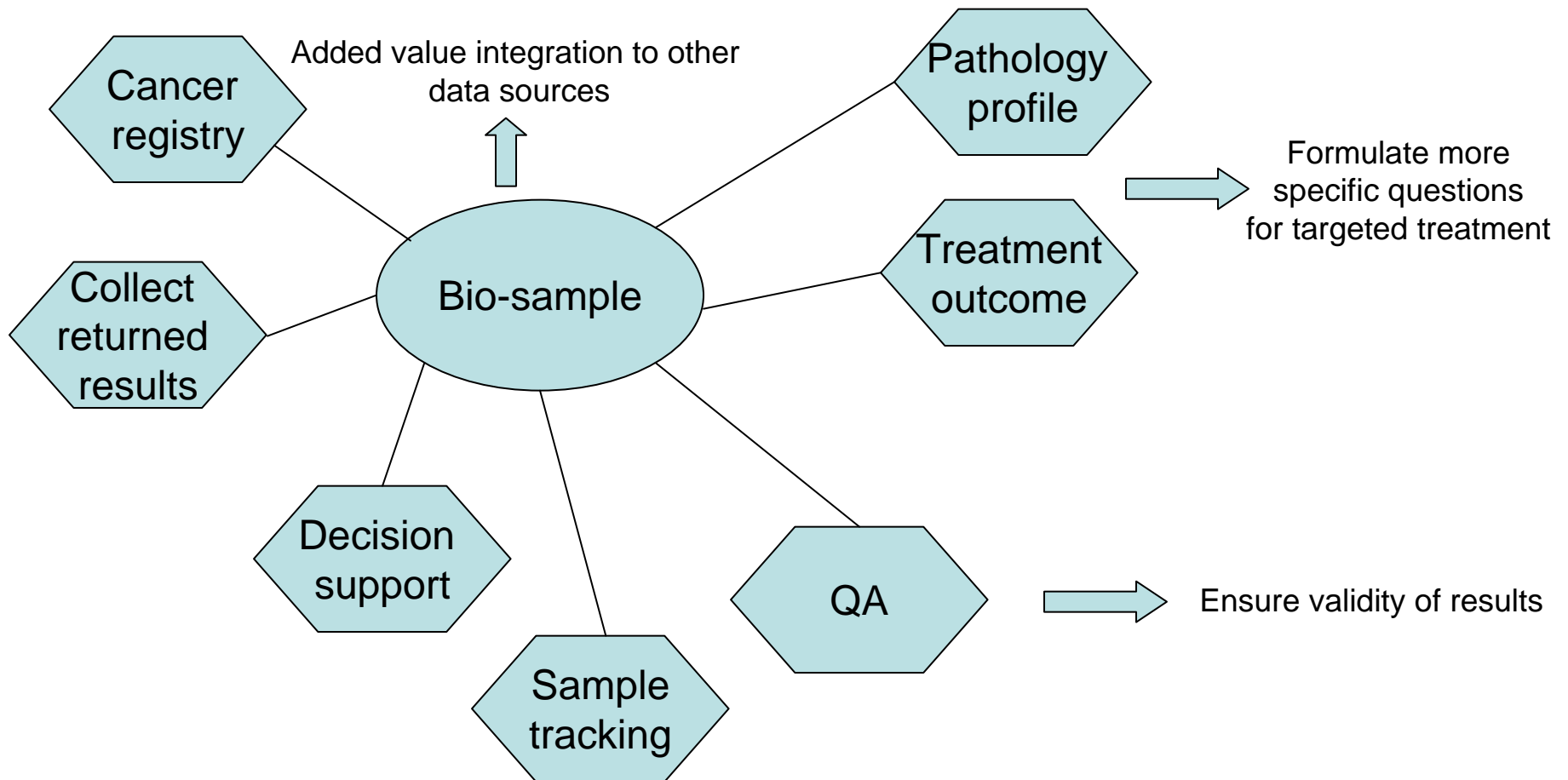
Patient Recruitment

- Started consenting patients in February 2005
- Collecting from a national network of seven hospitals around Wales
- 1,860 patients consented at end November 2007
- Overwhelming support from patients





Why IT is important





II. Project Setup

Main questions at the onset of the project:

- Buy off-the-shelf product and customise, or develop in-house?
- Hosting server security and integration?
- Help Desk?
- Training?



II. Project Setup

- WCB Project started March 2003
- IT sub committee first meeting August 2003
- Database manager appointed January 2004
- SLA with NHS trusts September 2005
- Hosting and Help desk set up November 2005
- Sample collection started January 2005



Software Requirement Specification

- Stakeholder interviews
- Joint Requirements Development Sessions (a.k.a. Requirement Workshops)
- Contract-style requirement lists
- Measurable goals
- Use cases
- Evolutionary Prototypes
- Data modeling/DFD



Risk Analysis

- Not enough time
- Not enough resources (similar projects failed)
- Many unproven tracking systems exist with no integrated solution
- Effort required to customise an off-the-shelf system
- Unknown/unclear workflows due to bank not being operational



Project Evolution

- Decided for a commercial biobank solution
- Company went into difficulties three months prior to WCB collection start
- The last prototype in evolution become the WCB system
- WCB system has taken three man years to develop and is still growing
- Integrated system that supports the WCB's operation at all levels and is highly adaptable for relatively low investment



III. Design Principles – Security

- Linked anonymised data
- High security (data separation and functions)
- Two level authentication
- Secure access over the internet (encryption)



Design Principles – System

- Facilitate integration with NHS database systems
- Highly configurable (storage, organisation, sample modalities, processes, reference data)
- Scalable, modular and highly generic
- Adaptable to different work lab flows
- Data store for images and documents



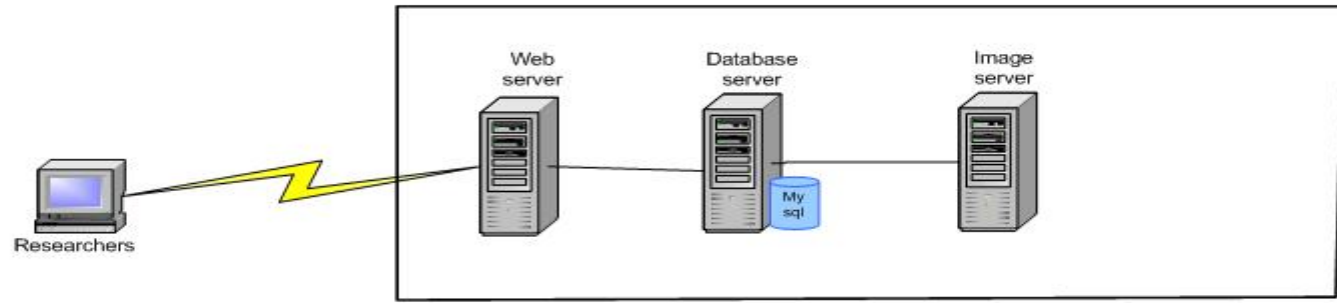
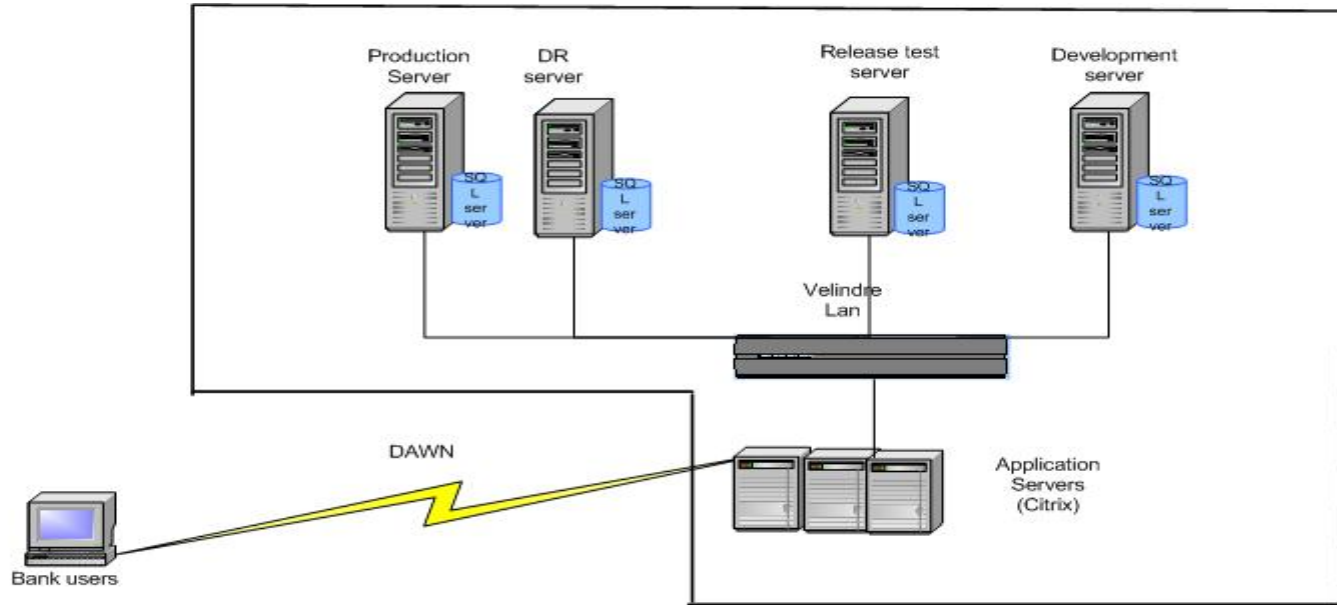
Design Principles – Samples Modelling

- Each sample has a unique record and location
- Sample lineage recorded
- Complete electronic audit trail
- Comprehensive annotation
- Each sample must have a label and a 2D barcode
- Digitise and store H&E slide and support TMA



Design Principles – User Interface

- Reduce human error as much as possible
- Intuitive to inexperienced users
- Integrated multimedia training solution
- Reporting and user queries with output MS Excel
- Facilitate inter site communication



Current Configuration



IV. System Functionality and Scope

- **Consent:** manages patients' consent information
- **Integration:** solution for linking to identifiable data sources
- **Sample Tracking:** graphical user interface for recording coordinates and configuring multilayer storage structures
- **Clinical Annotation:** records RCP cancer minimum datasets, patient treatment and outcome and patient's family history, clinical trials, QA
- **Workflows:** flexibility to adapt to different lab work flows using worksheets DNA, RNA processing
- **Order and Shipment Management**
- **Project Management**



Barcode

Printer



Collection: WCB Swansea Logged: WCB
Incomplete tasks: 0

HRB seminar in Ireland 10\11 Dec

Donation

WCB Number WCB Bank Site

Tissue Origin Entry Incomplete

Diagnosis Diagnosis Other

Consent Donor Record Collection Tissue/ Blood Operation / Biopsy Pre Op Treatment Clinical Trial

Consent

Donor Consent Date Recorded By

Control Consent Date Recorded By

Retrospective

Withdrawal Date Recorded By

Withdrawal Reason

Control Asked for Donation Control Gender

Comment

Reserve No

Assign ISCO

Donation

New Sample

List Selection

Collection

Stock Control

Tasks

Log book

Worksheets

Project

Order

Shipment

System Config

Help

Exit

Live Mode



Barcode

Printer

Microsoft Office Doc



Collection: WCB Swansea Logged: WCB

Incomplete tasks: 0

r in Ireland 10\11 Dec

HRB semina

Reserve No

Assign ISCO

Donation

New Sample

List Selection

Collection

Stock Control

Tasks

Log book

Worksheets

Project

Order

Shipment

System Config

Help

Exit

Description	In Situ Carcinoma	Invasive Carcinoma					
Pathology No	<input type="text" value="SH0502823"/>	Pathologist	<input type="text" value="Namor Williams"/>	SNOMED T	<input type="text" value="04000"/>	M	<input type="text" value="85003"/>
Side	<input type="text" value="Right"/>	Radiograph Seen?	<input type="checkbox"/>				
Weight	<input type="text" value="212"/> grams	Mammographic Abnormality	<input type="text" value="Yes"/>				
ER-Positive	<input type="text" value="Positive"/>	Allred score	<input type="text" value="8"/>				
Progesterone	<input type="text"/>	Allred score	<input type="text"/>				
HER-2	<input type="text"/>	Hercep Test	<input type="text"/>				
Comments	<input type="text"/>						

Path Reports

Donation

Bio Samples

Print Form

Save

Delete

Live Mode



Barcode

Printer Microsoft Office Doc



Collection: WCB Swansea Logged: WCB
Incomplete tasks: 0

seminar in Ireland 10\11 Dec

HRB

Bio Sample General Info

Select Bio Type: Date Taken: Time Taken:

Prepared In: Prepared By:

Comment:

Fixative Start: Fixative Duration: Fixative: Histology No:

Missing Data:

Coordinates

C,5

- Cardiff
- Wlthybush
- Gwynedd
- Swansea
 - WCB Freezer
 - 1
 - A
 - B
 - C
 - D
 - E
 - F
 - G

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

RVCC40000001BC 1

Bio Sample Specific Info

-
- RVCC40000006PT 2A
- RVCC40000007PT 1A
- RVCC40000008PT 1A
- RVCC40000009PT 1A
- RVCC40000011PT 1A
- RVCC40000012PT 1A
- RVCC40000013PT 1A
- RVCC40000014PT 1A

Add Bio Sample

- Reserve No
- Assign ISCO
- Donation
- New Sample
- List Selection
- Collection
- Stock Control
- Tasks
- Log book
- Worksheets
- Project
- Order
- Shipment
- System Config
- Help
- Exit

Live Mode



Barcode

Printer

Microsoft Office Doc

Collection: WCB Swansea Logged: WCB
Incomplete tasks: 0

10\11 Dec

HRB seminar in Ireland

Extraction Worksheet for RNA

Reserve No

Date

7/6/2007



Worksheet No

102

Gel Analysis by

Squires Emma

Assign ISCO

Prepared In

Singleton

Extracted by

Squires Emma

Agilent Analysis by

Squires Emma

Donation

New Sample

List Selection

Collection

Stock Control

Tasks

Log book

Worksheets

Project

Order

Shipment

System Config

Help

Exit

Coordinates

Data

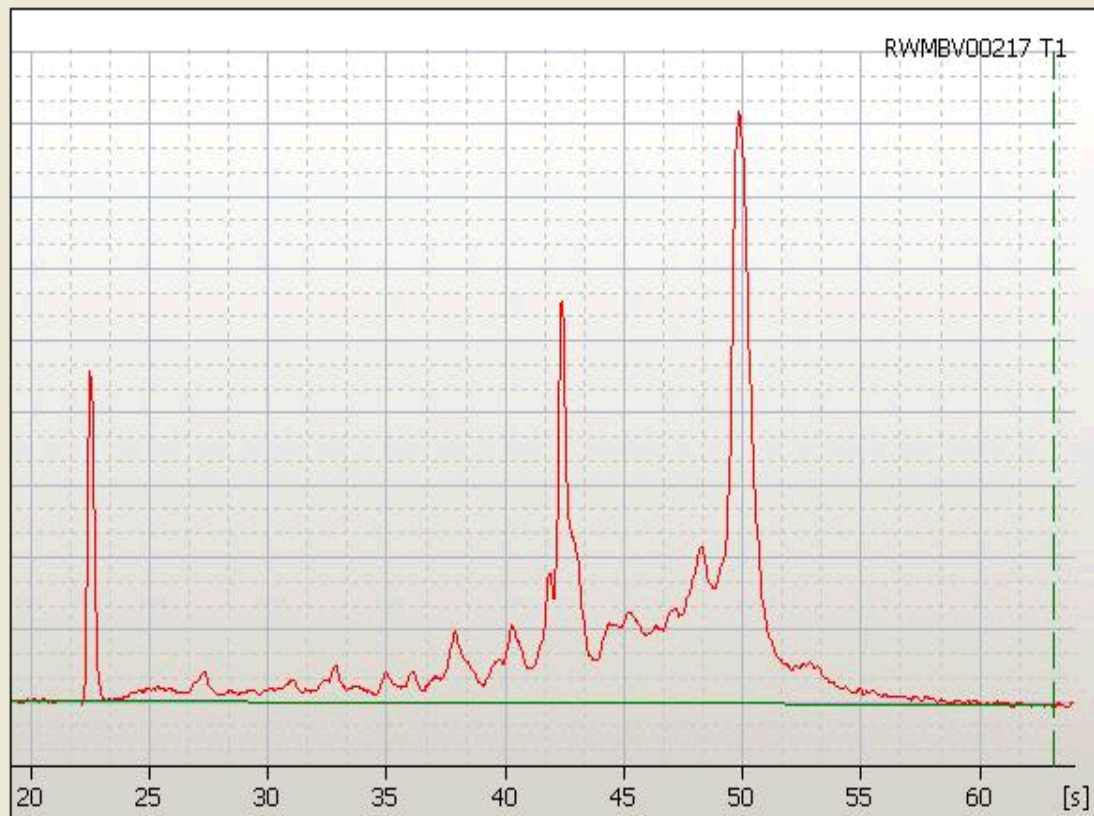
Agilent Trace

Gel Picture

Comment

Samples

Clear



4

Live Mode

Worksheets

Print Barcode

Create Sample

Save

Delete



Barcode

Printer



Collection: WCB Swansea Logged: WCB
Incomplete tasks: 0

HRB seminar in Ireland 10\11 Dec

Application

Application No

Principal Investigator +

Date

Application Type

Title

Proposal Document

Requirements Organisation / Contacts ERP Reports ERP Decision Orders Shipments Invoices Samples Sent

Shipments

Shipment Typ	description	Create Date	From Name	From Org	
▶ Bank External	QA for RNA	5/23/2007	WCB Admin	Swansea	Dr R



- Reserve No
- Assign ISCO
- Donation
- New Sample
- List Selection
- Collection
- Stock Control
- Tasks
- Log book
- Worksheets
- Project**
- Order
- Shipment
- System Config
- Help
- Exit



Live Mode



V. Current efforts – Future direction

- Develop an ASP AJAX version with additional capabilities for commercial use
- Design bio-informatics platform for data mining
- Incorporate slide server within the system
- Co-operate with CCB to develop a UK e-portal for researchers and a minimum standardised data set



VI. Lessons learned

- Do not underestimate the time and complexity of developing a bio-bank system
- Allocate sufficient qualified resources
- Assign separate IT budget
- Involve stakeholders as part of the project
- Demonstrate benefits to stakeholders
- System must be highly flexible, adaptable and integrated (cannot dictate new ways of working)
- IT has strategic role in success of bio-bank project



Acknowledgements

- Patients
- Nurses
- BMS
- Pathologists and surgeons