

# BRISKit: Biomedical Research Infrastructure Software Service kit

<http://www.le.ac.uk/brisikit>

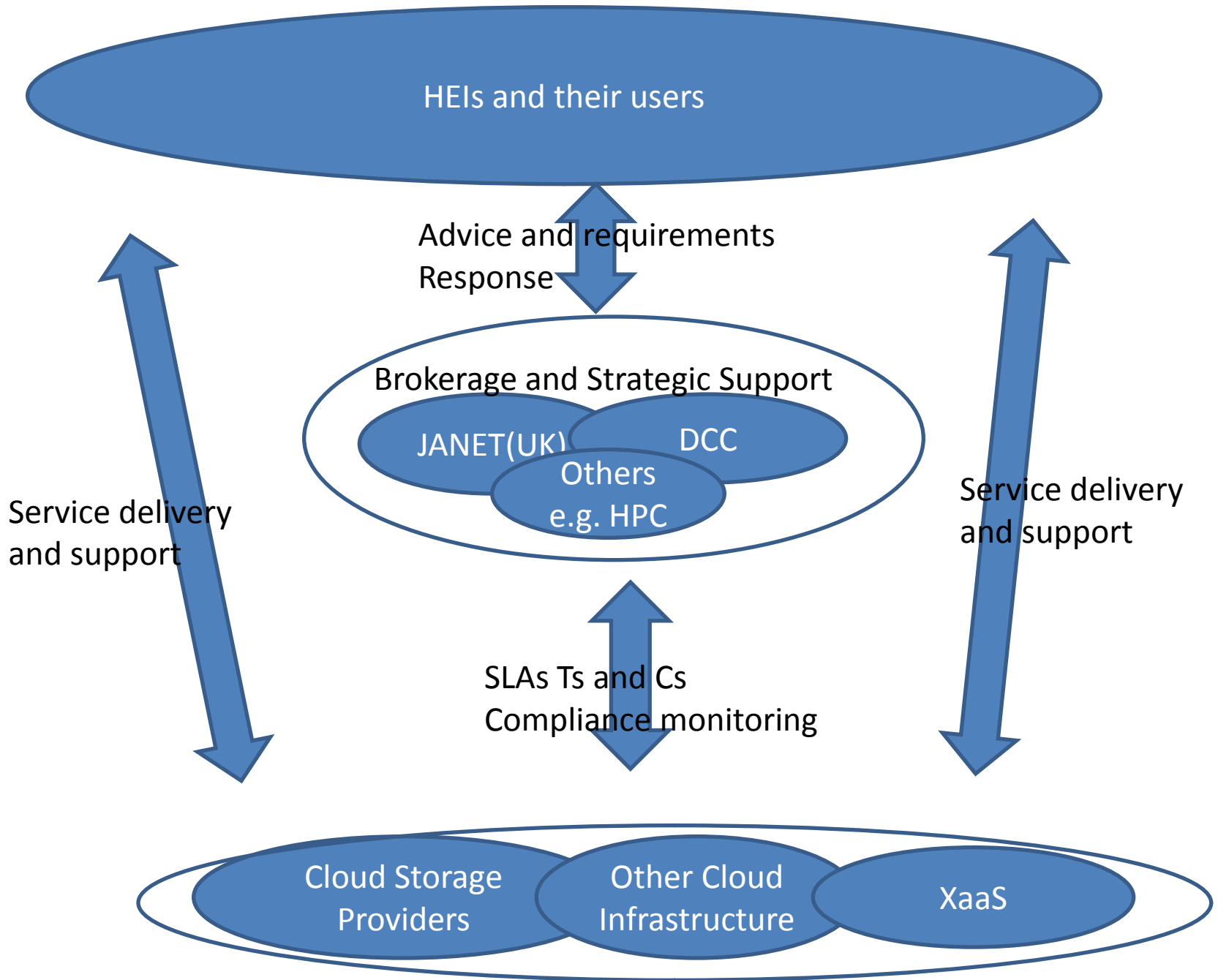
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Nick Holden (LCBRU BRICCS)  
Malcolm Newbury (GuildFoss)

- JISC University Modernisation Fund 2011/12
- Shared service in HE cloud
  - Eduserv UMF cloud platform for HE
  - Brokered by UK HE JANET network

**Workshop - Thurs 19<sup>th</sup>  
January, Leicester BRU**





## Community Services

DCC  
Services

EduBox

Disaster  
Recovery

VM  
launch pad

...

Access Control

Common Cloud Service Bus (CSB)

## Public Clouds

Amazon  
AWS

Microsoft  
Azure

Janet  
Brokerage  
&  
Connectivity  
Services

## JISC Community Cloud Consortium

Eduserv

MIMAS

Other

## Private Clouds

University  
A

University  
B

University  
C

University  
D

University  
E

University  
F

University  
G

# BRISKit Generic Use Cases 1

- *Researcher*
  - Designs study
  - Identifies potential patient profiles and authorises patient recruitment process
  - Authorises nurse and research informatics consent , tissue and data gathering activity
  - Analyses collected data and conducts study
  - Publishes study results
  - Transfers ownership of data BRU on completion of study
  
- *Research Informatics Lead*
  - Designs questionnaire and hospital dataset
  - Maps required ontology to dataflows
  - Authorises hospital informatics activities
  - Ensures readiness of questionnaires, samples and data gathering interfaces
  - Monitors patient consent to enable start/stop clinical data gathering and use of samples

# BRISKit Generic Use Cases 2

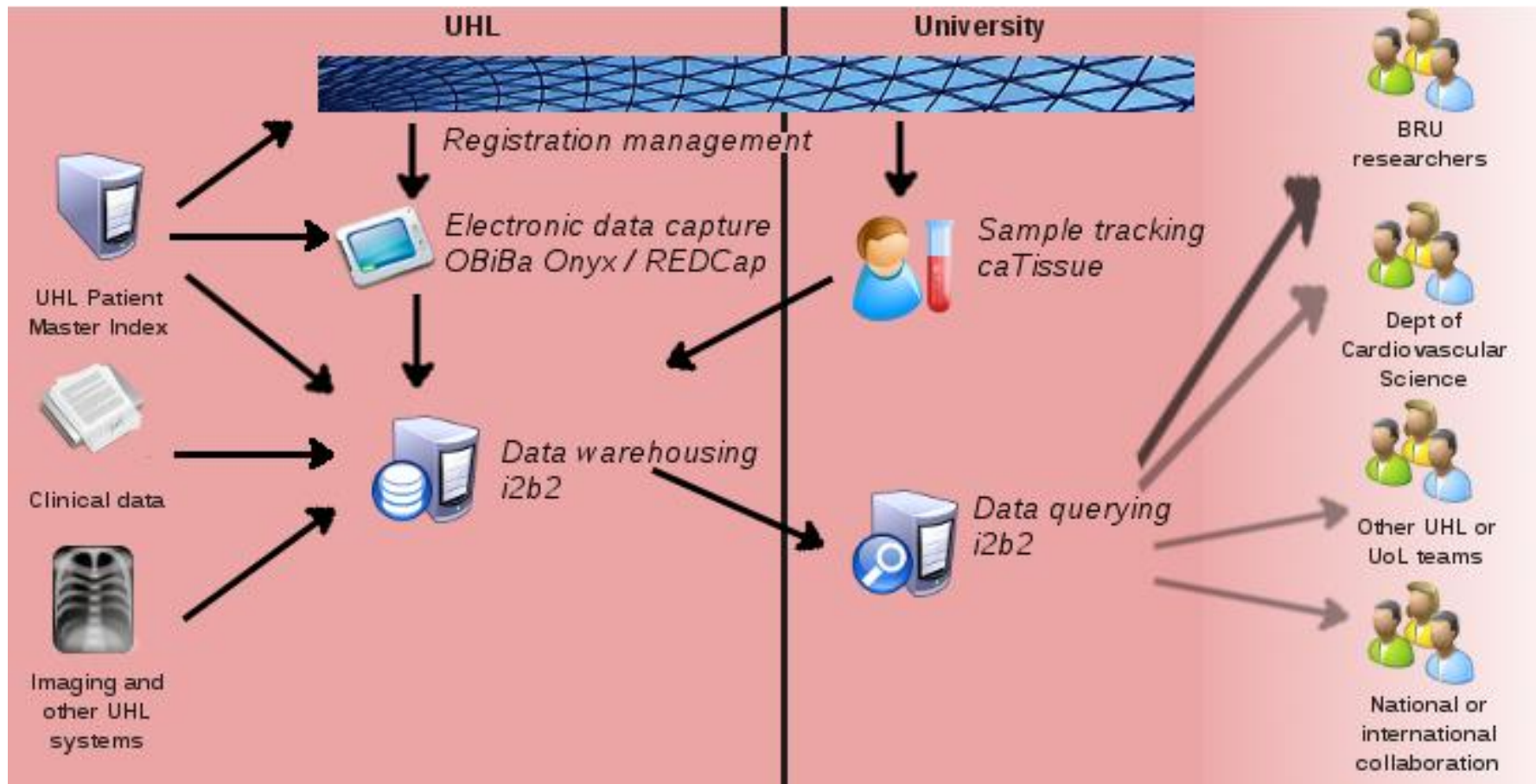
- *Patient*
  - Consents to participate in research/study
  - Provides data through questionnaires
  - Provides tissue samples
  - Provides data through clinical systems
- *Nurse*
  - Gains patient consent to participate
  - Supports patient completion of questionnaires
  - Takes blood and tissue samples from patient
  - Orders other clinical tests on patient
- *Clinical Informatics Lead*
  - Monitors existence of patient consent
  - Ensures readiness of clinical systems to share data
  - Initiates, monitors and closes sharing of patient data into research system for consenting patients

# BRISKit: Biomedical Research Infrastructure Software Service kit



National Institute for Health Research

- Electronic Data Capture / questionnaire – *OBiBa Onyx / REDcap*
- Specimen Inventory / sample tracking – *caTissue*
- Cohort selection and data querying - *i2b2*



# BRISKit: Biomedical Research Infrastructure Software Service kit

<http://www.le.ac.uk/brisskit>



- Prototype open source IT infrastructure for biomedical research Informatics – built on BRU BRICCS
- Web services – platform independent
- Bridge healthcare & research domains
  - *14health & ITFoM EU initiatives*
- Host, implement, deploy biomedical research DBs
  - **Remove duplication** of highly skilled development effort via
    - *Design from scratch*
    - *Buy & administer*



# Electronic Data Capture

The screenshot shows the Onyx software interface for data capture. It includes a header with the NHS logo and 'National Institute for Health Research, Leicester Cardiovascular Biomedical Research Unit'. The main window is titled 'Interview' and contains several sections:

- Participant:** Participant ID: BP100112928, First Name: VICTORIA, Last Name: SEIDU.
- Interview:** Start Date: 26-05-2010 14:54, End Date: 27-05-2010 10:27, Status: Completed. Buttons: Cancel, Print Reports.
- Log:** View, Comments (2), Add.
- Stages:** A table listing 12 stages of the interview process.

#	Name	Status	Start	End	Log
1	Acute Verbal Consent for samples collection	Skipped (Participant not an acute admission)	14:55	14:55	[Log]
2	Participant Consent	Completed	14:56	15:02	[Log]
3	Paper Consent	Completed	15:02	15:03	[Log]
4	Recruitment Context	Completed	15:06	15:06	[Log]
5	Risk Factor	Completed	15:07	15:16	[Log]
6	Samples Preliminary	Completed	15:16	15:18	[Log]
7	Blood Samples Collection	Completed	15:19	15:30	[Log]
8	Urine Sample Collection	Completed	16:07	16:07	[Log]
9	End of Patient Contact	Completed	15:31	15:32	[Log]
10	Medical History	Completed	15:32	15:59	[Log]
11	Data Submission	Completed	15:59	16:06	[Log]
12	Conclusion	Completed	10:26	10:27	[Log]

Buttons: Exit this interview

Footer: Nick Holden - 2010-06-08 - 16:02:30, OBiBa / 1.7.0-b8944@

*Onyx - from the OBiBa Open BioBank suite of software tools - manages baseline interviews.*

*Records participant consent, questionnaire data & primary specimen IDs.*

*Web-based, secure data entry by research staff. Used for all recruits to BRICCS prototype - mobile computing on wards and outpatient clinic*

*Ontario/Montreal/Perth (Aus)/East Coast US*

*Allows for integration with physical measurement devices, manages appointments, participant look-up to registry services or walk-in volunteers.*



# Electronic Data Capture

The screenshot displays the REDCap interface for a 'REDCap Demo Database' at Vanderbilt University. The main content area shows a data entry form for 'Month 1 Data' for Study ID 0000. The form includes the following fields:

- Study ID:** 0000
- Month 1:** (highlighted header)
- Date of Month 1 visit:** (calendar icon, Today button, Y-M-D format)
- Serum Albumin (g/dL):** (text input)
- Serum Prealbumin (mg/dL):** (text input, value: 1)
- Creatinine (mg/dL):** (text input)
- Normalized Protein Catabolic Rate (g/kg/d):** (text input)
- Cholesterol (mg/dL):** (text input, value: 111)
- Transferrin (mg/dL):** (text input, value: 111)
- Kt/V:** (text input, value: 111)
- Dry weight (kilograms):** (text input)
- Number of treatments missed:** (text input)
- How compliant was the patient in drinking the supplement?:** (dropdown menu)
- Hospitalization Data:** (highlighted header)
- Was patient hospitalized since last visit?:** (dropdown menu)
- What was the cause of hospitalization?:** (dropdown menu, value: Vascular access related events)
- Date of hospital admission:** (calendar icon, Today button, Y-M-D format, value: 2010-06-22)
- Date of hospital discharge:** (calendar icon, Today button, Y-M-D format, value: 2010-06-23)
- Discharge summary in patients binder?:** (dropdown menu, value: Yes)

*REDCap allows for common data elements to be re-used in building and managing online surveys and databases.*

*Create and design projects using your web browser using the Online Designer; and/or by constructing a 'data dictionary' template file in Microsoft Excel.*

*Both surveys and databases (or a mixture of the two) can be built.*

*REDCap provides audit trails for tracking data manipulation and user activity, as well as automated export procedures for seamless data downloads to Excel, PDF, and common statistical packages (SPSS, SAS, Stata, R).*

# Specimen Management

The screenshot displays the 'caTissue Suite v1.1.p5' web application. The interface includes a navigation menu with options like 'Home', 'Administrative Data', 'Biospecimen Data', 'Search', 'Bulk Operations', and 'Help'. The main content area is titled 'Specimen Details' and contains several sections:

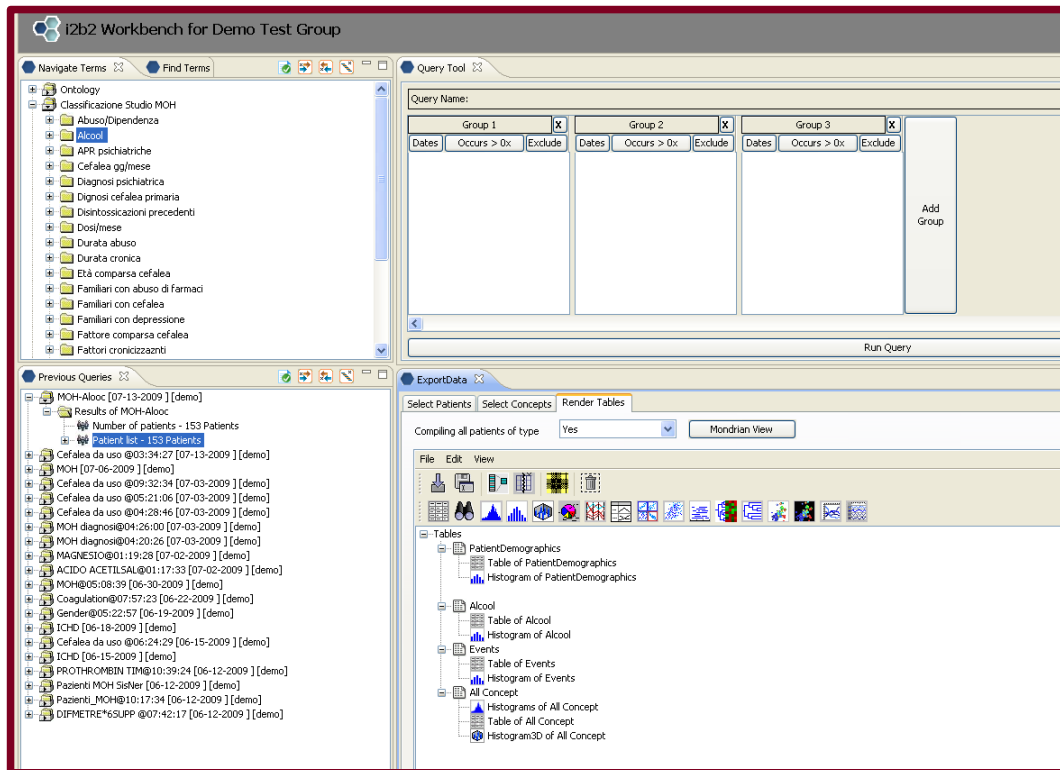
- Collection Protocol:** BRICCS, with fields for 'Participant (Protocol ID):' (BP40002641) and 'View Participant'.
- Specimen Details:** A list of specimens under 'T0.0: Blood collection: 10-28-2010', including IDs like 'e00244', '0099832048', '0083563736', etc.
- Specimen Details Form:**
  - Parent Label: c00244
  - Label: 0083563694
  - Class: Fluid
  - Tissue Site: Not Specified
  - Pathological Status: Not Specified
  - Initial Quantity: 0.5 ml
  - Is Available?:
  - Collection Status: Collected
  - Storage Position: P4 Citrate box: F3C12P4
  - Comments: (empty text area)
- External Identifier(s):** (empty field)
- Biohazard(s):** (empty field)
- Create Child Specimen(s):**
  - None (selected), Aliquot, Derivative, Create Aliquot/Derived Specimen as per CP
  - Count: (empty), Quantity per Aliquot: (empty)
  - Print Labels
- Buttons:** Submit, More, Add To My List

*caTissue is caBIG's biorepository tool for biospecimen inventory management, tracking, and annotation. This tool permits users to enter and retrieve data concerning the collection, storage, quality assurance, and distribution of biospecimens.*

*caTissue Suite is scalable and configurable for deployment across biospecimen resources of varying size and function, and that manage multiple types of biospecimens (tissue, biofluids, nucleic acid).*

*Recording of biospecimen shipping and tracking events across repositories in a single caTissue installation.*

# Translational Data Management



*i2b2 is a comprehensive software and methodological framework to enable clinical researchers to accelerate the translation of genomic and “traditional” clinical findings into novel diagnostics, prognostics, and therapeutics.*

*Data from disparate sources can be loaded into i2b2 under a sophisticated mechanism of ontology building, allowing for complex searching and cross-referencing of data, visualisations and export.*

*Plugins allow for natural language processing and data visualisation.*

# Central Participant Registration

The screenshot shows the C3PR web application interface. At the top, there is a navigation bar with tabs for Registrations, Studies, Persons & Organizations, Administration, and Reports. Below this, the main content area is divided into several sections:

- Frequently Used Shortcuts:** A list of actions such as 'Create Subject', 'Manage Study', 'Import Registrations', etc.
- Notifications:** A table with columns for Title and Date, showing recent updates to subject records.
- Incomplete Registrations\*:** A table listing registration details.
 

Subject name	Primary Identifier	Short title	Registration status
Thomas Gibson	TG-NCI-001	SMOKE_TEST_5	Pending
Jim Smoke	23232332323211	SMOKE_TEST_5	Pending
Thomas Gibson	TG-NCI-001	smoke_test_4	Pending
Don Quixote	2344524223312314d	SMOKE_TEST_5	Pending
Gina Smith	23324534	SMOKE_TEST_5	Pending
- Pending Studies\*:** A table listing study details.
 

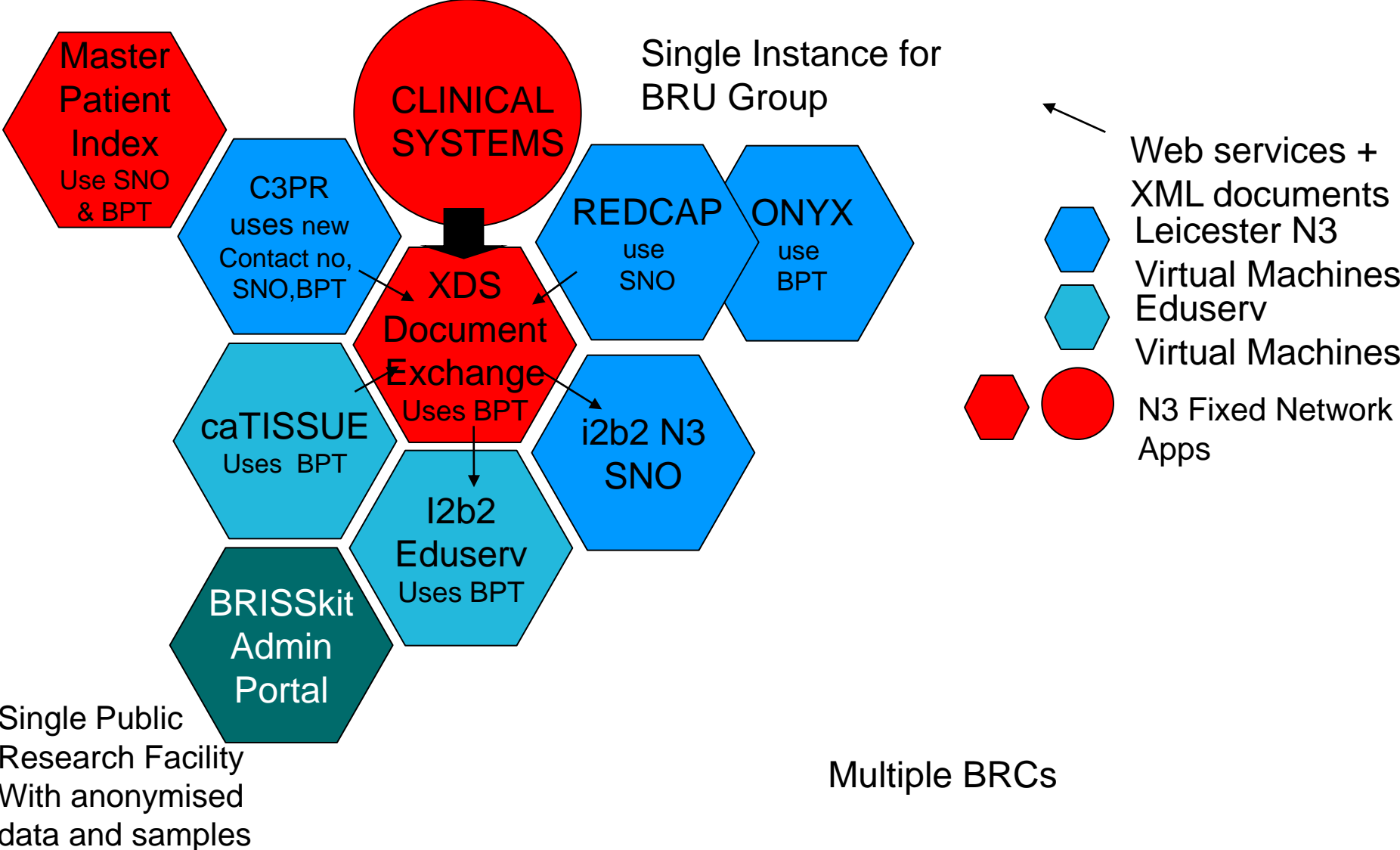
Short title	Primary Identifier	Coordinating center	Phase
Phase I and Pharmacokinetic Study of BAY 43-9006 (Sunitinib) in Patients with Kaposi's Sarcoma	NCI-2009-00122	National Cancer Institute HIV/AIDS Malignancy Branch	Phase I Trial
Phase I Trial and Pharmacokinetic Study of BMS-247550 (NSC 710428, Isabaptone), an Epothilone B Analog, in Pediatric Patients with Refractory Solid Tumors and Leukemias	NCI-2009-00025	National Cancer Institute Pediatric Oncology Branch	Phase I Trial
A Prospective Randomized Phase II Trial Comparing Consolidation Therapy with or without	NCI-2009-00018-retired1	M D Anderson Cancer Center	Phase II Trial
- C3PR Development Notes:** A section for development updates and links.

*C3PR - caBIG Central Clinical Participant Registry - enables efficient and streamlined registration of participants into studies. It can be used by an individual site, or by a multi-institutional organization with many, graphically dispersed sites.*

*C3PR helps to organize, and standardize a template for patient registration, informed consent, inclusion/exclusion criteria, stratification categories, and treatment arms.*

*The system tracks screening failures and enrollment statistics, and can be configured to alert study personnel when accrual thresholds are met.*

# BRISKit VMs



# BRISKit Key Requirements

- Global admin portal
- One mySQL server and Oracle server per customer
- One application config and database schema per customer
- Each application is a BRISKit Plugin architecture
  - XDS and management layer sit on same VM
  - One VM per application
- Ontology is a user problem, we just provide tools (ontology management cell)
- 3 levels of control, global, customer, user
- Customer (e.g. BRU) determines own admin roles . . .
- Patient identities managed by customer and linked to XDS Global
- Ontology changes – how do we handle

# BRISKit: Biomedical Research Infrastructure Software Service kit



**University of  
Leicester**

Theme	Core Components	Lead
Service Design	Detailed project plan (1.1) Engagement with key stakeholders (UoL / UHL / NHS / JISC / JANET / Eduserv / International) Revised project plan (1.2) Provision of Workshops (9.1, 9.2-9.5)	Jonathan Tedds (UoL) / Malcolm Newbury (GuildFoss)/ Chris Greengrass (UHL BRICCS) / Nilesh Samani (UoL Cardiovascular)/ Tony Brookes (UoL Genetics) Paul Burton (UoL Health Sciences) Peter Knight (NIHR)/ Kevin Harris (UHLT)/ Kevin Schurer (UoL PVC Research)/ JISC / JANET / Eduserv / HEFCE
Technical development	Generic deployment infrastructure VM Test facilities (2.2) caTissue API client (4.2) Data generation tools (5.4) Data warehouse application (7.3) UK customisations (7.1) Integration of caTissue / i2b2 (8.1)	Nick Holden (UHL)/ Jeff Lusted (UoL)// Debadutt Goswami & team (UoL)
Return on Investment	Baseline – NIHR BRU / BRC Baseline – non NIHR Biomedical Research Groups Model cost savings and develop Business Plan	Charles Beagrie Consultants / JISC / JANET / Eduserv / HEFCE UoL Business Development



National Institute for Health Research  
**Leicester Cardiovascular  
Biomedical Research Unit**

# BRISKit Sustainability - OS engagement

- *OS* community engagement
  - *standards compliance*
  - *service vision*
- *Cross-enterprise Service Architecture:*
  - how to join & use service for new groups & partners
  - Definition of service vision, organisational & service components
  - all relevant standards & tools which Brisskit partners will be expected to use and comply with
- *OS Community Engagement Charter*
  - defining engagement with existing & new OS communities
  - including adoption & code commitments



# BRISKit - meeting a challenge?

*Is there value in delivering cloud-based applications as a service to researchers?*

- Ease of deployment, administration and archiving
- Cost of computing can be scaled to projects
- Model lends itself to distributed projects and teams
- Infrastructure can be geared to integration
- Enhanced basis for data sharing and federation
  
- Need to ensure sustainability of the service
- Confidentiality and governance

***Workshop - Thurs 19<sup>th</sup> January, Leicester BRU***

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